

**SUMMARY MONTHLY SAFETY REPORT 6
for
ACTIVE SUBSTANCE: PF-07302048 (BNT162b2)**

ATC CODE: J07BX03¹

AUTHORISATION PROCEDURE in the EU: Centralised

INTERNATIONAL BIRTH DATE (IBD):² 19 December 2020

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INTERVAL COVERED BY THIS REPORT:

30⁴ APRIL 2021 through 31 MAY 2021

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Report Prepared by: Worldwide Medical & Safety

Pfizer - BioNTech

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¹ Temporary ATC code.

² It corresponds to the earliest conditional approval date.

³ Re-aligned with IBD as per EMA/630645/2012 Rev.101 Procedure Management Department.

⁴ Please consider that for the May month reporting period, start date is 30 April 2021 since 29 April 2021 was used as cut-off date for the April month reporting period due to MedDRA 24.0 up-versioning activities that prevented the use of cut-off date of 30 April 2021 for the April SMSR.

EXECUTIVE SUMMARY

This is the 6th Summary Monthly Safety Report (SMSR) for PF-07302048 [Coronavirus disease 2019 (COVID-19) mRNA Vaccine, hereafter referred to as BNT162b2)], covering the reporting interval 30 April 2021 through 31 May 2021.

BNT162b2 is a white to off-white frozen dispersion (pH: 6.9 - 7.9), provided as concentrate for dispersion for injection (sterile concentrate) as multidose vial to be diluted before use. The multidose vial contains 6 doses of 0.3 mL after dilution; low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Each dose contains 30 micrograms of BNT162b2 embedded in lipid nanoparticles (LNPs). The vaccine also contains (4-hydroxybutyl)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315), 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159), 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC), cholesterol, potassium chloride, potassium dihydrogen phosphate, sodium chloride, disodium hydrogen phosphate dihydrate, sucrose and water for injections as excipients.

BNT162b2 is highly purified single-stranded, 5'-capped mRNA produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The nucleoside-modified mRNA is formulated in LNPs, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits both neutralizing antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19.

BNT162b2 is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 12 years of age and older.⁵ No dosage adjustment is required in elderly individuals ≥ 65 years of age. It is administered intramuscularly in the deltoid muscle after dilution as a series of 2 doses (0.3 mL each) at greater than or equal to 21 days (preferably 3 weeks) apart.

It is estimated that approximately 639,868,710 doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 31 May 2021 and that approximately 220,976,340 doses of BNT162b2 were shipped worldwide during the current reporting interval from 30 April 2021 through 31 May 2021. Estimated worldwide shipped doses may serve as a reasonable indicator of subject exposure, considering that approximately 85% of the shipped doses were administered; this estimation is a weight average considering the proportion of doses

⁵ Please note that BNT162b2 was authorized for use in individuals 12 years – 15 years of age in Canada on 05 May 2021, in the US on 10 May 2021 and in Japan on 28 May 2021. On 28 May 2021, EMA CHMP recommended granting the extension of indication for use in children aged 12-15 years and the European Commission adopted a decision accordingly on 31 May 2021.

administered out of those shipped upon review of data currently available for the EU-EEA⁶ countries and the US.⁷

It is estimated that approximately (b) (4) doses of BNT162b2 were shipped in the EU-EEA countries from the receipt of the first conditional marketing approval authorisation on 21 December 2020 through 31 May 2021 and that approximately (b) (4) doses of BNT162b2 were shipped in the EU-EEA countries during the current reporting interval from 30 April 2021 through 31 May 2021. Estimated shipped doses in the EU-EEA countries may serve as a reasonable indicator of subject exposure, considering that approximately (b) (4) %⁶ of the shipped doses were administered in these countries.

BNT162b2 has received temporary authorisation for emergency supply in 35 countries and conditional marketing authorisation approval in 43 countries globally.

There were no authorisation withdrawals for safety reasons during the reporting interval.

During the reporting period, no actions have been taken with respect to BNT162b2 for safety reasons, either by a Health Authority or by the MAH.

The Reference Safety Information (RSI) for this SMSR is the BNT162b2 Core Data Sheet (CDS) Version 4.0, dated 19 May 2021, in effect at the end of the reporting period. The previous CDS Version 3.0, dated 20 April 2021, was also in effect during the reporting period, and was updated on 19 May 2021 with safety-related changes made. Among the safety-related changes made to the CDS, were the addition of Asthenia, Lethargy, Decreased appetite, Hyperhidrosis and Night sweats as ADRs in Section 4.8 Undesirable effects, and the addition of warning text for Vaccine stress-related responses (including Dizziness, Fainting, Palpitations, Increases in heart rate, Alterations in blood pressure, Feeling short of breath, Tingling sensations, Sweating and/or Anxiety) in Section 4.4 Special warnings and precautions for use.

During the reporting period, the following signals were addressed:

1. Appendicitis was evaluated and determined not to be a risk;

⁶ Approximately (b) (4) % of the doses shipped in the EU-EEA countries were administered; this proportion has been calculated considering, out of total number of vaccine doses distributed in the EU-EEA countries, the total number of vaccine doses administered as per report on <https://qap.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#distribution-tab>, as of 03 June 2021.

⁷ Approximately (b) (4) % of the doses shipped in the US were administered; this proportion has been calculated considering, out of total number of vaccine doses distributed in the US, the total number of vaccine doses administered as per report on <https://covid.cdc.gov/covid-data-tracker/#vaccinations>, as of 02 June 2021.

2. Dizziness was evaluated and determined not to be a risk;⁸
3. Myocarditis and Pericarditis evaluation is ongoing.

During the reporting period, the following safety topics were addressed and determined not to be validated signals:

1. Abnormal behaviour/Mental disorder;
2. Acquired hemophilia;⁹
3. Acute disseminated encephalomyelitis;
4. Acute pancreatitis;
5. Guillain-Barré syndrome;
6. Menstrual cycle abnormalities;
7. Transverse myelitis.

Based on the new safety and efficacy/effectiveness data from the reporting interval for BNT162b2, the benefit-risk profile of BNT162b2 remains favorable.

⁸ The available information supports dizziness associated with the vaccination process (i.e. stress-related response) but not a causal association with the vaccine itself.

⁹ Determined not to be a validated signal after the data-lock point of this SMSR, on 04 June 2021.

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LIST OF ABBREVIATIONS

Acronym	Term
AE	adverse event
ADR	adverse drug reaction
AESI	adverse event of special interest
AERP	adverse event reporting proportion
BC	Brighton Collaboration
BLA	biologics license application
BMI	body mass index
CDC	Centers for Disease Control and Prevention
CDS	core data sheet
CI	confidence interval
COPD	chronic obstructive pulmonary disease
COVAX	COVID-19 Vaccines Global Access
COVID-19	coronavirus disease 2019
DLP	data lock point
DME	designed medically event
DNA	deoxyribonucleic acid
DSPC	Distearoyl-sn-glycero-3-phosphocholine
EEA	European Economic Area
EMA	European Medicines Agency
EU	European Union
EUA	emergency use authorisation
EURD	European Union Reference Date
HA	health authority
HC	Health Canada
HBV	hepatitis B virus
HCP	healthcare professional
HCV	Hepatitis C virus
HIV	human immunodeficiency virus
HLGT	(MedDRA) High Group Level Term
HLT	(MedDRA) High Level Term
IBD	international birth date
ICH	International Conference on Harmonisation
LNP	lipid nanoparticle
MAH	marketing authorisation holder
MedDRA	medical dictionary for regulatory activities
MHRA	Medicines and Healthcare products Regulatory Agency
mRNA	messenger ribonucleic acid
NAAT	nucleic acid amplification tests
NSAID	non-steroidal anti-inflammatory drug
PM	post-marketing
PRAC	Pharmacovigilance Risk Assessment Committee
PT	(MedDRA) Preferred Term

Acronym	Term
PVP	pharmacovigilance plan
RMP	risk management plan
RNA	ribonucleic acid
ROW	rest of world
RT-PCR	Reverse Transcription-Polymerase Chain Reaction
RSI	reference safety information
TME	targeted medically event
SAE	serious adverse event
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SmPC	Summary of Product Characteristics
SMQ	standardised MedDRA query
SMSR	summary monthly safety report
SOC	(MedDRA) System Organ Class
UK	United Kingdom
US	United States
VAED	vaccine-associated enhanced disease
VAERD	vaccine-associated enhanced respiratory disease
VAERS	vaccine adverse event reporting system
WHO	World Health Organization

1. INTRODUCTION

This is the 6th SMSR for PF-07302048 (COVID-19 mRNA Vaccine, hereafter referred to as BNT162b2), covering the reporting interval 30 April 2021 through 31 May 2021. The format and content of this SMSR is in accordance with the EMA coreRMP19 Guidance (EMA/544966/2020) and, as applicable, with ICH Guideline E2C (R2) Periodic Benefit-Risk Evaluation Report [Step 5, January 2013] considering the information for the evidence from post-EUA/conditional marketing authorisation approval data sources.

BNT162b2 is a white to off-white frozen dispersion (pH: 6.9 – 7.9), provided as concentrate for dispersion for injection (sterile concentrate) as multidose vial to be diluted before use. The multidose vial contains 6 doses of 0.3 mL after dilution; low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Each dose contains 30 micrograms of BNT162b2 (embedded in LNPs). The vaccine also contains ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315), 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159), 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC), cholesterol, potassium chloride, potassium dihydrogen phosphate, sodium chloride, disodium hydrogen phosphate dihydrate, sucrose and water for injections as excipients.

BNT162b2 is highly purified single-stranded, 5'-capped mRNA produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2. The nucleoside-modified mRNA is formulated in LNPs, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits both neutralizing antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19.

BNT162b2 is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 12 years of age and older.⁵ No dosage adjustment is required in elderly individuals ≥ 65 years of age. It is administered intramuscularly in the deltoid muscle after dilution as a series of 2 doses (0.3 mL each) at greater than or equal to 21 days (preferably 3 weeks) apart.

Pfizer is responsible for the preparation of the SMSR on behalf of the MAH BioNTech according to the Pharmacovigilance Agreement in place. Data from BioNTech are included in the report when applicable.

A complete list of the finalized SMSRs is provided in Table 1 below.

Table 1. List of SMSRs

SMSR Number	Reporting Period
1	01 December 2020 through 31 December 2020
2	01 January 2021 through 31 January 2021
3	01 February 2021 through 28 February 2021
4	01 March 2021 through 31 March 2021
5	01 April 2021 through 29 April 2021

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2. WORLDWIDE APPROVAL OR AUTHORISATION STATUS

BNT162b2 received first temporary authorisation for emergency supply under regulation 174 in the UK¹⁰ on 01 December 2020 and is currently authorised for emergency use in 35 countries.

BNT162b2 received first regulatory conditional marketing authorisation approval in Switzerland on 19 December 2020 and is currently conditionally approved in 43 countries (including EEA).

Details of the current authorisation/approval status are presented in [Appendix 4](#).

There were no authorisation withdrawals for safety reasons during the reporting interval.

3. ACTIONS TAKEN IN THE REPORTING INTERVAL FOR SAFETY REASONS

During the reporting period, no actions have been taken with respect to BNT162b2 for safety reasons, either by a HA or by the MAH.

4. CHANGES TO REFERENCE SAFETY INFORMATION

The RSI for this SMSR is the BNT162b2 CDS Version 4.0, dated 19 May 2021, in effect at the end of the reporting period which is located in [Appendix 1](#).

The previous CDS Version 3.0, dated 20 April 2021, was also in effect during the reporting period, and it was updated on 19 May 2021 with safety-related changes made.

Among the safety-related changes made to the CDS, were the addition of Asthenia, Lethargy, Decreased appetite, Hyperhidrosis and Night sweats as ADRs in Section 4.8 Undesirable effects, and the addition of warning text for Vaccine stress-related responses (including Dizziness, Fainting, Palpitations, Increases in heart rate, Alterations in blood pressure, Feeling short of breath, Tingling sensations, Sweating and/or Anxiety) in Section 4.4 Special warnings and precautions for use.

All the safety-related changes made to the CDS are presented in [Appendix 1.1](#).

5. ESTIMATED EXPOSURE AND USE PATTERNS

5.1. Cumulative and Interval Exposure Data Worldwide

It is not possible to determine with certainty the number of individuals who received BNT162b2 during the period of this review. Estimated worldwide shipped doses may serve as a reasonable indicator of subject exposure, considering that approximately 85% of the shipped doses were administered; this estimation is based on a weight average considering

¹⁰ Upon that on 22 April 2021 conditional marketing authorisation approval was also granted in the UK, both the authorisation for emergency supply under regulation 174 and the conditional marketing authorization approval are currently active.

the proportion of doses administered out of those shipped upon review of data currently available for the EU-EEA⁶ countries and the US.⁷

With these caveats in mind, it is estimated that:

- approximately 639,868,710 doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 31 May 2021, corresponding to approximately 542,013,978 estimated administered doses;
- approximately 220,976,340 doses of BNT162b2 were shipped worldwide during the current reporting interval from 30 April 2021 through 31 May 2021, corresponding to approximately 188,860,682 estimated administered doses.

The estimated cumulative number of shipped and administered doses of BNT162b2 by region¹¹ based on data provided in the shipment tracker (b) (4)¹² from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 31 May 2021, are summarized in Table 2.

Table 2. Cumulative Estimated Shipped/Administered Doses of BNT162b2 by Region Worldwide

Region/Country/Other	% of Doses	Total Number of Shipped Doses	Total Number of Administered Doses
Europe	(b) (4)	(4)	214738754
European Union ^a (27)			175350318
Additional EEA Countries ^a (3)			2327068
Switzerland ^a			2089445
UK ^b			24664429
Other Countries ^c			10307495
Commonwealth of Independent States^d			938974
North America^e			177717838
US			160615090
Canada			17102748
Central and South America^f			35161542
Asia			106794714
Japan ^a			66954713
Other Countries ^g			39840002
Oceania			3717441
Australia/New Zealand ^a			3717441
Other Countries			0

¹¹ Currently there are no available data that allow to estimate exposure by gender; for age group data available for some EU-EEA countries see below data in Table 5.

¹² The (b) (4) is the most accurate tracker of shipment used as data source for all the Regions and Countries; US shipment data not available in the (b) (4) were taken from the (b) (4) and data for Hong Kong and Macau were provided by BioNTech.

Table 2. Cumulative Estimated Shipped/Administered Doses of BNT162b2 by Region Worldwide

Region/Country/Other	% of Doses	Total Number of Shipped Doses	Total Number of Administered Doses
Africa ^h	(b) (4)		2944715
Total	100.0%	639868710	542013978

- a. In this Region BNT162b2 was conditionally approved;
- b. In the UK, both the authorisation for emergency supply under regulation 174 and the conditional marketing authorisation approval are currently active for BNT162b2;
- c. Includes Albania and Kosovo where BNT162b2 was conditionally approved, Serbia where it received authorization for emergency supply, Bosnia where it was shipped for COVAX, North Macedonia where it was shipped for a non-COVAX agreement and Turkey where it was shipped according to a pharmacovigilance agreement in place by the MAH and the Turkish government;
- d. Includes Azerbaijan, Georgia, Moldova and Ukraine; in these countries BNT162b2 was shipped for COVAX;
- e. In this Region BNT162b2 received authorization for emergency supply;
- f. Includes Chile, Colombia, Costa Rica, Ecuador, El Salvador, Mexico, Panama, Peru and Uruguay where BNT162b2 received authorisation for emergency supply (some doses in Colombia and El Salvador were also shipped for COVAX), Brazil and Peru where BNT162b2 was conditionally approved (some doses in Peru were also shipped for COVAX), and Bolivia where BNT162b2 was shipped for COVAX;
- g. Includes Bahrain, Iraq, Israel, Jordan, Kuwait, Lebanon, Macau, Oman, Palestine, Qatar, Saudi Arabia, Singapore, United Arab Emirates where BNT162b2 received authorization for emergency supply, Hong Kong, Malaysia and South Korea where BNT162b2 was conditionally approved (some doses in South Korea were also shipped for COVAX), and Bangladesh, Bhutan, Laos, Maldives, Mongolia, Pakistan, Philippines and West Bank & Gaza where BNT162b2 was shipped for COVAX;
- h. Includes Angola, Botswana, Cape Verde, Rwanda and Togo where BNT162b2 was shipped for COVAX, Tunisia where BNT162b2 received authorisation for emergency supply (some doses were also shipped for COVAX), and South Africa where BNT162b2 received authorization for emergency supply.

The estimated interval number of shipped and administered doses of BNT162b2 by region¹³ based on data provided in the shipment tracker (b) (4)¹⁴ from 30 April 2021 through 31 May 2021, are summarized in Table 3.

Table 3. Interval Estimated Shipped/Administered Doses of BNT162b2 by Region Worldwide

Region/Country/Other	% of Doses	Total Number of Shipped Doses	Total Number of Administered Doses
Europe	(b) (4)		80113983
European Union ^a (27)			69436224
Additional EEA Countries ^a (3)			986357
Switzerland ^a			582777

¹³ Currently there were no available data that allow to estimate exposure by gender; for age group data available for some EU-EEA countries see below data in Table 6.

¹⁴ The (b) (4) is the most accurate tracker of shipment used as data source for all the Regions and Countries; US shipment data not available in the (b) (4) were taken from the (b) (4) and data for Hong Kong were provided by BioNTech.

Table 3. Interval Estimated Shipped/Administered Doses of BNT162b2 by Region Worldwide

Region/Country/Other	% of Doses	Total Number of Shipped Doses	Total Number of Administered Doses
UK ^b	(b) (4)	(4)	3827831
Other Countries ^c			5280795
Commonwealth of Independent States ^d			793777
North America ^e			36626885
US			27742022
Canada			8884863
Central and South America ^f			16866057
Asia			50351701
Japan ^a			37968021
Other Countries ^g			12383680
Oceania			1696617
Australia/New Zealand ^a			1696617
Other Countries			0
Africa ^h			2411663
Total			188860682
	100.0%	220976340	

- a. In this Region BNT162b2 was conditionally approved;
- b. In the UK, both the authorisation for emergency supply under regulation 174 and the conditional marketing authorisation approval are currently active for BNT162b2;
- c. Includes Albania where BNT162b2 was conditionally approved, Serbia where it received authorization for emergency supply, Bosnia and Kosovo where it was shipped for COVAX, North Macedonia where it was shipped for a non-COVAX agreement, and Turkey where it was shipped according to a manufacturing and supply agreement in place by the MAH and the Turkish government;
- d. Includes Azerbaijan, Georgia, Moldova and Ukraine; in these countries BNT162b2 was shipped for COVAX;
- e. In this Region BNT162b2 received authorization for emergency supply;
- f. Includes Chile, Colombia, Costa Rica, Ecuador, El Salvador, Mexico, Panama, and Uruguay where BNT162b2 received authorisation for emergency supply (some doses in Colombia, El Salvador were also shipped for COVAX), Brazil and Peru where BNT162b2 was conditionally approved, and Bolivia where BNT162b2 was shipped for COVAX;
- g. Includes Bahrain, Iraq, Israel, Jordan, Kuwait, Lebanon, Oman, Palestine, Qatar, Saudi Arabia, Singapore, United Arab Emirates where BNT162b2 received authorization for emergency supply, Hong Kong, Malaysia and South Korea where BNT162b2 was conditionally approved (some doses in South Korea were also shipped for COVAX), and Bangladesh, Bhutan, Laos, Mongolia, Pakistan, Philippines where BNT162b2 was shipped for COVAX;
- h. Includes Angola, Botswana, Rwanda and Togo where BNT162b2 was shipped for COVAX, Tunisia where BNT162b2 received authorisation for emergency supply (some doses were also shipped for COVAX), and South Africa where BNT162b2 received authorization for emergency supply.

5.2. Cumulative and Interval Exposure Data in the EU

Estimated shipped doses in the EU-EEA countries may serve as a reasonable indicator of subject exposure in these countries, considering that approximately (b) (4) % of the shipped doses were administered; this estimation is based on the proportion of doses administered out of those shipped upon review of data currently available for the EU⁶ countries.

With these caveats in mind, it is estimated that:

- approximately (b) (4) doses of BNT162b2 were shipped in the EU-EEA countries from the receipt of the first conditional marketing authorisation approval on 21 December 2020 through 31 May 2021, corresponding to 177,677,386 estimated administered doses;
- approximately (b) (4) doses of BNT162b2 were shipped in the EU-EEA countries during the current reporting interval from 30 April 2021 through 31 May 2021, corresponding to 70,422,581 estimated administered doses.

Table 4 provides the estimated interval/cumulative number of shipped doses of BNT162b2 from the receipt of the first conditional marketing authorisation approval through 31 May 2021 for the 27 EU Countries and for the 3 EEA Countries.

Table 4. Interval/Cumulative Estimated Shipped/Administered Doses of BNT162b2 by EU-EEA Countries (30)

EU Country	Total Number of Interval Shipped Doses	Total Number of Interval Administered Doses	Total Number of Cumulative Shipped Doses	Total Number of Cumulative Administered Doses
EU (27)	(b) (4)	69436224	(b) (4)	175350318
Austria		1525867		3388928
Belgium		1922263		4363273
Bulgaria		1325095		1850534
Croatia		791762		1276704
Cyprus		155470		387473
Czech Republic		2067437		4467434
Denmark		1306562		2961816
Estonia		194594		461089
Finland		1002830		2344914
France		10612087		26451454
Germany		9489823		33152262
Greece		1896523		4289657
Hungary		1563962		3807976
Ireland		905018		2082881
Italy		10645034		24492125
Latvia		388159		481681
Lithuania		497297		1122779
Luxembourg		109138		250708
Malta		117374		338910
Netherlands		2293949		6589783
Poland		5310677		14225297
Portugal		1807978		4099867
Romania		3416213		7873351
Slovakia		720720		1713254
Slovenia		297554		704418
Spain		7276183		17850862
Sweden		1796652		4320888
EEA (3)		986357		2327068

Table 4. Interval/Cumulative Estimated Shipped/Administered Doses of BNT162b2 by EU-EEA Countries (30)

EU Country	Total Number of Interval Shipped Doses	Total Number of Interval Administered Doses	Total Number of Cumulative Shipped Doses	Total Number of Cumulative Administered Doses
Iceland	(b) (4)	61776	(b) (4)	145002
Liechtenstein				
Norway		924581		2182066
Total		70422581		177677386

Table 5 and Table 6 provide, respectively cumulatively and in the interval period, the estimated number of persons who received 1 dose or 2 doses of BNT162b2, in total, and by age group where available, in the EU-EEA countries.

Table 5. Cumulative Administered 1&2 doses of BNT162b2 by Age Group in EU-EEA Countries^a

	18-24 years		25-49 years		50-59 years		60-69 years		70-79 years		≥80 years		Age Unknown		All	
Countries	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Austria	84668	24031	605106	182492	509165	139194	506310	180459	378527	273484	349676	322371	16051	3444	2449503	1125475
Belgium	69859	48200	558129	274818	517476	200906	764058	328693	542533	503979	386739	368678	3201	2749	2841995	1728023
Bulgaria	11946	7432	137707	98936	87144	66174	104363	73912	77373	49941	23718	14828	538	359	442789	311582
Croatia	29159	3622	264243	51140	176106	43082	204286	75295	126590	71209	56349	39215	968	121	857701	283684
Cyprus	11366	319	78592	49197	43113	36207	34466	30564	18753	18843	23187	23570	2982	10	212459	158710
Czech Republic	37610	18549	877498	232898	661868	133645	693927	127449	526861	395628	244663	223138	2226	579	3044653	1131886
Denmark	15391	19651	129235	141798	386314	91335	529912	149998	514583	487624	237188	232817	807	0	1813430	1123223
Estonia	10510	2783	91080	24478	55356	17918	54403	26145	60347	44224	42146	35507	251	48	314093	151103
Finland	30003	7236	393106	69669	428174	48875	328390	42801	442517	59214	254135	188992	0	0	1876325	416787
France													18708104	8941757	18708104	8941757
Germany													24010690	12508185	24010690	12508185
Greece	13554	9424	365677	197006	534211	185005	391006	191401	561724	480233	485780	460285	16812	8479	2368764	1531833
Hungary	152625	44431	789034	442791	290098	219468	357250	313885	301549	283105	202146	195078	6827	1527	2099529	1500285
Iceland	3190	1410	24454	11801	14331	7914	13047	12462	8632	8473	12370	12310	725	113	76749	54483
Ireland	20819	10389	171636	86654	280351	38035	66369	27886	301835	204245	165311	154040	3368	1595	1009689	522844
Italy	295396	178109	2247724	1469869	2790820	1177369	2677503	1511378	2276683	1695758	3440264	3247085	528533	8998	14256923	9288566
Latvia	17430	6493	99381	45421	35164	17699	27943	16835	12089	7224	5135	3066	27384	15461	224526	112199
Liechtenstein													4939	3797	4939	3797
Lithuania	27884	18245	176804	97774	123959	80725	142100	115507	96877	89273	55510	46532	1602	755	624736	448811
Luxembourg	1293	991	22307	8385	49043	23042	30447	28616	12867	12210	18445	17850	5649	5184	140051	96278
Malta	11493	4405	76503	55986	20578	19837	18419	19032	36176	41374	21508	19746	1220	1	185897	160381
Netherlands													4437701	2185126	4437701	2185126
Norway													884659	523835	884659	523835
Poland	322162	76070	2606842	656037	1431175	668092	1715117	1048041	1891417	1634391	936847	871669	62692	4858	8966252	4959158
Portugal	26383	18676	321831	240247	399656	142183	542329	241141	458503	393633	568748	543374	1030	322	2318480	1579576
Romania	248692	168291	1238654	1005262	616192	515312	726018	642546	431899	389955	141687	126786	1693	0	3404835	2846721
Slovakia													1112898	588348	1112898	588348
Slovenia	6211	1720	65355	21641	78474	42476	97384	77166	95055	86125	65212	59244	801	222	408492	288594
Spain	89225	73753	902216	775077	2721826	529150	992456	690911	3487077	3282890	2672010	2614592	2658	1816	10867468	7968189
Sweden	46201	18794	371353	130724	618182	83084	672372	171767	551484	428561	422838	396695	0	10	2682430	1229635
Total	1583070	763024	12614467	6370101	12868776	4526727	11689875	6143890	13211951	10941596	10831612	10217468	49847009	24806268	112646760	63769074

a. Source is <https://covid19-vaccine-report.ecdc.europa.eu/> (point 6, cumulative period as of week 21, 30 May 2021).

Table 6. Interval Administered 1&2 doses of BNT162b2 by Age Group in EU-EEA Countries^a

	18-24 years		25-49 years		50-59 years		60-69 years		70-79 years		≥80 years		Age Unknown		All	
Countries	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Austria	51675	5665	362884	49371	287958	47781	185263	104431	49268	131055	11740	26578	11400	1154	960188	366035
Belgium	16502	11598	261288	57821	269387	82833	249351	236734	17687	407131	6257	167314	447	442	820919	963873
Bulgaria	5787	4438	46634	45201	24874	25246	35724	34197	31940	28849	10174	8718	308	245	155441	146894
Croatia	23361	1516	194408	19419	115368	19873	97826	44870	37581	34541	12180	9560	812	47	481536	129826
Cyprus	11071	116	49184	45962	14219	32001	8813	16545	873	1165	41	110	0	0	84201	95899
Czech Republic	13317	3727	576518	49911	474649	30434	281565	51907	62081	109522	10830	8387	1212	164	1420172	254052
Denmark	3118	8234	28293	46156	315882	26264	314472	69903	25017	338698	3147	16515	0	0	689929	505770
Estonia	7155	786	61307	9037	31630	8293	25555	15646	28993	25937	12268	10817	168	23	167076	70539
Finland	9657	1931	226142	16331	254141	21162	112723	26227	9320	45899	4451	136886	0	0	616434	248436
France													7940280	3070747	7940280	3070747
Germany													7648415	6318539	7648415	6318539
Greece	4910	3916	186894	65815	410615	108694	216049	151246	83645	264246	22334	57753	13619	8402	938066	660072
Hungary	84122	24931	255939	277943	55828	134696	34094	154077	13879	73912	4882	24410	2658	599	451402	690568
Iceland	1681	895	11792	7340	5669	6003	465	8258	61	205	13	20	592	50	20273	22771
Ireland	6301	576	49032	3154	205549	2725	17848	6798	3324	83399	399	1434	1349	1011	283802	99097
Italy	142840	70146	1067286	445846	1874813	516718	1415496	952246	668473	1158834	141323	469036	12979	6707	5323210	3619533
Latvia	14684	5621	76351	42854	23506	16173	14609	15390	6383	5396	2797	2223	7843	2189	146173	89846
Liechtenstein													322	1645	322	1645
Lithuania	10562	11520	90094	55410	51932	43850	32128	54605	7340	23230	3486	8692	850	463	196392	197770
Luxembourg	294	344	13800	3376	25594	20632	1622	26843	558	1066	317	338	424	385	42609	52984
Malta	7778	1861	41537	37433	3745	10801	783	8807	356	8434	114	653	720	0	55033	67989
Netherlands													1525256	1125380	1525256	1125380
Norway													217952	446570	217952	446570
Poland	235520	15441	1600277	236214	492214	432635	368102	779525	133777	734060	34728	130548	56973	1447	2921591	2329870
Portugal	6389	7809	72065	107689	254136	80215	292606	191794	56367	316402	11217	44368	664	89	693444	748366
Romania													778426	1190951	778426	1190951
Slovakia													499210	138842	499210	138842
Slovenia	4477	280	44166	3069	62178	31239	26774	45571	9668	14395	3887	2311	567	88	151717	96953
Spain	14153	6932	119381	52285	2284034	126915	579004	419872	438675	2582859	28815	175158	894	597	3464956	3364618
Sweden	22585	6044	212406	33689	450954	20784	142830	107630	16811	299480	3343	67227	0	0	848929	534854
Total	946631	362618	6886332	2716588	8605067	2361279	5179720	4165668	2133976	7078670	470430	1495842	15321198	9468624	39543354	27649289

a. Source is <https://covid19-vaccine-report.ecdc.europa.eu/> (point 6, interval period weeks 18, 19, 20 and 21, as of 30 May 2021).

6. DATA IN SUMMARY TABULATIONS

6.1. Reference Information

The MedDRA version 24.0 was used to code adverse events/reactions in summary tabulations.

6.2. Cumulative and Interval Summary Tabulations from Post-Marketing Data Sources¹⁵

- [Appendix 2](#) and [Appendix 2.1](#) respectively provide interval and cumulative numbers of case reports (serious and non-serious, medically confirmed and non-medically confirmed) received from post-marketing authorisation data sources,¹⁵ overall, by sex, country, age groups and in special populations, and summary tabulations of events by PT and SOC respectively for the interval and cumulative periods.

The cumulative data include all data up to 31 May 2021 while the interval data are for the period from 30 April 2021 to 31 May 2021.

- [Appendix 2.2](#) provides an interval summary tabulation of case reports with DMEs from post-marketing data sources.¹⁵
- [Appendices 2.3](#) and [2.4](#) provide data stratified by country. In these appendices, spontaneous cases (including regulatory authority and literature cases) are presented separately from non-interventional cases:
 - [Appendix 2.3](#) provides a cumulative and interval summary tabulation of cases by medically confirmed and non-medically confirmed status (fatal, serious and non-serious).
 - [Appendix 2.4](#) provides a cumulative and interval summary tabulation of fatal cases.
- [Appendix 2.5](#) and [Appendix 2.6](#) provide a cumulative and interval summary tabulation of adverse reactions from post-marketing authorisation data sources¹⁵ respectively by PT and by HLT organized according to SOC. Please refer to [Appendix 2.5.1](#)¹⁶ and [Appendix 2.6.1](#)¹⁶ for data per country.

Adverse events totals presented in [Appendix 2](#), [Appendix 2.1](#) and for safety topic evaluations in [Section 9.5](#) may differ from those presented in [Appendix 2.5](#) and [Appendix 2.6](#), due to the

¹⁵ This refers to post-EUA/conditional marketing authorisation approval data sources. Only cases having a complete workflow cycle in the safety database (meaning that they went to Distribution or Closed workflow status at least once) have been included. This approach will prevent the inclusion of cases initially received and not fully processed since cases in early steps of the workflow process may still undergo changes and not accurately reflect final data. Each month, Pfizer applies a Late condition process that retrieves cases received in the reporting period but not included due to lack of completeness; this ensures no cases will be missed for inclusion in monthly reports.

¹⁶ Due to a technical formatting issue, blank pages may be present in this Appendix; the total data are however correctly displayed.

fact that [Appendix 2.5](#) and [Appendix 2.6](#) only display the number of serious and non-serious reactions from spontaneous sources, serious reactions from non-interventional studies and from solicited sources as described above, whereas [Appendix 2](#), [Appendix 2.1](#) and the safety topic evaluations includes all reported events.

[Appendix 2.5.2](#),¹⁶ [Appendix 2.5.3](#)¹⁶ and [Appendix 2.5.4](#)¹⁶ were added to include a cumulative and interval summary tabulation of adverse events from post-authorisation data sources¹⁵ by PT per country, stratified respectively for age, gender and relevant co-morbidities.

Available relevant information with regard to the differences in vaccination prioritization in EU countries,¹⁷ US¹⁸, UK and ROW¹⁹ was taken into account in the evaluation of adverse events trends, clusters or signals.

¹⁷ Overview of the implementation of COVID-19 vaccination strategies and vaccine deployment plans in the EU/EEA. ECDC, February 2021.

¹⁸ <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/evidence-table-phase-1b-1c.html>.

¹⁹ WHO Roadmap for Prioritizing Population Groups for Vaccines against COVID-19; ACIP COVID-19 Vaccines Working Group, Phased Allocation of COVID-19 Vaccines (Dec 01, 2020); JCVI updated interim advice on priority groups for COVID-19 vaccination (Sept 25, 2020)

7. MEDICATION ERRORS

Cases potentially indicative of medication errors²⁰ that occurred in the reporting period are summarized below.

- Number of cases: 2394 (5.1% of 47174 cases, the total PM¹⁵ dataset) of which 1487 (62.1%) are medically confirmed, compared to 1258 (4.1%) in the fifth monthly report of which 44.8% were medically confirmed. The increase in medication errors reported during this reporting period in comparison to the previous monthly report is mainly due to an approximate 3.7-fold increase in reported medication errors related to inappropriate administration or scheduling of the second vaccine dose more than 21 days from the first vaccine dose as recommended in the RSI and medication errors related to preparation, temperature excursion and poor quality administration of vaccine. In particular, the increase of medication errors related to preparation, temperature excursion and poor quality administration of vaccine is due to clusters of medication error cases. In the majority of the events reporting inappropriate administration or scheduling of second dose administered, the reasons for administration or scheduling of the dose were not provided.
- Of the 2394 cases, 22 cases were determined to be non-contributory and are not included in the discussion for the following reasons:
 - No indication that the medication error is associated to the vaccine in 7 cases;
 - Reporting information was not consistent for paediatric patients (e.g., height, weight, clinical details, etc. indicative of an adult patient) and did not meet the medication error criteria for product administered to patient of inappropriate age in 1 case;
 - Reporting information was not consistent to meet medication error criteria in 10 cases;
 - Medical inquiries only on dosage regimen of vaccine were reported in 4 cases;

²⁰ MedDRA (version 24.0) Higher Level Terms: Accidental exposures to product; Product administration errors and issues; Product confusion errors and issues; Product dispensing errors and issues; Product label issues; Product monitoring errors and issues; Product preparation errors and issues; Product selection errors and issues; Product storage errors and issues in the product use system; Product transcribing errors and communication issues, OR Preferred Terms: Accidental poisoning; Circumstance or information capable of leading to device use error; Circumstance or information capable of leading to medication error; Contraindicated device used; Deprescribing error; Device use error; Dose calculation error; Drug titration error; Expired device used; Exposure via direct contact; Exposure via eye contact; Exposure via mucosa; Exposure via skin contact; Failure of child resistant product closure; Inadequate aseptic technique in use of product; Incorrect disposal of product; Intercepted medication error; Intercepted product prescribing error; Medication error; Multiple use of single-use product; Product advertising issue; Product distribution issue; Product prescribing error; Product prescribing issue; Product substitution error; Product temperature excursion issue; Product use in unapproved therapeutic environment; Radiation underdose; Underdose; Unintentional medical device removal; Unintentional use for unapproved indication; Vaccination error; Wrong device used; Wrong dosage form; Wrong dosage formulation; Wrong dose; Wrong drug; Wrong patient; Wrong product procured; Wrong product stored; Wrong rate; Wrong route; Wrong schedule; Wrong strength; Wrong technique in device usage process; Wrong technique in product usage process.

- Number of relevant medication error cases: 2372
Number of relevant events: 3090.
- Number of medication errors by country:
 - There were 599 cases describing medication errors that occurred in the EU/EEA countries [France (233), Germany (94), Belgium (79), Italy (44), Romania and Spain (25 each), Portugal (15), Poland (13), Ireland (12), Sweden (11), Netherlands and Norway (9 each), Finland (7), Austria (6), Denmark and Greece (4 each), Czech Republic (3), Hungary (2), Croatia, Latvia, Liechtenstein and Malta (1 each).
 - There were 1773 cases with medication errors from non-EU/EEA countries [US (1083), UK (595), Mexico (25), Japan (15), Israel (12), Canada and Panama (9 each), Switzerland (6), Brazil (4), Chile, Saudi Arabia and Turkey (2 each), Australia, Colombia, Georgia, Jordan, New Zealand, Puerto Rico, Serbia, Singapore, United Arab Emirates (1 each).

In some instances, clusters of medication errors were reported, generally by HCPs, suggesting that rather than a systematic issue worldwide, these errors were repeated mistakes at certain vaccination centres:

- In the EU/EEA region there were 5 clusters, the largest reported cluster was received from France [(93 cases, 44 cases, and 20 cases (3 clusters))].
- In non-EU/EEA countries there were 10 clusters, the largest reported clusters were received from the US [309 cases, 47 cases, and 19 cases (3 clusters)].
- Medication error PTs in the EU/EEA and non-EU/EEA countries:²¹
 - In the EU/EEA countries, a total of 914 PTs indicative of medication errors were reported; those events reported at least thrice included: Poor quality product administered (233), Incorrect route of product administration (166), Product temperature excursion issue (164), Wrong technique in product usage process (87), Inappropriate schedule of product administration (80), Product preparation error (44), Underdose (27), Incorrect dose administered (22), Product preparation issue (19), Product storage error (16), Wrong product administered (13), Product administered at inappropriate site (10), Product administration error (8), Incomplete course of vaccination (6), Accidental exposure to product (4), Accidental overdose (3).²²

²¹ As per EMA assessment received on the first SMSR, the MAH was requested to keep medication errors under close scrutiny especially within the EU and discuss whether the current product information is sufficiently clear or whether there is room for improvement. The Rapporteurs should be notified immediately in case of unexpected findings or trends.

²² The PTs reported less than 3 times included: Exposure via skin contact and Extra dose administered (2 each), Booster dose missed, Circumstance or information capable of leading to medication error,

- In non-EU/EEA countries, a total of 2176 medication errors were reported; those events reported at least thrice included: Inappropriate schedule of product administration (743), Product preparation issue (358), Poor quality product administered (299), Product temperature excursion issue (145), Product storage error (96), Product preparation error (73), Underdose (63), Circumstance or information capable of leading to medication error and Incorrect route of product administration (52), Wrong product administered (45), Incorrect dose administered (38), Wrong technique in product usage process (36), Product dose omission issue (35), Expired product administered (31), Product administered at inappropriate site (28), Product administered to patient of inappropriate age (22), Accidental overdose (14), Product administration error (13), Accidental exposure to product (7), Exposure via skin contact (5), Medication error and Vaccination error (4 each).
- Medication errors by seriousness:
 - Serious (62 events of medication error):
 - Of these serious events of medication error, 26 serious medication errors²³ accompanied by clinical AEs were reported in EU/EEA countries [Romania (16), Ireland, Italy and Norway, (2 each), France, Germany, Hungary and Sweden (1 each)];
 - Seriousness criteria were medically significant events (19 events), Hospitalization (4 events), Disability (1 event), Fatal and Hospitalization²⁴ (1 event), Life-threatening and Disability (1 event each);
 - Of note, more than 1 serious criteria applied to 1 event;
 - All but 5 events were medically confirmed.
 - Non-serious (3028 events of medication error).

Please see the *Medication errors associated with harm* and *Medication errors without Harm* sections below for further details on co-reported AEs in cases involving serious medication error.

Contraindicated product administered, Expired product administered, Product administered to patient of inappropriate age, Product dose omission issue, Product prescribing error, Vaccination error (1 each).

²³ PTs Incorrect route of product administration (17), Incomplete course of vaccination and Incorrect dose administered (2 each), Accidental overdose, Extra dose administered, Product administered at inappropriate site, Product preparation error and Vaccination error (1 each).

²⁴ Upon review the fatal medication error did not lead to harm.

Medication Errors Harm Analysis

Among the medication error cases, the following scenarios, categorized according to the EMA guidance “Good practice guide on recording, coding, reporting and assessment of medication errors” (EMA/762563/2014) were described:

- Medication errors associated with harm [i.e., resulting in adverse reaction(s)] were reported in 23 cases (1 % of relevant medication error cases) compared to 34 cases (2.8%) in the fifth SMSR;
- Medication errors without harm [i.e. not resulting in adverse reaction(s)]²⁵ were reported in 2343 cases (98.8% of relevant medication error cases), of which 990 cases involved co-reported AEs, compared to 1157 cases (94.0%), of which 652 included co-reported AEs, in the fifth SMSR;
- Potential medication errors were reported in 6 cases (0.3% of relevant medication error cases) compared to 46 cases (3.7%) in the fifth SMSR.
- Similar to the fifth SMSR, intercepted medication errors were not reported during the reporting interval.

Of note, some cases involved more than one medication error.

Medication errors associated with harm (25 medication errors in 23 cases)

There were 18 cases from the EU/EEA area [Romania (15)²⁶, Germany, Hungary, and Italy (1 each)] and 5 from non-EU/EEA countries [US and UK (2 each), and Mexico (1)].

Serious medication errors

In 19 cases (involving 19 medication error events), serious medication errors potentially contributed to the occurrence of SAEs.

- Fifteen (15)²⁶ out of these 19 cases reported bradycardia and vasovagal syncope, occurred about 1 minute and 7-10 minutes respectively, after receiving the vaccine in patients of unspecified age and gender. The physician suspected these SAEs occurred due to the penetration into the vascular bed of the needle (PT: Incorrect route of product administration). The patients recovered from vasovagal syncope.
- A male patient of unspecified age received a third dose of vaccine 21 days after the previous one (PT: Incorrect dose administered) since some vials containing only saline were found at the hospital. It was unknown if the patient had previously received only saline. The patient experienced Pyrexia (40 °C) and Atrial fibrillation due to which he

²⁵ AEs may be co-reported in a case, but they are not considered to be a result of the medication error.

²⁶ These cases originated from a single cluster reported by the same HCP in Romania.

was hospitalized for four days. Treatment consisted of furosemide. Clinical outcomes for all events were unknown at the time of the report.

- A female patient of unspecified age experienced yellowish and greenish spots near the injection site after the needle had reached a blood vessel (PT: Incorrect route of product administration). Additionally, she had arm pain and pain in extremity (both considered non-serious). Following a medical examination, the patient was told that the needle may have reached a blood vessel. The events were not resolved.
- Following a vaccine application error (PT: Wrong technique in product usage process), a 67-year-old male patient experienced Injection bleeding, Chills and Nasal obstruction. The subject underwent hydrocortisone and recovered from Nasal obstruction. The outcome of the other events was unknown.
- Medication error, muscle and shoulder pain, bruise and allergic reaction were reported in a 64-year-old male patient with a medical history of penicillin and creosote allergies. The events were assessed as serious (disability). Muscle and shoulder pain were not resolved, and clinical outcomes for the other events were unknown at the time of the report.

Non-serious medication errors

In 4 cases (involving 6²⁷ medication error events), non-serious medication errors potentially contributed to the occurrence of non-serious AEs.

Errors in the route of administration (3 events, 3 cases)

- This error occurred in 2 cases from the EU/EEA area [Germany and Italy (1 each)] and in 1 case from non-EU/EEA country [UK (1)]. The vaccine was administered intravenously, cutaneously (1 each) in the first two cases. Local vaccination site reactions included Vaccination site swelling and Pain, Vaccination site oedema, Skin reaction and Vaccination site erythema (1 each). In addition, the third case reported an administration of vaccine into soft tissue (1), which led to an incomplete dose administered and Vaccination site pain.

Incorrect dilution (2 events, 1 case)

- These errors occurred in 1 case non-EU/EEA country US [(1)]. A pharmacist accidentally administered 6 shots of 0.3 mL undiluted vaccine to a 12-year-old female patient. The patient experienced Pain in extremity, Vomiting, Diarrhoea, Skin discolouration, Pyrexia, Chills, Nausea, Faeces discoloured, Illness. All events were considered non-serious.

²⁷ Upon review medication error PT "Vaccination error" was not considered, as the event "given into soft tissue" was already coded to the more specific PT "Incorrect route of product administration".

Medication errors without harm (3059 medication errors in 2343 cases)

These medication error PTs describe errors occurring during 1 or more steps of the vaccination process: preparation, administration, or scheduling of second dose.

Overall, there were:

- 581 cases from the EU/EEA area: France (233), Germany (93), Belgium (79), Italy (43), Spain (25), Portugal (15), Poland (13), Ireland (12), Sweden (11), Romania (10), Netherlands and Norway (9 each), Finland (7), Austria (6), Denmark and Greece (4 each), Czech Republic (3), Croatia, Hungary, Latvia, Liechtenstein and Malta (1 each).
- 1762 cases from non-EU/EEA countries: US (1075), UK (593), Mexico (24), Japan (15), Israel (12), Canada and Panama (9 each), Switzerland (6), Brazil (4), Chile, Saudi Arabia and Turkey (2 each), and Australia, Colombia, Georgia, Jordan, New Zealand, Puerto Rico, Serbia, Singapore and United Arab Emirates (1 each).

Vaccine preparation errors (1107 events): Events mainly described errors during dilution and temperature excursion issue.

- *Incorrect dilution (455 events):* In the vast majority of cases an improper dilution of vaccine was performed affecting the vaccine preparation. These errors involved more steps of dilution process: dilution with different solvents, use of a larger or smaller volume of diluent or resuspension with normal saline.
- *Temperature excursion (423 events):* These events reported incorrect temperature excursion errors during the preparation of vaccine not compliant with recommendations of RSI.
- *Other preparation errors (229 events):* In majority of the events, there are preparation issues with needle/syringe (91 events), vaccine doses prepared with other dilution technique (87 events), unspecified dosing errors (11 events) and problems of non-inverting vials (7 events). In addition, there were 4 events reported a preparation with expired vaccine, 26 events of other unspecified preparation issues and 3 events of preparation error underdose.

Vaccine administration errors (1795 events): Events mainly described errors in administering the second dose outside the recommended 21 days after the first dose per the RSI, errors in route of administration, errors in administration of vaccine dose not adequately prepared, errors in administration technique, errors in the volume or dosage of the vaccine administered, errors of vaccination at the wrong anatomical site.

- *Incorrect interval between doses (683 events):* Errors included second dose administration more than 21 days after the first dose (226 events), second dose administration less than 21 days after the first dose (52 events), and unspecified errors with the administration date of the second dose (405 events).

- *Errors in the route of administration (198 events)*: The route of administration for the vaccine was unspecified (other than intramuscular) in 82 events, subcutaneous (72 events), intravenous (23 events), intradermal/cutaneous (9 events), parenteral without any further detail and auricular (3 events each), oral (2 events), intra-articular, intra-amniotic, intra-meningeal and intra-ocular (1 event each).
- *Administration after inadequate preparation (467 events)*: These events referred to vaccine administered after inadequate preparation. There were: vaccines administered after temperature excursion (406 events), doses with particles issue (17 events) or colour issue (3 events). Additionally, 41 events reported other unspecified inadequate preparation errors.
- *Errors in administration technique (6 events)*: Errors included other unspecified administration technique errors (3 events), use of an incorrect needle/syringe (2 events), injury to blood vessel (1 event).
- *Errors in the volume administered (123 events)*: Errors included smaller volume administered (118 events), administration of partial doses due to syringe needle malfunction (3 events), higher volume administered (2 events).
- *Errors in vaccine dosage (79 events)*: These errors involved 2 vaccine doses administered on the same day and unspecified improper dilution errors (15 events each), 3 doses administered (12 events), dilution before use not performed (8 events), administration of entire vials (4 events), 3 events of dose larger than usual, administration of second dose date issue (1 event) and unspecified dosage errors (21 events).
- *Vaccination site other than deltoid muscle (41 events)*: The vaccine was administered at a site other than deltoid muscle (24 events), leg (9 events), thigh (4 events), forearm, gluteus muscle, shoulder and wrist (1 event each).
- *Wrong vaccine other than recommended in the RSI administered (62 events)*: Vaccinees received 1 dose of BioNTech-Pfizer vaccine and 1 dose of the Moderna vaccine (27 events), 1 dose of BioNTech-Pfizer vaccine and 1 dose of AstraZeneca vaccine (17 events) and wrong unspecified vaccines (18 events).
- *Use in unauthorized individuals (26 events)*: The vaccine was inadvertently administered to paediatric individuals below 16 years of age²⁸ (24 events), and patients with medical history of allergy (2 events).
- *Accidental exposure to vaccine (19 events)*: These errors involved exposure to the skin (17 events) and eye (2 events).

²⁸ Before the authorisation of vaccine use in individuals 12 years – 15 years or from countries in which the vaccine was not authorized yet below 16 years of age.

- *Dose of vaccine not administered (50 events)*: Errors included second dose of BioNTech-Pfizer vaccine not administered (49), missing administration of dose (1).
- *Other vaccine administration errors (41 events)*: Errors mainly included administration of expired vaccine²⁹ (33 events), the use of concomitant drugs (3 events) or concomitant vaccine (1 event). In addition, there were other unspecified dosage administration error (2 events), underdose due to syringe leakage and administration of third dose of vaccine (1 event each).

Vaccine scheduling errors (144 events): Events mainly described errors involving scheduled second dose vaccinations outside the recommended 21 days after the first dose.

- *Incorrect interval between doses (47 events)*: The second dose was scheduled more than 21 days after the first dose (24 events), and the second dose of the vaccine was scheduled less than 21 days after the first dose (3 events). Second dose was not administered (15 events) and there were errors in scheduling second dose administration date (5 events).
- *Other scheduling errors (97 events)*: The vaccinee cancelled or missed their appointment (3 events), there was Conflicting appointment / procedure with scheduled vaccination date (4 events), no scheduled appointment for the second dose (3 events), the second dose was not available due to a supply issue and second dose appointment cancelled by site (2 events each). Second dose of vaccine was not administered (4 events) and 79 events reported other unspecified scheduling errors.

Other medication errors (13 events): Events described patient resistance for second dose (3 events), patient question on scheduling and patient question on treatment/procedure (2 events each), question on counterfeit product, dosing, unspecified patient question (1 event each). In addition, there were HCP question, medication errors reported and details unknown (PT Medication Error) and patient was unable to get the appointment (1 event each).

Potential medication errors (6 medication errors in 6 cases, all non-serious)

There were 6 cases from non-EU/EEA countries (all from US).

- *Potential interaction error with drugs or patient's condition (4 events)*: Events mainly described potential errors due to possible interaction with patient condition and with product co-administered (2 events each).
- *Other potential errors (2 events)*: Events mainly described patient questions around scheduling.

²⁹ Vaccine was administered after an incorrect handling/storage.

Some medication errors are expected to occur despite written instructions and educational activities for HCPs administering the vaccine. The number and seriousness of the reported medication errors do not indicate a need for additional mitigation activity.

8. GENERAL OVERVIEW

A total of 47,174 case reports (26,272 medically confirmed and 20,902 non-medically confirmed) containing 174,446 events fulfilled criteria for inclusion in this SMSR. Refer to [Appendix 2](#) for the summary tabulations of all cases received during the current reporting period.

PRESENTATION OF CASE CHARACTERISTICS

Table 7. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

Characteristics		Relevant cases (N=47174)
Gender:	Female	32751
	Male	11506
	No Data	2917
Age range: 1 month -105 years Mean = 51 years Median = 49 years n = 39610	≤ 17	327 ^a
	18-30	5777
	31-50	14682
	51-64	8817
	65-74	4702
	≥ 75	5465
	Unknown	7391 ^b
Case outcome:	Resolved/Resolving	21669
	Resolved with sequelae	546
	Not resolved at the time of report	11840
	Fatal	971
	Unknown	12148
Presence of comorbidities	Yes	8621 ^c
	No	38553

a. Including 13 cases for which a paediatric age was initially reported but that they re-evaluated as not consistent with this age upon review, 1 paediatric case invalidated after DLP as duplicate case of an invalid case (see [Table 14](#), *Use in Paediatric Individuals <12 Years of Age*) and 86 breastfed babies for which paediatric age was reported;

b. Including 42 breastfed babies for whom age was not reported;

c. Cases retrieved applying the criteria in place to identify the reports involving the special populations of Immunocompromised patients, Patients with autoimmune or inflammatory disorders, Frail patients with comorbidities (e.g. COPD, diabetes, chronic neurological disease, cardiovascular disorders, active tuberculosis) described as Missing Information in [Table 14](#).

Case outcome by age group, gender and presence of relevant comorbidities is presented in [Figure 1](#), [Figure 2](#) and [Figure 3](#). Across all age groups, there were more females than males reporting adverse events. Overall, the proportion of cases with fatal outcome is higher when relevant comorbidities are reported ([Figure 1](#)). Among the cases with a fatal outcome, there is a similar pattern for gender both in presence or in absence of relevant comorbidities ([Figure 2-A](#)). Keeping in consideration the age group ([Figure 2-B](#)), when the age was known, there are no differences in the proportion of cases with a fatal outcome, with the

highest number of cases in individuals aged 75 years and older, either in presence or absence of relevant comorbidities (please also see *Death* in [Table 13](#) and *Frail patients with co-morbidities e.g. COPD, diabetes, chronic neurological disease, cardiovascular disorders, active tuberculosis*, described as Missing Information in [Table 14](#)).

Figure 1. Case Outcome by Presence of Relevant Comorbidities

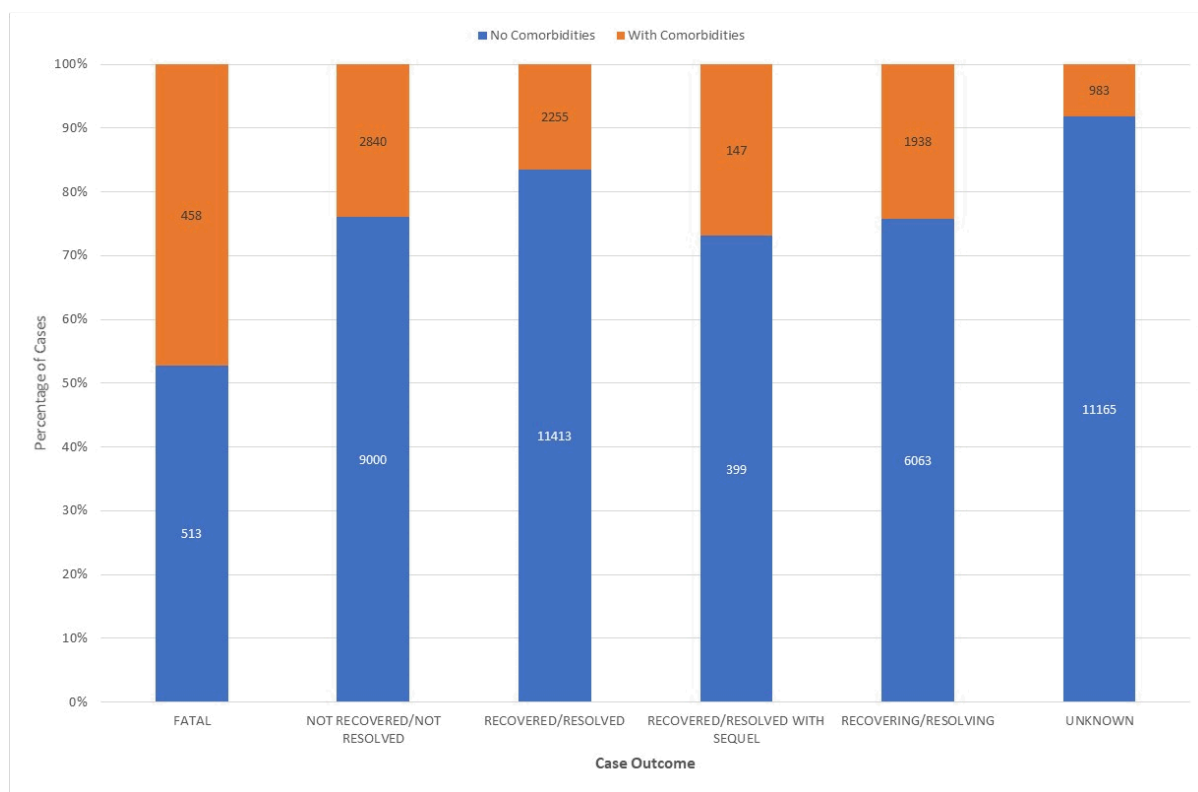
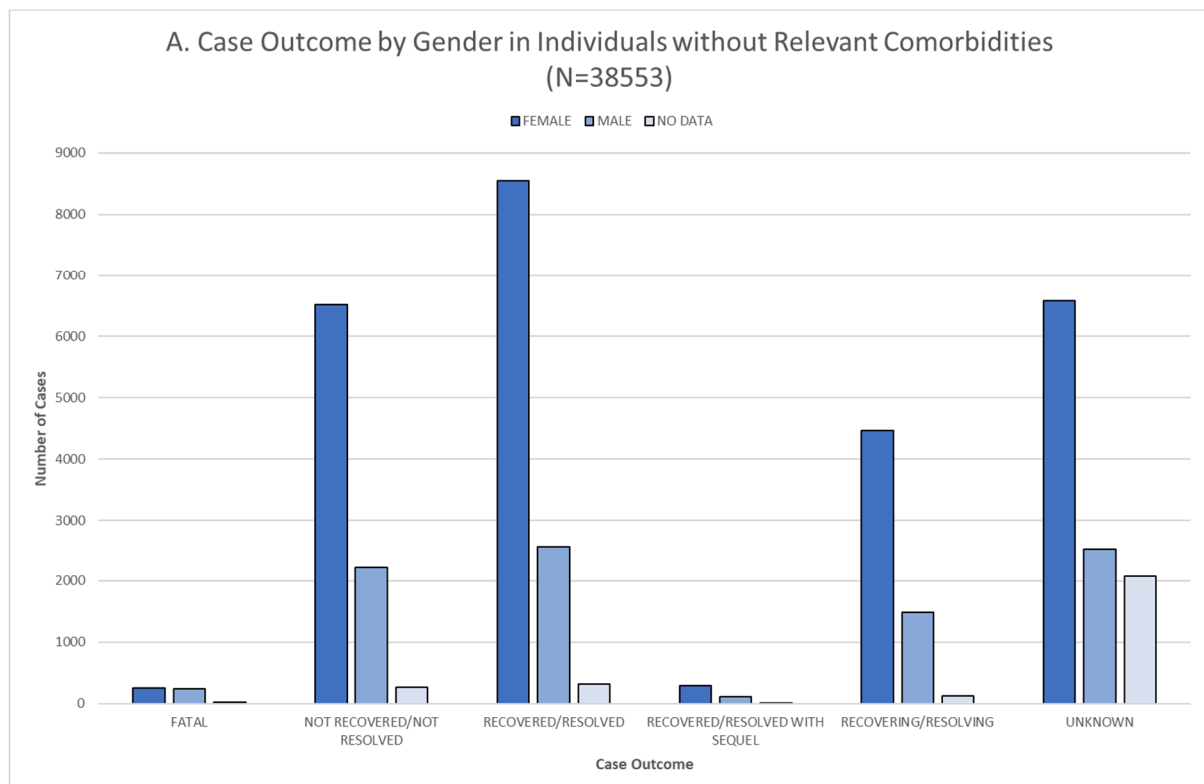
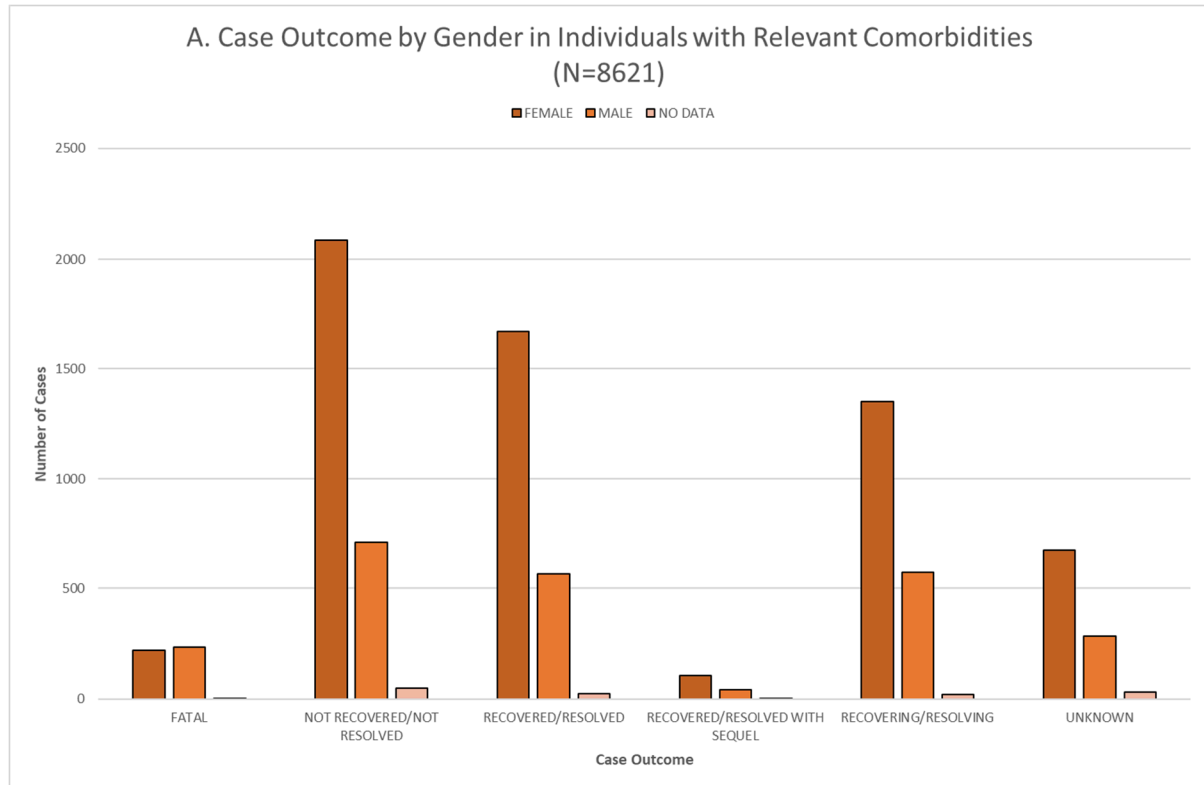


Figure 2. Case Outcome by Presence of Relevant Comorbidities, Gender and Age Group



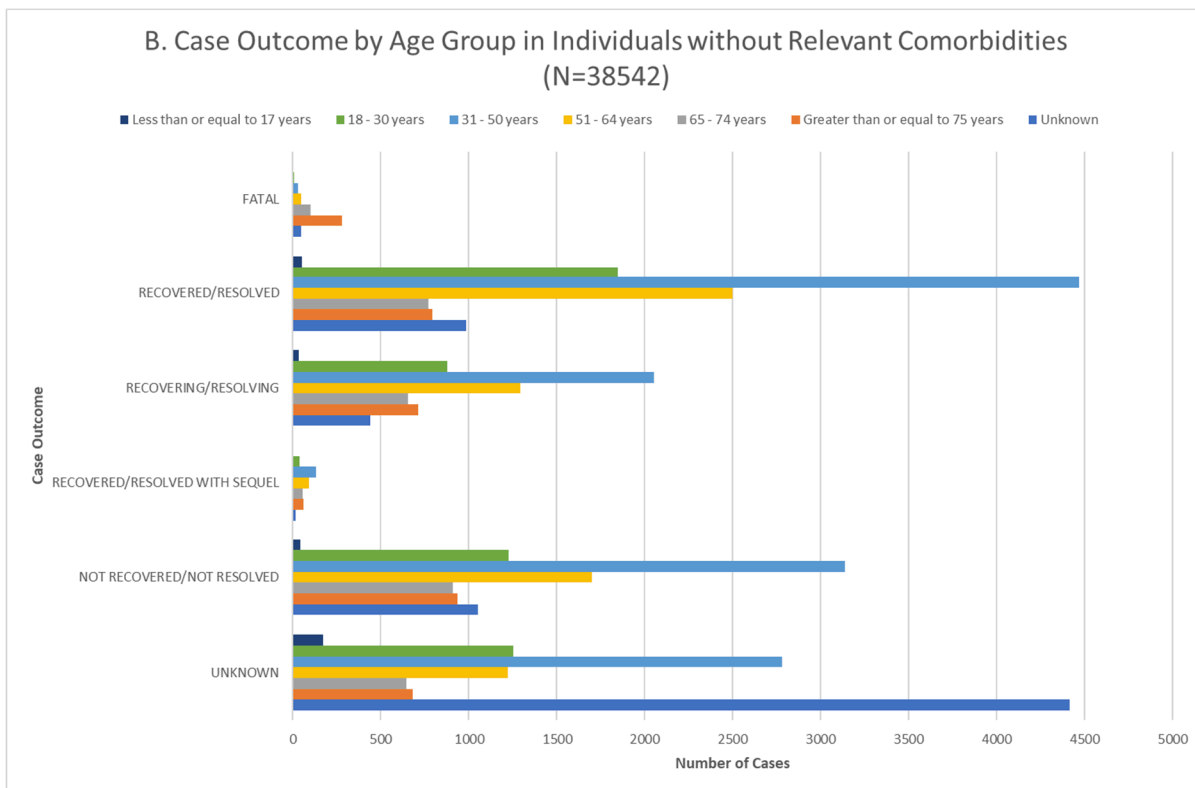
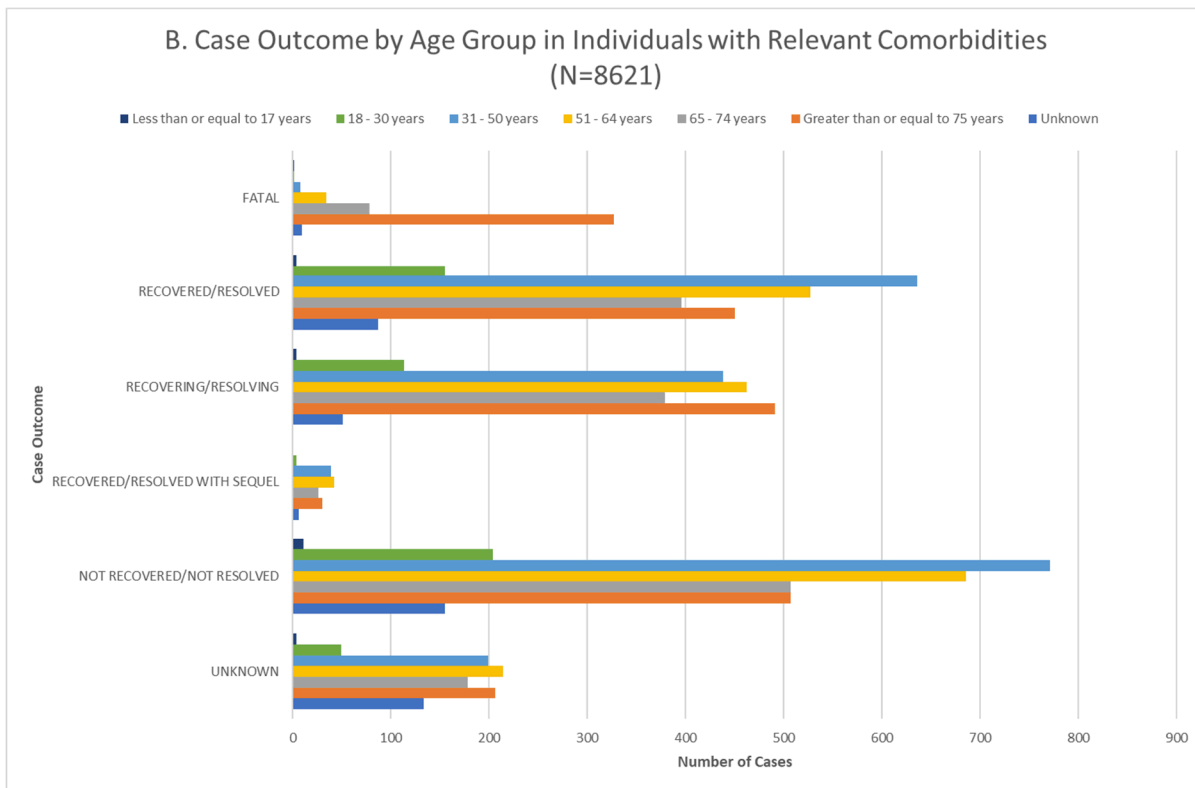
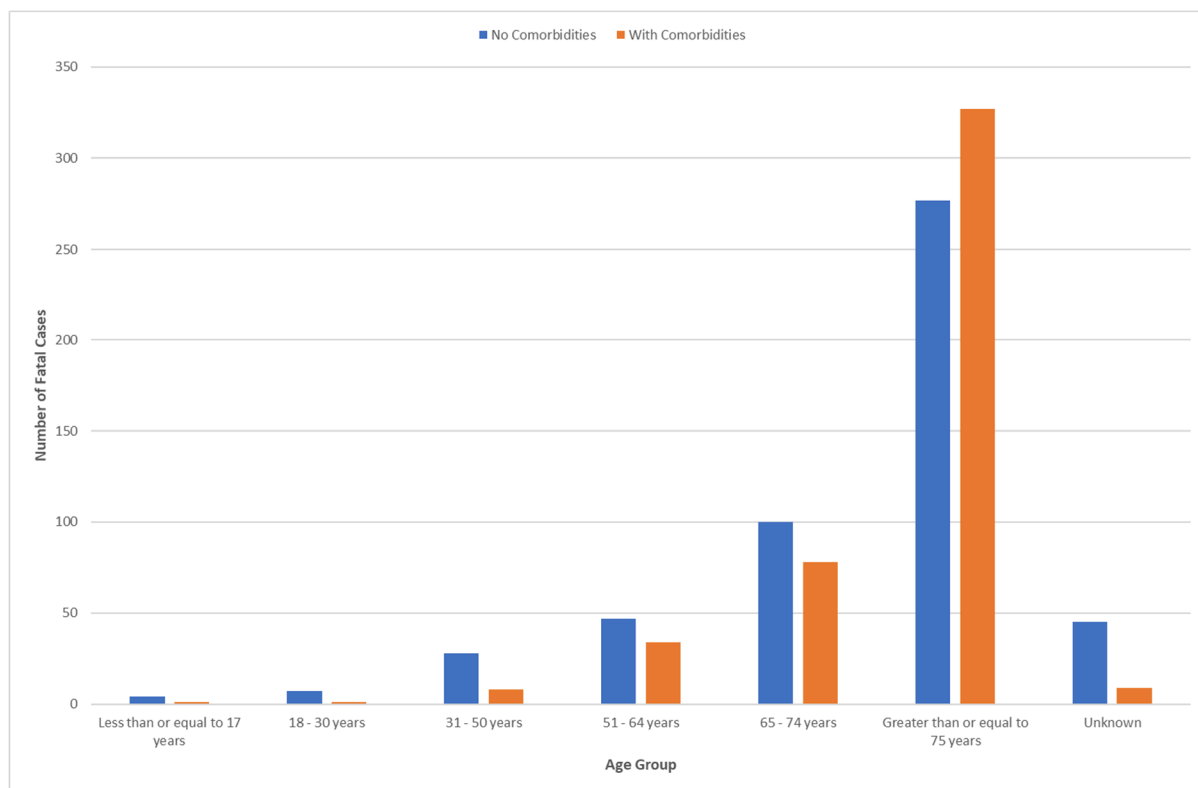


Figure 3. Fatal Case Outcome by Presence of Relevant Comorbidities and Age Group

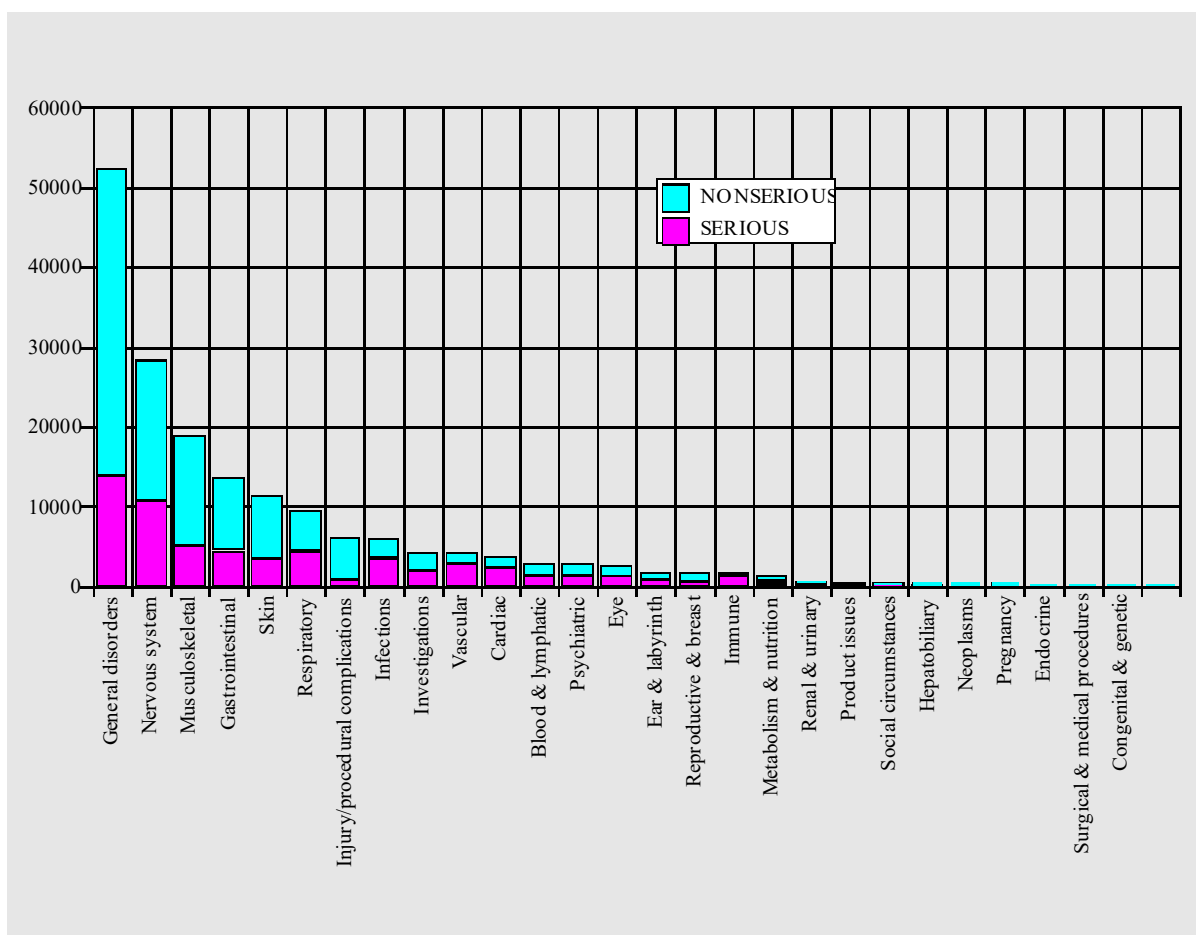


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ADVERSE EVENT DATA

As shown in Figure 4, the MedDRA SOC containing the greatest number of events ($\geq 2\%$) were General disorders and administration site conditions (52,360), Nervous system disorders (28,466), Musculoskeletal and connective tissue disorders (18,998), Gastrointestinal disorders (13,472), Skin and subcutaneous tissue disorders (11,416), Respiratory, thoracic and mediastinal disorders (9491), Injury, poisoning and procedural complications (6082), Infections and infestations (5772), Vascular disorders (4032), Investigations (4204), Cardiac disorders (3713). Of note, multiple adverse events may be reported in a single case.

Figure 4. General Overview: Total Number of Events by MedDRA SOC and Event Seriousness



The overall safety evaluation includes a review of the most frequently reported events by SOC and by the PT for events reported in ($\geq 2\%$) of all cases during the reporting interval as compared to the cumulative period since the first temporary authorisation for emergency supply on 01 December 2020.

Table 8. Events Reported in $\geq 2\%$ * Cases

	30 April 2021 Through 31 May 2021	Cumulatively Through 31 May 2021
MedDRA SOC MedDRA PT	AEs (AERP%) N = 47174	AEs (AERP%) N = 167956
Blood and lymphatic system disorders		
Lymphadenopathy ^a	1914 (4.06%)	8382 (4.99%)
Cardiac disorders		
Tachycardia ^a	1093 (2.32%)	3596 (2.14%)
Gastrointestinal disorders		
Nausea ^a	5053 (10.71%)	19303 (11.49%)
Diarrhoea ^a	1786 (3.79%)	6879 (4.10%)
Vomiting ^a	1664 (3.53%)	6253 (3.72%)
General disorders and administration site conditions		
Pyrexia ^a	7341 (15.56%)	29507 (17.57%)
Fatigue ^a	7076 (15.00%)	28432 (16.93%)
Chills ^a	4990 (10.58%)	20176 (12.01%)
Vaccination site pain ^a	4875 (10.33%)	18829 (11.21%)
Pain ^a	4185 (8.87%)	13770 (8.20%)
Asthenia ^a	3460 (7.33%)	10855 (6.46%)
Malaise ^a	2968 (6.29%)	12683 (7.55%)
Drug ineffective ^b	1030 (2.18%)	4545 (2.71%)
Feeling abnormal	967 (2.05%)	3399 (2.02%)
Infections and infestations		
COVID-19 ^b	1898 (4.02%)	7063 (4.21%)
Herpes zoster	1243 (2.63%)	2234 (1.33%)
Musculoskeletal and connective tissue disorders		
Myalgia ^a	5531 (11.72%)	21315 (12.69%)
Arthralgia ^a	4282 (9.08%)	16204 (9.65%)
Pain in extremity ^a	4103 (8.70%)	15661 (9.32%)
Nervous system disorders		
Headache ^a	11689 (24.78%)	40612 (24.18%)
Dizziness ^a	4039 (8.56%)	13267 (7.90%)
Paraesthesia ^a	1366 (2.90%)	5337 (3.18%)
Hypoaesthesia	1103 (2.34%)	3722 (2.22%)
Respiratory, thoracic and mediastinal disorders		
Dyspnoea ^c	1883 (3.99%)	7337 (4.37%)
Cough ^c	1413 (3.00%)	4434 (2.64%)
Oropharyngeal pain	1126 (2.39%)	3408 (2.03%)
Skin and subcutaneous tissue disorders		
Pruritus ^a	1949 (4.13%)	6121 (3.64%)
Rash ^a	1791 (3.80%)	5804 (3.46%)
Sensitive skin	1737 (3.68%)	2429 (1.45%)
Erythema ^a	1332 (2.82%)	4354 (2.59%)
Urticaria ^a	1002 (2.12%)	3275 (1.95%)
Total number of events	95889	349186

a. Listed or consistent with listed AEs in current RSI;

b. Listed per case processing conventions, except for fatal cases; for discussion of relevant cases of Drug ineffective/COVID-19 see Table 13, *Lack of Efficacy* subsection;

c. Consistent with anaphylactic reactions listed in the current RSI;

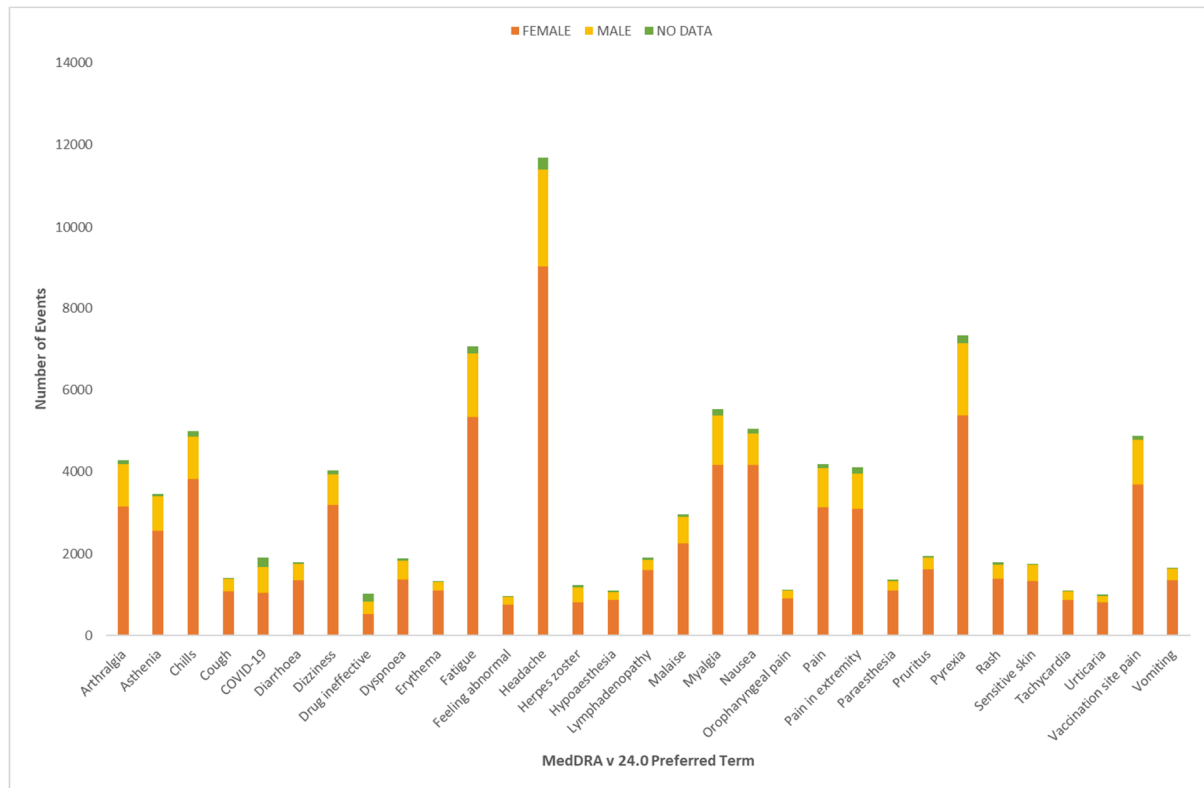
* Reporting proportion (% of total cases) in the current reporting period.

Most of the frequently reported events are listed or consistent with listed events as per the current RSI.

During the reporting interval, the distribution of the events reported in more than 2% of the cases by gender is presented in [Figure 5](#). The observed imbalance in the female gender distribution reflects the imbalance in the gender distribution of the cases received in the reporting period.

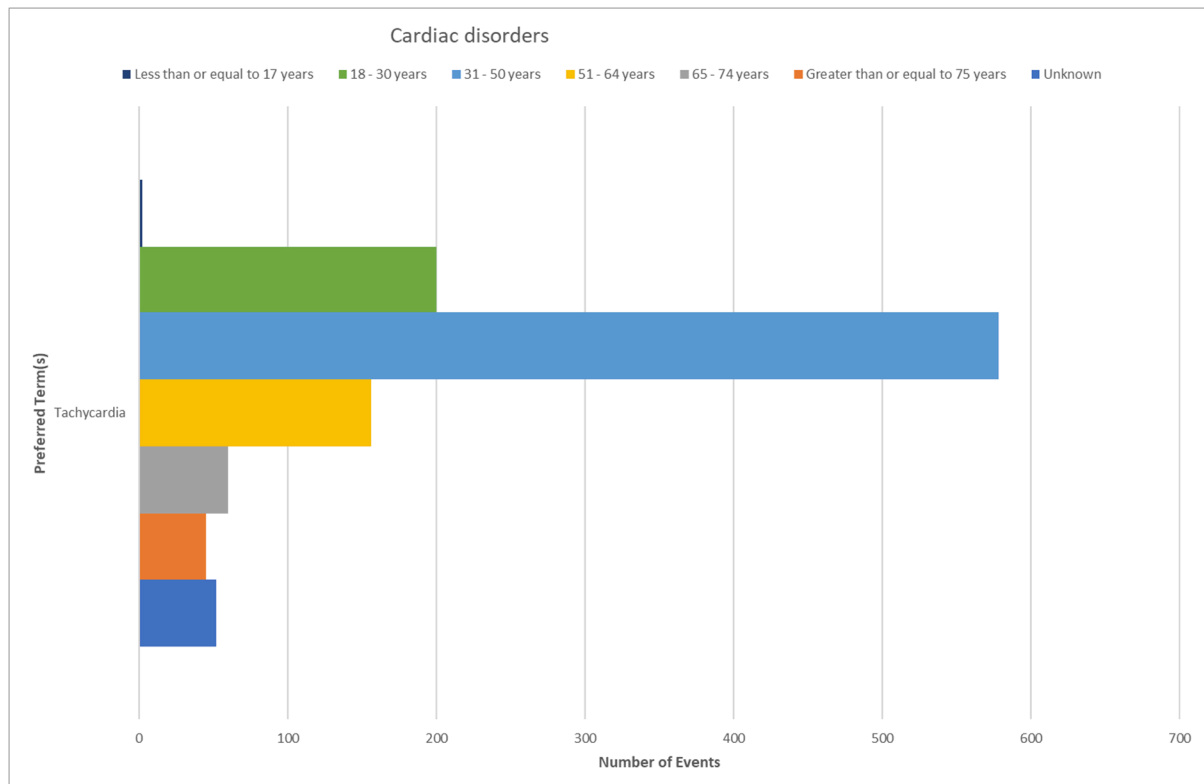
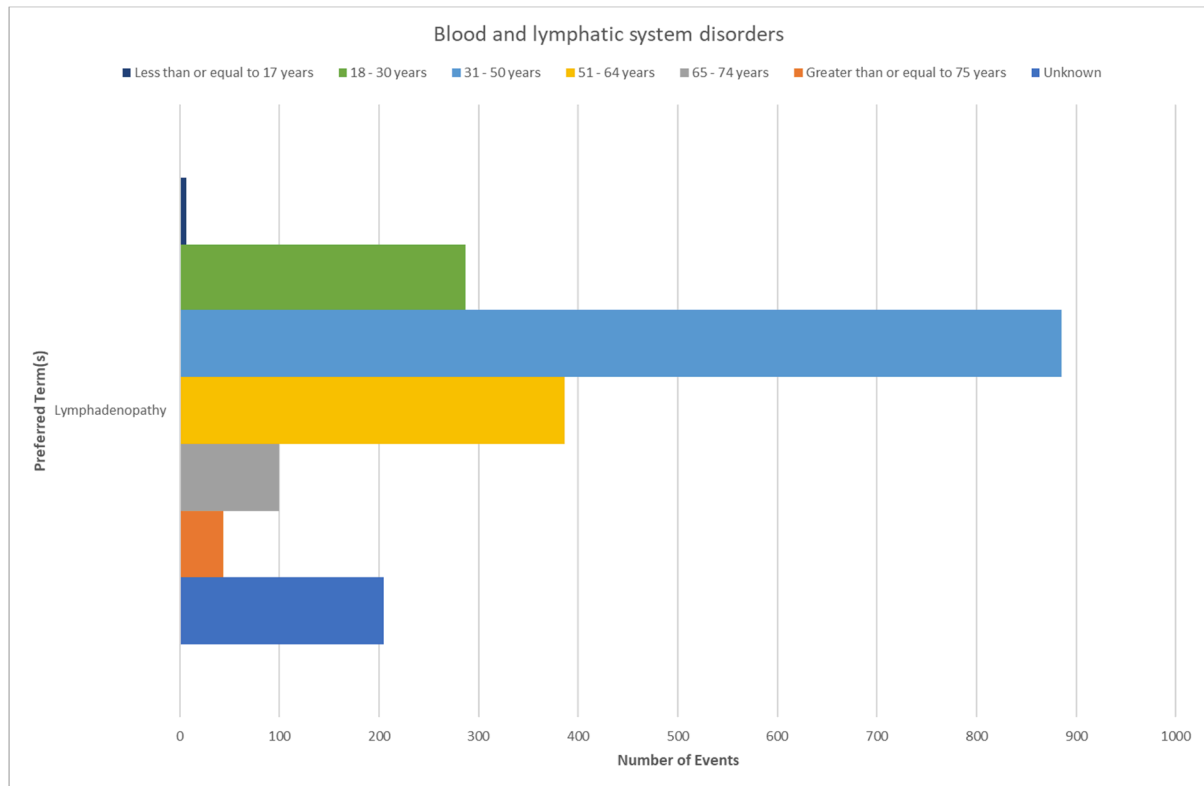
The distribution of the AEs reported in more than 2% of the cases by age group and by SOC is shown in [Figure 6](#) and [Figure 7](#). Across the SOC, the largest number of events is reported overall in the 31-50 years age group, except for the events included in the SOC Infection and infestations, COVID-19 and Herpes zoster, for which the largest number of occurrences is reported in the 75 years and older group (when the age was known).

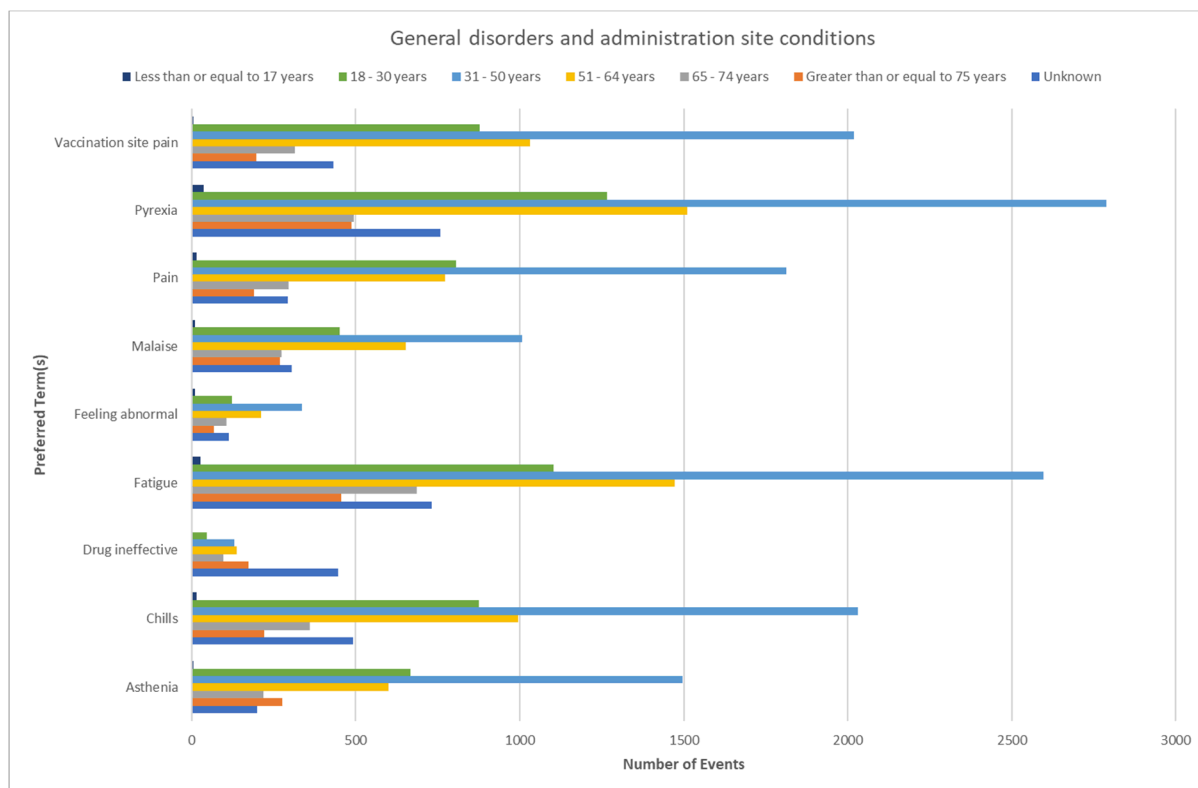
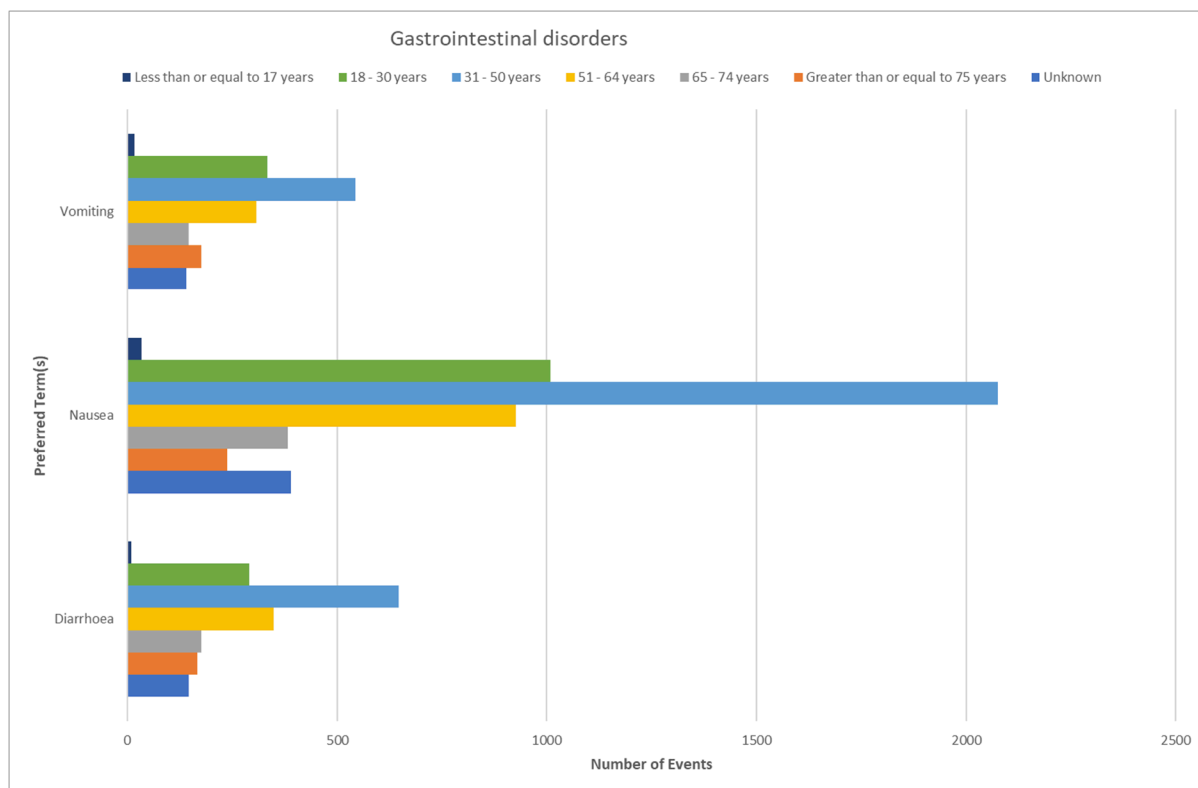
Figure 5. Events Reported in $\geq 2\%$ Cases in the Interval Period by Gender

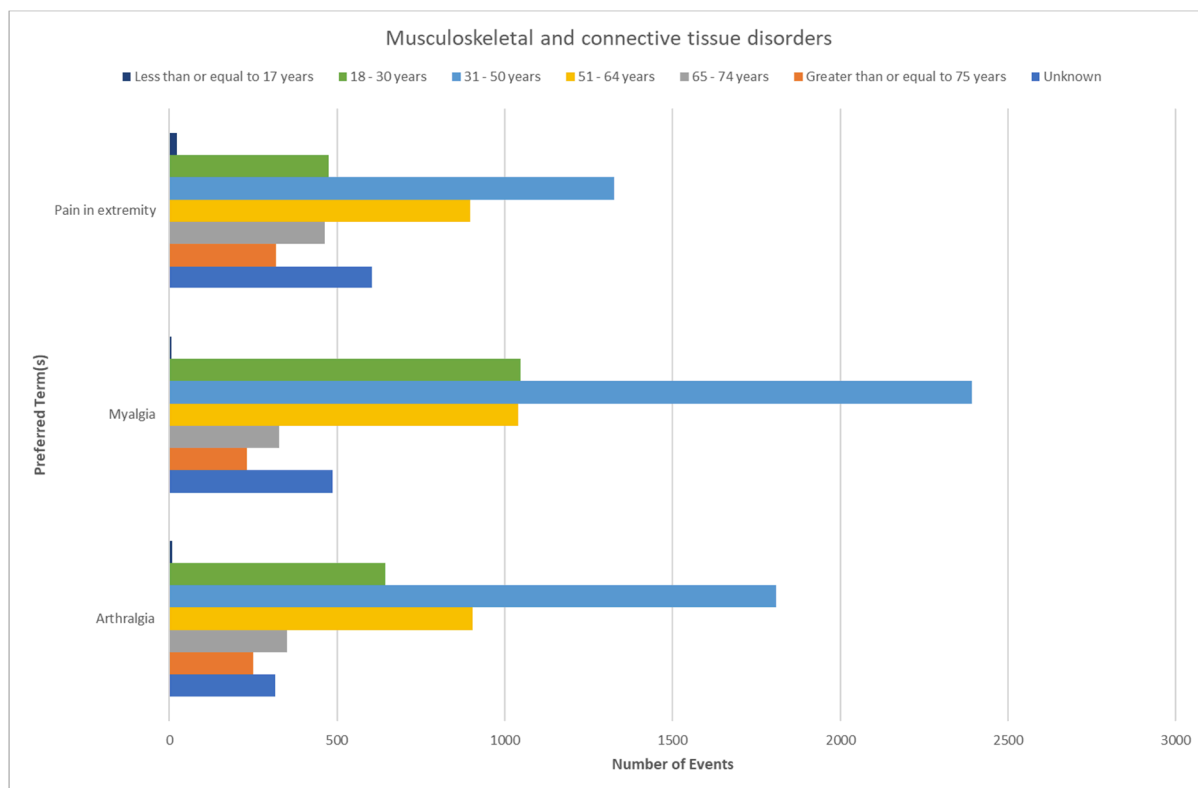
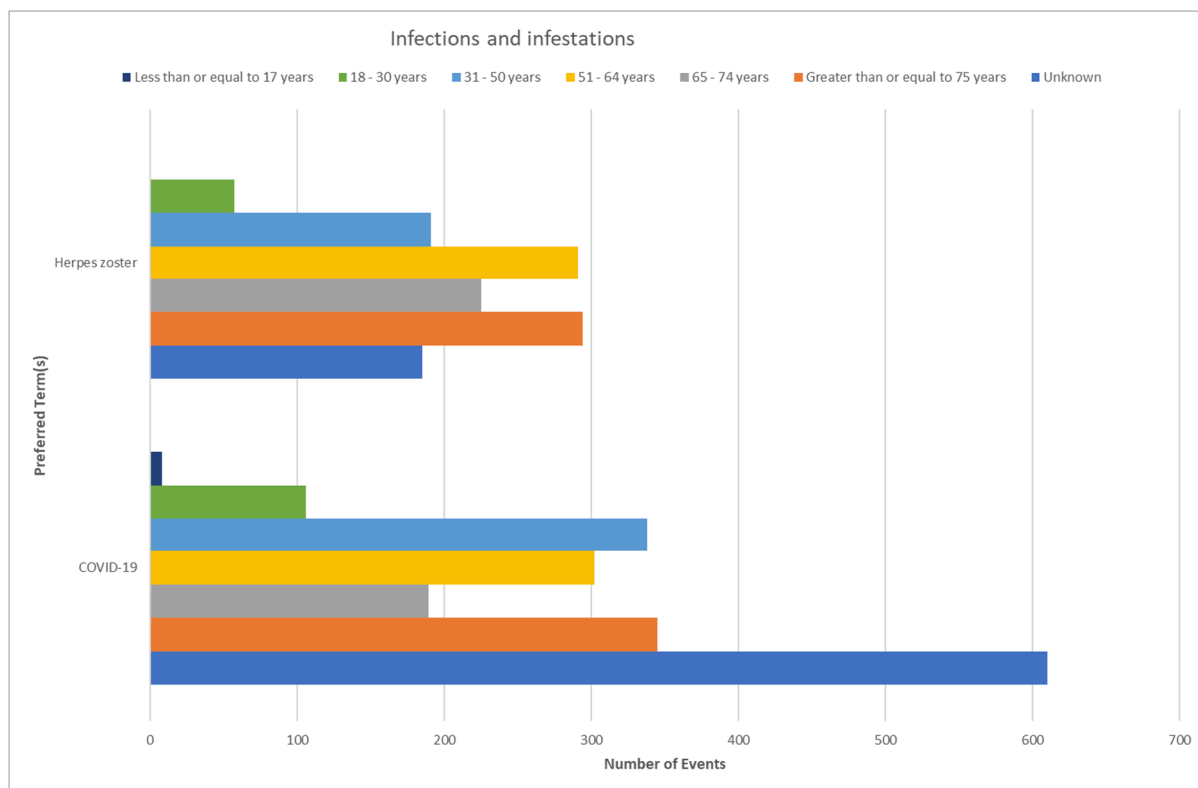


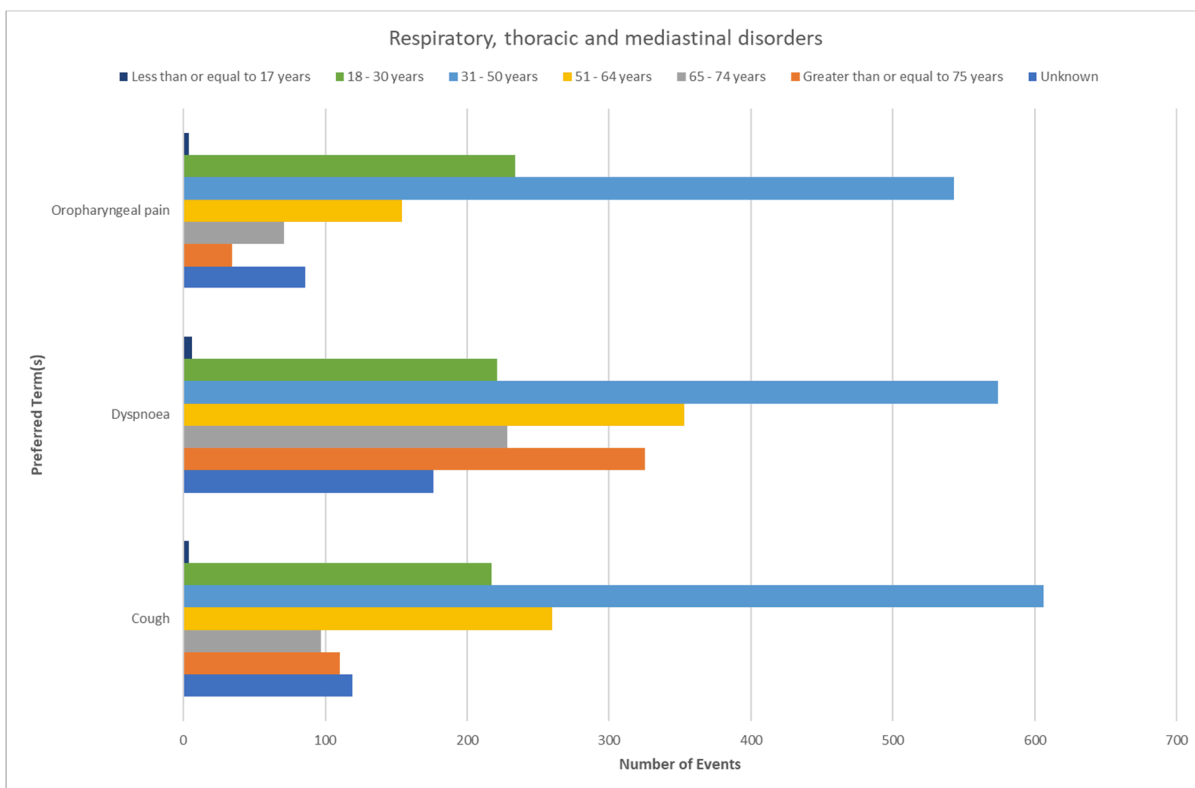
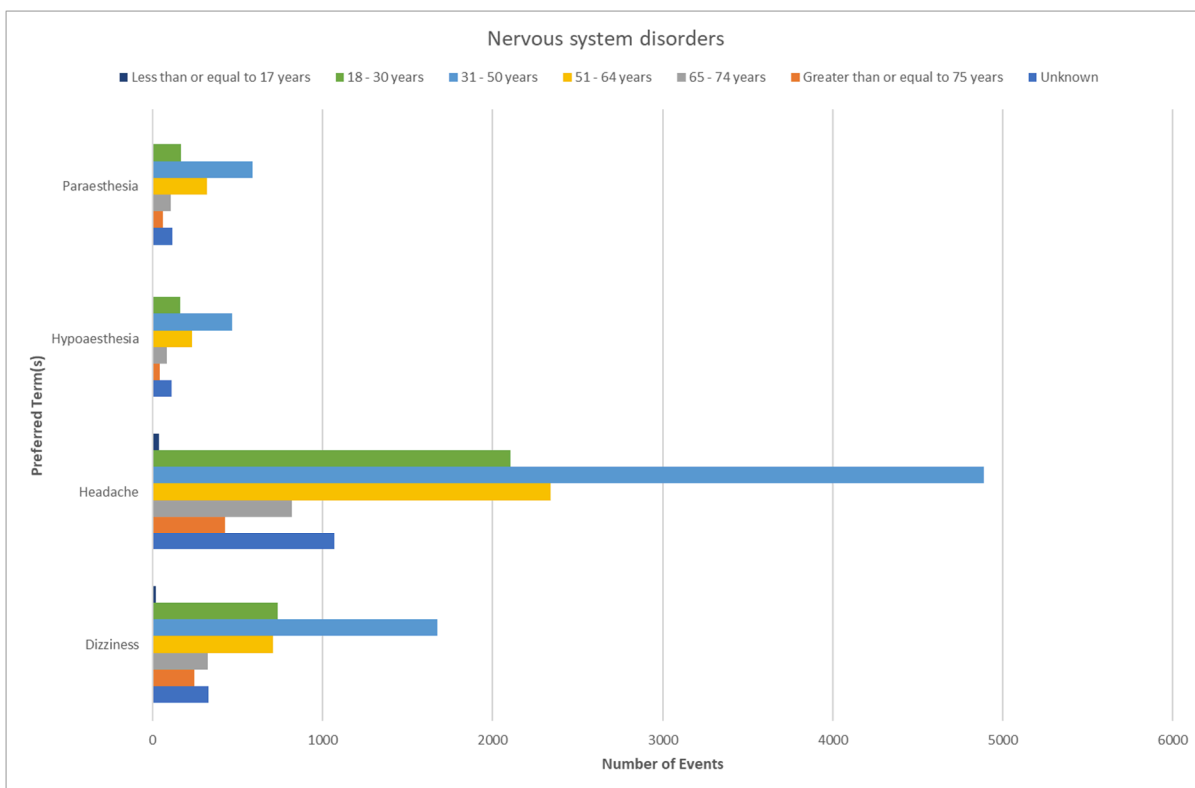
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Figure 6. PT Reported in $\geq 2\%$ in the Interval Period - by SOC and Age Group









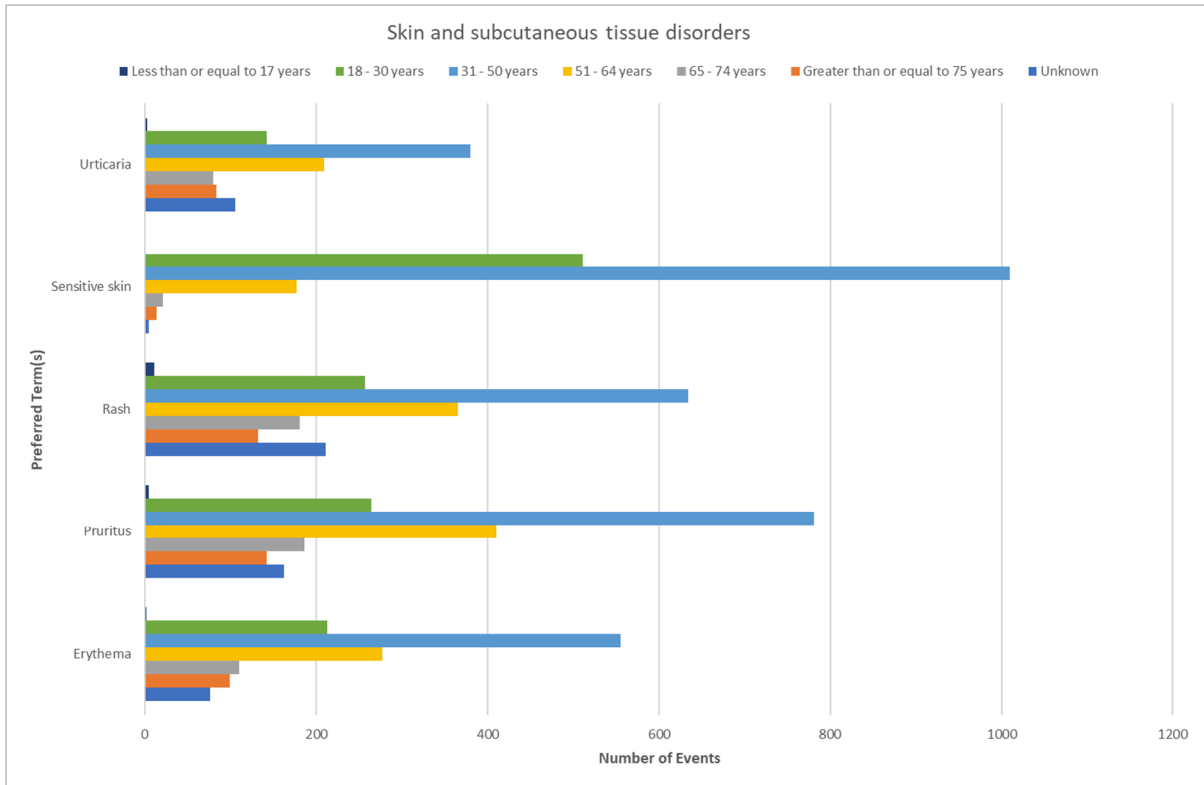
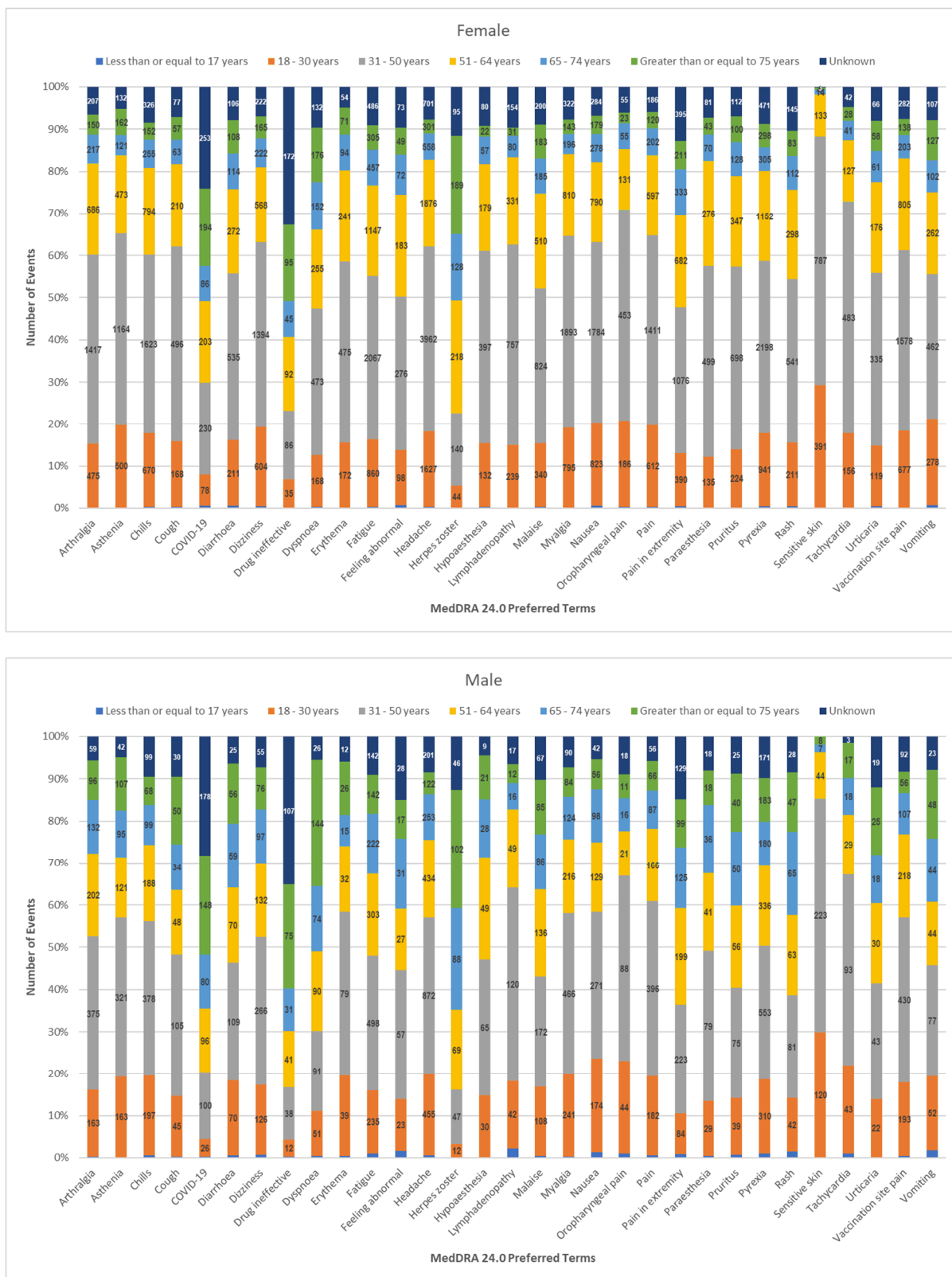


Figure 7. Events Reported in $\geq 2\%$ in the Interval Period by Age Group within Gender



9. SIGNAL AND RISK EVALUATION

9.1. Literature Review

Please refer to [Appendix 6](#) for a summary description of the interval literature review that is performed for the purpose of signal detection. There were no literature articles identifying new safety topics or signals for BNT162b2 during the reporting period.

9.2. Overview of Safety Topics and Signals During the Reporting Interval

Safety topics and Signals addressed during the reporting interval are presented below in Table 9.

Table 9. Overview of Safety Topics and Signals

Signal/Safety Topic	Status	Category
Appendicitis	Signal Closed	No Risk
Dizziness	Signal Closed	No Risk ^a
Myocarditis and Pericarditis	Signal Ongoing	Under evaluation
Abnormal behaviour/Mental disorder	Safety Topic Closed	No Validated Signal
Acquired hemophilia	Safety Topic Closed	No Validated Signal
Acute disseminated encephalomyelitis	Safety Topic Closed	No Validated Signal
Acute pancreatitis	Safety Topic Closed	No Validated Signal
Guillain-Barré syndrome	Safety Topic Closed	No Validated Signal
Menstrual cycle abnormalities	Safety Topic Closed	No Validated Signal
Transverse myelitis	Safety Topic Closed	No Validated Signal

a. The available information supports dizziness associated with the vaccination process (i.e. stress-related response) but not a causal association with the vaccine itself.

[Appendix 3](#) provides a summary of the safety topics and signals addressed during the reporting interval and [Appendix 3.1](#) an evaluation of these safety topics and signals.

As per EMA PRAC assessment report (Product No. EMEA/H/C/005735/MEA/002.3) received on the fourth SMSR, the following cumulative overview was performed for:

Appendicitis ([Appendix 3.2](#)).

As per EMA PRAC assessment report (Product No. EMEA/H/C/005735/MEA/002.4) received on the fifth SMSR, the following cumulative overviews were performed for:

ADEM ([Appendix 3.3](#));

Hepatic events ([Appendix 3.4](#));

TTS ([Appendix 3.5](#)).

As per requests received from different HAs, the following cumulative overview were performed for:

Transverse myelitis ([Appendix 3.6](#));

Dizziness ([Appendix 3.7](#));

GBS ([Appendix 3.8](#));

Myocarditis and Pericarditis ([Appendix 3.9](#)).

9.3. Summary of Safety Concerns

Table 10 summarises the comprehensive list of important risks and missing information reflected in risk management and pharmacovigilance plans globally for BNT162b2 at the beginning of the reporting period. The pharmacovigilance and risk management activities implemented for the safety concerns by Pfizer on behalf of BioNTech are global.

Table 10. Safety Concerns

Important Identified Risk	Anaphylaxis ^a
Important Potential Risk	Vaccine-Associated Enhanced Disease (VAED), Including Vaccine-Associated Enhanced Respiratory Disease (VAERD) ^a
Missing Information	Use in Pregnancy and While Breast Feeding ^a
	Use in Immunocompromised Patients ^b
	Use in Frail Patients With Co-Morbidities (e.g. COPD, Diabetes, Chronic Neurological Disease, Cardiovascular disorders, Active tuberculosis) ^{b,d}
	Use in Patients With Autoimmune or Inflammatory Disorders ^b
	Interaction With Other Vaccines ^b
	Long-Term Safety Data ^b
	Use in Paediatric Individuals <12 Years of Age ^c
	Vaccine Effectiveness ^{c,e}

Table 10. Safety Concerns

- a. As per both the EU RMP Version 1.1, approved on 15 April 2021 and the US PVP Version 0.4, dated 08 April 2021;
- b. As per the EU RMP Version 1.1, approved on 15 April 2021;
- c. As per the US PVP Version 0.4, dated 08 April 2021;
- d. As per the South Africa RMP, Version 1.0, dated 24 March 2021, active tuberculosis is included as an additional co-morbidity;
- e. As per the South Africa RMP, Version 1.0, dated 24 March 2021, this safety concern is stated as “Vaccine effectiveness against novel variant(s) in South Africa”. For vaccine effectiveness against novel variant(s) in South Africa, in the Lack of Efficacy Section ([Section 9.5.3](#)) it will be reviewed whether any reports and/or virological analysis of variant type on any breakthrough infection is reported among the relevant cases.

9.4. Summary of Adverse Events of Special Interest (AESIs)

The company’s AESI list takes into consideration the lists of AESIs from the following expert groups and regulatory authorities: Brighton Collaboration (SPEAC), ACCESS protocol, US CDC (preliminary list of AESI for VAERS surveillance), MHRA (unpublished guideline).

The AESI terms are incorporated into a TME list and include events of interest due to their association with severe COVID-19 and events of interest for vaccines in general.

The AESI list includes MedDRA PTs, HLTs, HLGTs or MedDRA SMQs and can be changed as appropriate based on the evolving safety profile of the vaccine.

Please refer to [Appendix 5](#) for the list of the company’s AESIs (TME List) for BNT162b2. Please refer to [Appendix 5.1](#) for the observed versus expected analysis for AESIs.

9.5. Evaluation of Safety Concerns

Evaluation of new information collected from post-marketing data sources¹⁵ for BNT162b2 during the interval reporting period for important identified and important potential risks, AESIs, special situations and missing information is provided below in [Section 9.5.1](#), [Section 9.5.2](#), [Section 9.5.3](#) and [Section 9.5.4](#).

9.5.1. Evaluation of Important Identified and Important Potential Risks

[Table 11](#) below presents the evaluation of new information received during the interval reporting period from post-marketing data sources¹⁵ for the important identified and important potential risks of BNT162b2.

Table 11. Risks Evaluation for BNT162b2

Safety Risk	Post-Marketing ^a Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
Important Identified Risk	
<p>Anaphylaxis^b</p> <p><i>Search criteria:</i>³⁰ PTs <i>Anaphylactic reaction, Anaphylactic shock, Anaphylactoid reaction, Anaphylactoid shock</i></p>	<p>Number of cases by searching the relevant PTs³⁰ 745 (1.6% compared to 4.7% of the total PM dataset of the previous SMSR) of which 648 were medically confirmed and 97 were non-medically confirmed.</p> <ul style="list-style-type: none"> Number of events: 2942 (of which 760 were PTs of interest); Country of incidence (>2%): Japan (459), UK (48), US (45), Germany and Australia (26 each), Norway (20), France (17) and Italy (16); Subjects' gender: female (624), male (90) and unknown (31); Subjects' age (n = 673): ranged from 1 year (1 subject) to 96 years (mean = 44.2 years, median = 44 years); Medical history (n=450): the most frequently (≥2%) reported medical conditions included Asthma (113), Food allergy (95), Drug hypersensitivity (56), Hypertension (45), Seasonal allergy (41), Hypersensitivity (36) and Anaphylactic reaction (27). Number of vaccine doses administered at the time of the event onset: 1 dose in 484 cases, 2 doses in 166 cases and number of doses was not specified in 95 cases. Time to event onset: <ul style="list-style-type: none"> Same day: 602 cases (305 within 15 minutes). 1 day: 25 cases 2-3-4 days: 10 cases 10-13-21 days: 5 cases 46 days: 1 case Not specified (102 cases) Most frequently reported individual PTs (≥2%): Anaphylactic reaction (672), Dyspnoea (110), Nausea (78), Anaphylactic shock (74), Cough (72), Pruritus (63), Erythema (60), Headache (57), Blood pressure increased (50), Malaise and Oropharyngeal discomfort (49 each), Feeling abnormal and Pyrexia (47 each), Dizziness and Rash (45 each), Tachycardia (44), Vomiting (42), Urticaria (40), Throat tightness (36), Palpitations (34), Heart rate increased (27), Hypoaesthesia (26), Chest discomfort (25), Chills and Oxygen saturation decreased (23), Hypersensitivity (22), Swollen tongue (21), Paraesthesia and Paraesthesia oral (20 each), Lip swelling and Tremor (19 each), Abdominal pain, Asthma, Dysphonia and Fatigue (17 each), Hypotension (16), Blood pressure

³⁰ Updated search criteria starting from the present SMSR (see 5th Monthly Safety Update preliminary PRAC Assessment Report; EMEA/H/C/005735/MEA/002.4). Previously, cases were retrieved by using the Anaphylactic reaction SMQ (Narrow and Broad, with the algorithm applied) selecting relevant cases according to Brighton Collaboration criteria.

Table 11. Risks Evaluation for BNT162b2

Safety Risk	Post-Marketing ^a Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
	<p>decreased, Flushing, Pallor, Pharyngeal swelling, Swelling face, Throat irritation and Wheezing (15 each).</p> <ul style="list-style-type: none"> • Relevant event seriousness: serious (759), non-serious (1); • Relevant event outcome:³¹ fatal (6), resolved/resolving (579), resolved with sequelae (13), not resolved (32), unknown (132). <p><u>Fatal cases: 5</u></p> <ul style="list-style-type: none"> • <u>Country: Ireland</u> The case involved an 82- year-old female patient suffering from several cardiac and respiratory comorbidities (Aortic valve replacement, Atrial fibrillation, Chronic obstructive pulmonary disease and Rheumatic heart disease). The patient experienced malaise and cardiopulmonary arrest about 7 hours after receiving the 2nd vaccine dose (Lot Number: EW8904). The patient was transferred to the hospital where reported hypoxic brain damage and died. The fatal event Cardio-respiratory arrest was judged a delayed Anaphylactoid reaction to the vaccine by the treating physician. All the events reported a fatal outcome (Anaphylactoid reaction, Cardio-respiratory arrest, Brain injury and Malaise). It was not reported if an autopsy was performed. • <u>Country: UK</u> The case described a 96-year-old male patient who died due to Anaphylactic reaction occurrence, 15 minutes after receiving the 1st vaccine dose (Lot number: EJ0724). The nature of the fatal event is still under evaluation. It was not reported if an autopsy was performed. • <u>Country: Sweden</u> The case involved a 55-year-old female patient who experienced first signs of Anaphylactic reaction 5 minutes after receiving the 1st vaccine dose (Lot number: EX6537) associated with Anaphylactic shock. Despite treatments with epinephrine and iv fluids the patient died. Both the events reported a fatal outcome. • <u>Country: Japan</u> The case described a 91-year-old female patient with a medical history of Cardiac failure chronic, Myocardial infarction (3 years before) and Dementia Alzheimer's type.

³¹ Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events.

Table 11. Risks Evaluation for BNT162b2

Safety Risk	Post-Marketing ^a Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
	<p>Two (2) hours and 15 minutes after receiving the 1st vaccine dose (Lot number: ET9096), the patient experienced Cardio-respiratory arrest and Apnoea. She was intubated and despite cardiac message and mechanical ventilation she died 4 hours and 25 minutes after receiving the vaccine. The reporting physician considered the baseline condition of the patient relevant to the event's onset but did not exclude that an anaphylactic reaction to the vaccine could have caused the sudden cardio-pulmonary arrest (although skin and mucosal manifestation of anaphylaxis were not confirmed). All the reported events had a fatal outcome (Cardio-respiratory arrest, Apnoea and Anaphylactic reaction). It was unknown if an autopsy was performed.</p> <ul style="list-style-type: none"> Country: US The case described a 60-year-old male patient suffering from an unspecified hypersensitivity who died due to Anaphylactic reaction following vaccine administration (number dose was not specified). No further information was available at the time of the report. <p>Discussion</p> <p>Anaphylaxis is an adverse reaction in Section 4.8 of the EU SmPC, in the CDS and local labels/fact sheets. It is also included as an Important identified risk in the EU RMP and in the US PVP. Based upon review of the available information, no additional change to the RSI is warranted at this time. Based on the assessment report for the post-authorisation measure LEG-022.1 for the 'cumulative review anaphylaxis' (EMA/PRAC/181346/2021), no amendment of the current labeling is warranted.</p> <p>Conclusion: Evaluation of Anaphylaxis cases did not reveal any significant new safety information. Anaphylaxis is appropriately described in the product labeling as are non-anaphylactic hypersensitivity events. Surveillance will continue.</p>
Important Potential Risk	
Vaccine-Associated Enhanced Disease (VAED) Including Vaccine-Associated Enhanced Respiratory Disease (VAERD) ^{b,c}	<p>VAED is a modified and/or severe presentation of an infectious disease affecting individuals exposed to the wild-type pathogen after having received vaccine designed to prevent infection.³²</p> <p>As noted by the Brighton Collaboration, there is currently no uniformly accepted definition of VAED (or VAERD) and the BC</p>

³² Flor M Munoz, et al. Vaccine-associated Enhanced Disease: Case Definition and Guidelines for Data Collection, Analysis, and Presentation of Immunization Safety Data. Brighton Collaboration. September 2020, Vaccine Journal Draft Manuscript.

Table 11. Risks Evaluation for BNT162b2

Safety Risk	Post-Marketing ^a Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
	<p>working group considers that a definitive case of VAED (Level 1 diagnostic certainty) cannot be ascertained with current knowledge of the mechanisms of pathogenesis of the condition; they have provided guidance on levels of diagnostic certainty of VAED cases based on various laboratory and clinical findings.</p> <p>No post-authorized AE reports have been identified as cases of VAED/VAERD, therefore, there is no observed data at this time. An expected rate of VAED is difficult to establish so a meaningful observed/expected analysis cannot be conducted at this point based on available data. The feasibility of conducting such an analysis will be re-evaluated on an ongoing basis as data on the virus grows and the vaccine safety data continues to accrue.</p> <p>The search criteria utilised to identify potential cases of VAED/VAERD for this SMSR include the PTs Vaccine associated enhanced disease and Vaccine associated enhanced respiratory disease³³ or other PTs indicating a lack of effect of the vaccine and medical disorders chosen because they are PTs potentially indicative of severe or atypical COVID-19.</p> <p>Overview</p> <ul style="list-style-type: none"> • Number of cases based on search strategy: 151³⁴ (0.3% of the total PM dataset, compared to 0.4% in the previous reporting period), all serious (of which 119 are medically confirmed). • Country of incidence: France (38), US (18), Italy (15), Austria (13), Hungary (12), Spain (7), Germany (6), Czech Republic, Norway, UK (4 each), Mexico (3); the remaining 27 cases originated from 18 different countries. • Gender: female (76), male (74), unknown (1). • Age: 17 to 100 years (n = 140), mean = 71.2 years, median = 77.0 years. • Respiratory system PTs: COVID-19 pneumonia (49), Dyspnoea (46), Respiratory failure (14), Acute respiratory distress syndrome, Hypoxia (4 each), and Tachypnoea (3) • Gastrointestinal/Hepatic system PTs: Diarrhoea (31), Vomiting (9), and Abdominal pain (6) • Cardiovascular system PTs: Cardiac failure (6), Arrhythmia (3), Acute myocardial infarction and Cardiogenic shock (1 each) • Vascular system PTs: Pulmonary embolism (6), Deep vein thrombosis (2), and Peripheral ischaemia (1)

³³ New PTs introduced with MedDRA version 24.0.

³⁴ Note: 3 additional cases retrieved with this search strategy were excluded from the discussion for the following reasons: 2 cases, where the PT Drug ineffective was coded, reported that the patients developed SARS-CoV-2 infection during the early days from the first dose (days 1 – 13); the vaccine has not had sufficient time to stimulate the immune system and, consequently, the development of a vaccine preventable disease during this time is not considered a potential lack of effect of the vaccine; in 1 case the PT Therapeutic product effect decreased did not refer to BNT162b2 vaccine.

Table 11. Risks Evaluation for BNT162b2

Safety Risk	Post-Marketing ^a Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
	<ul style="list-style-type: none"> Haematological system PTs: Thrombocytopenia (8) Renal system PTs: Acute kidney injury (6) and Renal failure (2) Neurological system PTs: Altered state of consciousness (3) Cerebrovascular accident, and Meningitis (1 each) Other systems, relevant PTs: Multiple organ dysfunction syndrome (4) Case outcome: resolved/resolving (54), resolved with sequelae (1), not resolved (33), unknown (20), and fatal (43). <p>COVID-19 positivity and severity of events</p> <ul style="list-style-type: none"> Suspected COVID-19 infection: 11 (no information on confirmatory tests performed or test negative). Confirmed COVID-19 infection: 140 (test positive or implied COVID-19 infection). Seriousness criteria for the total 151 cases: <ul style="list-style-type: none"> Medically significant: 60 (of which 1 serious also for disability) Hospitalisation required (non-fatal/non-life threatening): 40 Life threatening: 8 (of which 1 serious also for disability) Death: 43 <p>Seriousness criteria: medically significant (60)</p> <ul style="list-style-type: none"> In 52 out of 60 cases where the seriousness criterion was “medically significant”, the subjects had a confirmed COVID-19 infection after vaccination, while 8 subjects had unconfirmed suspected COVID-19 infection. These 60 subjects did not require hospitalisation. In the 52 confirmed COVID-19 cases, subjects’ age ranged from 27 to 99 years (n = 44), Mean = 56.5 years, Median = 51.0 years. Among the 52 confirmed COVID-19 cases, latency of COVID occurrence was reported for 40 cases: <ul style="list-style-type: none"> day 14 to 39 days after dose 1 (5). 7 days to 120 days after dose 2 (33). 17 days and 20 days after vaccination [dose number not reported] (2) <p>The commonly (>3 occurrences) reported events (PTs) in these 52 cases were: COVID-19 (46), Drug ineffective (29), Vaccination failure (23), Dyspnoea (20), Diarrhoea (16), Pyrexia (14), Fatigue (12), Cough (10), Headache (8), COVID-19 pneumonia (7), Asthenia, Myalgia (5 each), Ageusia, Anosmia, Chills, and Vomiting (4 each).</p> <p>The outcome of COVID-19 infection related events (54) reported in these 52 cases were: resolved/resolving (28), not resolved (11), and unknown (15).</p> <p>Seriousness criteria: hospitalisation (non-fatal, non-life threatening) (40)</p>

Table 11. Risks Evaluation for BNT162b2

Safety Risk	Post-Marketing ^a Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
	<ul style="list-style-type: none"> Hospitalisation occurred in 40 subjects, for 2 of them COVID-19 was not confirmed. In the 38 confirmed COVID-19 cases, subjects' age ranged from 37 to 98 years (n = 37), Mean = 77.5 years, Median = 83.0 years Among the 38 confirmed COVID-19 cases, latency of COVID occurrence was reported for 30 cases: <ul style="list-style-type: none"> Day 14 to 48 days after dose 1 (7). 1 day to 69 days after dose 2 (22). 3 days after vaccination [dose number not reported] (1) <p>The commonly (>3 occurrences) reported events (PTs) in these 38 cases were: COVID-19 (25), Vaccination failure (21), Drug ineffective (17), COVID-19 pneumonia (14), Dyspnoea (11), Pyrexia (10), Asthenia, Diarrhoea (6 each), Oxygen saturation decreased (5), Acute respiratory failure, and Cough (4 each).</p> <p>The outcome of COVID-19 infection related events (42) reported in these 38 cases were: resolved/resolving (15), not resolved (12), and unknown (15).</p> <p>Seriousness criteria: life threatening (8)</p> <ul style="list-style-type: none"> Hospitalisation occurred in 6 of the 8 cases characterised as life-threatening; COVID-19 was confirmed in all the 8 subjects. In these 8 confirmed COVID-19 cases, subject's age ranged from 65 to 86 years (n = 8), Mean = 74.6 years, Median = 74.0 years Latency of COVID-19 occurrence was reported in 7 of the 8 cases: <ul style="list-style-type: none"> 15 days and 71 days after dose 1 (2) 3 days to 67 days after dose 2 (4) 13 days after vaccination [dose number not reported] (1) <p>The events (PTs) reported more than once in these 8 cases were: Drug ineffective (6), COVID-19 (5), COVID-19 pneumonia (3), Dyspnoea, Thrombocytopenia, and Vaccination failure (2 each).</p> <p>The outcome of COVID-19 infection related events (9) reported in these 8 cases were: resolved/resolving (4), resolved with sequelae (1), not resolved (2), and unknown (2).</p> <p>Seriousness criteria: death (43)</p> <ul style="list-style-type: none"> Forty-three (43) subjects died, of which COVID-19 was not confirmed in 1 case; the remaining 42 confirmed cases are described below. <ul style="list-style-type: none"> Age: 17 to 100 years (n = 42), Mean = 81.1 years, Median = 82.5 years. Country of incidence: France (15), Hungary (8), Austria (6), Germany, Malta (2 each), Croatia, Greece, India, Norway, Peru, Portugal, Slovakia, Switzerland, and US (1 each)

Table 11. Risks Evaluation for BNT162b2

Safety Risk	Post-Marketing ^a Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
	<ul style="list-style-type: none"> ○ Gender: female (14), male (28). ○ Medical history (n = 37) of clinical significance included PTs in the following SOC: ▪ Vascular disorders: 22 (52.4%) [Hypertension (20), Peripheral arterial occlusive disease (2), Aortic aneurysm, Aortic stenosis, Arteriosclerosis, Essential hypertension, and Peripheral venous disease (1 each)] ▪ Cardiac disorders: 21 (50.0%) [Atrial fibrillation (12), Arrhythmia, Cardiac failure, Coronary artery disease (3 each), Cardiac disorder, Cardiac failure congestive, Myocardial ischaemia (2 each), Acute myocardial infarction, Atrial flutter, Atrioventricular block, Cardiac amyloidosis, Cardiac valve disease, Hypertensive cardiomyopathy, and Hypertensive heart disease (1 each)] ▪ Metabolism and nutrition disorders: 19 (45.2%) [Type 2 diabetes mellitus (8), Obesity (7), Diabetes mellitus (3), Hypercholesterolaemia, Hyperuricaemia, Type 1 diabetes mellitus (2 each), Glucose tolerance impaired, Haemochromatosis, Hyperkalaemia, Hyponatraemia, Ketosis-prone diabetes mellitus, and Marasmus (1 each)] ▪ Nervous system disorders: 14 (33.3%) [Cerebrovascular accident, Cognitive disorder (4 each), Dementia (2), Carotid arteriosclerosis, Cerebral ischaemia, Cerebrovascular disorder, Dementia Alzheimer's type, Haemorrhagic stroke, Ischaemic stroke, Neurodegenerative disorder, Parkinsonism, Transient ischaemic attack, Vascular dementia, and Vertebrobasilar insufficiency (1 each)] ▪ Respiratory, thoracic and mediastinal disorders: 14 (33.3%) [Chronic obstructive pulmonary disease (5), Sleep apnoea syndrome (4), Asthma, Bronchitis chronic, Hydrothorax, Pickwickian syndrome, Pulmonary fibrosis, and Respiratory disorder (1 each)] ▪ Renal and urinary disorders: 12 (28.6%) [Chronic kidney disease (7), Renal failure (3), Acute kidney injury, End stage renal disease, and Nephropathy (1 each)] ▪ Neoplasms benign, malignant and unspecified (incl cysts and polyps): 8 (19.0%) [Prostate cancer (3), Adenocarcinoma of colon, Adult T-cell lymphoma/leukaemia, Chronic lymphocytic leukaemia, Myelodysplastic syndrome, Myeloid leukaemia, Skin cancer, and Uterine neoplasm (1 each)] ▪ Gastrointestinal disorders: 4 (9.5%) [Ascites (2), Colitis microscopic, Gastrointestinal haemorrhage, Oesophagitis, and Peptic ulcer (1 each)]

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Table 11. Risks Evaluation for BNT162b2

Safety Risk	Post-Marketing ^a Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
	<ul style="list-style-type: none"> ▪ Hepatobiliary disorders: 3 (7.1%) [Cirrhosis alcoholic (2), Hepatic cirrhosis, Hepatic failure, and Liver disorder (1 each)] ▪ Infections and infestations: 2 (4.8%) [Candida infection, Endocarditis, and Pneumonia (1 each)] ▪ Congenital, familial and genetic disorders: 1 (2.4%) [Hypertrophic cardiomyopathy (1)] ▪ Injury, poisoning and procedural complications: 1 (2.4%) [Asbestosis (1)] ▪ Psychiatric disorders: 1 (2.4%) [Alcoholism (1)] ▪ Surgical and medical procedures: 1 (2.4%) [Renal transplant (1)] <ul style="list-style-type: none"> • Latency of COVID-19 occurrence was reported in 33 of the 42 cases: <ul style="list-style-type: none"> ○ 15 days to 23 days after dose 1 (5). ○ 5 days to 73 days after dose 2 (27). ○ 25 days after vaccination [dose number not reported] (1). <p>Cause of death (n = 42) reported more than twice were: COVID-19 pneumonia (22), COVID-19 (18), Vaccination failure (16), Drug ineffective (9), Respiratory failure (7), Dyspnoea (4), Acute respiratory failure, and Multiple organ dysfunction syndrome (3 each).</p> <p>In 26 fatal cases, vaccination failure was reported (cross ref. with Section 9.5.3– Lack of efficacy):</p> <ul style="list-style-type: none"> • Twenty-five (25) of these cases involved elderly subjects (aged 65 to 98 years), including 24 subjects with underlying medical history of clinical significance. • The remaining case involved a 54-year-old male subject with a medical history of hypertension, obesity and a surgical history of renal transplantation. The subject experienced COVID 19 pneumonia about 28 days after dose 2. The patient was hospitalised, but details of the treatment provided was not reported. The patient died a month after developing infection. <p>VAED may present as severe or unusual clinical manifestations of COVID-19. Overall, there were 140 subjects with confirmed COVID-19 following one or both doses of the vaccine; 89 of the 140 cases were severe, resulting in hospitalisation, disability, life-threatening consequences or death. None of the 140 cases could be definitively considered as having VAED/VAERD.</p> <p>Conclusion: In this review of subjects with COVID-19 following vaccination, based on the current evidence, VAED/VAERD remains a theoretical risk for the vaccine. Surveillance will continue.</p>

a. Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources;

Table 11. Risks Evaluation for BNT162b2

Safety Risk	Post-Marketing ^a Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
b. As per both the EU RMP Version 1.1, approved on 15 April 2021, and the US PVP, Version 0.4, dated 08 April 2021;	
c. Search criteria: PTs Vaccine associated enhanced respiratory disease OR Vaccine associated enhanced disease OR Standard Decreased Therapeutic Response Search AND PTs Dyspnoea; Tachypnoea; Hypoxia; COVID 19 pneumonia; Respiratory Failure; Acute Respiratory Distress Syndrome; Cardiac Failure; Cardiogenic shock; Acute myocardial infarction; Arrhythmia; Myocarditis; Vomiting; Diarrhoea; Abdominal pain; Jaundice; Acute hepatic failure; Deep vein thrombosis; Pulmonary embolism; Peripheral Ischaemia; Vasculitis; Shock; Acute kidney injury; Renal failure; Altered state of consciousness; Seizure; Encephalopathy; Meningitis; Cerebrovascular accident; Thrombocytopenia; Disseminated intravascular coagulation; Chillblains; Erythema multiforme; Multiple organ dysfunction syndrome; Multisystem inflammatory syndrome in children.	

9.5.2. Evaluation of AESIs

Table 12 below presents the evaluation of new information received during the interval reporting period from post-marketing data sources¹⁵ with regard to the AESIs for BNT162b2. Where applicable, observed versus expected analysis is provided in [Appendix 5.1](#).

Table 12. AESIs Evaluation for BNT162b2

AESIs ³⁵ Category	Post-Marketing ¹⁵ Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
Anaphylactic AESIs	Please refer to the Risk 'Anaphylaxis' in Table 11 .
Cardiovascular AESIs <i>Search criteria: PTs Acute myocardial infarction; Arrhythmia; Cardiac failure; Cardiac failure acute; Cardiogenic shock; Coronary artery disease; Myocardial infarction; Postural orthostatic tachycardia syndrome; Stress cardiomyopathy; Tachycardia</i>	<ul style="list-style-type: none"> Number of cases: 1585 (3.4 % of the total PM dataset, compared to 2.8% in the previous reporting period), of which 1217 are medically confirmed and 368 are non-medically confirmed; Country of incidence: Mexico (555); France (148); Italy (126); Japan (117); UK and US (88 each); Germany (74); Netherlands (55); Spain (45); Australia and Sweden (27 each); Greece and Portugal (21 each); Norway (20); Austria (19); Canada, Finland and Hungary (14 each); Poland (13); Czech Republic and Romania (10 each); Ireland (9); Belgium, Lithuania and Panama (6 each); Denmark, Hong Kong and Switzerland (5 each); the remaining 37 cases were distributed among 22 other countries; Subjects' gender: female (1135), male (428) and unknown (22); Subjects' age (n = 1502): ranged from 16 to 101 years (mean = 50.8 years, median = 46 years); Subjects' age group (n = 1514): Adult³⁶ (1088), Elderly³⁷ (422) and Adolescent³⁸ (4); Number of relevant events: 1645, of which 898 serious and 747 non-serious; when provided (n = 806) in the cases reporting relevant serious events, subject's age ranges from 16 to 101 years (mean = 60.1 years, median = 61.5 years); Reported relevant PTs: Tachycardia (1093), Arrhythmia* (177), Myocardial infarction* (170), Cardiac failure* (87), Acute myocardial infarction* (66), Cardiac failure acute* and Cardiogenic shock* (13 each), Coronary artery disease* and Postural orthostatic tachycardia syndrome* (10 each), Stress cardiomyopathy* (6); Relevant event onset latency (n = 1398): Range from <24 hours to 77 days, median □24 hours;

³⁵ For the complete list of the AESI (TME) List, please refer to Appendix 5. The MedDRA search terms for the AESIs reviewed in the SMSR include the terms in the AESI (TME) List and may also include additional PTs as appropriate. Overlapping terms among multiple categories were assigned to one category only based on their most clinical relevance.

³⁶ Subjects with age ranged between 18 and 64 years.

³⁷ Subjects with age equal to or above 65 years.

³⁸ Subjects with age between 12 and 17 years.

Table 12. AESIs Evaluation for BNT162b2

AESIs ³⁵ Category	Post-Marketing ¹⁵ Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
	<ul style="list-style-type: none"> Relevant event outcome:³⁹ resolved/resolving (727), not resolved (182), fatal (119), resolved with sequelae (22) and unknown (596); In 100 out of 1585 cases, 21 of which had fatal outcome, the subject's medical history was significant for the specific events of Arrhythmia (30), Cardiac failure (29), Myocardial infarction (20), Coronary artery disease (18), Tachycardia (13), Postural orthostatic tachycardia syndrome (3), Acute myocardial infarction and Cardiogenic shock (1 each). More than 1 relevant medical history event was reported in 13 cases. These cases involved 54 females, 45 males and 1 patient of unknown gender. When provided (n = 94), ages ranged from 25 to 95 years, mean was 69 years and median was 74 years. Additionally, in 150 out of 1585 cases, the subject's medical history was significant for other cardiac disorders, with the following conditions reported most frequently (≥3 cases): Atrial fibrillation (63); Myocardial ischaemia (22); Cardiac disorder (10); Cardiovascular disorder and Supraventricular tachycardia (9 each); Mitral valve incompetence (8); Cardiac failure congestive (6); Acute coronary syndrome, Extrasystoles and Hypertensive heart disease (5 each); Congestive cardiomyopathy (4); Angina pectoris, Aortic valve incompetence, Atrial flutter, Atrioventricular block and Tricuspid valve incompetence (3 each); In 60 out of 1585 cases, the subjects' medical history was significant for COVID-19 or suspected COVID-19. <p>* Observed/Expected analysis was performed for Arrhythmia, Acute myocardial infarction/Myocardial infarction, Cardiac failure/Cardiac failure acute, Cardiogenic shock, Coronary Artery disease, Postural orthostatic tachycardia syndrome, Stress cardiomyopathy (see Appendix 5.1).</p> <p>Conclusion: No cardiovascular signals have emerged from the review of post-authorisation data. The review of cases and O/E analysis do not raise new concerns. Safety surveillance will continue.</p>
COVID-19 AESIs <i>Search criteria: Covid-19 SMQ (Narrow and Broad) OR PTs Ageusia; Anosmia; Vaccine associated enhanced disease; Vaccine associated enhanced respiratory disease</i>	<ul style="list-style-type: none"> Number of cases: 2486 (5.3% of the total PM dataset, compared to 7.7% in the previous reporting period), of which 1449 are medically confirmed and 1037 are non-medically confirmed; Country of incidence: US (804); France and Italy (237 each); UK (186); Germany (154); Austria (91); Mexico (82); Croatia (61); Portugal (56); Hungary (49); Poland (45); Belgium (43); Spain (41); Japan (37); Czech Republic and Estonia (36 each); Netherlands (34); Ecuador (26); Sweden (20); Columbia (19); Greece and Norway (18 each); Romania (17); Canada, Ireland and Israel (12 each); the remaining 103 cases were distributed among 29 other countries; Subjects' gender: female (1407), male (825) and unknown (254);

³⁹ Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events.

Table 12. AESIs Evaluation for BNT162b2

AESIs ³⁵ Category	Post-Marketing ¹⁵ Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
	<ul style="list-style-type: none"> Subjects' age group (n=1785): Adult³⁶ (1065), Elderly³⁷ (711), Adolescent³⁸ (9); Number of relevant events: 2710, of which 1857 serious and 853 non-serious; Most frequently reported relevant PTs (>1 occurrence): COVID-19 (1898); Suspected COVID-19 (160); Ageusia* (155); Anosmia* (138); Asymptomatic COVID-19 (121); SARS-CoV-2 test positive (107); COVID-19 pneumonia (79); Exposure to SARS-CoV-2 (16); SARS-CoV-2 antibody test positive (10); Coronavirus infection (7); SARS-CoV-2 test negative (6); SARS-CoV-2 antibody test negative (5); Post-acute COVID-19 syndrome (4); Coronavirus test positive (2); Relevant event onset latency (n=1873): Range from <24 hours to 120 days, median 13 days; Relevant event outcome: resolved/resolving (745), not resolved (362), fatal (136), resolved with sequelae (15) and unknown (1452). <p>* Observed/Expected analysis was performed for Ageusia and Anosmia (see Appendix 5.1).</p> <p>Conclusion: No safety signals have emerged based on the review of these cases, or of the Observed versus Expected analysis. Safety surveillance will continue.</p>
Dermatological AESIs <i>Search criteria: PT Chillblains; Erythema multiforme</i>	<ul style="list-style-type: none"> Number of cases: 42 cases (0.1% of the total PM dataset, compared to 0.2% in the previous reporting period), of which 24 are medically confirmed and 18 are non-medically confirmed; Country of incidence: France (12), UK (10), Japan (6), US (5), Italy (3); the remaining 6 cases originated from 6 different countries; Subjects' gender: female (29), male (12) and unknown (1); Subjects' age group (n=38): Adult³⁶ (18), Elderly³⁷ (20); Number of relevant events: 42 events, 23 serious, 19 non-serious; Reported relevant PTs: Erythema multiforme* (17) and Chillblains* (25); Relevant event onset latency (n=33): Range from <24 hours to 41 days, median 5 days; Relevant event outcome: not resolved and resolved/resolving (17 each), resolved with sequelae (2) and unknown (6). <p>* Observed/Expected analysis was performed for Chillblains and Erythema multiforme (see Appendix 5.1).</p> <p>Conclusion: No safety signals have emerged based on the review of these cases, or of the Observed versus Expected analysis. Safety surveillance will continue.</p>

Table 12. AESIs Evaluation for BNT162b2

AESIs ³⁵ Category	Post-Marketing ¹⁵ Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
Facial Paralysis <i>Search criteria: PTs Bell's palsy, Facial paralysis, Facial paresis, Oculofacial paralysis</i>	<p>Number of cases: 477⁴⁰ (1.0% of the total PM dataset, compared to 1.4% of previous reporting period), of which 268 medically confirmed and 209 non-medically confirmed;</p> <p>Country of incidence: US (94), UK (63), France (56), Italy (46), Germany (35), Spain (24), Japan (16), Hong Kong (13), Belgium and Ireland (11 each), Australia and Austria (9 each), Finland (8), Greece, Netherlands, Sweden and Switzerland (7 each), Norway and Romania (6 each), Mexico (5), Denmark, Hungary, Macao and Portugal (4 each), Canada, Czech Republic, Israel and Poland (3 each); the remaining 9 cases originated from 9 different countries;</p> <p>Subjects' gender: female (300), male (161), unknown (16);</p> <p>Subjects' age group (n=424): Adolescent³⁸ (1), Adult³⁶ (279), Elderly³⁷ (144);</p> <p>Number of relevant events:⁴¹ 477, of which 452 serious, 25 non-serious;</p> <p>Reported relevant PTs: Bell's palsy* (208), Facial paralysis* (200), Facial paresis* (68), Oculofacial paralysis* (1);</p> <p>Relevant event onset latency (n = 399): Range from <24 hours to 109 days, median 5 days;</p> <p>Relevant event outcome: resolved/resolving (189), resolved with sequelae (7), not resolved at the time of the report (178) and unknown (103);</p> <p>Duration of events till resolution was reported in 39 out of 71 occurrences with outcome of resolved; it ranged from 20 minutes to 37 days, with a median value of 5 days.</p> <p>* Please see Appendix 5.1 for Observed versus Expected analysis of Bell's palsy/Facial paralysis/Facial paresis/Oculofacial paralysis.</p> <p>Interval conclusion: No new significant safety information was identified based on a review of these cases, or of the Observed versus Expected analysis. Safety surveillance will continue.</p> <p>It is anticipated that large epidemiologic surveillance studies will contribute to the assessment of facial paralysis in a meaningful way. Of note, cases of Bell's palsy are being collected in epidemiology studies that are both primary data collection studies (e.g. C4591008, C4591010) and secondary data collection studies (e.g. C4591009, C4591011, C4591012, C4591021).</p>

⁴⁰ Twenty-eight additional cases were excluded from the analysis as they were not cases of peripheral facial nerve palsy (BC Category 5) because they reported also other disorders (cerebrovascular accident, cerebral thrombosis or transient ischaemic attack).

⁴¹ If a case included both PT Facial paresis and PT Facial paralysis, only the PT Facial paralysis was considered in the descriptions of the events as it is most clinically important and if a case included both PT Bell's palsy and PT Facial paralysis, only the PT Bell's palsy was considered in the descriptions of the events as it is most clinically important.

Table 12. AESIs Evaluation for BNT162b2

AESIs ³⁵ Category	Post-Marketing ¹⁵ Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
Haematological AESIs <i>Search criteria: Leukopenias NEC (HLT) OR Neutropenias (HLT) OR PT Thrombocytopenia OR SMQ Haemorrhage terms (excl laboratory terms)</i>	<ul style="list-style-type: none"> Number of cases: 1923 (4.1% of the total PM dataset, compared to 4.6 % in the previous reporting period), of which 861 medically confirmed and 1062 non-medically confirmed; Country of incidence: UK (641), US (366), France (135), Italy (108), Japan (86), Netherlands (71), Germany and Spain (64 each), Mexico (39), Sweden (36), Canada (33), Israel (30), Australia and Czech Republic (23 each), Belgium (22), Norway and Portugal (20 each), Denmark (17), Greece and Switzerland (12 each), Austria and Romania (11 each), Finland and Poland (9 each), Brazil and Ireland (8 each), Hungary (7), Lithuania, Luxembourg, Malta, Saudi Arabia, Serbia and Slovenia (3 each), Croatia, Estonia, Malaysia, Panama, Slovakia and Turkey (2 each); the remaining 8 cases originated from 8 different countries; Subjects' gender: female (1471), male (422) and unknown (30); Subjects' age group (n = 1706): Adult³⁶ (1125), Elderly³⁷ (568), Adolescent³⁸ (13); Number of relevant events: 2287, of which 1447 serious, 840 non-serious; Most frequently reported relevant PTs (>10 occurrences) include: Heavy menstrual bleeding (323), Contusion (227), Epistaxis (196), Thrombocytopenia* (186), Haemorrhage* (121), Vaginal haemorrhage (104), Vaccination site bruising (73), Petechiae (70), Intermenstrual bleeding (68), Immune thrombocytopenia* (57), Vaccination site haematoma (52), Haematoma (51), Purpura (46), Haematochezia (42), Vaccination site haemorrhage (41), Eye haemorrhage, Postmenopausal haemorrhage and Rectal haemorrhage (34 each), Conjunctival haemorrhage and Haematuria (27 each), Blood urine present (24), Ecchymosis, Haemoptysis and Internal haemorrhage (22 each), Gingival bleeding (21), Neutropenia (18), Gastrointestinal haemorrhage (15), Lymphopenia (14), Diarrhoea haemorrhagic, Haematemesis and Haemorrhage subcutaneous (13 each) and Blood blister, Leukopenia and Subdural haematoma (12 each); Relevant event onset latency (n = 1552): Range from □24 hours to 99 days, median = 2 days; Relevant event outcome:³⁹ fatal (44), resolved/resolving (892), resolved with sequelae (21), not resolved (600) and unknown (738). <p>* Observed/Expected analysis was performed for Haemorrhage, Immune thrombocytopenia and Thrombocytopenia (see Appendix 5.1).</p> <p>Conclusion: No signals for the hematological AESIs have emerged based on a review of these cases, or of the Observed versus Expected analysis. Safety surveillance will continue.</p>
Hepatic AESIs <i>Search criteria: Liver related investigations, signs and symptoms (SMQ) (Narrow and Broad) OR PT Liver injury</i>	<ul style="list-style-type: none"> Number of cases: 115 cases (0.2% of the total PM dataset, compared to 0.3% of the previous reporting period), of which 84 medically confirmed and 31 non-medically confirmed; Country of incidence: France (21), US and UK (17 each), Japan (10), Germany (9), Spain (5), Greece, Hungary and Italy (4 each), Israel, Netherlands and Sweden (3 each), Austria, Belgium, Czech

Table 12. AESIs Evaluation for BNT162b2

AESIs ³⁵ Category	Post-Marketing ¹⁵ Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
	<p>republic and Portugal (2 each); the remaining 7 cases originated from 7 different countries;</p> <ul style="list-style-type: none"> Subjects' gender: female (80), male (34) and unknown (1); Subjects' age group (n=98): Adult³⁶ (53), Elderly³⁷ (44) Adolescent³⁸ (1); Number of relevant events: 144, of which 92 serious, 52 non-serious; Most frequently reported relevant PTs (≥2 occurrences): Alanine aminotransferase increased (19), Liver function test abnormal (16), Aspartate aminotransferase increased (15), Hepatic function abnormal and Transaminases increased (12 each), Hepatic enzyme increased (11), Hepatic pain (10), Gamma-glutamyltransferase increased (8), Blood bilirubin increased and Hepatomegaly (5 each), Hepatic enzyme abnormal and Liver function test increased (4 each), Blood alkaline phosphatase increased, Hypoalbuminaemia, Liver injury* (3 each), AST/ALT ratio abnormal, Congestive hepatopathy, Hyperbilirubinaemia (2 each) Relevant event onset latency (n = 89): Range from <24 hours to 74 days, median 5 days; Relevant event outcome: fatal (3), resolved/resolving (44), not resolved (23) and unknown (74). <p>* Observed/Expected analysis was performed for Liver injury (see Appendix 5.1).</p> <p>Conclusion: Hepatic events were a safety topic determined not to be validated signals (see Appendix 3, Appendix 3.1 and Appendix 3.4). No other safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis. Safety surveillance will continue.</p>
<p>Immune-Mediated/Autoimmune AESIs <i>Search criteria: Immune-mediated/autoimmune disorders (SMQ) (Broad and Narrow) OR Autoimmune disorders HLGT OR PTs Cytokine release syndrome; Cytokine storm; Hypersensitivity</i></p>	<ul style="list-style-type: none"> Number of cases: 1333 (2.8% of the total PM dataset, compared to 3.4% of the previous reporting period), of which 732 medically confirmed and 601 non-medically confirmed; Country of incidence: US (307), UK (256), France (126), Japan (111), Italy (90), Germany (81), Spain (30), Netherlands (26), Israel (23), Canada (21), Mexico, New Zealand and Norway (20 each), Belgium (17), Switzerland (16), Czech Republic and Sweden (15 each), Finland (13), Austria and Greece (12 each), Australia, Denmark and Ireland (11 each), Romania (10), Panama and Portugal (7 each); Hungary, Brazil and Poland (5 each), the remaining 30 cases originated from 18 different countries; Subjects' gender: female (883), male (394) and unknown (56). Subjects' age group (n=1179): Adult³⁶ (818), Elderly³⁷ (345) and Adolescent³⁸ (16) Number of relevant events: 1395, of which 1039 serious, 356 non-serious; Most frequently reported relevant PTs (≥10 occurrences): Hypersensitivity (560), Myocarditis* (98), Pericarditis* (89), Dermatitis (36), Autoimmune disorder (25), Psoriasis (24), Diabetes mellitus (22), Encephalitis* and Polymyalgia rheumatica* (21 each), Colitis ulcerative (20), Colitis and Myositis

Table 12. AESIs Evaluation for BNT162b2

AESIs ³⁵ Category	Post-Marketing ¹⁵ Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
	<p>(19 each), Interstitial lung disease (17), Dermatitis bullous and Raynaud's phenomenon (16 each), Pancreatitis (14), Hyperthyroidism (13), Pemphigoid (11), Crohn's disease, Hypothyroidism, Systemic lupus erythematosus, Vascular purpura (10 each);</p> <ul style="list-style-type: none"> Relevant event onset latency (n = 912): Range from <24 hours to 95 days, median 2 days; Relevant event outcome:³⁹ fatal (17), resolved/resolving (567), resolved with sequelae (14), not resolved (348) and unknown (452). <p>* Please see Appendix 5.1 for Observed/Expected analysis performed for Encephalitis, Myocarditis, Pericarditis and Polymyalgia rheumatica.</p> <p>Conclusion: Myocarditis and Pericarditis were signals ongoing under evaluation (see Appendix 3, Appendix 3.1 and Appendix 3.9). No new safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis. Safety surveillance will continue.</p>
<p>Musculoskeletal AESIs <i>Search criteria: PTs Arthralgia; Arthritis; Chronic fatigue syndrome; Polyarthrititis; Post viral fatigue syndrome; Rheumatoid arthritis</i></p>	<ul style="list-style-type: none"> Number of cases: 4412 (9.4% of the total PM dataset, compared to 8.3% of the previous reporting period), of which 2600 medically confirmed and 1812 non-medically confirmed; Country of incidence: Mexico (1139), UK (900), US (512), Italy (466), Japan (160), Netherlands (139), Czech Republic (129), Belgium (102), France (86), Germany (83), Austria (80), Spain (78), Portugal and Sweden (56 each), Australia (48), Ireland (43), Denmark (34), Canada (30), Finland and Greece (25 each), Hungary and Romania (22 each), Poland (21), Norway (20), Israel (18), Switzerland (17), Bulgaria, Latvia, Panama, and Serbia (8 each), Luxembourg (7), Turkey (6), Colombia, Lithuania and Slovakia (5 each), Brazil, Croatia, Cyprus and Estonia (4 each), Chile, Costa Rica, Iceland and Malta (3 each); the remaining 13 cases originated from 11 different countries; Subjects' gender: female (3257), male (1059) and unknown (96); Subjects' age group (n=4096): Adult³⁶ (3443), Elderly³⁷ (644), Adolescent³⁸ (7) and Child⁴² (2); Number of relevant events: 4480, of which 1143 serious, 3337 non-serious;⁴³ Reported relevant PTs: Arthralgia (4282), Arthritis (103), Rheumatoid arthritis* (56), Chronic fatigue syndrome* (14), Post viral fatigue syndrome* (12) and Polyarthrititis* (10); Relevant event onset latency (n = 3624): Range from <24 hours to 366 days, median 1 day;

⁴² Subjects with age between 2 and 11 years.

⁴³ Multiple episodes of the same PT event were reported with a different seriousness within 1 case hence the sum of the events seriousness exceeds the total number of PT events.

Table 12. AESIs Evaluation for BNT162b2

AESIs ³⁵ Category	Post-Marketing ¹⁵ Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
	<ul style="list-style-type: none"> Relevant event outcome:³⁹ fatal (2), resolved/resolving (2088), resolved with sequelae (38), not resolved (878) and unknown (1509). * Observed/Expected analysis was performed for Rheumatoid arthritis, Polyarthritis, Chronic fatigue syndrome and Post viral fatigue syndrome (see Appendix 5.1). Conclusion: No new safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis. Safety surveillance will continue.
Neurological AESIs (including demyelination) <i>Search criteria: Convulsions (SMQ) (Broad and Narrow) OR Demyelination (SMQ) (Broad and Narrow) OR PTs Ataxia; Cataplexy; Encephalopathy; Fibromyalgia; Intracranial pressure increased; Meningitis; Meningitis aseptic; Neuropathy peripheral; Polyneuropathy</i>	<ul style="list-style-type: none"> Number of cases: 719 (1.5% of the total PM dataset, compared to 2.1% of the previous reporting period), of which 432 medically confirmed and 287 non-medically confirmed; Country of incidence: US (154), UK (134), Japan (78), France (59), Italy (46), Mexico (38), Germany (28), Spain (26), Australia (18), Netherlands (16), Hong Kong (11), Austria Finland and Romania (9 each), Belgium, Denmark and Sweden (8 each), Poland (7), Canada and Switzerland (6 each), Ireland, Norway and Panama (5 each), Czech Republic and Israel (4 each), Portugal, Serbia, Turkey (3 each), Hungary and Greece (2); the remaining 5 cases originated from 5 different countries; Subjects' gender: female (476), male (221) and unknown (22); Subjects' age group (n=657): Adult³⁶ (464), Adolescent³⁸ (15), Elderly³⁷ (177) Child⁴² (1); Number of relevant events: 783, of which 729 serious, 54 non-serious; Most frequently reported relevant PTs (≥5 occurrences) included: Seizure* (236), Neuropathy peripheral* (101), Epilepsy (84), Guillain-Barre syndrome* (60), Generalised tonic-clonic seizure* (38), Fibromyalgia* (30), Febrile convulsion* and Multiple sclerosis* (23 each), Trigeminal neuralgia (22), Status epilepticus (16), Optic neuritis* (15), Multiple sclerosis relapse* (13), Ataxia (12), Myelitis transverse* (11), Tongue biting (8), Polyneuropathy (7), Acute disseminated encephalomyelitis*, Aura, Meningitis*, Meningitis aseptic*, Partial seizures*, Seizure like phenomena (6 each), Clonic convulsion, Intracranial pressure increased and Petit mal epilepsy (5 each); Relevant event onset latency (n=529): Range from <24 hours to 85 days, median 1 day; Relevant events outcome:³⁹ fatal (17), resolved/resolving (345), resolved with sequelae (16), not resolved (178) and unknown (228); A relevant medical history was reported in 457 out of 719 cases with medical history terms coded to: Epilepsy (75), Multiple sclerosis (32), Fibromyalgia (27), Seizure (26), Neuropathy peripheral (17), Trigeminal neuralgia (6), Partial seizure (4), Relapsing-remitting multiple sclerosis (3), Optic neuritis and Status epilepticus (2 each), Autonomic nervous system imbalance, Autonomic neuropathy, Axonal and demyelinating polyneuropathy, Chronic inflammatory demyelinating

Table 12. AESIs Evaluation for BNT162b2

AESIs ³⁵ Category	Post-Marketing ¹⁵ Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
	<p>polyradiculoneuropathy, Encephalopathy, Generalised tonic-clonic seizure, Leukoencephalopathy, Myoclonus, Neuralgia, Petit mal epilepsy, Polyneuropathy, Small fibre neuropathy, Vascular encephalopathy (1 each).</p> <p>* Observed/Expected analysis was performed for Acute disseminated encephalomyelitis, Guillain-Barre syndrome, Meningitis, Meningitis aseptic, Multiple sclerosis, Multiple sclerosis relapse, Myelitis transverse, Neuropathy peripheral, Optic neuritis and Seizure/Seizure disorders (see Appendix 5.1).</p> <p>Conclusion: ADEM, Guillain-Barre syndrome and Myelitis transverse were reviewed as safety topics and determined not to be validated signals (see respectively Appendix 3.3, Appendix 3.8 and Appendix 3.6). No new safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis. Safety surveillance will continue.</p>
<p>Other AESIs <i>Search criteria: Herpes viral infections (HLT) OR PTs Adverse event following immunisation; Inflammation; Manufacturing laboratory analytical testing issue; Manufacturing materials issue; Manufacturing production issue; MERS-CoV test; MERS-CoV test negative; MERS-CoV test positive; Multiple organ dysfunction syndrome; Occupational exposure to communicable disease; Patient isolation; Product availability issue; Product distribution issue; Product supply issue; Pyrexia; Quarantine; SARS-CoV-1 test; SARS-CoV-1 test negative; SARS-CoV-1 test positive; Systemic inflammatory response syndrome</i></p>	<ul style="list-style-type: none"> • Number of cases: 9100 (19.3% of the total PM dataset, compared to 15.6% of the previous reporting period), of which 5176 were medically confirmed and 3924 non-medically confirmed; • Country of incidence: UK (1510); US (1368); Italy (1116); Mexico (1072); Japan (492); Germany (410); France (400); Spain (394); Netherlands (254); Belgium (234); Czech Republic (215); Sweden (167); Austria (162); Portugal (130); Greece (95); Romania (93); Australia and Finland (86 each), Poland (79); Denmark (74); Ireland (69), Canada (65), Israel (64), Hungary (63), Norway (62), Switzerland (44); Panama (34), Croatia (26); Serbia (25); Brazil (21); Bulgaria (19); Latvia (16); Iceland and Luxembourg (14 each); the remaining 127 cases were distributed among 28 other countries; • Subjects' gender: female (6580), male (2237), unknown (283); • Subjects' age group (n = 8166): Adult³⁶ (6506), Elderly³⁷ (1628), Adolescent³⁸ (30), Infant⁴⁴ (1), Child⁴² (1); • Number of relevant events: 9344, of which 2193 serious, 7151 non-serious; • Most frequently reported relevant PTs (≥4 occurrences) included: Pyrexia (7338), Herpes zoster* (1243), Inflammation (411), Oral herpes (110), Ophthalmic herpes zoster* (51), Herpes simplex, Herpes virus infection, Herpes zoster reactivation* (23 each), Multiple organ dysfunction syndrome* (15), Herpes zoster oticus* (13), Product supply issue (12), Genital herpes (11), Herpes ophthalmic and Varicella (8 each), Disseminated varicella zoster virus infection, Herpes zoster cutaneous disseminated*, Systemic inflammatory response syndrome*, Varicella zoster virus infection* (6 each); Meningoencephalitis herpetic (4); • Relevant event onset latency (n =7557): Range from <24 hours to 367 days, median 1 day;

⁴⁴ Subjects between 28 days and 23 months.

Table 12. AESIs Evaluation for BNT162b2

AESIs ³⁵ Category	Post-Marketing ¹⁵ Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
	<ul style="list-style-type: none"> Relevant events outcome:³⁹ resolved/resolving (5280), not resolved (1374), resolved with sequelae (111), fatal (54), and unknown (2559). <p>* Among multiple different events grouped under this Other AESIs category, Observed/Expected analysis was performed on specific PTs relevant for Herpes zoster disorders and Multiple organ dysfunction syndrome/Systemic inflammatory response syndrome (see Appendix 5.1).</p> <p>Conclusion: No new safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis. Safety surveillance will continue.</p>
Pregnancy Related AESIs <i>Search criteria: PTs Amniotic cavity infection; Cesarean section; Congenital anomaly; Death neonatal; Eclampsia; Foetal distress syndrome; Low birth weight baby; Maternal exposure during pregnancy; Placenta praevia; Pre-eclampsia; Premature labour; Stillbirth; Uterine rupture; Vasa praevia</i>	<p>For relevant cases, please refer to the subsection <i>Use in Pregnancy and While Breast Feeding</i> in Table 14.</p>
Renal AESIs <i>Search criteria: PTs Acute kidney injury; Renal failure.</i>	<ul style="list-style-type: none"> Number of cases: 86 cases (0.2% of the total PM dataset, as in the previous reporting period), of which 68 medically confirmed and 18 non-medically confirmed; Country of incidence: France (20), US (10), Germany, and Italy (9 each), UK (6), Netherlands, and Spain (5 each), Belgium (3) Israel, Malta Norway and Sweden (2 each); the remaining 11 cases originated from 11 different countries; Subjects' gender: female (40), male (45) and unknown (1); Subjects' age group (n=84): Adult³⁶ (16), Elderly³⁷ (68); Number of relevant events: 87, all serious; Reported relevant PTs: Acute kidney injury* (51) and Renal failure* (36); Relevant event onset latency (n=51): Range from <24 hours to 60 days, median 6 days; Relevant event outcome: fatal (21), resolved/resolving (21), not resolved (15) and unknown (30). <p>* Observed/Expected analysis performed for Acute kidney injury and Renal failure (see Appendix 5.1).</p> <p>Conclusion: No new safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis performed. Surveillance will continue.</p>
Respiratory AESIs <i>Search criteria: Lower respiratory tract infections NEC (HLT) OR Respiratory failures (excl</i>	<ul style="list-style-type: none"> Number of cases: 463 cases (1.0% of the total PM dataset, compared to 1.2% of the previous reporting period), of which 322 medically confirmed.

Table 12. AESIs Evaluation for BNT162b2

AESIs ³⁵ Category	Post-Marketing ¹⁵ Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
<p><i>neonatal) (HLT) OR Viral lower respiratory tract infections (HLT) OR PTs: Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Pulmonary haemorrhage; Respiratory disorder</i></p>	<ul style="list-style-type: none"> Country of incidence: France (57), US (56), Japan (46), Italy (41), Spain, UK (31 each), Germany (24), Netherlands (22), Australia, Mexico (19 each), Hungary (17), Austria, Denmark (11 each), Belgium, Norway, Sweden (10 each); the remaining 48 cases originated from 24 different countries. Subjects' gender: female (267), male (190), unknown (6). Subjects' age group (n=426): Elderly³⁷ (299), Adult³⁶ (127). Number of relevant events: 461 serious events, 37 non-serious events. Reported relevant PTs: Pneumonia (165), Respiratory failure (62), Cardio-respiratory arrest (61), Respiratory disorder (51), Hypoxia (38), Lower respiratory tract infection (31), Bronchitis (28), Acute respiratory failure (20), Acute respiratory distress syndrome (15), Cardiopulmonary failure (11), Atypical pneumonia (6), Lung abscess, Pneumonia viral, Pulmonary haemorrhage, Pulmonary sepsis (2 each), Pneumonia mycoplasmal, and Pneumonia respiratory syncytial viral (1 each). Relevant event onset latency (n=350): range from < 24 hours to 94 days, median 5 days. Relevant events outcome: fatal (142), resolved/resolving (137), not resolved (73), resolved with sequelae (1) and unknown (145). Out of these 463 cases, 32 cases (14 fatal, 3 life-threatening, 12 hospitalisation, and 3 medically significant) in which the PTs Respiratory failure (14), Acute respiratory failure (6), Pneumonia (5), Acute respiratory distress syndrome, Hypoxia (4 each), Bronchitis, and Cardiopulmonary failure (1 each) were reported in a context of vaccine lack of efficacy (PTs Drug ineffective or Vaccination failure), were also reviewed among the potential relevant cases for the Risk 'VAED Including VAERD' in Table 11. <p>* Observed/Expected analysis performed for Acute respiratory distress syndrome (see Appendix 5.1).</p> <p>Conclusion: No new safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis performed Surveillance will continue.</p>
<p>Thromboembolic Events <i>Search criteria: Embolism and thrombosis (HLGT), excluding PTs reviewed as Stroke AESIs</i></p>	<ul style="list-style-type: none"> Number of cases: 1600 (3.4% of the total PM dataset, compared to 3.7% of the previous reporting period), which 1118 medically confirmed and 482 non-medically confirmed; Country of incidence: France (285), US (232), UK (197), Italy (138), Germany (131), Spain (105), Sweden (69), Netherlands (68), Norway (49) Australia (36), Belgium (30), Austria and Finland (27 each), Denmark (25), Czech Republic (24), Canada (23), Portugal (22), Greece (20), Japan (14), Hungary (11), Switzerland (10), Mexico and Poland (7 each), Romania (6), Croatia (4), Estonia, Luxembourg, Malta and Slovenia (3 each); the remaining 21 cases originated from 17 different countries; Subjects' gender: female (889), male (677) and unknown (34); Subjects' age group (n=1491): Adult³⁶ (519), Adolescent³⁸ (3), Elderly³⁷ (969);

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AESIs ³⁵ Category	Post-Marketing ¹⁵ Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
	<ul style="list-style-type: none"> Number of relevant events: 1855, of which 1813 serious, 42 non-serious; Most frequently reported relevant PTs (≥ 5 occurrences) included: Pulmonary embolism* (588), Deep vein thrombosis* (442), Thrombosis (339), Thrombophlebitis superficial (65), Thrombophlebitis (53), Venous thrombosis limb (37), Embolism (36), Pulmonary thrombosis (35), Venous thrombosis (24), Retinal vein occlusion (21), Retinal artery occlusion and Portal vein thrombosis (17 each), Mesenteric vein thrombosis (14), Retinal vein thrombosis (13), Jugular vein thrombosis and Peripheral artery thrombosis (11 each), Pelvic venous thrombosis (10), Arterial thrombosis, Intracardiac thrombus, Ophthalmic vein thrombosis and Subclavian vein thrombosis (8 each), Coronary artery thrombosis (7), Embolism venous and Pulmonary artery thrombosis (6), Retinal artery thrombosis (5); Relevant event onset latency (n = 1446): Range from <24 hours to 109 days, median 9 days; Relevant event outcome:³⁹ fatal (104), resolved/resolving (816), resolved with sequelae (53), not resolved (484) and unknown (404). <p>* Observed/Expected analysis performed for Deep vein thrombosis and Pulmonary embolism (see Appendix 5.1).</p> <p>Conclusion: The topic of thromboembolism, specifically in association with thrombocytopenia, has emerged as a concern for some COVID-19 vaccines and is being carefully monitored for the Pfizer/BTN COVID-19 vaccine. This current SMSR includes a review of cases that are of potential interest (see Appendix 3.5) and the MAH will continue to present these cases in the SMSR for the time being. No other safety signals have emerged based on a review of these cases and of the Observed versus Expected analysis performed. Surveillance will continue.</p>
Stroke <i>Search criteria: HLT Central nervous system haemorrhages and cerebrovascular accidents (Primary Path) OR HLT Cerebrovascular venous and sinus thrombosis (Primary Path)</i>	<ul style="list-style-type: none"> Number of cases: 814 (1.7% of the total PM dataset, compared to 2.2% of the previous reporting period), of which 554 medically confirmed and 260 non-medically confirmed; Country of incidence: France (134), US (95), UK (73), Italy (70), Netherlands (67), Germany (64), Japan (62), Sweden (42), Spain (36), Denmark and Portugal (21 each), Norway (18), Finland (14), Australia (13), Belgium (10), Austria and Greece (9 each), Canada (8), Ireland (7), Czech republic, Romania and Slovenia (4 each), Hungary and Poland (3 each), Bahrain, Estonia, Iraq, Mexico, Saudi Arabia and Switzerland (2 each); the remaining 11 cases originated from 11 different countries; Subjects' gender: female (473), male (322) and unknown (19); Subjects' age group (n=773): Adolescent³⁸ (2), Adult³⁶ (198), Elderly³⁷ (573); Number of relevant events: 941, all serious; Most frequently reported relevant PTs (≥ 5 occurrences) included: <ul style="list-style-type: none"> PTs indicative of Ischaemic stroke: Cerebrovascular accident* (308), Ischaemic stroke* (144), Cerebral

Table 12. AESIs Evaluation for BNT162b2

AESIs ³⁵ Category	Post-Marketing ¹⁵ Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
	<p>infarction* (106), Cerebral venous sinus thrombosis* (35), Cerebral thrombosis* (22), Cerebral ischaemia (18), Embolic stroke (14), Thrombotic stroke* (9), Cerebral artery embolism, Cerebral venous thrombosis and Ischaemic cerebral infarction (8 each), Brain stem infarction and Cerebral artery occlusion (6 each) and Carotid artery occlusion, Carotid artery thrombosis, Cerebellar stroke, Cerebral artery thrombosis and Lacunar infarction (5 each);</p> <ul style="list-style-type: none"> ○ PTs indicative of Haemorrhagic stroke: Cerebral haemorrhage* (93), Subarachnoid haemorrhage* (32), Haemorrhagic stroke* (18), Cerebral haematoma*, Haemorrhage intracranial* and Haemorrhagic transformation stroke (6 each); <ul style="list-style-type: none"> • Relevant event onset latency (n=759): Range from <24 hours to 101 days, median 5 days; • Relevant event outcome:³⁹ fatal (132), resolved/resolving (295), resolved with sequelae (78), not resolved (213) and unknown (224). <p>* Observed/Expected analysis was performed for Ischemic strokes and Hemorrhagic strokes (see Appendix 5.1).</p> <p>Conclusion: No new safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis performed. Safety surveillance will continue.</p>
<p>Vasculitic Events <i>Search criteria: Vasculitides HLT, or PTs Microangiopathy; Peripheral ischaemia</i></p>	<ul style="list-style-type: none"> • Number of cases: 86 cases (0.2% of the total PM dataset, compared to 0.3% of the previous reporting period), of which 69 medically confirmed and 17 non-medically confirmed; • Country of incidence: France (17), UK (16), Italy (11), Japan and US (8 each), Spain (5), Portugal (4), Denmark, Germany, Netherlands, Norway and Sweden (2 each); the remaining 7 cases originated from 7 different countries; • Subjects' gender: female (52), male (32) and unknown (2); • Subjects' age group (n=82): Adult³⁶ (28), Elderly³⁷ (54); • Number of relevant events: 91, of which 65 serious and 26 non-serious; • Most frequently reported relevant PTs (>1 occurrence) included: Vasculitis* (30), Peripheral ischaemia* (16) Cutaneous vasculitis* (14), Henoch-Schonlein purpura (9), Giant cell arteritis* (5), Anti-neutrophil cytoplasmic antibody positive vasculitis, Central nervous system vasculitis, Hypersensitivity vasculitis, Microangiopathy, Palpable purpura, Vasculitic rash* (2 each); • Relevant event onset latency (n=70): Range from □24 hours to 75 days, median 4 days; • Relevant event outcome: fatal (3), resolved/resolving (39), resolved with sequelae (1), not resolved (23) and unknown (25). <p>* Observed/Expected analysis was performed for Vasculitis and Cutaneous vasculitis disorders (see Appendix 5.1).</p>

Table 12. AESIs Evaluation for BNT162b2

AESIs ³⁵ Category	Post-Marketing ¹⁵ Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
	No new significant safety information was identified based on a review of these cases, or of the Observed versus Expected analysis. Safety surveillance will continue.

9.5.3. Evaluation of Special Situations

Table 13 below presents the evaluation of new information received during the current reporting period from post-marketing data sources for BNT162b2 in relation to special situations (Death, Lack of Efficacy and Vaccine Interactions).

Table 13. Evaluation of Special Situations for BNT162b2

Topic	Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=47174)
Death	<p>Overview</p> <ul style="list-style-type: none"> Number of fatal cases: 962⁴⁵ (2.0% of the total PM dataset, compared to 3.1% of the total PM cases received in the previous reporting period) of which 752 were medically confirmed and 210 non-medically confirmed; Country of incidence: the majority were from Germany (142), France (112), Japan (78), Hungary (70), Italy (69), Australia, Spain (55 each), Netherlands (53), UK (47), US (38), Sweden (31), Austria (22), and Poland (21); the remaining 169 cases occurred in 34 other countries; Subjects' Gender: females (474), males (470), unknown (18); Subjects' Age: 16 to 101 years (n = 903), mean = 78.1, median = 81; Paediatric⁴⁶ (2), Adults (124), Elderly (782), subjects with unknown age (54); Causes of death most frequently reported (>2% of total fatal cases): Death (198), COVID-19 (76), Cardiac arrest (72), Sudden death (63), Dyspnoea (58), Pulmonary embolism (56), Cardio-respiratory arrest (49), Myocardial infarction (45), Vaccination failure (41), Pyrexia (39), COVID-19 pneumonia (35), Respiratory failure (34), Cerebrovascular accident, Drug ineffective (31 each), Cerebral haemorrhage, Pneumonia (29 each), Cardiac failure (23), and Vomiting (20).

⁴⁵ During the current reporting interval, there were 20 additional cases reporting subjects' death that were excluded from further analysis in this subsection as: death was mentioned as an incidental information only with none of the reported events presenting a fatal outcome (6) and cases which reported foetal death and are reviewed in [Table 14](#) under *Use in Pregnancy and While Breast Feeding* (14). After DLP, one case was found to be a duplicate of an invalid case and is excluded from this analysis.

⁴⁶ These 2 cases reported use in patients >12 years of age (16 and 17 years old). Upon review of these cases, 1 subject committed suicide and another subject had many risk factors for developing fatal pulmonary embolism (and subsequent fatal cardiac arrest) such as medical history of JIA, ongoing immunodeficiency, chronic osteomyelitis, multiple focal non-bacterial osteomyelitis, multiple fractures, and history of recurrent DVTs.

Table 13. Evaluation of Special Situations for BNT162b2

Topic	Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=47174)
	<ul style="list-style-type: none"> ○ In addition, autopsy results were provided in 33 cases and Acute myocardial infarction, Pulmonary embolism, Pulmonary oedema (4 each), Arteriosclerosis coronary artery, Myocardial infarction, Pneumonia (3 each), Aortic dissection, Arteriosclerosis, Brain oedema, Cardiac hypertrophy, Circulatory collapse, and Deep vein thrombosis (2 each) were reported more than once. • PTs most frequently reported (>2% events): Death (202), COVID-19 (83), Cardiac arrest (74), Sudden death (69), Dyspnoea (60), Pulmonary embolism (57), Vaccination failure (53), Cardio-respiratory arrest (50), Drug ineffective (49), and Myocardial infarction (45). • Concomitant medications were reported in 345 out of 962 cases and the most frequently present (>2% of total fatal cases) are listed below: acetylsalicylic acid (71), furosemide (56), paracetamol (44), omeprazole (35), apixaban (31), bisoprolol fumarate (30), simvastatin (28), levothyroxine sodium (27), amlodipine, colecalciferol (26 each), pantoprazole (25), bisoprolol (24), atorvastatin (23), pantoprazole sodium sesquihydrate (22), metformin, spironolactone (21 each), allopurinol, and atorvastatin calcium (20 each). • Lot/Batch Number (#) information by Country was available in 579 cases with no related quality issues identified during investigations of the impacted lot/batch numbers. The list of Lot/Batch #s most frequently reported (>2% of total fatal cases) is presented hereinafter: <ul style="list-style-type: none"> ○ Lot # EW2246 in 26 cases from France (9), Italy (8), Spain (5), Finland (2), Austria, and Croatia (1 each). ○ Lot # EW2239 in 22 cases from Hungary (6), France (5), Spain, Sweden (3 each), Slovenia (2), Austria, Czech Republic, and Finland (1 each). ○ Lot # EP2166 in 21 cases from Hungary (8), France, Italy (4 each), Netherlands (2), Greece, Romania, and Spain (1 each). • Time to onset of fatal events was reported for 756 subjects and ranged from the day of vaccination to 121 days after vaccination: <ul style="list-style-type: none"> ○ Same day to 3 days after vaccination: 323 cases ○ 4-7 days after vaccination: 124 cases ○ 8-14 days after vaccination: 120 cases ○ 15-30 days after vaccination: 115 cases ○ 30+ days after vaccination: 74 cases • Number of vaccine doses administered at the time of the subjects' death: <ul style="list-style-type: none"> ○ First dose (369) ○ Second dose (357). Of the 357 cases, 94 cases (33.9%) reported a latency of same day to 3 days after vaccination. There were 847 fatal events. Of the 847 fatal events, there was 1 fatal anaphylaxis event⁴⁷ and 110

⁴⁷ Search aligned to the important identified risk of anaphylaxis.

Table 13. Evaluation of Special Situations for BNT162b2

Topic	Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=47174)
	<p>cardiovascular/stroke/thrombotic events⁴⁸. The most frequently reported (>2%) fatal events were coded to PTs Death (75), Vaccination failure (52), COVID-19 (51), Cardiac arrest (25), Sudden death (23), Dyspnoea (22), COVID-19 pneumonia (21), and Drug ineffective (20).</p> <ul style="list-style-type: none"> ○ Third dose (1). There was 1 case that reported a 57-year-old male subject who had a fatal outcome after receiving a third dose of BNT162b2 in an outpatient setting with “no effect or specific complaint immediately after”. It was not specified why a third dose was administered. One (1) day after he “spoke a little inconsistently” and was not feeling well. He was found deceased in his home 2 days later. Medical history included bipulmonary and hepatic transplant with COPD and non-alcoholic liver cirrhosis and concomitant medications were not reported. It was unknown if an autopsy was completed, however, the physician reported that there was no cardiovascular antecedent, no hypertension, normal coronary angiography and ultrasound, no kidney damage. The subject was hospitalized a few days before for suspected acute rejection and was given a corticosteroid bolus. ○ In the remaining cases (235), it was not specified if the subjects received the first or the second vaccine dose at the time of the fatal events. <ul style="list-style-type: none"> ● Test for COVID-19 was reported for 222 subjects as follows: in 126 cases subjects tested positive (35 after 1st vaccine dose, 81 after 2nd vaccine dose and in 10 cases there was no information available about the dose they received), 92 cases were negative, 1 case reported an inconclusive COVID-19 test, and in 3 cases, test results were unknown. <p>Analysis</p> <p>Most of the cases reporting a fatal outcome (62.7%) were in subjects over 75 years of age. This reflects one of the priority groups targeted for vaccination by many regions and countries, including Europe and the US, that is, elderly (with various lower age cut-offs across countries), because of their higher risk of severe disease and mortality if infected with SARS-CoV-2.^{17,18,19}</p> <p>Among the total of 962 cases with a fatal outcome, when the medical history was provided (in 664 cases), the majority had multiple concomitant comorbidities. The most frequently reported (>2% of total fatal cases) medical conditions included cardiac and vascular disorders (eg Hypertension, Atrial fibrillation, Cardiac failure, Myocardial ischaemia, Cerebrovascular accident, Dyslipidaemia, Coronary artery disease, Hypercholesterolaemia, Myocardial infarction, and Arrhythmia). Other frequently reported significant medical histories included Diabetes mellitus/Type 2 diabetes mellitus, Chronic obstructive pulmonary disease, Dementia, Chronic kidney disease, Obesity, COVID-19, Benign prostatic hyperplasia, Renal failure, Cognitive disorder, Osteoporosis, and Prostate cancer. No specific pattern regarding underlying conditions or cause of death have been identified. Further reports will continue to be closely monitored.</p> <p>Please see Appendix 5.1 for Observed versus Expected analysis of Death.</p> <p>Conclusion: No new risks were identified following review of the signal of death, particularly in the comorbid elderly population.</p>

⁴⁸ Search aligned to the cardiovascular, stroke, and thromboembolic events AESIs.

Table 13. Evaluation of Special Situations for BNT162b2

Topic	Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=47174)									
Lack of Efficacy	<p>Company conventions for coding cases indicative of lack of efficacy:</p> <ul style="list-style-type: none">The coding conventions for lack of efficacy in the context of administration of the COVID-19 vaccine was revised on 12 February 2021, as shown below: PT “Vaccination failure” is coded when ALL of the following criteria are met:<ul style="list-style-type: none">The subject has received the appropriate series of two doses based on the labeling.At least 7 days have elapsed since the second dose of vaccine has been administered.The subject experiences SARS-CoV-2 infection (confirmed laboratory tests).PT “Drug ineffective” is coded when either of the following applies:<ul style="list-style-type: none">The infection is not confirmed as SARS-CoV-2 through laboratory tests (irrespective of the vaccination schedule). This includes scenarios where LOE is stated or implied, e.g., “the vaccine did not work”, “I got COVID-19”.It is unknown:<ul style="list-style-type: none">Whether the subject has received the appropriate series of two doses in correct timing based on the labeling instructions;How many days have passed since the first dose (including unspecified number of days like “a few days”, “some days”, etc.);If 7 days have passed since the second dose of the vaccine administrationThe subject experiences a vaccine preventable illness 14 days after receiving the first dose up to and through 6 days after receipt of the second dose. <p>Note: after the immune system has had sufficient time (14 days) to respond to the vaccine, this is considered a potential lack of efficacy even if the vaccination course is not complete.</p> <p>This is the summary of the coding conventions for onset of vaccine preventable disease versus the vaccination date:</p> <table><tr><th>1st dose (day 1-13)</th><th>From day 14 post 1st dose to day 6 post 2nd dose</th><th>Day 7 post 2nd dose</th></tr><tr><td>Code only the events describing the SARS-CoV-2 infection</td><td>Code “Drug ineffective”</td><td>Code “Vaccination failure”</td></tr><tr><td>Scenario Not considered LOE</td><td>Scenario considered LOE as “Drug ineffective”</td><td>Scenario considered LOE as “Vaccination failure”</td></tr></table> <p>Lack of efficacy cases</p> <ul style="list-style-type: none">Number of cases⁴⁹: 1543 (3.3% of the total PM dataset, compared to 4.4% in the previous reporting period) of which 1028 were medically confirmed and 515 non-medically confirmed.	1 st dose (day 1-13)	From day 14 post 1 st dose to day 6 post 2 nd dose	Day 7 post 2 nd dose	Code only the events describing the SARS-CoV-2 infection	Code “Drug ineffective”	Code “Vaccination failure”	Scenario Not considered LOE	Scenario considered LOE as “Drug ineffective”	Scenario considered LOE as “Vaccination failure”
1 st dose (day 1-13)	From day 14 post 1 st dose to day 6 post 2 nd dose	Day 7 post 2 nd dose								
Code only the events describing the SARS-CoV-2 infection	Code “Drug ineffective”	Code “Vaccination failure”								
Scenario Not considered LOE	Scenario considered LOE as “Drug ineffective”	Scenario considered LOE as “Vaccination failure”								

⁴⁹ Twenty-eight (28) additional cases retrieved in this dataset were excluded from the analysis; upon review, 10 cases cannot be considered true lack of efficacy cases because the subjects developed SARS-CoV-2

Table 13. Evaluation of Special Situations for BNT162b2

Topic	Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=47174)
	<ul style="list-style-type: none"> Number of lack of efficacy events:⁵⁰ 1543 (Drug ineffective [1024] and Vaccination failure [519]). Country of incidence: US (437), France (229), Italy (183), Germany (90), Austria (83), UK (75), Croatia (62), Estonia (36), Belgium, Hungary, Spain (29 each), Poland (27), Ecuador (24), Netherlands (20), Japan (17), Czech Republic (15), Norway (14), Israel (12), Greece, Portugal (11 each), Mexico (10); the remaining 100 cases originated from 30 different countries. COVID-19 infection was confirmed in 1463 cases and suspected in 80 cases. Outcome was reported as resolved/resolving (386), resolved with sequelae (6), not resolved (174), or unknown (877) at the time of the reporting; there were 100 cases where a fatal outcome was reported (see also <i>Death</i> section above in this table). <p>Drug ineffective cases (1024)</p> <ul style="list-style-type: none"> Drug ineffective seriousness: all serious (1024)⁵¹ Lack of efficacy term was reported: <ul style="list-style-type: none"> after the first dose in 501 cases after the second dose in 320 cases in 203 cases it was unknown after which dose the lack of efficacy occurred Latency of lack of efficacy term reported after the first dose was known for 203 cases: <ul style="list-style-type: none"> day 14 to ≤ 30 days: 168 subjects ≥ 31 days to ≤ 60 days: 27 subjects ≥ 61 days to 99 days: 8 subjects Latency of lack of efficacy term reported after the second dose was known for 178 cases: <ul style="list-style-type: none"> before day 7: 53 subjects day 7 to ≤ 30 days: 44 subjects ≥ 31 days to ≤ 60 days: 49 subjects ≥ 61 days to ≤ 90 days: 26 subjects ≥ 91 days to ≤ 120 days: 6 subjects Latency of lack of efficacy term reported in cases where the number of doses administered was not provided, was known for 107 cases: <ul style="list-style-type: none"> before day 7: 6 subjects day 7 to ≤ 30 days: 42 subjects ≥ 31 days to ≤ 60 days: 29 subjects

infection during the early days from the first dose (days 1 – 13); the vaccine has not had sufficient time to stimulate the immune system and, consequently, the development of a vaccine preventable disease during this time is not considered a potential lack of effect of the vaccine; 7 cases were identified as not to report lack of efficacy, these patients did not develop COVID-19 infection; in 9 cases, the lack of efficacy PT did not refer to BNT162b2 vaccine; 2 cases were invalidated in the safety database after DLP.

⁵⁰ Relevant LOE PTs recorded in these 1543 cases were Drug ineffective (1009) and Vaccination failure (536). Upon review after DLP, the following changes were made: PT recoded from Vaccination failure to Drug ineffective (17) and PT Drug ineffective removed in cases reporting both Drug ineffective and Vaccination failure (2).

⁵¹ Includes 3 cases where event seriousness captured as non-serious was upgraded to serious after DLP.

Table 13. Evaluation of Special Situations for BNT162b2

Topic	Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=47174)
	<ul style="list-style-type: none"> ○ ≥ 61 days to ≤ 90 days: 11 subjects ○ 120 days: 19 subjects <p>According to the RSI, individuals may not be fully protected until 7 days after their second dose of vaccine, therefore for the above 1024 cases where lack of efficacy was reported after the first dose or the second dose, the reported events may represent signs and symptoms of intercurrent or undiagnosed COVID-19 infection or infection in an individual who was not fully vaccinated, rather than vaccine ineffectiveness.</p> <p><i>Vaccination failure cases (519)</i></p> <ul style="list-style-type: none"> • Vaccination failure seriousness: all serious⁵² • Lack of efficacy term was reported in all cases after the second dose • Latency of lack of efficacy term was known for 506 cases; in the remaining 13 cases, it was implied that lack of efficacy term was reported on or after day 7 post second dose, but specific information of latency was not provided. <ul style="list-style-type: none"> ○ day 7 to ≤ 30 days: 104 subjects ○ ≥ 31 days to ≤ 60 days: 212 subjects ○ ≥ 61 days to ≤ 90 days: 172 subjects ○ ≥ 91 days to ≤ 120 days: 18 subjects • COVID-19 (412), Asymptomatic COVID-19 (77), COVID-19 pneumonia, and SARS-CoV-2 test positive (27 each) were the reported vaccine preventable infections in these cases. <p><i>South African variant (7 cases)</i></p> <ul style="list-style-type: none"> • In 7 of the 1543 cases, COVID-19 infection with South African variant was reported. Country of incidence: France (3), Norway (3, from a single reporter), and Switzerland (1). • Lack of efficacy events: Vaccination failure (6) and Drug ineffective (1) <p>The outcome of COVID-19 infection related events (7) reported in these 7 cases were: fatal (1), resolving (2), not resolved (1), and unknown (3).</p> <p>Conclusion: No new safety signals have emerged based on a review of these cases.</p>
Vaccine Interactions	<ul style="list-style-type: none"> • Number of cases: 40⁵³ (0.08% of the total PM dataset, compared to 0.09% in the previous reporting period) of which, 6 cases were medically confirmed and 34 cases were non-medically confirmed. • Country of incidence: US (16), UK (9), Germany (3), Canada, Finland (2 each), Bulgaria, Czech Republic, France, Italy, Netherlands, Norway, Spain, and Switzerland (1 each). • Subject Gender: Female (22), Male (17), and Unknown (1); • Subjects' Age: 22 to 84 years; (n=33); mean=57.1; median 59;

⁵² Includes 1 case where event seriousness captured as non-serious was upgraded to serious after DLP.

⁵³ 1 case reported interaction with BCG vaccine after a 9-month-old baby was exposed to BNT162b2 during breast feeding. This case was excluded and will be reviewed in [Table 14](#) under Use in Pregnancy and While Breast Feeding.

Table 13. Evaluation of Special Situations for BNT162b2

Topic	Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=47174)
	<ul style="list-style-type: none"> • Relevant reported interaction PTs: Drug interaction (30), Potentiating drug interaction (6), Alcohol interaction (3), and Inhibitory drug interaction (1); • Relevant event seriousness: Serious (16) and Non-serious (24); • Relevant event outcome: Resolved/Resolving (10), Resolved with sequelae (1), Not resolved (2), and Unknown (27); • Co-reported events coded to the PTs (>1 event): Headache (6), Fatigue, Nausea, Pain in extremity (4 each), Heart rate increased, Loss of consciousness, Pruritus, Pyrexia, Somnolence (3 each), Arthralgia, Asthenia, Balance disorder, Discomfort, Dizziness, Dysphonia, Erythema, Glossodynia, Herpes virus infection, Herpes zoster, Hypertension, Hypoaesthesia, Inappropriate schedule of product administration, Insomnia, Myalgia, Off label use, Tremor, Urticaria, and Visual impairment (2 each). • Reported Interacting Agents (33 cases): Alcohol (3), clopidogrel, hydroxycarbamide, ibuprofen, methotrexate, polyethylene glycol microspheres, pregabalin, ropinirole (2 each), acenocoumarol, aciclovir, amlodipine, amoxicillin/clavulanate, acetylsalicylic acid, atorvastatin, bisoprolol, bupivacaine, carbidopa/levodopa, ciprofloxacin, fexofenadine, guselkumab, infliximab, insulin, lamotrigine, levodopa, macrogol 3350/potassium chloride/sodium bicarbonate/sodium chloride, methylprednisolone, mirtazapine, naproxen, olanzapine, osimertinib, paracetamol, ramipril, rasegiline, temazepam, tetanus vaccine (1 each). <ul style="list-style-type: none"> ○ Of the 33 cases, 1 case reported a potential interaction with tetanus vaccine. A 35-year-old female patient received her first dose of BNT162b2 and a tetanus vaccine 7 days later after sustaining an injury. The patient saw on the CDC website after she received the tetanus vaccine that she had to wait 14 days before or after the Covid-19 vaccination. Of note, previously, the CDC recommended COVID-19 vaccines to be administered alone 14 days before or after administration of other vaccines out of caution. The CDC guidance regarding coadministration with other vaccines was updated to state “COVID-19 vaccines and other vaccines may now be administered without regard to timing.”⁵⁴ • The remaining 7 cases reported potential interactions with unspecified medications such as blood thinner, hormone replacement, hormonal contraception, NSAIDs, immunosuppressant, MRI contrast, and sleep aid containing diphenhydramine (1 each). <p>Conclusion: There is no indication of a safety signal of interference of immune response of vaccines noted based on a review of these cases.</p>

a. Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources.

⁵⁴ <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>.

9.5.4. Evaluation of Missing Information

Table 14 below summarises the evaluation of new information received during the current reporting period from post-marketing data sources¹⁵ in relation to the Missing information associated with the use of BNT162b2.

Table 14. Evaluation of Missing Information for BNT162b2

Missing Information	Post-Marketing ¹⁵ Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
Use in Pregnancy and While Breast Feeding ⁵⁵	<ul style="list-style-type: none"> Number of cases: 473⁵⁶ (1.0% of the total PM dataset, compared to 0.9% of the total PM dataset in the previous reporting period) of which 330 cases involved use in pregnancy. Please refer to Appendix 9 for the interval and cumulative analysis of use in pregnancy cases. During the interval there were 143 cases involving the use of BNT162b2 while breast feeding. <p><u>Breast feeding baby cases: 128, of which</u></p> <ul style="list-style-type: none"> 107 cases reported exposure to vaccine during breastfeeding (PT Exposure via breast milk) without the occurrence of any clinical events; 21 cases, 8 serious and 13 non-serious, reported clinical events that occurred in the infant/child exposed to vaccine via breastfeeding (PT Exposure via breast milk); the events that were reported more than once coded to the PTs Pyrexia (3), Diarrhoea, Poor feeding infant, Poor quality sleep, and Rash (2 each). <p><u>Breast feeding mother cases: 15, of which</u></p> <ul style="list-style-type: none"> 13 were serious and 2 were non-serious. Of the 15 cases that reported events in mothers who were breast feeding, 3 cases reported lactation issues that coded to the PTs Galactostasis (2) and Lactation disorder (1). The other events reported in more than 1 case coded to the PTs Maternal exposure during breast feeding (12), Fatigue, Off label use (4 each), Headache, Pain, Pain in extremity, Product use issue, Vaccination site pain (3 each), Asthenia, Axillary pain, Dizziness, Lymphadenopathy, Mastitis, Muscular weakness, and Urticaria (2 each). <p>Conclusion: There were no safety signals that emerged from the review of these cases of use while breast feeding.</p>
Use in Immunocompromised Patients ⁵⁷	<ul style="list-style-type: none"> Number of cases: 1823 (3.9% of the total PM dataset, compared to 4.4% of the previous reporting period) of which 887 were medically confirmed and 936 non-medically confirmed; Case Seriousness: Serious (1217), Non-Serious (606); Country of incidence: UK (528), US (316), France (295), Czech Republic (142), Italy (116), Germany (48), Spain (43), Japan (35), Sweden (33),

⁵⁵ Missing information as per both the EU-RMP Version 1.1, approved on 15 April 2021 and the US PVP, Version 0.4, dated 08 April 2021.

⁵⁶ Eleven (11) cases were excluded from the analysis because pregnancy was not confirmed, or the case did not involve breast feeding.

⁵⁷ Missing information as per the EU-RMP Version 1.1, approved on 15 April 2021.

Table 14. Evaluation of Missing Information for BNT162b2

Missing Information	Post-Marketing ¹⁵ Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
	<p>Denmark (28), Netherlands (23), Belgium (22), Norway (20), Canada (19), Austria (18), Hungary (16), Mexico and Switzerland (15 each), Greece (12), Finland (9), Ireland, Poland and Portugal (8 each), Israel (6), Romania (5), Croatia and Luxembourg (4 each), Brazil, Iceland, Panama and Turkey (3 each) and Estonia, Lithuania and Malaysia (2 each); the remaining 9 cases originated from 9 different countries;</p> <ul style="list-style-type: none"> • Gender: females (1267), males (533) and unknown (23); • Age (n = 1707) ranged from 16 to 98 years, mean = 60.4 years, median = 62 years; • Relevant subjects' medical histories most frequently reported (≥20 cases) coded to the PTs: Immunodeficiency (306), Breast cancer (244), Neoplasm malignant (91), Renal transplant (86), Radiotherapy and Hysterectomy (82 each), Prostate cancer (77), Chemotherapy (68), Thyroidectomy (67), Liver transplant (54), Neoplasm (43), Lung neoplasm malignant (42), Chronic lymphocytic leukaemia (38), Thyroid cancer and Lymphoma (33 each), Colon cancer, Breast cancer female, Mastectomy and Immunosuppression (28 each), Splenectomy and Malignant melanoma (25 each), HIV infection and Nephrectomy (24 each), Breast conserving surgery (23) and Non-Hodgkin's lymphoma (21); • Of the 7560 clinical events overall reported, the most frequent (>60 occurrences) coded to the PTs: Headache (322), Fatigue (319), Pyrexia (234), Pain in extremity (202), Nausea (182), Vaccination site pain (163), Chills (153), Arthralgia (140), Myalgia (135), Malaise (131), Pain (121), Dyspnoea (118), Dizziness (115), Asthenia (93), Lymphadenopathy (88), Diarrhoea (84), Vomiting (75), COVID-19 (71), Herpes zoster (70), Pruritus and Rash (65 each) and Pulmonary embolism (64)); • Case outcome: fatal (77, see Table 13, <i>Death</i>), resolved/resolving (871), resolved with sequelae (37), not resolved (630) and unknown (208). <p>Conclusion: The most frequently reported clinical events observed in immunocompromised subjects were consistent with those observed in the overall population, except for pulmonary embolism which is consistent with what would be expected given the disease states of this population (e.g. cancers). The reporting proportion of cases with fatal outcome (4.2%), unresolved cases (34.6%) and cases resolved with sequelae (2.0%) in immunocompromised subjects is higher compared to the reporting proportion observed in the overall population (2.1% for fatal outcome, 25.1% for outcome of not resolved, 1.2% for outcome of resolved with sequelae), but this is expected considering that underlying comorbidities are likely to be contributory to delayed events recovery or to subjects' death.</p> <p>No safety signals have emerged that would be considered specific to this population.</p>
Use in Patients With Autoimmune or Inflammatory Disorders ⁵⁷	<ul style="list-style-type: none"> • Number of cases: 2708 (5.7% of the total PM dataset, compared to 6.5% of the previous reporting period) of which 1089 were medically confirmed and 1619 non-medically confirmed; • Case Seriousness: Serious (1590), Non-Serious (1118); • Country of incidence: UK (807), US (711), France (212), Italy (182), Germany (101), Japan (80), Czech Republic (65), Sweden (54), Spain (49), Canada (47), Finland (34), Greece (30), Austria (28), Belgium, Denmark and Norway (26 each), Ireland (25), Switzerland (24), Netherlands (21), Hungary and Portugal (20 each), Mexico (18), Israel (15), Romania (14), Panama (8), Brazil and Turkey (7 each), Croatia and Luxembourg (5 each), Puerto Rico (4), Bulgaria,

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Table 14. Evaluation of Missing Information for BNT162b2

Missing Information	Post-Marketing ¹⁵ Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
	<p>Chile, Lithuania, Serbia and Slovenia (3 each) and Island and Peru (2 each); the remaining 12 cases originated from 12 different countries;</p> <ul style="list-style-type: none"> • Gender: Females (2205), Males (455) and Unknown (48); • Age (n=2535) ranged from 12 to 99 years, mean=54.2 years, median=54 years; • Relevant subjects' medical histories most frequently reported (≥40 cases) coded to the PTs: Hypothyroidism (549), Rheumatoid arthritis (336), Autoimmune thyroiditis (228), Arthritis (213), Multiple sclerosis (138), Psoriasis (117), Thyroid disorder and Crohn's disease (115 each), Colitis ulcerative (110), Type 1 diabetes mellitus (101), Inflammatory bowel disease (82), Coeliac disease (77), Systemic lupus erythematosus (69), Psoriatic arthropathy (64), Diabetes mellitus (63), Sjogren's syndrome (57), Autoimmune disorder (55), Raynaud's phenomenon (48), Basedow's disease (44), Neuropathy peripheral (41) and Hyperthyroidism (40); • Of the 11338 events overall reported, the most frequent clinical events (>80 occurrences) coded to the PTs: Headache (601), Fatigue (515), Pyrexia (369), Pain in extremity (336), Nausea (283), Arthralgia (276), Myalgia (256), Pain (239), Dizziness (236), Vaccination site pain (230), Chills (225), Malaise (164), Asthenia (145), Pruritus (139), Dyspnoea and Lymphadenopathy (131 each), Herpes zoster (121), Paraesthesia (119), Rash (116), Diarrhoea (101), Hypoaesthesia (90), Vomiting (89), and Feeling abnormal (82); • Case outcome: fatal (31, see Table 13, <i>Death</i>), resolved/resolving (1278), resolved with sequelae (53), not resolved (1034) and unknown (312). <p>Conclusion: The most frequently reported clinical events observed in subjects with autoimmune or inflammatory disorders were consistent with those observed in the overall population. The reporting proportion of unresolved cases (38.2%) and cases resolved with sequelae (2.0%) is slightly higher compared to the reporting proportion observed in the overall population (25.1% for outcome of not resolved and 1.2% for outcome of resolved with sequelae) but this is expected considering that underlying comorbidities are likely to be contributory to delayed events recovery. Of note, the reporting proportion of cases with fatal outcome in subjects with autoimmune or inflammatory conditions (1.1%) is below the reporting proportion of cases with fatal outcome in the overall population (2.1%).</p> <p>No safety signals have emerged that would be considered specific to this population.</p>
Use in Frail Patients With Co-morbidities (e.g. COPD, Diabetes, Chronic Neurological Disease, Cardiovascular Disorders, Active tuberculosis) ⁵⁸	<ul style="list-style-type: none"> • Number of cases: 4090 (8.7% of the total PM dataset, compared to 10.6% of the previous reporting period) of which 2431 were medically confirmed and 1659 non-medically confirmed; • Case Seriousness: Serious (2733), Non-Serious (1357); • Country of incidence: UK (802), US (683), France (561), Japan (357), Italy (257), Spain (190), Czech Republic and Germany (153 each), Sweden (118), Netherlands (76), Denmark (69), Austria (65), Finland (58), Canada (50), Hungary and Portugal (47 each), Belgium, Mexico and Norway (40 each), Ireland (38), Switzerland (36), Panama (31), Greece (28), Poland (18), Romania (15), Israel (14), Croatia (13), Estonia (10), Brazil and Malta (8 each), Luxembourg (7), Costa Rica and Slovenia (5 each), Bulgaria, Latvia and

⁵⁸ Missing information as per the EU-RMP Version 1.1, approved on 15 April 2021; as per the South Africa RMP, Version 1.0, dated 24 March 2021, active tuberculosis is included as an additional co-morbidity.

Table 14. Evaluation of Missing Information for BNT162b2

Missing Information	Post-Marketing ¹⁵ Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
	<p>Turkey (4 each), Ecuador, Philippines, Puerto Rico and Slovakia (3 each); the remaining 24 cases originated from 16 different countries;</p> <ul style="list-style-type: none"> Gender: Females (2625), Males (1417) and Unknown (48); Age (n=3913) ranged from 3 to 101 years, mean = 63.2 years, median = 67 years; Relevant subjects' medical histories most frequently reported (>□0 cases) coded to the PTs: Asthma (1466), Diabetes mellitus (782), Type 2 diabetes mellitus (594), COPD (344), Chronic kidney disease (225), Cardiac failure (211), Pulmonary embolism (156), Dementia 153), Renal failure (98), Parkinson's disease (95), Dementia Alzheimer's type (89), Cognitive disorder (67) and Cardiac failure congestive (41); Of the 15871 events overall reported, the most frequent clinical events (□135 occurrences) coded to the PTs: Headache (626), Pyrexia (523), Fatigue (518), Dyspnoea (366), Nausea (330), Pain in extremity (312), Chills (302), Dizziness (287), Myalgia (262), Vaccination site pain (258), Pain (243), Arthralgia (241), Malaise (231), Asthenia (228), COVID-19 (193), Pruritus (185), Pulmonary embolism (172), Cough (170), Vomiting (160), Diarrhoea (140), Rash (136); all these events were consistent with the most frequent events observed in the overall population, except for pulmonary embolism which is consistent with what may be expected in this population given the underlying risk factors for pulmonary embolism; Case outcome: fatal (350, see Table 13, Death), resolved/resolving (2044), resolved with sequelae (57), not resolved (1176) and unknown (463). <p>Conclusion: The reporting proportion of not resolved cases (28.8%) and cases resolved with sequelae (1.4%) in frail subjects is similar to the reporting proportion observed in the overall population (25.1% for outcome of not resolved, 1.2% for outcome of resolved with sequelae).</p> <p>The reporting proportion of cases reporting fatal outcome (8.6%) in frail subjects is higher than the reporting proportion of cases reporting fatal outcome in the overall population (2.1%). This is expected, considering that most of the cases reporting a fatal outcome (76%) among the frail subjects involved subjects over 75 years of age who, due to their advanced age and underlying comorbidities, are more likely to die than younger individuals. Underlying comorbidities are likely to be contributory to their deaths.</p> <p>No safety signals have emerged that would be considered specific to this population.</p>
Interaction With Other Vaccines ⁵⁷	There was 1 case reporting a potential interaction with other vaccines during the reporting interval (please refer to Table 13, Vaccine Interactions).
Long-Term Safety Data ⁵⁷	Not applicable
Use in Paediatric Individuals <12 Years of Age ⁵⁹	<ul style="list-style-type: none"> Number of cases: 12⁶⁰ (0.03% of the total PM dataset, compared to 0.07% of the previous reporting period), of which 7 were medically confirmed and

⁵⁹ Missing information as per the US PVP, Version 0.4, dated 08 April 2021.

⁶⁰ Upon review, 13 additional cases were excluded from analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects and 1 case was invalidated after the DLP as

Table 14. Evaluation of Missing Information for BNT162b2

Missing Information	Post-Marketing ¹⁵ Cases Evaluation Total Number of Cases in the Reporting Period (N=47174)
	<p>5 were non-medically confirmed, and indicative of administration in paediatric subjects <12 years of age;</p> <ul style="list-style-type: none"> • Country of incidence: UK, US (5 each), Italy, Spain (1 each); • Cases Seriousness: Serious (1), Non-Serious (11); • Gender: Females (8), Males (3), Unknown (1); • Age (n=12) ranged from 1 month to 11 years, mean = 5.7, median = 5.5; • Case outcome: resolved/resolving, not resolved (3 each), and unknown (6). • Of the 27 reported events, <ul style="list-style-type: none"> ○ The most frequent (>1 case) were coded to the PTs Product administered to patient of inappropriate age (7, see Section 7 Medication Errors) and Product use issue (5); ○ There were 5 unlisted events reported in 5 cases. These events coded to the PTs Dysgeusia, Influenza like illness, Eye infection, Fibroblast growth factor 23, and Seizure (1 each). <p>No new significant safety information was identified based on a review of these cases.</p>
Vaccine effectiveness ⁶¹	Relevant cases for vaccine effectiveness during the reporting interval are reviewed in Table 13 , <i>Lack of Efficacy</i> .

found to be a duplicate of an invalid case; other paediatric cases, including a case involving a 1-month-old subject, might be reported with a miscoded pediatric age however, since they reported limited details and no follow-up is possible for clarification, they were conservatively discussed in this section.

⁶¹ As per the US PVP Version 0.4, dated 08 April 2021; as per the South Africa RMP, Version 1.0, dated 24 March 2021, this safety concern is stated as “Vaccine effectiveness against novel variant(s) in South Africa”.

10. OVERALL BENEFIT-RISK EVALUATION

10.1. Benefits

BNT162b2 is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 12 years of age and older.

Efficacy

Study 2 is a multicenter, placebo-controlled efficacy study in participants 12 years of age and older. Randomization was stratified by age: 12 through 15 years of age, 16 through 55 years of age, or 56 years of age and older, with a minimum of 40% of participants in the ≥ 56 -year stratum. The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19. Participants with pre-existing stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, were included as were participants with known stable infection with HIV, HCV, or HBV.

Efficacy in participants 16 years of age and older

In the Phase 2/3 portion of Study 2, based on data accrued through 14 November 2020, approximately 44,000 participants 12 years of age and older were randomised equally and were to receive 2 doses of COVID-19 mRNA Vaccine or placebo. The efficacy analyses included participants that received their second vaccination within 19 to 42 days after their first vaccination. The majority (93.1%) of vaccine recipients received the second dose 19 days to 23 days after Dose 1. Participants are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19.

The population for the analysis of the primary efficacy endpoint included 36,621 participants 12 years of age and older (18,242 in the COVID-19 mRNA Vaccine group and 18,379 in the placebo group) who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose.

At the time of the primary efficacy analysis, participants had been followed for symptomatic COVID-19 for in total 2,214 person-years for the COVID-19 mRNA Vaccine and in total 2,222 person-years in the placebo group. There were no meaningful clinical differences in overall vaccine efficacy in participants who were at risk of severe COVID-19 including those with 1 or more comorbidities that increase the risk of severe COVID-19 (e.g. asthma, body mass index (BMI) ≥ 30 kg/m², chronic pulmonary disease, diabetes mellitus, hypertension).

Updated efficacy analyses were performed with additional confirmed COVID-19 cases accrued during blinded placebo-controlled follow-up through 13 March 2021, representing up to 6 months of follow-up after Dose 2 for participants in the efficacy population.

Efficacy against severe COVID-19

Secondary efficacy analyses suggested benefit of the COVID-19 mRNA Vaccine in preventing severe COVID-19. As of 14 November 2020, efficacy against severe COVID-19 (as defined by the study protocol) occurring after the first dose was 88.9% (95% CI: 20.1,

99.7) (1 case in COVID-19 mRNA Vaccine group and 9 cases in placebo group), with an estimated vaccine efficacy of 75.0% (95% CI: -152.6, 99.5) (1 case in COVID-19 mRNA Vaccine group and 4 cases in placebo group) against severe COVID-19 occurring at least 7 days after Dose 2. Efficacy against severe COVID-19, defined by the Centers for Disease Control and Prevention as hospitalization, admission to the Intensive Care Unit, intubation or mechanical ventilation, or death occurring after the first dose, was 92.9% (95% CI: 53.2, 99.8) (1 case in COVID-19 mRNA Vaccine group and 14 cases in placebo group). As of 13 March 2021, vaccine efficacy against severe COVID-19 is presented only for participants with or without prior SARS-CoV-2 infection (Table 12) as the COVID-19 case counts in participants without prior SARS-CoV-2 infection were the same as those in participants with or without prior SARS-CoV-2 infection in both the vaccine and placebo groups.

Efficacy and immunogenicity in adolescents 12 to 15 years of age

In Study 2 an analysis of SARS-CoV-2 neutralizing titers in a randomly selected subset of participants was performed to demonstrate non-inferior immune responses (within 1.5-fold) comparing adolescents 12 to 15 years of age to participants 16 to 25 years of age who had no serological or virological evidence of past SARS-CoV-2 infection. The immune response to BNT162b2 in adolescents 12 to 15 years of age (n=190) was non-inferior to the immune response in participants 16 to 25 years of age (n=170), based on results for SARS-CoV-2 neutralizing titers at 1 month after Dose 2. The GMT ratio of the adolescents 12 to 15 years of age group to the participants 16 to 25 years of age group was 1.76, with a 2-sided 95% CI of 1.47 to 2.10, meeting the 1.5-fold non-inferiority criterion (the lower bound of the 2-sided 95% CI for the GMR >0.67) which indicates a statistically greater response in the adolescents 12 to 15 years of age than that of participants 16 to 25 years of age.

10.2. Risks

Based on pharmacovigilance monitoring activities, since first authorisation, anaphylaxis has been recognised as an important identified risk. Hypersensitivity reactions (other than Anaphylaxis), Diarrhoea, Pain in extremity (arm), Vomiting, Asthenia, Lethargy, Decreased appetite, Hyperhidrosis and Night sweats were also assessed as identified risks (not important for the purpose of inclusion in the RMPs and PVP) and added to the RSI as ADRs in Section 4.8 Undesirable effects. Vaccine stress-related responses (including Dizziness, Fainting, Palpitations, Increases in heart rate, Alterations in blood pressure, Feeling short of breath, Tingling sensations, Sweating and/or Anxiety) were evaluated to be identified risks (not important for the purpose of inclusion in the in the RMPs and PVP) and they were added to the RSI in Section 4.4 Special warnings and precautions for use.

Based on all available safety and efficacy data for BNT162b2 the benefit-risk profile of the vaccine remains favourable.

10.3. Overall Benefit-Risk

The identified risks associated with the use of BNT162b2 are mitigated through provision of relevant product information in the RSI to support safe use of the product. Risks have been evaluated in the context of the enumerated benefits of the product. Based on the available safety and efficacy data for BNT162b2, the overall benefit-risk profile of BNT162b2 remains favourable.

11. CONCLUSION AND ACTIONS

Based on all available safety and efficacy data for BNT162b2, the benefit-risk profile of the vaccine remains favourable.

The MAH will continue to review the safety of BNT162b2, including reports of adverse experiences and will revise the product documents if an evaluation of the safety data yields significant new information.

PREPARED BY PFIZER INC

CDS EFFECTIVE DATE: 19-MAY-2021

Date of Superseded CDS: 20-Apr-2021

COVID-19 mRNA Vaccine

CORE DATA SHEET

VERSION 4

PFIZER CONFIDENTIAL

1

1. NAME OF THE MEDICINAL PRODUCT

COVID-19 mRNA Vaccine (nucleoside modified) and COMIRNATY are called TRADENAME.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION^{1,2}

This is a multidose vial and must be diluted before use.

One vial (0.45 mL) contains 6 doses of 0.3 mL after dilution, see Section 6.6.

One dose (0.3 mL) contains 30 micrograms of COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).

TRADENAME is highly purified single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

For the full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM^{2,3}

Concentrate for solution for injection.

The vaccine is a white to off-white frozen solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

The following is a representative indication. Locally approved indications may differ.

Active immunization to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 virus, in individuals 12 years of age and older.^{4,49}

4.2. Posology and method of administration

Posology

Individuals 12 years of age and older

TRADENAME is administered intramuscularly after dilution as a series of 2 doses (0.3 mL each) at greater than or equal to 21 days (preferably 3 weeks) apart.^{5,49}

There are no data available on the interchangeability of TRADENAME with other COVID-19 vaccines to complete the vaccination series. Individuals who have received 1 dose of TRADENAME should receive a second dose of TRADENAME to complete the vaccination series.

Individuals may not be protected until at least 7 days after their second dose of the vaccine.⁶

For further information on efficacy, see Section 5.1.

Pediatric population

The safety and efficacy of TRADENAME in individuals under 12 years of age have not yet been established.

Geriatric population

Clinical studies of TRADENAME include participants 65 years of age and older and their data contributes to the overall assessment of safety and efficacy.⁷ Of the total number of TRADENAME recipients in Study 2 (N = 22,026), 16.5% (n = 3627) were 65 through 74 years of age and 4.2% (n = 925) were 75 years of age and older (see Section 5.1).⁵⁰

Method of administration

Administer TRADENAME intramuscularly in the deltoid muscle after dilution.

Do not inject the vaccine intravascularly, subcutaneously, or intradermally.

After dilution, vials of TRADENAME contain 6 doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.

Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Do not pool excess vaccine from multiple vials.

For instructions on the handling, dilution, and dose preparation of the vaccine before administration, see Section 6.6.

4.3. Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in Section 6.1.

4.4. Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

General recommendations

As with all injectable vaccines, appropriate medical treatment and supervision must always be readily available in case of a rare anaphylactic event following the administration of the vaccine.⁹

The administration of TRADENAME should be postponed in individuals suffering from acute severe febrile illness.⁹

Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection, should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration.⁹

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.

Some individuals may have stress-related responses associated with the process of vaccination itself. Stress-related responses are temporary and resolve on their own. They may include dizziness, fainting, palpitations, increases in heart rate, alterations in blood pressure, feeling short of breath, tingling sensations, sweating and/or anxiety. Individuals should be advised to bring symptoms to the attention of the vaccination provider for evaluation and precautions should be in place to avoid injury from fainting.⁶⁷

As with any vaccine, vaccination with TRADENAME may not protect all vaccine recipients.

4.5. Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Do not mix TRADENAME with other vaccines/products in the same syringe.

4.6. Fertility, pregnancy and lactation

Pregnancy

There are limited amount of data from the use of TRADENAME in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition, or post-natal development (see Section 5.3).^{10,11} Administration of TRADENAME in pregnancy should be considered when the potential benefits outweigh any potential risks for the mother and fetus.

Lactation

It is unknown whether TRADENAME is excreted in human milk.

Fertility

It is unknown whether TRADENAME has an impact on fertility. Animal studies do not indicate direct or indirect harmful effects with respect to female fertility or reproductive toxicity (see Section 5.3).^{10,11}

4.7. Effects on ability to drive and use machines

TRADENAME has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under Section 4.8 “Undesirable effects” may temporarily affect the ability to drive or use machines.

4.8. Undesirable effects

Summary of safety profile

The safety of TRADENAME was evaluated in participants 12 years of age and older in 2 clinical studies conducted in the United States, Europe, Turkey, South Africa, and South America.^{12,49} Study BNT162-01 (Study 1) enrolled 60 participants, 18 through 55 years of age and 36 participants, 56 through 85 years of age.⁶⁸ Study C4591001 (Study 2) enrolled approximately 46,000 participants,⁴¹ 12 years of age or older.¹²

Participants 16 years of age and older

In Study 2, a total of 22,026 participants 16 years of age or older received at least 1 dose of TRADENAME and a total of 22,021 participants 16 years of age or older received placebo.⁵⁰

The most frequent adverse reactions in participants 16 years of age and older (in order from highest to lowest frequencies) were injection site pain (>80%), fatigue (>60%), headache (>50%), myalgia (>40%), chills (>30%), arthralgia (>20%), pyrexia and injection site swelling (>10%) and were usually mild or moderate in intensity and resolved within a few days after vaccination.⁶⁴ A lower frequency of reactogenicity events was associated with greater age.¹⁵

The safety profile in 545 participants receiving TRADENAME, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.^{17,28,31}

Study 2 also included 200 participants with confirmed stable human immunodeficiency virus (HIV) infection. The safety profile of the participants receiving TRADENAME (n = 100) in the individuals with stable HIV infection was similar to that seen in the general population.⁵¹

Adolescents 12 through 15 years of age

In an analysis of Study 2, 2260 adolescents (1131 TRADENAME; 1129 placebo) were 12 through 15 years of age. Of these, 1308 adolescents (660 TRADENAME and 648 placebo) have been followed for at least 2 months after the second dose of TRADENAME.^{41,42} The safety evaluation in Study 2 is ongoing.

The most frequent adverse reactions in adolescents 12 through 15 years of age were injection site pain (>90%), fatigue and headache (>70%), myalgia and chills (>40%), arthralgia and pyrexia (>20%).^{43,44,45}

Table 1. Adverse Drug Reactions^{13,14,16,64}

System Organ Class	Adverse Drug Reactions
Blood and lymphatic system disorders	Lymphadenopathy
Metabolism and nutrition disorders	Decreased appetite
Nervous system disorders	Headache Lethargy
Gastrointestinal disorders	Nausea
Skin and subcutaneous tissue disorders	Hyperhidrosis Night sweats
Musculoskeletal and connective tissue disorders	Arthralgia Myalgia
General disorders and administration site conditions	Pyrexia Chills Asthenia Malaise Fatigue Injection site pain Injection site swelling Injection site redness

Adverse reactions from TRADENAME post-authorization experience

The following events have been identified as adverse reactions during the post-authorization use of TRADENAME.

Table 2. Adverse Drug Reactions³⁸

System Organ Class	Adverse Drug Reactions
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema)
Gastrointestinal disorders	Diarrhea Vomiting
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)

4.9. Overdose

Participants who received 58 micrograms of TRADENAME in clinical trials did not report an increase in reactogenicity or adverse events.¹⁸

In the event of overdose, monitoring of vital functions and possible symptomatic treatment is recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacological class, therapeutic class

Vaccines

Refer to the current ATC code index for the appropriate code assignment for the pharmacologic and/or therapeutic class.

Mechanism of action

The nucleoside-modified messenger RNA in TRADENAME is formulated in lipid nanoparticles, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits both neutralizing antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19.^{19,20}

Efficacy

Study 2 is a multicenter, placebo-controlled efficacy study in participants 12 years of age and older. Randomization was stratified by age: 12 through 15 years of age, 16 through 55 years of age, or 56 years of age and older, with a minimum of 40% of participants in the ≥ 56 -year stratum.¹² The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19.¹² Participants with pre-existing stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment,²¹ were included as were participants with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV).¹²

Efficacy in participants 16 years of age and older

In the Phase 2/3 portion of Study 2, based on data accrued through 14 November 2020, approximately 44,000 participants 12 years of age and older were randomized equally and received 2 doses of COVID-19 mRNA Vaccine or placebo. The efficacy analyses included participants that received their second vaccination within 19 to 42 days after their first vaccination. The majority (93.1%) of vaccine recipients received the second dose 19 days to 23 days after Dose 1.⁵² Participants are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19.^{12,27}

The population for the analysis of the primary efficacy endpoint included, 36,621 participants 12 years of age and older (18,242 in the COVID-19 mRNA Vaccine group and 18,379 in the placebo group) who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose.²² Table 3 presents the specific demographic characteristics in the studied population.

Table 3. Demographics (Population for the Primary Efficacy Endpoint)^{a,22}

	TRADENAME (N=18,242) n (%)	Placebo (N=18,379) n (%)
Sex		
Male	9318 (51.1)	9225 (50.2)
Female	8924 (48.9)	9154 (49.8)
Age (years)		
Mean (SD)	50.6 (15.70)	50.4 (15.81)
Median	52.0	52.0
Min, max	(12, 89)	(12, 91)
Age group		
12 to 15 years	46 (0.3)	42 (0.2)
16 to 17 years	66 (0.4)	68 (0.4)
16 to 64 years	14,216 (77.9)	14,299 (77.8)
65 to 74 years	3176 (17.4)	3226 (17.6)
≥75 years	804 (4.4)	812 (4.4)
Race		
White	15,110 (82.8)	15,301 (83.3)
Black or African American	1617 (8.9)	1617 (8.8)
American Indian or Alaska Native	118 (0.6)	106 (0.6)
Asian	815 (4.5)	810 (4.4)
Native Hawaiian or other Pacific Islander	48 (0.3)	29 (0.2)
Other ^b	534 (2.9)	516 (2.8)
Ethnicity		
Hispanic or Latino	4886 (26.8)	4857 (26.4)
Not Hispanic or Latino	13,253 (72.7)	13,412 (73.0)
Not reported	103 (0.6)	110 (0.6)
Comorbidities^c		
Yes	8432 (46.2)	8450 (46.0)
No	9810 (53.8)	9929 (54.0)

- All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window, have no other important protocol deviations as determined by the clinician, and have no evidence of SARS-CoV-2 infection prior to 7 days after Dose 2.
- Includes multiracial and not reported.
- Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19.
 - Chronic lung disease (e.g., emphysema and chronic bronchitis, idiopathic pulmonary fibrosis, and cystic fibrosis) or moderate to severe asthma
 - Significant cardiac disease (e.g., heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Table 3. Demographics (Population for the Primary Efficacy Endpoint)^{a,22}

	TRADENAME (N=18,242) n (%)	Placebo (N=18,379) n (%)
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- Obesity (body mass index ≥ 30 kg/m²)
- Diabetes (Type 1, Type 2, or gestational)
- Liver disease
- Human Immunodeficiency Virus (HIV) infection (not included in the efficacy evaluation)

At the time of the primary efficacy analysis, participants had been followed for symptomatic COVID-19 for at least 2214 person-years for the COVID-19 mRNA Vaccine and at least 2222 person-years in the placebo group.³²

There were no meaningful clinical differences in overall vaccine efficacy in participants who were at risk of severe COVID-19 including those with 1 or more comorbidities that increase the risk of severe COVID-19 [e.g., asthma, body mass index (BMI) ≥ 30 kg/m², chronic pulmonary disease, diabetes mellitus, hypertension].^{23,24}

The vaccine efficacy information is presented in Table 4.

Table 4. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection^{*,34}			
Subgroup	TRADENAME N^a=18,198 Cases n1^b Surveillance Time^c (n2^d)	Placebo N^a=18,325 Cases n1^b Surveillance Time^c (n2^d)	Vaccine Efficacy % (95% CI)
All participants ^e	8 2.214 (17,411)	162 2.222 (17,511)	95.0 (90.3, 97.6) ^f
16 to 64 years	7 1.706 (13,549)	143 1.710 (13,618)	95.1 (89.6, 98.1) ^g
≥ 65 years	1 0.508 (3848)	19 0.511 (3880)	94.7 (66.7, 99.9) ^g
65 to 74 years	1 0.406 (3074)	14 0.406 (3095)	92.9 (53.1, 99.8) ^g
≥ 75 years	0 0.102 (774)	5 0.106 (785)	100.0 (-13.1, 100.0) ^g

Table 4. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection^{*,34}			
Subgroup	TRADENAME N^a=18,198 Cases n1^b Surveillance Time^c (n2^d)	Placebo N^a=18,325 Cases n1^b Surveillance Time^c (n2^d)	Vaccine Efficacy % (95% CI)
First COVID-19 occurrence from 7 days after Dose 2 in participants with or without* evidence of prior SARS-CoV-2 infection²⁸			
Subgroup	TRADENAME N^a=19,965 Cases n1^b Surveillance Time^c (n2^d)	Placebo N^a=20,172 Cases n1^b Surveillance Time^c (n2^d)	Vaccine Efficacy % (95% CI)
All participants ^e	9 2.332 (18,559)	169 2.345 (18,708)	94.6 (89.9, 97.3) ^f
16 to 64 years	8 1.802 (14,501)	150 1.814 (14,627)	94.6 (89.1, 97.7) ^g
≥65 years	1 0.530 (4044)	19 0.532 (4067)	94.7 (66.8, 99.9) ^g
65 to 74 years	1 0.424 (3239)	14 0.423 (3255)	92.9 (53.2, 99.8) ^g
≥75 years	0 0.106 (805)	5 0.109 (812)	100.0 (-12.1, 100.0) ^g

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

Abbreviations: NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

- N = number of participants in the specified group.
- n1 = Number of participants meeting the endpoint definition.
- Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
- n2 = Number of participants at risk for the endpoint.
- No confirmed cases were identified in adolescents 12 to 15 years of age.
- Two-sided credible interval for vaccine efficacy (VE) was calculated using a beta-binomial model with a beta (0.700102, 1) prior for $\theta=r(1-VE)/(1+r(1-VE))$, where r is the ratio of surveillance time in the active vaccine group over that in the placebo group.
- Two-sided confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.

The subgroup analyses of vaccine efficacy including demographic characteristics is presented in Table 5.

Table 5. Subgroup Analyses of Vaccine Efficacy - Participants Without Evidence of Infection* Prior to 7 Days After Dose 2 - Evaluable Efficacy Population³³

Subgroup	TRADENAME N ^a =18,198	Placebo N ^a =18,325	Vaccine Efficacy % (95% CI)
	Cases n1 ^b Surveillance Time ^c (n2 ^d)	Cases n1 ^b Surveillance Time ^c (n2 ^d)	
Sex			
Female	5 1.090 (8536)	81 1.114 (8749)	93.7 (84.7, 98.0)
Male	3 1.124 (8875)	81 1.108 (8762)	96.4 (88.9, 99.3)
Ethnicity			
Hispanic or Latino	3 0.605 (4764)	53 0.600 (4746)	94.4 (82.7, 98.9)
Not Hispanic or Latino	5 1.596 (12,548)	109 1.608 (12,661)	95.4 (88.9, 98.5)
Race			
Black or African American	0 0.165 (1502)	7 0.164 (1486)	100.0 (31.2, 100.0)
White	7 1.889 (14,504)	146 1.903 (14,670)	95.2 (89.8, 98.1)
All others ^f	1 0.160 (1405)	9 0.155 (1355)	89.3 (22.6, 99.8)

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

- N = Number of participants in the specified group.
- n1 = Number of participants meeting the endpoint definition.
- Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
- n2 = Number of participants at risk for the endpoint.
- Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.
- All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.

Updated efficacy analyses were performed with additional confirmed COVID-19 cases accrued during blinded placebo-controlled follow-up through 13 March 2021, representing up to 6 months of follow-up after Dose 2 for participants in the efficacy population.

The updated vaccine efficacy information is presented in Table 6.

Table 6. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up Period

First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection^{*,53}			
Subgroup	TRADENAME N^a=20,998 Cases n^{1b} Surveillance Time^c (n2^d)	Placebo N^a=21,096 Cases n^{1b} Surveillance Time^c (n2^d)	Vaccine Efficacy % (95% CI^e)
All participants ^f	77 6.247 (20,712)	850 6.003 (20,713)	91.3 (89.0, 93.2)
16 through 64 years	70 4.859 (15,519)	710 4.654 (15,515)	90.6 (87.9, 92.7)
65 years and older	7 1.233 (4192)	124 1.202 (4226)	94.5 (88.3, 97.8)
65 through 74 years	6 0.994 (3350)	98 0.966 (3379)	94.1 (86.6, 97.9)
75 years and older	1 0.239 (842)	26 0.237 (847)	96.2 (76.9, 99.9)
First COVID-19 occurrence from 7 days after Dose 2 in participants with or without* evidence of prior SARS-CoV-2 infection⁵⁴			
Subgroup	TRADENAME N^a=22,166 Cases n^{1b} Surveillance Time^c (n2^d)	Placebo N^a=22,320 Cases n^{1b} Surveillance Time^c (n2^d)	Vaccine Efficacy % (95% CI^e)
All participants ^f	81 6.509 (21,642)	873 6.274 (21,689)	91.1 (88.8, 93.0)
16 through 64 years	74 5.073 (16,218)	727 4.879 (16,269)	90.2 (87.6, 92.4)
65 years and older	7 1.267 (4315)	128 1.232 (4326)	94.7 (88.7, 97.9)
65 through 74 years	6 1.021 (3450)	102 0.992 (3468)	94.3 (87.1, 98.0)
75 years and older	1 0.246 (865)	26 0.240 (858)	96.2 (77.2, 99.9)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.

b. n1 = Number of participants meeting the endpoint definition.

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- c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
- d. n2 = Number of participants at risk for the endpoint.
- e. Two-sided confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.
- f. Included confirmed cases in participants 12 through 15 years of age: 0 in the TRADENAME group (both without and with or without evidence of prior SARS-CoV-2 infection); 16 and 18 in the placebo group (without and with or without evidence of prior SARS-CoV-2 infection, respectively).

The updated subgroup analyses of vaccine efficacy by demographic characteristics are presented in Table 7 and Table 8.

Table 7. Vaccine Efficacy– First COVID-19 Occurrence From 7 Days After Dose 2 – Participants Without Evidence of Infection* Prior to 7 Days After Dose 2 by Demographic Characteristics – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up Period⁵³

Subgroup	TRADENAME N ^a =20,998 Cases n1 ^b Surveillance Time ^c (n2 ^d)	Placebo N ^a =21,096 Cases n1 ^b Surveillance Time ^c (n2 ^d)	Vaccine Efficacy % (95% CI) ^e
Sex			
Male	42 3.246 (10,637)	399 3.047 (10,433)	90.1 (86.4, 93.0)
Female	35 3.001 (10,075)	451 2.956 (10,280)	92.4 (89.2, 94.7)
Ethnicity			
Hispanic or Latino	29 1.786 (5161)	241 1.711 (5120)	88.5 (83.0, 92.4)
Not Hispanic or Latino	47 4.429 (15,449)	609 4.259 (15,484)	92.6 (90.0, 94.6)
Race			
Black or African American	4 0.545 (1737)	48 0.527 (1737)	91.9 (78.0, 97.9)
White	67 5.208 (17,186)	747 5.026 (17,256)	91.3 (88.9, 93.4)
All others ^f	6 0.494 (1789)	55 0.451 (1720)	90.0 (76.9, 96.5)

Table 7. Vaccine Efficacy– First COVID-19 Occurrence From 7 Days After Dose 2 – Participants Without Evidence of Infection* Prior to 7 Days After Dose 2 by Demographic Characteristics – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up Period⁵³

Subgroup	TRADENAME N ^a =20,998 Cases n1 ^b Surveillance Time ^c (n2 ^d)	Placebo N ^a =21,096 Cases n1 ^b Surveillance Time ^c (n2 ^d)	Vaccine Efficacy % (95% CI) ^e
Country			
Argentina	15 1.012 (2600)	108 0.986 (2586)	86.5 (76.7, 92.7)
Brazil	12 0.406 (1311)	80 0.374 (1293)	86.2 (74.5, 93.1)
Germany	0 0.047 (236)	1 0.048 (242)	100.0 (-3874.2, 100.0)
South Africa	0 0.080 (291)	9 0.074 (276)	100.0 (53.5, 100.0)
Turkey	0 0.027 (228)	5 0.025 (222)	100.0 (-0.1, 100.0)
United States	50 4.674 (16,046)	647 4.497 (16,094)	92.6 (90.1, 94.5)

Notes: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting). Included confirmed cases in participants 12 through 15 years of age: 0 in the TRADENAME group; 16 in the placebo group.

- * Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
- a. N = Number of participants in the specified group.
- b. n1 = Number of participants meeting the endpoint definition.
- c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
- d. n2 = Number of participants at risk for the endpoint.
- e. Two-sided confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.
- f. All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.

Table 8. Vaccine Efficacy– First COVID-19 Occurrence From 7 Days After Dose 2 – Participants With or Without* Evidence of Infection Prior to 7 Days After Dose 2 by Demographic Characteristics – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up Period⁵⁴

Subgroup	TRADENAME N^a=22,166 Cases n1^b Surveillance Time^c (n2^d)	Placebo N^a=22,320 Cases n1^b Surveillance Time^c (n2^d)	Vaccine Efficacy % (95% CI)^e
Sex			
Male	44 3.376 (11,103)	411 3.181 (10,920)	89.9 (86.2, 92.8)
Female	37 3.133 (10,539)	462 3.093 (10,769)	92.1 (88.9, 94.5)
Ethnicity			
Hispanic or Latino	32 1.862 (5408)	245 1.794 (5391)	87.4 (81.8, 91.6)
Not Hispanic or Latino	48 4.615 (16,128)	628 4.445 (16,186)	92.6 (90.1, 94.6)
Race			
Black or African American	4 0.611 (1958)	49 0.601 (1985)	92.0 (78.1, 97.9)
White	69 5.379 (17,801)	768 5.191 (17,880)	91.3 (88.9, 93.3)
All others ^f	8 0.519 (1883)	56 0.481 (1824)	86.8 (72.1, 94.5)
Country			
Argentina	16 1.033 (2655)	110 1.017 (2670)	85.7 (75.7, 92.1)
Brazil	14 0.441 (1419)	82 0.408 (1401)	84.2 (71.9, 91.7)
Germany	0 0.047 (237)	1 0.048 (243)	100.0 (-3868.6, 100.0)
South Africa	0 0.099 (358)	10 0.096 (358)	100.0 (56.6, 100.0)
Turkey	0 0.029 (238)	6 0.026 (232)	100.0 (22.2, 100.0)
United States	51 4.861 (16,735)	664 4.678 (16,785)	92.6 (90.2, 94.6)

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Table 8. Vaccine Efficacy– First COVID-19 Occurrence From 7 Days After Dose 2 – Participants With or Without* Evidence of Infection Prior to 7 Days After Dose 2 by Demographic Characteristics – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up Period⁵⁴

Subgroup	TRADENAME N^a=22,166 Cases n1^b Surveillance Time^c (n2^d)	Placebo N^a=22,320 Cases n1^b Surveillance Time^c (n2^d)	Vaccine Efficacy % (95% CI)^e
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Notes: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting). Included confirmed cases in participants 12 through 15 years of age: 0 in the TRADENAME group; 18 in the placebo group.

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

- N = Number of participants in the specified group.
- n1 = Number of participants meeting the endpoint definition.
- Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
- n2 = Number of participants at risk for the endpoint.
- Two-sided confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.
- All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.

The subgroup analyses of vaccine efficacy by risk status in participants is presented in Table 9.

Table 9. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Participants Without Evidence of Infection* Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population²³

Efficacy Endpoint Subgroup	TRADENAME N^a=18,198 Cases n1^b Surveillance Time^c (n2^d)	Placebo N^a=18,325 Cases n1^b Surveillance Time^c (n2^d)	Vaccine Efficacy % (95% CI)^e
First COVID-19 occurrence from 7 days after Dose 2			
At risk ^f			
Yes	4 1.025 (8030)	86 1.025 (8029)	95.3 (87.7, 98.8)
No	4 1.189 (9381)	76 1.197 (9482)	94.7 (85.9, 98.6)

Table 9. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Participants Without Evidence of Infection* Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population²³

Efficacy Endpoint Subgroup	TRADENAME N^a=18,198 Cases n1^b Surveillance Time^c (n2^d)	Placebo N^a=18,325 Cases n1^b Surveillance Time^c (n2^d)	Vaccine Efficacy % (95% CI^e)
Age group (years) and at risk			
16 to 64 and not at risk	4 0.962 (7671)	69 0.964 (7701)	94.2 (84.4, 98.5)
16 to 64 and at risk	3 0.744 (5878)	74 0.746 (5917)	95.9 (87.6, 99.2)
≥65 and not at risk	0 0.227 (1701)	7 0.233 (1771)	100.0 (29.0, 100.0)
≥65 and at risk	1 0.281 (2147)	12 0.279 (2109)	91.7 (44.2, 99.8)
Obese^g			
Yes	3 0.763 (6000)	67 0.782 (6103)	95.4 (86.0, 99.1)
No	5 1.451 (11,406)	95 1.439 (11,404)	94.8 (87.4, 98.3)
Age group (years) and obese			
16 to 64 and not obese	4 1.107 (8811)	83 1.101 (8825)	95.2 (87.3, 98.7)
16 to 64 and obese	3 0.598 (4734)	60 0.609 (4789)	94.9 (84.4, 99.0)
≥65 and not obese	1 0.343 (2582)	12 0.338 (2567)	91.8 (44.5, 99.8)
≥65 and obese	0 0.165 (1265)	7 0.173 (1313)	100.0 (27.1, 100.0)

Abbreviations: BMI = body mass index; N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

* Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = number of participants in the specified group.

b. n1 = Number of participants meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

d. n2 = Number of participants at risk for the endpoint.

Table 9. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Participants Without Evidence of Infection* Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population²³

Efficacy Endpoint Subgroup	TRADENAME N^a=18,198 Cases n1^b Surveillance Time^c (n2^d)	Placebo N^a=18,325 Cases n1^b Surveillance Time^c (n2^d)	Vaccine Efficacy % (95% CI)^e
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e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.

f. At risk is defined as having at least 1 of the Charlson Comorbidity Index (CMI) category or obesity (BMI ≥ 30 kg/m²).

g. Obese is defined as BMI ≥ 30 kg/m².

The updated subgroup analyses of vaccine efficacy by risk status in participants followed up to 6 months after Dose 2 (with a cut-off date of 13 March 2021) are presented in Tables 10 and 11.

Table 10. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Participants Without Evidence of Infection* Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up Period⁵⁵

Subgroup	TRADENAME N^a=20,998 Cases n1^b Surveillance Time^c (n2^d)	Placebo N^a=21,096 Cases n1^b Surveillance Time^c (n2^d)	Vaccine Efficacy % (95% CI)^e
First COVID-19 occurrence from 7 days after Dose 2 ^f	77 6.247 (20,712)	850 6.003 (20,713)	91.3 (89.0, 93.2)
At risk ^g			
Yes	35 2.797 (9167)	401 2.681 (9136)	91.6 (88.2, 94.3)
No	42 3.450 (11,545)	449 3.322 (11,577)	91.0 (87.6, 93.6)
Age group (years) and risk status			
16 through 64 and not at risk	41 2.776 (8887)	385 2.661 (8886)	89.8 (85.9, 92.8)
16 through 64 and at risk	29 2.083 (6632)	325 1.993 (6629)	91.5 (87.5, 94.4)
65 and older and not at risk	1 0.553 (1870)	53 0.546 (1922)	98.1 (89.2, 100.0)
65 and older and at risk	6 0.680 (2322)	71 0.656 (2304)	91.8 (81.4, 97.1)
Obese ^h			
Yes	27 2.103 (6796)	314 2.050 (6875)	91.6 (87.6, 94.6)

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Table 10. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Participants Without Evidence of Infection* Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up Period⁵⁵

Subgroup	TRADENAME N ^a =20,998 Cases n1 ^b Surveillance Time ^c (n2 ^d)	Placebo N ^a =21,096 Cases n1 ^b Surveillance Time ^c (n2 ^d)	Vaccine Efficacy % (95% CI) ^e
No	50 4.143 (13,911)	536 3.952 (13,833)	91.1 (88.1, 93.5)
Age group (years) and obesity status			
16 through 64 and not obese	46 3.178 (10,212)	444 3.028 (10,166)	90.1 (86.6, 92.9)
16 through 64 and obese	24 1.680 (5303)	266 1.624 (5344)	91.3 (86.7, 94.5)
65 and older and not obese	4 0.829 (2821)	79 0.793 (2800)	95.2 (87.1, 98.7)
65 and older and obese	3 0.404 (1370)	45 0.410 (1426)	93.2 (78.9, 98.7)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

- N = Number of participants in the specified group.
- n1 = Number of participants meeting the endpoint definition.
- Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
- n2 = Number of participants at risk for the endpoint.
- Two-sided confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time.
- Included confirmed cases in participants 12 through 15 years of age: 0 in the TRADENAME group; 16 in the placebo group.
- At risk is defined as having at least 1 of the Charlson Comorbidity Index (CMI) category or obesity (BMI ≥ 30 kg/m² or BMI $\geq 95^{\text{th}}$ percentile [12 through 15 Years of age]).
- Obese is defined as BMI ≥ 30 kg/m². For 12 through 15 years age group, obesity is defined as a BMI at or above the 95th percentile. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm.

Table 11. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Participants With or Without* Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up Period⁵⁶

Subgroup	TRADENAME N^a=22,166 Cases n1^b Surveillance Time^c (n2^d)	Placebo N^a=22,320 Cases n1^b Surveillance Time^c (n2^d)	Vaccine Efficacy % (95% CI)^e
First COVID-19 occurrence from 7 days after Dose 2 ^f	81 6.509 (21,642)	873 6.274 (21,689)	91.1 (88.8, 93.0)
At risk ^g			
Yes	36 2.925 (9601)	410 2.807 (9570)	91.6 (88.1, 94.2)
No	45 3.584 (12,041)	463 3.466 (12,119)	90.6 (87.2, 93.2)
Age group (years) and risk status			
16 through 64 and not at risk	44 2.887 (9254)	397 2.779 (9289)	89.3 (85.4, 92.4)
16 through 64 and at risk	30 2.186 (6964)	330 2.100 (6980)	91.3 (87.3, 94.2)
65 and older and not at risk	1 0.566 (1920)	55 0.559 (1966)	98.2 (89.6, 100.0)
65 and older and at risk	6 0.701 (2395)	73 0.672 (2360)	92.1 (82.0, 97.2)
Obese ^h			
Yes	28 2.207 (7139)	319 2.158 (7235)	91.4 (87.4, 94.4)
No	53 4.301 (14,497)	554 4.114 (14,448)	90.8 (87.9, 93.2)
Age group (years) and obesity status			
16 through 64 and not obese	49 3.303 (10,629)	458 3.158 (10,614)	89.8 (86.2, 92.5)
16 through 64 and obese	25 1.768 (5584)	269 1.719 (5649)	91.0 (86.4, 94.3)
65 and older and not obese	4 0.850 (2899)	82 0.811 (2864)	95.3 (87.6, 98.8)
65 and older and obese	3 0.417 (1415)	46 0.420 (1462)	93.4 (79.5, 98.7)

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Table 11. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Participants With or Without* Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up Period⁵⁶

	TRADENAME N^a=22,166 Cases n1^b	Placebo N^a=22,320 Cases n1^b	
Subgroup	Surveillance Time^c (n2^d)	Surveillance Time^c (n2^d)	Vaccine Efficacy % (95% CI)^e

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

- N = Number of participants in the specified group.
- n1 = Number of participants meeting the endpoint definition.
- Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
- n2 = Number of participants at risk for the endpoint.
- Two-sided confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time.
- Included confirmed cases in participants 12 to 15 years of age: 0 in the TRADENAME group; 18 in the placebo group.
- At risk is defined as having at least 1 of the Charlson Comorbidity Index (CMI) category or obesity (BMI ≥ 30 kg/m² or BMI $\geq 95^{\text{th}}$ percentile [12 through 15 years of age]).
- Obese is defined as BMI ≥ 30 kg/m². For the 12 through 15 years of age group, obesity is defined as a BMI at or above the 95th percentile. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm.

Efficacy against severe COVID-19

Secondary efficacy analyses suggested benefit of the COVID-19 mRNA Vaccine in preventing severe COVID-19.

As of 14 November 2020, efficacy against severe COVID-19 (as defined by the study protocol) occurring after the first dose was 88.9% (95% CI: 20.1, 99.7) (1 case in COVID-19 mRNA Vaccine group and 9 cases in placebo group), with an estimated vaccine efficacy of 75.0% (95% CI: -152.6, 99.5) (1 case in COVID-19 mRNA Vaccine group and 4 cases in placebo group) against severe COVID-19 occurring at least 7 days after Dose 2.³⁶ Efficacy against severe COVID-19, defined by the Centers for Disease Control and Prevention as hospitalization, admission to the Intensive Care Unit, intubation or mechanical ventilation, or death occurring after the first dose, was 92.9% (95% CI: 53.2, 99.8) (1 case in COVID-19 mRNA Vaccine group and 14 cases in placebo group).³⁷

As of 13 March 2021, vaccine efficacy against severe COVID-19 is presented only for participants with or without prior SARS-CoV-2 infection (Table 12) as the COVID-19 case counts in participants without prior SARS-CoV-2 infection were the same as those in participants with or without prior SARS-CoV-2 infection in both the TRADENAME and placebo groups.

Table 12. Vaccine Efficacy – First Severe COVID-19 Occurrence in Participants With or Without* Prior SARS-CoV-2 Infection Based on FDA[†] or Centers for Disease Control and Prevention (CDC)[‡] Definition After Dose 1 or From 7 Days After Dose 2 in the Placebo-Controlled Follow-up

Vaccine Efficacy – First Severe COVID-19 Occurrence Based on FDA Definition^{57,58}			
	TRADENAME Cases n1^a Surveillance Time (n2^b)	Placebo Cases n1^a Surveillance Time (n2^b)	Vaccine Efficacy % (95% CI^c)
After Dose 1 ^d	1 8.439 ^e (22,505)	30 8.288 ^e (22,435)	96.7 (80.3, 99.9)
7 days after Dose 2 ^f	1 6.522 ^g (21,649)	21 6.404 ^g (21,730)	95.3 (70.9, 99.9)
Vaccine Efficacy – First Severe COVID-19 Occurrence Based on CDC Definition^{59,60}			
	TRADENAME Cases n1^a Surveillance Time (n2^b)	Placebo Cases n1^a Surveillance Time (n2^b)	Vaccine Efficacy % (95% CI^c)
After Dose 1 ^d	1 8.427 ^e (22,473)	45 8.269 ^e (22,394)	97.8 (87.2, 99.9)
7 days after Dose 2 ^f	0 6.514 ^g (21,620)	32 6.391 ^g (21,693)	100 (88.0, 100.0)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

[†] Severe illness from COVID-19 as defined by FDA is confirmed COVID-19 and presence of at least 1 of the following:⁶¹

- Clinical signs at rest indicative of severe systemic illness (respiratory rate ≥ 30 breaths per minute, heart rate ≥ 125 beats per minute, saturation of oxygen $\leq 93\%$ on room air at sea level, or ratio of arterial oxygen partial pressure to fractional inspired oxygen < 300 mm Hg);
- Respiratory failure [defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation or extracorporeal membrane oxygenation (ECMO)];
- Evidence of shock (systolic blood pressure < 90 mm Hg, diastolic blood pressure < 60 mm Hg, or requiring vasopressors);
- Significant acute renal, hepatic, or neurologic dysfunction;
- Admission to an Intensive Care Unit;
- Death.

[‡] Severe illness from COVID-19 as defined by CDC is confirmed COVID-19 and presence of at least 1 of the following:⁶¹

- Hospitalization;
- Admission to the Intensive Care Unit;
- Intubation or mechanical ventilation;
- Death.

a. n1 = Number of participants meeting the endpoint definition.

b. n2 = Number of participants at risk for the endpoint.

- c. Two-side confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.
- d. Efficacy assessed based on the Dose 1 all available efficacy (modified intention-to-treat) population that included all randomized participants who received at least 1 dose of study intervention.⁶²
- e. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
- f. Efficacy assessed based on the evaluable efficacy (7 Days) population that included all eligible randomized participants who receive all dose(s) of study intervention as randomized within the predefined window, have no other important protocol deviations as determined by the clinician.⁶²
- g. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

Efficacy and immunogenicity in adolescents 12 to 15 years of age

An analysis of Study 2 has been performed in adolescents 12 to 15 years of age up to a data cutoff date of 13 March 2021.

The vaccine efficacy information in adolescents 12 to 15 years of age is presented in Table 13.

Table 13. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, Without Evidence of Infection and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period, Adolescents 12 to 15 Years of Age Evaluable Efficacy (7 Days) Population

First COVID-19 occurrence from 7 days after Dose 2 in adolescents 12 to 15 years of age without evidence of prior SARS-CoV-2 infection^{*,46}			
	TRADENAME N^a=1005 Cases n^{1b} Surveillance Time^c (n^{2d})	Placebo N^a=978 Cases n^{1b} Surveillance Time^c (n^{2d})	Vaccine Efficacy % (95% CI^e)
Adolescents 12 to 15 Years of Age	0 0.154 (1001)	16 0.147 (972)	100.0 (75.3, 100.0)
First COVID-19 occurrence from 7 days after Dose 2 in adolescents 12 to 15 years of age with or without* evidence of prior SARS-CoV-2 infection⁴⁷			
	TRADENAME N^a=1119 Cases n^{1b} Surveillance Time^c (n^{2d})	Placebo N^a=1110 Cases n^{1b} Surveillance Time^c (n^{2d})	Vaccine Efficacy % (95% CI^e)
Adolescents 12 to 15 Years of Age	0 0.170 (1109)	18 0.163 (1094)	100.0 (78.1, 100.0)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

-
- * Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
 - a. N = Number of participants in the specified group.
 - b. n1 = Number of participants meeting the endpoint definition.
 - c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
 - d. n2 = Number of participants at risk for the endpoint.
 - e. Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time.

In Study 2 an analysis of SARS-CoV-2 neutralizing titers in a randomly selected subset of participants was performed to demonstrate non-inferior immune responses (within 1.5-fold) comparing adolescents 12 to 15 years of age to participants 16 to 25 years of age who had no serological or virological evidence of past SARS-CoV-2 infection. The immune response to TRADENAME in adolescents 12 to 15 years of age (n=190) was non-inferior to the immune response in participants 16 to 25 years of age (n=170), based on results for SARS-CoV-2 neutralizing titers at 1 month after Dose 2. The geometric mean titers (GMT) ratio of the adolescents 12 to 15 years of age group to the participants 16 to 25 years of age group was 1.76, with a 2-sided 95% CI of 1.47 to 2.10, meeting the 1.5-fold non-inferiority criterion (the lower bound of the 2-sided 95% CI for the geometric mean ratio [GMR] >0.67) which indicates a statistically greater response in the adolescents 12 to 15 years of age than that of participants 16 to 25 years of age.⁴⁸

5.2. Pharmacokinetic properties

Not applicable.

5.3. Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of repeat dose toxicity and reproduction and developmental toxicity.^{10,11}

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients^{2,3}

(4-hydroxybutyl)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)

2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC0159)

1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)

Cholesterol

Potassium chloride

Potassium dihydrogen phosphate

Sodium chloride

Disodium hydrogen phosphate dihydrate

Sucrose

Water for injections

6.2. Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in Sections 6.3 and 6.6.

6.3. Shelf life

Unopened vial

6 months at -90 °C to -60 °C.

Alternatively, unopened vials may be stored and transported at -25 °C to -15 °C for a total of 2 weeks and can be returned to -90 °C to -60 °C.³⁹

Once removed from the freezer, the unopened vial can be stored for up to 1 month at 2 °C to 8 °C. Within the 1-month shelf-life at 2 °C to 8 °C, up to 12 hours may be used for transportation.^{29,63} Prior to use, the unopened vial can be stored for up to 2 hours at temperatures up to 30 °C.

Once thawed, the vaccine should not be re-frozen.

Transfers of frozen vials stored at ultra-low temperature (<-60 °C)

- Closed-lid vial trays containing 195 vials removed from ultra-low temperature frozen storage (<-60 °C) may be at temperatures up to 25 °C for up to 5 minutes.
- Open-lid vial trays, or vial trays containing less than 195 vials, removed from ultra-low temperature frozen storage (<-60 °C) may be at temperatures up to 25 °C for up to 3 minutes.
- After vial trays are returned to frozen storage following temperature exposure up to 25 °C, they must remain in frozen storage for at least 2 hours before they can be removed again.

Transfers of frozen vials stored at -25 °C to -15 °C⁴⁰

- Closed-lid vial trays containing 195 vials removed from frozen storage (-25 °C to -15 °C) may be at temperatures up to 25 °C for up to 3 minutes.
- Open-lid vial trays, or vial trays containing less than 195 vials, removed from frozen storage (-25 °C to -15 °C) may be at temperatures up to 25 °C for up to 1 minute.

Once a vial is removed from the vial tray, it should be thawed for use.

Diluted medicinal product

Chemical and physical in-use stability, including during transportation,³⁰ has been demonstrated for 6 hours at 2 °C to 30 °C after dilution in sodium chloride 9 mg/mL (0.9%) solution for injection. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

6.4. Special precautions for storage^{2,25}

Store in a freezer at -90 °C to -60 °C.

Store in the original package in order to protect from light.

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Thawed vials can be handled in room light conditions.

For storage conditions after thawing and dilution of the medicinal product, see Section 6.3.

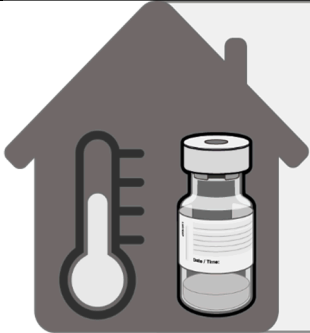
6.5. Nature and contents of container

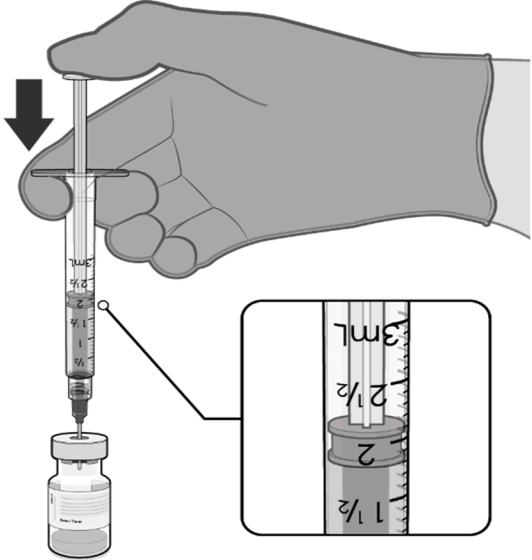
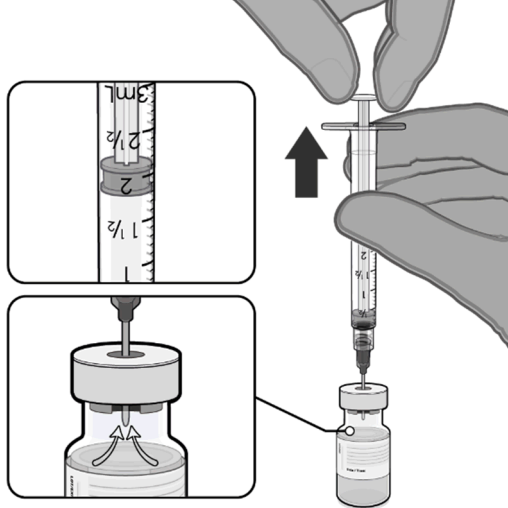
Information to be provided by local subsidiary.

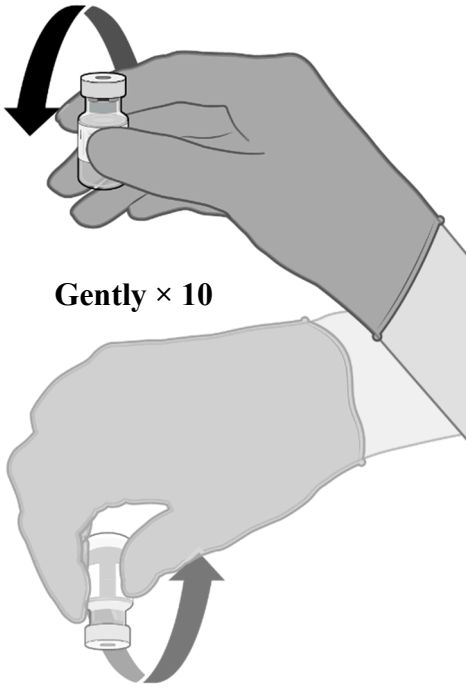

6.6. Special precautions for disposal and other handling^{2,3,26,29,30,35,63}

Handling instructions

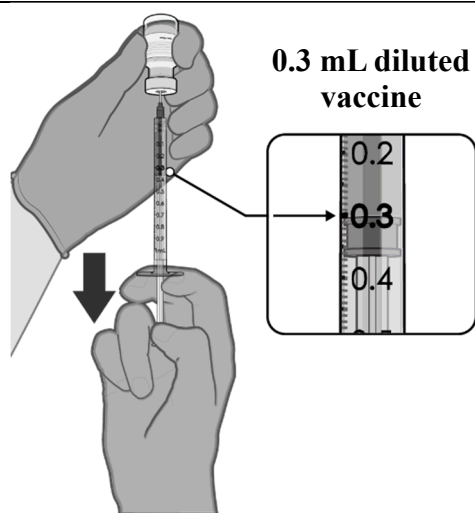
TRADENAME should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

THAWING PRIOR TO DILUTION	
 <p>No more than 2 hours at up to 30 °C</p>	<ul style="list-style-type: none"> • The multidose vial is stored frozen and must be thawed prior to dilution. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 195 vial pack may take 3 hours to thaw. Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30 °C for immediate use. • The unopened vial can be stored for up to 1 month at 2 °C to 8 °C. Within the 1-month shelf-life at 2 °C to 8 °C, up to 12 hours may be used for transportation. • Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake. • Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.

DILUTION	
 <p>1.8 mL of 0.9% sodium chloride injection</p>	<ul style="list-style-type: none"> The thawed vaccine must be diluted in its original vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.
 <p>Pull back plunger to 1.8 mL to remove air from vial.</p>	<ul style="list-style-type: none"> Equalize vial pressure before removing the needle from the vial stopper by withdrawing 1.8 mL air into the empty diluent syringe.

 <p>Gently x 10</p>	<ul style="list-style-type: none"> • Gently invert the diluted dispersion 10 times. Do not shake. • The diluted vaccine should present as an off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discoloration are present.
 <p>Record appropriate date and time. Use within 6 hours after dilution.</p>	<ul style="list-style-type: none"> • The diluted vials should be marked with the appropriate date and time. • After dilution, store at 2 °C to 30 °C and use within 6 hours, including any transportation time. • Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY



- After dilution, the vial contains 2.25 mL from which 6 doses of 0.3 mL can be extracted.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.3 mL of TRADENAME.

Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microliters.

If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Discard any unused vaccine within 6 hours after dilution.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. REFERENCES

1. BB-IND19736 Section 3.2.S.1.1
2. BB-IND19736 Section 3.2.P.2
3. BB-IND19736 Section 3.2.P.1
4. Global Emergency Use Authorization Application, Section 1.3 Intended Use
5. Global Emergency Use Authorization Application, Section 1.2 Description of Product
6. Vaccine Efficacy – First COVID-19 Occurrence ≥ 7 Days After Dose 2 – Subjects Without Evidence of Infection Before Vaccination, by Subgroup – Evaluable Efficacy (7 Days) Population
7. Global Emergency Use Authorization Application, Section 7.3.1 Geriatric use
8. ~~Module 5.3.5.1 Table 5: Demographic Characteristics – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population~~
Reference no longer applicable; removed in CDS version 4
9. Ezeanolue E, Harriman K, Hunter P, Kroger A, Pellegrini C. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)
10. Module 4.2.3 Study 20256434 (RN9391R58), Section 4.2.3.5 Final Report - A Combined Fertility and Developmental Study of BNT162b1, BNT162b2 and BNT162b3 by the Intramuscular Route in the Wistar Rat
11. Module 4.2.3.5 Study 20256434 (RN9391R58) Summary for BNT162b2 DART
12. Global Emergency Use Authorization Application, Section 6.2.1.2
13. Module 5.3.5.1 Study 20256434 (RN9391R58), Table Title: Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population
14. Module 5.3.5.1 Study 20256434 (RN9391R58), Table Title: Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population
15. Module 2.7.4 Summary of Clinical Safety, Section 2.7.4.5 Overall Conclusions
16. Module 2.5 Clinical Overview, COVID-19 Vaccine, 2021, CO for CDS (anaphylaxis & hypersensitivity)
17. Global Emergency Use Authorization, Section 6.2.4.1.1.3.1 Overview of Adverse Events
18. Module 2.7.4 Summary of Clinical Safety, Section 2.7.4.4.5
19. Global Emergency Use Authorization Application, Section 1.2.2 RNA-Lipid Nanoparticle Formulation
20. Global Emergency Use Authorization, Section 6.2.2.1.1.3 Study BNT162-01 Immunogenicity Conclusions in Phase 1
21. Global Emergency Use Authorization, Section 6.2.1.1 Phase 1 First-in-Human BNT162-01

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22. Module 5.3.5.1 Study C4591001, Table Title: Demographic Characteristics – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 Evaluable Efficacy (7 Days) Population
23. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
24. Baseline Charlson Comorbidities – ~38,000 Subjects for Phase 2/3 Analysis – Safety Population
25. BB-IND19736, Section 3.2.P.8
26. BB-IND19736, Section 3.2.P.5.2
27. Global Emergency Use Authorization, Table 5: Demographic Characteristics – Phase 2 – Dose 2 Evaluable Immunogenicity Population
28. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
29. BB-IND19736, Section 3.2.P.3.5
30. BB-IND19736, Section 3.2.P.2.6
31. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Baseline SARS-CoV-2 Status -- ~38000 Subjects for Phase 2/3 Analysis – Safety Population
32. Global Emergency Use Application, Table 35 Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
33. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
34. Vaccine Efficacy - First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup - Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy
35. Module 3.2.P Dosage and Administration Instructions for BNT162 (PF-07302048) Vaccine, 0.5 mg/mL
36. Module 5.3.5.1 C4591001 Clinical Study Report, Section 11.1.2.3.2.1.3 Table 40
37. Vaccine Efficacy – First Severe COVID-19 Occurrence Based on CDC-Definition After Dose 1 – Dose 1 All-Available Efficacy Population
38. Module 2.5, Clinical Overview to Support Inclusion of Pain in Extremity, Diarrhea, and Vomiting as Adverse Drug Reactions in Section 4.8 of the Core Data Sheet, February 2021
39. Module 3.2.P.8.1 Stability Summary and Conclusion
40. IND Section 3.2.P.2.3 Storage Shipping and Distribution

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41. Module 2.7.4 Summary of Clinical Safety, MAA Type II Variation (12-15 Years) Table 6: Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age – Safety Population
42. Table: Follow-up Time After Dose 2 – Subjects 12 Through 15 Years of Age – Safety Population
43. Table: Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population
44. Table: Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population
45. Table: Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population
46. Table: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects 12 Through 15 Years of Age and Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
47. Table: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects 12 Through 15 Years of Age and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
48. Table: Summary of Geometric Mean Ratio – NT50 – Comparison of Subjects 12 Through 15 Years of Age to Subjects 16 Through 25 Years of Age (Immunogenicity Subset) – Subjects Without Evidence of Infection up to 1 Month After Dose 2 – Dose 2 Evaluable Immunogenicity Population
49. Module 2.7.4 Summary of Clinical Safety, COVID-19 Vaccine – MAA Type II Variation (12-15 Years) April 2021
50. Interim Report – 6 Month Update: A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-COV-2 RNA Vaccine Candidates Against COVID-19 in Healthy Individuals [hereafter Interim Report – 6 Month Update] (13 March 2021), Supplemental Table 14.198 Demographic Characteristics, by Age Groups – Phase 2/3 Subjects ≥ 16 Years of Age – Safety Population
51. Interim Report – 6 Month Update (13 March 2021), Supplemental table 14.84 – Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV Positive Subjects ≥ 16 Years of Age – Safety Population
52. Final Analysis Interim Report: A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-COV-2 RNA Vaccine Candidates Against COVID-19 in Healthy

Individuals (04 November 2020), Section 10.3.3 Phase 2/3, Table 8 Vaccine Administration Timing – ~38000 Subjects for Phase 2/3 Analysis – All Randomized Subjects

53. Interim Report – 6 Month Update (13 March 2021), Table 19. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
54. Interim Report – 6 Month Update (13 March 2021), Supplemental Table 14.59. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup– Blinded Placebo-Controlled Follow-up Period–Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
55. Interim Report – 6 Month Update (13 March 2021), Table 20. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
56. Interim Report – 6 Month Update (13 March 2021), Table 21. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
57. Interim Report – 6 Month Update (13 March 2021), Table 25. Vaccine Efficacy – First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
58. Interim Report – 6 Month Update (13 March 2021), Table 26. Vaccine Efficacy – First Severe COVID-19 Occurrence After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population
59. Interim Report – 6 Month Update (13 March 2021), Supplemental Table 14.61. Vaccine Efficacy – First Severe COVID-19 Occurrence Based on CDC-Definition After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population
60. Interim Report – 6 Month Update (13 March 2021), Table 28. Vaccine Efficacy – First Severe COVID-19 Occurrence Based on CDC-Definition From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
61. EUA Amendment for Pfizer-BioNTech COVID-19 Vaccine, 6-Month Follow-Up Data from Participants 16 Years of Age and Older (13 March 2021), Section 6.2.1.2.1.2 Efficacy
62. Interim Report – 6 Month Update (13 March 2021), Table 4. Analysis Populations
63. Module 3.2.P.8.1 Stability Summary and Conclusion, April 2021
64. Adverse Drug Reaction Frequency Justification Document, COVID-19 Vaccine (BNT162B2), May 2021

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65. Interim Report – 6 Month Update (13 March 2021), Supplemental Table 14.72 – Local Reactions, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥ 16 Years of Age – Safety Population
66. Interim Report – 6 Month Update (13 March 2021), Supplemental Table 14.79 – Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥ 16 Years of Age – Safety Population
67. 2.5 Clinical Overview to Support Inclusion of Vaccine Stress-Related Reactions in Section 4.4 of the Core Data Sheet, May 2021
68. EUA Amendment for Pfizer-BioNTech COVID-19 Vaccine, 6-Month Follow-Up Data from Participants 16 Years of Age and Older (13 March 2021), Section 6.2.2.1.1 Study Populations – BNT162-01 Phase 1 Participants

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Appendix A: Adverse Drug Reactions (ADRs) and Numeric Frequencies Listed in Order of Decreasing Frequency Within Each System Organ Class (SOC)⁶⁴

Table A-1. Adverse Drug Reaction Table with Preferred Terms Listed by Decreasing Frequency Within Each System Organ Class: Individuals 16 Years of Age and Older (13 March 2021 Data Cut-off Date)

System Organ Class	ADR Term	Frequency n/N (%)
Blood and lymphatic system disorders	Lymphadenopathy	83/21926 (0.4%) ^a
Immune system disorders	Anaphylaxis ^d	Not known
	Hypersensitivity reactions	
	Rash ^d	54/21926 (0.2%) ^a
	Pruritus ^d	23/21926 (0.1%) ^a
	Urticaria ^d	15/21926 (0.1%) ^a
	Angioedema ^d	3/21926 (0.01%) ^a
Metabolism and Nutrition disorders	Decreased appetite	39/21926 (0.2%)
Nervous system disorders	Headache	2814/4924 (57.1%) ^b
	Lethargy	25/21926 (0.1%)
Gastrointestinal disorders	Diarrhea ^d	758/4924 (15.4%) ^b
	Vomiting ^d	110/4924 (2.2%) ^b
	Nausea	274/21926 (1.2%) ^a
Skin and Subcutaneous Tissue disorders	Hyperhidrosis	31/21926 (0.1%)
	Night sweats	17/21926 (0.1%)
Musculoskeletal and connective tissue disorders	Myalgia (muscle pain)	1980/4924 (40.2%) ^b
	Arthralgia (joint pain)	1232/4924 (25.0%) ^b
	Pain in extremity (arm) ^d	185/21926 (0.8%) ^a
General disorders and administration site conditions	Injection site pain	4153/4924 (84.3%) ^c
	Fatigue	3185/4924 (64.7%) ^b
	Chills	1707/4924 (34.7%) ^b
	Pyrexia	749/4924 (15.2%) ^b
	Injection site swelling	546/4924 (11.1%) ^c
	Injection site redness	486/4924 (9.9%) ^c
	Malaise	130/21926 (0.6%) ^a
	Asthenia	76/21926 (0.3%)

- Source: Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects >16 Years of Age – Safety Population (Cutoff date: 13March2021)
- Source: Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population (Cutoff date: 13March2021)
- Source: Local Reactions, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population (Cutoff date: 13March2021)
- These adverse reactions were identified in the post-authorization period.

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Table A-2. Adverse Drug Reaction Table with Preferred Terms Listed by Decreasing Frequency Within Each System Organ Class: Individuals 12 Through 15 Years of Age (13 March 2021 Data Cut-off Date)

System Organ Class	ADR Term	Frequency n/N (%)
Blood and lymphatic system disorders	Lymphadenopathy	9/1131 (0.8%) ^a
Immune system disorders	Anaphylaxis ^d	Not known
	Hypersensitivity reactions	
	Rash ^d	2/1131 (0.2%) ^a
	Urticaria ^d	2/1131 (0.2%) ^a
	Pruritus ^{d,e}	
	Angioedema ^{d,e}	
Metabolism and Nutrition disorders	Decreased appetite ^e	
Nervous system disorders	Headache	854/1131 (75.5%) ^b
	Lethargy ^e	
Gastrointestinal disorders	Diarrhea ^d	141/1131 (12.5%) ^b
	Vomiting ^d	59/1131 (5.2%) ^b
	Nausea	5/1131 (0.4%) ^a
Skin and Subcutaneous Tissue disorders	Hyperhidrosis ^e	
	Night sweats ^e	
Musculoskeletal and connective tissue disorders	Myalgia (muscle pain)	477/1131 (42.2%) ^b
	Arthralgia (joint pain) (new)	229/1131 (20.2%) ^b
	Pain in extremity (arm) ^d	1/1131 (0.1%) ^a
General disorders and administration site conditions	Injection site pain	1023/1131 (90.5%) ^c
	Fatigue	876/1131 (77.5%) ^b
	Chills	557/1131 (49.2%) ^b
	Pyrexia	275/1131 (24.3%) ^b
	Injection site swelling	104/1131 (9.2%) ^c
	Injection site redness	97/1131 (8.6%) ^c
	Malaise ^e	
	Asthenia ^e	

- Source: Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population (Cutoff date: 13March2021)
- Source: Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population (Cutoff date: 13March2021)
- Source: Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population (Cutoff date: 13March2021)
- These adverse reactions were identified in the post-authorization period.
- The following events were not reported in the 12 through 15 year old age group in Study C4591001 but were reported in individuals ≥16 years of age (see Table A-1): angioedema, pruritus, malaise, lethargy, asthenia, decreased appetite, hyperhidrosis, and night sweats.

Appendix B: Adverse Drug Reactions (ADRs) by System Organ Class and Council for International Organizations of Medical Science (CIOMS) Frequency Category Listed in Order of Decreasing Medical Seriousness or Clinical Importance Within Each Frequency Category and SOC⁶⁴

Table B-1. ADRs by SOC and CIOMS Frequency Category Listed in Order of Decreasing Medical Seriousness Within Each Frequency Category and SOC: Individuals 16 Years of Age and Older (13 March 2021 Data Cut-off Date)

System Organ Class	Very Common ≥1/10 (≥10%)	Common ≥1/100 to <1/10 (≥1% to <10%)	Uncommon ≥1/1,000 to <1/100 (≥0.1% to <1%)	Rare ≥1/10,000 to <1/1,000 (≥0.01% to <0.1%)	Very Rare <1/10,000 (<0.01%)	Frequency not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy			
Immune system disorders			Urticaria; ^{a,b} Pruritus; ^{a,b} Rash ^{a,b}	Angioedema ^{a,b}		Anaphylaxis ^a
Metabolism and Nutrition disorders			Decreased appetite			
Nervous system disorders	Headache		Lethargy			
Gastrointestinal disorders	Diarrhea ^a	Vomiting; ^a Nausea				
Skin and subcutaneous Tissue disorders			Hyperhidrosis; Night sweats			
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia		Pain in extremity (arm) ^a			
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia; Injection site swelling	Injection site redness	Asthenia; Malaise			

a. These adverse reactions were identified in the post-authorization period.

b. The following events are categorized as hypersensitivity reactions: urticaria, pruritus, rash, and angioedema.

Table B-2. ADRs by SOC and CIOMS Frequency Category Listed in order of Decreasing Medical Seriousness Within Each Frequency Category and SOC: Individuals 12 Through 15 Years of Age (13 March 2021 Data Cut-off Date)

System Organ Class	Very Common ≥1/10 (≥10%)	Common ≥1/100 to <1/10 (≥1% to <10%)	Uncommon ≥1/1,000 to <1/100 (≥0.1% to <1%)	Rare ≥1/10,000 to <1/1,000 (≥0.01% to <0.1%)	Very Rare <1/10,000 (<0.01%)	Frequency not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy			
Immune system disorders			Urticaria; ^{a,b} Rash ^{a,b}			Anaphylaxis ^a
Nervous system disorders	Headache					
Gastrointestinal disorders	Diarrhea ^a	Vomiting ^a	Nausea			
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia		Pain in extremity (arm) ^a			
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia	Injection site swelling; Injection site redness				

- a. These adverse reactions were identified in the post-authorization period. Please note that the following events were not reported in the 12 through 15 years of age group in Study C4591001 (see Table B-1): angioedema, pruritus, malaise, lethargy, asthenia, decreased appetite, hyperhidrosis, and night sweats.
- b. The following events are categorized as hypersensitivity reactions: urticaria, pruritus, rash, and angioedema.

Appendix C. HIV-Positive Participants 16 Years of Age and Older – Reactogenicity Frequency in the Safety Population Subset

Table C-1. Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – HIV-Positive Participants 16 Years of Age and Older – Reactogenicity Subset of the Safety Population^{*,65}

	TRADENAME Dose 1 N^a=54 n^b (%)	Placebo Dose 1 N^a=56 n^b (%)	TRADENAME Dose 2 N^a=60 n^b (%)	Placebo Dose 2 N^a=62 n^b (%)
Redness ^c				
Any (>2.0 cm)	2 (3.7)	3 (5.4)	4 (6.7)	1 (1.6)
Mild	2 (3.7)	1 (1.8)	3 (5.0)	1 (1.6)
Moderate	0	0	1 (1.7)	0
Severe	0	2 (3.6)	0	0
Swelling ^c				
Any (>2.0 cm)	3 (5.6)	1 (1.8)	5 (8.3)	0
Mild	2 (3.7)	0	2 (3.3)	0
Moderate	1 (1.9)	0	3 (5.0)	0
Severe	0	1 (1.8)	0	0
Pain at the injection site ^d				
Any	34 (63.0)	9 (16.1)	32 (53.3)	5 (8.1)
Mild	26 (48.1)	8 (14.3)	22 (36.7)	5 (8.1)
Moderate	8 (14.8)	1 (1.8)	9 (15.0)	0
Severe	0	0	1 (1.7)	0

Notes: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.

No Grade 4 solicited local reactions were reported in HIV-Positive participants 16 years of age and older.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. The N for each reaction was the same, therefore, this information was included in the column header.

b. n = Number of participants with the specified reaction.

c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.

d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

Table C-2. Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – HIV-Positive Participants 16 Years of Age and Older – Reactogenicity Subset of the Safety Population^{*,66}

	TRADENAME Dose 1 N^a=54 n^b (%)	Placebo Dose 1 N^a=56 n^b (%)	TRADENAME Dose 2 N^a=60 n^b (%)	Placebo Dose 2 N^a=62 n^b (%)
Fever				
≥38.0°C	1 (1.9)	4 (7.1)	9 (15.0)	5 (8.1)
≥38.0°C to 38.4°C	1 (1.9)	2 (3.6)	4 (6.7)	5 (8.1)
>38.4°C to 38.9°C	0	0	4 (6.7)	0
>38.9°C to 40.0°C	0	2 (3.6)	1 (1.7)	0
>40.0°C	0	0	0	0
Fatigue^c				
Any	22 (40.7)	15 (26.8)	24 (40.0)	12 (19.4)
Mild	15 (27.8)	9 (16.1)	12 (20.0)	5 (8.1)
Moderate	7 (13.0)	5 (8.9)	9 (15.0)	7 (11.3)
Severe	0	1 (1.8)	3 (5.0)	0
Headache^c				
Any	11 (20.4)	18 (32.1)	18 (30.0)	12 (19.4)
Mild	7 (13.0)	10 (17.9)	8 (13.3)	8 (12.9)
Moderate	4 (7.4)	7 (12.5)	8 (13.3)	4 (6.5)
Severe	0	1 (1.8)	2 (3.3)	0
Chills^c				
Any	6 (11.1)	5 (8.9)	14 (23.3)	4 (6.5)
Mild	5 (9.3)	4 (7.1)	5 (8.3)	3 (4.8)
Moderate	1 (1.9)	1 (1.8)	8 (13.3)	1 (1.6)
Severe	0	0	1 (1.7)	0
Vomiting^d				
Any	1 (1.9)	3 (5.4)	2 (3.3)	2 (3.2)
Mild	1 (1.9)	1 (1.8)	1 (1.7)	1 (1.6)
Moderate	0	0	1 (1.7)	1 (1.6)
Severe	0	2 (3.6)	0	0
Diarrhea^c				
Any	5 (9.3)	8 (14.3)	4 (6.7)	9 (14.5)
Mild	5 (9.3)	6 (10.7)	1 (1.7)	6 (9.7)
Moderate	0	1 (1.8)	2 (3.3)	3 (4.8)
Severe	0	1 (1.8)	1 (1.7)	0

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Table C-2. Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – HIV-Positive Participants 16 Years of Age and Older – Reactogenicity Subset of the Safety Population^{*,66}

	TRADENAME Dose 1 N^a=54 n^b (%)	Placebo Dose 1 N^a=56 n^b (%)	TRADENAME Dose 2 N^a=60 n^b (%)	Placebo Dose 2 N^a=62 n^b (%)
New or worsened muscle pain ^c				
Any	9 (16.7)	10 (17.9)	10 (16.7)	5 (8.1)
Mild	7 (13.0)	7 (12.5)	5 (8.3)	1 (1.6)
Moderate	2 (3.7)	3 (5.4)	5 (8.3)	4 (6.5)
Severe	0	0	0	0
New or worsened joint pain ^c				
Any	5 (9.3)	7 (12.5)	10 (16.7)	5 (8.1)
Mild	5 (9.3)	4 (7.1)	4 (6.7)	1 (1.6)
Moderate	0	3 (5.4)	6 (10.0)	4 (6.5)
Severe	0	0	0	0
Use of antipyretic or pain medication ^f	7 (13.0)	8 (14.3)	16 (26.7)	7 (11.3)

Notes: Reactions and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

No Grade 4 solicited systemic reactions were reported in HIV-positive participants 16 years of age and older.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

- N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. The N for each event or use of antipyretic or pain medication was the same, therefore, this information was included in the column header.
- n = Number of participants with the specified reaction.
- Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.
- Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.
- Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.
- Severity was not collected for use of antipyretic or pain medication.



GLOBAL LABELING MANAGEMENT CDS Safety Log

PRODUCT NAME: COVID-19 mRNA Vaccine

CDS Version History:

CDS version number	GDMS version number & GDMS link	Effective date	Sections changed
4	CDS_COVID 19 mRNA Vaccine <u>Version:</u> 8.0;CURRENT <u>Status:</u> Effective	19-May-2021	4.4 Special warnings and precautions for use 4.8 Undesirable effects 5.1 Pharmacodynamic properties Appendix A Appendix B Appendix C

1. NAME OF THE MEDICINAL PRODUCT

No safety changes during the reporting period

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

No safety changes during the reporting period

3. PHARMACEUTICAL FORM

No safety changes during the reporting period

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

No safety changes during the reporting period

4.2 Posology and method of administration

No safety changes during the reporting period

4.3 Contraindications

No safety changes during the reporting period

4.4 Special warnings and precautions for use

Version 4	Effective Date: 19-May-2021	PfLEET: 2021-0069122 2021-0069099 2021-0069406
<u>Safety/Non-safety:</u> Safety		
<u>Content change:</u> [...] <u>General recommendations</u> [...]		



GLOBAL LABELING MANAGEMENT CDS Safety Log

PRODUCT NAME: COVID-19 mRNA Vaccine

Some individuals may have stress-related responses associated with the process of vaccination itself. Stress-related responses are temporary and resolve on their own. They may include dizziness, fainting, palpitations, increases in heart rate, alterations in blood pressure, feeling short of breath, tingling sensations, sweating and/or anxiety. Individuals should be advised to bring symptoms to the attention of the vaccination provider for evaluation and precautions should be in place to avoid injury from fainting.⁶⁷

4.5 Interaction with other medicinal products and other forms of interaction

No safety changes during the reporting period

4.6 Fertility, pregnancy and lactation

No safety changes during the reporting period

4.7 Effects on ability to drive and use machines

No safety changes during the reporting period

4.8 Undesirable effects

Version 4	Effective Date: 19-May-2021	PfLEET: 2021-0069122 2021-0069099 2021-0069406
<p><u>Safety/Non-safety:</u> Safety</p> <p><u>Content change:</u></p> <p><u>Summary of safety profile</u></p> <p>The safety of TRADENAME was evaluated in participants 12 years of age and older in 2 clinical studies conducted in the United States, Europe, Turkey, South Africa, and South America.^{12,49} Study BNT162-01 (Study 1) enrolled 60 participants, 18 through 55 years of age <u>and 36 participants, 56 through 85 years of age.</u>⁶⁸ Study C4591001 (Study 2) enrolled approximately 46,000 participants,⁴¹ 12 years of age or older.¹²</p> <p><i>Participants 16 years of age and older</i></p> <p>In Study 2, a total of <u>21,720,022,026</u> participants 16 years of age or older received at least 1 dose of TRADENAME and a total of <u>21,728,021</u> participants 16 years of age or older received placebo.^{43,50}</p> <p>The most frequent adverse reactions in participants 16 years of age and older (in order from highest to lowest frequencies) were injection site pain (>80%),⁴⁴ fatigue (>60%),⁴³ headache (>50%),⁴³ myalgia (>40%), <u>and</u> chills (>30%),⁴³ arthralgia (>20%),⁴³ pyrexia⁴³ and injection site swelling⁴⁴ (>10%) and were usually mild or moderate in intensity and resolved within a few days after vaccination.⁶⁴ A lower frequency of reactogenicity events was associated with greater age.¹⁵</p> <p>[...]</p> <p><u>Study 2 also included 200 participants with confirmed stable human immunodeficiency virus (HIV) infection. The safety profile of the participants receiving TRADENAME (n = 100) in the individuals with stable HIV infection was similar to that seen in the general population.</u>⁵¹</p>		



GLOBAL LABELING MANAGEMENT CDS Safety Log

PRODUCT NAME: COVID-19 mRNA Vaccine

Adolescents 12 through 15 years of age

In an analysis of Study 2, ~~based on data up to the cutoff date of 13 March 2021~~, 2260 adolescents (1131 TRADENAME; 1129 placebo) were 12 ~~to~~through 15 years of age. Of these, 1308 adolescents (660 TRADENAME and 648 placebo) have been followed for at least 2 months after the second dose of TRADENAME.^{41,42} The safety evaluation in Study 2 is ongoing.

The most frequent adverse reactions in adolescents 12 through 15 years of age were injection site pain (>90%), fatigue and headache (>70%), myalgia and chills (>40%), arthralgia and ~~pyrexia~~fever (>20%).^{43,44,45}

Table 1. Adverse Drug Reactions^{13,14,16,64}

System Organ Class	Adverse Drug Reactions
Blood and lymphatic system disorders	Lymphadenopathy
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema)
Metabolism and nutrition disorders	Decreased appetite
Nervous system disorders	Headache Lethargy
Gastrointestinal disorders	Nausea
Skin and subcutaneous tissue disorders	Hyperhidrosis Night sweats
Musculoskeletal and connective tissue disorders	Arthralgia Myalgia
General disorders and administration site conditions	Pyrexia Chills Asthenia Malaise Fatigue Injection site pain Injection site swelling Injection site redness

Adverse reactions from TRADENAME post-authorization experience

[...]

Table 2. Adverse Drug Reactions³⁸

System Organ Class	Adverse Drug Reactions
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g., rash, pruritus, urticaria,



GLOBAL LABELING MANAGEMENT CDS Safety Log

PRODUCT NAME: COVID-19 mRNA Vaccine

	<u>angioedema)</u>
Gastrointestinal disorders	Diarrhea Vomiting
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)

4.9 Overdose

No safety changes during the reporting period

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Version 4	Effective Date: 19-May-2021	PfLEET: 2021-0069122 2021-0069099 2021-0069406
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Safety/Non-safety: Safety

Content change:

Updated efficacy analyses were performed with additional confirmed COVID-19 cases accrued during blinded placebo-controlled follow-up through 13 March 2021, representing up to 6 months of follow-up after Dose 2 for participants in the efficacy population.

The updated vaccine efficacy information is presented in Table 6.

Table 6. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up Period

<u>First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection^{*,53}</u>			
<u>Subgroup</u>	<u>TRADENAME N^a=20,998 Cases n1^b Surveillance Time^c (n2^d)</u>	<u>Placebo N^a=21,096 Cases n1^b Surveillance Time^c (n2^d)</u>	<u>Vaccine Efficacy % (95% CI^e)</u>
<u>All participants^f</u>	<u>77 6.247 (20,712)</u>	<u>850 6.003 (20,713)</u>	<u>91.3 (89.0, 93.2)</u>
<u>16 through 64 years</u>	<u>70 4.859 (15,519)</u>	<u>710 4.654 (15,515)</u>	<u>90.6 (87.9, 92.7)</u>
<u>65 years and older</u>	<u>7 1.233 (4192)</u>	<u>124 1.202 (4226)</u>	<u>94.5 (88.3, 97.8)</u>
<u>65 through 74 years</u>	<u>6 0.994 (3350)</u>	<u>98 0.966 (3379)</u>	<u>94.1 (86.6, 97.9)</u>



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PRODUCT NAME: **COVID-19 mRNA Vaccine**

<u>75 years and older</u>	<u>$\frac{1}{0.239 (842)}$</u>	<u>$\frac{26}{0.237 (847)}$</u>	<u>$\frac{96.2}{(76.9, 99.9)}$</u>
<u>First COVID-19 occurrence from 7 days after Dose 2 in participants with or without* evidence of prior SARS-CoV-2 infection⁵⁴</u>			
<u>Subgroup</u>	<u>TRADENAME</u> <u>N^a=22,166</u> <u>Cases</u> <u>n^{1b}</u> <u>Surveillance Time^c (n^{2d})</u>	<u>Placebo</u> <u>N^a=22,320</u> <u>Cases</u> <u>n^{1b}</u> <u>Surveillance Time^c (n^{2d})</u>	<u>Vaccine Efficacy %</u> <u>(95% CI^e)</u>
<u>All participants^f</u>	<u>$\frac{81}{6.509 (21,642)}$</u>	<u>$\frac{873}{6.274 (21,689)}$</u>	<u>$\frac{91.1}{(88.8, 93.0)}$</u>
<u>16 through 64 years</u>	<u>$\frac{74}{5.073 (16,218)}$</u>	<u>$\frac{727}{4.879 (16,269)}$</u>	<u>$\frac{90.2}{(87.6, 92.4)}$</u>
<u>65 years and older</u>	<u>$\frac{7}{1.267 (4315)}$</u>	<u>$\frac{128}{1.232 (4326)}$</u>	<u>$\frac{94.7}{(88.7, 97.9)}$</u>
<u>65 through 74 years</u>	<u>$\frac{6}{1.021 (3450)}$</u>	<u>$\frac{102}{0.992 (3468)}$</u>	<u>$\frac{94.3}{(87.1, 98.0)}$</u>
<u>75 years and older</u>	<u>$\frac{1}{0.246 (865)}$</u>	<u>$\frac{26}{0.240 (858)}$</u>	<u>$\frac{96.2}{(77.2, 99.9)}$</u>

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.

b. n1 = Number of participants meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

d. n2 = Number of participants at risk for the endpoint.

e. Two-sided confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.

f. Included confirmed cases in participants 12 through 15 years of age: 0 in the TRADENAME group (both without and with or without evidence of prior SARS-CoV-2 infection); 16 and 18 in the placebo group (without and with or without evidence of prior SARS-CoV-2 infection, respectively).

The updated subgroup analyses of vaccine efficacy by demographic characteristics are presented in Table 7 and Table 8.

Table 7. Vaccine Efficacy– First COVID-19 Occurrence From 7 Days After Dose 2 – Participants Without Evidence of Infection* Prior to 7 Days After Dose 2 by Demographic Characteristics – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up Period⁵³

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<u>Subgroup</u>	<u>TRADENAME</u> <u>N^a=20,998</u> <u>Cases</u> <u>n^{1b}</u> <u>Surveillance Time^c (n^{2d})</u>	<u>Placebo</u> <u>N^a=21,096</u> <u>Cases</u> <u>n^{1b}</u> <u>Surveillance Time^c (n^{2d})</u>	<u>Vaccine Efficacy %</u> <u>(95% CI)^e</u>
<u>Sex</u>			
<u>Male</u>	<u>42</u> <u>3.246 (10,637)</u>	<u>399</u> <u>3.047 (10,433)</u>	<u>90.1</u> <u>(86.4, 93.0)</u>
<u>Female</u>	<u>35</u> <u>3.001 (10075)</u>	<u>451</u> <u>2.956 (10,280)</u>	<u>92.4</u> <u>(89.2, 94.7)</u>
<u>Ethnicity</u>			
<u>Hispanic or Latino</u>	<u>29</u> <u>1.786 (5161)</u>	<u>241</u> <u>1.711 (5120)</u>	<u>88.5</u> <u>(83.0, 92.4)</u>
<u>Not Hispanic or Latino</u>	<u>47</u> <u>4.429 (15,449)</u>	<u>609</u> <u>4.259 (15,484)</u>	<u>92.6</u> <u>(90.0, 94.6)</u>
<u>Race</u>			
<u>Black or African American</u>	<u>4</u> <u>0.545 (1737)</u>	<u>48</u> <u>0.527 (1737)</u>	<u>91.9</u> <u>(78.0, 97.9)</u>
<u>White</u>	<u>67</u> <u>5.208 (17,186)</u>	<u>747</u> <u>5.026 (17,256)</u>	<u>91.3</u> <u>(88.9, 93.4)</u>
<u>All others^f</u>	<u>6</u> <u>0.494 (1789)</u>	<u>55</u> <u>0.451 (1720)</u>	<u>90.0</u> <u>(76.9, 96.5)</u>
<u>Country</u>			
<u>Argentina</u>	<u>15</u> <u>1.012 (2600)</u>	<u>108</u> <u>0.986 (2586)</u>	<u>86.5</u> <u>(76.7, 92.7)</u>
<u>Brazil</u>	<u>12</u> <u>0.406 (1311)</u>	<u>80</u> <u>0.374 (1293)</u>	<u>86.2</u> <u>(74.5, 93.1)</u>
<u>Germany</u>	<u>0</u> <u>0.047 (236)</u>	<u>1</u> <u>0.048 (242)</u>	<u>100.0</u> <u>(-3874.2, 100.0)</u>
<u>South Africa</u>	<u>0</u> <u>0.080 (291)</u>	<u>9</u> <u>0.074 (276)</u>	<u>100.0</u> <u>(53.5, 100.0)</u>
<u>Turkey</u>	<u>0</u> <u>0.027 (228)</u>	<u>5</u> <u>0.025 (222)</u>	<u>100.0</u> <u>(-0.1, 100.0)</u>
<u>United States</u>	<u>50</u> <u>4.674 (16,046)</u>	<u>647</u> <u>4.497 (16,094)</u>	<u>92.6</u> <u>(90.1, 94.5)</u>

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Notes: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting). Included confirmed cases in participants 12 through 15 years of age: 0 in the TRADENAME group; 16 in the placebo group.

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.

b. n1 = Number of participants meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

d. n2 = Number of participants at risk for the endpoint.

e. Two-sided confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.

f. All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.

Table 8. Vaccine Efficacy– First COVID-19 Occurrence From 7 Days After Dose 2 – Participants With or Without* Evidence of Infection Prior to 7 Days After Dose 2 by Demographic Characteristics – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up Period⁵⁴

Subgroup	TRADENAME N ^a =22,166 Cases n1 ^b Surveillance Time ^c (n2 ^d)	Placebo N ^a =22,320 Cases n1 ^b Surveillance Time ^c (n2 ^d)	Vaccine Efficacy % (95% CI) ^e
Sex			
Male	44 3.376 (11,103)	411 3.181 (10,920)	89.9 (86.2, 92.8)
Female	37 3.133 (10,539)	462 3.093 (10,769)	92.1 (88.9, 94.5)
Ethnicity			
Hispanic or Latino	32 1.862 (5408)	245 1.794 (5391)	87.4 (81.8, 91.6)
Not Hispanic or Latino	48 4.615 (16,128)	628 4.445 (16,186)	92.6 (90.1, 94.6)
Race			
Black or African American	4 0.611 (1958)	49 0.601 (1985)	92.0 (78.1, 97.9)
White	69 5.379 (17,801)	768 5.191 (17,880)	91.3 (88.9, 93.3)
All others ^f	8 0.519 (1883)	56 0.481 (1824)	86.8 (72.1, 94.5)
Country			
Argentina	16 1.033 (2655)	110 1.017 (2670)	85.7 (75.7, 92.1)



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<u>Brazil</u>	<u>14</u> <u>0.441 (1419)</u>	<u>82</u> <u>0.408 (1401)</u>	<u>84.2</u> <u>(71.9, 91.7)</u>
<u>Germany</u>	<u>0</u> <u>0.047 (237)</u>	<u>1</u> <u>0.048 (243)</u>	<u>100.0</u> <u>(-3868.6, 100.0)</u>
<u>South Africa</u>	<u>0</u> <u>0.099 (358)</u>	<u>10</u> <u>0.096 (358)</u>	<u>100.0</u> <u>(56.6, 100.0)</u>
<u>Turkey</u>	<u>0</u> <u>0.029 (238)</u>	<u>6</u> <u>0.026 (232)</u>	<u>100.0</u> <u>(22.2, 100.0)</u>
<u>United States</u>	<u>51</u> <u>4.861 (16,735)</u>	<u>664</u> <u>4.678 (16,785)</u>	<u>92.6</u> <u>(90.2, 94.6)</u>

Notes: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting). Included confirmed cases in participants 12 through 15 years of age: 0 in the TRADENAME group; 18 in the placebo group.

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.

b. n1 = Number of participants meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

d. n2 = Number of participants at risk for the endpoint.

e. Two-sided confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.

f. All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.

The subgroup analyses of vaccine efficacy by risk status in participants is presented in Table 96.

Table 96. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Participants Without Evidence of Infection* Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population²³

[...]			
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Abbreviations: BMI = body mass index; N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

[...]

The updated subgroup analyses of vaccine efficacy by risk status in participants followed up to 6 months after Dose 2 (with a cut-off date of 13 March 2021) are presented in Tables 10 and 11.

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Table 10. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Participants Without Evidence of Infection* Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up Period⁵⁵

Subgroup	TRADENAME N^a=20,998 Cases n^{1b} Surveillance Time^c (n^{2d})	Placebo N^a=21,096 Cases n^{1b} Surveillance Time^c (n^{2d})	Vaccine Efficacy % (95% CI)^e
<u>First COVID-19 occurrence from 7 days after Dose 2^f</u>	<u>77</u> <u>6.247 (20,712)</u>	<u>850</u> <u>6.003 (20,713)</u>	<u>91.3</u> <u>(89.0, 93.2)</u>
<u>At risk^g</u>			
<u>Yes</u>	<u>35</u> <u>2.797 (9167)</u>	<u>401</u> <u>2.681 (9136)</u>	<u>91.6</u> <u>(88.2, 94.3)</u>
<u>No</u>	<u>42</u> <u>3.450 (11,545)</u>	<u>449</u> <u>3.322 (11,577)</u>	<u>91.0</u> <u>(87.6, 93.6)</u>
<u>Age group (years) and risk status</u>			
<u>16 through 64 and not at risk</u>	<u>41</u> <u>2.776 (8887)</u>	<u>385</u> <u>2.661 (8886)</u>	<u>89.8</u> <u>(85.9, 92.8)</u>
<u>16 through 64 and at risk</u>	<u>29</u> <u>2.083 (6632)</u>	<u>325</u> <u>1.993 (6629)</u>	<u>91.5</u> <u>(87.5, 94.4)</u>
<u>65 and older and not at risk</u>	<u>1</u> <u>0.553 (1870)</u>	<u>53</u> <u>0.546 (1922)</u>	<u>98.1</u> <u>(89.2, 100.0)</u>
<u>65 and older and at risk</u>	<u>6</u> <u>0.680 (2322)</u>	<u>71</u> <u>0.656 (2304)</u>	<u>91.8</u> <u>(81.4, 97.1)</u>
<u>Obese^h</u>			
<u>Yes</u>	<u>27</u> <u>2.103 (6796)</u>	<u>314</u> <u>2.050 (6875)</u>	<u>91.6</u> <u>(87.6, 94.6)</u>
<u>No</u>	<u>50</u> <u>4.143 (13,911)</u>	<u>536</u> <u>3.952 (13,833)</u>	<u>91.1</u> <u>(88.1, 93.5)</u>
<u>Age group (years) and obesity status</u>			
<u>16 through 64 and not obese</u>	<u>46</u> <u>3.178 (10,212)</u>	<u>444</u> <u>3.028 (10,166)</u>	<u>90.1</u> <u>(86.6, 92.9)</u>
<u>16 through 64 and obese</u>	<u>24</u> <u>1.680 (5303)</u>	<u>266</u> <u>1.624 (5344)</u>	<u>91.3</u> <u>(86.7, 94.5)</u>
<u>65 and older and not obese</u>	<u>4</u> <u>0.829 (2821)</u>	<u>79</u> <u>0.793 (2800)</u>	<u>95.2</u> <u>(87.1, 98.7)</u>
<u>65 and older and obese</u>	<u>3</u> <u>0.404 (1370)</u>	<u>45</u> <u>0.410 (1426)</u>	<u>93.2</u> <u>(78.9, 98.7)</u>

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Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

- N = Number of participants in the specified group.
- n1 = Number of participants meeting the endpoint definition.
- Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
- n2 = Number of participants at risk for the endpoint.
- Two-sided confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time.
- Included confirmed cases in participants 12 through 15 years of age: 0 in the TRADENAME group; 16 in the placebo group.
- At risk is defined as having at least 1 of the Charlson Comorbidity Index (CMI) category or obesity (BMI ≥ 30 kg/m² or BMI $\geq 95^{\text{th}}$ percentile [12 through 15 Years of age]).
- Obese is defined as BMI ≥ 30 kg/m². For 12 through 15 years age group, obesity is defined as a BMI at or above the 95th percentile. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm.

Table 11. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Participants With or Without* Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up Period⁵⁶

Subgroup	<u>TRADENAME</u> N^a=22,166 Cases n1^b Surveillance Time^c (n2^d)	<u>Placebo</u> N^a=22,320 Cases n1^b Surveillance Time^c (n2^d)	<u>Vaccine Efficacy %</u> (95% CI)^e
<u>First COVID-19 occurrence from 7 days after Dose 2^f</u>	81 6.509 (21,642)	873 6.274 (21,689)	91.1 (88.8, 93.0)
<u>At risk^g</u>			
<u>Yes</u>	36 2.925 (9601)	410 2.807 (9570)	91.6 (88.1, 94.2)
<u>No</u>	45 3.584 (12,041)	463 3.466 (12,119)	90.6 (87.2, 93.2)
<u>Age group (years) and risk status</u>			
<u>16 through 64 and not at risk</u>	44 2.887 (9254)	397 2.779 (9289)	89.3 (85.4, 92.4)
<u>16 through 64 and at risk</u>	30 2.186 (6964)	330 2.100 (6980)	91.3 (87.3, 94.2)
<u>65 and older and not at risk</u>	1 0.566 (1920)	55 0.559 (1966)	98.2 (89.6, 100.0)
<u>65 and older and at risk</u>	6 0.701 (2395)	73 0.672 (2360)	92.1 (82.0, 97.2)



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<u>Obese^h</u>			
<u>Yes</u>	<u>28</u> <u>2.207 (7139)</u>	<u>319</u> <u>2.158 (7235)</u>	<u>91.4</u> <u>(87.4, 94.4)</u>
<u>No</u>	<u>53</u> <u>4.301 (14,497)</u>	<u>554</u> <u>4.114 (14,448)</u>	<u>90.8</u> <u>(87.9, 93.2)</u>
<u>Age group (years) and obesity status</u>			
<u>16 through 64 and not obese</u>	<u>49</u> <u>3.303 (10,629)</u>	<u>458</u> <u>3.158 (10,614)</u>	<u>89.8</u> <u>(86.2, 92.5)</u>
<u>16 through 64 and obese</u>	<u>25</u> <u>1.768 (5584)</u>	<u>269</u> <u>1.719 (5649)</u>	<u>91.0</u> <u>(86.4, 94.3)</u>
<u>65 and older and not obese</u>	<u>4</u> <u>0.850 (2899)</u>	<u>82</u> <u>0.811 (2864)</u>	<u>95.3</u> <u>(87.6, 98.8)</u>
<u>65 and older and obese</u>	<u>3</u> <u>0.417 (1415)</u>	<u>46</u> <u>0.420 (1462)</u>	<u>93.4</u> <u>(79.5, 98.7)</u>

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.

b. n1 = Number of participants meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

d. n2 = Number of participants at risk for the endpoint.

e. Two-sided confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time.

f. Included confirmed cases in participants 12 to 15 years of age: 0 in the TRADENAME group; 18 in the placebo group.

g. At risk is defined as having at least 1 of the Charlson Comorbidity Index (CMI) category or obesity (BMI ≥ 30 kg/m² or BMI $\geq 95^{\text{th}}$ percentile [12 through 15 years of age]).

h. Obese is defined as BMI ≥ 30 kg/m². For the 12 through 15 years of age group, obesity is defined as a BMI at or above the 95th percentile. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm.

Safety/Non-safety: Safety

Content change:

[...]

As of 13 March 2021, vaccine efficacy against severe COVID-19 is presented only for participants with or without prior SARS-CoV-2 infection (Table 12) as the COVID-19 case counts in participants without prior SARS-CoV-2 infection were the same as those in participants with or without prior SARS-CoV-2 infection in both the TRADENAME and placebo groups.



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Table 12. Vaccine Efficacy – First Severe COVID-19 Occurrence in Participants With or Without* Prior SARS-CoV-2 Infection Based on FDA† or Centers for Disease Control and Prevention (CDC)‡ Definition After Dose 1 or From 7 Days After Dose 2 in the Placebo-Controlled Follow-up

Vaccine Efficacy – First Severe COVID-19 Occurrence Based on FDA Definition^{57,58}			
	TRADENAME Cases n1^a Surveillance Time (n2^b)	Placebo Cases n1^a Surveillance Time (n2^b)	Vaccine Efficacy % (95% CI^c)
After Dose 1 ^d	<u>1</u> 8,439 ^e (22,505)	<u>30</u> 8,288 ^e (22,435)	<u>96.7</u> (80.3, 99.9)
7 days after Dose 2 ^f	<u>1</u> 6,522 ^g (21,649)	<u>21</u> 6,404 ^g (21,730)	<u>95.3</u> (70.9, 99.9)
Vaccine Efficacy – First Severe COVID-19 Occurrence Based on CDC Definition^{59,60}			
	TRADENAME Cases n1^a Surveillance Time (n2^b)	Placebo Cases n1^a Surveillance Time (n2^b)	Vaccine Efficacy % (95% CI^c)
After Dose 1 ^d	<u>1</u> 8,427 ^e (22,473)	<u>45</u> 8,269 ^e (22,394)	<u>97.8</u> (87.2, 99.9)
7 days after Dose 2 ^f	<u>0</u> 6,514 ^g (21,620)	<u>32</u> 6,391 ^g (21,693)	<u>100</u> (88.0, 100.0)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

† Severe illness from COVID-19 as defined by FDA is confirmed COVID-19 and presence of at least 1 of the following:⁶¹

- Clinical signs at rest indicative of severe systemic illness (respiratory rate ≥ 30 breaths per minute, heart rate ≥ 125 beats per minute, saturation of oxygen $< 93\%$ on room air at sea level, or ratio of arterial oxygen partial pressure to fractional inspired oxygen < 300 mm Hg);
- Respiratory failure [defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation or extracorporeal membrane oxygenation (ECMO)];
- Evidence of shock (systolic blood pressure < 90 mm Hg, diastolic blood pressure < 60 mm Hg, or requiring vasopressors);
- Significant acute renal, hepatic, or neurologic dysfunction;
- Admission to an Intensive Care Unit;
- Death.

‡ Severe illness from COVID-19 as defined by CDC is confirmed COVID-19 and presence of at least 1 of the following:⁶¹

- Hospitalization;
- Admission to the Intensive Care Unit;
- Intubation or mechanical ventilation;
- Death.

a. n1 = Number of participants meeting the endpoint definition.

b. n2 = Number of participants at risk for the endpoint.

c. Two-side confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method



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- adjusted to the surveillance time.
- d. Efficacy assessed based on the Dose 1 all available efficacy (modified intention-to-treat) population that included all randomized participants who received at least 1 dose of study intervention.⁶²
- e. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
- f. Efficacy assessed based on the evaluable efficacy (7 Days) population that included all eligible randomized participants who receive all dose(s) of study intervention as randomized within the predefined window, have no other important protocol deviations as determined by the clinician.⁶²
- g. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

Efficacy and immunogenicity in adolescents 12 to 15 years of age

An analysis of Study 2 has been performed in adolescents 12 to 15 years of age up to a data cutoff date of 13 March 2021.

The vaccine efficacy information in adolescents 12 to 15 years of age is presented in Table [137](#).

Table 713. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, Without Evidence of Infection and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period, Adolescents 12 to 15 Years of Age Evaluable Efficacy (7 Days) Population

First COVID-19 occurrence from 7 days after Dose 2 in adolescents 12 to 15 years of age without evidence of prior SARS-CoV-2 infection ^{*,46}			
	TRADENAME N ^a =1005 Cases n1 ^b Surveillance Time ^c (n2 ^d)	Placebo N ^a =978 Cases n1 ^b Surveillance Time ^c (n2 ^d)	Vaccine Efficacy % (95% CI ^e)
[...]			
First COVID-19 occurrence from 7 days after Dose 2 in adolescents 12 to 15 years of age with or without [*] evidence of prior SARS-CoV-2 infection ⁴⁷			
[...]			

5.2 Pharmacokinetic properties

No safety changes during the reporting period

5.3 Preclinical safety data

No safety changes during the reporting period

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

No safety changes during the reporting period



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6.2 Incompatibilities

No safety changes during the reporting period

6.3 Shelf life

No safety changes during the reporting period

6.4 Special precautions for storage

No safety changes during the reporting period

6.5 Nature and contents of container

No safety changes during the reporting period

6.6 Special precautions for disposal and other handling

No safety changes during the reporting period

7. REFERENCES

All new references can be found in the References section of the affected CDS.

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Appendix A. Adverse Drug Reactions (ADRs) and Numeric Frequencies Listed in Order of Decreasing Frequency Within Each System Organ Class (SOC)

Version 4	Effective Date: 19-May-2021	PfLEET: 2021-0069122 2021-0069099 2021-0069406
Safety/Non-safety: Safety		
Content change:		
Table A-1. Adverse Drug Reaction Table with Preferred Terms Listed by Decreasing Frequency Within Each System Organ Class: Individuals 16 Years of Age and Older (13 March 2021 Data Cut-off Date)		
System Organ Class	ADR Term	Frequency n/N (%)
Blood and lymphatic system disorders	Lymphadenopathy	83/21926 (0.4%) ^a
Immune system disorders	Anaphylaxis ^d	Not known
	Hypersensitivity reactions	
	Rash ^d	54/21926 (0.2%) ^a
	Pruritus ^d	23/21926 (0.1%) ^a
	Urticaria ^d	15/21926 (0.1%) ^a
	Angioedema ^d	3/21926 (0.01%) ^a
Metabolism and Nutrition disorders	Decreased appetite	39/21926 (0.2%)
Nervous system disorders	Headache	2814/4924 (57.1%) ^b
	Lethargy	25/21926 (0.1%)
Gastrointestinal disorders	Diarrhea ^d	758/4924 (15.4%) ^b
	Vomiting ^d	110/4924 (2.2%) ^b
	Nausea	274/21926 (1.2%) ^a
Skin and Subcutaneous Tissue disorders	Hyperhidrosis	31/21926 (0.1%)
	Night sweats	17/21926 (0.1%)
Musculoskeletal and connective tissue disorders	Myalgia (muscle pain)	1980/4924 (40.2%) ^b
	Arthralgia (joint pain)	1232/4924 (25.0%) ^b
	Pain in extremity (arm) ^d	185/21926 (0.8%) ^a
General disorders and administration site conditions	Injection site pain	4153/4924 (84.3%) ^c
	Fatigue	3185/4924 (64.7%) ^b
	Chills	1707/4924 (34.7%) ^b
	Pyrexia	749/4924 (15.2%) ^b
	Injection site swelling	546/4924 (11.1%) ^c
	Injection site redness	486/4924 (9.9%) ^c
	Malaise	130/21926 (0.6%) ^a
	Asthenia	76/21926 (0.3%)

a. Source: Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects >16 Years of Age – Safety Population (Cutoff date: 13March2021)

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- b. Source: Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population (Cutoff date: 13March2021)
- c. Source: Local Reactions, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population (Cutoff date: 13March2021)
- d. These adverse reactions were identified in the post-authorization period.

Table A-2. Adverse Drug Reaction Table with Preferred Terms Listed by Decreasing Frequency Within Each System Organ Class: Individuals 12 Through 15 Years of Age (13 March 2021 Data Cut-off Date)

<u>System Organ Class</u>	<u>ADR Term</u>	<u>Frequency n/N (%)</u>
<u>Blood and lymphatic system disorders</u>	<u>Lymphadenopathy</u>	<u>9/1131 (0.8%)^a</u>
<u>Immune system disorders</u>	<u>Anaphylaxis^d</u>	<u>Not known</u>
	<u>Hypersensitivity reactions</u>	
	<u>Rash^d</u>	<u>2/1131 (0.2%)^a</u>
	<u>Urticaria^d</u>	<u>2/1131 (0.2%)^a</u>
	<u>Pruritus^{d,e}</u>	
	<u>Angioedema^{d,e}</u>	
<u>Metabolism and Nutrition disorders</u>	<u>Decreased appetite^c</u>	
<u>Nervous system disorders</u>	<u>Headache</u>	<u>854/1131 (75.5%)^b</u>
	<u>Lethargy^c</u>	
<u>Gastrointestinal disorders</u>	<u>Diarrhea^d</u>	<u>141/1131 (12.5%)^b</u>
	<u>Vomiting^d</u>	<u>59/1131 (5.2%)^b</u>
	<u>Nausea</u>	<u>5/1131 (0.4%)^a</u>
<u>Skin and Subcutaneous Tissue disorders</u>	<u>Hyperhidrosis^c</u>	
	<u>Night sweats^c</u>	
<u>Musculoskeletal and connective tissue disorders</u>	<u>Myalgia (muscle pain)</u>	<u>477/1131 (42.2%)^b</u>
	<u>Arthralgia (joint pain) (new)</u>	<u>229/1131 (20.2%)^b</u>
	<u>Pain in extremity (arm)^d</u>	<u>1/1131 (0.1%)^a</u>
<u>General disorders and administration site conditions</u>	<u>Injection site pain</u>	<u>1023/1131 (90.5%)^c</u>
	<u>Fatigue</u>	<u>876/1131 (77.5%)^b</u>
	<u>Chills</u>	<u>557/1131 (49.2%)^b</u>
	<u>Pyrexia</u>	<u>275/1131 (24.3%)^b</u>
	<u>Injection site swelling</u>	<u>104/1131 (9.2%)^c</u>
	<u>Injection site redness</u>	<u>97/1131 (8.6%)^c</u>
	<u>Malaise^c</u>	
	<u>Asthenia^c</u>	

- a. Source: Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population (Cutoff date: 13March2021)
- b. Source: Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population (Cutoff date: 13March2021)
- c. Source: Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population (Cutoff date: 13March2021)



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- d. These adverse reactions were identified in the post-authorization period.
- e. The following events were not reported in the 12 through 15 year old age group in Study C4591001 but were reported in individuals ≥ 16 years of age (see Table A-1): angioedema, pruritus, malaise, lethargy, asthenia, decreased appetite, hyperhidrosis, and night sweats.

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Appendix B. Adverse Drug Reactions (ADRs) and Council for International Organizations of Medical Sciences (CIOMS) Frequency Categories Listed in Order of Decreasing Medical Seriousness or Clinical Importance Within Each Frequency Category and SOC

Version 4	Effective Date: 19-May-2021	PfLEET: 2021-0069122 2021-0069099 2021-0069406
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Safety/Non-safety: Safety

Content change:

Table B-1. ADRs by SOC and CIOMS Frequency Category Listed in Order of Decreasing Medical Seriousness Within Each Frequency Category and SOC: Individuals 16 Years of Age and Older (13 -March -2021 Data Cut-off Date)

System Organ Class	Very Common ≥1/10 (>10%)	Common ≥1/100 to <1/10 (≥1% to <10%)	Uncommon ≥1/1,000 to <1/100 (≥0.1% to <1%)	Rare ≥1/10,000 to <1/1,000 (≥0.01% to <0.1%)	Very Rare ≤1/10,000 (≤0.01%)	Frequency not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy			
Immune system disorders			Urticaria; ^{a,b} Pruritus; ^{a,b} Rash ^{a,b}	Angioedema ^{a,b}		Anaphylaxis ^a
Metabolism and Nutrition disorders			Decreased appetite			
Nervous system disorders	Headache		Lethargy			
Gastrointestinal disorders	Diarrhea ^a	Vomiting; ^a Nausea				
Skin and subcutaneous Tissue disorders			Hyperhidrosis; Night sweats			
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia		Pain in extremity (arm) ^a			
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Pyrexia; Injection site swelling	Injection site redness	Asthenia; Malaise			

a. These adverse reactions were identified in the post-authorization period.

b. The following events are categorized as hypersensitivity reactions: urticaria, pruritus, rash, and angioedema.

Table B-2. ADRs by SOC and CIOMS Frequency Category Listed in order of Decreasing Medical Seriousness Within Each Frequency Category and SOC: Individuals 12 Through 15 Years of Age (13 March 2021 Data Cut-off Date)



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<u>System Organ Class</u>	<u>Very Common</u> <u>>1/10</u> <u>(>10%)</u>	<u>Common</u> <u>>1/100 to</u> <u><1/10</u> <u>(>1% to</u> <u><10%)</u>	<u>Uncommon</u> <u>>1/1,000 to</u> <u><1/100</u> <u>(>0.1% to <1%)</u>	<u>Rare</u> <u>>1/10,000 to</u> <u><1/1,000</u> <u>(>0.01% to</u> <u><0.1%)</u>	<u>Very Rare</u> <u><1/10,000</u> <u>(<0.01%)</u>	<u>Frequency not known</u> <u>(cannot be estimated from the available data)</u>
<u>Blood and lymphatic system disorders</u>			<u>Lymphadenopathy</u>			
<u>Immune system disorders</u>			<u>Urticaria</u> ^{a,b} <u>Rash</u> ^{a,b}			<u>Anaphylaxis</u> ^a
<u>Nervous system disorders</u>	<u>Headache</u>					
<u>Gastrointestinal disorders</u>	<u>Diarrhea</u> ^a	<u>Vomiting</u> ^a	<u>Nausea</u>			
<u>Musculoskeletal and connective tissue disorders</u>	<u>Arthralgia</u> ; <u>Myalgia</u>		<u>Pain in extremity (arm)</u> ^a			
<u>General disorders and administration site conditions</u>	<u>Injection site pain</u> ; <u>Fatigue</u> ; <u>Chills</u> ; <u>Pyrexia</u>	<u>Injection site swelling</u> ; <u>Injection site redness</u>				

a. These adverse reactions were identified in the post-authorization period. Please note that the following events were not reported in the 12 through 15 years of age group in Study C4591001 (see Table B-1): angioedema, pruritus, malaise, lethargy, asthenia, decreased appetite, hyperhidrosis, and night sweats.

b. The following events are categorized as hypersensitivity reactions: urticaria, pruritus, rash, and angioedema.

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Appendix C. HIV-Positive Participants 16 Years of Age and Older – Reactogenicity Frequency in the Safety Population Subset

Version 4	Effective Date: 19-May-2021	PfLEET: 2021-0069122 2021-0069099 2021-0069406
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Safety/Non-safety: Safety

Content change:

Table C-1. Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – HIV-Positive Participants 16 Years of Age and Older – Reactogenicity Subset of the Safety Population^{*,65}

	<u>TRADENAME</u> <u>Dose 1</u> <u>N^a=54</u> <u>n^b (%)</u>	<u>Placebo</u> <u>Dose 1</u> <u>N^a=56</u> <u>n^b (%)</u>	<u>TRADENAME</u> <u>Dose 2</u> <u>N^a=60</u> <u>n^b (%)</u>	<u>Placebo</u> <u>Dose 2</u> <u>N^a=62</u> <u>n^b (%)</u>
<u>Redness^c</u>				
<u>Any (>2.0 cm)</u>	<u>2 (3.7)</u>	<u>3 (5.4)</u>	<u>4 (6.7)</u>	<u>1 (1.6)</u>
<u>Mild</u>	<u>2 (3.7)</u>	<u>1 (1.8)</u>	<u>3 (5.0)</u>	<u>1 (1.6)</u>
<u>Moderate</u>	<u>0</u>	<u>0</u>	<u>1 (1.7)</u>	<u>0</u>
<u>Severe</u>	<u>0</u>	<u>2 (3.6)</u>	<u>0</u>	<u>0</u>
<u>Swelling^c</u>				
<u>Any (>2.0 cm)</u>	<u>3 (5.6)</u>	<u>1 (1.8)</u>	<u>5 (8.3)</u>	<u>0</u>
<u>Mild</u>	<u>2 (3.7)</u>	<u>0</u>	<u>2 (3.3)</u>	<u>0</u>
<u>Moderate</u>	<u>1 (1.9)</u>	<u>0</u>	<u>3 (5.0)</u>	<u>0</u>
<u>Severe</u>	<u>0</u>	<u>1 (1.8)</u>	<u>0</u>	<u>0</u>
<u>Pain at the injection site^d</u>				
<u>Any</u>	<u>34 (63.0)</u>	<u>9 (16.1)</u>	<u>32 (53.3)</u>	<u>5 (8.1)</u>
<u>Mild</u>	<u>26 (48.1)</u>	<u>8 (14.3)</u>	<u>22 (36.7)</u>	<u>5 (8.1)</u>
<u>Moderate</u>	<u>8 (14.8)</u>	<u>1 (1.8)</u>	<u>9 (15.0)</u>	<u>0</u>
<u>Severe</u>	<u>0</u>	<u>0</u>	<u>1 (1.7)</u>	<u>0</u>

Notes: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.

No Grade 4 solicited local reactions were reported in HIV-Positive participants 16 years of age and older.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. The N for each reaction was the same, therefore, this information was included in the column header.

b. n = Number of participants with the specified reaction.

c. Mild: >2.0 to <5.0 cm; Moderate: >5.0 to <10.0 cm; Severe: >10.0 cm.

d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.



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Table C-2. Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – HIV-Positive Participants 16 Years of Age and Older – Reactogenicity Subset of the Safety Population*,⁶⁶

	<u>TRADENAME</u> <u>Dose 1</u> <u>N^a=54</u> <u>n^b (%)</u>	<u>Placebo</u> <u>Dose 1</u> <u>N^a=56</u> <u>n^b (%)</u>	<u>TRADENAME</u> <u>Dose 2</u> <u>N^a=60</u> <u>n^b (%)</u>	<u>Placebo</u> <u>Dose 2</u> <u>N^a=62</u> <u>n^b (%)</u>
<u>Fever</u>				
<u>>38.0°C</u>	<u>1 (1.9)</u>	<u>4 (7.1)</u>	<u>9 (15.0)</u>	<u>5 (8.1)</u>
<u>>38.0°C to 38.4°C</u>	<u>1 (1.9)</u>	<u>2 (3.6)</u>	<u>4 (6.7)</u>	<u>5 (8.1)</u>
<u>>38.4°C to 38.9°C</u>	<u>0</u>	<u>0</u>	<u>4 (6.7)</u>	<u>0</u>
<u>>38.9°C to 40.0°C</u>	<u>0</u>	<u>2 (3.6)</u>	<u>1 (1.7)</u>	<u>0</u>
<u>>40.0°C</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>
<u>Fatigue^c</u>				
<u>Any</u>	<u>22 (40.7)</u>	<u>15 (26.8)</u>	<u>24 (40.0)</u>	<u>12 (19.4)</u>
<u>Mild</u>	<u>15 (27.8)</u>	<u>9 (16.1)</u>	<u>12 (20.0)</u>	<u>5 (8.1)</u>
<u>Moderate</u>	<u>7 (13.0)</u>	<u>5 (8.9)</u>	<u>9 (15.0)</u>	<u>7 (11.3)</u>
<u>Severe</u>	<u>0</u>	<u>1 (1.8)</u>	<u>3 (5.0)</u>	<u>0</u>
<u>Headache^c</u>				
<u>Any</u>	<u>11 (20.4)</u>	<u>18 (32.1)</u>	<u>18 (30.0)</u>	<u>12 (19.4)</u>
<u>Mild</u>	<u>7 (13.0)</u>	<u>10 (17.9)</u>	<u>8 (13.3)</u>	<u>8 (12.9)</u>
<u>Moderate</u>	<u>4 (7.4)</u>	<u>7 (12.5)</u>	<u>8 (13.3)</u>	<u>4 (6.5)</u>
<u>Severe</u>	<u>0</u>	<u>1 (1.8)</u>	<u>2 (3.3)</u>	<u>0</u>
<u>Chills^c</u>				
<u>Any</u>	<u>6 (11.1)</u>	<u>5 (8.9)</u>	<u>14 (23.3)</u>	<u>4 (6.5)</u>
<u>Mild</u>	<u>5 (9.3)</u>	<u>4 (7.1)</u>	<u>5 (8.3)</u>	<u>3 (4.8)</u>
<u>Moderate</u>	<u>1 (1.9)</u>	<u>1 (1.8)</u>	<u>8 (13.3)</u>	<u>1 (1.6)</u>
<u>Severe</u>	<u>0</u>	<u>0</u>	<u>1 (1.7)</u>	<u>0</u>
<u>Vomiting^d</u>				
<u>Any</u>	<u>1 (1.9)</u>	<u>3 (5.4)</u>	<u>2 (3.3)</u>	<u>2 (3.2)</u>
<u>Mild</u>	<u>1 (1.9)</u>	<u>1 (1.8)</u>	<u>1 (1.7)</u>	<u>1 (1.6)</u>
<u>Moderate</u>	<u>0</u>	<u>0</u>	<u>1 (1.7)</u>	<u>1 (1.6)</u>
<u>Severe</u>	<u>0</u>	<u>2 (3.6)</u>	<u>0</u>	<u>0</u>
<u>Diarrhea^e</u>				
<u>Any</u>	<u>5 (9.3)</u>	<u>8 (14.3)</u>	<u>4 (6.7)</u>	<u>9 (14.5)</u>
<u>Mild</u>	<u>5 (9.3)</u>	<u>6 (10.7)</u>	<u>1 (1.7)</u>	<u>6 (9.7)</u>
<u>Moderate</u>	<u>0</u>	<u>1 (1.8)</u>	<u>2 (3.3)</u>	<u>3 (4.8)</u>
<u>Severe</u>	<u>0</u>	<u>1 (1.8)</u>	<u>1 (1.7)</u>	<u>0</u>
<u>New or worsened muscle pain^c</u>				
<u>Any</u>	<u>9 (16.7)</u>	<u>10 (17.9)</u>	<u>10 (16.7)</u>	<u>5 (8.1)</u>
<u>Mild</u>	<u>7 (13.0)</u>	<u>7 (12.5)</u>	<u>5 (8.3)</u>	<u>1 (1.6)</u>
<u>Moderate</u>	<u>2 (3.7)</u>	<u>3 (5.4)</u>	<u>5 (8.3)</u>	<u>4 (6.5)</u>
<u>Severe</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>
<u>New or worsened joint pain^c</u>				



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<u>Any</u>	<u>5 (9.3)</u>	<u>7 (12.5)</u>	<u>10 (16.7)</u>	<u>5 (8.1)</u>
<u>Mild</u>	<u>5 (9.3)</u>	<u>4 (7.1)</u>	<u>4 (6.7)</u>	<u>1 (1.6)</u>
<u>Moderate</u>	<u>0</u>	<u>3 (5.4)</u>	<u>6 (10.0)</u>	<u>4 (6.5)</u>
<u>Severe</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>
<u>Use of antipyretic or pain medication^f</u>	<u>7 (13.0)</u>	<u>8 (14.3)</u>	<u>16 (26.7)</u>	<u>7 (11.3)</u>

Notes: Reactions and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

No Grade 4 solicited systemic reactions were reported in HIV-positive participants 16 years of age and older.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. The N for each event or use of antipyretic or pain medication was the same, therefore, this information was included in the column header.

b. n = Number of participants with the specified reaction.

c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.

d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.

e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.

f. Severity was not collected for use of antipyretic or pain medication.

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APPENDIX 2 Interval Number of Case Reports (Serious and Non-Serious, Medically Confirmed and Non-Medically Confirmed) from Post-Marketing Data Sources, Overall, by Sex, Country, Age Groups and in Special Populations and Summary Tabulation by Preferred Term and MedDRA System Organ Class

BNT162B2 - ALL

Reporting Period: 30-APR-2021 Through 31-MAY-2021
Total Number of Cases: 47174 (100%) (ALL) / 47174 (OVERALL)
Total Number of Adverse Events (PT): 174446 (ALL)

NON CT

Total Number of Cases: 47174
Total Number of Adverse Events (PT): 174446

		Number of Cases	Percentage (%)
Sex			
	FEMALE	32751	69.4 %
	MALE	11506	24.4 %
	NO DATA	2916	6.2 %
	UNK	1	0.0 %
Age Range Min = 0.0 Years Max = 105.0 Years Mean = 51 Median = 49.0 Standard Deviation = 18.79 n = 39612			
	0 to 27 days	9	0.0 %
	28 days to 23 months	76	0.2 %
	2 to 11 years	32	0.1 %
	12 to 17 years	212	0.4 %
	18 - 30 years	5777	12.2 %
	31 - 50 years	14682	31.1 %
	51 - 64 years	8817	18.7 %
	65 - 74 years	4702	10.0 %
	Greater than or equal to 75 years	5465	11.6 %
	Unknown	7391	15.7 %
	N/A - age range only applies to post-birth patients	11	0.0 %
Country Where Event Occured			
	UNITED KINGDOM	10047	21.3 %
	UNITED STATES	8975	19.0 %
	ITALY	4000	8.5 %
	MEXICO	3990	8.5 %
	JAPAN	2942	6.2 %
	FRANCE	2720	5.8 %
	GERMANY	2107	4.5 %
	SPAIN	1357	2.9 %
	NETHERLANDS	1218	2.6 %
	BELGIUM	815	1.7 %
	PORTUGAL	794	1.7 %
	SWEDEN	711	1.5 %
	CZECH REPUBLIC	704	1.5 %
	AUSTRIA	567	1.2 %
	AUSTRALIA	521	1.1 %
	GREECE	478	1.0 %
	CANADA	423	0.9 %
	DENMARK	414	0.9 %

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		Number of Cases	Percentage (%)
Country Where Event Occured			
	ROMANIA	372	0.8 %
	HUNGARY	364	0.8 %
	NORWAY	364	0.8 %
	ISRAEL	348	0.7 %
	IRELAND	346	0.7 %
	FINLAND	333	0.7 %
	POLAND	301	0.6 %
	SWITZERLAND	252	0.5 %
	PANAMA	192	0.4 %
	CROATIA	151	0.3 %
	HONG KONG	133	0.3 %
	BRAZIL	108	0.2 %
	ESTONIA	86	0.2 %
	BULGARIA	81	0.2 %
	LUXEMBOURG	74	0.2 %
	TURKEY	67	0.1 %
	COSTA RICA	64	0.1 %
	SLOVAKIA	64	0.1 %
	SERBIA	59	0.1 %
	COLOMBIA	57	0.1 %
	CHILE	49	0.1 %
	LATVIA	41	0.1 %
	ECUADOR	38	0.1 %
	ICELAND	35	0.1 %
	LITHUANIA	34	0.1 %
	SLOVENIA	34	0.1 %
	CYPRUS	33	0.1 %
	MALTA	32	0.1 %
	NEW ZEALAND	29	0.1 %
	PHILIPPINES	25	0.1 %
	SAUDI ARABIA	23	0.0 %
	SINGAPORE	20	0.0 %
	LEBANON	18	0.0 %
	MALAYSIA	18	0.0 %
	SOUTH AFRICA	15	0.0 %
	PERU	14	0.0 %
	IRAQ	12	0.0 %
	PUERTO RICO	12	0.0 %
	BAHRAIN	11	0.0 %
	UNITED ARAB EMIRATES	10	0.0 %
	ARGENTINA	8	0.0 %
	JORDAN	8	0.0 %
	TUNISIA	8	0.0 %
	CAYMAN ISLANDS	6	0.0 %

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		Number of Cases	Percentage (%)
Country Where Event Occured			
	MACEDONIA, THE FORMER YUGOSLAV REPUBLIC OF	5	0.0 %
	MACAO	4	0.0 %
	URUGUAY	4	0.0 %
	BOLIVIA	3	0.0 %
	INDIA	3	0.0 %
	BERMUDA	2	0.0 %
	EL SALVADOR	2	0.0 %
	HONDURAS	2	0.0 %
	KOREA, REPUBLIC OF (SOUTH KOREA)	2	0.0 %
	KUWAIT	2	0.0 %
	LIECHTENSTEIN	2	0.0 %
	OMAN	2	0.0 %
	QATAR	2	0.0 %
	AMERICAN SAMOA	1	0.0 %
	BOSNIA AND HERZEGOVINA	1	0.0 %
	FRENCH GUIANA	1	0.0 %
	FRENCH POLYNESIA	1	0.0 %
	GEORGIA	1	0.0 %
	PALESTINIAN TERRITORY, OCCUPIED	1	0.0 %
	THAILAND	1	0.0 %
Source			
	Clinical Study	175	0.4 %
	Literature - Non Study	18	0.0 %
	Literature - Study	10	0.0 %
	Solicited	33	0.1 %
	Spontaneous	46938	99.5 %
Case Seriousness			
	SERIOUS	20288	43.0 %
	NONSERIOUS	26885	57.0 %
	NO DATA	1	0.0 %
HP/Medically Confirmed			
	Yes	26272	55.7 %
	No	20902	44.3 %
Special Populations	Pregnant/Breastfeeding Women		
	Yes	484	1.0 %
	Pediatric Non EIU		
	Yes	238	0.5 %
	Elderly		
	Yes	10167	21.6 %

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		Number of Cases	Percentage (%)
	Race/Ethnicity		
	ASIAN - HISPANIC OR LATINO	3	0.0 %
	ASIAN - NO DATA	1002	2.1 %
	ASIAN - NOT HISPANIC OR LATINO	161	0.3 %
	ASIAN - OTHER	2	0.0 %
	BLACK - HISPANIC OR LATINO	12	0.0 %
	BLACK - NO DATA	231	0.5 %
	BLACK - NOT HISPANIC OR LATINO	127	0.3 %
	BLACK - OTHER	7	0.0 %
	CAUCASIAN - HISPANIC OR LATINO	173	0.4 %
	CAUCASIAN - NO DATA	2023	4.3 %
	CAUCASIAN - NOT HISPANIC OR LATINO	1983	4.2 %
	CAUCASIAN - OTHER	20	0.0 %
	NATIVE AMERICAN - HISPANIC OR LATINO	8	0.0 %
	NATIVE AMERICAN - NO DATA	21	0.0 %
	NATIVE AMERICAN - NOT HISPANIC OR LATINO	14	0.0 %
	NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - HISPANIC OR LATINO	1	0.0 %
	NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - NO DATA	2	0.0 %
	NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - NOT HISPANIC OR LATINO	4	0.0 %
	NO DATA - HISPANIC OR LATINO	259	0.5 %
	NO DATA - NO DATA	40947	86.8 %
	NO DATA - NOT HISPANIC OR LATINO	83	0.2 %
	NO DATA - OTHER	91	0.2 %

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APPENDIX 2 Interval Number of Case Reports (Serious and Non-Serious, Medically Confirmed and Non-Medically Confirmed) from Post-Marketing Data Sources, Overall, by Sex, Country, Age Groups and in Special Populations and Summary Tabulation by Preferred Term and MedDRA System Organ Class

BNT162B2 - ALL

Reporting Period: 30-APR-2021 Through 31-MAY-2021

Total Number of Cases: 47174 (100%) (ALL) / 47174 (OVERALL)

Total Number of Adverse Events (PT): 174446 (ALL)

NON CT

Total Number of Cases: 47174

Total Number of Adverse Events (PT): 174446

Preferred Term	System Organ Class (SOC)	Number of Cases
Headache	Nervous system disorders	11689 (24.78%)
Pyrexia	General disorders and administration site conditions	7341 (15.56%)
Fatigue	General disorders and administration site conditions	7076 (15.00%)
Myalgia	Musculoskeletal and connective tissue disorders	5531 (11.72%)
Nausea	Gastrointestinal disorders	5053 (10.71%)
Chills	General disorders and administration site conditions	4990 (10.58%)
Vaccination site pain	General disorders and administration site conditions	4875 (10.33%)
Arthralgia	Musculoskeletal and connective tissue disorders	4282 (9.08%)
Pain	General disorders and administration site conditions	4185 (8.87%)
Pain in extremity	Musculoskeletal and connective tissue disorders	4103 (8.70%)
Dizziness	Nervous system disorders	4039 (8.56%)
Asthenia	General disorders and administration site conditions	3460 (7.33%)
Malaise	General disorders and administration site conditions	2968 (6.29%)
Pruritus	Skin and subcutaneous tissue disorders	1949 (4.13%)
Lymphadenopathy	Blood and lymphatic system disorders	1914 (4.06%)
COVID-19	Infections and infestations	1898 (4.02%)
Dyspnoea	Respiratory, thoracic and mediastinal disorders	1883 (3.99%)
Rash	Skin and subcutaneous tissue disorders	1791 (3.80%)
Diarrhoea	Gastrointestinal disorders	1786 (3.79%)
Sensitive skin	Skin and subcutaneous tissue disorders	1737 (3.68%)
Vomiting	Gastrointestinal disorders	1664 (3.53%)
Cough	Respiratory, thoracic and mediastinal disorders	1413 (3.00%)
Paraesthesia	Nervous system disorders	1366 (2.90%)
Erythema	Skin and subcutaneous tissue disorders	1332 (2.82%)
Herpes zoster	Infections and infestations	1243 (2.63%)
Oropharyngeal pain	Respiratory, thoracic and mediastinal disorders	1126 (2.39%)
Hypoaesthesia	Nervous system disorders	1103 (2.34%)
Tachycardia	Cardiac disorders	1093 (2.32%)
Drug ineffective	General disorders and administration site conditions	1030 (2.18%)
Urticaria	Skin and subcutaneous tissue disorders	1002 (2.12%)
Feeling abnormal	General disorders and administration site conditions	967 (2.05%)
Hypertension	Vascular disorders	888 (1.88%)
Chest pain	General disorders and administration site conditions	883 (1.87%)
Off label use	Injury, poisoning and procedural complications	869 (1.84%)
Influenza like illness	General disorders and administration site conditions	853 (1.81%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Back pain	Musculoskeletal and connective tissue disorders	840 (1.78%)
Inappropriate schedule of product administration	Injury, poisoning and procedural complications	829 (1.76%)
Abdominal pain	Gastrointestinal disorders	786 (1.67%)
Rhinorrhoea	Respiratory, thoracic and mediastinal disorders	770 (1.63%)
Blood pressure increased	Investigations	762 (1.62%)
Vaccination site swelling	General disorders and administration site conditions	753 (1.60%)
Peripheral swelling	General disorders and administration site conditions	746 (1.58%)
Hyperhidrosis	Skin and subcutaneous tissue disorders	745 (1.58%)
Palpitations	Cardiac disorders	728 (1.54%)
Vaccination site erythema	General disorders and administration site conditions	725 (1.54%)
Anaphylactic reaction	Immune system disorders	672 (1.42%)
Feeling hot	General disorders and administration site conditions	622 (1.32%)
Decreased appetite	Metabolism and nutrition disorders	620 (1.31%)
Overdose	Injury, poisoning and procedural complications	614 (1.30%)
Neck pain	Musculoskeletal and connective tissue disorders	598 (1.27%)
Pulmonary embolism	Respiratory, thoracic and mediastinal disorders	588 (1.25%)
Syncope	Nervous system disorders	588 (1.25%)
Swelling	General disorders and administration site conditions	570 (1.21%)
Insomnia	Psychiatric disorders	566 (1.20%)
Hypersensitivity	Immune system disorders	560 (1.19%)
Somnolence	Nervous system disorders	548 (1.16%)
Body temperature increased	Investigations	542 (1.15%)
Vaccination failure	General disorders and administration site conditions	537 (1.14%)
Poor quality product administered	Injury, poisoning and procedural complications	532 (1.13%)
Heart rate increased	Investigations	525 (1.11%)
Tremor	Nervous system disorders	521 (1.10%)
Chest discomfort	General disorders and administration site conditions	516 (1.09%)
Vertigo	Ear and labyrinth disorders	513 (1.09%)
Abdominal pain upper	Gastrointestinal disorders	506 (1.07%)
Tinnitus	Ear and labyrinth disorders	491 (1.04%)
Migraine	Nervous system disorders	468 (0.99%)
Loss of consciousness	Nervous system disorders	445 (0.94%)
Axillary pain	General disorders and administration site conditions	444 (0.94%)
Deep vein thrombosis	Vascular disorders	442 (0.94%)
Oedema	General disorders and administration site conditions	429 (0.91%)
Feeling cold	General disorders and administration site conditions	426 (0.90%)
Inflammation	General disorders and administration site conditions	411 (0.87%)
Limb discomfort	Musculoskeletal and connective tissue disorders	407 (0.86%)
Muscular weakness	Musculoskeletal and connective tissue disorders	407 (0.86%)
Musculoskeletal stiffness	Musculoskeletal and connective tissue disorders	406 (0.86%)
Illness	General disorders and administration site conditions	402 (0.85%)
Lethargy	Nervous system disorders	394 (0.84%)
Product preparation issue	Injury, poisoning and procedural complications	378 (0.80%)
Condition aggravated	General disorders and administration site conditions	358 (0.76%)
Vision blurred	Eye disorders	352 (0.75%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Discomfort	General disorders and administration site conditions	350 (0.74%)
Vaccination site warmth	General disorders and administration site conditions	350 (0.74%)
Dysgeusia	Nervous system disorders	339 (0.72%)
Thrombosis	Vascular disorders	339 (0.72%)
Paraesthesia oral	Gastrointestinal disorders	337 (0.71%)
Muscle spasms	Musculoskeletal and connective tissue disorders	335 (0.71%)
Vaccination site pruritus	General disorders and administration site conditions	325 (0.69%)
Heavy menstrual bleeding	Reproductive system and breast disorders	323 (0.68%)
Swelling face	General disorders and administration site conditions	323 (0.68%)
Lymph node pain	Blood and lymphatic system disorders	320 (0.68%)
Burning sensation	Nervous system disorders	316 (0.67%)
Presyncope	Nervous system disorders	316 (0.67%)
Nasopharyngitis	Infections and infestations	314 (0.67%)
Gait disturbance	General disorders and administration site conditions	311 (0.66%)
Cerebrovascular accident	Nervous system disorders	310 (0.66%)
Product temperature excursion issue	Product issues	309 (0.66%)
Nodule	General disorders and administration site conditions	307 (0.65%)
Induration	General disorders and administration site conditions	305 (0.65%)
Hypotension	Vascular disorders	299 (0.63%)
Eye pain	Eye disorders	298 (0.63%)
Vaccination site reaction	General disorders and administration site conditions	296 (0.63%)
Hot flush	Vascular disorders	283 (0.60%)
Fall	Injury, poisoning and procedural complications	275 (0.58%)
Confusional state	Psychiatric disorders	271 (0.57%)
Rash pruritic	Skin and subcutaneous tissue disorders	271 (0.57%)
Anxiety	Psychiatric disorders	260 (0.55%)
Influenza	Infections and infestations	256 (0.54%)
Ear pain	Ear and labyrinth disorders	250 (0.53%)
Rash erythematous	Skin and subcutaneous tissue disorders	246 (0.52%)
Flushing	Vascular disorders	245 (0.52%)
Oropharyngeal discomfort	Respiratory, thoracic and mediastinal disorders	236 (0.50%)
Seizure	Nervous system disorders	236 (0.50%)
Abdominal discomfort	Gastrointestinal disorders	234 (0.50%)
Menstruation irregular	Reproductive system and breast disorders	233 (0.49%)
Hypoaesthesia oral	Gastrointestinal disorders	232 (0.49%)
Vaccination site inflammation	General disorders and administration site conditions	231 (0.49%)
Facial paralysis	Nervous system disorders	230 (0.49%)
Contusion	Injury, poisoning and procedural complications	227 (0.48%)
Product use issue	Injury, poisoning and procedural complications	224 (0.47%)
Nasal congestion	Respiratory, thoracic and mediastinal disorders	221 (0.47%)
Incorrect route of product administration	Injury, poisoning and procedural complications	220 (0.47%)
Bell's palsy	Nervous system disorders	219 (0.46%)
Throat irritation	Respiratory, thoracic and mediastinal disorders	219 (0.46%)
Balance disorder	Nervous system disorders	216 (0.46%)
Disease recurrence	General disorders and administration site conditions	216 (0.46%)
Oxygen saturation decreased	Investigations	215 (0.46%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Lip swelling	Gastrointestinal disorders	206 (0.44%)
Atrial fibrillation	Cardiac disorders	205 (0.43%)
Death	General disorders and administration site conditions	205 (0.43%)
Dysphagia	Gastrointestinal disorders	205 (0.43%)
Visual impairment	Eye disorders	201 (0.43%)
Throat tightness	Respiratory, thoracic and mediastinal disorders	197 (0.42%)
Epistaxis	Respiratory, thoracic and mediastinal disorders	196 (0.42%)
Head discomfort	Nervous system disorders	195 (0.41%)
Local reaction	General disorders and administration site conditions	194 (0.41%)
Menstrual disorder	Reproductive system and breast disorders	187 (0.40%)
Thrombocytopenia	Blood and lymphatic system disorders	187 (0.40%)
Bone pain	Musculoskeletal and connective tissue disorders	181 (0.38%)
Arrhythmia	Cardiac disorders	177 (0.38%)
Pallor	Vascular disorders	177 (0.38%)
Asthma	Respiratory, thoracic and mediastinal disorders	173 (0.37%)
Maternal exposure during pregnancy	Injury, poisoning and procedural complications	171 (0.36%)
Myocardial infarction	Cardiac disorders	170 (0.36%)
Neuralgia	Nervous system disorders	169 (0.36%)
Vaccination site oedema	General disorders and administration site conditions	167 (0.35%)
Injection site pain	General disorders and administration site conditions	166 (0.35%)
Pneumonia	Infections and infestations	165 (0.35%)
Dry mouth	Gastrointestinal disorders	164 (0.35%)
Irritability	Psychiatric disorders	162 (0.34%)
Blood pressure decreased	Investigations	161 (0.34%)
Menstruation delayed	Reproductive system and breast disorders	161 (0.34%)
Suspected COVID-19	Infections and infestations	161 (0.34%)
Joint swelling	Musculoskeletal and connective tissue disorders	160 (0.34%)
Cold sweat	Skin and subcutaneous tissue disorders	158 (0.33%)
Rash macular	Skin and subcutaneous tissue disorders	158 (0.33%)
Ageusia	Nervous system disorders	155 (0.33%)
Peripheral coldness	Vascular disorders	155 (0.33%)
Swollen tongue	Gastrointestinal disorders	153 (0.32%)
Disturbance in attention	Nervous system disorders	151 (0.32%)
Mobility decreased	Musculoskeletal and connective tissue disorders	149 (0.32%)
Vaccination site induration	General disorders and administration site conditions	149 (0.32%)
Wheezing	Respiratory, thoracic and mediastinal disorders	146 (0.31%)
Ischaemic stroke	Nervous system disorders	144 (0.31%)
Transient ischaemic attack	Nervous system disorders	143 (0.30%)
Odynophagia	Gastrointestinal disorders	142 (0.30%)
Oedema peripheral	General disorders and administration site conditions	140 (0.30%)
Anosmia	Nervous system disorders	138 (0.29%)
Dysphonia	Respiratory, thoracic and mediastinal disorders	136 (0.29%)
Loss of personal independence in daily activities	Social circumstances	135 (0.29%)
Pharyngeal swelling	Respiratory, thoracic and mediastinal disorders	135 (0.29%)
Movement disorder	Nervous system disorders	133 (0.28%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Respiratory distress	Respiratory, thoracic and mediastinal disorders	133 (0.28%)
Sleep disorder	Psychiatric disorders	130 (0.28%)
Exposure via breast milk	Injury, poisoning and procedural complications	129 (0.27%)
Vaccination site mass	General disorders and administration site conditions	129 (0.27%)
Blister	Skin and subcutaneous tissue disorders	125 (0.26%)
Eye swelling	Eye disorders	125 (0.26%)
Wrong technique in product usage process	Injury, poisoning and procedural complications	123 (0.26%)
Asymptomatic COVID-19	Infections and infestations	121 (0.26%)
Haemorrhage	Vascular disorders	121 (0.26%)
Feeling of body temperature change	General disorders and administration site conditions	120 (0.25%)
Product preparation error	Injury, poisoning and procedural complications	116 (0.25%)
Speech disorder	Nervous system disorders	116 (0.25%)
Night sweats	Skin and subcutaneous tissue disorders	115 (0.24%)
Breast pain	Reproductive system and breast disorders	114 (0.24%)
Hypertensive crisis	Vascular disorders	114 (0.24%)
Photophobia	Eye disorders	112 (0.24%)
Product storage error	Injury, poisoning and procedural complications	112 (0.24%)
Oral herpes	Infections and infestations	110 (0.23%)
Dysmenorrhoea	Reproductive system and breast disorders	109 (0.23%)
Tenderness	General disorders and administration site conditions	109 (0.23%)
Angioedema	Skin and subcutaneous tissue disorders	108 (0.23%)
General physical health deterioration	General disorders and administration site conditions	107 (0.23%)
SARS-CoV-2 test positive	Investigations	107 (0.23%)
Cerebral infarction	Nervous system disorders	106 (0.22%)
Dehydration	Metabolism and nutrition disorders	105 (0.22%)
Sensory disturbance	Nervous system disorders	105 (0.22%)
Vaginal haemorrhage	Reproductive system and breast disorders	104 (0.22%)
Arthritis	Musculoskeletal and connective tissue disorders	103 (0.22%)
Cardiac arrest	Cardiac disorders	103 (0.22%)
Thirst	General disorders and administration site conditions	103 (0.22%)
Disorientation	Psychiatric disorders	102 (0.22%)
Musculoskeletal pain	Musculoskeletal and connective tissue disorders	102 (0.22%)
Neuropathy peripheral	Nervous system disorders	101 (0.21%)
Sneezing	Respiratory, thoracic and mediastinal disorders	101 (0.21%)
Vaccination site movement impairment	General disorders and administration site conditions	101 (0.21%)
Deafness	Ear and labyrinth disorders	100 (0.21%)
Dysarthria	Nervous system disorders	100 (0.21%)
Vaccination site rash	General disorders and administration site conditions	100 (0.21%)
Myocarditis	Cardiac disorders	98 (0.21%)
Aphasia	Nervous system disorders	97 (0.21%)
C-reactive protein increased	Investigations	95 (0.20%)
Dizziness postural	Nervous system disorders	95 (0.20%)
Abdominal distension	Gastrointestinal disorders	94 (0.20%)
Pain in jaw	Musculoskeletal and connective tissue disorders	94 (0.20%)
Cerebral haemorrhage	Nervous system disorders	93 (0.20%)
Pain of skin	Skin and subcutaneous tissue disorders	92 (0.20%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Ear discomfort	Ear and labyrinth disorders	91 (0.19%)
Underdose	Injury, poisoning and procedural complications	90 (0.19%)
Joint range of motion decreased	Musculoskeletal and connective tissue disorders	89 (0.19%)
Pericarditis	Cardiac disorders	89 (0.19%)
Weight decreased	Investigations	88 (0.19%)
Cardiac failure	Cardiac disorders	87 (0.18%)
Hypoacusis	Ear and labyrinth disorders	87 (0.18%)
Depressed level of consciousness	Nervous system disorders	86 (0.18%)
Dysstasia	Nervous system disorders	86 (0.18%)
Eye irritation	Eye disorders	86 (0.18%)
Muscle twitching	Musculoskeletal and connective tissue disorders	86 (0.18%)
Rash papular	Skin and subcutaneous tissue disorders	86 (0.18%)
Vaccination site discomfort	General disorders and administration site conditions	86 (0.18%)
Epilepsy	Nervous system disorders	84 (0.18%)
Ocular hyperaemia	Eye disorders	84 (0.18%)
Hypersomnia	Nervous system disorders	83 (0.18%)
Hyperventilation	Respiratory, thoracic and mediastinal disorders	83 (0.18%)
Taste disorder	Nervous system disorders	83 (0.18%)
Exposure during pregnancy	Injury, poisoning and procedural complications	82 (0.17%)
Angina pectoris	Cardiac disorders	81 (0.17%)
Eye pruritus	Eye disorders	81 (0.17%)
Nervousness	Psychiatric disorders	81 (0.17%)
Dyspnoea exertional	Respiratory, thoracic and mediastinal disorders	80 (0.17%)
COVID-19 pneumonia	Infections and infestations	79 (0.17%)
Facial paresis	Nervous system disorders	79 (0.17%)
Memory impairment	Nervous system disorders	79 (0.17%)
Urinary tract infection	Infections and infestations	79 (0.17%)
Depressed mood	Psychiatric disorders	78 (0.17%)
Hyperthermia	General disorders and administration site conditions	77 (0.16%)
Gait inability	General disorders and administration site conditions	76 (0.16%)
Hemiparesis	Nervous system disorders	76 (0.16%)
Lacrimation increased	Eye disorders	75 (0.16%)
Lymphadenitis	Blood and lymphatic system disorders	75 (0.16%)
Sensation of foreign body	General disorders and administration site conditions	75 (0.16%)
Anaphylactic shock	Immune system disorders	74 (0.16%)
Bradycardia	Cardiac disorders	74 (0.16%)
Diplopia	Eye disorders	74 (0.16%)
Bronchospasm	Respiratory, thoracic and mediastinal disorders	73 (0.15%)
Vaccination site bruising	General disorders and administration site conditions	73 (0.15%)
Amnesia	Nervous system disorders	72 (0.15%)
Face oedema	General disorders and administration site conditions	72 (0.15%)
Hallucination	Psychiatric disorders	71 (0.15%)
Petechiae	Skin and subcutaneous tissue disorders	71 (0.15%)
Productive cough	Respiratory, thoracic and mediastinal disorders	70 (0.15%)
Sudden death	General disorders and administration site conditions	69 (0.15%)
Gastrointestinal disorder	Gastrointestinal disorders	68 (0.14%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Intermenstrual bleeding	Reproductive system and breast disorders	68 (0.14%)
Platelet count decreased	Investigations	68 (0.14%)
Swelling of eyelid	Eye disorders	68 (0.14%)
Dyspepsia	Gastrointestinal disorders	67 (0.14%)
Musculoskeletal chest pain	Musculoskeletal and connective tissue disorders	67 (0.14%)
Paralysis	Nervous system disorders	67 (0.14%)
Acute myocardial infarction	Cardiac disorders	66 (0.14%)
Allergy to vaccine	Immune system disorders	66 (0.14%)
Parosmia	Nervous system disorders	66 (0.14%)
Skin burning sensation	Skin and subcutaneous tissue disorders	66 (0.14%)
Muscle tightness	Musculoskeletal and connective tissue disorders	65 (0.14%)
Polymenorrhoea	Reproductive system and breast disorders	65 (0.14%)
Skin discolouration	Skin and subcutaneous tissue disorders	65 (0.14%)
Therapeutic response unexpected	General disorders and administration site conditions	65 (0.14%)
Thrombophlebitis superficial	Vascular disorders	65 (0.14%)
Vaccination complication	Injury, poisoning and procedural complications	65 (0.14%)
Blood glucose increased	Investigations	64 (0.14%)
Fibrin D dimer increased	Investigations	64 (0.14%)
Crying	General disorders and administration site conditions	63 (0.13%)
Facial pain	General disorders and administration site conditions	62 (0.13%)
Impaired work ability	Social circumstances	62 (0.13%)
Infection	Infections and infestations	62 (0.13%)
Respiratory failure	Respiratory, thoracic and mediastinal disorders	62 (0.13%)
Anaemia	Blood and lymphatic system disorders	61 (0.13%)
Cardio-respiratory arrest	Cardiac disorders	61 (0.13%)
Constipation	Gastrointestinal disorders	61 (0.13%)
Restlessness	Psychiatric disorders	61 (0.13%)
Dry skin	Skin and subcutaneous tissue disorders	60 (0.13%)
Guillain-Barre syndrome	Nervous system disorders	60 (0.13%)
Incorrect dose administered	Injury, poisoning and procedural complications	60 (0.13%)
Eczema	Skin and subcutaneous tissue disorders	59 (0.13%)
Hypokinesia	Nervous system disorders	59 (0.13%)
Circumstance or information capable of leading to medication error	Injury, poisoning and procedural complications	58 (0.12%)
Renal pain	Renal and urinary disorders	58 (0.12%)
Wrong product administered	Injury, poisoning and procedural complications	58 (0.12%)
Feeding disorder	Metabolism and nutrition disorders	57 (0.12%)
Immune thrombocytopenia	Blood and lymphatic system disorders	57 (0.12%)
Poor quality sleep	Psychiatric disorders	57 (0.12%)
Rheumatoid arthritis	Musculoskeletal and connective tissue disorders	56 (0.12%)
Blood pressure fluctuation	Vascular disorders	55 (0.12%)
Joint stiffness	Musculoskeletal and connective tissue disorders	55 (0.12%)
Musculoskeletal discomfort	Musculoskeletal and connective tissue disorders	55 (0.12%)
Oral discomfort	Gastrointestinal disorders	54 (0.11%)
Skin disorder	Skin and subcutaneous tissue disorders	54 (0.11%)
Blood pressure abnormal	Investigations	53 (0.11%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Cellulitis	Infections and infestations	53 (0.11%)
Circulatory collapse	Vascular disorders	53 (0.11%)
Eyelid oedema	Eye disorders	53 (0.11%)
Thrombophlebitis	Vascular disorders	53 (0.11%)
Abortion spontaneous	Pregnancy, puerperium and perinatal conditions	52 (0.11%)
Lip oedema	Gastrointestinal disorders	52 (0.11%)
Tension headache	Nervous system disorders	52 (0.11%)
Vaccination site haematoma	General disorders and administration site conditions	52 (0.11%)
Acute kidney injury	Renal and urinary disorders	51 (0.11%)
Haematoma	Vascular disorders	51 (0.11%)
Ophthalmic herpes zoster	Infections and infestations	51 (0.11%)
Respiratory disorder	Respiratory, thoracic and mediastinal disorders	51 (0.11%)
Abdominal pain lower	Gastrointestinal disorders	50 (0.11%)
Depression	Psychiatric disorders	50 (0.11%)
Vaccination site paraesthesia	General disorders and administration site conditions	50 (0.11%)
Agitation	Psychiatric disorders	49 (0.10%)
Axillary mass	Musculoskeletal and connective tissue disorders	49 (0.10%)
Cognitive disorder	Nervous system disorders	49 (0.10%)
Head injury	Injury, poisoning and procedural complications	49 (0.10%)
Heart rate decreased	Investigations	49 (0.10%)
Photopsia	Eye disorders	49 (0.10%)
Spinal pain	Musculoskeletal and connective tissue disorders	49 (0.10%)
White blood cell count increased	Investigations	49 (0.10%)
Cardiovascular disorder	Cardiac disorders	48 (0.10%)
Hyperpyrexia	General disorders and administration site conditions	48 (0.10%)
Nervous system disorder	Nervous system disorders	48 (0.10%)
Flatulence	Gastrointestinal disorders	47 (0.10%)
Toothache	Gastrointestinal disorders	47 (0.10%)
Amenorrhoea	Reproductive system and breast disorders	46 (0.10%)
Blindness	Eye disorders	46 (0.10%)
Cyanosis	Vascular disorders	46 (0.10%)
Extrasystoles	Cardiac disorders	46 (0.10%)
Purpura	Skin and subcutaneous tissue disorders	46 (0.10%)
Aphonia	Respiratory, thoracic and mediastinal disorders	45 (0.10%)
Dry throat	Respiratory, thoracic and mediastinal disorders	45 (0.10%)
Dermatitis allergic	Skin and subcutaneous tissue disorders	44 (0.09%)
Dyskinesia	Nervous system disorders	44 (0.09%)
Hyperaesthesia	Nervous system disorders	44 (0.09%)
Hypoglycaemia	Metabolism and nutrition disorders	44 (0.09%)
Sinusitis	Infections and infestations	44 (0.09%)
Skin sensitisation	Skin and subcutaneous tissue disorders	44 (0.09%)
Dysaesthesia	Nervous system disorders	43 (0.09%)
Haematochezia	Gastrointestinal disorders	43 (0.09%)
Ocular discomfort	Eye disorders	43 (0.09%)
Tachypnoea	Respiratory, thoracic and mediastinal disorders	43 (0.09%)
Blood pressure systolic increased	Investigations	42 (0.09%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Gastrointestinal pain	Gastrointestinal disorders	42 (0.09%)
Glossodynia	Gastrointestinal disorders	42 (0.09%)
Altered state of consciousness	Nervous system disorders	41 (0.09%)
Dysphoria	Psychiatric disorders	41 (0.09%)
Monoparesis	Nervous system disorders	41 (0.09%)
Nightmare	Psychiatric disorders	41 (0.09%)
Vaccination site haemorrhage	General disorders and administration site conditions	41 (0.09%)
Cardiac flutter	Cardiac disorders	40 (0.08%)
Heart rate irregular	Investigations	40 (0.08%)
Mouth ulceration	Gastrointestinal disorders	40 (0.08%)
Panic attack	Psychiatric disorders	40 (0.08%)
Pleural effusion	Respiratory, thoracic and mediastinal disorders	40 (0.08%)
Pulmonary pain	Respiratory, thoracic and mediastinal disorders	40 (0.08%)
Rash maculo-papular	Skin and subcutaneous tissue disorders	40 (0.08%)
Skin lesion	Skin and subcutaneous tissue disorders	40 (0.08%)
Urinary incontinence	Renal and urinary disorders	40 (0.08%)
Groin pain	Musculoskeletal and connective tissue disorders	39 (0.08%)
Injection site erythema	General disorders and administration site conditions	39 (0.08%)
Pericardial effusion	Cardiac disorders	39 (0.08%)
Periorbital swelling	Eye disorders	39 (0.08%)
Skin reaction	Skin and subcutaneous tissue disorders	39 (0.08%)
Alopecia	Skin and subcutaneous tissue disorders	38 (0.08%)
Cardiac disorder	Cardiac disorders	38 (0.08%)
Generalised tonic-clonic seizure	Nervous system disorders	38 (0.08%)
Hemiplegia	Nervous system disorders	38 (0.08%)
Hypoxia	Respiratory, thoracic and mediastinal disorders	38 (0.08%)
Oral pain	Gastrointestinal disorders	38 (0.08%)
Product administered at inappropriate site	Injury, poisoning and procedural complications	38 (0.08%)
Product dose omission issue	Injury, poisoning and procedural complications	38 (0.08%)
Rash vesicular	Skin and subcutaneous tissue disorders	38 (0.08%)
Deafness unilateral	Ear and labyrinth disorders	37 (0.08%)
Dry eye	Eye disorders	37 (0.08%)
Lymphoedema	Vascular disorders	37 (0.08%)
Mouth swelling	Gastrointestinal disorders	37 (0.08%)
Rhinitis	Infections and infestations	37 (0.08%)
Sensory loss	Nervous system disorders	37 (0.08%)
Vaccination site lymphadenopathy	General disorders and administration site conditions	37 (0.08%)
Venous thrombosis limb	Vascular disorders	37 (0.08%)
Asthenopia	Eye disorders	36 (0.08%)
Conjunctivitis	Infections and infestations	36 (0.08%)
Dermatitis	Skin and subcutaneous tissue disorders	36 (0.08%)
Embolism	Vascular disorders	36 (0.08%)
Mass	General disorders and administration site conditions	36 (0.08%)
Muscle fatigue	Musculoskeletal and connective tissue disorders	36 (0.08%)
Renal failure	Renal and urinary disorders	36 (0.08%)
Salivary hypersecretion	Gastrointestinal disorders	36 (0.08%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Cerebral venous sinus thrombosis	Nervous system disorders	35 (0.07%)
Cystitis	Infections and infestations	35 (0.07%)
Pollakiuria	Renal and urinary disorders	35 (0.07%)
Pulmonary thrombosis	Respiratory, thoracic and mediastinal disorders	35 (0.07%)
Retching	Gastrointestinal disorders	35 (0.07%)
Body temperature abnormal	Investigations	34 (0.07%)
Body temperature decreased	Investigations	34 (0.07%)
Expired product administered	Injury, poisoning and procedural complications	34 (0.07%)
Eye disorder	Eye disorders	34 (0.07%)
Eye haemorrhage	Eye disorders	34 (0.07%)
Postmenopausal haemorrhage	Reproductive system and breast disorders	34 (0.07%)
Rectal haemorrhage	Gastrointestinal disorders	34 (0.07%)
Coagulopathy	Blood and lymphatic system disorders	33 (0.07%)
Delirium	Psychiatric disorders	33 (0.07%)
Gastroesophageal reflux disease	Gastrointestinal disorders	33 (0.07%)
Hyperglycaemia	Metabolism and nutrition disorders	33 (0.07%)
Injected limb mobility decreased	General disorders and administration site conditions	33 (0.07%)
Laryngeal oedema	Respiratory, thoracic and mediastinal disorders	33 (0.07%)
Motor dysfunction	Nervous system disorders	33 (0.07%)
Skin exfoliation	Skin and subcutaneous tissue disorders	33 (0.07%)
Stomatitis	Gastrointestinal disorders	33 (0.07%)
Eating disorder	Psychiatric disorders	32 (0.07%)
Monoplegia	Nervous system disorders	32 (0.07%)
Respiratory rate increased	Investigations	32 (0.07%)
Sepsis	Infections and infestations	32 (0.07%)
Sinus headache	Nervous system disorders	32 (0.07%)
Subarachnoid haemorrhage	Nervous system disorders	32 (0.07%)
White blood cell count decreased	Investigations	32 (0.07%)
Abnormal dreams	Psychiatric disorders	31 (0.07%)
Acne	Skin and subcutaneous tissue disorders	31 (0.07%)
Appendicitis	Infections and infestations	31 (0.07%)
Bedridden	Social circumstances	31 (0.07%)
Blepharospasm	Eye disorders	31 (0.07%)
Drug interaction	General disorders and administration site conditions	31 (0.07%)
Extensive swelling of vaccinated limb	General disorders and administration site conditions	31 (0.07%)
Gout	Metabolism and nutrition disorders	31 (0.07%)
Heart rate abnormal	Investigations	31 (0.07%)
Lower respiratory tract infection	Infections and infestations	31 (0.07%)
Muscle strain	Injury, poisoning and procedural complications	31 (0.07%)
Pharyngeal paraesthesia	Respiratory, thoracic and mediastinal disorders	31 (0.07%)
Photosensitivity reaction	Skin and subcutaneous tissue disorders	31 (0.07%)
Sciatica	Nervous system disorders	31 (0.07%)
Dysuria	Renal and urinary disorders	30 (0.06%)
Fibromyalgia	Musculoskeletal and connective tissue disorders	30 (0.06%)
Mental impairment	Nervous system disorders	30 (0.06%)
Pulmonary oedema	Respiratory, thoracic and mediastinal disorders	30 (0.06%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Vaccination site urticaria	General disorders and administration site conditions	30 (0.06%)
Vasculitis	Vascular disorders	30 (0.06%)
Breast swelling	Reproductive system and breast disorders	29 (0.06%)
Immune system disorder	Immune system disorders	29 (0.06%)
Musculoskeletal disorder	Musculoskeletal and connective tissue disorders	29 (0.06%)
Neurological symptom	Nervous system disorders	29 (0.06%)
Oral pruritus	Gastrointestinal disorders	29 (0.06%)
Troponin increased	Investigations	29 (0.06%)
Vaccination site hypoaesthesia	General disorders and administration site conditions	29 (0.06%)
Bronchitis	Infections and infestations	28 (0.06%)
Erysipelas	Infections and infestations	28 (0.06%)
Hypothermia	General disorders and administration site conditions	28 (0.06%)
Phlebitis	Vascular disorders	28 (0.06%)
Stress	Psychiatric disorders	28 (0.06%)
Tongue oedema	Gastrointestinal disorders	28 (0.06%)
Viral infection	Infections and infestations	28 (0.06%)
Visual field defect	Eye disorders	28 (0.06%)
Coma	Nervous system disorders	27 (0.06%)
Conjunctival haemorrhage	Eye disorders	27 (0.06%)
Eye injury	Injury, poisoning and procedural complications	27 (0.06%)
Haematuria	Renal and urinary disorders	27 (0.06%)
Hallucination, visual	Psychiatric disorders	27 (0.06%)
Localised oedema	General disorders and administration site conditions	27 (0.06%)
Lung disorder	Respiratory, thoracic and mediastinal disorders	27 (0.06%)
Skin irritation	Skin and subcutaneous tissue disorders	27 (0.06%)
Arthropathy	Musculoskeletal and connective tissue disorders	26 (0.06%)
Blood glucose decreased	Investigations	26 (0.06%)
Chromaturia	Renal and urinary disorders	26 (0.06%)
Migraine with aura	Nervous system disorders	26 (0.06%)
Mydriasis	Eye disorders	26 (0.06%)
Renal impairment	Renal and urinary disorders	26 (0.06%)
Vaccination site hypersensitivity	General disorders and administration site conditions	26 (0.06%)
Vaccination site nodule	General disorders and administration site conditions	26 (0.06%)
Autoimmune disorder	Immune system disorders	25 (0.05%)
Chillblains	Injury, poisoning and procedural complications	25 (0.05%)
Feeling drunk	General disorders and administration site conditions	25 (0.05%)
No adverse event	General disorders and administration site conditions	25 (0.05%)
Painful respiration	Respiratory, thoracic and mediastinal disorders	25 (0.05%)
Periarthritis	Musculoskeletal and connective tissue disorders	25 (0.05%)
Pharyngeal oedema	Respiratory, thoracic and mediastinal disorders	25 (0.05%)
Product administered to patient of inappropriate age	Injury, poisoning and procedural complications	25 (0.05%)
Seasonal allergy	Immune system disorders	25 (0.05%)
Shock	Vascular disorders	25 (0.05%)
Sinus tachycardia	Cardiac disorders	25 (0.05%)
Skin warm	Skin and subcutaneous tissue disorders	25 (0.05%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Tongue discomfort	Gastrointestinal disorders	25 (0.05%)
Blood urine present	Investigations	24 (0.05%)
Ear swelling	Ear and labyrinth disorders	24 (0.05%)
Psoriasis	Skin and subcutaneous tissue disorders	24 (0.05%)
Thinking abnormal	Psychiatric disorders	24 (0.05%)
Vaccination site discolouration	General disorders and administration site conditions	24 (0.05%)
Venous thrombosis	Vascular disorders	24 (0.05%)
Aphthous ulcer	Gastrointestinal disorders	23 (0.05%)
Coordination abnormal	Nervous system disorders	23 (0.05%)
Drug hypersensitivity	Immune system disorders	23 (0.05%)
Febrile convulsion	Nervous system disorders	23 (0.05%)
Haemoglobin decreased	Investigations	23 (0.05%)
Herpes simplex	Infections and infestations	23 (0.05%)
Herpes virus infection	Infections and infestations	23 (0.05%)
Herpes zoster reactivation	Infections and infestations	23 (0.05%)
Multiple sclerosis	Nervous system disorders	23 (0.05%)
Nasal discomfort	Respiratory, thoracic and mediastinal disorders	23 (0.05%)
Papule	Skin and subcutaneous tissue disorders	23 (0.05%)
Sinus pain	Respiratory, thoracic and mediastinal disorders	23 (0.05%)
Vaccination site joint pain	General disorders and administration site conditions	23 (0.05%)
Vitreous floaters	Eye disorders	23 (0.05%)
Cerebral thrombosis	Nervous system disorders	22 (0.05%)
Cluster headache	Nervous system disorders	22 (0.05%)
Diabetes mellitus	Metabolism and nutrition disorders	22 (0.05%)
Ecchymosis	Skin and subcutaneous tissue disorders	22 (0.05%)
Emotional disorder	Psychiatric disorders	22 (0.05%)
Fear	Psychiatric disorders	22 (0.05%)
Haemoptysis	Respiratory, thoracic and mediastinal disorders	22 (0.05%)
Hangover	General disorders and administration site conditions	22 (0.05%)
Hypopnoea	Respiratory, thoracic and mediastinal disorders	22 (0.05%)
Internal haemorrhage	Vascular disorders	22 (0.05%)
Middle insomnia	Psychiatric disorders	22 (0.05%)
Pneumonia aspiration	Respiratory, thoracic and mediastinal disorders	22 (0.05%)
Skin swelling	Skin and subcutaneous tissue disorders	22 (0.05%)
Trigeminal neuralgia	Nervous system disorders	22 (0.05%)
Urinary retention	Renal and urinary disorders	22 (0.05%)
		22 (0.05%)
Abnormal faeces	Gastrointestinal disorders	21 (0.04%)
Breast tenderness	Reproductive system and breast disorders	21 (0.04%)
Chronic obstructive pulmonary disease	Respiratory, thoracic and mediastinal disorders	21 (0.04%)
Conjunctival hyperaemia	Eye disorders	21 (0.04%)
Encephalitis	Infections and infestations	21 (0.04%)
Formication	Nervous system disorders	21 (0.04%)
Gingival bleeding	Gastrointestinal disorders	21 (0.04%)
Hyperacusis	Ear and labyrinth disorders	21 (0.04%)
Hypotonia	Nervous system disorders	21 (0.04%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Pelvic pain	Reproductive system and breast disorders	21 (0.04%)
Polymyalgia rheumatica	Musculoskeletal and connective tissue disorders	21 (0.04%)
Product administration error	Injury, poisoning and procedural complications	21 (0.04%)
Retinal vein occlusion	Eye disorders	21 (0.04%)
Suffocation feeling	Respiratory, thoracic and mediastinal disorders	21 (0.04%)
Supraventricular tachycardia	Cardiac disorders	21 (0.04%)
Temperature regulation disorder	General disorders and administration site conditions	21 (0.04%)
Tongue disorder	Gastrointestinal disorders	21 (0.04%)
Vertigo positional	Ear and labyrinth disorders	21 (0.04%)
Acute coronary syndrome	Cardiac disorders	20 (0.04%)
Acute respiratory failure	Respiratory, thoracic and mediastinal disorders	20 (0.04%)
Colitis ulcerative	Gastrointestinal disorders	20 (0.04%)
Deafness neurosensory	Ear and labyrinth disorders	20 (0.04%)
Ear infection	Infections and infestations	20 (0.04%)
Electric shock sensation	Nervous system disorders	20 (0.04%)
International normalised ratio increased	Investigations	20 (0.04%)
Laryngeal discomfort	Respiratory, thoracic and mediastinal disorders	20 (0.04%)
Mental fatigue	Psychiatric disorders	20 (0.04%)
Muscle rigidity	Musculoskeletal and connective tissue disorders	20 (0.04%)
Obstructive airways disorder	Respiratory, thoracic and mediastinal disorders	20 (0.04%)
Sudden hearing loss	Ear and labyrinth disorders	20 (0.04%)
Suicidal ideation	Psychiatric disorders	20 (0.04%)
Tension	Psychiatric disorders	20 (0.04%)
Unresponsive to stimuli	Nervous system disorders	20 (0.04%)
Ventricular extrasystoles	Cardiac disorders	20 (0.04%)
Alanine aminotransferase increased	Investigations	19 (0.04%)
Colitis	Gastrointestinal disorders	19 (0.04%)
Eyelid ptosis	Eye disorders	19 (0.04%)
Inflammatory marker increased	Investigations	19 (0.04%)
Injection site swelling	General disorders and administration site conditions	19 (0.04%)
Limb injury	Injury, poisoning and procedural complications	19 (0.04%)
Myositis	Musculoskeletal and connective tissue disorders	19 (0.04%)
Nerve injury	Injury, poisoning and procedural complications	19 (0.04%)
Osteoarthritis	Musculoskeletal and connective tissue disorders	19 (0.04%)
Pancreatitis acute	Gastrointestinal disorders	19 (0.04%)
Post herpetic neuralgia	Nervous system disorders	19 (0.04%)
Tendonitis	Musculoskeletal and connective tissue disorders	19 (0.04%)
Tongue pruritus	Gastrointestinal disorders	19 (0.04%)
Visual acuity reduced	Eye disorders	19 (0.04%)
Apathy	Psychiatric disorders	18 (0.04%)
Cerebral ischaemia	Nervous system disorders	18 (0.04%)
Gastritis	Gastrointestinal disorders	18 (0.04%)
Haemorrhagic stroke	Nervous system disorders	18 (0.04%)
Hemiparaesthesia	Nervous system disorders	18 (0.04%)
Neutropenia	Blood and lymphatic system disorders	18 (0.04%)
Pharyngitis	Infections and infestations	18 (0.04%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Ventricular tachycardia	Cardiac disorders	18 (0.04%)
Vitreous detachment	Eye disorders	18 (0.04%)
Weight increased	Investigations	18 (0.04%)
Accidental overdose	Injury, poisoning and procedural complications	17 (0.04%)
Bursitis	Musculoskeletal and connective tissue disorders	17 (0.04%)
Dysentery	Infections and infestations	17 (0.04%)
Erythema multiforme	Skin and subcutaneous tissue disorders	17 (0.04%)
Eye movement disorder	Eye disorders	17 (0.04%)
Grip strength decreased	Investigations	17 (0.04%)
Interstitial lung disease	Respiratory, thoracic and mediastinal disorders	17 (0.04%)
Lip pain	Gastrointestinal disorders	17 (0.04%)
Portal vein thrombosis	Hepatobiliary disorders	17 (0.04%)
Pulmonary infarction	Respiratory, thoracic and mediastinal disorders	17 (0.04%)
Respiratory arrest	Respiratory, thoracic and mediastinal disorders	17 (0.04%)
Retinal artery occlusion	Eye disorders	17 (0.04%)
Scab	Skin and subcutaneous tissue disorders	17 (0.04%)
Sinus disorder	Respiratory, thoracic and mediastinal disorders	17 (0.04%)
Tonsillitis	Infections and infestations	17 (0.04%)
Blood creatinine increased	Investigations	16 (0.03%)
Dermatitis bullous	Skin and subcutaneous tissue disorders	16 (0.03%)
Eructation	Gastrointestinal disorders	16 (0.03%)
Exposure to SARS-CoV-2	Injury, poisoning and procedural complications	16 (0.03%)
Eye inflammation	Eye disorders	16 (0.03%)
Eye oedema	Eye disorders	16 (0.03%)
Hyperaemia	Vascular disorders	16 (0.03%)
Hypomenorrhoea	Reproductive system and breast disorders	16 (0.03%)
Jaundice	Hepatobiliary disorders	16 (0.03%)
Labyrinthitis	Infections and infestations	16 (0.03%)
Liver function test abnormal	Investigations	16 (0.03%)
Mental disorder	Psychiatric disorders	16 (0.03%)
Muscle contractions involuntary	Nervous system disorders	16 (0.03%)
Near death experience	Psychiatric disorders	16 (0.03%)
Peripheral ischaemia	Vascular disorders	16 (0.03%)
Polyuria	Renal and urinary disorders	16 (0.03%)
Raynaud's phenomenon	Vascular disorders	16 (0.03%)
Road traffic accident	Injury, poisoning and procedural complications	16 (0.03%)
Sluggishness	General disorders and administration site conditions	16 (0.03%)
Status epilepticus	Nervous system disorders	16 (0.03%)
Stridor	Respiratory, thoracic and mediastinal disorders	16 (0.03%)
Vaccination site joint movement impairment	General disorders and administration site conditions	16 (0.03%)
Vestibular neuronitis	Infections and infestations	16 (0.03%)
Acute respiratory distress syndrome	Respiratory, thoracic and mediastinal disorders	15 (0.03%)
Adverse event	General disorders and administration site conditions	15 (0.03%)
Aspartate aminotransferase increased	Investigations	15 (0.03%)
Asthmatic crisis	Respiratory, thoracic and mediastinal disorders	15 (0.03%)
Blindness unilateral	Eye disorders	15 (0.03%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Blood fibrinogen increased	Investigations	15 (0.03%)
Body temperature fluctuation	Investigations	15 (0.03%)
Drug eruption	Skin and subcutaneous tissue disorders	15 (0.03%)
Fluid retention	Metabolism and nutrition disorders	15 (0.03%)
Gastrointestinal haemorrhage	Gastrointestinal disorders	15 (0.03%)
Gingival pain	Gastrointestinal disorders	15 (0.03%)
Hyponatraemia	Metabolism and nutrition disorders	15 (0.03%)
Hypophagia	Metabolism and nutrition disorders	15 (0.03%)
Irritable bowel syndrome	Gastrointestinal disorders	15 (0.03%)
Multiple organ dysfunction syndrome	General disorders and administration site conditions	15 (0.03%)
Nystagmus	Nervous system disorders	15 (0.03%)
Optic neuritis	Nervous system disorders	15 (0.03%)
Pneumonitis	Respiratory, thoracic and mediastinal disorders	15 (0.03%)
Rash morbilliform	Skin and subcutaneous tissue disorders	15 (0.03%)
Rotator cuff syndrome	Musculoskeletal and connective tissue disorders	15 (0.03%)
Scratch	Injury, poisoning and procedural complications	15 (0.03%)
Sinus congestion	Respiratory, thoracic and mediastinal disorders	15 (0.03%)
Vaccination site cellulitis	Infections and infestations	15 (0.03%)
Vein disorder	Vascular disorders	15 (0.03%)
Back disorder	Musculoskeletal and connective tissue disorders	14 (0.03%)
Blood creatine phosphokinase increased	Investigations	14 (0.03%)
Blood urea increased	Investigations	14 (0.03%)
Cardiomegaly	Cardiac disorders	14 (0.03%)
Choking sensation	Respiratory, thoracic and mediastinal disorders	14 (0.03%)
Chronic fatigue syndrome	General disorders and administration site conditions	14 (0.03%)
Cutaneous vasculitis	Skin and subcutaneous tissue disorders	14 (0.03%)
Ear pruritus	Ear and labyrinth disorders	14 (0.03%)
Embolic stroke	Nervous system disorders	14 (0.03%)
Emotional distress	Psychiatric disorders	14 (0.03%)
Euphoric mood	Psychiatric disorders	14 (0.03%)
Eye discharge	Eye disorders	14 (0.03%)
Ischaemia	Vascular disorders	14 (0.03%)
Joint injury	Injury, poisoning and procedural complications	14 (0.03%)
Limb mass	Musculoskeletal and connective tissue disorders	14 (0.03%)
Lymphopenia	Blood and lymphatic system disorders	14 (0.03%)
Mastitis	Infections and infestations	14 (0.03%)
Maternal exposure during breast feeding	Injury, poisoning and procedural complications	14 (0.03%)
Mesenteric vein thrombosis	Gastrointestinal disorders	14 (0.03%)
Mood altered	Psychiatric disorders	14 (0.03%)
Nasal obstruction	Respiratory, thoracic and mediastinal disorders	14 (0.03%)
Oral mucosal blistering	Gastrointestinal disorders	14 (0.03%)
Pancreatitis	Gastrointestinal disorders	14 (0.03%)
Peripheral vascular disorder	Vascular disorders	14 (0.03%)
Renal disorder	Renal and urinary disorders	14 (0.03%)
Respiration abnormal	Respiratory, thoracic and mediastinal disorders	14 (0.03%)
Restless legs syndrome	Nervous system disorders	14 (0.03%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Tachyarrhythmia	Cardiac disorders	14 (0.03%)
Abnormal behaviour	Psychiatric disorders	13 (0.03%)
Application site pain	General disorders and administration site conditions	13 (0.03%)
Ataxia	Nervous system disorders	13 (0.03%)
Bradyphrenia	Psychiatric disorders	13 (0.03%)
Brain oedema	Nervous system disorders	13 (0.03%)
Cardiac failure acute	Cardiac disorders	13 (0.03%)
Cardiac failure congestive	Cardiac disorders	13 (0.03%)
Cardiogenic shock	Cardiac disorders	13 (0.03%)
Diarrhoea haemorrhagic	Gastrointestinal disorders	13 (0.03%)
Dyspnoea at rest	Respiratory, thoracic and mediastinal disorders	13 (0.03%)
Faeces soft	Gastrointestinal disorders	13 (0.03%)
Flank pain	Musculoskeletal and connective tissue disorders	13 (0.03%)
Haematemesis	Gastrointestinal disorders	13 (0.03%)
Haemorrhage subcutaneous	Skin and subcutaneous tissue disorders	13 (0.03%)
Herpes zoster oticus	Infections and infestations	13 (0.03%)
Hyperthyroidism	Endocrine disorders	13 (0.03%)
Impaired driving ability	Social circumstances	13 (0.03%)
Listless	Psychiatric disorders	13 (0.03%)
Livedo reticularis	Skin and subcutaneous tissue disorders	13 (0.03%)
Lymphocyte count decreased	Investigations	13 (0.03%)
Miliaria	Skin and subcutaneous tissue disorders	13 (0.03%)
Multiple sclerosis relapse	Nervous system disorders	13 (0.03%)
Myocardial ischaemia	Cardiac disorders	13 (0.03%)
Neck mass	Musculoskeletal and connective tissue disorders	13 (0.03%)
Nephrolithiasis	Renal and urinary disorders	13 (0.03%)
Oral disorder	Gastrointestinal disorders	13 (0.03%)
Panic reaction	Psychiatric disorders	13 (0.03%)
Paranasal sinus discomfort	Respiratory, thoracic and mediastinal disorders	13 (0.03%)
Pulmonary congestion	Respiratory, thoracic and mediastinal disorders	13 (0.03%)
Pulse abnormal	Investigations	13 (0.03%)
Retinal vein thrombosis	Eye disorders	13 (0.03%)
Trismus	Musculoskeletal and connective tissue disorders	13 (0.03%)
Upper respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	13 (0.03%)
Anal incontinence	Gastrointestinal disorders	12 (0.03%)
Anaphylactoid reaction	Immune system disorders	12 (0.03%)
Anger	Psychiatric disorders	12 (0.03%)
Apnoea	Respiratory, thoracic and mediastinal disorders	12 (0.03%)
Arteriosclerosis	Vascular disorders	12 (0.03%)
Blindness transient	Eye disorders	12 (0.03%)
Blood blister	Skin and subcutaneous tissue disorders	12 (0.03%)
Blood cholesterol increased	Investigations	12 (0.03%)
Bowel movement irregularity	Gastrointestinal disorders	12 (0.03%)
Bradykinesia	Nervous system disorders	12 (0.03%)
Breath sounds abnormal	Investigations	12 (0.03%)
Cataract	Eye disorders	12 (0.03%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Cerebral disorder	Nervous system disorders	12 (0.03%)
Electrocardiogram abnormal	Investigations	12 (0.03%)
Eyelids pruritus	Eye disorders	12 (0.03%)
Frustration tolerance decreased	Psychiatric disorders	12 (0.03%)
Hepatic enzyme increased	Investigations	12 (0.03%)
Hepatic function abnormal	Hepatobiliary disorders	12 (0.03%)
Hunger	General disorders and administration site conditions	12 (0.03%)
Hypokalaemia	Metabolism and nutrition disorders	12 (0.03%)
Incoherent	Nervous system disorders	12 (0.03%)
Incontinence	Renal and urinary disorders	12 (0.03%)
Injury	Injury, poisoning and procedural complications	12 (0.03%)
Intestinal ischaemia	Gastrointestinal disorders	12 (0.03%)
Leukopenia	Blood and lymphatic system disorders	12 (0.03%)
Liquid product physical issue	Product issues	12 (0.03%)
Micturition urgency	Renal and urinary disorders	12 (0.03%)
Mood swings	Psychiatric disorders	12 (0.03%)
Nasal oedema	Respiratory, thoracic and mediastinal disorders	12 (0.03%)
Platelet count increased	Investigations	12 (0.03%)
Post viral fatigue syndrome	Infections and infestations	12 (0.03%)
Product supply issue	Product issues	12 (0.03%)
Pyelonephritis	Infections and infestations	12 (0.03%)
Respiratory symptom	Respiratory, thoracic and mediastinal disorders	12 (0.03%)
Secretion discharge	General disorders and administration site conditions	12 (0.03%)
Septic shock	Infections and infestations	12 (0.03%)
Skin mass	Skin and subcutaneous tissue disorders	12 (0.03%)
Subdural haematoma	Injury, poisoning and procedural complications	12 (0.03%)
Synovial cyst	Musculoskeletal and connective tissue disorders	12 (0.03%)
Testicular pain	Reproductive system and breast disorders	12 (0.03%)
Tonsillar hypertrophy	Respiratory, thoracic and mediastinal disorders	12 (0.03%)
Transaminases increased	Investigations	12 (0.03%)
Vaccination site hyperaesthesia	General disorders and administration site conditions	12 (0.03%)
Ventricular fibrillation	Cardiac disorders	12 (0.03%)
Wound	Injury, poisoning and procedural complications	12 (0.03%)
Abscess	Infections and infestations	11 (0.02%)
Accidental exposure to product	Injury, poisoning and procedural complications	11 (0.02%)
Asphyxia	Respiratory, thoracic and mediastinal disorders	11 (0.02%)
Aspiration	Respiratory, thoracic and mediastinal disorders	11 (0.02%)
Cardiopulmonary failure	Cardiac disorders	11 (0.02%)
Cheilitis	Gastrointestinal disorders	11 (0.02%)
Choking	Respiratory, thoracic and mediastinal disorders	11 (0.02%)
Costochondritis	Musculoskeletal and connective tissue disorders	11 (0.02%)
Ear disorder	Ear and labyrinth disorders	11 (0.02%)
Erectile dysfunction	Reproductive system and breast disorders	11 (0.02%)
Facial discomfort	General disorders and administration site conditions	11 (0.02%)
Genital herpes	Infections and infestations	11 (0.02%)
Glomerular filtration rate decreased	Investigations	11 (0.02%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Hemianaesthesia	Nervous system disorders	11 (0.02%)
Hyperaesthesia teeth	Gastrointestinal disorders	11 (0.02%)
Jugular vein thrombosis	Vascular disorders	11 (0.02%)
Leukocytosis	Blood and lymphatic system disorders	11 (0.02%)
Ligament sprain	Injury, poisoning and procedural complications	11 (0.02%)
Myelitis transverse	Nervous system disorders	11 (0.02%)
Myoclonus	Nervous system disorders	11 (0.02%)
Nasal dryness	Respiratory, thoracic and mediastinal disorders	11 (0.02%)
Nephrotic syndrome	Renal and urinary disorders	11 (0.02%)
Neutrophil count decreased	Investigations	11 (0.02%)
Neutrophil count increased	Investigations	11 (0.02%)
Pemphigoid	Skin and subcutaneous tissue disorders	11 (0.02%)
Peripheral artery thrombosis	Vascular disorders	11 (0.02%)
Physical deconditioning	General disorders and administration site conditions	11 (0.02%)
Piloerection	Skin and subcutaneous tissue disorders	11 (0.02%)
Pleurisy	Respiratory, thoracic and mediastinal disorders	11 (0.02%)
Psychomotor hyperactivity	Nervous system disorders	11 (0.02%)
Rhabdomyolysis	Musculoskeletal and connective tissue disorders	11 (0.02%)
Scar	Injury, poisoning and procedural complications	11 (0.02%)
Skin tightness	Skin and subcutaneous tissue disorders	11 (0.02%)
Transient global amnesia	Nervous system disorders	11 (0.02%)
Activated partial thromboplastin time prolonged	Investigations	10 (0.02%)
Atrial flutter	Cardiac disorders	10 (0.02%)
Atrioventricular block	Cardiac disorders	10 (0.02%)
Blood lactate dehydrogenase increased	Investigations	10 (0.02%)
Body temperature	Investigations	10 (0.02%)
Bruxism	Psychiatric disorders	10 (0.02%)
Coronary artery disease	Cardiac disorders	10 (0.02%)
Crohn's disease	Gastrointestinal disorders	10 (0.02%)
Disease progression	General disorders and administration site conditions	10 (0.02%)
Ear congestion	Ear and labyrinth disorders	10 (0.02%)
Faeces discoloured	Gastrointestinal disorders	10 (0.02%)
Feeling jittery	General disorders and administration site conditions	10 (0.02%)
Gastric disorder	Gastrointestinal disorders	10 (0.02%)
Gingivitis	Infections and infestations	10 (0.02%)
Glossitis	Gastrointestinal disorders	10 (0.02%)
Goitre	Endocrine disorders	10 (0.02%)
Hepatic cytolysis	Hepatobiliary disorders	10 (0.02%)
Hepatic pain	Hepatobiliary disorders	10 (0.02%)
Hypoaesthesia eye	Eye disorders	10 (0.02%)
Hypothyroidism	Endocrine disorders	10 (0.02%)
Immobile	Social circumstances	10 (0.02%)
Impaired quality of life	Social circumstances	10 (0.02%)
Initial insomnia	Psychiatric disorders	10 (0.02%)
Injection site pruritus	General disorders and administration site conditions	10 (0.02%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Injection site warmth	General disorders and administration site conditions	10 (0.02%)
Kidney infection	Infections and infestations	10 (0.02%)
Lip dry	Gastrointestinal disorders	10 (0.02%)
Maternal exposure timing unspecified	Injury, poisoning and procedural complications	10 (0.02%)
Muscle discomfort	Musculoskeletal and connective tissue disorders	10 (0.02%)
Muscle swelling	Musculoskeletal and connective tissue disorders	10 (0.02%)
Oligomenorrhoea	Reproductive system and breast disorders	10 (0.02%)
Orthostatic hypotension	Vascular disorders	10 (0.02%)
Paresis	Nervous system disorders	10 (0.02%)
Pelvic venous thrombosis	Vascular disorders	10 (0.02%)
Peripheral venous disease	Vascular disorders	10 (0.02%)
Pharyngeal erythema	Respiratory, thoracic and mediastinal disorders	10 (0.02%)
Phlebitis superficial	Vascular disorders	10 (0.02%)
Polyarthritis	Musculoskeletal and connective tissue disorders	10 (0.02%)
Postural orthostatic tachycardia syndrome	Cardiac disorders	10 (0.02%)
Red blood cell sedimentation rate increased	Investigations	10 (0.02%)
Rhinalgia	Respiratory, thoracic and mediastinal disorders	10 (0.02%)
SARS-CoV-2 antibody test positive	Investigations	10 (0.02%)
Systemic lupus erythematosus	Musculoskeletal and connective tissue disorders	10 (0.02%)
Tongue discolouration	Gastrointestinal disorders	10 (0.02%)
Type I hypersensitivity	Immune system disorders	10 (0.02%)
Vaccination site irritation	General disorders and administration site conditions	10 (0.02%)
Vascular purpura	Skin and subcutaneous tissue disorders	10 (0.02%)
Vomiting projectile	Gastrointestinal disorders	10 (0.02%)
Abnormal sensation in eye	Eye disorders	9 (0.02%)
Acute pulmonary oedema	Respiratory, thoracic and mediastinal disorders	9 (0.02%)
Aggression	Psychiatric disorders	9 (0.02%)
Arthritis reactive	Musculoskeletal and connective tissue disorders	9 (0.02%)
Atrioventricular block complete	Cardiac disorders	9 (0.02%)
Bacterial infection	Infections and infestations	9 (0.02%)
Blood pressure diastolic decreased	Investigations	9 (0.02%)
Cerebrovascular disorder	Nervous system disorders	9 (0.02%)
Cholestasis	Hepatobiliary disorders	9 (0.02%)
Deafness bilateral	Ear and labyrinth disorders	9 (0.02%)
Diverticulitis	Infections and infestations	9 (0.02%)
Dysphemia	Psychiatric disorders	9 (0.02%)
Endometriosis	Reproductive system and breast disorders	9 (0.02%)
Fine motor skill dysfunction	Nervous system disorders	9 (0.02%)
Frequent bowel movements	Gastrointestinal disorders	9 (0.02%)
Gastroenteritis	Infections and infestations	9 (0.02%)
Henoch-Schonlein purpura	Skin and subcutaneous tissue disorders	9 (0.02%)
Hyperkalaemia	Metabolism and nutrition disorders	9 (0.02%)
Hypogeusia	Nervous system disorders	9 (0.02%)
Hyposmia	Nervous system disorders	9 (0.02%)
Increased appetite	Metabolism and nutrition disorders	9 (0.02%)
Jaw disorder	Musculoskeletal and connective tissue disorders	9 (0.02%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Joint effusion	Musculoskeletal and connective tissue disorders	9 (0.02%)
Lip pruritus	Gastrointestinal disorders	9 (0.02%)
Neuritis	Nervous system disorders	9 (0.02%)
Performance status decreased	General disorders and administration site conditions	9 (0.02%)
Pharyngitis streptococcal	Infections and infestations	9 (0.02%)
Pityriasis rosea	Skin and subcutaneous tissue disorders	9 (0.02%)
Product quality issue	Product issues	9 (0.02%)
Rales	Respiratory, thoracic and mediastinal disorders	9 (0.02%)
Rib fracture	Injury, poisoning and procedural complications	9 (0.02%)
Supraventricular extrasystoles	Cardiac disorders	9 (0.02%)
Thrombotic stroke	Nervous system disorders	9 (0.02%)
Tongue blistering	Gastrointestinal disorders	9 (0.02%)
Tongue ulceration	Gastrointestinal disorders	9 (0.02%)
Vestibular disorder	Ear and labyrinth disorders	9 (0.02%)
Walking disability	Social circumstances	9 (0.02%)
Aortic arteriosclerosis	Vascular disorders	8 (0.02%)
Arterial thrombosis	Vascular disorders	8 (0.02%)
Back injury	Injury, poisoning and procedural complications	8 (0.02%)
Breast cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8 (0.02%)
Cerebral artery embolism	Nervous system disorders	8 (0.02%)
Cerebral venous thrombosis	Nervous system disorders	8 (0.02%)
Clumsiness	Nervous system disorders	8 (0.02%)
Communication disorder	Psychiatric disorders	8 (0.02%)
Dementia	Nervous system disorders	8 (0.02%)
Dermatitis contact	Skin and subcutaneous tissue disorders	8 (0.02%)
Diabetes mellitus inadequate control	Metabolism and nutrition disorders	8 (0.02%)
Epicondylitis	Injury, poisoning and procedural complications	8 (0.02%)
Erythema nodosum	Skin and subcutaneous tissue disorders	8 (0.02%)
Erythema of eyelid	Eye disorders	8 (0.02%)
Exercise tolerance decreased	General disorders and administration site conditions	8 (0.02%)
Facial spasm	Nervous system disorders	8 (0.02%)
Gamma-glutamyltransferase increased	Investigations	8 (0.02%)
Gastrointestinal sounds abnormal	Gastrointestinal disorders	8 (0.02%)
Haemorrhage urinary tract	Renal and urinary disorders	8 (0.02%)
Herpes ophthalmic	Infections and infestations	8 (0.02%)
Hiatus hernia	Gastrointestinal disorders	8 (0.02%)
Immunodeficiency	Immune system disorders	8 (0.02%)
Incomplete course of vaccination	Injury, poisoning and procedural complications	8 (0.02%)
Intracardiac thrombus	Cardiac disorders	8 (0.02%)
Ischaemic cerebral infarction	Nervous system disorders	8 (0.02%)
Lung infiltration	Respiratory, thoracic and mediastinal disorders	8 (0.02%)
Melaena	Gastrointestinal disorders	8 (0.02%)
Metamorphopsia	Eye disorders	8 (0.02%)
Mitral valve incompetence	Cardiac disorders	8 (0.02%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Neoplasm malignant	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8 (0.02%)
Nerve compression	Nervous system disorders	8 (0.02%)
Occipital neuralgia	Nervous system disorders	8 (0.02%)
Ocular vascular disorder	Eye disorders	8 (0.02%)
Ophthalmic migraine	Nervous system disorders	8 (0.02%)
Ophthalmic vein thrombosis	Eye disorders	8 (0.02%)
Parotitis	Infections and infestations	8 (0.02%)
Pharyngeal hypoaesthesia	Respiratory, thoracic and mediastinal disorders	8 (0.02%)
Pharyngeal inflammation	Respiratory, thoracic and mediastinal disorders	8 (0.02%)
Pneumothorax	Respiratory, thoracic and mediastinal disorders	8 (0.02%)
Poor peripheral circulation	Vascular disorders	8 (0.02%)
Product leakage	Product issues	8 (0.02%)
Red blood cell count decreased	Investigations	8 (0.02%)
Renal colic	Renal and urinary disorders	8 (0.02%)
Retinal detachment	Eye disorders	8 (0.02%)
Salivary gland pain	Gastrointestinal disorders	8 (0.02%)
Skin haemorrhage	Skin and subcutaneous tissue disorders	8 (0.02%)
Skin ulcer	Skin and subcutaneous tissue disorders	8 (0.02%)
Strabismus	Eye disorders	8 (0.02%)
Subclavian vein thrombosis	Vascular disorders	8 (0.02%)
Sudden cardiac death	General disorders and administration site conditions	8 (0.02%)
Tendon pain	Musculoskeletal and connective tissue disorders	8 (0.02%)
Thyroiditis	Endocrine disorders	8 (0.02%)
Tic	Psychiatric disorders	8 (0.02%)
Tongue biting	Nervous system disorders	8 (0.02%)
Ulcer	General disorders and administration site conditions	8 (0.02%)
Uterine haemorrhage	Reproductive system and breast disorders	8 (0.02%)
Varicella	Infections and infestations	8 (0.02%)
Vasodilatation	Vascular disorders	8 (0.02%)
Weight bearing difficulty	Musculoskeletal and connective tissue disorders	8 (0.02%)
Abdominal tenderness	Gastrointestinal disorders	7 (0.01%)
Abnormal loss of weight	Metabolism and nutrition disorders	7 (0.01%)
Abortion missed	Pregnancy, puerperium and perinatal conditions	7 (0.01%)
Ankylosing spondylitis	Musculoskeletal and connective tissue disorders	7 (0.01%)
Areflexia	Nervous system disorders	7 (0.01%)
Arterial occlusive disease	Vascular disorders	7 (0.01%)
Atelectasis	Respiratory, thoracic and mediastinal disorders	7 (0.01%)
Autoimmune haemolytic anaemia	Blood and lymphatic system disorders	7 (0.01%)
Biliary colic	Hepatobiliary disorders	7 (0.01%)
Bladder pain	Renal and urinary disorders	7 (0.01%)
Blood glucose abnormal	Investigations	7 (0.01%)
Blood iron decreased	Investigations	7 (0.01%)
Blood potassium decreased	Investigations	7 (0.01%)
Blood pressure diastolic increased	Investigations	7 (0.01%)
Blood pressure systolic decreased	Investigations	7 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Blood test abnormal	Investigations	7 (0.01%)
Brain injury	Nervous system disorders	7 (0.01%)
Breast mass	Reproductive system and breast disorders	7 (0.01%)
Cardiac tamponade	Cardiac disorders	7 (0.01%)
Carpal tunnel syndrome	Nervous system disorders	7 (0.01%)
Catarrh	Respiratory, thoracic and mediastinal disorders	7 (0.01%)
Cervical radiculopathy	Nervous system disorders	7 (0.01%)
Chest injury	Injury, poisoning and procedural complications	7 (0.01%)
Cholelithiasis	Hepatobiliary disorders	7 (0.01%)
Chronic kidney disease	Renal and urinary disorders	7 (0.01%)
Circumoral swelling	Skin and subcutaneous tissue disorders	7 (0.01%)
Concussion	Injury, poisoning and procedural complications	7 (0.01%)
Coronary artery thrombosis	Cardiac disorders	7 (0.01%)
Coronavirus infection	Infections and infestations	7 (0.01%)
Cranio-cerebral injury	Injury, poisoning and procedural complications	7 (0.01%)
Defaecation urgency	Gastrointestinal disorders	7 (0.01%)
Diplegia	Nervous system disorders	7 (0.01%)
Electrocardiogram ST segment elevation	Investigations	7 (0.01%)
Enlarged uvula	Gastrointestinal disorders	7 (0.01%)
Enuresis	Psychiatric disorders	7 (0.01%)
Exposure via skin contact	Injury, poisoning and procedural complications	7 (0.01%)
Eye infection	Infections and infestations	7 (0.01%)
Eyelid pain	Eye disorders	7 (0.01%)
Facial neuralgia	Nervous system disorders	7 (0.01%)
Feeling of despair	Psychiatric disorders	7 (0.01%)
Foetal death	Pregnancy, puerperium and perinatal conditions	7 (0.01%)
Food allergy	Immune system disorders	7 (0.01%)
Generalised oedema	General disorders and administration site conditions	7 (0.01%)
Gingival swelling	Gastrointestinal disorders	7 (0.01%)
Haematocrit decreased	Investigations	7 (0.01%)
Haemodynamic instability	Vascular disorders	7 (0.01%)
Haemolysis	Blood and lymphatic system disorders	7 (0.01%)
Haemorrhoids	Gastrointestinal disorders	7 (0.01%)
Hepatitis	Hepatobiliary disorders	7 (0.01%)
Hiccups	Respiratory, thoracic and mediastinal disorders	7 (0.01%)
Hormone level abnormal	Investigations	7 (0.01%)
Illusion	Psychiatric disorders	7 (0.01%)
Impaired gastric emptying	Gastrointestinal disorders	7 (0.01%)
Injection site mass	General disorders and administration site conditions	7 (0.01%)
Injection site rash	General disorders and administration site conditions	7 (0.01%)
Laryngitis	Infections and infestations	7 (0.01%)
Limb immobilisation	Surgical and medical procedures	7 (0.01%)
Liver disorder	Hepatobiliary disorders	7 (0.01%)
Low density lipoprotein increased	Investigations	7 (0.01%)
Lymphocyte count increased	Investigations	7 (0.01%)
Mastication disorder	Musculoskeletal and connective tissue disorders	7 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Mechanical urticaria	Skin and subcutaneous tissue disorders	7 (0.01%)
Metabolic acidosis	Metabolism and nutrition disorders	7 (0.01%)
Motion sickness	Ear and labyrinth disorders	7 (0.01%)
Mouth haemorrhage	Gastrointestinal disorders	7 (0.01%)
Muscle disorder	Musculoskeletal and connective tissue disorders	7 (0.01%)
Muscle spasticity	Nervous system disorders	7 (0.01%)
Neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (0.01%)
Neoplasm progression	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (0.01%)
Neuralgic amyotrophy	Nervous system disorders	7 (0.01%)
Oculomucocutaneous syndrome	Skin and subcutaneous tissue disorders	7 (0.01%)
Oedema mouth	Gastrointestinal disorders	7 (0.01%)
Oedema mucosal	General disorders and administration site conditions	7 (0.01%)
Oral candidiasis	Infections and infestations	7 (0.01%)
Palatal oedema	Gastrointestinal disorders	7 (0.01%)
Pancytopenia	Blood and lymphatic system disorders	7 (0.01%)
Papilloedema	Eye disorders	7 (0.01%)
Periorbital oedema	Eye disorders	7 (0.01%)
Pharyngeal disorder	Respiratory, thoracic and mediastinal disorders	7 (0.01%)
Pigmentation disorder	Skin and subcutaneous tissue disorders	7 (0.01%)
Pleuritic pain	Respiratory, thoracic and mediastinal disorders	7 (0.01%)
Polymerase chain reaction positive	Investigations	7 (0.01%)
Polyneuropathy	Nervous system disorders	7 (0.01%)
Premenstrual syndrome	Reproductive system and breast disorders	7 (0.01%)
Pustule	Infections and infestations	7 (0.01%)
Quality of life decreased	Investigations	7 (0.01%)
Rash pustular	Infections and infestations	7 (0.01%)
Respiratory alkalosis	Respiratory, thoracic and mediastinal disorders	7 (0.01%)
Respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	7 (0.01%)
Respiratory tract infection	Infections and infestations	7 (0.01%)
Retinal haemorrhage	Eye disorders	7 (0.01%)
Rhinitis allergic	Respiratory, thoracic and mediastinal disorders	7 (0.01%)
Sinus bradycardia	Cardiac disorders	7 (0.01%)
Skin laceration	Injury, poisoning and procedural complications	7 (0.01%)
Skin odour abnormal	Skin and subcutaneous tissue disorders	7 (0.01%)
Sleep disorder due to a general medical condition	Psychiatric disorders	7 (0.01%)
Sunburn	Injury, poisoning and procedural complications	7 (0.01%)
Syringe issue	Product issues	7 (0.01%)
Tendon rupture	Injury, poisoning and procedural complications	7 (0.01%)
Thermal burn	Injury, poisoning and procedural complications	7 (0.01%)
Thrombocytopenic purpura	Blood and lymphatic system disorders	7 (0.01%)
Tongue dry	Gastrointestinal disorders	7 (0.01%)
Tongue erythema	Gastrointestinal disorders	7 (0.01%)
Toxic skin eruption	Skin and subcutaneous tissue disorders	7 (0.01%)
Urine abnormality	Renal and urinary disorders	7 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Urine output decreased	Investigations	7 (0.01%)
Uterine leiomyoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (0.01%)
Uveitis	Eye disorders	7 (0.01%)
Acute disseminated encephalomyelitis	Nervous system disorders	6 (0.01%)
Allodynia	Nervous system disorders	6 (0.01%)
Amaurosis fugax	Eye disorders	6 (0.01%)
Anaesthesia	Nervous system disorders	6 (0.01%)
Anaesthesia oral	Gastrointestinal disorders	6 (0.01%)
Anuria	Renal and urinary disorders	6 (0.01%)
Aortic dissection	Vascular disorders	6 (0.01%)
Atypical pneumonia	Infections and infestations	6 (0.01%)
Aura	Nervous system disorders	6 (0.01%)
Autonomic nervous system imbalance	Nervous system disorders	6 (0.01%)
Bladder disorder	Renal and urinary disorders	6 (0.01%)
Blood disorder	Blood and lymphatic system disorders	6 (0.01%)
Blood lactic acid increased	Investigations	6 (0.01%)
Blood pressure immeasurable	Investigations	6 (0.01%)
Bone swelling	Musculoskeletal and connective tissue disorders	6 (0.01%)
Brain stem infarction	Nervous system disorders	6 (0.01%)
Breast discomfort	Reproductive system and breast disorders	6 (0.01%)
Bronchiectasis	Respiratory, thoracic and mediastinal disorders	6 (0.01%)
Bundle branch block right	Cardiac disorders	6 (0.01%)
Cardiac fibrillation	Cardiac disorders	6 (0.01%)
Cardiac murmur	Investigations	6 (0.01%)
Cardiomyopathy	Cardiac disorders	6 (0.01%)
Cerebral artery occlusion	Nervous system disorders	6 (0.01%)
Cerebral haematoma	Nervous system disorders	6 (0.01%)
Concomitant disease progression	General disorders and administration site conditions	6 (0.01%)
Coronary artery stenosis	Cardiac disorders	6 (0.01%)
Cranial nerve paralysis	Nervous system disorders	6 (0.01%)
Delusion	Psychiatric disorders	6 (0.01%)
Disseminated varicella zoster virus infection	Infections and infestations	6 (0.01%)
Embolism venous	Vascular disorders	6 (0.01%)
Enteritis	Gastrointestinal disorders	6 (0.01%)
Eosinophilia	Blood and lymphatic system disorders	6 (0.01%)
Eyelid disorder	Eye disorders	6 (0.01%)
Face injury	Injury, poisoning and procedural complications	6 (0.01%)
Foreign body sensation in eyes	Eye disorders	6 (0.01%)
Haemorrhage intracranial	Nervous system disorders	6 (0.01%)
Haemorrhagic transformation stroke	Nervous system disorders	6 (0.01%)
Heart rate	Investigations	6 (0.01%)
Hepatitis acute	Hepatobiliary disorders	6 (0.01%)
Herpes zoster cutaneous disseminated	Infections and infestations	6 (0.01%)
Hordeolum	Infections and infestations	6 (0.01%)
Illrd nerve paralysis	Nervous system disorders	6 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Infarction	Vascular disorders	6 (0.01%)
Infectious mononucleosis	Infections and infestations	6 (0.01%)
Injection site hypoaesthesia	General disorders and administration site conditions	6 (0.01%)
Intestinal obstruction	Gastrointestinal disorders	6 (0.01%)
Iridocyclitis	Eye disorders	6 (0.01%)
Joint noise	Musculoskeletal and connective tissue disorders	6 (0.01%)
Joint warmth	Musculoskeletal and connective tissue disorders	6 (0.01%)
Language disorder	Nervous system disorders	6 (0.01%)
Localised infection	Infections and infestations	6 (0.01%)
Loss of control of legs	General disorders and administration site conditions	6 (0.01%)
Lymph node abscess	Infections and infestations	6 (0.01%)
Macule	Skin and subcutaneous tissue disorders	6 (0.01%)
Malnutrition	Metabolism and nutrition disorders	6 (0.01%)
Meniere's disease	Ear and labyrinth disorders	6 (0.01%)
Meningitis	Infections and infestations	6 (0.01%)
Meningitis aseptic	Infections and infestations	6 (0.01%)
Menopause	Social circumstances	6 (0.01%)
Myopathy	Musculoskeletal and connective tissue disorders	6 (0.01%)
Nasal pruritus	Respiratory, thoracic and mediastinal disorders	6 (0.01%)
Nocturnal dyspnoea	Respiratory, thoracic and mediastinal disorders	6 (0.01%)
Noninfective gingivitis	Gastrointestinal disorders	6 (0.01%)
Oropharyngeal blistering	Respiratory, thoracic and mediastinal disorders	6 (0.01%)
Orthopnoea	Respiratory, thoracic and mediastinal disorders	6 (0.01%)
Otitis media	Infections and infestations	6 (0.01%)
Palmar erythema	Skin and subcutaneous tissue disorders	6 (0.01%)
Paranoia	Psychiatric disorders	6 (0.01%)
Parkinson's disease	Nervous system disorders	6 (0.01%)
Partial seizures	Nervous system disorders	6 (0.01%)
Pleuropericarditis	Cardiac disorders	6 (0.01%)
Polydipsia	Metabolism and nutrition disorders	6 (0.01%)
Potentiating drug interaction	General disorders and administration site conditions	6 (0.01%)
Product physical issue	Product issues	6 (0.01%)
Pulmonary artery thrombosis	Respiratory, thoracic and mediastinal disorders	6 (0.01%)
Radiculitis brachial	Nervous system disorders	6 (0.01%)
Reaction to excipient	Immune system disorders	6 (0.01%)
Respiratory tract oedema	Respiratory, thoracic and mediastinal disorders	6 (0.01%)
Rosacea	Skin and subcutaneous tissue disorders	6 (0.01%)
SARS-CoV-2 test negative	Investigations	6 (0.01%)
Seizure like phenomena	Nervous system disorders	6 (0.01%)
Skin erosion	Skin and subcutaneous tissue disorders	6 (0.01%)
Sleep disorder due to general medical condition, insomnia type	Psychiatric disorders	6 (0.01%)
Stevens-Johnson syndrome	Skin and subcutaneous tissue disorders	6 (0.01%)
Stress cardiomyopathy	Cardiac disorders	6 (0.01%)
Sweating fever	Infections and infestations	6 (0.01%)
Systemic inflammatory response syndrome	General disorders and administration site conditions	6 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Tendon disorder	Musculoskeletal and connective tissue disorders	6 (0.01%)
Tetany	Metabolism and nutrition disorders	6 (0.01%)
Thyroid disorder	Endocrine disorders	6 (0.01%)
Tooth abscess	Infections and infestations	6 (0.01%)
Upper-airway cough syndrome	Respiratory, thoracic and mediastinal disorders	6 (0.01%)
Vaccination error	Injury, poisoning and procedural complications	6 (0.01%)
Vaccination site joint swelling	General disorders and administration site conditions	6 (0.01%)
Varicella zoster virus infection	Infections and infestations	6 (0.01%)
Ventricular arrhythmia	Cardiac disorders	6 (0.01%)
Vulvovaginal pain	Reproductive system and breast disorders	6 (0.01%)
Yawning	Respiratory, thoracic and mediastinal disorders	6 (0.01%)
Alopecia areata	Skin and subcutaneous tissue disorders	5 (0.01%)
Aneurysm	Vascular disorders	5 (0.01%)
Angiopathy	Vascular disorders	5 (0.01%)
Aortic aneurysm	Vascular disorders	5 (0.01%)
Atrioventricular block second degree	Cardiac disorders	5 (0.01%)
Autoimmune thyroiditis	Endocrine disorders	5 (0.01%)
Basedow's disease	Endocrine disorders	5 (0.01%)
Blepharitis	Eye disorders	5 (0.01%)
Blood bilirubin increased	Investigations	5 (0.01%)
Blood sodium decreased	Investigations	5 (0.01%)
Body height decreased	Investigations	5 (0.01%)
Bone disorder	Musculoskeletal and connective tissue disorders	5 (0.01%)
Breast inflammation	Reproductive system and breast disorders	5 (0.01%)
Carotid artery occlusion	Nervous system disorders	5 (0.01%)
Carotid artery thrombosis	Nervous system disorders	5 (0.01%)
Cerebellar stroke	Nervous system disorders	5 (0.01%)
Cerebral artery thrombosis	Nervous system disorders	5 (0.01%)
Cervicobrachial syndrome	Nervous system disorders	5 (0.01%)
Circumoral oedema	Skin and subcutaneous tissue disorders	5 (0.01%)
Clonic convulsion	Nervous system disorders	5 (0.01%)
Coccydynia	Musculoskeletal and connective tissue disorders	5 (0.01%)
Colitis ischaemic	Gastrointestinal disorders	5 (0.01%)
Coronary artery occlusion	Cardiac disorders	5 (0.01%)
Dermatitis atopic	Skin and subcutaneous tissue disorders	5 (0.01%)
Diaphragmalgia	Respiratory, thoracic and mediastinal disorders	5 (0.01%)
Dysgraphia	Nervous system disorders	5 (0.01%)
Ear haemorrhage	Ear and labyrinth disorders	5 (0.01%)
Emphysema	Respiratory, thoracic and mediastinal disorders	5 (0.01%)
Enthesopathy	Musculoskeletal and connective tissue disorders	5 (0.01%)
Exfoliative rash	Skin and subcutaneous tissue disorders	5 (0.01%)
Extra dose administered	Injury, poisoning and procedural complications	5 (0.01%)
Eyelid rash	Eye disorders	5 (0.01%)
Facial asymmetry	Musculoskeletal and connective tissue disorders	5 (0.01%)
Fluid overload	Metabolism and nutrition disorders	5 (0.01%)
Foetal growth restriction	Pregnancy, puerperium and perinatal conditions	5 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Furuncle	Infections and infestations	5 (0.01%)
Gastric ulcer	Gastrointestinal disorders	5 (0.01%)
Gaze palsy	Eye disorders	5 (0.01%)
Genital haemorrhage	Reproductive system and breast disorders	5 (0.01%)
Giant cell arteritis	Vascular disorders	5 (0.01%)
Glaucoma	Eye disorders	5 (0.01%)
Glycosylated haemoglobin increased	Investigations	5 (0.01%)
Haemarthrosis	Musculoskeletal and connective tissue disorders	5 (0.01%)
Haemorrhagic diathesis	Blood and lymphatic system disorders	5 (0.01%)
Hallucination, auditory	Psychiatric disorders	5 (0.01%)
Hepatic steatosis	Hepatobiliary disorders	5 (0.01%)
Hepatomegaly	Hepatobiliary disorders	5 (0.01%)
Hypertensive emergency	Vascular disorders	5 (0.01%)
Hypertonia	Nervous system disorders	5 (0.01%)
Immunisation reaction	Immune system disorders	5 (0.01%)
Inflammatory pain	General disorders and administration site conditions	5 (0.01%)
Intermittent claudication	Vascular disorders	5 (0.01%)
Intervertebral disc protrusion	Musculoskeletal and connective tissue disorders	5 (0.01%)
Intracranial pressure increased	Nervous system disorders	5 (0.01%)
Intraocular pressure increased	Investigations	5 (0.01%)
Iron deficiency	Metabolism and nutrition disorders	5 (0.01%)
Iron deficiency anaemia	Blood and lymphatic system disorders	5 (0.01%)
Irritability postvaccinal	General disorders and administration site conditions	5 (0.01%)
Lack of spontaneous speech	Psychiatric disorders	5 (0.01%)
Lacunar infarction	Nervous system disorders	5 (0.01%)
Laryngospasm	Respiratory, thoracic and mediastinal disorders	5 (0.01%)
Lip blister	Gastrointestinal disorders	5 (0.01%)
Lip disorder	Gastrointestinal disorders	5 (0.01%)
Lip exfoliation	Gastrointestinal disorders	5 (0.01%)
Lip injury	Injury, poisoning and procedural complications	5 (0.01%)
Lung opacity	Respiratory, thoracic and mediastinal disorders	5 (0.01%)
Lyme disease	Infections and infestations	5 (0.01%)
Lymphangitis	Infections and infestations	5 (0.01%)
Lymph node palpable	Investigations	5 (0.01%)
Monocytosis	Blood and lymphatic system disorders	5 (0.01%)
Muscle strength abnormal	Investigations	5 (0.01%)
Myasthenia gravis	Nervous system disorders	5 (0.01%)
Myelitis	Infections and infestations	5 (0.01%)
Myocardial necrosis marker increased	Investigations	5 (0.01%)
N-terminal prohormone brain natriuretic peptide increased	Investigations	5 (0.01%)
Oral mucosal eruption	Gastrointestinal disorders	5 (0.01%)
Organising pneumonia	Respiratory, thoracic and mediastinal disorders	5 (0.01%)
Osteoarthropathy	Musculoskeletal and connective tissue disorders	5 (0.01%)
Oxygen saturation abnormal	Investigations	5 (0.01%)
Palatal swelling	Gastrointestinal disorders	5 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Parotid gland enlargement	Gastrointestinal disorders	5 (0.01%)
Peritonitis	Infections and infestations	5 (0.01%)
Petit mal epilepsy	Nervous system disorders	5 (0.01%)
Pneumonia bacterial	Infections and infestations	5 (0.01%)
Polycystic ovaries	Reproductive system and breast disorders	5 (0.01%)
Posture abnormal	Musculoskeletal and connective tissue disorders	5 (0.01%)
Premature baby	Pregnancy, puerperium and perinatal conditions	5 (0.01%)
Procalcitonin increased	Investigations	5 (0.01%)
Proteinuria	Renal and urinary disorders	5 (0.01%)
Pulmonary arterial hypertension	Respiratory, thoracic and mediastinal disorders	5 (0.01%)
Pulmonary hypertension	Respiratory, thoracic and mediastinal disorders	5 (0.01%)
Respiratory acidosis	Respiratory, thoracic and mediastinal disorders	5 (0.01%)
Retinal artery thrombosis	Eye disorders	5 (0.01%)
Sarcoidosis	Immune system disorders	5 (0.01%)
SARS-CoV-2 antibody test negative	Investigations	5 (0.01%)
Serum ferritin increased	Investigations	5 (0.01%)
Skin discomfort	Skin and subcutaneous tissue disorders	5 (0.01%)
Sleep apnoea syndrome	Respiratory, thoracic and mediastinal disorders	5 (0.01%)
Tearfulness	Psychiatric disorders	5 (0.01%)
Thrombotic thrombocytopenic purpura	Blood and lymphatic system disorders	5 (0.01%)
Thyroiditis acute	Endocrine disorders	5 (0.01%)
Thyroid mass	Endocrine disorders	5 (0.01%)
Tongue coated	Gastrointestinal disorders	5 (0.01%)
Tongue paralysis	Nervous system disorders	5 (0.01%)
Tooth infection	Infections and infestations	5 (0.01%)
Torticollis	Musculoskeletal and connective tissue disorders	5 (0.01%)
Tunnel vision	Nervous system disorders	5 (0.01%)
Urine odour abnormal	Renal and urinary disorders	5 (0.01%)
Vaccination site joint erythema	General disorders and administration site conditions	5 (0.01%)
Vaccination site papule	General disorders and administration site conditions	5 (0.01%)
Vaccination site vesicles	General disorders and administration site conditions	5 (0.01%)
Varicose vein	Vascular disorders	5 (0.01%)
Vascular injury	Injury, poisoning and procedural complications	5 (0.01%)
Vascular pain	Vascular disorders	5 (0.01%)
Viral rash	Infections and infestations	5 (0.01%)
Vlth nerve paralysis	Nervous system disorders	5 (0.01%)
Walking aid user	Social circumstances	5 (0.01%)
Accident	Injury, poisoning and procedural complications	4 (0.01%)
Accommodation disorder	Eye disorders	4 (0.01%)
Administration site pain	General disorders and administration site conditions	4 (0.01%)
Adverse drug reaction	General disorders and administration site conditions	4 (0.01%)
Affect lability	Psychiatric disorders	4 (0.01%)
Allergic reaction to excipient	Immune system disorders	4 (0.01%)
Aneurysm ruptured	Vascular disorders	4 (0.01%)
Arterial stenosis	Vascular disorders	4 (0.01%)
Arthropod bite	Injury, poisoning and procedural complications	4 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Auditory disorder	Ear and labyrinth disorders	4 (0.01%)
Autoimmune hepatitis	Hepatobiliary disorders	4 (0.01%)
Behaviour disorder	Psychiatric disorders	4 (0.01%)
Bipolar disorder	Psychiatric disorders	4 (0.01%)
Bladder dysfunction	Renal and urinary disorders	4 (0.01%)
Blood creatinine decreased	Investigations	4 (0.01%)
Blood glucose fluctuation	Investigations	4 (0.01%)
Blood sodium increased	Investigations	4 (0.01%)
Blood uric acid increased	Investigations	4 (0.01%)
Blood urine	Investigations	4 (0.01%)
Brain herniation	Injury, poisoning and procedural complications	4 (0.01%)
Breath odour	Gastrointestinal disorders	4 (0.01%)
Candida infection	Infections and infestations	4 (0.01%)
Capillary fragility	Vascular disorders	4 (0.01%)
Cardiac death	General disorders and administration site conditions	4 (0.01%)
Cardiac discomfort	Cardiac disorders	4 (0.01%)
Cardiac dysfunction	Cardiac disorders	4 (0.01%)
Cardiovascular insufficiency	Cardiac disorders	4 (0.01%)
Carotid arteriosclerosis	Nervous system disorders	4 (0.01%)
Central nervous system lesion	Nervous system disorders	4 (0.01%)
Cerebellar haemorrhage	Nervous system disorders	4 (0.01%)
Cerebral small vessel ischaemic disease	Nervous system disorders	4 (0.01%)
Cholecystitis	Hepatobiliary disorders	4 (0.01%)
Chronic lymphocytic leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (0.01%)
Clonus	Nervous system disorders	4 (0.01%)
Clostridium difficile infection	Infections and infestations	4 (0.01%)
Completed suicide	Psychiatric disorders	4 (0.01%)
C-reactive protein abnormal	Investigations	4 (0.01%)
Crepitations	General disorders and administration site conditions	4 (0.01%)
Decreased activity	General disorders and administration site conditions	4 (0.01%)
Decreased immune responsiveness	Immune system disorders	4 (0.01%)
Decreased interest	Psychiatric disorders	4 (0.01%)
Demyelination	Nervous system disorders	4 (0.01%)
Derealisation	Psychiatric disorders	4 (0.01%)
Dermatitis acneiform	Skin and subcutaneous tissue disorders	4 (0.01%)
Disseminated intravascular coagulation	Blood and lymphatic system disorders	4 (0.01%)
Drainage	Surgical and medical procedures	4 (0.01%)
Drooling	Nervous system disorders	4 (0.01%)
Dyshidrotic eczema	Skin and subcutaneous tissue disorders	4 (0.01%)
Encephalopathy	Nervous system disorders	4 (0.01%)
Escherichia urinary tract infection	Infections and infestations	4 (0.01%)
Exophthalmos	Eye disorders	4 (0.01%)
Eye contusion	Injury, poisoning and procedural complications	4 (0.01%)
Eye haematoma	Eye disorders	4 (0.01%)
Eyelid function disorder	Eye disorders	4 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Eyelid irritation	Eye disorders	4 (0.01%)
Faecal calprotectin increased	Investigations	4 (0.01%)
Feeling of relaxation	General disorders and administration site conditions	4 (0.01%)
Foaming at mouth	General disorders and administration site conditions	4 (0.01%)
Folate deficiency	Metabolism and nutrition disorders	4 (0.01%)
Food intolerance	Metabolism and nutrition disorders	4 (0.01%)
Fungal infection	Infections and infestations	4 (0.01%)
Gastroenteritis viral	Infections and infestations	4 (0.01%)
General symptom	General disorders and administration site conditions	4 (0.01%)
Genital pain	Reproductive system and breast disorders	4 (0.01%)
Haematoma muscle	Musculoskeletal and connective tissue disorders	4 (0.01%)
Haemolytic anaemia	Blood and lymphatic system disorders	4 (0.01%)
Halo vision	Eye disorders	4 (0.01%)
Hepatic enzyme abnormal	Investigations	4 (0.01%)
Hernia	General disorders and administration site conditions	4 (0.01%)
Hyperchlorhydria	Gastrointestinal disorders	4 (0.01%)
Hypercoagulation	Blood and lymphatic system disorders	4 (0.01%)
Hyperleukocytosis	Blood and lymphatic system disorders	4 (0.01%)
Hypernatraemia	Metabolism and nutrition disorders	4 (0.01%)
Hypocalcaemia	Metabolism and nutrition disorders	4 (0.01%)
Hypotonic-hyporesponsive episode	Nervous system disorders	4 (0.01%)
Ileus	Gastrointestinal disorders	4 (0.01%)
Ileus paralytic	Gastrointestinal disorders	4 (0.01%)
Immune-mediated adverse reaction	Immune system disorders	4 (0.01%)
Increased tendency to bruise	Blood and lymphatic system disorders	4 (0.01%)
Injection site haematoma	General disorders and administration site conditions	4 (0.01%)
Injection site haemorrhage	General disorders and administration site conditions	4 (0.01%)
Injection site inflammation	General disorders and administration site conditions	4 (0.01%)
Inner ear inflammation	Ear and labyrinth disorders	4 (0.01%)
Intentional product use issue	Injury, poisoning and procedural complications	4 (0.01%)
Intracranial aneurysm	Nervous system disorders	4 (0.01%)
Intraventricular haemorrhage	Nervous system disorders	4 (0.01%)
IVth nerve paralysis	Nervous system disorders	4 (0.01%)
Joint dislocation	Injury, poisoning and procedural complications	4 (0.01%)
Laboratory test abnormal	Investigations	4 (0.01%)
Laryngeal pain	Respiratory, thoracic and mediastinal disorders	4 (0.01%)
Left ventricular failure	Cardiac disorders	4 (0.01%)
Leukocyturia	Renal and urinary disorders	4 (0.01%)
Lip discolouration	Gastrointestinal disorders	4 (0.01%)
Lip erythema	Gastrointestinal disorders	4 (0.01%)
Liver function test increased	Investigations	4 (0.01%)
Lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (0.01%)
Macroglossia	Congenital, familial and genetic disorders	4 (0.01%)
Marasmus	Metabolism and nutrition disorders	4 (0.01%)
Medication error	Injury, poisoning and procedural complications	4 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Meningoencephalitis herpetic	Infections and infestations	4 (0.01%)
Migraine without aura	Nervous system disorders	4 (0.01%)
Mononeuritis	Nervous system disorders	4 (0.01%)
Mouth injury	Injury, poisoning and procedural complications	4 (0.01%)
Mucosal disorder	General disorders and administration site conditions	4 (0.01%)
Mumps	Infections and infestations	4 (0.01%)
Muscle injury	Injury, poisoning and procedural complications	4 (0.01%)
Necrosis	General disorders and administration site conditions	4 (0.01%)
Neutrophil count abnormal	Investigations	4 (0.01%)
Nipple pain	Reproductive system and breast disorders	4 (0.01%)
Noninfective encephalitis	Nervous system disorders	4 (0.01%)
Nuchal rigidity	Musculoskeletal and connective tissue disorders	4 (0.01%)
Occupational exposure to product	Injury, poisoning and procedural complications	4 (0.01%)
Oral blood blister	Gastrointestinal disorders	4 (0.01%)
Oral dysaesthesia	Gastrointestinal disorders	4 (0.01%)
Osteitis	Musculoskeletal and connective tissue disorders	4 (0.01%)
Panic disorder	Psychiatric disorders	4 (0.01%)
Pelvic fracture	Injury, poisoning and procedural complications	4 (0.01%)
Periorbital haematoma	Injury, poisoning and procedural complications	4 (0.01%)
Peripheral circulatory failure	Vascular disorders	4 (0.01%)
Peripheral embolism	Vascular disorders	4 (0.01%)
Post-acute COVID-19 syndrome	Infections and infestations	4 (0.01%)
Proctalgia	Gastrointestinal disorders	4 (0.01%)
Psychomotor skills impaired	Nervous system disorders	4 (0.01%)
Pulmonary fibrosis	Respiratory, thoracic and mediastinal disorders	4 (0.01%)
Pulse absent	Investigations	4 (0.01%)
Pulseless electrical activity	Cardiac disorders	4 (0.01%)
Pupils unequal	Eye disorders	4 (0.01%)
Quadriplegia	Nervous system disorders	4 (0.01%)
Rectal discharge	Gastrointestinal disorders	4 (0.01%)
Reduced facial expression	Nervous system disorders	4 (0.01%)
Reflux gastritis	Gastrointestinal disorders	4 (0.01%)
Renal function test abnormal	Investigations	4 (0.01%)
Renal infarct	Renal and urinary disorders	4 (0.01%)
Respiratory fatigue	Respiratory, thoracic and mediastinal disorders	4 (0.01%)
Rhonchi	Respiratory, thoracic and mediastinal disorders	4 (0.01%)
Right ventricular failure	Cardiac disorders	4 (0.01%)
Scleritis	Eye disorders	4 (0.01%)
Screaming	General disorders and administration site conditions	4 (0.01%)
Sjogren's syndrome	Musculoskeletal and connective tissue disorders	4 (0.01%)
Skin abrasion	Injury, poisoning and procedural complications	4 (0.01%)
Skin hypertrophy	Skin and subcutaneous tissue disorders	4 (0.01%)
Skin infection	Infections and infestations	4 (0.01%)
Skin plaque	Skin and subcutaneous tissue disorders	4 (0.01%)
Skin weeping	Skin and subcutaneous tissue disorders	4 (0.01%)
Sleep deficit	Nervous system disorders	4 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Sleep terror	Psychiatric disorders	4 (0.01%)
Slow speech	Nervous system disorders	4 (0.01%)
Snoring	Respiratory, thoracic and mediastinal disorders	4 (0.01%)
Soft tissue swelling	Musculoskeletal and connective tissue disorders	4 (0.01%)
Speech disorder developmental	Nervous system disorders	4 (0.01%)
Spinal disorder	Musculoskeletal and connective tissue disorders	4 (0.01%)
Spinal fracture	Injury, poisoning and procedural complications	4 (0.01%)
Splenic vein thrombosis	Blood and lymphatic system disorders	4 (0.01%)
Spondylitis	Musculoskeletal and connective tissue disorders	4 (0.01%)
Spontaneous haematoma	Blood and lymphatic system disorders	4 (0.01%)
Sputum increased	Respiratory, thoracic and mediastinal disorders	4 (0.01%)
Superinfection	Infections and infestations	4 (0.01%)
Synovitis	Musculoskeletal and connective tissue disorders	4 (0.01%)
Tenosynovitis	Musculoskeletal and connective tissue disorders	4 (0.01%)
Throat clearing	Respiratory, thoracic and mediastinal disorders	4 (0.01%)
Thunderclap headache	Nervous system disorders	4 (0.01%)
Tonsillitis bacterial	Infections and infestations	4 (0.01%)
Tracheitis	Infections and infestations	4 (0.01%)
Transverse sinus thrombosis	Nervous system disorders	4 (0.01%)
Type IV hypersensitivity reaction	Immune system disorders	4 (0.01%)
Urine analysis abnormal	Investigations	4 (0.01%)
Urosepsis	Infections and infestations	4 (0.01%)
Urticaria chronic	Skin and subcutaneous tissue disorders	4 (0.01%)
Urticaria papular	Skin and subcutaneous tissue disorders	4 (0.01%)
Uterine pain	Reproductive system and breast disorders	4 (0.01%)
Vaccination site coldness	General disorders and administration site conditions	4 (0.01%)
Vaginal discharge	Reproductive system and breast disorders	4 (0.01%)
Vascular graft thrombosis	Injury, poisoning and procedural complications	4 (0.01%)
Vascular headache	Nervous system disorders	4 (0.01%)
Vascular rupture	Vascular disorders	4 (0.01%)
Vertigo labyrinthine	Ear and labyrinth disorders	4 (0.01%)
Vulvovaginal candidiasis	Infections and infestations	4 (0.01%)
Yellow skin	Skin and subcutaneous tissue disorders	4 (0.01%)
Abnormal uterine bleeding	Reproductive system and breast disorders	3 (0.01%)
Abnormal weight gain	Metabolism and nutrition disorders	3 (0.01%)
Acquired haemophilia	Blood and lymphatic system disorders	3 (0.01%)
Adnexa uteri pain	Reproductive system and breast disorders	3 (0.01%)
Adrenocortical insufficiency acute	Endocrine disorders	3 (0.01%)
Adverse event following immunisation	Injury, poisoning and procedural complications	3 (0.01%)
Alcohol interaction	General disorders and administration site conditions	3 (0.01%)
Allergic oedema	Immune system disorders	3 (0.01%)
Allergy to chemicals	Immune system disorders	3 (0.01%)
Anal haemorrhage	Gastrointestinal disorders	3 (0.01%)
Anovulatory cycle	Endocrine disorders	3 (0.01%)
Antinuclear antibody positive	Investigations	3 (0.01%)
Anxiety disorder	Psychiatric disorders	3 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Apnoeic attack	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Application site acne	General disorders and administration site conditions	3 (0.01%)
Apraxia	Nervous system disorders	3 (0.01%)
Arterial disorder	Vascular disorders	3 (0.01%)
Artery dissection	Vascular disorders	3 (0.01%)
Arthritis infective	Infections and infestations	3 (0.01%)
Atrial tachycardia	Cardiac disorders	3 (0.01%)
Autonomic dysreflexia	Injury, poisoning and procedural complications	3 (0.01%)
Bacille Calmette-Guerin scar reactivation	Immune system disorders	3 (0.01%)
Bacteraemia	Infections and infestations	3 (0.01%)
Bacterial test positive	Investigations	3 (0.01%)
Bacteriuria	Infections and infestations	3 (0.01%)
Basilar artery thrombosis	Nervous system disorders	3 (0.01%)
Benign prostatic hyperplasia	Reproductive system and breast disorders	3 (0.01%)
Beta haemolytic streptococcal infection	Infections and infestations	3 (0.01%)
Bicytopenia	Blood and lymphatic system disorders	3 (0.01%)
Blood alcohol increased	Investigations	3 (0.01%)
Blood alkaline phosphatase increased	Investigations	3 (0.01%)
Blood calcium decreased	Investigations	3 (0.01%)
Blood immunoglobulin G increased	Investigations	3 (0.01%)
Blood thyroid stimulating hormone increased	Investigations	3 (0.01%)
Blue toe syndrome	Vascular disorders	3 (0.01%)
Bone marrow disorder	Blood and lymphatic system disorders	3 (0.01%)
Brain natriuretic peptide increased	Investigations	3 (0.01%)
Brain stem stroke	Nervous system disorders	3 (0.01%)
Breast abscess	Infections and infestations	3 (0.01%)
Breast disorder	Reproductive system and breast disorders	3 (0.01%)
Breast haematoma	Reproductive system and breast disorders	3 (0.01%)
Bronchial disorder	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Cachexia	Metabolism and nutrition disorders	3 (0.01%)
Cardiac amyloidosis	Cardiac disorders	3 (0.01%)
Cardiac hypertrophy	Cardiac disorders	3 (0.01%)
Carotid artery stenosis	Nervous system disorders	3 (0.01%)
Cerebellar syndrome	Nervous system disorders	3 (0.01%)
Cerebral arteriosclerosis	Nervous system disorders	3 (0.01%)
Cerebral atrophy	Nervous system disorders	3 (0.01%)
Chest X-ray abnormal	Investigations	3 (0.01%)
Coating in mouth	Gastrointestinal disorders	3 (0.01%)
Coeliac disease	Gastrointestinal disorders	3 (0.01%)
Cold-stimulus headache	Nervous system disorders	3 (0.01%)
Colitis microscopic	Gastrointestinal disorders	3 (0.01%)
Coma scale abnormal	Investigations	3 (0.01%)
Conjunctival oedema	Eye disorders	3 (0.01%)
Conversion disorder	Psychiatric disorders	3 (0.01%)
Corneal graft rejection	Immune system disorders	3 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Cranial nerve disorder	Nervous system disorders	3 (0.01%)
CSF protein increased	Investigations	3 (0.01%)
Cyst	General disorders and administration site conditions	3 (0.01%)
Dark circles under eyes	Eye disorders	3 (0.01%)
Dental paraesthesia	Gastrointestinal disorders	3 (0.01%)
Depressive symptom	Psychiatric disorders	3 (0.01%)
Dermal cyst	Skin and subcutaneous tissue disorders	3 (0.01%)
Dermatosis	Skin and subcutaneous tissue disorders	3 (0.01%)
Distractibility	Psychiatric disorders	3 (0.01%)
Dizziness exertional	Nervous system disorders	3 (0.01%)
Drug intolerance	General disorders and administration site conditions	3 (0.01%)
Drug reaction with eosinophilia and systemic symptoms	Skin and subcutaneous tissue disorders	3 (0.01%)
Dyschezia	Gastrointestinal disorders	3 (0.01%)
Dyschromatopsia	Eye disorders	3 (0.01%)
Dyslalia	Nervous system disorders	3 (0.01%)
Dyspraxia	Nervous system disorders	3 (0.01%)
Dystonia	Nervous system disorders	3 (0.01%)
Eczema asteatotic	Skin and subcutaneous tissue disorders	3 (0.01%)
Ejection fraction decreased	Investigations	3 (0.01%)
Electrocardiogram change	Investigations	3 (0.01%)
Electrocardiogram ST segment depression	Investigations	3 (0.01%)
Embolic cerebral infarction	Nervous system disorders	3 (0.01%)
Energy increased	General disorders and administration site conditions	3 (0.01%)
Enterocolitis	Gastrointestinal disorders	3 (0.01%)
Epididymitis	Infections and infestations	3 (0.01%)
Epigastric discomfort	Gastrointestinal disorders	3 (0.01%)
Epstein-Barr virus infection	Infections and infestations	3 (0.01%)
Escherichia infection	Infections and infestations	3 (0.01%)
Extremity contracture	Musculoskeletal and connective tissue disorders	3 (0.01%)
Eye paraesthesia	Eye disorders	3 (0.01%)
Facial bones fracture	Injury, poisoning and procedural complications	3 (0.01%)
Faeces pale	Gastrointestinal disorders	3 (0.01%)
Fear of death	Psychiatric disorders	3 (0.01%)
Febrile neutropenia	Blood and lymphatic system disorders	3 (0.01%)
Femur fracture	Injury, poisoning and procedural complications	3 (0.01%)
Finger deformity	Musculoskeletal and connective tissue disorders	3 (0.01%)
Flat affect	Psychiatric disorders	3 (0.01%)
Fluid intake reduced	Metabolism and nutrition disorders	3 (0.01%)
Food craving	Metabolism and nutrition disorders	3 (0.01%)
Foot fracture	Injury, poisoning and procedural complications	3 (0.01%)
Freezing phenomenon	Nervous system disorders	3 (0.01%)
Frostbite	Injury, poisoning and procedural complications	3 (0.01%)
Functional gastrointestinal disorder	Gastrointestinal disorders	3 (0.01%)
Gastric ulcer haemorrhage	Gastrointestinal disorders	3 (0.01%)
Gastrointestinal motility disorder	Gastrointestinal disorders	3 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Gastrointestinal necrosis	Gastrointestinal disorders	3 (0.01%)
Gastrointestinal oedema	Gastrointestinal disorders	3 (0.01%)
Genital herpes simplex	Infections and infestations	3 (0.01%)
Gingival discomfort	Gastrointestinal disorders	3 (0.01%)
Gingival disorder	Gastrointestinal disorders	3 (0.01%)
Glomerulonephritis minimal lesion	Renal and urinary disorders	3 (0.01%)
Haemorrhagic disorder	Blood and lymphatic system disorders	3 (0.01%)
Haemorrhoids thrombosed	Gastrointestinal disorders	3 (0.01%)
Hand dermatitis	Skin and subcutaneous tissue disorders	3 (0.01%)
Head titubation	Nervous system disorders	3 (0.01%)
Heart sounds abnormal	Investigations	3 (0.01%)
Hemianopia	Nervous system disorders	3 (0.01%)
Hemiataxia	Nervous system disorders	3 (0.01%)
Hepatitis E	Infections and infestations	3 (0.01%)
Herpes zoster infection neurological	Infections and infestations	3 (0.01%)
Hip fracture	Injury, poisoning and procedural complications	3 (0.01%)
Hydrocephalus	Nervous system disorders	3 (0.01%)
Hyperferritinaemia	Metabolism and nutrition disorders	3 (0.01%)
Hyperlactacidaemia	Metabolism and nutrition disorders	3 (0.01%)
Hyperreflexia	Nervous system disorders	3 (0.01%)
Hypertensive encephalopathy	Nervous system disorders	3 (0.01%)
Hypoalbuminaemia	Metabolism and nutrition disorders	3 (0.01%)
Hyporeflexia	Nervous system disorders	3 (0.01%)
Hypoventilation	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Idiopathic intracranial hypertension	Nervous system disorders	3 (0.01%)
Impaired healing	General disorders and administration site conditions	3 (0.01%)
Impetigo	Infections and infestations	3 (0.01%)
Increased upper airway secretion	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Injection related reaction	Injury, poisoning and procedural complications	3 (0.01%)
Injection site bruising	General disorders and administration site conditions	3 (0.01%)
Injection site discomfort	General disorders and administration site conditions	3 (0.01%)
Injection site reaction	General disorders and administration site conditions	3 (0.01%)
Inner ear disorder	Ear and labyrinth disorders	3 (0.01%)
Intestinal haemorrhage	Gastrointestinal disorders	3 (0.01%)
Irregular breathing	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Joint instability	Musculoskeletal and connective tissue disorders	3 (0.01%)
Joint lock	Musculoskeletal and connective tissue disorders	3 (0.01%)
Klebsiella infection	Infections and infestations	3 (0.01%)
Labile blood pressure	Vascular disorders	3 (0.01%)
Larynx irritation	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Left atrial dilatation	Cardiac disorders	3 (0.01%)
Left ventricular dysfunction	Cardiac disorders	3 (0.01%)
Left ventricular hypertrophy	Cardiac disorders	3 (0.01%)
Limb deformity	Musculoskeletal and connective tissue disorders	3 (0.01%)
Lipase increased	Investigations	3 (0.01%)
Liver injury	Hepatobiliary disorders	3 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Lower respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Lymphadenopathy mediastinal	Blood and lymphatic system disorders	3 (0.01%)
Lymphatic disorder	Blood and lymphatic system disorders	3 (0.01%)
Major depression	Psychiatric disorders	3 (0.01%)
Mania	Psychiatric disorders	3 (0.01%)
Maternal exposure before pregnancy	Injury, poisoning and procedural complications	3 (0.01%)
Measles	Infections and infestations	3 (0.01%)
Menometrorrhagia	Reproductive system and breast disorders	3 (0.01%)
Menstrual cycle management	Surgical and medical procedures	3 (0.01%)
Mental status changes	Psychiatric disorders	3 (0.01%)
Mesenteric artery thrombosis	Gastrointestinal disorders	3 (0.01%)
Miller Fisher syndrome	Nervous system disorders	3 (0.01%)
Miosis	Eye disorders	3 (0.01%)
Mucous stools	Gastrointestinal disorders	3 (0.01%)
Muscle contracture	Musculoskeletal and connective tissue disorders	3 (0.01%)
Muscle rupture	Injury, poisoning and procedural complications	3 (0.01%)
Mutism	Psychiatric disorders	3 (0.01%)
Myosclerosis	Musculoskeletal and connective tissue disorders	3 (0.01%)
Nasal injury	Injury, poisoning and procedural complications	3 (0.01%)
Needle issue	Product issues	3 (0.01%)
Nephritis	Renal and urinary disorders	3 (0.01%)
Nephropathy	Renal and urinary disorders	3 (0.01%)
Neurodermatitis	Skin and subcutaneous tissue disorders	3 (0.01%)
Neurogenic shock	Vascular disorders	3 (0.01%)
Neutrophilia	Blood and lymphatic system disorders	3 (0.01%)
Nocturia	Renal and urinary disorders	3 (0.01%)
Ocular icterus	Hepatobiliary disorders	3 (0.01%)
Ophthalmic artery thrombosis	Eye disorders	3 (0.01%)
Ophthalmoplegia	Eye disorders	3 (0.01%)
Optic nerve disorder	Eye disorders	3 (0.01%)
Oral mucosal erythema	Gastrointestinal disorders	3 (0.01%)
Oropharyngeal swelling	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Orthostatic hypertension	Vascular disorders	3 (0.01%)
Ovarian cyst	Reproductive system and breast disorders	3 (0.01%)
Oversensing	Product issues	3 (0.01%)
Ovulation pain	Reproductive system and breast disorders	3 (0.01%)
Paraesthesia ear	Ear and labyrinth disorders	3 (0.01%)
Paranasal sinus hypersecretion	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Paraparesis	Nervous system disorders	3 (0.01%)
Paraplegia	Nervous system disorders	3 (0.01%)
Patient elopement	Nervous system disorders	3 (0.01%)
PCO2 increased	Investigations	3 (0.01%)
Pemphigus	Skin and subcutaneous tissue disorders	3 (0.01%)
Peripheral nerve palsy	Nervous system disorders	3 (0.01%)
Pharyngeal abscess	Infections and infestations	3 (0.01%)
Pharyngeal haemorrhage	Respiratory, thoracic and mediastinal disorders	3 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Pharyngeal mass	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Pharyngeal stenosis	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Pharyngeal ulceration	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Physical disability	Social circumstances	3 (0.01%)
Pituitary tumour benign	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.01%)
Polymyositis	Musculoskeletal and connective tissue disorders	3 (0.01%)
Pre-existing condition improved	General disorders and administration site conditions	3 (0.01%)
Premenstrual pain	Reproductive system and breast disorders	3 (0.01%)
Product prescribing error	Injury, poisoning and procedural complications	3 (0.01%)
Prostatic specific antigen increased	Investigations	3 (0.01%)
Prostatitis	Reproductive system and breast disorders	3 (0.01%)
Protein urine present	Investigations	3 (0.01%)
Prothrombin time prolonged	Investigations	3 (0.01%)
Prothrombin time shortened	Investigations	3 (0.01%)
Prurigo	Skin and subcutaneous tissue disorders	3 (0.01%)
Psoriatic arthropathy	Musculoskeletal and connective tissue disorders	3 (0.01%)
Psychotic disorder	Psychiatric disorders	3 (0.01%)
Pulmonary mass	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Pulse pressure increased	Investigations	3 (0.01%)
Putamen haemorrhage	Nervous system disorders	3 (0.01%)
Pyelonephritis acute	Infections and infestations	3 (0.01%)
Radial pulse abnormal	Investigations	3 (0.01%)
Reading disorder	Psychiatric disorders	3 (0.01%)
Respiratory rate decreased	Investigations	3 (0.01%)
Retinal migraine	Nervous system disorders	3 (0.01%)
Retinal vascular thrombosis	Eye disorders	3 (0.01%)
Rheumatic disorder	Musculoskeletal and connective tissue disorders	3 (0.01%)
Right ventricular dysfunction	Cardiac disorders	3 (0.01%)
Ruptured cerebral aneurysm	Nervous system disorders	3 (0.01%)
Salivary gland enlargement	Gastrointestinal disorders	3 (0.01%)
Scar pain	Skin and subcutaneous tissue disorders	3 (0.01%)
Scintillating scotoma	Eye disorders	3 (0.01%)
Secondary hypertension	Vascular disorders	3 (0.01%)
Sedation	Nervous system disorders	3 (0.01%)
Sense of oppression	General disorders and administration site conditions	3 (0.01%)
Sensitisation	Immune system disorders	3 (0.01%)
Shoulder injury related to vaccine administration	General disorders and administration site conditions	3 (0.01%)
Sitting disability	Social circumstances	3 (0.01%)
Skin cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.01%)
Skin fissures	Skin and subcutaneous tissue disorders	3 (0.01%)
Somnambulism	Psychiatric disorders	3 (0.01%)
Sopor	Psychiatric disorders	3 (0.01%)
Splenic infarction	Blood and lymphatic system disorders	3 (0.01%)
Splenomegaly	Blood and lymphatic system disorders	3 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Sputum discoloured	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Starvation	Metabolism and nutrition disorders	3 (0.01%)
Stenosis	General disorders and administration site conditions	3 (0.01%)
Stupor	Nervous system disorders	3 (0.01%)
Subdural haemorrhage	Injury, poisoning and procedural complications	3 (0.01%)
Systolic dysfunction	Cardiac disorders	3 (0.01%)
Tachycardia paroxysmal	Cardiac disorders	3 (0.01%)
Temperature intolerance	General disorders and administration site conditions	3 (0.01%)
Temporomandibular joint syndrome	Musculoskeletal and connective tissue disorders	3 (0.01%)
Terminal insomnia	Psychiatric disorders	3 (0.01%)
Terminal state	General disorders and administration site conditions	3 (0.01%)
Testicular swelling	Reproductive system and breast disorders	3 (0.01%)
Thalamus haemorrhage	Nervous system disorders	3 (0.01%)
Therapeutic product effect decreased	General disorders and administration site conditions	3 (0.01%)
Thermal burns of eye	Injury, poisoning and procedural complications	3 (0.01%)
Thyroiditis subacute	Endocrine disorders	3 (0.01%)
Tongue rough	Gastrointestinal disorders	3 (0.01%)
Tonic convulsion	Nervous system disorders	3 (0.01%)
Tonsillar disorder	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Tonsillar inflammation	Respiratory, thoracic and mediastinal disorders	3 (0.01%)
Tooth fracture	Injury, poisoning and procedural complications	3 (0.01%)
Traumatic haematoma	Injury, poisoning and procedural complications	3 (0.01%)
Trichoglossia	Gastrointestinal disorders	3 (0.01%)
Tricuspid valve incompetence	Cardiac disorders	3 (0.01%)
Trigeminal neuritis	Nervous system disorders	3 (0.01%)
Troponin I increased	Investigations	3 (0.01%)
Type 1 diabetes mellitus	Metabolism and nutrition disorders	3 (0.01%)
Type 2 diabetes mellitus	Metabolism and nutrition disorders	3 (0.01%)
Urinary occult blood positive	Investigations	3 (0.01%)
Vaccination site abscess	Infections and infestations	3 (0.01%)
Vaccination site discharge	General disorders and administration site conditions	3 (0.01%)
Vaccination site extravasation	General disorders and administration site conditions	3 (0.01%)
Vaccination site infection	Infections and infestations	3 (0.01%)
Vaccination site macule	General disorders and administration site conditions	3 (0.01%)
Varicophlebitis	Vascular disorders	3 (0.01%)
Vascular occlusion	Vascular disorders	3 (0.01%)
Ventricular hypokinesia	Cardiac disorders	3 (0.01%)
Viral pharyngitis	Infections and infestations	3 (0.01%)
Vitamin D decreased	Investigations	3 (0.01%)
Weight fluctuation	Metabolism and nutrition disorders	3 (0.01%)
White blood cells urine positive	Investigations	3 (0.01%)
Withdrawal syndrome	General disorders and administration site conditions	3 (0.01%)
Wound complication	Injury, poisoning and procedural complications	3 (0.01%)
Wrist fracture	Injury, poisoning and procedural complications	3 (0.01%)
Abdominal mass	Gastrointestinal disorders	2 (0.00%)
Abdominal sepsis	Infections and infestations	2 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Abdominal symptom	Gastrointestinal disorders	2 (0.00%)
Abdominal wall haematoma	Gastrointestinal disorders	2 (0.00%)
Abnormal clotting factor	Blood and lymphatic system disorders	2 (0.00%)
Abortion	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Abortion threatened	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Acarodermatitis	Infections and infestations	2 (0.00%)
Acidosis	Metabolism and nutrition disorders	2 (0.00%)
Activated partial thromboplastin time shortened	Investigations	2 (0.00%)
Acute aortic syndrome	Vascular disorders	2 (0.00%)
Acute hepatic failure	Hepatobiliary disorders	2 (0.00%)
Acute polyneuropathy	Nervous system disorders	2 (0.00%)
Acute stress disorder	Psychiatric disorders	2 (0.00%)
Administration site bruise	General disorders and administration site conditions	2 (0.00%)
Adrenal haemorrhage	Endocrine disorders	2 (0.00%)
Affective disorder	Psychiatric disorders	2 (0.00%)
Akathisia	Nervous system disorders	2 (0.00%)
Allergic cough	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Amylase increased	Investigations	2 (0.00%)
Amyloidosis	Immune system disorders	2 (0.00%)
Anal abscess	Infections and infestations	2 (0.00%)
Anamnestic reaction	Immune system disorders	2 (0.00%)
Anaphylactoid shock	Immune system disorders	2 (0.00%)
Angina unstable	Cardiac disorders	2 (0.00%)
Anterograde amnesia	Nervous system disorders	2 (0.00%)
Antibody test negative	Investigations	2 (0.00%)
Anti-neutrophil cytoplasmic antibody positive vasculitis	Immune system disorders	2 (0.00%)
Antiphospholipid syndrome	Blood and lymphatic system disorders	2 (0.00%)
Aortic stenosis	Vascular disorders	2 (0.00%)
Aortic thrombosis	Vascular disorders	2 (0.00%)
Apallic syndrome	Nervous system disorders	2 (0.00%)
Appendicitis perforated	Infections and infestations	2 (0.00%)
Appetite disorder	Metabolism and nutrition disorders	2 (0.00%)
Application site erythema	General disorders and administration site conditions	2 (0.00%)
Arrhythmia supraventricular	Cardiac disorders	2 (0.00%)
Arteriosclerosis coronary artery	Cardiac disorders	2 (0.00%)
Arteritis	Vascular disorders	2 (0.00%)
AST/ALT ratio abnormal	Investigations	2 (0.00%)
Atrioventricular block first degree	Cardiac disorders	2 (0.00%)
Attention deficit hyperactivity disorder	Psychiatric disorders	2 (0.00%)
Autism spectrum disorder	Psychiatric disorders	2 (0.00%)
Axillary vein thrombosis	Vascular disorders	2 (0.00%)
Basilar artery occlusion	Nervous system disorders	2 (0.00%)
Bile duct stone	Hepatobiliary disorders	2 (0.00%)
Bladder discomfort	Renal and urinary disorders	2 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Bleeding time prolonged	Investigations	2 (0.00%)
Blood chloride increased	Investigations	2 (0.00%)
Blood count abnormal	Investigations	2 (0.00%)
Blood immunoglobulin G decreased	Investigations	2 (0.00%)
Blood immunoglobulin M increased	Investigations	2 (0.00%)
Blood parathyroid hormone increased	Investigations	2 (0.00%)
Blood phosphorus decreased	Investigations	2 (0.00%)
Blood phosphorus increased	Investigations	2 (0.00%)
Blood potassium increased	Investigations	2 (0.00%)
Blood pressure ambulatory abnormal	Investigations	2 (0.00%)
Blood pressure ambulatory increased	Investigations	2 (0.00%)
Blood pressure inadequately controlled	Vascular disorders	2 (0.00%)
Blood pressure measurement	Investigations	2 (0.00%)
Blood thyroid stimulating hormone decreased	Investigations	2 (0.00%)
Blood triglycerides increased	Investigations	2 (0.00%)
Borrelia infection	Infections and infestations	2 (0.00%)
Brain stem haemorrhage	Nervous system disorders	2 (0.00%)
Brain stem ischaemia	Nervous system disorders	2 (0.00%)
Breast cyst	Reproductive system and breast disorders	2 (0.00%)
Bronchial hyperreactivity	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Bronchitis chronic	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Bronchostenosis	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Bundle branch block left	Cardiac disorders	2 (0.00%)
Burning mouth syndrome	Gastrointestinal disorders	2 (0.00%)
Burning sensation mucosal	Nervous system disorders	2 (0.00%)
Burn oesophageal	Injury, poisoning and procedural complications	2 (0.00%)
Burns second degree	Injury, poisoning and procedural complications	2 (0.00%)
Burns third degree	Injury, poisoning and procedural complications	2 (0.00%)
Cardiac failure chronic	Cardiac disorders	2 (0.00%)
Cardiac valve disease	Cardiac disorders	2 (0.00%)
Cardiac ventricular thrombosis	Cardiac disorders	2 (0.00%)
Carotid artery dissection	Nervous system disorders	2 (0.00%)
CD4 lymphocytes decreased	Investigations	2 (0.00%)
Central nervous system vasculitis	Nervous system disorders	2 (0.00%)
Cerebellar ataxia	Nervous system disorders	2 (0.00%)
Cerebellar infarction	Nervous system disorders	2 (0.00%)
Cerebral amyloid angiopathy	Nervous system disorders	2 (0.00%)
Cerebral artery stenosis	Nervous system disorders	2 (0.00%)
Cerebral palsy	Congenital, familial and genetic disorders	2 (0.00%)
Change of bowel habit	Gastrointestinal disorders	2 (0.00%)
Chapped lips	Gastrointestinal disorders	2 (0.00%)
Chloropsia	Eye disorders	2 (0.00%)
Cholestatic liver injury	Hepatobiliary disorders	2 (0.00%)
Chronic pigmented purpura	Skin and subcutaneous tissue disorders	2 (0.00%)
Chronic sinusitis	Infections and infestations	2 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Complicated appendicitis	Infections and infestations	2 (0.00%)
Congestive hepatopathy	Hepatobiliary disorders	2 (0.00%)
Conjunctivitis allergic	Eye disorders	2 (0.00%)
Conjunctivitis viral	Infections and infestations	2 (0.00%)
Contraindicated product administered	Injury, poisoning and procedural complications	2 (0.00%)
Coronavirus test positive	Investigations	2 (0.00%)
Cor pulmonale	Cardiac disorders	2 (0.00%)
Cough variant asthma	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
C-reactive protein	Investigations	2 (0.00%)
CSF cell count increased	Investigations	2 (0.00%)
Cutaneous symptom	Skin and subcutaneous tissue disorders	2 (0.00%)
Cytomegalovirus infection reactivation	Infections and infestations	2 (0.00%)
Decubitus ulcer	Skin and subcutaneous tissue disorders	2 (0.00%)
Delusional perception	Psychiatric disorders	2 (0.00%)
Dementia Alzheimer's type	Nervous system disorders	2 (0.00%)
Dental discomfort	Gastrointestinal disorders	2 (0.00%)
Dermatitis exfoliative	Skin and subcutaneous tissue disorders	2 (0.00%)
Dermatitis exfoliative generalised	Skin and subcutaneous tissue disorders	2 (0.00%)
Dermatitis psoriasiform	Skin and subcutaneous tissue disorders	2 (0.00%)
Dermatomyositis	Skin and subcutaneous tissue disorders	2 (0.00%)
Diabetes insipidus	Endocrine disorders	2 (0.00%)
Diabetic ketoacidosis	Metabolism and nutrition disorders	2 (0.00%)
Diabetic ketosis	Metabolism and nutrition disorders	2 (0.00%)
Dilatation ventricular	Cardiac disorders	2 (0.00%)
Disorganised speech	Psychiatric disorders	2 (0.00%)
Dissociation	Psychiatric disorders	2 (0.00%)
Dissociative disorder	Psychiatric disorders	2 (0.00%)
Diverticulum	Gastrointestinal disorders	2 (0.00%)
Drug withdrawal syndrome	General disorders and administration site conditions	2 (0.00%)
Duodenal ulcer haemorrhage	Gastrointestinal disorders	2 (0.00%)
Dysacusis	Ear and labyrinth disorders	2 (0.00%)
Eating disorder symptom	Metabolism and nutrition disorders	2 (0.00%)
Ectopic pregnancy	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Effusion	General disorders and administration site conditions	2 (0.00%)
Electrocardiogram QRS complex prolonged	Investigations	2 (0.00%)
Electrocardiogram QT prolonged	Investigations	2 (0.00%)
Electrocardiogram T wave inversion	Investigations	2 (0.00%)
Electrolyte imbalance	Metabolism and nutrition disorders	2 (0.00%)
Embolism arterial	Vascular disorders	2 (0.00%)
Enanthema	General disorders and administration site conditions	2 (0.00%)
Encephalitis autoimmune	Nervous system disorders	2 (0.00%)
Endocarditis	Infections and infestations	2 (0.00%)
Endocrine ophthalmopathy	Eye disorders	2 (0.00%)
Enterococcal infection	Infections and infestations	2 (0.00%)
Enterocolitis haemorrhagic	Gastrointestinal disorders	2 (0.00%)
Epstein-Barr virus infection reactivation	Infections and infestations	2 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Erythrospia	Eye disorders	2 (0.00%)
Escherichia bacteraemia	Infections and infestations	2 (0.00%)
Escherichia sepsis	Infections and infestations	2 (0.00%)
Essential hypertension	Vascular disorders	2 (0.00%)
Eustachian tube dysfunction	Ear and labyrinth disorders	2 (0.00%)
Extremity necrosis	Vascular disorders	2 (0.00%)
Eye colour change	Eye disorders	2 (0.00%)
Eyelid exfoliation	Eye disorders	2 (0.00%)
Facial nerve disorder	Nervous system disorders	2 (0.00%)
Faecaloma	Gastrointestinal disorders	2 (0.00%)
Fear of disease	Psychiatric disorders	2 (0.00%)
Fear of injection	Psychiatric disorders	2 (0.00%)
Female reproductive tract disorder	Reproductive system and breast disorders	2 (0.00%)
Femoral artery embolism	Vascular disorders	2 (0.00%)
Femoral neck fracture	Injury, poisoning and procedural complications	2 (0.00%)
Foetal heart rate abnormal	Investigations	2 (0.00%)
Food aversion	Metabolism and nutrition disorders	2 (0.00%)
Food poisoning	Gastrointestinal disorders	2 (0.00%)
Food refusal	Metabolism and nutrition disorders	2 (0.00%)
Fracture	Injury, poisoning and procedural complications	2 (0.00%)
Galactostasis	Reproductive system and breast disorders	2 (0.00%)
Gallbladder disorder	Hepatobiliary disorders	2 (0.00%)
Gastric antral vascular ectasia	Gastrointestinal disorders	2 (0.00%)
Gastric dilatation	Gastrointestinal disorders	2 (0.00%)
Gastrointestinal infection	Infections and infestations	2 (0.00%)
Gastrointestinal inflammation	Gastrointestinal disorders	2 (0.00%)
General physical condition abnormal	Investigations	2 (0.00%)
Genital discomfort	Reproductive system and breast disorders	2 (0.00%)
Genital rash	Reproductive system and breast disorders	2 (0.00%)
Gestational diabetes	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Gingival abscess	Infections and infestations	2 (0.00%)
Gingival blister	Gastrointestinal disorders	2 (0.00%)
Gingival erythema	Gastrointestinal disorders	2 (0.00%)
Glare	Eye disorders	2 (0.00%)
Glucose tolerance impaired	Metabolism and nutrition disorders	2 (0.00%)
Granuloma	General disorders and administration site conditions	2 (0.00%)
Guttate psoriasis	Skin and subcutaneous tissue disorders	2 (0.00%)
Haematocrit increased	Investigations	2 (0.00%)
Haemorrhagic cerebral infarction	Nervous system disorders	2 (0.00%)
Hair texture abnormal	Skin and subcutaneous tissue disorders	2 (0.00%)
Hallucination, olfactory	Psychiatric disorders	2 (0.00%)
Head banging	Psychiatric disorders	2 (0.00%)
Hearing disability	Social circumstances	2 (0.00%)
Heart injury	Injury, poisoning and procedural complications	2 (0.00%)
Heat stroke	Injury, poisoning and procedural complications	2 (0.00%)
Hemiplegic migraine	Nervous system disorders	2 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Hepatic failure	Hepatobiliary disorders	2 (0.00%)
Hepatic infarction	Hepatobiliary disorders	2 (0.00%)
Hepatic vein thrombosis	Hepatobiliary disorders	2 (0.00%)
Hepatitis C	Infections and infestations	2 (0.00%)
Hepatocellular injury	Hepatobiliary disorders	2 (0.00%)
Herpes simplex test positive	Investigations	2 (0.00%)
Herpes zoster meningitis	Infections and infestations	2 (0.00%)
Herpes zoster meningoradiculitis	Infections and infestations	2 (0.00%)
High density lipoprotein decreased	Investigations	2 (0.00%)
Hilar lymphadenopathy	Blood and lymphatic system disorders	2 (0.00%)
Humerus fracture	Injury, poisoning and procedural complications	2 (0.00%)
Hyperbilirubinaemia	Hepatobiliary disorders	2 (0.00%)
Hypercalcaemia	Metabolism and nutrition disorders	2 (0.00%)
Hypercapnia	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Hypercholesterolaemia	Metabolism and nutrition disorders	2 (0.00%)
Hypermetabolism	Metabolism and nutrition disorders	2 (0.00%)
Hypersensitivity vasculitis	Skin and subcutaneous tissue disorders	2 (0.00%)
Hypertriglyceridaemia	Metabolism and nutrition disorders	2 (0.00%)
Hypertrophy of tongue papillae	Gastrointestinal disorders	2 (0.00%)
Hyperuricaemia	Metabolism and nutrition disorders	2 (0.00%)
Hypoaesthesia teeth	Gastrointestinal disorders	2 (0.00%)
Hypochromic anaemia	Blood and lymphatic system disorders	2 (0.00%)
Hypogammaglobulinaemia	Immune system disorders	2 (0.00%)
Hypopituitarism	Endocrine disorders	2 (0.00%)
Hyporesponsive to stimuli	Nervous system disorders	2 (0.00%)
Hypovolaemic shock	Vascular disorders	2 (0.00%)
IgA nephropathy	Renal and urinary disorders	2 (0.00%)
Immunoglobulins increased	Investigations	2 (0.00%)
Increased bronchial secretion	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Infective tenosynovitis	Infections and infestations	2 (0.00%)
Inflammatory bowel disease	Gastrointestinal disorders	2 (0.00%)
Infusion related reaction	Injury, poisoning and procedural complications	2 (0.00%)
Injection site oedema	General disorders and administration site conditions	2 (0.00%)
Injection site paraesthesia	General disorders and administration site conditions	2 (0.00%)
Inspiratory capacity decreased	Investigations	2 (0.00%)
Insulin resistance	Metabolism and nutrition disorders	2 (0.00%)
International normalised ratio decreased	Investigations	2 (0.00%)
Intervertebral disc disorder	Musculoskeletal and connective tissue disorders	2 (0.00%)
Intestinal infarction	Gastrointestinal disorders	2 (0.00%)
Intra-abdominal haematoma	Gastrointestinal disorders	2 (0.00%)
Intranasal paraesthesia	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Iritis	Eye disorders	2 (0.00%)
Ischaemic cardiomyopathy	Cardiac disorders	2 (0.00%)
Jaw clicking	Musculoskeletal and connective tissue disorders	2 (0.00%)
Ketoacidosis	Metabolism and nutrition disorders	2 (0.00%)
Lactic acidosis	Metabolism and nutrition disorders	2 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Lactose intolerance	Metabolism and nutrition disorders	2 (0.00%)
Large intestine perforation	Gastrointestinal disorders	2 (0.00%)
Laryngeal stenosis	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Lateral medullary syndrome	Nervous system disorders	2 (0.00%)
Laziness	Psychiatric disorders	2 (0.00%)
Leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Lichen planus	Skin and subcutaneous tissue disorders	2 (0.00%)
Lichen sclerosus	Skin and subcutaneous tissue disorders	2 (0.00%)
Ligament rupture	Injury, poisoning and procedural complications	2 (0.00%)
Lipids increased	Investigations	2 (0.00%)
Liver abscess	Infections and infestations	2 (0.00%)
Lividity	Skin and subcutaneous tissue disorders	2 (0.00%)
Logorrhoea	Psychiatric disorders	2 (0.00%)
Loss of libido	Psychiatric disorders	2 (0.00%)
Lower limb fracture	Injury, poisoning and procedural complications	2 (0.00%)
Lung abscess	Infections and infestations	2 (0.00%)
Lung cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Lung consolidation	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Lymph gland infection	Infections and infestations	2 (0.00%)
Lymphocytosis	Blood and lymphatic system disorders	2 (0.00%)
Macular oedema	Eye disorders	2 (0.00%)
Malignant peritoneal neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Mast cell activation syndrome	Blood and lymphatic system disorders	2 (0.00%)
Mean cell haemoglobin concentration decreased	Investigations	2 (0.00%)
Mean cell haemoglobin concentration increased	Investigations	2 (0.00%)
Mean cell haemoglobin decreased	Investigations	2 (0.00%)
Mean cell haemoglobin increased	Investigations	2 (0.00%)
Mean cell volume decreased	Investigations	2 (0.00%)
Mean cell volume increased	Investigations	2 (0.00%)
Mechanical ventilation	Surgical and medical procedures	2 (0.00%)
Meningeal disorder	Nervous system disorders	2 (0.00%)
Meningitis viral	Infections and infestations	2 (0.00%)
Menstrual discomfort	Reproductive system and breast disorders	2 (0.00%)
Microangiopathy	Vascular disorders	2 (0.00%)
Microcytic anaemia	Blood and lymphatic system disorders	2 (0.00%)
Micturition disorder	Renal and urinary disorders	2 (0.00%)
Misophonia	Ear and labyrinth disorders	2 (0.00%)
Moaning	General disorders and administration site conditions	2 (0.00%)
Mononeuropathy multiplex	Nervous system disorders	2 (0.00%)
Morning sickness	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Mucosal dryness	General disorders and administration site conditions	2 (0.00%)
Mucosal haemorrhage	General disorders and administration site conditions	2 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Mucosal inflammation	General disorders and administration site conditions	2 (0.00%)
Muscle atrophy	Musculoskeletal and connective tissue disorders	2 (0.00%)
Muscle haemorrhage	Musculoskeletal and connective tissue disorders	2 (0.00%)
Muscle mass	Musculoskeletal and connective tissue disorders	2 (0.00%)
Myokymia	Musculoskeletal and connective tissue disorders	2 (0.00%)
Nail discolouration	Skin and subcutaneous tissue disorders	2 (0.00%)
Nasal herpes	Infections and infestations	2 (0.00%)
Neck injury	Injury, poisoning and procedural complications	2 (0.00%)
Necrotising fasciitis	Infections and infestations	2 (0.00%)
Neoplasm recurrence	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Neurologic neglect syndrome	Nervous system disorders	2 (0.00%)
Neuromuscular pain	Nervous system disorders	2 (0.00%)
Normocytic anaemia	Blood and lymphatic system disorders	2 (0.00%)
Obesity	Metabolism and nutrition disorders	2 (0.00%)
Obstruction	General disorders and administration site conditions	2 (0.00%)
Occult blood positive	Investigations	2 (0.00%)
Ocular myasthenia	Eye disorders	2 (0.00%)
Oesophageal pain	Gastrointestinal disorders	2 (0.00%)
Oesophageal spasm	Gastrointestinal disorders	2 (0.00%)
Oliguria	Renal and urinary disorders	2 (0.00%)
Onychalgia	Skin and subcutaneous tissue disorders	2 (0.00%)
Ophthalmic herpes simplex	Infections and infestations	2 (0.00%)
Optic disc haemorrhage	Eye disorders	2 (0.00%)
Optic ischaemic neuropathy	Eye disorders	2 (0.00%)
Oral allergy syndrome	Immune system disorders	2 (0.00%)
Osteopenia	Musculoskeletal and connective tissue disorders	2 (0.00%)
Osteoporosis	Musculoskeletal and connective tissue disorders	2 (0.00%)
Ovarian haemorrhage	Reproductive system and breast disorders	2 (0.00%)
Ovarian vein thrombosis	Reproductive system and breast disorders	2 (0.00%)
Overweight	Metabolism and nutrition disorders	2 (0.00%)
Ovulation disorder	Reproductive system and breast disorders	2 (0.00%)
Oxygen saturation immeasurable	Investigations	2 (0.00%)
Palatal disorder	Gastrointestinal disorders	2 (0.00%)
Palpable purpura	Skin and subcutaneous tissue disorders	2 (0.00%)
Panniculitis	Skin and subcutaneous tissue disorders	2 (0.00%)
Paraesthesia mucosal	Nervous system disorders	2 (0.00%)
Parkinsonism	Nervous system disorders	2 (0.00%)
Paronychia	Infections and infestations	2 (0.00%)
Paternal exposure during pregnancy	Injury, poisoning and procedural complications	2 (0.00%)
Penis disorder	Reproductive system and breast disorders	2 (0.00%)
Peptic ulcer haemorrhage	Gastrointestinal disorders	2 (0.00%)
Perforation	General disorders and administration site conditions	2 (0.00%)
Periorbital discomfort	Eye disorders	2 (0.00%)
Peripheral arterial occlusive disease	Vascular disorders	2 (0.00%)
Peripheral artery occlusion	Vascular disorders	2 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Peripheral paralysis	Nervous system disorders	2 (0.00%)
Peripheral sensory neuropathy	Nervous system disorders	2 (0.00%)
Peroneal nerve palsy	Nervous system disorders	2 (0.00%)
Persistent depressive disorder	Psychiatric disorders	2 (0.00%)
Personality change	Psychiatric disorders	2 (0.00%)
Pharyngitis bacterial	Infections and infestations	2 (0.00%)
Pharyngotonsillitis	Infections and infestations	2 (0.00%)
Pityriasis	Skin and subcutaneous tissue disorders	2 (0.00%)
Pityriasis lichenoides et varioliformis acuta	Skin and subcutaneous tissue disorders	2 (0.00%)
Plicated tongue	Gastrointestinal disorders	2 (0.00%)
Pneumonia viral	Infections and infestations	2 (0.00%)
Polycythaemia	Blood and lymphatic system disorders	2 (0.00%)
Poor feeding infant	Metabolism and nutrition disorders	2 (0.00%)
Portal hypertension	Hepatobiliary disorders	2 (0.00%)
Post-traumatic neck syndrome	Injury, poisoning and procedural complications	2 (0.00%)
Post-traumatic stress disorder	Psychiatric disorders	2 (0.00%)
Prehypertension	Vascular disorders	2 (0.00%)
Premature separation of placenta	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Premenstrual dysphoric disorder	Reproductive system and breast disorders	2 (0.00%)
Prerenal failure	Renal and urinary disorders	2 (0.00%)
Product complaint	Product issues	2 (0.00%)
Product container issue	Product issues	2 (0.00%)
Product contamination physical	Product issues	2 (0.00%)
Prohormone brain natriuretic peptide increased	Investigations	2 (0.00%)
Protein total decreased	Investigations	2 (0.00%)
Pruritus allergic	Skin and subcutaneous tissue disorders	2 (0.00%)
Pseudomonal bacteraemia	Infections and infestations	2 (0.00%)
Psychiatric decompensation	Psychiatric disorders	2 (0.00%)
Psychogenic seizure	Nervous system disorders	2 (0.00%)
Psychomotor retardation	Psychiatric disorders	2 (0.00%)
Pulmonary haemorrhage	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Pulmonary sepsis	Infections and infestations	2 (0.00%)
Puncture site pain	General disorders and administration site conditions	2 (0.00%)
Pupillary reflex impaired	Eye disorders	2 (0.00%)
Q fever	Infections and infestations	2 (0.00%)
Radiculopathy	Nervous system disorders	2 (0.00%)
Red blood cell count increased	Investigations	2 (0.00%)
Red cell distribution width decreased	Investigations	2 (0.00%)
Red ear syndrome	Ear and labyrinth disorders	2 (0.00%)
Renal artery thrombosis	Renal and urinary disorders	2 (0.00%)
Renal cyst	Renal and urinary disorders	2 (0.00%)
Renal mass	Renal and urinary disorders	2 (0.00%)
Respiratory tract irritation	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Resting tremor	Nervous system disorders	2 (0.00%)
Restless arm syndrome	Nervous system disorders	2 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Retinal artery embolism	Eye disorders	2 (0.00%)
Retinal ischaemia	Eye disorders	2 (0.00%)
Retinal tear	Eye disorders	2 (0.00%)
Rheumatoid factor increased	Investigations	2 (0.00%)
Right ventricular dilatation	Cardiac disorders	2 (0.00%)
Scalloped tongue	Gastrointestinal disorders	2 (0.00%)
Sciatic nerve neuropathy	Nervous system disorders	2 (0.00%)
Scleral discolouration	Eye disorders	2 (0.00%)
Senile dementia	Nervous system disorders	2 (0.00%)
Sensation of blood flow	General disorders and administration site conditions	2 (0.00%)
Sensitivity to weather change	General disorders and administration site conditions	2 (0.00%)
Sensorimotor disorder	Nervous system disorders	2 (0.00%)
Serratia infection	Infections and infestations	2 (0.00%)
Shock haemorrhagic	Vascular disorders	2 (0.00%)
Shock symptom	Vascular disorders	2 (0.00%)
Sinus arrhythmia	Cardiac disorders	2 (0.00%)
Skin hyperpigmentation	Skin and subcutaneous tissue disorders	2 (0.00%)
Skin indentation	Skin and subcutaneous tissue disorders	2 (0.00%)
Skin induration	Skin and subcutaneous tissue disorders	2 (0.00%)
Skin injury	Injury, poisoning and procedural complications	2 (0.00%)
Skin necrosis	Skin and subcutaneous tissue disorders	2 (0.00%)
Skin papilloma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Skin temperature	Investigations	2 (0.00%)
Skull fracture	Injury, poisoning and procedural complications	2 (0.00%)
Skull fractured base	Injury, poisoning and procedural complications	2 (0.00%)
Sleep attacks	Psychiatric disorders	2 (0.00%)
Sleep paralysis	Nervous system disorders	2 (0.00%)
Sleep talking	Psychiatric disorders	2 (0.00%)
Slow response to stimuli	Nervous system disorders	2 (0.00%)
Small fibre neuropathy	Nervous system disorders	2 (0.00%)
Small intestinal haemorrhage	Gastrointestinal disorders	2 (0.00%)
Social avoidant behaviour	Psychiatric disorders	2 (0.00%)
Soliloquy	Psychiatric disorders	2 (0.00%)
Somatic symptom disorder	Psychiatric disorders	2 (0.00%)
Spinal cord disorder	Nervous system disorders	2 (0.00%)
Sputum retention	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Squamous cell carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Staphylococcal infection	Infections and infestations	2 (0.00%)
Steroid diabetes	Metabolism and nutrition disorders	2 (0.00%)
Stiff tongue	Gastrointestinal disorders	2 (0.00%)
Stoma site haemorrhage	Injury, poisoning and procedural complications	2 (0.00%)
Subcutaneous haematoma	Injury, poisoning and procedural complications	2 (0.00%)
Superior sagittal sinus thrombosis	Nervous system disorders	2 (0.00%)
Suspected counterfeit product	Product issues	2 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Symptom recurrence	General disorders and administration site conditions	2 (0.00%)
Systolic hypertension	Vascular disorders	2 (0.00%)
Tardive dyskinesia	Nervous system disorders	2 (0.00%)
Teething	Gastrointestinal disorders	2 (0.00%)
Telangiectasia	Skin and subcutaneous tissue disorders	2 (0.00%)
Tendon injury	Injury, poisoning and procedural complications	2 (0.00%)
Testicular disorder	Reproductive system and breast disorders	2 (0.00%)
Thalamic infarction	Nervous system disorders	2 (0.00%)
Throat lesion	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Thrombocytosis	Blood and lymphatic system disorders	2 (0.00%)
Thrombosed varicose vein	Vascular disorders	2 (0.00%)
Thrombosis mesenteric vessel	Gastrointestinal disorders	2 (0.00%)
Thyroid pain	Endocrine disorders	2 (0.00%)
Tongue exfoliation	Gastrointestinal disorders	2 (0.00%)
Tongue injury	Injury, poisoning and procedural complications	2 (0.00%)
Tongue movement disturbance	Gastrointestinal disorders	2 (0.00%)
Tongue spasm	Gastrointestinal disorders	2 (0.00%)
Tooth disorder	Gastrointestinal disorders	2 (0.00%)
Tooth injury	Injury, poisoning and procedural complications	2 (0.00%)
Tooth loss	Gastrointestinal disorders	2 (0.00%)
Tracheal pain	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Tracheal stenosis	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Trigeminal nerve disorder	Nervous system disorders	2 (0.00%)
Trigeminal nerve paresis	Nervous system disorders	2 (0.00%)
Trigger finger	Musculoskeletal and connective tissue disorders	2 (0.00%)
Troponin abnormal	Investigations	2 (0.00%)
Troponin T increased	Investigations	2 (0.00%)
Tumour marker increased	Investigations	2 (0.00%)
Tumour pain	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Tympanic membrane perforation	Ear and labyrinth disorders	2 (0.00%)
Type III immune complex mediated reaction	Immune system disorders	2 (0.00%)
Typical aura without headache	Nervous system disorders	2 (0.00%)
Upper limb fracture	Injury, poisoning and procedural complications	2 (0.00%)
Upper respiratory tract infection	Infections and infestations	2 (0.00%)
Upper respiratory tract inflammation	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Urge incontinence	Renal and urinary disorders	2 (0.00%)
Urinary tract disorder	Renal and urinary disorders	2 (0.00%)
Urine flow decreased	Renal and urinary disorders	2 (0.00%)
Urine output increased	Investigations	2 (0.00%)
Urticarial vasculitis	Skin and subcutaneous tissue disorders	2 (0.00%)
Vaccination site dermatitis	General disorders and administration site conditions	2 (0.00%)
Vaccination site nerve damage	General disorders and administration site conditions	2 (0.00%)
Vaccination site scab	General disorders and administration site conditions	2 (0.00%)
Vaccination site scar	General disorders and administration site conditions	2 (0.00%)
Vaginal infection	Infections and infestations	2 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Vascular calcification	Vascular disorders	2 (0.00%)
Vasculitic rash	Skin and subcutaneous tissue disorders	2 (0.00%)
Vasoplegia syndrome	Injury, poisoning and procedural complications	2 (0.00%)
Vein discolouration	Vascular disorders	2 (0.00%)
Vena cava thrombosis	Vascular disorders	2 (0.00%)
Venous occlusion	Vascular disorders	2 (0.00%)
Ventricular dysfunction	Cardiac disorders	2 (0.00%)
Vertebral artery occlusion	Nervous system disorders	2 (0.00%)
Vertebrobasilar stroke	Nervous system disorders	2 (0.00%)
Viral sepsis	Infections and infestations	2 (0.00%)
Vital functions abnormal	Investigations	2 (0.00%)
Vitamin B12 deficiency	Metabolism and nutrition disorders	2 (0.00%)
Vitamin D deficiency	Metabolism and nutrition disorders	2 (0.00%)
Vitreous haemorrhage	Eye disorders	2 (0.00%)
Vulval ulceration	Reproductive system and breast disorders	2 (0.00%)
Vulvovaginal burning sensation	Reproductive system and breast disorders	2 (0.00%)
Vulvovaginal dryness	Reproductive system and breast disorders	2 (0.00%)
Vulvovaginal mycotic infection	Infections and infestations	2 (0.00%)
Vulvovaginal swelling	Reproductive system and breast disorders	2 (0.00%)
White blood cells urine	Investigations	2 (0.00%)
White matter lesion	Nervous system disorders	2 (0.00%)
Withdrawal hypertension	Vascular disorders	2 (0.00%)
Wound haemorrhage	Injury, poisoning and procedural complications	2 (0.00%)
Abdominal lymphadenopathy	Blood and lymphatic system disorders	1 (0.00%)
Abdominal migraine	Gastrointestinal disorders	1 (0.00%)
Abdominal rigidity	Gastrointestinal disorders	1 (0.00%)
Abnormal sleep-related event	Psychiatric disorders	1 (0.00%)
Abscess limb	Infections and infestations	1 (0.00%)
Abscess of salivary gland	Infections and infestations	1 (0.00%)
Abscess rupture	Infections and infestations	1 (0.00%)
Abulia	Psychiatric disorders	1 (0.00%)
Accidental exposure to product by child	Injury, poisoning and procedural complications	1 (0.00%)
Acetonaemia	Metabolism and nutrition disorders	1 (0.00%)
Acute abdomen	Gastrointestinal disorders	1 (0.00%)
Acute cardiac event	Cardiac disorders	1 (0.00%)
Acute generalised exanthematous pustulosis	Skin and subcutaneous tissue disorders	1 (0.00%)
Acute haemorrhagic conjunctivitis	Infections and infestations	1 (0.00%)
Acute macular outer retinopathy	Eye disorders	1 (0.00%)
Acute vestibular syndrome	Ear and labyrinth disorders	1 (0.00%)
Adenomyosis	Reproductive system and breast disorders	1 (0.00%)
Adiposis dolorosa	Skin and subcutaneous tissue disorders	1 (0.00%)
Administration site induration	General disorders and administration site conditions	1 (0.00%)
Administration site joint pain	General disorders and administration site conditions	1 (0.00%)
Adrenomegaly	Endocrine disorders	1 (0.00%)
Adult failure to thrive	Metabolism and nutrition disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Advanced sleep phase	Nervous system disorders	1 (0.00%)
Aerophagia	Gastrointestinal disorders	1 (0.00%)
Age-related macular degeneration	Eye disorders	1 (0.00%)
Agnosia	Nervous system disorders	1 (0.00%)
Agonal respiration	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Agranulocytosis	Blood and lymphatic system disorders	1 (0.00%)
Akinesia	Nervous system disorders	1 (0.00%)
Albumin CSF increased	Investigations	1 (0.00%)
Allergic gastroenteritis	Gastrointestinal disorders	1 (0.00%)
Allergic pharyngitis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Allergy to animal	Immune system disorders	1 (0.00%)
Allergy to arthropod sting	Immune system disorders	1 (0.00%)
Allergy to metals	Immune system disorders	1 (0.00%)
Alopecia universalis	Skin and subcutaneous tissue disorders	1 (0.00%)
Amaurosis	Eye disorders	1 (0.00%)
Amino acid level increased	Investigations	1 (0.00%)
Amnesic disorder	Nervous system disorders	1 (0.00%)
Amphetamines positive	Investigations	1 (0.00%)
Amputation stump pain	Nervous system disorders	1 (0.00%)
Amylase decreased	Investigations	1 (0.00%)
Amyloidosis senile	Immune system disorders	1 (0.00%)
Analgesic therapy	Surgical and medical procedures	1 (0.00%)
Anal hypoaesthesia	Gastrointestinal disorders	1 (0.00%)
Anal rash	Gastrointestinal disorders	1 (0.00%)
Anembryonic gestation	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Anencephaly	Congenital, familial and genetic disorders	1 (0.00%)
Aneurysmal bone cyst	Musculoskeletal and connective tissue disorders	1 (0.00%)
Angle closure glaucoma	Eye disorders	1 (0.00%)
Angular cheilitis	Gastrointestinal disorders	1 (0.00%)
Anisocytosis	Blood and lymphatic system disorders	1 (0.00%)
Ankyloglossia congenital	Congenital, familial and genetic disorders	1 (0.00%)
Anorgasmia	Psychiatric disorders	1 (0.00%)
Antibody test abnormal	Investigations	1 (0.00%)
Antibody test positive	Investigations	1 (0.00%)
Antineutrophil cytoplasmic antibody positive	Investigations	1 (0.00%)
Antinuclear antibody	Investigations	1 (0.00%)
Antinuclear antibody increased	Investigations	1 (0.00%)
Antisynthetase syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Anti-thyroid antibody positive	Investigations	1 (0.00%)
Aortic aneurysm rupture	Vascular disorders	1 (0.00%)
Aortic dilatation	Vascular disorders	1 (0.00%)
Aortic elongation	Vascular disorders	1 (0.00%)
Aortic rupture	Vascular disorders	1 (0.00%)
Aortic valve calcification	Cardiac disorders	1 (0.00%)
Aortic valve incompetence	Cardiac disorders	1 (0.00%)
Apical granuloma	Gastrointestinal disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Aplasia pure red cell	Blood and lymphatic system disorders	1 (0.00%)
Application site hyperaesthesia	General disorders and administration site conditions	1 (0.00%)
Application site hypoaesthesia	General disorders and administration site conditions	1 (0.00%)
Application site induration	General disorders and administration site conditions	1 (0.00%)
Application site oedema	General disorders and administration site conditions	1 (0.00%)
Application site swelling	General disorders and administration site conditions	1 (0.00%)
Application site warmth	General disorders and administration site conditions	1 (0.00%)
Aptyalism	Gastrointestinal disorders	1 (0.00%)
Arrested labour	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Arteriovenous fistula thrombosis	Injury, poisoning and procedural complications	1 (0.00%)
Arteriovenous malformation	Congenital, familial and genetic disorders	1 (0.00%)
Ascites	Gastrointestinal disorders	1 (0.00%)
Aspermia	Reproductive system and breast disorders	1 (0.00%)
Aspiration joint	Investigations	1 (0.00%)
Asymptomatic bacteriuria	Infections and infestations	1 (0.00%)
Atopy	Immune system disorders	1 (0.00%)
Atrial septal defect	Congenital, familial and genetic disorders	1 (0.00%)
Atrial thrombosis	Cardiac disorders	1 (0.00%)
Auricular swelling	Ear and labyrinth disorders	1 (0.00%)
Autoimmune anaemia	Blood and lymphatic system disorders	1 (0.00%)
Autoimmune arthritis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Autoimmune myocarditis	Cardiac disorders	1 (0.00%)
Autoimmune neuropathy	Nervous system disorders	1 (0.00%)
Autoimmune pancreatitis	Gastrointestinal disorders	1 (0.00%)
Autoimmune thyroid disorder	Endocrine disorders	1 (0.00%)
Autonomic neuropathy	Nervous system disorders	1 (0.00%)
Autoscopy	Psychiatric disorders	1 (0.00%)
Aversion	Psychiatric disorders	1 (0.00%)
Azotaemia	Renal and urinary disorders	1 (0.00%)
Bacterial sepsis	Infections and infestations	1 (0.00%)
Bacterial vaginosis	Infections and infestations	1 (0.00%)
Ballismus	Nervous system disorders	1 (0.00%)
Band sensation	Nervous system disorders	1 (0.00%)
Barotitis media	Injury, poisoning and procedural complications	1 (0.00%)
Basal cell carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Basal ganglia haematoma	Nervous system disorders	1 (0.00%)
Basal ganglia stroke	Nervous system disorders	1 (0.00%)
Bed rest	Surgical and medical procedures	1 (0.00%)
Benign hydatidiform mole	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Benign lymph node neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Bile duct cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Biliary dilatation	Hepatobiliary disorders	1 (0.00%)
Biliary sepsis	Infections and infestations	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Bilirubin conjugated increased	Investigations	1 (0.00%)
Biopsy muscle abnormal	Investigations	1 (0.00%)
Bladder dilatation	Renal and urinary disorders	1 (0.00%)
Bladder hypertrophy	Renal and urinary disorders	1 (0.00%)
Bladder irritation	Renal and urinary disorders	1 (0.00%)
Bladder spasm	Renal and urinary disorders	1 (0.00%)
Bleeding varicose vein	Vascular disorders	1 (0.00%)
Blindness cortical	Eye disorders	1 (0.00%)
Blister rupture	Skin and subcutaneous tissue disorders	1 (0.00%)
Block vertebra	Congenital, familial and genetic disorders	1 (0.00%)
Blood albumin increased	Investigations	1 (0.00%)
Blood alcohol decreased	Investigations	1 (0.00%)
Blood bilirubin abnormal	Investigations	1 (0.00%)
Blood calcium increased	Investigations	1 (0.00%)
Blood cholesterol decreased	Investigations	1 (0.00%)
Blood count	Investigations	1 (0.00%)
Blood creatine increased	Investigations	1 (0.00%)
Blood creatine phosphokinase MB increased	Investigations	1 (0.00%)
Blood creatinine abnormal	Investigations	1 (0.00%)
Blood electrolytes decreased	Investigations	1 (0.00%)
Blood fibrinogen decreased	Investigations	1 (0.00%)
Blood folate decreased	Investigations	1 (0.00%)
Blood follicle stimulating hormone increased	Investigations	1 (0.00%)
Blood glucose	Investigations	1 (0.00%)
Blood immunoglobulin M decreased	Investigations	1 (0.00%)
Blood ketone body	Investigations	1 (0.00%)
Blood magnesium decreased	Investigations	1 (0.00%)
Blood magnesium increased	Investigations	1 (0.00%)
Blood osmolality increased	Investigations	1 (0.00%)
Blood parathyroid hormone decreased	Investigations	1 (0.00%)
Blood pH abnormal	Investigations	1 (0.00%)
Blood pH increased	Investigations	1 (0.00%)
Blood pressure normal	Investigations	1 (0.00%)
Blood pressure orthostatic abnormal	Investigations	1 (0.00%)
Blood pressure orthostatic decreased	Investigations	1 (0.00%)
Blood prolactin increased	Investigations	1 (0.00%)
Blood test	Investigations	1 (0.00%)
Blood thyroid stimulating hormone abnormal	Investigations	1 (0.00%)
Blood zinc decreased	Investigations	1 (0.00%)
B-lymphocyte abnormalities	Blood and lymphatic system disorders	1 (0.00%)
Body mass index increased	Investigations	1 (0.00%)
Bone contusion	Injury, poisoning and procedural complications	1 (0.00%)
Bone neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Booster dose missed	Injury, poisoning and procedural complications	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Brachial plexopathy	Nervous system disorders	1 (0.00%)
Brachiocephalic vein thrombosis	Vascular disorders	1 (0.00%)
Bradyarrhythmia	Cardiac disorders	1 (0.00%)
Brain contusion	Injury, poisoning and procedural complications	1 (0.00%)
Brain neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Breakthrough pain	General disorders and administration site conditions	1 (0.00%)
Breast cancer recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Breast cancer stage I	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Breast cellulitis	Infections and infestations	1 (0.00%)
Breast enlargement	Reproductive system and breast disorders	1 (0.00%)
Breast induration	Reproductive system and breast disorders	1 (0.00%)
Bronchial irritation	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Bronchial neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Bronchial wall thickening	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Bronchitis bacterial	Infections and infestations	1 (0.00%)
Brown-Sequard syndrome	Nervous system disorders	1 (0.00%)
Bulbar palsy	Nervous system disorders	1 (0.00%)
Bullous haemorrhagic dermatosis	Skin and subcutaneous tissue disorders	1 (0.00%)
Burning feet syndrome	Nervous system disorders	1 (0.00%)
Burn oral cavity	Injury, poisoning and procedural complications	1 (0.00%)
Burnout syndrome	Psychiatric disorders	1 (0.00%)
Bursal haematoma	Musculoskeletal and connective tissue disorders	1 (0.00%)
Calcinosis	General disorders and administration site conditions	1 (0.00%)
Calcium ionised decreased	Investigations	1 (0.00%)
Calculus bladder	Renal and urinary disorders	1 (0.00%)
Calculus urinary	Renal and urinary disorders	1 (0.00%)
Campocormia	Musculoskeletal and connective tissue disorders	1 (0.00%)
Campylobacter gastroenteritis	Infections and infestations	1 (0.00%)
Campylobacter infection	Infections and infestations	1 (0.00%)
Capillary leak syndrome	Vascular disorders	1 (0.00%)
Capsular contracture associated with breast implant	General disorders and administration site conditions	1 (0.00%)
Carcinoembryonic antigen increased	Investigations	1 (0.00%)
Cardiac procedure complication	Injury, poisoning and procedural complications	1 (0.00%)
Cardiospasm	Gastrointestinal disorders	1 (0.00%)
Cardiovascular symptom	Cardiac disorders	1 (0.00%)
Cardioversion	Surgical and medical procedures	1 (0.00%)
Carotid bruit	Investigations	1 (0.00%)
Cartilage injury	Injury, poisoning and procedural complications	1 (0.00%)
Castleman's disease	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Catatonia	Psychiatric disorders	1 (0.00%)
Cauda equina syndrome	Nervous system disorders	1 (0.00%)
CD4 lymphocytes increased	Investigations	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Cerebellar embolism	Nervous system disorders	1 (0.00%)
Cerebral congestion	Nervous system disorders	1 (0.00%)
Cerebral cyst	Nervous system disorders	1 (0.00%)
Cerebral mass effect	Nervous system disorders	1 (0.00%)
Cerebral vascular occlusion	Nervous system disorders	1 (0.00%)
Cerebral ventricular rupture	Nervous system disorders	1 (0.00%)
Cerebrovascular insufficiency	Nervous system disorders	1 (0.00%)
Cervical incompetence	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Cervical spinal stenosis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Cervical vertebral fracture	Injury, poisoning and procedural complications	1 (0.00%)
Cervicogenic headache	Nervous system disorders	1 (0.00%)
Cervicogenic vertigo	Nervous system disorders	1 (0.00%)
Chest crushing	Injury, poisoning and procedural complications	1 (0.00%)
Cholangitis	Hepatobiliary disorders	1 (0.00%)
Cholecystitis acute	Hepatobiliary disorders	1 (0.00%)
Cholinergic syndrome	Nervous system disorders	1 (0.00%)
Choluria	Renal and urinary disorders	1 (0.00%)
Chondrocalcinosis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Chorea	Nervous system disorders	1 (0.00%)
Chorioretinitis	Infections and infestations	1 (0.00%)
Chorioretinopathy	Eye disorders	1 (0.00%)
Choroidal neovascularisation	Eye disorders	1 (0.00%)
Chromatopsia	Eye disorders	1 (0.00%)
Chronic idiopathic pain syndrome	Psychiatric disorders	1 (0.00%)
Chronic inflammatory demyelinating polyradiculoneuropathy	Nervous system disorders	1 (0.00%)
Chronic lymphocytic leukaemia recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Chronic respiratory disease	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Chronic spontaneous urticaria	Skin and subcutaneous tissue disorders	1 (0.00%)
Circadian rhythm sleep disorder	Nervous system disorders	1 (0.00%)
Claudication of jaw muscles	Vascular disorders	1 (0.00%)
Claustrophobia	Psychiatric disorders	1 (0.00%)
Clavicle fracture	Injury, poisoning and procedural complications	1 (0.00%)
Cleft palate	Congenital, familial and genetic disorders	1 (0.00%)
Clinically isolated syndrome	Nervous system disorders	1 (0.00%)
Clostridial infection	Infections and infestations	1 (0.00%)
Clostridium difficile colitis	Infections and infestations	1 (0.00%)
Clostridium test positive	Investigations	1 (0.00%)
Coagulation factor increased	Investigations	1 (0.00%)
Coagulation factor VIII level increased	Investigations	1 (0.00%)
Coagulation test abnormal	Investigations	1 (0.00%)
Coagulation time prolonged	Investigations	1 (0.00%)
Coagulation time shortened	Investigations	1 (0.00%)
Coccidioidomycosis	Infections and infestations	1 (0.00%)
Cogwheel rigidity	Nervous system disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Coital bleeding	Reproductive system and breast disorders	1 (0.00%)
Cold burn	Injury, poisoning and procedural complications	1 (0.00%)
Cold urticaria	Skin and subcutaneous tissue disorders	1 (0.00%)
Complement factor C1 increased	Investigations	1 (0.00%)
Complement factor C3 increased	Investigations	1 (0.00%)
Complement factor increased	Investigations	1 (0.00%)
Complex regional pain syndrome	Nervous system disorders	1 (0.00%)
Complications of transplanted kidney	Injury, poisoning and procedural complications	1 (0.00%)
Compression fracture	Injury, poisoning and procedural complications	1 (0.00%)
Concentric sclerosis	Nervous system disorders	1 (0.00%)
Concomitant disease aggravated	General disorders and administration site conditions	1 (0.00%)
Conduction disorder	Cardiac disorders	1 (0.00%)
Conductive deafness	Ear and labyrinth disorders	1 (0.00%)
Congenital absence of cranial vault	Congenital, familial and genetic disorders	1 (0.00%)
Congenital anomaly	Congenital, familial and genetic disorders	1 (0.00%)
Congestive cardiomyopathy	Cardiac disorders	1 (0.00%)
Conjunctival disorder	Eye disorders	1 (0.00%)
Conjunctival irritation	Eye disorders	1 (0.00%)
Conjunctivitis bacterial	Infections and infestations	1 (0.00%)
Connective tissue disorder	Musculoskeletal and connective tissue disorders	1 (0.00%)
Contraindicated product prescribed	Injury, poisoning and procedural complications	1 (0.00%)
Contraindication to vaccination	Social circumstances	1 (0.00%)
Convulsions local	Nervous system disorders	1 (0.00%)
Coombs negative haemolytic anaemia	Blood and lymphatic system disorders	1 (0.00%)
Coprolalia	Psychiatric disorders	1 (0.00%)
Corneal opacity	Eye disorders	1 (0.00%)
Coronary artery dissection	Cardiac disorders	1 (0.00%)
Cor pulmonale acute	Cardiac disorders	1 (0.00%)
Cough decreased	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Counterfeit product administered	Injury, poisoning and procedural complications	1 (0.00%)
Cranial nerve injury	Injury, poisoning and procedural complications	1 (0.00%)
Cranial nerve neoplasm benign	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Cranial nerve palsies multiple	Nervous system disorders	1 (0.00%)
C-reactive protein decreased	Investigations	1 (0.00%)
Creatinine renal clearance decreased	Investigations	1 (0.00%)
Croup infectious	Infections and infestations	1 (0.00%)
Cryoglobulins present	Investigations	1 (0.00%)
CSF glucose increased	Investigations	1 (0.00%)
Cubital tunnel syndrome	Nervous system disorders	1 (0.00%)
Cutaneous T-cell lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Cyanopsia	Eye disorders	1 (0.00%)
Cystitis bacterial	Infections and infestations	1 (0.00%)
Cystitis haemorrhagic	Renal and urinary disorders	1 (0.00%)
Cytogenetic analysis abnormal	Investigations	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Cytomegalovirus infection	Infections and infestations	1 (0.00%)
Dacryocystitis	Infections and infestations	1 (0.00%)
Dairy intolerance	Metabolism and nutrition disorders	1 (0.00%)
Daydreaming	Psychiatric disorders	1 (0.00%)
Deafness transitory	Ear and labyrinth disorders	1 (0.00%)
Decreased insulin requirement	Metabolism and nutrition disorders	1 (0.00%)
Defect conduction intraventricular	Cardiac disorders	1 (0.00%)
Degenerative bone disease	Musculoskeletal and connective tissue disorders	1 (0.00%)
Degenerative mitral valve disease	Cardiac disorders	1 (0.00%)
Delayed ischaemic neurological deficit	Nervous system disorders	1 (0.00%)
Delayed recovery from anaesthesia	Injury, poisoning and procedural complications	1 (0.00%)
Delirium febrile	Psychiatric disorders	1 (0.00%)
Delusional disorder, unspecified type	Psychiatric disorders	1 (0.00%)
Demyelinating polyneuropathy	Nervous system disorders	1 (0.00%)
Dental caries	Gastrointestinal disorders	1 (0.00%)
Dental dysaesthesia	Gastrointestinal disorders	1 (0.00%)
Dental restoration failure	Injury, poisoning and procedural complications	1 (0.00%)
Depression suicidal	Psychiatric disorders	1 (0.00%)
Dermatologic examination abnormal	Investigations	1 (0.00%)
Detachment of retinal pigment epithelium	Eye disorders	1 (0.00%)
Device connection issue	Product issues	1 (0.00%)
Device related thrombosis	General disorders and administration site conditions	1 (0.00%)
Diabetic hyperosmolar coma	Nervous system disorders	1 (0.00%)
Diabetic metabolic decompensation	Metabolism and nutrition disorders	1 (0.00%)
Diabetic nephropathy	Renal and urinary disorders	1 (0.00%)
Diaphragmatic disorder	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Diet refusal	Metabolism and nutrition disorders	1 (0.00%)
Diffuse alveolar damage	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Discouragement	Psychiatric disorders	1 (0.00%)
Disseminated Bacillus Calmette-Guerin infection	Infections and infestations	1 (0.00%)
Disseminated varicella zoster vaccine virus infection	Infections and infestations	1 (0.00%)
Diverticulitis intestinal haemorrhagic	Infections and infestations	1 (0.00%)
Diverticulum intestinal	Gastrointestinal disorders	1 (0.00%)
Diverticulum intestinal haemorrhagic	Gastrointestinal disorders	1 (0.00%)
Double stranded DNA antibody positive	Investigations	1 (0.00%)
Drop attacks	Nervous system disorders	1 (0.00%)
Drowning	General disorders and administration site conditions	1 (0.00%)
Drug abuser	Social circumstances	1 (0.00%)
Drug effective for unapproved indication	General disorders and administration site conditions	1 (0.00%)
Drug-induced liver injury	Hepatobiliary disorders	1 (0.00%)
Dry lung syndrome	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Duodenal ulcer	Gastrointestinal disorders	1 (0.00%)
Duodenogastric reflux	Gastrointestinal disorders	1 (0.00%)
Dyslexia	Nervous system disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Dyslipidaemia	Metabolism and nutrition disorders	1 (0.00%)
Dysmetria	Nervous system disorders	1 (0.00%)
Dyspnoea paroxysmal nocturnal	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Dyssomnia	Psychiatric disorders	1 (0.00%)
Echolalia	Psychiatric disorders	1 (0.00%)
Eczema eyelids	Eye disorders	1 (0.00%)
Eczema infantile	Skin and subcutaneous tissue disorders	1 (0.00%)
Ehlers-Danlos syndrome	Congenital, familial and genetic disorders	1 (0.00%)
Ejection fraction abnormal	Investigations	1 (0.00%)
Electric shock	Injury, poisoning and procedural complications	1 (0.00%)
Electrocardiogram P wave abnormal	Investigations	1 (0.00%)
Electrocardiogram QRS complex shortened	Investigations	1 (0.00%)
Electrocardiogram repolarisation abnormality	Investigations	1 (0.00%)
Electrocardiogram ST-T segment depression	Investigations	1 (0.00%)
Electroencephalogram abnormal	Investigations	1 (0.00%)
Embolic cerebellar infarction	Nervous system disorders	1 (0.00%)
Emergency care	Surgical and medical procedures	1 (0.00%)
Encephalitis brain stem	Infections and infestations	1 (0.00%)
Encephalitis viral	Infections and infestations	1 (0.00%)
Endocarditis bacterial	Infections and infestations	1 (0.00%)
Endocrine disorder	Endocrine disorders	1 (0.00%)
Endodontic procedure	Surgical and medical procedures	1 (0.00%)
Endolymphatic hydrops	Ear and labyrinth disorders	1 (0.00%)
Endometrial cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Endometritis	Infections and infestations	1 (0.00%)
Endophthalmitis	Infections and infestations	1 (0.00%)
Endothelial dysfunction	Vascular disorders	1 (0.00%)
Enterovesical fistula	Gastrointestinal disorders	1 (0.00%)
Enzyme level increased	Investigations	1 (0.00%)
Eosinophil count decreased	Investigations	1 (0.00%)
Eosinophil count increased	Investigations	1 (0.00%)
Eosinophilic oesophagitis	Gastrointestinal disorders	1 (0.00%)
Epididymal tenderness	Reproductive system and breast disorders	1 (0.00%)
Epidural haemorrhage	Injury, poisoning and procedural complications	1 (0.00%)
Epinephrine increased	Investigations	1 (0.00%)
Epiploic appendagitis	Gastrointestinal disorders	1 (0.00%)
Episcleritis	Eye disorders	1 (0.00%)
Epstein-Barr virus antibody positive	Investigations	1 (0.00%)
Epstein-Barr virus test positive	Investigations	1 (0.00%)
Erythema induratum	Infections and infestations	1 (0.00%)
Erythema migrans	Infections and infestations	1 (0.00%)
Erythrodermic psoriasis	Skin and subcutaneous tissue disorders	1 (0.00%)
Erythromelalgia	Vascular disorders	1 (0.00%)
Erythrosis	Skin and subcutaneous tissue disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Escherichia pyelonephritis	Infections and infestations	1 (0.00%)
Essential tremor	Nervous system disorders	1 (0.00%)
Eustachian tube disorder	Ear and labyrinth disorders	1 (0.00%)
Eustachian tube obstruction	Ear and labyrinth disorders	1 (0.00%)
Exaggerated startle response	Nervous system disorders	1 (0.00%)
Excessive cerumen production	Ear and labyrinth disorders	1 (0.00%)
Excessive exercise	Social circumstances	1 (0.00%)
Excessive eye blinking	Eye disorders	1 (0.00%)
Exercise electrocardiogram abnormal	Investigations	1 (0.00%)
Exploding head syndrome	Psychiatric disorders	1 (0.00%)
Exposure via eye contact	Injury, poisoning and procedural complications	1 (0.00%)
Extensor plantar response	Nervous system disorders	1 (0.00%)
External ear disorder	Ear and labyrinth disorders	1 (0.00%)
External ear inflammation	Ear and labyrinth disorders	1 (0.00%)
External ear pain	Ear and labyrinth disorders	1 (0.00%)
Extraocular muscle disorder	Eye disorders	1 (0.00%)
Extraocular muscle paresis	Eye disorders	1 (0.00%)
Extravasation	General disorders and administration site conditions	1 (0.00%)
Eye allergy	Eye disorders	1 (0.00%)
Eye infarction	Eye disorders	1 (0.00%)
Eyelid bleeding	Eye disorders	1 (0.00%)
Eyelid haematoma	Eye disorders	1 (0.00%)
Eyelid infection	Infections and infestations	1 (0.00%)
Eyelid injury	Injury, poisoning and procedural complications	1 (0.00%)
Eyelid sensory disorder	Eye disorders	1 (0.00%)
Eyelid skin dryness	Eye disorders	1 (0.00%)
Eye symptom	Eye disorders	1 (0.00%)
Eye ulcer	Eye disorders	1 (0.00%)
Facet joint syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Factor VIII deficiency	Congenital, familial and genetic disorders	1 (0.00%)
Faecal calprotectin decreased	Investigations	1 (0.00%)
Faecal volume decreased	Investigations	1 (0.00%)
Faecal vomiting	Gastrointestinal disorders	1 (0.00%)
Faeces hard	Gastrointestinal disorders	1 (0.00%)
Failure to thrive	Metabolism and nutrition disorders	1 (0.00%)
Familial mediterranean fever	Congenital, familial and genetic disorders	1 (0.00%)
Fasciitis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Fear of falling	Psychiatric disorders	1 (0.00%)
Fear-related avoidance of activities	Psychiatric disorders	1 (0.00%)
Febrile bone marrow aplasia	Blood and lymphatic system disorders	1 (0.00%)
Febrile infection	Infections and infestations	1 (0.00%)
Feeding intolerance	Metabolism and nutrition disorders	1 (0.00%)
Fever neonatal	General disorders and administration site conditions	1 (0.00%)
Fibrinolysis abnormal	Investigations	1 (0.00%)
Fibroblast growth factor 23	Investigations	1 (0.00%)
Fibroblast growth factor 23 increased	Investigations	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Fibromuscular dysplasia	Vascular disorders	1 (0.00%)
Fibrosis	General disorders and administration site conditions	1 (0.00%)
Fingerprint loss	Skin and subcutaneous tissue disorders	1 (0.00%)
Flea infestation	Infections and infestations	1 (0.00%)
Focal dyscognitive seizures	Nervous system disorders	1 (0.00%)
Foetal cystic hygroma	Congenital, familial and genetic disorders	1 (0.00%)
Foetal exposure during pregnancy	Injury, poisoning and procedural complications	1 (0.00%)
Foetal heart rate disorder	Cardiac disorders	1 (0.00%)
Foetal hypokinesia	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Follicular lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Foot deformity	Musculoskeletal and connective tissue disorders	1 (0.00%)
Forced expiratory flow	Investigations	1 (0.00%)
Foreign body in respiratory tract	Injury, poisoning and procedural complications	1 (0.00%)
Foreign body in throat	Injury, poisoning and procedural complications	1 (0.00%)
Foreign body in urogenital tract	Injury, poisoning and procedural complications	1 (0.00%)
Foreign body reaction	General disorders and administration site conditions	1 (0.00%)
Fracture pain	Musculoskeletal and connective tissue disorders	1 (0.00%)
Full blood count abnormal	Investigations	1 (0.00%)
Fumbling	Nervous system disorders	1 (0.00%)
Gait deviation	General disorders and administration site conditions	1 (0.00%)
Galactorrhoea	Reproductive system and breast disorders	1 (0.00%)
Gallbladder enlargement	Hepatobiliary disorders	1 (0.00%)
Gastric haemorrhage	Gastrointestinal disorders	1 (0.00%)
Gastric pH decreased	Investigations	1 (0.00%)
Gastrointestinal bacterial infection	Infections and infestations	1 (0.00%)
Gastrointestinal hypermotility	Gastrointestinal disorders	1 (0.00%)
Gastrointestinal hypomotility	Gastrointestinal disorders	1 (0.00%)
Generalised onset non-motor seizure	Nervous system disorders	1 (0.00%)
Genital lesion	Reproductive system and breast disorders	1 (0.00%)
Genital ulceration	Reproductive system and breast disorders	1 (0.00%)
Gilbert's syndrome	Congenital, familial and genetic disorders	1 (0.00%)
Gingival discolouration	Gastrointestinal disorders	1 (0.00%)
Gingival hypertrophy	Gastrointestinal disorders	1 (0.00%)
Glassy eyes	General disorders and administration site conditions	1 (0.00%)
Glioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Glomerulonephritis	Renal and urinary disorders	1 (0.00%)
Glomerulonephritis chronic	Renal and urinary disorders	1 (0.00%)
Glucose urine present	Investigations	1 (0.00%)
Gluten sensitivity	Metabolism and nutrition disorders	1 (0.00%)
Glycosylated haemoglobin decreased	Investigations	1 (0.00%)
Granulocytopenia	Blood and lymphatic system disorders	1 (0.00%)
Granulomatosis with polyangiitis	Vascular disorders	1 (0.00%)
Granulomatous liver disease	Hepatobiliary disorders	1 (0.00%)
Gravitational oedema	General disorders and administration site conditions	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Gross motor delay	Nervous system disorders	1 (0.00%)
Growing pains	Musculoskeletal and connective tissue disorders	1 (0.00%)
Grunting	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Gun shot wound	Injury, poisoning and procedural complications	1 (0.00%)
Gynaecomastia	Reproductive system and breast disorders	1 (0.00%)
Habit cough	Psychiatric disorders	1 (0.00%)
Haemangioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Haemangioma of liver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Haematology test abnormal	Investigations	1 (0.00%)
Haematospermia	Reproductive system and breast disorders	1 (0.00%)
Haemoconcentration	Blood and lymphatic system disorders	1 (0.00%)
Haemoglobin abnormal	Investigations	1 (0.00%)
Haemoglobinaemia	Blood and lymphatic system disorders	1 (0.00%)
Haemoglobin increased	Investigations	1 (0.00%)
Haemoglobin urine present	Investigations	1 (0.00%)
Haemolytic uraemic syndrome	Blood and lymphatic system disorders	1 (0.00%)
Haemophagocytic lymphohistiocytosis	Immune system disorders	1 (0.00%)
Haemorrhagic fever with renal syndrome	Infections and infestations	1 (0.00%)
Haemorrhagic infarction	Vascular disorders	1 (0.00%)
Hair colour changes	Skin and subcutaneous tissue disorders	1 (0.00%)
Hair disorder	Skin and subcutaneous tissue disorders	1 (0.00%)
Hair dye user	Social circumstances	1 (0.00%)
Hair injury	Injury, poisoning and procedural complications	1 (0.00%)
Hallucinations, mixed	Psychiatric disorders	1 (0.00%)
Hand deformity	Musculoskeletal and connective tissue disorders	1 (0.00%)
Hand fracture	Injury, poisoning and procedural complications	1 (0.00%)
Heart valve incompetence	Cardiac disorders	1 (0.00%)
Heat exhaustion	Injury, poisoning and procedural complications	1 (0.00%)
Heat illness	Injury, poisoning and procedural complications	1 (0.00%)
Heat oedema	Injury, poisoning and procedural complications	1 (0.00%)
Helplessness	Psychiatric disorders	1 (0.00%)
Hemianopia homonymous	Nervous system disorders	1 (0.00%)
Hemidysaesthesia	Nervous system disorders	1 (0.00%)
Hemihyperaesthesia	Nervous system disorders	1 (0.00%)
Hepatic cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Hepatic cirrhosis	Hepatobiliary disorders	1 (0.00%)
Hepatic cyst	Hepatobiliary disorders	1 (0.00%)
Hepatic encephalopathy	Nervous system disorders	1 (0.00%)
Hepatic haemorrhage	Hepatobiliary disorders	1 (0.00%)
Hepatic lesion	Hepatobiliary disorders	1 (0.00%)
Hepatic mass	Hepatobiliary disorders	1 (0.00%)
Hepatic vascular thrombosis	Hepatobiliary disorders	1 (0.00%)
Hepatitis cholestatic	Hepatobiliary disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Hepatocellular carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Hepatorenal syndrome	Hepatobiliary disorders	1 (0.00%)
Herpes dermatitis	Infections and infestations	1 (0.00%)
Herpes simplex gastritis	Infections and infestations	1 (0.00%)
Herpes simplex meningoencephalitis	Infections and infestations	1 (0.00%)
Herpes simplex reactivation	Infections and infestations	1 (0.00%)
Herpes zoster meningoencephalitis	Infections and infestations	1 (0.00%)
High density lipoprotein increased	Investigations	1 (0.00%)
High risk pregnancy	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Hirsutism	Skin and subcutaneous tissue disorders	1 (0.00%)
Histiocytosis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
HIV infection	Infections and infestations	1 (0.00%)
HIV test false positive	Investigations	1 (0.00%)
HIV test positive	Investigations	1 (0.00%)
Hodgkin's disease	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Homicidal ideation	Psychiatric disorders	1 (0.00%)
Horner's syndrome	Nervous system disorders	1 (0.00%)
Hostility	Psychiatric disorders	1 (0.00%)
Human chorionic gonadotropin increased	Investigations	1 (0.00%)
Human herpesvirus 6 infection	Infections and infestations	1 (0.00%)
Huntington's disease	Congenital, familial and genetic disorders	1 (0.00%)
Hydrocholecystis	Hepatobiliary disorders	1 (0.00%)
Hydrothorax	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Hyperaesthesia eye	Eye disorders	1 (0.00%)
Hyperaldosteronism	Endocrine disorders	1 (0.00%)
Hypercapnic coma	Nervous system disorders	1 (0.00%)
Hyper eosinophilic syndrome	Blood and lymphatic system disorders	1 (0.00%)
Hyperexplexia	Congenital, familial and genetic disorders	1 (0.00%)
Hypergammaglobulinaemia	Blood and lymphatic system disorders	1 (0.00%)
Hypergammaglobulinaemia benign monoclonal	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Hypergeusia	Nervous system disorders	1 (0.00%)
Hyperhomocysteinaemia	Metabolism and nutrition disorders	1 (0.00%)
Hyperintensity in brain deep nuclei	Nervous system disorders	1 (0.00%)
Hypermetropia	Eye disorders	1 (0.00%)
Hypermobility syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Hyperoxia	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Hyperparathyroidism	Endocrine disorders	1 (0.00%)
Hyperpathia	Nervous system disorders	1 (0.00%)
Hyperphagia	Metabolism and nutrition disorders	1 (0.00%)
Hyperresponsive to stimuli	Nervous system disorders	1 (0.00%)
Hypersensitivity pneumonitis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Hypersexuality	Psychiatric disorders	1 (0.00%)
Hypersomnia-bulimia syndrome	Psychiatric disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Hypertensive heart disease	Cardiac disorders	1 (0.00%)
Hypertensive urgency	Vascular disorders	1 (0.00%)
Hypertonic bladder	Renal and urinary disorders	1 (0.00%)
Hypertransaminasaemia	Hepatobiliary disorders	1 (0.00%)
Hypertrophic cardiomyopathy	Congenital, familial and genetic disorders	1 (0.00%)
Hypervigilance	Psychiatric disorders	1 (0.00%)
Hypnopompic hallucination	Psychiatric disorders	1 (0.00%)
Hypocapnia	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Hypochromasia	Blood and lymphatic system disorders	1 (0.00%)
Hypoglycaemic unconsciousness	Nervous system disorders	1 (0.00%)
Hypomagnesaemia	Metabolism and nutrition disorders	1 (0.00%)
Hypoperfusion	Vascular disorders	1 (0.00%)
Hypophosphataemia	Metabolism and nutrition disorders	1 (0.00%)
Hypoproteinaemia	Metabolism and nutrition disorders	1 (0.00%)
Hypotensive crisis	Vascular disorders	1 (0.00%)
Hypovitaminosis	Metabolism and nutrition disorders	1 (0.00%)
Hypoxic-ischaemic encephalopathy	Nervous system disorders	1 (0.00%)
Hysteroscopy	Investigations	1 (0.00%)
Idiopathic angioedema	Skin and subcutaneous tissue disorders	1 (0.00%)
Idiopathic pulmonary fibrosis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Idiopathic urticaria	Skin and subcutaneous tissue disorders	1 (0.00%)
Idiosyncratic drug reaction	General disorders and administration site conditions	1 (0.00%)
Ilird nerve paresis	Nervous system disorders	1 (0.00%)
Ileal perforation	Gastrointestinal disorders	1 (0.00%)
Iliac bruit	Investigations	1 (0.00%)
Ill-defined disorder	General disorders and administration site conditions	1 (0.00%)
Imaging procedure abnormal	Investigations	1 (0.00%)
Immobilisation prolonged	Social circumstances	1 (0.00%)
Immobilisation syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Immune-mediated neuropathy	Nervous system disorders	1 (0.00%)
Immune reconstitution inflammatory syndrome	Immune system disorders	1 (0.00%)
Immunisation	Surgical and medical procedures	1 (0.00%)
Immunisation anxiety related reaction	Psychiatric disorders	1 (0.00%)
Immunodeficiency common variable	Immune system disorders	1 (0.00%)
Immunoglobulin G4 related disease	Musculoskeletal and connective tissue disorders	1 (0.00%)
Immunology test	Investigations	1 (0.00%)
Immunosuppression	Immune system disorders	1 (0.00%)
Impaired fasting glucose	Metabolism and nutrition disorders	1 (0.00%)
Impatience	Psychiatric disorders	1 (0.00%)
Implant site pain	General disorders and administration site conditions	1 (0.00%)
Implant site swelling	General disorders and administration site conditions	1 (0.00%)
Inappropriate affect	Psychiatric disorders	1 (0.00%)
Increased insulin requirement	Metabolism and nutrition disorders	1 (0.00%)
Increased viscosity of bronchial secretion	Respiratory, thoracic and mediastinal disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Increased viscosity of upper respiratory secretion	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Indifference	Psychiatric disorders	1 (0.00%)
Infected cyst	Infections and infestations	1 (0.00%)
Infection reactivation	Infections and infestations	1 (0.00%)
Infection susceptibility increased	Infections and infestations	1 (0.00%)
Infective pericardial effusion	Infections and infestations	1 (0.00%)
Infective spondylitis	Infections and infestations	1 (0.00%)
Inflammatory carcinoma of the breast	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Ingrown hair	Skin and subcutaneous tissue disorders	1 (0.00%)
Inguinal hernia	Gastrointestinal disorders	1 (0.00%)
Inhibitory drug interaction	General disorders and administration site conditions	1 (0.00%)
Injection site cellulitis	Infections and infestations	1 (0.00%)
Injection site extravasation	General disorders and administration site conditions	1 (0.00%)
Injection site hypersensitivity	General disorders and administration site conditions	1 (0.00%)
Injection site indentation	General disorders and administration site conditions	1 (0.00%)
Injection site induration	General disorders and administration site conditions	1 (0.00%)
Injection site infection	Infections and infestations	1 (0.00%)
Injection site joint erythema	General disorders and administration site conditions	1 (0.00%)
Injection site joint pain	General disorders and administration site conditions	1 (0.00%)
Injection site scab	General disorders and administration site conditions	1 (0.00%)
Injection site urticaria	General disorders and administration site conditions	1 (0.00%)
Injury associated with device	General disorders and administration site conditions	1 (0.00%)
Inspiratory capacity abnormal	Investigations	1 (0.00%)
Instillation site warmth	General disorders and administration site conditions	1 (0.00%)
Insulin resistant diabetes	Metabolism and nutrition disorders	1 (0.00%)
Intellectual disability	Nervous system disorders	1 (0.00%)
Intentional product misuse	Injury, poisoning and procedural complications	1 (0.00%)
Intentional self-injury	Psychiatric disorders	1 (0.00%)
Intention tremor	Nervous system disorders	1 (0.00%)
International normalised ratio fluctuation	Investigations	1 (0.00%)
Intertrigo	Skin and subcutaneous tissue disorders	1 (0.00%)
Intervertebral disc degeneration	Musculoskeletal and connective tissue disorders	1 (0.00%)
Intestinal angina	Gastrointestinal disorders	1 (0.00%)
Intestinal angioedema	Gastrointestinal disorders	1 (0.00%)
Intestinal perforation	Gastrointestinal disorders	1 (0.00%)
Intestinal ulcer	Gastrointestinal disorders	1 (0.00%)
Intra-abdominal haemorrhage	Gastrointestinal disorders	1 (0.00%)
Intracranial artery dissection	Nervous system disorders	1 (0.00%)
Intracranial hypotension	Nervous system disorders	1 (0.00%)
Intraocular pressure test abnormal	Investigations	1 (0.00%)
Invasive ductal breast carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Investigation abnormal	Investigations	1 (0.00%)
Iron binding capacity total abnormal	Investigations	1 (0.00%)
Ischaemic hepatitis	Hepatobiliary disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Jaw fracture	Injury, poisoning and procedural complications	1 (0.00%)
Joint adhesion	Musculoskeletal and connective tissue disorders	1 (0.00%)
Joint ankylosis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Joint contracture	Musculoskeletal and connective tissue disorders	1 (0.00%)
Joint microhaemorrhage	Musculoskeletal and connective tissue disorders	1 (0.00%)
Joint stabilisation	Surgical and medical procedures	1 (0.00%)
Kawasaki's disease	Vascular disorders	1 (0.00%)
Keratitis	Eye disorders	1 (0.00%)
Keratosis pilaris	Skin and subcutaneous tissue disorders	1 (0.00%)
Ketonuria	Renal and urinary disorders	1 (0.00%)
Klippel-Trenaunay syndrome	Congenital, familial and genetic disorders	1 (0.00%)
Koebner phenomenon	Skin and subcutaneous tissue disorders	1 (0.00%)
Labia enlarged	Reproductive system and breast disorders	1 (0.00%)
Labile hypertension	Vascular disorders	1 (0.00%)
Laboratory test interference	Investigations	1 (0.00%)
Lack of vaccination site rotation	Injury, poisoning and procedural complications	1 (0.00%)
Lacrimal disorder	Eye disorders	1 (0.00%)
Lacrimal structural disorder	Eye disorders	1 (0.00%)
Lactation disorder	Reproductive system and breast disorders	1 (0.00%)
Lacunar stroke	Nervous system disorders	1 (0.00%)
Lagophthalmos	Eye disorders	1 (0.00%)
Laryngeal obstruction	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Lead dislodgement	Product issues	1 (0.00%)
Learning disorder	Psychiatric disorders	1 (0.00%)
Lens disorder	Eye disorders	1 (0.00%)
Leukocyte alkaline phosphatase increased	Investigations	1 (0.00%)
Leukoencephalopathy	Nervous system disorders	1 (0.00%)
Libido increased	Psychiatric disorders	1 (0.00%)
Lichenoid keratosis	Skin and subcutaneous tissue disorders	1 (0.00%)
Lid sulcus deepened	Eye disorders	1 (0.00%)
Ligament disorder	Musculoskeletal and connective tissue disorders	1 (0.00%)
Ligament injury	Injury, poisoning and procedural complications	1 (0.00%)
Ligamentitis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Ligament pain	Musculoskeletal and connective tissue disorders	1 (0.00%)
Limb crushing injury	Injury, poisoning and procedural complications	1 (0.00%)
Limbic encephalitis	Nervous system disorders	1 (0.00%)
Lip haemorrhage	Gastrointestinal disorders	1 (0.00%)
Lip neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Lipoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Listeriosis	Infections and infestations	1 (0.00%)
Liver tenderness	Hepatobiliary disorders	1 (0.00%)
Lordosis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Lower motor neurone lesion	Nervous system disorders	1 (0.00%)
Lower respiratory tract infection bacterial	Infections and infestations	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Lumbar puncture	Investigations	1 (0.00%)
Lung carcinoma cell type unspecified recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Lung neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Lupus-like syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Lupus nephritis	Renal and urinary disorders	1 (0.00%)
Macular degeneration	Eye disorders	1 (0.00%)
Macular hole	Eye disorders	1 (0.00%)
Maculopathy	Eye disorders	1 (0.00%)
Madarosis	Skin and subcutaneous tissue disorders	1 (0.00%)
Magnetic resonance imaging head abnormal	Investigations	1 (0.00%)
Malabsorption	Gastrointestinal disorders	1 (0.00%)
Malignant hypertension	Vascular disorders	1 (0.00%)
Malignant melanoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Mallory-Weiss syndrome	Gastrointestinal disorders	1 (0.00%)
Malocclusion	Gastrointestinal disorders	1 (0.00%)
Mandibular mass	Musculoskeletal and connective tissue disorders	1 (0.00%)
Mastoiditis	Infections and infestations	1 (0.00%)
May-Thurner syndrome	Vascular disorders	1 (0.00%)
Mean platelet volume decreased	Investigations	1 (0.00%)
Mean platelet volume increased	Investigations	1 (0.00%)
Mechanic's hand	Skin and subcutaneous tissue disorders	1 (0.00%)
Meconium aspiration syndrome	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Medial tibial stress syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Mediastinal disorder	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Mediastinal mass	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Mediastinitis	Infections and infestations	1 (0.00%)
Medical induction of coma	Surgical and medical procedures	1 (0.00%)
Medication overuse headache	Nervous system disorders	1 (0.00%)
Melanocytic naevus	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Meningioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Meningitis bacterial	Infections and infestations	1 (0.00%)
Mesenteric arterial occlusion	Gastrointestinal disorders	1 (0.00%)
Mesenteric artery stenosis	Gastrointestinal disorders	1 (0.00%)
Mesenteric artery stent insertion	Surgical and medical procedures	1 (0.00%)
Mesenteric panniculitis	Gastrointestinal disorders	1 (0.00%)
Mesenteric vascular occlusion	Gastrointestinal disorders	1 (0.00%)
Metastases to lung	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Metastases to lymph nodes	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Microangiopathic haemolytic anaemia	Blood and lymphatic system disorders	1 (0.00%)
Microcytosis	Blood and lymphatic system disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Microscopic polyangiitis	Vascular disorders	1 (0.00%)
Middle ear disorder	Ear and labyrinth disorders	1 (0.00%)
Middle ear effusion	Ear and labyrinth disorders	1 (0.00%)
Mineral metabolism disorder	Metabolism and nutrition disorders	1 (0.00%)
Misleading laboratory test result	Investigations	1 (0.00%)
Mitral valve calcification	Cardiac disorders	1 (0.00%)
Mitral valve stenosis	Cardiac disorders	1 (0.00%)
Mixed connective tissue disease	Musculoskeletal and connective tissue disorders	1 (0.00%)
Mixed liver injury	Hepatobiliary disorders	1 (0.00%)
Moebius II syndrome	Congenital, familial and genetic disorders	1 (0.00%)
Monoclonal gammopathy	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Monocyte count increased	Investigations	1 (0.00%)
Morphoea	Musculoskeletal and connective tissue disorders	1 (0.00%)
Mouth cyst	Gastrointestinal disorders	1 (0.00%)
Mucocutaneous rash	Skin and subcutaneous tissue disorders	1 (0.00%)
Mucosal pain	General disorders and administration site conditions	1 (0.00%)
Multi-organ disorder	General disorders and administration site conditions	1 (0.00%)
Multiple allergies	Immune system disorders	1 (0.00%)
Multisystem inflammatory syndrome in children	Immune system disorders	1 (0.00%)
Muscle abscess	Infections and infestations	1 (0.00%)
Muscle contusion	Injury, poisoning and procedural complications	1 (0.00%)
Muscle hypertrophy	Musculoskeletal and connective tissue disorders	1 (0.00%)
Myalgia intercostal	Musculoskeletal and connective tissue disorders	1 (0.00%)
Myasthenia gravis crisis	Nervous system disorders	1 (0.00%)
Myelodysplastic syndrome	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Myeloid leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Myocardial calcification	Cardiac disorders	1 (0.00%)
Myocardial oedema	Cardiac disorders	1 (0.00%)
Myocardial rupture	Cardiac disorders	1 (0.00%)
Myoclonic epilepsy	Nervous system disorders	1 (0.00%)
Myofascial spasm	Musculoskeletal and connective tissue disorders	1 (0.00%)
Nail bed inflammation	Skin and subcutaneous tissue disorders	1 (0.00%)
Nail pigmentation	Skin and subcutaneous tissue disorders	1 (0.00%)
Nasal crusting	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Nasal disorder	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Nasal mucosal disorder	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Nasal odour	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Nasal turbinate hypertrophy	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Neck deformity	Musculoskeletal and connective tissue disorders	1 (0.00%)
Necrosis ischaemic	Vascular disorders	1 (0.00%)
Neonatal respiratory acidosis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Neoplasm skin	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Nephrogenic diabetes insipidus	Renal and urinary disorders	1 (0.00%)
Nerve block	Surgical and medical procedures	1 (0.00%)
Neurofibromatosis	Congenital, familial and genetic disorders	1 (0.00%)
Neuroleptic malignant syndrome	Nervous system disorders	1 (0.00%)
Neurological decompensation	Nervous system disorders	1 (0.00%)
Neurological infection	Infections and infestations	1 (0.00%)
Neurological procedural complication	Injury, poisoning and procedural complications	1 (0.00%)
Neuromyelitis optica spectrum disorder	Nervous system disorders	1 (0.00%)
Neuropathic muscular atrophy	Musculoskeletal and connective tissue disorders	1 (0.00%)
Neuropsychiatric symptoms	Psychiatric disorders	1 (0.00%)
Neurosensory hypoacusis	Ear and labyrinth disorders	1 (0.00%)
Neutrophil percentage increased	Investigations	1 (0.00%)
Nipple disorder	Reproductive system and breast disorders	1 (0.00%)
Nodular rash	Skin and subcutaneous tissue disorders	1 (0.00%)
Non-cardiac chest pain	General disorders and administration site conditions	1 (0.00%)
Non-Hodgkin's lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Noninfective conjunctivitis	Eye disorders	1 (0.00%)
Nonspecific reaction	General disorders and administration site conditions	1 (0.00%)
No reaction on previous exposure to drug	General disorders and administration site conditions	1 (0.00%)
Normal pressure hydrocephalus	Nervous system disorders	1 (0.00%)
Norovirus infection	Infections and infestations	1 (0.00%)
Nucleated red cells	Blood and lymphatic system disorders	1 (0.00%)
Obsessive-compulsive personality disorder	Psychiatric disorders	1 (0.00%)
Obstructive shock	Vascular disorders	1 (0.00%)
Occupational exposure to SARS-CoV-2	Injury, poisoning and procedural complications	1 (0.00%)
Ocular ischaemic syndrome	Eye disorders	1 (0.00%)
Oculofacial paralysis	Nervous system disorders	1 (0.00%)
Oculogyric crisis	Eye disorders	1 (0.00%)
Oedema genital	Reproductive system and breast disorders	1 (0.00%)
Oedematous pancreatitis	Gastrointestinal disorders	1 (0.00%)
Oesophageal discomfort	Gastrointestinal disorders	1 (0.00%)
Oesophageal disorder	Gastrointestinal disorders	1 (0.00%)
Oesophageal haemorrhage	Gastrointestinal disorders	1 (0.00%)
Oesophageal irritation	Gastrointestinal disorders	1 (0.00%)
Oesophageal oedema	Gastrointestinal disorders	1 (0.00%)
Oesophageal varices haemorrhage	Gastrointestinal disorders	1 (0.00%)
Oesophagitis	Gastrointestinal disorders	1 (0.00%)
Olfactory nerve disorder	Nervous system disorders	1 (0.00%)
Oligoarthritis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Oncologic complication	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Open angle glaucoma	Eye disorders	1 (0.00%)
Oppositional defiant disorder	Psychiatric disorders	1 (0.00%)
Optic atrophy	Eye disorders	1 (0.00%)
Optic neuropathy	Eye disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Oral contusion	Injury, poisoning and procedural complications	1 (0.00%)
Oral hyperaesthesia	Gastrointestinal disorders	1 (0.00%)
Oral infection	Infections and infestations	1 (0.00%)
Oral mucosal discolouration	Gastrointestinal disorders	1 (0.00%)
Oral mucosal roughening	Gastrointestinal disorders	1 (0.00%)
Orbital haematoma	Eye disorders	1 (0.00%)
Orbital oedema	Eye disorders	1 (0.00%)
Orbital swelling	Eye disorders	1 (0.00%)
Orchitis	Infections and infestations	1 (0.00%)
Organ failure	General disorders and administration site conditions	1 (0.00%)
Oropharyngeal oedema	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Oropharyngeal plaque	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Oropharyngeal spasm	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Orthostatic intolerance	Nervous system disorders	1 (0.00%)
Osteolysis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Osteomyelitis	Infections and infestations	1 (0.00%)
Otitis externa	Infections and infestations	1 (0.00%)
Otitis media acute	Infections and infestations	1 (0.00%)
Otolithiasis	Ear and labyrinth disorders	1 (0.00%)
Otorrhoea	Ear and labyrinth disorders	1 (0.00%)
Ovarian cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Ovarian cyst ruptured	Reproductive system and breast disorders	1 (0.00%)
Ovarian neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Ovulation delayed	Endocrine disorders	1 (0.00%)
Oxygen consumption decreased	Investigations	1 (0.00%)
Oxygen saturation	Investigations	1 (0.00%)
Oxygen saturation increased	Investigations	1 (0.00%)
Palatal ulcer	Gastrointestinal disorders	1 (0.00%)
Palate injury	Injury, poisoning and procedural complications	1 (0.00%)
Palmoplantar pustulosis	Skin and subcutaneous tissue disorders	1 (0.00%)
Pancreatic carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Pancreatic carcinoma metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Pancreatic cyst	Gastrointestinal disorders	1 (0.00%)
Pancreatic steatosis	Gastrointestinal disorders	1 (0.00%)
Pancreatitis chronic	Gastrointestinal disorders	1 (0.00%)
Pancreatitis haemorrhagic	Gastrointestinal disorders	1 (0.00%)
Pancreatitis necrotising	Gastrointestinal disorders	1 (0.00%)
Parainfluenzae virus infection	Infections and infestations	1 (0.00%)
Parapsoriasis	Skin and subcutaneous tissue disorders	1 (0.00%)
Parasympathetic nerve injury	Injury, poisoning and procedural complications	1 (0.00%)
Paresis cranial nerve	Nervous system disorders	1 (0.00%)
Parkinsonian gait	Nervous system disorders	1 (0.00%)
Paroxysmal atrioventricular block	Cardiac disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Paroxysmal sympathetic hyperactivity	Nervous system disorders	1 (0.00%)
Partial seizures with secondary generalisation	Nervous system disorders	1 (0.00%)
Parvovirus B19 test positive	Investigations	1 (0.00%)
Paternal exposure timing unspecified	Injury, poisoning and procedural complications	1 (0.00%)
Pathological fracture	Musculoskeletal and connective tissue disorders	1 (0.00%)
Patient-device incompatibility	Product issues	1 (0.00%)
Peau d'orange	Skin and subcutaneous tissue disorders	1 (0.00%)
Pelvic haematoma	Reproductive system and breast disorders	1 (0.00%)
Pelvic haemorrhage	Reproductive system and breast disorders	1 (0.00%)
Pelvic inflammatory disease	Infections and infestations	1 (0.00%)
Penile erythema	Reproductive system and breast disorders	1 (0.00%)
Penile haemorrhage	Reproductive system and breast disorders	1 (0.00%)
Penile oedema	Reproductive system and breast disorders	1 (0.00%)
Penile rash	Reproductive system and breast disorders	1 (0.00%)
Penile swelling	Reproductive system and breast disorders	1 (0.00%)
Pericardial haemorrhage	Cardiac disorders	1 (0.00%)
Perinatal depression	Psychiatric disorders	1 (0.00%)
Perineal pain	Reproductive system and breast disorders	1 (0.00%)
Perioral dermatitis	Skin and subcutaneous tissue disorders	1 (0.00%)
Periorbital infection	Infections and infestations	1 (0.00%)
Periorbital inflammation	Eye disorders	1 (0.00%)
Peripheral nerve lesion	Nervous system disorders	1 (0.00%)
Peripheral sensorimotor neuropathy	Nervous system disorders	1 (0.00%)
Periportal oedema	Hepatobiliary disorders	1 (0.00%)
Peritonsillar abscess	Infections and infestations	1 (0.00%)
Periventricular leukomalacia	Nervous system disorders	1 (0.00%)
Persecutory delusion	Psychiatric disorders	1 (0.00%)
Persistent genital arousal disorder	Nervous system disorders	1 (0.00%)
Personality disorder	Psychiatric disorders	1 (0.00%)
Pertussis	Infections and infestations	1 (0.00%)
Pharyngeal lesion	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Phobia	Psychiatric disorders	1 (0.00%)
Phobic postural vertigo	Ear and labyrinth disorders	1 (0.00%)
Phonophobia	Psychiatric disorders	1 (0.00%)
pH urine abnormal	Investigations	1 (0.00%)
Physical examination abnormal	Investigations	1 (0.00%)
Pituitary tumour	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Plasma cell leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Plasma cell myeloma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Platelet aggregation abnormal	Investigations	1 (0.00%)
Platelet disorder	Blood and lymphatic system disorders	1 (0.00%)
Platelet function test abnormal	Investigations	1 (0.00%)
Pleural rub	Respiratory, thoracic and mediastinal disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Pneumobilia	Hepatobiliary disorders	1 (0.00%)
Pneumocephalus	Injury, poisoning and procedural complications	1 (0.00%)
Pneumonia mycoplasmal	Infections and infestations	1 (0.00%)
Pneumonia pseudomonal	Infections and infestations	1 (0.00%)
Pneumonia respiratory syncytial viral	Infections and infestations	1 (0.00%)
Pneumonia streptococcal	Infections and infestations	1 (0.00%)
Pneumothorax spontaneous	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
PO2 decreased	Investigations	1 (0.00%)
PO2 increased	Investigations	1 (0.00%)
POEMS syndrome	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Poisoning	Injury, poisoning and procedural complications	1 (0.00%)
Polyneuropathy chronic	Nervous system disorders	1 (0.00%)
Polyneuropathy in malignant disease	Nervous system disorders	1 (0.00%)
Poor venous access	Vascular disorders	1 (0.00%)
Portal vein embolism	Hepatobiliary disorders	1 (0.00%)
Portal vein phlebitis	Hepatobiliary disorders	1 (0.00%)
Portosplenomesenteric venous thrombosis	Hepatobiliary disorders	1 (0.00%)
Post concussion syndrome	Injury, poisoning and procedural complications	1 (0.00%)
Post lumbar puncture syndrome	Injury, poisoning and procedural complications	1 (0.00%)
Postoperative wound infection	Infections and infestations	1 (0.00%)
Postpartum haemorrhage	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Post procedural infection	Infections and infestations	1 (0.00%)
Post thrombotic syndrome	Vascular disorders	1 (0.00%)
Posturing	Psychiatric disorders	1 (0.00%)
Post vaccination syndrome	Injury, poisoning and procedural complications	1 (0.00%)
Pre-eclampsia	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Pregnancy after post coital contraception	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Pregnancy with contraceptive device	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Pregnancy with implant contraceptive	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Premature labour	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Premature menarche	Endocrine disorders	1 (0.00%)
Premature menopause	Reproductive system and breast disorders	1 (0.00%)
Premature ovulation	Reproductive system and breast disorders	1 (0.00%)
Premature rupture of membranes	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Priapism	Reproductive system and breast disorders	1 (0.00%)
Primary cough headache	Nervous system disorders	1 (0.00%)
Primary hyperaldosteronism	Endocrine disorders	1 (0.00%)
Primary hyperthyroidism	Endocrine disorders	1 (0.00%)
Procalcitonin decreased	Investigations	1 (0.00%)
Procedural pain	Injury, poisoning and procedural complications	1 (0.00%)
Proctitis	Gastrointestinal disorders	1 (0.00%)
Proctitis haemorrhagic	Gastrointestinal disorders	1 (0.00%)
Product administration interrupted	Injury, poisoning and procedural complications	1 (0.00%)
Product colour issue	Product issues	1 (0.00%)
Product contamination	Product issues	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Product expiration date issue	Product issues	1 (0.00%)
Product label issue	Product issues	1 (0.00%)
Product packaging issue	Product issues	1 (0.00%)
Product packaging quantity issue	Product issues	1 (0.00%)
Product residue present	Investigations	1 (0.00%)
Product use in unapproved indication	Injury, poisoning and procedural complications	1 (0.00%)
Progressive macular hypomelanosis	Skin and subcutaneous tissue disorders	1 (0.00%)
Progressive multifocal leukoencephalopathy	Infections and infestations	1 (0.00%)
Prolonged expiration	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Prophylaxis of nausea and vomiting	Surgical and medical procedures	1 (0.00%)
Prostate cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Prostate examination abnormal	Investigations	1 (0.00%)
Prostate infection	Infections and infestations	1 (0.00%)
Prostatic disorder	Reproductive system and breast disorders	1 (0.00%)
Prostatomegaly	Reproductive system and breast disorders	1 (0.00%)
Protein C increased	Investigations	1 (0.00%)
Protein urine	Investigations	1 (0.00%)
Prothrombin level increased	Investigations	1 (0.00%)
Pseudofolliculitis	Skin and subcutaneous tissue disorders	1 (0.00%)
Pseudomembranous colitis	Infections and infestations	1 (0.00%)
Pseudomonal sepsis	Infections and infestations	1 (0.00%)
Psychiatric symptom	Psychiatric disorders	1 (0.00%)
Psychogenic pseudosyncope	Psychiatric disorders	1 (0.00%)
Psychological trauma	Psychiatric disorders	1 (0.00%)
Psychotic symptom	Psychiatric disorders	1 (0.00%)
Pudendal canal syndrome	Nervous system disorders	1 (0.00%)
Pulmonary air leakage	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary arterial pressure increased	Investigations	1 (0.00%)
Pulmonary cavitation	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary hypoperfusion	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulpitis dental	Infections and infestations	1 (0.00%)
Punctate keratitis	Eye disorders	1 (0.00%)
Puncture site bruise	General disorders and administration site conditions	1 (0.00%)
Puncture site erythema	General disorders and administration site conditions	1 (0.00%)
Pupillary disorder	Eye disorders	1 (0.00%)
Purpura non-thrombocytopenic	Blood and lymphatic system disorders	1 (0.00%)
Pustular psoriasis	Skin and subcutaneous tissue disorders	1 (0.00%)
Pyelitis	Infections and infestations	1 (0.00%)
Quadrantanopia	Nervous system disorders	1 (0.00%)
Radial nerve injury	Injury, poisoning and procedural complications	1 (0.00%)
Radial nerve palsy	Nervous system disorders	1 (0.00%)
Radiation injury	Injury, poisoning and procedural complications	1 (0.00%)
Radiation pneumonitis	Injury, poisoning and procedural complications	1 (0.00%)
Radius fracture	Injury, poisoning and procedural complications	1 (0.00%)
Rash maculovesicular	Skin and subcutaneous tissue disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Rash neonatal	Skin and subcutaneous tissue disorders	1 (0.00%)
Rash papulosquamous	Skin and subcutaneous tissue disorders	1 (0.00%)
Rash rubelliform	Skin and subcutaneous tissue disorders	1 (0.00%)
Reaction to preservatives	Immune system disorders	1 (0.00%)
Red blood cell abnormality	Blood and lymphatic system disorders	1 (0.00%)
Red blood cell count abnormal	Investigations	1 (0.00%)
Red blood cells urine positive	Investigations	1 (0.00%)
Red cell distribution width increased	Investigations	1 (0.00%)
Regurgitation	Gastrointestinal disorders	1 (0.00%)
Renal injury	Renal and urinary disorders	1 (0.00%)
Renal ischaemia	Renal and urinary disorders	1 (0.00%)
Renal tubular necrosis	Renal and urinary disorders	1 (0.00%)
Repetitive speech	Nervous system disorders	1 (0.00%)
Respiratory depression	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Respiratory muscle weakness	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Respiratory rate	Investigations	1 (0.00%)
Restrictive cardiomyopathy	Cardiac disorders	1 (0.00%)
Resuscitation	Surgical and medical procedures	1 (0.00%)
Retinal aneurysm	Eye disorders	1 (0.00%)
Retinal infarction	Eye disorders	1 (0.00%)
Retinal injury	Injury, poisoning and procedural complications	1 (0.00%)
Retinal pigment epitheliopathy	Eye disorders	1 (0.00%)
Retinal vascular occlusion	Eye disorders	1 (0.00%)
Retinogram abnormal	Investigations	1 (0.00%)
Retrograde amnesia	Nervous system disorders	1 (0.00%)
Retroperitoneal lymphadenopathy	Blood and lymphatic system disorders	1 (0.00%)
Retroplacental haematoma	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Reversed hot-cold sensation	Nervous system disorders	1 (0.00%)
Reversible cerebral vasoconstriction syndrome	Nervous system disorders	1 (0.00%)
Reynold's syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Rheumatoid factor positive	Investigations	1 (0.00%)
Rhinolaryngitis	Infections and infestations	1 (0.00%)
Right ventricular hypertrophy	Cardiac disorders	1 (0.00%)
Rosai-Dorfman syndrome	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Rotavirus infection	Infections and infestations	1 (0.00%)
Saliva altered	Gastrointestinal disorders	1 (0.00%)
Salivary gland calculus	Gastrointestinal disorders	1 (0.00%)
Salivary gland disorder	Gastrointestinal disorders	1 (0.00%)
Salivary gland mass	Gastrointestinal disorders	1 (0.00%)
Salivary gland neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Scan abdomen abnormal	Investigations	1 (0.00%)
Scan abnormal	Investigations	1 (0.00%)
Sciatic nerve injury	Injury, poisoning and procedural complications	1 (0.00%)
Scleral disorder	Eye disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Scleral haemorrhage	Eye disorders	1 (0.00%)
Scoliosis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Scrotal pain	Reproductive system and breast disorders	1 (0.00%)
Seborrhoea	Skin and subcutaneous tissue disorders	1 (0.00%)
Seborrhoeic dermatitis	Skin and subcutaneous tissue disorders	1 (0.00%)
Seizure anoxic	Nervous system disorders	1 (0.00%)
Sensory overload	Nervous system disorders	1 (0.00%)
Sepsis syndrome	Infections and infestations	1 (0.00%)
Septic embolus	Infections and infestations	1 (0.00%)
Seroconversion test negative	Investigations	1 (0.00%)
Seronegative arthritis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Serum ferritin abnormal	Investigations	1 (0.00%)
Serum ferritin decreased	Investigations	1 (0.00%)
Serum sickness	Immune system disorders	1 (0.00%)
Sexual dysfunction	Reproductive system and breast disorders	1 (0.00%)
Shift to the left	Investigations	1 (0.00%)
Shock hypoglycaemic	Metabolism and nutrition disorders	1 (0.00%)
Sialoadenitis	Infections and infestations	1 (0.00%)
Sickle cell anaemia with crisis	Blood and lymphatic system disorders	1 (0.00%)
Sight disability	Social circumstances	1 (0.00%)
Simple partial seizures	Nervous system disorders	1 (0.00%)
Sinoatrial block	Cardiac disorders	1 (0.00%)
Sinonasal obstruction	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Sinus node dysfunction	Cardiac disorders	1 (0.00%)
Sinus rhythm	Investigations	1 (0.00%)
Skin atrophy	Skin and subcutaneous tissue disorders	1 (0.00%)
Skin bacterial infection	Infections and infestations	1 (0.00%)
Skin depigmentation	Skin and subcutaneous tissue disorders	1 (0.00%)
Skin discharge	Skin and subcutaneous tissue disorders	1 (0.00%)
Skin lesion inflammation	Skin and subcutaneous tissue disorders	1 (0.00%)
Skin striae	Skin and subcutaneous tissue disorders	1 (0.00%)
Skin test positive	Investigations	1 (0.00%)
Skin texture abnormal	Skin and subcutaneous tissue disorders	1 (0.00%)
Skin wrinkling	Skin and subcutaneous tissue disorders	1 (0.00%)
Small intestinal obstruction	Gastrointestinal disorders	1 (0.00%)
Small intestinal resection	Surgical and medical procedures	1 (0.00%)
Soft tissue infection	Infections and infestations	1 (0.00%)
Soft tissue inflammation	General disorders and administration site conditions	1 (0.00%)
Soft tissue injury	Injury, poisoning and procedural complications	1 (0.00%)
Solar dermatitis	Skin and subcutaneous tissue disorders	1 (0.00%)
Solar lentigo	Skin and subcutaneous tissue disorders	1 (0.00%)
Solar urticaria	Skin and subcutaneous tissue disorders	1 (0.00%)
Solid organ transplant rejection	Immune system disorders	1 (0.00%)
Speech sound disorder	Psychiatric disorders	1 (0.00%)
Spina bifida	Congenital, familial and genetic disorders	1 (0.00%)
Spinal compression fracture	Injury, poisoning and procedural complications	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Spinal cord infarction	Nervous system disorders	1 (0.00%)
Spinal cord injury	Injury, poisoning and procedural complications	1 (0.00%)
Spinal epidural haematoma	Nervous system disorders	1 (0.00%)
Spinal osteoarthritis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Spinal stenosis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Spinal subdural haemorrhage	Nervous system disorders	1 (0.00%)
Spinal vascular disorder	Nervous system disorders	1 (0.00%)
Spine malformation	Congenital, familial and genetic disorders	1 (0.00%)
Spleen disorder	Blood and lymphatic system disorders	1 (0.00%)
Splenic artery aneurysm	Gastrointestinal disorders	1 (0.00%)
Splenic artery thrombosis	Blood and lymphatic system disorders	1 (0.00%)
Splenic rupture	Injury, poisoning and procedural complications	1 (0.00%)
Sputum purulent	Infections and infestations	1 (0.00%)
Staring	Psychiatric disorders	1 (0.00%)
Status asthmaticus	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Status migrainosus	Nervous system disorders	1 (0.00%)
Steatorrhoea	Gastrointestinal disorders	1 (0.00%)
Stertor	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Stillbirth	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Still's disease	Musculoskeletal and connective tissue disorders	1 (0.00%)
Stomach mass	Gastrointestinal disorders	1 (0.00%)
Strangury	Renal and urinary disorders	1 (0.00%)
Streptobacillus infection	Infections and infestations	1 (0.00%)
Streptococcal endocarditis	Infections and infestations	1 (0.00%)
Streptococcal infection	Infections and infestations	1 (0.00%)
Streptococcal sepsis	Infections and infestations	1 (0.00%)
Streptococcal urinary tract infection	Infections and infestations	1 (0.00%)
Streptococcus test positive	Investigations	1 (0.00%)
Stress urinary incontinence	Renal and urinary disorders	1 (0.00%)
Stroke in evolution	Nervous system disorders	1 (0.00%)
Stroke volume decreased	Investigations	1 (0.00%)
Subcutaneous abscess	Infections and infestations	1 (0.00%)
Subileus	Gastrointestinal disorders	1 (0.00%)
Submaxillary gland enlargement	Gastrointestinal disorders	1 (0.00%)
Subretinal haematoma	Eye disorders	1 (0.00%)
Sudden onset of sleep	Nervous system disorders	1 (0.00%)
Sudden visual loss	Eye disorders	1 (0.00%)
Suicidal behaviour	Psychiatric disorders	1 (0.00%)
Suicide attempt	Psychiatric disorders	1 (0.00%)
Superinfection bacterial	Infections and infestations	1 (0.00%)
Suprapubic pain	General disorders and administration site conditions	1 (0.00%)
Supraventricular tachyarrhythmia	Cardiac disorders	1 (0.00%)
Surgery	Surgical and medical procedures	1 (0.00%)
Suspiciousness	Psychiatric disorders	1 (0.00%)
Symmetrical drug-related intertriginous and flexural exanthema	Skin and subcutaneous tissue disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Sympathicotonia	Nervous system disorders	1 (0.00%)
Syndactyly	Congenital, familial and genetic disorders	1 (0.00%)
Synovial fluid analysis abnormal	Investigations	1 (0.00%)
Syphilis	Infections and infestations	1 (0.00%)
Systemic lupus erythematosus rash	Skin and subcutaneous tissue disorders	1 (0.00%)
Takayasu's arteritis	Vascular disorders	1 (0.00%)
T-cell lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Therapeutic response decreased	General disorders and administration site conditions	1 (0.00%)
Therapeutic response shortened	General disorders and administration site conditions	1 (0.00%)
Thirst decreased	General disorders and administration site conditions	1 (0.00%)
Thoracic outlet syndrome	Nervous system disorders	1 (0.00%)
Thrombolysis	Surgical and medical procedures	1 (0.00%)
Thrombophlebitis septic	Infections and infestations	1 (0.00%)
Thrombosis in device	Product issues	1 (0.00%)
Thrombotic cerebral infarction	Nervous system disorders	1 (0.00%)
Thrombotic microangiopathy	Blood and lymphatic system disorders	1 (0.00%)
Thymoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Thyroid cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Thyroid function test abnormal	Investigations	1 (0.00%)
Thyroid neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Thyroxine free increased	Investigations	1 (0.00%)
Tinea infection	Infections and infestations	1 (0.00%)
Tinea versicolour	Infections and infestations	1 (0.00%)
T-lymphocyte count decreased	Investigations	1 (0.00%)
T-lymphocyte count increased	Investigations	1 (0.00%)
Tobacco user	Social circumstances	1 (0.00%)
Tongue eruption	Gastrointestinal disorders	1 (0.00%)
Tongue geographic	Gastrointestinal disorders	1 (0.00%)
Tonsillitis streptococcal	Infections and infestations	1 (0.00%)
Tonsillolith	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Tooth discolouration	Gastrointestinal disorders	1 (0.00%)
Torsade de pointes	Cardiac disorders	1 (0.00%)
Total cholesterol/HDL ratio decreased	Investigations	1 (0.00%)
Total lung capacity decreased	Investigations	1 (0.00%)
Toxic anterior segment syndrome	Injury, poisoning and procedural complications	1 (0.00%)
Toxicity to various agents	Injury, poisoning and procedural complications	1 (0.00%)
Tracheobronchitis bacterial	Infections and infestations	1 (0.00%)
Trance	Psychiatric disorders	1 (0.00%)
Transferrin abnormal	Investigations	1 (0.00%)
Transient aphasia	Nervous system disorders	1 (0.00%)
Transplant rejection	Immune system disorders	1 (0.00%)
Transposition of the great vessels	Congenital, familial and genetic disorders	1 (0.00%)
Traumatic haemorrhage	Injury, poisoning and procedural complications	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Traumatic intracranial haemorrhage	Injury, poisoning and procedural complications	1 (0.00%)
Trichodynia	Skin and subcutaneous tissue disorders	1 (0.00%)
Trichorrhexis	Skin and subcutaneous tissue disorders	1 (0.00%)
Trigeminal palsy	Nervous system disorders	1 (0.00%)
Tri-iodothyronine increased	Investigations	1 (0.00%)
Triple negative breast cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Trisomy 21	Congenital, familial and genetic disorders	1 (0.00%)
Troponin	Investigations	1 (0.00%)
Tubulointerstitial nephritis	Renal and urinary disorders	1 (0.00%)
Tumour pseudoprogression	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Tumour thrombosis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Ulcerative keratitis	Eye disorders	1 (0.00%)
Ulcer haemorrhage	General disorders and administration site conditions	1 (0.00%)
Ulnar nerve injury	Injury, poisoning and procedural complications	1 (0.00%)
Ulnar nerve palsy	Nervous system disorders	1 (0.00%)
Ultrasound breast abnormal	Investigations	1 (0.00%)
Ultrasound scan abnormal	Investigations	1 (0.00%)
Umbilical cord abnormality	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Umbilical cord thrombosis	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Undersensing	Product issues	1 (0.00%)
Underweight	Metabolism and nutrition disorders	1 (0.00%)
Upper airway obstruction	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Upper gastrointestinal haemorrhage	Gastrointestinal disorders	1 (0.00%)
Upper respiratory tract irritation	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Urea urine	Investigations	1 (0.00%)
Urethritis noninfective	Renal and urinary disorders	1 (0.00%)
Urinary bladder haemorrhage	Renal and urinary disorders	1 (0.00%)
Urinary occult blood	Investigations	1 (0.00%)
Urinary straining	Renal and urinary disorders	1 (0.00%)
Urinary tract infection bacterial	Infections and infestations	1 (0.00%)
Urinary tract inflammation	Renal and urinary disorders	1 (0.00%)
Urine ketone body present	Investigations	1 (0.00%)
Urine sodium increased	Investigations	1 (0.00%)
Urticaria contact	Skin and subcutaneous tissue disorders	1 (0.00%)
Urticarial dermatitis	Skin and subcutaneous tissue disorders	1 (0.00%)
Urticaria physical	Skin and subcutaneous tissue disorders	1 (0.00%)
Urticaria thermal	Skin and subcutaneous tissue disorders	1 (0.00%)
Use of accessory respiratory muscles	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Uterine abscess	Infections and infestations	1 (0.00%)
Uterine contractions abnormal	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Uterine contractions during pregnancy	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Uterine disorder	Reproductive system and breast disorders	1 (0.00%)
Uterine polyp	Reproductive system and breast disorders	1 (0.00%)
Uterine prolapse	Reproductive system and breast disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Uterine spasm	Reproductive system and breast disorders	1 (0.00%)
Uvulitis	Gastrointestinal disorders	1 (0.00%)
Vaccination site cyst	General disorders and administration site conditions	1 (0.00%)
Vaccination site dryness	General disorders and administration site conditions	1 (0.00%)
Vaccination site dysaesthesia	General disorders and administration site conditions	1 (0.00%)
Vaccination site exfoliation	General disorders and administration site conditions	1 (0.00%)
Vaccination site hypertrophy	General disorders and administration site conditions	1 (0.00%)
Vaccination site phlebitis	General disorders and administration site conditions	1 (0.00%)
Vaccination site photosensitivity reaction	General disorders and administration site conditions	1 (0.00%)
Vaccination site plaque	General disorders and administration site conditions	1 (0.00%)
Vaccination site pustule	Infections and infestations	1 (0.00%)
Vaccination site ulcer	General disorders and administration site conditions	1 (0.00%)
Vaginal abscess	Infections and infestations	1 (0.00%)
Vaginal lesion	Reproductive system and breast disorders	1 (0.00%)
Vaginal ulceration	Reproductive system and breast disorders	1 (0.00%)
Varicella virus test positive	Investigations	1 (0.00%)
Vascular anastomosis	Surgical and medical procedures	1 (0.00%)
Vascular dementia	Nervous system disorders	1 (0.00%)
Vascular device infection	Infections and infestations	1 (0.00%)
Vascular parkinsonism	Nervous system disorders	1 (0.00%)
Vascular skin disorder	Skin and subcutaneous tissue disorders	1 (0.00%)
Vascular stent stenosis	General disorders and administration site conditions	1 (0.00%)
Vascular test abnormal	Investigations	1 (0.00%)
Vasculitis necrotising	Vascular disorders	1 (0.00%)
Vasospasm	Vascular disorders	1 (0.00%)
Vein wall hypertrophy	Vascular disorders	1 (0.00%)
Venous arterialisation	Surgical and medical procedures	1 (0.00%)
Venous bruit	Investigations	1 (0.00%)
Venous haemorrhage	Vascular disorders	1 (0.00%)
Venous pressure	Investigations	1 (0.00%)
Ventricle rupture	Cardiac disorders	1 (0.00%)
Ventricular flutter	Cardiac disorders	1 (0.00%)
Vertebral lesion	Musculoskeletal and connective tissue disorders	1 (0.00%)
Vertebrobasilar insufficiency	Nervous system disorders	1 (0.00%)
Vertigo CNS origin	Nervous system disorders	1 (0.00%)
Vestibular function test abnormal	Investigations	1 (0.00%)
Vestibulitis	Infections and infestations	1 (0.00%)
Viral labyrinthitis	Infections and infestations	1 (0.00%)
Viral myelitis	Infections and infestations	1 (0.00%)
Viral myocarditis	Infections and infestations	1 (0.00%)
Virologic failure	Infections and infestations	1 (0.00%)
Visceral venous thrombosis	Gastrointestinal disorders	1 (0.00%)
Visual brightness	Eye disorders	1 (0.00%)
Visuospatial deficit	Nervous system disorders	1 (0.00%)
Vitamin B12 decreased	Investigations	1 (0.00%)
Vitamin B12 increased	Investigations	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Vitamin B complex deficiency	Metabolism and nutrition disorders	1 (0.00%)
Vitiligo	Skin and subcutaneous tissue disorders	1 (0.00%)
Vitreoretinal traction syndrome	Eye disorders	1 (0.00%)
Vitreous disorder	Eye disorders	1 (0.00%)
Vitreous haze	Eye disorders	1 (0.00%)
Vitreous opacities	Eye disorders	1 (0.00%)
Vocal cord disorder	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Vocal cord inflammation	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Vocal cord paralysis	Nervous system disorders	1 (0.00%)
Vogt-Koyanagi-Harada disease	Eye disorders	1 (0.00%)
Volvulus of small bowel	Gastrointestinal disorders	1 (0.00%)
Vulval abscess	Infections and infestations	1 (0.00%)
Vulval haemorrhage	Reproductive system and breast disorders	1 (0.00%)
Vulvovaginal discomfort	Reproductive system and breast disorders	1 (0.00%)
Vulvovaginal erythema	Reproductive system and breast disorders	1 (0.00%)
Vulvovaginal injury	Injury, poisoning and procedural complications	1 (0.00%)
Vulvovaginal pruritus	Reproductive system and breast disorders	1 (0.00%)
Vulvovaginal rash	Reproductive system and breast disorders	1 (0.00%)
White blood cell count abnormal	Investigations	1 (0.00%)
White coat hypertension	Vascular disorders	1 (0.00%)
Williams syndrome	Congenital, familial and genetic disorders	1 (0.00%)
Wound drainage	Surgical and medical procedures	1 (0.00%)
Wrong technique in device usage process	Injury, poisoning and procedural complications	1 (0.00%)
Xanthopsia	Eye disorders	1 (0.00%)
X-ray abnormal	Investigations	1 (0.00%)
Yellow fever	Infections and infestations	1 (0.00%)
Yersinia bacteraemia	Infections and infestations	1 (0.00%)
Yersinia infection	Infections and infestations	1 (0.00%)
Yolk sac tumour site unspecified	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)

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APPENDIX 2.1 Cumulative Number of Case Reports (Serious and Non-Serious, Medically Confirmed and Non Medically-Confirmed) from Post-Marketing Data Sources, Overall, by Sex, Country, Age Groups and in Special Populations and Summary Tabulation by Preferred Term and MedDRA System Organ Class

BNT162B2 - ALL

Reporting Period: Through 31-MAY-2021

Total Number of Cases: 167956 (100%) (ALL) / 167956 (OVERALL)

Total Number of Adverse Events (PT): 632103 (ALL)

NON CT

Total Number of Cases: 167956

Total Number of Adverse Events (PT): 632103

		Number of Cases	Percentage (%)
Sex			
	FEMALE	118873	70.8 %
	MALE	39537	23.5 %
	NO DATA	9544	5.7 %
	UNK	2	0.0 %
Age Range			
Min = 0.0 Years	0 to 27 days	29	0.0 %
Max = 109.0 Years	28 days to 23 months	224	0.1 %
	2 to 11 years	93	0.1 %
Mean = 51.5	12 to 17 years	444	0.3 %
Median = 50.0	18 - 30 years	20094	12.0 %
Standard Deviation = 18.88	31 - 50 years	52894	31.5 %
n = 142387	51 - 64 years	33339	19.8 %
	65 - 74 years	15030	8.9 %
	Greater than or equal to 75 years	20934	12.5 %
	Unknown	24844	14.8 %
	N/A - age range only applies to post-birth patients	31	0.0 %
Country Where Event Occurred			
	UNITED KINGDOM	43417	25.9 %
	UNITED STATES	41430	24.7 %
	ITALY	20452	12.2 %
	FRANCE	8144	4.8 %
	GERMANY	6065	3.6 %
	MEXICO	6054	3.6 %
	JAPAN	5366	3.2 %
	NETHERLANDS	4446	2.6 %
	SPAIN	3824	2.3 %
	PORTUGAL	3105	1.8 %
	BELGIUM	2129	1.3 %
	SWEDEN	2115	1.3 %
	CZECH REPUBLIC	1700	1.0 %
	GREECE	1631	1.0 %
	DENMARK	1572	0.9 %
	ISRAEL	1451	0.9 %
	AUSTRIA	1323	0.8 %
	ROMANIA	1319	0.8 %

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		Number of Cases	Percentage (%)
Country Where Event Occured			
	CANADA	1142	0.7 %
	AUSTRALIA	1093	0.7 %
	POLAND	1048	0.6 %
	NORWAY	1025	0.6 %
	IRELAND	935	0.6 %
	FINLAND	934	0.6 %
	HUNGARY	908	0.5 %
	SWITZERLAND	577	0.3 %
	CROATIA	449	0.3 %
	SLOVAKIA	357	0.2 %
	BULGARIA	283	0.2 %
	HONG KONG	254	0.2 %
	LATVIA	253	0.2 %
	ESTONIA	249	0.1 %
	COSTA RICA	240	0.1 %
	PANAMA	222	0.1 %
	LUXEMBOURG	204	0.1 %
	SLOVENIA	178	0.1 %
	CHILE	177	0.1 %
	SERBIA	169	0.1 %
	ICELAND	157	0.1 %
	CYPRUS	155	0.1 %
	SINGAPORE	130	0.1 %
	LITHUANIA	123	0.1 %
	MALTA	120	0.1 %
	COLOMBIA	117	0.1 %
	BRAZIL	109	0.1 %
	PUERTO RICO	103	0.1 %
	TURKEY	88	0.1 %
	LEBANON	72	0.0 %
	UNITED ARAB EMIRATES	68	0.0 %
	ECUADOR	66	0.0 %
	SAUDI ARABIA	60	0.0 %
	NEW ZEALAND	39	0.0 %
	MALAYSIA	28	0.0 %
	PERU	27	0.0 %
	JORDAN	25	0.0 %
	PHILIPPINES	25	0.0 %
	QATAR	23	0.0 %
	BAHRAIN	16	0.0 %
	SOUTH AFRICA	15	0.0 %
	IRAQ	14	0.0 %
	TUNISIA	14	0.0 %

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		Number of Cases	Percentage (%)
Country Where Event Occured			
	ARGENTINA	13	0.0 %
	MACEDONIA, THE FORMER YUGOSLAV REPUBLIC OF	11	0.0 %
	BERMUDA	10	0.0 %
	KUWAIT	9	0.0 %
	CAYMAN ISLANDS	7	0.0 %
	INDIA	6	0.0 %
	MACAO	5	0.0 %
	OMAN	5	0.0 %
	URUGUAY	5	0.0 %
	NORTHERN MARIANA ISLANDS	4	0.0 %
	ALBANIA	3	0.0 %
	BOLIVIA	3	0.0 %
	FRENCH POLYNESIA	3	0.0 %
	GEORGIA	3	0.0 %
	KOREA, REPUBLIC OF (SOUTH KOREA)	3	0.0 %
	LIECHTENSTEIN	3	0.0 %
	UNITED STATES MINOR OUTLYING ISLANDS	3	0.0 %
	AMERICAN SAMOA	2	0.0 %
	ANGOLA	2	0.0 %
	BOSNIA AND HERZEGOVINA	2	0.0 %
	EL SALVADOR	2	0.0 %
	HOLY SEE (VATICAN CITY STATE)	2	0.0 %
	HONDURAS	2	0.0 %
	TURKS AND CAICOS ISLANDS	2	0.0 %
	AFGHANISTAN	1	0.0 %
	ANDORRA	1	0.0 %
	EGYPT	1	0.0 %
	FRENCH GUIANA	1	0.0 %
	FRENCH SOUTHERN TERRITORIES	1	0.0 %
	GAMBIA	1	0.0 %
	GUINEA	1	0.0 %
	HAITI	1	0.0 %
	MONACO	1	0.0 %
	PALESTINIAN TERRITORY, OCCUPIED	1	0.0 %
	THAILAND	1	0.0 %
	UKRAINE	1	0.0 %
Source			
	Clinical Study	618	0.4 %
	Literature - Non Study	117	0.1 %
	Literature - Study	38	0.0 %
	Solicited	54	0.0 %
	Spontaneous	167129	99.5 %

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		Number of Cases	Percentage (%)
Case Seriousness			
	SERIOUS	77811	46.3 %
	NONSERIOUS	90144	53.7 %
	NO DATA	1	0.0 %
HP/Medically Confirmed			
	Yes	93545	55.7 %
	No	74411	44.3 %
Special Populations	Pregnant/Breastfeeding Women		
	Yes	1583	0.9 %
	Pediatric Non EIU		
	Yes	516	0.3 %
	Elderly		
	Yes	35964	21.4 %
	Race/Ethnicity		
	ASIAN - HISPANIC OR LATINO	23	0.0 %
	ASIAN - NO DATA	2282	1.4 %
	ASIAN - NOT HISPANIC OR LATINO	911	0.5 %
	ASIAN - OTHER	5	0.0 %
	BLACK - HISPANIC OR LATINO	52	0.0 %
	BLACK - NO DATA	984	0.6 %
	BLACK - NOT HISPANIC OR LATINO	572	0.3 %
	BLACK - OTHER	15	0.0 %
	CAUCASIAN - HISPANIC OR LATINO	815	0.5 %
	CAUCASIAN - NO DATA	10090	6.0 %
	CAUCASIAN - NOT HISPANIC OR LATINO	9918	5.9 %
	CAUCASIAN - OTHER	60	0.0 %
	NATIVE AMERICAN - HISPANIC OR LATINO	36	0.0 %
	NATIVE AMERICAN - NO DATA	134	0.1 %
	NATIVE AMERICAN - NOT HISPANIC OR LATINO	56	0.0 %
	NATIVE AMERICAN - OTHER	3	0.0 %
	NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - HISPANIC OR LATINO	9	0.0 %
	NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - NO DATA	18	0.0 %
	NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - NOT HISPANIC OR LATINO	36	0.0 %
	NO DATA - HISPANIC OR LATINO	1143	0.7 %
	NO DATA - NO DATA	140162	83.5 %
	NO DATA - NOT HISPANIC OR LATINO	343	0.2 %
	NO DATA - OTHER	289	0.2 %

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APPENDIX 2.1 Cumulative Number of Case Reports (Serious and Non-Serious, Medically Confirmed and Non Medically-Confirmed) from Post-Marketing Data Sources, Overall, by Sex, Country, Age Groups and in Special Populations and Summary Tabulation by Preferred Term and MedDRA System Organ Class

BNT162B2 - ALL

Reporting Period: Through 31-MAY-2021

Total Number of Cases: 167956 (100%) (ALL) / 167956 (OVERALL)

Total Number of Adverse Events (PT): 632103 (ALL)

NON CT

Total Number of Cases: 167956

Total Number of Adverse Events (PT): 632103

Preferred Term	System Organ Class (SOC)	Number of Cases
Headache	Nervous system disorders	40612 (24.18%)
Pyrexia	General disorders and administration site conditions	29507 (17.57%)
Fatigue	General disorders and administration site conditions	28432 (16.93%)
Myalgia	Musculoskeletal and connective tissue disorders	21315 (12.69%)
Chills	General disorders and administration site conditions	20176 (12.01%)
Nausea	Gastrointestinal disorders	19303 (11.49%)
Vaccination site pain	General disorders and administration site conditions	18829 (11.21%)
Arthralgia	Musculoskeletal and connective tissue disorders	16204 (9.65%)
Pain in extremity	Musculoskeletal and connective tissue disorders	15661 (9.32%)
Pain	General disorders and administration site conditions	13770 (8.20%)
Dizziness	Nervous system disorders	13267 (7.90%)
Malaise	General disorders and administration site conditions	12683 (7.55%)
Asthenia	General disorders and administration site conditions	10855 (6.46%)
Lymphadenopathy	Blood and lymphatic system disorders	8382 (4.99%)
Dyspnoea	Respiratory, thoracic and mediastinal disorders	7337 (4.37%)
COVID-19	Infections and infestations	7063 (4.21%)
Diarrhoea	Gastrointestinal disorders	6879 (4.10%)
Vomiting	Gastrointestinal disorders	6253 (3.72%)
Pruritus	Skin and subcutaneous tissue disorders	6121 (3.64%)
Rash	Skin and subcutaneous tissue disorders	5804 (3.46%)
Paraesthesia	Nervous system disorders	5337 (3.18%)
Drug ineffective	General disorders and administration site conditions	4545 (2.71%)
Cough	Respiratory, thoracic and mediastinal disorders	4434 (2.64%)
Erythema	Skin and subcutaneous tissue disorders	4354 (2.59%)
Hypoaesthesia	Nervous system disorders	3722 (2.22%)
Tachycardia	Cardiac disorders	3596 (2.14%)
Influenza like illness	General disorders and administration site conditions	3531 (2.10%)
Oropharyngeal pain	Respiratory, thoracic and mediastinal disorders	3408 (2.03%)
Feeling abnormal	General disorders and administration site conditions	3399 (2.02%)
Urticaria	Skin and subcutaneous tissue disorders	3275 (1.95%)
Vaccination site swelling	General disorders and administration site conditions	3156 (1.88%)
Vaccination site erythema	General disorders and administration site conditions	3144 (1.87%)
Back pain	Musculoskeletal and connective tissue disorders	3056 (1.82%)
Hyperhidrosis	Skin and subcutaneous tissue disorders	3015 (1.80%)
Chest pain	General disorders and administration site conditions	2990 (1.78%)
Off label use	Injury, poisoning and procedural complications	2928 (1.74%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Hypertension	Vascular disorders	2884 (1.72%)
Peripheral swelling	General disorders and administration site conditions	2683 (1.60%)
Palpitations	Cardiac disorders	2679 (1.60%)
Anaphylactic reaction	Immune system disorders	2665 (1.59%)
Injection site pain	General disorders and administration site conditions	2649 (1.58%)
Inappropriate schedule of product administration	Injury, poisoning and procedural complications	2565 (1.53%)
Abdominal pain	Gastrointestinal disorders	2466 (1.47%)
Sensitive skin	Skin and subcutaneous tissue disorders	2429 (1.45%)
Feeling hot	General disorders and administration site conditions	2425 (1.44%)
Decreased appetite	Metabolism and nutrition disorders	2388 (1.42%)
Syncope	Nervous system disorders	2385 (1.42%)
Neck pain	Musculoskeletal and connective tissue disorders	2380 (1.42%)
Tremor	Nervous system disorders	2311 (1.38%)
Insomnia	Psychiatric disorders	2245 (1.34%)
Herpes zoster	Infections and infestations	2234 (1.33%)
Vertigo	Ear and labyrinth disorders	2117 (1.26%)
Somnolence	Nervous system disorders	2105 (1.25%)
Migraine	Nervous system disorders	2084 (1.24%)
Swelling	General disorders and administration site conditions	2044 (1.22%)
Hypersensitivity	Immune system disorders	2038 (1.21%)
Blood pressure increased	Investigations	2029 (1.21%)
Chest discomfort	General disorders and administration site conditions	2016 (1.20%)
Heart rate increased	Investigations	1995 (1.19%)
Rhinorrhoea	Respiratory, thoracic and mediastinal disorders	1947 (1.16%)
Abdominal pain upper	Gastrointestinal disorders	1945 (1.16%)
Feeling cold	General disorders and administration site conditions	1883 (1.12%)
Lethargy	Nervous system disorders	1715 (1.02%)
Paraesthesia oral	Gastrointestinal disorders	1696 (1.01%)
Illness	General disorders and administration site conditions	1693 (1.01%)
Axillary pain	General disorders and administration site conditions	1656 (0.99%)
Vaccination site warmth	General disorders and administration site conditions	1616 (0.96%)
Body temperature increased	Investigations	1613 (0.96%)
Muscular weakness	Musculoskeletal and connective tissue disorders	1577 (0.94%)
Loss of consciousness	Nervous system disorders	1574 (0.94%)
Musculoskeletal stiffness	Musculoskeletal and connective tissue disorders	1565 (0.93%)
Tinnitus	Ear and labyrinth disorders	1477 (0.88%)
Limb discomfort	Musculoskeletal and connective tissue disorders	1457 (0.87%)
Poor quality product administered	Injury, poisoning and procedural complications	1434 (0.85%)
Dysgeusia	Nervous system disorders	1432 (0.85%)
Product use issue	Injury, poisoning and procedural complications	1356 (0.81%)
Swelling face	General disorders and administration site conditions	1336 (0.80%)
Lymph node pain	Blood and lymphatic system disorders	1320 (0.79%)
Condition aggravated	General disorders and administration site conditions	1293 (0.77%)
Pulmonary embolism	Respiratory, thoracic and mediastinal disorders	1289 (0.77%)
Vaccination site pruritus	General disorders and administration site conditions	1264 (0.75%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Presyncope	Nervous system disorders	1239 (0.74%)
Hypotension	Vascular disorders	1224 (0.73%)
Flushing	Vascular disorders	1201 (0.72%)
Muscle spasms	Musculoskeletal and connective tissue disorders	1190 (0.71%)
Confusional state	Psychiatric disorders	1187 (0.71%)
Vaccination failure	General disorders and administration site conditions	1184 (0.70%)
Vision blurred	Eye disorders	1183 (0.70%)
Nasopharyngitis	Infections and infestations	1152 (0.69%)
Gait disturbance	General disorders and administration site conditions	1122 (0.67%)
Hot flush	Vascular disorders	1093 (0.65%)
Influenza	Infections and infestations	1074 (0.64%)
Death	General disorders and administration site conditions	1054 (0.63%)
Eye pain	Eye disorders	1041 (0.62%)
Respiratory distress	Respiratory, thoracic and mediastinal disorders	1040 (0.62%)
Anxiety	Psychiatric disorders	1035 (0.62%)
Overdose	Injury, poisoning and procedural complications	1030 (0.61%)
Circumstance or information capable of leading to medication error	Injury, poisoning and procedural complications	1029 (0.61%)
Burning sensation	Nervous system disorders	1002 (0.60%)
Fall	Injury, poisoning and procedural complications	1002 (0.60%)
Cerebrovascular accident	Nervous system disorders	998 (0.59%)
Rash pruritic	Skin and subcutaneous tissue disorders	997 (0.59%)
Rash erythematous	Skin and subcutaneous tissue disorders	984 (0.59%)
Vaccination site reaction	General disorders and administration site conditions	972 (0.58%)
Discomfort	General disorders and administration site conditions	963 (0.57%)
Facial paralysis	Nervous system disorders	929 (0.55%)
Hypoaesthesia oral	Gastrointestinal disorders	917 (0.55%)
Dysphagia	Gastrointestinal disorders	905 (0.54%)
Throat tightness	Respiratory, thoracic and mediastinal disorders	895 (0.53%)
Abdominal discomfort	Gastrointestinal disorders	893 (0.53%)
Seizure	Nervous system disorders	889 (0.53%)
Inflammation	General disorders and administration site conditions	883 (0.53%)
Ear pain	Ear and labyrinth disorders	872 (0.52%)
Lip swelling	Gastrointestinal disorders	862 (0.51%)
Deep vein thrombosis	Vascular disorders	854 (0.51%)
Vaccination site inflammation	General disorders and administration site conditions	848 (0.50%)
Bone pain	Musculoskeletal and connective tissue disorders	831 (0.49%)
Vaccination site oedema	General disorders and administration site conditions	831 (0.49%)
Bell's palsy	Nervous system disorders	823 (0.49%)
Oxygen saturation decreased	Investigations	818 (0.49%)
Throat irritation	Respiratory, thoracic and mediastinal disorders	812 (0.48%)
Nasal congestion	Respiratory, thoracic and mediastinal disorders	800 (0.48%)
Product temperature excursion issue	Product issues	793 (0.47%)
Disease recurrence	General disorders and administration site conditions	783 (0.47%)
Oedema	General disorders and administration site conditions	779 (0.46%)
Swollen tongue	Gastrointestinal disorders	763 (0.45%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Cold sweat	Skin and subcutaneous tissue disorders	759 (0.45%)
Thrombosis	Vascular disorders	759 (0.45%)
Balance disorder	Nervous system disorders	742 (0.44%)
Suspected COVID-19	Infections and infestations	727 (0.43%)
Atrial fibrillation	Cardiac disorders	721 (0.43%)
Dry mouth	Gastrointestinal disorders	714 (0.43%)
Contusion	Injury, poisoning and procedural complications	705 (0.42%)
Incorrect route of product administration	Injury, poisoning and procedural complications	693 (0.41%)
Musculoskeletal pain	Musculoskeletal and connective tissue disorders	688 (0.41%)
Product preparation issue	Injury, poisoning and procedural complications	686 (0.41%)
Ageusia	Nervous system disorders	678 (0.40%)
Epistaxis	Respiratory, thoracic and mediastinal disorders	672 (0.40%)
Visual impairment	Eye disorders	654 (0.39%)
Pneumonia	Infections and infestations	638 (0.38%)
Oropharyngeal discomfort	Respiratory, thoracic and mediastinal disorders	622 (0.37%)
Head discomfort	Nervous system disorders	620 (0.37%)
Pallor	Vascular disorders	611 (0.36%)
Angioedema	Skin and subcutaneous tissue disorders	609 (0.36%)
SARS-CoV-2 test positive	Investigations	603 (0.36%)
Wheezing	Respiratory, thoracic and mediastinal disorders	593 (0.35%)
Pharyngeal swelling	Respiratory, thoracic and mediastinal disorders	589 (0.35%)
Joint swelling	Musculoskeletal and connective tissue disorders	584 (0.35%)
Disturbance in attention	Nervous system disorders	582 (0.35%)
Mobility decreased	Musculoskeletal and connective tissue disorders	575 (0.34%)
Peripheral coldness	Vascular disorders	574 (0.34%)
Rash macular	Skin and subcutaneous tissue disorders	574 (0.34%)
Asthma	Respiratory, thoracic and mediastinal disorders	571 (0.34%)
Dysphonia	Respiratory, thoracic and mediastinal disorders	563 (0.34%)
Neuralgia	Nervous system disorders	557 (0.33%)
Sleep disorder	Psychiatric disorders	555 (0.33%)
Arrhythmia	Cardiac disorders	553 (0.33%)
Night sweats	Skin and subcutaneous tissue disorders	552 (0.33%)
Maternal exposure during pregnancy	Injury, poisoning and procedural complications	548 (0.33%)
Anosmia	Nervous system disorders	545 (0.32%)
Nodule	General disorders and administration site conditions	531 (0.32%)
Vaccination site mass	General disorders and administration site conditions	527 (0.31%)
Eye swelling	Eye disorders	526 (0.31%)
Hypertensive crisis	Vascular disorders	522 (0.31%)
General physical health deterioration	General disorders and administration site conditions	517 (0.31%)
Blood pressure decreased	Investigations	508 (0.30%)
Induration	General disorders and administration site conditions	502 (0.30%)
Myocardial infarction	Cardiac disorders	492 (0.29%)
Loss of personal independence in daily activities	Social circumstances	479 (0.29%)
Vaccination site induration	General disorders and administration site conditions	479 (0.29%)
Exposure via breast milk	Injury, poisoning and procedural complications	463 (0.28%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Feeling of body temperature change	General disorders and administration site conditions	454 (0.27%)
Photophobia	Eye disorders	449 (0.27%)
Heavy menstrual bleeding	Reproductive system and breast disorders	446 (0.27%)
Speech disorder	Nervous system disorders	436 (0.26%)
Dizziness postural	Nervous system disorders	435 (0.26%)
Vaccination site rash	General disorders and administration site conditions	434 (0.26%)
Underdose	Injury, poisoning and procedural complications	431 (0.26%)
Movement disorder	Nervous system disorders	427 (0.25%)
Oedema peripheral	General disorders and administration site conditions	424 (0.25%)
Disorientation	Psychiatric disorders	423 (0.25%)
Sneezing	Respiratory, thoracic and mediastinal disorders	412 (0.25%)
Product preparation error	Injury, poisoning and procedural complications	411 (0.24%)
Transient ischaemic attack	Nervous system disorders	410 (0.24%)
Dehydration	Metabolism and nutrition disorders	405 (0.24%)
Tenderness	General disorders and administration site conditions	405 (0.24%)
Hypersomnia	Nervous system disorders	399 (0.24%)
Thrombocytopenia	Blood and lymphatic system disorders	396 (0.24%)
Vaccination site movement impairment	General disorders and administration site conditions	392 (0.23%)
Extensive swelling of vaccinated limb	General disorders and administration site conditions	391 (0.23%)
Cardiac arrest	Cardiac disorders	385 (0.23%)
Ocular hyperaemia	Eye disorders	385 (0.23%)
Pain in jaw	Musculoskeletal and connective tissue disorders	385 (0.23%)
Cardiac failure	Cardiac disorders	382 (0.23%)
Blister	Skin and subcutaneous tissue disorders	381 (0.23%)
Hyperpyrexia	General disorders and administration site conditions	380 (0.23%)
Irritability	Psychiatric disorders	379 (0.23%)
Taste disorder	Nervous system disorders	377 (0.22%)
Breast pain	Reproductive system and breast disorders	376 (0.22%)
Asymptomatic COVID-19	Infections and infestations	375 (0.22%)
Nervousness	Psychiatric disorders	370 (0.22%)
Oral herpes	Infections and infestations	363 (0.22%)
Thirst	General disorders and administration site conditions	358 (0.21%)
C-reactive protein increased	Investigations	351 (0.21%)
Eye pruritus	Eye disorders	349 (0.21%)
Dyspepsia	Gastrointestinal disorders	346 (0.21%)
Urinary tract infection	Infections and infestations	345 (0.21%)
Depressed level of consciousness	Nervous system disorders	340 (0.20%)
Dysarthria	Nervous system disorders	339 (0.20%)
Joint range of motion decreased	Musculoskeletal and connective tissue disorders	336 (0.20%)
Ischaemic stroke	Nervous system disorders	335 (0.20%)
Abdominal distension	Gastrointestinal disorders	333 (0.20%)
Wrong technique in product usage process	Injury, poisoning and procedural complications	330 (0.20%)
Injection site erythema	General disorders and administration site conditions	328 (0.20%)
Arthritis	Musculoskeletal and connective tissue disorders	326 (0.19%)
Facial paresis	Nervous system disorders	326 (0.19%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Lacrimation increased	Eye disorders	326 (0.19%)
Pain of skin	Skin and subcutaneous tissue disorders	323 (0.19%)
Vaccination site bruising	General disorders and administration site conditions	322 (0.19%)
Epilepsy	Nervous system disorders	321 (0.19%)
Local reaction	General disorders and administration site conditions	321 (0.19%)
Odynophagia	Gastrointestinal disorders	321 (0.19%)
Ear discomfort	Ear and labyrinth disorders	320 (0.19%)
Facial pain	General disorders and administration site conditions	320 (0.19%)
Haemorrhage	Vascular disorders	318 (0.19%)
Muscle twitching	Musculoskeletal and connective tissue disorders	316 (0.19%)
Eye irritation	Eye disorders	315 (0.19%)
Gait inability	General disorders and administration site conditions	315 (0.19%)
Anaphylactic shock	Immune system disorders	313 (0.19%)
Injection site oedema	General disorders and administration site conditions	312 (0.19%)
Aphasia	Nervous system disorders	307 (0.18%)
Neuropathy peripheral	Nervous system disorders	306 (0.18%)
Bronchospasm	Respiratory, thoracic and mediastinal disorders	303 (0.18%)
Lymphadenitis	Blood and lymphatic system disorders	300 (0.18%)
Menstruation irregular	Reproductive system and breast disorders	300 (0.18%)
Dysstasia	Nervous system disorders	297 (0.18%)
Deafness	Ear and labyrinth disorders	294 (0.18%)
Weight decreased	Investigations	293 (0.17%)
Blood glucose increased	Investigations	291 (0.17%)
Dyspnoea exertional	Respiratory, thoracic and mediastinal disorders	291 (0.17%)
Restlessness	Psychiatric disorders	289 (0.17%)
Vaccination site discomfort	General disorders and administration site conditions	289 (0.17%)
Face oedema	General disorders and administration site conditions	288 (0.17%)
Rash papular	Skin and subcutaneous tissue disorders	288 (0.17%)
Allergy to vaccine	Immune system disorders	286 (0.17%)
Hypoacusis	Ear and labyrinth disorders	285 (0.17%)
Sudden death	General disorders and administration site conditions	285 (0.17%)
Musculoskeletal chest pain	Musculoskeletal and connective tissue disorders	284 (0.17%)
Bradycardia	Cardiac disorders	283 (0.17%)
Sensation of foreign body	General disorders and administration site conditions	280 (0.17%)
Memory impairment	Nervous system disorders	278 (0.17%)
Diplopia	Eye disorders	271 (0.16%)
Tension headache	Nervous system disorders	269 (0.16%)
Productive cough	Respiratory, thoracic and mediastinal disorders	267 (0.16%)
Vaccination complication	Injury, poisoning and procedural complications	264 (0.16%)
Hallucination	Psychiatric disorders	263 (0.16%)
Cellulitis	Infections and infestations	262 (0.16%)
COVID-19 pneumonia	Infections and infestations	261 (0.16%)
Muscle tightness	Musculoskeletal and connective tissue disorders	261 (0.16%)
Myocarditis	Cardiac disorders	257 (0.15%)
Skin burning sensation	Skin and subcutaneous tissue disorders	257 (0.15%)
Sensory disturbance	Nervous system disorders	256 (0.15%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Hemiparesis	Nervous system disorders	253 (0.15%)
Menstrual disorder	Reproductive system and breast disorders	253 (0.15%)
Constipation	Gastrointestinal disorders	250 (0.15%)
Joint stiffness	Musculoskeletal and connective tissue disorders	249 (0.15%)
Angina pectoris	Cardiac disorders	248 (0.15%)
Skin discolouration	Skin and subcutaneous tissue disorders	248 (0.15%)
Infection	Infections and infestations	245 (0.15%)
Exposure during pregnancy	Injury, poisoning and procedural complications	242 (0.14%)
Circulatory collapse	Vascular disorders	241 (0.14%)
Depressed mood	Psychiatric disorders	240 (0.14%)
Respiratory disorder	Respiratory, thoracic and mediastinal disorders	240 (0.14%)
Parosmia	Nervous system disorders	239 (0.14%)
Poor quality sleep	Psychiatric disorders	237 (0.14%)
Pericarditis	Cardiac disorders	234 (0.14%)
Tachypnoea	Respiratory, thoracic and mediastinal disorders	234 (0.14%)
Cerebral haemorrhage	Nervous system disorders	229 (0.14%)
Cerebral infarction	Nervous system disorders	229 (0.14%)
Gastrointestinal disorder	Gastrointestinal disorders	228 (0.14%)
Retching	Gastrointestinal disorders	227 (0.14%)
Musculoskeletal discomfort	Musculoskeletal and connective tissue disorders	226 (0.13%)
Hyperthermia	General disorders and administration site conditions	225 (0.13%)
Amnesia	Nervous system disorders	224 (0.13%)
Paralysis	Nervous system disorders	224 (0.13%)
Swelling of eyelid	Eye disorders	224 (0.13%)
Lip oedema	Gastrointestinal disorders	220 (0.13%)
Vaccination site haematoma	General disorders and administration site conditions	220 (0.13%)
Vaginal haemorrhage	Reproductive system and breast disorders	220 (0.13%)
Flatulence	Gastrointestinal disorders	218 (0.13%)
Hyperaesthesia	Nervous system disorders	218 (0.13%)
Respiratory failure	Respiratory, thoracic and mediastinal disorders	218 (0.13%)
Hyperventilation	Respiratory, thoracic and mediastinal disorders	217 (0.13%)
Muscle fatigue	Musculoskeletal and connective tissue disorders	217 (0.13%)
Petechiae	Skin and subcutaneous tissue disorders	217 (0.13%)
Therapeutic response unexpected	General disorders and administration site conditions	216 (0.13%)
Menstruation delayed	Reproductive system and breast disorders	214 (0.13%)
Renal pain	Renal and urinary disorders	212 (0.13%)
Agitation	Psychiatric disorders	209 (0.12%)
Dry throat	Respiratory, thoracic and mediastinal disorders	206 (0.12%)
Dysentery	Infections and infestations	205 (0.12%)
Delirium	Psychiatric disorders	204 (0.12%)
Product dose omission issue	Injury, poisoning and procedural complications	203 (0.12%)
Vaccination site paraesthesia	General disorders and administration site conditions	201 (0.12%)
Rheumatoid arthritis	Musculoskeletal and connective tissue disorders	197 (0.12%)
Oral discomfort	Gastrointestinal disorders	196 (0.12%)
Product administered at inappropriate site	Injury, poisoning and procedural complications	196 (0.12%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Acute myocardial infarction	Cardiac disorders	191 (0.11%)
Cardiovascular disorder	Cardiac disorders	190 (0.11%)
Dermatitis allergic	Skin and subcutaneous tissue disorders	190 (0.11%)
Feeding disorder	Metabolism and nutrition disorders	190 (0.11%)
Laryngeal oedema	Respiratory, thoracic and mediastinal disorders	190 (0.11%)
Depression	Psychiatric disorders	188 (0.11%)
Toothache	Gastrointestinal disorders	188 (0.11%)
Abortion spontaneous	Pregnancy, puerperium and perinatal conditions	187 (0.11%)
Crying	General disorders and administration site conditions	187 (0.11%)
Platelet count decreased	Investigations	187 (0.11%)
Sinusitis	Infections and infestations	187 (0.11%)
Glossodynia	Gastrointestinal disorders	186 (0.11%)
Product storage error	Injury, poisoning and procedural complications	185 (0.11%)
Sinus headache	Nervous system disorders	184 (0.11%)
Eyelid oedema	Eye disorders	183 (0.11%)
Mouth ulceration	Gastrointestinal disorders	183 (0.11%)
Hypokinesia	Nervous system disorders	182 (0.11%)
Impaired work ability	Social circumstances	181 (0.11%)
Acute kidney injury	Renal and urinary disorders	180 (0.11%)
Spinal pain	Musculoskeletal and connective tissue disorders	180 (0.11%)
Cyanosis	Vascular disorders	179 (0.11%)
Axillary mass	Musculoskeletal and connective tissue disorders	177 (0.11%)
Dry skin	Skin and subcutaneous tissue disorders	177 (0.11%)
Heart rate decreased	Investigations	177 (0.11%)
Head injury	Injury, poisoning and procedural complications	176 (0.10%)
Heart rate irregular	Investigations	176 (0.10%)
Incorrect dose administered	Injury, poisoning and procedural complications	176 (0.10%)
Skin disorder	Skin and subcutaneous tissue disorders	175 (0.10%)
Haematoma	Vascular disorders	174 (0.10%)
Injection site swelling	General disorders and administration site conditions	174 (0.10%)
Eczema	Skin and subcutaneous tissue disorders	173 (0.10%)
Guillain-Barre syndrome	Nervous system disorders	170 (0.10%)
Periorbital swelling	Eye disorders	169 (0.10%)
Haematochezia	Gastrointestinal disorders	165 (0.10%)
Vaccination site lymphadenopathy	General disorders and administration site conditions	165 (0.10%)
Dyskinesia	Nervous system disorders	164 (0.10%)
Hypoxia	Respiratory, thoracic and mediastinal disorders	163 (0.10%)
Extrasystoles	Cardiac disorders	162 (0.10%)
Vaccination site urticaria	General disorders and administration site conditions	162 (0.10%)
Asthenopia	Eye disorders	160 (0.10%)
Hypothermia	General disorders and administration site conditions	160 (0.10%)
Dysmenorrhoea	Reproductive system and breast disorders	158 (0.09%)
Oral pain	Gastrointestinal disorders	156 (0.09%)
Rash maculo-papular	Skin and subcutaneous tissue disorders	156 (0.09%)
Immune thrombocytopenia	Blood and lymphatic system disorders	155 (0.09%)
Pharyngeal paraesthesia	Respiratory, thoracic and mediastinal disorders	155 (0.09%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Cardio-respiratory arrest	Cardiac disorders	154 (0.09%)
Cognitive disorder	Nervous system disorders	153 (0.09%)
Hypoglycaemia	Metabolism and nutrition disorders	153 (0.09%)
Tongue oedema	Gastrointestinal disorders	153 (0.09%)
Mouth swelling	Gastrointestinal disorders	152 (0.09%)
Sensory loss	Nervous system disorders	152 (0.09%)
Abdominal pain lower	Gastrointestinal disorders	151 (0.09%)
Skin warm	Skin and subcutaneous tissue disorders	151 (0.09%)
Unresponsive to stimuli	Nervous system disorders	151 (0.09%)
Blindness	Eye disorders	150 (0.09%)
Eye disorder	Eye disorders	149 (0.09%)
Injected limb mobility decreased	General disorders and administration site conditions	149 (0.09%)
Gastrointestinal pain	Gastrointestinal disorders	148 (0.09%)
Ocular discomfort	Eye disorders	148 (0.09%)
Urinary incontinence	Renal and urinary disorders	148 (0.09%)
Vaccination site haemorrhage	General disorders and administration site conditions	148 (0.09%)
Nervous system disorder	Nervous system disorders	147 (0.09%)
Nightmare	Psychiatric disorders	147 (0.09%)
Panic attack	Psychiatric disorders	147 (0.09%)
Dry eye	Eye disorders	146 (0.09%)
Sinus tachycardia	Cardiac disorders	146 (0.09%)
Generalised tonic-clonic seizure	Nervous system disorders	144 (0.09%)
Photopsia	Eye disorders	143 (0.09%)
Body temperature abnormal	Investigations	142 (0.08%)
Middle insomnia	Psychiatric disorders	142 (0.08%)
SARS-CoV-2 antibody test negative	Investigations	142 (0.08%)
White blood cell count increased	Investigations	142 (0.08%)
Anaemia	Blood and lymphatic system disorders	140 (0.08%)
Fibrin D dimer increased	Investigations	140 (0.08%)
Blood pressure fluctuation	Vascular disorders	139 (0.08%)
Rhinitis	Infections and infestations	139 (0.08%)
Deafness unilateral	Ear and labyrinth disorders	138 (0.08%)
Dysaesthesia	Nervous system disorders	138 (0.08%)
Hyperglycaemia	Metabolism and nutrition disorders	138 (0.08%)
Abnormal dreams	Psychiatric disorders	137 (0.08%)
Aphonia	Respiratory, thoracic and mediastinal disorders	137 (0.08%)
Drug hypersensitivity	Immune system disorders	137 (0.08%)
Gastrooesophageal reflux disease	Gastrointestinal disorders	137 (0.08%)
Pulmonary pain	Respiratory, thoracic and mediastinal disorders	137 (0.08%)
Sepsis	Infections and infestations	137 (0.08%)
Lower respiratory tract infection	Infections and infestations	136 (0.08%)
Body temperature decreased	Investigations	135 (0.08%)
Cardiac disorder	Cardiac disorders	134 (0.08%)
Respiratory rate increased	Investigations	134 (0.08%)
Cardiac flutter	Cardiac disorders	133 (0.08%)
Conjunctivitis	Infections and infestations	133 (0.08%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Lung disorder	Respiratory, thoracic and mediastinal disorders	133 (0.08%)
Skin reaction	Skin and subcutaneous tissue disorders	133 (0.08%)
Thrombophlebitis superficial	Vascular disorders	131 (0.08%)
Altered state of consciousness	Nervous system disorders	130 (0.08%)
Groin pain	Musculoskeletal and connective tissue disorders	130 (0.08%)
Renal failure	Renal and urinary disorders	129 (0.08%)
Wrong product administered	Injury, poisoning and procedural complications	129 (0.08%)
Vaccination site hypoaesthesia	General disorders and administration site conditions	128 (0.08%)
Blood pressure abnormal	Investigations	127 (0.08%)
Eating disorder	Psychiatric disorders	127 (0.08%)
Pulmonary oedema	Respiratory, thoracic and mediastinal disorders	127 (0.08%)
Stress	Psychiatric disorders	127 (0.08%)
Skin lesion	Skin and subcutaneous tissue disorders	126 (0.08%)
Hemiplegia	Nervous system disorders	125 (0.07%)
Stomatitis	Gastrointestinal disorders	124 (0.07%)
Dysuria	Renal and urinary disorders	123 (0.07%)
Lymphoedema	Vascular disorders	123 (0.07%)
Mental impairment	Nervous system disorders	123 (0.07%)
Skin exfoliation	Skin and subcutaneous tissue disorders	123 (0.07%)
Blood pressure systolic increased	Investigations	122 (0.07%)
Exposure to SARS-CoV-2	Injury, poisoning and procedural complications	122 (0.07%)
Intermenstrual bleeding	Reproductive system and breast disorders	122 (0.07%)
Pollakiuria	Renal and urinary disorders	120 (0.07%)
Alopecia	Skin and subcutaneous tissue disorders	119 (0.07%)
Feeling drunk	General disorders and administration site conditions	119 (0.07%)
Mass	General disorders and administration site conditions	118 (0.07%)
Tongue discomfort	Gastrointestinal disorders	117 (0.07%)
Dermatitis	Skin and subcutaneous tissue disorders	116 (0.07%)
Migraine with aura	Nervous system disorders	116 (0.07%)
Rash vesicular	Skin and subcutaneous tissue disorders	115 (0.07%)
Motor dysfunction	Nervous system disorders	114 (0.07%)
Oral pruritus	Gastrointestinal disorders	114 (0.07%)
Eye haemorrhage	Eye disorders	113 (0.07%)
Localised oedema	General disorders and administration site conditions	113 (0.07%)
Bedridden	Social circumstances	112 (0.07%)
Thrombophlebitis	Vascular disorders	112 (0.07%)
Conjunctival haemorrhage	Eye disorders	110 (0.07%)
Pleural effusion	Respiratory, thoracic and mediastinal disorders	110 (0.07%)
Chronic obstructive pulmonary disease	Respiratory, thoracic and mediastinal disorders	108 (0.06%)
Sinus pain	Respiratory, thoracic and mediastinal disorders	108 (0.06%)
Expired product administered	Injury, poisoning and procedural complications	106 (0.06%)
Purpura	Skin and subcutaneous tissue disorders	106 (0.06%)
Rectal haemorrhage	Gastrointestinal disorders	106 (0.06%)
Skin irritation	Skin and subcutaneous tissue disorders	106 (0.06%)
Heart rate abnormal	Investigations	105 (0.06%)
Injection site pruritus	General disorders and administration site conditions	105 (0.06%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Monoplegia	Nervous system disorders	105 (0.06%)
Accidental overdose	Injury, poisoning and procedural complications	104 (0.06%)
Breast swelling	Reproductive system and breast disorders	104 (0.06%)
Pneumonia aspiration	Respiratory, thoracic and mediastinal disorders	104 (0.06%)
Blood glucose decreased	Investigations	103 (0.06%)
Tongue disorder	Gastrointestinal disorders	103 (0.06%)
Cystitis	Infections and infestations	102 (0.06%)
Sciatica	Nervous system disorders	102 (0.06%)
Haemoglobin decreased	Investigations	101 (0.06%)
Vaccination site hypersensitivity	General disorders and administration site conditions	101 (0.06%)
Appendicitis	Infections and infestations	100 (0.06%)
Cluster headache	Nervous system disorders	100 (0.06%)
Aphthous ulcer	Gastrointestinal disorders	99 (0.06%)
Ophthalmic herpes zoster	Infections and infestations	99 (0.06%)
Coordination abnormal	Nervous system disorders	98 (0.06%)
No adverse event	General disorders and administration site conditions	98 (0.06%)
Salivary hypersecretion	Gastrointestinal disorders	98 (0.06%)
Bronchitis	Infections and infestations	97 (0.06%)
Drug interaction	General disorders and administration site conditions	97 (0.06%)
Painful respiration	Respiratory, thoracic and mediastinal disorders	97 (0.06%)
Febrile convulsion	Nervous system disorders	96 (0.06%)
Mental fatigue	Psychiatric disorders	96 (0.06%)
Monoparesis	Nervous system disorders	96 (0.06%)
Administration site pain	General disorders and administration site conditions	95 (0.06%)
Ear infection	Infections and infestations	95 (0.06%)
Gout	Metabolism and nutrition disorders	95 (0.06%)
Haemoptysis	Respiratory, thoracic and mediastinal disorders	94 (0.06%)
Vasculitis	Vascular disorders	94 (0.06%)
Ventricular extrasystoles	Cardiac disorders	94 (0.06%)
Embolism	Vascular disorders	93 (0.06%)
Hypotonia	Nervous system disorders	93 (0.06%)
Pulmonary thrombosis	Respiratory, thoracic and mediastinal disorders	93 (0.06%)
Pericardial effusion	Cardiac disorders	92 (0.05%)
Troponin increased	Investigations	92 (0.05%)
Hyperacusis	Ear and labyrinth disorders	91 (0.05%)
Limb injury	Injury, poisoning and procedural complications	91 (0.05%)
SARS-CoV-2 antibody test positive	Investigations	91 (0.05%)
Shock	Vascular disorders	91 (0.05%)
Nasal discomfort	Respiratory, thoracic and mediastinal disorders	90 (0.05%)
Photosensitivity reaction	Skin and subcutaneous tissue disorders	90 (0.05%)
Vaccination site cellulitis	Infections and infestations	89 (0.05%)
Sudden hearing loss	Ear and labyrinth disorders	88 (0.05%)
Thinking abnormal	Psychiatric disorders	88 (0.05%)
Fear	Psychiatric disorders	87 (0.05%)
International normalised ratio increased	Investigations	87 (0.05%)
Muscle strain	Injury, poisoning and procedural complications	87 (0.05%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Psoriasis	Skin and subcutaneous tissue disorders	87 (0.05%)
Sinus disorder	Respiratory, thoracic and mediastinal disorders	87 (0.05%)
Immune system disorder	Immune system disorders	86 (0.05%)
Eyelid ptosis	Eye disorders	85 (0.05%)
Fibromyalgia	Musculoskeletal and connective tissue disorders	85 (0.05%)
Formication	Nervous system disorders	85 (0.05%)
Hypopnoea	Respiratory, thoracic and mediastinal disorders	85 (0.05%)
Urinary retention	Renal and urinary disorders	85 (0.05%)
Arthropathy	Musculoskeletal and connective tissue disorders	84 (0.05%)
Musculoskeletal disorder	Musculoskeletal and connective tissue disorders	84 (0.05%)
Pharyngeal oedema	Respiratory, thoracic and mediastinal disorders	84 (0.05%)
Haematuria	Renal and urinary disorders	83 (0.05%)
Apathy	Psychiatric disorders	82 (0.05%)
Blepharospasm	Eye disorders	82 (0.05%)
Hallucination, visual	Psychiatric disorders	82 (0.05%)
Polymenorrhoea	Reproductive system and breast disorders	82 (0.05%)
Vertigo positional	Ear and labyrinth disorders	82 (0.05%)
Acne	Skin and subcutaneous tissue disorders	81 (0.05%)
Acute respiratory failure	Respiratory, thoracic and mediastinal disorders	81 (0.05%)
Blood urine present	Investigations	80 (0.05%)
Chromaturia	Renal and urinary disorders	79 (0.05%)
Coagulopathy	Blood and lymphatic system disorders	79 (0.05%)
Diabetes mellitus	Metabolism and nutrition disorders	79 (0.05%)
Hemiparaesthesia	Nervous system disorders	79 (0.05%)
Respiratory arrest	Respiratory, thoracic and mediastinal disorders	79 (0.05%)
Sinus congestion	Respiratory, thoracic and mediastinal disorders	79 (0.05%)
Supraventricular tachycardia	Cardiac disorders	79 (0.05%)
Vaccination site joint movement impairment	General disorders and administration site conditions	79 (0.05%)
Chillblains	Injury, poisoning and procedural complications	78 (0.05%)
Ear swelling	Ear and labyrinth disorders	77 (0.05%)
Feeling jittery	General disorders and administration site conditions	77 (0.05%)
Gingival pain	Gastrointestinal disorders	77 (0.05%)
Multiple sclerosis	Nervous system disorders	77 (0.05%)
Stridor	Respiratory, thoracic and mediastinal disorders	77 (0.05%)
Muscle contractions involuntary	Nervous system disorders	76 (0.05%)
Phlebitis	Vascular disorders	76 (0.05%)
Tongue pruritus	Gastrointestinal disorders	76 (0.05%)
Viral infection	Infections and infestations	76 (0.05%)
Visual field defect	Eye disorders	76 (0.05%)
White blood cell count decreased	Investigations	76 (0.05%)
Eructation	Gastrointestinal disorders	75 (0.04%)
Haematemesis	Gastrointestinal disorders	75 (0.04%)
Vaccination site discolouration	General disorders and administration site conditions	75 (0.04%)
Alanine aminotransferase increased	Investigations	74 (0.04%)
Flank pain	Musculoskeletal and connective tissue disorders	74 (0.04%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Neurological symptom	Nervous system disorders	74 (0.04%)
Pelvic pain	Reproductive system and breast disorders	74 (0.04%)
Trigeminal neuralgia	Nervous system disorders	73 (0.04%)
Skin swelling	Skin and subcutaneous tissue disorders	72 (0.04%)
Sluggishness	General disorders and administration site conditions	72 (0.04%)
Vaccination site nodule	General disorders and administration site conditions	72 (0.04%)
Autoimmune disorder	Immune system disorders	71 (0.04%)
Hangover	General disorders and administration site conditions	71 (0.04%)
Herpes simplex	Infections and infestations	71 (0.04%)
Lip pruritus	Gastrointestinal disorders	71 (0.04%)
Subarachnoid haemorrhage	Nervous system disorders	71 (0.04%)
Vaccination site joint pain	General disorders and administration site conditions	71 (0.04%)
Acute coronary syndrome	Cardiac disorders	70 (0.04%)
Amenorrhoea	Reproductive system and breast disorders	70 (0.04%)
Cerebral venous sinus thrombosis	Nervous system disorders	70 (0.04%)
Erysipelas	Infections and infestations	69 (0.04%)
Labyrinthitis	Infections and infestations	69 (0.04%)
Respiration abnormal	Respiratory, thoracic and mediastinal disorders	69 (0.04%)
Accidental exposure to product	Injury, poisoning and procedural complications	68 (0.04%)
Coma	Nervous system disorders	68 (0.04%)
Grip strength decreased	Investigations	68 (0.04%)
Periarthritis	Musculoskeletal and connective tissue disorders	68 (0.04%)
Venous thrombosis limb	Vascular disorders	68 (0.04%)
Cerebral thrombosis	Nervous system disorders	67 (0.04%)
Electric shock sensation	Nervous system disorders	67 (0.04%)
Lip pain	Gastrointestinal disorders	67 (0.04%)
Neutropenia	Blood and lymphatic system disorders	67 (0.04%)
Product administered to patient of inappropriate age	Injury, poisoning and procedural complications	67 (0.04%)
Renal impairment	Renal and urinary disorders	67 (0.04%)
Gastric disorder	Gastrointestinal disorders	66 (0.04%)
Herpes virus infection	Infections and infestations	66 (0.04%)
Temperature regulation disorder	General disorders and administration site conditions	66 (0.04%)
Bursitis	Musculoskeletal and connective tissue disorders	65 (0.04%)
Emotional disorder	Psychiatric disorders	65 (0.04%)
Abnormal faeces	Gastrointestinal disorders	64 (0.04%)
Anaphylactoid reaction	Immune system disorders	64 (0.04%)
Muscle rigidity	Musculoskeletal and connective tissue disorders	64 (0.04%)
Paranasal sinus discomfort	Respiratory, thoracic and mediastinal disorders	64 (0.04%)
Pharyngitis	Infections and infestations	64 (0.04%)
Raynaud's phenomenon	Vascular disorders	64 (0.04%)
Restless legs syndrome	Nervous system disorders	64 (0.04%)
Skin sensitisation	Skin and subcutaneous tissue disorders	64 (0.04%)
Sweating fever	Infections and infestations	64 (0.04%)
Tendonitis	Musculoskeletal and connective tissue disorders	64 (0.04%)
Choking	Respiratory, thoracic and mediastinal disorders	63 (0.04%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Polymyalgia rheumatica	Musculoskeletal and connective tissue disorders	63 (0.04%)
Product administration error	Injury, poisoning and procedural complications	63 (0.04%)
Status epilepticus	Nervous system disorders	63 (0.04%)
Conjunctival hyperaemia	Eye disorders	62 (0.04%)
Livedo reticularis	Skin and subcutaneous tissue disorders	62 (0.04%)
Nerve injury	Injury, poisoning and procedural complications	62 (0.04%)
Vitreous floaters	Eye disorders	62 (0.04%)
Body temperature fluctuation	Investigations	61 (0.04%)
Erythema multiforme	Skin and subcutaneous tissue disorders	61 (0.04%)
Hypophagia	Metabolism and nutrition disorders	61 (0.04%)
Initial insomnia	Psychiatric disorders	61 (0.04%)
Papule	Skin and subcutaneous tissue disorders	61 (0.04%)
Eye movement disorder	Eye disorders	60 (0.04%)
Gingival bleeding	Gastrointestinal disorders	60 (0.04%)
Multiple organ dysfunction syndrome	General disorders and administration site conditions	60 (0.04%)
Pharyngeal hypoaesthesia	Respiratory, thoracic and mediastinal disorders	60 (0.04%)
Upper respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	60 (0.04%)
Deafness neurosensory	Ear and labyrinth disorders	59 (0.04%)
Ear pruritus	Ear and labyrinth disorders	59 (0.04%)
Gastritis	Gastrointestinal disorders	59 (0.04%)
Jaundice	Hepatobiliary disorders	59 (0.04%)
Pulse abnormal	Investigations	59 (0.04%)
Bradyphrenia	Psychiatric disorders	58 (0.03%)
Dementia	Nervous system disorders	58 (0.03%)
Faeces discoloured	Gastrointestinal disorders	58 (0.03%)
Irritable bowel syndrome	Gastrointestinal disorders	58 (0.03%)
Suffocation feeling	Respiratory, thoracic and mediastinal disorders	58 (0.03%)
Choking sensation	Respiratory, thoracic and mediastinal disorders	57 (0.03%)
Hypokalaemia	Metabolism and nutrition disorders	57 (0.03%)
Panic reaction	Psychiatric disorders	57 (0.03%)
Seasonal allergy	Immune system disorders	57 (0.03%)
Skin tightness	Skin and subcutaneous tissue disorders	57 (0.03%)
Tonsillitis	Infections and infestations	57 (0.03%)
Type I hypersensitivity	Immune system disorders	57 (0.03%)
Weight increased	Investigations	57 (0.03%)
Colitis ulcerative	Gastrointestinal disorders	56 (0.03%)
Haemorrhagic stroke	Nervous system disorders	56 (0.03%)
Injection site reaction	General disorders and administration site conditions	56 (0.03%)
Lymphopenia	Blood and lymphatic system disorders	56 (0.03%)
Oral mucosal blistering	Gastrointestinal disorders	56 (0.03%)
Tonsillar hypertrophy	Respiratory, thoracic and mediastinal disorders	56 (0.03%)
Vomiting projectile	Gastrointestinal disorders	56 (0.03%)
Drug eruption	Skin and subcutaneous tissue disorders	55 (0.03%)
Encephalitis	Infections and infestations	55 (0.03%)
Impaired driving ability	Social circumstances	55 (0.03%)
Mental disorder	Psychiatric disorders	55 (0.03%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Miliaria	Skin and subcutaneous tissue disorders	55 (0.03%)
Respiratory tract infection	Infections and infestations	55 (0.03%)
Colitis	Gastrointestinal disorders	54 (0.03%)
Diarrhoea haemorrhagic	Gastrointestinal disorders	54 (0.03%)
Dysphoria	Psychiatric disorders	54 (0.03%)
Eye injury	Injury, poisoning and procedural complications	54 (0.03%)
Fluid retention	Metabolism and nutrition disorders	54 (0.03%)
Gastroenteritis	Infections and infestations	54 (0.03%)
Limb mass	Musculoskeletal and connective tissue disorders	54 (0.03%)
Peripheral vascular disorder	Vascular disorders	54 (0.03%)
Product supply issue	Product issues	54 (0.03%)
Diverticulitis	Infections and infestations	53 (0.03%)
Ear disorder	Ear and labyrinth disorders	53 (0.03%)
Incontinence	Renal and urinary disorders	53 (0.03%)
Laryngospasm	Respiratory, thoracic and mediastinal disorders	53 (0.03%)
Obstructive airways disorder	Respiratory, thoracic and mediastinal disorders	53 (0.03%)
Osteoarthritis	Musculoskeletal and connective tissue disorders	53 (0.03%)
Acute respiratory distress syndrome	Respiratory, thoracic and mediastinal disorders	52 (0.03%)
Gastrointestinal haemorrhage	Gastrointestinal disorders	52 (0.03%)
Myositis	Musculoskeletal and connective tissue disorders	52 (0.03%)
Oral disorder	Gastrointestinal disorders	52 (0.03%)
Palatal oedema	Gastrointestinal disorders	52 (0.03%)
Paresis	Nervous system disorders	52 (0.03%)
Pharyngeal erythema	Respiratory, thoracic and mediastinal disorders	52 (0.03%)
Pneumonitis	Respiratory, thoracic and mediastinal disorders	52 (0.03%)
Postmenopausal haemorrhage	Reproductive system and breast disorders	52 (0.03%)
Post viral fatigue syndrome	Infections and infestations	52 (0.03%)
Tension	Psychiatric disorders	52 (0.03%)
Vestibular neuronitis	Infections and infestations	52 (0.03%)
Anaesthesia	Nervous system disorders	51 (0.03%)
Breast tenderness	Reproductive system and breast disorders	51 (0.03%)
Hepatic enzyme increased	Investigations	51 (0.03%)
Injection site warmth	General disorders and administration site conditions	51 (0.03%)
Mydriasis	Eye disorders	51 (0.03%)
Respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	51 (0.03%)
Ataxia	Nervous system disorders	50 (0.03%)
Chronic fatigue syndrome	General disorders and administration site conditions	50 (0.03%)
Euphoric mood	Psychiatric disorders	50 (0.03%)
Joint injury	Injury, poisoning and procedural complications	50 (0.03%)
Motion sickness	Ear and labyrinth disorders	50 (0.03%)
Renal disorder	Renal and urinary disorders	50 (0.03%)
Suicidal ideation	Psychiatric disorders	50 (0.03%)
Visual acuity reduced	Eye disorders	50 (0.03%)
		50 (0.03%)
Anal incontinence	Gastrointestinal disorders	49 (0.03%)
Blood creatinine increased	Investigations	49 (0.03%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Cerebral ischaemia	Nervous system disorders	49 (0.03%)
Dermatitis bullous	Skin and subcutaneous tissue disorders	49 (0.03%)
Lip dry	Gastrointestinal disorders	49 (0.03%)
Nystagmus	Nervous system disorders	49 (0.03%)
Blindness unilateral	Eye disorders	48 (0.03%)
Eye oedema	Eye disorders	48 (0.03%)
Multiple sclerosis relapse	Nervous system disorders	48 (0.03%)
Orthostatic hypotension	Vascular disorders	48 (0.03%)
Scratch	Injury, poisoning and procedural complications	48 (0.03%)
Blood creatine phosphokinase increased	Investigations	47 (0.03%)
Cardiac failure congestive	Cardiac disorders	47 (0.03%)
Hemianaesthesia	Nervous system disorders	47 (0.03%)
Mastitis	Infections and infestations	47 (0.03%)
Near death experience	Psychiatric disorders	47 (0.03%)
Nerve compression	Nervous system disorders	47 (0.03%)
Optic neuritis	Nervous system disorders	47 (0.03%)
Pulmonary congestion	Respiratory, thoracic and mediastinal disorders	47 (0.03%)
Retinal vein occlusion	Eye disorders	47 (0.03%)
Rhinalgia	Respiratory, thoracic and mediastinal disorders	47 (0.03%)
Secretion discharge	General disorders and administration site conditions	47 (0.03%)
Venous thrombosis	Vascular disorders	47 (0.03%)
Asthmatic crisis	Respiratory, thoracic and mediastinal disorders	46 (0.03%)
Atrial flutter	Cardiac disorders	46 (0.03%)
Dyspnoea at rest	Respiratory, thoracic and mediastinal disorders	46 (0.03%)
Erectile dysfunction	Reproductive system and breast disorders	46 (0.03%)
Exposure via skin contact	Injury, poisoning and procedural complications	46 (0.03%)
Frequent bowel movements	Gastrointestinal disorders	46 (0.03%)
Leukocytosis	Blood and lymphatic system disorders	46 (0.03%)
Liquid product physical issue	Product issues	46 (0.03%)
Neck mass	Musculoskeletal and connective tissue disorders	46 (0.03%)
Neuritis	Nervous system disorders	46 (0.03%)
Petit mal epilepsy	Nervous system disorders	46 (0.03%)
Rales	Respiratory, thoracic and mediastinal disorders	46 (0.03%)
Red blood cell sedimentation rate increased	Investigations	46 (0.03%)
Aspartate aminotransferase increased	Investigations	45 (0.03%)
Blood potassium decreased	Investigations	45 (0.03%)
Breast mass	Reproductive system and breast disorders	45 (0.03%)
Cardiogenic shock	Cardiac disorders	45 (0.03%)
Eye discharge	Eye disorders	45 (0.03%)
Hyponatraemia	Metabolism and nutrition disorders	45 (0.03%)
Incomplete course of vaccination	Injury, poisoning and procedural complications	45 (0.03%)
Ischaemic cerebral infarction	Nervous system disorders	45 (0.03%)
Myelitis transverse	Nervous system disorders	45 (0.03%)
Myoclonus	Nervous system disorders	45 (0.03%)
Nasal oedema	Respiratory, thoracic and mediastinal disorders	45 (0.03%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Neutrophil count increased	Investigations	45 (0.03%)
Pancreatitis acute	Gastrointestinal disorders	45 (0.03%)
Psychomotor hyperactivity	Nervous system disorders	45 (0.03%)
Ventricular fibrillation	Cardiac disorders	45 (0.03%)
Ventricular tachycardia	Cardiac disorders	45 (0.03%)
Acute pulmonary oedema	Respiratory, thoracic and mediastinal disorders	44 (0.03%)
Ecchymosis	Skin and subcutaneous tissue disorders	44 (0.03%)
Emotional distress	Psychiatric disorders	44 (0.03%)
Injection site urticaria	General disorders and administration site conditions	44 (0.03%)
Nephrolithiasis	Renal and urinary disorders	44 (0.03%)
Aggression	Psychiatric disorders	43 (0.03%)
Diabetes mellitus inadequate control	Metabolism and nutrition disorders	43 (0.03%)
Faeces soft	Gastrointestinal disorders	43 (0.03%)
Internal haemorrhage	Vascular disorders	43 (0.03%)
Leukopenia	Blood and lymphatic system disorders	43 (0.03%)
Muscle disorder	Musculoskeletal and connective tissue disorders	43 (0.03%)
Nuchal rigidity	Musculoskeletal and connective tissue disorders	43 (0.03%)
Periorbital oedema	Eye disorders	43 (0.03%)
Product colour issue	Product issues	43 (0.03%)
Wound	Injury, poisoning and procedural complications	43 (0.03%)
Injection site rash	General disorders and administration site conditions	42 (0.03%)
Injury	Injury, poisoning and procedural complications	42 (0.03%)
Micturition urgency	Renal and urinary disorders	42 (0.03%)
Mood altered	Psychiatric disorders	42 (0.03%)
Myocardial ischaemia	Cardiac disorders	42 (0.03%)
Polyuria	Renal and urinary disorders	42 (0.03%)
Pulmonary infarction	Respiratory, thoracic and mediastinal disorders	42 (0.03%)
Systemic lupus erythematosus	Musculoskeletal and connective tissue disorders	42 (0.03%)
Upper-airway cough syndrome	Respiratory, thoracic and mediastinal disorders	42 (0.03%)
Abnormal behaviour	Psychiatric disorders	41 (0.02%)
Arthritis reactive	Musculoskeletal and connective tissue disorders	41 (0.02%)
Eye inflammation	Eye disorders	41 (0.02%)
Gingival swelling	Gastrointestinal disorders	41 (0.02%)
Hypovolaemic shock	Vascular disorders	41 (0.02%)
Incoherent	Nervous system disorders	41 (0.02%)
Muscle discomfort	Musculoskeletal and connective tissue disorders	41 (0.02%)
Pancreatitis	Gastrointestinal disorders	41 (0.02%)
Scab	Skin and subcutaneous tissue disorders	41 (0.02%)
Septic shock	Infections and infestations	41 (0.02%)
Sleep disorder due to general medical condition, insomnia type	Psychiatric disorders	41 (0.02%)
Vaccination site vesicles	General disorders and administration site conditions	41 (0.02%)
Abnormal sensation in eye	Eye disorders	40 (0.02%)
Cardiac failure acute	Cardiac disorders	40 (0.02%)
Facial discomfort	General disorders and administration site conditions	40 (0.02%)
Glossitis	Gastrointestinal disorders	40 (0.02%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Oral candidiasis	Infections and infestations	40 (0.02%)
Pityriasis rosea	Skin and subcutaneous tissue disorders	40 (0.02%)
Rash morbilliform	Skin and subcutaneous tissue disorders	40 (0.02%)
Trismus	Musculoskeletal and connective tissue disorders	40 (0.02%)
Vaccination site infection	Infections and infestations	40 (0.02%)
Vitreous detachment	Eye disorders	40 (0.02%)
Apnoea	Respiratory, thoracic and mediastinal disorders	39 (0.02%)
Blindness transient	Eye disorders	39 (0.02%)
Electrocardiogram abnormal	Investigations	39 (0.02%)
Intestinal ischaemia	Gastrointestinal disorders	39 (0.02%)
Joint effusion	Musculoskeletal and connective tissue disorders	39 (0.02%)
Listless	Psychiatric disorders	39 (0.02%)
Localised infection	Infections and infestations	39 (0.02%)
Piloerection	Skin and subcutaneous tissue disorders	39 (0.02%)
Platelet count increased	Investigations	39 (0.02%)
Potentiating drug interaction	General disorders and administration site conditions	39 (0.02%)
Uveitis	Eye disorders	39 (0.02%)
Aspiration	Respiratory, thoracic and mediastinal disorders	38 (0.02%)
Hyperaemia	Vascular disorders	38 (0.02%)
Peripheral ischaemia	Vascular disorders	38 (0.02%)
Road traffic accident	Injury, poisoning and procedural complications	38 (0.02%)
Skin mass	Skin and subcutaneous tissue disorders	38 (0.02%)
Tachyarrhythmia	Cardiac disorders	38 (0.02%)
Tongue ulceration	Gastrointestinal disorders	38 (0.02%)
Vaccination site hyperaesthesia	General disorders and administration site conditions	38 (0.02%)
Bowel movement irregularity	Gastrointestinal disorders	37 (0.02%)
Glomerular filtration rate decreased	Investigations	37 (0.02%)
Herpes zoster reactivation	Infections and infestations	37 (0.02%)
Hyperthyroidism	Endocrine disorders	37 (0.02%)
Pleurisy	Respiratory, thoracic and mediastinal disorders	37 (0.02%)
Pleuritic pain	Respiratory, thoracic and mediastinal disorders	37 (0.02%)
Retinal artery occlusion	Eye disorders	37 (0.02%)
Body height decreased	Investigations	36 (0.02%)
Hunger	General disorders and administration site conditions	36 (0.02%)
Interstitial lung disease	Respiratory, thoracic and mediastinal disorders	36 (0.02%)
Kidney infection	Infections and infestations	36 (0.02%)
Laryngeal discomfort	Respiratory, thoracic and mediastinal disorders	36 (0.02%)
Lip blister	Gastrointestinal disorders	36 (0.02%)
Muscle contracture	Musculoskeletal and connective tissue disorders	36 (0.02%)
Muscle swelling	Musculoskeletal and connective tissue disorders	36 (0.02%)
Rhabdomyolysis	Musculoskeletal and connective tissue disorders	36 (0.02%)
Skin laceration	Injury, poisoning and procedural complications	36 (0.02%)
Temperature intolerance	General disorders and administration site conditions	36 (0.02%)
Abscess	Infections and infestations	35 (0.02%)
Blood glucose fluctuation	Investigations	35 (0.02%)
Breath sounds abnormal	Investigations	35 (0.02%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Costochondritis	Musculoskeletal and connective tissue disorders	35 (0.02%)
Crohn's disease	Gastrointestinal disorders	35 (0.02%)
Eyelids pruritus	Eye disorders	35 (0.02%)
Hallucination, auditory	Psychiatric disorders	35 (0.02%)
Inflammatory marker increased	Investigations	35 (0.02%)
Lymphocyte count decreased	Investigations	35 (0.02%)
Polyarthritis	Musculoskeletal and connective tissue disorders	35 (0.02%)
Pustule	Infections and infestations	35 (0.02%)
Synovial cyst	Musculoskeletal and connective tissue disorders	35 (0.02%)
Tongue discolouration	Gastrointestinal disorders	35 (0.02%)
Transaminases increased	Investigations	35 (0.02%)
Tunnel vision	Nervous system disorders	35 (0.02%)
Blood blister	Skin and subcutaneous tissue disorders	34 (0.02%)
Body temperature	Investigations	34 (0.02%)
Bradykinesia	Nervous system disorders	34 (0.02%)
Enlarged uvula	Gastrointestinal disorders	34 (0.02%)
Erythema of eyelid	Eye disorders	34 (0.02%)
Haemorrhage subcutaneous	Skin and subcutaneous tissue disorders	34 (0.02%)
Hypotonic-hyporesponsive episode	Nervous system disorders	34 (0.02%)
Liver function test abnormal	Investigations	34 (0.02%)
Maternal exposure during breast feeding	Injury, poisoning and procedural complications	34 (0.02%)
Oedema mouth	Gastrointestinal disorders	34 (0.02%)
Oxygen saturation abnormal	Investigations	34 (0.02%)
Product complaint	Product issues	34 (0.02%)
Vaccination site irritation	General disorders and administration site conditions	34 (0.02%)
Vaccination site joint swelling	General disorders and administration site conditions	34 (0.02%)
Adverse drug reaction	General disorders and administration site conditions	33 (0.02%)
Brain oedema	Nervous system disorders	33 (0.02%)
Cheilitis	Gastrointestinal disorders	33 (0.02%)
Erythema nodosum	Skin and subcutaneous tissue disorders	33 (0.02%)
Facial spasm	Nervous system disorders	33 (0.02%)
Herpes ophthalmic	Infections and infestations	33 (0.02%)
Hypothyroidism	Endocrine disorders	33 (0.02%)
Lymphangitis	Infections and infestations	33 (0.02%)
Melaena	Gastrointestinal disorders	33 (0.02%)
Product quality issue	Product issues	33 (0.02%)
Upper respiratory tract infection	Infections and infestations	33 (0.02%)
Cutaneous vasculitis	Skin and subcutaneous tissue disorders	32 (0.02%)
Foreign body sensation in eyes	Eye disorders	32 (0.02%)
Gastrointestinal sounds abnormal	Gastrointestinal disorders	32 (0.02%)
Hyposmia	Nervous system disorders	32 (0.02%)
Sleep disorder due to a general medical condition	Psychiatric disorders	32 (0.02%)
Vein disorder	Vascular disorders	32 (0.02%)
Adverse event	General disorders and administration site conditions	31 (0.02%)
Arteriosclerosis	Vascular disorders	31 (0.02%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Back disorder	Musculoskeletal and connective tissue disorders	31 (0.02%)
Blood urea increased	Investigations	31 (0.02%)
Coronavirus infection	Infections and infestations	31 (0.02%)
Delusion	Psychiatric disorders	31 (0.02%)
Exercise tolerance decreased	General disorders and administration site conditions	31 (0.02%)
Eyelid pain	Eye disorders	31 (0.02%)
Hepatic pain	Hepatobiliary disorders	31 (0.02%)
Herpes zoster oticus	Infections and infestations	31 (0.02%)
Hypoaesthesia eye	Eye disorders	31 (0.02%)
Increased upper airway secretion	Respiratory, thoracic and mediastinal disorders	31 (0.02%)
Ligament sprain	Injury, poisoning and procedural complications	31 (0.02%)
Lip disorder	Gastrointestinal disorders	31 (0.02%)
Nasal dryness	Respiratory, thoracic and mediastinal disorders	31 (0.02%)
Palatal swelling	Gastrointestinal disorders	31 (0.02%)
Polyneuropathy	Nervous system disorders	31 (0.02%)
Respiratory rate decreased	Investigations	31 (0.02%)
Supraventricular extrasystoles	Cardiac disorders	31 (0.02%)
Tendon pain	Musculoskeletal and connective tissue disorders	31 (0.02%)
Tongue dry	Gastrointestinal disorders	31 (0.02%)
Blood cholesterol increased	Investigations	30 (0.02%)
Blood sodium decreased	Investigations	30 (0.02%)
Dizziness exertional	Nervous system disorders	30 (0.02%)
Embolus stroke	Nervous system disorders	30 (0.02%)
Eye contusion	Injury, poisoning and procedural complications	30 (0.02%)
Gamma-glutamyltransferase increased	Investigations	30 (0.02%)
Goitre	Endocrine disorders	30 (0.02%)
Meniere's disease	Ear and labyrinth disorders	30 (0.02%)
Mouth haemorrhage	Gastrointestinal disorders	30 (0.02%)
Pancytopenia	Blood and lymphatic system disorders	30 (0.02%)
Postural orthostatic tachycardia syndrome	Cardiac disorders	30 (0.02%)
Respiratory symptom	Respiratory, thoracic and mediastinal disorders	30 (0.02%)
Respiratory tract oedema	Respiratory, thoracic and mediastinal disorders	30 (0.02%)
Skin ulcer	Skin and subcutaneous tissue disorders	30 (0.02%)
Systemic inflammatory response syndrome	General disorders and administration site conditions	30 (0.02%)
Vaccination site joint erythema	General disorders and administration site conditions	30 (0.02%)
Anger	Psychiatric disorders	29 (0.02%)
Antibody test abnormal	Investigations	29 (0.02%)
Atrioventricular block complete	Cardiac disorders	29 (0.02%)
Blood glucose abnormal	Investigations	29 (0.02%)
Cerebral disorder	Nervous system disorders	29 (0.02%)
Concussion	Injury, poisoning and procedural complications	29 (0.02%)
Dissociation	Psychiatric disorders	29 (0.02%)
Drooling	Nervous system disorders	29 (0.02%)
Dysphemia	Psychiatric disorders	29 (0.02%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Eye infection	Infections and infestations	29 (0.02%)
Face injury	Injury, poisoning and procedural complications	29 (0.02%)
Frustration tolerance decreased	Psychiatric disorders	29 (0.02%)
Gastroenteritis viral	Infections and infestations	29 (0.02%)
Gingivitis	Infections and infestations	29 (0.02%)
Haemorrhoids	Gastrointestinal disorders	29 (0.02%)
Immobile	Social circumstances	29 (0.02%)
Nasal obstruction	Respiratory, thoracic and mediastinal disorders	29 (0.02%)
Ophthalmic migraine	Nervous system disorders	29 (0.02%)
Pemphigoid	Skin and subcutaneous tissue disorders	29 (0.02%)
Pharyngeal inflammation	Respiratory, thoracic and mediastinal disorders	29 (0.02%)
Post herpetic neuralgia	Nervous system disorders	29 (0.02%)
Psoriatic arthropathy	Musculoskeletal and connective tissue disorders	29 (0.02%)
Reaction to excipient	Immune system disorders	29 (0.02%)
Sedation	Nervous system disorders	29 (0.02%)
Skin haemorrhage	Skin and subcutaneous tissue disorders	29 (0.02%)
Tearfulness	Psychiatric disorders	29 (0.02%)
Vasodilatation	Vascular disorders	29 (0.02%)
Asphyxia	Respiratory, thoracic and mediastinal disorders	28 (0.02%)
Aura	Nervous system disorders	28 (0.02%)
Blood pressure diastolic increased	Investigations	28 (0.02%)
Defaecation urgency	Gastrointestinal disorders	28 (0.02%)
Facial neuralgia	Nervous system disorders	28 (0.02%)
Genital herpes	Infections and infestations	28 (0.02%)
Hypomenorrhoea	Reproductive system and breast disorders	28 (0.02%)
International normalised ratio decreased	Investigations	28 (0.02%)
Laryngitis	Infections and infestations	28 (0.02%)
Lung infiltration	Respiratory, thoracic and mediastinal disorders	28 (0.02%)
Mastication disorder	Musculoskeletal and connective tissue disorders	28 (0.02%)
Mood swings	Psychiatric disorders	28 (0.02%)
Neuralgic amyotrophy	Nervous system disorders	28 (0.02%)
Neutrophil count decreased	Investigations	28 (0.02%)
Partial seizures	Nervous system disorders	28 (0.02%)
Pyelonephritis	Infections and infestations	28 (0.02%)
Rotator cuff syndrome	Musculoskeletal and connective tissue disorders	28 (0.02%)
Scar	Injury, poisoning and procedural complications	28 (0.02%)
Testicular pain	Reproductive system and breast disorders	28 (0.02%)
Urosepsis	Infections and infestations	28 (0.02%)
Blood test abnormal	Investigations	27 (0.02%)
Catarrh	Respiratory, thoracic and mediastinal disorders	27 (0.02%)
Chronic kidney disease	Renal and urinary disorders	27 (0.02%)
Communication disorder	Psychiatric disorders	27 (0.02%)
Ear congestion	Ear and labyrinth disorders	27 (0.02%)
Hepatic function abnormal	Hepatobiliary disorders	27 (0.02%)
Hepatitis	Hepatobiliary disorders	27 (0.02%)
Hypogeusia	Nervous system disorders	27 (0.02%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Liver function test increased	Investigations	27 (0.02%)
Maternal exposure timing unspecified	Injury, poisoning and procedural complications	27 (0.02%)
Medication error	Injury, poisoning and procedural complications	27 (0.02%)
Meningitis	Infections and infestations	27 (0.02%)
Nasal pruritus	Respiratory, thoracic and mediastinal disorders	27 (0.02%)
Paranoia	Psychiatric disorders	27 (0.02%)
Parkinson's disease	Nervous system disorders	27 (0.02%)
Product leakage	Product issues	27 (0.02%)
Red blood cell count decreased	Investigations	27 (0.02%)
Anuria	Renal and urinary disorders	26 (0.02%)
Bone swelling	Musculoskeletal and connective tissue disorders	26 (0.02%)
Cardiomegaly	Cardiac disorders	26 (0.02%)
Coronary artery disease	Cardiac disorders	26 (0.02%)
Energy increased	General disorders and administration site conditions	26 (0.02%)
Facial nerve disorder	Nervous system disorders	26 (0.02%)
Haematocrit decreased	Investigations	26 (0.02%)
Haemorrhage urinary tract	Renal and urinary disorders	26 (0.02%)
Hepatic cytolysis	Hepatobiliary disorders	26 (0.02%)
Ischaemia	Vascular disorders	26 (0.02%)
Needle issue	Product issues	26 (0.02%)
Nephrotic syndrome	Renal and urinary disorders	26 (0.02%)
Physical deconditioning	General disorders and administration site conditions	26 (0.02%)
Portal vein thrombosis	Hepatobiliary disorders	26 (0.02%)
Subdural haematoma	Injury, poisoning and procedural complications	26 (0.02%)
Tongue blistering	Gastrointestinal disorders	26 (0.02%)
Urine output decreased	Investigations	26 (0.02%)
Atelectasis	Respiratory, thoracic and mediastinal disorders	25 (0.01%)
Autoimmune thyroiditis	Endocrine disorders	25 (0.01%)
Blood pressure diastolic decreased	Investigations	25 (0.01%)
Breast discomfort	Reproductive system and breast disorders	25 (0.01%)
Bundle branch block right	Cardiac disorders	25 (0.01%)
Cardiopulmonary failure	Cardiac disorders	25 (0.01%)
Dermatitis atopic	Skin and subcutaneous tissue disorders	25 (0.01%)
Food allergy	Immune system disorders	25 (0.01%)
Hordeolum	Infections and infestations	25 (0.01%)
Iridocyclitis	Eye disorders	25 (0.01%)
Neoplasm malignant	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	25 (0.01%)
Nipple pain	Reproductive system and breast disorders	25 (0.01%)
Parotitis	Infections and infestations	25 (0.01%)
Pneumonia bacterial	Infections and infestations	25 (0.01%)
Polydipsia	Metabolism and nutrition disorders	25 (0.01%)
Poor peripheral circulation	Vascular disorders	25 (0.01%)
Rib fracture	Injury, poisoning and procedural complications	25 (0.01%)
Sense of oppression	General disorders and administration site conditions	25 (0.01%)
Sudden cardiac death	General disorders and administration site conditions	25 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Tongue erythema	Gastrointestinal disorders	25 (0.01%)
Tooth disorder	Gastrointestinal disorders	25 (0.01%)
Vlth nerve paralysis	Nervous system disorders	25 (0.01%)
Yawning	Respiratory, thoracic and mediastinal disorders	25 (0.01%)
Dermatitis contact	Skin and subcutaneous tissue disorders	24 (0.01%)
Diplegia	Nervous system disorders	24 (0.01%)
Dystonia	Nervous system disorders	24 (0.01%)
Furuncle	Infections and infestations	24 (0.01%)
Giant cell arteritis	Vascular disorders	24 (0.01%)
Hyperaesthesia teeth	Gastrointestinal disorders	24 (0.01%)
Hyperkalaemia	Metabolism and nutrition disorders	24 (0.01%)
Injection related reaction	Injury, poisoning and procedural complications	24 (0.01%)
Intestinal obstruction	Gastrointestinal disorders	24 (0.01%)
Jaw disorder	Musculoskeletal and connective tissue disorders	24 (0.01%)
Loss of control of legs	General disorders and administration site conditions	24 (0.01%)
Mesenteric vein thrombosis	Gastrointestinal disorders	24 (0.01%)
Neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	24 (0.01%)
Trigeminal nerve disorder	Nervous system disorders	24 (0.01%)
Type IV hypersensitivity reaction	Immune system disorders	24 (0.01%)
Vaccination site extravasation	General disorders and administration site conditions	24 (0.01%)
Allodynia	Nervous system disorders	23 (0.01%)
Atrioventricular block	Cardiac disorders	23 (0.01%)
Blood alkaline phosphatase increased	Investigations	23 (0.01%)
Blood bilirubin increased	Investigations	23 (0.01%)
Blood lactate dehydrogenase increased	Investigations	23 (0.01%)
Cardiac discomfort	Cardiac disorders	23 (0.01%)
Cervicobrachial syndrome	Nervous system disorders	23 (0.01%)
Disease progression	General disorders and administration site conditions	23 (0.01%)
Hypernatraemia	Metabolism and nutrition disorders	23 (0.01%)
Mechanical urticaria	Skin and subcutaneous tissue disorders	23 (0.01%)
Metamorphopsia	Eye disorders	23 (0.01%)
Myelitis	Infections and infestations	23 (0.01%)
Occupational exposure to product	Injury, poisoning and procedural complications	23 (0.01%)
Pharyngeal disorder	Respiratory, thoracic and mediastinal disorders	23 (0.01%)
Psychotic disorder	Psychiatric disorders	23 (0.01%)
Stupor	Nervous system disorders	23 (0.01%)
Transient global amnesia	Nervous system disorders	23 (0.01%)
Vestibular disorder	Ear and labyrinth disorders	23 (0.01%)
Viral rash	Infections and infestations	23 (0.01%)
Activated partial thromboplastin time prolonged	Investigations	22 (0.01%)
Allergic reaction to excipient	Immune system disorders	22 (0.01%)
Autonomic nervous system imbalance	Nervous system disorders	22 (0.01%)
Brain injury	Nervous system disorders	22 (0.01%)
Cholestasis	Hepatobiliary disorders	22 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Fine motor skill dysfunction	Nervous system disorders	22 (0.01%)
Functional gastrointestinal disorder	Gastrointestinal disorders	22 (0.01%)
Hip fracture	Injury, poisoning and procedural complications	22 (0.01%)
Hyperleukocytosis	Blood and lymphatic system disorders	22 (0.01%)
Joint lock	Musculoskeletal and connective tissue disorders	22 (0.01%)
Lymph node palpable	Investigations	22 (0.01%)
Myasthenia gravis	Nervous system disorders	22 (0.01%)
Occipital neuralgia	Nervous system disorders	22 (0.01%)
Oropharyngeal blistering	Respiratory, thoracic and mediastinal disorders	22 (0.01%)
Palmar erythema	Skin and subcutaneous tissue disorders	22 (0.01%)
Peripheral venous disease	Vascular disorders	22 (0.01%)
Personality change	Psychiatric disorders	22 (0.01%)
Product packaging quantity issue	Product issues	22 (0.01%)
Tongue coated	Gastrointestinal disorders	22 (0.01%)
Yellow skin	Skin and subcutaneous tissue disorders	22 (0.01%)
Ankylosing spondylitis	Musculoskeletal and connective tissue disorders	21 (0.01%)
Bacterial infection	Infections and infestations	21 (0.01%)
Blood lactic acid increased	Investigations	21 (0.01%)
Breast cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	21 (0.01%)
Breath odour	Gastrointestinal disorders	21 (0.01%)
Cataract	Eye disorders	21 (0.01%)
Cerebral haematoma	Nervous system disorders	21 (0.01%)
Clumsiness	Nervous system disorders	21 (0.01%)
Epigastric discomfort	Gastrointestinal disorders	21 (0.01%)
Eyelid disorder	Eye disorders	21 (0.01%)
Hepatitis acute	Hepatobiliary disorders	21 (0.01%)
Hypertonia	Nervous system disorders	21 (0.01%)
Impaired quality of life	Social circumstances	21 (0.01%)
Infarction	Vascular disorders	21 (0.01%)
Injection site paraesthesia	General disorders and administration site conditions	21 (0.01%)
Lip erythema	Gastrointestinal disorders	21 (0.01%)
Lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	21 (0.01%)
Metabolic acidosis	Metabolism and nutrition disorders	21 (0.01%)
Muscle spasticity	Nervous system disorders	21 (0.01%)
Neurogenic shock	Vascular disorders	21 (0.01%)
Noninfective gingivitis	Gastrointestinal disorders	21 (0.01%)
Rash pustular	Infections and infestations	21 (0.01%)
Retinal vein thrombosis	Eye disorders	21 (0.01%)
Salivary gland pain	Gastrointestinal disorders	21 (0.01%)
Sputum discoloured	Respiratory, thoracic and mediastinal disorders	21 (0.01%)
Thermal burn	Injury, poisoning and procedural complications	21 (0.01%)
Varicella	Infections and infestations	21 (0.01%)
Varicose vein	Vascular disorders	21 (0.01%)
Weight bearing difficulty	Musculoskeletal and connective tissue disorders	21 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Abdominal rigidity	Gastrointestinal disorders	20 (0.01%)
Blood fibrinogen increased	Investigations	20 (0.01%)
Blood thyroid stimulating hormone increased	Investigations	20 (0.01%)
Carpal tunnel syndrome	Nervous system disorders	20 (0.01%)
Cholelithiasis	Hepatobiliary disorders	20 (0.01%)
Diabetic ketoacidosis	Metabolism and nutrition disorders	20 (0.01%)
Eyelid function disorder	Eye disorders	20 (0.01%)
Fluid intake reduced	Metabolism and nutrition disorders	20 (0.01%)
Generalised oedema	General disorders and administration site conditions	20 (0.01%)
Hiccups	Respiratory, thoracic and mediastinal disorders	20 (0.01%)
Illrd nerve paralysis	Nervous system disorders	20 (0.01%)
Injection site mass	General disorders and administration site conditions	20 (0.01%)
Irregular breathing	Respiratory, thoracic and mediastinal disorders	20 (0.01%)
Liver disorder	Hepatobiliary disorders	20 (0.01%)
Meningitis aseptic	Infections and infestations	20 (0.01%)
Orthopnoea	Respiratory, thoracic and mediastinal disorders	20 (0.01%)
Paraparesis	Nervous system disorders	20 (0.01%)
Pharyngitis streptococcal	Infections and infestations	20 (0.01%)
Pneumothorax	Respiratory, thoracic and mediastinal disorders	20 (0.01%)
Quality of life decreased	Investigations	20 (0.01%)
SARS-CoV-2 test negative	Investigations	20 (0.01%)
Slow speech	Nervous system disorders	20 (0.01%)
Sunburn	Injury, poisoning and procedural complications	20 (0.01%)
Temporomandibular joint syndrome	Musculoskeletal and connective tissue disorders	20 (0.01%)
Throat clearing	Respiratory, thoracic and mediastinal disorders	20 (0.01%)
Thyroid disorder	Endocrine disorders	20 (0.01%)
Tonic convulsion	Nervous system disorders	20 (0.01%)
Tooth infection	Infections and infestations	20 (0.01%)
Torticollis	Musculoskeletal and connective tissue disorders	20 (0.01%)
Ulcer	General disorders and administration site conditions	20 (0.01%)
Urine odour abnormal	Renal and urinary disorders	20 (0.01%)
Use of accessory respiratory muscles	Respiratory, thoracic and mediastinal disorders	20 (0.01%)
Vascular purpura	Skin and subcutaneous tissue disorders	20 (0.01%)
Walking disability	Social circumstances	20 (0.01%)
Abdominal tenderness	Gastrointestinal disorders	19 (0.01%)
Abortion missed	Pregnancy, puerperium and perinatal conditions	19 (0.01%)
Administration site oedema	General disorders and administration site conditions	19 (0.01%)
Adnexa uteri pain	Reproductive system and breast disorders	19 (0.01%)
Arterial thrombosis	Vascular disorders	19 (0.01%)
Behaviour disorder	Psychiatric disorders	19 (0.01%)
Bladder disorder	Renal and urinary disorders	19 (0.01%)
Blepharitis	Eye disorders	19 (0.01%)
Cerebral venous thrombosis	Nervous system disorders	19 (0.01%)
Derealisation	Psychiatric disorders	19 (0.01%)
Dysgraphia	Nervous system disorders	19 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Emphysema	Respiratory, thoracic and mediastinal disorders	19 (0.01%)
Encephalopathy	Nervous system disorders	19 (0.01%)
Glaucoma	Eye disorders	19 (0.01%)
Heart rate	Investigations	19 (0.01%)
Immunodeficiency	Immune system disorders	19 (0.01%)
Increased appetite	Metabolism and nutrition disorders	19 (0.01%)
Injection site discomfort	General disorders and administration site conditions	19 (0.01%)
Intervertebral disc protrusion	Musculoskeletal and connective tissue disorders	19 (0.01%)
Joint warmth	Musculoskeletal and connective tissue disorders	19 (0.01%)
Peripheral artery thrombosis	Vascular disorders	19 (0.01%)
Peripheral circulatory failure	Vascular disorders	19 (0.01%)
Proteinuria	Renal and urinary disorders	19 (0.01%)
Rhinitis allergic	Respiratory, thoracic and mediastinal disorders	19 (0.01%)
Skin abrasion	Injury, poisoning and procedural complications	19 (0.01%)
Sleep deficit	Nervous system disorders	19 (0.01%)
Sopor	Psychiatric disorders	19 (0.01%)
Stevens-Johnson syndrome	Skin and subcutaneous tissue disorders	19 (0.01%)
Toxic skin eruption	Skin and subcutaneous tissue disorders	19 (0.01%)
Type 1 diabetes mellitus	Metabolism and nutrition disorders	19 (0.01%)
Vaccination site coldness	General disorders and administration site conditions	19 (0.01%)
Vaccine breakthrough infection	Infections and infestations	19 (0.01%)
Bladder pain	Renal and urinary disorders	18 (0.01%)
Candida infection	Infections and infestations	18 (0.01%)
Cardiac fibrillation	Cardiac disorders	18 (0.01%)
Cerebrovascular disorder	Nervous system disorders	18 (0.01%)
Coronary artery stenosis	Cardiac disorders	18 (0.01%)
Demyelination	Nervous system disorders	18 (0.01%)
Eosinophilia	Blood and lymphatic system disorders	18 (0.01%)
Facial asymmetry	Musculoskeletal and connective tissue disorders	18 (0.01%)
Feeling of despair	Psychiatric disorders	18 (0.01%)
Haemolytic anaemia	Blood and lymphatic system disorders	18 (0.01%)
Hypertensive emergency	Vascular disorders	18 (0.01%)
Infectious mononucleosis	Infections and infestations	18 (0.01%)
Injection site induration	General disorders and administration site conditions	18 (0.01%)
Liver injury	Hepatobiliary disorders	18 (0.01%)
Macule	Skin and subcutaneous tissue disorders	18 (0.01%)
Mitral valve incompetence	Cardiac disorders	18 (0.01%)
Mutism	Psychiatric disorders	18 (0.01%)
Oral mucosal eruption	Gastrointestinal disorders	18 (0.01%)
Peroneal nerve palsy	Nervous system disorders	18 (0.01%)
Phlebitis superficial	Vascular disorders	18 (0.01%)
Pigmentation disorder	Skin and subcutaneous tissue disorders	18 (0.01%)
Pulmonary fibrosis	Respiratory, thoracic and mediastinal disorders	18 (0.01%)
Q fever	Infections and infestations	18 (0.01%)
Reduced facial expression	Nervous system disorders	18 (0.01%)
Respiratory acidosis	Respiratory, thoracic and mediastinal disorders	18 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Sarcoidosis	Immune system disorders	18 (0.01%)
Sinus bradycardia	Cardiac disorders	18 (0.01%)
Sjogren's syndrome	Musculoskeletal and connective tissue disorders	18 (0.01%)
Strabismus	Eye disorders	18 (0.01%)
Syringe issue	Product issues	18 (0.01%)
Tic	Psychiatric disorders	18 (0.01%)
Upper limb fracture	Injury, poisoning and procedural complications	18 (0.01%)
Anaesthesia oral	Gastrointestinal disorders	17 (0.01%)
Anal haemorrhage	Gastrointestinal disorders	17 (0.01%)
Appetite disorder	Metabolism and nutrition disorders	17 (0.01%)
Blood disorder	Blood and lymphatic system disorders	17 (0.01%)
Blood iron decreased	Investigations	17 (0.01%)
Blood pressure systolic decreased	Investigations	17 (0.01%)
Cardiomyopathy	Cardiac disorders	17 (0.01%)
Chest injury	Injury, poisoning and procedural complications	17 (0.01%)
Craniocerebral injury	Injury, poisoning and procedural complications	17 (0.01%)
Deafness bilateral	Ear and labyrinth disorders	17 (0.01%)
Diaphragmalgia	Respiratory, thoracic and mediastinal disorders	17 (0.01%)
Electrocardiogram ST segment elevation	Investigations	17 (0.01%)
Enteritis	Gastrointestinal disorders	17 (0.01%)
Foaming at mouth	General disorders and administration site conditions	17 (0.01%)
Foetal death	Pregnancy, puerperium and perinatal conditions	17 (0.01%)
Fungal infection	Infections and infestations	17 (0.01%)
Gaze palsy	Eye disorders	17 (0.01%)
Grunting	Respiratory, thoracic and mediastinal disorders	17 (0.01%)
Haemorrhage intracranial	Nervous system disorders	17 (0.01%)
Hyporeflexia	Nervous system disorders	17 (0.01%)
Increased tendency to bruise	Blood and lymphatic system disorders	17 (0.01%)
Joint noise	Musculoskeletal and connective tissue disorders	17 (0.01%)
Left ventricular failure	Cardiac disorders	17 (0.01%)
Lymph node abscess	Infections and infestations	17 (0.01%)
Lymphocyte count increased	Investigations	17 (0.01%)
Monocyte count increased	Investigations	17 (0.01%)
Mucous stools	Gastrointestinal disorders	17 (0.01%)
Nail discolouration	Skin and subcutaneous tissue disorders	17 (0.01%)
Oral dysaesthesia	Gastrointestinal disorders	17 (0.01%)
Oral mucosal erythema	Gastrointestinal disorders	17 (0.01%)
Peripheral sensory neuropathy	Nervous system disorders	17 (0.01%)
Pulmonary hypertension	Respiratory, thoracic and mediastinal disorders	17 (0.01%)
Radiculitis brachial	Nervous system disorders	17 (0.01%)
Rosacea	Skin and subcutaneous tissue disorders	17 (0.01%)
Screaming	General disorders and administration site conditions	17 (0.01%)
Sitting disability	Social circumstances	17 (0.01%)
Snoring	Respiratory, thoracic and mediastinal disorders	17 (0.01%)
Tongue biting	Nervous system disorders	17 (0.01%)
Tonic clonic movements	Nervous system disorders	17 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Vaccination site abscess	Infections and infestations	17 (0.01%)
Vulvovaginal pain	Reproductive system and breast disorders	17 (0.01%)
Adrenocortical insufficiency acute	Endocrine disorders	16 (0.01%)
Allergic oedema	Immune system disorders	16 (0.01%)
Aortic arteriosclerosis	Vascular disorders	16 (0.01%)
Aortic dissection	Vascular disorders	16 (0.01%)
Application site pain	General disorders and administration site conditions	16 (0.01%)
Auditory disorder	Ear and labyrinth disorders	16 (0.01%)
Autoimmune haemolytic anaemia	Blood and lymphatic system disorders	16 (0.01%)
Blood calcium decreased	Investigations	16 (0.01%)
Bruxism	Psychiatric disorders	16 (0.01%)
Cervical radiculopathy	Nervous system disorders	16 (0.01%)
Chapped lips	Gastrointestinal disorders	16 (0.01%)
Clonus	Nervous system disorders	16 (0.01%)
Coronary artery thrombosis	Cardiac disorders	16 (0.01%)
Decreased interest	Psychiatric disorders	16 (0.01%)
Enuresis	Psychiatric disorders	16 (0.01%)
Epicondylitis	Injury, poisoning and procedural complications	16 (0.01%)
Facial bones fracture	Injury, poisoning and procedural complications	16 (0.01%)
Femur fracture	Injury, poisoning and procedural complications	16 (0.01%)
Gastrointestinal motility disorder	Gastrointestinal disorders	16 (0.01%)
Heart injury	Injury, poisoning and procedural complications	16 (0.01%)
Injection site haematoma	General disorders and administration site conditions	16 (0.01%)
Intentional product misuse	Injury, poisoning and procedural complications	16 (0.01%)
Intracardiac thrombus	Cardiac disorders	16 (0.01%)
Jugular vein thrombosis	Vascular disorders	16 (0.01%)
Language disorder	Nervous system disorders	16 (0.01%)
Lipase increased	Investigations	16 (0.01%)
Lung opacity	Respiratory, thoracic and mediastinal disorders	16 (0.01%)
Muscle atrophy	Musculoskeletal and connective tissue disorders	16 (0.01%)
Oedema mucosal	General disorders and administration site conditions	16 (0.01%)
Panic disorder	Psychiatric disorders	16 (0.01%)
Performance status decreased	General disorders and administration site conditions	16 (0.01%)
Radiculopathy	Nervous system disorders	16 (0.01%)
Salivary gland enlargement	Gastrointestinal disorders	16 (0.01%)
Sialoadenitis	Infections and infestations	16 (0.01%)
Splenomegaly	Blood and lymphatic system disorders	16 (0.01%)
Tetany	Metabolism and nutrition disorders	16 (0.01%)
Tongue eruption	Gastrointestinal disorders	16 (0.01%)
Urine abnormality	Renal and urinary disorders	16 (0.01%)
Uterine haemorrhage	Reproductive system and breast disorders	16 (0.01%)
Acute disseminated encephalomyelitis	Nervous system disorders	15 (0.01%)
Amaurosis fugax	Eye disorders	15 (0.01%)
Arrhythmia supraventricular	Cardiac disorders	15 (0.01%)
Arthropod bite	Injury, poisoning and procedural complications	15 (0.01%)
Back injury	Injury, poisoning and procedural complications	15 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Basedow's disease	Endocrine disorders	15 (0.01%)
Biliary colic	Hepatobiliary disorders	15 (0.01%)
Cachexia	Metabolism and nutrition disorders	15 (0.01%)
Endometriosis	Reproductive system and breast disorders	15 (0.01%)
Eosinophil count increased	Investigations	15 (0.01%)
Eyelid irritation	Eye disorders	15 (0.01%)
Hiatus hernia	Gastrointestinal disorders	15 (0.01%)
Hyporesponsive to stimuli	Nervous system disorders	15 (0.01%)
Immunisation anxiety related reaction	Psychiatric disorders	15 (0.01%)
Injection site infection	Infections and infestations	15 (0.01%)
Intraocular pressure increased	Investigations	15 (0.01%)
Joint dislocation	Injury, poisoning and procedural complications	15 (0.01%)
Laryngeal pain	Respiratory, thoracic and mediastinal disorders	15 (0.01%)
Limb immobilisation	Surgical and medical procedures	15 (0.01%)
Mucosal dryness	General disorders and administration site conditions	15 (0.01%)
N-terminal prohormone brain natriuretic peptide increased	Investigations	15 (0.01%)
Oculomucocutaneous syndrome	Skin and subcutaneous tissue disorders	15 (0.01%)
Parotid gland enlargement	Gastrointestinal disorders	15 (0.01%)
Pelvic venous thrombosis	Vascular disorders	15 (0.01%)
Pre-existing condition improved	General disorders and administration site conditions	15 (0.01%)
Premenstrual syndrome	Reproductive system and breast disorders	15 (0.01%)
Retinal detachment	Eye disorders	15 (0.01%)
Retinal haemorrhage	Eye disorders	15 (0.01%)
Skin erosion	Skin and subcutaneous tissue disorders	15 (0.01%)
Skin infection	Infections and infestations	15 (0.01%)
Skin odour abnormal	Skin and subcutaneous tissue disorders	15 (0.01%)
Stress cardiomyopathy	Cardiac disorders	15 (0.01%)
Subclavian vein thrombosis	Vascular disorders	15 (0.01%)
Tenosynovitis	Musculoskeletal and connective tissue disorders	15 (0.01%)
Thrombotic stroke	Nervous system disorders	15 (0.01%)
Tooth abscess	Infections and infestations	15 (0.01%)
Trigger finger	Musculoskeletal and connective tissue disorders	15 (0.01%)
Urine analysis abnormal	Investigations	15 (0.01%)
Vaccination error	Injury, poisoning and procedural complications	15 (0.01%)
Vaccination site papule	General disorders and administration site conditions	15 (0.01%)
Vitamin D deficiency	Metabolism and nutrition disorders	15 (0.01%)
Vulvovaginal candidiasis	Infections and infestations	15 (0.01%)
Accident	Injury, poisoning and procedural complications	14 (0.01%)
Affect lability	Psychiatric disorders	14 (0.01%)
Areflexia	Nervous system disorders	14 (0.01%)
Blue toe syndrome	Vascular disorders	14 (0.01%)
Bronchiectasis	Respiratory, thoracic and mediastinal disorders	14 (0.01%)
Bundle branch block left	Cardiac disorders	14 (0.01%)
Cardiac death	General disorders and administration site conditions	14 (0.01%)
Cardiac murmur	Investigations	14 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Circumoral oedema	Skin and subcutaneous tissue disorders	14 (0.01%)
Circumoral swelling	Skin and subcutaneous tissue disorders	14 (0.01%)
Decreased activity	General disorders and administration site conditions	14 (0.01%)
Food aversion	Metabolism and nutrition disorders	14 (0.01%)
Food refusal	Metabolism and nutrition disorders	14 (0.01%)
Gallbladder disorder	Hepatobiliary disorders	14 (0.01%)
Gastric ulcer	Gastrointestinal disorders	14 (0.01%)
General physical condition abnormal	Investigations	14 (0.01%)
Haemorrhagic disorder	Blood and lymphatic system disorders	14 (0.01%)
Hepatic failure	Hepatobiliary disorders	14 (0.01%)
Inflammatory pain	General disorders and administration site conditions	14 (0.01%)
Injection site haemorrhage	General disorders and administration site conditions	14 (0.01%)
Injection site inflammation	General disorders and administration site conditions	14 (0.01%)
Intracranial pressure increased	Nervous system disorders	14 (0.01%)
Laboratory test abnormal	Investigations	14 (0.01%)
Lack of spontaneous speech	Psychiatric disorders	14 (0.01%)
Low density lipoprotein increased	Investigations	14 (0.01%)
Mucosal disorder	General disorders and administration site conditions	14 (0.01%)
Myocardial necrosis marker increased	Investigations	14 (0.01%)
Neutrophilia	Blood and lymphatic system disorders	14 (0.01%)
Ocular vascular disorder	Eye disorders	14 (0.01%)
Oligomenorrhoea	Reproductive system and breast disorders	14 (0.01%)
Oliguria	Renal and urinary disorders	14 (0.01%)
Peripheral embolism	Vascular disorders	14 (0.01%)
Prothrombin time prolonged	Investigations	14 (0.01%)
Pulse absent	Investigations	14 (0.01%)
Pupils unequal	Eye disorders	14 (0.01%)
Respiratory fatigue	Respiratory, thoracic and mediastinal disorders	14 (0.01%)
Seizure like phenomena	Nervous system disorders	14 (0.01%)
Sleep apnoea syndrome	Respiratory, thoracic and mediastinal disorders	14 (0.01%)
Staphylococcal infection	Infections and infestations	14 (0.01%)
Tachycardia paroxysmal	Cardiac disorders	14 (0.01%)
Terminal insomnia	Psychiatric disorders	14 (0.01%)
Tongue movement disturbance	Gastrointestinal disorders	14 (0.01%)
Urinary tract infection bacterial	Infections and infestations	14 (0.01%)
Vaccination site macule	General disorders and administration site conditions	14 (0.01%)
Vascular pain	Vascular disorders	14 (0.01%)
Vasoconstriction	Vascular disorders	14 (0.01%)
Ventricular arrhythmia	Cardiac disorders	14 (0.01%)
Aneurysm	Vascular disorders	13 (0.01%)
Angiopathy	Vascular disorders	13 (0.01%)
Blood count abnormal	Investigations	13 (0.01%)
Blood potassium increased	Investigations	13 (0.01%)
Bone disorder	Musculoskeletal and connective tissue disorders	13 (0.01%)
Carotid artery occlusion	Nervous system disorders	13 (0.01%)
Cerebellar stroke	Nervous system disorders	13 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Cerebral artery embolism	Nervous system disorders	13 (0.01%)
Cholecystitis	Hepatobiliary disorders	13 (0.01%)
Coma scale abnormal	Investigations	13 (0.01%)
Contraindicated product administered	Injury, poisoning and procedural complications	13 (0.01%)
Cranial nerve disorder	Nervous system disorders	13 (0.01%)
Crepitations	General disorders and administration site conditions	13 (0.01%)
Dementia Alzheimer's type	Nervous system disorders	13 (0.01%)
Dental discomfort	Gastrointestinal disorders	13 (0.01%)
Disorganised speech	Psychiatric disorders	13 (0.01%)
Disseminated Bacillus Calmette-Guerin infection	Infections and infestations	13 (0.01%)
Episcleritis	Eye disorders	13 (0.01%)
Eyelid rash	Eye disorders	13 (0.01%)
Eye paraesthesia	Eye disorders	13 (0.01%)
Gingival discomfort	Gastrointestinal disorders	13 (0.01%)
Haemarthrosis	Musculoskeletal and connective tissue disorders	13 (0.01%)
Haemodynamic instability	Vascular disorders	13 (0.01%)
Henoch-Schonlein purpura	Skin and subcutaneous tissue disorders	13 (0.01%)
Hormone level abnormal	Investigations	13 (0.01%)
Hyperchlorhydria	Gastrointestinal disorders	13 (0.01%)
Illusion	Psychiatric disorders	13 (0.01%)
Impaired gastric emptying	Gastrointestinal disorders	13 (0.01%)
Injection site bruising	General disorders and administration site conditions	13 (0.01%)
Intestinal haemorrhage	Gastrointestinal disorders	13 (0.01%)
Intussusception	Gastrointestinal disorders	13 (0.01%)
Lower respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	13 (0.01%)
Malnutrition	Metabolism and nutrition disorders	13 (0.01%)
Meningitis viral	Infections and infestations	13 (0.01%)
Mental status changes	Psychiatric disorders	13 (0.01%)
Miosis	Eye disorders	13 (0.01%)
Morning sickness	Pregnancy, puerperium and perinatal conditions	13 (0.01%)
Muscle injury	Injury, poisoning and procedural complications	13 (0.01%)
Neoplasm progression	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	13 (0.01%)
Oesophageal pain	Gastrointestinal disorders	13 (0.01%)
Ophthalmic vein thrombosis	Eye disorders	13 (0.01%)
Oropharyngeal oedema	Respiratory, thoracic and mediastinal disorders	13 (0.01%)
Otitis media	Infections and infestations	13 (0.01%)
Papilloedema	Eye disorders	13 (0.01%)
Pharyngeal mass	Respiratory, thoracic and mediastinal disorders	13 (0.01%)
Premature baby	Pregnancy, puerperium and perinatal conditions	13 (0.01%)
Proctalgia	Gastrointestinal disorders	13 (0.01%)
Product prescribing error	Injury, poisoning and procedural complications	13 (0.01%)
Renal colic	Renal and urinary disorders	13 (0.01%)
Respiratory tract irritation	Respiratory, thoracic and mediastinal disorders	13 (0.01%)
Rheumatic disorder	Musculoskeletal and connective tissue disorders	13 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Scleritis	Eye disorders	13 (0.01%)
Sleep terror	Psychiatric disorders	13 (0.01%)
Soft tissue swelling	Musculoskeletal and connective tissue disorders	13 (0.01%)
Spinal disorder	Musculoskeletal and connective tissue disorders	13 (0.01%)
Thrombocytopenic purpura	Blood and lymphatic system disorders	13 (0.01%)
Thyroiditis	Endocrine disorders	13 (0.01%)
Thyroiditis subacute	Endocrine disorders	13 (0.01%)
Tongue paralysis	Nervous system disorders	13 (0.01%)
Toxicity to various agents	Injury, poisoning and procedural complications	13 (0.01%)
Tracheitis	Infections and infestations	13 (0.01%)
Vaginal discharge	Reproductive system and breast disorders	13 (0.01%)
Vasculitic rash	Skin and subcutaneous tissue disorders	13 (0.01%)
Wound haemorrhage	Injury, poisoning and procedural complications	13 (0.01%)
Wrong schedule	Injury, poisoning and procedural complications	13 (0.01%)
Acute abdomen	Gastrointestinal disorders	12 (0.01%)
Administration site reaction	General disorders and administration site conditions	12 (0.01%)
Aortic aneurysm	Vascular disorders	12 (0.01%)
Appendicitis perforated	Infections and infestations	12 (0.01%)
Arterial occlusive disease	Vascular disorders	12 (0.01%)
Bacille Calmette-Guerin scar reactivation	Immune system disorders	12 (0.01%)
Bacterial test positive	Investigations	12 (0.01%)
Cardiac tamponade	Cardiac disorders	12 (0.01%)
Cardiovascular insufficiency	Cardiac disorders	12 (0.01%)
Cerebral artery occlusion	Nervous system disorders	12 (0.01%)
Cerebral artery thrombosis	Nervous system disorders	12 (0.01%)
Contraindication to vaccination	Social circumstances	12 (0.01%)
Cyst	General disorders and administration site conditions	12 (0.01%)
Disseminated intravascular coagulation	Blood and lymphatic system disorders	12 (0.01%)
Ear haemorrhage	Ear and labyrinth disorders	12 (0.01%)
Electrolyte imbalance	Metabolism and nutrition disorders	12 (0.01%)
Exfoliative rash	Skin and subcutaneous tissue disorders	12 (0.01%)
Freezing phenomenon	Nervous system disorders	12 (0.01%)
Glomerulonephritis minimal lesion	Renal and urinary disorders	12 (0.01%)
Haemorrhagic diathesis	Blood and lymphatic system disorders	12 (0.01%)
Hepatic steatosis	Hepatobiliary disorders	12 (0.01%)
Hepatomegaly	Hepatobiliary disorders	12 (0.01%)
Hypocalcaemia	Metabolism and nutrition disorders	12 (0.01%)
Impaired healing	General disorders and administration site conditions	12 (0.01%)
Increased bronchial secretion	Respiratory, thoracic and mediastinal disorders	12 (0.01%)
Injection site hypoaesthesia	General disorders and administration site conditions	12 (0.01%)
Inner ear disorder	Ear and labyrinth disorders	12 (0.01%)
Intranasal paraesthesia	Respiratory, thoracic and mediastinal disorders	12 (0.01%)
Lip injury	Injury, poisoning and procedural complications	12 (0.01%)
Lymphocytosis	Blood and lymphatic system disorders	12 (0.01%)
Macroglossia	Congenital, familial and genetic disorders	12 (0.01%)
Mania	Psychiatric disorders	12 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Maternal exposure before pregnancy	Injury, poisoning and procedural complications	12 (0.01%)
Narcolepsy	Nervous system disorders	12 (0.01%)
Nasal disorder	Respiratory, thoracic and mediastinal disorders	12 (0.01%)
Oral blood blister	Gastrointestinal disorders	12 (0.01%)
Oversensing	Product issues	12 (0.01%)
Periorbital pain	Eye disorders	12 (0.01%)
Pharyngeal ulceration	Respiratory, thoracic and mediastinal disorders	12 (0.01%)
Renal cyst	Renal and urinary disorders	12 (0.01%)
Respiratory alkalosis	Respiratory, thoracic and mediastinal disorders	12 (0.01%)
Respiratory depression	Respiratory, thoracic and mediastinal disorders	12 (0.01%)
Retinal migraine	Nervous system disorders	12 (0.01%)
Shoulder injury related to vaccine administration	General disorders and administration site conditions	12 (0.01%)
Skin fissures	Skin and subcutaneous tissue disorders	12 (0.01%)
Skin plaque	Skin and subcutaneous tissue disorders	12 (0.01%)
Somatic symptom disorder	Psychiatric disorders	12 (0.01%)
Testicular swelling	Reproductive system and breast disorders	12 (0.01%)
Thermal burns of eye	Injury, poisoning and procedural complications	12 (0.01%)
Troponin I increased	Investigations	12 (0.01%)
Type 2 diabetes mellitus	Metabolism and nutrition disorders	12 (0.01%)
Upper gastrointestinal haemorrhage	Gastrointestinal disorders	12 (0.01%)
Abdominal symptom	Gastrointestinal disorders	11 (0.01%)
Antibody test negative	Investigations	11 (0.01%)
Arteriosclerosis coronary artery	Cardiac disorders	11 (0.01%)
Atrial tachycardia	Cardiac disorders	11 (0.01%)
Atypical pneumonia	Infections and infestations	11 (0.01%)
Autoscopy	Psychiatric disorders	11 (0.01%)
Breast inflammation	Reproductive system and breast disorders	11 (0.01%)
Carotid artery thrombosis	Nervous system disorders	11 (0.01%)
Cerebral atrophy	Nervous system disorders	11 (0.01%)
Colitis ischaemic	Gastrointestinal disorders	11 (0.01%)
Complex regional pain syndrome	Nervous system disorders	11 (0.01%)
Concomitant disease aggravated	General disorders and administration site conditions	11 (0.01%)
Coronary artery occlusion	Cardiac disorders	11 (0.01%)
Dermatomyositis	Skin and subcutaneous tissue disorders	11 (0.01%)
Disseminated varicella zoster virus infection	Infections and infestations	11 (0.01%)
Embolism venous	Vascular disorders	11 (0.01%)
Escherichia urinary tract infection	Infections and infestations	11 (0.01%)
Fear of death	Psychiatric disorders	11 (0.01%)
Femoral neck fracture	Injury, poisoning and procedural complications	11 (0.01%)
Fracture	Injury, poisoning and procedural complications	11 (0.01%)
Gastric haemorrhage	Gastrointestinal disorders	11 (0.01%)
Gastrointestinal necrosis	Gastrointestinal disorders	11 (0.01%)
Haemolysis	Blood and lymphatic system disorders	11 (0.01%)
Herpes zoster cutaneous disseminated	Infections and infestations	11 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Hypersensitivity vasculitis	Skin and subcutaneous tissue disorders	11 (0.01%)
Hypertensive heart disease	Cardiac disorders	11 (0.01%)
Hypoventilation	Respiratory, thoracic and mediastinal disorders	11 (0.01%)
Ileus paralytic	Gastrointestinal disorders	11 (0.01%)
Increased viscosity of upper respiratory secretion	Respiratory, thoracic and mediastinal disorders	11 (0.01%)
Intentional dose omission	Injury, poisoning and procedural complications	11 (0.01%)
Intracranial aneurysm	Nervous system disorders	11 (0.01%)
Irritability postvaccinal	General disorders and administration site conditions	11 (0.01%)
Lacunar infarction	Nervous system disorders	11 (0.01%)
Left ventricular hypertrophy	Cardiac disorders	11 (0.01%)
Leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	11 (0.01%)
Lyme disease	Infections and infestations	11 (0.01%)
Lymph gland infection	Infections and infestations	11 (0.01%)
Micturition disorder	Renal and urinary disorders	11 (0.01%)
Moaning	General disorders and administration site conditions	11 (0.01%)
Monocytosis	Blood and lymphatic system disorders	11 (0.01%)
Oropharyngeal swelling	Respiratory, thoracic and mediastinal disorders	11 (0.01%)
Paraesthesia ear	Ear and labyrinth disorders	11 (0.01%)
Paranasal sinus hypersecretion	Respiratory, thoracic and mediastinal disorders	11 (0.01%)
Parkinsonism	Nervous system disorders	11 (0.01%)
Polymerase chain reaction positive	Investigations	11 (0.01%)
Posture abnormal	Musculoskeletal and connective tissue disorders	11 (0.01%)
Prostatitis	Reproductive system and breast disorders	11 (0.01%)
Pulmonary artery thrombosis	Respiratory, thoracic and mediastinal disorders	11 (0.01%)
Pulmonary mass	Respiratory, thoracic and mediastinal disorders	11 (0.01%)
Quadriplegia	Nervous system disorders	11 (0.01%)
Retinal tear	Eye disorders	11 (0.01%)
Rhonchi	Respiratory, thoracic and mediastinal disorders	11 (0.01%)
SARS-CoV-2 test false positive	Investigations	11 (0.01%)
Serum ferritin increased	Investigations	11 (0.01%)
Skin hypertrophy	Skin and subcutaneous tissue disorders	11 (0.01%)
Suspected counterfeit product	Product issues	11 (0.01%)
Synovitis	Musculoskeletal and connective tissue disorders	11 (0.01%)
Tendon disorder	Musculoskeletal and connective tissue disorders	11 (0.01%)
Thrombotic thrombocytopenic purpura	Blood and lymphatic system disorders	11 (0.01%)
Thyroid mass	Endocrine disorders	11 (0.01%)
Tonsillar inflammation	Respiratory, thoracic and mediastinal disorders	11 (0.01%)
Tonsillitis bacterial	Infections and infestations	11 (0.01%)
Troponin T increased	Investigations	11 (0.01%)
Upper airway obstruction	Respiratory, thoracic and mediastinal disorders	11 (0.01%)
Urticaria chronic	Skin and subcutaneous tissue disorders	11 (0.01%)
Vaccination site discharge	General disorders and administration site conditions	11 (0.01%)
Vascular headache	Nervous system disorders	11 (0.01%)
Vitamin D decreased	Investigations	11 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Abnormal loss of weight	Metabolism and nutrition disorders	10 (0.01%)
Accommodation disorder	Eye disorders	10 (0.01%)
Allergic cough	Respiratory, thoracic and mediastinal disorders	10 (0.01%)
Alopecia areata	Skin and subcutaneous tissue disorders	10 (0.01%)
Amylase increased	Investigations	10 (0.01%)
Auricular swelling	Ear and labyrinth disorders	10 (0.01%)
Basilar artery thrombosis	Nervous system disorders	10 (0.01%)
Blood pressure immeasurable	Investigations	10 (0.01%)
Blood uric acid increased	Investigations	10 (0.01%)
Blood urine	Investigations	10 (0.01%)
Brain natriuretic peptide increased	Investigations	10 (0.01%)
Bronchial disorder	Respiratory, thoracic and mediastinal disorders	10 (0.01%)
Central nervous system lesion	Nervous system disorders	10 (0.01%)
Cerebellar syndrome	Nervous system disorders	10 (0.01%)
Deafness transitory	Ear and labyrinth disorders	10 (0.01%)
Decubitus ulcer	Skin and subcutaneous tissue disorders	10 (0.01%)
Dyshidrotic eczema	Skin and subcutaneous tissue disorders	10 (0.01%)
Electrocardiogram T wave inversion	Investigations	10 (0.01%)
Escherichia infection	Infections and infestations	10 (0.01%)
Exophthalmos	Eye disorders	10 (0.01%)
Extra dose administered	Injury, poisoning and procedural complications	10 (0.01%)
Foetal growth restriction	Pregnancy, puerperium and perinatal conditions	10 (0.01%)
Food poisoning	Gastrointestinal disorders	10 (0.01%)
Foreign body in throat	Injury, poisoning and procedural complications	10 (0.01%)
Gastrointestinal hypermotility	Gastrointestinal disorders	10 (0.01%)
Glassy eyes	General disorders and administration site conditions	10 (0.01%)
Glycosylated haemoglobin increased	Investigations	10 (0.01%)
Hallucination, olfactory	Psychiatric disorders	10 (0.01%)
Hallucinations, mixed	Psychiatric disorders	10 (0.01%)
Hyperbilirubinaemia	Hepatobiliary disorders	10 (0.01%)
Immunisation reaction	Immune system disorders	10 (0.01%)
Iron deficiency	Metabolism and nutrition disorders	10 (0.01%)
IVth nerve paralysis	Nervous system disorders	10 (0.01%)
Keratitis	Eye disorders	10 (0.01%)
Larynx irritation	Respiratory, thoracic and mediastinal disorders	10 (0.01%)
Leukocyturia	Renal and urinary disorders	10 (0.01%)
Lividity	Skin and subcutaneous tissue disorders	10 (0.01%)
Major depression	Psychiatric disorders	10 (0.01%)
Migraine without aura	Nervous system disorders	10 (0.01%)
Mouth injury	Injury, poisoning and procedural complications	10 (0.01%)
Nephropathy	Renal and urinary disorders	10 (0.01%)
Nocturia	Renal and urinary disorders	10 (0.01%)
Nocturnal dyspnoea	Respiratory, thoracic and mediastinal disorders	10 (0.01%)
Noninfective encephalitis	Nervous system disorders	10 (0.01%)
Optic ischaemic neuropathy	Eye disorders	10 (0.01%)
Pelvic fracture	Injury, poisoning and procedural complications	10 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Pemphigus	Skin and subcutaneous tissue disorders	10 (0.01%)
Pneumonia viral	Infections and infestations	10 (0.01%)
Pulseless electrical activity	Cardiac disorders	10 (0.01%)
Right ventricular failure	Cardiac disorders	10 (0.01%)
Sensitisation	Immune system disorders	10 (0.01%)
Skin discomfort	Skin and subcutaneous tissue disorders	10 (0.01%)
Skin temperature	Investigations	10 (0.01%)
Sleep paralysis	Nervous system disorders	10 (0.01%)
Sputum increased	Respiratory, thoracic and mediastinal disorders	10 (0.01%)
Staring	Psychiatric disorders	10 (0.01%)
Subcutaneous abscess	Infections and infestations	10 (0.01%)
Tendon rupture	Injury, poisoning and procedural complications	10 (0.01%)
Thyroid pain	Endocrine disorders	10 (0.01%)
Tonsillar disorder	Respiratory, thoracic and mediastinal disorders	10 (0.01%)
Urticaria papular	Skin and subcutaneous tissue disorders	10 (0.01%)
Vaccination site scab	General disorders and administration site conditions	10 (0.01%)
Varicella zoster virus infection	Infections and infestations	10 (0.01%)
Vestibular migraine	Nervous system disorders	10 (0.01%)
Walking aid user	Social circumstances	10 (0.01%)
White matter lesion	Nervous system disorders	10 (0.01%)
Acidosis	Metabolism and nutrition disorders	9 (0.01%)
Acute vestibular syndrome	Ear and labyrinth disorders	9 (0.01%)
Blood chloride increased	Investigations	9 (0.01%)
Brain stem infarction	Nervous system disorders	9 (0.01%)
Brain stem stroke	Nervous system disorders	9 (0.01%)
Breast disorder	Reproductive system and breast disorders	9 (0.01%)
Butterfly rash	Skin and subcutaneous tissue disorders	9 (0.01%)
Cerebellar infarction	Nervous system disorders	9 (0.01%)
Chest X-ray abnormal	Investigations	9 (0.01%)
Chronic lymphocytic leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	9 (0.01%)
Clonic convulsion	Nervous system disorders	9 (0.01%)
Coccydynia	Musculoskeletal and connective tissue disorders	9 (0.01%)
Coeliac disease	Gastrointestinal disorders	9 (0.01%)
Cold-stimulus headache	Nervous system disorders	9 (0.01%)
Conjunctivitis allergic	Eye disorders	9 (0.01%)
C-reactive protein abnormal	Investigations	9 (0.01%)
Ejection fraction decreased	Investigations	9 (0.01%)
Enterocolitis	Gastrointestinal disorders	9 (0.01%)
Enthesopathy	Musculoskeletal and connective tissue disorders	9 (0.01%)
Essential hypertension	Vascular disorders	9 (0.01%)
Excessive cerumen production	Ear and labyrinth disorders	9 (0.01%)
Eye haematoma	Eye disorders	9 (0.01%)
Faeces pale	Gastrointestinal disorders	9 (0.01%)
Flat affect	Psychiatric disorders	9 (0.01%)
Fluid overload	Metabolism and nutrition disorders	9 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Folliculitis	Infections and infestations	9 (0.01%)
Food intolerance	Metabolism and nutrition disorders	9 (0.01%)
Gastric dilatation	Gastrointestinal disorders	9 (0.01%)
Genital haemorrhage	Reproductive system and breast disorders	9 (0.01%)
Gingival disorder	Gastrointestinal disorders	9 (0.01%)
Gingival erythema	Gastrointestinal disorders	9 (0.01%)
Haematoma muscle	Musculoskeletal and connective tissue disorders	9 (0.01%)
Haemophagocytic lymphohistiocytosis	Immune system disorders	9 (0.01%)
Head titubation	Nervous system disorders	9 (0.01%)
Heat stroke	Injury, poisoning and procedural complications	9 (0.01%)
Hemianopia	Nervous system disorders	9 (0.01%)
Hemidysaesthesia	Nervous system disorders	9 (0.01%)
Herpes simplex reactivation	Infections and infestations	9 (0.01%)
Hyperreflexia	Nervous system disorders	9 (0.01%)
Hypotensive crisis	Vascular disorders	9 (0.01%)
Idiopathic intracranial hypertension	Nervous system disorders	9 (0.01%)
Immune-mediated adverse reaction	Immune system disorders	9 (0.01%)
Insulin resistance	Metabolism and nutrition disorders	9 (0.01%)
Intraventricular haemorrhage	Nervous system disorders	9 (0.01%)
Iritis	Eye disorders	9 (0.01%)
Iron deficiency anaemia	Blood and lymphatic system disorders	9 (0.01%)
Joint instability	Musculoskeletal and connective tissue disorders	9 (0.01%)
Ketoacidosis	Metabolism and nutrition disorders	9 (0.01%)
Lactic acidosis	Metabolism and nutrition disorders	9 (0.01%)
Lacunar stroke	Nervous system disorders	9 (0.01%)
Left ventricular dysfunction	Cardiac disorders	9 (0.01%)
Lip discolouration	Gastrointestinal disorders	9 (0.01%)
Lip exfoliation	Gastrointestinal disorders	9 (0.01%)
Lower limb fracture	Injury, poisoning and procedural complications	9 (0.01%)
Macular degeneration	Eye disorders	9 (0.01%)
Macular oedema	Eye disorders	9 (0.01%)
Meningism	Nervous system disorders	9 (0.01%)
Menopause	Social circumstances	9 (0.01%)
Neck injury	Injury, poisoning and procedural complications	9 (0.01%)
Necrosis	General disorders and administration site conditions	9 (0.01%)
Non-cardiac chest pain	General disorders and administration site conditions	9 (0.01%)
Occupational exposure to SARS-CoV-2	Injury, poisoning and procedural complications	9 (0.01%)
Peritonitis	Infections and infestations	9 (0.01%)
Plantar fasciitis	Musculoskeletal and connective tissue disorders	9 (0.01%)
PO2 decreased	Investigations	9 (0.01%)
Procalcitonin increased	Investigations	9 (0.01%)
Psychomotor skills impaired	Nervous system disorders	9 (0.01%)
Pulmonary arterial hypertension	Respiratory, thoracic and mediastinal disorders	9 (0.01%)
Pulmonary sepsis	Infections and infestations	9 (0.01%)
Retinal vascular thrombosis	Eye disorders	9 (0.01%)
Scleral discolouration	Eye disorders	9 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Sensation of blood flow	General disorders and administration site conditions	9 (0.01%)
Sensitivity to weather change	General disorders and administration site conditions	9 (0.01%)
Shock symptom	Vascular disorders	9 (0.01%)
Skin induration	Skin and subcutaneous tissue disorders	9 (0.01%)
Skin injury	Injury, poisoning and procedural complications	9 (0.01%)
Skin weeping	Skin and subcutaneous tissue disorders	9 (0.01%)
Slow response to stimuli	Nervous system disorders	9 (0.01%)
Streptococcal infection	Infections and infestations	9 (0.01%)
Sudden visual loss	Eye disorders	9 (0.01%)
Thunderclap headache	Nervous system disorders	9 (0.01%)
Tooth fracture	Injury, poisoning and procedural complications	9 (0.01%)
Tooth injury	Injury, poisoning and procedural complications	9 (0.01%)
Tricuspid valve incompetence	Cardiac disorders	9 (0.01%)
Vascular injury	Injury, poisoning and procedural complications	9 (0.01%)
Weight fluctuation	Metabolism and nutrition disorders	9 (0.01%)
Acquired haemophilia	Blood and lymphatic system disorders	8 (0.00%)
Activated partial thromboplastin time shortened	Investigations	8 (0.00%)
Acute myeloid leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8 (0.00%)
Aneurysm ruptured	Vascular disorders	8 (0.00%)
Angina unstable	Cardiac disorders	8 (0.00%)
Ascites	Gastrointestinal disorders	8 (0.00%)
Bacteraemia	Infections and infestations	8 (0.00%)
Bed rest	Surgical and medical procedures	8 (0.00%)
Bladder discomfort	Renal and urinary disorders	8 (0.00%)
Bladder dysfunction	Renal and urinary disorders	8 (0.00%)
Blood albumin decreased	Investigations	8 (0.00%)
Blood creatinine decreased	Investigations	8 (0.00%)
Blood phosphorus decreased	Investigations	8 (0.00%)
Brain death	General disorders and administration site conditions	8 (0.00%)
Breast enlargement	Reproductive system and breast disorders	8 (0.00%)
Capillary fragility	Vascular disorders	8 (0.00%)
Cardiac failure chronic	Cardiac disorders	8 (0.00%)
Cardiac valve disease	Cardiac disorders	8 (0.00%)
Cerebellar haemorrhage	Nervous system disorders	8 (0.00%)
Conjunctival irritation	Eye disorders	8 (0.00%)
Conjunctival oedema	Eye disorders	8 (0.00%)
Conversion disorder	Psychiatric disorders	8 (0.00%)
COVID-19 immunisation	Surgical and medical procedures	8 (0.00%)
Cranial nerve paralysis	Nervous system disorders	8 (0.00%)
Cutaneous symptom	Skin and subcutaneous tissue disorders	8 (0.00%)
Cystitis haemorrhagic	Renal and urinary disorders	8 (0.00%)
Dark circles under eyes	Eye disorders	8 (0.00%)
Daydreaming	Psychiatric disorders	8 (0.00%)
Decreased immune responsiveness	Immune system disorders	8 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Demyelinating polyneuropathy	Nervous system disorders	8 (0.00%)
Dermal cyst	Skin and subcutaneous tissue disorders	8 (0.00%)
Dermatitis acneiform	Skin and subcutaneous tissue disorders	8 (0.00%)
Dermatitis exfoliative generalised	Skin and subcutaneous tissue disorders	8 (0.00%)
Diet refusal	Metabolism and nutrition disorders	8 (0.00%)
Eating disorder symptom	Metabolism and nutrition disorders	8 (0.00%)
Electrocardiogram ST segment depression	Investigations	8 (0.00%)
Endocrine ophthalmopathy	Eye disorders	8 (0.00%)
Eosinophil count decreased	Investigations	8 (0.00%)
Epstein-Barr virus infection reactivation	Infections and infestations	8 (0.00%)
External ear pain	Ear and labyrinth disorders	8 (0.00%)
Extrapyramidal disorder	Nervous system disorders	8 (0.00%)
Eye allergy	Eye disorders	8 (0.00%)
Eye colour change	Eye disorders	8 (0.00%)
Fear of injection	Psychiatric disorders	8 (0.00%)
Food craving	Metabolism and nutrition disorders	8 (0.00%)
Haemoglobin increased	Investigations	8 (0.00%)
Haemorrhagic transformation stroke	Nervous system disorders	8 (0.00%)
Hand dermatitis	Skin and subcutaneous tissue disorders	8 (0.00%)
Hand fracture	Injury, poisoning and procedural complications	8 (0.00%)
Heart sounds abnormal	Investigations	8 (0.00%)
Hepatic cyst	Hepatobiliary disorders	8 (0.00%)
Hepatic enzyme abnormal	Investigations	8 (0.00%)
Hepatitis cholestatic	Hepatobiliary disorders	8 (0.00%)
Hypercapnia	Respiratory, thoracic and mediastinal disorders	8 (0.00%)
Hypertensive urgency	Vascular disorders	8 (0.00%)
Infant irritability	Nervous system disorders	8 (0.00%)
Intentional product use issue	Injury, poisoning and procedural complications	8 (0.00%)
Lagophthalmos	Eye disorders	8 (0.00%)
Laziness	Psychiatric disorders	8 (0.00%)
Leukoencephalopathy	Nervous system disorders	8 (0.00%)
Loss of libido	Psychiatric disorders	8 (0.00%)
Measles	Infections and infestations	8 (0.00%)
Metastases to lymph nodes	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8 (0.00%)
Multi-organ disorder	General disorders and administration site conditions	8 (0.00%)
Mumps	Infections and infestations	8 (0.00%)
Muscle strength abnormal	Investigations	8 (0.00%)
Myosclerosis	Musculoskeletal and connective tissue disorders	8 (0.00%)
Nasal herpes	Infections and infestations	8 (0.00%)
Nasal injury	Injury, poisoning and procedural complications	8 (0.00%)
Neurodermatitis	Skin and subcutaneous tissue disorders	8 (0.00%)
Neutrophil count abnormal	Investigations	8 (0.00%)
Nipple swelling	Reproductive system and breast disorders	8 (0.00%)
Oesophageal spasm	Gastrointestinal disorders	8 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Otitis externa	Infections and infestations	8 (0.00%)
Paraesthesia mucosal	Nervous system disorders	8 (0.00%)
Pityriasis	Skin and subcutaneous tissue disorders	8 (0.00%)
Pleuropericarditis	Cardiac disorders	8 (0.00%)
Poisoning	Injury, poisoning and procedural complications	8 (0.00%)
Prostate cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8 (0.00%)
Protein total decreased	Investigations	8 (0.00%)
Protein urine present	Investigations	8 (0.00%)
Prurigo	Skin and subcutaneous tissue disorders	8 (0.00%)
Pruritus allergic	Skin and subcutaneous tissue disorders	8 (0.00%)
Pulse volume decreased	Investigations	8 (0.00%)
Pupil fixed	Eye disorders	8 (0.00%)
Radial pulse abnormal	Investigations	8 (0.00%)
Reflux gastritis	Gastrointestinal disorders	8 (0.00%)
Renal infarct	Renal and urinary disorders	8 (0.00%)
Ruptured cerebral aneurysm	Nervous system disorders	8 (0.00%)
Sensorimotor disorder	Nervous system disorders	8 (0.00%)
Sensory level abnormal	Investigations	8 (0.00%)
Sleep talking	Psychiatric disorders	8 (0.00%)
Spinal osteoarthritis	Musculoskeletal and connective tissue disorders	8 (0.00%)
Splenic infarction	Blood and lymphatic system disorders	8 (0.00%)
Spondylitis	Musculoskeletal and connective tissue disorders	8 (0.00%)
Stenosis	General disorders and administration site conditions	8 (0.00%)
Stiff tongue	Gastrointestinal disorders	8 (0.00%)
Superinfection bacterial	Infections and infestations	8 (0.00%)
Superior sagittal sinus thrombosis	Nervous system disorders	8 (0.00%)
Suppressed lactation	Reproductive system and breast disorders	8 (0.00%)
Systolic hypertension	Vascular disorders	8 (0.00%)
Tachypnea	Psychiatric disorders	8 (0.00%)
Thyroiditis acute	Endocrine disorders	8 (0.00%)
Uterine pain	Reproductive system and breast disorders	8 (0.00%)
Vaginal infection	Infections and infestations	8 (0.00%)
Vascular dementia	Nervous system disorders	8 (0.00%)
White blood cells urine positive	Investigations	8 (0.00%)
Wound complication	Injury, poisoning and procedural complications	8 (0.00%)
Abdominal infection	Infections and infestations	7 (0.00%)
Abnormal weight gain	Metabolism and nutrition disorders	7 (0.00%)
Acute febrile neutrophilic dermatosis	Skin and subcutaneous tissue disorders	7 (0.00%)
Administration site swelling	General disorders and administration site conditions	7 (0.00%)
Affective disorder	Psychiatric disorders	7 (0.00%)
Antinuclear antibody positive	Investigations	7 (0.00%)
Aortic stenosis	Vascular disorders	7 (0.00%)
Aptalism	Gastrointestinal disorders	7 (0.00%)
Arthropod sting	Injury, poisoning and procedural complications	7 (0.00%)
Atrioventricular block second degree	Cardiac disorders	7 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Autoimmune hepatitis	Hepatobiliary disorders	7 (0.00%)
Band sensation	Nervous system disorders	7 (0.00%)
Bipolar disorder	Psychiatric disorders	7 (0.00%)
Blood sodium increased	Investigations	7 (0.00%)
Blood triglycerides increased	Investigations	7 (0.00%)
Breast abscess	Infections and infestations	7 (0.00%)
Breast cyst	Reproductive system and breast disorders	7 (0.00%)
Breast oedema	Reproductive system and breast disorders	7 (0.00%)
Burning sensation mucosal	Nervous system disorders	7 (0.00%)
Burn oral cavity	Injury, poisoning and procedural complications	7 (0.00%)
Cardiac asthma	Cardiac disorders	7 (0.00%)
Cholinergic syndrome	Nervous system disorders	7 (0.00%)
Circadian rhythm sleep disorder	Nervous system disorders	7 (0.00%)
Circumstance or information capable of leading to device use error	Injury, poisoning and procedural complications	7 (0.00%)
Clostridium difficile infection	Infections and infestations	7 (0.00%)
Concomitant disease progression	General disorders and administration site conditions	7 (0.00%)
Consciousness fluctuating	Nervous system disorders	7 (0.00%)
Coronavirus test positive	Investigations	7 (0.00%)
CSF protein increased	Investigations	7 (0.00%)
Delusional perception	Psychiatric disorders	7 (0.00%)
Depersonalisation/derealisation disorder	Psychiatric disorders	7 (0.00%)
Dermatitis exfoliative	Skin and subcutaneous tissue disorders	7 (0.00%)
Dermatosis	Skin and subcutaneous tissue disorders	7 (0.00%)
Dermo-hypodermatitis	Infections and infestations	7 (0.00%)
Diverticulum intestinal	Gastrointestinal disorders	7 (0.00%)
Drug effective for unapproved indication	General disorders and administration site conditions	7 (0.00%)
Dyschezia	Gastrointestinal disorders	7 (0.00%)
Dyschromatopsia	Eye disorders	7 (0.00%)
Dyslalia	Nervous system disorders	7 (0.00%)
Electrocardiogram QT prolonged	Investigations	7 (0.00%)
Embolus cerebral infarction	Nervous system disorders	7 (0.00%)
Eustachian tube dysfunction	Ear and labyrinth disorders	7 (0.00%)
Extremity contracture	Musculoskeletal and connective tissue disorders	7 (0.00%)
Faecaloma	Gastrointestinal disorders	7 (0.00%)
Feeling of relaxation	General disorders and administration site conditions	7 (0.00%)
Foot fracture	Injury, poisoning and procedural complications	7 (0.00%)
General symptom	General disorders and administration site conditions	7 (0.00%)
Haematocrit increased	Investigations	7 (0.00%)
Hemianopia homonymous	Nervous system disorders	7 (0.00%)
Hemiplegic migraine	Nervous system disorders	7 (0.00%)
Hypertransaminasaemia	Hepatobiliary disorders	7 (0.00%)
Hypoaesthesia teeth	Gastrointestinal disorders	7 (0.00%)
Hypoperfusion	Vascular disorders	7 (0.00%)
Ill-defined disorder	General disorders and administration site conditions	7 (0.00%)
Immunisation	Surgical and medical procedures	7 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Inflammatory bowel disease	Gastrointestinal disorders	7 (0.00%)
Injection site joint pain	General disorders and administration site conditions	7 (0.00%)
Inner ear inflammation	Ear and labyrinth disorders	7 (0.00%)
Jaw clicking	Musculoskeletal and connective tissue disorders	7 (0.00%)
Klebsiella infection	Infections and infestations	7 (0.00%)
Laryngeal obstruction	Respiratory, thoracic and mediastinal disorders	7 (0.00%)
Lipoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (0.00%)
Logorrhoea	Psychiatric disorders	7 (0.00%)
Lung neoplasm malignant	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (0.00%)
Malignant hypertension	Vascular disorders	7 (0.00%)
Marasmus	Metabolism and nutrition disorders	7 (0.00%)
Mean cell haemoglobin concentration decreased	Investigations	7 (0.00%)
Mean cell haemoglobin decreased	Investigations	7 (0.00%)
Mean cell volume decreased	Investigations	7 (0.00%)
Mean cell volume increased	Investigations	7 (0.00%)
Muscle rupture	Injury, poisoning and procedural complications	7 (0.00%)
Myalgia intercostal	Musculoskeletal and connective tissue disorders	7 (0.00%)
Myasthenia gravis crisis	Nervous system disorders	7 (0.00%)
Myokymia	Musculoskeletal and connective tissue disorders	7 (0.00%)
Myopathy	Musculoskeletal and connective tissue disorders	7 (0.00%)
Oral mucosal exfoliation	Gastrointestinal disorders	7 (0.00%)
Orchitis	Infections and infestations	7 (0.00%)
Oropharyngeal spasm	Respiratory, thoracic and mediastinal disorders	7 (0.00%)
Osteoporosis	Musculoskeletal and connective tissue disorders	7 (0.00%)
Overweight	Metabolism and nutrition disorders	7 (0.00%)
Paraplegia	Nervous system disorders	7 (0.00%)
Patient elopement	Nervous system disorders	7 (0.00%)
Peak expiratory flow rate decreased	Investigations	7 (0.00%)
Pericardial haemorrhage	Cardiac disorders	7 (0.00%)
Periorbital haematoma	Injury, poisoning and procedural complications	7 (0.00%)
Platelet disorder	Blood and lymphatic system disorders	7 (0.00%)
Product label confusion	Injury, poisoning and procedural complications	7 (0.00%)
Product physical issue	Product issues	7 (0.00%)
Prostatomegaly	Reproductive system and breast disorders	7 (0.00%)
Psychiatric symptom	Psychiatric disorders	7 (0.00%)
Psychogenic seizure	Nervous system disorders	7 (0.00%)
Pulmonary haemorrhage	Respiratory, thoracic and mediastinal disorders	7 (0.00%)
Pulpitis dental	Infections and infestations	7 (0.00%)
Puncture site pain	General disorders and administration site conditions	7 (0.00%)
Rectal discharge	Gastrointestinal disorders	7 (0.00%)
Red blood cell count increased	Investigations	7 (0.00%)
Sacroiliitis	Musculoskeletal and connective tissue disorders	7 (0.00%)
Scar pain	Skin and subcutaneous tissue disorders	7 (0.00%)
Scintillating scotoma	Eye disorders	7 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Scrotal pain	Reproductive system and breast disorders	7 (0.00%)
Serum sickness	Immune system disorders	7 (0.00%)
Skin necrosis	Skin and subcutaneous tissue disorders	7 (0.00%)
Small intestinal obstruction	Gastrointestinal disorders	7 (0.00%)
Spinal cord disorder	Nervous system disorders	7 (0.00%)
Spontaneous haematoma	Blood and lymphatic system disorders	7 (0.00%)
Sputum purulent	Infections and infestations	7 (0.00%)
Subdural haemorrhage	Injury, poisoning and procedural complications	7 (0.00%)
Sudden onset of sleep	Nervous system disorders	7 (0.00%)
Suicide attempt	Psychiatric disorders	7 (0.00%)
Systemic lupus erythematosus rash	Skin and subcutaneous tissue disorders	7 (0.00%)
Tendon injury	Injury, poisoning and procedural complications	7 (0.00%)
Thalamic infarction	Nervous system disorders	7 (0.00%)
Thrombocytosis	Blood and lymphatic system disorders	7 (0.00%)
Thyroid function test abnormal	Investigations	7 (0.00%)
Tongue spasm	Gastrointestinal disorders	7 (0.00%)
Urine flow decreased	Renal and urinary disorders	7 (0.00%)
Urine output increased	Investigations	7 (0.00%)
Uterine leiomyoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (0.00%)
Uvulitis	Gastrointestinal disorders	7 (0.00%)
Vaccination site dermatitis	General disorders and administration site conditions	7 (0.00%)
Vaccination site pustule	Infections and infestations	7 (0.00%)
Vaccination site scar	General disorders and administration site conditions	7 (0.00%)
Vein discolouration	Vascular disorders	7 (0.00%)
Ventricular hypokinesia	Cardiac disorders	7 (0.00%)
Vertigo labyrinthine	Ear and labyrinth disorders	7 (0.00%)
Viral pharyngitis	Infections and infestations	7 (0.00%)
Vitreous haemorrhage	Eye disorders	7 (0.00%)
Vulvovaginal burning sensation	Reproductive system and breast disorders	7 (0.00%)
Vulvovaginal swelling	Reproductive system and breast disorders	7 (0.00%)
Abdominal mass	Gastrointestinal disorders	6 (0.00%)
Abortion	Pregnancy, puerperium and perinatal conditions	6 (0.00%)
Acute cardiac event	Cardiac disorders	6 (0.00%)
Acute stress disorder	Psychiatric disorders	6 (0.00%)
Akathisia	Nervous system disorders	6 (0.00%)
Anorectal discomfort	Gastrointestinal disorders	6 (0.00%)
Anxiety disorder	Psychiatric disorders	6 (0.00%)
Aortic valve stenosis	Cardiac disorders	6 (0.00%)
Apraxia	Nervous system disorders	6 (0.00%)
Arteriospasm coronary	Cardiac disorders	6 (0.00%)
Atrioventricular block first degree	Cardiac disorders	6 (0.00%)
Azotaemia	Renal and urinary disorders	6 (0.00%)
Bacterial sepsis	Infections and infestations	6 (0.00%)
Blood creatine increased	Investigations	6 (0.00%)
Blood immunoglobulin G increased	Investigations	6 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Blood immunoglobulin M increased	Investigations	6 (0.00%)
Blood magnesium decreased	Investigations	6 (0.00%)
Blood thyroid stimulating hormone decreased	Investigations	6 (0.00%)
Brain stem haemorrhage	Nervous system disorders	6 (0.00%)
Brain stem syndrome	Nervous system disorders	6 (0.00%)
Breast haematoma	Reproductive system and breast disorders	6 (0.00%)
Bronchostenosis	Respiratory, thoracic and mediastinal disorders	6 (0.00%)
Cardiac hypertrophy	Cardiac disorders	6 (0.00%)
Carotid arteriosclerosis	Nervous system disorders	6 (0.00%)
Carotid artery dissection	Nervous system disorders	6 (0.00%)
Catatonias	Psychiatric disorders	6 (0.00%)
Cerebellar ataxia	Nervous system disorders	6 (0.00%)
Chorea	Nervous system disorders	6 (0.00%)
Chromatopsia	Eye disorders	6 (0.00%)
Coagulation time prolonged	Investigations	6 (0.00%)
Colitis microscopic	Gastrointestinal disorders	6 (0.00%)
Corneal reflex decreased	Investigations	6 (0.00%)
Counterfeit product administered	Injury, poisoning and procedural complications	6 (0.00%)
Dental paraesthesia	Gastrointestinal disorders	6 (0.00%)
Diabetic metabolic decompensation	Metabolism and nutrition disorders	6 (0.00%)
Diverticulum	Gastrointestinal disorders	6 (0.00%)
Drainage	Surgical and medical procedures	6 (0.00%)
Drowning	General disorders and administration site conditions	6 (0.00%)
Drug-induced liver injury	Hepatobiliary disorders	6 (0.00%)
Drug reaction with eosinophilia and systemic symptoms	Skin and subcutaneous tissue disorders	6 (0.00%)
Electric shock	Injury, poisoning and procedural complications	6 (0.00%)
Electrocardiogram repolarisation abnormality	Investigations	6 (0.00%)
Endocarditis	Infections and infestations	6 (0.00%)
Enterococcal infection	Infections and infestations	6 (0.00%)
Epstein-Barr virus infection	Infections and infestations	6 (0.00%)
Extraocular muscle paresis	Eye disorders	6 (0.00%)
Eyelid sensory disorder	Eye disorders	6 (0.00%)
Faecal calprotectin increased	Investigations	6 (0.00%)
Finger deformity	Musculoskeletal and connective tissue disorders	6 (0.00%)
Foetal exposure during pregnancy	Injury, poisoning and procedural complications	6 (0.00%)
Foot deformity	Musculoskeletal and connective tissue disorders	6 (0.00%)
Frostbite	Injury, poisoning and procedural complications	6 (0.00%)
Full blood count abnormal	Investigations	6 (0.00%)
Gastric pH decreased	Investigations	6 (0.00%)
Genital pain	Reproductive system and breast disorders	6 (0.00%)
Gingival blister	Gastrointestinal disorders	6 (0.00%)
Guttate psoriasis	Skin and subcutaneous tissue disorders	6 (0.00%)
Hair texture abnormal	Skin and subcutaneous tissue disorders	6 (0.00%)
Halo vision	Eye disorders	6 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Hand deformity	Musculoskeletal and connective tissue disorders	6 (0.00%)
Head banging	Psychiatric disorders	6 (0.00%)
Hepatocellular injury	Hepatobiliary disorders	6 (0.00%)
Hernia	General disorders and administration site conditions	6 (0.00%)
Herpes zoster infection neurological	Infections and infestations	6 (0.00%)
Huntington's disease	Congenital, familial and genetic disorders	6 (0.00%)
Hydrocephalus	Nervous system disorders	6 (0.00%)
Hypercalcaemia	Metabolism and nutrition disorders	6 (0.00%)
Hyperlactacidaemia	Metabolism and nutrition disorders	6 (0.00%)
Hypertrophic cardiomyopathy	Congenital, familial and genetic disorders	6 (0.00%)
Hypoalbuminaemia	Metabolism and nutrition disorders	6 (0.00%)
Ileus	Gastrointestinal disorders	6 (0.00%)
Incorrect dosage administered	Injury, poisoning and procedural complications	6 (0.00%)
Intermittent claudication	Vascular disorders	6 (0.00%)
International normalised ratio abnormal	Investigations	6 (0.00%)
Itching scar	Skin and subcutaneous tissue disorders	6 (0.00%)
Labile blood pressure	Vascular disorders	6 (0.00%)
Laryngeal dyspnoea	Respiratory, thoracic and mediastinal disorders	6 (0.00%)
Lip ulceration	Gastrointestinal disorders	6 (0.00%)
Maculopathy	Eye disorders	6 (0.00%)
Mast cell activation syndrome	Blood and lymphatic system disorders	6 (0.00%)
Mean platelet volume decreased	Investigations	6 (0.00%)
Meningoencephalitis herpetic	Infections and infestations	6 (0.00%)
Mesenteric artery thrombosis	Gastrointestinal disorders	6 (0.00%)
Neurologic neglect syndrome	Nervous system disorders	6 (0.00%)
Ocular icterus	Hepatobiliary disorders	6 (0.00%)
Onychoclasia	Skin and subcutaneous tissue disorders	6 (0.00%)
Ophthalmic herpes simplex	Infections and infestations	6 (0.00%)
Ophthalmoplegia	Eye disorders	6 (0.00%)
Oral fungal infection	Infections and infestations	6 (0.00%)
Orbital oedema	Eye disorders	6 (0.00%)
Organising pneumonia	Respiratory, thoracic and mediastinal disorders	6 (0.00%)
Orthostatic intolerance	Nervous system disorders	6 (0.00%)
Osteoarthropathy	Musculoskeletal and connective tissue disorders	6 (0.00%)
Ovarian cyst	Reproductive system and breast disorders	6 (0.00%)
Palatal disorder	Gastrointestinal disorders	6 (0.00%)
Periorbital discomfort	Eye disorders	6 (0.00%)
Pharyngeal haemorrhage	Respiratory, thoracic and mediastinal disorders	6 (0.00%)
Phonophobia	Psychiatric disorders	6 (0.00%)
Plicated tongue	Gastrointestinal disorders	6 (0.00%)
Polymyositis	Musculoskeletal and connective tissue disorders	6 (0.00%)
Postictal state	Nervous system disorders	6 (0.00%)
Post-traumatic stress disorder	Psychiatric disorders	6 (0.00%)
Prerenal failure	Renal and urinary disorders	6 (0.00%)
Prostatic specific antigen increased	Investigations	6 (0.00%)
Pulmonary arterial pressure increased	Investigations	6 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Pupillary disorder	Eye disorders	6 (0.00%)
Reaction to preservatives	Immune system disorders	6 (0.00%)
Regurgitation	Gastrointestinal disorders	6 (0.00%)
Retinal artery thrombosis	Eye disorders	6 (0.00%)
Retrograde amnesia	Nervous system disorders	6 (0.00%)
Rheumatoid factor increased	Investigations	6 (0.00%)
Right ventricular dilatation	Cardiac disorders	6 (0.00%)
Severe acute respiratory syndrome	Infections and infestations	6 (0.00%)
Sinonasal obstruction	Respiratory, thoracic and mediastinal disorders	6 (0.00%)
Skin depigmentation	Skin and subcutaneous tissue disorders	6 (0.00%)
Skin indentation	Skin and subcutaneous tissue disorders	6 (0.00%)
Skin wrinkling	Skin and subcutaneous tissue disorders	6 (0.00%)
Sleep attacks	Psychiatric disorders	6 (0.00%)
Small intestinal haemorrhage	Gastrointestinal disorders	6 (0.00%)
Somnambulism	Psychiatric disorders	6 (0.00%)
Spinal fracture	Injury, poisoning and procedural complications	6 (0.00%)
Splenic vein thrombosis	Blood and lymphatic system disorders	6 (0.00%)
Staphylococcal sepsis	Infections and infestations	6 (0.00%)
Subcutaneous haematoma	Injury, poisoning and procedural complications	6 (0.00%)
Symptom recurrence	General disorders and administration site conditions	6 (0.00%)
Teething	Gastrointestinal disorders	6 (0.00%)
Terminal state	General disorders and administration site conditions	6 (0.00%)
Tongue injury	Injury, poisoning and procedural complications	6 (0.00%)
Toxic epidermal necrolysis	Skin and subcutaneous tissue disorders	6 (0.00%)
Trichoglossia	Gastrointestinal disorders	6 (0.00%)
Trigeminal neuritis	Nervous system disorders	6 (0.00%)
Type III immune complex mediated reaction	Immune system disorders	6 (0.00%)
Ulcerative keratitis	Eye disorders	6 (0.00%)
Urinary tract inflammation	Renal and urinary disorders	6 (0.00%)
Vaccination site joint inflammation	General disorders and administration site conditions	6 (0.00%)
Vaccination site necrosis	General disorders and administration site conditions	6 (0.00%)
Vascular rupture	Vascular disorders	6 (0.00%)
Vena cava thrombosis	Vascular disorders	6 (0.00%)
Viral labyrinthitis	Infections and infestations	6 (0.00%)
Vitamin B12 decreased	Investigations	6 (0.00%)
Vocal cord disorder	Respiratory, thoracic and mediastinal disorders	6 (0.00%)
Vulvovaginal mycotic infection	Infections and infestations	6 (0.00%)
Withdrawal syndrome	General disorders and administration site conditions	6 (0.00%)
Wrist fracture	Injury, poisoning and procedural complications	6 (0.00%)
Acarodermatitis	Infections and infestations	5 (0.00%)
Accidental underdose	Injury, poisoning and procedural complications	5 (0.00%)
Acute hepatic failure	Hepatobiliary disorders	5 (0.00%)
Administration site bruise	General disorders and administration site conditions	5 (0.00%)
Administration site erythema	General disorders and administration site conditions	5 (0.00%)
Administration site pruritus	General disorders and administration site conditions	5 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Adverse event following immunisation	Injury, poisoning and procedural complications	5 (0.00%)
Adverse reaction	General disorders and administration site conditions	5 (0.00%)
Agranulocytosis	Blood and lymphatic system disorders	5 (0.00%)
Alcohol interaction	General disorders and administration site conditions	5 (0.00%)
Allergy to chemicals	Immune system disorders	5 (0.00%)
Anal sphincter atony	Gastrointestinal disorders	5 (0.00%)
Anaphylactoid shock	Immune system disorders	5 (0.00%)
Angular cheilitis	Gastrointestinal disorders	5 (0.00%)
Ankle fracture	Injury, poisoning and procedural complications	5 (0.00%)
Anterograde amnesia	Nervous system disorders	5 (0.00%)
Antiphospholipid syndrome	Blood and lymphatic system disorders	5 (0.00%)
Anti-thyroid antibody positive	Investigations	5 (0.00%)
Aortic aneurysm rupture	Vascular disorders	5 (0.00%)
Aortic valve incompetence	Cardiac disorders	5 (0.00%)
Apallic syndrome	Nervous system disorders	5 (0.00%)
Apnoeic attack	Respiratory, thoracic and mediastinal disorders	5 (0.00%)
Application site erythema	General disorders and administration site conditions	5 (0.00%)
Arterial disorder	Vascular disorders	5 (0.00%)
Arterial stenosis	Vascular disorders	5 (0.00%)
Attention deficit hyperactivity disorder	Psychiatric disorders	5 (0.00%)
Basal ganglia haemorrhage	Nervous system disorders	5 (0.00%)
Basal ganglia stroke	Nervous system disorders	5 (0.00%)
Behcet's syndrome	Vascular disorders	5 (0.00%)
Benign prostatic hyperplasia	Reproductive system and breast disorders	5 (0.00%)
Bladder spasm	Renal and urinary disorders	5 (0.00%)
Blood calcium increased	Investigations	5 (0.00%)
Blood chloride decreased	Investigations	5 (0.00%)
Blood cholesterol abnormal	Investigations	5 (0.00%)
Blood creatinine abnormal	Investigations	5 (0.00%)
Blood fibrinogen decreased	Investigations	5 (0.00%)
Blood immunoglobulin G decreased	Investigations	5 (0.00%)
Blood pH increased	Investigations	5 (0.00%)
Blood pressure ambulatory increased	Investigations	5 (0.00%)
Blood pressure inadequately controlled	Vascular disorders	5 (0.00%)
Blood pressure measurement	Investigations	5 (0.00%)
Bone neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5 (0.00%)
Brain herniation	Injury, poisoning and procedural complications	5 (0.00%)
Brain neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5 (0.00%)
Bronchial hyperreactivity	Respiratory, thoracic and mediastinal disorders	5 (0.00%)
Bronchial obstruction	Respiratory, thoracic and mediastinal disorders	5 (0.00%)
Burning mouth syndrome	Gastrointestinal disorders	5 (0.00%)
Burns second degree	Injury, poisoning and procedural complications	5 (0.00%)
Cardiospasm	Gastrointestinal disorders	5 (0.00%)
Carotid artery stenosis	Nervous system disorders	5 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Cell death	Metabolism and nutrition disorders	5 (0.00%)
Cerebral palsy	Congenital, familial and genetic disorders	5 (0.00%)
Cerebral small vessel ischaemic disease	Nervous system disorders	5 (0.00%)
Change of bowel habit	Gastrointestinal disorders	5 (0.00%)
Chronic inflammatory demyelinating polyradiculoneuropathy	Nervous system disorders	5 (0.00%)
Clostridium difficile colitis	Infections and infestations	5 (0.00%)
Completed suicide	Psychiatric disorders	5 (0.00%)
Congestive cardiomyopathy	Cardiac disorders	5 (0.00%)
Congestive hepatopathy	Hepatobiliary disorders	5 (0.00%)
Conjunctivitis bacterial	Infections and infestations	5 (0.00%)
Cor pulmonale	Cardiac disorders	5 (0.00%)
Dental caries	Gastrointestinal disorders	5 (0.00%)
Dilatation ventricular	Cardiac disorders	5 (0.00%)
Discoloured vomit	Gastrointestinal disorders	5 (0.00%)
Dissociative disorder	Psychiatric disorders	5 (0.00%)
Distractibility	Psychiatric disorders	5 (0.00%)
Duodenogastric reflux	Gastrointestinal disorders	5 (0.00%)
Dysacusis	Ear and labyrinth disorders	5 (0.00%)
Dyslexia	Nervous system disorders	5 (0.00%)
Dyslipidaemia	Metabolism and nutrition disorders	5 (0.00%)
Dysmetria	Nervous system disorders	5 (0.00%)
Eczema herpeticum	Infections and infestations	5 (0.00%)
Electrocardiogram change	Investigations	5 (0.00%)
Enanthema	General disorders and administration site conditions	5 (0.00%)
Epididymitis	Infections and infestations	5 (0.00%)
Epiglottic oedema	Respiratory, thoracic and mediastinal disorders	5 (0.00%)
Escherichia bacteraemia	Infections and infestations	5 (0.00%)
Escherichia sepsis	Infections and infestations	5 (0.00%)
Essential tremor	Nervous system disorders	5 (0.00%)
Extensor plantar response	Nervous system disorders	5 (0.00%)
Extremity necrosis	Vascular disorders	5 (0.00%)
Focal dyscognitive seizures	Nervous system disorders	5 (0.00%)
Foetal heart rate abnormal	Investigations	5 (0.00%)
Folate deficiency	Metabolism and nutrition disorders	5 (0.00%)
Fungal skin infection	Infections and infestations	5 (0.00%)
Galactorrhoea	Reproductive system and breast disorders	5 (0.00%)
Gastrointestinal oedema	Gastrointestinal disorders	5 (0.00%)
Genital herpes simplex	Infections and infestations	5 (0.00%)
Glare	Eye disorders	5 (0.00%)
Haemorrhoids thrombosed	Gastrointestinal disorders	5 (0.00%)
Hearing disability	Social circumstances	5 (0.00%)
Heat oedema	Injury, poisoning and procedural complications	5 (0.00%)
Hepatic cirrhosis	Hepatobiliary disorders	5 (0.00%)
Hidradenitis	Skin and subcutaneous tissue disorders	5 (0.00%)
Horner's syndrome	Nervous system disorders	5 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Humerus fracture	Injury, poisoning and procedural complications	5 (0.00%)
Hypercholesterolaemia	Metabolism and nutrition disorders	5 (0.00%)
Hypercoagulation	Blood and lymphatic system disorders	5 (0.00%)
Hypertensive encephalopathy	Nervous system disorders	5 (0.00%)
Hypertonic bladder	Renal and urinary disorders	5 (0.00%)
Immunoglobulins increased	Investigations	5 (0.00%)
Impetigo	Infections and infestations	5 (0.00%)
Inappropriate affect	Psychiatric disorders	5 (0.00%)
Indifference	Psychiatric disorders	5 (0.00%)
Infusion related reaction	Injury, poisoning and procedural complications	5 (0.00%)
Injection site extravasation	General disorders and administration site conditions	5 (0.00%)
Injection site hypersensitivity	General disorders and administration site conditions	5 (0.00%)
Injection site muscle weakness	General disorders and administration site conditions	5 (0.00%)
Inspiratory capacity decreased	Investigations	5 (0.00%)
Intestinal infarction	Gastrointestinal disorders	5 (0.00%)
Lichenoid keratosis	Skin and subcutaneous tissue disorders	5 (0.00%)
Lichen planus	Skin and subcutaneous tissue disorders	5 (0.00%)
Lip haemorrhage	Gastrointestinal disorders	5 (0.00%)
Lipids increased	Investigations	5 (0.00%)
Lung consolidation	Respiratory, thoracic and mediastinal disorders	5 (0.00%)
Lymphadenopathy mediastinal	Blood and lymphatic system disorders	5 (0.00%)
Lymphatic disorder	Blood and lymphatic system disorders	5 (0.00%)
Madarosis	Skin and subcutaneous tissue disorders	5 (0.00%)
Mean cell haemoglobin concentration increased	Investigations	5 (0.00%)
Meningeal disorder	Nervous system disorders	5 (0.00%)
Menopausal symptoms	Reproductive system and breast disorders	5 (0.00%)
Microembolism	Vascular disorders	5 (0.00%)
Monocyte count decreased	Investigations	5 (0.00%)
Mononeuropathy	Nervous system disorders	5 (0.00%)
Mucosal haemorrhage	General disorders and administration site conditions	5 (0.00%)
Mucosal inflammation	General disorders and administration site conditions	5 (0.00%)
Muscle mass	Musculoskeletal and connective tissue disorders	5 (0.00%)
Muscle oedema	Musculoskeletal and connective tissue disorders	5 (0.00%)
Myelosuppression	Blood and lymphatic system disorders	5 (0.00%)
Myocardial rupture	Cardiac disorders	5 (0.00%)
Myofascial pain syndrome	Musculoskeletal and connective tissue disorders	5 (0.00%)
Necrotising fasciitis	Infections and infestations	5 (0.00%)
Neoplasm skin	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5 (0.00%)
Neuromuscular pain	Nervous system disorders	5 (0.00%)
Neuromyelitis optica spectrum disorder	Nervous system disorders	5 (0.00%)
Non-Hodgkin's lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5 (0.00%)
Obstruction	General disorders and administration site conditions	5 (0.00%)
Ocular myasthenia	Eye disorders	5 (0.00%)
Oesophageal disorder	Gastrointestinal disorders	5 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Optic nerve disorder	Eye disorders	5 (0.00%)
Osteomyelitis	Infections and infestations	5 (0.00%)
Oxygen saturation	Investigations	5 (0.00%)
Palpable purpura	Skin and subcutaneous tissue disorders	5 (0.00%)
Pancreatic disorder	Gastrointestinal disorders	5 (0.00%)
Panniculitis	Skin and subcutaneous tissue disorders	5 (0.00%)
Peripheral arterial occlusive disease	Vascular disorders	5 (0.00%)
Persistent depressive disorder	Psychiatric disorders	5 (0.00%)
Pharyngeal stenosis	Respiratory, thoracic and mediastinal disorders	5 (0.00%)
Platelet count abnormal	Investigations	5 (0.00%)
Polycystic ovaries	Reproductive system and breast disorders	5 (0.00%)
Post-acute COVID-19 syndrome	Infections and infestations	5 (0.00%)
Post procedural complication	Injury, poisoning and procedural complications	5 (0.00%)
Post-traumatic neck syndrome	Injury, poisoning and procedural complications	5 (0.00%)
Premenstrual pain	Reproductive system and breast disorders	5 (0.00%)
Product container issue	Product issues	5 (0.00%)
Product contamination physical	Product issues	5 (0.00%)
Product use in unapproved indication	Injury, poisoning and procedural complications	5 (0.00%)
Prothrombin time shortened	Investigations	5 (0.00%)
Psychotic symptom	Psychiatric disorders	5 (0.00%)
Pupillary reflex impaired	Eye disorders	5 (0.00%)
Reading disorder	Psychiatric disorders	5 (0.00%)
Red blood cells urine positive	Investigations	5 (0.00%)
Red cell distribution width increased	Investigations	5 (0.00%)
Renal haemorrhage	Renal and urinary disorders	5 (0.00%)
Salivary gland disorder	Gastrointestinal disorders	5 (0.00%)
SARS-CoV-2 antibody test	Investigations	5 (0.00%)
SARS-CoV-2 test	Investigations	5 (0.00%)
Sciatic nerve neuropathy	Nervous system disorders	5 (0.00%)
Secondary hypertension	Vascular disorders	5 (0.00%)
Seroconversion test negative	Investigations	5 (0.00%)
Serum ferritin decreased	Investigations	5 (0.00%)
Shock haemorrhagic	Vascular disorders	5 (0.00%)
Sinus rhythm	Investigations	5 (0.00%)
Skin hyperpigmentation	Skin and subcutaneous tissue disorders	5 (0.00%)
Soft tissue infection	Infections and infestations	5 (0.00%)
Spinal stenosis	Musculoskeletal and connective tissue disorders	5 (0.00%)
Subileus	Gastrointestinal disorders	5 (0.00%)
Submaxillary gland enlargement	Gastrointestinal disorders	5 (0.00%)
Superficial vein prominence	Vascular disorders	5 (0.00%)
Superinfection	Infections and infestations	5 (0.00%)
Suspected product quality issue	Product issues	5 (0.00%)
Systemic immune activation	Immune system disorders	5 (0.00%)
Tardive dyskinesia	Nervous system disorders	5 (0.00%)
Thrombosis mesenteric vessel	Gastrointestinal disorders	5 (0.00%)
Thrombotic microangiopathy	Blood and lymphatic system disorders	5 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Tongue rough	Gastrointestinal disorders	5 (0.00%)
Tooth extraction	Surgical and medical procedures	5 (0.00%)
Tracheal pain	Respiratory, thoracic and mediastinal disorders	5 (0.00%)
Tracheal stenosis	Respiratory, thoracic and mediastinal disorders	5 (0.00%)
Transient aphasia	Nervous system disorders	5 (0.00%)
Transverse sinus thrombosis	Nervous system disorders	5 (0.00%)
Ulnar nerve injury	Injury, poisoning and procedural complications	5 (0.00%)
Urinary tract disorder	Renal and urinary disorders	5 (0.00%)
Urticaria thermal	Skin and subcutaneous tissue disorders	5 (0.00%)
Vaccination site dysaesthesia	General disorders and administration site conditions	5 (0.00%)
Vaccination site eczema	General disorders and administration site conditions	5 (0.00%)
Vaccination site injury	General disorders and administration site conditions	5 (0.00%)
Vascular occlusion	Vascular disorders	5 (0.00%)
Vein rupture	Vascular disorders	5 (0.00%)
Vitreous disorder	Eye disorders	5 (0.00%)
Vulval haemorrhage	Reproductive system and breast disorders	5 (0.00%)
Abnormal clotting factor	Blood and lymphatic system disorders	4 (0.00%)
Abnormal uterine bleeding	Reproductive system and breast disorders	4 (0.00%)
Acoustic neuroma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (0.00%)
Acute generalised exanthematous pustulosis	Skin and subcutaneous tissue disorders	4 (0.00%)
Adrenal disorder	Endocrine disorders	4 (0.00%)
Adrenal insufficiency	Endocrine disorders	4 (0.00%)
Age-related macular degeneration	Eye disorders	4 (0.00%)
Akinesia	Nervous system disorders	4 (0.00%)
Alanine aminotransferase decreased	Investigations	4 (0.00%)
Allergy to arthropod sting	Immune system disorders	4 (0.00%)
Amnesic disorder	Nervous system disorders	4 (0.00%)
Anal pruritus	Gastrointestinal disorders	4 (0.00%)
Angle closure glaucoma	Eye disorders	4 (0.00%)
Anovulatory cycle	Endocrine disorders	4 (0.00%)
Application site oedema	General disorders and administration site conditions	4 (0.00%)
Arteriovenous fistula thrombosis	Injury, poisoning and procedural complications	4 (0.00%)
Arthritis infective	Infections and infestations	4 (0.00%)
Atonic seizures	Nervous system disorders	4 (0.00%)
Axillary vein thrombosis	Vascular disorders	4 (0.00%)
Axonal neuropathy	Nervous system disorders	4 (0.00%)
Bacteriuria	Infections and infestations	4 (0.00%)
Basal cell carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (0.00%)
Basilar artery occlusion	Nervous system disorders	4 (0.00%)
Beta haemolytic streptococcal infection	Infections and infestations	4 (0.00%)
Bicytopenia	Blood and lymphatic system disorders	4 (0.00%)
Biliary tract disorder	Hepatobiliary disorders	4 (0.00%)
Bite	Injury, poisoning and procedural complications	4 (0.00%)
Blood bicarbonate decreased	Investigations	4 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Blood creatine phosphokinase MB increased	Investigations	4 (0.00%)
Blood folate decreased	Investigations	4 (0.00%)
Bloody discharge	Vascular disorders	4 (0.00%)
Bone marrow disorder	Blood and lymphatic system disorders	4 (0.00%)
Booster dose missed	Injury, poisoning and procedural complications	4 (0.00%)
Borrelia infection	Infections and infestations	4 (0.00%)
Brachial plexopathy	Nervous system disorders	4 (0.00%)
Brachial plexus injury	Injury, poisoning and procedural complications	4 (0.00%)
Brain stem ischaemia	Nervous system disorders	4 (0.00%)
Breast discharge	Reproductive system and breast disorders	4 (0.00%)
Breast engorgement	Reproductive system and breast disorders	4 (0.00%)
Breast induration	Reproductive system and breast disorders	4 (0.00%)
Bronchiolitis	Infections and infestations	4 (0.00%)
Bronchitis bacterial	Infections and infestations	4 (0.00%)
Bronchitis chronic	Respiratory, thoracic and mediastinal disorders	4 (0.00%)
Bronchopneumopathy	Respiratory, thoracic and mediastinal disorders	4 (0.00%)
Burn oesophageal	Injury, poisoning and procedural complications	4 (0.00%)
Capillary nail refill test abnormal	Investigations	4 (0.00%)
Cardiac dysfunction	Cardiac disorders	4 (0.00%)
Cardiac ventricular thrombosis	Cardiac disorders	4 (0.00%)
Cartilage injury	Injury, poisoning and procedural complications	4 (0.00%)
Cerebral amyloid angiopathy	Nervous system disorders	4 (0.00%)
Cerebral arteriosclerosis	Nervous system disorders	4 (0.00%)
Chest crushing	Injury, poisoning and procedural complications	4 (0.00%)
Cholangitis	Hepatobiliary disorders	4 (0.00%)
Choroidal neovascularisation	Eye disorders	4 (0.00%)
Chronic respiratory failure	Respiratory, thoracic and mediastinal disorders	4 (0.00%)
Chronic sinusitis	Infections and infestations	4 (0.00%)
Complicated appendicitis	Infections and infestations	4 (0.00%)
Conjunctivitis viral	Infections and infestations	4 (0.00%)
Convulsions local	Nervous system disorders	4 (0.00%)
Corneal graft rejection	Immune system disorders	4 (0.00%)
Cor pulmonale acute	Cardiac disorders	4 (0.00%)
Costovertebral angle tenderness	Renal and urinary disorders	4 (0.00%)
Creutzfeldt-Jakob disease	Infections and infestations	4 (0.00%)
Delirium febrile	Psychiatric disorders	4 (0.00%)
Dermatitis herpetiformis	Skin and subcutaneous tissue disorders	4 (0.00%)
Dermatitis infected	Infections and infestations	4 (0.00%)
Diabetic complication	Metabolism and nutrition disorders	4 (0.00%)
Diaphragmatic disorder	Respiratory, thoracic and mediastinal disorders	4 (0.00%)
Diastolic hypertension	Vascular disorders	4 (0.00%)
Discharge	General disorders and administration site conditions	4 (0.00%)
Drug intolerance	General disorders and administration site conditions	4 (0.00%)
Duodenal ulcer haemorrhage	Gastrointestinal disorders	4 (0.00%)
Dyspraxia	Nervous system disorders	4 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Ectopic pregnancy	Pregnancy, puerperium and perinatal conditions	4 (0.00%)
Eczema asteatotic	Skin and subcutaneous tissue disorders	4 (0.00%)
Eczema eyelids	Eye disorders	4 (0.00%)
Effusion	General disorders and administration site conditions	4 (0.00%)
Electrocardiogram QRS complex prolonged	Investigations	4 (0.00%)
Electrocardiogram QRS complex shortened	Investigations	4 (0.00%)
Embolism arterial	Vascular disorders	4 (0.00%)
Encephalitis autoimmune	Nervous system disorders	4 (0.00%)
Encephalitis viral	Infections and infestations	4 (0.00%)
Epinephrine increased	Investigations	4 (0.00%)
Epstein-Barr virus antibody positive	Investigations	4 (0.00%)
Erythroptosis	Eye disorders	4 (0.00%)
Exertional headache	Nervous system disorders	4 (0.00%)
Exposure via eye contact	Injury, poisoning and procedural complications	4 (0.00%)
Faecal vomiting	Gastrointestinal disorders	4 (0.00%)
Faeces hard	Gastrointestinal disorders	4 (0.00%)
Fasciitis	Musculoskeletal and connective tissue disorders	4 (0.00%)
Fear of falling	Psychiatric disorders	4 (0.00%)
Febrile infection	Infections and infestations	4 (0.00%)
Febrile neutropenia	Blood and lymphatic system disorders	4 (0.00%)
Gastric antral vascular ectasia	Gastrointestinal disorders	4 (0.00%)
Gastrointestinal hypomotility	Gastrointestinal disorders	4 (0.00%)
Gastrointestinal infection	Infections and infestations	4 (0.00%)
Gastrointestinal inflammation	Gastrointestinal disorders	4 (0.00%)
Generalised anxiety disorder	Psychiatric disorders	4 (0.00%)
Genital ulceration	Reproductive system and breast disorders	4 (0.00%)
Gestational diabetes	Pregnancy, puerperium and perinatal conditions	4 (0.00%)
Glomerulonephritis	Renal and urinary disorders	4 (0.00%)
Glucose tolerance impaired	Metabolism and nutrition disorders	4 (0.00%)
Habit cough	Psychiatric disorders	4 (0.00%)
Haemoglobin abnormal	Investigations	4 (0.00%)
Haemorrhagic infarction	Vascular disorders	4 (0.00%)
Heat illness	Injury, poisoning and procedural complications	4 (0.00%)
Helplessness	Psychiatric disorders	4 (0.00%)
Hemihyperaesthesia	Nervous system disorders	4 (0.00%)
Hepatic infarction	Hepatobiliary disorders	4 (0.00%)
Hepatic lesion	Hepatobiliary disorders	4 (0.00%)
Hepatitis viral	Infections and infestations	4 (0.00%)
Herpes dermatitis	Infections and infestations	4 (0.00%)
Herpes simplex encephalitis	Infections and infestations	4 (0.00%)
Herpes zoster meningitis	Infections and infestations	4 (0.00%)
Herpes zoster meningoencephalitis	Infections and infestations	4 (0.00%)
Histamine level increased	Investigations	4 (0.00%)
HIV test false positive	Investigations	4 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Hyperferritinaemia	Metabolism and nutrition disorders	4 (0.00%)
Hyperphagia	Metabolism and nutrition disorders	4 (0.00%)
Hyperuricaemia	Metabolism and nutrition disorders	4 (0.00%)
Hypervigilance	Psychiatric disorders	4 (0.00%)
Hypogammaglobulinaemia	Immune system disorders	4 (0.00%)
Hypovitaminosis	Metabolism and nutrition disorders	4 (0.00%)
Illrd nerve disorder	Nervous system disorders	4 (0.00%)
Increased viscosity of bronchial secretion	Respiratory, thoracic and mediastinal disorders	4 (0.00%)
Infective exacerbation of chronic obstructive airways disease	Infections and infestations	4 (0.00%)
Infusion site pain	General disorders and administration site conditions	4 (0.00%)
Inhibitory drug interaction	General disorders and administration site conditions	4 (0.00%)
Injury associated with device	General disorders and administration site conditions	4 (0.00%)
Intentional self-injury	Psychiatric disorders	4 (0.00%)
Intervertebral disc degeneration	Musculoskeletal and connective tissue disorders	4 (0.00%)
Intervertebral disc disorder	Musculoskeletal and connective tissue disorders	4 (0.00%)
Intestinal perforation	Gastrointestinal disorders	4 (0.00%)
Intranasal hypoaesthesia	Respiratory, thoracic and mediastinal disorders	4 (0.00%)
Ischaemic cardiomyopathy	Cardiac disorders	4 (0.00%)
Joint ankylosis	Musculoskeletal and connective tissue disorders	4 (0.00%)
Joint contracture	Musculoskeletal and connective tissue disorders	4 (0.00%)
Lactation disorder	Reproductive system and breast disorders	4 (0.00%)
Large intestine infection	Infections and infestations	4 (0.00%)
Left atrial dilatation	Cardiac disorders	4 (0.00%)
Ligament injury	Injury, poisoning and procedural complications	4 (0.00%)
Limb deformity	Musculoskeletal and connective tissue disorders	4 (0.00%)
Magnetic resonance imaging head abnormal	Investigations	4 (0.00%)
Meningioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (0.00%)
Menometrorrhagia	Reproductive system and breast disorders	4 (0.00%)
Menstrual cycle management	Surgical and medical procedures	4 (0.00%)
Menstrual discomfort	Reproductive system and breast disorders	4 (0.00%)
Microcytic anaemia	Blood and lymphatic system disorders	4 (0.00%)
Middle ear effusion	Ear and labyrinth disorders	4 (0.00%)
Misophonia	Ear and labyrinth disorders	4 (0.00%)
Monoclonal gammopathy	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (0.00%)
Mononeuritis	Nervous system disorders	4 (0.00%)
Mouth cyst	Gastrointestinal disorders	4 (0.00%)
Multiple allergies	Immune system disorders	4 (0.00%)
Myelodysplastic syndrome	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (0.00%)
Nasal odour	Respiratory, thoracic and mediastinal disorders	4 (0.00%)
Nephritis	Renal and urinary disorders	4 (0.00%)
Normocytic anaemia	Blood and lymphatic system disorders	4 (0.00%)
Oesophagitis	Gastrointestinal disorders	4 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Ophthalmic artery thrombosis	Eye disorders	4 (0.00%)
Optic neuropathy	Eye disorders	4 (0.00%)
Oral mucosa erosion	Gastrointestinal disorders	4 (0.00%)
Oral mucosal roughening	Gastrointestinal disorders	4 (0.00%)
Orthostatic hypertension	Vascular disorders	4 (0.00%)
Osteitis	Musculoskeletal and connective tissue disorders	4 (0.00%)
Otorrhoea	Ear and labyrinth disorders	4 (0.00%)
Ovulation pain	Reproductive system and breast disorders	4 (0.00%)
Oxygen consumption decreased	Investigations	4 (0.00%)
Pancreatic carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (0.00%)
Paresis cranial nerve	Nervous system disorders	4 (0.00%)
PCO2 increased	Investigations	4 (0.00%)
Pelvic haemorrhage	Reproductive system and breast disorders	4 (0.00%)
Penile swelling	Reproductive system and breast disorders	4 (0.00%)
Penis disorder	Reproductive system and breast disorders	4 (0.00%)
Peptic ulcer haemorrhage	Gastrointestinal disorders	4 (0.00%)
Perineal pain	Reproductive system and breast disorders	4 (0.00%)
Perioral dermatitis	Skin and subcutaneous tissue disorders	4 (0.00%)
Peripheral artery occlusion	Vascular disorders	4 (0.00%)
Peripheral nerve palsy	Nervous system disorders	4 (0.00%)
Peripheral paralysis	Nervous system disorders	4 (0.00%)
Pernio-like erythema	Skin and subcutaneous tissue disorders	4 (0.00%)
Persistent postural-perceptual dizziness	Nervous system disorders	4 (0.00%)
Pertussis	Infections and infestations	4 (0.00%)
Pharyngotonsillitis	Infections and infestations	4 (0.00%)
Physical disability	Social circumstances	4 (0.00%)
Pituitary tumour benign	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (0.00%)
Pleocytosis	Nervous system disorders	4 (0.00%)
Pneumothorax spontaneous	Respiratory, thoracic and mediastinal disorders	4 (0.00%)
Polychondritis	Musculoskeletal and connective tissue disorders	4 (0.00%)
Poor feeding infant	Metabolism and nutrition disorders	4 (0.00%)
Pregnancy	Pregnancy, puerperium and perinatal conditions	4 (0.00%)
Premature labour	Pregnancy, puerperium and perinatal conditions	4 (0.00%)
Primary cough headache	Nervous system disorders	4 (0.00%)
Procedural dizziness	Injury, poisoning and procedural complications	4 (0.00%)
Procedural nausea	Injury, poisoning and procedural complications	4 (0.00%)
Procedural pain	Injury, poisoning and procedural complications	4 (0.00%)
Proctitis	Gastrointestinal disorders	4 (0.00%)
Protein total increased	Investigations	4 (0.00%)
Pruritus genital	Reproductive system and breast disorders	4 (0.00%)
Psychomotor retardation	Psychiatric disorders	4 (0.00%)
Pulse pressure increased	Investigations	4 (0.00%)
Puncture site induration	General disorders and administration site conditions	4 (0.00%)
Putamen haemorrhage	Nervous system disorders	4 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Radial nerve palsy	Nervous system disorders	4 (0.00%)
Red ear syndrome	Ear and labyrinth disorders	4 (0.00%)
Renal function test abnormal	Investigations	4 (0.00%)
Resting tremor	Nervous system disorders	4 (0.00%)
Retinal disorder	Eye disorders	4 (0.00%)
Rhinovirus infection	Infections and infestations	4 (0.00%)
Right ventricular dysfunction	Cardiac disorders	4 (0.00%)
Seizure cluster	Nervous system disorders	4 (0.00%)
Self-injurious ideation	Psychiatric disorders	4 (0.00%)
Sense of a foreshortened future	Psychiatric disorders	4 (0.00%)
Sickle cell anaemia with crisis	Blood and lymphatic system disorders	4 (0.00%)
Sinus arrest	Cardiac disorders	4 (0.00%)
Skin cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (0.00%)
Skin laxity	Skin and subcutaneous tissue disorders	4 (0.00%)
Skin oedema	Skin and subcutaneous tissue disorders	4 (0.00%)
Skin striae	Skin and subcutaneous tissue disorders	4 (0.00%)
Skull fracture	Injury, poisoning and procedural complications	4 (0.00%)
Small fibre neuropathy	Nervous system disorders	4 (0.00%)
Soliloquy	Psychiatric disorders	4 (0.00%)
Speech disorder developmental	Nervous system disorders	4 (0.00%)
Spinal compression fracture	Injury, poisoning and procedural complications	4 (0.00%)
Splenic rupture	Injury, poisoning and procedural complications	4 (0.00%)
Sputum retention	Respiratory, thoracic and mediastinal disorders	4 (0.00%)
Staphylococcal bacteraemia	Infections and infestations	4 (0.00%)
Starvation	Metabolism and nutrition disorders	4 (0.00%)
Stoma site haemorrhage	Injury, poisoning and procedural complications	4 (0.00%)
Streptococcus test positive	Investigations	4 (0.00%)
Temperature difference of extremities	Investigations	4 (0.00%)
Therapeutic product effect decreased	General disorders and administration site conditions	4 (0.00%)
Thrombosed varicose vein	Vascular disorders	4 (0.00%)
Thyroxine free increased	Investigations	4 (0.00%)
Tonsillar erythema	Respiratory, thoracic and mediastinal disorders	4 (0.00%)
Traumatic haematoma	Injury, poisoning and procedural complications	4 (0.00%)
Tumour marker increased	Investigations	4 (0.00%)
Typical aura without headache	Nervous system disorders	4 (0.00%)
Underweight	Metabolism and nutrition disorders	4 (0.00%)
Upper respiratory tract inflammation	Respiratory, thoracic and mediastinal disorders	4 (0.00%)
Urge incontinence	Renal and urinary disorders	4 (0.00%)
Urine ketone body present	Investigations	4 (0.00%)
Uterine spasm	Reproductive system and breast disorders	4 (0.00%)
Vaccination site dryness	General disorders and administration site conditions	4 (0.00%)
Vaccination site joint discomfort	General disorders and administration site conditions	4 (0.00%)
Vaccination site thrombosis	General disorders and administration site conditions	4 (0.00%)
Vascular encephalopathy	Nervous system disorders	4 (0.00%)
Vascular graft thrombosis	Injury, poisoning and procedural complications	4 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Vascular stent thrombosis	General disorders and administration site conditions	4 (0.00%)
Vasoplegia syndrome	Injury, poisoning and procedural complications	4 (0.00%)
Vasospasm	Vascular disorders	4 (0.00%)
Vertebral artery dissection	Nervous system disorders	4 (0.00%)
Viral upper respiratory tract infection	Infections and infestations	4 (0.00%)
Vocal cord paralysis	Nervous system disorders	4 (0.00%)
Vulval ulceration	Reproductive system and breast disorders	4 (0.00%)
Vulvovaginal pruritus	Reproductive system and breast disorders	4 (0.00%)
White blood cell count abnormal	Investigations	4 (0.00%)
White blood cells urine	Investigations	4 (0.00%)
White coat hypertension	Vascular disorders	4 (0.00%)
Withdrawal hypertension	Vascular disorders	4 (0.00%)
Wound infection	Infections and infestations	4 (0.00%)
Abdominal lymphadenopathy	Blood and lymphatic system disorders	3 (0.00%)
Abdominal migraine	Gastrointestinal disorders	3 (0.00%)
Abdominal wall haematoma	Gastrointestinal disorders	3 (0.00%)
Abdominal wall haemorrhage	Gastrointestinal disorders	3 (0.00%)
Abscess limb	Infections and infestations	3 (0.00%)
Abscess oral	Infections and infestations	3 (0.00%)
Acoustic neuritis	Nervous system disorders	3 (0.00%)
Acute leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.00%)
Acute macular outer retinopathy	Eye disorders	3 (0.00%)
Acute polyneuropathy	Nervous system disorders	3 (0.00%)
Acute psychosis	Psychiatric disorders	3 (0.00%)
Administration site movement impairment	General disorders and administration site conditions	3 (0.00%)
Adrenomegaly	Endocrine disorders	3 (0.00%)
Aerophagia	Gastrointestinal disorders	3 (0.00%)
Airway burns	Injury, poisoning and procedural complications	3 (0.00%)
Alcohol intolerance	Metabolism and nutrition disorders	3 (0.00%)
Allergic respiratory symptom	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Allergic sinusitis	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Alopecia universalis	Skin and subcutaneous tissue disorders	3 (0.00%)
Amaurosis	Eye disorders	3 (0.00%)
Amyloidosis	Immune system disorders	3 (0.00%)
Anaemia vitamin B12 deficiency	Blood and lymphatic system disorders	3 (0.00%)
Anamnestic reaction	Immune system disorders	3 (0.00%)
Anembryonic gestation	Pregnancy, puerperium and perinatal conditions	3 (0.00%)
Animal bite	Injury, poisoning and procedural complications	3 (0.00%)
Anisocytosis	Blood and lymphatic system disorders	3 (0.00%)
Anticoagulation drug level below therapeutic	Investigations	3 (0.00%)
Anti-neutrophil cytoplasmic antibody positive vasculitis	Immune system disorders	3 (0.00%)
Aortic valve calcification	Cardiac disorders	3 (0.00%)
Application site acne	General disorders and administration site conditions	3 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Arteritis	Vascular disorders	3 (0.00%)
Artery dissection	Vascular disorders	3 (0.00%)
Asthma exercise induced	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Asthma prophylaxis	Surgical and medical procedures	3 (0.00%)
Atrial septal defect	Congenital, familial and genetic disorders	3 (0.00%)
Atrial thrombosis	Cardiac disorders	3 (0.00%)
Autism spectrum disorder	Psychiatric disorders	3 (0.00%)
Autonomic dysreflexia	Injury, poisoning and procedural complications	3 (0.00%)
Autonomic neuropathy	Nervous system disorders	3 (0.00%)
Axillary lymphadenectomy	Surgical and medical procedures	3 (0.00%)
Bacterial vaginosis	Infections and infestations	3 (0.00%)
Bile duct stone	Hepatobiliary disorders	3 (0.00%)
Binocular eye movement disorder	Eye disorders	3 (0.00%)
Blister infected	Infections and infestations	3 (0.00%)
Blood alcohol increased	Investigations	3 (0.00%)
Blood bilirubin abnormal	Investigations	3 (0.00%)
Blood bilirubin decreased	Investigations	3 (0.00%)
Blood cholesterol decreased	Investigations	3 (0.00%)
Blood glucose	Investigations	3 (0.00%)
Blood iron increased	Investigations	3 (0.00%)
Blood parathyroid hormone increased	Investigations	3 (0.00%)
Bone contusion	Injury, poisoning and procedural complications	3 (0.00%)
Bradyarrhythmia	Cardiac disorders	3 (0.00%)
Brain contusion	Injury, poisoning and procedural complications	3 (0.00%)
Brain hypoxia	Nervous system disorders	3 (0.00%)
Breakthrough pain	General disorders and administration site conditions	3 (0.00%)
Breath sounds	Investigations	3 (0.00%)
Carcinoembryonic antigen increased	Investigations	3 (0.00%)
Cardiac amyloidosis	Cardiac disorders	3 (0.00%)
Cardio-respiratory distress	Cardiac disorders	3 (0.00%)
Carotid bruit	Investigations	3 (0.00%)
Central nervous system vasculitis	Nervous system disorders	3 (0.00%)
Central pain syndrome	Nervous system disorders	3 (0.00%)
Cerebral artery stenosis	Nervous system disorders	3 (0.00%)
Cervical spinal stenosis	Musculoskeletal and connective tissue disorders	3 (0.00%)
Cervicogenic headache	Nervous system disorders	3 (0.00%)
Chalazion	Eye disorders	3 (0.00%)
Cholecystitis acute	Hepatobiliary disorders	3 (0.00%)
Cholestatic liver injury	Hepatobiliary disorders	3 (0.00%)
Choluria	Renal and urinary disorders	3 (0.00%)
Chorioretinopathy	Eye disorders	3 (0.00%)
Chronic gastritis	Gastrointestinal disorders	3 (0.00%)
Coating in mouth	Gastrointestinal disorders	3 (0.00%)
Coccidioidomycosis	Infections and infestations	3 (0.00%)
Cold burn	Injury, poisoning and procedural complications	3 (0.00%)
Cold urticaria	Skin and subcutaneous tissue disorders	3 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Complement factor C3 increased	Investigations	3 (0.00%)
Complication associated with device	General disorders and administration site conditions	3 (0.00%)
Conductive deafness	Ear and labyrinth disorders	3 (0.00%)
Connective tissue disorder	Musculoskeletal and connective tissue disorders	3 (0.00%)
Coombs negative haemolytic anaemia	Blood and lymphatic system disorders	3 (0.00%)
Corneal opacity	Eye disorders	3 (0.00%)
Coronary artery dissection	Cardiac disorders	3 (0.00%)
Cough variant asthma	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Cranial nerve palsies multiple	Nervous system disorders	3 (0.00%)
Creatinine renal clearance decreased	Investigations	3 (0.00%)
Cytomegalovirus infection	Infections and infestations	3 (0.00%)
Cytomegalovirus infection reactivation	Infections and infestations	3 (0.00%)
Cytomegalovirus test positive	Investigations	3 (0.00%)
Decreased vibratory sense	Nervous system disorders	3 (0.00%)
Defect conduction intraventricular	Cardiac disorders	3 (0.00%)
Delayed recovery from anaesthesia	Injury, poisoning and procedural complications	3 (0.00%)
Dental restoration failure	Injury, poisoning and procedural complications	3 (0.00%)
Depression suicidal	Psychiatric disorders	3 (0.00%)
Depressive symptom	Psychiatric disorders	3 (0.00%)
Dermatitis psoriasiform	Skin and subcutaneous tissue disorders	3 (0.00%)
Device related infection	Infections and infestations	3 (0.00%)
Diabetes insipidus	Endocrine disorders	3 (0.00%)
Diabetic coma	Nervous system disorders	3 (0.00%)
Diabetic ketosis	Metabolism and nutrition disorders	3 (0.00%)
Diaphragmatic spasm	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Diastolic hypotension	Vascular disorders	3 (0.00%)
Dilatation atrial	Cardiac disorders	3 (0.00%)
Discouragement	Psychiatric disorders	3 (0.00%)
Dreamy state	Nervous system disorders	3 (0.00%)
Drug withdrawal syndrome	General disorders and administration site conditions	3 (0.00%)
Ear canal erythema	Ear and labyrinth disorders	3 (0.00%)
Eczema nummular	Skin and subcutaneous tissue disorders	3 (0.00%)
Endolymphatic hydrops	Ear and labyrinth disorders	3 (0.00%)
Enterocolitis haemorrhagic	Gastrointestinal disorders	3 (0.00%)
Eosinophilic oesophagitis	Gastrointestinal disorders	3 (0.00%)
Epiglottitis	Infections and infestations	3 (0.00%)
Erection increased	Reproductive system and breast disorders	3 (0.00%)
Erythema annulare	Skin and subcutaneous tissue disorders	3 (0.00%)
Eustachian tube disorder	Ear and labyrinth disorders	3 (0.00%)
Excessive eye blinking	Eye disorders	3 (0.00%)
External ear inflammation	Ear and labyrinth disorders	3 (0.00%)
Extraocular muscle disorder	Eye disorders	3 (0.00%)
Eyelid exfoliation	Eye disorders	3 (0.00%)
Eyelid haematoma	Eye disorders	3 (0.00%)
Eyelid myoclonus	Eye disorders	3 (0.00%)
Eye symptom	Eye disorders	3 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Eye ulcer	Eye disorders	3 (0.00%)
Femoral artery embolism	Vascular disorders	3 (0.00%)
Fever neonatal	General disorders and administration site conditions	3 (0.00%)
Fistula	Musculoskeletal and connective tissue disorders	3 (0.00%)
Fixed eruption	Skin and subcutaneous tissue disorders	3 (0.00%)
Fluid imbalance	Metabolism and nutrition disorders	3 (0.00%)
Foetal hypokinesia	Pregnancy, puerperium and perinatal conditions	3 (0.00%)
Galactostasis	Reproductive system and breast disorders	3 (0.00%)
Gangrene	Infections and infestations	3 (0.00%)
Gastric ulcer haemorrhage	Gastrointestinal disorders	3 (0.00%)
Gastrointestinal tract irritation	Gastrointestinal disorders	3 (0.00%)
Genital discomfort	Reproductive system and breast disorders	3 (0.00%)
Genital herpes zoster	Infections and infestations	3 (0.00%)
Genital lesion	Reproductive system and breast disorders	3 (0.00%)
Genital rash	Reproductive system and breast disorders	3 (0.00%)
Gingival abscess	Infections and infestations	3 (0.00%)
Gingival discolouration	Gastrointestinal disorders	3 (0.00%)
Granuloma	General disorders and administration site conditions	3 (0.00%)
Haemangioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.00%)
Haematology test abnormal	Investigations	3 (0.00%)
Haematospermia	Reproductive system and breast disorders	3 (0.00%)
Haemorrhagic cerebral infarction	Nervous system disorders	3 (0.00%)
Haemothorax	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Hair colour changes	Skin and subcutaneous tissue disorders	3 (0.00%)
Hair disorder	Skin and subcutaneous tissue disorders	3 (0.00%)
Heart valve incompetence	Cardiac disorders	3 (0.00%)
Hemiataxia	Nervous system disorders	3 (0.00%)
Hepatitis C	Infections and infestations	3 (0.00%)
Hepatitis E	Infections and infestations	3 (0.00%)
Herpes simplex test positive	Investigations	3 (0.00%)
High density lipoprotein decreased	Investigations	3 (0.00%)
Histamine intolerance	Metabolism and nutrition disorders	3 (0.00%)
HIV infection	Infections and infestations	3 (0.00%)
HIV test positive	Investigations	3 (0.00%)
Hostility	Psychiatric disorders	3 (0.00%)
Hypertriglyceridaemia	Metabolism and nutrition disorders	3 (0.00%)
Hypertrophy of tongue papillae	Gastrointestinal disorders	3 (0.00%)
Hypokalaemic syndrome	Metabolism and nutrition disorders	3 (0.00%)
Hypomagnesaemia	Metabolism and nutrition disorders	3 (0.00%)
Hypoxic-ischaemic encephalopathy	Nervous system disorders	3 (0.00%)
Idiopathic angioedema	Skin and subcutaneous tissue disorders	3 (0.00%)
Idiopathic pulmonary fibrosis	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
IgA nephropathy	Renal and urinary disorders	3 (0.00%)
Illrd nerve paresis	Nervous system disorders	3 (0.00%)
Impaired self-care	General disorders and administration site conditions	3 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Incision site pain	Injury, poisoning and procedural complications	3 (0.00%)
Infantile vomiting	Gastrointestinal disorders	3 (0.00%)
Injection site joint erythema	General disorders and administration site conditions	3 (0.00%)
Injection site nodule	General disorders and administration site conditions	3 (0.00%)
Intention tremor	Nervous system disorders	3 (0.00%)
Intercepted medication error	Injury, poisoning and procedural complications	3 (0.00%)
Intercostal neuralgia	Nervous system disorders	3 (0.00%)
International normalised ratio fluctuation	Investigations	3 (0.00%)
Intra-abdominal haematoma	Gastrointestinal disorders	3 (0.00%)
Intrusive thoughts	Psychiatric disorders	3 (0.00%)
Irregular sleep wake rhythm disorder	Nervous system disorders	3 (0.00%)
Jaw fracture	Injury, poisoning and procedural complications	3 (0.00%)
Jugular vein distension	Vascular disorders	3 (0.00%)
Keratosis pilaris	Skin and subcutaneous tissue disorders	3 (0.00%)
Lacrimonial disorder	Eye disorders	3 (0.00%)
Lactose intolerance	Metabolism and nutrition disorders	3 (0.00%)
Large intestine perforation	Gastrointestinal disorders	3 (0.00%)
Laryngeal stenosis	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Lateral medullary syndrome	Nervous system disorders	3 (0.00%)
Lhermitte's sign	Nervous system disorders	3 (0.00%)
Lichen sclerosus	Skin and subcutaneous tissue disorders	3 (0.00%)
Ligament disorder	Musculoskeletal and connective tissue disorders	3 (0.00%)
Ligament pain	Musculoskeletal and connective tissue disorders	3 (0.00%)
Ligament rupture	Injury, poisoning and procedural complications	3 (0.00%)
Liver tenderness	Hepatobiliary disorders	3 (0.00%)
Loss of proprioception	Nervous system disorders	3 (0.00%)
Lung abscess	Infections and infestations	3 (0.00%)
Lymph nodes scan abnormal	Investigations	3 (0.00%)
Lymphocyte count abnormal	Investigations	3 (0.00%)
Macular hole	Eye disorders	3 (0.00%)
Mallory-Weiss syndrome	Gastrointestinal disorders	3 (0.00%)
Mean cell haemoglobin increased	Investigations	3 (0.00%)
Mechanical ventilation	Surgical and medical procedures	3 (0.00%)
Meningitis bacterial	Infections and infestations	3 (0.00%)
Meniscus injury	Injury, poisoning and procedural complications	3 (0.00%)
Metabolic disorder	Metabolism and nutrition disorders	3 (0.00%)
Metabolic function test abnormal	Investigations	3 (0.00%)
Microscopic polyangiitis	Vascular disorders	3 (0.00%)
Miller Fisher syndrome	Nervous system disorders	3 (0.00%)
Mitral valve calcification	Cardiac disorders	3 (0.00%)
Mitral valve stenosis	Cardiac disorders	3 (0.00%)
Mononeuropathy multiplex	Nervous system disorders	3 (0.00%)
Morose	Psychiatric disorders	3 (0.00%)
Mouth breathing	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Myelopathy	Nervous system disorders	3 (0.00%)
Myocardial fibrosis	Cardiac disorders	3 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Myocardial hypoxia	Cardiac disorders	3 (0.00%)
Myocardial oedema	Cardiac disorders	3 (0.00%)
Myopia	Eye disorders	3 (0.00%)
Nasal mucosal disorder	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Necrotic lymphadenopathy	Blood and lymphatic system disorders	3 (0.00%)
Negative thoughts	Psychiatric disorders	3 (0.00%)
Neuritis cranial	Nervous system disorders	3 (0.00%)
Neurological decompensation	Nervous system disorders	3 (0.00%)
Neuromyopathy	Nervous system disorders	3 (0.00%)
Neurosensory hypoacusis	Ear and labyrinth disorders	3 (0.00%)
Neutrophilic dermatosis	Skin and subcutaneous tissue disorders	3 (0.00%)
Neutrophil percentage increased	Investigations	3 (0.00%)
Nitrite urine present	Investigations	3 (0.00%)
Noninfective sialoadenitis	Gastrointestinal disorders	3 (0.00%)
Non-pitting oedema	General disorders and administration site conditions	3 (0.00%)
No reaction on previous exposure to drug	General disorders and administration site conditions	3 (0.00%)
Normal pressure hydrocephalus	Nervous system disorders	3 (0.00%)
Normochromic normocytic anaemia	Blood and lymphatic system disorders	3 (0.00%)
Obesity	Metabolism and nutrition disorders	3 (0.00%)
Obstructive pancreatitis	Gastrointestinal disorders	3 (0.00%)
Oculofacial paralysis	Nervous system disorders	3 (0.00%)
Oculogyric crisis	Eye disorders	3 (0.00%)
Oedematous pancreatitis	Gastrointestinal disorders	3 (0.00%)
Oesophageal irritation	Gastrointestinal disorders	3 (0.00%)
Onychalgia	Skin and subcutaneous tissue disorders	3 (0.00%)
Oral allergy syndrome	Immune system disorders	3 (0.00%)
Oral lichen planus	Gastrointestinal disorders	3 (0.00%)
Oral viral infection	Infections and infestations	3 (0.00%)
Orbital haematoma	Eye disorders	3 (0.00%)
Organ failure	General disorders and administration site conditions	3 (0.00%)
Organic brain syndrome	Psychiatric disorders	3 (0.00%)
Oropharyngeal plaque	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Osteopenia	Musculoskeletal and connective tissue disorders	3 (0.00%)
Oxygen saturation immeasurable	Investigations	3 (0.00%)
Oxygen saturation increased	Investigations	3 (0.00%)
Paratracheal lymphadenopathy	Blood and lymphatic system disorders	3 (0.00%)
Peau d'orange	Skin and subcutaneous tissue disorders	3 (0.00%)
Pelvic discomfort	Reproductive system and breast disorders	3 (0.00%)
Penile haemorrhage	Reproductive system and breast disorders	3 (0.00%)
Periorbital cellulitis	Infections and infestations	3 (0.00%)
Peripheral motor neuropathy	Nervous system disorders	3 (0.00%)
Peritonsillar abscess	Infections and infestations	3 (0.00%)
Persecutory delusion	Psychiatric disorders	3 (0.00%)
Phantom limb syndrome	Nervous system disorders	3 (0.00%)
Pharyngeal abscess	Infections and infestations	3 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Pharyngeal enanthema	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Pharyngitis bacterial	Infections and infestations	3 (0.00%)
Pityriasis lichenoides et varioliformis acuta	Skin and subcutaneous tissue disorders	3 (0.00%)
Plantar erythema	Skin and subcutaneous tissue disorders	3 (0.00%)
Plasma cell myeloma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.00%)
Pneumonia pneumococcal	Infections and infestations	3 (0.00%)
Pneumonia staphylococcal	Infections and infestations	3 (0.00%)
Polycythaemia	Blood and lymphatic system disorders	3 (0.00%)
Polyp	General disorders and administration site conditions	3 (0.00%)
Posterior reversible encephalopathy syndrome	Nervous system disorders	3 (0.00%)
Post lumbar puncture syndrome	Injury, poisoning and procedural complications	3 (0.00%)
Post thrombotic syndrome	Vascular disorders	3 (0.00%)
Pregnancy with contraceptive device	Pregnancy, puerperium and perinatal conditions	3 (0.00%)
Prehypertension	Vascular disorders	3 (0.00%)
Pressure of speech	Psychiatric disorders	3 (0.00%)
Prohormone brain natriuretic peptide increased	Investigations	3 (0.00%)
Prolonged expiration	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Pulmonary sarcoidosis	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Puncture site bruise	General disorders and administration site conditions	3 (0.00%)
Pustular psoriasis	Skin and subcutaneous tissue disorders	3 (0.00%)
Pyelonephritis acute	Infections and infestations	3 (0.00%)
Quadrantanopia	Nervous system disorders	3 (0.00%)
Quadriplegia	Nervous system disorders	3 (0.00%)
Rash rubelliform	Skin and subcutaneous tissue disorders	3 (0.00%)
Rectal tenesmus	Gastrointestinal disorders	3 (0.00%)
Red blood cell count abnormal	Investigations	3 (0.00%)
Red cell distribution width decreased	Investigations	3 (0.00%)
Reflexes abnormal	Nervous system disorders	3 (0.00%)
Renal tubular necrosis	Renal and urinary disorders	3 (0.00%)
Respiratory tract infection viral	Infections and infestations	3 (0.00%)
Resuscitation	Surgical and medical procedures	3 (0.00%)
Retinal injury	Injury, poisoning and procedural complications	3 (0.00%)
Reversible cerebral vasoconstriction syndrome	Nervous system disorders	3 (0.00%)
Rheumatoid factor positive	Investigations	3 (0.00%)
Root canal infection	Infections and infestations	3 (0.00%)
SARS-CoV-1 test positive	Investigations	3 (0.00%)
Scalloped tongue	Gastrointestinal disorders	3 (0.00%)
Scarlet fever	Infections and infestations	3 (0.00%)
Schizophrenia	Psychiatric disorders	3 (0.00%)
Scrotal erythema	Reproductive system and breast disorders	3 (0.00%)
Scrotal swelling	Reproductive system and breast disorders	3 (0.00%)
Seborrhoea	Skin and subcutaneous tissue disorders	3 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Senile dementia	Nervous system disorders	3 (0.00%)
Seronegative arthritis	Musculoskeletal and connective tissue disorders	3 (0.00%)
Sinus arrhythmia	Cardiac disorders	3 (0.00%)
Skeletal injury	Injury, poisoning and procedural complications	3 (0.00%)
Skin discharge	Skin and subcutaneous tissue disorders	3 (0.00%)
Skin papilloma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.00%)
Skull fractured base	Injury, poisoning and procedural complications	3 (0.00%)
Social avoidant behaviour	Psychiatric disorders	3 (0.00%)
Soft tissue injury	Injury, poisoning and procedural complications	3 (0.00%)
Solar lentigo	Skin and subcutaneous tissue disorders	3 (0.00%)
Speech sound disorder	Psychiatric disorders	3 (0.00%)
Spinal cord infarction	Nervous system disorders	3 (0.00%)
Spinal cord injury	Injury, poisoning and procedural complications	3 (0.00%)
Spinal cord ischaemia	Nervous system disorders	3 (0.00%)
Spleen disorder	Blood and lymphatic system disorders	3 (0.00%)
Sputum abnormal	Investigations	3 (0.00%)
Status migrainosus	Nervous system disorders	3 (0.00%)
Steatorrhoea	Gastrointestinal disorders	3 (0.00%)
Stereotypy	Psychiatric disorders	3 (0.00%)
Stertor	Respiratory, thoracic and mediastinal disorders	3 (0.00%)
Stillbirth	Pregnancy, puerperium and perinatal conditions	3 (0.00%)
Sympathicotonia	Nervous system disorders	3 (0.00%)
Systolic dysfunction	Cardiac disorders	3 (0.00%)
Telangiectasia	Skin and subcutaneous tissue disorders	3 (0.00%)
Thalamus haemorrhage	Nervous system disorders	3 (0.00%)
Thirst decreased	General disorders and administration site conditions	3 (0.00%)
Thoracic outlet syndrome	Nervous system disorders	3 (0.00%)
Thrombosis in device	Product issues	3 (0.00%)
Thyroid hormones increased	Investigations	3 (0.00%)
Thyrotoxic crisis	Endocrine disorders	3 (0.00%)
Tongue haematoma	Gastrointestinal disorders	3 (0.00%)
Tooth loss	Gastrointestinal disorders	3 (0.00%)
Total lung capacity decreased	Investigations	3 (0.00%)
Tracheal obstruction	Injury, poisoning and procedural complications	3 (0.00%)
Traumatic haemorrhage	Injury, poisoning and procedural complications	3 (0.00%)
Trigeminal nerve paresis	Nervous system disorders	3 (0.00%)
Trigeminal palsy	Nervous system disorders	3 (0.00%)
Tri-iodothyronine decreased	Investigations	3 (0.00%)
Troponin abnormal	Investigations	3 (0.00%)
Tuberculosis	Infections and infestations	3 (0.00%)
Tubulointerstitial nephritis	Renal and urinary disorders	3 (0.00%)
Ulnar nerve palsy	Nervous system disorders	3 (0.00%)
Urinary bladder haemorrhage	Renal and urinary disorders	3 (0.00%)
Urinary occult blood positive	Investigations	3 (0.00%)
Urine output	Investigations	3 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Urticarial vasculitis	Skin and subcutaneous tissue disorders	3 (0.00%)
Uterine contractions abnormal	Pregnancy, puerperium and perinatal conditions	3 (0.00%)
Uterine contractions during pregnancy	Pregnancy, puerperium and perinatal conditions	3 (0.00%)
Vaccination site anaesthesia	General disorders and administration site conditions	3 (0.00%)
Vaccination site exfoliation	General disorders and administration site conditions	3 (0.00%)
Vaccination site granuloma	General disorders and administration site conditions	3 (0.00%)
Vaccination site pallor	General disorders and administration site conditions	3 (0.00%)
Vaccination site phlebitis	General disorders and administration site conditions	3 (0.00%)
Vaccination site plaque	General disorders and administration site conditions	3 (0.00%)
Vaccination site ulcer	General disorders and administration site conditions	3 (0.00%)
Vaginal disorder	Reproductive system and breast disorders	3 (0.00%)
Vagus nerve disorder	Nervous system disorders	3 (0.00%)
Varicophlebitis	Vascular disorders	3 (0.00%)
Vasculitis necrotising	Vascular disorders	3 (0.00%)
Venous injury	Injury, poisoning and procedural complications	3 (0.00%)
Venous occlusion	Vascular disorders	3 (0.00%)
Ventricular dysfunction	Cardiac disorders	3 (0.00%)
Ventricular hypertrophy	Cardiac disorders	3 (0.00%)
Vertebrobasilar stroke	Nervous system disorders	3 (0.00%)
Viral sepsis	Infections and infestations	3 (0.00%)
Visceral venous thrombosis	Gastrointestinal disorders	3 (0.00%)
Visual brightness	Eye disorders	3 (0.00%)
Vital functions abnormal	Investigations	3 (0.00%)
Vitamin B12 deficiency	Metabolism and nutrition disorders	3 (0.00%)
Vitamin B12 increased	Investigations	3 (0.00%)
Volvulus	Gastrointestinal disorders	3 (0.00%)
Vulvovaginal rash	Reproductive system and breast disorders	3 (0.00%)
Vulvovaginal ulceration	Reproductive system and breast disorders	3 (0.00%)
Water pollution	Social circumstances	3 (0.00%)
Wound secretion	Injury, poisoning and procedural complications	3 (0.00%)
Wrong technique in device usage process	Injury, poisoning and procedural complications	3 (0.00%)
Xanthopsia	Eye disorders	3 (0.00%)
Xerophthalmia	Eye disorders	3 (0.00%)
Abdominal adhesions	Gastrointestinal disorders	2 (0.00%)
Abdominal sepsis	Infections and infestations	2 (0.00%)
Abortion threatened	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Abscess of salivary gland	Infections and infestations	2 (0.00%)
Acetonaemia	Metabolism and nutrition disorders	2 (0.00%)
Acne pustular	Infections and infestations	2 (0.00%)
Acute aortic syndrome	Vascular disorders	2 (0.00%)
Acute left ventricular failure	Cardiac disorders	2 (0.00%)
Acute motor axonal neuropathy	Nervous system disorders	2 (0.00%)
Adenoma benign	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Adenopathy syphilitic	Infections and infestations	2 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Administration site joint movement impairment	General disorders and administration site conditions	2 (0.00%)
Administration site paraesthesia	General disorders and administration site conditions	2 (0.00%)
Administration site warmth	General disorders and administration site conditions	2 (0.00%)
Adrenal haemorrhage	Endocrine disorders	2 (0.00%)
Adrenal mass	Endocrine disorders	2 (0.00%)
Adult failure to thrive	Metabolism and nutrition disorders	2 (0.00%)
African trypanosomiasis	Infections and infestations	2 (0.00%)
Agnosia	Nervous system disorders	2 (0.00%)
Albumin globulin ratio decreased	Investigations	2 (0.00%)
Albuminuria	Renal and urinary disorders	2 (0.00%)
Alcohol poisoning	Injury, poisoning and procedural complications	2 (0.00%)
Alexia	Nervous system disorders	2 (0.00%)
Allergy to arthropod bite	Immune system disorders	2 (0.00%)
Altered visual depth perception	Eye disorders	2 (0.00%)
Amblyopia	Eye disorders	2 (0.00%)
Anaemia macrocytic	Blood and lymphatic system disorders	2 (0.00%)
Anal abscess	Infections and infestations	2 (0.00%)
Androgenetic alopecia	Skin and subcutaneous tissue disorders	2 (0.00%)
Anencephaly	Congenital, familial and genetic disorders	2 (0.00%)
Anion gap increased	Investigations	2 (0.00%)
Anisomastia	Reproductive system and breast disorders	2 (0.00%)
Anorgasmia	Psychiatric disorders	2 (0.00%)
Antibody test positive	Investigations	2 (0.00%)
Antinuclear antibody increased	Investigations	2 (0.00%)
Antiphospholipid antibodies positive	Investigations	2 (0.00%)
Antisynthetase syndrome	Musculoskeletal and connective tissue disorders	2 (0.00%)
Aortic dilatation	Vascular disorders	2 (0.00%)
Aortic embolus	Vascular disorders	2 (0.00%)
Aortic thrombosis	Vascular disorders	2 (0.00%)
Aortitis	Vascular disorders	2 (0.00%)
Appendix disorder	Gastrointestinal disorders	2 (0.00%)
Application site coldness	General disorders and administration site conditions	2 (0.00%)
Application site swelling	General disorders and administration site conditions	2 (0.00%)
Application site vesicles	General disorders and administration site conditions	2 (0.00%)
Application site warmth	General disorders and administration site conditions	2 (0.00%)
Arterial rupture	Vascular disorders	2 (0.00%)
Arthritis bacterial	Infections and infestations	2 (0.00%)
Arthritis viral	Infections and infestations	2 (0.00%)
AST/ALT ratio abnormal	Investigations	2 (0.00%)
Asymptomatic bacteriuria	Infections and infestations	2 (0.00%)
Atopy	Immune system disorders	2 (0.00%)
Atrophy	General disorders and administration site conditions	2 (0.00%)
Autoimmune anaemia	Blood and lymphatic system disorders	2 (0.00%)
Autoimmune arthritis	Musculoskeletal and connective tissue disorders	2 (0.00%)
Autoimmune neutropenia	Blood and lymphatic system disorders	2 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Autoimmune thyroid disorder	Endocrine disorders	2 (0.00%)
Autophony	Ear and labyrinth disorders	2 (0.00%)
Aversion	Psychiatric disorders	2 (0.00%)
Bacterial disease carrier	Infections and infestations	2 (0.00%)
Bacterial pyelonephritis	Infections and infestations	2 (0.00%)
Basal ganglia infarction	Nervous system disorders	2 (0.00%)
Basophil count decreased	Investigations	2 (0.00%)
Basophil count increased	Investigations	2 (0.00%)
B-cell lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
B-cell type acute leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Biliary dilatation	Hepatobiliary disorders	2 (0.00%)
Biliary sepsis	Infections and infestations	2 (0.00%)
Bilirubin conjugated increased	Investigations	2 (0.00%)
Bladder dilatation	Renal and urinary disorders	2 (0.00%)
Bladder irritation	Renal and urinary disorders	2 (0.00%)
Bladder sphincter atony	Renal and urinary disorders	2 (0.00%)
Bleeding time prolonged	Investigations	2 (0.00%)
Bleeding varicose vein	Vascular disorders	2 (0.00%)
Blister rupture	Skin and subcutaneous tissue disorders	2 (0.00%)
Blood albumin increased	Investigations	2 (0.00%)
Blood alcohol decreased	Investigations	2 (0.00%)
Blood cholesterol	Investigations	2 (0.00%)
Blood copper increased	Investigations	2 (0.00%)
Blood electrolytes decreased	Investigations	2 (0.00%)
Blood follicle stimulating hormone increased	Investigations	2 (0.00%)
Blood gases abnormal	Investigations	2 (0.00%)
Blood growth hormone abnormal	Investigations	2 (0.00%)
Blood immunoglobulin E increased	Investigations	2 (0.00%)
Blood immunoglobulin M abnormal	Investigations	2 (0.00%)
Blood immunoglobulin M decreased	Investigations	2 (0.00%)
Blood ketone body increased	Investigations	2 (0.00%)
Blood lactic acid decreased	Investigations	2 (0.00%)
Blood loss anaemia	Blood and lymphatic system disorders	2 (0.00%)
Blood magnesium increased	Investigations	2 (0.00%)
Blood osmolarity increased	Investigations	2 (0.00%)
Blood pH	Investigations	2 (0.00%)
Blood phosphorus increased	Investigations	2 (0.00%)
Blood pressure ambulatory abnormal	Investigations	2 (0.00%)
Blood pressure orthostatic abnormal	Investigations	2 (0.00%)
Blood pressure orthostatic decreased	Investigations	2 (0.00%)
Blood pressure systolic	Investigations	2 (0.00%)
Blood prolactin increased	Investigations	2 (0.00%)
Blood triglycerides decreased	Investigations	2 (0.00%)
Blood urea decreased	Investigations	2 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Bone marrow oedema	Blood and lymphatic system disorders	2 (0.00%)
Bradypnoea	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Brain compression	Nervous system disorders	2 (0.00%)
Brain scan abnormal	Investigations	2 (0.00%)
Breast cellulitis	Infections and infestations	2 (0.00%)
Breast milk discolouration	Reproductive system and breast disorders	2 (0.00%)
Bronchial oedema	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Bronchial secretion retention	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Bronchial wall thickening	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Bulbar palsy	Nervous system disorders	2 (0.00%)
Bundle branch block	Cardiac disorders	2 (0.00%)
Burning feet syndrome	Nervous system disorders	2 (0.00%)
Burns third degree	Injury, poisoning and procedural complications	2 (0.00%)
Bursal haematoma	Musculoskeletal and connective tissue disorders	2 (0.00%)
Calculus urinary	Renal and urinary disorders	2 (0.00%)
Capillaritis	Skin and subcutaneous tissue disorders	2 (0.00%)
Capillary disorder	Vascular disorders	2 (0.00%)
Carbohydrate antigen 125 increased	Investigations	2 (0.00%)
Carbon dioxide increased	Investigations	2 (0.00%)
Cataplexy	Nervous system disorders	2 (0.00%)
Catheter site pain	General disorders and administration site conditions	2 (0.00%)
CD4 lymphocytes decreased	Investigations	2 (0.00%)
Central vision loss	Eye disorders	2 (0.00%)
Cerebellar haematoma	Nervous system disorders	2 (0.00%)
Cerebral congestion	Nervous system disorders	2 (0.00%)
Cerebral ventricle collapse	Injury, poisoning and procedural complications	2 (0.00%)
Cerebral ventricular rupture	Nervous system disorders	2 (0.00%)
Cerebrospinal fluid leakage	Nervous system disorders	2 (0.00%)
Cerebrovascular insufficiency	Nervous system disorders	2 (0.00%)
Cerumen impaction	Ear and labyrinth disorders	2 (0.00%)
Chloropsia	Eye disorders	2 (0.00%)
Cholecystitis infective	Infections and infestations	2 (0.00%)
Chondritis	Musculoskeletal and connective tissue disorders	2 (0.00%)
Chondrocalcinosis	Musculoskeletal and connective tissue disorders	2 (0.00%)
Chorioretinitis	Infections and infestations	2 (0.00%)
Chronic pigmented purpura	Skin and subcutaneous tissue disorders	2 (0.00%)
Chronic spontaneous urticaria	Skin and subcutaneous tissue disorders	2 (0.00%)
Citrobacter infection	Infections and infestations	2 (0.00%)
Claudication of jaw muscles	Vascular disorders	2 (0.00%)
Claustrophobia	Psychiatric disorders	2 (0.00%)
Clavicle fracture	Injury, poisoning and procedural complications	2 (0.00%)
Clostridium test positive	Investigations	2 (0.00%)
Coagulation factor increased	Investigations	2 (0.00%)
Colon cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Coma hepatic	Nervous system disorders	2 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Conduction disorder	Cardiac disorders	2 (0.00%)
Conjunctival disorder	Eye disorders	2 (0.00%)
Contraindicated product prescribed	Injury, poisoning and procedural complications	2 (0.00%)
Corneal disorder	Eye disorders	2 (0.00%)
Corneal infection	Infections and infestations	2 (0.00%)
Cortisol decreased	Investigations	2 (0.00%)
Cough decreased	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Cramp-fasciculation syndrome	Nervous system disorders	2 (0.00%)
C-reactive protein	Investigations	2 (0.00%)
C-reactive protein decreased	Investigations	2 (0.00%)
CSF cell count increased	Investigations	2 (0.00%)
CT hypotension complex	Vascular disorders	2 (0.00%)
Culture urine positive	Investigations	2 (0.00%)
Cutaneous lupus erythematosus	Skin and subcutaneous tissue disorders	2 (0.00%)
Cutaneous sarcoidosis	Skin and subcutaneous tissue disorders	2 (0.00%)
Cyanopsia	Eye disorders	2 (0.00%)
Cystitis bacterial	Infections and infestations	2 (0.00%)
Cystitis interstitial	Renal and urinary disorders	2 (0.00%)
Cystitis noninfective	Renal and urinary disorders	2 (0.00%)
Dacryocystitis	Infections and infestations	2 (0.00%)
Dairy intolerance	Metabolism and nutrition disorders	2 (0.00%)
Decreased insulin requirement	Metabolism and nutrition disorders	2 (0.00%)
Decreased nasolabial fold	Musculoskeletal and connective tissue disorders	2 (0.00%)
Defaecation disorder	Gastrointestinal disorders	2 (0.00%)
Deformity	General disorders and administration site conditions	2 (0.00%)
Degenerative bone disease	Musculoskeletal and connective tissue disorders	2 (0.00%)
Delusional disorder, unspecified type	Psychiatric disorders	2 (0.00%)
Dermatitis diaper	Skin and subcutaneous tissue disorders	2 (0.00%)
Device issue	Product issues	2 (0.00%)
Diabetic hyperosmolar coma	Nervous system disorders	2 (0.00%)
Diarrhoea infectious	Infections and infestations	2 (0.00%)
Disability	Social circumstances	2 (0.00%)
Disturbance in social behaviour	Psychiatric disorders	2 (0.00%)
Dose calculation error	Injury, poisoning and procedural complications	2 (0.00%)
Drop attacks	Nervous system disorders	2 (0.00%)
Dropped head syndrome	Nervous system disorders	2 (0.00%)
Drug level increased	Investigations	2 (0.00%)
Duodenal ulcer	Gastrointestinal disorders	2 (0.00%)
Dupuytren's contracture	Musculoskeletal and connective tissue disorders	2 (0.00%)
Dysaesthesia pharynx	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Dysbiosis	Gastrointestinal disorders	2 (0.00%)
Dyssomnia	Psychiatric disorders	2 (0.00%)
Ear infection bacterial	Infections and infestations	2 (0.00%)
Ehlers-Danlos syndrome	Congenital, familial and genetic disorders	2 (0.00%)
Ejection fraction abnormal	Investigations	2 (0.00%)
Electrocardiogram ST segment abnormal	Investigations	2 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Electrocardiogram ST-T change	Investigations	2 (0.00%)
Electrocardiogram T wave abnormal	Investigations	2 (0.00%)
Electroencephalogram abnormal	Investigations	2 (0.00%)
Encephalitis post immunisation	Nervous system disorders	2 (0.00%)
Endometrial cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Epstein-Barr virus test positive	Investigations	2 (0.00%)
Escherichia test positive	Investigations	2 (0.00%)
Evans syndrome	Blood and lymphatic system disorders	2 (0.00%)
Exaggerated startle response	Nervous system disorders	2 (0.00%)
Exercise electrocardiogram abnormal	Investigations	2 (0.00%)
Exploding head syndrome	Psychiatric disorders	2 (0.00%)
External ear disorder	Ear and labyrinth disorders	2 (0.00%)
Extravasation	General disorders and administration site conditions	2 (0.00%)
Eyelid bleeding	Eye disorders	2 (0.00%)
Eyelid infection	Infections and infestations	2 (0.00%)
Eyelid margin crusting	Eye disorders	2 (0.00%)
Facet joint syndrome	Musculoskeletal and connective tissue disorders	2 (0.00%)
Failure to thrive	Metabolism and nutrition disorders	2 (0.00%)
False positive investigation result	Investigations	2 (0.00%)
Familial mediterranean fever	Congenital, familial and genetic disorders	2 (0.00%)
Fear of disease	Psychiatric disorders	2 (0.00%)
Female reproductive tract disorder	Reproductive system and breast disorders	2 (0.00%)
Fibroma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Fibromuscular dysplasia	Vascular disorders	2 (0.00%)
Fibrosis	General disorders and administration site conditions	2 (0.00%)
Flashback	Psychiatric disorders	2 (0.00%)
Foetal cystic hygroma	Congenital, familial and genetic disorders	2 (0.00%)
Follicular lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Forced expiratory volume increased	Investigations	2 (0.00%)
Foreign body aspiration	Injury, poisoning and procedural complications	2 (0.00%)
Full blood count increased	Investigations	2 (0.00%)
Fumbling	Nervous system disorders	2 (0.00%)
Gallbladder enlargement	Hepatobiliary disorders	2 (0.00%)
Gallbladder oedema	Hepatobiliary disorders	2 (0.00%)
Gastritis erosive	Gastrointestinal disorders	2 (0.00%)
Gastrointestinal stoma complication	Injury, poisoning and procedural complications	2 (0.00%)
Gastrointestinal viral infection	Infections and infestations	2 (0.00%)
Gastrointestinal wall thickening	Gastrointestinal disorders	2 (0.00%)
Generalised onset non-motor seizure	Nervous system disorders	2 (0.00%)
Genital paraesthesia	Reproductive system and breast disorders	2 (0.00%)
Genital tract inflammation	Reproductive system and breast disorders	2 (0.00%)
Gingival oedema	Gastrointestinal disorders	2 (0.00%)
Gingivitis ulcerative	Gastrointestinal disorders	2 (0.00%)
Gliosis	Nervous system disorders	2 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Glomerulonephritis chronic	Renal and urinary disorders	2 (0.00%)
Glucose urine present	Investigations	2 (0.00%)
Glycosylated haemoglobin decreased	Investigations	2 (0.00%)
Gonorrhoea	Infections and infestations	2 (0.00%)
Graft versus host disease	Immune system disorders	2 (0.00%)
Granulocytes abnormal	Investigations	2 (0.00%)
Granuloma annulare	Skin and subcutaneous tissue disorders	2 (0.00%)
Granuloma skin	Skin and subcutaneous tissue disorders	2 (0.00%)
Granulomatous liver disease	Hepatobiliary disorders	2 (0.00%)
Gross motor delay	Nervous system disorders	2 (0.00%)
Gynaecomastia	Reproductive system and breast disorders	2 (0.00%)
Haemoglobinuria	Renal and urinary disorders	2 (0.00%)
Haemolytic uraemic syndrome	Blood and lymphatic system disorders	2 (0.00%)
Haemoperitoneum	Gastrointestinal disorders	2 (0.00%)
Haemophilia	Congenital, familial and genetic disorders	2 (0.00%)
Haemorrhage in pregnancy	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Hair growth abnormal	Skin and subcutaneous tissue disorders	2 (0.00%)
Hair injury	Injury, poisoning and procedural complications	2 (0.00%)
Hallucination, tactile	Psychiatric disorders	2 (0.00%)
Hand-arm vibration syndrome	Nervous system disorders	2 (0.00%)
Hand-eye coordination impaired	Nervous system disorders	2 (0.00%)
Haptoglobin increased	Investigations	2 (0.00%)
Head deformity	Musculoskeletal and connective tissue disorders	2 (0.00%)
Heart disease congenital	Congenital, familial and genetic disorders	2 (0.00%)
Helicobacter infection	Infections and infestations	2 (0.00%)
Hepatic haemorrhage	Hepatobiliary disorders	2 (0.00%)
Hepatic mass	Hepatobiliary disorders	2 (0.00%)
Hepatic vein thrombosis	Hepatobiliary disorders	2 (0.00%)
Hernia pain	General disorders and administration site conditions	2 (0.00%)
Herpes zoster meningoradiculitis	Infections and infestations	2 (0.00%)
Hilar lymphadenopathy	Blood and lymphatic system disorders	2 (0.00%)
Hippocampal atrophy	Nervous system disorders	2 (0.00%)
Hirsutism	Skin and subcutaneous tissue disorders	2 (0.00%)
HIV antibody positive	Investigations	2 (0.00%)
Hydronephrosis	Renal and urinary disorders	2 (0.00%)
Hydrothorax	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Hyperactive pharyngeal reflex	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Hypergeusia	Nervous system disorders	2 (0.00%)
Hyperintensity in brain deep nuclei	Nervous system disorders	2 (0.00%)
Hyperlipidaemia	Metabolism and nutrition disorders	2 (0.00%)
Hypermetabolism	Metabolism and nutrition disorders	2 (0.00%)
Hypermetropia	Eye disorders	2 (0.00%)
Hyperoxia	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Hyperparathyroidism	Endocrine disorders	2 (0.00%)
Hypersensitivity pneumonitis	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Hypersexuality	Psychiatric disorders	2 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Hypersomnia-bulimia syndrome	Psychiatric disorders	2 (0.00%)
Hypnagogic hallucination	Psychiatric disorders	2 (0.00%)
Hypochromasia	Blood and lymphatic system disorders	2 (0.00%)
Hypochromic anaemia	Blood and lymphatic system disorders	2 (0.00%)
Hypoglycaemic coma	Nervous system disorders	2 (0.00%)
Hyponatraemic syndrome	Metabolism and nutrition disorders	2 (0.00%)
Hypophosphataemia	Metabolism and nutrition disorders	2 (0.00%)
Hypopituitarism	Endocrine disorders	2 (0.00%)
Hypovolaemia	Metabolism and nutrition disorders	2 (0.00%)
Idiopathic urticaria	Skin and subcutaneous tissue disorders	2 (0.00%)
Idiosyncratic drug reaction	General disorders and administration site conditions	2 (0.00%)
Immature granulocyte count increased	Investigations	2 (0.00%)
Immobilisation syndrome	Musculoskeletal and connective tissue disorders	2 (0.00%)
Immunodeficiency common variable	Immune system disorders	2 (0.00%)
Immunoglobulins abnormal	Investigations	2 (0.00%)
Immunoglobulins decreased	Investigations	2 (0.00%)
Immunology test	Investigations	2 (0.00%)
Immunology test abnormal	Investigations	2 (0.00%)
Immunosuppression	Immune system disorders	2 (0.00%)
Imperception	Psychiatric disorders	2 (0.00%)
Implant site pain	General disorders and administration site conditions	2 (0.00%)
Inadequate aseptic technique in use of product	Injury, poisoning and procedural complications	2 (0.00%)
Incorrect product administration duration	Injury, poisoning and procedural complications	2 (0.00%)
Increased insulin requirement	Metabolism and nutrition disorders	2 (0.00%)
Infected cyst	Infections and infestations	2 (0.00%)
Infection susceptibility increased	Infections and infestations	2 (0.00%)
Infective tenosynovitis	Infections and infestations	2 (0.00%)
Infrequent bowel movements	Gastrointestinal disorders	2 (0.00%)
Injection	Surgical and medical procedures	2 (0.00%)
Injection site cellulitis	Infections and infestations	2 (0.00%)
Injection site discolouration	General disorders and administration site conditions	2 (0.00%)
Injection site hyperaesthesia	General disorders and administration site conditions	2 (0.00%)
Injection site indentation	General disorders and administration site conditions	2 (0.00%)
Injection site lymphadenopathy	General disorders and administration site conditions	2 (0.00%)
Injection site scab	General disorders and administration site conditions	2 (0.00%)
Injection site vesicles	General disorders and administration site conditions	2 (0.00%)
Inspiratory capacity abnormal	Investigations	2 (0.00%)
Insulin resistant diabetes	Metabolism and nutrition disorders	2 (0.00%)
Intentional overdose	Injury, poisoning and procedural complications	2 (0.00%)
Intercepted product preparation error	Injury, poisoning and procedural complications	2 (0.00%)
Intervertebral disc compression	Musculoskeletal and connective tissue disorders	2 (0.00%)
Intervertebral discitis	Infections and infestations	2 (0.00%)
Intestinal pseudo-obstruction	Gastrointestinal disorders	2 (0.00%)
Intraocular pressure test abnormal	Investigations	2 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Invasive ductal breast carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
IVth nerve disorder	Nervous system disorders	2 (0.00%)
Jaundice cholestatic	Hepatobiliary disorders	2 (0.00%)
Joint laxity	Musculoskeletal and connective tissue disorders	2 (0.00%)
Joint microhaemorrhage	Musculoskeletal and connective tissue disorders	2 (0.00%)
Joint stabilisation	Surgical and medical procedures	2 (0.00%)
Keratic precipitates	Eye disorders	2 (0.00%)
Labile hypertension	Vascular disorders	2 (0.00%)
Lacrimation decreased	Eye disorders	2 (0.00%)
Laryngeal disorder	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Laryngeal inflammation	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Latent autoimmune diabetes in adults	Metabolism and nutrition disorders	2 (0.00%)
Lateropulsion	Nervous system disorders	2 (0.00%)
Left ventricular dilatation	Cardiac disorders	2 (0.00%)
Libido decreased	Psychiatric disorders	2 (0.00%)
Libido increased	Psychiatric disorders	2 (0.00%)
Ligamentitis	Musculoskeletal and connective tissue disorders	2 (0.00%)
Limb crushing injury	Injury, poisoning and procedural complications	2 (0.00%)
Lipase decreased	Investigations	2 (0.00%)
Listeriosis	Infections and infestations	2 (0.00%)
Liver abscess	Infections and infestations	2 (0.00%)
Locked-in syndrome	Nervous system disorders	2 (0.00%)
Loss of bladder sensation	Renal and urinary disorders	2 (0.00%)
Lower gastrointestinal haemorrhage	Gastrointestinal disorders	2 (0.00%)
Lumbar radiculopathy	Nervous system disorders	2 (0.00%)
Lung cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Lung hyperinflation	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Lupus-like syndrome	Musculoskeletal and connective tissue disorders	2 (0.00%)
Lymphocyte percentage decreased	Investigations	2 (0.00%)
Macular rupture	Eye disorders	2 (0.00%)
Malignant melanoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Malignant peritoneal neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Mandibular mass	Musculoskeletal and connective tissue disorders	2 (0.00%)
Mastoid disorder	Ear and labyrinth disorders	2 (0.00%)
May-Thurner syndrome	Vascular disorders	2 (0.00%)
Mean platelet volume increased	Investigations	2 (0.00%)
Medial tibial stress syndrome	Musculoskeletal and connective tissue disorders	2 (0.00%)
Medication overuse headache	Nervous system disorders	2 (0.00%)
Meibomian gland dysfunction	Eye disorders	2 (0.00%)
Melanocytic naevus	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Melanoma recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Meningitis herpes	Infections and infestations	2 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Mesenteric arterial occlusion	Gastrointestinal disorders	2 (0.00%)
Mesenteric artery embolism	Gastrointestinal disorders	2 (0.00%)
Mesenteric panniculitis	Gastrointestinal disorders	2 (0.00%)
Metastases to peritoneum	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Metastasis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Microangiopathic haemolytic anaemia	Blood and lymphatic system disorders	2 (0.00%)
Microangiopathy	Vascular disorders	2 (0.00%)
Microvascular coronary artery disease	Cardiac disorders	2 (0.00%)
Mitral valve disease	Cardiac disorders	2 (0.00%)
Mitral valve prolapse	Cardiac disorders	2 (0.00%)
Mixed connective tissue disease	Musculoskeletal and connective tissue disorders	2 (0.00%)
Monocyte percentage increased	Investigations	2 (0.00%)
Mucosal discolouration	General disorders and administration site conditions	2 (0.00%)
Mucosal pain	General disorders and administration site conditions	2 (0.00%)
Multimorbidity	General disorders and administration site conditions	2 (0.00%)
Multiple fractures	Injury, poisoning and procedural complications	2 (0.00%)
Muscle haemorrhage	Musculoskeletal and connective tissue disorders	2 (0.00%)
Muscle tone disorder	Nervous system disorders	2 (0.00%)
Myelocyte count increased	Investigations	2 (0.00%)
Myoclonic dystonia	Congenital, familial and genetic disorders	2 (0.00%)
Myoclonic epilepsy	Nervous system disorders	2 (0.00%)
Myoglobin blood increased	Investigations	2 (0.00%)
Nail pigmentation	Skin and subcutaneous tissue disorders	2 (0.00%)
Nasal crusting	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Nasal discharge discolouration	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Neoplasm recurrence	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Nerve conduction studies abnormal	Investigations	2 (0.00%)
Nerve degeneration	Nervous system disorders	2 (0.00%)
Neurogenic bladder	Renal and urinary disorders	2 (0.00%)
Neuropsychiatric symptoms	Psychiatric disorders	2 (0.00%)
Neurotoxicity	Nervous system disorders	2 (0.00%)
Neutropenic sepsis	Infections and infestations	2 (0.00%)
Nipple disorder	Reproductive system and breast disorders	2 (0.00%)
Nipple exudate bloody	Reproductive system and breast disorders	2 (0.00%)
Nodal rhythm	Cardiac disorders	2 (0.00%)
Nonspecific reaction	General disorders and administration site conditions	2 (0.00%)
Nose deformity	Musculoskeletal and connective tissue disorders	2 (0.00%)
Nucleated red cells	Blood and lymphatic system disorders	2 (0.00%)
Obstructive shock	Vascular disorders	2 (0.00%)
Occult blood positive	Investigations	2 (0.00%)
Oedema genital	Reproductive system and breast disorders	2 (0.00%)
Oesophageal discomfort	Gastrointestinal disorders	2 (0.00%)
Oesophageal oedema	Gastrointestinal disorders	2 (0.00%)
Oesophageal stenosis	Gastrointestinal disorders	2 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Oesophageal varices haemorrhage	Gastrointestinal disorders	2 (0.00%)
Oligoarthritis	Musculoskeletal and connective tissue disorders	2 (0.00%)
Opisthotonus	Nervous system disorders	2 (0.00%)
Optic atrophy	Eye disorders	2 (0.00%)
Optic disc haemorrhage	Eye disorders	2 (0.00%)
Oral mucosa haematoma	Gastrointestinal disorders	2 (0.00%)
Oral mucosal discolouration	Gastrointestinal disorders	2 (0.00%)
Oropharyngeal candidiasis	Infections and infestations	2 (0.00%)
Oscillopsia	Eye disorders	2 (0.00%)
Osteochondritis	Musculoskeletal and connective tissue disorders	2 (0.00%)
Osteonecrosis of jaw	Musculoskeletal and connective tissue disorders	2 (0.00%)
Otitis media acute	Infections and infestations	2 (0.00%)
Otolithiasis	Ear and labyrinth disorders	2 (0.00%)
Ovarian cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Ovarian haemorrhage	Reproductive system and breast disorders	2 (0.00%)
Ovarian vein thrombosis	Reproductive system and breast disorders	2 (0.00%)
Ovulation disorder	Reproductive system and breast disorders	2 (0.00%)
Palatal ulcer	Gastrointestinal disorders	2 (0.00%)
Palate injury	Injury, poisoning and procedural complications	2 (0.00%)
Palmoplantar pustulosis	Skin and subcutaneous tissue disorders	2 (0.00%)
Pancreatic cyst	Gastrointestinal disorders	2 (0.00%)
Pancreatitis chronic	Gastrointestinal disorders	2 (0.00%)
Pancreatitis necrotising	Gastrointestinal disorders	2 (0.00%)
Pancreatitis relapsing	Gastrointestinal disorders	2 (0.00%)
Paramnesia	Psychiatric disorders	2 (0.00%)
Paronychia	Infections and infestations	2 (0.00%)
Parophthalmia	Eye disorders	2 (0.00%)
Paroxysmal arrhythmia	Cardiac disorders	2 (0.00%)
Paroxysmal sympathetic hyperactivity	Nervous system disorders	2 (0.00%)
Parvovirus B19 test positive	Investigations	2 (0.00%)
Patella fracture	Injury, poisoning and procedural complications	2 (0.00%)
Paternal exposure during pregnancy	Injury, poisoning and procedural complications	2 (0.00%)
PCO2 decreased	Investigations	2 (0.00%)
Pelvic inflammatory disease	Infections and infestations	2 (0.00%)
Pelvic mass	General disorders and administration site conditions	2 (0.00%)
Penile erythema	Reproductive system and breast disorders	2 (0.00%)
Perforation	General disorders and administration site conditions	2 (0.00%)
Pericardial disease	Cardiac disorders	2 (0.00%)
Periorbital disorder	Eye disorders	2 (0.00%)
Peripheral nerve injury	Injury, poisoning and procedural complications	2 (0.00%)
Peripheral nerve paresis	Nervous system disorders	2 (0.00%)
Peripheral sensorimotor neuropathy	Nervous system disorders	2 (0.00%)
Peroneal nerve injury	Injury, poisoning and procedural complications	2 (0.00%)
Personality disorder	Psychiatric disorders	2 (0.00%)
Pharyngeal cyst	Respiratory, thoracic and mediastinal disorders	2 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Pharyngeal lesion	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Phobia	Psychiatric disorders	2 (0.00%)
Physical examination abnormal	Investigations	2 (0.00%)
Pneumonia streptococcal	Infections and infestations	2 (0.00%)
Polychromasia	Blood and lymphatic system disorders	2 (0.00%)
Polyserositis	General disorders and administration site conditions	2 (0.00%)
Poor venous access	Vascular disorders	2 (0.00%)
Portal hypertension	Hepatobiliary disorders	2 (0.00%)
Post concussion syndrome	Injury, poisoning and procedural complications	2 (0.00%)
Postoperative wound infection	Infections and infestations	2 (0.00%)
Postpartum haemorrhage	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Post procedural haemorrhage	Injury, poisoning and procedural complications	2 (0.00%)
Post procedural infection	Infections and infestations	2 (0.00%)
Posturing	Psychiatric disorders	2 (0.00%)
Pre-eclampsia	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Premature delivery	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Premature menarche	Endocrine disorders	2 (0.00%)
Premature menopause	Reproductive system and breast disorders	2 (0.00%)
Premature rupture of membranes	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Premature separation of placenta	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Premenstrual dysphoric disorder	Reproductive system and breast disorders	2 (0.00%)
Presbycusis	Ear and labyrinth disorders	2 (0.00%)
Preterm premature rupture of membranes	Pregnancy, puerperium and perinatal conditions	2 (0.00%)
Priapism	Reproductive system and breast disorders	2 (0.00%)
Primary headache associated with sexual activity	Nervous system disorders	2 (0.00%)
Primary hyperaldosteronism	Endocrine disorders	2 (0.00%)
Prinzmetal angina	Cardiac disorders	2 (0.00%)
Procedural haemorrhage	Injury, poisoning and procedural complications	2 (0.00%)
Product confusion	Injury, poisoning and procedural complications	2 (0.00%)
Product dose omission in error	Injury, poisoning and procedural complications	2 (0.00%)
Product residue present	Investigations	2 (0.00%)
Prolapse	General disorders and administration site conditions	2 (0.00%)
Prophylaxis of nausea and vomiting	Surgical and medical procedures	2 (0.00%)
Prostate infection	Infections and infestations	2 (0.00%)
Prostatic disorder	Reproductive system and breast disorders	2 (0.00%)
Protein C increased	Investigations	2 (0.00%)
Prothrombin level increased	Investigations	2 (0.00%)
Pseudoallergic reaction	General disorders and administration site conditions	2 (0.00%)
Pseudofolliculitis	Skin and subcutaneous tissue disorders	2 (0.00%)
Pseudomonal bacteraemia	Infections and infestations	2 (0.00%)
Pseudomonal sepsis	Infections and infestations	2 (0.00%)
Pseudomonas infection	Infections and infestations	2 (0.00%)
Psychiatric decompensation	Psychiatric disorders	2 (0.00%)
Psychological trauma	Psychiatric disorders	2 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Pulmonary artery dilatation	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Pulmonary hypoperfusion	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Pulmonary sensitisation	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Pulse pressure decreased	Investigations	2 (0.00%)
Rash maculovesicular	Skin and subcutaneous tissue disorders	2 (0.00%)
Rash neonatal	Skin and subcutaneous tissue disorders	2 (0.00%)
Rash papulosquamous	Skin and subcutaneous tissue disorders	2 (0.00%)
Reactogenicity event	General disorders and administration site conditions	2 (0.00%)
Recall phenomenon	Injury, poisoning and procedural complications	2 (0.00%)
Rectal polyp	Gastrointestinal disorders	2 (0.00%)
Red blood cell abnormality	Blood and lymphatic system disorders	2 (0.00%)
Red blood cell sedimentation rate abnormal	Investigations	2 (0.00%)
Renal artery thrombosis	Renal and urinary disorders	2 (0.00%)
Renal atrophy	Renal and urinary disorders	2 (0.00%)
Renal cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Renal injury	Renal and urinary disorders	2 (0.00%)
Renal mass	Renal and urinary disorders	2 (0.00%)
Repetitive speech	Nervous system disorders	2 (0.00%)
Respiratory muscle weakness	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Respiratory tract infection bacterial	Infections and infestations	2 (0.00%)
Respiratory tract inflammation	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Restless arm syndrome	Nervous system disorders	2 (0.00%)
Retinal aneurysm	Eye disorders	2 (0.00%)
Retinal artery embolism	Eye disorders	2 (0.00%)
Retinal exudates	Eye disorders	2 (0.00%)
Retinal fovea disorder	Eye disorders	2 (0.00%)
Retinal ischaemia	Eye disorders	2 (0.00%)
Retinal vascular occlusion	Eye disorders	2 (0.00%)
Retinitis pigmentosa	Congenital, familial and genetic disorders	2 (0.00%)
Retinopathy	Eye disorders	2 (0.00%)
Retroperitoneal haemorrhage	Gastrointestinal disorders	2 (0.00%)
Reversed hot-cold sensation	Nervous system disorders	2 (0.00%)
Right ventricular enlargement	Cardiac disorders	2 (0.00%)
Rubber sensitivity	Immune system disorders	2 (0.00%)
Scleral disorder	Eye disorders	2 (0.00%)
Scleral haemorrhage	Eye disorders	2 (0.00%)
Scleroderma	Musculoskeletal and connective tissue disorders	2 (0.00%)
Scoliosis	Musculoskeletal and connective tissue disorders	2 (0.00%)
Seborrhoeic dermatitis	Skin and subcutaneous tissue disorders	2 (0.00%)
Seizure anoxic	Nervous system disorders	2 (0.00%)
Sepsis syndrome	Infections and infestations	2 (0.00%)
Septic arthritis staphylococcal	Infections and infestations	2 (0.00%)
Serology negative	Investigations	2 (0.00%)
Serositis	General disorders and administration site conditions	2 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Serotonin syndrome	Nervous system disorders	2 (0.00%)
Serratia infection	Infections and infestations	2 (0.00%)
Serum ferritin abnormal	Investigations	2 (0.00%)
Serum sickness-like reaction	Immune system disorders	2 (0.00%)
Shift to the left	Investigations	2 (0.00%)
Sight disability	Social circumstances	2 (0.00%)
Sinoatrial block	Cardiac disorders	2 (0.00%)
Sinusitis bacterial	Infections and infestations	2 (0.00%)
Sinus node dysfunction	Cardiac disorders	2 (0.00%)
Skin bacterial infection	Infections and infestations	2 (0.00%)
Skin texture abnormal	Skin and subcutaneous tissue disorders	2 (0.00%)
Skin turgor decreased	Investigations	2 (0.00%)
SLE arthritis	Musculoskeletal and connective tissue disorders	2 (0.00%)
Soft tissue disorder	Musculoskeletal and connective tissue disorders	2 (0.00%)
Soft tissue inflammation	General disorders and administration site conditions	2 (0.00%)
Solar dermatitis	Skin and subcutaneous tissue disorders	2 (0.00%)
Spinal column injury	Injury, poisoning and procedural complications	2 (0.00%)
Spinal cord compression	Nervous system disorders	2 (0.00%)
Splinter haemorrhages	Skin and subcutaneous tissue disorders	2 (0.00%)
Squamous cell carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Status asthmaticus	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Steroid diabetes	Metabolism and nutrition disorders	2 (0.00%)
Still's disease	Musculoskeletal and connective tissue disorders	2 (0.00%)
Streptobacillus infection	Infections and infestations	2 (0.00%)
Stress urinary incontinence	Renal and urinary disorders	2 (0.00%)
Stroke in evolution	Nervous system disorders	2 (0.00%)
Suicidal behaviour	Psychiatric disorders	2 (0.00%)
Superficial injury of eye	Injury, poisoning and procedural complications	2 (0.00%)
Suprapubic pain	General disorders and administration site conditions	2 (0.00%)
Supraventricular tachyarrhythmia	Cardiac disorders	2 (0.00%)
Suspiciousness	Psychiatric disorders	2 (0.00%)
Syndactyly	Congenital, familial and genetic disorders	2 (0.00%)
Syphilis	Infections and infestations	2 (0.00%)
Takayasu's arteritis	Vascular disorders	2 (0.00%)
Temporal lobe epilepsy	Nervous system disorders	2 (0.00%)
Tenosynovitis stenans	Musculoskeletal and connective tissue disorders	2 (0.00%)
Testicular disorder	Reproductive system and breast disorders	2 (0.00%)
Testis discomfort	Reproductive system and breast disorders	2 (0.00%)
Therapeutic product effect delayed	General disorders and administration site conditions	2 (0.00%)
Throat lesion	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Thrombolysis	Surgical and medical procedures	2 (0.00%)
Thrombotic cerebral infarction	Nervous system disorders	2 (0.00%)
Thyroid cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Thyroid neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Thyroxine decreased	Investigations	2 (0.00%)
T-lymphocyte count increased	Investigations	2 (0.00%)
Tongue cyst	Gastrointestinal disorders	2 (0.00%)
Tongue exfoliation	Gastrointestinal disorders	2 (0.00%)
Tongue haemorrhage	Gastrointestinal disorders	2 (0.00%)
Tonsillar ulcer	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Tonsillolith	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Tooth avulsion	Injury, poisoning and procedural complications	2 (0.00%)
Tooth discolouration	Gastrointestinal disorders	2 (0.00%)
Torsade de pointes	Cardiac disorders	2 (0.00%)
Toxocariasis	Infections and infestations	2 (0.00%)
Tracheal oedema	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Trance	Psychiatric disorders	2 (0.00%)
Transplant failure	Injury, poisoning and procedural complications	2 (0.00%)
Traumatic intracranial haemorrhage	Injury, poisoning and procedural complications	2 (0.00%)
Traumatic lung injury	Injury, poisoning and procedural complications	2 (0.00%)
Trichodynia	Skin and subcutaneous tissue disorders	2 (0.00%)
Triple negative breast cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Troponin	Investigations	2 (0.00%)
Tryptase decreased	Investigations	2 (0.00%)
Tryptase increased	Investigations	2 (0.00%)
Tumour pain	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.00%)
Tympanic membrane hyperaemia	Ear and labyrinth disorders	2 (0.00%)
Tympanic membrane perforation	Ear and labyrinth disorders	2 (0.00%)
Type II hypersensitivity	Immune system disorders	2 (0.00%)
Type V hyperlipidaemia	Congenital, familial and genetic disorders	2 (0.00%)
Ulcer haemorrhage	General disorders and administration site conditions	2 (0.00%)
Undersensing	Product issues	2 (0.00%)
Unevaluable event	General disorders and administration site conditions	2 (0.00%)
Ureteric stenosis	Renal and urinary disorders	2 (0.00%)
Urinary tract pain	Renal and urinary disorders	2 (0.00%)
Urine leukocyte esterase positive	Investigations	2 (0.00%)
Urogenital haemorrhage	Renal and urinary disorders	2 (0.00%)
Urticaria cholinergic	Skin and subcutaneous tissue disorders	2 (0.00%)
Urticaria physical	Skin and subcutaneous tissue disorders	2 (0.00%)
Uterine inflammation	Reproductive system and breast disorders	2 (0.00%)
Vaccination site abscess sterile	General disorders and administration site conditions	2 (0.00%)
Vaccination site atrophy	General disorders and administration site conditions	2 (0.00%)
Vaccination site cyst	General disorders and administration site conditions	2 (0.00%)
Vaccination site hypertrophy	General disorders and administration site conditions	2 (0.00%)
Vaccination site joint warmth	General disorders and administration site conditions	2 (0.00%)
Vaccination site nerve damage	General disorders and administration site conditions	2 (0.00%)
Vaginal cyst	Reproductive system and breast disorders	2 (0.00%)
Vaginal lesion	Reproductive system and breast disorders	2 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Vaginal ulceration	Reproductive system and breast disorders	2 (0.00%)
Varicella virus test positive	Investigations	2 (0.00%)
Vascular calcification	Vascular disorders	2 (0.00%)
Vascular test abnormal	Investigations	2 (0.00%)
Venous haemorrhage	Vascular disorders	2 (0.00%)
Venous oxygen saturation decreased	Investigations	2 (0.00%)
Vertebral artery occlusion	Nervous system disorders	2 (0.00%)
Vertebral lesion	Musculoskeletal and connective tissue disorders	2 (0.00%)
Vestibulitis	Infections and infestations	2 (0.00%)
Viral myocarditis	Infections and infestations	2 (0.00%)
Viral pericarditis	Infections and infestations	2 (0.00%)
Virologic failure	Infections and infestations	2 (0.00%)
Vitiligo	Skin and subcutaneous tissue disorders	2 (0.00%)
Vitreoretinal traction syndrome	Eye disorders	2 (0.00%)
Vitreous degeneration	Eye disorders	2 (0.00%)
Vocal cord dysfunction	Respiratory, thoracic and mediastinal disorders	2 (0.00%)
Vulval abscess	Infections and infestations	2 (0.00%)
Vulval disorder	Reproductive system and breast disorders	2 (0.00%)
Vulvitis	Infections and infestations	2 (0.00%)
Vulvovaginal discomfort	Reproductive system and breast disorders	2 (0.00%)
Vulvovaginal dryness	Reproductive system and breast disorders	2 (0.00%)
White blood cell disorder	Blood and lymphatic system disorders	2 (0.00%)
X-ray abnormal	Investigations	2 (0.00%)
Abdominal abscess	Infections and infestations	1 (0.00%)
Abdominal operation	Surgical and medical procedures	1 (0.00%)
Abdominal wall abscess	Infections and infestations	1 (0.00%)
Abnormal sleep-related event	Psychiatric disorders	1 (0.00%)
Abnormal withdrawal bleeding	Reproductive system and breast disorders	1 (0.00%)
Aborted pregnancy	Social circumstances	1 (0.00%)
Abortion induced	Surgical and medical procedures	1 (0.00%)
Abscess drainage	Surgical and medical procedures	1 (0.00%)
Abscess jaw	Infections and infestations	1 (0.00%)
Abscess neck	Infections and infestations	1 (0.00%)
Abscess rupture	Infections and infestations	1 (0.00%)
Abulia	Psychiatric disorders	1 (0.00%)
Accelerated hypertension	Vascular disorders	1 (0.00%)
Accidental exposure to product by child	Injury, poisoning and procedural complications	1 (0.00%)
Accident at work	Injury, poisoning and procedural complications	1 (0.00%)
Achenbach syndrome	Vascular disorders	1 (0.00%)
Achlorhydria	Gastrointestinal disorders	1 (0.00%)
Acidosis hyperchloraemic	Metabolism and nutrition disorders	1 (0.00%)
Acquired macroglossia	Gastrointestinal disorders	1 (0.00%)
Acrochordon	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Activated partial thromboplastin time abnormal	Investigations	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Activated partial thromboplastin time ratio increased	Investigations	1 (0.00%)
Acute endocarditis	Infections and infestations	1 (0.00%)
Acute haemorrhagic conjunctivitis	Infections and infestations	1 (0.00%)
Acute lymphocytic leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Acute phase reaction	General disorders and administration site conditions	1 (0.00%)
Acute right ventricular failure	Cardiac disorders	1 (0.00%)
Acute sinusitis	Infections and infestations	1 (0.00%)
Addison's disease	Endocrine disorders	1 (0.00%)
Adenomyosis	Reproductive system and breast disorders	1 (0.00%)
Adenoviral conjunctivitis	Infections and infestations	1 (0.00%)
Adhesion	General disorders and administration site conditions	1 (0.00%)
Adiposis dolorosa	Skin and subcutaneous tissue disorders	1 (0.00%)
Adjustment disorder with depressed mood	Psychiatric disorders	1 (0.00%)
Administration site discomfort	General disorders and administration site conditions	1 (0.00%)
Administration site hypoaesthesia	General disorders and administration site conditions	1 (0.00%)
Administration site induration	General disorders and administration site conditions	1 (0.00%)
Administration site irritation	General disorders and administration site conditions	1 (0.00%)
Administration site joint erythema	General disorders and administration site conditions	1 (0.00%)
Administration site joint pain	General disorders and administration site conditions	1 (0.00%)
Administration site rash	General disorders and administration site conditions	1 (0.00%)
Adrenergic syndrome	Nervous system disorders	1 (0.00%)
Advanced sleep phase	Nervous system disorders	1 (0.00%)
Aerococcus urinae infection	Infections and infestations	1 (0.00%)
Agitated depression	Psychiatric disorders	1 (0.00%)
Agonal respiration	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Air embolism	Vascular disorders	1 (0.00%)
Airway secretion clearance therapy	Surgical and medical procedures	1 (0.00%)
Alanine aminotransferase	Investigations	1 (0.00%)
Alanine aminotransferase abnormal	Investigations	1 (0.00%)
Albumin CSF increased	Investigations	1 (0.00%)
Alcoholic hangover	Psychiatric disorders	1 (0.00%)
Alexithymia	Psychiatric disorders	1 (0.00%)
Allergic gastroenteritis	Gastrointestinal disorders	1 (0.00%)
Allergic pharyngitis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Allergic respiratory disease	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Allergy test positive	Investigations	1 (0.00%)
Allergy to animal	Immune system disorders	1 (0.00%)
Allergy to metals	Immune system disorders	1 (0.00%)
Alopecia totalis	Skin and subcutaneous tissue disorders	1 (0.00%)
Alpha globulin increased	Investigations	1 (0.00%)
Alpha tumour necrosis factor increased	Investigations	1 (0.00%)
Altered pitch perception	Nervous system disorders	1 (0.00%)
Alveolitis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Amegakaryocytic thrombocytopenia	Congenital, familial and genetic disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Amino acid level decreased	Investigations	1 (0.00%)
Amino acid level increased	Investigations	1 (0.00%)
Ammonia abnormal	Investigations	1 (0.00%)
Ammonia increased	Investigations	1 (0.00%)
Amniotic cavity infection	Infections and infestations	1 (0.00%)
Amphetamines positive	Investigations	1 (0.00%)
Amputation stump pain	Nervous system disorders	1 (0.00%)
Amylase decreased	Investigations	1 (0.00%)
Amyloidosis senile	Immune system disorders	1 (0.00%)
Amyotrophy	Musculoskeletal and connective tissue disorders	1 (0.00%)
Anaemia megaloblastic	Blood and lymphatic system disorders	1 (0.00%)
Anaesthesia dolorosa	Nervous system disorders	1 (0.00%)
Anal erythema	Gastrointestinal disorders	1 (0.00%)
Anal fissure	Gastrointestinal disorders	1 (0.00%)
Analgesic drug level	Investigations	1 (0.00%)
Analgesic drug level above therapeutic	Investigations	1 (0.00%)
Analgesic therapy	Surgical and medical procedures	1 (0.00%)
Anal hypoaesthesia	Gastrointestinal disorders	1 (0.00%)
Anal infection	Infections and infestations	1 (0.00%)
Anal rash	Gastrointestinal disorders	1 (0.00%)
Anal skin tags	Gastrointestinal disorders	1 (0.00%)
Anal sphincter hypertonia	Gastrointestinal disorders	1 (0.00%)
Anaphylaxis prophylaxis	Surgical and medical procedures	1 (0.00%)
Aneurysmal bone cyst	Musculoskeletal and connective tissue disorders	1 (0.00%)
Angina bullosa haemorrhagica	Gastrointestinal disorders	1 (0.00%)
Angiokeratoma	Skin and subcutaneous tissue disorders	1 (0.00%)
Angiolymphoid hyperplasia with eosinophilia	Skin and subcutaneous tissue disorders	1 (0.00%)
Angiomyolipoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Angiotensin converting enzyme increased	Investigations	1 (0.00%)
Anhedonia	Psychiatric disorders	1 (0.00%)
Animal attack	Injury, poisoning and procedural complications	1 (0.00%)
Anion gap abnormal	Investigations	1 (0.00%)
Anion gap decreased	Investigations	1 (0.00%)
Anisometropia	Eye disorders	1 (0.00%)
Ankyloglossia congenital	Congenital, familial and genetic disorders	1 (0.00%)
Anomalous pulmonary venous connection	Congenital, familial and genetic disorders	1 (0.00%)
Anorectal disorder	Gastrointestinal disorders	1 (0.00%)
Anorectal swelling	Gastrointestinal disorders	1 (0.00%)
Anterior chamber cell	Eye disorders	1 (0.00%)
Antibody test normal	Investigations	1 (0.00%)
Anticholinergic syndrome	Nervous system disorders	1 (0.00%)
Anticoagulation drug level increased	Investigations	1 (0.00%)
Anti factor VIII antibody positive	Investigations	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Anti-glomerular basement membrane disease	Renal and urinary disorders	1 (0.00%)
Anti Kell antibody test positive	Investigations	1 (0.00%)
Anti-myelin-associated glycoprotein antibodies positive	Investigations	1 (0.00%)
Antineutrophil cytoplasmic antibody positive	Investigations	1 (0.00%)
Antinuclear antibody	Investigations	1 (0.00%)
Anti-platelet antibody	Investigations	1 (0.00%)
Antipsychotic drug level increased	Investigations	1 (0.00%)
Anti-thyroid antibody	Investigations	1 (0.00%)
Anxiety disorder due to a general medical condition	Psychiatric disorders	1 (0.00%)
Aortic bruit	Investigations	1 (0.00%)
Aortic disorder	Vascular disorders	1 (0.00%)
Aortic elongation	Vascular disorders	1 (0.00%)
Aortic rupture	Vascular disorders	1 (0.00%)
Aortic valve disease	Cardiac disorders	1 (0.00%)
Apical granuloma	Gastrointestinal disorders	1 (0.00%)
Aplasia	Congenital, familial and genetic disorders	1 (0.00%)
Aplasia pure red cell	Blood and lymphatic system disorders	1 (0.00%)
Aplastic anaemia	Blood and lymphatic system disorders	1 (0.00%)
Apparent death	General disorders and administration site conditions	1 (0.00%)
Appendectomy	Surgical and medical procedures	1 (0.00%)
Application site haemorrhage	General disorders and administration site conditions	1 (0.00%)
Application site hyperaesthesia	General disorders and administration site conditions	1 (0.00%)
Application site hypoaesthesia	General disorders and administration site conditions	1 (0.00%)
Application site induration	General disorders and administration site conditions	1 (0.00%)
Application site inflammation	General disorders and administration site conditions	1 (0.00%)
Application site paraesthesia	General disorders and administration site conditions	1 (0.00%)
Arachnoid cyst	Nervous system disorders	1 (0.00%)
Arrested labour	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Arterial haemorrhage	Vascular disorders	1 (0.00%)
Arteriosclerotic retinopathy	Eye disorders	1 (0.00%)
Arteriovenous fistula	Vascular disorders	1 (0.00%)
Arteriovenous graft thrombosis	Injury, poisoning and procedural complications	1 (0.00%)
Arteriovenous malformation	Congenital, familial and genetic disorders	1 (0.00%)
Arthritis allergic	Musculoskeletal and connective tissue disorders	1 (0.00%)
Arthritis enteropathic	Musculoskeletal and connective tissue disorders	1 (0.00%)
Arthropod infestation	Infections and infestations	1 (0.00%)
Aspartate aminotransferase	Investigations	1 (0.00%)
Aspartate aminotransferase decreased	Investigations	1 (0.00%)
Aspermia	Reproductive system and breast disorders	1 (0.00%)
Aspiration joint	Investigations	1 (0.00%)
Asterixis	Nervous system disorders	1 (0.00%)
Asthma late onset	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Atrophic glossitis	Gastrointestinal disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Atypical femur fracture	Injury, poisoning and procedural complications	1 (0.00%)
Atypical haemolytic uraemic syndrome	Blood and lymphatic system disorders	1 (0.00%)
Audiogram abnormal	Investigations	1 (0.00%)
Auscultation	Investigations	1 (0.00%)
Autoantibody negative	Investigations	1 (0.00%)
Autoimmune demyelinating disease	Nervous system disorders	1 (0.00%)
Autoimmune hypothyroidism	Endocrine disorders	1 (0.00%)
Autoimmune myocarditis	Cardiac disorders	1 (0.00%)
Autoimmune neuropathy	Nervous system disorders	1 (0.00%)
Autoimmune pancreatitis	Gastrointestinal disorders	1 (0.00%)
Autoimmune uveitis	Eye disorders	1 (0.00%)
Automatism	Psychiatric disorders	1 (0.00%)
Babesiosis	Infections and infestations	1 (0.00%)
Bacterial diarrhoea	Infections and infestations	1 (0.00%)
Bacterial rhinitis	Infections and infestations	1 (0.00%)
Bacterial test	Investigations	1 (0.00%)
Ballismus	Nervous system disorders	1 (0.00%)
Band neutrophil count increased	Investigations	1 (0.00%)
Barotitis media	Injury, poisoning and procedural complications	1 (0.00%)
Barotrauma	Injury, poisoning and procedural complications	1 (0.00%)
Barrett's oesophagus	Gastrointestinal disorders	1 (0.00%)
Basal ganglia haematoma	Nervous system disorders	1 (0.00%)
Base excess decreased	Investigations	1 (0.00%)
Basilar migraine	Nervous system disorders	1 (0.00%)
Basophil count abnormal	Investigations	1 (0.00%)
Basophil percentage increased	Investigations	1 (0.00%)
Belligerence	Psychiatric disorders	1 (0.00%)
Benign breast neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Benign hydatidiform mole	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Benign lymph node neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Beta 2 microglobulin increased	Investigations	1 (0.00%)
Beta globulin increased	Investigations	1 (0.00%)
Bezold-Jarisch reflex	Cardiac disorders	1 (0.00%)
Bile acid malabsorption	Gastrointestinal disorders	1 (0.00%)
Bile duct cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Biliary cyst	Hepatobiliary disorders	1 (0.00%)
Bilirubinuria	Renal and urinary disorders	1 (0.00%)
Bilirubin urine present	Investigations	1 (0.00%)
Binge eating	Psychiatric disorders	1 (0.00%)
Biopsy	Investigations	1 (0.00%)
Biopsy muscle abnormal	Investigations	1 (0.00%)
Bipolar I disorder	Psychiatric disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Bladder cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Bladder hypertrophy	Renal and urinary disorders	1 (0.00%)
Bladder neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Bladder obstruction	Renal and urinary disorders	1 (0.00%)
Blast cell count increased	Investigations	1 (0.00%)
Blast cell crisis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Blastocystis infection	Infections and infestations	1 (0.00%)
Bleeding time abnormal	Investigations	1 (0.00%)
Blepharochalasis	Eye disorders	1 (0.00%)
Blindness cortical	Eye disorders	1 (0.00%)
Block vertebra	Congenital, familial and genetic disorders	1 (0.00%)
Blood 25-hydroxycholecalciferol decreased	Investigations	1 (0.00%)
Blood alkaline phosphatase	Investigations	1 (0.00%)
Blood alkaline phosphatase decreased	Investigations	1 (0.00%)
Blood bicarbonate increased	Investigations	1 (0.00%)
Blood bilirubin unconjugated increased	Investigations	1 (0.00%)
Blood chromium increased	Investigations	1 (0.00%)
Blood count	Investigations	1 (0.00%)
Blood creatine phosphokinase abnormal	Investigations	1 (0.00%)
Blood culture positive	Investigations	1 (0.00%)
Blood electrolytes increased	Investigations	1 (0.00%)
Blood folate increased	Investigations	1 (0.00%)
Blood heavy metal increased	Investigations	1 (0.00%)
Blood immunoglobulin G	Investigations	1 (0.00%)
Blood immunoglobulin G abnormal	Investigations	1 (0.00%)
Blood insulin increased	Investigations	1 (0.00%)
Blood ketone body	Investigations	1 (0.00%)
Blood ketone body present	Investigations	1 (0.00%)
Blood lactate dehydrogenase abnormal	Investigations	1 (0.00%)
Blood luteinising hormone abnormal	Investigations	1 (0.00%)
Blood methaemoglobin present	Investigations	1 (0.00%)
Blood oestrogen increased	Investigations	1 (0.00%)
Blood osmolarity decreased	Investigations	1 (0.00%)
Blood parathyroid hormone decreased	Investigations	1 (0.00%)
Blood pH abnormal	Investigations	1 (0.00%)
Blood pH decreased	Investigations	1 (0.00%)
Blood potassium abnormal	Investigations	1 (0.00%)
Blood pressure normal	Investigations	1 (0.00%)
Blood pressure orthostatic increased	Investigations	1 (0.00%)
Blood pressure systolic abnormal	Investigations	1 (0.00%)
Blood smear test abnormal	Investigations	1 (0.00%)
Blood test	Investigations	1 (0.00%)
Blood testosterone decreased	Investigations	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Blood testosterone increased	Investigations	1 (0.00%)
Blood thrombin	Investigations	1 (0.00%)
Blood thyroid stimulating hormone abnormal	Investigations	1 (0.00%)
Blood triglycerides abnormal	Investigations	1 (0.00%)
Blood urea abnormal	Investigations	1 (0.00%)
Blood uric acid abnormal	Investigations	1 (0.00%)
Blood viscosity increased	Investigations	1 (0.00%)
Blood zinc decreased	Investigations	1 (0.00%)
B-lymphocyte abnormalities	Blood and lymphatic system disorders	1 (0.00%)
B-lymphocyte count decreased	Investigations	1 (0.00%)
Body dysmorphic disorder	Psychiatric disorders	1 (0.00%)
Body fat disorder	Metabolism and nutrition disorders	1 (0.00%)
Body mass index increased	Investigations	1 (0.00%)
Body tinea	Infections and infestations	1 (0.00%)
Bone abscess	Infections and infestations	1 (0.00%)
Bone cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Bone density abnormal	Investigations	1 (0.00%)
Bone density decreased	Investigations	1 (0.00%)
Bone development abnormal	Musculoskeletal and connective tissue disorders	1 (0.00%)
Bone formation increased	Musculoskeletal and connective tissue disorders	1 (0.00%)
Brachiocephalic vein thrombosis	Vascular disorders	1 (0.00%)
Brain cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Breast cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Breast cancer recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Breast cancer stage I	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Breast cancer stage III	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Breast disorder female	Reproductive system and breast disorders	1 (0.00%)
Breast prosthesis user	Social circumstances	1 (0.00%)
Bronchial haemorrhage	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Bronchial irritation	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Bronchial neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Bronchopulmonary aspergillosis	Infections and infestations	1 (0.00%)
Brown-Sequard syndrome	Nervous system disorders	1 (0.00%)
Brow ptosis	Skin and subcutaneous tissue disorders	1 (0.00%)
Bulimia nervosa	Psychiatric disorders	1 (0.00%)
Bullous haemorrhagic dermatosis	Skin and subcutaneous tissue disorders	1 (0.00%)
Burn of internal organs	Injury, poisoning and procedural complications	1 (0.00%)
Burnout syndrome	Psychiatric disorders	1 (0.00%)
Bursa disorder	Musculoskeletal and connective tissue disorders	1 (0.00%)
Bursal fluid accumulation	Musculoskeletal and connective tissue disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Bursitis infective	Infections and infestations	1 (0.00%)
Caffeine consumption	Social circumstances	1 (0.00%)
Calcinosis	General disorders and administration site conditions	1 (0.00%)
Calcium ionised decreased	Investigations	1 (0.00%)
Calcium ionised increased	Investigations	1 (0.00%)
Calculus bladder	Renal and urinary disorders	1 (0.00%)
Camptocormia	Musculoskeletal and connective tissue disorders	1 (0.00%)
Campylobacter gastroenteritis	Infections and infestations	1 (0.00%)
Campylobacter infection	Infections and infestations	1 (0.00%)
Capillary leak syndrome	Vascular disorders	1 (0.00%)
Capsular contracture associated with breast implant	General disorders and administration site conditions	1 (0.00%)
Carbon dioxide decreased	Investigations	1 (0.00%)
Carbon monoxide poisoning	Injury, poisoning and procedural complications	1 (0.00%)
Cardiac aneurysm	Cardiac disorders	1 (0.00%)
Cardiac neoplasm unspecified	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Cardiac procedure complication	Injury, poisoning and procedural complications	1 (0.00%)
Cardiac valve sclerosis	Cardiac disorders	1 (0.00%)
Cardiac valve vegetation	Infections and infestations	1 (0.00%)
Cardio-ankle vascular index	Investigations	1 (0.00%)
Cardiothoracic ratio increased	Investigations	1 (0.00%)
Cardiovascular symptom	Cardiac disorders	1 (0.00%)
Cardioversion	Surgical and medical procedures	1 (0.00%)
Carotid artery disease	Nervous system disorders	1 (0.00%)
Castleman's disease	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Cataract nuclear	Eye disorders	1 (0.00%)
Catheter site haemorrhage	General disorders and administration site conditions	1 (0.00%)
Cauda equina syndrome	Nervous system disorders	1 (0.00%)
Cavernous sinus thrombosis	Infections and infestations	1 (0.00%)
CD4 lymphocytes increased	Investigations	1 (0.00%)
Cell marker decreased	Investigations	1 (0.00%)
Cells in urine	Investigations	1 (0.00%)
Cellulitis gangrenous	Infections and infestations	1 (0.00%)
Cellulitis staphylococcal	Infections and infestations	1 (0.00%)
Central cord syndrome	Injury, poisoning and procedural complications	1 (0.00%)
Central nervous system infection	Infections and infestations	1 (0.00%)
Central nervous system inflammation	Nervous system disorders	1 (0.00%)
Central nervous system stimulation	Surgical and medical procedures	1 (0.00%)
Central venous pressure abnormal	Investigations	1 (0.00%)
Cephalhaematoma	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Cerebellar atrophy	Nervous system disorders	1 (0.00%)
Cerebellar embolism	Nervous system disorders	1 (0.00%)
Cerebellar ischaemia	Nervous system disorders	1 (0.00%)
Cerebral cyst	Nervous system disorders	1 (0.00%)
Cerebral hyperperfusion syndrome	Injury, poisoning and procedural complications	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Cerebral mass effect	Nervous system disorders	1 (0.00%)
Cerebral microangiopathy	Nervous system disorders	1 (0.00%)
Cerebral vascular occlusion	Nervous system disorders	1 (0.00%)
Cervical cord compression	Nervous system disorders	1 (0.00%)
Cervical dysplasia	Reproductive system and breast disorders	1 (0.00%)
Cervical incompetence	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Cervical neuritis	Nervous system disorders	1 (0.00%)
Cervical vertebral fracture	Injury, poisoning and procedural complications	1 (0.00%)
Cervicogenic vertigo	Nervous system disorders	1 (0.00%)
Cervix erythema	Reproductive system and breast disorders	1 (0.00%)
Cervix haematoma uterine	Reproductive system and breast disorders	1 (0.00%)
Cervix oedema	Reproductive system and breast disorders	1 (0.00%)
Change in sustained attention	Psychiatric disorders	1 (0.00%)
Charles Bonnet syndrome	Eye disorders	1 (0.00%)
Chest expansion decreased	Investigations	1 (0.00%)
Cheyne-Stokes respiration	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Cholelithiasis obstructive	Hepatobiliary disorders	1 (0.00%)
Choroiditis	Eye disorders	1 (0.00%)
Chronic idiopathic pain syndrome	Psychiatric disorders	1 (0.00%)
Chronic lymphocytic leukaemia recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Chronic myeloid leukaemia recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Chronic respiratory disease	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Ciliary muscle spasm	Eye disorders	1 (0.00%)
Cleft palate	Congenital, familial and genetic disorders	1 (0.00%)
Clinically isolated syndrome	Nervous system disorders	1 (0.00%)
Clinomania	Psychiatric disorders	1 (0.00%)
Clostridial infection	Infections and infestations	1 (0.00%)
Clot retraction	Investigations	1 (0.00%)
Coagulation factor VIII level increased	Investigations	1 (0.00%)
Coagulation test abnormal	Investigations	1 (0.00%)
Coagulation time shortened	Investigations	1 (0.00%)
Coeliac artery stenosis	Gastrointestinal disorders	1 (0.00%)
Cogwheel rigidity	Nervous system disorders	1 (0.00%)
Coital bleeding	Reproductive system and breast disorders	1 (0.00%)
Colon neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Colour blindness	Congenital, familial and genetic disorders	1 (0.00%)
Complement factor C1 increased	Investigations	1 (0.00%)
Complement factor C3 decreased	Investigations	1 (0.00%)
Complement factor increased	Investigations	1 (0.00%)
Complications of transplanted kidney	Injury, poisoning and procedural complications	1 (0.00%)
Compression fracture	Injury, poisoning and procedural complications	1 (0.00%)
Compulsions	Psychiatric disorders	1 (0.00%)
Computerised tomogram normal	Investigations	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Computerised tomogram thorax abnormal	Investigations	1 (0.00%)
Computer vision syndrome	Eye disorders	1 (0.00%)
Concentric sclerosis	Nervous system disorders	1 (0.00%)
Confusional arousal	Psychiatric disorders	1 (0.00%)
Congenital absence of cranial vault	Congenital, familial and genetic disorders	1 (0.00%)
Congenital anomaly	Congenital, familial and genetic disorders	1 (0.00%)
Congenital cystic lung	Congenital, familial and genetic disorders	1 (0.00%)
Conjunctival laceration	Injury, poisoning and procedural complications	1 (0.00%)
Conjunctival pallor	Eye disorders	1 (0.00%)
Connective tissue inflammation	Musculoskeletal and connective tissue disorders	1 (0.00%)
Constricted affect	Psychiatric disorders	1 (0.00%)
Contraceptive diaphragm	Surgical and medical procedures	1 (0.00%)
Contraindication to medical treatment	Social circumstances	1 (0.00%)
Contrast media allergy	Immune system disorders	1 (0.00%)
Contrast media reaction	Immune system disorders	1 (0.00%)
Conus medullaris syndrome	Nervous system disorders	1 (0.00%)
Cooling therapy	Surgical and medical procedures	1 (0.00%)
Coombs positive haemolytic anaemia	Blood and lymphatic system disorders	1 (0.00%)
Coprolalia	Psychiatric disorders	1 (0.00%)
Corneal abrasion	Injury, poisoning and procedural complications	1 (0.00%)
Corneal bleeding	Eye disorders	1 (0.00%)
Corneal degeneration	Eye disorders	1 (0.00%)
Corneal dystrophy	Congenital, familial and genetic disorders	1 (0.00%)
Corneal erosion	Eye disorders	1 (0.00%)
Corneal infiltrates	Eye disorders	1 (0.00%)
Corneal oedema	Eye disorders	1 (0.00%)
Coronary artery insufficiency	Cardiac disorders	1 (0.00%)
Cranial nerve decompression	Surgical and medical procedures	1 (0.00%)
Cranial nerve injury	Injury, poisoning and procedural complications	1 (0.00%)
Cranial nerve neoplasm benign	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Craniofacial fracture	Injury, poisoning and procedural complications	1 (0.00%)
CREST syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Croup infectious	Infections and infestations	1 (0.00%)
Cryoglobulins present	Investigations	1 (0.00%)
Crystal arthropathy	Musculoskeletal and connective tissue disorders	1 (0.00%)
Crystal urine	Investigations	1 (0.00%)
CSF glucose increased	Investigations	1 (0.00%)
CSF immunoglobulin increased	Investigations	1 (0.00%)
CSF oligoclonal band present	Investigations	1 (0.00%)
CSF polymorphonuclear cell count increased	Investigations	1 (0.00%)
CSF test abnormal	Investigations	1 (0.00%)
Cubital tunnel syndrome	Nervous system disorders	1 (0.00%)
Culture negative	Investigations	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Cutaneous T-cell lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Cyanosis central	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Cyclic vomiting syndrome	Gastrointestinal disorders	1 (0.00%)
Cyclothymic disorder	Psychiatric disorders	1 (0.00%)
Cystic lung disease	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Cystic lymphangioma	Congenital, familial and genetic disorders	1 (0.00%)
Cystitis escherichia	Infections and infestations	1 (0.00%)
Cystitis klebsiella	Infections and infestations	1 (0.00%)
Cystitis-like symptom	Renal and urinary disorders	1 (0.00%)
Cyst rupture	General disorders and administration site conditions	1 (0.00%)
Cytogenetic analysis abnormal	Investigations	1 (0.00%)
Cytokine storm	Immune system disorders	1 (0.00%)
Dactylitis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Dandruff	Skin and subcutaneous tissue disorders	1 (0.00%)
Death neonatal	General disorders and administration site conditions	1 (0.00%)
Decreased embryo viability	Injury, poisoning and procedural complications	1 (0.00%)
Deficiency anaemia	Blood and lymphatic system disorders	1 (0.00%)
Deficiency of bile secretion	Hepatobiliary disorders	1 (0.00%)
Degenerative mitral valve disease	Cardiac disorders	1 (0.00%)
Deja vu	Psychiatric disorders	1 (0.00%)
Delayed ischaemic neurological deficit	Nervous system disorders	1 (0.00%)
Dementia of the Alzheimer's type, with delirium	Nervous system disorders	1 (0.00%)
Dementia with Lewy bodies	Nervous system disorders	1 (0.00%)
Dental dysaesthesia	Gastrointestinal disorders	1 (0.00%)
Dependent rubor	Vascular disorders	1 (0.00%)
Dermabrasion	Surgical and medical procedures	1 (0.00%)
Dermal filler injection	Surgical and medical procedures	1 (0.00%)
Dermatochalasis	Eye disorders	1 (0.00%)
Dermatologic examination abnormal	Investigations	1 (0.00%)
Dermatophytosis of nail	Infections and infestations	1 (0.00%)
Dermoid cyst	Congenital, familial and genetic disorders	1 (0.00%)
Detachment of retinal pigment epithelium	Eye disorders	1 (0.00%)
Device breakage	Product issues	1 (0.00%)
Device connection issue	Product issues	1 (0.00%)
Device infusion issue	Product issues	1 (0.00%)
Device leakage	Product issues	1 (0.00%)
Device pacing issue	Product issues	1 (0.00%)
Device related thrombosis	General disorders and administration site conditions	1 (0.00%)
Device stimulation issue	Product issues	1 (0.00%)
Diabetic diet	Surgical and medical procedures	1 (0.00%)
Diabetic eye disease	Eye disorders	1 (0.00%)
Diabetic foot infection	Infections and infestations	1 (0.00%)
Diabetic nephropathy	Renal and urinary disorders	1 (0.00%)
Diabetic neuropathy	Nervous system disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Diabetic wound	Skin and subcutaneous tissue disorders	1 (0.00%)
Diaphragmatic paralysis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Differential white blood cell count abnormal	Investigations	1 (0.00%)
Diffuse alopecia	Skin and subcutaneous tissue disorders	1 (0.00%)
Diffuse alveolar damage	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Diffuse large B-cell lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Digestive enzyme abnormal	Investigations	1 (0.00%)
Discontinued product administered	Injury, poisoning and procedural complications	1 (0.00%)
Disinhibition	Psychiatric disorders	1 (0.00%)
Disseminated varicella zoster vaccine virus infection	Infections and infestations	1 (0.00%)
Dissociative amnesia	Psychiatric disorders	1 (0.00%)
Diverticulitis intestinal haemorrhagic	Infections and infestations	1 (0.00%)
Diverticulum intestinal haemorrhagic	Gastrointestinal disorders	1 (0.00%)
Double stranded DNA antibody positive	Investigations	1 (0.00%)
Droping shoulder syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Drug abuse	Psychiatric disorders	1 (0.00%)
Drug abuser	Social circumstances	1 (0.00%)
Drug administered in wrong device	Injury, poisoning and procedural complications	1 (0.00%)
Drug level decreased	Investigations	1 (0.00%)
Drug level fluctuating	Investigations	1 (0.00%)
Drug resistance	General disorders and administration site conditions	1 (0.00%)
Drug screen positive	Investigations	1 (0.00%)
Dry age-related macular degeneration	Eye disorders	1 (0.00%)
Dry lung syndrome	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Ductus arteriosus premature closure	Congenital, familial and genetic disorders	1 (0.00%)
Dumping syndrome	Gastrointestinal disorders	1 (0.00%)
Duodenal ulcer perforation	Gastrointestinal disorders	1 (0.00%)
Duodenitis	Gastrointestinal disorders	1 (0.00%)
Dysdiadochokinesis	Nervous system disorders	1 (0.00%)
Dysmorphism	Congenital, familial and genetic disorders	1 (0.00%)
Dyspareunia	Reproductive system and breast disorders	1 (0.00%)
Dyspnoea paroxysmal nocturnal	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Ear infection viral	Infections and infestations	1 (0.00%)
Ear injury	Injury, poisoning and procedural complications	1 (0.00%)
Ear neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Ear, nose and throat examination abnormal	Investigations	1 (0.00%)
Eastern Cooperative Oncology Group performance status worsened	Investigations	1 (0.00%)
Ebola disease	Infections and infestations	1 (0.00%)
Echolalia	Psychiatric disorders	1 (0.00%)
Eczema infantile	Skin and subcutaneous tissue disorders	1 (0.00%)
Eczema weeping	Skin and subcutaneous tissue disorders	1 (0.00%)
Electrocardiogram normal	Investigations	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Electrocardiogram PR prolongation	Investigations	1 (0.00%)
Electrocardiogram PR shortened	Investigations	1 (0.00%)
Electrocardiogram P wave abnormal	Investigations	1 (0.00%)
Electrocardiogram QT interval abnormal	Investigations	1 (0.00%)
Electrocardiogram ST-T segment abnormal	Investigations	1 (0.00%)
Electrocardiogram ST-T segment depression	Investigations	1 (0.00%)
Electrocardiogram T wave peaked	Investigations	1 (0.00%)
Electrolyte depletion	Metabolism and nutrition disorders	1 (0.00%)
Electromyogram abnormal	Investigations	1 (0.00%)
Embedded device	Product issues	1 (0.00%)
Embolic cerebellar infarction	Nervous system disorders	1 (0.00%)
Emergency care	Surgical and medical procedures	1 (0.00%)
Emotional poverty	Psychiatric disorders	1 (0.00%)
Encephalitis brain stem	Infections and infestations	1 (0.00%)
Encephalitis enteroviral	Infections and infestations	1 (0.00%)
Encephalomalacia	Nervous system disorders	1 (0.00%)
Endocarditis bacterial	Infections and infestations	1 (0.00%)
Endocrine disorder	Endocrine disorders	1 (0.00%)
Endodontic procedure	Surgical and medical procedures	1 (0.00%)
Endometrial thickening	Reproductive system and breast disorders	1 (0.00%)
Endometritis	Infections and infestations	1 (0.00%)
Endophthalmitis	Infections and infestations	1 (0.00%)
Endothelial dysfunction	Vascular disorders	1 (0.00%)
End stage renal disease	Renal and urinary disorders	1 (0.00%)
Enteritis infectious	Infections and infestations	1 (0.00%)
Enterovesical fistula	Gastrointestinal disorders	1 (0.00%)
Enzyme level increased	Investigations	1 (0.00%)
Eosinophilic bronchitis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Eosinophilic pneumonia acute	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Ephelides	Skin and subcutaneous tissue disorders	1 (0.00%)
Epidermal necrosis	Skin and subcutaneous tissue disorders	1 (0.00%)
Epididymal tenderness	Reproductive system and breast disorders	1 (0.00%)
Epidural haemorrhage	Injury, poisoning and procedural complications	1 (0.00%)
Epileptic aura	Nervous system disorders	1 (0.00%)
Epileptic encephalopathy	Nervous system disorders	1 (0.00%)
Epiphyses premature fusion	Musculoskeletal and connective tissue disorders	1 (0.00%)
Epiploic appendagitis	Gastrointestinal disorders	1 (0.00%)
Epstein-Barr viraemia	Infections and infestations	1 (0.00%)
Epstein-Barr virus antibody	Investigations	1 (0.00%)
Epstein-Barr virus antigen positive	Investigations	1 (0.00%)
Erosive oesophagitis	Gastrointestinal disorders	1 (0.00%)
Erysipeloid	Infections and infestations	1 (0.00%)
Erythema ab igne	Skin and subcutaneous tissue disorders	1 (0.00%)
Erythema induratum	Infections and infestations	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Erythema marginatum	Skin and subcutaneous tissue disorders	1 (0.00%)
Erythema migrans	Infections and infestations	1 (0.00%)
Erythematotelangiectatic rosacea	Skin and subcutaneous tissue disorders	1 (0.00%)
Erythrodermic psoriasis	Skin and subcutaneous tissue disorders	1 (0.00%)
Erythromelalgia	Vascular disorders	1 (0.00%)
Erythropenia	Blood and lymphatic system disorders	1 (0.00%)
Erythroslis	Skin and subcutaneous tissue disorders	1 (0.00%)
Eschar	Injury, poisoning and procedural complications	1 (0.00%)
Escherichia pyelonephritis	Infections and infestations	1 (0.00%)
Essential thrombocythaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Eustachian tube obstruction	Ear and labyrinth disorders	1 (0.00%)
Excessive exercise	Social circumstances	1 (0.00%)
Excessive granulation tissue	Skin and subcutaneous tissue disorders	1 (0.00%)
Excessive ocular convergence	Eye disorders	1 (0.00%)
Exercise lack of	Social circumstances	1 (0.00%)
Exposure keratitis	Eye disorders	1 (0.00%)
Exposure to contaminated water	Injury, poisoning and procedural complications	1 (0.00%)
Exposure to extreme temperature	Injury, poisoning and procedural complications	1 (0.00%)
Exposure to toxic agent	Injury, poisoning and procedural complications	1 (0.00%)
External ear cellulitis	Infections and infestations	1 (0.00%)
Extradural haematoma	Injury, poisoning and procedural complications	1 (0.00%)
Eye abscess	Infections and infestations	1 (0.00%)
Eye complication associated with device	General disorders and administration site conditions	1 (0.00%)
Eye infarction	Eye disorders	1 (0.00%)
Eyelid contusion	Injury, poisoning and procedural complications	1 (0.00%)
Eyelid cyst	Eye disorders	1 (0.00%)
Eyelid injury	Injury, poisoning and procedural complications	1 (0.00%)
Eyelid myokymia	Eye disorders	1 (0.00%)
Eyelid retraction	Eye disorders	1 (0.00%)
Eyelid skin dryness	Eye disorders	1 (0.00%)
Eyelid vascular disorder	Eye disorders	1 (0.00%)
Eye opacity	Eye disorders	1 (0.00%)
Face crushing	Injury, poisoning and procedural complications	1 (0.00%)
Face presentation	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Factitious disorder	Psychiatric disorders	1 (0.00%)
Factor II mutation	Congenital, familial and genetic disorders	1 (0.00%)
Factor VIII deficiency	Congenital, familial and genetic disorders	1 (0.00%)
Factor VIII inhibition	Blood and lymphatic system disorders	1 (0.00%)
Factor V Leiden mutation	Congenital, familial and genetic disorders	1 (0.00%)
Faecal calprotectin	Investigations	1 (0.00%)
Faecal calprotectin decreased	Investigations	1 (0.00%)
Faecal volume decreased	Investigations	1 (0.00%)
Failed in vitro fertilisation	Injury, poisoning and procedural complications	1 (0.00%)
False negative investigation result	Investigations	1 (0.00%)
Familial hemiplegic migraine	Congenital, familial and genetic disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Familial periodic paralysis	Congenital, familial and genetic disorders	1 (0.00%)
Fasting	Social circumstances	1 (0.00%)
Fat tissue increased	General disorders and administration site conditions	1 (0.00%)
Fear-related avoidance of activities	Psychiatric disorders	1 (0.00%)
Febrile bone marrow aplasia	Blood and lymphatic system disorders	1 (0.00%)
Feeding intolerance	Metabolism and nutrition disorders	1 (0.00%)
Female genital tract fistula	Reproductive system and breast disorders	1 (0.00%)
Female sexual dysfunction	Reproductive system and breast disorders	1 (0.00%)
Fibrin degradation products increased	Investigations	1 (0.00%)
Fibrinolysis	Investigations	1 (0.00%)
Fibrinolysis abnormal	Investigations	1 (0.00%)
Fibroblast growth factor 23	Investigations	1 (0.00%)
Fibroblast growth factor 23 increased	Investigations	1 (0.00%)
Fingerprint loss	Skin and subcutaneous tissue disorders	1 (0.00%)
Flea infestation	Infections and infestations	1 (0.00%)
Floppy eyelid syndrome	Eye disorders	1 (0.00%)
Foetal heart rate decreased	Investigations	1 (0.00%)
Foetal heart rate disorder	Cardiac disorders	1 (0.00%)
Foetal malformation	Congenital, familial and genetic disorders	1 (0.00%)
Foetal movement disorder	Nervous system disorders	1 (0.00%)
Forced expiratory flow	Investigations	1 (0.00%)
Foreign body in eye	Injury, poisoning and procedural complications	1 (0.00%)
Foreign body in gastrointestinal tract	Injury, poisoning and procedural complications	1 (0.00%)
Foreign body in mouth	Injury, poisoning and procedural complications	1 (0.00%)
Foreign body in respiratory tract	Injury, poisoning and procedural complications	1 (0.00%)
Foreign body in urogenital tract	Injury, poisoning and procedural complications	1 (0.00%)
Foreign body reaction	General disorders and administration site conditions	1 (0.00%)
Foveal reflex abnormal	Investigations	1 (0.00%)
Fracture blisters	Skin and subcutaneous tissue disorders	1 (0.00%)
Fractured skull depressed	Injury, poisoning and procedural complications	1 (0.00%)
Fracture pain	Musculoskeletal and connective tissue disorders	1 (0.00%)
Full blood count	Investigations	1 (0.00%)
Fungal peritonitis	Infections and infestations	1 (0.00%)
Gait deviation	General disorders and administration site conditions	1 (0.00%)
Gallbladder injury	Injury, poisoning and procedural complications	1 (0.00%)
Gallbladder polyp	Hepatobiliary disorders	1 (0.00%)
Gastric cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Gastric infection	Infections and infestations	1 (0.00%)
Gastric varices haemorrhage	Gastrointestinal disorders	1 (0.00%)
Gastric volvulus	Gastrointestinal disorders	1 (0.00%)
Gastritis bacterial	Infections and infestations	1 (0.00%)
Gastroenteritis bacterial	Infections and infestations	1 (0.00%)
Gastroenteritis norovirus	Infections and infestations	1 (0.00%)
Gastroenteritis rotavirus	Infections and infestations	1 (0.00%)
Gastrointestinal bacterial infection	Infections and infestations	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Gastrointestinal carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Gastrointestinal injury	Injury, poisoning and procedural complications	1 (0.00%)
Gastrointestinal mucosal disorder	Gastrointestinal disorders	1 (0.00%)
Gastrointestinal obstruction	Gastrointestinal disorders	1 (0.00%)
Gastrointestinal somatic symptom disorder	Psychiatric disorders	1 (0.00%)
Gastrointestinal surgery	Surgical and medical procedures	1 (0.00%)
Gastroschisis	Congenital, familial and genetic disorders	1 (0.00%)
Genital blister	Reproductive system and breast disorders	1 (0.00%)
Genital swelling	Reproductive system and breast disorders	1 (0.00%)
Genitourinary symptom	Renal and urinary disorders	1 (0.00%)
Gianotti-Crosti syndrome	Infections and infestations	1 (0.00%)
Giant papillary conjunctivitis	Eye disorders	1 (0.00%)
Gilbert's syndrome	Congenital, familial and genetic disorders	1 (0.00%)
Gingival hypertrophy	Gastrointestinal disorders	1 (0.00%)
Gingival pruritus	Gastrointestinal disorders	1 (0.00%)
Gingival recession	Gastrointestinal disorders	1 (0.00%)
Gingival ulceration	Gastrointestinal disorders	1 (0.00%)
Glabella reflex abnormal	Nervous system disorders	1 (0.00%)
Glioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Glomerular filtration rate abnormal	Investigations	1 (0.00%)
Glomerulonephritis rapidly progressive	Renal and urinary disorders	1 (0.00%)
Glossopharyngeal nerve disorder	Nervous system disorders	1 (0.00%)
Glottal incompetence	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Gluten sensitivity	Metabolism and nutrition disorders	1 (0.00%)
Glycopenia	Metabolism and nutrition disorders	1 (0.00%)
Good syndrome	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Gouty tophus	Musculoskeletal and connective tissue disorders	1 (0.00%)
Granulocyte count increased	Investigations	1 (0.00%)
Granulocytopenia	Blood and lymphatic system disorders	1 (0.00%)
Granulomatosis with polyangiitis	Vascular disorders	1 (0.00%)
Gravitational oedema	General disorders and administration site conditions	1 (0.00%)
Grief reaction	Psychiatric disorders	1 (0.00%)
Grip strength	Investigations	1 (0.00%)
Groin abscess	Infections and infestations	1 (0.00%)
Growing pains	Musculoskeletal and connective tissue disorders	1 (0.00%)
Gun shot wound	Injury, poisoning and procedural complications	1 (0.00%)
Haemangioma of liver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Haematoma infection	Infections and infestations	1 (0.00%)
Haemochromatosis	Metabolism and nutrition disorders	1 (0.00%)
Haemoconcentration	Blood and lymphatic system disorders	1 (0.00%)
Haemodialysis	Surgical and medical procedures	1 (0.00%)
Haemoglobinaemia	Blood and lymphatic system disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Haemoglobin urine present	Investigations	1 (0.00%)
Haemorrhagic fever with renal syndrome	Infections and infestations	1 (0.00%)
Haemorrhagic urticaria	Skin and subcutaneous tissue disorders	1 (0.00%)
Haemorrhagic varicella syndrome	Infections and infestations	1 (0.00%)
Haemorrhoidal haemorrhage	Gastrointestinal disorders	1 (0.00%)
Hair dye user	Social circumstances	1 (0.00%)
Haptoglobin decreased	Investigations	1 (0.00%)
Heart alternation	Cardiac disorders	1 (0.00%)
Heart rate normal	Investigations	1 (0.00%)
Heat exhaustion	Injury, poisoning and procedural complications	1 (0.00%)
Hemianopia heteronymous	Nervous system disorders	1 (0.00%)
Hemiapraxia	Nervous system disorders	1 (0.00%)
Heparin-induced thrombocytopenia	Blood and lymphatic system disorders	1 (0.00%)
Heparin-induced thrombocytopenia test positive	Investigations	1 (0.00%)
Hepatic artery embolism	Hepatobiliary disorders	1 (0.00%)
Hepatic cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Hepatic cyst infection	Infections and infestations	1 (0.00%)
Hepatic encephalopathy	Nervous system disorders	1 (0.00%)
Hepatic haematoma	Hepatobiliary disorders	1 (0.00%)
Hepatic necrosis	Hepatobiliary disorders	1 (0.00%)
Hepatic vascular thrombosis	Hepatobiliary disorders	1 (0.00%)
Hepatitis A	Infections and infestations	1 (0.00%)
Hepatitis A antibody positive	Investigations	1 (0.00%)
Hepatitis A virus test positive	Investigations	1 (0.00%)
Hepatitis B	Infections and infestations	1 (0.00%)
Hepatitis B antibody positive	Investigations	1 (0.00%)
Hepatitis B virus test positive	Investigations	1 (0.00%)
Hepatitis D	Infections and infestations	1 (0.00%)
Hepatitis infectious mononucleosis	Infections and infestations	1 (0.00%)
Hepatocellular carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Hepatojugular reflux	Cardiac disorders	1 (0.00%)
Hepatorenal syndrome	Hepatobiliary disorders	1 (0.00%)
Hereditary angioedema with normal C1 esterase inhibitor	Congenital, familial and genetic disorders	1 (0.00%)
Hereditary haemorrhagic telangiectasia	Congenital, familial and genetic disorders	1 (0.00%)
Hereditary neuropathy with liability to pressure palsies	Congenital, familial and genetic disorders	1 (0.00%)
Hernia repair	Surgical and medical procedures	1 (0.00%)
Herpangina	Infections and infestations	1 (0.00%)
Herpes pharyngitis	Infections and infestations	1 (0.00%)
Herpes simplex gastritis	Infections and infestations	1 (0.00%)
Herpes simplex meningoencephalitis	Infections and infestations	1 (0.00%)
Herpes virus test	Investigations	1 (0.00%)
Heterophoria	Eye disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
High density lipoprotein increased	Investigations	1 (0.00%)
High-pitched crying	General disorders and administration site conditions	1 (0.00%)
High risk pregnancy	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Histiocytosis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
HIV test negative	Investigations	1 (0.00%)
Hodgkin's disease	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Hoffmann's sign	Nervous system disorders	1 (0.00%)
Homicidal ideation	Psychiatric disorders	1 (0.00%)
Hospitalisation	Surgical and medical procedures	1 (0.00%)
Human chorionic gonadotropin increased	Investigations	1 (0.00%)
Human epidermal growth factor receptor decreased	Investigations	1 (0.00%)
Human herpesvirus 6 infection	Infections and infestations	1 (0.00%)
Hydrocholecystis	Hepatobiliary disorders	1 (0.00%)
Hydrophobia	Psychiatric disorders	1 (0.00%)
Hyperaesthesia eye	Eye disorders	1 (0.00%)
Hyperaldosteronism	Endocrine disorders	1 (0.00%)
Hypercalcaemia of malignancy	Endocrine disorders	1 (0.00%)
Hypercapnic coma	Nervous system disorders	1 (0.00%)
Hyperchloraemia	Metabolism and nutrition disorders	1 (0.00%)
Hyperchromic anaemia	Blood and lymphatic system disorders	1 (0.00%)
Hypercreatininaemia	Metabolism and nutrition disorders	1 (0.00%)
Hyperdynamic left ventricle	Cardiac disorders	1 (0.00%)
Hypereosinophilic syndrome	Blood and lymphatic system disorders	1 (0.00%)
Hyperexplexia	Congenital, familial and genetic disorders	1 (0.00%)
Hyperfibrinogenaemia	Blood and lymphatic system disorders	1 (0.00%)
Hypergammaglobulinaemia	Blood and lymphatic system disorders	1 (0.00%)
Hypergammaglobulinaemia benign monoclonal	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Hyperglycaemic hyperosmolar nonketotic syndrome	Metabolism and nutrition disorders	1 (0.00%)
Hyperglycinaemia	Congenital, familial and genetic disorders	1 (0.00%)
Hyperhomocysteinaemia	Metabolism and nutrition disorders	1 (0.00%)
Hyperkinesia	Nervous system disorders	1 (0.00%)
Hypermobility syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Hyperparathyroidism primary	Endocrine disorders	1 (0.00%)
Hyperpathia	Nervous system disorders	1 (0.00%)
Hyperresponsive to stimuli	Nervous system disorders	1 (0.00%)
Hypertrichosis	Skin and subcutaneous tissue disorders	1 (0.00%)
Hypervitaminosis B12	Metabolism and nutrition disorders	1 (0.00%)
Hypervolaemia	Metabolism and nutrition disorders	1 (0.00%)
Hyphaema	Injury, poisoning and procedural complications	1 (0.00%)
Hypnopompic hallucination	Psychiatric disorders	1 (0.00%)
Hypobarism	Injury, poisoning and procedural complications	1 (0.00%)
Hypocapnia	Respiratory, thoracic and mediastinal disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Hypoglossal nerve disorder	Nervous system disorders	1 (0.00%)
Hypoglossal nerve paresis	Nervous system disorders	1 (0.00%)
Hypoglycaemic unconsciousness	Nervous system disorders	1 (0.00%)
Hypomania	Psychiatric disorders	1 (0.00%)
Hypoproteinaemia	Metabolism and nutrition disorders	1 (0.00%)
Hyposomnia	Psychiatric disorders	1 (0.00%)
Hysterectomy	Surgical and medical procedures	1 (0.00%)
Hysteroscopy	Investigations	1 (0.00%)
Ileal perforation	Gastrointestinal disorders	1 (0.00%)
Ileectomy	Surgical and medical procedures	1 (0.00%)
Iliac artery occlusion	Vascular disorders	1 (0.00%)
Iliac bruit	Investigations	1 (0.00%)
Iliotibial band syndrome	Injury, poisoning and procedural complications	1 (0.00%)
Illiteracy	Social circumstances	1 (0.00%)
Illness anxiety disorder	Psychiatric disorders	1 (0.00%)
Imaging procedure abnormal	Investigations	1 (0.00%)
Immediate post-injection reaction	General disorders and administration site conditions	1 (0.00%)
Immobilisation prolonged	Social circumstances	1 (0.00%)
Immune-mediated arthritis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Immune-mediated hepatic disorder	Hepatobiliary disorders	1 (0.00%)
Immune-mediated hepatitis	Hepatobiliary disorders	1 (0.00%)
Immune-mediated neuropathy	Nervous system disorders	1 (0.00%)
Immune reconstitution inflammatory syndrome	Immune system disorders	1 (0.00%)
Immunoglobulin G4 related disease	Musculoskeletal and connective tissue disorders	1 (0.00%)
Impaired fasting glucose	Metabolism and nutrition disorders	1 (0.00%)
Impaired reasoning	Psychiatric disorders	1 (0.00%)
Impatience	Psychiatric disorders	1 (0.00%)
Implant site nodule	General disorders and administration site conditions	1 (0.00%)
Implant site swelling	General disorders and administration site conditions	1 (0.00%)
Impulsive behaviour	Psychiatric disorders	1 (0.00%)
Inability to crawl	Nervous system disorders	1 (0.00%)
Inadequate analgesia	General disorders and administration site conditions	1 (0.00%)
Incision site haemorrhage	Injury, poisoning and procedural complications	1 (0.00%)
Incorrect dose administered by device	Injury, poisoning and procedural complications	1 (0.00%)
Incorrect dose administered by product	Injury, poisoning and procedural complications	1 (0.00%)
Incorrect product formulation administered	Injury, poisoning and procedural complications	1 (0.00%)
Infected dermal cyst	Infections and infestations	1 (0.00%)
Infected skin ulcer	Infections and infestations	1 (0.00%)
Infection parasitic	Infections and infestations	1 (0.00%)
Infection reactivation	Infections and infestations	1 (0.00%)
Infectious pleural effusion	Infections and infestations	1 (0.00%)
Infective exacerbation of bronchiectasis	Infections and infestations	1 (0.00%)
Infective pericardial effusion	Infections and infestations	1 (0.00%)
Infective spondylitis	Infections and infestations	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Inferior vena caval occlusion	Vascular disorders	1 (0.00%)
Infertility	Reproductive system and breast disorders	1 (0.00%)
Infertility female	Reproductive system and breast disorders	1 (0.00%)
Inflammation of wound	Injury, poisoning and procedural complications	1 (0.00%)
Inflammatory carcinoma of the breast	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Influenza A virus test positive	Investigations	1 (0.00%)
Influenza B virus test positive	Investigations	1 (0.00%)
Infusion site bruising	General disorders and administration site conditions	1 (0.00%)
Infusion site infection	Infections and infestations	1 (0.00%)
Infusion site joint swelling	General disorders and administration site conditions	1 (0.00%)
Infusion site lymphadenopathy	General disorders and administration site conditions	1 (0.00%)
Infusion site mobility decreased	General disorders and administration site conditions	1 (0.00%)
Infusion site paraesthesia	General disorders and administration site conditions	1 (0.00%)
Infusion site warmth	General disorders and administration site conditions	1 (0.00%)
Ingrowing nail	Skin and subcutaneous tissue disorders	1 (0.00%)
Ingrown hair	Skin and subcutaneous tissue disorders	1 (0.00%)
Inguinal hernia	Gastrointestinal disorders	1 (0.00%)
Inguinal mass	Musculoskeletal and connective tissue disorders	1 (0.00%)
Injection site abscess	Infections and infestations	1 (0.00%)
Injection site coldness	General disorders and administration site conditions	1 (0.00%)
Injection site discharge	General disorders and administration site conditions	1 (0.00%)
Injection site injury	General disorders and administration site conditions	1 (0.00%)
Injection site joint movement impairment	General disorders and administration site conditions	1 (0.00%)
Injection site joint swelling	General disorders and administration site conditions	1 (0.00%)
Injection site movement impairment	General disorders and administration site conditions	1 (0.00%)
Injection site papule	General disorders and administration site conditions	1 (0.00%)
Injection site pustule	Infections and infestations	1 (0.00%)
Injection site scar	General disorders and administration site conditions	1 (0.00%)
Injury corneal	Injury, poisoning and procedural complications	1 (0.00%)
Instillation site bruise	General disorders and administration site conditions	1 (0.00%)
Instillation site pain	General disorders and administration site conditions	1 (0.00%)
Instillation site warmth	General disorders and administration site conditions	1 (0.00%)
Insulin-requiring type 2 diabetes mellitus	Metabolism and nutrition disorders	1 (0.00%)
Intellectual disability	Nervous system disorders	1 (0.00%)
Interleukin level increased	Investigations	1 (0.00%)
Internal hernia	Gastrointestinal disorders	1 (0.00%)
Intertrigo	Skin and subcutaneous tissue disorders	1 (0.00%)
Intestinal angina	Gastrointestinal disorders	1 (0.00%)
Intestinal angioedema	Gastrointestinal disorders	1 (0.00%)
Intestinal congestion	Gastrointestinal disorders	1 (0.00%)
Intestinal dilatation	Gastrointestinal disorders	1 (0.00%)
Intestinal gangrene	Infections and infestations	1 (0.00%)
Intestinal mass	Gastrointestinal disorders	1 (0.00%)
Intestinal ulcer	Gastrointestinal disorders	1 (0.00%)
Intra-abdominal haemorrhage	Gastrointestinal disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Intracranial artery dissection	Nervous system disorders	1 (0.00%)
Intracranial haematoma	Nervous system disorders	1 (0.00%)
Intracranial hypotension	Nervous system disorders	1 (0.00%)
Intracranial mass	Nervous system disorders	1 (0.00%)
Intravascular haemolysis	Blood and lymphatic system disorders	1 (0.00%)
Investigation abnormal	Investigations	1 (0.00%)
Iodine uptake decreased	Investigations	1 (0.00%)
Iodine uptake increased	Investigations	1 (0.00%)
Iron binding capacity total abnormal	Investigations	1 (0.00%)
Ischaemic hepatitis	Hepatobiliary disorders	1 (0.00%)
Ischaemic limb pain	Vascular disorders	1 (0.00%)
IVth nerve paresis	Nervous system disorders	1 (0.00%)
Jaw cyst	Musculoskeletal and connective tissue disorders	1 (0.00%)
Job dissatisfaction	Social circumstances	1 (0.00%)
Joint abscess	Infections and infestations	1 (0.00%)
Joint adhesion	Musculoskeletal and connective tissue disorders	1 (0.00%)
Joint destruction	Musculoskeletal and connective tissue disorders	1 (0.00%)
Joint hyperextension	Musculoskeletal and connective tissue disorders	1 (0.00%)
Joint prosthesis user	Social circumstances	1 (0.00%)
Joint vibration	Musculoskeletal and connective tissue disorders	1 (0.00%)
Kaposi's sarcoma AIDS related	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Kawasaki's disease	Vascular disorders	1 (0.00%)
Keratoconus	Eye disorders	1 (0.00%)
Ketonuria	Renal and urinary disorders	1 (0.00%)
Kidney fibrosis	Renal and urinary disorders	1 (0.00%)
Kidney small	Renal and urinary disorders	1 (0.00%)
Kidney transplant rejection	Immune system disorders	1 (0.00%)
Klippel-Trenaunay syndrome	Congenital, familial and genetic disorders	1 (0.00%)
Knee deformity	Musculoskeletal and connective tissue disorders	1 (0.00%)
Knee operation	Surgical and medical procedures	1 (0.00%)
Koebner phenomenon	Skin and subcutaneous tissue disorders	1 (0.00%)
Labia enlarged	Reproductive system and breast disorders	1 (0.00%)
Laboratory test interference	Investigations	1 (0.00%)
Laboratory test normal	Investigations	1 (0.00%)
Lack of vaccination site rotation	Injury, poisoning and procedural complications	1 (0.00%)
Lacrimal structural disorder	Eye disorders	1 (0.00%)
Lacrimation disorder	Eye disorders	1 (0.00%)
Lactobacillus infection	Infections and infestations	1 (0.00%)
Large intestinal haemorrhage	Gastrointestinal disorders	1 (0.00%)
Large intestinal obstruction	Gastrointestinal disorders	1 (0.00%)
Large intestine polyp	Gastrointestinal disorders	1 (0.00%)
Laryngeal erythema	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Laryngitis allergic	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Laryngitis bacterial	Infections and infestations	1 (0.00%)
Lead dislodgement	Product issues	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Learning disability	Psychiatric disorders	1 (0.00%)
Learning disorder	Psychiatric disorders	1 (0.00%)
Left ventricular end-diastolic pressure increased	Investigations	1 (0.00%)
Lennox-Gastaut syndrome	Nervous system disorders	1 (0.00%)
Lens disorder	Eye disorders	1 (0.00%)
Leukaemia recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Leukaemoid reaction	Blood and lymphatic system disorders	1 (0.00%)
Leukocyte alkaline phosphatase increased	Investigations	1 (0.00%)
Leukoplakia	Skin and subcutaneous tissue disorders	1 (0.00%)
Lid margin discharge	Eye disorders	1 (0.00%)
Lid sulcus deepened	Eye disorders	1 (0.00%)
Limbal swelling	Eye disorders	1 (0.00%)
Limbic encephalitis	Nervous system disorders	1 (0.00%)
Limb operation	Surgical and medical procedures	1 (0.00%)
Lip erosion	Gastrointestinal disorders	1 (0.00%)
Lip haematoma	Gastrointestinal disorders	1 (0.00%)
Lipid metabolism disorder	Metabolism and nutrition disorders	1 (0.00%)
Lipids abnormal	Investigations	1 (0.00%)
Lip infection	Infections and infestations	1 (0.00%)
Lip neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Lipodystrophy acquired	Skin and subcutaneous tissue disorders	1 (0.00%)
Lip scab	Gastrointestinal disorders	1 (0.00%)
Listeria test positive	Investigations	1 (0.00%)
Lithiasis	General disorders and administration site conditions	1 (0.00%)
Liver contusion	Injury, poisoning and procedural complications	1 (0.00%)
Local anaesthesia	Surgical and medical procedures	1 (0.00%)
Long thoracic nerve palsy	Nervous system disorders	1 (0.00%)
Loose body in joint	Musculoskeletal and connective tissue disorders	1 (0.00%)
Loose tooth	Gastrointestinal disorders	1 (0.00%)
Lordosis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Loss of employment	Social circumstances	1 (0.00%)
Lower motor neurone lesion	Nervous system disorders	1 (0.00%)
Lower respiratory tract infection bacterial	Infections and infestations	1 (0.00%)
Lower respiratory tract infection viral	Infections and infestations	1 (0.00%)
Lumbar puncture	Investigations	1 (0.00%)
Lumbar puncture abnormal	Investigations	1 (0.00%)
Lung carcinoma cell type unspecified recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Lung carcinoma cell type unspecified stage I	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Lung neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Lung transplant rejection	Immune system disorders	1 (0.00%)
Lupus myositis	Musculoskeletal and connective tissue disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Lupus nephritis	Renal and urinary disorders	1 (0.00%)
Lymphadenitis bacterial	Infections and infestations	1 (0.00%)
Lymphangiectasia	Vascular disorders	1 (0.00%)
Lymphangioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Lymphangiopathy	Vascular disorders	1 (0.00%)
Lymphatic obstruction	Blood and lymphatic system disorders	1 (0.00%)
Lymphoblast count	Investigations	1 (0.00%)
Lymphocyte percentage increased	Investigations	1 (0.00%)
Lymphocytic infiltration	Blood and lymphatic system disorders	1 (0.00%)
Lymphoproliferative disorder	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
MAGIC syndrome	Vascular disorders	1 (0.00%)
Magnetic resonance imaging abnormal	Investigations	1 (0.00%)
Malabsorption	Gastrointestinal disorders	1 (0.00%)
Malignant lymphoid neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Malignant pleural effusion	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Malocclusion	Gastrointestinal disorders	1 (0.00%)
Mammogram abnormal	Investigations	1 (0.00%)
Mass excision	Surgical and medical procedures	1 (0.00%)
Mast cell degranulation present	Investigations	1 (0.00%)
Masticatory pain	Musculoskeletal and connective tissue disorders	1 (0.00%)
Mastocytosis	Blood and lymphatic system disorders	1 (0.00%)
Mastoiditis	Infections and infestations	1 (0.00%)
Mean cell haemoglobin	Investigations	1 (0.00%)
Mechanic's hand	Skin and subcutaneous tissue disorders	1 (0.00%)
Meconium aspiration syndrome	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Mediastinal disorder	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Mediastinal haemorrhage	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Mediastinal mass	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Mediastinitis	Infections and infestations	1 (0.00%)
Medical induction of coma	Surgical and medical procedures	1 (0.00%)
Megacolon	Gastrointestinal disorders	1 (0.00%)
Meningitis noninfective	Nervous system disorders	1 (0.00%)
Meningitis pneumococcal	Infections and infestations	1 (0.00%)
Meningomyelitis herpes	Infections and infestations	1 (0.00%)
Meningoradiculitis	Nervous system disorders	1 (0.00%)
Meningorrhagia	Nervous system disorders	1 (0.00%)
Meralgia paraesthetica	Nervous system disorders	1 (0.00%)
Mesenteric abscess	Infections and infestations	1 (0.00%)
Mesenteric artery aneurysm	Gastrointestinal disorders	1 (0.00%)
Mesenteric artery stenosis	Gastrointestinal disorders	1 (0.00%)
Mesenteric artery stent insertion	Surgical and medical procedures	1 (0.00%)
Mesenteric vascular insufficiency	Gastrointestinal disorders	1 (0.00%)
Mesenteric vascular occlusion	Gastrointestinal disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Metabolic alkalosis	Metabolism and nutrition disorders	1 (0.00%)
Metabolic encephalopathy	Nervous system disorders	1 (0.00%)
Metabolic syndrome	Metabolism and nutrition disorders	1 (0.00%)
Metamyelocyte count increased	Investigations	1 (0.00%)
Metastases to lung	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Metastases to meninges	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Metastatic neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Methylenetetrahydrofolate reductase gene mutation	Congenital, familial and genetic disorders	1 (0.00%)
Microcytosis	Blood and lymphatic system disorders	1 (0.00%)
Micturition frequency decreased	Renal and urinary disorders	1 (0.00%)
Middle ear disorder	Ear and labyrinth disorders	1 (0.00%)
Middle ear inflammation	Ear and labyrinth disorders	1 (0.00%)
Migraine prophylaxis	Surgical and medical procedures	1 (0.00%)
Mineral metabolism disorder	Metabolism and nutrition disorders	1 (0.00%)
Mini mental status examination abnormal	Investigations	1 (0.00%)
Misleading laboratory test result	Investigations	1 (0.00%)
Mixed liver injury	Hepatobiliary disorders	1 (0.00%)
Moebius II syndrome	Congenital, familial and genetic disorders	1 (0.00%)
Monoclonal immunoglobulin increased	Investigations	1 (0.00%)
Monocyte count abnormal	Investigations	1 (0.00%)
Mononucleosis syndrome	Infections and infestations	1 (0.00%)
Mood disorder due to a general medical condition	Psychiatric disorders	1 (0.00%)
Moraxella infection	Infections and infestations	1 (0.00%)
Morganella infection	Infections and infestations	1 (0.00%)
Morphoea	Musculoskeletal and connective tissue disorders	1 (0.00%)
Morton's neuralgia	Nervous system disorders	1 (0.00%)
Mucocutaneous disorder	Skin and subcutaneous tissue disorders	1 (0.00%)
Mucocutaneous rash	Skin and subcutaneous tissue disorders	1 (0.00%)
Mucosal hyperaemia	General disorders and administration site conditions	1 (0.00%)
Mucosal ulceration	General disorders and administration site conditions	1 (0.00%)
Mucosa vesicle	General disorders and administration site conditions	1 (0.00%)
Multiple injuries	Injury, poisoning and procedural complications	1 (0.00%)
Multiple sclerosis relapse prophylaxis	Surgical and medical procedures	1 (0.00%)
Multisystem inflammatory syndrome in children	Immune system disorders	1 (0.00%)
Muscle abscess	Infections and infestations	1 (0.00%)
Muscle contusion	Injury, poisoning and procedural complications	1 (0.00%)
Muscle hypertrophy	Musculoskeletal and connective tissue disorders	1 (0.00%)
Musculoskeletal deformity	Musculoskeletal and connective tissue disorders	1 (0.00%)
Mycoplasma infection	Infections and infestations	1 (0.00%)
Myelocytosis	Blood and lymphatic system disorders	1 (0.00%)
Myelofibrosis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Myeloid leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Myocardial calcification	Cardiac disorders	1 (0.00%)
Myocardial haemorrhage	Cardiac disorders	1 (0.00%)
Myocardial necrosis	Cardiac disorders	1 (0.00%)
Myocardial strain	Investigations	1 (0.00%)
Myocarditis infectious	Infections and infestations	1 (0.00%)
Myocarditis septic	Infections and infestations	1 (0.00%)
Myofascial spasm	Musculoskeletal and connective tissue disorders	1 (0.00%)
Myoglobinuria	Renal and urinary disorders	1 (0.00%)
Myringitis	Infections and infestations	1 (0.00%)
Nail avulsion	Injury, poisoning and procedural complications	1 (0.00%)
Nail bed inflammation	Skin and subcutaneous tissue disorders	1 (0.00%)
Nail infection	Infections and infestations	1 (0.00%)
Nail ridging	Skin and subcutaneous tissue disorders	1 (0.00%)
Nasal abscess	Infections and infestations	1 (0.00%)
Nasal inflammation	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Nasal turbinate hypertrophy	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Nasal vestibulitis	Infections and infestations	1 (0.00%)
Natural killer T cell count decreased	Investigations	1 (0.00%)
Natural killer T cell count increased	Investigations	1 (0.00%)
Neck deformity	Musculoskeletal and connective tissue disorders	1 (0.00%)
Necrosis ischaemic	Vascular disorders	1 (0.00%)
Necrotising colitis	Gastrointestinal disorders	1 (0.00%)
Necrotising retinitis	Eye disorders	1 (0.00%)
Neglect of personal appearance	Psychiatric disorders	1 (0.00%)
Neonatal pneumothorax	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Neonatal respiratory acidosis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Neonatal respiratory distress	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Nephrogenic diabetes insipidus	Renal and urinary disorders	1 (0.00%)
Nephrosclerosis	Renal and urinary disorders	1 (0.00%)
Nerve block	Surgical and medical procedures	1 (0.00%)
Neuroborreliosis	Infections and infestations	1 (0.00%)
Neurofibromatosis	Congenital, familial and genetic disorders	1 (0.00%)
Neuroleptic malignant syndrome	Nervous system disorders	1 (0.00%)
Neurological examination abnormal	Investigations	1 (0.00%)
Neurological examination normal	Investigations	1 (0.00%)
Neurological infection	Infections and infestations	1 (0.00%)
Neurological procedural complication	Injury, poisoning and procedural complications	1 (0.00%)
Neuronal neuropathy	Nervous system disorders	1 (0.00%)
Neuropathic muscular atrophy	Musculoskeletal and connective tissue disorders	1 (0.00%)
Neutralising antibodies negative	Investigations	1 (0.00%)
Neutropenia neonatal	Blood and lymphatic system disorders	1 (0.00%)
New daily persistent headache	Nervous system disorders	1 (0.00%)
Night blindness	Eye disorders	1 (0.00%)
NIH stroke scale score decreased	Investigations	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Nipple infection	Infections and infestations	1 (0.00%)
Nodular rash	Skin and subcutaneous tissue disorders	1 (0.00%)
Noninfective chorioretinitis	Eye disorders	1 (0.00%)
Noninfective conjunctivitis	Eye disorders	1 (0.00%)
Non-tobacco user	Social circumstances	1 (0.00%)
Norepinephrine increased	Investigations	1 (0.00%)
Normochromic anaemia	Blood and lymphatic system disorders	1 (0.00%)
Norovirus infection	Infections and infestations	1 (0.00%)
Numb chin syndrome	Nervous system disorders	1 (0.00%)
Obliterative bronchiolitis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Obsessive-compulsive personality disorder	Psychiatric disorders	1 (0.00%)
Obsessive-compulsive symptom	Psychiatric disorders	1 (0.00%)
Obsessive thoughts	Psychiatric disorders	1 (0.00%)
Obstruction gastric	Gastrointestinal disorders	1 (0.00%)
Ocular dysmetria	Eye disorders	1 (0.00%)
Ocular hypertension	Eye disorders	1 (0.00%)
Ocular ischaemic syndrome	Eye disorders	1 (0.00%)
Ocular sarcoidosis	Eye disorders	1 (0.00%)
Oedema blister	Skin and subcutaneous tissue disorders	1 (0.00%)
Oesophageal achalasia	Gastrointestinal disorders	1 (0.00%)
Oesophageal haemorrhage	Gastrointestinal disorders	1 (0.00%)
Oesophageal perforation	Gastrointestinal disorders	1 (0.00%)
Oesophageal rupture	Gastrointestinal disorders	1 (0.00%)
Oesophageal ulcer haemorrhage	Gastrointestinal disorders	1 (0.00%)
Olfactory nerve disorder	Nervous system disorders	1 (0.00%)
Oligodendroglioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Oligodipsia	Metabolism and nutrition disorders	1 (0.00%)
Oligohydramnios	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Omphalitis	Infections and infestations	1 (0.00%)
Oncologic complication	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Onycholysis	Skin and subcutaneous tissue disorders	1 (0.00%)
Oophoritis	Infections and infestations	1 (0.00%)
Open angle glaucoma	Eye disorders	1 (0.00%)
Ophthalmological examination abnormal	Investigations	1 (0.00%)
Ophthalmoplegic migraine	Nervous system disorders	1 (0.00%)
Opiates positive	Investigations	1 (0.00%)
Oppositional defiant disorder	Psychiatric disorders	1 (0.00%)
Optic nerve infarction	Eye disorders	1 (0.00%)
Oral administration complication	General disorders and administration site conditions	1 (0.00%)
Oral bacterial infection	Infections and infestations	1 (0.00%)
Oral contusion	Injury, poisoning and procedural complications	1 (0.00%)
Oral discharge	Gastrointestinal disorders	1 (0.00%)
Oral hyperaesthesia	Gastrointestinal disorders	1 (0.00%)
Oral infection	Infections and infestations	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Oral papule	Gastrointestinal disorders	1 (0.00%)
Oral pigmentation	Gastrointestinal disorders	1 (0.00%)
Oral purpura	Gastrointestinal disorders	1 (0.00%)
Oral pustule	Infections and infestations	1 (0.00%)
Orbital swelling	Eye disorders	1 (0.00%)
Orchitis noninfective	Reproductive system and breast disorders	1 (0.00%)
Oromandibular dystonia	Nervous system disorders	1 (0.00%)
Oropharyngeal cobble stone mucosa	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Orthostatic heart rate response increased	Investigations	1 (0.00%)
Orthostatic tremor	Nervous system disorders	1 (0.00%)
Osmophobia	Psychiatric disorders	1 (0.00%)
Osteogenesis imperfecta	Congenital, familial and genetic disorders	1 (0.00%)
Osteolysis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Ovarian cyst ruptured	Reproductive system and breast disorders	1 (0.00%)
Ovarian disorder	Reproductive system and breast disorders	1 (0.00%)
Ovarian enlargement	Reproductive system and breast disorders	1 (0.00%)
Ovarian neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Overfeeding of infant	Metabolism and nutrition disorders	1 (0.00%)
Overflow diarrhoea	Gastrointestinal disorders	1 (0.00%)
Ovulation delayed	Endocrine disorders	1 (0.00%)
Oxygen consumption	Investigations	1 (0.00%)
Oxygen consumption increased	Investigations	1 (0.00%)
Palindromic rheumatism	Musculoskeletal and connective tissue disorders	1 (0.00%)
Palmar-plantar erythrodysaesthesia syndrome	Skin and subcutaneous tissue disorders	1 (0.00%)
Pancreatic carcinoma metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Pancreatic enzymes increased	Investigations	1 (0.00%)
Pancreatic infarction	Gastrointestinal disorders	1 (0.00%)
Pancreatic steatosis	Gastrointestinal disorders	1 (0.00%)
Pancreatitis haemorrhagic	Gastrointestinal disorders	1 (0.00%)
Parainfluenzae viral laryngotracheobronchitis	Infections and infestations	1 (0.00%)
Parainfluenzae virus infection	Infections and infestations	1 (0.00%)
Paranasal sinus haemorrhage	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Paranasal sinus hyposecretion	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Paranasal sinus inflammation	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Paranoid personality disorder	Psychiatric disorders	1 (0.00%)
Parapharyngeal space infection	Infections and infestations	1 (0.00%)
Parapsoriasis	Skin and subcutaneous tissue disorders	1 (0.00%)
Parasympathetic nerve injury	Injury, poisoning and procedural complications	1 (0.00%)
Parkinsonian gait	Nervous system disorders	1 (0.00%)
Parkinsonian rest tremor	Nervous system disorders	1 (0.00%)
Parotid duct obstruction	Gastrointestinal disorders	1 (0.00%)
Paroxysmal atrioventricular block	Cardiac disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Partial seizures with secondary generalisation	Nervous system disorders	1 (0.00%)
Partner stress	Social circumstances	1 (0.00%)
Parvovirus infection	Infections and infestations	1 (0.00%)
Patellofemoral pain syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Paternal exposure before pregnancy	Injury, poisoning and procedural complications	1 (0.00%)
Paternal exposure timing unspecified	Injury, poisoning and procedural complications	1 (0.00%)
Pathogen resistance	Infections and infestations	1 (0.00%)
Pathological fracture	Musculoskeletal and connective tissue disorders	1 (0.00%)
Patient-device incompatibility	Product issues	1 (0.00%)
Patient uncooperative	Social circumstances	1 (0.00%)
PCO2 abnormal	Investigations	1 (0.00%)
Peak expiratory flow rate	Investigations	1 (0.00%)
Peak expiratory flow rate abnormal	Investigations	1 (0.00%)
Pelvic haematoma	Reproductive system and breast disorders	1 (0.00%)
Penile discomfort	Reproductive system and breast disorders	1 (0.00%)
Penile oedema	Reproductive system and breast disorders	1 (0.00%)
Penile rash	Reproductive system and breast disorders	1 (0.00%)
Penile ulceration	Skin and subcutaneous tissue disorders	1 (0.00%)
Peptic ulcer	Gastrointestinal disorders	1 (0.00%)
Perichondritis	Infections and infestations	1 (0.00%)
Perinatal depression	Psychiatric disorders	1 (0.00%)
Periodontitis	Infections and infestations	1 (0.00%)
Periorbital abscess	Infections and infestations	1 (0.00%)
Periorbital infection	Infections and infestations	1 (0.00%)
Periorbital inflammation	Eye disorders	1 (0.00%)
Peripheral artery stenosis	Vascular disorders	1 (0.00%)
Peripheral nerve lesion	Nervous system disorders	1 (0.00%)
Peripheral vein stenosis	Vascular disorders	1 (0.00%)
Peripheral vein thrombus extension	Vascular disorders	1 (0.00%)
Periportal oedema	Hepatobiliary disorders	1 (0.00%)
Peristalsis visible	Gastrointestinal disorders	1 (0.00%)
Perivascular dermatitis	Skin and subcutaneous tissue disorders	1 (0.00%)
Periventricular leukomalacia	Nervous system disorders	1 (0.00%)
Persistent generalised lymphadenopathy	Infections and infestations	1 (0.00%)
Persistent genital arousal disorder	Nervous system disorders	1 (0.00%)
Phaeochromocytoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Pharyngeal leukoplakia	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pharyngeal pustule	Infections and infestations	1 (0.00%)
Phlebitis deep	Vascular disorders	1 (0.00%)
Phobic postural vertigo	Ear and labyrinth disorders	1 (0.00%)
Phrenic nerve injury	Injury, poisoning and procedural complications	1 (0.00%)
pH urine	Investigations	1 (0.00%)
pH urine abnormal	Investigations	1 (0.00%)
pH urine increased	Investigations	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Pigmentary glaucoma	Eye disorders	1 (0.00%)
Pineal gland cyst	Nervous system disorders	1 (0.00%)
Pituitary apoplexy	Endocrine disorders	1 (0.00%)
Pituitary tumour	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Plasma cell leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Plasma viscosity abnormal	Investigations	1 (0.00%)
Platelet aggregation abnormal	Investigations	1 (0.00%)
Platelet anisocytosis	Blood and lymphatic system disorders	1 (0.00%)
Platelet function test abnormal	Investigations	1 (0.00%)
Pleural rub	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pneumatosis	General disorders and administration site conditions	1 (0.00%)
Pneumobilia	Hepatobiliary disorders	1 (0.00%)
Pneumocephalus	Injury, poisoning and procedural complications	1 (0.00%)
Pneumococcal sepsis	Infections and infestations	1 (0.00%)
Pneumoconiosis	Injury, poisoning and procedural complications	1 (0.00%)
Pneumocystis jirovecii pneumonia	Infections and infestations	1 (0.00%)
Pneumonia fungal	Infections and infestations	1 (0.00%)
Pneumonia klebsiella	Infections and infestations	1 (0.00%)
Pneumonia legionella	Infections and infestations	1 (0.00%)
Pneumonia moraxella	Infections and infestations	1 (0.00%)
Pneumonia mycoplasmal	Infections and infestations	1 (0.00%)
Pneumonia pseudomonal	Infections and infestations	1 (0.00%)
Pneumonia respiratory syncytial viral	Infections and infestations	1 (0.00%)
Pneumoperitoneum	Gastrointestinal disorders	1 (0.00%)
PO2 increased	Investigations	1 (0.00%)
POEMS syndrome	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Polycythaemia vera	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Polyneuropathy chronic	Nervous system disorders	1 (0.00%)
Polyneuropathy in malignant disease	Nervous system disorders	1 (0.00%)
Porphyria	Congenital, familial and genetic disorders	1 (0.00%)
Porphyria acute	Congenital, familial and genetic disorders	1 (0.00%)
Portal vein embolism	Hepatobiliary disorders	1 (0.00%)
Portal vein phlebitis	Hepatobiliary disorders	1 (0.00%)
Portosplenomesenteric venous thrombosis	Hepatobiliary disorders	1 (0.00%)
Positron emission tomogram	Investigations	1 (0.00%)
Postictal paralysis	Nervous system disorders	1 (0.00%)
Post inflammatory pigmentation change	Skin and subcutaneous tissue disorders	1 (0.00%)
Post laminectomy syndrome	Injury, poisoning and procedural complications	1 (0.00%)
Postoperative ileus	Injury, poisoning and procedural complications	1 (0.00%)
Postoperative wound complication	Injury, poisoning and procedural complications	1 (0.00%)
Postpartum disorder	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Postprandial hypoglycaemia	Metabolism and nutrition disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Post procedural constipation	Injury, poisoning and procedural complications	1 (0.00%)
Post procedural oedema	Injury, poisoning and procedural complications	1 (0.00%)
Post stroke epilepsy	Nervous system disorders	1 (0.00%)
Post stroke seizure	Nervous system disorders	1 (0.00%)
Post-traumatic neuralgia	Nervous system disorders	1 (0.00%)
Postural tremor	Nervous system disorders	1 (0.00%)
Post vaccination syndrome	Injury, poisoning and procedural complications	1 (0.00%)
Pouchitis	Gastrointestinal disorders	1 (0.00%)
Pregnancy after post coital contraception	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Pregnancy test positive	Investigations	1 (0.00%)
Pregnancy with implant contraceptive	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Premature ovulation	Reproductive system and breast disorders	1 (0.00%)
Prescribed overdose	Injury, poisoning and procedural complications	1 (0.00%)
Primary biliary cholangitis	Hepatobiliary disorders	1 (0.00%)
Primary gastrointestinal follicular lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Primary hyperthyroidism	Endocrine disorders	1 (0.00%)
Prion disease	Infections and infestations	1 (0.00%)
Procalcitonin decreased	Investigations	1 (0.00%)
Procedural site reaction	Injury, poisoning and procedural complications	1 (0.00%)
Proctitis haemorrhagic	Gastrointestinal disorders	1 (0.00%)
Proctitis ulcerative	Gastrointestinal disorders	1 (0.00%)
Product administration interrupted	Injury, poisoning and procedural complications	1 (0.00%)
Product communication issue	Injury, poisoning and procedural complications	1 (0.00%)
Product compounding quality issue	Product issues	1 (0.00%)
Product contamination	Product issues	1 (0.00%)
Product deposit	Product issues	1 (0.00%)
Product dispensing issue	Injury, poisoning and procedural complications	1 (0.00%)
Product expiration date issue	Product issues	1 (0.00%)
Product formulation issue	Product issues	1 (0.00%)
Product label issue	Product issues	1 (0.00%)
Product lot number issue	Product issues	1 (0.00%)
Product odour abnormal	Product issues	1 (0.00%)
Product packaging issue	Product issues	1 (0.00%)
Product substitution error	Injury, poisoning and procedural complications	1 (0.00%)
Product taste abnormal	Product issues	1 (0.00%)
Product use complaint	Injury, poisoning and procedural complications	1 (0.00%)
Progressive macular hypomelanosis	Skin and subcutaneous tissue disorders	1 (0.00%)
Progressive multifocal leukoencephalopathy	Infections and infestations	1 (0.00%)
Progressive supranuclear palsy	Nervous system disorders	1 (0.00%)
Prostate examination abnormal	Investigations	1 (0.00%)
Prostatic abscess	Infections and infestations	1 (0.00%)
Prostatic pain	Reproductive system and breast disorders	1 (0.00%)
Protein urine	Investigations	1 (0.00%)
Prothrombin level abnormal	Investigations	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Prothrombin level decreased	Investigations	1 (0.00%)
Prothrombin time ratio increased	Investigations	1 (0.00%)
Pseudodementia	Psychiatric disorders	1 (0.00%)
Pseudolymphoma	Blood and lymphatic system disorders	1 (0.00%)
Pseudomembranous colitis	Infections and infestations	1 (0.00%)
Psychogenic pseudosyncope	Psychiatric disorders	1 (0.00%)
Psychological factor affecting medical condition	Psychiatric disorders	1 (0.00%)
Psychotic behaviour	Psychiatric disorders	1 (0.00%)
Psychotic disorder due to a general medical condition	Psychiatric disorders	1 (0.00%)
Pudendal canal syndrome	Nervous system disorders	1 (0.00%)
Pulmonary air leakage	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary alveolar haemorrhage	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary arterial pressure abnormal	Investigations	1 (0.00%)
Pulmonary artery occlusion	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary calcification	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary cavitation	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary function test	Investigations	1 (0.00%)
Pulmonary function test decreased	Investigations	1 (0.00%)
Pulmonary hypertensive crisis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary microemboli	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary necrosis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary tuberculosis	Infections and infestations	1 (0.00%)
Pulmonary vasculitis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulmonary venous thrombosis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Pulse waveform abnormal	Investigations	1 (0.00%)
Punctate keratitis	Eye disorders	1 (0.00%)
Puncture site discharge	General disorders and administration site conditions	1 (0.00%)
Puncture site erythema	General disorders and administration site conditions	1 (0.00%)
Puncture site haematoma	General disorders and administration site conditions	1 (0.00%)
Puncture site oedema	General disorders and administration site conditions	1 (0.00%)
Puncture site swelling	General disorders and administration site conditions	1 (0.00%)
Pupillary light reflex tests abnormal	Investigations	1 (0.00%)
Purging	Psychiatric disorders	1 (0.00%)
Purple glove syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Purpura non-thrombocytopenic	Blood and lymphatic system disorders	1 (0.00%)
Pyelitis	Infections and infestations	1 (0.00%)
Pylorospasm	Gastrointestinal disorders	1 (0.00%)
Pyramidal tract syndrome	Nervous system disorders	1 (0.00%)
Radial nerve injury	Injury, poisoning and procedural complications	1 (0.00%)
Radial pulse increased	Investigations	1 (0.00%)
Radiation injury	Injury, poisoning and procedural complications	1 (0.00%)
Radiation pneumonitis	Injury, poisoning and procedural complications	1 (0.00%)
Radicular pain	Nervous system disorders	1 (0.00%)
Radioisotope uptake increased	Investigations	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Radius fracture	Injury, poisoning and procedural complications	1 (0.00%)
Rash scarlatiniform	Skin and subcutaneous tissue disorders	1 (0.00%)
Reaction to colouring	Immune system disorders	1 (0.00%)
Reaction to previous exposure to any vaccine	Injury, poisoning and procedural complications	1 (0.00%)
Rebound effect	General disorders and administration site conditions	1 (0.00%)
Recalled product administered	Injury, poisoning and procedural complications	1 (0.00%)
Rectal abscess	Infections and infestations	1 (0.00%)
Rectal injury	Injury, poisoning and procedural complications	1 (0.00%)
Rectal prolapse	Gastrointestinal disorders	1 (0.00%)
Rectal spasm	Gastrointestinal disorders	1 (0.00%)
Rectal ulcer	Gastrointestinal disorders	1 (0.00%)
Red blood cells urine	Investigations	1 (0.00%)
Red man syndrome	Skin and subcutaneous tissue disorders	1 (0.00%)
Relapsing fever	Infections and infestations	1 (0.00%)
Renal artery stenosis	Renal and urinary disorders	1 (0.00%)
Renal cyst haemorrhage	Renal and urinary disorders	1 (0.00%)
Renal ischaemia	Renal and urinary disorders	1 (0.00%)
Renal neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Renal transplant failure	Immune system disorders	1 (0.00%)
Renal tubular disorder	Renal and urinary disorders	1 (0.00%)
Renal tubular injury	Renal and urinary disorders	1 (0.00%)
Renal vasculitis	Renal and urinary disorders	1 (0.00%)
Respiratory disorder neonatal	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Respiratory fume inhalation disorder	Injury, poisoning and procedural complications	1 (0.00%)
Respiratory paralysis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Respiratory rate	Investigations	1 (0.00%)
Respiratory tract haemorrhage	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Restrictive cardiomyopathy	Cardiac disorders	1 (0.00%)
Restrictive pulmonary disease	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Reticulocyte count decreased	Investigations	1 (0.00%)
Reticulocyte count increased	Investigations	1 (0.00%)
Retinal degeneration	Eye disorders	1 (0.00%)
Retinal drusen	Eye disorders	1 (0.00%)
Retinal infarction	Eye disorders	1 (0.00%)
Retinal oedema	Eye disorders	1 (0.00%)
Retinal pigment epitheliopathy	Eye disorders	1 (0.00%)
Retinal toxicity	Eye disorders	1 (0.00%)
Retinal vasculitis	Eye disorders	1 (0.00%)
Retinitis	Infections and infestations	1 (0.00%)
Retinogram abnormal	Investigations	1 (0.00%)
Retinopathy hypertensive	Eye disorders	1 (0.00%)
Retroperitoneal lymphadenopathy	Blood and lymphatic system disorders	1 (0.00%)
Retroplacental haematoma	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Reversible airways obstruction	Respiratory, thoracic and mediastinal disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Reynold's syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Rheumatic fever	Musculoskeletal and connective tissue disorders	1 (0.00%)
Rhinolaryngitis	Infections and infestations	1 (0.00%)
Rhythm idioventricular	Cardiac disorders	1 (0.00%)
Right ventricular hypertrophy	Cardiac disorders	1 (0.00%)
Rinne tuning fork test abnormal	Investigations	1 (0.00%)
Romberg test positive	Investigations	1 (0.00%)
Rosai-Dorfman syndrome	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Roseola	Infections and infestations	1 (0.00%)
Rotavirus infection	Infections and infestations	1 (0.00%)
Rubella	Infections and infestations	1 (0.00%)
Saliva altered	Gastrointestinal disorders	1 (0.00%)
Saliva discolouration	Gastrointestinal disorders	1 (0.00%)
Salivary duct obstruction	Gastrointestinal disorders	1 (0.00%)
Salivary gland calculus	Gastrointestinal disorders	1 (0.00%)
Salivary gland mass	Gastrointestinal disorders	1 (0.00%)
Salivary gland neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Salmonella test positive	Investigations	1 (0.00%)
Salt craving	Metabolism and nutrition disorders	1 (0.00%)
SAPHO syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Sarcoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
SARS-CoV-2 sepsis	Infections and infestations	1 (0.00%)
Scan abdomen abnormal	Investigations	1 (0.00%)
Scan abnormal	Investigations	1 (0.00%)
Scapula fracture	Injury, poisoning and procedural complications	1 (0.00%)
Schwannoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Sciatic nerve injury	Injury, poisoning and procedural complications	1 (0.00%)
Scleral hyperaemia	Eye disorders	1 (0.00%)
Scleroderma associated digital ulcer	Skin and subcutaneous tissue disorders	1 (0.00%)
Scrotal dermatitis	Reproductive system and breast disorders	1 (0.00%)
Scrotal disorder	Reproductive system and breast disorders	1 (0.00%)
Scrotal exfoliation	Reproductive system and breast disorders	1 (0.00%)
Scrotal infection	Infections and infestations	1 (0.00%)
Scrotal inflammation	Reproductive system and breast disorders	1 (0.00%)
Scrotal injury	Injury, poisoning and procedural complications	1 (0.00%)
Secondary adrenocortical insufficiency	Endocrine disorders	1 (0.00%)
Secondary transmission	Infections and infestations	1 (0.00%)
Second primary malignancy	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Sedation complication	Injury, poisoning and procedural complications	1 (0.00%)
Semen discolouration	Reproductive system and breast disorders	1 (0.00%)
Sensory overload	Nervous system disorders	1 (0.00%)
Septic embolus	Infections and infestations	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Septic pulmonary embolism	Infections and infestations	1 (0.00%)
Serratia test positive	Investigations	1 (0.00%)
Sexual dysfunction	Reproductive system and breast disorders	1 (0.00%)
Shock hypoglycaemic	Metabolism and nutrition disorders	1 (0.00%)
Sigmoidoscopy abnormal	Investigations	1 (0.00%)
Silent thyroiditis	Endocrine disorders	1 (0.00%)
Simple partial seizures	Nervous system disorders	1 (0.00%)
Sinus operation	Surgical and medical procedures	1 (0.00%)
Sinus tarsi syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Sitophobia	Psychiatric disorders	1 (0.00%)
Skin atrophy	Skin and subcutaneous tissue disorders	1 (0.00%)
Skin lesion inflammation	Skin and subcutaneous tissue disorders	1 (0.00%)
Skin lesion removal	Surgical and medical procedures	1 (0.00%)
Skin test positive	Investigations	1 (0.00%)
Skin wound	Injury, poisoning and procedural complications	1 (0.00%)
Sleep disorder due to general medical condition, hypersomnia type	Psychiatric disorders	1 (0.00%)
Sleep inertia	Psychiatric disorders	1 (0.00%)
Small for dates baby	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Small intestinal resection	Surgical and medical procedures	1 (0.00%)
Snapping hip syndrome	Musculoskeletal and connective tissue disorders	1 (0.00%)
Social fear	Psychiatric disorders	1 (0.00%)
Soft tissue atrophy	Musculoskeletal and connective tissue disorders	1 (0.00%)
Soft tissue haemorrhage	Musculoskeletal and connective tissue disorders	1 (0.00%)
Solar urticaria	Skin and subcutaneous tissue disorders	1 (0.00%)
Solid organ transplant rejection	Immune system disorders	1 (0.00%)
Somatic dysfunction	Musculoskeletal and connective tissue disorders	1 (0.00%)
Spasmodic dysphonia	Nervous system disorders	1 (0.00%)
Spider vein	Vascular disorders	1 (0.00%)
Spina bifida	Congenital, familial and genetic disorders	1 (0.00%)
Spinal epidural haematoma	Nervous system disorders	1 (0.00%)
Spinal epidural haemorrhage	Nervous system disorders	1 (0.00%)
Spinal fusion surgery	Surgical and medical procedures	1 (0.00%)
Spinal meningeal cyst	Nervous system disorders	1 (0.00%)
Spinal subdural haemorrhage	Nervous system disorders	1 (0.00%)
Spinal vascular disorder	Nervous system disorders	1 (0.00%)
Spine malformation	Congenital, familial and genetic disorders	1 (0.00%)
Spleen atrophy	Blood and lymphatic system disorders	1 (0.00%)
Splenic artery aneurysm	Gastrointestinal disorders	1 (0.00%)
Splenic artery embolisation	Surgical and medical procedures	1 (0.00%)
Splenic artery thrombosis	Blood and lymphatic system disorders	1 (0.00%)
Splenic haemorrhage	Blood and lymphatic system disorders	1 (0.00%)
Splenic infection	Infections and infestations	1 (0.00%)
Splenitis	Blood and lymphatic system disorders	1 (0.00%)
Splinter	Injury, poisoning and procedural complications	1 (0.00%)
Spondyloarthropathy	Musculoskeletal and connective tissue disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Staphylococcal abscess	Infections and infestations	1 (0.00%)
Staphylococcal skin infection	Infections and infestations	1 (0.00%)
Stasis dermatitis	Skin and subcutaneous tissue disorders	1 (0.00%)
Stenotrophomonas test positive	Investigations	1 (0.00%)
Sternal fracture	Injury, poisoning and procedural complications	1 (0.00%)
Sticky skin	Skin and subcutaneous tissue disorders	1 (0.00%)
Stiff leg syndrome	Nervous system disorders	1 (0.00%)
Stomach mass	Gastrointestinal disorders	1 (0.00%)
Stoma site discharge	Injury, poisoning and procedural complications	1 (0.00%)
Stoma site extravasation	Injury, poisoning and procedural complications	1 (0.00%)
Stoma site pain	Injury, poisoning and procedural complications	1 (0.00%)
Stoma site pruritus	Injury, poisoning and procedural complications	1 (0.00%)
Strangury	Renal and urinary disorders	1 (0.00%)
Strawberry tongue	Gastrointestinal disorders	1 (0.00%)
Streptococcal abscess	Infections and infestations	1 (0.00%)
Streptococcal bacteraemia	Infections and infestations	1 (0.00%)
Streptococcal endocarditis	Infections and infestations	1 (0.00%)
Streptococcal sepsis	Infections and infestations	1 (0.00%)
Streptococcal urinary tract infection	Infections and infestations	1 (0.00%)
Stress fracture	Injury, poisoning and procedural complications	1 (0.00%)
Stroke volume decreased	Investigations	1 (0.00%)
Subacute inflammatory demyelinating polyneuropathy	Nervous system disorders	1 (0.00%)
Subclavian artery thrombosis	Vascular disorders	1 (0.00%)
Subclavian vein stenosis	Vascular disorders	1 (0.00%)
Subretinal haematoma	Eye disorders	1 (0.00%)
Substance abuse	Psychiatric disorders	1 (0.00%)
Sudden infant death syndrome	General disorders and administration site conditions	1 (0.00%)
Superinfection viral	Infections and infestations	1 (0.00%)
Superior vena cava syndrome	Vascular disorders	1 (0.00%)
Surgery	Surgical and medical procedures	1 (0.00%)
Suture related complication	Injury, poisoning and procedural complications	1 (0.00%)
Swollen joint count increased	Investigations	1 (0.00%)
Symmetrical drug-related intertriginous and flexural exanthema	Skin and subcutaneous tissue disorders	1 (0.00%)
Symphysiolysis	Musculoskeletal and connective tissue disorders	1 (0.00%)
Synovial disorder	Musculoskeletal and connective tissue disorders	1 (0.00%)
Synovial fluid analysis abnormal	Investigations	1 (0.00%)
Synovial fluid white blood cells positive	Investigations	1 (0.00%)
Synovial rupture	Injury, poisoning and procedural complications	1 (0.00%)
Systemic candida	Infections and infestations	1 (0.00%)
Systemic scleroderma	Musculoskeletal and connective tissue disorders	1 (0.00%)
Tachycardia foetal	Cardiac disorders	1 (0.00%)
Tachycardia induced cardiomyopathy	Cardiac disorders	1 (0.00%)
Tanning	Social circumstances	1 (0.00%)
Target skin lesion	Skin and subcutaneous tissue disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
T-cell lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Teeth brittle	Gastrointestinal disorders	1 (0.00%)
Temperature perception test increased	Investigations	1 (0.00%)
TEMPI syndrome	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Tendon discomfort	Musculoskeletal and connective tissue disorders	1 (0.00%)
Terminal ileitis	Gastrointestinal disorders	1 (0.00%)
Testicular neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Testicular retraction	Reproductive system and breast disorders	1 (0.00%)
Testicular torsion	Reproductive system and breast disorders	1 (0.00%)
Tetanus	Infections and infestations	1 (0.00%)
Thanatophobia	Psychiatric disorders	1 (0.00%)
Therapeutic procedure	Surgical and medical procedures	1 (0.00%)
Therapeutic product effect incomplete	General disorders and administration site conditions	1 (0.00%)
Therapeutic product effect increased	General disorders and administration site conditions	1 (0.00%)
Therapeutic product effect prolonged	General disorders and administration site conditions	1 (0.00%)
Therapeutic product ineffective	General disorders and administration site conditions	1 (0.00%)
Therapeutic response decreased	General disorders and administration site conditions	1 (0.00%)
Therapeutic response increased	General disorders and administration site conditions	1 (0.00%)
Therapeutic response shortened	General disorders and administration site conditions	1 (0.00%)
Thermohypoaesthesia	Nervous system disorders	1 (0.00%)
Thoracic vertebral fracture	Injury, poisoning and procedural complications	1 (0.00%)
Thought blocking	Psychiatric disorders	1 (0.00%)
Threatened labour	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Thrombectomy	Surgical and medical procedures	1 (0.00%)
Thromboangiitis obliterans	Vascular disorders	1 (0.00%)
Thrombophlebitis septic	Infections and infestations	1 (0.00%)
Thymoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Thyroglobulin increased	Investigations	1 (0.00%)
Thyroglossal cyst	Congenital, familial and genetic disorders	1 (0.00%)
Thyroid cyst	Endocrine disorders	1 (0.00%)
Thyroxine free decreased	Investigations	1 (0.00%)
Tibia fracture	Injury, poisoning and procedural complications	1 (0.00%)
Tidal volume decreased	Investigations	1 (0.00%)
Time perception altered	Psychiatric disorders	1 (0.00%)
Tinea infection	Infections and infestations	1 (0.00%)
Tinea pedis	Infections and infestations	1 (0.00%)
Tinea versicolour	Infections and infestations	1 (0.00%)
Tissue infiltration	General disorders and administration site conditions	1 (0.00%)
T-lymphocyte count decreased	Investigations	1 (0.00%)
Tobacco user	Social circumstances	1 (0.00%)
Tongue fungal infection	Infections and infestations	1 (0.00%)
Tongue geographic	Gastrointestinal disorders	1 (0.00%)
Tonsillar cyst	Respiratory, thoracic and mediastinal disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Tonsillar haemorrhage	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Tonsillitis streptococcal	Infections and infestations	1 (0.00%)
Tooth erosion	Gastrointestinal disorders	1 (0.00%)
Total cholesterol/HDL ratio decreased	Investigations	1 (0.00%)
Tourette's disorder	Congenital, familial and genetic disorders	1 (0.00%)
Toxic anterior segment syndrome	Injury, poisoning and procedural complications	1 (0.00%)
Toxic neuropathy	Nervous system disorders	1 (0.00%)
Toxoplasma serology positive	Investigations	1 (0.00%)
Toxoplasmosis	Infections and infestations	1 (0.00%)
Tracheal deviation	Injury, poisoning and procedural complications	1 (0.00%)
Tracheal haemorrhage	Injury, poisoning and procedural complications	1 (0.00%)
Tracheal inflammation	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Tracheobronchitis bacterial	Infections and infestations	1 (0.00%)
Tracheomalacia	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Transaminases decreased	Investigations	1 (0.00%)
Transcription medication error	Injury, poisoning and procedural complications	1 (0.00%)
Transferrin abnormal	Investigations	1 (0.00%)
Transferrin decreased	Investigations	1 (0.00%)
Transferrin increased	Investigations	1 (0.00%)
Transfusion reaction	Injury, poisoning and procedural complications	1 (0.00%)
Transplant rejection	Immune system disorders	1 (0.00%)
Transposition of the great vessels	Congenital, familial and genetic disorders	1 (0.00%)
Transverse sinus stenosis	Nervous system disorders	1 (0.00%)
Traumatic fracture	Injury, poisoning and procedural complications	1 (0.00%)
Treatment failure	General disorders and administration site conditions	1 (0.00%)
Treatment noncompliance	General disorders and administration site conditions	1 (0.00%)
Trichorrhexis	Skin and subcutaneous tissue disorders	1 (0.00%)
Tri-iodothyronine	Investigations	1 (0.00%)
Tri-iodothyronine free decreased	Investigations	1 (0.00%)
Tri-iodothyronine free increased	Investigations	1 (0.00%)
Tri-iodothyronine increased	Investigations	1 (0.00%)
Trisomy 21	Congenital, familial and genetic disorders	1 (0.00%)
Troponin I decreased	Investigations	1 (0.00%)
Truncus coeliacus thrombosis	Gastrointestinal disorders	1 (0.00%)
Tuberculin test positive	Investigations	1 (0.00%)
Tumefactive multiple sclerosis	Nervous system disorders	1 (0.00%)
Tumour marker abnormal	Investigations	1 (0.00%)
Tumour marker decreased	Investigations	1 (0.00%)
Tumour perforation	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Tumour pseudoprogression	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Tumour thrombosis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)
Twin pregnancy	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Tympanic membrane disorder	Ear and labyrinth disorders	1 (0.00%)
Ulnar neuritis	Nervous system disorders	1 (0.00%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Ultrasound breast abnormal	Investigations	1 (0.00%)
Ultrasound scan abnormal	Investigations	1 (0.00%)
Umbilical cord abnormality	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Umbilical cord thrombosis	Pregnancy, puerperium and perinatal conditions	1 (0.00%)
Umbilical haematoma	Skin and subcutaneous tissue disorders	1 (0.00%)
Undifferentiated connective tissue disease	Musculoskeletal and connective tissue disorders	1 (0.00%)
Upper respiratory tract irritation	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Urea urine	Investigations	1 (0.00%)
Urethral disorder	Renal and urinary disorders	1 (0.00%)
Urethral haemorrhage	Renal and urinary disorders	1 (0.00%)
Urethral stenosis	Renal and urinary disorders	1 (0.00%)
Urethritis noninfective	Renal and urinary disorders	1 (0.00%)
Urinary assistance device user	Social circumstances	1 (0.00%)
Urinary occult blood	Investigations	1 (0.00%)
Urinary sediment abnormal	Investigations	1 (0.00%)
Urinary sediment present	Investigations	1 (0.00%)
Urinary straining	Renal and urinary disorders	1 (0.00%)
Urinary tract candidiasis	Infections and infestations	1 (0.00%)
Urinary tract discomfort	Renal and urinary disorders	1 (0.00%)
Urinary tract infection enterococcal	Infections and infestations	1 (0.00%)
Urinary tract infection pseudomonal	Infections and infestations	1 (0.00%)
Urine porphobilinogen increased	Investigations	1 (0.00%)
Urine sodium increased	Investigations	1 (0.00%)
Urobilinogen urine increased	Investigations	1 (0.00%)
Urogenital infection bacterial	Infections and infestations	1 (0.00%)
Urticaria contact	Skin and subcutaneous tissue disorders	1 (0.00%)
Urticarial dermatitis	Skin and subcutaneous tissue disorders	1 (0.00%)
Urticaria pressure	Skin and subcutaneous tissue disorders	1 (0.00%)
Urticaria vesiculosa	Skin and subcutaneous tissue disorders	1 (0.00%)
Uterine abscess	Infections and infestations	1 (0.00%)
Uterine disorder	Reproductive system and breast disorders	1 (0.00%)
Uterine polyp	Reproductive system and breast disorders	1 (0.00%)
Uterine prolapse	Reproductive system and breast disorders	1 (0.00%)
Vaccination site calcification	General disorders and administration site conditions	1 (0.00%)
Vaccination site erosion	General disorders and administration site conditions	1 (0.00%)
Vaccination site ischaemia	General disorders and administration site conditions	1 (0.00%)
Vaccination site photosensitivity reaction	General disorders and administration site conditions	1 (0.00%)
Vaccination site recall reaction	General disorders and administration site conditions	1 (0.00%)
Vaccination site streaking	General disorders and administration site conditions	1 (0.00%)
Vaginal abscess	Infections and infestations	1 (0.00%)
Varicocele	Reproductive system and breast disorders	1 (0.00%)
Vascular anastomosis	Surgical and medical procedures	1 (0.00%)
Vascular device infection	Infections and infestations	1 (0.00%)
Vascular parkinsonism	Nervous system disorders	1 (0.00%)
Vascular skin disorder	Skin and subcutaneous tissue disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Vascular stenosis	Vascular disorders	1 (0.00%)
Vascular stent stenosis	General disorders and administration site conditions	1 (0.00%)
Vasomotor rhinitis	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Vein wall hypertrophy	Vascular disorders	1 (0.00%)
Vena cava embolism	Vascular disorders	1 (0.00%)
Venous arterialisation	Surgical and medical procedures	1 (0.00%)
Venous bruit	Investigations	1 (0.00%)
Venous pressure	Investigations	1 (0.00%)
Venous thrombosis in pregnancy	Vascular disorders	1 (0.00%)
Ventricle rupture	Cardiac disorders	1 (0.00%)
Ventricular enlargement	Cardiac disorders	1 (0.00%)
Ventricular failure	Cardiac disorders	1 (0.00%)
Ventricular flutter	Cardiac disorders	1 (0.00%)
Vertebral artery stenosis	Nervous system disorders	1 (0.00%)
Vertebral artery thrombosis	Nervous system disorders	1 (0.00%)
Vertebral wedging	Musculoskeletal and connective tissue disorders	1 (0.00%)
Vertebrobasilar insufficiency	Nervous system disorders	1 (0.00%)
Vertigo CNS origin	Nervous system disorders	1 (0.00%)
Vessel puncture site bruise	General disorders and administration site conditions	1 (0.00%)
Vessel puncture site haemorrhage	General disorders and administration site conditions	1 (0.00%)
Vessel puncture site injury	General disorders and administration site conditions	1 (0.00%)
Vessel puncture site swelling	General disorders and administration site conditions	1 (0.00%)
Vestibular function test abnormal	Investigations	1 (0.00%)
Vibratory sense increased	Nervous system disorders	1 (0.00%)
VIIIth nerve lesion	Nervous system disorders	1 (0.00%)
Viral corneal ulcer	Infections and infestations	1 (0.00%)
Viral keratouveitis	Infections and infestations	1 (0.00%)
Viral myelitis	Infections and infestations	1 (0.00%)
Viral test	Investigations	1 (0.00%)
Viral test positive	Investigations	1 (0.00%)
Viral tonsillitis	Infections and infestations	1 (0.00%)
Visceral pain	General disorders and administration site conditions	1 (0.00%)
Visual acuity reduced transiently	Eye disorders	1 (0.00%)
Visual perseveration	Nervous system disorders	1 (0.00%)
Visual snow syndrome	Eye disorders	1 (0.00%)
Visuospatial deficit	Nervous system disorders	1 (0.00%)
Vital capacity	Investigations	1 (0.00%)
Vitamin B complex deficiency	Metabolism and nutrition disorders	1 (0.00%)
Vitamin D	Investigations	1 (0.00%)
VIth nerve disorder	Nervous system disorders	1 (0.00%)
VIth nerve paresis	Nervous system disorders	1 (0.00%)
Vitreous haze	Eye disorders	1 (0.00%)
Vitreous opacities	Eye disorders	1 (0.00%)
Vitritis	Eye disorders	1 (0.00%)
Vocal cord inflammation	Respiratory, thoracic and mediastinal disorders	1 (0.00%)
Vocal cord paresis	Nervous system disorders	1 (0.00%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Vogt-Koyanagi-Harada disease	Eye disorders	1 (0.00%)
Volvulus of small bowel	Gastrointestinal disorders	1 (0.00%)
Vomiting psychogenic	Psychiatric disorders	1 (0.00%)
Von Willebrand's disease	Congenital, familial and genetic disorders	1 (0.00%)
Von Willebrand's factor activity decreased	Investigations	1 (0.00%)
Vth nerve injury	Injury, poisoning and procedural complications	1 (0.00%)
Vulval oedema	Reproductive system and breast disorders	1 (0.00%)
Vulvovaginal erythema	Reproductive system and breast disorders	1 (0.00%)
Vulvovaginal inflammation	Reproductive system and breast disorders	1 (0.00%)
Vulvovaginal injury	Injury, poisoning and procedural complications	1 (0.00%)
Wandering pacemaker	Cardiac disorders	1 (0.00%)
Weber tuning fork test abnormal	Investigations	1 (0.00%)
Weight abnormal	Investigations	1 (0.00%)
Weight loss diet	Surgical and medical procedures	1 (0.00%)
Weight loss poor	Metabolism and nutrition disorders	1 (0.00%)
Wheat-free diet	Surgical and medical procedures	1 (0.00%)
Williams syndrome	Congenital, familial and genetic disorders	1 (0.00%)
Winged scapula	Musculoskeletal and connective tissue disorders	1 (0.00%)
Withdrawal bleed	Reproductive system and breast disorders	1 (0.00%)
Wound closure	Surgical and medical procedures	1 (0.00%)
Wound drainage	Surgical and medical procedures	1 (0.00%)
Wound necrosis	Injury, poisoning and procedural complications	1 (0.00%)
Writer's cramp	Nervous system disorders	1 (0.00%)
Wrong dose	Injury, poisoning and procedural complications	1 (0.00%)
Wrong patient received product	Injury, poisoning and procedural complications	1 (0.00%)
Xerosis	General disorders and administration site conditions	1 (0.00%)
Yellow fever	Infections and infestations	1 (0.00%)
Yersinia bacteraemia	Infections and infestations	1 (0.00%)
Yersinia infection	Infections and infestations	1 (0.00%)
Yolk sac tumour site unspecified	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.00%)

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Appendix 2.2 Interval Summary Tabulation of Case Reports with DME Events from Post-Marketing Data Sources

BNT162B2 - ALL

Interval Reporting Period: 30-APR-2021 Through 31-MAY-2021

Total Number of Cases: 47,174 (Interval)

Total Number of Cases with DME 1,252 (Interval)

Total Number of Adverse Events (PT) (DME only) 1,331 (Interval)

MedDRA Version: v.24.0J

SOC and PT	Number of Events	Percentage (%)
Blood and lymphatic system disorders	3	
Agranulocytosis	1	0.0 %
Febrile bone marrow aplasia	1	0.0 %
Hypereosinophilic syndrome	1	0.0 %
Cardiac disorders	1	
Torsade de pointes	1	0.0 %
Eye disorders	1	
Angle closure glaucoma	1	0.0 %
Gastrointestinal disorders	65	
Intestinal angioedema	1	0.0 %
Oedematous pancreatitis	1	0.0 %
Pancreatitis	14	0.0 %
Pancreatitis acute	19	0.0 %
Pancreatitis haemorrhagic	1	0.0 %
Pancreatitis necrotising	1	0.0 %
Tongue oedema	28	0.1 %
General disorders and administration site conditions	72	
Face oedema	72	0.2 %

Multiple adverse event coding to the same Preferred Term (DME) may have been reported in some cases. Counts are provided for the number of unique Preferred Terms Reported.

Hepatobiliary disorders	5	
Acute hepatic failure	2	0.0 %
Hepatic failure	2	0.0 %
Hepatorenal syndrome	1	0.0 %
Immune system disorders	770	
Anaphylactic reaction	672	1.4 %
Anaphylactic shock	74	0.2 %
Anaphylactoid reaction	12	0.0 %
Anaphylactoid shock	2	0.0 %
Type I hypersensitivity	10	0.0 %
Injury, poisoning and procedural complications	5	
Burn oesophageal	2	0.0 %
Contraindicated product administered	2	0.0 %
Contraindicated product prescribed	1	0.0 %
Investigations	2	
Electrocardiogram QT prolonged	2	0.0 %
Metabolism and nutrition disorders	9	
Hyperkalaemia	9	0.0 %
Musculoskeletal and connective tissue disorders	36	
Myopathy	6	0.0 %
Myositis	19	0.0 %
Rhabdomyolysis	11	0.0 %
Nervous system disorders	1	
Hepatic encephalopathy	1	0.0 %

Psychiatric disorders	28	
Completed suicide	4	0.0 %
Depression suicidal	1	0.0 %
Intentional self-injury	1	0.0 %
Suicidal behaviour	1	0.0 %
Suicidal ideation	20	0.0 %
Suicide attempt	1	0.0 %
Renal and urinary disorders	1	
Tubulointerstitial nephritis	1	0.0 %
Respiratory, thoracic and mediastinal disorders	170	
Hypersensitivity pneumonitis	1	0.0 %
Laryngeal oedema	33	0.1 %
Oropharyngeal oedema	1	0.0 %
Pharyngeal swelling	135	0.3 %
Skin and subcutaneous tissue disorders	162	
Angioedema	108	0.2 %
Circumoral swelling	7	0.0 %
Dermatitis exfoliative	2	0.0 %
Dermatitis exfoliative generalised	2	0.0 %
Drug reaction with eosinophilia and systemic symptoms	3	0.0 %
Idiopathic angioedema	1	0.0 %
Skin exfoliation	33	0.1 %
Stevens-Johnson syndrome	6	0.0 %

APPENDIX 2.3: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Case Reports From Post-Marketing Data Sources by Medically Confirmed and Non Medically Confirmed, Region and Country

Cumulative Reporting Period: Through 31-MAY-2021

Interval Reporting Period: 30-APR-2021 Through 31-MAY-2021

Total Number of Cases: 47,174 (Interval) / 167,956 (Cumulative)

MedDRA Version: v.24.0J

Medically Confirmed

Region : European Countries (27 EU)

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Non Interventional Study				Spontaneous					
			Serious Fatal		Serious Non Fatal		Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C	I	C	I	C
AUSTRIA	272	831					72	172	21	81	179	578
BELGIUM	370	1,036					245	489	13	88	112	459
BULGARIA	34	151					31	123			3	28
CROATIA	115	362					42	153	3	11	70	198
CYPRUS	13	116					10	72		2	3	42
CZECH REPUBLIC	554	1,328					371	620	5	16	178	692
DENMARK	319	1,301					154	688	10	84	155	529
ESTONIA	73	190					27	85	4	7	42	98
FINLAND	210	710					94	224	10	53	106	433
FRANCE	2,070	6,547					611	1626	101	533	1358	4388
GERMANY	893	2,879			1	112	451	1066	84	436	358	1377
GREECE	340	1,379					256	789	8	24	76	566
HUNGARY	249	610					156	411	69	91	24	108
IRELAND	237	683					86	189	11	36	140	458
ITALY	3,294	17,968	1	3	82	192	2357	13870	55	168	882	3930
LATVIA	20	145					15	93	1	1	4	51
LITHUANIA	11	44					2	11		3	9	30
LUXEMBOURG	67	195					46	87	1	3	20	105
MALTA	24	76					16	42	2	9	6	25
NETHERLANDS	306	928	2	2	8	16	98	249	33	205	175	474
POLAND	103	648					61	280	15	51	27	317
PORTUGAL	674	2,698					487	1058	7	30	180	1610
ROMANIA	188	901					121	494	3	106	64	301
SLOVAKIA	48	245					41	186	3	4	4	55

* I=Interval, C=Cumulative

Medically Confirmed

Region : European Countries (27 EU)

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Non Interventional Study				Spontaneous					
			Serious Fatal		Serious Non Fatal		Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C	I	C	I	C
SLOVENIA	28	158					10	77	2	14	16	67
SPAIN	1,175	3,372				1	648	1428	54	151	473	1793
SWEDEN	304	1,262					102	305	23	179	179	778
	11,991	46,763	3	5	91	321	6610	24887	538	2386	4843	19490

Region : European Economic Area (3 EEA)

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Spontaneous					
			Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C
ICELAND	33	143	23	103	1	13	9	27
LIECHTENSTEIN	2	3	1	2			1	1
NORWAY	320	892	110	289	16	150	194	453
	355	1,038	134	394	17	163	204	481

Region : Non-European Countries

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Non Interventional Study		Spontaneous					
			Serious Non Fatal		Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C	I	C
AFGHANISTAN		1								1
ALBANIA		2				2				
AMERICAN SAMOA	1	1			1	1				
ANGOLA		2				1				1
AUSTRALIA	520	1,082			246	554	55	115	219	413
BAHRAIN	11	11			1	1			10	10
BERMUDA		7				4				3
BOLIVIA	1	1			1	1				
BOSNIA AND HERZEGOVINA	1	1			1	1				
BRAZIL	45	45			40	40	1	1	4	4
CANADA	203	709			123	425	3	5	77	279
CAYMAN ISLANDS		1				1				
CHILE	2	52			1	43			1	9

* I=Interval, C=Cumulative

Medically Confirmed

Region : Non-European Countries

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Non Interventional Study		Spontaneous					
			Serious Non Fatal		Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C	I	C
COLOMBIA	27	77			19	56		1	8	20
COSTA RICA	33	153			28	125	1	2	4	26
ECUADOR	30	53			6	25			24	28
FRENCH GUIANA	1	1							1	1
FRENCH POLYNESIA	1	3					1		1	2
GAMBIA		1				1				
GEORGIA	1	2			1	1				1
HOLY SEE (VATICAN CITY STATE)		2				2				
HONG KONG	128	221			22	56	7	9	99	156
INDIA	1	2					1	1		1
IRAQ	7	7			4	4	1	1	2	2
ISRAEL	111	629		1	59	238	2	61	50	330
JAPAN	2,879	5,267			854	1801	78	97	1947	3369
JORDAN	4	11			3	9			1	2
KOREA, REPUBLIC OF (SOUTH KOREA)		1				1				
KUWAIT		4				4				
LEBANON	16	63			11	29	1	12	4	22
MACAO	4	4							4	4
MACEDONIA, THE FORMER YUGOSLAV REPUBLIC OF	4	10			4	9				1
MALAYSIA	12	20			10	14		1	2	5
MEXICO	3,909	5,793			3252	3840	6	20	651	1933
NEW ZEALAND	29	39			2	5			27	34
NORTHERN MARIANA ISLANDS		1				1				
OMAN	2	2							2	2
PANAMA	189	213			149	160			40	53
PERU	6	7			3	4	1	1	2	2
PHILIPPINES	21	21			21	21				
PUERTO RICO	2	56			2	51				5
QATAR	1	9				5			1	4
SAUDI ARABIA	7	24			3	15			4	9

* I=Interval, C=Cumulative

Medically Confirmed

Region : Non-European Countries

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Non Interventional Study		Spontaneous					
			Serious Non Fatal		Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C	I	C
SERBIA	26	88			16	59			10	29
SINGAPORE	1	18			1	11				7
SOUTH AFRICA	11	11			10	10	1	1		
SWITZERLAND	216	512			95	125	6	28	115	359
THAILAND	1	1							1	1
TUNISIA	6	12			6	12				
TURKEY	18	23			10	15			8	8
TURKS AND CAICOS ISLANDS		1								1
UNITED ARAB EMIRATES	1	16				10		1	1	5
UNITED KINGDOM	3,060	16,477	79	289	2254	9417	29	289	777	6771
UNITED STATES	2,197	13,344	6	8	1609	9685	10	100	578	3559
UNITED STATES MINOR OUTLYING ISLANDS		3				3				
URUGUAY	1	1			1	1				
	13,747	45,118	85	298	8869	26899	203	747	4675	17472

* I=Interval, C=Cumulative

Non Medically Confirmed

Region : European Countries (27 EU)

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Non Interventional Study		Spontaneous					
			Serious Non Fatal		Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C	I	C
AUSTRIA	295	492			204	247	1	5	90	240
BELGIUM	445	1,093			240	337	4	16	201	740
BULGARIA	47	132			40	99			7	33
CROATIA	36	87			25	51			11	36
CYPRUS	20	39			17	32			3	7
CZECH REPUBLIC	150	372			24	78	4	23	122	271
DENMARK	95	271			65	219	1	1	29	51
ESTONIA	13	59			6	38	1	2	6	19
FINLAND	123	224			20	45	1	6	102	173
FRANCE	650	1,597			179	448	12	52	459	1097
GERMANY	1,212	3,073	1	1	881	2095	60	184	271	794
GREECE	138	252			77	128	5	12	56	112
HUNGARY	115	298			69	201	2	5	44	92
IRELAND	109	252			51	100	2	4	56	148
ITALY	623	2,289			387	1745	14	29	222	515
LATVIA	21	108			18	77			3	31
LITHUANIA	23	79			3	24	1	2	19	53
LUXEMBOURG	7	9				1			7	8
MALTA	8	44			4	28			4	16
NETHERLANDS	902	3,500			675	2794	18	80	209	626
POLAND	198	400			115	211	6	29	77	160
PORTUGAL	120	407			59	132	1	5	60	270
ROMANIA	184	418			53	112	1	1	130	305
SLOVAKIA	16	112			12	85		1	4	26
SLOVENIA	6	20			3	13			3	7
SPAIN	182	451			112	219	3	12	67	220
SWEDEN	407	853			225	479	8	21	174	353
	6,145	16,931	1	1	3564	10038	145	490	2436	6403

Region : European Economic Area (3 EEA)

Interval Total #

Cumulative Total #

Spontaneous		
Nonserious	Serious Fatal	Serious Non Fatal

* I=Interval, C=Cumulative

Non Medically Confirmed

Region : European Economic Area (3 EEA)

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Spontaneous					
			Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C
ICELAND	2	14	2	8		2		4
NORWAY	44	133	14	60	1	3	29	70
	46	147	16	68	1	5	29	74

Region : Non-European Countries

Region : Non-European Countries			Non Interventional Study				Spontaneous					
	Interval Total #	Cumulative Total #	Serious Fatal		Serious Non Fatal		Nonserious		Serious Fatal		Serious Non Fatal	
Country where Event Occurred	Spontaneous Cases	Spontaneous Cases	I	C	I	C	I	C	I	C	I	C
ALBANIA		1						1				
AMERICAN SAMOA		1						1				
ANDORRA		1						1				
ARGENTINA	8	13					4	8			4	5
AUSTRALIA	1	11					1	9		1		1
BAHRAIN		5						4				1
BERMUDA	2	3					2	3				
BOLIVIA	2	2									2	2
BOSNIA AND HERZEGOVINA		1						1				
BRAZIL	63	64					55	56	1	1	7	7
CANADA	220	433					90	205	3	6	127	222
CAYMAN ISLANDS	6	6					6	6				
CHILE	47	125					46	104			1	21
COLOMBIA	30	40					16	24	2	2	12	14
COSTA RICA	31	87					22	64	3	9	6	14
ECUADOR	8	13					4	5			4	8
EGYPT		1										1
EL SALVADOR	2	2									2	2
FRENCH SOUTHERN TERRITORIES		1								1		
GEORGIA		1										1
GUINEA		1										1
HAITI		1						1				
HONDURAS	2	2					2	2				

* I=Interval, C=Cumulative

Non Medically Confirmed

Region : Non-European Countries

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Non Interventional Study				Spontaneous					
			Serious Fatal		Serious Non Fatal		Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C	I	C	I	C
HONG KONG	5	33					3	12			2	21
INDIA	2	4						1	2	2		1
IRAQ	5	7					2	4			3	3
ISRAEL	237	821					217	609		12	20	200
JAPAN	63	99					28	48			35	51
JORDAN	4	14					3	6			1	8
KOREA, REPUBLIC OF (SOUTH KOREA)	2	2					1	1			1	1
KUWAIT	2	5					1	4			1	1
LEBANON	2	9					1	4			1	5
MACAO		1										1
MACEDONIA, THE FORMER YUGOSLAV REPUBLIC OF	1	1									1	1
MALAYSIA	6	8					3	4	2	3	1	1
MEXICO	81	261					60	197	1	4	20	60
MONACO		1										1
NORTHERN MARIANA ISLANDS		3						3				
OMAN		3						3				
PALESTINIAN TERRITORY, OCCUPIED	1	1					1	1				
PANAMA	3	9					1	7			2	2
PERU	8	20					6	16			2	4
PHILIPPINES	4	4					2	2	1	1	1	1
PUERTO RICO	10	47					6	38		1	4	8
QATAR	1	14					1	6				8
SAUDI ARABIA	16	36					12	27	2	3	2	6
SERBIA	33	81					29	62		1	4	18
SINGAPORE	19	112					14	44		1	5	67
SOUTH AFRICA	4	4					3	3	1	1		
SWITZERLAND	36	65					19	29		2	17	34
TUNISIA	2	2					2	2				
TURKEY	49	65					39	51			10	14
TURKS AND CAICOS ISLANDS		1										1

* I=Interval, C=Cumulative

Non Medically Confirmed

Region : Non-European Countries

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Non Interventional Study				Spontaneous					
			Serious Fatal		Serious Non Fatal		Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C	I	C	I	C
UKRAINE		1						1				
UNITED ARAB EMIRATES	9	52					6	29		1	3	22
UNITED KINGDOM	6,908	26,648				1	2483	5599	22	137	4403	20912
UNITED STATES	6,744	28,034		1	28	43	4498	20544	35	198	2211	7292
URUGUAY	3	4					3	4				
	14,682	57,287		1	28	44	7692	27856	75	387	6915	29044

* I=Interval, C=Cumulative

Appendix 2.4: Cumulative and Interval Summary Tabulation of Fatal Case Reports From Post-Marketing Data Sources by Country

Cumulative Reporting Period: Through 31-MAY-2021

Interval Reporting Period: 30-APR-2021 Through 31-MAY-2021

Total Number of Cases: 983 (Interval) / 4,186 (Cumulative)

MedDRA Version: v.24.0J

Country Where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Non Interventional Study		Spontaneous			
			Serious Fatal		Nonserious		Serious Fatal	
			I	C	I	C	I	C
AUSTRALIA	55	116					55	116
AUSTRIA	22	86					22	86
BELGIUM	17	104					17	104
BRAZIL	2	2					2	2
CANADA	6	11					6	11
COLOMBIA	2	3					2	3
COSTA RICA	4	11					4	11
CROATIA	3	11					3	11
CYPRUS		2						2
CZECH REPUBLIC	9	39					9	39
DENMARK	11	85					11	85
ESTONIA	5	9					5	9
FINLAND	11	59					11	59
FRANCE	113	585					113	585
FRENCH POLYNESIA		1						1
FRENCH SOUTHERN TERRITORIES		1						1
GERMANY	144	620					144	620
GREECE	13	36					13	36
HONG KONG	7	9					7	9
HUNGARY	71	96					71	96
ICELAND	1	15					1	15
INDIA	3	3					3	3
IRAQ	1	1					1	1
IRELAND	13	40					13	40
ISRAEL	2	73					2	73

* I=Interval, C=Cumulative

Country Where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Non Interventional Study		Spontaneous			
			Serious Fatal		Nonserious		Serious Fatal	
			I	C	I	C	I	C
ITALY	69	197	1	3			69	197
JAPAN	78	97					78	97
LATVIA	1	1					1	1
LEBANON	1	12					1	12
LITHUANIA	1	5					1	5
LUXEMBOURG	1	3					1	3
MALAYSIA	2	4					2	4
MALTA	2	9					2	9
MEXICO	7	24					7	24
NETHERLANDS	51	285	2	2			51	285
NORWAY	17	153					17	153
PERU	1	1					1	1
PHILIPPINES	1	1					1	1
POLAND	21	80					21	80
PORTUGAL	8	35					8	35
PUERTO RICO		1						1
ROMANIA	4	107					4	107
SAUDI ARABIA	2	3					2	3
SERBIA		1						1
SINGAPORE		1						1
SLOVAKIA	3	5					3	5
SLOVENIA	2	14					2	14
SOUTH AFRICA	2	2					2	2
SPAIN	57	163					57	163
SWEDEN	31	200					31	200
SWITZERLAND	6	30					6	30
UNITED ARAB EMIRATES		2						2
UNITED KINGDOM	52	427			1	1	51	426
UNITED STATES	45	299		1		1	45	298
	980	4,180	3	6	1	2	979	4178

* I=Interval, C=Cumulative

APPENDIX 2.5: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per MedDRA System Organ Class by Preferred Term

Cumulative Reporting Period: Through 31-MAY-2021

Interval Reporting Period: 30-APR-2021 Through 31-MAY-2021

Total Number of Cases: 47,174 (Interval) / 167,956 (Cumulative)

Total Number of Adverse Events (PT): 174,177 (Interval) / 631,356 (Cumulative)

MedDRA Version: v.24.0J

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal lymphadenopathy	1	3			1	1		2
Abnormal clotting factor	2	4			1	1	1	3
Acquired haemophilia	2	8	1	1			2	8
Agranulocytosis	1	5					1	5
Anaemia	60	139	1	1	15	37	45	102
Anaemia macrocytic		2						2
Anaemia megaloblastic		1						1
Anaemia vitamin B12 deficiency		3				2		1
Anisocytosis	1	3			1	1		2
Antiphospholipid syndrome	2	5					2	5
Aplasia pure red cell	1	1					1	1
Aplastic anaemia		1						1
Atypical haemolytic uraemic syndrome		1						1
Autoimmune anaemia	1	2					1	2
Autoimmune haemolytic anaemia	7	16					7	16
Autoimmune neutropenia		2						2
Bicytopenia	3	4					3	4
Blood disorder	6	17			2	10	4	7
Blood loss anaemia		2						2
B-lymphocyte abnormalities	1	1			1	1		
Bone marrow disorder	3	4			2	3	1	1
Bone marrow oedema		2						2
Coagulopathy	33	79			7	15	26	64

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Coombs negative haemolytic anaemia	1	3
Coombs positive haemolytic anaemia		1
Deficiency anaemia		1
Disseminated intravascular coagulation	4	12
Eosinophilia	6	18
Erythropenia		1
Evans syndrome		2
Factor VIII inhibition		1
Febrile bone marrow aplasia	1	1
Febrile neutropenia	3	4
Granulocytopenia	1	1
Haemoconcentration	1	1
Haemoglobinaemia	1	1
Haemolysis	7	11
Haemolytic anaemia	4	18
Haemolytic uraemic syndrome	1	2
Haemorrhagic diathesis	5	12
Haemorrhagic disorder	3	14
Heparin-induced thrombocytopenia		1
Hilar lymphadenopathy	2	2
Hyperchromic anaemia		1
Hypercoagulation	4	5
Hypereosinophilic syndrome	1	1
Hyperfibrinogenaemia		1
Hypergammaglobulinaemia	1	1
Hyperleukocytosis	4	22
Hypochromasia	1	2
Hypochromic anaemia	2	2
Immune thrombocytopenia	57	154
Increased tendency to bruise	4	17
Intravascular haemolysis		1
Iron deficiency anaemia	5	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
					1
			1		
				4	12
		2	5	4	13
					1
					2
					1
				1	1
				3	4
				1	1
		1	1		
				1	1
				7	11
				4	18
				1	2
				5	12
				3	14
					1
		1	1	1	1
					1
				4	5
				1	1
					1
		1	1		
				4	22
		1	2		
				2	2
	1			57	154
		1	8	3	9
					1
		2	3	3	6

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Leukaemoid reaction		1
Leukocytosis	11	45
Leukopenia	12	42
Lymphadenitis	75	300
Lymphadenopathy	1,910	8,356
Lymphadenopathy mediastinal	3	5
Lymphatic disorder	3	5
Lymphatic obstruction		1
Lymph node pain	317	1,311
Lymphocytic infiltration		1
Lymphocytosis	2	12
Lymphopenia	14	56
Mast cell activation syndrome	2	6
Mastocytosis		1
Microangiopathic haemolytic anaemia	1	2
Microcytic anaemia	2	4
Microcytosis	1	1
Monocytosis	5	11
Myelocytosis		1
Myelosuppression		5
Necrotic lymphadenopathy		3
Neutropenia	18	66
Neutropenia neonatal		1
Neutrophilia	3	14
Normochromic anaemia		1
Normochromic normocytic anaemia		3
Normocytic anaemia	2	4
Nucleated red cells	1	2
Pancytopenia	7	30
Paratracheal lymphadenopathy		3
Platelet anisocytosis		1
Platelet disorder	1	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
	1	3	16	8	29
	1			12	42
		56	176	19	124
4	24	1272	5313	638	3043
		1	3	2	2
		3	4		1
					1
3	9	188	736	129	575
					1
		2	8		4
		8	24	6	32
				2	6
					1
				1	2
		1	1	1	3
		1	1		
		3	6	2	5
					1
					5
					3
	1			18	66
					1
		2	6	1	8
					1
			3		
		1	2	1	2
		1	2		
				7	30
			1		2
					1
			2	1	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Polychromasia		2						2
Polycythaemia	2	3			1	2	1	1
Pseudolymphoma		1						1
Purpura non-thrombocytopenic	1	1					1	1
Red blood cell abnormality	1	2			1	1		1
Retroperitoneal lymphadenopathy	1	1					1	1
Sickle cell anaemia with crisis	1	4					1	4
Spleen atrophy		1						1
Spleen disorder	1	3			1	1		2
Splenic artery thrombosis	1	1					1	1
Splenic haemorrhage		1						1
Splenic infarction	3	8					3	8
Splenic vein thrombosis	4	6					4	6
Splenitis		1						1
Splenomegaly	3	16			1	6	2	10
Spontaneous haematoma	3	6	1	1	1	1	2	5
Thrombocytopenia	186	394	1	2	2	2	184	392
Thrombocytopenic purpura	7	13				2	7	11
Thrombocytosis	2	7				2	2	5
Thrombotic microangiopathy	1	5					1	5
Thrombotic thrombocytopenic purpura	5	11					5	11
White blood cell disorder		2						2
	2,855	11,418	11	42	1588	6414	1267	5004

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute cardiac event	1	6					1	6
Acute coronary syndrome	20	70					20	70

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acute left ventricular failure		2
Acute myocardial infarction	66	191
Acute right ventricular failure		1
Angina pectoris	81	247
Angina unstable	2	8
Aortic valve calcification	1	3
Aortic valve disease		1
Aortic valve incompetence	1	5
Aortic valve stenosis		6
Arrhythmia	176	550
Arrhythmia supraventricular	2	15
Arteriosclerosis coronary artery	2	11
Arteriospasm coronary		6
Atrial fibrillation	199	713
Atrial flutter	10	45
Atrial tachycardia	3	11
Atrial thrombosis	1	3
Atrioventricular block	9	22
Atrioventricular block complete	9	29
Atrioventricular block first degree	2	6
Atrioventricular block second degree	5	7
Autoimmune myocarditis	1	1
Bezold-Jarisch reflex		1
Bradyarrhythmia	1	3
Bradycardia	70	278
Bundle branch block		2
Bundle branch block left	2	14
Bundle branch block right	6	25
Cardiac amyloidosis	3	3
Cardiac aneurysm		1
Cardiac arrest	100	379
Cardiac asthma		7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
				66	191
					1
				81	247
				2	8
				1	3
					1
				1	5
					6
1	2	1	1	175	549
			1	2	14
		1	2	1	9
					6
2	4	1	1	198	712
			7	10	38
			3	3	8
				1	3
1	1	1	2	8	20
				9	29
			3	2	3
		1	1	4	6
				1	1
			1		
		1	1		2
3	4		1	70	277
					2
		1	3	1	11
		1	7	5	18
				3	3
					1
				100	379
					7

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiac discomfort	4	23
Cardiac disorder	37	132
Cardiac dysfunction	4	4
Cardiac failure	84	377
Cardiac failure acute	13	39
Cardiac failure chronic	1	7
Cardiac failure congestive	12	46
Cardiac fibrillation	6	18
Cardiac flutter	40	133
Cardiac hypertrophy	3	6
Cardiac tamponade	7	12
Cardiac valve disease	2	8
Cardiac valve sclerosis		1
Cardiac ventricular thrombosis	2	4
Cardiogenic shock	13	45
Cardiomegaly	14	25
Cardiomyopathy	6	17
Cardiopulmonary failure	11	25
Cardio-respiratory arrest	60	153
Cardio-respiratory distress		3
Cardiovascular disorder	48	188
Cardiovascular insufficiency	4	12
Cardiovascular symptom	1	1
Conduction disorder	1	2
Congestive cardiomyopathy	1	5
Coronary artery disease	10	26
Coronary artery dissection	1	3
Coronary artery insufficiency		1
Coronary artery occlusion	5	11
Coronary artery stenosis	6	18
Coronary artery thrombosis	7	16
Cor pulmonale	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	12	2	11
		11	51	26	81
				4	4
1	1			84	377
				13	39
				1	7
				12	46
				6	18
				40	133
		2	2	1	4
				7	12
			2	2	6
					1
				2	4
				13	45
		7	10	7	15
				6	17
				11	25
				60	153
					3
		29	85	19	103
				4	12
				1	1
		1	1		1
				1	5
		1	1	9	25
				1	3
					1
				5	11
				6	18
				7	16
				1	4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cor pulmonale acute	1	4
Defect conduction intraventricular	1	3
Degenerative mitral valve disease	1	1
Dilatation atrial		3
Dilatation ventricular	2	5
Extrasystoles	45	161
Foetal heart rate disorder	1	1
Heart alternation		1
Heart valve incompetence	1	3
Hepatojugular reflux		1
Hyperdynamic left ventricle		1
Hypertensive heart disease	1	11
Intracardiac thrombus	8	16
Ischaemic cardiomyopathy	2	4
Left atrial dilatation	3	4
Left ventricular dilatation		2
Left ventricular dysfunction	3	9
Left ventricular failure	4	17
Left ventricular hypertrophy	3	11
Microvascular coronary artery disease		2
Mitral valve calcification	1	3
Mitral valve disease		2
Mitral valve incompetence	6	16
Mitral valve prolapse		2
Mitral valve stenosis	1	3
Myocardial calcification	1	1
Myocardial fibrosis		3
Myocardial haemorrhage		1
Myocardial hypoxia		2
Myocardial infarction	170	490
Myocardial ischaemia	13	42
Myocardial necrosis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	4
				1	3
				1	1
					3
		1	2	1	3
1	1	16	66	29	95
				1	1
			1		
		1	2		1
			1		
					1
				1	11
				8	16
				2	4
		1	1	2	3
			2		
		1	2	2	7
				4	17
		2	3	1	8
					2
				1	3
					2
				6	16
					2
				1	3
		1	1		
					3
					1
					2
			2	170	488
				13	42
					1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myocardial oedema	1	3
Myocardial rupture	1	5
Myocarditis	98	257
Nodal rhythm		2
Palpitations	727	2,673
Paroxysmal arrhythmia		2
Paroxysmal atrioventricular block	1	1
Pericardial disease		2
Pericardial effusion	39	92
Pericardial haemorrhage	1	7
Pericarditis	89	234
Pleuropericarditis	6	8
Postural orthostatic tachycardia syndrome	10	29
Prinzmetal angina		2
Pulseless electrical activity	4	10
Restrictive cardiomyopathy	1	1
Rhythm idioventricular		1
Right ventricular dilatation	2	6
Right ventricular dysfunction	3	4
Right ventricular enlargement		2
Right ventricular failure	4	10
Right ventricular hypertrophy	1	1
Sinoatrial block	1	2
Sinus arrest		4
Sinus arrhythmia	2	3
Sinus bradycardia	7	18
Sinus node dysfunction	1	2
Sinus tachycardia	25	145
Stress cardiomyopathy	6	15
Supraventricular extrasystoles	9	31
Supraventricular tachyarrhythmia	1	2
Supraventricular tachycardia	21	79

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
				1	5
		1	2	97	255
			1		1
1	6	409	1356	318	1317
					2
				1	1
			1		1
				39	92
				1	7
				89	234
				6	8
	1	3	7	7	22
					2
				4	10
				1	1
					1
		1	3	1	3
				3	4
			2		
				4	10
				1	1
				1	2
					4
		2	2		1
		2	7	5	11
				1	2
	1	10	50	15	95
			1	6	14
		3	10	6	21
				1	2
		7	18	14	61

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Systolic dysfunction	3	3					3	3
Tachyarrhythmia	13	37	1	1	3	12	10	25
Tachycardia	1,089	3,581	3	15	742	1984	347	1597
Tachycardia foetal		1						1
Tachycardia induced cardiomyopathy		1						1
Tachycardia paroxysmal	3	13		1	1	5	2	8
Torsade de pointes	1	2					1	2
Tricuspid valve incompetence	3	9					3	9
Ventricle rupture	1	1					1	1
Ventricular arrhythmia	6	14					6	14
Ventricular dysfunction	2	3			1	1	1	2
Ventricular enlargement		1						1
Ventricular extrasystoles	20	93			5	34	15	59
Ventricular failure		1						1
Ventricular f brillation	12	45					12	45
Ventricular flutter	1	1					1	1
Ventricular hypertrophy		3						3
Ventricular hypokinesia	3	7					3	7
Ventricular tachycardia	18	45					18	45
Wandering pacemaker		1						1
	3,681	12,378	14	38	1274	3777	2407	8601

System Organ Class

Congenital, familial and genetic disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Amegakaryocytic thrombocytopenia		1						1
Anencephaly	1	2					1	2
Ankyloglossia congenital	1	1					1	1
Anomalous pulmonary venous connection		1						1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Congenital, familial and genetic disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Aplasia		1
Arteriovenous malformation	1	1
Atrial septal defect	1	2
Block vertebra	1	1
Cerebral palsy	2	5
Cleft palate	1	1
Colour blindness		1
Congenital absence of cranial vault	1	1
Congenital anomaly	1	1
Congenital cystic lung		1
Corneal dystrophy		1
Cystic lymphangioma		1
Dermoid cyst		1
Ductus arteriosus premature closure		1
Dysmorphism		1
Ehlers-Danlos syndrome	1	2
Factor II mutation		1
Factor VIII deficiency	1	1
Factor V Leiden mutation		1
Familial hemiplegic migraine		1
Familial mediterranean fever	1	2
Familial periodic paralysis		1
Foetal cystic hygroma	1	2
Foetal malformation		1
Gastroschisis		1
Gilbert's syndrome	1	1
Haemophilia		2
Heart disease congenital		2
Hereditary angioedema with normal C1 esterase inhibitor		1
Hereditary haemorrhagic telangiectasia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
				1	2
				1	1
				2	5
				1	1
			1		
				1	1
				1	1
					1
					1
					1
					1
					1
					1
				1	2
			1		
				1	1
					1
					1
				1	2
					1
				1	2
					1
		1	1		
					2
					2
					1
			1		

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Congenital, familial and genetic disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Hereditary neuropathy with liability to pressure palsies		1						1
Huntington's disease	1	6			1	2		4
Hyperreflexia	1	1			1	1		
Hyperglycinaemia		1						1
Hypertrophic cardiomyopathy	1	6					1	6
Klippel-Trenaunay syndrome	1	1					1	1
Macroglossia	3	11	1	1			3	11
Methylenetetrahydrofolate reductase gene mutation		1				1		
Moebius II syndrome	1	1					1	1
Myoclonic dystonia		2						2
Neurofibromatosis	1	1					1	1
Osteogenesis imperfecta		1						1
Porphyria		1						1
Porphyria acute		1						1
Retinitis pigmentosa		2						2
Spina bifida	1	1					1	1
Spine malformation	1	1					1	1
Syndactyly	1	2					1	2
Thyroglossal cyst		1						1
Tourette's disorder		1						1
Transposition of the great vessels	1	1					1	1
Trisomy 21	1	1					1	1
Type V hyperlipidaemia		2						2
Von Willebrand's disease		1						1
Williams syndrome	1	1					1	1
	30	94	1	1	3	8	27	86

System Organ Class

Ear and labyrinth disorders

Non Interventional Study	Spontaneous
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* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acute vestibular syndrome	1	9
Auditory disorder	4	16
Auricular swelling	1	10
Autophony		2
Cerumen impaction		2
Conductive deafness	1	3
Deafness	100	294
Deafness bilateral	9	17
Deafness neurosensory	20	59
Deafness transitory	1	10
Deafness unilateral	36	137
Dysacusis	2	5
Ear canal erythema		3
Ear congestion	10	27
Ear discomfort	91	319
Ear disorder	11	52
Ear haemorrhage	5	12
Ear pain	249	869
Ear pruritus	14	59
Ear swelling	24	77
Endolymphatic hydrops	1	3
Eustachian tube disorder	1	3
Eustachian tube dysfunction	2	7
Eustachian tube obstruction	1	1
Excessive cerumen production	1	8
External ear disorder	1	2
External ear inflammation	1	3
External ear pain	1	8
Hyperacusis	21	91
Hypoacusis	87	284
Inner ear disorder	3	12
Inner ear inflammation	4	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	1	7
		1	6	3	10
		1	5		5
			1		1
			2		
				1	3
			1	100	293
				9	17
		1	1	19	58
				1	10
1	1		1	36	136
		1	3	1	2
			2		1
		4	13	6	14
		64	230	27	89
		8	37	3	15
		1	4	4	8
		146	483	103	386
		9	42	5	17
		19	48	5	29
				1	3
			1	1	2
		2	4		3
		1	1		
			4	1	4
			1	1	1
		1	2		1
		1	6		2
		12	52	9	39
1	1	48	159	39	125
		2	5	1	7
		1	3	3	4

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Mastoid disorder		2				1		1
Meniere's disease	6	30					6	30
Middle ear disorder	1	1					1	1
Middle ear effusion	1	4			1	3		1
Middle ear inflammation		1						1
Misophonia	2	4			1	1	1	3
Motion sickness	7	50			3	28	4	22
Neurosensory hypoacusis		2	1	1				2
Otolithiasis	1	2					1	2
Otorrhoea	1	4			1	3		1
Paraesthesia ear	3	11			1	6	2	5
Phobic postural vertigo	1	1			1	1		
Presbycusis		2				1		1
Red ear syndrome	2	4			2	4		
Sudden hearing loss	20	87					20	87
Tinnitus	488	1,473	2	3	256	736	232	737
Tympanic membrane disorder		1				1		
Tympanic membrane hyperaemia		2				1		1
Tympanic membrane perforation	2	2					2	2
Vertigo	509	2,108	4	8	299	1191	210	917
Vertigo labyrinthine	4	7			2	2	2	5
Vertigo positional	20	80		1	5	18	15	62
Vestibular disorder	9	23			5	11	4	12
	1,780	6,312	9	15	900	3127	880	3185

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Addison's disease		1				1

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adrenal disorder		4				
Adrenal haemorrhage	2	2		2		2
Adrenal insufficiency		4			2	2
Adrenal mass		2		2		4
Adrenocortical insufficiency acute	3	16			3	16
Adrenomegaly	1	3	1	3		
Anovulatory cycle	3	4	2	2	1	2
Autoimmune hypothyroidism		1				1
Autoimmune thyroid disorder	1	2			1	2
Autoimmune thyroiditis	5	25			5	25
Basedow's disease	5	15			5	15
Diabetes insipidus	2	3			2	3
Endocrine disorder	1	1	1	1		
Goitre	10	30	5	14	5	16
Hyperaldosteronism	1	1			1	1
Hypercalcaemia of malignancy		1		1		
Hyperparathyroidism	1	2		1	1	1
Hyperparathyroidism primary		1		1		
Hyperthyroidism	13	37			13	37
Hypopituitarism	2	2	2	2		
Hypothyroidism	10	33			10	33
Ovulation delayed	1	1	1	1		
Pituitary apoplexy		1				1
Premature menarche	1	2	1	2		
Primary hyperaldosteronism	1	2		1	1	1
Primary hyperthyroidism	1	1			1	1
Secondary adrenocortical insufficiency		1				1
Silent thyroiditis		1				1
Thyroid cyst		1				1
Thyroid disorder	6	20	4	16	2	4
Thyroiditis	8	13	4	6	4	7
Thyroiditis acute	5	8			5	8

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* AE=Adverse Event

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System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thyroiditis subacute	3	13	2	12	1	1
Thyroid mass	5	11	3	5	2	6
Thyroid pain	2	10	2	7		3
Thyrotoxic crisis		3				3
	93	278	28	79	65	199

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal sensation in eye	9	40			5	26	4	14
Accommodation disorder	4	10			3	7	1	3
Acute macular outer retinopathy	1	3					1	3
Age-related macular degeneration	1	4					1	4
Altered visual depth perception		2				2		
Amaurosis	1	3					1	3
Amaurosis fugax	6	15					6	15
Amblyopia		2				1		1
Angle closure glaucoma	1	4					1	4
Anisometropia		1				1		
Anterior chamber cell		1						1
Arteriosclerotic retinopathy		1						1
Asthenopia	36	160			27	88	9	72
Autoimmune uveitis		1						1
Binocular eye movement disorder		3						3
Blepharitis	5	19			2	11	3	8
Blepharochalasis		1				1		
Blepharospasm	31	82			18	46	13	36
Blindness	46	149		1			46	149
Blindness cortical	1	1					1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blindness transient	12	39
Blindness unilateral	15	48
Cataract	12	21
Cataract nuclear		1
Central vision loss		2
Chalazion		3
Charles Bonnet syndrome		1
Chloropsia	2	2
Chorioretinopathy	1	3
Choroidal neovascularisation	1	4
Choroiditis		1
Chromatopsia	1	6
Ciliary muscle spasm		1
Computer vision syndrome		1
Conjunctival disorder	1	2
Conjunctival haemorrhage	26	107
Conjunctival hyperaemia	21	62
Conjunctival irritation	1	8
Conjunctival oedema	3	8
Conjunctival pallor		1
Conjunctivitis allergic	2	9
Corneal bleeding		1
Corneal degeneration		1
Corneal disorder		2
Corneal erosion		1
Corneal infiltrates		1
Corneal oedema		1
Corneal opacity	1	3
Cyanopsia	1	2
Dark circles under eyes	3	8
Dermatochalasis		1
Detachment of retinal pigment epithelium	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				12	39
				15	48
				12	21
					1
					2
			1		2
					1
				2	2
				1	3
				1	4
					1
			4	1	2
			1		
			1		
				1	2
1	3			26	107
		11	30	10	32
		1	5		3
		2	4	1	4
					1
		1	7	1	2
					1
					1
					2
					1
					1
			1		
				1	3
				1	2
		2	5	1	3
			1		
				1	1

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Diabetic eye disease		1
Diplopia	74	271
Dry age-related macular degeneration		1
Dry eye	37	146
Dyschromatopsia	3	7
Eczema eyelids	1	4
Endocrine ophthalmopathy	2	8
Episcleritis	1	13
Erythema of eyelid	8	34
Erythroptosis	2	4
Excessive eye blinking	1	3
Excessive ocular convergence		1
Exophthalmos	4	10
Exposure keratitis		1
Extraocular muscle disorder	1	3
Extraocular muscle paresis	1	6
Eye allergy	1	8
Eye colour change	2	8
Eye discharge	14	45
Eye disorder	34	148
Eye haematoma	4	9
Eye haemorrhage	34	113
Eye infarction	1	1
Eye inflammation	16	41
Eye irritation	86	314
Eyelid bleeding	1	2
Eyelid cyst		1
Eyelid disorder	6	21
Eyelid exfoliation	2	3
Eyelid function disorder	4	20
Eyelid haematoma	1	3
Eyelid irritation	4	15

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		13	105	61	166
					1
		28	98	9	48
			3	3	4
		1	4		
				2	8
			5	1	8
		5	19	3	15
		2	3		1
		1	1		2
					1
				4	10
			1		
		1	2		1
				1	6
		1	7		1
		2	4		4
		11	31	3	14
		19	93	15	55
				4	9
				34	113
				1	1
		6	19	10	22
	1	69	233	17	81
				1	2
					1
		5	16	1	5
		1	1	1	2
		3	7	1	13
		1	3		
		3	9	1	6

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eyelid margin crusting		2
Eyelid myoclonus		3
Eyelid myokymia		1
Eyelid oedema	53	182
Eyelid pain	7	31
Eyelid ptosis	19	85
Eyelid rash	5	13
Eyelid retraction		1
Eyelid sensory disorder	1	6
Eyelid skin dryness	1	1
Eyelids pruritus	12	35
Eyelid vascular disorder		1
Eye movement disorder	17	60
Eye oedema	16	48
Eye opacity		1
Eye pain	298	1,040
Eye paraesthesia	3	13
Eye pruritus	81	347
Eye swelling	125	524
Eye symptom	1	3
Eye ulcer	1	3
Floppy eyelid syndrome		1
Foreign body sensation in eyes	6	32
Gaze palsy	5	17
Giant papillary conjunctivitis		1
Glare	2	5
Glaucoma	5	19
Halo vision	4	6
Heterophoria		1
Hyperaesthesia eye	1	1
Hypermetropia	1	2
Hypoaesthesia eye	10	31

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
					3
					1
	1	33	93	20	89
		2	19	5	12
		7	40	12	45
		1	6	4	7
					1
		1	6		
				1	1
		8	20	4	15
			1		
		9	22	8	38
		12	31	4	17
			1		
	1	192	579	106	461
		3	9		4
	2	51	216	30	131
	2	68	278	57	246
		1	2		1
			2	1	1
					1
		6	21		11
				5	17
					1
		2	5		
		1	2	4	17
		2	3	2	3
					1
		1	1		
			1	1	1
		8	19	2	12

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Iridocyclitis	6	25
Iritis	2	9
Keratic precipitates		2
Keratitis	1	10
Keratoconus		1
Lacrimonial disorder	1	3
Lacrimonial structural disorder	1	1
Lacrimation decreased		2
Lacrimation disorder		1
Lacrimation increased	74	325
Lagophthalmos	1	8
Lens disorder	1	1
Lid margin discharge		1
Lid sulcus deepened	1	1
Limbal swelling		1
Macular degeneration		8
Macular hole		2
Macular oedema	2	9
Macular rupture		2
Maculopathy	1	6
Meibomian gland dysfunction		2
Metamorphopsia	8	23
Miosis	3	13
Mydriasis	26	51
Myopia		3
Necrotising retinitis		1
Night blindness		1
Noninfective chorioretinitis		1
Noninfective conjunctivitis	1	1
Ocular discomfort	43	148
Ocular dysmetria		1
Ocular hyperaemia	84	384

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				6	25
		1	5	1	4
					2
			3	1	7
					1
		1	2		1
				1	1
					2
					1
		57	214	17	111
			4	1	4
		1	1		
			1		
				1	1
					1
1	1				8
1	1				2
				2	9
					2
				1	6
			1		1
		5	8	3	15
		3	7		6
		18	33	8	18
			1		2
					1
			1		
					1
		1	1		
		35	118	8	30
			1		
		54	244	30	140

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ocular hypertension		1
Ocular ischaemic syndrome	1	1
Ocular myasthenia	2	5
Ocular sarcoidosis		1
Ocular vascular disorder	8	14
Oculogyric crisis	1	3
Open angle glaucoma	1	1
Ophthalmic artery thrombosis	3	4
Ophthalmic vein thrombosis	8	13
Ophthalmoplegia	3	6
Optic atrophy	1	2
Optic disc haemorrhage	2	2
Optic ischaemic neuropathy	2	10
Optic nerve disorder	2	4
Optic nerve infarction		1
Optic neuropathy	1	4
Orbital haematoma	1	3
Orbital oedema	1	6
Orbital swelling	1	1
Oscillopsia		2
Papilloedema	7	13
Parophthalmia		2
Periorbital discomfort	2	6
Periorbital disorder		2
Periorbital inflammation	1	1
Periorbital oedema	7	43
Periorbital pain		12
Periorbital swelling	39	169
Photophobia	112	449
Photopsia	49	143
Pigmentary glaucoma		1
Punctate keratitis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
				2	5
					1
		2	4	6	10
				1	3
				1	1
				3	4
				8	13
				3	6
				1	2
				2	2
				2	10
1	1	1	1	1	3
					1
				1	4
				1	3
				1	6
				1	1
			2		
		1	1	6	12
					2
		2	4		2
			2		
				1	1
		5	22	2	21
			6		6
		23	95	16	74
		75	242	37	207
		26	70	23	73
					1
				1	1

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pupil fixed		8
Pupillary disorder	1	6
Pupillary reflex impaired	2	5
Pupils unequal	4	14
Retinal aneurysm	1	2
Retinal artery embolism	2	2
Retinal artery occlusion	17	37
Retinal artery thrombosis	5	6
Retinal degeneration		1
Retinal detachment	8	15
Retinal disorder		4
Retinal drusen		1
Retinal exudates		2
Retinal fovea disorder		2
Retinal haemorrhage	7	15
Retinal infarction	1	1
Retinal ischaemia	2	2
Retinal oedema		1
Retinal pigment epitheliopathy	1	1
Retinal tear	2	10
Retinal toxicity		1
Retinal vascular occlusion	1	2
Retinal vascular thrombosis	3	8
Retinal vasculitis		1
Retinal vein occlusion	21	47
Retinal vein thrombosis	13	21
Retinopathy		2
Retinopathy hypertensive		1
Scintillating scotoma	3	7
Scleral discolouration	2	9
Scleral disorder	1	2
Scleral haemorrhage	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					8
		1	5		1
			1	2	4
		2	5	2	9
				1	2
				2	2
				17	37
		1	1	4	5
					1
		2	2	6	13
			2		2
					1
					2
					2
				7	15
				1	1
				2	2
					1
				1	1
				2	10
					1
				1	2
	1		1	3	7
					1
				21	47
		2	2	11	19
					2
					1
		2	5	1	2
		2	5		4
		1	1		1
				1	2

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Scleral hyperaemia		1
Scleritis	4	13
Strabismus	8	18
Subretinal haematoma	1	1
Sudden visual loss	1	9
Swelling of eyelid	68	224
Ulcerative keratitis	1	6
Uveitis	6	38
Vision blurred	351	1,181
Visual acuity reduced	19	49
Visual acuity reduced transiently		1
Visual brightness	1	3
Visual field defect	28	76
Visual impairment	201	651
Visual snow syndrome		1
Vitreoretinal traction syndrome	1	2
Vitreous degeneration		2
Vitreous detachment	18	39
Vitreous disorder	1	5
Vitreous floaters	23	62
Vitreous haemorrhage	2	7
Vitreous haze	1	1
Vitritis		1
Vogt-Koyanagi-Harada disease	1	1
Xanthopsia	1	3
Xerophthalmia		3
	2,612	9,244

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				4	13
		2	6	6	12
				1	1
				1	9
		38	129	30	95
				1	6
1	1			6	38
1	1	210	640	141	541
	1	4	15	15	34
					1
			1	1	2
		10	31	18	45
	2	99	301	102	350
					1
				1	2
					2
	1			18	39
			1	1	4
		11	27	12	35
				2	7
				1	1
					1
				1	1
			1	1	2
					3
6	21	1350	4564	1262	4680

System Organ Class

Gastrointestinal disorders

Non Interventional Study	Spontaneous
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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Abdominal adhesions		2
Abdominal discomfort	233	889
Abdominal distension	93	331
Abdominal mass	2	6
Abdominal migraine	1	3
Abdominal pain	783	2,461
Abdominal pain lower	50	150
Abdominal pain upper	502	1,934
Abdominal rigidity	1	20
Abdominal symptom	2	11
Abdominal tenderness	7	19
Abdominal wall haematoma	2	3
Abdominal wall haemorrhage		3
Abnormal faeces	21	64
Achlorhydria		1
Acquired macroglossia		1
Acute abdomen	1	12
Aerophagia	1	3
Allergic gastroenteritis	1	1
Anaesthesia oral	6	17
Anal erythema		1
Anal fissure		1
Anal haemorrhage	3	17
Anal hypoaesthesia	1	1
Anal incontinence	12	48
Anal pruritus		4
Anal rash	1	1
Anal skin tags		1
Anal sphincter atony		5
Anal sphincter hypertonia		1
Angina bullosa haemorrhagica		1
Angular cheilitis	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
1	4	161	597	72	292
		48	189	45	142
		1	4	1	2
		1	2		1
3	6	568	1583	215	878
		29	80	21	70
2	6	279	1056	223	878
		1	13		7
		1	6	1	5
		5	10	2	9
				2	3
					3
		20	52	1	12
			1		
					1
				1	12
		1	1		2
				1	1
		6	12		5
					1
					1
		1	7	2	10
				1	1
	1	4	24	8	24
			3		1
		1	1		
			1		
					5
			1		
					1
		1	4		1

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anorectal discomfort		6
Anorectal disorder		1
Anorectal swelling		1
Aphthous ulcer	23	98
Apical granuloma	1	1
Appendix disorder		2
Aptyalism	1	7
Ascites	1	8
Atrophic glossitis		1
Autoimmune pancreatitis	1	1
Barrett's oesophagus		1
Bile acid malabsorption		1
Bowel movement irregularity	12	37
Breath odour	4	21
Burning mouth syndrome	2	5
Cardiospasm	1	5
Change of bowel habit	2	5
Chapped lips	2	16
Cheilitis	11	33
Chronic gastritis		3
Coating in mouth	3	3
Coeliac artery stenosis		1
Coeliac disease	3	9
Colitis	19	54
Colitis ischaemic	5	11
Colitis microscopic	3	6
Colitis ulcerative	18	53
Constipation	61	250
Crohn's disease	9	34
Cyclic vomiting syndrome		1
Defaecation disorder		2
Defaecation urgency	7	28

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			5		1
					1
					1
	1	18	63	5	35
		1	1		
			1		1
			5	1	2
				1	8
					1
				1	1
					1
			1		
		10	32	2	5
		4	12		9
			2	2	3
			3	1	2
		1	3	1	2
		2	11		5
		8	21	3	12
			1		2
		1	1	2	2
					1
				3	9
		9	25	10	29
				5	11
				3	6
2	3			18	53
		43	151	18	99
1	1			9	34
					1
			1		1
		7	19		9

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dental caries	1	5
Dental discomfort	2	13
Dental dysaesthesia	1	1
Dental paraesthesia	3	6
Diarrhoea	1,780	6,847
Diarrhoea haemorrhagic	13	54
Discoloured vomit		5
Diverticulum	2	6
Diverticulum intestinal	1	7
Diverticulum intestinal haemorrhagic	1	1
Dry mouth	164	712
Dumping syndrome		1
Duodenal ulcer	1	2
Duodenal ulcer haemorrhage	2	4
Duodenal ulcer perforation		1
Duodenitis		1
Duodenogastric reflux	1	5
Dysbiosis		2
Dyschezia	3	7
Dyspepsia	66	345
Dysphagia	202	898
Enlarged uvula	7	34
Enteritis	5	16
Enterocolitis	3	9
Enterocolitis haemorrhagic	2	3
Enterovesical fistula	1	1
Eosinophilic oesophagitis	1	3
Epigastric discomfort	3	21
Epiplcic appendagitis	1	1
Erosive oesophagitis		1
Eructation	16	75
Faecaloma	2	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4		1
		1	11	1	2
				1	1
		1	4	2	2
4	23	1310	4384	470	2463
				13	54
			2		3
			3	2	3
			1	1	6
				1	1
	2	121	444	43	268
			1		
				1	2
				2	4
					1
					1
		1	4		1
					2
		1	3	2	4
		48	227	18	118
2	6	92	420	110	478
		4	14	3	20
1	1	2	5	3	11
				3	9
				2	3
				1	1
			2	1	1
		1	9	2	12
				1	1
					1
		13	47	3	28
				2	7

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Faecal vomiting	1	4
Faeces discoloured	10	58
Faeces hard	1	4
Faeces pale	3	9
Faeces soft	13	43
Flatulence	46	215
Food poisoning	2	10
Frequent bowel movements	9	45
Functional gastrointestinal disorder	3	22
Gastric antral vascular ectasia	2	4
Gastric dilatation	2	9
Gastric disorder	10	66
Gastric haemorrhage	1	11
Gastric ulcer	5	14
Gastric ulcer haemorrhage	3	3
Gastric varices haemorrhage		1
Gastric volvulus		1
Gastritis	18	58
Gastritis erosive		2
Gastrointestinal disorder	68	224
Gastrointestinal haemorrhage	15	52
Gastrointestinal hypermotility	1	10
Gastrointestinal hypomotility	1	4
Gastrointestinal inflammation	2	4
Gastrointestinal motility disorder	3	16
Gastrointestinal mucosal disorder		1
Gastrointestinal necrosis	3	11
Gastrointestinal obstruction		1
Gastrointestinal oedema	3	5
Gastrointestinal pain	42	147
Gastrointestinal sounds abnormal	8	32
Gastrointestinal tract irritation		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	4
		6	39	4	19
		1	2		2
		1	4	2	5
		9	29	4	14
	1	30	136	16	79
		2	7		3
		7	26	2	19
			9	3	13
				2	4
		1	4	1	5
		9	47	1	19
				1	11
				5	14
				3	3
					1
					1
		9	30	9	28
					2
	1	55	174	13	50
				15	52
		1	4		6
			2	1	2
		2	3		1
		2	13	1	3
					1
				3	11
					1
				3	5
	1	28	79	14	68
		6	20	2	12
			3		

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastrointestinal wall thickening		2
Gastroesophageal reflux disease	33	137
Gingival bleeding	20	59
Gingival blister	2	6
Gingival discolouration	1	3
Gingival discomfort	3	12
Gingival disorder	3	9
Gingival erythema	2	9
Gingival hypertrophy	1	1
Gingival oedema		2
Gingival pain	15	77
Gingival pruritus		1
Gingival recession		1
Gingival swelling	7	41
Gingival ulceration		1
Gingivitis ulcerative		2
Glossitis	10	40
Glossodynia	42	186
Haematemesis	12	74
Haematochezia	42	164
Haemoperitoneum		2
Haemorrhoidal haemorrhage		1
Haemorrhoids	7	29
Haemorrhoids thrombosed	3	5
Hiatus hernia	8	15
Hyperaesthesia teeth	11	24
Hyperchlorhydria	4	13
Hypertrophy of tongue papillae	2	3
Hypoaesthesia oral	233	919
Hypoaesthesia teeth	2	7
Ileal perforation	1	1
Ileus	4	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		19	77	14	60
		6	28	14	31
		2	5		1
		1	1		2
	1	3	8		4
		2	6	1	3
			6	2	3
		1	1		
			1		1
		9	38	6	39
					1
			1		
		2	24	5	17
			1		
					2
		6	27	4	13
		29	115	13	71
1	1			12	74
1	1		1	42	163
					2
			1		
		6	14	1	15
				3	5
		3	7	5	8
		7	16	4	8
		2	5	2	8
		2	2		1
		161	575	72	344
			5	2	2
				1	1
				4	6

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ileus paralytic	4	11
Impaired gastric emptying	7	13
Infantile vomiting		3
Inflammatory bowel disease	2	7
Infrequent bowel movements		2
Inguinal hernia	1	1
Internal hernia		1
Intestinal angina	1	1
Intestinal angioedema	1	1
Intestinal congestion		1
Intestinal dilatation		1
Intestinal haemorrhage	2	12
Intestinal infarction	2	5
Intestinal ischaemia	12	39
Intestinal mass		1
Intestinal obstruction	6	24
Intestinal perforation	1	4
Intestinal pseudo-obstruction		2
Intestinal ulcer	1	1
Intra-abdominal haematoma	2	3
Intra-abdominal haemorrhage	1	1
Intussusception		13
Irritable bowel syndrome	15	58
Large intestinal haemorrhage		1
Large intestinal obstruction		1
Large intestine perforation	2	3
Large intestine polyp		1
Lip blister	5	36
Lip discolouration	4	9
Lip disorder	5	31
Lip dry	10	49
Lip erosion		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				4	11
				7	13
			3		
				2	7
			2		
				1	1
					1
				1	1
				1	1
			1		
					1
1	1			2	12
				2	5
				12	39
					1
				6	24
				1	4
					2
				1	1
				2	3
				1	1
					13
		10	24	5	34
					1
					1
				2	3
			1		
		1	17	4	19
		2	4	2	5
		3	24	2	7
		4	24	6	25
					1

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lip erythema	4	21
Lip exfoliation	5	9
Lip haematoma		1
Lip haemorrhage	1	5
Lip oedema	52	219
Lip pain	17	67
Lip pruritus	9	71
Lip scab		1
Lip swelling	206	860
Lip ulceration		6
Loose tooth		1
Lower gastrointestinal haemorrhage		2
Malabsorption	1	1
Mallory-Weiss syndrome	1	3
Malocclusion	1	1
Megacolon		1
Melaena	8	33
Mesenteric arterial occlusion	1	2
Mesenteric artery aneurysm		1
Mesenteric artery embolism		2
Mesenteric artery stenosis	1	1
Mesenteric artery thrombosis	3	6
Mesenteric panniculitis	1	2
Mesenteric vascular insufficiency		1
Mesenteric vascular occlusion	1	1
Mesenteric vein thrombosis	14	24
Mouth cyst	1	4
Mouth haemorrhage	7	30
Mouth swelling	37	151
Mouth ulceration	39	181
Mucous stools	3	17
Nausea	5,039	19,209

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	13	1	8
		3	5	2	4
					1
		1	2		3
	1	28	103	24	116
		10	40	7	27
		4	36	5	35
					1
	2	120	428	86	432
			4		2
					1
					2
				1	1
				1	3
				1	1
					1
				8	33
				1	2
					1
					2
				1	1
				3	6
				1	2
					1
				1	1
				14	24
		1	3		1
		4	15	3	15
		16	65	21	86
1	1	25	85	14	96
		1	11	2	6
9	77	3660	12373	1379	6836

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Necrotising colitis		1
Noninfective gingivitis	6	21
Noninfective sialoadenitis		3
Obstruction gastric		1
Obstructive pancreatitis		3
Odynophagia	142	319
Oedema mouth	7	33
Oedematous pancreatitis	1	3
Oesophageal achalasia		1
Oesophageal discomfort	1	2
Oesophageal disorder	1	5
Oesophageal haemorrhage	1	1
Oesophageal irritation	1	3
Oesophageal oedema	1	2
Oesophageal pain	2	13
Oesophageal perforation		1
Oesophageal spasm	2	8
Oesophageal stenosis		2
Oesophageal ulcer haemorrhage		1
Oesophageal varices haemorrhage	1	2
Oesophagitis	1	4
Oral blood blister	4	12
Oral discharge		1
Oral discomfort	54	195
Oral disorder	12	51
Oral dysaesthesia	4	17
Oral hyperaesthesia	1	1
Oral lichen planus		3
Oral mucosa erosion		4
Oral mucosa haematoma		2
Oral mucosal blistering	14	56
Oral mucosal discolouration	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		5	13	1	8
			1		2
					1
					3
	2	119	229	23	90
	1	2	11	5	22
				1	3
			1		
			1	1	1
			1	1	4
				1	1
		1	2		1
				1	2
		1	7	1	6
					1
		2	4		4
					2
					1
				1	2
		1	3		1
		4	7		5
			1		
	1	36	131	18	64
		9	34	3	17
		2	11	2	6
				1	1
			1		2
			4		
			1		1
		11	43	3	13
		1	1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral mucosal eruption	5	18
Oral mucosal erythema	3	17
Oral mucosal exfoliation		7
Oral mucosal roughening	1	4
Oral pain	38	156
Oral papule		1
Oral pigmentation		1
Oral pruritus	29	114
Oral purpura		1
Overflow diarrhoea		1
Palatal disorder	2	6
Palatal oedema	7	52
Palatal swelling	5	31
Palatal ulcer	1	2
Pancreatic cyst	1	2
Pancreatic disorder		5
Pancreatic infarction		1
Pancreatic steatosis	1	1
Pancreatitis	14	41
Pancreatitis acute	19	45
Pancreatitis chronic	1	2
Pancreatitis haemorrhagic	1	1
Pancreatitis necrotising	1	2
Pancreatitis relapsing		2
Paraesthesia oral	336	1,691
Parotid duct obstruction		1
Parotid gland enlargement	5	15
Peptic ulcer		1
Peptic ulcer haemorrhage	2	4
Peristalsis vis ble		1
Plicated tongue	2	6
Pneumoperitoneum		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	12	3	6
		2	9	1	8
			4		3
		1	2		2
		26	94	12	62
					1
			1		
		16	56	13	58
					1
			1		
		2	4		2
		2	16	5	36
		2	14	3	17
		1	1		1
			1	1	1
			2		3
					1
		1	1		
				14	41
				19	45
				1	2
				1	1
				1	2
					2
1	5	223	1044	113	647
					1
		3	9	2	6
					1
				2	4
			1		
		2	4		2
					1

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pouchitis		1
Proctalgia	4	13
Proctitis	1	4
Proctitis haemorrhagic	1	1
Proctitis ulcerative		1
Pylorospasm		1
Rectal discharge	4	7
Rectal haemorrhage	34	106
Rectal polyp		2
Rectal prolapse		1
Rectal spasm		1
Rectal tenesmus		3
Rectal ulcer		1
Reflux gastritis	4	8
Regurgitation	1	6
Retching	34	225
Retroperitoneal haemorrhage		2
Saliva altered	1	1
Saliva discolouration		1
Salivary duct obstruction		1
Salivary gland calculus	1	1
Salivary gland disorder	1	5
Salivary gland enlargement	3	16
Salivary gland mass	1	1
Salivary gland pain	8	21
Salivary hypersecretion	36	98
Scalloped tongue	2	3
Small intestinal haemorrhage	2	6
Small intestinal obstruction		6
Splenic artery aneurysm	1	1
Steatorrhoea	1	3
Stiff tongue	2	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		2	8	2	5
		1	3		1
				1	1
					1
			1		
		1	3	3	4
				34	106
			1		1
					1
			1		
			1		2
					1
		4	7		1
		1	4		2
1	2	19	137	15	88
					2
		1	1		
					1
					1
		1	1		
			2	1	3
		1	8	2	8
				1	1
		7	15	1	6
		25	57	11	41
		1	1	1	2
				2	6
					6
				1	1
			1	1	2
		1	3	1	5

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Stomach mass	1	1
Stomatitis	32	122
Strawberry tongue		1
Subileus	1	5
Submaxillary gland enlargement	1	5
Swollen tongue	153	762
Teeth brittle		1
Teething	2	6
Terminal ileitis		1
Thrombosis mesenteric vessel	2	5
Tongue blistering	9	25
Tongue coated	5	21
Tongue cyst		2
Tongue discolouration	10	35
Tongue discomfort	25	117
Tongue disorder	21	103
Tongue dry	7	31
Tongue eruption	1	16
Tongue erythema	7	25
Tongue exfoliation	1	1
Tongue geographic	1	1
Tongue haematoma		3
Tongue haemorrhage		2
Tongue movement disturbance	2	14
Tongue oedema	28	152
Tongue pruritus	19	76
Tongue rough	3	5
Tongue spasm	2	7
Tongue ulceration	9	38
Toothache	47	188
Tooth discolouration	1	2
Tooth disorder	2	25

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
	1	20	78	12	44
			1		
			1	1	4
			4	1	1
	1	67	314	86	448
			1		
		2	3		3
					1
				2	5
		8	17	1	8
	1	3	12	2	9
			1		1
		5	20	5	15
		15	75	10	42
		12	55	9	48
		3	18	4	13
			7	1	9
		5	18	2	7
				1	1
		1	1		
			3		
			2		
		1	5	1	9
	1	9	39	19	113
		10	40	9	36
		2	4	1	1
		2	3		4
		6	24	3	14
		31	130	16	58
			1	1	1
		2	23		2

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tooth erosion		1				1		
Tooth loss	2	3			1	1	1	2
Trichoglossia	3	6			1	4	2	2
Truncus coeliacus thrombosis		1						1
Upper gastrointestinal haemorrhage	1	12					1	12
Uvulitis	1	7				3	1	4
Visceral venous thrombosis	1	3					1	3
Volvulus		3						3
Volvulus of small bowel	1	1					1	1
Vomiting	1,658	6,230	5	25	1063	3465	595	2765
Vomiting projectile	10	56			2	23	8	33
	13,418	51,710	36	182	8967	30906	4451	20804

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute phase reaction		1				1		
Adhesion		1						1
Administration site bruise	2	5			2	5		
Administration site discomfort		1				1		
Administration site erythema		5				5		
Administration site hypoaesthesia		1				1		
Administration site induration	1	1			1	1		
Administration site irritation		1				1		
Administration site joint erythema		1				1		
Administration site joint movement impairment		2						2
Administration site joint pain	1	1			1	1		
Administration site movement impairment		3				2		1
Administration site oedema		19				19		

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Administration site pain	4	95
Administration site paraesthesia		2
Administration site pruritus		5
Administration site rash		1
Administration site reaction		12
Administration site swelling		7
Administration site warmth		2
Adverse drug reaction	4	33
Adverse event	15	31
Adverse reaction		4
Alcohol interaction	3	5
Apparent death		1
Application site acne	3	3
Application site coldness		2
Application site erythema	2	5
Application site haemorrhage		1
Application site hyperaesthesia	1	1
Application site hypoaesthesia	1	1
Application site induration	1	1
Application site inflammation		1
Application site oedema	1	4
Application site pain	13	16
Application site paraesthesia		1
Application site swelling	1	2
Application site vesicles		2
Application site warmth	1	2
Asthenia	3,447	10,823
Atrophy		2
Axillary pain	444	1,650
Brain death		8
Breakthrough pain	1	3
Calcinosis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	94		1
			2		
			5		
			1		
			11		1
			7		
			2		
		4	24		9
		14	30	1	1
	1		4		
		1	1	2	4
					1
		2	2	1	1
			1		1
		2	4		1
					1
		1	1		
		1	1		
		1	1		
			1		
		1	4		
		12	15	1	1
			1		
		1	2		
					2
		1	2		
9	22	2815	7871	632	2952
			1		1
	6	240	892	204	758
					8
		1	2		1
		1	1		

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Capsular contracture associated with breast implant	1	1
Cardiac death	4	14
Catheter site haemorrhage		1
Catheter site pain		2
Chest discomfort	514	2,010
Chest pain	875	2,974
Chills	4,974	20,105
Chronic fatigue syndrome	14	49
Complication associated with device		3
Concomitant disease aggravated	1	11
Concomitant disease progression	6	7
Condition aggravated	354	1,288
Crepitations	4	13
Crying	62	186
Cyst	3	12
Cyst rupture		1
Death	204	1,045
Death neonatal		1
Decreased activity	4	13
Deformity		2
Device related thrombosis	1	1
Discharge		4
Discomfort	350	958
Disease progression	10	23
Disease recurrence	214	781
Drowning	1	6
Drug effective for unapproved indication	1	7
Drug ineffective	1,017	4,522
Drug interaction	30	96
Drug intolerance	3	4
Drug resistance		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				4	14
			1		
			2		
2	5	311	1056	203	954
6	11	425	1324	450	1650
9	59	4087	14750	887	5355
	1	9	12	5	37
			1		2
				1	11
		1	1	5	6
2	4	155	585	199	703
		4	10		3
1	1	55	136	7	50
		1	7	2	5
			1		
	1			204	1045
					1
		2	9	2	4
			2		
				1	1
			2		2
	4	266	656	84	302
		2	5	8	18
1	3	52	184	162	597
				1	6
		1	7		
10	17	4	6	1013	4516
1	1	17	56	13	40
		1	2	2	2
					1

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Drug withdrawal syndrome	2	3
Effusion	2	4
Enanthema	2	5
Energy increased	3	26
Exercise tolerance decreased	8	30
Extensive swelling of vaccinated limb	31	390
Extravasation	1	2
Eye complication associated with device		1
Face oedema	70	286
Facial discomfort	11	40
Facial pain	62	320
Fatigue	7,037	28,225
Fat tissue increased		1
Feeling abnormal	964	3,394
Feeling cold	425	1,874
Feeling drunk	25	119
Feeling hot	621	2,424
Feeling jittery	10	76
Feeling of body temperature change	120	454
Feeling of relaxation	4	7
Fever neonatal	1	3
Fibrosis	1	2
Foaming at mouth	4	17
Foreign body reaction	1	1
Gait deviation	1	1
Gait disturbance	309	1,118
Gait inability	76	314
Generalised oedema	7	20
General physical health deterioration	107	514
General symptom	4	7
Glassy eyes	1	10
Granuloma	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	2
				2	4
		1	2	1	3
		2	21	1	5
	1	4	14	4	16
		9	329	22	61
			1	1	1
					1
2	2	30	92	40	194
		9	31	2	9
		39	180	23	140
26	174	5276	19010	1761	9215
			1		
2	5	647	2305	317	1089
1	7	273	1129	152	745
		18	70	7	49
1	1	410	1568	211	856
	1	6	51	4	25
		79	256	41	198
		3	4	1	3
				1	3
			1	1	1
		2	6	2	11
				1	1
				1	1
1	2	164	577	145	541
	1	32	122	44	192
		4	9	3	11
		34	129	73	385
		4	4		3
			7	1	3
		2	2		1

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gravitational oedema	1	1
Hangover	22	71
Hernia	4	5
Hernia pain		1
High-pitched crying		1
Hunger	12	36
Hyperpyrexia	46	374
Hyperthermia	77	225
Hypothermia	28	160
Idiosyncratic drug reaction	1	2
III-defined disorder	1	7
Illness	399	1,684
Immediate post-injection reaction		1
Impaired healing	3	12
Impaired self-care		3
Implant site nodule		1
Implant site pain	1	2
Implant site swelling	1	1
Inadequate analgesia		1
Induration	305	502
Inflammation	410	882
Inflammatory pain	5	14
Influenza like illness	848	3,521
Infusion site joint swelling		1
Infusion site lymphadenopathy		1
Infusion site mobility decreased		1
Infusion site pain		4
Infusion site paraesthesia		1
Infusion site warmth		1
Inhibitory drug interaction	1	4
Injected limb mobility decreased	33	148
Injection site bruising	3	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		17	44	5	27
		2	2	2	3
			1		
			1		
		9	30	3	6
1	5			46	374
		50	124	27	101
		1	1	27	159
		1	2		
		1	4		3
	3	278	1020	121	664
			1		
		2	7	1	5
			1		2
			1		
		1	1		1
		1	1		
					1
		292	469	13	33
		333	653	77	229
		2	7	3	7
4	9	598	1954	250	1567
			1		
			1		
			1		
			4		
			1		
			1		
		1	3		1
	1	26	103	7	45
		3	13		

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site coldness		1
Injection site discharge		1
Injection site discolouration		2
Injection site discomfort	3	19
Injection site erythema	39	328
Injection site extravasation	1	5
Injection site haematoma	4	16
Injection site haemorrhage	4	14
Injection site hyperaesthesia		2
Injection site hypersensitivity	1	5
Injection site hypoaesthesia	6	12
Injection site indentation	1	2
Injection site induration	1	18
Injection site inflammation	4	14
Injection site injury		1
Injection site joint erythema	1	3
Injection site joint movement impairment		1
Injection site joint pain	1	7
Injection site joint swelling		1
Injection site lymphadenopathy		2
Injection site mass	7	20
Injection site movement impairment		1
Injection site muscle weakness		5
Injection site nodule		3
Injection site oedema	2	312
Injection site pain	166	2,648
Injection site papule		1
Injection site paraesthesia	2	21
Injection site pruritus	10	105
Injection site rash	7	41
Injection site reaction	3	56
Injection site scab	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
			2		
		3	19		
		37	321	2	7
		1	5		
		4	15		1
		4	14		
			2		
		1	4		1
		6	12		
			1	1	1
		1	18		
		4	14		
			1		
		1	3		
					1
		1	7		
			1		
			2		
		5	16	2	4
					1
			4		1
			3		
		2	312		
		155	2612	11	36
			1		
		2	21		
		9	103	1	2
		6	38	1	3
		3	48		8
		1	2		

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site scar		1
Injection site swelling	19	174
Injection site urticaria	1	44
Injection site vesicles		2
Injection site warmth	10	51
Injury associated with device	1	4
Instillation site bruise		1
Instillation site pain		1
Instillation site warmth	1	1
Irritability postvaccinal	5	11
Lithiasis		1
Localised oedema	27	112
Local reaction	194	321
Loss of control of legs	6	24
Malaise	2,950	12,594
Mass	36	118
Moaning	2	11
Mucosal discolouration		2
Mucosal disorder	4	14
Mucosal dryness	2	15
Mucosal haemorrhage	2	5
Mucosal hyperaemia		1
Mucosal inflammation	2	5
Mucosal pain	1	2
Mucosal ulceration		1
Mucosa vesicle		1
Multimorbidity		2
Multi-organ disorder	1	8
Multiple organ dysfunction syndrome	15	58
Necrosis	4	9
No adverse event	25	98
Nodule	307	531

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		18	171	1	3
		1	41		3
			1		1
		8	47	2	4
			3	1	1
			1		
			1		
		1	1		
		3	8	2	3
			1		
	1	19	65	8	47
		186	287	8	34
				6	24
12	76	2099	8426	851	4168
		26	83	10	35
		1	3	1	8
			1		1
		4	11		3
		1	10	1	5
			1	2	4
					1
			2	2	3
		1	2		
					1
					1
					2
			3	1	5
	1			15	58
				4	9
		25	98		
		294	490	13	41

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Non-cardiac chest pain	1	9
Non-pitting oedema		3
Nonspecific reaction	1	2
No reaction on previous exposure to drug	1	3
Obstruction	2	5
Oedema	428	778
Oedema mucosal	7	16
Oedema peripheral	134	415
Oral administration complication		1
Organ failure	1	3
Pain	4,180	13,748
Pelvic mass		2
Perforation	2	2
Performance status decreased	9	17
Peripheral swelling	744	2,675
Physical deconditioning	11	26
Pneumatosis		1
Polyp		3
Polyserositis		2
Potentiating drug interaction	6	39
Pre-existing condition improved	3	15
Prolapse		2
Pseudoallergic reaction		2
Puncture site bruise	1	3
Puncture site discharge		1
Puncture site erythema	1	1
Puncture site haematoma		1
Puncture site induration		4
Puncture site oedema		1
Puncture site pain	2	7
Puncture site swelling		1
Pyrexia	7,317	29,390

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			4	1	5
			1		2
		1	2		
		1	3		
		1	2	1	3
		357	615	71	163
		4	5	3	11
4	6	64	194	70	221
			1		
				1	3
3	15	3338	10156	842	3592
					2
				2	2
		7	11	2	6
1	5	416	1472	328	1203
		4	13	7	13
					1
			2		1
					2
		6	38		1
		3	14		1
			1		1
			1		1
		1	1		2
					1
		1	1		
					1
			4		
			1		
		1	6	1	1
			1		
20	108	5815	20448	1502	8942

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Reactogenicity event		2
Rebound effect		1
Screaming	4	17
Secretion discharge	12	47
Sensation of blood flow	2	9
Sensation of foreign body	75	280
Sense of oppression	2	24
Sensitivity to weather change	2	9
Serositis		2
Shoulder injury related to vaccine administration	3	12
Sluggishness	16	72
Soft tissue inflammation	1	2
Stenosis	3	8
Sudden cardiac death	8	25
Sudden death	69	282
Sudden infant death syndrome		1
Suprapubic pain	1	2
Swelling	567	2,038
Swelling face	323	1,331
Symptom recurrence	2	6
Systemic inflammatory response syndrome	6	30
Temperature intolerance	3	36
Temperature regulation disorder	21	66
Tenderness	107	399
Terminal state	3	6
Therapeutic product effect decreased	3	4
Therapeutic product effect delayed		2
Therapeutic product effect incomplete		1
Therapeutic product effect increased		1
Therapeutic product effect prolonged		1
Therapeutic product ineffective		1
Therapeutic response decreased	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
					1
		3	12	1	5
		8	32	4	15
		2	5		4
		39	127	36	153
1	1	1	9	1	15
		1	6	1	3
					2
			4	3	8
		14	57	2	15
		1	2		
			1	3	7
				8	25
	1			69	282
					1
			1	1	1
2	2	324	1209	243	829
	5	181	692	142	639
		1	3	1	3
		1	1	5	29
		2	20	1	16
		15	39	6	27
1	4	79	292	28	107
				3	6
		3	4		
			1		1
					1
					1
			1		
					1
		1	1		

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Therapeutic response increased		1
Therapeutic response unexpected	65	216
Thirst	103	357
Thirst decreased	1	3
Tissue infiltration		1
Treatment noncompliance		1
Ulcer	8	20
Ulcer haemorrhage	1	2
Unevaluable event		2
Vaccination failure	532	1,176
Vaccination site abscess sterile		2
Vaccination site anaesthesia		3
Vaccination site atrophy		2
Vaccination site bruising	72	321
Vaccination site calcification		1
Vaccination site coldness	4	19
Vaccination site cyst	1	2
Vaccination site dermatitis	2	7
Vaccination site discharge	3	11
Vaccination site discolouration	24	75
Vaccination site discomfort	86	289
Vaccination site dryness	1	4
Vaccination site dysaesthesia	1	5
Vaccination site eczema		5
Vaccination site erosion		1
Vaccination site erythema	723	3,142
Vaccination site exfoliation	1	3
Vaccination site extravasation	3	24
Vaccination site granuloma		3
Vaccination site haematoma	52	220
Vaccination site haemorrhage	41	148
Vaccination site hyperaesthesia	12	38

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		65	207		9
	1	63	211	40	146
		1	2		1
			1		
					1
		5	12	3	8
				1	2
			2		
5	8	1	8	531	1168
					2
					3
			1		1
1	1	60	241	12	80
					1
		3	16	1	3
		1	1		1
		1	4	1	3
		3	9		2
		18	55	6	20
		74	230	12	59
		1	3		1
		1	3		2
			3		2
			1		
1	2	610	2461	113	681
		1	2		1
		3	22		2
			2		1
		45	184	7	36
		26	108	15	40
		8	23	4	15

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site hypersensitivity	26	101
Vaccination site hypertrophy	1	2
Vaccination site hypoaesthesia	29	128
Vaccination site induration	149	478
Vaccination site inflammation	230	845
Vaccination site injury		5
Vaccination site irritation	10	34
Vaccination site ischaemia		1
Vaccination site joint discomfort		4
Vaccination site joint erythema	5	30
Vaccination site joint inflammation		6
Vaccination site joint movement impairment	16	79
Vaccination site joint pain	23	71
Vaccination site joint swelling	6	34
Vaccination site joint warmth		2
Vaccination site lymphadenopathy	37	165
Vaccination site macule	3	14
Vaccination site mass	128	525
Vaccination site movement impairment	101	392
Vaccination site necrosis		6
Vaccination site nerve damage	2	2
Vaccination site nodule	26	72
Vaccination site oedema	167	830
Vaccination site pain	4,872	18,730
Vaccination site pallor		3
Vaccination site papule	5	15
Vaccination site paraesthesia	50	201
Vaccination site phlebitis	1	3
Vaccination site photosensitivity reaction	1	1
Vaccination site plaque	1	3
Vaccination site pruritus	324	1,262
Vaccination site rash	100	434

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		21	90	5	11
		1	1		1
		20	87	9	41
		128	385	21	93
	1	214	754	16	91
			4		1
		9	25	1	9
					1
			4		
		5	21		9
			2		4
		11	50	5	29
		19	54	4	17
		5	31	1	3
			2		
		33	114	4	51
		3	14		
1	2	86	333	42	192
		59	255	42	137
					6
		2	2		
		24	64	2	8
	1	154	685	13	145
1	72	4363	15463	509	3267
			2		1
		4	12	1	3
		40	150	10	51
			2	1	1
		1	1		
		1	2		1
1	1	269	1007	55	255
		81	313	19	121

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site reaction	294	967
Vaccination site recall reaction		1
Vaccination site scab	2	10
Vaccination site scar	2	7
Vaccination site streaking		1
Vaccination site swelling	752	3,136
Vaccination site thrombosis		4
Vaccination site ulcer	1	3
Vaccination site urticaria	30	162
Vaccination site vesicles	5	41
Vaccination site warmth	350	1,612
Vascular stent stenosis	1	1
Vascular stent thrombosis		4
Vessel puncture site bruise		1
Vessel puncture site haemorrhage		1
Vessel puncture site injury		1
Vessel puncture site swelling		1
Visceral pain		1
Withdrawal syndrome	3	6
Xerosis		1
	52,160	200,613

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
2	2	200	563	94	404
			1		
		2	7		3
		2	6		1
			1		
	14	639	2453	113	683
					4
			1	1	2
		26	125	4	37
		5	31		10
	2	305	1317	45	295
				1	1
					4
			1		
			1		
			1		
			1		
			2	3	4
					1
135	680	38518	135343	13642	65270

System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acute hepatic failure	2	5
Autoimmune hepatitis	4	7
Bile duct stone	2	3
Biliary colic	7	15

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	5
				4	7
				2	3
		4	5	3	10

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System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Biliary cyst		1
Biliary dilatation	1	2
Biliary tract disorder		4
Cholangitis	1	4
Cholecystitis	4	13
Cholecystitis acute	1	3
Cholelithiasis	7	20
Cholelithiasis obstructive		1
Cholestasis	9	22
Cholestatic liver injury	2	3
Congestive hepatopathy	2	4
Deficiency of bile secretion		1
Drug-induced liver injury	1	6
Gallbladder disorder	2	14
Gallbladder enlargement	1	2
Gallbladder oedema		2
Gallbladder polyp		1
Granulomatous liver disease	1	2
Hepatic artery embolism		1
Hepatic cirrhosis	1	5
Hepatic cyst	1	8
Hepatic cytolysis	10	26
Hepatic failure	2	14
Hepatic function abnormal	12	27
Hepatic haematoma		1
Hepatic haemorrhage	1	2
Hepatic infarction	2	4
Hepatic lesion	1	4
Hepatic mass	1	2
Hepatic necrosis		1
Hepatic pain	10	31
Hepatic steatosis	5	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	2
			1		3
				1	4
				4	13
				1	3
		1	6	6	14
					1
				9	22
				2	3
				2	4
					1
				1	6
		1	6	1	8
				1	2
					2
			1		
				1	2
					1
				1	5
		1	5		3
				10	26
				2	14
		4	9	8	18
					1
				1	2
				2	4
			1	1	3
		1	2		
					1
		5	15	5	16
		3	8	2	4

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* AE=Adverse Event

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System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Hepatic vascular thrombosis	1	1					1	1
Hepatic vein thrombosis	2	2					2	2
Hepatitis	7	27					7	27
Hepatitis acute	6	21					6	21
Hepatitis cholestatic	1	8					1	8
Hepatocellular injury	2	6					2	6
Hepatomegaly	5	12			1	3	4	9
Hepatorenal syndrome	1	1					1	1
Hydrocholecystis	1	1					1	1
Hyperbilirubinaemia	2	10					2	10
Hypertransaminasaemia		6	1	1		1		5
Immune-mediated hepatic disorder		1						1
Immune-mediated hepatitis		1						1
Ischaemic hepatitis	1	1					1	1
Jaundice	16	59			2	14	14	45
Jaundice cholestatic		2						2
Liver disorder	7	20				4	7	16
Liver injury	3	17				1	3	16
Liver tenderness	1	3				1	1	2
Mixed liver injury	1	1					1	1
Ocular icterus	3	6			3	6		
Periportal oedema	1	1					1	1
Pneumobilia	1	1					1	1
Portal hypertension	2	2					2	2
Portal vein embolism	1	1					1	1
Portal vein phlebitis	1	1					1	1
Portal vein thrombosis	17	26					17	26
Portosplenomesenteric venous thrombosis	1	1					1	1
Primary biliary cholangitis		1						1
	177	513	1	1	26	90	151	423

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System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Allergic oedema	3	16				3	3	13
Allergic reaction to excipient	4	22			3	11	1	11
Allergy to animal	1	1			1	1		
Allergy to arthropod bite		2				1		1
Allergy to arthropod sting	1	4				2	1	2
Allergy to chemicals	3	5			1	3	2	2
Allergy to metals	1	1			1	1		
Allergy to vaccine	65	284	1	2	31	142	34	142
Amyloidosis	2	3					2	3
Amyloidosis senile	1	1					1	1
Anamnestic reaction	2	3			1	1	1	2
Anaphylactic reaction	671	2,661	1	4	1	5	670	2656
Anaphylactic shock	74	311		2			74	311
Anaphylactoid reaction	12	64					12	64
Anaphylactoid shock	2	5					2	5
Anti-neutrophil cytoplasmic antibody positive vasculitis	2	3					2	3
Atopy	1	2			1	1		1
Autoimmune disorder	25	71					25	71
Bacille Calmette-Guerin scar reactivation	3	12			1	6	2	6
Contrast media allergy		1				1		
Contrast media reaction		1						1
Corneal graft rejection	3	4					3	4
Cytokine storm		1						1
Decreased immune responsiveness	4	8			3	4	1	4
Drug hypersensitivity	23	136			9	76	14	60
Food allergy	7	25			3	10	4	15
Graft versus host disease		2						2
Haemophagocytic lymphohistiocytosis	1	9					1	9
Hypersensitivity	558	2,029	3	10	254	913	304	1116
Hypogammaglobulinaemia	2	4					2	4
Immune-mediated adverse reaction	4	9			1	3	3	6

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System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Immune reconstitution inflammatory syndrome	1	1					1	1
Immune system disorder	29	86			15	46	14	40
Immunisation reaction	4	9	1	1	2	3	2	6
Immunodeficiency	6	17	2	2			6	17
Immunodeficiency common variable	1	2					1	2
Immunosuppression	1	2					1	2
Kidney transplant rejection		1						1
Lung transplant rejection		1						1
Multiple allergies	1	4				2	1	2
Multisystem inflammatory syndrome in children	1	1					1	1
Oral allergy syndrome	2	3			1	1	1	2
Reaction to colouring		1						1
Reaction to excipient	6	29			3	13	3	16
Reaction to preservatives	1	6			1	3		3
Renal transplant failure		1						1
Rubber sensitivity		2				1		1
Sarcoidosis	5	18					5	18
Seasonal allergy	25	56			13	36	12	20
Sensitisation	3	10			2	7	1	3
Serum sickness	1	7					1	7
Serum sickness-like reaction		2						2
Solid organ transplant rejection	1	1					1	1
Systemic immune activation		5						5
Transplant rejection	1	1					1	1
Type I hypersensitivity	10	57					10	57
Type II hypersensitivity		2						2
Type III immune complex mediated reaction	2	6					2	6
Type IV hypersensitivity reaction	4	24			2	12	2	12
	1,580	6,055	8	21	350	1308	1230	4747

System Organ Class

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Abdominal abscess		1
Abdominal infection		7
Abdominal sepsis	2	2
Abdominal wall abscess		1
Abscess	11	35
Abscess jaw		1
Abscess limb	1	3
Abscess neck		1
Abscess of salivary gland	1	2
Abscess oral		3
Abscess rupture	1	1
Acarodermatitis	2	5
Acne pustular		2
Acute endocarditis		1
Acute haemorrhagic conjunctivitis	1	1
Acute sinusitis		1
Adenopathy syphilitic		2
Adenoviral conjunctivitis		1
Aerococcus urinae infection		1
African trypanosomiasis		2
Amniotic cavity infection		1
Anal abscess	2	2
Anal infection		1
Appendicitis	31	99
Appendicitis perforated	2	12
Arthritis bacterial		2
Arthritis infective	3	4
Arthritis viral		2
Arthropod infestation		1
Asymptomatic bacteriuria	1	2
Asymptomatic COVID-19	121	375
Atypical pneumonia	6	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					7
				2	2
					1
		9	21	2	14
					1
			1	1	2
					1
				1	2
			1		2
				1	1
			1	2	4
			1		1
					1
		1	1		
			1		
					2
			1		
					1
				2	2
	1		1		
				31	99
				2	12
					2
				3	4
			1		1
					1
				1	2
		9	41	112	334
				6	11

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Babesiosis		1
Bacteraemia	3	8
Bacterial diarrhoea		1
Bacterial disease carrier		2
Bacterial infection	9	21
Bacterial pyelonephritis		2
Bacterial rhinitis		1
Bacterial sepsis	1	6
Bacterial vaginosis	1	3
Bacteriuria	3	4
Beta haemolytic streptococcal infection	3	4
Biliary sepsis	1	2
Blastocystis infection		1
Blister infected		3
Body tinea		1
Bone abscess		1
Borrelia infection	2	4
Breast abscess	3	7
Breast cellulitis	1	2
Bronchiolitis		4
Bronchitis	28	97
Bronchitis bacterial	1	4
Bronchopulmonary aspergillosis		1
Bursitis infective		1
Campylobacter gastroenteritis	1	1
Campylobacter infection	1	1
Candida infection	4	18
Cardiac valve vegetation		1
Cavernous sinus thrombosis		1
Cellulitis	53	261
Cellulitis gangrenous		1
Cellulitis staphylococcal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				3	8
					1
			1		1
		5	9	4	12
					2
					1
				1	6
		1	3		
		2	2	1	2
				3	4
				1	2
					1
			3		
			1		
					1
				2	4
			1	3	6
				1	2
					4
		18	52	10	45
				1	4
					1
					1
				1	1
				1	1
		3	11	1	7
					1
					1
				53	261
					1
					1

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Central nervous system infection		1
Cholecystitis infective		2
Chorioretinitis	1	2
Chronic sinusitis	2	4
Citrobacter infection		2
Clostridial infection	1	1
Clostridium difficile colitis	1	5
Clostridium difficile infection	4	7
Coccidioidomycosis	1	3
Complicated appendicitis	2	4
Conjunctivitis	36	133
Conjunctivitis bacterial	1	5
Conjunctivitis viral	2	4
Corneal infection		2
Coronavirus infection	7	31
COVID-19	1,882	7,023
COVID-19 pneumonia	76	255
Creutzfeldt-Jakob disease		4
Croup infectious	1	1
Cystitis	35	101
Cystitis bacterial	1	2
Cystitis escherichia		1
Cystitis klebsiella		1
Cytomegalovirus infection	1	3
Cytomegalovirus infection reactivation	2	3
Dacryocystitis	1	2
Dermatitis infected		4
Dermatophytosis of nail		1
Dermo-hypodermatitis		7
Device related infection		3
Diabetic foot infection		1
Diarrhoea infectious		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					2
				1	2
		2	4		
					2
				1	1
				1	5
				4	7
				1	3
				2	4
		28	90	8	43
				1	5
		1	3	1	1
					2
			13	7	18
14	25	485	1681	1397	5342
2	4			76	255
					4
				1	1
		18	54	17	47
				1	2
					1
					1
				1	3
				2	3
				1	2
			2		2
			1		
					7
					3
			1		
					2

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Disseminated Bacillus Calmette-Guerin infection	1	13
Disseminated varicella zoster vaccine virus infection	1	1
Disseminated varicella zoster virus infection	6	11
Diverticulitis	9	52
Diverticulitis intestinal haemorrhagic	1	1
Dysentery	15	197
Ear infection	20	94
Ear infection bacterial		2
Ear infection viral		1
Ebola disease		1
Eczema herpeticum		5
Encephalitis	21	55
Encephalitis brain stem	1	1
Encephalitis enteroviral		1
Encephalitis viral	1	4
Endocarditis	2	6
Endocarditis bacterial	1	1
Endometritis	1	1
Endophthalmitis	1	1
Enteritis infectious		1
Enterococcal infection	2	6
Epididymitis	3	5
Epiglottitis		3
Epstein-Barr viraemia		1
Epstein-Barr virus infection	3	6
Epstein-Barr virus infection reactivation	2	8
Erysipelas	27	68
Erysipeloid		1
Erythema induratum	1	1
Erythema migrans	1	1
Escherichia bacteraemia	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	13
				1	1
				6	11
		1	1	8	51
				1	1
2	8			15	197
		14	54	6	40
					2
			1		
					1
					5
				21	55
				1	1
					1
				1	4
				2	6
				1	1
				1	1
					1
				2	6
				3	5
					3
			1		
		1	1	2	5
				2	8
1	1			27	68
					1
				1	1
		1	1		
				2	5

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Escherichia infection	3	10
Escherichia pyelonephritis	1	1
Escherichia sepsis	2	4
Escherichia urinary tract infection	4	11
External ear cellulitis		1
Eye abscess		1
Eye infection	7	28
Eyelid infection	1	2
Febrile infection	1	4
Flea infestation	1	1
Folliculitis		9
Fungal infection	4	16
Fungal peritonitis		1
Fungal skin infection		5
Furuncle	5	24
Gangrene		3
Gastric infection		1
Gastritis bacterial		1
Gastroenteritis	9	54
Gastroenteritis bacterial		1
Gastroenteritis norovirus		1
Gastroenteritis rotavirus		1
Gastroenteritis viral	4	28
Gastrointestinal bacterial infection	1	1
Gastrointestinal infection	1	3
Gastrointestinal viral infection		2
Genital herpes	11	28
Genital herpes simplex	3	5
Genital herpes zoster		3
Gianotti-Crosti syndrome		1
Gingival abscess	2	3
Gingivitis	10	29

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	10
				1	1
				2	4
				4	11
					1
					1
		4	14	3	14
			1	1	1
				1	4
		1	1		
			7		2
		3	13	1	3
					1
			3		2
		4	11	1	13
					3
					1
		4	24	5	30
					1
					1
					1
		3	19	1	9
				1	1
			1	1	2
			1		1
		2	11	9	17
		1	3	2	2
					3
			1		
		2	2		1
		8	23	2	6

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gonorrhoea		2
Groin abscess		1
Haematoma infection		1
Haemorrhagic fever with renal syndrome	1	1
Haemorrhagic varicella syndrome		1
Helicobacter infection		2
Hepatic cyst infection		1
Hepatitis A		1
Hepatitis B		1
Hepatitis C	2	3
Hepatitis D		1
Hepatitis E	3	3
Hepatitis infectious mononucleosis		1
Hepatitis viral		4
Herpangina		1
Herpes dermatitis	1	4
Herpes ophthalmic	8	33
Herpes pharyngitis		1
Herpes simplex	22	70
Herpes simplex encephalitis		4
Herpes simplex gastritis	1	1
Herpes simplex meningoencephalitis	1	1
Herpes simplex reactivation	1	9
Herpes virus infection	23	66
Herpes zoster	1,242	2,228
Herpes zoster cutaneous disseminated	6	11
Herpes zoster infection neurological	3	6
Herpes zoster meningitis	2	4
Herpes zoster meningoencephalitis	1	4
Herpes zoster meningoradiculitis	2	2
Herpes zoster oticus	12	30
Herpes zoster reactivation	23	37

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
					1
				1	1
					1
					2
					1
					1
					1
				2	3
					1
				3	3
					1
					4
			1		
		1	2		2
				8	33
					1
		13	44	9	26
					4
				1	1
				1	1
			6	1	3
		15	46	8	20
	2	839	1309	403	919
				6	11
				3	6
				2	4
				1	4
				2	2
1	1			12	30
		20	23	3	14

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
HIV infection	1	3
Hordeolum	6	25
Human herpesvirus 6 infection	1	1
Impetigo	3	5
Infected cyst	1	2
Infected dermal cyst		1
Infected skin ulcer		1
Infection	61	243
Infection parasitic		1
Infection reactivation	1	1
Infection susceptibility increased	1	2
Infectious mononucleosis	6	18
Infectious pleural effusion		1
Infective exacerbation of bronchiectasis		1
Infective exacerbation of chronic obstructive airways disease		4
Infective pericardial effusion	1	1
Infective tenosynovitis	2	2
Influenza	249	1,062
Infusion site infection		1
Injection site abscess		1
Injection site cellulitis	1	2
Injection site infection	1	15
Injection site pustule		1
Intervertebral discitis		2
Intestinal gangrene		1
Joint abscess		1
Kidney infection	10	36
Klebsiella infection	3	7
Labyrinthitis	16	69
Lactobacillus infection		1
Large intestine infection		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	2
		2	14	4	11
				1	1
				3	5
				1	2
					1
					1
	1	20	93	41	150
			1		
		1	1		
				1	2
		2	8	4	10
					1
					1
					4
				1	1
				2	2
3	7	157	504	92	558
					1
			1		
		1	1		1
		1	15		
					1
					2
					1
					1
				10	36
				3	7
		5	16	11	53
					1
					4

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Laryngitis	7	28
Laryngitis bacterial		1
Lip infection		1
Listeriosis	1	2
Liver abscess	2	2
Localised infection	6	39
Lower respiratory tract infection	31	136
Lower respiratory tract infection bacterial	1	1
Lower respiratory tract infection viral		1
Lung abscess	2	3
Lyme disease	5	11
Lymphadenitis bacterial		1
Lymphangitis	5	33
Lymph gland infection	2	11
Lymph node abscess	6	17
Mastitis	14	47
Mastoiditis	1	1
Measles	3	8
Mediastinitis	1	1
Meningitis	6	27
Meningitis aseptic	6	20
Meningitis bacterial	1	3
Meningitis herpes		2
Meningitis pneumococcal		1
Meningitis viral	2	13
Meningoencephalitis herpetic	4	6
Meningomyelitis herpes		1
Mononucleosis syndrome		1
Moraxella infection		1
Morganella infection		1
Mumps	4	8
Muscle abscess	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	18	1	10
					1
			1		
				1	2
				2	2
		4	19	2	20
				31	136
				1	1
					1
				2	3
				5	11
					1
				5	33
		1	5	1	6
				6	17
				14	47
				1	1
				3	8
				1	1
		1	1	5	26
				6	20
				1	3
					2
					1
				2	13
				4	6
					1
					1
					1
					1
		2	3	2	5
				1	1

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mycoplasma infection		1
Myelitis	5	23
Myocarditis infectious		1
Myocarditis septic		1
Myringitis		1
Nail infection		1
Nasal abscess		1
Nasal herpes	2	8
Nasal vestibulitis		1
Nasopharyngitis	314	1,142
Necrotising fasciitis	2	5
Neuroborreliosis		1
Neurological infection	1	1
Neutropenic sepsis		2
Nipple infection		1
Norovirus infection	1	1
Omphalitis		1
Oophoritis		1
Ophthalmic herpes simplex	2	6
Ophthalmic herpes zoster	51	99
Oral bacterial infection		1
Oral candidiasis	7	40
Oral fungal infection		6
Oral herpes	110	360
Oral infection	1	1
Oral pustule		1
Oral viral infection		3
Orchitis	1	7
Oropharyngeal candidiasis		2
Osteomyelitis	1	5
Otitis externa	1	7
Otitis media	6	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				5	23
					1
					1
			1		
					1
		1	5	1	3
					1
	1	232	824	82	318
				2	5
					1
				1	1
					2
			1		
		1	1		
					1
					1
				2	6
		1	1	50	98
					1
		3	22	4	18
			5		1
	1	82	246	28	114
				1	1
			1		
			2		1
			1	1	6
			1		1
				1	5
		1	5		2
		4	9	2	3

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Otitis media acute	1	2
Parainfluenzae viral laryngotracheobronchitis		1
Parainfluenzae virus infection	1	1
Parapharyngeal space infection		1
Paronychia	2	2
Parotitis	8	25
Parvovirus infection		1
Pathogen resistance		1
Pelvic inflammatory disease	1	2
Perichondritis		1
Periodontitis		1
Periorbital abscess		1
Periorbital cellulitis		3
Periorbital infection	1	1
Peritonitis	5	9
Peritonsillar abscess	1	3
Persistent generalised lymphadenopathy		1
Pertussis	1	4
Pharyngeal abscess	3	3
Pharyngeal pustule		1
Pharyngitis	18	63
Pharyngitis bacterial	2	3
Pharyngitis streptococcal	9	20
Pharyngotonsillitis	2	4
Pneumococcal sepsis		1
Pneumocystis jirovecii pneumonia		1
Pneumonia	160	629
Pneumonia bacterial	5	25
Pneumonia fungal		1
Pneumonia klebsiella		1
Pneumonia legionella		1
Pneumonia moraxella		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
					1
				1	1
					1
		2	2		
		4	14	4	11
			1		
					1
				1	2
			1		
			1		
					1
					3
				1	1
				5	9
				1	3
					1
				1	4
				3	3
			1		
	1	14	43	4	20
				2	3
		7	14	2	6
				2	4
					1
					1
2	2		2	160	627
				5	25
					1
					1
					1
					1

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pneumonia mycoplasmal	1	1
Pneumonia pneumococcal		3
Pneumonia pseudomonal	1	1
Pneumonia respiratory syncytial viral	1	1
Pneumonia staphylococcal		3
Pneumonia streptococcal	1	2
Pneumonia viral	2	10
Post-acute COVID-19 syndrome	4	5
Postoperative wound infection	1	2
Post procedural infection	1	2
Post viral fatigue syndrome	12	51
Prion disease		1
Progressive multifocal leukoencephalopathy	1	1
Prostate infection	1	2
Prostatic abscess		1
Pseudomembranous colitis	1	1
Pseudomonal bacteraemia	2	2
Pseudomonal sepsis	1	2
Pseudomonas infection		2
Pulmonary sepsis	2	9
Pulmonary tuberculosis		1
Pulpitis dental	1	7
Pustule	7	34
Pyelitis	1	1
Pyelonephritis	12	28
Pyelonephritis acute	3	3
Q fever	2	18
Rash pustular	7	21
Rectal abscess		1
Relapsing fever		1
Respiratory tract infection	7	53
Respiratory tract infection bacterial		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					3
				1	1
				1	1
					3
				1	2
				2	10
		1	2	3	3
				1	2
		1	1		1
	1	3	6	9	45
					1
				1	1
				1	2
					1
				1	1
				2	2
				1	2
					2
				2	9
					1
			3	1	4
	1	6	20	1	14
				1	1
				12	28
				3	3
				2	18
		3	10	4	11
					1
					1
				7	53
					2

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory tract infection viral		3
Retinitis		1
Rhinitis	36	138
Rhinolaryngitis	1	1
Rhinovirus infection		4
Root canal infection		3
Roseola		1
Rotavirus infection	1	1
Rubella		1
SARS-CoV-2 sepsis		1
Scarlet fever		2
Scrotal infection		1
Secondary transmission		1
Sepsis	31	135
Sepsis syndrome	1	2
Septic arthritis staphylococcal		2
Septic embolus	1	1
Septic pulmonary embolism		1
Septic shock	12	41
Serratia infection	2	2
Severe acute respiratory syndrome		6
Sialoadenitis	1	16
Sinusitis	43	184
Sinusitis bacterial		2
Skin bacterial infection	1	2
Skin infection	4	15
Soft tissue infection	1	5
Splenic infection		1
Sputum purulent	1	7
Staphylococcal abscess		1
Staphylococcal bacteraemia		4
Staphylococcal infection	2	14

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		1
					1
1	1	29	98	7	40
		1	1		
			3		1
			3		
			1		
		1	1		
			1		
					1
	1				2
					1
					1
				31	135
				1	2
					2
				1	1
					1
				12	41
				2	2
					6
				1	16
		32	131	11	53
					2
		1	1		1
		2	8	2	7
				1	5
					1
				1	7
			1		
					4
			1	2	13

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Staphylococcal sepsis		6
Staphylococcal skin infection		1
Streptobacillus infection	1	2
Streptococcal abscess		1
Streptococcal bacteraemia		1
Streptococcal endocarditis	1	1
Streptococcal infection	1	9
Streptococcal sepsis	1	1
Streptococcal urinary tract infection	1	1
Subcutaneous abscess	1	10
Superinfection	4	5
Superinfection bacterial	1	8
Superinfection viral		1
Suspected COVID-19	158	724
Sweating fever	6	64
Syphilis	1	2
Systemic candida		1
Tetanus		1
Thrombophlebitis septic	1	1
Tinea infection	1	1
Tinea pedis		1
Tinea versicolour	1	1
Tongue fungal infection		1
Tonsillitis	17	55
Tonsillitis bacterial	4	11
Tonsillitis streptococcal	1	1
Tooth abscess	6	15
Tooth infection	5	20
Toxocariasis		2
Toxoplasmosis		1
Tracheitis	4	13
Tracheobronchitis bacterial	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					6
					1
				1	2
					1
					1
				1	1
		1	6		3
				1	1
				1	1
		1	3		7
		2	2	2	3
				1	8
					1
		66	273	92	451
				6	64
				1	2
					1
					1
				1	1
		1	1		
			1		
		1	1		
			1		
	1	9	23	8	32
				4	11
				1	1
		3	9	3	6
		3	15	2	5
					2
			1		
		3	9	1	4
				1	1

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tuberculosis		3
Upper respiratory tract infection	2	33
Urinary tract candidiasis		1
Urinary tract infection	77	341
Urinary tract infection bacterial	1	14
Urinary tract infection enterococcal		1
Urinary tract infection pseudomonal		1
Urogenital infection bacterial		1
Urosepsis	4	27
Uterine abscess	1	1
Vaccination site abscess	3	17
Vaccination site cellulitis	15	89
Vaccination site infection	3	40
Vaccination site pustule	1	7
Vaccine breakthrough infection		19
Vaginal abscess	1	1
Vaginal infection	2	8
Varicella	8	21
Varicella zoster virus infection	6	10
Vascular device infection	1	1
Vestibular neuritis	16	52
Vestibulitis	1	2
Viral corneal ulcer		1
Viral infection	28	76
Viral keratouveitis		1
Viral labyrinthitis	1	6
Viral myelitis	1	1
Viral myocarditis	1	2
Viral pericarditis		2
Viral pharyngitis	3	7
Viral rash	5	23
Viral sepsis	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
		2	20		13
					1
	1	33	147	44	194
		1	1		13
					1
					1
				4	27
				1	1
			8	3	9
		9	36	6	53
		3	20		20
		1	6		1
					19
				1	1
		2	6		2
		4	12	4	9
		3	5	3	5
				1	1
		1	6	15	46
				1	2
					1
		12	37	16	39
					1
		1	4		2
				1	1
				1	2
					2
				3	7
		2	11	3	12
				2	3

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Viral tonsillitis		1						1
Viral upper respiratory tract infection		4				2		2
Virologic failure	1	2			1	1		1
Vulval abscess	1	2					1	2
Vulvitis		2				1		1
Vulvovaginal candidiasis	4	15			3	6	1	9
Vulvovaginal mycotic infection	2	6			2	5		1
Wound infection		4						4
Yellow fever	1	1					1	1
Yersinia bacteraemia	1	1					1	1
Yersinia infection	1	1					1	1
	5,724	19,229	26	61	2325	6510	3399	12719

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accident	4	13			1	5	3	8
Accidental exposure to product	11	68			11	67		1
Accidental exposure to product by child	1	1			1	1		
Accidental overdose	17	104			15	94	2	10
Accidental underdose		5				5		
Adverse event following immunisation	3	5					3	5
Airway burns		3						3
Alcohol poisoning		2						2
Animal attack		1				1		
Animal bite		3				3		
Ankle fracture		5						5
Arteriovenous fistula thrombosis	1	4					1	4
Arteriovenous graft thrombosis		1						1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arthropod bite	4	15
Arthropod sting		7
Atypical femur fracture		1
Autonomic dysreflexia	3	3
Back injury	8	15
Barotitis media	1	1
Barotrauma		1
Bite		4
Bone contusion	1	3
Booster dose missed	1	4
Brachial plexus injury		4
Brain contusion	1	3
Brain herniation	4	5
Burn oesophageal	2	4
Burn of internal organs		1
Burn oral cavity	1	7
Burns second degree	2	5
Burns third degree	2	2
Carbon monoxide poisoning		1
Cardiac procedure complication	1	1
Cartilage injury	1	4
Central cord syndrome		1
Cerebral hyperperfusion syndrome		1
Cerebral ventricle collapse		2
Cervical vertebral fracture	1	1
Chest crushing	1	4
Chest injury	6	16
Chillblains	25	78
Circumstance or information capable of leading to device use error		7
Circumstance or information capable of leading to medication error	58	1,029

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	13	1	2
			7		
					1
				3	3
		4	9	4	6
		1	1		
			1		
			3		1
		1	2		1
		1	4		
					4
				1	3
				4	5
		1	2	1	2
					1
				1	7
			2	2	3
				2	2
					1
				1	1
			1	1	3
					1
					1
					2
				1	1
				1	4
1	1			6	16
		19	59	6	19
			7		
		56	1027	2	2

* I=Interval, C=Cumulative
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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Clavicle fracture	1	2
Cold burn	1	3
Complications of transplanted kidney	1	1
Compression fracture	1	1
Concussion	7	29
Conjunctival laceration		1
Contraindicated product administered	2	13
Contraindicated product prescribed	1	2
Contusion	226	701
Corneal abrasion		1
Counterfeit product administered	1	6
Cranial nerve injury	1	1
Craniocerebral injury	7	17
Craniofacial fracture		1
Decreased embryo viability		1
Delayed recovery from anaesthesia	1	3
Dental restoration failure	1	3
Discontinued product administered		1
Dose calculation error		2
Drug administered in wrong device		1
Ear injury		1
Electric shock	1	6
Epicondylitis	8	16
Epidural haemorrhage	1	1
Eschar		1
Expired product administered	34	106
Exposure during pregnancy	82	241
Exposure to contaminated water		1
Exposure to extreme temperature		1
Exposure to SARS-CoV-2	16	120
Exposure to toxic agent		1
Exposure via breast milk	129	463

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		1
			2	1	1
				1	1
				1	1
		2	9	5	20
			1		
		2	10		3
			1	1	1
	2	121	399	105	302
					1
		1	6		
				1	1
			1	7	16
					1
					1
			1	1	2
		1	3		
			1		
			2		
			1		
			1		
		1	3		3
		4	9	4	7
				1	1
					1
		33	102	1	4
	1	67	204	15	37
			1		
					1
	1	15	104	1	16
			1		
		118	415	11	48

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Exposure via eye contact	1	4
Exposure via skin contact	7	46
Extra dose administered	5	10
Extradural haematoma		1
Eye contusion	4	29
Eye injury	27	54
Eyelid contusion		1
Eyelid injury	1	1
Face crushing		1
Face injury	6	29
Facial bones fracture	3	16
Failed in vitro fertilisation		1
Fall	272	994
Femoral neck fracture	2	11
Femur fracture	3	16
Foetal exposure during pregnancy	1	6
Foot fracture	3	6
Foreign body aspiration		2
Foreign body in eye		1
Foreign body in gastrointestinal tract		1
Foreign body in mouth		1
Foreign body in respiratory tract	1	1
Foreign body in throat	1	10
Foreign body in urogenital tract	1	1
Fracture	2	11
Fractured skull depressed		1
Frostbite	3	6
Gallbladder injury		1
Gastrointestinal injury		1
Gastrointestinal stoma complication		2
Gun shot wound	1	1
Hair injury	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4		
		7	46		
		4	9	1	1
					1
	1	3	22	1	7
		19	36	8	18
					1
				1	1
					1
			8	6	21
				3	16
					1
3	4	95	349	177	645
				2	11
				3	16
		1	3		3
			1	3	5
					2
			1		
					1
					1
				1	1
				1	10
				1	1
			1	2	10
					1
		2	4	1	2
			1		
			1		
			1		1
				1	1
		1	2		

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hand fracture	1	8
Head injury	47	174
Heart injury	2	16
Heat exhaustion	1	1
Heat illness	1	4
Heat oedema	1	5
Heat stroke	2	9
Hip fracture	3	22
Humerus fracture	2	5
Hyphaema		1
Hypobarism		1
Iliotibial band syndrome		1
Inadequate aseptic technique in use of product		2
Inappropriate schedule of product administration	821	2,550
Incision site haemorrhage		1
Incision site pain		3
Incomplete course of vaccination	8	45
Incorrect dosage administered		6
Incorrect dose administered	60	176
Incorrect dose administered by device		1
Incorrect dose administered by product		1
Incorrect product administration duration		2
Incorrect product formulation administered		1
Incorrect route of product administration	220	692
Inflammation of wound		1
Infusion related reaction	1	4
Injection related reaction	3	24
Injury	12	41
Injury corneal		1
Intentional dose omission		11
Intentional overdose		2
Intentional product misuse	1	16

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	8
2	2	17	57	30	117
				2	16
		1	1		
			2	1	2
			1	1	4
		2	6		3
				3	22
				2	5
					1
					1
			1		
			2		
2	2	800	2508	21	42
					1
					3
		6	43	2	2
			6		
		57	169	3	7
			1		
			1		
			2		
			1		
		202	661	18	31
			1		
				1	4
			6	3	18
		4	17	8	24
					1
			11		
			1		1
		1	16		

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Intentional product use issue	3	7
Intercepted medication error		3
Intercepted product preparation error		2
Jaw fracture	1	3
Joint dislocation	4	15
Joint injury	14	50
Lack of vaccination site rotation	1	1
Ligament injury	1	4
Ligament rupture	2	3
Ligament sprain	11	31
Limb crushing injury	1	2
Limb injury	18	89
Lip injury	5	12
Liver contusion		1
Lower limb fracture	2	9
Maternal exposure before pregnancy	3	12
Maternal exposure during breast feeding	14	34
Maternal exposure during pregnancy	165	535
Maternal exposure timing unspecified	10	27
Medication error	4	27
Meniscus injury		3
Mouth injury	4	10
Multiple fractures		2
Multiple injuries		1
Muscle contusion	1	1
Muscle injury	4	13
Muscle rupture	3	7
Muscle strain	31	86
Nail avulsion		1
Nasal injury	3	8
Neck injury	2	9
Nerve injury	19	62

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	7		
			3		
			2		
				1	3
		2	3	2	12
		9	33	5	17
		1	1		
		1	4		
		2	2		1
		3	16	8	15
				1	2
1	1	10	59	8	30
		4	8	1	4
					1
			1	2	8
		3	9		3
		7	19	7	15
5	9	123	450	42	85
		8	24	2	3
		3	23	1	4
			2		1
		2	7	2	3
					2
					1
		1	1		
		3	9	1	4
				3	7
	1	22	50	9	36
			1		
		1	5	2	3
		1	6	1	3
		8	30	11	32

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neurological procedural complication	1	1
Occupational exposure to product	4	23
Occupational exposure to SARS-CoV-2	1	9
Off label use	862	2,914
Oral contusion	1	1
Overdose	614	1,030
Palate injury	1	2
Parasympathetic nerve injury	1	1
Patella fracture		2
Paternal exposure before pregnancy		1
Paternal exposure during pregnancy	2	2
Paternal exposure timing unspecified	1	1
Pelvic fracture	4	10
Periorbital haematoma	4	7
Peripheral nerve injury		2
Peroneal nerve injury		2
Phrenic nerve injury		1
Pneumocephalus	1	1
Pneumoconiosis		1
Poisoning	1	8
Poor quality product administered	532	1,434
Post concussion syndrome	1	2
Post laminectomy syndrome		1
Post lumbar puncture syndrome	1	3
Postoperative ileus		1
Postoperative wound complication		1
Post procedural complication		4
Post procedural constipation		1
Post procedural haemorrhage		2
Post procedural oedema		1
Post-traumatic neck syndrome	2	5
Post vaccination syndrome	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		4	23		
		1	8		1
2	2	840	2836	22	78
		1	1		
		608	1014	6	16
			1	1	1
				1	1
					2
					1
		2	2		
		1	1		
				4	10
		4	4		3
					2
					2
					1
				1	1
					1
				1	8
		532	1432		2
		1	2		
					1
		1	2		1
					1
	1				4
			1		
					2
			1		
		2	2		3
				1	1

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Prescribed overdose		1
Procedural dizziness		4
Procedural haemorrhage		2
Procedural nausea		4
Procedural pain	1	4
Procedural site reaction		1
Product administered at inappropriate site	38	196
Product administered to patient of inappropriate age	25	67
Product administration error	21	63
Product administration interrupted	1	1
Product communication issue		1
Product confusion		2
Product dispensing issue		1
Product dose omission in error		2
Product dose omission issue	38	203
Product label confusion		7
Product preparation error	116	411
Product preparation issue	377	685
Product prescribing error	3	13
Product storage error	112	185
Product substitution error		1
Product use complaint		1
Product use in unapproved indication	1	5
Product use issue	223	1,354
Radial nerve injury	1	1
Radiation injury	1	1
Radiation pneumonitis	1	1
Radius fracture	1	1
Reaction to previous exposure to any vaccine		1
Recalled product administered		1
Recall phenomenon		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		3
					2
					4
			1	1	3
					1
		37	186	1	10
		24	65	1	2
		20	57	1	6
		1	1		
			1		
			2		
			1		
			2		
		38	200		3
			7		
		115	407	1	4
		377	681		4
		3	13		
		112	185		
			1		
			1		
		1	5		
		216	1308	7	46
				1	1
		1	1		
		1	1		
				1	1
					1
			1		
			2		

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rectal injury		1
Respiratory fume inhalation disorder		1
Retinal injury	1	3
Rib fracture	9	24
Road traffic accident	14	36
Scapula fracture		1
Scar	11	28
Sciatic nerve injury	1	1
Scratch	15	48
Scrotal injury		1
Sedation complication		1
Skeletal injury		3
Skin abrasion	4	19
Skin injury	2	9
Skin laceration	7	36
Skin wound		1
Skull fracture	2	4
Skull fractured base	2	3
Soft tissue injury	1	3
Spinal column injury		2
Spinal compression fracture	1	4
Spinal cord injury	1	3
Spinal fracture	4	6
Splenic rupture	1	4
Splinter		1
Sternal fracture		1
Stoma site discharge		1
Stoma site extravasation		1
Stoma site haemorrhage	2	4
Stoma site pain		1
Stoma site pruritus		1
Subcutaneous haematoma	2	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				1	3
			1	9	23
		6	12	8	24
					1
		6	14	5	14
				1	1
		11	35	4	13
			1		
					1
			2		1
		4	11		8
		1	8	1	1
		3	17	4	19
					1
				2	4
				2	3
			1	1	2
			1		1
				1	4
				1	3
				4	6
				1	4
			1		
					1
					1
			1		
				2	4
					1
			1		
		1	2	1	4

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Subdural haematoma	12	26
Subdural haemorrhage	2	6
Sunburn	7	20
Superficial injury of eye		2
Suture related complication		1
Synovial rupture		1
Tendon injury	2	7
Tendon rupture	7	10
Thermal burn	7	21
Thermal burns of eye	3	12
Thoracic vertebral fracture		1
Tibia fracture		1
Tongue injury	2	6
Tooth avulsion		2
Tooth fracture	3	9
Tooth injury	2	9
Toxic anterior segment syndrome	1	1
Toxicity to various agents	1	12
Tracheal deviation		1
Tracheal haemorrhage		1
Tracheal obstruction		3
Transcription medication error		1
Transfusion reaction		1
Transplant failure		2
Traumatic fracture		1
Traumatic haematoma	3	4
Traumatic haemorrhage	1	3
Traumatic intracranial haemorrhage	1	2
Traumatic lung injury		2
Ulnar nerve injury	1	5
Underdose	90	431
Upper limb fracture	2	18

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				12	26
				2	6
		5	14	2	6
			1		1
					1
			1		
		1	1	1	6
		3	3	4	7
		5	11	2	10
				3	12
					1
					1
		1	4	1	2
					2
		3	6		3
		1	5	1	4
				1	1
	1			1	12
					1
					1
					3
			1		
			1		
					2
					1
				3	4
				1	3
				1	2
			2		
		1	1		4
		88	427	2	4
			2	2	16

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination complication	63	259
Vaccination error	6	15
Vascular graft thrombosis	4	4
Vascular injury	5	9
Vasoplegia syndrome	2	4
Venous injury		3
Vth nerve injury		1
Vulvovaginal injury	1	1
Wound	11	42
Wound complication	3	8
Wound haemorrhage	2	13
Wound necrosis		1
Wound secretion		3
Wrist fracture	3	6
Wrong dose		1
Wrong patient received product		1
Wrong product administered	58	129
Wrong schedule		13
Wrong technique in device usage process	1	3
Wrong technique in product usage process	123	330
	6,043	19,781

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	4	50	192	13	67
		4	13	2	2
				4	4
		2	3	3	6
				2	4
					3
					1
				1	1
1	1	6	23	5	19
		2	6	1	2
		1	7	1	6
					1
					3
				3	6
			1		
			1		
		57	127	1	2
			13		
		1	3		
		121	324	2	6
18	34	5248	17133	795	2648

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Activated partial thromboplastin time abnormal		1
Activated partial thromboplastin time prolonged	10	22
Activated partial thromboplastin time ratio increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		2	6	8	16
			1		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Activated partial thromboplastin time shortened	2	8
Alanine aminotransferase		1
Alanine aminotransferase abnormal		1
Alanine aminotransferase decreased		4
Alanine aminotransferase increased	19	74
A bumin CSF increased	1	1
A bumin globulin ratio decreased		2
Allergy test positive		1
Alpha globulin increased		1
Alpha tumour necrosis factor increased		1
Amino acid level decreased		1
Amino acid level increased	1	1
Ammonia abnormal		1
Ammonia increased		1
Amphetamines positive	1	1
Amylase decreased	1	1
Amylase increased	2	10
Analgesic drug level		1
Analgesic drug level above therapeutic		1
Angiotensin converting enzyme increased		1
Anion gap abnormal		1
Anion gap decreased		1
Anion gap increased		2
Antibody test abnormal	1	29
Antibody test negative	2	11
Antibody test normal		1
Antibody test positive	1	2
Anticoagulation drug level below therapeutic		3
Anticoagulation drug level increased		1
Anti factor VIII ant body positive		2
Anti Kell antibody test positive		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	4		4
			1		
			1		
			3		1
		10	39	9	35
				1	1
			2		
			1		
			1		
					1
			1		
		1	1		
			1		
					1
		1	1		
		1	1		
			5	2	5
					1
					1
					1
			1		
			1		
			1		1
		1	29		
			9	2	2
			1		
		1	2		
			1		2
					1
					2
			1		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anti-myelin-associated glycoprotein antibodies positive		1
Antineutrophil cytoplasmic antibody positive	1	1
Antinuclear antibody	1	1
Antinuclear ant body increased	1	2
Antinuclear ant body positive	3	7
Antiphospholipid antibodies positive		2
Anti-platelet ant body		1
Antipsychotic drug level increased		1
Anti-thyroid antibody		1
Anti-thyroid antibody positive	1	5
Aortic bruit		1
Aspartate aminotransferase		1
Aspartate aminotransferase decreased		1
Aspartate aminotransferase increased	15	45
Aspiration joint	1	1
AST/ALT ratio abnormal	2	2
Audiogram abnormal		1
Auscultation		1
Autoantibody negative		1
Bacterial test		1
Bacterial test positive	3	12
Band neutrophil count increased		1
Base excess decreased		1
Basophil count abnormal		1
Basophil count decreased		2
Basophil count increased		2
Basophil percentage increased		1
Beta 2 microglobulin increased		1
Beta globulin increased		1
Bilirubin conjugated increased	1	2
Bilirubin urine present		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1		
				1	1
		1	2		
		2	4	1	3
					2
					1
					1
			1		
		1	3		2
			1		
			1		
		6	26	9	19
		1	1		
		2	2		
			1		
			1		
					1
					1
		3	7		5
					1
			1		
			1		
			2		
			2		
			1		
			1		
			1		
			1	1	1
			1		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Biopsy		1
Biopsy muscle abnormal	1	1
Blast cell count increased		1
Bleeding time abnormal		1
Bleeding time prolonged	2	2
Blood 25-hydroxycholecalciferol decreased		1
Blood albumin decreased		8
Blood albumin increased	1	2
Blood alcohol decreased	1	2
Blood alcohol increased	3	3
Blood alkaline phosphatase		1
Blood alkaline phosphatase decreased		1
Blood alkaline phosphatase increased	3	23
Blood bicarbonate decreased		4
Blood bicarbonate increased		1
Blood bilirubin abnormal	1	3
Blood bilirubin decreased		3
Blood bilirubin increased	5	24
Blood bilirubin unconjugated increased		1
Blood calcium decreased	3	16
Blood calcium increased	1	5
Blood chloride decreased		5
Blood chloride increased	2	9
Blood cholesterol		2
Blood cholesterol abnormal		5
Blood cholesterol decreased	1	3
Blood cholesterol increased	12	30
Blood chromium increased		1
Blood copper increased		2
Blood count	1	1
Blood count abnormal	2	13
Blood creatine increased	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
					1
				2	2
			1		
			7		1
			1	1	1
			1	1	1
		1	1	2	2
			1		
			1		
		1	14	2	9
			2		2
			1		
			1	1	2
			3		
		3	14	2	10
			1		
		2	13	1	3
		1	4		1
			4		1
		1	7	1	2
			2		
			5		
		1	3		
		8	22	4	8
					1
			2		
		1	1		
		2	8		5
		1	3		2

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood creatine phosphokinase abnormal		1
Blood creatine phosphokinase increased	14	47
Blood creatine phosphokinase MB increased	1	4
Blood creatinine abnormal	1	5
Blood creatinine decreased	4	8
Blood creatinine increased	16	49
Blood culture positive		1
Blood electrolytes decreased	1	2
Blood electrolytes increased		1
Blood fibrinogen decreased	1	5
Blood fibrinogen increased	15	20
Blood folate decreased	1	4
Blood folate increased		1
Blood follicle stimulating hormone increased	1	2
Blood gases abnormal		2
Blood glucose	1	3
Blood glucose abnormal	7	28
Blood glucose decreased	26	103
Blood glucose fluctuation	4	35
Blood glucose increased	64	290
Blood growth hormone abnormal		2
Blood heavy metal increased		1
Blood immunoglobulin E increased		2
Blood immunoglobulin G		1
Blood immunoglobulin G abnormal		1
Blood immunoglobulin G decreased	1	4
Blood immunoglobulin G increased	3	6
Blood immunoglobulin M abnormal		2
Blood immunoglobulin M decreased	1	2
Blood immunoglobulin M increased	2	6
Blood insulin increased		1
Blood iron decreased	6	16

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		3	17	11	30
		1	3		1
			2	1	3
		4	6		2
		9	34	7	15
					1
				1	2
			1		
			2	1	3
		12	17	3	3
			2	1	2
			1		
				1	2
					2
		1	1		2
		3	17	4	11
		13	52	13	51
		2	19	2	16
		31	168	33	122
			2		
			1		
					2
			1		
			1		
		1	4		
		1	4	2	2
			1		1
			1	1	1
		2	6		
			1		
		2	8	4	8

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood iron increased		3
Blood ketone body	1	1
Blood ketone body increased		2
Blood ketone body present		1
Blood lactate dehydrogenase abnormal		1
Blood lactate dehydrogenase increased	10	23
Blood lactic acid decreased		2
Blood lactic acid increased	6	21
Blood luteinising hormone abnormal		1
Blood magnesium decreased	1	6
Blood magnesium increased	1	2
Blood methaemoglobin present		1
Blood oestrogen increased		1
Blood osmolarity decreased		1
Blood osmolarity increased	1	2
Blood parathyroid hormone decreased	1	1
Blood parathyroid hormone increased	2	3
Blood pH		2
Blood pH abnormal	1	1
Blood pH decreased		1
Blood pH increased	1	5
Blood phosphorus decreased	2	8
Blood phosphorus increased	2	2
Blood potassium abnormal		1
Blood potassium decreased	7	45
Blood potassium increased	2	13
Blood pressure abnormal	53	127
Blood pressure ambulatory abnormal	2	2
Blood pressure ambulatory increased	2	5
Blood pressure decreased	161	506
Blood pressure diastolic decreased	9	25
Blood pressure diastolic increased	7	28

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		1
				1	1
					2
					1
			1		
		6	11	4	12
			2		
		3	9	3	12
			1		
			2	1	4
		1	2		
			1		
					1
			1		
		1	2		
		1	1		
		2	3		
					2
				1	1
					1
			2	1	3
		1	4	1	4
		1	1	1	1
					1
		3	23	4	22
			6	2	7
		31	76	22	51
				2	2
		2	4		1
	2	66	201	95	305
		5	17	4	8
		3	12	4	16

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood pressure immeasurable	6	10
Blood pressure increased	758	2,024
Blood pressure measurement	2	5
Blood pressure normal	1	1
Blood pressure orthostatic abnormal	1	2
Blood pressure orthostatic decreased	1	2
Blood pressure orthostatic increased		1
Blood pressure systolic		2
Blood pressure systolic abnormal		1
Blood pressure systolic decreased	7	17
Blood pressure systolic increased	42	121
Blood prolactin increased	1	2
Blood smear test abnormal		1
Blood sodium decreased	5	30
Blood sodium increased	4	7
Blood test	1	1
Blood test abnormal	7	27
Blood testosterone decreased		1
Blood testosterone increased		1
Blood thrombin		1
Blood thyroid stimulating hormone abnormal	1	1
Blood thyroid stimulating hormone decreased	2	6
Blood thyroid stimulating hormone increased	3	20
Blood triglycerides abnormal		1
Blood triglycerides decreased		2
Blood triglycerides increased	2	7
Blood urea abnormal		1
Blood urea decreased		2
Blood urea increased	14	31
Blood uric acid abnormal		1
Blood uric acid increased	4	10
Blood urine	4	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2	5	8
4	6	315	930	443	1094
			3	2	2
				1	1
				1	2
				1	2
			1		
			1		1
					1
		5	8	2	9
		17	48	25	73
		1	2		
			1		
		3	18	2	12
		3	4	1	3
				1	1
		5	14	2	13
			1		
			1		
					1
		1	1		
		1	3	1	3
		1	13	2	7
			1		
			2		
		1	3	1	4
			1		
			1		1
		11	24	3	7
			1		
		3	7	1	3
			4	4	6

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood urine present	24	80
Blood viscosity increased		1
Blood zinc decreased	1	1
B-lymphocyte count decreased		1
Body height decreased	5	36
Body mass index increased	1	1
Body temperature	10	34
Body temperature abnormal	34	142
Body temperature decreased	34	135
Body temperature fluctuation	15	61
Body temperature increased	539	1,607
Bone density abnormal		1
Bone density decreased		1
Brain natriuretic peptide increased	3	10
Brain scan abnormal		2
Breath sounds		3
Breath sounds abnormal	12	35
Calcium ionised decreased	1	1
Calcium ionised increased		1
Capillary nail refill test abnormal		4
Carbohydrate antigen 125 increased		2
Carbon dioxide decreased		1
Carbon dioxide increased		2
Carcinoembryonic antigen increased	1	3
Cardiac murmur	6	14
Cardio-ankle vascular index		1
Cardiothoracic ratio increased		1
Carotid bruit	1	3
CD4 lymphocytes decreased	2	2
Cell marker decreased		1
Cells in urine		1
Central venous pressure abnormal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		16	48	8	32
			1		
		1	1		
			1		
		5	35		1
		1	1		
		6	22	4	12
		22	82	12	60
		22	80	12	55
		10	31	5	30
3	6	472	1302	67	305
			1		
			1		
		1	5	2	5
					2
			2		1
		4	11	8	24
		1	1		
			1		
			3		1
			2		
					1
			1		1
				1	3
		3	4	3	10
			1		
					1
				1	3
				2	2
					1
					1
			1		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chest expansion decreased		1
Chest X-ray abnormal	3	9
Clostridium test positive	1	2
Clot retraction		1
Coagulation factor increased	1	2
Coagulation factor VIII level increased	1	1
Coagulation test abnormal	1	1
Coagulation time prolonged	1	6
Coagulation time shortened	1	1
Coma scale abnormal	3	12
Complement factor C1 increased	1	1
Complement factor C3 decreased		1
Complement factor C3 increased	1	3
Complement factor increased	1	1
Computerised tomogram normal		1
Computerised tomogram thorax abnormal		1
Corneal reflex decreased		6
Coronavirus test positive	2	7
Cortisol decreased		2
C-reactive protein	2	2
C-reactive protein abnormal	4	9
C-reactive protein decreased	1	2
C-reactive protein increased	95	350
Creatinine renal clearance decreased	1	3
Cryoglobulins present	1	1
Crystal urine		1
CSF cell count increased	2	2
CSF glucose increased	1	1
CSF immunoglobulin increased		1
CSF oligoclonal band present		1
CSF polymorphonuclear cell count increased		1
CSF protein increased	3	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		2	3	1	6
				1	2
					1
				1	2
		1	1		
		1	1		
			2	1	4
				1	1
				3	12
		1	1		
			1		
		1	2		1
		1	1		
			1		
			1		
			2		4
		1	3	1	4
					2
		1	1	1	1
		2	4	2	5
		1	2		
		47	162	48	188
		1	1		2
		1	1		
			1		
				2	2
				1	1
					1
					1
					1
				3	7

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
CSF test abnormal		1
Culture negative		1
Culture urine positive		2
Cytogenetic analysis abnormal	1	1
Cytomegalovirus test positive		3
Dermatologic examination abnormal	1	1
Differential white blood cell count abnormal		1
Digestive enzyme abnormal		1
Double stranded DNA antibody positive	1	1
Drug level decreased		1
Drug level fluctuating		1
Drug level increased		2
Drug screen positive		1
Ear, nose and throat examination abnormal		1
Eastern Cooperative Oncology Group performance status worsened		1
Ejection fraction abnormal	1	2
Ejection fraction decreased	3	9
Electrocardiogram abnormal	12	39
Electrocardiogram change	3	5
Electrocardiogram normal		1
Electrocardiogram PR prolongation		1
Electrocardiogram PR shortened		1
Electrocardiogram P wave abnormal	1	1
Electrocardiogram QRS complex prolonged	2	4
Electrocardiogram QRS complex shortened	1	4
Electrocardiogram QT interval abnormal		1
Electrocardiogram QT prolonged	2	7
Electrocardiogram repolarisation abnormality	1	6
Electrocardiogram ST segment abnormal		2
Electrocardiogram ST segment depression	3	8
Electrocardiogram ST segment elevation	7	17

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
			2		
				1	1
			2		1
				1	1
					1
			1		
				1	1
					1
					1
			1		1
			1		
			1		
			1		
			1	1	1
		1	1	2	8
		3	17	9	22
			1	3	4
					1
					1
					1
		1	1		
				2	4
				1	4
					1
				2	7
				1	6
					2
		1	1	2	7
				7	17

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Electrocardiogram ST-T change		2
Electrocardiogram ST-T segment abnormal		1
Electrocardiogram ST-T segment depression	1	1
Electrocardiogram T wave abnormal		2
Electrocardiogram T wave inversion	2	9
Electrocardiogram T wave peaked		1
Electroencephalogram abnormal	1	2
Electromyogram abnormal		1
Enzyme level increased	1	1
Eosinophil count decreased	1	8
Eosinophil count increased	1	15
Epinephrine increased	1	4
Epstein-Barr virus antibody		1
Epstein-Barr virus antibody positive	1	4
Epstein-Barr virus antigen positive		1
Epstein-Barr virus test positive	1	2
Escherichia test positive		2
Exercise electrocardiogram abnormal	1	2
Faecal calprotectin		1
Faecal calprotectin decreased	1	1
Faecal calprotectin increased	4	6
Faecal volume decreased	1	1
False negative investigation result		1
False positive investigation result		2
Fibrin D dimer increased	63	139
Fibrin degradation products increased		1
Fibrinolysis		1
Fibrinolysis abnormal	1	1
Fibroblast growth factor 23	1	1
Fibroblast growth factor 23 increased	1	1
Foetal heart rate abnormal	2	5
Foetal heart rate decreased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
				1	1
			2		
	1			2	9
			1		
		1	1		1
			1		
				1	1
		1	6		2
		1	6		9
		1	3		1
			1		
			2	1	2
			1		
			1	1	1
			2		
		1	1		1
					1
		1	1		
		3	3	1	3
		1	1		
					1
			1		1
1	1	26	57	37	82
					1
					1
				1	1
		1	1		
		1	1		
		1	1	1	4
					1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Forced expiratory flow	1	1
Forced expiratory volume increased		2
Foveal reflex abnormal		1
Full blood count		1
Full blood count abnormal	1	6
Full blood count increased		2
Gamma-glutamyltransferase increased	8	30
Gastric pH decreased	1	6
General physical condition abnormal	2	14
Glomerular filtration rate abnormal		1
Glomerular filtration rate decreased	11	37
Glucose urine present	1	2
Glycosylated haemoglobin decreased	1	2
Glycosylated haemoglobin increased	5	10
Granulocyte count increased		1
Granulocytes abnormal		2
Grip strength		1
Grip strength decreased	17	68
Haematocrit decreased	7	26
Haematocrit increased	2	7
Haematology test abnormal	1	3
Haemoglobin abnormal	1	3
Haemoglobin decreased	23	101
Haemoglobin increased	1	8
Haemoglobin urine present	1	1
Haptoglobin decreased		1
Haptoglobin increased		2
Heart rate	6	19
Heart rate abnormal	31	104
Heart rate decreased	49	177
Heart rate increased	525	1,994
Heart rate irregular	39	175

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					2
					1
			1		
		1	3		3
			1		1
		5	19	3	11
			5	1	1
		1	3	1	11
			1		
		5	22	6	15
		1	1		1
		1	2		
		3	5	2	5
			1		
			1		1
					1
		6	35	11	33
		7	24		2
			3	2	4
			1	1	2
			1	1	2
		12	49	11	52
			4	1	4
		1	1		
					1
			1		1
		4	8	2	11
	1	16	58	15	46
		22	74	27	103
		287	1162	238	832
1	1	16	82	23	93

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Heart rate normal		1
Heart sounds abnormal	3	8
Heparin-induced thrombocytopenia test positive		1
Hepatic enzyme abnormal	4	8
Hepatic enzyme increased	12	50
Hepatitis A antibody positive		1
Hepatitis A virus test positive		1
Hepatitis B antibody positive		1
Hepatitis B virus test positive		1
Herpes simplex test positive	2	3
Herpes virus test		1
High density lipoprotein decreased	2	3
High density lipoprotein increased	1	1
Histamine level increased		4
HIV antibody positive		2
HIV test false positive	1	4
HIV test negative		1
HIV test positive	1	3
Hormone level abnormal	7	13
Human chorionic gonadotropin increased	1	1
Human epidermal growth factor receptor decreased		1
Hysteroscopy	1	1
Iliac bruit	1	1
Imaging procedure abnormal	1	1
Immature granulocyte count increased		2
Immunoglobulins abnormal		2
Immunoglobulins decreased		2
Immunoglobulins increased	2	5
Immunology test	1	2
Immunology test abnormal		2
Inflammatory marker increased	18	34

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		3	4		4
			1		
				4	8
	1	3	24	9	26
			1		
			1		
			1		
		1	2	1	1
			1		
		2	3		
		1	1		
			3		1
			2		
		1	4		
					1
		1	2		1
		4	6	3	7
				1	1
					1
				1	1
				1	1
			2		
			2		
			2		
		2	4		1
			1	1	1
			2		
		8	12	10	22

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Influenza A virus test positive		1
Influenza B virus test positive		1
Inspiratory capacity abnormal	1	2
Inspiratory capacity decreased	2	5
Interleukin level increased		1
International normalised ratio abnormal		6
International normalised ratio decreased	2	28
International normalised ratio fluctuation	1	3
International normalised ratio increased	20	87
Intraocular pressure increased	5	15
Intraocular pressure test abnormal	1	2
Investigation abnormal	1	1
Iodine uptake decreased		1
Iodine uptake increased		1
Iron binding capacity total abnormal	1	1
Laboratory test abnormal	4	14
Laboratory test interference	1	1
Laboratory test normal		1
Left ventricular end-diastolic pressure increased		1
Leukocyte alkaline phosphatase increased	1	1
Lipase decreased		2
Lipase increased	3	16
Lipids abnormal		1
Lipids increased	2	5
Listeria test positive		1
Liver function test abnormal	16	34
Liver function test increased	4	26
Low density lipoprotein increased	7	14
Lumbar puncture	1	1
Lumbar puncture abnormal		1
Lymph node palpable	5	22
Lymph nodes scan abnormal		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
		1	2		
		2	3		2
					1
			2		4
		1	10	1	18
				1	3
		7	28	13	59
		2	8	3	7
		1	2		
		1	1		
			1		
					1
				1	1
		2	9	2	5
		1	1		
			1		
					1
				1	1
			2		
		2	10	1	6
			1		
		1	4	1	1
			1		
		4	8	12	26
		2	11	2	15
		4	10	3	4
				1	1
					1
		4	18	1	4
			1		2

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lymphoblast count		1
Lymphocyte count abnormal		3
Lymphocyte count decreased	13	36
Lymphocyte count increased	7	17
Lymphocyte percentage decreased		2
Lymphocyte percentage increased		1
Magnetic resonance imaging abnormal		1
Magnetic resonance imaging head abnormal	1	4
Mammogram abnormal		1
Mast cell degranulation present		1
Mean cell haemoglobin		1
Mean cell haemoglobin concentration decreased	2	7
Mean cell haemoglobin concentration increased	2	5
Mean cell haemoglobin decreased	2	7
Mean cell haemoglobin increased	2	3
Mean cell volume decreased	2	7
Mean cell volume increased	2	7
Mean platelet volume decreased	1	6
Mean platelet volume increased	1	2
Metabolic function test abnormal		3
Metamyelocyte count increased		1
Mini mental status examination abnormal		1
Misleading laboratory test result	1	1
Monoclonal immunoglobulin increased		1
Monocyte count abnormal		1
Monocyte count decreased		5
Monocyte count increased	1	17
Monocyte percentage increased		2
Muscle strength abnormal	5	8
Myelocyte count increased		2
Myocardial necrosis marker increased	5	14
Myocardial strain		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2		1
		9	28	4	8
		5	11	2	6
			2		
			1		
					1
			1	1	3
			1		
			1		
		2	7		
		2	5		
		2	6		1
		2	3		
		2	5		2
		2	7		
		1	6		
		1	2		
			2		1
					1
					1
		1	1		
					1
			1		
			4		1
		1	15		2
			2		
		3	5	2	3
			1		1
				5	14
					1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myoglobin blood increased		2
Natural killer T cell count decreased		1
Natural killer T cell count increased		1
Nerve conduction studies abnormal		2
Neurological examination abnormal		1
Neurological examination normal		1
Neutralising antibodies negative		1
Neutrophil count abnormal	4	8
Neutrophil count decreased	11	28
Neutrophil count increased	11	45
Neutrophil percentage increased	1	3
NIH stroke scale score decreased		1
Nitrite urine present		3
Norepinephrine increased		1
N-terminal prohormone brain natriuretic peptide increased	5	15
Occult blood positive	2	2
Ophthalmological examination abnormal		1
Opiates positive		1
Orthostatic heart rate response increased		1
Oxygen consumption		1
Oxygen consumption decreased	1	4
Oxygen consumption increased		1
Oxygen saturation	1	5
Oxygen saturation abnormal	5	33
Oxygen saturation decreased	211	813
Oxygen saturation immeasurable	2	3
Oxygen saturation increased	1	3
Pancreatic enzymes increased		1
Parvovirus B19 test positive	1	2
PCO2 abnormal		1
PCO2 decreased		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
			1		
			1		
			1		1
					1
			1		
			1		
		4	4		4
		8	18	3	10
		10	38	1	7
		1	2		1
					1
			3		
			1		
		4	6	1	9
		1	1	1	1
			1		
					1
			1		
			2	1	2
			1		
			2	1	3
	1	4	21	1	12
2	3	52	179	159	634
				2	3
				1	3
			1		
			1	1	1
					1
			1		1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
PCO2 increased	3	4
Peak expiratory flow rate		1
Peak expiratory flow rate abnormal		1
Peak expiratory flow rate decreased		7
pH urine		1
pH urine abnormal	1	1
pH urine increased		1
Physical examination abnormal	1	2
Plasma viscosity abnormal		1
Platelet aggregation abnormal	1	1
Platelet count abnormal		5
Platelet count decreased	67	186
Platelet count increased	12	39
Platelet function test abnormal	1	1
PO2 decreased	1	9
PO2 increased	1	1
Polymerase chain reaction positive	7	11
Positron emission tomogram		1
Pregnancy test positive		1
Procalcitonin decreased	1	1
Procalcitonin increased	5	9
Product residue present	1	2
Prohormone brain natriuretic peptide increased	2	3
Prostate examination abnormal	1	1
Prostatic specific antigen increased	3	6
Protein C increased	1	2
Protein total decreased	2	8
Protein total increased		4
Protein urine	1	1
Protein urine present	3	8
Prothrombin level abnormal		1
Prothrombin level decreased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3	1	1
					1
					1
					7
					1
				1	1
					1
		1	1		1
					1
		1	1		
			2		3
1	1	28	69	39	117
		7	24	5	15
		1	1		
		1	5		4
				1	1
		3	6	4	5
					1
			1		
		1	1		
		2	4	3	5
		1	1		1
		1	1	1	2
		1	1		
		1	3	2	3
				1	2
		2	8		
			3		1
				1	1
		1	6	2	2
					1
					1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Prothrombin level increased	1	2
Prothrombin time prolonged	3	14
Prothrombin time ratio increased		1
Prothrombin time shortened	3	5
Pulmonary arterial pressure abnormal		1
Pulmonary arterial pressure increased	1	6
Pulmonary function test		1
Pulmonary function test decreased		1
Pulse abnormal	13	59
Pulse absent	4	14
Pulse pressure decreased		2
Pulse pressure increased	3	4
Pulse volume decreased		8
Pulse waveform abnormal		1
Pupillary light reflex tests abnormal		1
Quality of life decreased	7	20
Radial pulse abnormal	3	8
Radial pulse increased		1
Radioisotope uptake increased		1
Red blood cell count abnormal	1	3
Red blood cell count decreased	8	27
Red blood cell count increased	2	7
Red blood cell sedimentation rate abnormal		2
Red blood cell sedimentation rate increased	10	46
Red blood cells urine		1
Red blood cells urine positive	1	5
Red cell distribution width decreased	2	3
Red cell distribution width increased	1	5
Renal function test abnormal	4	4
Respiratory rate	1	1
Respiratory rate decreased	3	31
Respiratory rate increased	32	134

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
		1	9	2	5
			1		
		3	4		1
					1
		1	2		4
					1
			1		
		4	23	9	36
			2	4	12
			1		1
		3	4		
			6		2
			1		
					1
		3	8	4	12
		1	2	2	6
					1
					1
			2	1	1
		5	19	3	8
		1	6	1	1
			1		1
		9	27	1	19
					1
			2	1	3
		1	2	1	1
		1	4		1
		3	3	1	1
		1	1		
		2	14	1	17
		15	49	17	85

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Reticulocyte count decreased		1
Reticulocyte count increased		1
Retinogram abnormal	1	1
Rheumatoid factor increased	2	6
Rheumatoid factor positive	1	3
Rinne tuning fork test abnormal		1
Romberg test positive		1
Salmonella test positive		1
SARS-CoV-1 test positive		3
SARS-CoV-2 ant body test		5
SARS-CoV-2 ant body test negative	4	141
SARS-CoV-2 ant body test positive	10	91
SARS-CoV-2 test		5
SARS-CoV-2 test false positive		11
SARS-CoV-2 test negative	6	20
SARS-CoV-2 test positive	103	598
Scan abdomen abnormal	1	1
Scan abnormal	1	1
Sensory level abnormal		8
Seroconversion test negative	1	5
Serology negative		2
Serratia test positive		1
Serum ferritin abnormal	1	2
Serum ferritin decreased	1	5
Serum ferritin increased	5	11
Shift to the left	1	2
Sigmoidoscopy abnormal		1
Sinus rhythm	1	5
Skin temperature	2	10
Skin test positive	1	1
Skin turgor decreased		2
Sputum abnormal		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
				1	1
		1	1	1	5
		1	3		
			1		
			1		
					1
			3		
			3		2
		3	121	1	20
		8	83	2	8
			2		3
			10		1
		3	13	3	7
4	4	37	173	66	425
				1	1
				1	1
			5		3
			3	1	2
			2		
					1
				1	2
			1	1	4
		2	7	3	4
		1	1		1
					1
			2	1	3
		2	5		5
		1	1		
					2
					3

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Stenotrophomonas test positive		1
Streptococcus test positive	1	4
Stroke volume decreased	1	1
Swollen joint count increased		1
Synovial fluid analysis abnormal	1	1
Synovial fluid white blood cells positive		1
Temperature difference of extremities		4
Temperature perception test increased		1
Thyroglobulin increased		1
Thyroid function test abnormal	1	7
Thyroid hormones increased		3
Thyroxine decreased		2
Thyroxine free decreased		1
Thyroxine free increased	1	4
Tidal volume decreased		1
T-lymphocyte count decreased	1	1
T-lymphocyte count increased		1
Total cholesterol/HDL ratio decreased	1	1
Total lung capacity decreased	1	3
Toxoplasma serology positive		1
Transaminases decreased		1
Transaminases increased	12	35
Transferrin abnormal	1	1
Transferrin decreased		1
Transferrin increased		1
Tri-iodothyronine		1
Tri-iodothyronine decreased		3
Tri-iodothyronine free decreased		1
Tri-iodothyronine free increased		1
Tri-iodothyronine increased	1	1
Troponin	1	2
Troponin abnormal	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1	1	3
				1	1
					1
				1	1
					1
					4
					1
					1
		1	7		
			2		1
			2		
			1		
		1	2		2
					1
				1	1
			1		
		1	1		
		1	2		1
			1		
					1
		4	12	8	23
				1	1
			1		
			1		
			1		
			1		
				1	1
				1	2
			1		
			1		
				1	1
				1	2
				2	3

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Troponin I decreased		1
Troponin I increased	3	12
Troponin increased	29	92
Troponin T increased	2	11
Tryptase decreased		2
Tryptase increased		2
Tuberculin test positive		1
Tumour marker abnormal		1
Tumour marker decreased		1
Tumour marker increased	2	4
Ultrasound breast abnormal	1	1
Ultrasound scan abnormal	1	1
Urea urine	1	1
Urinary occult blood	1	1
Urinary occult blood positive	3	3
Urinary sediment abnormal		1
Urinary sediment present		1
Urine analysis abnormal	4	15
Urine ketone body present	1	4
Urine leukocyte esterase positive		2
Urine output		3
Urine output decreased	7	26
Urine output increased	2	7
Urine porphobilinogen increased		1
Urine sodium increased	1	1
Urobilinogen urine increased		1
Varicella virus test positive	1	2
Vascular test abnormal	1	2
Venous bruit	1	1
Venous oxygen saturation decreased		2
Venous pressure	1	1
Vestibular function test abnormal	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			3	3	9
		4	16	25	76
		1	1	1	10
			2		
			1		1
			1		
					1
			1		
			2	2	2
				1	1
				1	1
		1	1		
				1	1
				3	3
			1		
			1		
		3	11	1	4
			2	1	2
			2		
			1		2
		3	14	4	12
		1	5	1	2
					1
				1	1
			1		
				1	2
			1	1	1
		1	1		
					2
		1	1		
				1	1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Viral test		1						1
Viral test positive		1				1		
Vital capacity		1						1
Vital functions abnormal	2	3			1	1	1	2
Vitamin B12 decreased	1	6			1	2		4
Vitamin B12 increased	1	3			1	2		1
Vitamin D		1						1
Vitamin D decreased	3	10			3	9		1
Von Willebrand's factor activity decreased		1						1
Weber tuning fork test abnormal		1				1		
Weight abnormal		1				1		
Weight decreased	88	293			52	170	36	123
Weight increased	18	57			14	43	4	14
White blood cell count abnormal	1	4				2	1	2
White blood cell count decreased	31	75	1	1	18	45	13	30
White blood cell count increased	49	142			34	86	15	56
White blood cells urine	2	4			2	2		2
White blood cells urine positive	3	8			1	5	2	3
X-ray abnormal	1	2			1	1		1
	4,179	14,320	17	29	2191	7562	1988	6758

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal loss of weight	7	10			1	2	6	8
Abnormal weight gain	3	6			2	2	1	4
Acetonaemia	1	2				1	1	1
Acidosis	2	9				1	2	8
Acidosis hyperchloraemic		1						1

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Adult failure to thrive	1	2
Alcohol intolerance		3
Appetite disorder	2	17
Body fat disorder		1
Cachexia	3	15
Cell death		5
Dairy intolerance	1	2
Decreased appetite	618	2,379
Decreased insulin requirement	1	2
Dehydration	105	402
Diabetes mellitus	22	79
Diabetes mellitus inadequate control	8	43
Diabetic complication		4
Diabetic ketoacidosis	2	20
Diabetic ketosis	2	3
Diabetic metabolic decompensation	1	6
Diet refusal	1	8
Dyslipidaemia	1	5
Eating disorder symptom	2	8
Electrolyte depletion		1
Electrolyte imbalance	2	12
Failure to thrive	1	2
Feeding disorder	57	190
Feeding intolerance	1	1
Fluid imbalance		3
Fluid intake reduced	3	20
Fluid overload	3	7
Fluid retention	15	54
Folate deficiency	4	5
Food aversion	2	14
Food craving	3	8
Food intolerance	4	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
			1		2
		2	10		7
			1		
				3	15
					5
				1	2
2	7	427	1427	191	952
		1	1		1
		40	167	65	235
				22	79
				8	43
					4
				2	20
				2	3
				1	6
				1	8
		1	5		
		2	6		2
			1		
		1	3	1	9
				1	2
		33	115	24	75
		1	1		
			1		2
			7	3	13
		2	2	1	5
		7	26	8	28
		3	4	1	1
		2	7		7
		1	3	2	5
		2	4	2	5

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Food refusal	2	14
Glucose tolerance impaired	2	4
Gluten sensitivity	1	1
Glycopenia		1
Gout	31	95
Haemochromatosis		1
Histamine intolerance		3
Hypercalcaemia	2	6
Hyperchloraemia		1
Hypercholesterolaemia	2	5
Hypercreatininaemia		1
Hyperferritinaemia	3	4
Hyperglycaemia	33	138
Hyperglycaemic hyperosmolar nonketotic syndrome		1
Hyperhomocysteinaemia	1	1
Hyperkalaemia	9	24
Hyperlactacidaemia	3	6
Hyperlipidaemia		2
Hypermetabolism	2	2
Hypernatraemia	4	23
Hyperphagia	1	4
Hypertriglyceridaemia	2	3
Hyperuricaemia	2	4
Hypervitaminosis B12		1
Hypervolaemia		1
Hypoalbuminaemia	3	6
Hypocalcaemia	4	12
Hypoglycaemia	44	153
Hypokalaemia	12	57
Hypokalaemic syndrome		3
Hypomagnesaemia	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4	1	10
			2	2	2
				1	1
			1		
		11	41	20	54
			1		
			1		2
			1	2	5
					1
		1	3	1	2
					1
		1	1	2	3
		9	31	24	107
					1
		1	1		
				9	24
				3	6
			1		1
		1	1	1	1
		1	5	3	18
		1	3		1
		1	1	1	2
		1	3	1	1
					1
					1
		1	3	2	3
		2	3	2	9
		14	48	30	105
			1	12	56
			1		2
			1	1	2

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyponatraemia	14	43
Hyponatraemic syndrome		2
Hypophagia	15	61
Hypophosphataemia	1	2
Hypoproteinaemia	1	1
Hypovitaminosis	1	4
Hypovolaemia		2
Impaired fasting glucose	1	1
Increased appetite	9	19
Increased insulin requirement	1	2
Insulin-requiring type 2 diabetes mellitus		1
Insulin resistance	2	9
Insulin resistant diabetes	1	2
Iron deficiency	5	10
Ketoacidosis	2	9
Lactic acidosis	2	9
Lactose intolerance	2	3
Latent autoimmune diabetes in adults		2
Lipid metabolism disorder		1
Malnutrition	6	13
Marasmus	3	6
Metabolic acidosis	7	21
Metabolic alkalosis		1
Metabolic disorder		3
Metabolic syndrome		1
Mineral metabolism disorder	1	1
Obesity	2	3
Oligodipsia		1
Overfeeding of infant		1
Overweight	2	7
Polydipsia	6	25
Poor feeding infant	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1	4	13	10	30
			1		1
		5	16	10	45
		1	2		
		1	1		
		1	2		2
					2
				1	1
		8	17	1	2
		1	1		1
					1
			1	2	8
				1	2
		4	6	1	4
				2	9
			1	2	8
		2	3		
					2
			1		
		2	6	4	7
				3	6
			2	7	19
			1		
			1		2
					1
				1	1
		2	3		
					1
			1		
		2	5		2
		3	13	3	12
		2	3		1

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Postprandial hypoglycaemia		1						1
Salt craving		1						1
Shock hypoglycaemic	1	1					1	1
Starvation	3	4					3	4
Tetany	6	16			3	5	3	11
Type 1 diabetes mellitus	3	19					3	19
Type 2 diabetes mellitus	3	12				1	3	11
Underweight	1	4			1	2		2
Vitamin B12 deficiency	2	3			2	2		1
Vitamin B complex deficiency	1	1			1	1		
Vitamin D deficiency	2	15			2	9		6
Weight fluctuation	1	7			1	7		
Weight loss poor		1						1
	1,151	4,293	3	8	622	2083	529	2210

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Amyotrophy		1						1
Aneurysmal bone cyst	1	1			1	1		
Ankylosing spondylitis	7	21					7	21
Antisynthetase syndrome	1	2			1	1		1
Arthralgia	4,272	16,129	8	64	3275	11255	997	4874
Arthritis	103	326			45	156	58	170
Arthritis allergic		1						1
Arthritis enteropathic		1						1
Arthritis reactive	9	40		1			9	40
Arthropathy	26	84			19	63	7	21
Autoimmune arthritis	1	2					1	2

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Axillary mass	49	177
Back disorder	14	30
Back pain	839	3,049
Bone development abnormal		1
Bone disorder	5	13
Bone formation increased		1
Bone pain	181	828
Bone swelling	6	26
Bursa disorder		1
Bursal fluid accumulation		1
Bursal haematoma	1	2
Bursitis	17	63
Camptocormia	1	1
Cervical spinal stenosis	1	3
Chondritis		2
Chondrocalcinosis	1	2
Coccydynia	5	9
Connective tissue disorder	1	3
Connective tissue inflammation		1
Costochondritis	11	35
CREST syndrome		1
Crystal arthropathy		1
Dactylitis		1
Decreased nasolabial fold		2
Degenerative bone disease	1	2
Drooping shoulder syndrome		1
Dupuytren's contracture		2
Enthesopathy	5	9
Epiphyses premature fusion		1
Extremity contracture	3	7
Facet joint syndrome	1	2
Facial asymmetry	5	18

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		26	90	23	87
		12	27	2	3
	6	572	1870	267	1179
			1		
		4	10	1	3
			1		
	3	127	551	54	277
		3	17	3	9
			1		
			1		
				1	2
	1	8	25	9	38
		1	1		
				1	3
			1		1
				1	2
		4	8	1	1
				1	3
			1		
		6	10	5	25
					1
					1
					1
			1		1
		1	2		
			1		
					2
		1	2	4	7
					1
		2	6	1	1
		1	2		
		2	5	3	13

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Fasciitis	1	4
Fibromyalgia	30	84
Finger deformity	3	6
Fistula		3
Flank pain	13	74
Foot deformity	1	6
Fracture pain	1	1
Gouty tophus		1
Groin pain	39	128
Growing pains	1	1
Haemarthrosis	5	13
Haematoma muscle	4	9
Hand deformity	1	6
Head deformity		2
Hypermobility syndrome	1	1
Immobilisation syndrome	1	2
Immune-mediated arthritis		1
Immunoglobulin G4 related disease	1	1
Inguinal mass		1
Intervertebral disc compression		2
Intervertebral disc degeneration	1	4
Intervertebral disc disorder	2	4
Intervertebral disc protrusion	5	19
Jaw clicking	2	7
Jaw cyst		1
Jaw disorder	9	23
Joint adhesion	1	1
Joint ankylosis	1	4
Joint contracture	1	4
Joint destruction		1
Joint effusion	9	39
Joint hyperextension		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	3
	1	19	39	11	45
		1	4	2	2
			2		1
		4	42	9	32
		1	5		1
				1	1
					1
	2	21	68	18	60
		1	1		
				5	13
		1	1	3	8
		1	2		4
			1		1
				1	1
			1	1	1
					1
				1	1
					1
					2
			3	1	1
		2	4		
			8	5	11
		1	4	1	3
			1		
	1	7	17	2	6
		1	1		
		1	2		2
		1	4		
					1
		5	16	4	23
			1		

* I=Interval, C=Cumulative

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Joint instability	3	9
Joint laxity		2
Joint lock	3	22
Joint microhaemorrhage	1	2
Joint noise	6	17
Joint range of motion decreased	89	335
Joint stiffness	55	249
Joint swelling	161	584
Joint vibration		1
Joint warmth	6	19
Knee deformity		1
Ligament disorder	1	3
Ligamentitis	1	2
Ligament pain	1	3
Limb deformity	3	4
Limb discomfort	402	1,446
Limb mass	14	54
Loose body in joint		1
Lordosis	1	1
Lupus-like syndrome	1	2
Lupus myositis		1
Mandibular mass	1	2
Mastication disorder	7	28
Masticatory pain		1
Medial tibial stress syndrome	1	2
Mixed connective tissue disease	1	2
Mobility decreased	148	574
Morphoea	1	1
Muscle atrophy	2	16
Muscle contracture	3	35
Muscle discomfort	10	40
Muscle disorder	7	43

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	3	7
					2
		1	13	2	9
				1	2
		3	8	3	9
	1	43	160	46	175
		29	112	26	137
		88	308	73	276
					1
		4	10	2	9
			1		
				1	3
				1	2
			2	1	1
		3	4		
3	8	281	921	121	525
		7	31	7	23
					1
				1	1
				1	2
					1
		1	2		
		4	18	3	10
			1		
				1	2
				1	2
		84	301	64	273
				1	1
			8	2	8
	1	3	25		10
		6	33	4	7
		3	30	4	13

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* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle fatigue	35	216
Muscle haemorrhage	2	2
Muscle hypertrophy	1	1
Muscle mass	2	5
Muscle oedema		5
Muscle rigidity	20	63
Muscle spasms	331	1,184
Muscle swelling	10	36
Muscle tightness	65	260
Muscle twitching	86	316
Muscular weakness	404	1,573
Musculoskeletal chest pain	67	284
Musculoskeletal deformity		1
Musculoskeletal discomfort	55	226
Musculoskeletal disorder	29	84
Musculoskeletal pain	102	687
Musculoskeletal stiffness	404	1,562
Myalgia	5,523	21,221
Myalgia intercostal	1	7
Myofascial pain syndrome		5
Myofascial spasm	1	1
Myokymia	2	7
Myopathy	6	7
Myosclerosis	3	8
Myositis	19	51
Neck deformity	1	1
Neck mass	13	46
Neck pain	597	2,375
Neuropathic muscular atrophy	1	1
Nose deformity		2
Nuchal rigidity	4	43
Oligoarthritis	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1	18	89	17	127
				2	2
				1	1
		1	3	1	2
			3		2
	1	14	36	6	27
2	4	199	697	132	487
		7	22	3	14
	1	48	186	17	74
		64	198	22	118
2	2	194	741	210	832
		38	152	29	132
					1
		39	156	16	70
		19	42	10	42
	1	85	546	17	141
1	3	270	890	134	672
5	81	4598	15255	925	5966
		1	3		4
			2		3
		1	1		
		1	5	1	2
		1	2	5	5
				3	8
	1	11	20	8	31
		1	1		
		11	34	2	12
	4	371	1413	226	962
				1	1
			2		
		2	23	2	20
				1	2

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Osteitis	4	4
Osteoarthritis	18	52
Osteoarthropathy	5	6
Osteochondritis		2
Osteolysis	1	1
Osteonecrosis of jaw		2
Osteopenia	2	3
Osteoporosis	2	7
Pain in extremity	4,085	15,592
Pain in jaw	94	384
Palindromic rheumatism		1
Patellofemoral pain syndrome		1
Pathological fracture	1	1
Periarthritis	25	66
Plantar fasciitis		9
Polyarthritis	10	35
Polychondritis		4
Polymyalgia rheumatica	21	63
Polymyositis	3	6
Posture abnormal	5	11
Psoriatic arthropathy	2	28
Purple glove syndrome		1
Reynold's syndrome	1	1
Rhabdomyolysis	11	36
Rheumatic disorder	3	13
Rheumatic fever		1
Rheumatoid arthritis	51	190
Rotator cuff syndrome	15	28
Sacroiliitis		7
SAPHO syndrome		1
Scleroderma		2
Scoliosis	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	3	1	1
		8	26	10	26
		5	6		
			2		
		1	1		
					2
		1	2	1	1
		1	5	1	2
14	63	3035	11006	1050	4586
	1	60	219	34	165
					1
					1
				1	1
	1	6	15	19	51
			4		5
				10	35
					4
				21	63
				3	6
		1	6	4	5
1	1			2	28
					1
				1	1
				11	36
		2	8	1	5
					1
5	7			51	190
		8	10	7	18
			3		4
					1
					2
		1	1		1

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* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Seronegative arthritis	1	3
Sinus tarsi syndrome		1
Sjogren's syndrome	4	18
SLE arthritis		2
Snapping hip syndrome		1
Soft tissue atrophy		1
Soft tissue disorder		2
Soft tissue haemorrhage		1
Soft tissue swelling	4	13
Somatic dysfunction		1
Spinal disorder	4	13
Spinal osteoarthritis	1	8
Spinal pain	49	180
Spinal stenosis	1	5
Spondylitis	4	8
Spondyloarthropathy		1
Still's disease		1
Symphysiolysis		1
Synovial cyst	12	35
Synovial disorder		1
Synovitis	4	11
Systemic lupus erythematosus	9	40
Systemic scleroderma		1
Temporomandibular joint syndrome	3	20
Tendon discomfort		1
Tendon disorder	6	11
Tendonitis	19	64
Tendon pain	8	31
Tenosynovitis	4	15
Tenosynovitis stenosans		2
Torticollis	5	20
Trigger finger	2	15

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
			1		
				4	18
					2
			1		
					1
			2		
			1		
		4	9		4
					1
		3	6	1	7
			5	1	3
		35	116	14	64
			3	1	2
		2	2	2	6
			1		
1	1				1
					1
		10	16	2	19
			1		
		1	3	3	8
1	2			9	40
					1
		1	13	2	7
			1		
		2	4	4	7
		8	30	11	34
		4	18	4	13
		3	9	1	6
					2
		4	15	1	5
		1	11	1	4

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* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Trismus	13	40			9	23	4	17
Undifferentiated connective tissue disease		1						1
Vertebral lesion	1	2					1	2
Vertebral wedging		1						1
Weight bearing difficulty	8	21			3	8	5	13
Winged scapula		1				1		
	18,936	72,294	44	264	13954	48467	4982	23827

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acoustic neuroma		4				4
Acrochordon		1				1
Acute leukaemia		3				3
Acute lymphocytic leukaemia		1				1
Acute myeloid leukaemia		8		1		7
Adenoma benign		2		1		1
Angiomyolipoma		1				1
Basal cell carcinoma	1	4			1	4
B-cell lymphoma		2				2
B-cell type acute leukaemia		2				2
Benign breast neoplasm		1		1		
Benign hydatidiform mole	1	1			1	1
Benign lymph node neoplasm	1	1			1	1
Bile duct cancer	1	1			1	1
Bladder cancer		1				1
Bladder neoplasm		1				1
Blast cell crisis		1				1
Bone neoplasm	1	5		2	1	3

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* AE=Adverse Event

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Brain cancer metastatic		1				1
Brain neoplasm	1	5			1	5
Breast cancer	8	21			8	21
Breast cancer metastatic		1				1
Breast cancer recurrent	1	1			1	1
Breast cancer stage I	1	1			1	1
Breast cancer stage III		1				1
Bronchial neoplasm	1	1			1	1
Cardiac neoplasm unspecified		1				1
Castleman's disease	1	1			1	1
Chronic lymphocytic leukaemia	4	9			4	9
Chronic lymphocytic leukaemia recurrent	1	1			1	1
Chronic myeloid leukaemia recurrent		1				1
Colon cancer		2				2
Colon neoplasm		1				1
Cranial nerve neoplasm benign	1	1			1	1
Cutaneous T-cell lymphoma	1	1			1	1
Diffuse large B-cell lymphoma		1				1
Ear neoplasm		1		1		
Endometrial cancer	1	2			1	2
Essential thrombocythaemia		1				1
Fibroma		2		2		
Follicular lymphoma	1	2			1	2
Gastric cancer		1				1
Gastrointestinal carcinoma		1				1
Good syndrome		1				1
Haemangioma	1	3	1	2		1
Haemangioma of liver	1	1	1	1		
Hepatic cancer	1	1			1	1
Hepatocellular carcinoma	1	1			1	1
Histiocytosis	1	1			1	1
Hodgkin's disease	1	1			1	1

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypergammaglobulinaemia benign monoclonal	1	1
Inflammatory carcinoma of the breast	1	1
Invasive ductal breast carcinoma	1	2
Kaposi's sarcoma AIDS related		1
Leukaemia	2	11
Leukaemia recurrent		1
Lip neoplasm	1	1
Lipoma	1	7
Lung cancer metastatic	2	2
Lung carcinoma cell type unspecified recurrent	1	1
Lung carcinoma cell type unspecified stage I		1
Lung neoplasm	1	1
Lung neoplasm malignant		7
Lymphangioma		1
Lymphoma	4	21
Lymphoproliferative disorder		1
Malignant lymphoid neoplasm		1
Malignant melanoma	1	2
Malignant peritoneal neoplasm	2	2
Malignant pleural effusion		1
Melanocytic naevus	1	2
Melanoma recurrent		2
Meningioma	1	3
Metastases to lung	1	1
Metastases to lymph nodes	1	8
Metastases to meninges		1
Metastases to peritoneum		2
Metastasis		2
Metastatic neoplasm		1
Monoclonal gammopathy	1	4
Myelodysplastic syndrome	1	4
Myelofibrosis		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	1
		1	2
			1
		2	11
			1
		1	1
1	4		3
		2	2
		1	1
			1
		1	1
			7
			1
		4	21
			1
			1
		1	2
		2	2
			1
1	1		1
			2
		1	3
		1	1
		1	8
			1
			2
			2
			1
	1	1	3
		1	4
			1

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myeloid leukaemia	1	1			1	1
Neoplasm	7	24	4	14	3	10
Neoplasm malignant	8	24			8	24
Neoplasm progression	7	13	3	4	4	9
Neoplasm recurrence	2	2	1	1	1	1
Neoplasm skin	1	5	1	4		1
Non-Hodgkin's lymphoma	1	5			1	5
Oligodendroglioma		1				1
Oncologic complication	1	1	1	1		
Ovarian cancer	1	2			1	2
Ovarian neoplasm	1	1			1	1
Pancreatic carcinoma	1	4			1	4
Pancreatic carcinoma metastatic	1	1			1	1
Phaeochromocytoma		1				1
Pituitary tumour	1	1			1	1
Pituitary tumour benign	3	4	1	1	2	3
Plasma cell leukaemia	1	1			1	1
Plasma cell myeloma	1	3			1	3
POEMS syndrome	1	1			1	1
Polycythaemia vera		1				1
Primary gastrointestinal follicular lymphoma		1				1
Prostate cancer	1	7			1	7
Renal cancer		2				2
Renal neoplasm		1				1
Rosai-Dorfman syndrome	1	1			1	1
Salivary gland neoplasm	1	1			1	1
Sarcoma		1				1
Schwannoma		1				1
Second primary malignancy		1				1
Skin cancer	3	4			3	4
Skin papilloma	2	3	1	1	1	2
Squamous cell carcinoma	2	2			2	2

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
TEMPI syndrome		1				1
Testicular neoplasm		1				1
Thymoma	1	1			1	1
Thyroid cancer	1	2			1	2
Thyroid neoplasm	1	1			1	1
Triple negative breast cancer	1	2			1	2
Tumour pain	2	2			2	2
Tumour perforation		1				1
Tumour pseudoprogression	1	1			1	1
Tumour thrombosis	1	1			1	1
Uterine leiomyoma	7	7	1	1	6	6
Yolk sac tumour site unspecified	1	1			1	1
	122	349	17	44	105	305

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acoustic neuritis		3				1		2
Acute disseminated encephalomyelitis	6	14					6	14
Acute motor axonal neuropathy		2						2
Acute polyneuropathy	2	3					2	3
Adrenergic syndrome		1				1		
Advanced sleep phase	1	1			1	1		
Ageusia	151	668	2	5	109	465	42	203
Agnosia	1	2			1	1		1
Akathisia	2	6			1	4	1	2
Akinesia	1	4					1	4
Alexia		2				1		1
Allodynia	6	23			5	14	1	9

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Altered pitch perception		1
Altered state of consciousness	42	130
Amnesia	72	224
Amnesic disorder	1	4
Amputation stump pain	1	1
Anaesthesia	6	51
Anaesthesia dolorosa		1
Anosmia	135	537
Anterograde amnesia	2	5
Anticholinergic syndrome		1
Apallic syndrome	2	5
Aphasia	95	304
Apraxia	3	6
Arachnoid cyst		1
Areflexia	7	14
Asterixis		1
Ataxia	13	50
Atonic seizures		4
Aura	6	28
Autoimmune demyelinating disease		1
Autoimmune neuropathy	1	1
Autonomic nervous system imbalance	6	22
Autonomic neuropathy	1	3
Axonal neuropathy		4
Balance disorder	213	734
Ballismus	1	1
Band sensation		6
Basal ganglia haematoma	1	1
Basal ganglia haemorrhage		5
Basal ganglia infarction		2
Basal ganglia stroke	1	5
Basilar artery occlusion	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
	1	1	1	41	129
		33	91	39	133
				1	4
		1	1		
		5	43	1	8
					1
2	4	110	398	25	139
				2	5
					1
				2	5
2	3	21	75	74	229
		1	2	2	4
					1
			1	7	13
					1
		3	14	10	36
					4
		5	17	1	11
					1
				1	1
		1	4	5	18
				1	3
			1		3
2	5	117	347	96	387
				1	1
1	1		4		2
				1	1
					5
					2
				1	5
				2	4

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Basilar artery thrombosis	3	10
Basilar migraine		1
Bell's palsy	217	820
Brachial plexopathy	1	4
Bradykinesia	11	33
Brain compression		2
Brain hypoxia		3
Brain injury	7	21
Brain oedema	13	32
Brain stem haemorrhage	2	6
Brain stem infarction	6	8
Brain stem ischaemia	2	4
Brain stem stroke	3	9
Brain stem syndrome		6
Brown-Sequard syndrome	1	1
Bulbar palsy	1	2
Burning feet syndrome	1	2
Burning sensation	314	999
Burning sensation mucosal	2	7
Carotid arteriosclerosis	4	6
Carotid artery disease		1
Carotid artery dissection	2	6
Carotid artery occlusion	5	13
Carotid artery stenosis	3	5
Carotid artery thrombosis	5	11
Carpal tunnel syndrome	7	20
Cataplexy		2
Cauda equina syndrome	1	1
Central nervous system inflammation		1
Central nervous system lesion	4	10
Central nervous system vasculitis	2	3
Central pain syndrome		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	10
					1
1	2		4	217	816
		1	2		2
1	1	7	19	4	14
					2
					3
				7	21
			1	13	31
				2	6
				6	8
				2	4
				3	9
					6
				1	1
				1	2
		1	1		1
		201	621	113	378
		2	6		1
		2	3	2	3
					1
				2	6
				5	13
				3	5
				5	11
		3	9	4	11
					2
				1	1
					1
		1	3	3	7
				2	3
			2		1

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebellar ataxia	2	6
Cerebellar atrophy		1
Cerebellar embolism	1	1
Cerebellar haematoma		2
Cerebellar haemorrhage	4	8
Cerebellar infarction	2	9
Cerebellar ischaemia		1
Cerebellar stroke	5	13
Cerebellar syndrome	3	10
Cerebral amyloid angiopathy	2	4
Cerebral arteriosclerosis	3	4
Cerebral artery embolism	8	13
Cerebral artery occlusion	6	12
Cerebral artery stenosis	2	3
Cerebral artery thrombosis	5	12
Cerebral atrophy	3	11
Cerebral congestion	1	2
Cerebral cyst	1	1
Cerebral disorder	12	29
Cerebral haematoma	6	21
Cerebral haemorrhage	93	227
Cerebral infarction	106	227
Cerebral ischaemia	18	49
Cerebral mass effect	1	1
Cerebral microangiopathy		1
Cerebral small vessel ischaemic disease	4	5
Cerebral thrombosis	20	64
Cerebral vascular occlusion	1	1
Cerebral venous sinus thrombosis	34	69
Cerebral venous thrombosis	8	19
Cerebral ventricular rupture	1	1
Cerebrospinal fluid leakage		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3	1	3
					1
				1	1
					2
				4	8
				2	9
					1
				5	13
				3	10
				2	4
		1	1	2	3
				8	13
				6	12
				2	3
				5	12
				3	11
				1	2
				1	1
		9	20	3	9
				6	21
				93	227
1	1			106	227
				18	49
				1	1
					1
				4	5
2	2			20	64
				1	1
1	1			34	69
				8	19
				1	1
					2

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebrovascular accident	308	993
Cerebrovascular disorder	8	17
Cerebrovascular insufficiency	1	2
Cervical cord compression		1
Cervical neuritis		1
Cervical radiculopathy	7	16
Cervicobrachial syndrome	5	23
Cervicogenic headache	1	3
Cervicogenic vertigo	1	1
Cholinergic syndrome	1	7
Chorea	1	6
Chronic inflammatory demyelinating polyradiculoneuropathy	1	5
Circadian rhythm sleep disorder	1	7
Clinically isolated syndrome	1	1
Clonic convulsion	5	9
Clonus	4	16
Clumsiness	8	21
Cluster headache	21	99
Cognitive disorder	49	152
Cogwheel rigidity	1	1
Cold-stimulus headache	3	9
Coma	27	68
Coma hepatic		2
Complex regional pain syndrome	1	11
Concentric sclerosis	1	1
Consciousness fluctuating		7
Conus medullaris syndrome		1
Convulsions local	1	4
Coordination abnormal	23	97
Cramp-fasciculation syndrome		2
Cranial nerve disorder	3	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	3			308	993
1	1		1	8	16
				1	2
					1
			1		
		4	8	3	8
		2	12	3	11
			1	1	2
		1	1		
				1	7
			1	1	5
				1	5
		1	5		2
				1	1
				5	9
		2	6	2	10
		5	11	3	10
1	1	5	30	16	69
	1	24	60	25	92
		1	1		
		1	3	2	6
				27	68
					2
			3	1	8
				1	1
					7
					1
				1	4
	1	9	31	14	66
			1		1
			5	3	8

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cranial nerve palsies multiple	1	3
Cranial nerve paralysis	6	8
Cubital tunnel syndrome	1	1
Decreased vibratory sense		3
Delayed ischaemic neurological deficit	1	1
Dementia	8	58
Dementia Alzheimer's type	2	13
Dementia of the Alzheimer's type, with delirium		1
Dementia with Lewy bodies		1
Demyelinating polyneuropathy	1	8
Demyelination	4	18
Depressed level of consciousness	86	338
Diabetic coma		3
Diabetic hyperosmolar coma	1	2
Diabetic neuropathy		1
Diplegia	7	24
Disturbance in attention	151	579
Dizziness	4,030	13,193
Dizziness exertional	3	30
Dizziness postural	95	433
Dreamy state		3
Drooling	4	29
Drop attacks	1	2
Dropped head syndrome		2
Dysaesthesia	43	138
Dysarthria	95	333
Dysdiadochokinesis		1
Dysgeusia	339	1,428
Dysgraphia	5	19
Dyskinesia	44	164
Dyslalia	3	7
Dyslexia	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
				6	8
				1	1
					3
				1	1
				8	58
				2	13
					1
					1
				1	8
				4	18
1	2	1	2	85	336
					3
				1	2
			1		
				7	24
	2	89	295	62	284
6	65	2888	8286	1142	4907
		2	7	1	23
	1	47	173	48	260
			2		1
		2	16	2	13
				1	2
					2
		25	78	18	60
5	6	36	96	59	237
					1
	4	270	1051	69	377
		3	10	2	9
		26	90	18	74
		1	2	2	5
		1	2		3

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysmetria	1	5
Dyspraxia	3	4
Dysstasia	85	296
Dystonia	3	24
Electric shock sensation	20	67
Embolic cerebellar infarction	1	1
Embolic cerebral infarction	3	7
Embolic stroke	14	30
Encephalitis autoimmune	2	4
Encephalitis post immunisation		2
Encephalomalacia		1
Encephalopathy	4	19
Epilepsy	83	318
Epileptic aura		1
Epileptic encephalopathy		1
Essential tremor	1	5
Exaggerated startle response	1	2
Exertional headache		4
Extensor plantar response	1	5
Extrapyramidal disorder		8
Facial nerve disorder	2	26
Facial neuralgia	7	27
Facial paralysis	230	925
Facial paresis	78	325
Facial spasm	8	33
Febrile convulsion	23	96
Fine motor skill dysfunction	9	22
Focal dyscognitive seizures	1	5
Foetal movement disorder		1
Formication	21	85
Freezing phenomenon	3	12
Fumbling	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	5
		1	1	2	3
1	1	42	138	43	158
				3	24
		14	48	6	19
				1	1
				3	7
				14	30
				2	4
					2
					1
				4	19
1	1			83	318
					1
					1
		1	2		3
		1	2		
			2		2
			2	1	3
			2		6
			15	2	11
		4	14	3	13
	3		2	230	923
1	1	29	110	49	215
		2	16	6	17
		10	48	13	48
		6	12	3	10
				1	5
					1
		11	43	10	42
		2	8	1	4
				1	2

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Generalised onset non-motor seizure	1	2
Generalised tonic-clonic seizure	38	144
Glabellar reflex abnormal		1
Gliosis		2
Glossopharyngeal nerve disorder		1
Gross motor delay	1	2
Guillain-Barre syndrome	60	169
Haemorrhage intracranial	6	17
Haemorrhagic cerebral infarction	2	3
Haemorrhagic stroke	18	56
Haemorrhagic transformation stroke	6	8
Hand-arm vibration syndrome		2
Hand-eye coordination impaired		2
Headache	11,660	40,453
Head discomfort	195	620
Head titubation	3	9
Hemianaesthesia	10	46
Hemianopia	3	9
Hemianopia heteronymous		1
Hemianopia homonymous	1	7
Hemiapraxia		1
Hemiataxia	3	3
Hemidysaesthesia	1	9
Hemihyperaesthesia	1	4
Hemiparaesthesia	18	79
Hemiparesis	75	252
Hemiplegia	38	125
Hemiplegic migraine	2	7
Hepatic encephalopathy		
Hippocampal atrophy		2
Hoffmann's sign		1
Horner's syndrome	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
				38	144
			1		
			1		1
					1
				1	2
		1	1	59	168
				6	17
				2	3
				18	56
				6	8
					2
					2
23	144	9360	28383	2300	12070
		139	411	56	209
		2	6	1	3
1	1			10	46
				3	9
					1
				1	7
					1
				3	3
				1	9
				1	4
				18	79
1	1			75	252
				38	125
		1	1	1	6
1	1				
			1		1
			1		
				1	5

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hydrocephalus	3	6
Hyperaesthesia	44	218
Hypercapnic coma	1	1
Hypergeusia	1	2
Hyperintensity in brain deep nuclei	1	2
Hyperkinesia		1
Hyperpathia	1	1
Hyperreflexia	3	9
Hyperresponsive to stimuli	1	1
Hypersomnia	83	399
Hypertensive encephalopathy	3	5
Hypertonia	4	20
Hypoaesthesia	1,101	3,714
Hypogeusia	9	27
Hypoglossal nerve disorder		1
Hypoglossal nerve paresis		1
Hypoglycaemic coma		2
Hypoglycaemic unconsciousness	1	1
Hypokinesia	59	182
Hyporeflexia	3	17
Hyporesponsive to stimuli	2	15
Hyposmia	9	32
Hypotonia	21	93
Hypotonic-hyporesponsive episode	4	34
Hypoxic-ischaemic encephalopathy	1	3
Idiopathic intracranial hypertension	3	9
IIIrd nerve disorder		4
IIIrd nerve paralysis	6	20
IIIrd nerve paresis	1	3
Immune-mediated neuropathy	1	1
Inability to crawl		1
Incoherent	12	41

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	6
		32	141	12	77
				1	1
		1	1		1
				1	2
			1		
		1	1		
		1	3	2	6
				1	1
		49	245	34	154
				3	5
1	1		8	4	12
	9	686	2217	415	1497
		8	23	1	4
					1
					1
					2
				1	1
		32	97	27	85
		2	6	1	11
			5	2	10
		4	21	5	11
		12	49	9	44
		1	7	3	27
				1	3
				3	9
					4
				6	20
				1	3
				1	1
					1
		7	19	5	22

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Infant irritability		8
Intellectual disability	1	1
Intention tremor	1	3
Intercostal neuralgia		3
Intracranial aneurysm	4	11
Intracranial artery dissection	1	1
Intracranial haematoma		1
Intracranial hypotension	1	1
Intracranial mass		1
Intracranial pressure increased	5	13
Intraventricular haemorrhage	4	9
Irregular sleep wake rhythm disorder		3
Ischaemic cerebral infarction	8	45
Ischaemic stroke	142	332
IVth nerve disorder		2
IVth nerve paralysis	4	10
IVth nerve paresis		1
Lacunar infarction	5	11
Lacunar stroke	1	9
Language disorder	6	16
Lateral medullary syndrome	2	3
Lateropulsion		2
Lennox-Gastaut syndrome		1
Lethargy	392	1,703
Leukoencephalopathy	1	8
Lhermitte's sign		3
Limbic encephalitis	1	1
Locked-in syndrome		2
Long thoracic nerve palsy		1
Loss of consciousness	442	1,568
Loss of proprioception		3
Lower motor neurone lesion	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			5		3
				1	1
				1	3
			1		2
				4	11
				1	1
					1
		1	1		
					1
		1	1	4	12
				4	9
			3		
				8	45
1	1	1	1	141	331
					2
			1	4	9
					1
				5	11
				1	9
		2	4	4	12
				2	3
					2
					1
2	9	258	935	134	768
				1	8
			2		1
				1	1
					2
			1		
2	2	2	3	440	1565
					3
				1	1

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lumbar radiculopathy		2
Medication overuse headache	1	2
Memory impairment	79	276
Meningeal disorder	2	5
Meningism		9
Meningitis noninfective		1
Meningoradiculitis		1
Meningorrhagia		1
Mental impairment	30	122
Meralgia paraesthetica		1
Metabolic encephalopathy		1
Migraine	466	2,075
Migraine with aura	26	115
Migraine without aura	4	10
Miller Fisher syndrome	3	3
Mononeuritis	4	4
Mononeuropathy		5
Mononeuropathy multiplex	2	3
Monoparesis	40	95
Monoplegia	32	104
Morton's neuralgia		1
Motor dysfunction	32	113
Movement disorder	132	424
Multiple sclerosis	22	75
Multiple sclerosis relapse	12	47
Muscle contractions involuntary	16	76
Muscle spasticity	7	21
Muscle tone disorder		2
Myasthenia gravis	5	22
Myasthenia gravis crisis	1	7
Myelitis transverse	11	45
Myelopathy		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		1	1		1
		48	154	31	122
		1	2	1	3
			4		5
					1
					1
					1
	1			30	122
					1
					1
2	9	250	1021	216	1054
	1	13	44	13	71
		2	3	2	7
				3	3
		1	1	3	3
					5
				2	3
1	1	26	33	14	62
		1	1	31	103
					1
1	1	15	48	17	65
1	1	91	262	41	162
1	1			22	75
1	1			12	47
		7	42	9	34
		3	6	4	15
					2
				5	22
				1	7
				11	45
					3

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myoclonic epilepsy	1	2
Myoclonus	11	45
Narcolepsy		12
Nerve compression	7	46
Nerve degeneration		2
Nervous system disorder	48	147
Neuralgia	169	556
Neuralgic amyotrophy	7	27
Neuritis	9	46
Neuritis cranial		3
Neuroleptic malignant syndrome	1	1
Neurological decompensation	1	3
Neurological symptom	28	72
Neurologic neglect syndrome	2	6
Neuromuscular pain	2	5
Neuromyelitis optica spectrum disorder	1	5
Neuromyopathy		3
Neuronal neuropathy		1
Neuropathy peripheral	101	306
Neurotoxicity		2
New daily persistent headache		1
Noninfective encephalitis	4	10
Normal pressure hydrocephalus	1	3
Numb chin syndrome		1
Nystagmus	15	49
Occipital neuralgia	8	22
Oculofacial paralysis	1	3
Olfactory nerve disorder	1	1
Ophthalmic migraine	8	29
Ophthalmoplegic migraine		1
Opisthotonus		2
Optic neuritis	15	47

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
		4	11	7	34
					12
		2	27	5	19
					2
		20	53	28	94
	1	95	281	74	275
	1	2	7	5	20
		4	26	5	20
					3
				1	1
			1	1	2
1	2	7	21	21	51
				2	6
		1	2	1	3
				1	5
					3
					1
		2	2	99	304
					2
			1		
				4	10
				1	3
					1
		8	19	7	30
		2	7	6	15
				1	3
		1	1		
		2	13	6	16
			1		
					2
				15	47

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oromandibular dystonia		1
Orthostatic intolerance	1	6
Orthostatic tremor		1
Paraesthesia	1,359	5,323
Paraesthesia mucosal	2	8
Paralysis	67	223
Paraparesis	3	20
Paraplegia	3	7
Paresis	10	51
Paresis cranial nerve	1	4
Parkinsonian gait	1	1
Parkinsonian rest tremor		1
Parkinsonism	2	11
Parkinson's disease	6	27
Parosmia	66	239
Paroxysmal sympathetic hyperactivity	1	2
Partial seizures	6	28
Partial seizures with secondary generalisation	1	1
Patient elopement	3	7
Peripheral motor neuropathy		3
Peripheral nerve lesion	1	1
Peripheral nerve palsy	3	4
Peripheral nerve paresis		2
Peripheral paralysis	2	4
Peripheral sensorimotor neuropathy	1	2
Peripheral sensory neuropathy	2	17
Periventricular leukomalacia	1	1
Peroneal nerve palsy	2	18
Persistent genital arousal disorder	1	1
Persistent postural-perceptual dizziness		4
Petit mal epilepsy	5	46
Phantom limb syndrome		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2	1	4
			1		
6	16	916	3276	443	2047
		1	2	1	6
	1		2	67	221
		1	1	2	19
				3	7
		6	17	4	34
			1	1	3
		1	1		
			1		
			2	2	9
				6	27
		47	159	19	80
				1	2
				6	28
				1	1
		3	5		2
					3
		1	1		
		3	3		1
					2
				2	4
				1	2
		1	6	1	11
				1	1
		1	7	1	11
		1	1		
			1		3
				5	46
			1		2

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pineal gland cyst		1
Pleocytosis		4
Polyneuropathy	6	29
Polyneuropathy chronic	1	1
Polyneuropathy in malignant disease	1	1
Posterior revers ble encephalopathy syndrome		3
Post herpetic neuralgia	19	29
Postictal paralysis		1
Postictal state		6
Post stroke epilepsy		1
Post stroke seizure		1
Post-traumatic neuralgia		1
Postural tremor		1
Presyncope	313	1,233
Primary cough headache	1	4
Primary headache associated with sexual activity		2
Progressive supranuclear palsy		1
Psychogenic seizure	2	7
Psychomotor hyperactivity	11	45
Psychomotor skills impaired	4	9
Pudendal canal syndrome	1	1
Putamen haemorrhage	3	3
Pyramidal tract syndrome		1
Quadrantanopia	1	3
Quadripareisis	4	10
Quadriplegia		3
Radial nerve palsy	1	4
Radicular pain		1
Radiculitis brachial	6	17
Radiculopathy	2	16
Reduced facial expression	4	18

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		3
1	1			6	29
		1	1		
				1	1
					3
		9	13	10	16
					1
			3		3
					1
					1
			1		
					1
2	4	164	640	149	593
		1	2		2
					2
					1
			1	2	6
		4	20	7	25
		3	5	1	4
				1	1
				3	3
					1
				1	3
				4	10
					3
			1	1	3
			1		
			5	6	12
			5	2	11
		2	9	2	9

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Reflexes abnormal		3
Repetitive speech	1	2
Resting tremor	2	4
Restless arm syndrome	2	2
Restless legs syndrome	14	64
Retinal migraine	3	12
Retrograde amnesia	1	6
Reversed hot-cold sensation	1	2
Reversible cerebral vasoconstriction syndrome	1	3
Ruptured cerebral aneurysm	3	8
Sciatica	31	101
Sciatic nerve neuropathy	2	5
Sedation	3	28
Seizure	235	886
Seizure anoxic	1	2
Seizure cluster		4
Seizure like phenomena	6	14
Senile dementia	2	3
Sensorimotor disorder	1	7
Sensory disturbance	104	255
Sensory loss	37	152
Sensory overload	1	1
Serotonin syndrome		2
Simple partial seizures	1	1
Sinus headache	31	182
Sleep deficit	4	19
Sleep paralysis	2	10
Slow response to stimuli	2	9
Slow speech	4	19
Small fibre neuropathy	2	4
Somnolence	547	2,100
Spasmodic dysphonia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		2
		1	1		1
		1	2	1	2
		1	1	1	1
		10	32	4	32
		1	3	2	9
		1	3		3
		1	1		1
				1	3
				3	8
		16	53	15	48
		2	3		2
		1	17	2	11
			1	235	885
				1	2
					4
				6	14
				2	3
		1	2		5
		61	157	43	98
		14	65	23	87
				1	1
					2
				1	1
1	2	14	91	17	91
		3	12	1	7
		2	8		2
		2	6		3
		3	9	1	10
		1	2	1	2
	3	396	1378	151	722
			1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Speech disorder	116	434
Speech disorder developmental	4	4
Spinal cord compression		2
Spinal cord disorder	2	7
Spinal cord infarction	1	3
Spinal cord ischaemia		3
Spinal epidural haematoma	1	1
Spinal epidural haemorrhage		1
Spinal meningeal cyst		1
Spinal subdural haemorrhage	1	1
Spinal vascular disorder	1	1
Status epilepticus	16	63
Status migrainosus	1	3
Stiff leg syndrome		1
Stroke in evolution	1	2
Stupor	3	23
Subacute inflammatory demyelinating polyneuropathy		1
Subarachnoid haemorrhage	31	70
Sudden onset of sleep	1	7
Superior sagittal sinus thrombosis	2	8
Sympathicotonia	1	3
Syncope	581	2,369
Tardive dyskinesia	2	5
Taste disorder	83	377
Temporal lobe epilepsy		2
Tension headache	52	267
Thalamic infarction	2	7
Thalamus haemorrhage	3	3
Thermohypoaesthesia		1
Thoracic outlet syndrome	1	3
Thrombotic cerebral infarction	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	2	46	191	70	243
		4	4		
					2
				2	7
				1	3
					3
				1	1
					1
					1
				1	1
				1	1
				16	63
				1	3
					1
				1	2
		3	11		12
					1
				31	70
				1	7
				2	8
		1	2		1
8	15	4	5	577	2364
				2	5
		57	254	26	123
					2
	2	27	118	25	149
				2	7
				3	3
			1		
			1	1	2
				1	2

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Thrombotic stroke	9	15
Thunderclap headache	4	9
Tongue biting	8	17
Tongue paralysis	5	13
Tonic clonic movements		17
Tonic convulsion	3	20
Toxic neuropathy		1
Transient aphasia	1	5
Transient global amnesia	11	23
Transient ischaemic attack	143	409
Transverse sinus stenosis		1
Transverse sinus thrombosis	4	5
Tremor	518	2,302
Trigeminal nerve disorder	2	24
Trigeminal nerve paresis	2	3
Trigeminal neuralgia	22	72
Trigeminal neuritis	3	6
Trigeminal palsy	1	3
Tumefactive multiple sclerosis		1
Tunnel vision	5	35
Typical aura without headache	2	4
Ulnar nerve palsy	1	3
Ulnar neuritis		1
Unresponsive to stimuli	20	151
Vagus nerve disorder		3
Vascular dementia	1	8
Vascular encephalopathy		4
Vascular headache	4	11
Vascular parkinsonism	1	1
Vertebral artery dissection		4
Vertebral artery occlusion	2	2
Vertebral artery stenosis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				9	15
		1	1	3	8
		1	3	7	14
				5	13
					17
				3	20
					1
				1	5
		2	6	9	17
	1			143	409
					1
				4	5
3	9	308	1174	210	1128
		1	11	1	13
				2	3
		8	29	14	43
		2	3	1	3
				1	3
					1
		1	1	4	34
		1	1	1	3
			1	1	2
					1
				20	151
					3
				1	8
					4
		1	4	3	7
				1	1
					4
				2	2
					1

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vertebral artery thrombosis		1						1
Vertebrobasilar insufficiency	1	1					1	1
Vertebrobasilar stroke	2	3					2	3
Vertigo CNS origin	1	1					1	1
Vestibular migraine		10				2		8
Vibratory sense increased		1				1		
VIIIth nerve lesion		1						1
Visual perseveration		1						1
Visuospatial deficit	1	1					1	1
VIth nerve disorder		1						1
VIth nerve paralysis	5	25					5	25
VIth nerve paresis		1				1		
Vocal cord paralysis	1	4					1	4
Vocal cord paresis		1				1		
White matter lesion	2	10				4	2	6
Writer's cramp		1						1
	28,347	100,737	94	364	17592	55523	10755	45214

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abortion	2	6					2	6
Abortion missed	7	19					7	19
Abortion spontaneous	50	182	2	2			50	182
Abortion threatened	2	2					2	2
Anembryonic gestation	1	3					1	3
Arrested labour	1	1					1	1
Cephalhaematoma		1						1
Cervical incompetence	1	1					1	1

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System Organ Class

Pregnancy, puerperium and perinatal conditions

	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
<i>Preferred Term</i>		
Ectopic pregnancy	2	4
Face presentation		1
Foetal death	7	17
Foetal growth restriction	5	10
Foetal hypokinesia	1	3
Gestational diabetes	2	4
Haemorrhage in pregnancy		2
High risk pregnancy	1	1
Morning sickness	2	13
Oligohydramnios		1
Postpartum disorder		1
Postpartum haemorrhage	1	2
Pre-eclampsia	1	1
Pregnancy		4
Pregnancy after post coital contraception	1	1
Pregnancy with contraceptive device	1	3
Pregnancy with implant contraceptive	1	1
Premature baby	5	13
Premature delivery		2
Premature labour	1	4
Premature rupture of membranes	1	2
Premature separation of placenta	2	2
Preterm premature rupture of membranes		2
Retroplacental haematoma	1	1
Small for dates baby		1
Still birth	1	3
Threatened labour		1
Twin pregnancy		1
Umbilical cord abnormality	1	1
Umbilical cord thrombosis	1	1
Uterine contractions abnormal	1	3
Uterine contractions during pregnancy	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	4
			1		
				7	17
				5	10
				1	3
		1	1	1	3
					2
		1	1		
		1	3	1	10
					1
			1		
			1	1	1
				1	1
			3		1
				1	1
				1	3
				1	1
		1	1	4	12
					2
				1	4
				1	2
				2	2
					2
				1	1
					1
				1	3
			1		
			1		
				1	1
				1	1
			1	1	2
			1	1	2

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System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
	104	324	2	2	4	16	100	308

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Device breakage		1				1
Device connection issue	1	1	1	1		
Device infusion issue		1				1
Device issue		2		2		
Device leakage		1		1		
Device pacing issue		1				1
Device stimulation issue		1		1		
Embedded device		1				1
Lead dislodgement	1	1			1	1
Liquid product physical issue	12	46	12	46		
Needle issue	3	26	3	24		2
Oversensing	3	12	1	4	2	8
Patient-device incompatibility	1	1	1	1		
Product colour issue	1	43	1	43		
Product complaint	2	34	2	32		2
Product compounding quality issue		1		1		
Product container issue	2	5	2	5		
Product contamination	1	1	1	1		
Product contamination physical	2	5	2	5		
Product deposit		1		1		
Product expiration date issue	1	1	1	1		
Product formulation issue		1				1
Product label issue	1	1	1	1		
Product leakage	8	27	8	27		

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System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product lot number issue		1		1		
Product odour abnormal		1		1		
Product packaging issue	1	1	1	1		
Product packaging quantity issue	1	22	1	22		
Product physical issue	6	7	6	7		
Product quality issue	9	33	9	33		
Product supply issue	12	54	12	54		
Product taste abnormal		1		1		
Product temperature excursion issue	309	793	309	791		2
Suspected counterfeit product	2	11	2	11		
Suspected product quality issue		5		5		
Syringe issue	7	18	7	18		
Thrombosis in device	1	3			1	3
Undersensing	1	2	1	1		1
	388	1,167	384	1143	4	24

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal behaviour	13	41			8	22	5	19
Abnormal dreams	31	137			21	97	10	40
Abnormal sleep-related event	1	1			1	1		
Abulia	1	1			1	1		
Acute psychosis		3						3
Acute stress disorder	2	6			1	1	1	5
Adjustment disorder with depressed mood		1						1
Affective disorder	2	7				4	2	3
Affect lability	4	14			3	8	1	6
Aggression	8	42	1	1	1	12	7	30

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Agitated depression		1
Agitation	49	208
Alcoholic hangover		1
Alexithymia		1
Anger	12	29
Anhedonia		1
Anorgasmia	1	2
Anxiety	260	1,032
Anxiety disorder	3	6
Anxiety disorder due to a general medical condition		1
Apathy	18	82
Attention deficit hyperactivity disorder	2	5
Autism spectrum disorder	2	3
Automatism		1
Autoscopy	1	11
Aversion	1	2
Behaviour disorder	4	19
Belligerence		1
Binge eating		1
Bipolar disorder	4	7
Bipolar I disorder		1
Body dysmorphic disorder		1
Bradyphrenia	12	57
Bruxism	10	16
Bulimia nervosa		1
Burnout syndrome	1	1
Catatonia	1	6
Change in sustained attention		1
Chronic idiopathic pain syndrome	1	1
Claustrophobia	1	2
Clinomania		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
	1	29	106	20	102
					1
			1		
		12	24		5
			1		
		1	1		1
		187	657	73	375
			2	3	4
			1		
		7	35	11	47
		2	3		2
				2	3
					1
		1	5		6
		1	2		
			1	4	18
					1
					1
				4	7
					1
					1
1	1	8	27	4	30
		5	7	5	9
					1
		1	1		
			2	1	4
			1		
		1	1		
		1	2		
			1		

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Communication disorder	8	27
Completed suicide	4	5
Compulsions		1
Confusional arousal		1
Confusional state	267	1,176
Constricted affect		1
Conversion disorder	3	8
Coprolalia	1	1
Cyclothymic disorder		1
Daydreaming	1	8
Decreased interest	4	16
Deja vu		1
Delirium	33	204
Delirium febrile	1	4
Delusion	6	31
Delusional disorder, unspecified type	1	2
Delusional perception	2	7
Depersonalisation/derealisation disorder		7
Depressed mood	78	238
Depression	50	188
Depression suicidal	1	3
Depressive symptom	3	3
Derealisation	4	19
Discouragement	1	3
Disinhibition		1
Disorganised speech	2	13
Disorientation	100	419
Dissociation	2	29
Dissociative amnesia		1
Dissociative disorder	2	5
Distractibility	3	5
Disturbance in social behaviour		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	11	6	16
				4	5
					1
					1
4	11	109	454	158	722
					1
			3	3	5
		1	1		
					1
		1	4		4
		3	8	1	8
					1
			1	33	203
				1	4
		2	13	4	18
				1	2
		1	4	1	3
			5		2
	1	42	117	36	121
		23	78	27	110
				1	3
		2	2	1	1
		2	11	2	8
		1	3		
					1
		1	4	1	9
2	4	38	163	62	256
		1	17	1	12
			1		
		2	4		1
		3	5		
			2		

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Drug abuse		1
Dysphemia	9	29
Dysphoria	41	54
Dyssomnia	1	2
Eating disorder	32	127
Echolalia	1	1
Emotional disorder	21	64
Emotional distress	14	44
Emotional poverty		1
Enuresis	7	16
Euphoric mood	14	50
Exploding head syndrome	1	2
Factitious disorder		1
Fear	22	87
Fear of death	3	11
Fear of disease	2	2
Fear of falling	1	4
Fear of injection	2	8
Fear-related avoidance of activities	1	1
Feeling of despair	7	18
Flashback		2
Flat affect	3	9
Frustration tolerance decreased	12	29
Gastrointestinal somatic symptom disorder		1
Generalised anxiety disorder		4
Grief reaction		1
Habit cough	1	4
Hallucination	69	261
Hallucination, auditory	4	34
Hallucination, olfactory	2	10
Hallucinations, mixed	1	10
Hallucination, tactile		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		5	11	4	18
		17	20	24	34
		1	2		
		23	79	9	48
		1	1		
		12	37	9	27
		5	18	9	26
					1
		1	4	6	12
		9	34	5	16
				1	2
					1
		13	58	9	29
		3	8		3
		1	1	1	1
		1	2		2
		1	7	1	1
		1	1		
		6	11	1	7
					2
		2	6	1	3
		9	25	3	4
			1		
			3		1
					1
			1	1	3
2	2	1	1	68	260
1	1			4	34
				2	10
				1	10
					2

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hallucination, visual	27	82
Head banging	2	6
Helplessness	1	4
Homicidal ideation	1	1
Hostility	1	3
Hydrophobia		1
Hypersexuality	1	2
Hypersomnia-bulimia syndrome	1	2
Hypervigilance	1	4
Hypnagogic hallucination		2
Hypnopompic hallucination	1	1
Hypomania		1
Hyposomnia		1
Illness anxiety disorder		1
Illusion	7	13
Immunisation anxiety related reaction	1	15
Impaired reasoning		1
Impatience	1	1
Imperception		2
Impulsive behaviour		1
Inappropriate affect	1	5
Indifference	1	5
Initial insomnia	10	61
Insomnia	566	2,242
Intentional self-injury	1	4
Intrusive thoughts		3
Irritability	162	379
Lack of spontaneous speech	5	14
Laziness	2	8
Learning disability		1
Learning disorder	1	1
L bido decreased		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				27	82
		1	3	1	3
		1	2		2
		1	1		
		1	1		2
			1		
		1	1		1
				1	2
			2	1	2
					2
				1	1
					1
					1
			1		
		5	8	2	5
			10	1	5
					1
		1	1		
			1		1
			1		
			2	1	3
		1	2		3
		6	47	4	14
	1	372	1440	194	802
				1	4
			2		1
		132	283	30	96
		3	5	2	9
		2	7		1
					1
				1	1
			1		1

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
L bido increased	1	2
Listless	12	38
Logorrhoea	2	7
Loss of libido	2	8
Major depression	3	10
Mania	3	12
Mental disorder	16	55
Mental fatigue	20	96
Mental status changes	3	13
Middle insomnia	22	141
Mood altered	14	42
Mood disorder due to a general medical condition		1
Mood swings	12	28
Morose		3
Mutism	3	18
Near death experience	16	47
Negative thoughts		3
Neglect of personal appearance		1
Nervousness	81	370
Neuropsychiatric symptoms	1	2
Nightmare	41	147
Obsessive-compulsive personality disorder	1	1
Obsessive-compulsive symptom		1
Obsessive thoughts		1
Oppositional defiant disorder	1	1
Organic brain syndrome		3
Osmophobia		1
Panic attack	40	147
Panic disorder	4	16
Panic reaction	13	57
Paramnesia		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
		8	23	4	15
			1	2	6
		1	4	1	4
				3	10
		3	5		7
		10	36	6	19
		7	23	13	73
		2	8	1	5
		17	97	5	44
		8	24	6	18
					1
		3	9	9	19
			2		1
			8	3	10
				16	47
					3
			1		
		64	248	17	122
			1	1	1
		21	84	20	63
		1	1		
					1
					1
				1	1
					3
					1
		25	82	15	65
		2	11	2	5
		9	38	4	19
					2

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Paranoia	6	27
Paranoid personality disorder		1
Perinatal depression	1	1
Persecutory delusion	1	3
Persistent depressive disorder	2	5
Personality change	2	22
Personality disorder	1	2
Phobia	1	2
Phonophobia	1	6
Poor quality sleep	57	236
Post-traumatic stress disorder	2	6
Posturing	1	2
Pressure of speech		3
Pseudodementia		1
Psychiatric decompensation	2	2
Psychiatric symptom	1	7
Psychogenic pseudosyncope	1	1
Psychological factor affecting medical condition		1
Psychological trauma	1	2
Psychomotor retardation	2	4
Psychotic behaviour		1
Psychotic disorder	3	23
Psychotic disorder due to a general medical condition		1
Psychotic symptom		4
Purging		1
Reading disorder	3	5
Restlessness	61	288
Schizophrenia		3
Self-injurious ideation		4
Sense of a foreshortened future		4
Sitophobia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	14	2	13
			1		
				1	1
			1	1	2
		1	2	1	3
		1	6	1	16
			1	1	1
		1	1		1
		1	3		3
	1	37	145	20	91
			2	2	4
		1	1		1
			1		2
					1
		1	1	1	1
		1	3		4
		1	1		
					1
			1	1	1
		1	1	1	3
					1
		2	6	1	17
					1
					4
					1
		2	2	1	3
		36	163	25	125
					3
			1		3
			2		2
			1		

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sleep attacks	2	6
Sleep disorder	129	552
Sleep disorder due to a general medical condition	7	32
Sleep disorder due to general medical condition, hypersomnia type		1
Sleep disorder due to general medical condition, insomnia type	6	41
Sleep inertia		1
Sleep talking	2	8
Sleep terror	4	12
Social avoidant behaviour	2	3
Social fear		1
Soliloquy	2	4
Somatic symptom disorder	2	12
Somnambulism	3	6
Sopor	2	16
Speech sound disorder	1	3
Staring	1	10
Stereotypy		3
Stress	28	127
Substance abuse		1
Suicidal behaviour	1	2
Suicidal ideation	20	50
Suicide attempt	1	7
Suspiciousness	1	2
Tachyphrenia		8
Tearfulness	5	29
Tension	20	52
Terminal insomnia	3	14
Thanatophobia		1
Thinking abnormal	24	88

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	4		2
		84	353	45	199
		4	23	3	9
			1		
		5	21	1	20
					1
		2	7		1
		2	5	2	7
		1	1	1	2
					1
		2	4		
		1	6	1	6
		2	5	1	1
1	3		4	2	12
			2	1	1
			1	1	9
					3
		18	92	10	35
					1
				1	2
		1	1	19	49
				1	7
			1	1	1
			6		2
		3	11	2	18
		12	36	8	16
		1	9	2	5
			1		
		19	65	5	23

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Thought blocking		1						1
Tic	8	18			6	9	2	9
Time perception altered		1				1		
Trance	1	2			1	2		
Vomiting psychogenic		1						1
	2,822	11,002	12	27	1603	5830	1219	5172

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute kidney injury	51	179		1		1	51	178
A buminuria		2						2
Anti-glomerular basement membrane disease		1						1
Anuria	5	25	1	1			5	25
Azotaemia	1	6					1	6
Bilirubinuria		1						1
Bladder dilatation	1	2			1	1		1
Bladder discomfort	2	8			2	7		1
Bladder disorder	6	19			3	9	3	10
Bladder dysfunction	4	8			1	2	3	6
Bladder hypertrophy	1	1					1	1
Bladder irritation	1	2			1	1		1
Bladder obstruction		1						1
Bladder pain	7	18			1	5	6	13
Bladder spasm	1	5				2	1	3
Bladder sphincter atony		2						2
Calculus bladder	1	1			1	1		
Calculus urinary	1	2			1	2		
Choluria	1	3			1	1		2

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System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chromaturia	26	79
Chronic kidney disease	7	27
Costovertebral angle tenderness		4
Cystitis haemorrhagic	1	7
Cystitis interstitial		2
Cystitis-like symptom		1
Cystitis noninfective		2
Diabetic nephropathy	1	1
Dysuria	30	122
End stage renal disease		1
Genitourinary symptom		1
Glomerulonephritis	1	4
Glomerulonephritis chronic	1	2
Glomerulonephritis minimal lesion	3	12
Glomerulonephritis rapidly progressive		1
Haematuria	26	82
Haemoglobinuria		2
Haemorrhage urinary tract	8	26
Hydronephrosis		2
Hypertonic bladder	1	4
IgA nephropathy	2	3
Incontinence	12	53
Ketonuria	1	1
Kidney fibrosis		1
Kidney small		1
Leukocyturia	4	10
Loss of bladder sensation		2
Lupus nephritis	1	1
Micturition disorder	2	11
Micturition frequency decreased		1
Micturition urgency	12	42
Myoglobinuria		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		13	50	13	29
				7	27
			3		1
				1	7
					2
					1
			1		1
		1	1		
		16	59	14	63
					1
					1
				1	4
				1	2
				3	12
					1
		7	22	19	60
					2
				8	26
					2
			3	1	1
				2	3
		5	16	7	37
				1	1
					1
					1
		1	6	3	4
					2
				1	1
		2	7		4
			1		
		7	18	5	24
					1

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System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nephritis	3	4
Nephrogenic diabetes insipidus	1	1
Nephrolithiasis	12	43
Nephropathy	3	10
Nephrosclerosis		1
Nephrotic syndrome	11	26
Neurogenic bladder		2
Nocturia	3	10
Oliguria	2	14
Pollakiuria	35	120
Polyuria	15	41
Prerenal failure	2	6
Proteinuria	5	19
Renal artery stenosis		1
Renal artery thrombosis	2	2
Renal atrophy		2
Renal colic	8	13
Renal cyst	2	12
Renal cyst haemorrhage		1
Renal disorder	14	50
Renal failure	36	126
Renal haemorrhage		4
Renal impairment	26	67
Renal infarct	4	8
Renal injury	1	2
Renal ischaemia	1	1
Renal mass	2	2
Renal pain	58	212
Renal tubular disorder		1
Renal tubular injury		1
Renal tubular necrosis	1	3
Renal vasculitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	4
				1	1
				12	43
		2	3	1	7
					1
				11	26
					2
		3	9		1
			5	2	9
		23	80	12	40
		8	24	7	17
				2	6
		3	10	2	9
					1
				2	2
					2
		1	3	7	10
		2	6		6
					1
		2	20	12	30
				36	126
					4
				26	67
				4	8
				1	2
				1	1
				2	2
		30	101	28	111
					1
					1
				1	3
					1

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System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Strangury			1	1				
Stress urinary incontinence	1	2			1	2		
Tubulointerstitial nephritis	1	3					1	3
Ureteric stenosis		2						2
Urethral disorder		1				1		
Urethral haemorrhage		1						1
Urethral stenosis		1						1
Urethritis noninfective	1	1			1	1		
Urge incontinence	2	4				2	2	2
Urinary bladder haemorrhage	1	3					1	3
Urinary incontinence	39	146			20	61	19	85
Urinary retention	22	84					22	84
Urinary straining	1	1					1	1
Urinary tract discomfort		1				1		
Urinary tract disorder	2	5			2	4		1
Urinary tract inflammation	1	6			1	2		4
Urinary tract pain		2				1		1
Urine abnormality	7	16			4	11	3	5
Urine flow decreased	2	7				2	2	5
Urine odour abnormal	5	20			4	14	1	6
Urogenital haemorrhage		2						2
	554	1,909	2	3	171	582	383	1327

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal uterine bleeding	3	4			2	2	1	2
Abnormal withdrawal bleeding		1				1		
Adenomyosis	1	1					1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Adnexa uteri pain	3	19
Amenorrhoea	46	70
Anisomastia		2
Aspermia	1	1
Benign prostatic hyperplasia	3	5
Breast cyst	2	7
Breast discharge		4
Breast discomfort	6	25
Breast disorder	3	9
Breast disorder female		1
Breast engorgement		4
Breast enlargement	1	8
Breast haematoma	3	6
Breast induration	1	4
Breast inflammation	5	11
Breast mass	7	45
Breast milk discolouration		2
Breast oedema		7
Breast pain	114	374
Breast swelling	29	104
Breast tenderness	21	51
Cervical dysplasia		1
Cervix erythema		1
Cervix haematoma uterine		1
Cervix oedema		1
Coital bleeding	1	1
Dysmenorrhoea	109	158
Dyspareunia		1
Endometrial thickening		1
Endometriosis	9	15
Epididymal tenderness	1	1
Erectile dysfunction	11	46

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	12	1	7
		29	37	17	33
			2		
		1	1		
		2	3	1	2
		1	4	1	3
			4		
		4	17	2	8
		1	6	2	3
			1		
			3		1
		1	5		3
		1	2	2	4
		1	3		1
		3	5	2	6
		2	19	5	26
			2		
			4		3
	1	62	190	52	184
		11	48	18	56
		15	30	6	21
					1
					1
					1
			1		
				1	1
		60	90	49	68
			1		
			1		
		2	3	7	12
				1	1
				11	46

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System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Erection increased		3
Female genital tract fistula		1
Female reproductive tract disorder	2	2
Female sexual dysfunction		1
Galactorrhoea	1	5
Galactostasis	2	3
Genital blister		1
Genital discomfort	2	3
Genital haemorrhage	5	9
Genital lesion	1	3
Genital pain	4	6
Genital paraesthesia		2
Genital rash	2	3
Genital swelling		1
Genital tract inflammation		2
Genital ulceration	1	4
Gynaecomastia	1	2
Haematospermia	1	3
Heavy menstrual bleeding	323	445
Hypomenorrhoea	16	28
Infertility		1
Infertility female		1
Intermenstrual bleeding	68	122
Labia enlarged	1	1
Lactation disorder	1	4
Menometrorrhagia	3	4
Menopausal symptoms		5
Menstrual discomfort	2	4
Menstrual disorder	186	251
Menstruation delayed	159	212
Menstruation irregular	233	299
Nipple disorder	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
					1
		1	1	1	1
			1		
				1	5
		2	3		
			1		
		2	2		1
				5	9
		1	3		
		2	2	2	4
			2		
		1	2	1	1
			1		
			2		
		1	2		2
		1	1		1
			1	1	2
	1	200	261	123	184
		12	21	4	7
					1
					1
		46	73	22	49
				1	1
			1	1	3
		1	1	2	3
			3		2
			1	2	3
	1	149	198	37	53
1	1	133	153	26	59
	1	184	227	49	72
		1	2		

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System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nipple exudate bloody		2
Nipple pain	4	25
Nipple swelling		8
Oedema genital	1	2
Oligomenorrhoea	10	14
Orchitis noninfective		1
Ovarian cyst	3	6
Ovarian cyst ruptured	1	1
Ovarian disorder		1
Ovarian enlargement		1
Ovarian haemorrhage	2	2
Ovarian vein thrombosis	2	2
Ovulation disorder	2	2
Ovulation pain	3	4
Pelvic discomfort		3
Pelvic haematoma	1	1
Pelvic haemorrhage	1	4
Pelvic pain	21	74
Penile discomfort		1
Penile erythema	1	2
Penile haemorrhage	1	3
Penile oedema	1	1
Penile rash	1	1
Penile swelling	1	4
Penis disorder	2	4
Perineal pain	1	4
Polycystic ovaries	5	5
Polymenorrhoea	65	81
Postmenopausal haemorrhage	34	52
Premature menopause	1	2
Premature ovulation	1	1
Premenstrual dysphoric disorder	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
		3	17	1	8
			6		2
				1	2
		7	8	3	6
			1		
		3	4		2
				1	1
					1
			1		
				2	2
				2	2
		1	1	1	1
		1	1	2	3
			1		2
		1	1		
				1	4
		7	37	14	37
			1		
		1	2		
				1	3
		1	1		
		1	1		
		1	2		2
		2	3		1
			2	1	2
		3	3	2	2
	1	51	62	14	19
				34	52
		1	1		1
		1	1		
				2	2

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System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Premenstrual pain	3	5
Premenstrual syndrome	7	15
Priapism	1	2
Prostatic disorder	1	2
Prostatic pain		1
Prostatitis	3	11
Prostatomegaly	1	6
Pruritus genital		4
Scrotal dermatitis		1
Scrotal disorder		1
Scrotal erythema		3
Scrotal exfoliation		1
Scrotal inflammation		1
Scrotal pain	1	7
Scrotal swelling		3
Semen discolouration		1
Sexual dysfunction	1	1
Suppressed lactation		8
Testicular disorder	2	2
Testicular pain	12	28
Testicular retraction		1
Testicular swelling	3	12
Testicular torsion		1
Testis discomfort		2
Uterine disorder	1	1
Uterine haemorrhage	8	16
Uterine inflammation		2
Uterine pain	4	8
Uterine polyp	1	1
Uterine prolapse	1	1
Uterine spasm	1	4
Vaginal cyst		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	4	1	1
		7	14		1
				1	2
		1	2		
					1
		1	3	2	8
		1	4		2
			3		1
			1		
			1		
			1		2
					1
			1		
		1	5		2
					3
					1
		1	1		
			4		4
		2	2		
		7	17	5	11
					1
		2	8	1	4
					1
			1		1
		1	1		
				8	16
			1		1
		3	4	1	4
				1	1
				1	1
			2	1	2
					2

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System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaginal discharge	4	13
Vaginal disorder		3
Vaginal haemorrhage	104	220
Vaginal lesion	1	2
Vaginal ulceration	1	2
Varicocele		1
Vulval disorder		2
Vulval haemorrhage	1	5
Vulval oedema		1
Vulval ulceration	2	4
Vulvovaginal burning sensation	2	7
Vulvovaginal discomfort	1	2
Vulvovaginal dryness	2	2
Vulvovaginal erythema	1	1
Vulvovaginal inflammation		1
Vulvovaginal pain	6	17
Vulvovaginal pruritus	1	4
Vulvovaginal rash	1	3
Vulvovaginal swelling	2	7
Vulvovaginal ulceration		3
Withdrawal bleed		1
	1,742	3,196

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	10	2	3
			2		1
		42	90	62	130
			1	1	1
		1	1		1
			1		
			1		1
				1	5
			1		
		2	3		1
		1	3	1	4
				1	2
		1	1	1	1
		1	1		
					1
		3	9	3	8
		1	3		1
		1	2		1
		1	3	1	4
					3
			1		
1	6	1107	1833	635	1363

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acute pulmonary oedema	9	44
Acute respiratory distress syndrome	15	52
Acute respiratory failure	18	79

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				9	44
				15	52
1	1			18	79

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Agonal respiration	1	1
Allergic cough	2	10
Allergic pharyngitis	1	1
Allergic respiratory disease		1
Allergic respiratory symptom		3
Allergic sinusitis		3
Alveolitis		1
Aphonia	45	136
Apnoea	11	38
Apnoeic attack	3	5
Asphyxia	11	28
Aspiration	11	38
Asthma	173	571
Asthma exercise induced		3
Asthma late onset		1
Asthmatic crisis	14	42
Atelectasis	7	25
Bradypnoea		2
Bronchial disorder	3	10
Bronchial haemorrhage		1
Bronchial hyperreactivity	2	5
Bronchial irritation	1	1
Bronchial obstruction		5
Bronchial oedema		2
Bronchial secretion retention		2
Bronchial wall thickening	1	2
Bronchiectasis	6	13
Bronchitis chronic	2	4
Bronchopneumopathy		4
Bronchospasm	73	302
Bronchostenosis	2	6
Catarrh	7	27

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		2	4		6
				1	1
			1		
					3
			2		1
					1
	1	29	67	16	69
				11	38
				3	5
				11	28
				11	38
		74	222	99	349
			1		2
					1
1	4			14	42
		3	7	4	18
					2
		1	5	2	5
					1
				2	5
		1	1		
					5
					2
			2		
		1	1		1
				6	13
		2	4		
			1		3
	1	35	113	38	189
				2	6
		5	18	2	9

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cheyne-Stokes respiration		1
Choking	11	62
Choking sensation	14	57
Chronic obstructive pulmonary disease	20	105
Chronic respiratory disease	1	1
Chronic respiratory failure		4
Cough	1,405	4,413
Cough decreased	1	2
Cough variant asthma	2	3
Cyanosis central		1
Cystic lung disease		1
Diaphragmalgia	5	17
Diaphragmatic disorder	1	4
Diaphragmatic paralysis		1
Diaphragmatic spasm		3
Diffuse alveolar damage	1	1
Dry lung syndrome	1	1
Dry throat	45	204
Dysaesthesia pharynx		2
Dysphonia	134	561
Dyspnoea	1,874	7,313
Dyspnoea at rest	13	46
Dyspnoea exertional	77	286
Dyspnoea paroxysmal nocturnal	1	1
Emphysema	5	19
Eosinophilic bronchitis		1
Eosinophilic pneumonia acute		1
Epiglottic oedema		5
Epistaxis	193	667
Glottal incompetence		1
Grunting	1	17
Haemoptysis	22	93

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
	1			11	62
		4	19	10	38
	1	9	19	11	86
		1	1		
					4
4	10	998	2770	407	1643
		1	2		
		1	1	1	2
					1
			1		
		4	11	1	6
			2	1	2
					1
			1		2
				1	1
				1	1
	2	32	131	13	73
			2		
1	2	72	294	62	267
10	23	832	3072	1042	4241
				13	46
1	1	26	111	51	175
				1	1
		4	8	1	11
					1
					1
					5
1	2	115	350	78	317
					1
			11	1	6
		4	30	18	63

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haemothorax		3
Hiccups	7	20
Hydrothorax	1	2
Hyperactive pharyngeal reflex		2
Hypercapnia	2	8
Hyperoxia	1	2
Hypersensitivity pneumonitis	1	2
Hyperventilation	83	216
Hypocapnia	1	1
Hypopnoea	22	85
Hypoventilation	3	11
Hypoxia	38	163
Idiopathic pulmonary fibrosis	1	3
Increased bronchial secretion	2	12
Increased upper airway secretion	3	31
Increased viscosity of bronchial secretion	1	4
Increased viscosity of upper respiratory secretion	1	11
Interstitial lung disease	17	36
Intranasal hypoesthesia		4
Intranasal paraesthesia	2	12
Irregular breathing	3	20
Laryngeal discomfort	20	36
Laryngeal disorder		2
Laryngeal dyspnoea		6
Laryngeal erythema		1
Laryngeal inflammation		2
Laryngeal obstruction	1	7
Laryngeal oedema	33	190
Laryngeal pain	4	15
Laryngeal stenosis	2	3
Laryngitis allergic		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
		3	12	4	8
				1	2
			1		1
				2	8
		1	1		1
				1	2
	1	30	89	53	127
		1	1		
		9	24	13	61
				3	11
				38	163
				1	3
		1	3	1	9
		1	14	2	17
		1	1		3
			4	1	7
				17	36
			3		1
		2	12		
			5	3	15
		6	13	14	23
					2
					6
					1
			1		1
				1	7
		2	3	31	187
		4	9		6
				2	3
					1

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Laryngospasm	5	53
Larynx irritation	3	10
Lower respiratory tract congestion	3	13
Lung consolidation	2	5
Lung disorder	27	132
Lung hyperinflation		2
Lung infiltration	8	27
Lung opacity	5	16
Meconium aspiration syndrome	1	1
Mediastinal disorder	1	1
Mediastinal haemorrhage		1
Mediastinal mass	1	1
Mouth breathing		3
Nasal congestion	221	798
Nasal crusting	1	2
Nasal discharge discolouration		2
Nasal discomfort	23	90
Nasal disorder	1	12
Nasal dryness	11	31
Nasal inflammation		1
Nasal mucosal disorder	1	3
Nasal obstruction	14	29
Nasal odour	1	4
Nasal oedema	12	45
Nasal pruritus	6	27
Nasal turbinate hypertrophy	1	1
Neonatal pneumothorax		1
Neonatal respiratory acidosis	1	1
Neonatal respiratory distress		1
Nocturnal dyspnoea	6	9
Obliterative bronchiolitis		1
Obstructive airways disorder	20	53

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	11	3	42
		1	3	2	7
		1	5	2	8
		1	1	1	4
		12	54	15	78
			2		
		2	7	6	20
		1	5	4	11
				1	1
		1	1		
					1
		1	1		
					3
	1	169	620	52	178
		1	2		
			2		
		16	61	7	29
		1	10		2
		8	21	3	10
			1		
		1	2		1
		7	15	7	14
			1	1	3
		6	25	6	20
		6	17		10
		1	1		
					1
				1	1
					1
		6	6		3
					1
		3	7	17	46

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Organising pneumonia	5	6
Oropharyngeal blistering	6	22
Oropharyngeal cobble stone mucosa		1
Oropharyngeal discomfort	236	622
Oropharyngeal oedema	1	13
Oropharyngeal pain	1,122	3,396
Oropharyngeal plaque	1	3
Oropharyngeal spasm	1	7
Oropharyngeal swelling	3	11
Orthopnoea	6	20
Painful respiration	25	97
Paranasal sinus discomfort	13	64
Paranasal sinus haemorrhage		1
Paranasal sinus hypersecretion	3	11
Paranasal sinus hyposecretion		1
Paranasal sinus inflammation		1
Pharyngeal cyst		2
Pharyngeal disorder	7	23
Pharyngeal enanthema		3
Pharyngeal erythema	10	52
Pharyngeal haemorrhage	3	6
Pharyngeal hypoaesthesia	8	60
Pharyngeal inflammation	8	29
Pharyngeal lesion	1	2
Pharyngeal leukoplakia		1
Pharyngeal mass	3	13
Pharyngeal oedema	25	83
Pharyngeal paraesthesia	31	155
Pharyngeal stenosis	3	5
Pharyngeal swelling	135	588
Pharyngeal ulceration	3	12
Pleural effusion	39	109

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				5	6
				6	22
			1		
		108	310	128	312
			2	1	11
2	7	922	2458	200	938
		1	2		1
				1	7
		2	5	1	6
		3	4	3	16
		9	41	16	56
		10	53	3	11
			1		
		3	10		1
			1		
					1
					2
		5	15	2	8
			2		1
		8	35	2	17
				3	6
		4	31	4	29
		5	14	3	15
		1	2		
			1		
			7	3	6
	1	7	21	18	62
		21	77	10	78
				3	5
	1	58	240	77	348
		2	5	1	7
		6	16	33	93

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pleural rub	1	1
Pleurisy	11	37
Pleuritic pain	7	37
Pneumonia aspiration	21	103
Pneumonitis	15	52
Pneumothorax	8	20
Pneumothorax spontaneous		3
Productive cough	69	265
Prolonged expiration	1	3
Pulmonary air leakage	1	1
Pulmonary alveolar haemorrhage		1
Pulmonary arterial hypertension	3	7
Pulmonary artery dilatation		2
Pulmonary artery occlusion		1
Pulmonary artery thrombosis	6	11
Pulmonary calcification		1
Pulmonary cavitation	1	1
Pulmonary congestion	13	46
Pulmonary embolism	580	1,271
Pulmonary fibrosis	3	17
Pulmonary haemorrhage	2	7
Pulmonary hypertension	4	15
Pulmonary hypertensive crisis		1
Pulmonary hypoperfusion	1	2
Pulmonary infarction	17	42
Pulmonary mass	3	11
Pulmonary microemboli		1
Pulmonary necrosis		1
Pulmonary oedema	30	127
Pulmonary pain	40	137
Pulmonary sarcoidosis		3
Pulmonary sensitisation		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		4	7	7	30
		2	16	5	21
				21	103
		3	7	12	45
				8	20
					3
1	1	40	140	29	125
			1	1	2
		1	1		
					1
				3	7
					2
					1
				6	11
			1		
				1	1
			1	13	45
4	6		1	580	1270
1	1			3	17
				2	7
1	2			4	15
					1
				1	2
				17	42
		1	4	2	7
					1
					1
		1	2	29	125
		25	67	15	70
			1		2
			1		1

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pulmonary thrombosis	35	92
Pulmonary vasculitis		1
Pulmonary venous thrombosis		1
Rales	9	46
Respiration abnormal	14	69
Respiratory acidosis	5	18
Respiratory alkalosis	7	12
Respiratory arrest	17	78
Respiratory depression	1	12
Respiratory disorder	51	240
Respiratory disorder neonatal		1
Respiratory distress	133	1,038
Respiratory failure	60	215
Respiratory fatigue	4	14
Respiratory muscle weakness	1	2
Respiratory paralysis		1
Respiratory symptom	12	29
Respiratory tract congestion	7	51
Respiratory tract haemorrhage		1
Respiratory tract inflammation		2
Respiratory tract irritation	2	13
Respiratory tract oedema	6	30
Restrictive pulmonary disease		1
Reversible airways obstruction		1
Rhinalgia	10	47
Rhinitis allergic	7	19
Rhinorrhoea	770	1,938
Rhonchi	4	11
Sinonasal obstruction	1	6
Sinus congestion	15	77
Sinus disorder	17	86
Sinus pain	23	108

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1			35	92
					1
					1
		6	12	3	34
		11	33	3	36
		1	2	4	16
		1	2	6	10
	1			17	78
				1	12
		19	72	32	168
					1
	1		1	133	1037
1	1			60	215
		1	3	3	11
				1	2
					1
	1	6	13	6	16
		4	40	3	11
					1
			1		1
		1	8	1	5
				6	30
					1
					1
		9	37	1	10
		6	13	1	6
	5	672	1581	98	357
		2	4	2	7
			2	1	4
		12	58	3	19
		13	70	4	16
		14	55	9	53

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sleep apnoea syndrome	5	14
Sneezing	101	409
Snoring	4	17
Sputum discoloured	3	21
Sputum increased	4	10
Sputum retention	2	4
Status asthmaticus	1	2
Stertor	1	3
Stridor	16	76
Suffocation feeling	21	58
Tachypnoea	43	234
Throat clearing	4	20
Throat irritation	219	812
Throat lesion	2	2
Throat tightness	196	891
Tonsillar cyst		1
Tonsillar disorder	3	10
Tonsillar erythema		4
Tonsillar haemorrhage		1
Tonsillar hypertrophy	12	56
Tonsillar inflammation	3	11
Tonsillar ulcer		2
Tonsillolith	1	2
Tracheal inflammation		1
Tracheal oedema		2
Tracheal pain	2	5
Tracheal stenosis	2	5
Tracheomalacia		1
Upper-airway cough syndrome	6	41
Upper airway obstruction	1	11
Upper respiratory tract congestion	13	60
Upper respiratory tract inflammation	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3	4	11
	1	71	299	30	110
		2	10	2	7
		2	10	1	11
			4	4	6
		1	2	1	2
				1	2
				1	3
		4	18	12	58
		10	23	11	35
		17	97	26	137
		3	11	1	9
	1	152	511	67	301
		2	2		
1	3	87	381	109	510
			1		
		2	7	1	3
			3		1
					1
		7	37	5	19
		2	8	1	3
			1		1
		1	2		
			1		
					2
		1	3	1	2
				2	5
					1
		3	31	3	10
				1	11
		12	52	1	8
		2	3		1

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Upper respiratory tract irritation	1	1
Use of accessory respiratory muscles	1	20
Vasomotor rhinitis		1
Vocal cord disorder	1	6
Vocal cord dysfunction		2
Vocal cord inflammation	1	1
Wheezing	145	592
Yawning	6	25
	9,437	32,995

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			7	1	13
			1		
				1	6
			1		1
				1	1
		62	228	83	364
		5	14	1	11
30	85	5044	15745	4393	17250

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acne	31	81
Acute febrile neutrophilic dermatosis		7
Acute generalised exanthematous pustulosis	1	4
Adiposis dolorosa	1	1
Alopecia	36	117
Alopecia areata	4	9
Alopecia totalis		1
Alopecia universalis		2
Androgenetic alopecia		2
Angioedema	108	609
Angiokeratoma		1
Angiolymphoid hyperplasia with eosinophilia		1
Blister	125	381
Blister rupture	1	2
Blood blister	12	34
Brow ptosis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		24	63	7	18
					7
				1	4
				1	1
		18	61	18	56
		1	4	3	5
					1
			2		
					2
		2	4	106	605
			1		
			1		
		75	215	50	166
		1	2		
		7	14	5	20
			1		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bullous haemorrhagic dermatosis	1	1
Butterfly rash		9
Capillaritis		2
Chronic pigmented purpura	1	1
Chronic spontaneous urticaria	1	2
Circumoral oedema	5	14
Circumoral swelling	7	14
Cold sweat	158	758
Cold urticaria	1	3
Cutaneous lupus erythematosus		2
Cutaneous sarcoidosis		2
Cutaneous symptom	2	8
Cutaneous vasculitis	14	32
Dandruff		1
Decubitus ulcer	2	10
Dermal cyst	3	8
Dermatitis	36	116
Dermatitis acneiform	4	8
Dermatitis allergic	44	189
Dermatitis atopic	5	25
Dermatitis bullous	16	48
Dermatitis contact	7	23
Dermatitis diaper		2
Dermatitis exfoliative	2	7
Dermatitis exfoliative generalised	2	8
Dermatitis herpetiformis		4
Dermatitis psoriasiform	2	3
Dermatomyositis	2	11
Dermatosis	3	7
Diabetic wound		1
Diffuse alopecia		1
Drug eruption	15	54

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			5		4
			2		
		1	1		
				1	2
		2	8	3	6
		2	7	5	7
		79	382	79	376
		1	3		
					2
					2
			2	2	6
			2	14	30
			1		
		1	4	1	6
		3	6		2
		21	69	15	47
		3	6	1	2
		24	83	20	106
		3	14	2	11
	1			16	48
		4	16	3	7
			1		1
				2	7
				2	8
			2		2
		1	2	1	1
				2	11
		2	5	1	2
					1
					1
		6	25	9	29

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Drug reaction with eosinophilia and systemic symptoms	3	6					3	6
Dry skin	60	177			35	103	25	74
Dyshidrotic eczema	4	10			1	3	3	7
Ecchymosis	22	44			9	20	13	24
Eczema	59	171		1	30	88	29	83
Eczema asteatotic	3	4			2	2	1	2
Eczema infantile	1	1			1	1		
Eczema nummular		3				2		1
Eczema weeping		1				1		
Ephelides		1				1		
Epidermal necrosis		1						1
Erythema	1,326	4,342	5	11	891	2852	435	1490
Erythema ab igne		1				1		
Erythema annulare		3						3
Erythema marginatum		1				1		
Erythema multiforme	17	61					17	61
Erythema nodosum	8	33			1	10	7	23
Erythematotelangiectatic rosacea		1				1		
Erythrodermic psoriasis	1	1			1	1		
Erythrosis	1	1			1	1		
Excessive granulation tissue		1						1
Exfoliative rash	5	12			1	1	4	11
Fingerprint loss	1	1			1	1		
Fixed eruption		3				3		
Fracture blisters		1				1		
Granuloma annulare		2				2		
Granuloma skin		2				1		1
Guttate psoriasis	2	6			1	2	1	4
Haemorrhage subcutaneous	13	34					13	34
Haemorrhagic urticaria		1						1
Hair colour changes	1	3				2	1	1

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hair disorder	1	3
Hair growth abnormal		2
Hair texture abnormal	2	6
Hand dermatitis	3	8
Henoch-Schonlein purpura	9	13
Hidradenitis		5
Hirsutism	1	2
Hyperhidrosis	743	3,010
Hypersensitivity vasculitis	2	11
Hypertrichosis		1
Idiopathic angioedema	1	3
Idiopathic urticaria	1	2
Ingrowing nail		1
Ingrown hair	1	1
Intertrigo	1	1
Itching scar		6
Keratosis pilaris	1	3
Koebner phenomenon	1	1
Leukoplakia		1
Lichenoid keratosis	1	5
Lichen planus	2	5
Lichen sclerosus	2	3
Lipodystrophy acquired		1
Livedo reticularis	13	61
Lividity	2	10
Macule	6	18
Madarosis	1	5
Mechanical urticaria	7	21
Mechanic's hand	1	1
Miliaria	13	55
Mucocutaneous disorder		1
Mucocutaneous rash	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		
			2		
		1	3	1	3
		2	7	1	1
		3	5	6	8
			3		2
			1	1	1
1	4	496	1805	247	1205
				2	11
			1		
				1	3
			1	1	1
			1		
				1	1
		1	1		
			4		2
		1	3		
		1	1		
			1		
			1	1	4
			1	2	4
			1	2	2
					1
	1	8	29	5	32
			1	2	9
		4	12	2	6
			1	1	4
	2	3	13	4	8
				1	1
		8	31	5	24
			1		
				1	1

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nail discolouration	2	17
Nail pigmentation	1	2
Nail ridging		1
Neurodermatitis	2	7
Neutrophilic dermatosis		3
Night sweats	115	548
Nodular rash	1	1
Oculomucocutaneous syndrome	7	15
Oedema blister		1
Onychalgia	2	3
Onychoclasia		6
Onycholysis		1
Pain of skin	90	321
Palmar erythema	6	22
Palmar-plantar erythrodysesthesia syndrome		1
Palmoplantar pustulosis	1	2
Palpable purpura	2	5
Panniculitis	2	5
Papule	23	61
Parapsoriasis	1	1
Peau d'orange	1	3
Pemphigoid	11	29
Pemphigus	3	10
Penile ulceration		1
Perioral dermatitis	1	4
Perivascular dermatitis		1
Pernio-like erythema		4
Petechiae	70	215
Photosensitivity reaction	30	89
Pigmentation disorder	7	18
Piloerection	11	39
Pityriasis	2	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	11	1	6
				1	2
					1
		2	7		
			1		2
	3	83	355	32	193
		1	1		
				7	15
					1
		1	2	1	1
			5		1
			1		
1	1	63	175	27	146
		1	13	5	9
					1
			1	1	1
			2	2	3
				2	5
		15	36	8	25
		1	1		
		1	3		
				11	29
				3	10
			1		
			3	1	1
			1		
			3		1
	1	28	97	42	118
1	1	21	50	9	39
		6	14	1	4
		11	22		17
		1	5	1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pityriasis lichenoides et varioliformis acuta	2	3
Pityriasis rosea	9	40
Plantar erythema		3
Post inflammatory pigmentation change		1
Progressive macular hypomelanosis	1	1
Prurigo	3	8
Pruritus	1,943	6,110
Pruritus allergic	2	8
Pseudofolliculitis	1	2
Psoriasis	24	87
Purpura	45	104
Pustular psoriasis	1	3
Rash	1,788	5,787
Rash erythematous	245	978
Rash macular	158	574
Rash maculo-papular	40	155
Rash maculovesicular	1	2
Rash morbilliform	15	40
Rash neonatal	1	2
Rash papular	86	288
Rash papulosquamous	1	2
Rash pruritic	271	997
Rash rubelliform	1	3
Rash scarlatiniform		1
Rash vesicular	38	115
Red man syndrome		1
Rosacea	6	17
Scab	17	41
Scar pain	3	7
Scleroderma associated digital ulcer		1
Seborrhoea	1	3
Seborrhoeic dermatitis	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2	1	1
		5	23	4	17
			2		1
			1		
				1	1
		2	6	1	2
4	10	1295	3953	648	2157
		2	4		4
		1	1		1
		13	45	11	42
1	2	21	47	24	57
		1	1		2
	9	1198	3704	590	2083
	4	147	548	98	430
		122	379	36	195
		21	83	19	72
			1	1	1
		6	19	9	21
		1	2		
		59	181	27	107
		1	2		
		199	596	72	401
				1	3
			1		
		30	75	8	40
					1
			7	6	10
		12	30	5	11
		3	6		1
					1
		1	2		1
			1	1	1

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sensitive skin	1,737	2,429
Skin atrophy	1	1
Skin burning sensation	66	255
Skin depigmentation	1	6
Skin discharge	1	3
Skin discolouration	65	248
Skin discomfort	5	10
Skin disorder	54	175
Skin erosion	6	15
Skin exfoliation	33	124
Skin fissures	3	12
Skin haemorrhage	8	29
Skin hyperpigmentation	2	5
Skin hypertrophy	4	11
Skin indentation	2	6
Skin induration	2	9
Skin irritation	27	105
Skin laxity		4
Skin lesion	39	125
Skin lesion inflammation	1	1
Skin mass	12	38
Skin necrosis	2	7
Skin odour abnormal	7	15
Skin oedema		4
Skin plaque	4	12
Skin reaction	39	133
Skin sensitisation	44	64
Skin striae	1	4
Skin swelling	22	72
Skin texture abnormal	1	2
Skin tightness	11	57
Skin ulcer	8	30

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1638	2215	99	214
		1	1		
	2	47	163	19	92
		1	4		2
		1	1		2
		45	157	20	91
		3	8	2	2
		34	97	20	78
		5	8	1	7
		17	70	16	54
		2	7	1	5
		3	17	5	12
		2	4		1
		3	8	1	3
		2	6		
		2	6		3
		25	70	2	35
			3		1
1	1	25	80	14	45
				1	1
		10	27	2	11
				2	7
		2	9	5	6
			4		
		3	7	1	5
		30	87	9	46
		44	54		10
			2	1	2
		15	48	7	24
		1	2		
		8	30	3	27
		2	11	6	19

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin warm	25	150
Skin weeping	4	9
Skin wrinkling	1	6
Solar dermatitis	1	2
Solar lentigo	1	3
Solar urticaria	1	1
Splinter haemorrhages		2
Stasis dermatitis		1
Stevens-Johnson syndrome	6	19
Sticky skin		1
Symmetrical drug-related intertriginous and flexural exanthema	1	1
Systemic lupus erythematosus rash	1	7
Target skin lesion		1
Telangiectasia	2	3
Toxic epidermal necrolysis		5
Toxic skin eruption	7	19
Trichodynia	1	2
Trichorrhexis	1	1
Umbilical haematoma		1
Urticaria	1,001	3,273
Urticaria cholinergic		2
Urticaria chronic	4	11
Urticaria contact	1	1
Urticarial dermatitis	1	1
Urticarial vasculitis	2	3
Urticaria papular	4	10
Urticaria physical	1	2
Urticaria pressure		1
Urticaria thermal	1	5
Urticaria vesiculosa		1
Vascular purpura	10	20

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	13	71	12	79
		2	2	2	7
		1	4		2
				1	2
				1	3
				1	1
			1		1
			1		
				6	19
			1		
				1	1
			2	1	5
					1
		1	1	1	2
	1				5
				7	19
		1	1		1
		1	1		
					1
1	2	643	2021	358	1252
			2		
		1	3	3	8
				1	1
		1	1		
				2	3
		1	5	3	5
		1	2		
					1
		1	5		
					1
		2	5	8	15

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vascular skin disorder	1	1					1	1
Vasculitic rash	2	13			1	6	1	7
Vitiligo	1	2			1	1		1
Yellow skin	4	22			3	14	1	8
	11,383	35,266	15	58	7807	21936	3576	13330

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aborted pregnancy		1				1
Bedridden	31	112	16	59	15	53
Breast prosthesis user		1		1		
Caffeine consumption		1		1		
Contraindication to medical treatment		1		1		
Contraindication to vaccination	1	12	1	12		
Disability		2		1		1
Drug abuser	1	1			1	1
Excessive exercise	1	1			1	1
Exercise lack of		1		1		
Fasting		1		1		
Hair dye user	1	1			1	1
Hearing disability	2	5		3	2	2
Illiteracy		1				1
Immobile	10	29			10	29
Immobilisation prolonged	1	1			1	1
Impaired driving ability	13	55	8	31	5	24
Impaired quality of life	10	21	4	10	6	11
Impaired work ability	62	181	24	63	38	118
Job dissatisfaction		1		1		

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System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint prosthesis user		1				1
Loss of employment		1		1		
Loss of personal independence in daily activities	135	479	64	265	71	214
Menopause	6	9	3	5	3	4
Non-tobacco user		1		1		
Partner stress		1		1		
Patient uncooperative		1		1		
Physical disability	3	4	1	1	2	3
Sight disability	1	2	1	1		1
Sitting disability	3	17	1	10	2	7
Tanning		1		1		
Tobacco user	1	1	1	1		
Urinary assistance device user		1		1		
Wa king aid user	5	10	3	7	2	3
Wa king disability	9	20	4	9	5	11
Water pollution		3		1		2
	296	981	131	491	165	490

System Organ Class

SOC Not Yet Coded

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
	22	51	22	51
	22	51	22	51

System Organ Class

Surgical and medical procedures

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Surgical and medical procedures

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal operation		1		1		
Abortion induced		1				1
Abscess drainage		1				1
Airway secretion clearance therapy		1				1
Analgesic therapy	1	1	1	1		
Anaphylaxis prophylaxis		1				1
Appendectomy		1		1		
Asthma prophylaxis		3		1		2
Axillary lymphadenectomy		3				3
Bed rest	1	8	1	6		2
Cardioversion	1	1	1	1		
Central nervous system stimulation		1				1
Contraceptive diaphragm		1		1		
Cooling therapy		1		1		
COVID-19 immunisation		8		5		3
Cranial nerve decompression		1				1
Dermabrasion		1		1		
Dermal filler injection		1		1		
Diabetic diet		1				1
Drainage	4	6	4	6		
Emergency care	1	1	1	1		
Endodontic procedure	1	1	1	1		
Gastrointestinal surgery		1				1
Haemodialysis		1		1		
Hernia repair		1				1
Hospitalisation		1				1
Hysterectomy		1				1
Ileectomy		1				1
Immunisation	1	7	1	5		2
Injection		2		2		
Joint stabilisation	1	2	1	1		1
Knee operation		1				1

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System Organ Class

Surgical and medical procedures

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Limb immobilisation	7	15	5	11	2	4
Limb operation		1				1
Local anaesthesia		1		1		
Mass excision		1		1		
Mechanical ventilation	2	3			2	3
Medical induction of coma	1	1			1	1
Menstrual cycle management	3	4	3	4		
Mesenteric artery stent insertion	1	1			1	1
Migraine prophylaxis		1				1
Multiple sclerosis relapse prophylaxis		1				1
Nerve block	1	1			1	1
Prophylaxis of nausea and vomiting	1	2	1	1		1
Resuscitation	1	3			1	3
Sinus operation		1		1		
Skin lesion removal		1		1		
Small intestinal resection	1	1			1	1
Spinal fusion surgery		1				1
Splenic artery embolisation		1				1
Surgery	1	1	1	1		
Therapeutic procedure		1		1		
Thrombectomy		1				1
Thrombolysis	1	2			1	2
Tooth extraction		5		4		1
Vascular anastomosis	1	1			1	1
Venous arterialisation	1	1			1	1
Weight loss diet		1				1
Wheat-free diet		1				1
Wound closure		1		1		
Wound drainage	1	1			1	1
	34	119	21	64	13	55

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System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accelerated hypertension		1				1		
Achenbach syndrome		1				1		
Acute aortic syndrome	2	2					2	2
Air embolism		1						1
Aneurysm	5	13			1	1	4	12
Aneurysm ruptured	4	8					4	8
Angiopathy	5	13			2	7	3	6
Aortic aneurysm	5	12			1	1	4	11
Aortic aneurysm rupture	1	5					1	5
Aortic arteriosclerosis	8	16			5	8	3	8
Aortic dilatation	1	2				1	1	1
Aortic disorder		1						1
Aortic dissection	5	15					5	15
Aortic elongation	1	1			1	1		
Aortic embolus		2						2
Aortic rupture	1	1					1	1
Aortic stenosis	2	7					2	7
Aortic thrombosis	2	2					2	2
Aortitis		2						2
Arterial disorder	3	5			1	1	2	4
Arterial haemorrhage		1						1
Arterial occlusive disease	7	12			1	1	6	11
Arterial rupture		1						1
Arterial stenosis	4	5					4	5
Arterial thrombosis	7	18	1	1	1	1	6	17
Arteriosclerosis	12	30			2	5	10	25
Arteriovenous fistula		1						1
Arteritis	2	3					2	3
Artery dissection	3	3					3	3
Axillary vein thrombosis	2	4				1	2	3
Behcet's syndrome		5						5
Bleeding varicose vein	1	2					1	2

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System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood pressure fluctuation	55	139
Blood pressure inadequately controlled	2	5
Bloody discharge		4
Blue toe syndrome	3	13
Brachiocephalic vein thrombosis	1	1
Capillary disorder		2
Capillary fragility	4	8
Capillary leak syndrome	1	1
Circulatory collapse	52	239
Claudication of jaw muscles	1	2
CT hypotension complex		2
Cyanosis	45	177
Deep vein thrombosis	442	849
Dependent rubor		1
Diastolic hypertension		4
Diastolic hypotension		3
Embolism	35	92
Embolism arterial	2	4
Embolism venous	6	11
Endothelial dysfunction	1	1
Erythromelalgia	1	1
Essential hypertension	1	8
Extremity necrosis	2	5
Femoral artery embolism	2	3
Fibromuscular dysplasia	1	2
Flushing	243	1,197
Giant cell arteritis	5	24
Granulomatosis with polyangiitis	1	1
Haematoma	51	174
Haemodynamic instability	7	13
Haemorrhage	121	316
Haemorrhagic infarction	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		29	77	26	62
			2	2	3
			1		3
		1	4	2	9
				1	1
			2		
		2	5	2	3
				1	1
	1			52	239
				1	2
					2
		15	64	30	113
	2			442	849
					1
			1		3
					3
1	1			35	92
				2	4
				6	11
		1	1		
				1	1
1	1		1	1	7
			1	2	4
				2	3
				1	2
2	3	162	768	81	429
				5	24
				1	1
		17	76	34	98
		1	3	6	10
	2		2	121	314
				1	3

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System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hot flush	283	1,093
Hyperaemia	16	38
Hypertension	884	2,871
Hypertensive crisis	114	520
Hypertensive emergency	5	18
Hypertensive urgency	1	8
Hypoperfusion	1	7
Hypotension	296	1,216
Hypotensive crisis	1	9
Hypovolaemic shock	2	41
Iliac artery occlusion		1
Infarction	6	21
Inferior vena caval occlusion		1
Intermittent claudication	5	6
Internal haemorrhage	22	43
Ischaemia	14	26
Ischaemic limb pain		1
Jugular vein distension		3
Jugular vein thrombosis	11	16
Kawasaki's disease	1	1
Labile blood pressure	3	6
Labile hypertension	1	2
Lymphangiectasia		1
Lymphangiopathy		1
Lymphoedema	36	121
MAGIC syndrome		1
Malignant hypertension	1	7
May-Thurner syndrome	1	2
Microangiopathy	2	2
Microembolism		5
Microscopic polyangiitis	1	3
Necrosis ischaemic	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		179	666	104	427
		13	27	3	11
1	7	334	992	550	1879
	2			114	520
				5	18
				1	8
		1	2		5
2	6	143	442	153	774
				1	9
				2	41
					1
				6	21
					1
		1	2	4	4
		1	1	21	42
		1	2	13	24
					1
			1		2
			1	11	15
				1	1
				3	6
			1	1	1
					1
					1
1	2	21	62	15	59
					1
				1	7
				1	2
		1	1	1	1
					5
				1	3
				1	1

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System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neurogenic shock	3	21
Obstructive shock	1	2
Orthostatic hypertension	3	4
Orthostatic hypotension	10	47
Pallor	174	607
Pelvic venous thrombosis	10	15
Peripheral arterial occlusive disease	2	5
Peripheral artery occlusion	2	4
Peripheral artery stenosis		1
Peripheral artery thrombosis	10	18
Peripheral circulatory failure	4	19
Peripheral coldness	154	571
Peripheral embolism	4	14
Peripheral ischaemia	16	38
Peripheral vascular disorder	14	53
Peripheral vein stenosis		1
Peripheral vein thrombus extension		1
Peripheral venous disease	10	22
Phlebitis	28	76
Phlebitis deep		1
Phlebitis superficial	10	18
Poor peripheral circulation	8	25
Poor venous access	1	2
Post thrombotic syndrome	1	3
Prehypertension	2	3
Raynaud's phenomenon	16	64
Secondary hypertension	3	5
Shock	24	89
Shock haemorrhagic	2	5
Shock symptom	2	9
Spider vein		1
Subclavian artery thrombosis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	21
				1	2
				3	4
		4	20	6	27
2	3	97	286	77	321
				10	15
			1	2	4
				2	4
					1
			1	10	17
		2	6	2	13
1	3	84	326	70	245
			1	4	13
		5	8	11	30
	1	12	28	2	25
					1
					1
		6	13	4	9
		6	30	22	46
					1
		2	8	8	10
		4	18	4	7
			1	1	1
				1	3
		2	3		
		8	31	8	33
		2	3	1	2
1	1			24	89
				2	5
				2	9
			1		
					1

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System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Subclavian vein stenosis		1
Subclavian vein thrombosis	8	15
Superficial vein prominence		5
Superior vena cava syndrome		1
Systolic hypertension	2	8
Takayasu's arteritis	1	2
Thromboangiitis obliterans		1
Thrombophlebitis	53	112
Thrombophlebitis superficial	66	130
Thrombosed varicose vein	2	4
Thrombosis	333	750
Varicophlebitis	3	3
Varicose vein	5	21
Vascular calcification	2	2
Vascular occlusion	3	5
Vascular pain	5	14
Vascular rupture	4	6
Vascular stenosis		1
Vasculitis	30	94
Vasculitis necrotising	1	3
Vasoconstriction		14
Vasodilatation	8	29
Vasospasm	1	4
Vein discolouration	2	7
Vein disorder	15	32
Vein rupture		5
Vein wall hypertrophy	1	1
Vena cava embolism		1
Vena cava thrombosis	2	6
Venous haemorrhage	1	2
Venous occlusion	2	3
Venous thrombosis	24	47

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				8	15
			3		2
					1
				2	8
				1	2
					1
		19	43	34	69
	1	11	32	55	98
		2	2		2
4	6	1	1	332	749
		1	1	2	2
		4	15	1	6
		1	1	1	1
				3	5
		3	8	2	6
		3	4	1	2
					1
		15	41	15	53
		1	1		2
			5		9
		3	13	5	16
		1	2		2
		2	7		
		11	22	4	10
					5
				1	1
					1
				2	6
				1	2
				2	3
		2	3	22	44

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Venous thrombosis in pregnancy		1						1
Venous thrombosis limb	37	66		2	4	7	33	59
White coat hypertension	1	4			1	3		1
Withdrawal hypertension	2	4			1	2	1	2
	4,005	12,741	17	45	1258	4239	2747	8502

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

APPENDIX 2.5.1: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per MedDRA System Organ Class by Preferred Term per Country

Cumulative Reporting Period: Through 31-MAY-2021

Interval Reporting Period: 30-APR-2021 Through 31-MAY-2021

Total Number of Cases: 47,174 (Interval) / 167,956 (Cumulative)

Total Number of Adverse Events (PT): 174,177 (Interval) / 631,356 (Cumulative)

MedDRA Version: v.24.0J

Country Where Event Occurred

AFGHANISTAN

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills		1		1
Feeling of body temperature change		1		1
Swelling face		1		1
		3		3

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle tightness		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial paralysis		1				1
Paraesthesia		1		1		
		2		1		1

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Erythema		1		1
Pruritus		1		1
Rash		1		1
		3		3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ALBANIA

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19		2		2
		2		2

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Off label use		1		1
Product use issue		1		1
		2		2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

AMERICAN SAMOA

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills		1		1
Feeling cold	1	1	1	1
Pain		1		1
	1	3	1	3

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ANDORRA

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product administered to patient of inappropriate age		1		1
		1		1

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ANGOLA

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Swollen tongue		1		1
Vomiting		1		1
		2		2

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Pyrexia		1		1
		1		1

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Nasopharyngitis		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration		1		1
		1		1

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ARGENTINA

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Vertigo	1	1	1	1
	1	1	1	1

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Thyroid disorder	1	1	1	1
	1	1	1	1

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Nausea	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug ineffective	2	2			2	2
Gait disturbance	1	1	1	1		
Gait inability	1	1	1	1		
Injection site erythema	1	1	1	1		
Malaise	1	1	1	1		
Pain	1	1	1	1		
Pyrexia	2	2	1	1	1	1
	9	9	6	6	3	3

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypersensitivity		1		1
		1		1

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	3	3	2	2	1	1
Influenza	1	1	1	1		
Suspected COVID-19	1	1			1	1
	5	5	3	3	2	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Circumstance or information capable of leading to medication error		1		1
Intentional product misuse		1		1
		2		2

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood immunoglobulin G decreased		1		1		
Blood immunoglobulin M decreased		1		1		
Blood pressure increased	1	1			1	1
SARS-CoV-2 ant body test negative		1		1		
	1	4		3	1	1

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Diabetes mellitus	1	2	1	2
	1	2	1	2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Intervertebral disc protrusion	1	1			1	1
Mobility decreased	1	1	1	1		
Pain in extremity		1		1		
	2	3	1	2	1	1

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cognitive disorder	1	1	1	1
Dizziness	1	1	1	1
Headache	1	1	1	1
Memory impairment	1	1	1	1
Motor dysfunction	1	1	1	1
Thunderclap headache	1	1	1	1
	6	6	6	6

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	1	1	1	1		
Confusional state	1	1			1	1
	2	2	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lung disorder	1	1	1	1		
Pulmonary thrombosis	1	1			1	1
	2	2	1	1	1	1

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperhidrosis	1	1			1	1
Pruritus	1	1	1	1		
Rash papular	1	1	1	1		
	3	3	2	2	1	1

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hot flush	1	1			1	1
Hypertension	1	1	1	1		
	2	2	1	1	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

AUSTRALIA

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia	1	1	1	1		
Bicytopenia	1	1			1	1
Blood disorder		1		1		
Disseminated intravascular coagulation	1	1			1	1
Febrile neutropenia	1	1			1	1
Lymphadenopathy	12	32	12	31		1
Lymph node pain	1	1	1	1		
Splenomegaly	1	1	1	1		
Thrombocytopenia	7	7			7	7
	25	46	15	35	10	11

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome		1				1
Angina pectoris	1	1			1	1
Arrhythmia	2	4			2	4
Atrioventricular block complete	1	1			1	1
Bradycardia	4	8			4	8
Cardiac arrest	2	7			2	7
Cardiac fibrillation	1	1			1	1
Cardiogenic shock	2	2			2	2
Myocardial infarction	2	3			2	3
Palpitations	5	16	5	16		
Pericarditis	1	1			1	1
Postural orthostatic tachycardia syndrome	1	1	1	1		
Sinus tachycardia		1		1		
Tachycardia	20	36	19	32	1	4
	42	83	25	50	17	33

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness	1	4			1	4
Deafness neurosensory	2	2			2	2
Deafness unilateral	1	3			1	3
Ear pain	3	4	3	4		
Paraesthesia ear		1		1		
Tinnitus	1	4	1	4		
Vertigo		4		4		
Vertigo positional		1				1
	8	23	4	13	4	10

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Adrenocortical insufficiency acute		1		1
Hyperaldosteronism	1	1	1	1
Hyperthyroidism	2	4	2	4
	3	6	3	6

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute macular outer retinopathy	1	1			1	1
Amaurosis fugax	1	1			1	1
Conjunctival haemorrhage	3	5			3	5
Dry eye	1	1	1	1		
Eye discharge		1		1		
Eye pain		4		4		
Eye pruritus	1	3	1	3		
Eye swelling	1	1	1	1		
Iridocyclitis		1				1
Mydriasis		2				2
Ocular discomfort		1		1		
Ocular hyperaemia	1	5	1	5		
Photophobia	1	4	1	4		
Pupil fixed		3				3
Pupils unequal		1				1
Retinal artery occlusion		1				1
Swelling of eyelid	1	1	1	1		
Vision blurred	7	9	6	8	1	1
Visual acuity reduced	1	1	1	1		
Visual impairment		3		3		
	19	49	13	33	6	16

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	3	2	3		
Abdominal pain	16	32	16	31		1
Abdominal pain lower		1		1		
Abdominal pain upper		1		1		
Abdominal tenderness		1		1		
Anal haemorrhage		1		1		
Aphthous ulcer	1	1	1	1		
Diarrhoea	17	30	17	30		
Dry mouth	1	2	1	2		
Dysphagia	1	5		2	1	3
Gastrointestinal disorder	1	1	1	1		
Gastrointestinal haemorrhage		1				1
Haematemesis		1				1
Hypoaesthesia oral	3	4	3	3		1
Intestinal obstruction	1	1			1	1
Lip oedema	1	1	1	1		
Lip swelling	7	10	7	10		
Mouth ulceration	1	1	1	1		
Nausea	47	121	46	118	1	3
Odynophagia		1		1		
Pancreatitis		1				1
Paraesthesia oral	9	20	9	19		1
Rectal haemorrhage	2	5			2	5
Retching	2	3	2	3		
Swollen tongue	6	10	6	9		1
Tongue oedema	1	1	1	1		
Vomiting	14	49	13	38	1	11
	133	308	127	278	6	30

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	4	12	4	12		
Axillary pain		1		1		
Chest discomfort	22	36	22	35		1
Chest pain	11	21	10	20	1	1
Chills	35	78	35	77		1
Concomitant disease aggravated	1	2			1	2
Concomitant disease progression	6	6	1	1	5	5
Condition aggravated	2	5	1	1	1	4
Crying		1		1		
Death	13	19			13	19
Disease progression	1	2	1	1		1
Drug ineffective	1	2			1	2
Extensive swelling of vaccinated limb	4	6	4	5		1
Face oedema	1	2	1	2		
Facial pain		1		1		
Fatigue	61	129	61	128		1
Feeling abnormal	1	6	1	5		1
Feeling cold	1	2	1	2		
Feeling hot	5	13	5	12		1
Feeling jittery		1		1		
Feeling of body temperature change	1	5	1	5		
Foaming at mouth	1	2	1	1		1
Gait disturbance	3	6	3	6		
General physical health deterioration	1	5			1	5
Hangover	1	1	1	1		
Illness		1		1		
Inflammation		1		1		
Influenza like illness	5	10	5	10		
Injected limb mobility decreased		1		1		
Injection site discomfort	1	1	1	1		
Injection site hypersensitivity	1	1	1	1		
Injection site pain		2		2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site reaction		2		2		
Localised oedema		1		1		
Local reaction	1	1	1	1		
Malaise	12	31	11	24	1	7
Multiple organ dysfunction syndrome	1	2			1	2
Oedema	1	1	1	1		
Oedema peripheral	1	2			1	2
Pain	7	15	5	13	2	2
Peripheral swelling	3	4	1	2	2	2
Pyrexia	81	153	78	145	3	8
Sensation of foreign body		1		1		
Soft tissue inflammation		1		1		
Swelling	9	12	9	12		
Swelling face	2	5	2	5		
Terminal state	3	3			3	3
Thirst	1	1	1	1		
Vaccination site bruising	1	3	1	3		
Vaccination site discomfort	3	4	3	4		
Vaccination site erythema		7		6		1
Vaccination site hypersensitivity	2	2	2	2		
Vaccination site pain	13	43	13	42		1
Vaccination site pruritus		2		2		
Vaccination site rash	1	1	1	1		
Vaccination site reaction	61	111	61	111		
Vaccination site swelling	2	9	2	8		1
Vaccination site vesicles		1		1		
Vaccination site warmth		1		1		
	388	800	352	725	36	75

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Liver injury		1		1
		1		1

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	26	80			26	80
Hypersensitivity	4	8	4	8		
	30	88	4	8	26	80

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal sepsis	1	1			1	1
Appendicitis		1				1
Bronchitis	1	1	1	1		
Cellulitis	3	5			3	5
COVID-19	1	3		1	1	2
Herpes zoster	1	3	1	3		
Laryngitis	1	2	1	2		
Lower respiratory tract infection	12	12			12	12
Nasopharyngitis	1	3	1	3		
Oral herpes	1	2	1	2		
Peritonsillar abscess	1	1			1	1
Pharyngitis	2	2	2	2		
Pneumonia	4	15			4	15
Pneumonia viral		1				1
Pulmonary sepsis		1				1
Respiratory tract infection		1				1
Rhinovirus infection		1		1		
Sepsis	5	8			5	8
Septic shock		1				1
Sinusitis	1	1	1	1		
Sweating fever	1	1			1	1
Tonsillitis	1	2	1	2		
Urinary tract infection	1	1			1	1
Urosepsis		2				2
Vaccination site cellulitis		1		1		
	38	72	9	19	29	53

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose		2		2		
Adverse event following immunisation	3	5			3	5
Circumstance or information capable of leading to medication error	1	2	1	2		
Contusion	4	11	3	9	1	2
Exposure via breast milk		1		1		
Fall	7	12	3	5	4	7
Inadequate aseptic technique in use of product		1		1		
Maternal exposure during pregnancy	1	1	1	1		
Muscle injury	1	1	1	1		
Nerve injury		1		1		
Off label use		2		2		
Oral contusion	1	1	1	1		
Pelvic fracture		1				1
Poor quality product administered		1		1		
Product preparation error		2		2		
Product use issue		3		3		
Scar		1		1		
Subdural haemorrhage	1	1			1	1
Tendon rupture	1	1	1	1		
	20	50	11	34	9	16

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood creatine phosphokinase increased		1				1
Blood pressure decreased		2		2		
Blood pressure immeasurable	1	1			1	1
Blood pressure increased	5	11	5	9		2
Blood thyroid stimulating hormone increased	1	1	1	1		
Body temperature decreased	1	1			1	1
Body temperature increased	1	3		2	1	1
Coma scale abnormal	2	3			2	3
Fibrin D dimer increased	3	3	3	3		
Heart rate increased	3	7	3	6		1
Heart rate irregular		1				1
Liver function test abnormal	1	1	1	1		
Liver function test increased		1		1		
Lymphocyte count increased	1	1	1	1		
Neutrophil count decreased		1		1		
Oxygen saturation decreased	4	9	4	5		4
Oxygen saturation immeasurable	1	1			1	1
Platelet count increased	1	1	1	1		
Respiratory rate increased	1	3	1	1		2
Weight decreased		1				1
White blood cell count decreased		1		1		
	26	54	20	35	6	19

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	2	9	1	6	1	3
Diabetes mellitus		1				1
Diabetic ketoacidosis	1	2			1	2
Food refusal		1		1		
Hyperglycaemia		1				1
Hyperglycaemic hyperosmolar nonketotic syndrome		1				1
Hyperkalaemia	1	1			1	1
Hypoglycaemia		1		1		
Hypophagia	1	2			1	2
	5	19	1	8	4	11

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	48	97	48	97		
Arthritis	1	1	1	1		
Back pain	3	6	3	6		
Joint stiffness		1		1		
Joint swelling	1	2	1	2		
Limb discomfort	3	5	3	5		
Mobility decreased		1		1		
Muscle spasms		2		2		
Muscle tightness		2		2		
Muscle twitching		1		1		
Muscular weakness	1	2	1	2		
Musculoskeletal stiffness	1	3	1	3		
Myalgia	92	168	92	167		1
Myalgia intercostal	1	1	1	1		
Myokymia	1	1	1	1		
Neck pain	2	6	2	6		
Pain in extremity	8	17	8	17		
Pain in jaw	1	1	1	1		
Rotator cuff syndrome	1	1	1	1		
Spinal pain		1		1		
Systemic lupus erythematosus	1	1			1	1
	165	320	164	318	1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	4	6	4	6		
Altered state of consciousness		1				1
Anosmia	1	1	1	1		
Aphasia	1	2	1	1		1
Areflexia		1				1
Balance disorder	1	3	1	2		1
Bell's palsy	6	8			6	8
Brain stem stroke	2	2			2	2
Burning sensation	2	3	2	3		
Cerebral haemorrhage	1	2			1	2
Cerebral venous sinus thrombosis	1	1			1	1
Cerebrovascular accident	5	12			5	12
Cognitive disorder		1				1
Consciousness fluctuating		1				1
Demyelination	1	2			1	2
Depressed level of consciousness	4	9			4	9
Dizziness	33	81	33	75		6
Droling		1				1
Dysarthria	1	4			1	4
Dysgeusia	3	5	3	5		
Dyskinesia		1		1		
Epilepsy	1	1			1	1
Facial paralysis	2	9			2	9
Facial paresis	2	7	2	3		4
Fine motor skill dysfunction	1	1			1	1
Generalised tonic-clonic seizure	3	3			3	3
Haemorrhage intracranial	1	1			1	1
Headache	118	245	118	243		2
Head discomfort		1		1		
Hemiparesis	1	2			1	2
Hemiplegia	1	1			1	1
Hypoaesthesia	5	13	5	13		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyporesponsive to stimuli		1				1
Incoherent	1	1			1	1
Ischaemic stroke		2				2
Lacunar infarction	1	1			1	1
Lethargy	78	125	77	122	1	3
Loss of consciousness	5	14			5	14
Migraine	3	7	3	7		
Migraine with aura		1		1		
Monoplegia	1	3			1	3
Multiple sclerosis	1	3			1	3
Multiple sclerosis relapse		1				1
Neuropathy peripheral		1				1
Nystagmus	1	1	1	1		
Occipital neuralgia		1		1		
Orthostatic tremor		1		1		
Paraesthesia	4	29	4	29		
Petit mal epilepsy	1	1			1	1
Presyncope	3	26	3	24		2
Seizure	9	19			9	19
Seizure like phenomena	1	1			1	1
Sensory disturbance		1		1		
Sensory loss		1		1		
Somnolence	4	10	3	7	1	3
Speech disorder		1		1		
Speech disorder developmental	1	1	1	1		
Syncope	47	86			47	86
Taste disorder	1	1	1	1		
Thrombotic stroke	1	1			1	1
Thunderclap headache	1	1	1	1		
Transient ischaemic attack	1	3			1	3
Transverse sinus thrombosis	1	1			1	1
Tremor	2	12	2	12		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Trigeminal neuralgia		1		1		
Unresponsive to stimuli	4	13			4	13
	373	803	266	566	107	237

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion spontaneous	2	2	2	2
	2	2	2	2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation	1	2		1	1	1
Anxiety		8		3		5
Confusional state	2	7	2	6		1
Delirium		2				2
Depressed mood		1		1		
Disorientation		2		2		
Feeling of despair	1	1	1	1		
Hallucination	2	4			2	4
Hallucination, tactile		1				1
Insomnia	2	6	2	6		
Nervousness		2		1		1
Panic reaction		1		1		
Restlessness	1	1	1	1		
Somatic symptom disorder		1				1
	9	39	6	23	3	16

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	3			1	3
Dysuria	1	1	1	1		
Incontinence		1		1		
Nephrolithiasis	1	1			1	1
Renal impairment	2	2			2	2
Urinary incontinence		1				1
	5	9	1	2	4	7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Endometriosis	1	1			1	1
Menstruation irregular	2	2	1	1	1	1
Pelvic pain	1	1	1	1		
Vaginal haemorrhage	1	1	1	1		
	5	5	3	3	2	2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute pulmonary oedema		1				1
Aphonia	3	3	3	3		
Apnoea	1	2			1	2
Aspiration		1				1
Asthma	6	7	6	7		
Bronchospasm	1	2	1	2		
Chronic obstructive pulmonary disease	1	1	1	1		
Cough	53	88	53	86		2
Dry throat	1	3	1	3		
Dysphonia	3	6	3	6		
Dyspnoea	75	105	68	86	7	19
Epistaxis	2	3	2	3		
Hypopnoea		2		2		
Hypoxia	1	4			1	4
Nasal congestion	7	10	7	10		
Nasal pruritus	1	1	1	1		
Oropharyngeal pain	21	37	21	37		
Pharyngeal swelling	3	5	3	3		2
Pleuritic pain		2		2		
Pneumonia aspiration	3	6			3	6
Pneumothorax	1	1			1	1
Productive cough	1	1	1	1		
Pulmonary congestion	2	3			2	3
Pulmonary embolism	4	9			4	9
Pulmonary oedema		1				1
Rales	1	2	1	1		1
Respiratory distress		2				2
Respiratory failure	1	4			1	4
Respiratory symptom	1	1	1	1		
Rhinorrhoea	8	21	8	21		
Sinus congestion	2	2	2	2		
Sinus pain		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stridor	2	2	2	2		
Tachypnoea		3		2		1
Throat irritation	11	19	11	19		
Throat tightness	9	15	9	13		2
Wheezing	11	18	10	16	1	2
	236	394	215	331	21	63

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	11	14			11	14
Blister	1	1	1	1		
Blood blister	1	1	1	1		
Cold sweat	2	12	2	9		3
Dermatitis allergic		1		1		
Dermatitis bullous	1	1			1	1
Erythema	6	15	6	15		
Hyperhidrosis	3	17	3	16		1
Miliaria	1	1	1	1		
Night sweats		2		2		
Petechiae	1	1	1	1		
Photosensitivity reaction		1		1		
Pruritus	18	36	17	35	1	1
Rash	62	90	62	88		2
Rash erythematous		1		1		
Rash macular		1				1
Rash maculo-papular	1	1	1	1		
Rash pruritic	5	8	5	8		
Sensitive skin		1		1		
Skin sensitisation		1		1		
Urticaria	24	40	24	40		
	137	246	124	223	13	23

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circulatory collapse		1				1
Cyanosis	1	3		1	1	2
Deep vein thrombosis	23	26			23	26
Flushing	11	25	11	25		
Haemorrhage	3	3			3	3
Hot flush	4	7	4	7		
Hypertension	10	38	10	37		1
Hypotension	6	19	3	13	3	6
Lymphoedema	1	1	1	1		
Pallor	2	4	1	2	1	2
Peripheral circulatory failure		1				1
Peripheral coldness		1		1		
Thrombophlebitis		2		2		
Thrombosis	8	8			8	8
Vasculitis	1	1	1	1		
Vasoconstriction		1		1		
Venous thrombosis		1		1		
	70	142	31	92	39	50

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

AUSTRIA

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agranulocytosis		1				1
Anaemia	3	5			3	5
Antiphospholipid syndrome		1				1
Autoimmune haemolytic anaemia		1				1
Bone marrow oedema		1				1
Coagulopathy		1				1
Haemolytic anaemia	1	1			1	1
Hyperchromic anaemia		1				1
Hypereosinophilic syndrome	1	1			1	1
Immune thrombocytopenia		1				1
Leukocytosis		2				2
Leukopenia	2	6			2	6
Lymphadenopathy	17	51	14	31	3	20
Lymph node pain	8	15	8	13		2
Lymphocytosis		1				1
Lymphopenia		1		1		
Myelosuppression		1				1
Neutropenia		1				1
Pancytopenia	1	2			1	2
Splenic vein thrombosis		1				1
Splenomegaly		1		1		
Spontaneous haematoma		1				1
Thrombocytopenia	3	7			3	7
	36	104	22	46	14	58

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome		2				2
Acute left ventricular failure		1				1
Acute myocardial infarction	1	2			1	2
Angina pectoris	3	9			3	9
Arrhythmia	5	12			5	12
Arteriosclerosis coronary artery		2				2
Atrial fibrillation	1	9			1	9
Bradycardia		4				4
Bundle branch block left		1				1
Bundle branch block right		1				1
Cardiac arrest		4				4
Cardiac failure	3	12			3	12
Cardiac failure acute		1				1
Cardiac hypertrophy		1				1
Cardiomegaly	1	2		1	1	1
Cardiomyopathy		1				1
Cardiopulmonary failure	1	3			1	3
Cardio-respiratory arrest		2				2
Cardiovascular disorder	7	19	7	17		2
Coronary artery stenosis		1				1
Coronary artery thrombosis	1	1			1	1
Extrasystoles	2	5	1	2	1	3
Ischaemic cardiomyopathy	1	1			1	1
Left ventricular failure		2				2
Mitral valve incompetence	1	1			1	1
Myocardial infarction	4	7			4	7
Myocarditis	3	7			3	7
Palpitations	5	27	4	12	1	15
Pericardial effusion		2				2
Pericarditis		1				1
Sinus tachycardia		3				3
Supraventricular tachycardia		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia	8	24	2	4	6	20
Tachycardia paroxysmal		1				1
Ventricular extrasystoles		1				1
Ventricular f brillation		1				1
	47	174	14	36	33	138

System Organ Class

Congenital, familial and genetic disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hereditary angioedema with normal C1 esterase inhibitor		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness	1	1			1	1
Dysacusis	1	1	1	1		
Ear discomfort		2		2		
Ear pain		2		2		
Ear pruritus	1	1	1	1		
Ear swelling	1	1	1	1		
External ear pain		1				1
Hypoacusis	3	4	2	2	1	2
Phobic postural vertigo	1	1	1	1		
Sudden hearing loss		2				2
Tinnitus	3	7	1	4	2	3
Vertigo	8	32	6	17	2	15
Vertigo positional	1	1			1	1
	20	56	13	31	7	25

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Autoimmune thyroiditis		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accommodation disorder	2	2	2	2		
Acute macular outer retinopathy		1				1
Altered visual depth perception		1		1		
Blepharospasm	2	3	2	2		1
Blindness unilateral	1	1			1	1
Conjunctival haemorrhage		2				2
Conjunctival hyperaemia	1	1	1	1		
Diplopia	2	4		1	2	3
Dyschromatopsia	1	1			1	1
Endocrine ophthalmopathy		1				1
Eye haemorrhage		1				1
Eye irritation		1				1
Eyelid oedema	1	2	1	1		1
Eyelid ptosis	1	2			1	2
Eye movement disorder		1				1
Eye pain	1	4		2	1	2
Eye pruritus		2		2		
Eye swelling	1	2	1	2		
Lacrimation increased		1		1		
Ocular hyperaemia		2		2		
Ocular myasthenia	1	1			1	1
Ophthalmoplegia	1	1			1	1
Periorbital swelling	1	2	1	1		1
Photophobia	1	5		4	1	1
Pupillary reflex impaired		1				1
Pupils unequal		1				1
Retinal artery occlusion	1	2			1	2
Retinal tear		1				1
Retinal vein thrombosis	1	1			1	1
Strabismus	1	2		1	1	1
Swelling of eyelid		1				1
Vision blurred	2	8	2	6		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Visual acuity reduced	1	1			1	1
Visual field defect	1	4		1	1	3
Visual impairment	5	14	1	2	4	12
Vitreous detachment	1	1			1	1
Vitreous haemorrhage		2				2
	30	83	11	32	19	51

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1		1		
Abdominal pain	3	7	2	3	1	4
Abdominal pain lower		2				2
Abdominal pain upper	1	5		2	1	3
Chapped lips		1				1
Colitis		1				1
Defaecation urgency		1		1		
Diarrhoea	18	45	16	36	2	9
Diarrhoea haemorrhagic		3				3
Dry mouth	1	9		6	1	3
Dysphagia		10		3		7
Faeces pale	1	1			1	1
Flatulence		1		1		
Gastrointestinal disorder		2		2		
Gastrointestinal hypermotility		1		1		
Gastrointestinal motility disorder		1		1		
Gastrointestinal pain		1				1
Glossodynia		1				1
Haematemesis		2				2
Hypoaesthesia oral	2	11	2	6		5
Ileus	1	1			1	1
Inflammatory bowel disease	1	1			1	1
Lip dry		2		1		1
Lip erythema		1				1
Lip oedema	1	1	1	1		
Lip pruritus		1				1
Lip swelling		6				6
Mesenteric vein thrombosis	1	1			1	1
Mouth haemorrhage		1				1
Mouth swelling		2				2
Mouth ulceration	1	1			1	1
Nausea	54	134	48	98	6	36

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral discomfort		2				2
Oral disorder		1		1		
Oral mucosa erosion		1		1		
Oral mucosal erythema		1				1
Oral pruritus		2				2
Palatal swelling		1				1
Pancreatitis	1	1			1	1
Paraesthesia oral	3	8	2	3	1	5
Retching		2		2		
Stomatitis		1		1		
Swollen tongue	1	11		2	1	9
Thrombosis mesenteric vessel		1				1
Tongue discomfort	1	5	1	2		3
Toothache		1				1
Trichoglossia		1		1		
Vomiting	13	42	10	29	3	13
	104	339	82	205	22	134

* I=Interval, C=Cumulative
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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site hypoaesthesia		1		1		
Application site pain		1		1		
Asthenia	14	47	9	34	5	13
Axillary pain		2		1		1
Cardiac death		1				1
Chest discomfort	3	14		3	3	11
Chest pain	6	20	1	6	5	14
Chills	59	149	56	114	3	35
Complication associated with device		1		1		
Concomitant disease aggravated		2				2
Concomitant disease progression		1				1
Condition aggravated	4	7	1	2	3	5
Death	2	19			2	19
Discomfort	2	3	1	2	1	1
Disease progression		1				1
Disease recurrence	2	4			2	4
Drug ineffective	31	62			31	62
Exercise tolerance decreased		1		1		
Face oedema		4		1		3
Facial pain	1	1			1	1
Fatigue	129	258	117	215	12	43
Feeling abnormal	2	9	2	7		2
Feeling cold	3	9	3	4		5
Feeling drunk		2		2		
Feeling hot	1	10	1	5		5
Feeling jittery	1	2		1	1	1
Feeling of body temperature change	1	3	1	3		
Gait disturbance	5	13	4	9	1	4
Generalised oedema		1		1		
General physical health deterioration	8	21	2	4	6	17
Hangover		1		1		
Hypothermia	3	3			3	3

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Illness		1				1
Impaired healing	1	1	1	1		
Inflammation	1	2			1	2
Influenza like illness	5	16	5	14		2
Injected limb mobility decreased		1				1
Injection site bruising		1		1		
Injection site pain		2		2		
Injection site paraesthesia		1		1		
Localised oedema		1				1
Malaise	8	21	7	14	1	7
Mass	1	1	1	1		
Multiple organ dysfunction syndrome	1	4			1	4
Necrosis	1	1			1	1
Oedema		1				1
Oedema mucosal		1		1		
Oedema peripheral	1	3			1	3
Pain	8	26	6	17	2	9
Performance status decreased	1	4		2	1	2
Peripheral swelling	6	16	3	7	3	9
Pyrexia	145	288	131	218	14	70
Sensation of foreign body	2	8	1	1	1	7
Sense of oppression		1				1
Sudden cardiac death	1	1			1	1
Swelling	1	9		5	1	4
Swelling face	1	9	1	3		6
Systemic inflammatory response syndrome		1				1
Therapeutic response unexpected	1	1	1	1		
Thirst		1		1		
Vaccination failure	52	69	1	1	51	68
Vaccination site anaesthesia		1				1
Vaccination site discolouration		2				2
Vaccination site dysaesthesia		1				1

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site erythema	12	26	11	19	1	7
Vaccination site haematoma	1	1	1	1		
Vaccination site haemorrhage		1		1		
Vaccination site hypoaesthesia		7		4		3
Vaccination site induration	5	9	4	6	1	3
Vaccination site inflammation	3	4	2	2	1	2
Vaccination site joint pain	1	3	1	2		1
Vaccination site lymphadenopathy	8	15	8	12		3
Vaccination site movement impairment	3	9	3	8		1
Vaccination site pain	86	178	84	159	2	19
Vaccination site paraesthesia		2		1		1
Vaccination site pruritus	6	11	5	7	1	4
Vaccination site rash		4		3		1
Vaccination site reaction	5	10	4	9	1	1
Vaccination site swelling	24	43	23	35	1	8
Vaccination site urticaria	1	3	1	2		1
Vaccination site warmth	1	7	1	5		2
	670	1,502	504	986	166	516

System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Biliary colic		1				1
Cholestasis		1				1
Congestive hepatopathy		1				1
Hepatic pain		2		1		1
Hepatic steatosis		1		1		
Jaundice	1	1			1	1
	1	7		2	1	5

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System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	2	2	1	1	1	1
Anaphylactic reaction	3	11			3	11
Anaphylactic shock		6				6
Anaphylactoid reaction		2				2
Autoimmune disorder		1				1
Hypersensitivity	4	20	1	2	3	18
Type I hypersensitivity		1				1
	9	43	2	3	7	40

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthritis infective	1	1			1	1
Asymptomatic COVID-19	16	25	1	1	15	24
Bacterial sepsis		1				1
Bronchiolitis		1				1
Bronchitis		1				1
Central nervous system infection		1				1
Conjunctivitis		1				1
Coronavirus infection		1				1
COVID-19	66	113	4	9	62	104
COVID-19 pneumonia	5	9			5	9
Device related infection		1				1
Disseminated varicella zoster virus infection		1				1
Ear infection		1				1
Epstein-Barr virus infection	1	1			1	1
Erysipelas		1				1
Escherichia infection	1	1			1	1
Escherichia sepsis	1	2			1	2
Gastroenteritis		1		1		
Gingivitis		1		1		
Helicobacter infection		1				1
Herpes simplex encephalitis		1				1
Herpes simplex reactivation	1	1			1	1
Herpes zoster	13	22	10	15	3	7
Herpes zoster cutaneous disseminated		1				1
Infection	1	3			1	3
Influenza		1		1		
Meningitis bacterial		1				1
Nasopharyngitis	1	2	1	2		
Oral herpes	3	3	1	1	2	2
Oral pustule		1		1		
Pneumonia	2	12			2	12
Pneumonia bacterial		2				2

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulpitis dental	1	1			1	1
Pustule		1		1		
Rash pustular		3		1		2
Rhinitis	1	3		2	1	1
Sepsis	1	3			1	3
Septic shock		1				1
Suspected COVID-19	1	3	1	1		2
Tonsillitis	1	1	1	1		
Tonsillitis bacterial	1	2			1	2
Urinary tract infection	1	2			1	2
Uterine abscess	1	1			1	1
Vaccination site abscess	1	1			1	1
Vaccination site pustule		1		1		
Vestibular neuronitis		1				1
Viral infection		1		1		
Viral rash		1				1
	121	241	19	40	102	201

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chillblains	1	1			1	1
Concussion		1				1
Contusion		1				1
Craniocerebral injury		1				1
Exposure during pregnancy		1		1		
Eye contusion		1				1
Eyelid contusion		1				1
Facial bones fracture		1				1
Fall	2	10	1	2	1	8
Foreign body aspiration		1				1
Head injury		1				1
Inappropriate schedule of product administration	3	5	3	5		
Incorrect dose administered		1		1		
Incorrect route of product administration	2	11	2	11		
Injury		1				1
Intentional overdose		1				1
Maternal exposure during pregnancy		1		1		
Off label use	4	12	4	12		
Poor quality product administered		1		1		
Product administered at inappropriate site		1		1		
Product preparation error		1		1		
Product use issue	1	7	1	7		
Rib fracture		1				1
Road traffic accident		1				1
Subcutaneous haematoma		1				1
Subdural haemorrhage		1				1
Toxicity to various agents		1				1
Underdose	1	2	1	2		
Vaccination complication		1				1
Wound haemorrhage		1				1
Wrong technique in product usage process		3		3		
	14	74	12	48	2	26

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- * AE=Adverse Event
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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Activated partial thromboplastin time prolonged		1				1
Alanine aminotransferase increased	1	2		1	1	1
Analgesic drug level above therapeutic		1				1
Antibody test abnormal		1		1		
Anti-platelet ant body		1				1
Aspartate aminotransferase increased	1	2		1	1	1
Beta globulin increased		1		1		
Bleeding time prolonged	1	1			1	1
Blood albumin decreased		1		1		
Blood creatine phosphokinase increased		4		2		2
Blood creatine phosphokinase MB increased		2		1		1
Blood creatinine increased		1		1		
Blood fibrinogen increased	1	1	1	1		
Blood glucose decreased	2	2			2	2
Blood glucose fluctuation	2	3			2	3
Blood glucose increased	1	3	1	2		1
Blood lactate dehydrogenase increased	1	2		1	1	1
Blood lactic acid increased	1	1			1	1
Blood pressure abnormal		3				3
Blood pressure decreased	1	4		1	1	3
Blood pressure immeasurable		1				1
Blood pressure increased	3	14	3	8		6
Blood pressure systolic increased		1				1
Blood sodium decreased		1		1		
Blood urea increased		1		1		
Body temperature abnormal	1	1	1	1		
Body temperature increased	5	20	4	17	1	3
Brain natriuretic peptide increased		1				1
Breath sounds		1		1		
Breath sounds abnormal		1				1
Coagulation factor increased	1	1			1	1
C-reactive protein increased	3	7	2	4	1	3

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Electrocardiogram abnormal		1		1		
Electrocardiogram change		1				1
Electrocardiogram ST segment elevation		1				1
Electrocardiogram ST-T change		1				1
Faecal calprotectin increased		1				1
Fibrin D dimer increased	3	5	3	4		1
Heart rate decreased		2				2
Heart rate increased	1	5	1	3		2
Inflammatory marker increased	3	3			3	3
Interleukin level increased		1				1
International normalised ratio fluctuation	1	1			1	1
Intraocular pressure increased		1				1
Low density lipoprotein increased	1	1			1	1
Lymph node palpable		1		1		
Lymphocyte count increased		2		1		1
Mean platelet volume decreased		1		1		
Nerve conduction studies abnormal		1				1
Neutralising antibodies negative		1		1		
Opiates positive		1				1
Oxygen saturation		1				1
Oxygen saturation abnormal	1	1	1	1		
Oxygen saturation decreased	1	8		2	1	6
Oxygen saturation immeasurable		1				1
Platelet count decreased	1	2		1	1	1
Platelet count increased		1		1		
Prohormone brain natriuretic peptide increased	1	1	1	1		
Pulmonary function test decreased		1		1		
Red blood cell sedimentation rate increased		1		1		
Renal function test abnormal	1	1	1	1		
Respiratory rate decreased	1	2	1	1		1
SARS-CoV-2 ant body test negative		3				3
SARS-CoV-2 test positive	21	26	1	1	20	25

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensory level abnormal		2				2
Serum ferritin decreased		1		1		
Serum ferritin increased	1	2		1	1	1
Shift to the left		1				1
Transaminases increased	1	3		1	1	2
Transferrin increased		1		1		
Troponin I increased		1				1
Troponin increased		1				1
Troponin T increased		3				3
Urine ketone body present		1		1		
Weight increased	1	1	1	1		
White blood cell count increased		2		2		
White blood cells urine		1				1
	64	187	22	78	42	109

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cachexia		2				2
Decreased appetite	5	11	4	9	1	2
Dehydration		2		1		1
Fluid retention	1	1	1	1		
Histamine intolerance		1				1
Hyperglycaemia		2				2
Hyperkalaemia	2	2			2	2
Hypernatraemia		1				1
Hypoglycaemia	2	3			2	3
Hypokalaemia		1				1
Hyponatraemia	3	3			3	3
Hypophagia		1				1
Marasmus	1	2			1	2
	14	32	5	11	9	21

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	79	136	76	108	3	28
Arthritis	2	2	2	2		
Back pain	3	14	1	5	2	9
Bone pain	2	3	2	3		
Bursitis		2		1		1
Facial asymmetry		1				1
Flank pain		1				1
Groin pain		1		1		
Immobilisation syndrome	1	1			1	1
Intervertebral disc protrusion	1	2			1	2
Joint effusion	1	1			1	1
Joint range of motion decreased		1				1
Joint swelling	1	7	1	3		4
Limb discomfort		1				1
Muscle atrophy		1		1		
Muscle disorder		1				1
Muscle rigidity	1	1	1	1		
Muscle spasms	2	11		5	2	6
Muscle twitching	1	2	1	2		
Muscular weakness	1	12		3	1	9
Musculoskeletal chest pain		1				1
Musculoskeletal disorder	1	3	1	1		2
Musculoskeletal stiffness	1	1			1	1
Myalgia	70	123	69	103	1	20
Myosclerosis	1	1			1	1
Neck pain	5	11	5	10		1
Nuchal rigidity		2		1		1
Pain in extremity	33	104	30	80	3	24
Pain in jaw	2	2	2	2		
Rhabdomyolysis		1				1
Rheumatoid arthritis		1				1
Spinal pain		4		2		2

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* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tendon disorder		1		1		
Trismus	1	1			1	1
Weight bearing difficulty	1	2		1	1	1
	210	459	191	336	19	123

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Neoplasm malignant		1		1
		1		1

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute disseminated encephalomyelitis	1	4			1	4
Ageusia	4	7	3	6	1	1
Allodynia		1		1		
Amnesia		1		1		
Anosmia	2	3	1	2	1	1
Aphasia	2	6	1	2	1	4
Balance disorder	2	5	2	3		2
Basal ganglia stroke		1				1
Basilar migraine		1				1
Bell's palsy		1				1
Bradykinesia		2		1		1
Burning feet syndrome	1	1	1	1		
Burning sensation		3		2		1
Cerebellar stroke		1				1
Cerebral artery occlusion		1				1
Cerebral haemorrhage		3				3
Cerebral infarction		3				3
Cerebral ischaemia		1				1
Cerebral venous sinus thrombosis	2	3			2	3
Cerebrovascular accident	5	12			5	12
Clonus		1				1
Cognitive disorder	1	1			1	1
Coma	1	1			1	1
Depressed level of consciousness		1				1
Disturbance in attention	3	10	3	6		4
Dizziness	37	108	31	77	6	31
Dizziness postural		1		1		
Dysaesthesia	3	9	1	2	2	7
Dysarthria	1	3			1	3
Dysgeusia	4	12	3	7	1	5
Dysgraphia		1		1		
Dyskinesia		1				1

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* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysstasia		2		1		1
Epilepsy	1	5			1	5
Facial paralysis	5	11			5	11
Facial paresis	4	15			4	15
Facial spasm		1				1
Febrile convulsion	3	4		1	3	3
Formication	1	2		1	1	1
Generalised tonic-clonic seizure		3				3
Glossopharyngeal nerve disorder		1				1
Guillain-Barre syndrome	2	2			2	2
Haemorrhage intracranial	1	1			1	1
Headache	147	309	137	249	10	60
Head discomfort	1	3	1	2		1
Hemianaesthesia		2				2
Hemiataxia	1	1			1	1
Hemidysaesthesia		2				2
Hemiparaesthesia	2	4			2	4
Hemiparesis	4	7			4	7
Hemiplegia	1	2			1	2
Hyperaesthesia		1				1
Hyperreflexia		1				1
Hypersomnia	1	3	1	3		
Hypertonia		1				1
Hypoaesthesia	5	29	2	12	3	17
Hypogeusia		2		1		1
Hypoglossal nerve paresis		1				1
Hypokinesia		1		1		
Hyposmia		1				1
Hypotonia		4		3		1
Intraventricular haemorrhage		1				1
Ischaemic cerebral infarction		1				1
Ischaemic stroke		1				1

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Language disorder		1		1		
Leukoencephalopathy		1				1
Locked-in syndrome		1				1
Loss of consciousness	2	10			2	10
Memory impairment	1	6		2	1	4
Meningism		1				1
Migraine	1	7		4	1	3
Migraine with aura	1	1	1	1		
Monoparesis	1	3			1	3
Monoplegia	1	3			1	3
Movement disorder		3		2		1
Multiple sclerosis	1	3			1	3
Muscle contractions involuntary		3		1		2
Muscle spasticity		1				1
Myasthenia gravis	1	1			1	1
Myoclonus		1				1
Narcolepsy		1				1
Nervous system disorder		1				1
Neuralgia		3		1		2
Neuralgic amyotrophy		1				1
Neuritis		1				1
Neurological symptom		1				1
Neuropathy peripheral		1				1
Occipital neuralgia		1		1		
Oculofacial paralysis	1	1			1	1
Optic neuritis	1	1			1	1
Paraesthesia	8	50	3	19	5	31
Paralysis	2	2			2	2
Paresis		1				1
Parosmia		2		2		
Peroneal nerve palsy		1				1
Petit mal epilepsy		1				1

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Post herpetic neuralgia		1				1
Presyncope	6	27	4	9	2	18
Radial nerve palsy		1				1
Radiculopathy		1				1
Reduced facial expression		1		1		
Retrograde amnesia	1	1	1	1		
Ruptured cerebral aneurysm		1				1
Sciatica	2	2			2	2
Seizure	1	6			1	6
Sensory disturbance		2				2
Somnolence	12	39	7	25	5	14
Speech disorder	1	6	1	2		4
Status epilepticus	1	2			1	2
Subarachnoid haemorrhage		2				2
Syncope	8	30			8	30
Taste disorder	1	4	1	3		1
Tension headache		2		1		1
Thalamic infarction	1	2			1	2
Transient ischaemic attack	1	2			1	2
Tremor	3	7	1	3	2	4
Trigeminal neuralgia		2				2
Tunnel vision	1	3	1	1		2
Unresponsive to stimuli	1	5			1	5
Vascular encephalopathy		1				1
	309	898	207	467	102	431

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Syringe issue		1		1
		1		1

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* AE=Adverse Event
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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation	1	3	1	3		
Anxiety	1	5	1	3		2
Apathy		2		2		
Confusional state	2	9	2	3		6
Daydreaming		1				1
Delirium		1				1
Depression	1	1			1	1
Disorganised speech		1		1		
Disorientation	1	4	1	3		1
Fear of disease	1	1			1	1
Hallucination		1				1
Head banging		1				1
Helplessness	1	1	1	1		
Immunisation anxiety related reaction	1	1			1	1
Insomnia	1	7		4	1	3
Lack of spontaneous speech		1				1
Listless	1	1			1	1
Mania		1				1
Panic attack		1				1
Panic reaction		1		1		
Personality change		1				1
Psychotic disorder		1				1
Restlessness	1	6		4	1	2
Sleep attacks		1		1		
Sleep disorder	2	3	1	1	1	2
Sleep disorder due to general medical condition, hypersomnia type		1		1		
Somatic symptom disorder		1				1
Sopor		1				1
Stress		1		1		
Tension		1		1		
Thinking abnormal		2		1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	14	63	7	31	7	32

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury		1				1
Chromaturia	2	2	1	1	1	1
Chronic kidney disease		1				1
Dysuria		1		1		
Haematuria		2				2
Incontinence		1				1
Pollakiuria		1		1		
Renal disorder		1		1		
Renal failure	1	3			1	3
Renal pain		3				3
Urinary retention	1	2			1	2
	4	18	1	4	3	14

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amenorrhoea		1				1
Benign prostatic hyperplasia	1	1			1	1
Breast pain		1		1		
Epididymal tenderness	1	1			1	1
Genital discomfort	1	1	1	1		
Heavy menstrual bleeding	2	3	1	1	1	2
Intermenstrual bleeding	1	2	1	1		1
Menstruation irregular	2	3	1	1	1	2
Oedema genital	1	1			1	1
Vaginal discharge		1		1		
Vaginal haemorrhage		2				2
	9	17	4	6	5	11

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphonia		1				1
Apnoea		1				1
Aspiration		1				1
Asthma		2				2
Atelectasis	1	2	1	1		1
Bronchial obstruction		1				1
Choking		1				1
Chronic obstructive pulmonary disease	1	3	1	1		2
Cough	8	20	5	14	3	6
Diffuse alveolar damage	1	1			1	1
Dry throat		1		1		
Dyspnoea	25	71	5	12	20	59
Dyspnoea at rest	2	2			2	2
Dyspnoea exertional	3	13		2	3	11
Emphysema		2		1		1
Epistaxis	1	5	1	4		1
Grunting		1		1		
Hyperventilation	1	4		1	1	3
Hypopnoea		1				1
Hypoxia	1	1			1	1
Laryngeal oedema		1				1
Laryngeal pain		1				1
Laryngospasm		1				1
Lung disorder		1		1		
Lung infiltration		1				1
Nasal congestion	1	1	1	1		
Obstructive airways disorder		1		1		
Organising pneumonia	1	1			1	1
Oropharyngeal pain	7	18	4	12	3	6
Oropharyngeal swelling	1	1	1	1		
Painful respiration	1	2		1	1	1
Pharyngeal lesion		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal swelling	1	7	1	2		5
Pleural effusion	3	6			3	6
Pleurisy		1				1
Pneumonia aspiration		4				4
Pneumothorax spontaneous		1				1
Productive cough		1		1		
Pulmonary congestion	1	2			1	2
Pulmonary embolism	14	37			14	37
Pulmonary hypertensive crisis		1				1
Pulmonary infarction	2	4			2	4
Pulmonary oedema		3				3
Pulmonary pain	1	1			1	1
Rales		2		1		1
Respiratory acidosis		1				1
Respiratory depression		1				1
Respiratory disorder	3	4		1	3	3
Respiratory distress	1	2			1	2
Respiratory failure	4	6			4	6
Respiratory symptom	1	1	1	1		
Rhinitis allergic		1				1
Rhinorrhoea	1	1	1	1		
Sinus congestion		1		1		
Tachypnoea	1	2		1	1	1
Throat irritation	1	7	1	4		3
Throat tightness	1	5			1	5
Use of accessory respiratory muscles		1		1		
	90	267	23	70	67	197

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecia	1	3	1	3		
Angioedema		2				2
Blister	1	2	1	1		1
Cold sweat		1				1
Cutaneous vasculitis	1	1			1	1
Dermatitis allergic	1	3			1	3
Dermatitis bullous		1				1
Drug eruption		2				2
Eczema	1	4	1	2		2
Erythema	1	16	1	10		6
Haemorrhage subcutaneous	1	1			1	1
Hand dermatitis		1		1		
Hirsutism		1		1		
Hyperhidrosis	4	9	2	6	2	3
Idiopathic angioedema		1				1
Lividity		1		1		
Night sweats	1	3	1	2		1
Onychoclasia		1		1		
Pain of skin	1	3		1	1	2
Palmar erythema		1				1
Pemphigus		1				1
Petechiae	2	6		1	2	5
Prurigo		1				1
Pruritus	7	39	2	9	5	30
Pruritus allergic		1				1
Psoriasis		1				1
Rash	8	40	5	12	3	28
Rash erythematous	1	1			1	1
Rash macular		5		1		4
Rash morbilliform		1				1
Rash papular	1	1			1	1
Rash pruritic	1	8	1	3		5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin burning sensation		1				1
Skin discolouration		1				1
Skin exfoliation		2		1		1
Skin indentation		1		1		
Skin irritation	1	1	1	1		
Skin laxity		1		1		
Skin lesion		1				1
Skin reaction		1		1		
Skin striae		1		1		
Skin tightness		1				1
Urticaria	7	24		2	7	22
Urticaria pressure		1				1
	41	198	16	63	25	135

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden		1		1		
Impaired driving ability		1				1
Impaired quality of life		1				1
Impaired work ability	6	18	1	6	5	12
Loss of personal independence in daily activities	1	3			1	3
	7	24	1	7	6	17

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Surgical and medical procedures

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Mechanical ventilation	1	1	1	1
Resuscitation	1	1	1	1
	2	2	2	2

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* AE=Adverse Event
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System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aneurysm ruptured		1				1
Arterial occlusive disease		1				1
Arterial thrombosis	1	1			1	1
Arteriosclerosis		1				1
Blood pressure fluctuation	1	1			1	1
Circulatory collapse	11	35			11	35
Cyanosis	1	1			1	1
Deep vein thrombosis	12	20			12	20
Flushing	1	12		1	1	11
Haematoma		2				2
Haemorrhage		1				1
Hot flush		5		2		3
Hypertension	4	16	1	2	3	14
Hypertensive crisis	4	14			4	14
Hypertensive emergency	1	2			1	2
Hypotension	3	15	3	6		9
Lymphoedema	2	2			2	2
Pallor		7		2		5
Pelvic venous thrombosis	1	1			1	1
Peripheral coldness		3		2		1
Peripheral embolism	1	1			1	1
Phlebitis superficial	1	1			1	1
Poor peripheral circulation		1		1		
Shock		1				1
Thrombophlebitis	1	2			1	2
Thrombosed varicose vein		1				1
Thrombosis	1	5			1	5
Varicophlebitis	1	1			1	1
Vascular occlusion	1	1			1	1
Vasculitis		1				1
Venous thrombosis limb	1	6		1	1	5
	49	162	4	17	45	145

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

BAHRAIN

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy		1		1
		1		1

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute myocardial infarction	1	1	1	1
Atrioventricular block	1	1	1	1
	2	2	2	2

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Photophobia	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	1	2		1	1	1
Vomiting	1	1			1	1
	2	3		1	2	2

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Axillary pain		1				1
Chest pain	1	1			1	1
Chills		3		2		1
Drug ineffective	1	1			1	1
Fatigue	2	2	2	2		
Pain		2		1		1
Pyrexia	2	5	2	4		1
Secretion discharge	1	1	1	1		
Swelling		1				1
Vaccination site pain		1		1		
	7	18	5	11	2	7

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic reaction	2	2	2	2
	2	2	2	2

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* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19	1	1	1	1
	1	1	1	1

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Heart rate increased		1		1
Troponin increased	1	1	1	1
	1	2	1	2

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Limb discomfort	1	1	1	1		
Muscle spasms		1				1
Muscular weakness	2	2	2	2		
Myalgia		2		2		
Neck pain		1		1		
	3	7	3	6		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Anosmia	1	1	1	1		
Cerebral artery occlusion	1	1			1	1
Cerebrovascular accident	2	2			2	2
Dizziness	1	1	1	1		
Dysarthria	1	1			1	1
Guillain-Barre syndrome	1	1			1	1
Headache	5	6	3	4	2	2
Hypoaesthesia	3	3	1	1	2	2
Paraesthesia		1				1
Sensory loss	1	1	1	1		
Syncope	1	1			1	1
	18	20	8	9	10	11

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	1	1	1	1		
Dyspnoea	1	2	1	1		1
Nasal congestion	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
	4	5	4	4		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperhidrosis	1	2			1	2
Pruritus		1		1		
	1	3		1	1	2

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hot flush		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

BELGIUM

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coagulopathy	23	40	4	7	19	33
Leukocytosis	1	2			1	2
Lymphadenitis		2		1		1
Lymphadenopathy	26	60	20	25	6	35
Lymph node pain	3	11	2	2	1	9
Microangiopathic haemolytic anaemia	1	1			1	1
Neutropenia		1				1
Neutrophilia		1				1
Thrombocytopenia	7	9			7	9
	61	127	26	35	35	92

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris	3	6			3	6
Arrhythmia	1	5			1	5
Atrial fibrillation		3				3
Atrioventricular block complete		2				2
Bradycardia		10				10
Bundle branch block left		1				1
Cardiac arrest		9				9
Cardiac discomfort	1	1			1	1
Cardiac disorder		2				2
Cardiac failure		4				4
Cardiogenic shock		2				2
Cardiomegaly	1	2			1	2
Cardio-respiratory arrest	1	4			1	4
Cardiovascular disorder	7	64	2	10	5	54
Coronary artery thrombosis		1				1
Extrasystoles	1	1			1	1
Myocardial infarction		1				1
Myocarditis	2	2			2	2
Palpitations	7	21	1	6	6	15
Pericardial effusion	1	2			1	2
Pericarditis	3	4			3	4
Rhythm idioventricular		1				1
Sinus tachycardia		1				1
Stress cardiomyopathy		1		1		
Supraventricular tachycardia		1				1
Tachyarrhythmia		1				1
Tachycardia	5	34	3	5	2	29
Ventricular tachycardia		1				1
	33	187	6	22	27	165

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Auditory disorder	1	1	1	1		
Deafness		2				2
Deafness unilateral		1				1
Dysacusis		1				1
Ear discomfort	1	3		2	1	1
Ear pain	2	8	1	2	1	6
Endolymphatic hydrops		2				2
Hyperacusis		2				2
Hypoacusis		1				1
Meniere's disease	1	1			1	1
Sudden hearing loss		1				1
Tinnitus	1	8		1	1	7
Vertigo	9	37	8	14	1	23
Vertigo positional	1	1	1	1		
Vestibular disorder	1	1			1	1
	17	70	11	21	6	49

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute macular outer retinopathy		1				1
Angle closure glaucoma		1				1
Asthenopia	1	3		2	1	1
Blepharospasm	1	1			1	1
Blindness		3				3
Conjunctival hyperaemia	1	1			1	1
Diplopia	2	3			2	3
Endocrine ophthalmopathy		1				1
Eye irritation		1				1
Eye movement disorder		1				1
Eye pain	2	8	1	4	1	4
Eye swelling	1	4	1	1		3
Glaucoma		1				1
Iridocyclitis	1	1			1	1
Lacrimation increased	1	3		1	1	2
Mydriasis		1		1		
Ocular discomfort	1	3	1	3		
Ocular hyperaemia	1	2	1	2		
Photophobia	1	4			1	4
Photopsia		1				1
Retinal pigment epitheliopathy	1	1			1	1
Retinal vein occlusion	1	1			1	1
Retinal vein thrombosis	1	1	1	1		
Scleral discolouration		1				1
Swelling of eyelid	1	2			1	2
Vision blurred	3	13	3	8		5
Visual acuity reduced	1	1			1	1
Visual field defect	1	3			1	3
Visual impairment	5	11	1	3	4	8
	27	78	9	26	18	52

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	3	7	2	4	1	3
Abdominal distension	1	3	1	2		1
Abdominal pain	6	16	2	3	4	13
Abdominal pain upper	13	21	5	7	8	14
Abdominal symptom		1		1		
Anal incontinence		1		1		
Aphthous ulcer	1	4	1	1		3
Breath odour		2				2
Constipation		1				1
Diarrhoea	18	46	6	11	12	35
Diarrhoea haemorrhagic		1				1
Dry mouth	1	4	1	1		3
Dyspepsia	2	3	2	2		1
Dysphagia	1	6		2	1	4
Faecal vomiting		1				1
Faeces discoloured	1	2			1	2
Flatulence	1	3		2	1	1
Gastric dilatation	1	3		1	1	2
Gastric disorder		1				1
Gastritis	1	1			1	1
Gastrointestinal disorder	3	5	2	2	1	3
Gastrointestinal pain	5	8	2	2	3	6
Gastrooesophageal reflux disease	1	2	1	1		1
Gingival pain		1				1
Hyperaesthesia teeth		1				1
Hypoaesthesia oral		1		1		
Intestinal dilatation		1				1
Intestinal ischaemia		2				2
Intestinal obstruction		1				1
Lip swelling	1	6	1	2		4
Nausea	142	449	65	95	77	354
Noninfective gingivitis	1	2	1	1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Odynophagia		1		1		
Oral pruritus		1				1
Pancreatitis	1	1			1	1
Pancreatitis acute	1	1			1	1
Paraesthesia oral	2	8	1	2	1	6
Parotid gland enlargement	1	1			1	1
Rectal haemorrhage	1	1			1	1
Retching		4				4
Salivary gland pain	1	1			1	1
Salivary hypersecretion	1	3		1	1	2
Stomatitis		1				1
Swollen tongue		8		1		7
Tongue discomfort		1				1
Tongue oedema	1	1			1	1
Tooth disorder	1	1	1	1		
Vomiting	23	66	11	14	12	52
	236	706	105	162	131	544

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	24	60	13	22	11	38
Axillary pain	15	21	11	11	4	10
Chest discomfort	3	16	1	3	2	13
Chest pain	14	38	7	13	7	25
Chills	166	551	66	102	100	449
Condition aggravated	2	4		1	2	3
Crying		2				2
Death	8	12			8	12
Discomfort	4	8		1	4	7
Disease recurrence		2				2
Drug ineffective	28	97			28	97
Drug resistance		1				1
Exercise tolerance decreased		3				3
Extensive swelling of vaccinated limb	16	25		1	16	24
Face oedema		3		2		1
Facial pain		2		1		1
Fatigue	259	745	115	187	144	558
Feeling abnormal	12	23	6	10	6	13
Feeling cold	8	18	4	7	4	11
Feeling drunk	1	2	1	2		
Feeling hot	13	19	10	13	3	6
Feeling of body temperature change	9	15	8	8	1	7
Gait disturbance	1	4			1	4
Gait inability	1	1			1	1
General physical health deterioration	2	19		1	2	18
Hangover	2	2	1	1	1	1
Hunger	1	1	1	1		
Hyperthermia		2		2		
Hypothermia		4				4
Illness	2	7	2	6		1
Inflammation	2	5		1	2	4
Influenza like illness	60	133	45	57	15	76

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site discomfort		1		1		
Injection site erythema		1				1
Injection site haematoma		1		1		
Injection site hypersensitivity		1				1
Injection site pain	1	4	1	4		
Injection site reaction	1	10	1	4		6
Injection site swelling	1	1	1	1		
Injection site warmth	1	1	1	1		
Local reaction	1	1	1	1		
Malaise	102	392	37	66	65	326
Multiple organ dysfunction syndrome		2				2
Oedema peripheral	1	2			1	2
Pain	23	43	15	21	8	22
Peripheral swelling	13	55	11	18	2	37
Pyrexia	218	619	134	201	84	418
Screaming	1	1	1	1		
Sensation of foreign body		2		1		1
Sense of oppression	1	7	1	4		3
Sudden death	5	21			5	21
Swelling	3	5	2	2	1	3
Swelling face	1	6	1	2		4
Therapeutic response unexpected		1		1		
Thirst	4	6	2	3	2	3
Vaccination failure	1	18			1	18
Vaccination site bruising	1	1	1	1		
Vaccination site discolouration	1	1	1	1		
Vaccination site discomfort	4	5	3	4	1	1
Vaccination site erythema	19	54	15	40	4	14
Vaccination site haematoma	1	6	1	4		2
Vaccination site hypersensitivity		1				1
Vaccination site hypertrophy		1				1
Vaccination site induration	9	20	8	15	1	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site inflammation	1	2		1	1	1
Vaccination site joint pain	1	1			1	1
Vaccination site lymphadenopathy	1	3			1	3
Vaccination site movement impairment	5	9	2	3	3	6
Vaccination site oedema	1	1	1	1		
Vaccination site pain	63	146	49	79	14	67
Vaccination site pruritus	3	6	2	3	1	3
Vaccination site rash		1		1		
Vaccination site reaction	107	327	32	61	75	266
Vaccination site swelling	7	29	5	16	2	13
Vaccination site warmth	5	14	3	6	2	8
	1,260	3,674	623	1022	637	2652

System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Biliary colic		1				1
Cholelithiasis	1	1			1	1
Hepatic cytolysis	1	1			1	1
Hepatic failure		1				1
Hepatic pain	1	1	1	1		
Hepatitis	1	3			1	3
Liver disorder	4	8		2	4	6
	8	16	1	3	7	13

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic reaction to excipient		2		1		1
Allergy to vaccine		1				1
Anaphylactic reaction	2	35			2	35
Anaphylactic shock		5				5
Anaphylactoid reaction		1				1
Autoimmune disorder	2	8			2	8
Food allergy		1				1
Haemophagocytic lymphohistiocytosis	1	1			1	1
Hypersensitivity	4	25		3	4	22
Type III immune complex mediated reaction	1	1			1	1
	10	80		4	10	76

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appendicitis	1	3			1	3
Asymptomatic COVID-19		25				25
Bronchitis	1	1			1	1
COVID-19	41	133	5	22	36	111
COVID-19 pneumonia		3				3
Dermo-hypodermatitis		1				1
Diverticulitis	1	1			1	1
Ear infection	1	1	1	1		
Erysipelas	1	2			1	2
Gastroenteritis viral	1	1			1	1
Herpes ophthalmic		3				3
Herpes simplex		1				1
Herpes virus infection		1				1
Herpes zoster	10	15	9	13	1	2
Herpes zoster meningoradiculitis	1	1			1	1
Infection		3		2		1
Influenza	12	16	9	11	3	5
Laryngitis		1				1
Localised infection		1				1
Mumps	1	1	1	1		
Nasopharyngitis	7	9	2	2	5	7
Ophthalmic herpes zoster	1	1			1	1
Oral herpes	3	8	2	3	1	5
Parapharyngeal space infection		1				1
Pharyngitis	1	1			1	1
Pneumonia	1	5			1	5
Pneumonia bacterial		1				1
Pyelonephritis		2				2
Respiratory tract infection		3				3
Rhinitis	1	2	1	1		1
Rhinolaryngitis	1	1	1	1		
Scarlet fever		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sepsis		2				2
Septic shock		2				2
Sinusitis	2	3	1	1	1	2
Subcutaneous abscess	1	1	1	1		
Suspected COVID-19		1				1
Tonsillitis		2		1		1
Tracheitis	1	1	1	1		
Urinary tract infection		1		1		
Urosepsis		1				1
Vaginal abscess	1	1			1	1
Vestibular neuronitis		1				1
Vulval abscess	1	1			1	1
	92	266	34	62	58	204

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Brain contusion	1	1			1	1
Chest injury	1	1			1	1
Chillblains		1				1
Concussion		1				1
Contusion	3	6	2	3	1	3
Drug administered in wrong device		1		1		
Epicondylitis	1	1			1	1
Eschar		1				1
Expired product administered		2		1		1
Exposure via breast milk	2	4	2	4		
Exposure via skin contact		1		1		
Facial bones fracture		1				1
Fall	3	14		2	3	12
Inappropriate schedule of product administration	1	2	1	2		
Incorrect dose administered		1		1		
Incorrect route of product administration	78	127	78	127		
Maternal exposure during pregnancy	3	5	2	4	1	1
Muscle strain	9	20	5	7	4	13
Nerve injury	2	2	1	1	1	1
Occupational exposure to product		1		1		
Off label use	3	7	3	7		
Procedural pain		1				1
Product administered at inappropriate site		1				1
Product preparation issue		1		1		
Product use issue	3	7	3	7		
Subdural haematoma	1	1			1	1
Underdose		1		1		
Wrong product administered		2		2		
Wrong technique in product usage process	77	112	77	112		
	188	326	174	285	14	41

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased		1		1		
Aspartate aminotransferase increased		1		1		
Blood alkaline phosphatase increased	1	1			1	1
Blood glucose decreased		1		1		
Blood glucose increased		1		1		
Blood lactic acid increased		2				2
Blood pressure abnormal		3		1		2
Blood pressure decreased	5	15	4	5	1	10
Blood pressure increased	3	11		1	3	10
Blood pressure systolic increased		1		1		
Blood test abnormal	1	2	1	1		1
Blood urine present		1				1
Body temperature decreased		1				1
Body temperature fluctuation		1				1
Body temperature increased	6	18	5	10	1	8
C-reactive protein increased	4	8	1	3	3	5
Fibrin D dimer increased	3	6	1	1	2	5
Gamma-glutamyltransferase increased		1		1		
Heart rate decreased		2				2
Heart rate increased	4	16	3	7	1	9
Heart rate irregular		1		1		
Hepatic enzyme increased		1		1		
International normalised ratio increased	1	1			1	1
Lipase increased	1	1	1	1		
Liver function test abnormal		3				3
N-terminal prohormone brain natriuretic peptide increased		1				1
Oxygen saturation abnormal		1				1
Oxygen saturation decreased	2	27		1	2	26
Platelet count decreased	1	1			1	1
Prohormone brain natriuretic peptide increased		1				1
Red blood cell sedimentation rate increased		1		1		

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory rate increased		1				1
SARS-CoV-2 ant body test negative	1	1			1	1
SARS-CoV-2 ant body test positive		1		1		
SARS-CoV-2 test positive		1				1
Serum ferritin increased		1		1		
Troponin increased	1	4			1	4
Troponin T increased		1				1
Weight decreased	2	3	1	1	1	2
White blood cell count decreased	1	2		1	1	1
	37	147	17	44	20	103

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	9	23	3	7	6	16
Dehydration		1				1
Diabetic complication		1				1
Feeding disorder	1	1			1	1
Fluid retention	1	1	1	1		
Folate deficiency	1	1	1	1		
Hyperferritinaemia	1	1			1	1
Hyperglycaemia	2	2			2	2
Hypoglycaemia	2	7	1	1	1	6
Hypokalaemia		1				1
Hyponatraemia		1				1
Ketoacidosis		3				3
Lactic acidosis		2				2
Metabolic acidosis		1				1
Tetany		1				1
Vitamin B complex deficiency	1	1	1	1		
Vitamin D deficiency		1				1
	18	49	7	11	11	38

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	102	280	38	55	64	225
Arthritis		4		1		3
Arthropathy	1	1	1	1		
Axillary mass		1				1
Back pain	23	31	13	15	10	16
Bone pain	2	7	1	1	1	6
Bone swelling	1	1	1	1		
Coccydynia	1	1	1	1		
Facial asymmetry		1				1
Fasciitis	1	1			1	1
Jaw disorder		1		1		
Joint range of motion decreased	2	4	1	1	1	3
Joint stiffness		1				1
Joint swelling		1				1
Limb discomfort	7	13	4	5	3	8
Mastication disorder	1	1			1	1
Mobility decreased	2	6	2	3		3
Muscle contracture		1				1
Muscle disorder	1	1			1	1
Muscle fatigue		2		1		1
Muscle spasms	2	4	1	1	1	3
Muscle tightness	1	2	1	1		1
Muscular weakness	5	10	5	6		4
Musculoskeletal chest pain		3		2		1
Musculoskeletal discomfort	1	2	1	1		1
Musculoskeletal pain	2	2	2	2		
Musculoskeletal stiffness	41	91	35	62	6	29
Myalgia	225	613	118	167	107	446
Myosclerosis		1				1
Neck pain	15	29	14	16	1	13
Neuropathic muscular atrophy	1	1			1	1
Pain in extremity	68	122	41	68	27	54

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in jaw	1	2	1	1		1
Posture abnormal		1		1		
SAPHO syndrome		1				1
Spinal pain	2	4	1	3	1	1
Synovial cyst	1	1	1	1		
Tendonitis	1	1			1	1
	510	1,249	283	418	227	831

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Tumour thrombosis	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	2	1	2		
Allodynia		1				1
Altered state of consciousness		5				5
Amnesia		1				1
Anosmia	1	2	1	1		1
Aphasia	4	6			4	6
Balance disorder	2	10			2	10
Bell's palsy	2	3			2	3
Brain injury		1				1
Burning sensation	4	10	1	3	3	7
Carotid artery occlusion	2	2			2	2
Carotid artery thrombosis	1	1			1	1
Carpal tunnel syndrome	1	1			1	1
Cerebral haemorrhage		1				1
Cerebral ischaemia		1				1
Cerebral thrombosis	1	3			1	3
Cerebrovascular accident	6	17			6	17
Circadian rhythm sleep disorder	1	1	1	1		
Coma		1				1
Decreased vibratory sense		1				1
Depressed level of consciousness		10				10
Disturbance in attention	2	4		1	2	3
Dizziness	24	79	18	29	6	50
Dizziness postural		1				1
Dysaesthesia		1				1
Dysgeusia	6	16	3	6	3	10
Dyskinesia	1	1			1	1
Dyspraxia		1				1
Dysstasia	2	4	2	2		2
Dystonia		1				1
Electric shock sensation		2				2
Epilepsy	4	14			4	14

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial nerve disorder	1	1			1	1
Facial paralysis	6	18			6	18
Facial paresis	3	9			3	9
Facial spasm		2		2		
Formication		1				1
Generalised tonic-clonic seizure	1	4			1	4
Haemorrhage intracranial		1				1
Haemorrhagic stroke		1				1
Haemorrhagic transformation stroke	1	1			1	1
Headache	305	816	173	248	132	568
Head discomfort	1	2			1	2
Hemianaesthesia		1				1
Hemiparaesthesia	1	2			1	2
Hemiparesis	1	3			1	3
Hemiplegia	5	8			5	8
Hyperaesthesia	2	3	1	1	1	2
Hyperresponsive to stimuli	1	1			1	1
Hypersomnia	2	4	2	2		2
Hypoaesthesia	9	18	6	8	3	10
Hyporeflexia		1				1
Hyporesponsive to stimuli		1				1
Ischaemic cerebral infarction	1	1			1	1
Ischaemic stroke	3	3			3	3
Lethargy		3		1		2
Loss of consciousness	5	14			5	14
Memory impairment		2		1		1
Migraine	12	27	6	6	6	21
Migraine with aura		2				2
Monoplegia	2	2			2	2
Motor dysfunction	1	1			1	1
Movement disorder	1	1	1	1		
Muscle contractions involuntary		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nerve compression	1	1			1	1
Nervous system disorder	14	52	3	9	11	43
Neuralgia		3		1		2
Neuritis		1				1
Neuropathy peripheral		1				1
Noninfective encephalitis	1	1			1	1
Orthostatic intolerance		1				1
Paraesthesia	16	33	12	20	4	13
Paralysis	1	2			1	2
Paresis		1				1
Parkinson's disease		2				2
Parosmia	1	3	1	2		1
Patient elopement		1				1
Peripheral motor neuropathy		1				1
Polyneuropathy		1				1
Presyncope	2	14	2	4		10
Psychomotor hyperactivity	1	1			1	1
Restless legs syndrome		1		1		
Sedation		2				2
Seizure	2	14			2	14
Sensory disturbance		2		2		
Sensory loss		1				1
Sinus headache		1				1
Sleep deficit		1				1
Somnolence	6	16	2	3	4	13
Speech disorder	3	6		3	3	3
Syncope	6	36			6	36
Taste disorder	3	4	1	2	2	2
Tension headache	1	1	1	1		
Thoracic outlet syndrome		1				1
Thrombotic stroke	1	1			1	1
Transient ischaemic attack	1	2			1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tremor	6	18	5	6	1	12
Trigeminal neuralgia	2	2			2	2
Unresponsive to stimuli		3				3
	497	1,390	243	369	254	1021

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Syringe issue		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal dreams	1	2			1	2
Acute psychosis		1				1
Aggression	1	1			1	1
Agitation	1	7	1	2		5
Anxiety		9		2		7
Apathy		3		1		2
Aversion	1	1	1	1		
Confusional state	1	6		2	1	4
Delirium	1	2			1	2
Delusion	1	1			1	1
Depressive symptom	1	1	1	1		
Disorientation	1	3			1	3
Hallucination	1	5			1	5
Hallucination, visual		1				1
Illusion		1				1
Insomnia	11	32	5	11	6	21
Irritability		1				1
Middle insomnia	5	5	4	4	1	1
Nightmare		1				1
Poor quality sleep	3	7	3	5		2
Restlessness		3		1		2
Sleep disorder	1	7		2	1	5
Sleep disorder due to a general medical condition		1		1		
Sleep disorder due to general medical condition, insomnia type	1	1			1	1
Staring		1				1
Tension	1	1			1	1
Thinking abnormal		1				1
	32	105	15	33	17	72

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	3	6			3	6
Chromaturia	1	1			1	1
Haematuria	2	2	1	1	1	1
Leukocyturia		1		1		
Polyuria	2	2	1	1	1	1
Renal disorder	2	7			2	7
Renal failure		3				3
Renal pain	1	4			1	4
Urinary retention		1				1
	11	27	2	3	9	24

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast pain		3		1		2
Pelvic pain	1	1	1	1		
Suppressed lactation		1				1
Vaginal haemorrhage	1	2	1	1		1
	2	7	2	3		4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute pulmonary oedema		1				1
Acute respiratory failure		4				4
Aphonia	1	1	1	1		
Asthma	1	3	1	1		2
Asthma exercise induced		1				1
Bradypnoea		1				1
Bronchial disorder		1				1
Bronchospasm	1	4			1	4
Cheyne-Stokes respiration		1				1
Cough	7	24	1	5	6	19
Diaphragmalgia	1	2	1	1		1
Dry throat		2		1		1
Dysphonia	4	6	3	3	1	3
Dyspnoea	24	78	9	13	15	65
Dyspnoea exertional	2	7	1	1	1	6
Epistaxis	1	3	1	1		2
Haemoptysis	1	1			1	1
Hyperventilation	1	5	1	2		3
Hypoxia		1				1
Laryngeal discomfort	1	1			1	1
Laryngeal oedema		1				1
Laryngospasm		1				1
Lower respiratory tract congestion		1				1
Lung disorder		1				1
Lung infiltration		1				1
Nasal congestion	3	4	2	3	1	1
Oropharyngeal discomfort	1	1	1	1		
Oropharyngeal pain	5	18	3	9	2	9
Painful respiration	1	4	1	1		3
Pharyngeal erythema		1				1
Pharyngeal inflammation	2	2	1	1	1	1
Pharyngeal swelling		6				6

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pleural effusion		2				2
Pleuritic pain	1	1	1	1		
Pneumonia aspiration	1	2			1	2
Pneumonitis		3				3
Productive cough	2	3			2	3
Pulmonary arterial hypertension		1				1
Pulmonary embolism	12	21			12	21
Pulmonary infarction		1				1
Pulmonary oedema		3				3
Rales		2				2
Respiration abnormal		2				2
Respiratory acidosis		1				1
Respiratory arrest	1	2			1	2
Respiratory disorder	7	64	1	5	6	59
Respiratory distress		4				4
Respiratory failure	1	2			1	2
Rhinitis allergic	1	1			1	1
Rhinorrhoea	5	12	2	5	3	7
Sinus pain		1				1
Sneezing	2	6	1	3	1	3
Suffocation feeling		1				1
Tachypnoea	1	3			1	3
Throat tightness		3				3
Tonsillar inflammation		1				1
Upper airway obstruction		1				1
Wheezing		3				3
	91	334	32	58	59	276

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	1	5			1	5
Cold sweat		2				2
Cutaneous vasculitis	1	2			1	2
Dermatitis	1	1	1	1		
Dry skin		1				1
Eczema	3	4	2	3	1	1
Erythema	14	34	10	15	4	19
Erythema multiforme	1	1			1	1
Hyperhidrosis	23	35	18	20	5	15
Livedo reticularis		1				1
Night sweats	3	5	2	2	1	3
Pain of skin	1	4	1	1		3
Palmoplantar pustulosis		1		1		
Papule		2		1		1
Petechiae	2	3	1	2	1	1
Pruritus	8	32	4	12	4	20
Pruritus allergic		1				1
Rash	7	18	5	10	2	8
Rash erythematous	2	6	2	5		1
Rash macular	1	3	1	1		2
Rash maculo-papular	1	2	1	1		1
Rash papular	1	1	1	1		
Rash pruritic		1				1
Sensitive skin	2	6	2	3		3
Skin burning sensation		1				1
Skin discolouration	1	1	1	1		
Skin disorder	23	60	9	14	14	46
Skin haemorrhage	1	1	1	1		
Skin mass		1				1
Skin odour abnormal	1	1	1	1		
Skin reaction	1	1	1	1		
Skin sensitisation		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria	5	11	3	3	2	8
Yellow skin		1				1
	104	250	67	100	37	150

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden	1	1			1	1
Immobile		1				1
Impaired work ability		1		1		
Loss of personal independence in daily activities	2	3		1	2	2
	3	6		2	3	4

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* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cyanosis	1	4			1	4
Deep vein thrombosis	9	14			9	14
Flushing		1				1
Haematoma	3	5	2	3	1	2
Haemorrhage		1				1
Hot flush	4	16	1	4	3	12
Hypertension	6	42	2	5	4	37
Hypertensive crisis		1				1
Hypotension	4	21	3	4	1	17
Hypovolaemic shock		1				1
Lymphoedema		1				1
Neurogenic shock		2				2
Orthostatic hypotension	2	2	2	2		
Pallor		3				3
Peripheral coldness	1	2			1	2
Peripheral venous disease	1	1			1	1
Phlebitis	2	3	1	1	1	2
Phlebitis superficial	2	2			2	2
Thrombophlebitis		1				1
Thrombophlebitis superficial	1	1	1	1		
Thrombosis	4	7			4	7
Vasculitis		2		1		1
Vasodilatation	2	2	1	1	1	1
Vein disorder	1	1	1	1		
Venous thrombosis	1	1			1	1
Venous thrombosis limb	1	1			1	1
	45	138	14	23	31	115

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

BERMUDA

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	1	1	1	1
	1	1	1	1

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear congestion		1		1
Ear discomfort		1		1
		2		2

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Sudden visual loss		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea		1		1
		1		1

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills		1		1		
Feeling cold		1		1		
Pain		1				1
Peripheral swelling	1	2	1	1		1
Pyrexia		1		1		
	1	6	1	4		2

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Maternal exposure during pregnancy	1	1	1	1
	1	1	1	1

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* AE=Adverse Event
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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
Pain in extremity	1	1	1	1
	2	2	2	2

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Balance disorder		1		1
Dizziness		1		1
Paraesthesia		1		1
		3		3

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Dyspnoea		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema		1				1
Night sweats		1		1		
Rash		1		1		
		3		2		1

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

BOLIVIA

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Tachycardia	1	1	1	1
	1	1	1	1

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Pancreatitis	1	1	1	1
	1	1	1	1

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Feeling hot	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Blood pressure decreased	1	1	1	1
Heart rate increased	1	1	1	1
	2	2	2	2

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dizziness	1	1	1	1
	1	1	1	1

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cough	1	1	1	1
Oropharyngeal pain	1	1	1	1
	2	2	2	2

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypertension	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

BOSNIA AND HERZEGOVINA

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	1	1	1	1
	1	1	1	1

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Axillary pain	1	1	1	1
Oedema	1	1	1	1
	2	2	2	2

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

BRAZIL

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	4	4	4	4
Lymphopenia	1	1	1	1
	5	5	5	5

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardio-respiratory arrest	1	1			1	1
Tachycardia	2	2	2	2		
	3	3	2	2	1	1

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenopia	1	1	1	1
Eyelid oedema	1	1	1	1
Eyelid pain	1	1	1	1
Eye pain	1	1	1	1
Eye swelling	1	1	1	1
Visual impairment	1	1	1	1
	6	6	6	6

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal discomfort	1	1	1	1
Abdominal pain	3	3	3	3
Diarrhoea	5	5	5	5
Dry mouth	3	3	3	3
Hypoaesthesia oral	1	1	1	1
Nausea	9	9	9	9
Vomiting	1	1	1	1
	23	23	23	23

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	7	7	7	7		
Chest discomfort	1	1	1	1		
Chills	16	16	16	16		
Drug ineffective	2	2			2	2
Fatigue	13	13	12	12	1	1
Feeling abnormal	2	2	2	2		
Feeling hot	1	1	1	1		
Gait disturbance	1	1	1	1		
Influenza like illness	4	4	4	4		
Malaise	6	6	6	6		
Pain	13	14	13	14		
Peripheral swelling	1	1	1	1		
Pyrexia	21	21	20	20	1	1
Sluggishness	2	2	2	2		
Swelling face	1	1	1	1		
Therapeutic response unexpected	1	1	1	1		
Thirst	2	2	2	2		
Vaccination site bruising	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site haematoma	1	1	1	1		
Vaccination site haemorrhage	2	2	1	1	1	1
Vaccination site inflammation	1	1			1	1
Vaccination site mass	2	2	1	1	1	1
Vaccination site pain	28	28	26	26	2	2
Vaccination site swelling	2	2	2	2		
	132	133	123	124	9	9

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypersensitivity	5	5	4	4	1	1
	5	5	4	4	1	1

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	3	3	2	2	1	1
Rhinitis	1	1	1	1		
Suspected COVID-19	1	1			1	1
	5	5	3	3	2	2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Contusion	1	1	1	1		
Exposure during pregnancy	1	1			1	1
Exposure via breast milk	1	1	1	1		
Incorrect dose administered	1	1	1	1		
Maternal exposure during pregnancy	4	4	2	2	2	2
Maternal exposure timing unspecified	1	1	1	1		
Off label use	1	1	1	1		
Overdose	4	4	4	4		
Poor quality product administered	1	1	1	1		
Product administered at inappropriate site	1	1	1	1		
Product preparation error	1	1	1	1		
Product use issue	1	1	1	1		
Wrong technique in product usage process	1	1	1	1		
	19	19	16	16	3	3

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood glucose increased	1	1	1	1		
Body temperature increased	1	1	1	1		
Heart rate increased	1	1	1	1		
Lymphocyte count decreased	1	1	1	1		
Neutrophil count decreased	1	1	1	1		
SARS-CoV-2 test positive	2	2	1	1	1	1
White blood cell count decreased	1	1	1	1		
	8	8	7	7	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorder	1	1	1	1
Decreased appetite	2	2	2	2
	3	3	3	3

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	4	4	4	4
Back pain	3	3	3	3
Bone pain	1	1	1	1
Limb discomfort	2	2	2	2
Mobility decreased	1	1	1	1
Myalgia	11	11	11	11
Neck pain	1	1	1	1
Pain in extremity	17	17	17	17
Pain in jaw	1	1	1	1
	41	41	41	41

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Burning sensation	2	2	2	2		
Dizziness	3	3	3	3		
Dyskinesia	1	1	1	1		
Headache	26	26	26	26		
Head discomfort	2	2	2	2		
Hypokinesia	1	1	1	1		
Seizure	1	1			1	1
Somnolence	3	3	3	3		
Speech disorder	1	1	1	1		
Tremor	2	2	2	2		
	43	43	42	42	1	1

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Foetal death	1	1	1	1
Premature baby	1	1	1	1
Premature labour	1	1	1	1
	3	3	3	3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Agitation	1	1	1	1
Anxiety	1	1	1	1
Insomnia	1	1	1	1
Sleep disorder	1	1	1	1
	4	4	4	4

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pollakiuria	1	1	1	1
	1	1	1	1

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Menstrual disorder	1	1	1	1
Polymenorrhoea	1	1	1	1
	2	2	2	2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	5	5	5	5		
Dry throat	1	1	1	1		
Dysphonia	1	1	1	1		
Dyspnoea	2	2	1	1	1	1
Epistaxis	1	1	1	1		
Nasal congestion	2	2	2	2		
Oropharyngeal pain	1	1	1	1		
Painful respiration	1	1	1	1		
Pleural effusion	1	1			1	1
Productive cough	1	1	1	1		
Rhinorrhoea	1	1	1	1		
Throat irritation	2	2	2	2		
	19	19	17	17	2	2

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	3	3	3	3		
Hyperhidrosis	2	2	2	2		
Papule	1	1			1	1
Pruritus	4	4	3	3	1	1
Rash	2	2	1	1	1	1
Urticaria	2	2	1	1	1	1
	14	14	10	10	4	4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemorrhage	1	1			1	1
Hypotension	1	1	1	1		
Peripheral coldness	1	1	1	1		
Thrombosis	1	1			1	1
	4	4	2	2	2	2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

BULGARIA

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Iron deficiency anaemia	1	1	1	1		
Leukopenia		1				1
Lymphadenopathy	5	21	4	19	1	2
Lymph node pain		4		4		
	6	27	5	24	1	3

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris		1				1
Arrhythmia		1				1
Extrasystoles		2		2		
Heart alternation		1		1		
Palpitations	1	5	1	4		1
Tachycardia	1	4	1	2		2
Ventricular extrasystoles		1				1
	2	15	2	9		6

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness unilateral		1				1
Tinnitus		2		2		
Vertigo	2	14	2	10		4
	2	17	2	12		5

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Conjunctivitis allergic		1		1
Eye irritation	1	1	1	1
Eye pain	3	5	3	5
Lacrimation increased	1	3	1	3
Photophobia	1	2	1	2
Vision blurred	1	1	1	1
	7	13	7	13

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		2		1		1
Abdominal pain upper	1	2	1	1		1
Dental discomfort		1		1		
Diarrhoea	1	3	1	3		
Dry mouth		2		2		
Dysphagia	1	1	1	1		
Epigastric discomfort		1		1		
Gastrointestinal disorder		1		1		
Lip swelling	1	2	1	1		1
Mouth swelling	1	1			1	1
Nausea	6	20	6	19		1
Paraesthesia oral		1		1		
Swollen tongue		1				1
Vomiting	3	7	3	6		1
	14	46	13	39	1	7

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Application site erythema	1	1	1	1		
Application site swelling	1	1	1	1		
Asthenia	4	22	4	20		2
Axillary pain	1	2	1	2		
Chest discomfort	1	1	1	1		
Chest pain		1		1		
Chills	9	36	8	32	1	4
Condition aggravated		2		2		
Discomfort	2	4	2	4		
Drug ineffective	2	13			2	13
Drug interaction	1	1			1	1
Fatigue	14	41	14	41		
Feeling abnormal	1	1	1	1		
Feeling cold		1		1		
Feeling hot		1		1		
Gait disturbance	1	4	1	3		1
Hypothermia		1				1
Influenza like illness	3	5	3	5		
Injection site pain	1	5	1	5		
Injection site swelling		3		3		
Malaise	4	14	4	14		
Oedema peripheral	1	3	1	3		
Pain		5		5		
Peripheral swelling	2	4	1	3	1	1
Pyrexia	18	49	18	47		2
Swelling		3		3		
Swelling face	2	2	2	2		
Thirst		1		1		
Vaccination site erythema	7	24	7	21		3
Vaccination site extravasation		1		1		
Vaccination site induration	1	3	1	2		1
Vaccination site oedema	1	2	1	2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	22	82	21	80	1	2
Vaccination site paraesthesia	1	2	1	2		
Vaccination site pruritus	1	1	1	1		
Vaccination site reaction		2		1		1
Vaccination site swelling	4	23	4	21		2
	106	367	100	333	6	34

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		1		1		
Anaphylactoid reaction		1				1
Hypersensitivity	4	4	1	1	3	3
	4	6	1	2	3	4

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchitis		1		1		
COVID-19	4	18	2	5	2	13
COVID-19 pneumonia		2				2
Cystitis	1	1			1	1
Groin abscess		1				1
Herpes simplex		1		1		
Herpes zoster	1	1	1	1		
Nasopharyngitis		3		3		
Pneumonia	1	2			1	2
Sinusitis		1		1		
Sweating fever		1				1
Tracheitis		1		1		
	7	33	3	13	4	20

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial bones fracture		1				1
Inappropriate schedule of product administration		1		1		
Joint injury		1				1
Off label use		1		1		
Overdose		2		2		
		6		4		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Antibody test abnormal		1		1		
Anti-thyroid antibody positive		1				1
Blood fibrinogen increased	1	1			1	1
Blood glucose increased	1	3		1	1	2
Blood pressure ambulatory increased	1	2	1	1		1
Blood pressure decreased		1				1
Blood pressure diastolic decreased		1		1		
Blood pressure increased	1	8	1	6		2
Body temperature abnormal	1	2	1	2		
Body temperature increased	20	44	19	41	1	3
C-reactive protein increased		1				1
Grip strength decreased		1		1		
Heart rate increased	1	2	1	2		
Heart rate irregular		1		1		
HIV test positive		1		1		
Lymphocyte count decreased		1		1		
Rheumatoid factor increased		1				1
Rheumatoid factor positive		1		1		
SARS-CoV-2 test positive		1				1
	26	74	23	60	3	14

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	3	5	3	4		1
Hyperglycaemia	1	1			1	1
	4	6	3	4	1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	8	36	6	34	2	2
Arthritis		1		1		
Back pain	5	9	4	8	1	1
Bone pain		1		1		
Coccydynia	1	1			1	1
Joint swelling	1	1	1	1		
Joint warmth	1	1	1	1		
Limb discomfort		2		2		
Mastication disorder		1		1		
Mobility decreased		1		1		
Muscle spasms	2	2	2	2		
Muscular weakness	1	1	1	1		
Musculoskeletal pain		1		1		
Musculoskeletal stiffness	3	5	2	3	1	2
Myalgia	12	46	12	46		
Neck pain	1	2	1	2		
Pain in extremity	9	22	7	20	2	2
Rheumatoid arthritis		1				1
Spinal pain		1		1		
Trismus		1		1		
	44	136	37	127	7	9

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		1		1		
Anosmia		2		2		
Disturbance in attention	1	2	1	2		
Dizziness	5	19	5	18		1
Dizziness postural		1		1		
Facial paralysis		3				3
Headache	21	63	20	58	1	5
Head discomfort		2		1		1
Hypoaesthesia	2	3	2	3		
Lethargy		1		1		
Meningism		1		1		
Movement disorder		2		1		1
Myelitis transverse		1				1
Neuralgia	1	2	1	2		
Neuromyelitis optica spectrum disorder		1				1
Paraesthesia	3	11	2	9	1	2
Peripheral sensory neuropathy		1		1		
Presyncope		1		1		
Seizure		1				1
Somnolence	2	2	2	2		
Syncope		2				2
Tremor		5		4		1
	35	127	33	108	2	19

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Agitation		2		2
Communication disorder	1	1	1	1
Confusional state	1	1	1	1
Fear	1	1	1	1
Insomnia	1	2	1	2
Panic attack		2		2
	4	9	4	9

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Renal pain	1	2	1	2
	1	2	1	2

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast pain	1	2	1	2		
Erectile dysfunction		1				1
Polymenorrhoea	1	1	1	1		
	2	4	2	3		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	3	7	3	7		
Dysphonia		1		1		
Dyspnoea	3	9	3	7		2
Epistaxis	1	2	1	2		
Interstitial lung disease		1				1
Oropharyngeal discomfort	1	1	1	1		
Oropharyngeal pain	3	7	3	7		
Painful respiration		1		1		
Paranasal sinus discomfort		1		1		
Productive cough		1		1		
Rhinorrhoea		2		2		
Throat irritation		1		1		
	11	34	11	31		3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat		1		1		
Drug eruption		1		1		
Erythema	3	8	3	8		
Hyperhidrosis	1	6	1	4		2
Pruritus	2	5	1	3	1	2
Rash	4	8	3	7	1	1
Rash erythematous	1	2		1	1	1
Rash macular		1				1
Rash papular	1	1			1	1
Rash pruritic		1		1		
Sensitive skin	1	1	1	1		
Urticaria	3	6	1	3	2	3
	16	41	10	30	6	11

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure fluctuation		1		1		
Blood pressure inadequately controlled		1		1		
Circulatory collapse		1				1
Haematoma		1				1
Hot flush		1		1		
Hypertension	3	6	2	4	1	2
Jugular vein distension		1				1
Pallor		1		1		
Peripheral coldness		1		1		
Poor peripheral circulation	1	1	1	1		
Vasodilatation		1		1		
Vasospasm		1				1
	4	17	3	11	1	6

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

CANADA

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy	10	37	9	31	1	6
Lymph node pain		3		3		
Neutropenia	1	1			1	1
Splenitis		1				1
Thrombocytopenia		2				2
	11	44	9	34	2	10

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arrhythmia	7	10			7	10
Atrial fibrillation	1	5			1	5
Bradycardia		1				1
Cardiac arrest	1	1			1	1
Cardiac disorder		1				1
Cardiac failure		1				1
Cardiac flutter	2	5			2	5
Cardiovascular disorder		1		1		
Extrasystoles		1		1		
Myocardial infarction	3	5			3	5
Myocarditis	1	3			1	3
Palpitations	7	13	3	8	4	5
Pericardial effusion	1	2			1	2
Pericarditis	4	5			4	5
Postural orthostatic tachycardia syndrome	1	1			1	1
Tachycardia	6	19	2	9	4	10
Ventricular tachycardia		1				1
	34	75	5	19	29	56

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerumen impaction		1		1		
Deafness	4	6			4	6
Deafness neurosensory	1	1			1	1
Deafness unilateral	2	3			2	3
Ear discomfort	1	6		5	1	1
Ear pain	1	1	1	1		
Ear pruritus	2	3	2	3		
Ear swelling	2	3	2	3		
Excessive cerumen production		1		1		
Hyperacusis	1	1	1	1		
Hypoacusis	1	4	1	4		
Motion sickness	1	1	1	1		
Sudden hearing loss	1	1			1	1
Tinnitus	8	19	5	12	3	7
Vertigo	10	16	4	9	6	7
	35	67	17	41	18	26

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Thyroid disorder		1		1
Thyroiditis	1	1	1	1
	1	2	1	2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal sensation in eye	1	1			1	1
Blindness transient	1	1			1	1
Conjunctival haemorrhage	1	1			1	1
Dermatochalasis		1		1		
Diplopia		2		1		1
Dry eye		1		1		
Eye haemorrhage	1	1			1	1
Eye irritation		1				1
Eyelid disorder		1		1		
Eyelid function disorder		1				1
Eyelid oedema		1				1
Eyelid ptosis		1				1
Eyelid sensory disorder		1		1		
Eyelids pruritus	1	2	1	1		1
Eye movement disorder	2	2			2	2
Eye pain	5	6	2	3	3	3
Eye pruritus	2	3	2	3		
Eye swelling	3	7	2	5	1	2
Hypoaesthesia eye	1	2	1	2		
Lacrimation increased		3		3		
Miosis	1	1	1	1		
Ocular discomfort	2	2	1	1	1	1
Ocular hyperaemia	1	2		1	1	1
Optic nerve disorder	1	1	1	1		
Periorbital swelling	1	4	1	4		
Photophobia	2	2	2	2		
Retinal vascular thrombosis	1	1			1	1
Scleral disorder	1	1	1	1		
Swelling of eyelid	2	4	2	4		
Uveitis		1				1
Vision blurred	7	13	3	7	4	6
Visual acuity reduced	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Visual impairment	1	3		1	1	2
Vitreous detachment		1				1
Vitreous floaters	1	2		1	1	1
	40	78	21	47	19	31

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		3		3		
Abdominal distension		1		1		
Abdominal pain	4	8	3	6	1	2
Abdominal pain lower	1	3	1	3		
Abdominal pain upper	7	15	6	13	1	2
Anal incontinence	1	1			1	1
Aphthous ulcer		2		2		
Change of bowel habit		1		1		
Chapped lips		1		1		
Coeliac disease		1				1
Colitis ischaemic	1	1			1	1
Colitis ulcerative		1				1
Constipation	1	1	1	1		
Defaecation urgency	1	2	1	2		
Diarrhoea	15	42	11	35	4	7
Dry mouth	1	5	1	4		1
Dysphagia	3	13	2	10	1	3
Eructation		1		1		
Faeces discoloured		1		1		
Faeces soft		1		1		
Flatulence		2		2		
Frequent bowel movements	1	1	1	1		
Gastric disorder		1		1		
Gastric ulcer		2				2
Gastrointestinal disorder	1	2	1	2		
Gastrointestinal pain	1	2	1	2		
Gastrooesophageal reflux disease		1		1		
Haematemesis		1				1
Haematochezia		1				1
Hiatus hernia		1		1		
Hyperaesthesia teeth	2	3	1	2	1	1
Hypoaesthesia oral	4	12	3	5	1	7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lip blister		1		1		
Lip disorder		1		1		
Lip haemorrhage		1		1		
Lip oedema	1	1	1	1		
Lip pain		2		2		
Lip pruritus		1		1		
Lip swelling	5	12	3	8	2	4
Melaena		1				1
Mouth swelling	2	3	1	1	1	2
Nausea	38	97	31	81	7	16
Odynophagia	1	2	1	2		
Oesophageal disorder		1				1
Oesophagitis		1				1
Oral discomfort		3		3		
Oral mucosal blistering		1		1		
Oral pain		1		1		
Palatal swelling	1	1	1	1		
Paraesthesia oral	5	17	2	10	3	7
Rectal haemorrhage		1				1
Rectal polyp		1				1
Stomatitis	1	2	1	2		
Swollen tongue	2	10	1	7	1	3
Tongue discomfort	1	1			1	1
Tongue disorder		5		4		1
Tongue oedema	1	1	1	1		
Tongue pruritus		2		2		
Toothache	1	1			1	1
Vomiting	13	36	10	26	3	10
Vomiting projectile		1		1		
	116	341	86	260	30	81

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse event	1	1	1	1		
Asthenia	11	38	10	31	1	7
Axillary pain	2	8	2	8		
Chest discomfort	4	18	1	9	3	9
Chest pain	13	19	11	16	2	3
Chills	27	78	24	73	3	5
Condition aggravated	6	16	3	5	3	11
Crying	1	1	1	1		
Death	1	2			1	2
Discomfort	3	6	2	5	1	1
Disease recurrence	6	14	2	5	4	9
Drug ineffective	8	51			8	51
Drug interaction	2	4	1	1	1	3
Face oedema	1	2			1	2
Facial pain	2	5	1	4	1	1
Fatigue	69	173	58	149	11	24
Feeling abnormal	15	29	13	27	2	2
Feeling cold	1	6	1	4		2
Feeling drunk	1	2		1	1	1
Feeling hot	11	20	11	19		1
Feeling of body temperature change		2		2		
Gait disturbance	10	13	10	11		2
Hunger	2	2	1	1	1	1
Illness	3	5	2	4	1	1
Inflammation	2	3	2	3		
Inflammatory pain	1	1			1	1
Influenza like illness		9		7		2
Infusion site warmth		1		1		
Injection site bruising	1	1	1	1		
Injection site erythema	1	3	1	3		
Injection site haemorrhage	1	1	1	1		
Injection site pain	1	8	1	8		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site scar		1		1		
Malaise	18	47	15	43	3	4
Mass		1		1		
Mucosal discolouration		1		1		
Mucosal disorder		1		1		
Multiple organ dysfunction syndrome	1	1			1	1
Necrosis		1				1
No adverse event	2	4	2	4		
Oedema		1				1
Oedema peripheral		1		1		
Pain	23	63	22	57	1	6
Peripheral swelling	11	22	7	16	4	6
Pyrexia	31	92	27	82	4	10
Screaming		1		1		
Secretion discharge		2		2		
Shoulder injury related to vaccine administration		1		1		
Sluggishness	1	1	1	1		
Sudden death	1	1			1	1
Swelling	8	15	5	11	3	4
Swelling face	7	17	5	11	2	6
Tenderness		2		2		
Therapeutic product effect decreased	1	1	1	1		
Therapeutic response unexpected	2	8	2	8		
Thirst	2	5	2	5		
Vaccination failure		3				3
Vaccination site bruising	1	2	1	2		
Vaccination site discomfort	1	4	1	3		1
Vaccination site erythema	3	9	1	7	2	2
Vaccination site hyperaesthesia	1	1	1	1		
Vaccination site hypersensitivity	1	1	1	1		
Vaccination site hypoaesthesia	1	1	1	1		
Vaccination site induration	2	4	1	3	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site inflammation		1		1		
Vaccination site joint movement impairment		1		1		
Vaccination site lymphadenopathy		1		1		
Vaccination site mass	1	3	1	3		
Vaccination site movement impairment		1		1		
Vaccination site nodule	1	1			1	1
Vaccination site oedema		3		3		
Vaccination site pain	36	89	31	82	5	7
Vaccination site paraesthesia	1	1	1	1		
Vaccination site pruritus		1		1		
Vaccination site rash		3		3		
Vaccination site reaction	1	3	1	3		
Vaccination site swelling	3	12	2	11	1	1
Vaccination site urticaria	1	6	1	4		2
Vaccination site warmth	2	7		5	2	2
	371	990	294	789	77	201

System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Portal vein thrombosis	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		1		1		
Amyloidosis	1	1			1	1
Anaphylactic reaction	4	44			4	44
Anaphylactic shock	2	5			2	5
Autoimmune disorder	2	3			2	3
Drug hypersensitivity		1		1		
Hypersensitivity	9	27	7	13	2	14
Seasonal allergy	1	1	1	1		
Sensitisation	1	1	1	1		
Type I hypersensitivity		2				2
Type IV hypersensitivity reaction		1		1		
	20	87	9	18	11	69

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19		1				1
Beta haemolytic streptococcal infection		1				1
Bronchitis		1		1		
Candida infection	1	1	1	1		
Cellulitis		1				1
Conjunctivitis	1	2	1	2		
COVID-19	10	56	3	4	7	52
COVID-19 pneumonia		1				1
Cystitis		1		1		
Dermatitis infected		1		1		
Disseminated varicella zoster virus infection	1	2			1	2
Diverticulitis	1	1			1	1
Ear infection		1				1
Fungal skin infection		1		1		
Gastroenteritis		1		1		
Gastroenteritis viral		1		1		
Herpes ophthalmic	1	1			1	1
Herpes simplex	1	2			1	2
Herpes zoster	25	34	23	29	2	5
Herpes zoster oticus		1				1
Infection		1		1		
Labyrinthitis	1	1			1	1
Mastitis	1	1			1	1
Meningitis aseptic		1				1
Nasopharyngitis	1	4	1	4		
Ophthalmic herpes zoster	2	2			2	2
Oral candidiasis		1		1		
Oral herpes	1	3		2	1	1
Parvovirus infection		1		1		
Pneumonia	1	3			1	3
Rash pustular		1		1		
Roseola		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sepsis		2				2
Suspected COVID-19		3		2		1
Urinary tract infection	1	2		1	1	1
Vaccination site cellulitis	1	1	1	1		
Varicella		1		1		
Viral rash		1		1		
Vulvitis		1		1		
	50	142	30	60	20	82

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental exposure to product		1		1		
Accidental overdose	1	1	1	1		
Chillblains	1	1	1	1		
Circumstance or information capable of leading to medication error		3		3		
Contusion	5	11	3	7	2	4
Exposure during pregnancy	4	16	4	14		2
Exposure via breast milk	14	33	14	33		
Fall	1	7	1	2		5
Hip fracture		1				1
Inappropriate schedule of product administration	5	53	5	53		
Incomplete course of vaccination		2		2		
Incorrect dose administered	1	4	1	4		
Incorrect route of product administration		2		2		
Intentional product misuse		1		1		
Ligament sprain		1		1		
Maternal exposure before pregnancy		4		3		1
Maternal exposure during pregnancy	1	20	1	20		
Maternal exposure timing unspecified		2		2		
Muscle injury		1		1		
Off label use	20	88	20	87		1
Overdose		12		12		
Product administered at inappropriate site	1	6	1	6		
Product preparation error	1	4	1	4		
Product preparation issue		14		14		
Product use issue	16	48	16	47		1
Rib fracture		1				1
Road traffic accident		1				1
Scar	1	1			1	1
Skin injury		1		1		
Skin laceration		1		1		
Toxicity to various agents		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Underdose		13		13		
Wrong product administered	1	2	1	2		
	73	357	70	338	3	19

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* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase decreased		1		1		
Alanine aminotransferase increased		3		2		1
Aspartate aminotransferase increased		1				1
Blood cholesterol decreased		1		1		
Blood creatine phosphokinase increased		1				1
Blood creatinine abnormal		1		1		
Blood glucose decreased	2	4	1	1	1	3
Blood glucose increased		1		1		
Blood immunoglobulin G increased		1		1		
Blood iron decreased	1	1	1	1		
Blood pressure decreased	3	7	2	3	1	4
Blood pressure increased		4		3		1
Blood pressure orthostatic abnormal	1	1			1	1
Blood pressure systolic increased	1	1	1	1		
Blood urine		1		1		
Blood urine present		2		2		
Body temperature increased	3	4	3	4		
C-reactive protein increased	1	3	1	2		1
Drug level increased		2		1		1
Eosinophil count increased		1		1		
Fibrin D dimer increased	2	2	1	1	1	1
Grip strength decreased		1		1		
Haematocrit decreased		1		1		
Haemoglobin decreased	1	3		2	1	1
Haemoglobin increased		1		1		
Heart rate decreased	1	4	1	2		2
Heart rate increased	7	16	4	9	3	7
Heart rate irregular	1	1			1	1
Hepatic enzyme increased		2				2
Intraocular pressure increased	1	1			1	1
Liver function test increased		1				1
Lymphocyte count decreased		1		1		

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mean cell haemoglobin		1		1		
Mean cell haemoglobin concentration increased		1		1		
Mean cell volume increased		1		1		
Monocyte count increased		2		2		
Monocyte percentage increased		1		1		
Myelocyte count increased		1		1		
Neutrophil count decreased		1		1		
Oxygen saturation decreased		1				1
Platelet count decreased	1	2		1	1	1
Platelet count increased	1	1	1	1		
Pulse volume decreased		2		1		1
Red blood cell count decreased		1		1		
Respiratory rate increased	1	1			1	1
SARS-CoV-2 test positive	1	2			1	2
Troponin increased		2		2		
Venous bruit	1	1	1	1		
Vital functions abnormal		1				1
Vitamin B12 increased	1	2	1	1		1
Weight decreased	3	5	2	4	1	1
Weight increased		1		1		
White blood cell count decreased		1		1		
White blood cell count increased	2	2	2	2		
	36	108	22	69	14	39

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	3	11	1	8	2	3
Dehydration	2	3	2	3		
Diabetes mellitus		1				1
Fluid retention	1	4	1	4		
Gout	4	4	3	3	1	1
Hyperuricaemia		1		1		
Polydipsia		1		1		
	10	25	7	20	3	5

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	28	64	20	52	8	12
Arthritis	8	10	3	5	5	5
Arthritis reactive	1	1			1	1
Axillary mass	1	2	1	2		
Back pain	9	16	7	12	2	4
Bursitis		1		1		
Connective tissue disorder		1				1
Costochondritis	1	1	1	1		
Fibromyalgia		1		1		
Hand deformity	1	1	1	1		
Joint noise		1		1		
Joint range of motion decreased		1		1		
Joint stiffness	3	3	2	2	1	1
Joint swelling	5	10	3	6	2	4
Joint warmth	2	2	1	1	1	1
Limb discomfort	9	11	7	9	2	2
Mobility decreased	2	4		2	2	2
Muscle rigidity	1	1	1	1		
Muscle spasms	4	7	2	4	2	3
Muscle tightness	1	2	1	2		
Muscle twitching	3	5	3	5		
Muscular weakness	7	14	4	10	3	4
Musculoskeletal chest pain	2	2	2	2		
Musculoskeletal discomfort	1	1	1	1		
Musculoskeletal pain	1	2	1	2		
Musculoskeletal stiffness	4	15	4	15		
Myalgia	17	67	15	61	2	6
Myositis	1	1	1	1		
Neck mass	1	1	1	1		
Neck pain	4	15	4	14		1
Osteoarthritis	1	1	1	1		
Pain in extremity	49	99	43	87	6	12

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in jaw		3		2		1
Rheumatoid arthritis	1	5			1	5
Spinal pain	3	3	2	2	1	1
Synovitis	2	2			2	2
Systemic lupus erythematosus		1				1
Temporomandibular joint syndrome		1		1		
Tendon disorder	1	2		1	1	1
Tendonitis		2		2		
	174	382	132	312	42	70

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	5	1	5		
Anosmia	2	3	2	3		
Aphasia		2		2		
Ataxia	1	2		1	1	1
Balance disorder	3	7	3	5		2
Bell's palsy	3	16			3	16
Burning sensation	10	12	8	10	2	2
Carotid artery dissection		1				1
Carotid artery thrombosis		1				1
Cerebral artery occlusion	1	1			1	1
Cerebral haemorrhage	2	2			2	2
Cerebrovascular accident	7	11			7	11
Cognitive disorder	1	2	1	2		
Coma	2	2			2	2
Depressed level of consciousness	1	3			1	3
Disturbance in attention	3	10	2	8	1	2
Dizziness	43	95	30	71	13	24
Dizziness postural	2	3	2	3		
Dysarthria		1				1
Dysgeusia	3	14	2	13	1	1
Dyskinesia	1	2	1	2		
Dysstasia		1		1		
Electric shock sensation	1	3			1	3
Encephalitis autoimmune	1	1			1	1
Facial paralysis		2				2
Generalised tonic-clonic seizure		1				1
Headache	64	176	52	155	12	21
Head discomfort	6	7	6	7		
Hemiparesis		1				1
Hyperaesthesia	1	4	1	3		1
Hypersomnia		4		4		
Hypoaesthesia	29	57	19	34	10	23

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypokinesia		1		1		
Incoherent	1	1	1	1		
Ischaemic stroke	1	2	1	1		1
IVth nerve paralysis		1				1
Language disorder	1	1	1	1		
Lateral medullary syndrome	1	1			1	1
Lethargy	3	9	3	9		
Loss of consciousness	6	14			6	14
Memory impairment		1		1		
Mental impairment	1	2			1	2
Migraine	6	15	6	14		1
Migraine with aura		1				1
Monoparesis		1				1
Movement disorder	3	4	3	4		
Multiple sclerosis	1	2			1	2
Multiple sclerosis relapse		1				1
Nervous system disorder		1				1
Neuralgia	1	3	1	1		2
Neurological symptom	1	2	1	1		1
Neuropathy peripheral	3	3			3	3
Paraesthesia	21	49	15	31	6	18
Paralysis		1				1
Paraparesis		1				1
Presyncope	2	9	2	6		3
Psychomotor hyperactivity	1	1			1	1
Reflexes abnormal		1				1
Restless arm syndrome	1	1	1	1		
Restless legs syndrome	1	1	1	1		
Seizure		4				4
Seizure like phenomena	1	1			1	1
Sensory disturbance		1				1
Sensory loss	2	4	1	3	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Small fibre neuropathy	1	1	1	1		
Somnolence	6	14	5	9	1	5
Speech disorder	4	6	4	6		
Superior sagittal sinus thrombosis		1				1
Syncope	8	23			8	23
Taste disorder		3		3		
Tension headache		1		1		
Transient ischaemic attack		2				2
Tremor	3	10	2	8	1	2
Trigeminal nerve disorder	1	1			1	1
Unresponsive to stimuli	1	1			1	1
Vertebral artery dissection		1				1
	270	656	179	433	91	223

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion spontaneous		3				3
Ectopic pregnancy		1				1
Foetal growth restriction		3				3
Gestational diabetes		1				1
Postpartum haemorrhage		1		1		
Threatened labour		1		1		
		10		2		8

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Needle issue		1		1
Oversensing	1	1	1	1
Product complaint		4		4
Product container issue		1		1
Product quality issue		1		1
Product supply issue	1	3	1	3
	2	11	2	11

* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal dreams		1		1		
Affect lability	1	2	1	2		
Agitation	1	2	1	2		
Anger	1	1	1	1		
Anxiety	4	11	1	7	3	4
Bradyphrenia	1	1	1	1		
Communication disorder	1	1			1	1
Confusional state	4	6	3	5	1	1
Conversion disorder	1	1			1	1
Delirium		1				1
Depressed mood	1	1			1	1
Depression		2		2		
Distract bility		1		1		
Eating disorder	1	1	1	1		
Euphoric mood	1	1	1	1		
Fear	1	2	1	2		
Frustration tolerance decreased	1	1			1	1
Hallucination	1	1			1	1
Insomnia	8	13	6	11	2	2
Irritability		1		1		
Lack of spontaneous speech		1		1		
Mental disorder	1	1	1	1		
Nervousness	1	2	1	1		1
Nightmare	1	1			1	1
Panic reaction	1	1	1	1		
Poor quality sleep	1	1			1	1
Psychotic disorder due to a general medical condition		1				1
Sleep disorder	4	7	3	6	1	1
Stress	2	5	2	5		
Suicidal ideation		1				1
	39	72	25	53	14	19

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury		1				1
Bladder spasm		1		1		
Chromaturia		1		1		
Dysuria		2		1		1
Haemorrhage urinary tract		4				4
Incontinence		1				1
Micturition urgency	1	2	1	2		
Polyuria		1		1		
Renal failure	1	1			1	1
Urinary incontinence	1	2			1	2
Urinary retention	1	1			1	1
	4	17	1	6	3	11

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amenorrhoea	1	1	1	1		
Breast pain	2	4	2	3		1
Breast swelling		1		1		
Breast tenderness		1		1		
Dysmenorrhoea	4	6	4	6		
Galactostasis	1	1	1	1		
Heavy menstrual bleeding	14	17	10	12	4	5
Hypomenorrhoea	1	1	1	1		
Intermenstrual bleeding	3	3	3	3		
Menstrual disorder	7	8	5	6	2	2
Menstruation delayed	1	2	1	2		
Menstruation irregular	18	20	17	19	1	1
Pelvic pain	1	1			1	1
Penis disorder		1				1
Polymenorrhoea	6	7	6	7		
Postmenopausal haemorrhage	1	1			1	1
Premenstrual pain	1	1	1	1		
Testicular pain		1		1		
Testicular retraction		1				1
Vaginal discharge		1		1		
Vaginal haemorrhage	6	9	1	4	5	5
Vulval disorder		1				1
	67	89	53	70	14	19

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma	1	2		1	1	1
Bronchospasm		1				1
Choking	1	1			1	1
Chronic obstructive pulmonary disease		1				1
Cough	5	17	5	14		3
Dry throat		1		1		
Dysphonia	2	6	2	5		1
Dyspnoea	12	45	8	30	4	15
Epistaxis		1		1		
Hiccups	1	1			1	1
Hypopnoea	1	2	1	2		
Hypoxia		1				1
Laryngeal oedema	1	1			1	1
Laryngospasm		1				1
Lung disorder		3				3
Nasal congestion		2		1		1
Oropharyngeal discomfort		1		1		
Oropharyngeal pain	4	13	4	13		
Pharyngeal hypoaesthesia	1	4	1	3		1
Pharyngeal oedema	1	1	1	1		
Pharyngeal paraesthesia		1				1
Pharyngeal swelling	2	7	1	4	1	3
Pleural effusion	1	2			1	2
Pneumonia aspiration		1				1
Productive cough		3		2		1
Pulmonary congestion	1	1			1	1
Pulmonary embolism	5	8			5	8
Pulmonary infarction		1				1
Pulmonary oedema		1				1
Pulmonary pain		1				1
Respiratory disorder	1	2		1	1	1
Respiratory distress		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory failure		2				2
Rhinorrhoea	2	9	1	7	1	2
Sinus disorder	1	1	1	1		
Sinus pain	1	2		1	1	1
Sneezing	1	4	1	4		
Tachypnoea		3		3		
Throat irritation		3		3		
Throat tightness	3	11		3	3	8
Upper-airway cough syndrome		1		1		
Wheezing	2	6		3	2	3
	50	176	26	106	24	70

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne	1	2	1	2		
Angioedema	3	5			3	5
Blister	2	2			2	2
Cold sweat	1	5		3	1	2
Dermatitis	1	2	1	1		1
Eczema		1		1		
Erythema	10	26	8	20	2	6
Erythema multiforme		1				1
Hyperhidrosis	12	16	11	13	1	3
Idiopathic angioedema	1	1			1	1
Leukoplakia		1		1		
Livedo reticularis	2	2	2	2		
Night sweats		2		1		1
Pain of skin		2		2		
Palmar erythema	1	1			1	1
Petechiae		2		2		
Photosensitivity reaction	3	3	2	2	1	1
Pruritus	13	41	6	27	7	14
Purpura		2		2		
Rash	12	41	8	35	4	6
Rash erythematous	2	8	1	6	1	2
Rash macular	3	6	3	6		
Rash maculo-papular		3		2		1
Rash papular	1	3	1	2		1
Rash pruritic	4	10	1	5	3	5
Rash vesicular	1	1			1	1
Skin burning sensation	4	6	4	6		
Skin discolouration	2	3	2	3		
Skin disorder	1	2	1	2		
Skin exfoliation	1	2		1	1	1
Skin induration	1	1	1	1		
Skin lesion		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin reaction		2		2		
Skin warm		1		1		
Stevens-Johnson syndrome		1				1
Urticaria	17	47	13	36	4	11
	99	255	66	188	33	67

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden	1	1			1	1
Impaired driving ability	2	2	2	2		
Impaired quality of life	1	2	1	2		
Impaired work ability		2		2		
Loss of personal independence in daily activities	1	5	1	4		1
	5	12	4	10	1	2

System Organ Class

Surgical and medical procedures

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Vascular anastomosis	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aneurysm	1	2			1	2
Angiopathy		1		1		
Blood pressure fluctuation	1	2		1	1	1
Deep vein thrombosis	1	2			1	2
Flushing	5	9	4	7	1	2
Haemorrhage	1	1			1	1
Hot flush	3	7	3	6		1
Hypertension	7	24	2	9	5	15
Hypertensive crisis		1				1
Hypotension	6	14	4	9	2	5
Iliac artery occlusion		1				1
Lymphoedema	3	3	3	3		
Neurogenic shock	2	2			2	2
Pallor	3	6	3	5		1
Peripheral arterial occlusive disease		1		1		
Peripheral artery thrombosis	1	1			1	1
Peripheral coldness	3	5	2	3	1	2
Phlebitis	1	1			1	1
Poor peripheral circulation		1		1		
Raynaud's phenomenon		1				1
Shock	1	1			1	1
Thrombophlebitis	1	1			1	1
Thrombosis	13	20	1	1	12	19
Venous thrombosis limb	1	1			1	1
White coat hypertension		1				1
	54	109	22	47	32	62

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

CAYMAN ISLANDS

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Palpitations		1		1
		1		1

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dyspepsia		1		1
		1		1

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fatigue		1		1
		1		1

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite		1		1
		1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Back pain	6	6	6	6
Muscle spasms		1		1
Muscle twitching		1		1
Pain in extremity	6	6	6	6
	12	14	12	14

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headache		1		1
		1		1

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Irritability		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

CHILE

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenitis	2	2	2	2		
Lymphadenopathy	3	10	3	9		1
Lymph node pain		3		3		
Splenomegaly		1				1
	5	16	5	14		2

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris		1				1
Arrhythmia		1				1
Myocardial infarction	1	1			1	1
Myocardial ischaemia	1	1			1	1
Tachycardia	1	5	1	3		2
	3	9	1	3	2	6

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear discomfort		1		1
Tinnitus		1		1
Vestibular disorder		1		1
		3		3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye discharge		1		1		
Eye inflammation	1	1			1	1
Eye irritation		1		1		
Eyelid oedema	1	1			1	1
Eyelids pruritus	1	1			1	1
Eye movement disorder		1				1
Eye pain		1		1		
Eye pruritus		1				1
Eye swelling	1	3		1	1	2
Ocular discomfort	1	1			1	1
Ocular hyperaemia		1				1
Photophobia		1				1
	5	14		4	5	10

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		2		2		
Abdominal pain upper	2	8	2	7		1
Abnormal faeces		1		1		
Colitis		1		1		
Diarrhoea		9		9		
Dry mouth		1				1
Dysbiosis		1				1
Dyspepsia	2	2	2	2		
Flatulence	1	1	1	1		
Glossitis		1		1		
Haemorrhoids	1	1	1	1		
Nausea	4	19	4	17		2
Pancreatitis		1				1
Proctalgia	1	1	1	1		
Swollen tongue		1		1		
Tongue movement disturbance		1				1
Toothache		1		1		
Vomiting	1	4	1	3		1
	12	57	12	49		8

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse event	1	1	1	1		
Asthenia	2	4	2	4		
Axillary pain	1	2	1	2		
Chest discomfort	1	3	1	3		
Chest pain	1	5	1	3		2
Chills	2	14	2	13		1
Crying		1				1
Cyst		1		1		
Discomfort	2	4	2	4		
Disease recurrence		1		1		
Drug ineffective		1				1
Face oedema		2				2
Fatigue	4	22	4	22		
Feeling abnormal	2	3	2	3		
Feeling cold	2	6	2	6		
Gait disturbance		4		3		1
Gait inability		1				1
General physical health deterioration	1	1	1	1		
Inflammation		1		1		
Injected limb mobility decreased	1	1	1	1		
Localised oedema		1				1
Malaise	8	26	8	25		1
Mass		1		1		
Oedema	1	1			1	1
Oedema peripheral		1		1		
Pain	3	17	3	16		1
Peripheral swelling		4		3		1
Pyrexia	9	39	9	37		2
Stenosis		1		1		
Swelling	1	1			1	1
Swelling face	1	2			1	2
Therapeutic response unexpected	1	2	1	2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thirst	2	2	2	2		
Vaccination site discomfort		1		1		
Vaccination site erythema		3		3		
Vaccination site inflammation		4		4		
Vaccination site mass		1		1		
Vaccination site pain	8	29	8	26		3
Vaccination site paraesthesia		1		1		
Vaccination site pruritus		1		1		
Vaccination site swelling		1		1		
	54	217	51	195	3	22

System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug-induced liver injury		1				1
Hepatic steatosis		1		1		
		2		1		1

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	1	1	1	1		
Anaphylactic reaction		3				3
Hypersensitivity	2	10	2	10		
	3	14	3	11		3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchitis	1	1	1	1		
Coronavirus infection		1		1		
COVID-19	1	2	1	1		1
Herpes zoster	1	1	1	1		
Suspected COVID-19		1				1
	3	6	3	4		2

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circumstance or information capable of leading to medication error	1	1	1	1		
Contusion	1	3	1	3		
Exposure via breast milk	1	2	1	2		
Fall		1				1
Head injury		1				1
Inappropriate schedule of product administration	1	3	1	3		
Incomplete course of vaccination		9		9		
Incorrect route of product administration		1		1		
Maternal exposure during pregnancy		1		1		
Maternal exposure timing unspecified		1		1		
Off label use	1	4	1	4		
Overdose		1		1		
Product preparation error		1		1		
Product use issue	1	3	1	3		
Splenic rupture		1				1
Wound haemorrhage		1				1
Wrong product administered		2		2		
	6	36	6	32		4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood glucose decreased		1		1		
Blood glucose increased		1				1
Blood pressure increased	1	2	1	2		
Blood test abnormal		1		1		
Complement factor C3 decreased		1		1		
C-reactive protein decreased		1		1		
Hepatic enzyme increased		1				1
Laboratory test interference	1	1	1	1		
Monocyte count decreased		1		1		
Oxygen saturation decreased		1		1		
SARS-CoV-2 ant body test negative		1		1		
Transaminases increased		1		1		
Urine analysis abnormal		1				1
	2	14	2	11		3

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite	1	3	1	3
Polydipsia		1		1
Type 2 diabetes mellitus		1		1
	1	5	1	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	2	10	2	9		1
Arthritis	1	2			1	2
Axillary mass		1		1		
Back pain	3	6	3	6		
Bone pain		2		2		
Costochondritis	1	1	1	1		
Joint swelling		2		1		1
Limb discomfort		1		1		
Mobility decreased	1	1	1	1		
Muscle discomfort		1		1		
Muscle spasms	1	4	1	4		
Muscular weakness		1		1		
Musculoskeletal chest pain		1		1		
Musculoskeletal pain		1		1		
Myalgia	2	31	2	29		2
Neck pain		2		2		
Pain in extremity	8	19	8	19		
Rhabdomyolysis		1				1
Synovial cyst		1		1		
	19	88	18	81	1	7

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphasia		1				1
Burning sensation	1	3	1	3		
Dizziness	3	8	3	8		
Dysgeusia		1				1
Facial paralysis		1				1
Guillain-Barre syndrome		2				2
Headache	13	55	13	53		2
Head discomfort		1		1		
Hemiparaesthesia		1				1
Hemiparesis		1				1
Hemiplegia		1				1
Hyperaesthesia		2		2		
Hypertonia		1		1		
Hypoaesthesia	1	5	1	4		1
Loss of consciousness		2				2
Neuralgia		1				1
Paraesthesia		7		5		2
Seizure		2				2
Sensory loss		1		1		
Somnolence		3		3		
Syncope		1				1
	18	100	18	81		19

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product supply issue	1	2	1	2
	1	2	1	2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anxiety		1		1
Aversion		1		1
Depressed mood	3	4	3	4
Discouragement		1		1
Emotional distress		1		1
Fear	1	2	1	2
Fear of disease	1	1	1	1
Insomnia	2	5	2	5
Mental disorder		1		1
Panic attack		1		1
Panic reaction	1	2	1	2
Stress		1		1
	8	21	8	21

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breast engorgement		1		1
Breast pain	1	2	1	2
Breast swelling	1	1	1	1
Galactostasis		1		1
Nipple pain	1	1	1	1
	3	6	3	6

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Choking		1				1
Cough	1	4	1	3		1
Dyspnoea	2	8	2	5		3
Hyperventilation		1				1
Nasal congestion		2		2		
Oropharyngeal pain		2		1		1
Pharyngeal swelling	1	1			1	1
Respiratory disorder	1	2	1	1		1
Respiratory distress		1				1
Rhinorrhoea		3		3		
Throat irritation		3		3		
Wheezing	1	1	1	1		
	6	29	5	19	1	10

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema		2				2
Cold sweat		1		1		
Dermatitis acneiform	1	1	1	1		
Dermatitis allergic		5		4		1
Dry skin		1		1		
Erythema	2	5	1	4	1	1
Erythema nodosum		1				1
Hyperhidrosis		1		1		
Pruritus	2	4	1	3	1	1
Rash	1	3		1	1	2
Rash papular	1	1			1	1
Rash pruritic		1				1
Skin burning sensation		2		2		
Skin discomfort	1	1	1	1		
Skin swelling	1	1	1	1		
Urticaria	1	3		1	1	2
	10	33	5	21	5	12

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Loss of personal independence in daily activities	2	4	2	4
	2	4	2	4

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure fluctuation		1		1		
Hot flush	1	2	1	2		
Hypertension		2		2		
Hypotension		1				1
Internal haemorrhage		1				1
Pallor		1				1
Vasculitis		1				1
Vein disorder	1	1	1	1		
Venous thrombosis		1				1
	2	11	2	6		5

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

COLOMBIA

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Leukocytosis		1		1
Lymphadenopathy	2	4	2	4
	2	5	2	5

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorder	1	1			1	1
Myocardial infarction	1	1			1	1
Tachycardia	1	2	1	2		
	3	4	1	2	2	2

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tinnitus	1	1	1	1		
Vertigo	3	4	3	3		1
	4	5	4	4		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenopia	1	1	1	1		
Diplopia	1	1			1	1
Eye inflammation	1	1	1	1		
Eye pain	2	3	2	3		
Ocular hyperaemia		1		1		
Vision blurred	1	1			1	1
	6	8	4	6	2	2

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	1	1	1	1		
Abdominal pain upper		1		1		
Anal rash	1	1	1	1		
Aphthous ulcer	1	1	1	1		
Bowel movement irregularity	1	1			1	1
Diarrhoea	2	4	2	3		1
Dry mouth	1	1	1	1		
Lip dry	1	1			1	1
Nausea	2	4	1	3	1	1
Odynophagia	2	2	2	2		
Stomatitis		1		1		
Vomiting	4	7	4	6		1
	17	26	14	21	3	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	3	7	3	6		1
Axillary pain	1	1			1	1
Chest pain		1		1		
Chills	5	12	5	11		1
Death		1				1
Discomfort	4	5	3	3	1	2
Drug ineffective	8	9			8	9
Fatigue	4	5	4	4		1
Feeling hot		3		3		
Gait disturbance	1	1	1	1		
Gait inability		1		1		
General physical health deterioration	1	1	1	1		
Inflammation	1	1	1	1		
Influenza like illness		1		1		
Malaise	6	16	6	15		1
Oedema		1		1		
Pain	4	6	4	6		
Puncture site pain		1		1		
Pyrexia	5	11	5	10		1
Secretion discharge		1		1		
Swelling	1	1	1	1		
Swelling face	1	1	1	1		
Thirst	1	1	1	1		
Vaccination failure	1	1			1	1
Vaccination site erythema		1		1		
Vaccination site pain	4	11	4	11		
	51	101	40	82	11	19

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	4			1	4
Anaphylactic shock		1				1
Drug hypersensitivity		1		1		
Hypersensitivity	3	7	1	5	2	2
	4	13	1	6	3	7

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19	2	3			2	3
Candida infection		1		1		
COVID-19	15	19	8	10	7	9
COVID-19 pneumonia	1	1			1	1
Gingivitis		1		1		
Herpes virus infection	1	1	1	1		
Herpes zoster	3	3	3	3		
Influenza		2		2		
Oral candidiasis		1		1		
Pharyngitis	1	1	1	1		
Pneumonia	1	1			1	1
Suspected COVID-19	1	1	1	1		
	25	35	14	21	11	14

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposure during pregnancy		1		1
Inappropriate schedule of product administration	1	2	1	2
Off label use		1		1
Product use issue	1	2	1	2
Underdose		1		1
	2	7	2	7

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased		1		1		
Body temperature decreased	2	2	2	2		
Lymph node palpable	1	1	1	1		
Oxygen saturation abnormal	1	1			1	1
Oxygen saturation decreased	2	4		2	2	2
	6	9	3	6	3	3

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	4	10	4	10		
Arthritis	1	1	1	1		
Axillary mass	1	1			1	1
Back pain		1		1		
Bone pain	2	3	2	3		
Joint swelling	1	1	1	1		
Limb discomfort	1	1	1	1		
Mobility decreased	1	1			1	1
Muscle spasms	1	2	1	2		
Musculoskeletal pain	1	1	1	1		
Myalgia	5	9	5	9		
Neck pain	2	2	2	2		
Pain in extremity	3	3	3	3		
	23	36	21	34	2	2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burning sensation	2	3	2	3		
Dizziness	6	9	5	8	1	1
Dysgeusia	1	1			1	1
Facial paralysis	1	1			1	1
Headache	12	26	12	24		2
Hypoaesthesia		1		1		
Hypokinesia	1	1	1	1		
Neuralgia	1	1	1	1		
Paraesthesia	1	4	1	4		
Post herpetic neuralgia	1	1	1	1		
Sedation	1	1			1	1
Seizure		1				1
Syncope		1				1
Tremor	1	1			1	1
	28	52	23	43	5	9

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety		1				1
Insomnia	1	1	1	1		
	1	2	1	1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Renal disorder	1	1	1	1
	1	1	1	1

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphonia	1	1	1	1		
Asphyxia	1	2			1	2
Choking sensation	1	1			1	1
Cough	2	8	2	7		1
Dry throat	1	1	1	1		
Dysphonia		1		1		
Dyspnoea	2	6	1	4	1	2
Lung disorder	1	1			1	1
Nasal congestion	1	1	1	1		
Oropharyngeal pain	2	4	2	4		
Pharyngeal erythema		1		1		
Pharyngeal oedema	1	1			1	1
Pharyngeal swelling	1	1	1	1		
Respiratory distress		1				1
Rhinitis allergic	1	1	1	1		
Rhinorrhoea		1		1		
Sneezing		1		1		
Suffocation feeling		1		1		
	15	34	10	25	5	9

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blister	1	2	1	2		
Erythema	2	6	2	6		
Hyperhidrosis		1		1		
Papule	1	1	1	1		
Pruritus	1	2	1	2		
Pruritus allergic	1	1	1	1		
Rash	5	10	3	6	2	4
Skin discolouration		1		1		
Skin plaque		1		1		
Urticaria		4		4		
	11	29	9	25	2	4

System Organ Class

SOC Not Yet Coded

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
		1		1
		1		1

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cyanosis		1		1		
Hypertension		2		1		1
Thrombophlebitis	1	1	1	1		
Thrombosed varicose vein	1	1	1	1		
	2	5	2	4		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

COSTA RICA

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Immune thrombocytopenia		1				1
Lymphadenopathy	1	4	1	4		
Lymph node pain		2		2		
Splenomegaly		1				1
	1	8	1	6		2

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac arrest	1	1			1	1
Myocardial infarction		2				2
Tachycardia	1	4	1	4		
	2	7	1	4	1	3

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness		1				1
Ear discomfort		1		1		
Ear pain	1	1	1	1		
Tinnitus		2		2		
Vertigo	2	2	2	2		
	3	7	3	6		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry eye		1		1		
Erythema of eyelid		1		1		
Eye allergy		1		1		
Eye inflammation		1		1		
Eyelid irritation		1		1		
Eye pain	2	3	2	3		
Eye pruritus		2		2		
Lacrimation increased	1	1	1	1		
Miosis		1				1
Ocular hyperaemia		3		3		
Photopsia		1		1		
Vision blurred	1	2	1	2		
	4	18	4	17		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal distension		1				1
Abdominal pain	1	3	1	3		
Abdominal pain upper	1	5	1	2		3
Aphthous ulcer		1		1		
Bowel movement irregularity	1	1	1	1		
Colitis	1	1	1	1		
Constipation		2		2		
Diarrhoea	5	14	5	12		2
Dry mouth		1				1
Dyspepsia		2				2
Faeces soft		1		1		
Flatulence		1		1		
Gastric disorder		1		1		
Gastritis		2		1		1
Gastrointestinal pain		1		1		
Gastrointestinal sounds abnormal		1		1		
Gingival bleeding		1		1		
Gingival disorder		1		1		
Gingival pain		1		1		
Mouth swelling		1		1		
Nausea	1	11	1	9		2
Odynophagia		1		1		
Toothache	1	1	1	1		
Tooth disorder		1		1		
Vomiting	1	6	1	4		2
	13	63	13	49		14

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Application site inflammation		1		1		
Application site pain	2	3	2	3		
Asthenia	3	13	3	11		2
Axillary pain	1	3	1	3		
Chest discomfort		1				1
Chest pain		1				1
Chills	5	17	5	15		2
Condition aggravated		2		1		1
Death	1	3			1	3
Discomfort	2	5	2	4		1
Drug ineffective	4	9			4	9
Energy increased		1		1		
Extensive swelling of vaccinated limb		1		1		
Face oedema	1	1	1	1		
Fatigue	17	49	17	47		2
Feeling abnormal	1	5	1	4		1
Feeling cold	1	5	1	5		
Feeling hot	2	3	2	3		
Hyperthermia		1		1		
Hypothermia		1				1
Influenza like illness	1	2	1	1		1
Malaise	4	11	4	10		1
Multiple organ dysfunction syndrome	1	1			1	1
Pain	16	32	16	32		
Peripheral swelling	1	4	1	4		
Pyrexia	8	33	8	31		2
Sensation of foreign body		1		1		
Swelling	1	1	1	1		
Swelling face		1		1		
Thirst		2				2
Vaccination failure	4	6			4	6
Vaccination site discomfort		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site erythema	1	2	1	2		
Vaccination site induration	1	2	1	2		
Vaccination site mass		1		1		
Vaccination site movement impairment		1		1		
Vaccination site nodule		1		1		
Vaccination site pain	14	61	14	61		
Vaccination site swelling	1	1	1	1		
Vaccination site urticaria		1		1		
Vaccination site warmth	1	1	1	1		
	94	291	84	254	10	37

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Anaphylactic shock		2				2
Hypersensitivity		1		1		
		4		1		3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	8	19		2	8	17
Gingivitis		1		1		
Infection		2		2		
Influenza	2	3	2	3		
Lymphangitis		1				1
Nasopharyngitis		1		1		
Suspected COVID-19		1		1		
	10	28	2	10	8	18

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Contusion		2		1		1
Exposure via breast milk	1	1	1	1		
Fall		1				1
Incorrect route of product administration		2		2		
Intentional product use issue		1		1		
Poor quality product administered		1		1		
Vaccination complication		1		1		
	1	9	1	7		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacterial test positive	1	1	1	1		
Blood cholesterol increased	1	1	1	1		
Blood pressure increased		1		1		
Fibrin D dimer increased		1		1		
Heart rate increased	1	2			1	2
Heart rate irregular		1		1		
Hepatic enzyme increased		1				1
High density lipoprotein decreased	1	1	1	1		
Immunology test abnormal		1		1		
Low density lipoprotein increased	1	1	1	1		
Oxygen saturation abnormal		1				1
Oxygen saturation decreased		4		1		3
Platelet count abnormal		2				2
Red blood cell sedimentation rate increased		1		1		
SARS-CoV-2 ant body test negative		1		1		
	5	20	4	11	1	9

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	3	11	3	11		
Back pain	1	4	1	4		
Bone pain		1		1		
Joint range of motion decreased		1				1
Joint swelling		1		1		
Limb discomfort		4		4		
Mobility decreased	1	3	1	2		1
Muscle contracture		1		1		
Muscle spasms		3		3		
Muscle tightness	1	1	1	1		
Musculoskeletal chest pain		1		1		
Myalgia	7	30	7	28		2
Neck pain		1		1		
Pain in extremity	8	39	8	39		
	21	101	21	97		4

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burning sensation		2		2		
Cerebrovascular accident		3				3
Dizziness	4	12	4	9		3
Dysgeusia		3		2		1
Dysstasia	1	1	1	1		
Encephalopathy		1				1
Headache	22	58	22	55		3
Head discomfort		1		1		
Hyperaesthesia	1	1	1	1		
Hypersomnia		1		1		
Hypoaesthesia	1	2	1	2		
Hyposmia		1		1		
Incoherent		1		1		
Lethargy		2		2		
Migraine	3	7	3	6		1
Nervous system disorder		1		1		
Paraesthesia	1	3	1	3		
Seizure		1				1
Somnolence	3	7	3	7		
Syncope		1				1
Tremor		1		1		
	36	110	36	96		14

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion spontaneous		1		1
		1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Communication disorder		1		1
Depression		1		1
Euphoric mood		1		1
Insomnia		1		1
Sleep disorder		2		2
		6		6

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal disorder	1	2		1	1	1
	1	2		1	1	1

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Adnexa uteri pain		2		2
Breast discomfort		1		1
		3		3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphonia		1		1		
Bronchospasm		1		1		
Cough	1	5	1	5		
Dysphonia		2		2		
Dyspnoea	1	9	1	7		2
Epistaxis		2		1		1
Lung disorder		2		1		1
Nasal congestion		1		1		
Nasal discomfort	1	1	1	1		
Oropharyngeal discomfort		1				1
Oropharyngeal pain		4		4		
Pleural effusion		1				1
Pleuritic pain		1		1		
Pneumonitis		1				1
Respiratory disorder		1				1
Respiratory distress		1				1
Respiratory symptom	1	1	1	1		
Respiratory tract congestion		1		1		
Rhinorrhoea	1	2	1	2		
Tachypnoea		2		2		
Throat clearing		1		1		
Throat irritation		2		2		
Throat tightness		1				1
	5	44	5	34		10

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat		1		1		
Dermatitis allergic		2		1		1
Drug reaction with eosinophilia and systemic symptoms	2	2			2	2
Ecchymosis		1		1		
Erythema	1	2	1	2		
Hyperhidrosis	4	6	4	5		1
Pain of skin	1	1	1	1		
Petechiae		2		1		1
Pruritus	1	8	1	8		
Rash	3	8	3	8		
Rash macular	1	1	1	1		
Rash papular		1		1		
Skin burning sensation		1		1		
Skin discolouration		1		1		
Skin lesion		1		1		
Urticaria		2		2		
	13	40	11	35	2	5

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Impaired work ability	1	2		1	1	1
Loss of personal independence in daily activities		2		2		
	1	4		3	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemorrhage		1				1
Hypertension		1				1
Hypertensive crisis		1				1
Infarction	1	1			1	1
Ischaemia		1		1		
Peripheral coldness		1		1		
Thrombophlebitis	1	1	1	1		
Thrombosis	1	1			1	1
Vasculitis		1		1		
Venous thrombosis		1				1
	3	10	1	4	2	6

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

CROATIA

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia		1				1
Lymphadenitis		2		1		1
Lymphadenopathy	3	12	3	10		2
Lymph node pain	3	6	3	5		1
Lymphopenia		1		1		
Thrombocytopenia		1				1
	6	23	6	17		6

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris		1				1
Arrhythmia		7				7
Atrial fibrillation		2				2
Cardiac arrest		1				1
Cardiac disorder		1				1
Cardiac failure	1	4			1	4
Cardiac failure acute		1				1
Cardiac failure congestive		1				1
Cardiomyopathy		1				1
Cardio-respiratory arrest		1				1
Myocardial infarction	1	1			1	1
Palpitations		12		5		7
Stress cardiomyopathy		1				1
Tachycardia	1	14	1	7		7
	3	48	1	12	2	36

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness bilateral		1				1
Deafness unilateral		1				1
Ear canal erythema		1				1
Ear pain		3		1		2
Ear pruritus		1				1
Hypoacusis		2		1		1
Tinnitus	1	7		3	1	4
Vertigo	3	8	2	5	1	3
	4	24	2	10	2	14

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival haemorrhage		3				3
Conjunctivitis allergic		1				1
Dry eye		1				1
Eye haematoma		1				1
Eye haemorrhage		1				1
Eyelid function disorder		1				1
Eyelid oedema		2		1		1
Eyelid pain		1		1		
Eyelid ptosis		2				2
Eye opacity		1		1		
Eye pain		3		3		
Lacrimation increased		2		2		
Ocular discomfort		2		2		
Ocular hyperaemia		1		1		
Photophobia	1	1	1	1		
Vision blurred		1				1
Visual impairment	1	2	1	1		1
Vitreous detachment		1				1
	2	27	2	13		14

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Abdominal pain upper	1	4		3	1	1
Aphthous ulcer		1		1		
Aptyalism		1				1
Defaecation urgency		1		1		
Diarrhoea	3	8	3	6		2
Dry mouth		3		1		2
Dyspepsia		1		1		
Dysphagia		3				3
Eructation		1		1		
Gastritis		1		1		
Gastrointestinal pain		1		1		
Gingival bleeding		1		1		
Hypoaesthesia oral		2		1		1
Irritable bowel syndrome		1		1		
Lip disorder		1				1
Lip oedema	1	3			1	3
Lip swelling		1				1
Melaena		1				1
Nausea	7	36	7	29		7
Oedema mouth		1				1
Oral mucosal erythema		1		1		
Oral pain		1		1		
Paraesthesia oral	1	7		2	1	5
Rectal haemorrhage		1				1
Retching		3		3		
Salivary hypersecretion		1				1
Swollen tongue		3				3
Tongue disorder		1				1
Tongue oedema	1	4			1	4
Vomiting	2	15	2	10		5
	16	110	12	65	4	45

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Application site oedema		1		1		
Asthenia	10	41	8	31	2	10
Axillary pain	2	3	2	2		1
Chest discomfort	1	7		1	1	6
Chest pain	5	11	1	4	4	7
Chills	15	65	14	57	1	8
Condition aggravated		2				2
Death		3				3
Discomfort		1		1		
Drug ineffective	4	6			4	6
Extensive swelling of vaccinated limb	2	23			2	23
Face oedema	1	1			1	1
Facial pain		1		1		
Fatigue	21	54	18	44	3	10
Feeling abnormal	1	4	1	3		1
Feeling cold		1		1		
Feeling hot		10		6		4
Gait disturbance	3	5	1	1	2	4
General physical health deterioration		1				1
Illness		1		1		
Influenza like illness	1	1	1	1		
Localised oedema		1		1		
Malaise	5	24	3	19	2	5
Moaning		1				1
Multi-organ disorder		1				1
Multiple organ dysfunction syndrome	1	1			1	1
Oedema peripheral	1	4		1	1	3
Pain	4	10	3	9	1	1
Peripheral swelling	2	5		2	2	3
Pyrexia	23	111	21	84	2	27
Sensation of foreign body		1		1		
Swelling face		2				2

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* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thirst	1	1			1	1
Vaccination failure	58	72			58	72
Vaccination site erythema	5	43	5	33		10
Vaccination site haematoma		3		3		
Vaccination site hypersensitivity		1		1		
Vaccination site induration		7		5		2
Vaccination site joint erythema		1		1		
Vaccination site joint movement impairment		1		1		
Vaccination site lymphadenopathy		3		3		
Vaccination site mass		1				1
Vaccination site movement impairment		1				1
Vaccination site oedema	2	12	2	9		3
Vaccination site pain	19	120	19	104		16
Vaccination site paraesthesia	1	1	1	1		
Vaccination site pruritus	1	5	1	4		1
Vaccination site reaction		1		1		
Vaccination site swelling	5	24	5	18		6
Vaccination site warmth		1		1		
	194	701	106	457	88	244

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to chemicals		1		1		
Anaphylactic reaction		2				2
Anaphylactic shock		2				2
Hypersensitivity		4				4
Immune system disorder		1		1		
Serum sickness		1				1
Type I hypersensitivity		20				20
		31		2		29

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19	26	26			26	26
Bronchitis		1				1
COVID-19	35	54		3	35	51
Ear infection		1				1
Escherichia urinary tract infection		1				1
Herpes zoster	1	1	1	1		
Nasopharyngitis	2	4		2	2	2
Oral herpes	1	1	1	1		
Pneumonia		3				3
Pneumonia klebsiella		1				1
Pneumonia staphylococcal		1				1
Sepsis syndrome	1	1			1	1
Sinusitis	1	1			1	1
Urinary tract infection		1				1
Viral infection		1		1		
	67	98	2	8	65	90

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Contusion	1	1			1	1
Exposure during pregnancy		1		1		
Fall	1	4			1	4
Incorrect dose administered		1				1
Incorrect route of product administration		1		1		
Off label use		1		1		
Overdose	1	2	1	2		
Product preparation error	1	2	1	2		
Product use issue		1		1		
Underdose		1				1
Vaccination error		1		1		
Wrong technique in product usage process		1		1		
	4	17	2	10	2	7

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood creatine phosphokinase increased		2		2		
Blood creatinine increased	1	1			1	1
Blood glucose increased		3		2		1
Blood pressure decreased		2		2		
Blood pressure increased		17		5		12
Body temperature increased	7	22	6	19	1	3
Breath sounds abnormal		1				1
C-reactive protein increased	1	1	1	1		
Heart rate increased	2	5	1	3	1	2
Hepatic enzyme abnormal	1	1			1	1
Intraocular pressure increased		1		1		
Neutrophil count increased		1		1		
Oxygen saturation decreased	1	2			1	2
Pulse absent		1				1
Respiratory rate decreased		1		1		
Rheumatoid factor positive		1		1		
White blood cell count increased		1		1		
	13	63	8	39	5	24

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	1	6	1	5		1
Diabetes mellitus		1				1
Feeding disorder		1		1		
Increased appetite		1		1		
	1	9	1	7		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	4	22	4	19		3
Arthritis	1	1			1	1
Arthritis reactive		1				1
Axillary mass	1	1	1	1		
Back pain		5		3		2
Bone pain	3	10	2	9	1	1
Fibromyalgia		1				1
Joint effusion		1				1
Joint swelling		1		1		
Muscle spasms		3		2		1
Muscle tightness		1		1		
Muscular weakness	1	6		3	1	3
Musculoskeletal stiffness		2		1		1
Myalgia	20	67	19	59	1	8
Myosclerosis		1				1
Neck pain	3	9	3	8		1
Pain in extremity	10	31	8	23	2	8
Spinal pain	1	2		1	1	1
Synovitis		1				1
Trismus	1	1	1	1		
	45	167	38	132	7	35

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	2	2			2	2
Altered state of consciousness		1				1
Anosmia	2	3			2	3
Balance disorder		2				2
Bell's palsy		1				1
Burning sensation	2	5	1	1	1	4
Cerebral artery thrombosis		1				1
Cerebral haemorrhage		2				2
Cerebral infarction		1				1
Cerebrovascular accident		1				1
Cerebrovascular disorder		1				1
Coma		1				1
Coordination abnormal	1	1	1	1		
Disturbance in attention	1	2	1	2		
Dizziness	3	15	1	10	2	5
Dizziness postural	1	1	1	1		
Dysarthria		1		1		
Dysgeusia		2		1		1
Dyskinesia		1				1
Encephalitis post immunisation		1				1
Epilepsy		1				1
Extensor plantar response		1		1		
Extrapyramidal disorder		1				1
Facial nerve disorder		1		1		
Facial paresis	1	10		1	1	9
Headache	27	108	23	83	4	25
Head discomfort		1				1
Head titubation		1				1
Hemiparesis		2				2
Hemiplegia		1				1
Hyperaesthesia		1		1		
Hypoaesthesia		5		3		2

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypogeusia		1		1		
Hypokinesia		1				1
Hyporesponsive to stimuli		1				1
Ischaemic cerebral infarction		1				1
Ischaemic stroke		1				1
Loss of consciousness	3	8			3	8
Memory impairment		1		1		
Migraine		1		1		
Monoparesis	1	2	1	1		1
Motor dysfunction	1	1			1	1
Movement disorder	1	1			1	1
Muscle contractions involuntary		2		1		1
Neuritis		1		1		
Neurological symptom		1		1		
Nystagmus		1				1
Paraesthesia	4	17	3	10	1	7
Paresis		1				1
Parosmia	1	1			1	1
Presyncope		3		1		2
Sensory disturbance	1	2			1	2
Sensory loss	1	2			1	2
Sleep paralysis		1		1		
Somnolence	1	5	1	3		2
Speech disorder		2				2
Syncope	1	5			1	5
Tension headache	1	1	1	1		
Transient ischaemic attack	1	2			1	2
Tremor	3	14	2	11	1	3
Unresponsive to stimuli		1				1
	60	259	36	141	24	118

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion spontaneous		1		1
		1		1

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	1	1	1	1		
Communication disorder		1				1
Confusional state	3	5	2	3	1	2
Disorientation	1	2	1	1		1
Fear		1				1
Insomnia	1	7	1	7		
Organic brain syndrome		1				1
Panic attack		2				2
Restlessness		1				1
Sleep terror		1		1		
Tension		1		1		
	6	23	5	14	1	9

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal pain		1		1		
Urinary incontinence		1				1
Urine odour abnormal		1		1		
		3		2		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breast pain		1		1
Heavy menstrual bleeding	1	1	1	1
Menstrual disorder		1		1
Polymenorrhoea	1	2	1	2
	2	5	2	5

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma		1				1
Bronchospasm		4				4
Catarrh		1				1
Choking sensation		1				1
Cough	3	11	1	5	2	6
Diaphragmatic spasm		1				1
Dysphonia		1				1
Dyspnoea	5	24	1	5	4	19
Dyspnoea exertional	1	2		1	1	1
Hypopnoea		1				1
Hypoxia		1				1
Nasal congestion	2	3		1	2	2
Oropharyngeal discomfort		1		1		
Oropharyngeal pain	1	5		4	1	1
Pharyngeal paraesthesia		1				1
Pharyngeal swelling		1		1		
Pleural effusion		1				1
Pulmonary embolism	3	5			3	5
Pulmonary pain		1		1		
Rales		1				1
Respiratory distress		1				1
Respiratory failure		1				1
Respiratory symptom	1	1			1	1
Respiratory tract oedema		1				1
Rhinorrhoea	1	5		3	1	2
Sneezing		1				1
Snoring		2		1		1
Stridor		2				2
Suffocation feeling		1				1
Tachypnoea		2				2
Throat tightness		3				3
Use of accessory respiratory muscles		2				2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Wheezing		4				4
	17	93	2	23	15	70

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema		2				2
Blister		1				1
Cold sweat		2		1		1
Dermatitis	1	1			1	1
Dermatitis allergic		2		1		1
Drug eruption	1	1			1	1
Erythema	5	25	3	6	2	19
Haemorrhage subcutaneous		1				1
Hyperhidrosis		9		6		3
Livedo reticularis		1				1
Night sweats		1		1		
Pain of skin		1				1
Pruritus	5	16	4	6	1	10
Psoriasis		1		1		
Rash	4	17	2	4	2	13
Rash erythematous		2		1		1
Rash macular	1	4	1	1		3
Rash maculo-papular	2	6	1	1	1	5
Rash pruritic	1	1	1	1		
Skin burning sensation		3		1		2
Skin discolouration		1				1
Skin hypertrophy		1				1
Skin oedema		1		1		
Skin reaction		1				1
Skin sensitisation		1		1		
Skin tightness		2				2
Urticaria	4	9	4	4		5
	24	113	16	37	8	76

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Loss of personal independence in daily activities		2		2
		2		2

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Capillary fragility		1		1		
Cyanosis		4				4
Deep vein thrombosis	1	3			1	3
Flushing	1	1	1	1		
Haematoma		1		1		
Hot flush		2		1		1
Hypertension	2	13	1	2	1	11
Hypertensive crisis		1				1
Hypotension		4		1		3
Pallor		3				3
Peripheral coldness		3		1		2
Poor peripheral circulation		1				1
Thrombophlebitis		1				1
Thrombosis		1				1
	4	39	2	8	2	31

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

CYPRUS

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy	1	7	1	6		1
	1	7	1	6		1

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris		1				1
Bradycardia		1				1
Myocardial infarction		2				2
Tachyarrhythmia		1				1
Tachycardia	3	5	3	4		1
	3	10	3	4		6

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear discomfort		1		1
Ear pain		1		1
Hypoacusis		1		1
Vertigo		1		1
		4		4

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye disorder		1		1		
Eyelid ptosis		1		1		
Eye pain		1		1		
Hypoaesthesia eye		1				1
Vision blurred	1	1	1	1		
	1	5	1	4		1

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Abdominal pain upper		1		1		
Diarrhoea		2		2		
Dry mouth	1	1	1	1		
Dysphagia		1		1		
Gastric haemorrhage		1				1
Hypoaesthesia oral		3		1		2
Nausea		10		10		
Swollen tongue		2		2		
Tongue rough	1	1	1	1		
Vomiting	1	8	1	7		1
	4	31	4	27		4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse event	1	1	1	1		
Asthenia	6	11	6	11		
Axillary pain		2		2		
Chest pain	1	2	1	2		
Chills	8	25	8	25		
Condition aggravated	1	2	1	2		
Death		1				1
Discomfort		1		1		
Drug ineffective	2	8			2	8
Drug interaction		1		1		
Face oedema		2		1		1
Fatigue	4	19	4	19		
Feeling of relaxation	1	1	1	1		
Gait disturbance		2		2		
Gait inability		1		1		
Inflammation		1		1		
Influenza like illness	1	4	1	4		
Injection site pain		1		1		
Malaise	1	15	1	15		
Multiple organ dysfunction syndrome		1				1
Oedema	1	1	1	1		
Pain		3		3		
Peripheral swelling		1		1		
Pyrexia	6	24	6	24		
Sluggishness		1		1		
Swelling face	1	1	1	1		
Therapeutic response unexpected		1		1		
Thirst	1	1	1	1		
Vaccination failure	1	2			1	2
Vaccination site oedema		3		3		
Vaccination site pain	5	21	5	21		
Vaccination site swelling		2		2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	41	162	38	149	3	13

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		2				2
Hypersensitivity		1		1		
		3		1		2

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19	1	1			1	1
Bacterial sepsis		1				1
COVID-19	3	16		1	3	15
Gastrointestinal infection		1				1
Herpes zoster	3	3	3	3		
Influenza		1		1		
Myelitis		1				1
Nasopharyngitis	1	2	1	2		
Sialoadenitis		1				1
Viral sepsis		1				1
	8	28	4	7	4	21

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Contusion		2		2
Inappropriate schedule of product administration		2		2
Off label use		2		2
Overdose		1		1
Product use issue		1		1
		8		8

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased		1				1
Body temperature increased	1	2	1	2		
C-reactive protein increased		1		1		
Fibrin D dimer increased		1		1		
Oxygen saturation decreased		3		1		2
SARS-CoV-2 ant body test negative		1				1
	1	9	1	5		4

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dehydration		1				1
Hyponatraemia		2		2		
		3		2		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	4	21	4	21		
Back pain		2		2		
Bone pain		1		1		
Jaw disorder	1	1	1	1		
Mobility decreased		1		1		
Muscle contracture		1		1		
Muscle spasms	1	1	1	1		
Muscular weakness		2		1		1
Musculoskeletal stiffness	1	1	1	1		
Myalgia	10	41	10	41		
Neck pain		1		1		
Pain in extremity	1	2	1	2		
	18	75	18	74		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Balance disorder		1		1		
Cerebrovascular accident		1				1
Dizziness	3	10	3	10		
Dysaesthesia		1				1
Dysgeusia		2		2		
Facial paralysis		2				2
Facial paresis	1	7	1	1		6
Generalised tonic-clonic seizure		1				1
Guillain-Barre syndrome		1				1
Headache	7	25	7	25		
Head titubation		1		1		
Hypoaesthesia	2	7	2	6		1
Migraine		2		2		
Paraesthesia		1		1		
Somnolence	2	2	2	2		
Syncope		3				3
Tremor		1		1		
Unresponsive to stimuli		1				1
	15	69	15	52		17

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Confusional state		2		2
Insomnia	1	4	1	4
	1	6	1	6

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute kidney injury		1		1
Urinary retention		1		1
		2		2

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Amenorrhoea	1	1	1	1
Cervix oedema		1		1
	1	2	1	2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory distress syndrome		1				1
Cough	2	2	2	2		
Dyspnoea	5	12	3	8	2	4
Epistaxis		1				1
Nasal congestion		1		1		
Oropharyngeal discomfort	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Pharyngeal oedema		1		1		
Pulmonary embolism		6				6
Pulmonary oedema		1				1
Respiratory distress		1				1
Respiratory tract oedema		1				1
Sinus congestion	1	1	1	1		
Upper respiratory tract congestion	1	1	1	1		
	11	31	9	16	2	15

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cold sweat	1	1	1	1
Dermatitis atopic		1		1
Eczema		1		1
Erythema		1		1
Hyperhidrosis	2	5	2	5
Rash		2		2
Rash erythematous		1		1
	3	12	3	12

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysm		1				1
Hypertension		2		1		1
Hypotension		3				3
Pallor		1		1		
Shock		1				1
Vasculitis		2		1		1
		10		3		7

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

CZECH REPUBLIC

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acquired haemophilia	1	1			1	1
Anaemia		3		1		2
Autoimmune haemolytic anaemia	1	1			1	1
Coagulopathy		1				1
Hypercoagulation	1	1			1	1
Immune thrombocytopenia	1	1			1	1
Leukocytosis	1	3	1	3		
Leukopenia		2				2
Lymphadenitis	1	6		1	1	5
Lymphadenopathy	37	116	28	64	9	52
Lymph node pain	9	24	6	17	3	7
Neutropenia		1				1
Splenic infarction		1				1
Thrombocytopenia	2	3			2	3
	54	164	35	86	19	78

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction		2				2
Angina pectoris	3	7			3	7
Arrhythmia	2	7			2	7
Atrial fibrillation	1	6			1	6
Atrial flutter		1				1
Bradycardia	1	6			1	6
Bundle branch block right	1	2			1	2
Cardiac arrest		3				3
Cardiac disorder		1				1
Cardiac failure	1	5			1	5
Cardiac failure acute	1	1			1	1
Cardiac failure congestive		1				1
Cardiac hypertrophy		1				1
Cardiomegaly	1	1	1	1		
Cardiomyopathy		1				1
Cardio-respiratory arrest		2				2
Cor pulmonale		1				1
Defect conduction intraventricular	1	1			1	1
Extrasystoles		1		1		
Myocardial infarction	1	4			1	4
Myocarditis		1				1
Palpitations	9	30	6	13	3	17
Right ventricular dilatation		1				1
Sinus bradycardia		1		1		
Sinus tachycardia	1	2	1	1		1
Supraventricular extrasystoles		1		1		
Supraventricular tachycardia		1				1
Tachycardia	5	40	1	18	4	22
Ventricular tachycardia		2				2
	28	133	9	36	19	97

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute vestibular syndrome		1				1
Auditory disorder	1	1			1	1
Conductive deafness		1				1
Deafness	1	2			1	2
Deafness neurosensory	1	3			1	3
Deafness unilateral		2				2
Ear discomfort	3	13	1	6	2	7
Ear pain	5	8	4	7	1	1
Ear pruritus		1				1
Ear swelling		1				1
Endolymphatic hydrops	1	1			1	1
Hyperacusis		1				1
Hypoacusis	2	6		2	2	4
Tinnitus	3	16		4	3	12
Vertigo	16	60	10	39	6	21
Vertigo positional	1	1			1	1
	34	118	15	58	19	60

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Premature menarche	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blepharospasm	1	1			1	1
Blindness		2				2
Conjunctivitis allergic		1		1		
Diplopia	2	5	1	3	1	2
Dry eye		1				1
Eye disorder		1		1		
Eye haemorrhage	1	4			1	4
Eye inflammation		1		1		
Eye irritation	4	8	3	3	1	5
Eyelid function disorder		1				1
Eyelid oedema	4	8			4	8
Eye movement disorder		1		1		
Eye pain	7	17	6	14	1	3
Eye pruritus		3		2		1
Eye swelling		4		2		2
Gaze palsy		1				1
Glaucoma		1				1
Lacrimation increased	2	5	2	4		1
Lagophthalmos		1		1		
Mydriasis		1				1
Ocular discomfort	1	3	1	1		2
Ocular hyperaemia		1		1		
Orbital oedema		1				1
Photophobia		5		4		1
Photopsia		2		1		1
Retinal artery thrombosis	1	1			1	1
Swelling of eyelid	2	4			2	4
Vision blurred	12	29	5	10	7	19
Visual acuity reduced	1	1			1	1
Visual field defect		2				2
Visual impairment	2	5		1	2	4
	40	121	18	51	22	70

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	6		2	1	4
Abdominal pain	2	18	2	10		8
Abdominal pain lower	2	4	2	3		1
Abdominal pain upper	5	12	5	10		2
Anaesthesia oral		1				1
Anal incontinence		1		1		
Aphthous ulcer		4				4
Constipation		3		2		1
Diarrhoea	16	59	13	43	3	16
Dry mouth	4	10	3	6	1	4
Duodenal ulcer		1				1
Dyspepsia		9		5		4
Dysphagia	3	12	2	3	1	9
Flatulence	1	5	1	4		1
Frequent bowel movements		1		1		
Functional gastrointestinal disorder		1		1		
Gastric ulcer		2				2
Gastrointestinal disorder		2		2		
Gastrointestinal hypermotility		1				1
Gastrointestinal necrosis	1	2			1	2
Gastrointestinal pain		1		1		
Gastrooesophageal reflux disease		1				1
Gingival bleeding	2	2	1	1	1	1
Gingival pain		1		1		
Haematochezia		2				2
Hypoaesthesia oral		3		1		2
Ileus	1	1			1	1
Intestinal haemorrhage	1	1			1	1
Intestinal infarction		1				1
Lip dry		1		1		
Lip oedema		1				1
Lip swelling	3	10		1	3	9

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Melaena		1				1
Mesenteric arterial occlusion		1				1
Mesenteric vascular insufficiency		1				1
Nausea	65	167	58	140	7	27
Oedema mouth		1				1
Oesophageal irritation		1		1		
Oral discomfort		4		2		2
Oral mucosal blistering		1		1		
Oral pruritus	1	2	1	2		
Palatal swelling	1	3			1	3
Pancreatic infarction		1				1
Paraesthesia oral	6	34		2	6	32
Retching	3	11	3	7		4
Salivary gland pain	1	1	1	1		
Salivary hypersecretion		1				1
Swollen tongue		6				6
Tongue discomfort		3		1		2
Tongue erythema	1	1	1	1		
Tongue oedema	1	9			1	9
Toothache	3	8	2	6	1	2
Truncus coeliacus thrombosis		1				1
Vomiting	16	76	15	56	1	20
	140	513	110	319	30	194

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Application site coldness		1				1
Application site erythema		2		1		1
Asthenia	41	128	36	97	5	31
Axillary pain	8	18	6	14	2	4
Chest discomfort	5	24	3	11	2	13
Chest pain	11	27	2	11	9	16
Chills	139	322	136	294	3	28
Condition aggravated	2	4		1	2	3
Death	1	4			1	4
Decreased activity		2		2		
Discomfort	1	2		1	1	1
Disease progression	1	1			1	1
Disease recurrence		6		1		5
Drug ineffective	12	28			12	28
Drug interaction	1	2	1	1		1
Extensive swelling of vaccinated limb	1	1			1	1
Face oedema		2				2
Facial pain	1	3		1	1	2
Fatigue	206	436	203	387	3	49
Feeling abnormal	4	11	1	7	3	4
Feeling cold	1	4	1	4		
Feeling hot	5	22	2	12	3	10
Feeling of body temperature change	2	2	2	2		
Gait disturbance	3	12		2	3	10
Gait inability	1	5		2	1	3
Generalised oedema		1		1		
General physical health deterioration	3	12	1	4	2	8
Hangover	1	1	1	1		
Hyperpyrexia	1	2			1	2
Induration	1	2		1	1	1
Inflammation	1	3		1	1	2
Influenza like illness	70	163	61	127	9	36

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injected limb mobility decreased		2		2		
Injection site erythema		1				1
Localised oedema	1	6	1	1		5
Local reaction		1		1		
Malaise	23	52	23	46		6
Mass		2		1		1
Mucosal disorder		1				1
Mucosal dryness		2		1		1
Mucosal haemorrhage	1	1			1	1
Multiple organ dysfunction syndrome		2				2
Nodule	1	2	1	1		1
Oedema	1	4		3	1	1
Oedema peripheral	7	20	3	9	4	11
Pain	21	49	17	38	4	11
Peripheral swelling	8	23	4	11	4	12
Puncture site erythema	1	1	1	1		
Puncture site oedema		1		1		
Pyrexia	199	476	170	343	29	133
Sensation of foreign body		6		1		5
Sudden death		3				3
Swelling	3	10	1	6	2	4
Swelling face	4	29	1	4	3	25
Tenderness		2		1		1
Thirst		3		3		
Vaccination failure	4	17			4	17
Vaccination site anaesthesia		1				1
Vaccination site atrophy		2		1		1
Vaccination site bruising	1	3	1	2		1
Vaccination site discolouration		1		1		
Vaccination site discomfort	3	7	3	6		1
Vaccination site erythema	33	112	26	65	7	47
Vaccination site extravasation		1		1		

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site haematoma	2	5	2	3		2
Vaccination site hyperaesthesia	2	2	2	2		
Vaccination site hypersensitivity	3	4	2	2	1	2
Vaccination site induration	6	17	5	11	1	6
Vaccination site joint movement impairment		3		1		2
Vaccination site joint pain	1	3	1	3		
Vaccination site joint swelling	1	1			1	1
Vaccination site lymphadenopathy	1	2	1	2		
Vaccination site mass	1	5	1	2		3
Vaccination site movement impairment	4	10	2	6	2	4
Vaccination site oedema	18	57	17	38	1	19
Vaccination site pain	190	345	187	305	3	40
Vaccination site papule		1				1
Vaccination site paraesthesia	1	3		2	1	1
Vaccination site pruritus	8	26	7	20	1	6
Vaccination site rash	3	8	2	4	1	4
Vaccination site reaction		6		4		2
Vaccination site swelling	19	53	18	38	1	15
Vaccination site urticaria		4		1		3
Vaccination site warmth	4	17	4	12		5
	1,098	2,668	959	1992	139	676

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System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Biliary colic	1	1	1	1		
Gallbladder disorder		1		1		
Hepatic function abnormal		1				1
Hepatic infarction	1	2			1	2
Hepatitis		1				1
Jaundice		1		1		
Pneumobilia	1	1			1	1
	3	8	1	3	2	5

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic oedema		1				1
Allergy to vaccine		6		1		5
Anaphylactic reaction		18				18
Anaphylactoid reaction		1				1
Drug hypersensitivity		3		1		2
Hypersensitivity	12	58	5	19	7	39
Immune system disorder		1				1
Renal transplant failure		1				1
	12	89	5	21	7	68

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abscess of salivary gland		1				1
Asymptomatic COVID-19	2	2	1	1	1	1
Bacterial rhinitis		1				1
Bacterial sepsis	1	1			1	1
Borrelia infection		1				1
Bronchitis		1				1
Clostridium difficile colitis	1	1			1	1
Conjunctivitis	1	1	1	1		
COVID-19	33	80	9	20	24	60
COVID-19 pneumonia	2	9			2	9
Diverticulitis		1				1
Ear infection	1	1			1	1
Eczema herpeticum		1				1
Enterococcal infection		1				1
Erysipelas		2				2
Escherichia infection		1				1
Gastroenteritis		1		1		
Herpes dermatitis		1				1
Herpes ophthalmic	1	1			1	1
Herpes simplex		2				2
Herpes virus infection		1		1		
Herpes zoster	13	26			13	26
Herpes zoster reactivation	1	1			1	1
Hordeolum		1				1
Infection		1		1		
Influenza	3	4	3	4		
Klebsiella infection	1	2			1	2
Myelitis		1				1
Nasopharyngitis	3	4	3	4		
Oral herpes	1	3		1	1	2
Pneumonia	1	7			1	7
Pulpitis dental		1				1

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash pustular		1		1		
Rhinitis	2	10	2	9		1
Sepsis		2				2
Splenic infection		1				1
Sputum purulent		1				1
Tooth infection		1				1
Urinary tract infection		4		1		3
Urinary tract infection enterococcal		1				1
Urogenital infection bacterial		1				1
Urosepsis	1	2			1	2
Vaccination site cellulitis		1				1
Vaccination site pustule		1		1		
Vestibular neuronitis		1				1
Viral infection		2		1		1
	68	191	19	47	49	144

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Airway burns		2				2
Concussion	1	2	1	1		1
Contusion	1	4	1	1		3
Exposure via breast milk		1		1		
Fall	2	12		3	2	9
Femur fracture	1	1			1	1
Humerus fracture		1				1
Inappropriate schedule of product administration	1	8	1	8		
Incorrect route of product administration	1	5	1	5		
Ligament sprain	1	2			1	2
Maternal exposure during pregnancy		1		1		
Muscle strain	1	1	1	1		
Off label use	1	11	1	11		
Overdose	2	6	2	6		
Pneumoconiosis		1				1
Poor quality product administered		83		83		
Product administered at inappropriate site		3		3		
Product preparation error		83		83		
Product preparation issue		1		1		
Product use issue		6		6		
Scratch	1	1			1	1
Skin laceration		1				1
Underdose	1	1	1	1		
Vaccination complication		4		3		1
Wound	1	1	1	1		
	15	242	10	219	5	23

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* AE=Adverse Event

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased	1	1	1	1		
Antibody test abnormal		1		1		
Aspartate aminotransferase increased	1	1	1	1		
Bacterial test positive		1		1		
Blood chloride increased		1		1		
Blood glucose fluctuation	1	1	1	1		
Blood glucose increased		2		2		
Blood lactic acid increased		1		1		
Blood pressure abnormal		1				1
Blood pressure decreased	3	5	2	2	1	3
Blood pressure diastolic increased		1		1		
Blood pressure increased	8	23	5	12	3	11
Blood pressure systolic increased	1	5		2	1	3
Blood urea increased		1		1		
Blood urine	1	1			1	1
Blood urine present		2		2		
Body temperature decreased		1		1		
Body temperature fluctuation	1	1	1	1		
Body temperature increased	7	15	7	12		3
C-reactive protein increased	4	9	3	5	1	4
Cytomegalovirus test positive		1		1		
Electrocardiogram abnormal		2		1		1
Fibrin D dimer increased	1	1	1	1		
Glomerular filtration rate decreased		1		1		
Grip strength decreased	1	1			1	1
Haemoglobin decreased	1	1	1	1		
Heart rate decreased		1		1		
Heart rate increased	4	9	3	4	1	5
Heart rate irregular		2		2		
Immunoglobulins increased		1		1		
Inflammatory marker increased	2	2	1	1	1	1
International normalised ratio increased		2		1		1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Intraocular pressure increased	1	1	1	1		
Laboratory test abnormal		1		1		
Mean cell haemoglobin concentration increased	1	1	1	1		
Mean cell haemoglobin decreased	1	1	1	1		
Neutrophil count increased	1	1	1	1		
Oxygen saturation decreased		6		2		4
Platelet count decreased	1	1			1	1
Procalcitonin increased	1	1	1	1		
Pulse abnormal		1		1		
Red blood cell sedimentation rate increased		1		1		
SARS-CoV-2 ant body test negative		2				2
SARS-CoV-2 test positive		4		2		2
Troponin I increased		1				1
Weight decreased		1		1		
White blood cell count decreased	2	2	1	1	1	1
White blood cell count increased	1	1	1	1		
	46	124	34	78	12	46

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	6	40	5	30	1	10
Dehydration	1	3	1	2		1
Fluid intake reduced		1		1		
Food intolerance		1				1
Gout		1		1		
Hyperglycaemia	1	6		1	1	5
Hyperlipidaemia		1		1		
Hyperphagia		1		1		
Hypoglycaemia		2		1		1
Hypokalaemia		6				6
Hypomagnesaemia		1		1		
Hypophagia	1	2		1	1	1
Mineral metabolism disorder	1	1			1	1
Starvation	1	1			1	1
Tetany	1	1			1	1
	12	68	6	40	6	28

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	128	290	118	237	10	53
Arthritis	2	2			2	2
Axillary mass		1		1		
Back pain	19	42	16	36	3	6
Bone pain	3	6	2	4	1	2
Bursitis	1	1			1	1
Facial asymmetry		1				1
Flank pain		1		1		
Groin pain	1	2		1	1	1
Haemarthrosis	1	1			1	1
Joint effusion		1				1
Joint instability		1				1
Joint range of motion decreased	3	7	2	5	1	2
Joint stiffness	1	3		1	1	2
Joint swelling	5	11	3	8	2	3
Joint warmth		1		1		
Ligament pain		1		1		
Limb discomfort	2	5		1	2	4
Mobility decreased	5	9	1	5	4	4
Muscle atrophy		1				1
Muscle spasms	5	10	4	6	1	4
Muscle tightness		1		1		
Muscle twitching	2	6	1	3	1	3
Muscular weakness	7	22	4	14	3	8
Musculoskeletal chest pain	1	3		2	1	1
Musculoskeletal disorder	2	3	2	3		
Musculoskeletal pain		1		1		
Musculoskeletal stiffness	6	18	6	14		4
Myalgia	99	214	93	179	6	35
Myosclerosis		1				1
Myositis		1				1
Neck pain	4	11	4	9		2

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nuchal rigidity	1	2		1	1	1
Pain in extremity	115	210	99	174	16	36
Pain in jaw		1		1		
Polyarthrititis		3				3
Posture abnormal		1		1		
Rheumatoid arthritis	1	3			1	3
Spinal disorder	1	2	1	1		1
Spinal pain	7	13	6	8	1	5
Tendon pain		1				1
	422	914	362	720	60	194

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Prostate cancer		1		1
		1		1

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	6		3	1	3
Akathisia		1		1		
Akinesia		1				1
Altered state of consciousness		5				5
Amnesia	1	3			1	3
Anosmia	1	10		6	1	4
Aphasia		5		2		3
Balance disorder	5	6	3	3	2	3
Basal ganglia haemorrhage		1				1
Bell's palsy		2				2
Brain oedema		3				3
Burning sensation	4	10	2	6	2	4
Burning sensation mucosal		2		2		
Carpal tunnel syndrome		1				1
Cerebral atrophy		1				1
Cerebral haemorrhage		1				1
Cerebral ischaemia		1				1
Cerebral thrombosis		1				1
Cerebral venous sinus thrombosis		1				1
Cerebrovascular accident		14				14
Clumsiness	1	1	1	1		
Cognitive disorder	1	2			1	2
Coma	1	2			1	2
Coordination abnormal	1	2			1	2
Cranial nerve palsies multiple		1				1
Dementia		1				1
Disturbance in attention	4	10	3	5	1	5
Dizziness	27	64	19	47	8	17
Dizziness postural		1				1
Dysaesthesia	1	2			1	2
Dysarthria		3		1		2
Dysgeusia	1	5	1	3		2

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* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyskinesia		1				1
Dysstasia	1	2	1	1		1
Epilepsy		2				2
Facial paralysis	1	8			1	8
Facial paresis	2	7			2	7
Febrile convulsion		1				1
Formication	3	6	2	4	1	2
Generalised onset non-motor seizure	1	1			1	1
Guillain-Barre syndrome		1				1
Haemorrhage intracranial		1				1
Headache	152	353	146	317	6	36
Head discomfort	1	3	1	2		1
Hemiparesis		2				2
Hemiplegia		2				2
Hyperaesthesia	1	2	1	2		
Hypersomnia	1	5	1	1		4
Hypoaesthesia	5	17	1	6	4	11
Hypogeusia	1	1	1	1		
Hypokinesia	1	4	1	4		
Hypotonia		1		1		
Hypotonic-hyporesponsive episode		1				1
Ischaemic stroke	3	6			3	6
Language disorder		1				1
Lethargy		1		1		
Loss of consciousness	8	23			8	23
Memory impairment	4	5			4	5
Mental impairment	2	2			2	2
Migraine	3	15	3	9		6
Migraine with aura		1		1		
Monoparesis	1	3	1	1		2
Monoplegia	1	3			1	3
Motor dysfunction	1	1	1	1		

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Movement disorder	4	5			4	5
Multiple sclerosis		1				1
Multiple sclerosis relapse		1				1
Muscle spasticity		1		1		
Myoclonic epilepsy	1	1			1	1
Narcolepsy		2				2
Neuralgia	1	2			1	2
Neuralgic amyotrophy	1	1			1	1
Neuropathy peripheral		4				4
Nystagmus		2		2		
Paraesthesia	45	105	18	38	27	67
Paraesthesia mucosal		1				1
Paralysis		3				3
Paraparesis		1				1
Paresis		2				2
Paresis cranial nerve		1				1
Parosmia		2		1		1
Peripheral nerve palsy		1				1
Presyncope	7	19		2	7	17
Psychomotor hyperactivity		1				1
Quadripareisis		1				1
Radiculitis brachial		1				1
Radiculopathy		1				1
Reduced facial expression	2	2	1	1	1	1
Sciatica	1	1			1	1
Seizure	2	9			2	9
Sensory loss	1	1			1	1
Sleep deficit		1				1
Somnolence	10	38	10	28		10
Speech disorder	1	5		2	1	3
Subarachnoid haemorrhage	1	1			1	1
Syncope	7	29			7	29

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Taste disorder		1				1
Tension headache		4		2		2
Transient ischaemic attack		2				2
Transverse sinus thrombosis		1				1
Tremor	6	22	3	11	3	11
	332	927	221	520	111	407

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion spontaneous		1		1
Foetal death		1		1
		2		2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal dreams	1	3	1	3		
Anxiety	3	13	2	9	1	4
Apathy	4	11	2	4	2	7
Attention deficit hyperactivity disorder		1		1		
Bradyphrenia	1	3	1	2		1
Communication disorder	1	2			1	2
Confusional state	5	14	2	5	3	9
Decreased interest		1		1		
Delirium		3				3
Depression		3		1		2
Disorganised speech		1				1
Disorientation	4	11	2	4	2	7
Dysphemia		1				1
Eating disorder		2		1		1
Fear		1		1		
Fear of death		1		1		
Hallucination	1	3			1	3
Hallucinations, mixed		1				1
Illusion		1		1		
Insomnia	11	30	10	23	1	7
Irritability	1	2	1	2		
Logorrhoea		1		1		
Mental disorder		1		1		
Mental fatigue	1	1	1	1		
Middle insomnia	1	1	1	1		
Mood swings	1	1			1	1
Nervousness	2	4	1	2	1	2
Panic attack	1	1			1	1
Panic reaction	1	1	1	1		
Poor quality sleep	2	2	2	2		
Restlessness	2	7	2	6		1
Sleep disorder	1	4	1	3		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sleep talking		1		1		
Sopor		1				1
Suicidal ideation	1	1			1	1
	45	135	30	78	15	57

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* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	2			1	2
Anuria		1				1
Bladder pain	1	1			1	1
Cystitis noninfective		1		1		
Dysuria	2	3	2	2		1
Haematuria	1	1	1	1		
Incontinence	1	1	1	1		
Micturition disorder	1	1	1	1		
Micturition urgency	1	1			1	1
Nephrosclerosis		1				1
Renal colic	1	1			1	1
Renal cyst		1				1
Renal disorder		1		1		
Renal failure		3				3
Renal impairment		2				2
Renal infarct	1	1			1	1
Renal mass	1	1			1	1
Renal pain	1	3		2	1	1
Urinary incontinence		2				2
Urinary straining	1	1			1	1
Urinary tract disorder	1	1	1	1		
Urinary tract inflammation		3		1		2
	14	33	6	11	8	22

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amenorrhoea	1	1			1	1
Breast pain	3	7	2	4	1	3
Breast swelling	1	3		1	1	2
Dysmenorrhoea	1	1			1	1
Genital pain	1	1			1	1
Heavy menstrual bleeding	3	3	2	2	1	1
Intermenstrual bleeding	4	5	2	3	2	2
Menstrual disorder	2	3	1	2	1	1
Menstruation delayed		1		1		
Menstruation irregular	8	8	5	5	3	3
Oligomenorrhoea	1	1			1	1
Polymenorrhoea	1	1			1	1
	26	35	12	18	14	17

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory failure		2				2
Aphonia		1				1
Apnoea		1				1
Asthma	2	4		1	2	3
Bronchitis chronic		1		1		
Bronchospasm		2		1		1
Choking	1	1			1	1
Choking sensation		1				1
Cough	18	52	15	41	3	11
Cough decreased	1	1	1	1		
Dry throat		1		1		
Dysphonia	1	2	1	2		
Dyspnoea	28	102	7	25	21	77
Dyspnoea at rest		1				1
Dyspnoea exertional	1	3		1	1	2
Epistaxis	4	11	2	5	2	6
Grunting		2		1		1
Haemoptysis		1				1
Hyperventilation	3	4	2	3	1	1
Hypoxia		2				2
Increased bronchial secretion	1	1	1	1		
Laryngeal oedema		1				1
Laryngospasm		1				1
Nasal congestion	4	9		5	4	4
Nasal discomfort		1				1
Nasal dryness		1		1		
Nasal oedema		1		1		
Oropharyngeal discomfort		3		2		1
Oropharyngeal pain	7	18	7	16		2
Pharyngeal oedema		2				2
Pharyngeal paraesthesia		1				1
Pharyngeal swelling	1	7			1	7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pleurisy	1	1			1	1
Pneumonitis		1				1
Productive cough	1	5	1	2		3
Prolonged expiration		1		1		
Pulmonary embolism	6	10			6	10
Pulmonary hypoperfusion	1	1			1	1
Pulmonary oedema		1				1
Pulmonary pain		2		1		1
Pulmonary sensitisation		2		1		1
Respiration abnormal		1				1
Respiratory acidosis		1		1		
Respiratory depression		2				2
Respiratory disorder		1				1
Respiratory distress		1				1
Respiratory failure	1	6			1	6
Respiratory tract oedema	2	5			2	5
Rhinalgia		2		2		
Rhinorrhoea	7	21	7	19		2
Sinus pain		1		1		
Sneezing		2		2		
Sputum discoloured		1				1
Stridor		2		2		
Tachypnoea		8		1		7
Throat irritation		5		2		3
Throat tightness	4	14	1	3	3	11
Tracheal pain	1	1	1	1		
Wheezing		3		2		1
	96	342	46	150	50	192

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne	1	2		1	1	1
Alopecia	1	3		1	1	2
Angioedema		2				2
Blister		2				2
Circumoral swelling	1	1			1	1
Cold sweat	1	3	1	3		
Dermatitis		2		1		1
Dermatitis allergic	3	12	1	2	2	10
Dermatitis atopic	1	1			1	1
Drug eruption	1	5			1	5
Dry skin		2				2
Eczema	2	3			2	3
Erythema	3	37	2	21	1	16
Erythema nodosum		1				1
Hyperhidrosis	9	34	9	29		5
Livedo reticularis		1		1		
Night sweats	1	5	1	4		1
Pain of skin		3		2		1
Pemphigoid	1	1			1	1
Petechiae		4				4
Photosensitivity reaction	1	2	1	2		
Pigmentation disorder	1	1	1	1		
Pruritus	9	52	3	18	6	34
Purpura		1				1
Rash	17	68	7	25	10	43
Rash erythematous		3				3
Rash macular	2	13	1	2	1	11
Rash maculo-papular	2	6			2	6
Rash papular	1	1			1	1
Rash pruritic	8	21	4	7	4	14
Rash vesicular		1		1		
Scab		2		2		

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin burning sensation	2	8	1	4	1	4
Skin discolouration	1	2		1	1	1
Skin disorder		2				2
Skin exfoliation		2		1		1
Skin mass		1		1		
Skin reaction		1		1		
Skin warm	1	1			1	1
Urticaria	7	18		2	7	16
Urticarial dermatitis	1	1	1	1		
Yellow skin		1				1
	78	332	33	134	45	198

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Impaired work ability		1				1
Loss of personal independence in daily activities	1	3		2	1	1
Patient uncooperative		1		1		
Sitting disability		1				1
	1	6		3	1	3

System Organ Class

Surgical and medical procedures

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Limb immobilisation		1		1
		1		1

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- * I=Interval, C=Cumulative
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System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aneurysm		1				1
Aortic arteriosclerosis		1				1
Aortic stenosis		1				1
Arteriosclerosis		2				2
Blood pressure fluctuation	2	4	1	2	1	2
Circulatory collapse		10				10
Cyanosis		1				1
Deep vein thrombosis	12	14			12	14
Embolism	1	1			1	1
Flushing	2	6		2	2	4
Haematoma	3	7		1	3	6
Haemorrhage	1	2			1	2
Hot flush	4	21	3	13	1	8
Hyperaemia		1		1		
Hypertension	11	47		9	11	38
Hypertensive crisis	1	1			1	1
Hypotension	7	30	2	7	5	23
Intermittent claudication	1	1	1	1		
Jugular vein distension		1		1		
Lymphoedema		1		1		
Necrosis ischaemic	1	1			1	1
Pallor		9		5		4
Peripheral coldness	2	12	1	9	1	3
Peripheral ischaemia	1	1			1	1
Peripheral venous disease		1				1
Poor peripheral circulation	1	1			1	1
Shock		3				3
Thrombophlebitis	1	1			1	1
Thrombophlebitis superficial		1				1
Thrombosis	5	6			5	6
Vascular pain	1	2	1	1		1
Vena cava thrombosis		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Venous thrombosis	1	1			1	1
Venous thrombosis limb		1				1
White coat hypertension		1		1		
	58	195	9	54	49	141

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Country Where Event Occurred

DENMARK

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal lymphadenopathy	1	1	1	1		
Anaemia		2		1		1
Disseminated intravascular coagulation		1				1
Haemoconcentration	1	1	1	1		
Haemolysis		1				1
Haemorrhagic diathesis		1				1
Immune thrombocytopenia		1				1
Leukocytosis		1		1		
Leukopenia	1	2			1	2
Lymphadenitis		2		1		1
Lymphadenopathy	4	33	4	24		9
Lymph node pain	1	5	1	5		
Lymphopenia		3		1		2
Myelosuppression		1				1
Pancytopenia		1				1
Splenic haemorrhage		1				1
Splenic infarction		1				1
Thrombocytopenia	2	6			2	6
Thrombocytosis		1				1
	10	65	7	35	3	30

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome	2	2			2	2
Acute myocardial infarction	2	7			2	7
Angina pectoris		1				1
Atrial f brillation	1	10			1	10
Atrial flutter		2				2
Bradycardia	1	5			1	5
Cardiac arrest	5	13			5	13
Cardiac disorder		1				1
Cardiac failure	1	3			1	3
Cardiogenic shock		3				3
Cardiovascular disorder		2				2
Cardiovascular symptom	1	1			1	1
Coronary artery thrombosis		2				2
Intracardiac thrombus	2	4			2	4
Myocardial infarction		1				1
Myocardial ischaemia	1	1			1	1
Myocarditis		1				1
Palpitations	7	34	3	18	4	16
Pericarditis	1	3			1	3
Sinus node dysfunction	1	1			1	1
Sinus tachycardia		2		2		
Stress cardiomyopathy		1				1
Tachycardia	2	9	1	2	1	7
Ventricular f brillation	1	1			1	1
Ventricular tachycardia		1				1
	28	111	4	22	24	89

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Congenital, familial and genetic disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anencephaly	1	1	1	1
Cleft palate	1	1	1	1
Congenital absence of cranial vault	1	1	1	1
	3	3	3	3

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Auricular swelling		1		1		
Ear discomfort	1	2	1	2		
Ear pruritus		1				1
Hyperacusis	1	3		1	1	2
Hypoacusis		4		2		2
Inner ear disorder	1	1	1	1		
Meniere's disease		1				1
Tinnitus	2	7	1	4	1	3
Vertigo		3		1		2
	5	23	3	12	2	11

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Adrenal insufficiency		1		1
Adrenocortical insufficiency acute	1	1	1	1
Hyperthyroidism	1	1	1	1
	2	3	2	3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blindness	2	2			2	2
Conjunctival haemorrhage		1				1
Conjunctival hyperaemia		1		1		
Conjunctival oedema	1	1			1	1
Diplopia	3	6			3	6
Dry eye		1		1		
Eye irritation		1		1		
Eyelid oedema		1		1		
Eyelid ptosis		2				2
Eye pain	2	9	1	8	1	1
Eye pruritus		5		4		1
Eye swelling	1	2		1	1	1
Lacrimation increased		3		3		
Mydriasis		1		1		
Ocular hyperaemia		1		1		
Periorbital swelling	2	5		1	2	4
Photophobia		5		1		4
Photopsia		3		1		2
Retinal vascular thrombosis		1				1
Strabismus	1	1			1	1
Swelling of eyelid		2		1		1
Vision blurred	2	6		1	2	5
Visual field defect	1	1			1	1
Visual impairment	3	5	1	2	2	3
	18	66	2	29	16	37

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2		2		
Abdominal distension	1	2		1	1	1
Abdominal pain	5	23	4	13	1	10
Abdominal pain lower	1	2	1	1		1
Abdominal pain upper	3	12	1	5	2	7
Abdominal tenderness		1				1
Colitis		2		1		1
Constipation	2	2	1	1	1	1
Diarrhoea	17	54	6	28	11	26
Dry mouth		5		4		1
Dyspepsia		1		1		
Dysphagia	1	9		2	1	7
Faeces soft		1		1		
Flatulence	1	2		1	1	1
Functional gastrointestinal disorder	1	1			1	1
Gastric ulcer		1				1
Gastrointestinal disorder		1		1		
Gastrointestinal necrosis		1				1
Gastrointestinal sounds abnormal	1	1			1	1
Gastrooesophageal reflux disease		3		2		1
Glossodynia		1		1		
Haematemesis		1				1
Haematochezia		1				1
Hyperchlorhydria		1		1		
Hypoaesthesia oral		2				2
Ileus paralytic		1				1
Intestinal ischaemia		1				1
Lip pruritus		1				1
Lip swelling	1	6	1	1		5
Melaena		1				1
Mesenteric artery thrombosis		1				1
Mouth swelling		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	49	196	31	124	18	72
Odynophagia		3		2		1
Oesophageal spasm		1		1		
Oral discomfort		2		1		1
Oral mucosal blistering		1		1		
Oral mucosal eruption		1		1		
Oral pruritus		2		2		
Pancreatitis acute	1	2			1	2
Paraesthesia oral	4	19	3	10	1	9
Salivary gland enlargement		1		1		
Salivary gland pain		1		1		
Salivary hypersecretion		1				1
Stomatitis		1		1		
Swollen tongue		11		2		9
Tongue discomfort	1	2		1	1	1
Tongue pruritus	1	3			1	3
Vomiting	20	70	6	31	14	39
	110	461	54	246	56	215

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	3	26	2	8	1	18
Axillary pain	1	5	1	5		
Chest discomfort	4	26	1	8	3	18
Chest pain	11	30	1	6	10	24
Chills	19	83	11	56	8	27
Condition aggravated	1	13	1	1		12
Crying		1				1
Death		16				16
Discomfort	7	21	5	9	2	12
Disease progression	1	1			1	1
Disease recurrence	1	3		2	1	1
Drug ineffective		9				9
Drug interaction		1				1
Extensive swelling of vaccinated limb	1	1			1	1
Extravasation	1	1			1	1
Face oedema		2				2
Facial pain		1		1		
Fatigue	67	251	47	172	20	79
Feeling abnormal	3	8	2	5	1	3
Feeling cold	4	18	2	11	2	7
Feeling drunk		1		1		
Feeling hot	5	32	3	17	2	15
Feeling of body temperature change	1	4	1	1		3
Foaming at mouth		2		1		1
Gait disturbance	1	5		1	1	4
Gait inability	1	1			1	1
General physical health deterioration	2	19	1	2	1	17
General symptom	1	1	1	1		
Hypothermia		2				2
Illness		1		1		
Influenza like illness	13	40	11	29	2	11
Injected limb mobility decreased		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site pain		1		1		
Loss of control of legs		1				1
Malaise	29	165	14	84	15	81
Multimorbidity		1				1
No adverse event	1	1	1	1		
Oedema	2	4			2	4
Oedema mucosal		1				1
Oedema peripheral	1	8		3	1	5
Pain	13	43	12	32	1	11
Peripheral swelling	3	13	2	7	1	6
Pyrexia	68	291	49	194	19	97
Sensation of foreign body		4				4
Sudden cardiac death		1				1
Sudden death		4				4
Swelling	4	11	3	9	1	2
Swelling face	1	19	1	7		12
Systemic inflammatory response syndrome		1				1
Tenderness	4	16	4	12		4
Therapeutic response unexpected	1	1	1	1		
Vaccination site discolouration	1	2	1	1		1
Vaccination site discomfort	1	3	1	3		
Vaccination site erythema	17	53	17	50		3
Vaccination site haematoma	2	5	1	4	1	1
Vaccination site haemorrhage	3	4	1	2	2	2
Vaccination site hypoaesthesia		1		1		
Vaccination site induration		2		2		
Vaccination site inflammation		4		4		
Vaccination site irritation	1	3	1	2		1
Vaccination site lymphadenopathy		1		1		
Vaccination site movement impairment	2	4	2	4		
Vaccination site necrosis		1				1
Vaccination site nodule		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	60	257	55	235	5	22
Vaccination site paraesthesia	1	4	1	4		
Vaccination site pruritus	1	11	1	10		1
Vaccination site rash	3	9	3	6		3
Vaccination site reaction		1		1		
Vaccination site swelling	14	64	14	58		6
Vaccination site thrombosis		1				1
Vaccination site warmth	3	21	3	20		1
	384	1,664	278	1099	106	565

System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hepatic cyst		1		1		
Hepatic vein thrombosis	1	1			1	1
Immune-mediated hepatitis		1				1
	1	3		1	1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	2	3			2	3
Anaphylactic reaction		23				23
Anaphylactic shock	2	8			2	8
Hypersensitivity	6	30	3	9	3	21
Immune-mediated adverse reaction		1				1
Immunisation reaction	1	1	1	1		
Reaction to excipient		2				2
Seasonal allergy		1		1		
Systemic immune activation		2				2
Type I hypersensitivity		1				1
	11	72	4	11	7	61

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal wall abscess		1				1
Appendicitis		3				3
Bacteraemia		1				1
Bacterial infection		1				1
Beta haemolytic streptococcal infection	1	1			1	1
Bronchitis		1				1
Chorioretinitis		1				1
COVID-19		22		4		18
Cystitis		1		1		
Encephalitis	1	1			1	1
Endocarditis bacterial	1	1			1	1
Endophthalmitis	1	1			1	1
Erysipelas	2	3			2	3
Herpes simplex meningoencephalitis	1	1			1	1
Herpes zoster	5	7	5	6		1
Infection	4	7		2	4	5
Influenza	2	13	2	8		5
Lymphangitis		1				1
Meningitis	1	1			1	1
Myelitis		1				1
Nasopharyngitis	2	5	2	5		
Oral fungal infection		1		1		
Pharyngitis		1				1
Pneumonia	9	29			9	29
Pneumonia bacterial		1				1
Respiratory tract infection bacterial		1				1
Rhinitis		1		1		
Sepsis		2				2
Septic embolus	1	1			1	1
Septic shock		1				1
Severe acute respiratory syndrome		1				1
Staphylococcal infection		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tooth infection	1	1			1	1
Upper respiratory tract infection		1		1		
Urinary tract infection		3				3
Urinary tract infection bacterial		1				1
Urosepsis		1				1
Vaccination site abscess		1				1
Vaccination site infection	1	1	1	1		
Viral infection		1		1		
Wound infection		1				1
	33	125	10	31	23	94

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental exposure to product		1		1		
Carbon monoxide poisoning		1				1
Contusion		2		1		1
Exposure via breast milk		1		1		
Exposure via skin contact		1		1		
Fall	4	14	1	1	3	13
Femoral neck fracture	1	1			1	1
Femur fracture		1				1
Head injury	1	3	1	1		2
Inappropriate schedule of product administration	2	7	2	7		
Incorrect route of product administration	1	5	1	4		1
Maternal exposure during pregnancy	4	5	2	2	2	3
Off label use	2	12	2	12		
Product administration error		1		1		
Product preparation issue		1		1		
Product use issue		8		8		
Scratch	1	2			1	2
Skin abrasion		1				1
Toxicity to various agents		1				1
Transplant failure		1				1
Underdose		2		2		
Vaccination complication		2		1		1
Wound		1				1
Wound complication		1		1		
Wrong product administered	1	1	1	1		
	17	76	10	46	7	30

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased		1		1		
Blood albumin decreased		1		1		
Blood alkaline phosphatase increased		1		1		
Blood bilirubin decreased		1		1		
Blood chloride increased		1		1		
Blood count abnormal		1		1		
Blood creatine phosphokinase increased		1				1
Blood creatinine abnormal	1	1			1	1
Blood creatinine increased		1				1
Blood glucose increased		2		2		
Blood iron decreased		1		1		
Blood lactate dehydrogenase abnormal		1		1		
Blood lactic acid increased	1	2	1	2		
Blood potassium decreased		1		1		
Blood potassium increased		1		1		
Blood pressure abnormal		1				1
Blood pressure decreased	4	7	2	3	2	4
Blood pressure increased	2	11		3	2	8
Blood pressure systolic increased		3		1		2
Blood prolactin increased	1	1	1	1		
Blood sodium decreased		1		1		
Blood test abnormal	1	1	1	1		
Blood urea decreased		1				1
Blood uric acid abnormal		1		1		
Body temperature increased		7		6		1
Breath sounds abnormal		1				1
Calcium ionised increased		1		1		
C-reactive protein abnormal		1				1
C-reactive protein increased	2	19	1	6	1	13
Electrocardiogram QT prolonged		1				1
Electrocardiogram ST segment depression		1				1
Fibrin D dimer increased		3		1		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Glomerular filtration rate decreased		1				1
Haematology test abnormal		1				1
Haemoglobin abnormal	1	1			1	1
Haemoglobin decreased	1	4	1	1		3
Heart rate abnormal		1		1		
Heart rate decreased	1	4	1	4		
Heart rate increased	3	17	1	10	2	7
Heart rate irregular		1				1
Hepatic enzyme increased	1	2	1	2		
Liver function test increased		1		1		
Low density lipoprotein increased		1		1		
Neutrophil count increased		2		2		
Oxygen saturation decreased	1	9		1	1	8
Platelet count abnormal		1				1
Platelet count decreased	3	3	2	2	1	1
Protein total decreased	1	1	1	1		
Pulmonary arterial pressure increased		1		1		
Pulse abnormal	1	2			1	2
Respiratory rate decreased		1				1
Respiratory rate increased	1	1	1	1		
Rheumatoid factor increased		1				1
SARS-CoV-2 test positive		1				1
Troponin I increased		2		1		1
Troponin increased		2				2
Weight increased		1		1		
White blood cell count increased	2	4	2	4		
White blood cells urine positive	1	1			1	1
	29	145	16	73	13	72

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	4	12	2	4	2	8
Dehydration	4	6			4	6
Diabetic complication		1				1
Fluid intake reduced	1	4		1	1	3
Hyperglycaemia		1				1
Hypermetabolism	1	1	1	1		
Hypoglycaemia		2		1		1
Hypokalaemia	1	3			1	3
Hyponatraemia	1	1			1	1
Hypophagia	1	3		2	1	1
Ketoacidosis		1				1
Metabolic acidosis		1				1
Metabolic alkalosis		1		1		
	13	37	3	10	10	27

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	33	88	23	57	10	31
Arthritis		1		1		
Arthritis reactive	1	2			1	2
Back pain	2	11	1	8	1	3
Bursitis		1				1
Groin pain		2		2		
Joint range of motion decreased	1	1	1	1		
Joint stiffness		2		1		1
Joint swelling	3	8	1	3	2	5
Joint warmth		1		1		
Limb discomfort		10		5		5
Mobility decreased	1	6	1	3		3
Muscle discomfort		2		1		1
Muscle fatigue		3		3		
Muscle spasms	5	11	1	4	4	7
Muscle tightness	1	2	1	1		1
Muscle twitching	2	4	1	2	1	2
Muscular weakness	6	19	1	6	5	13
Musculoskeletal chest pain	1	1	1	1		
Musculoskeletal discomfort		1				1
Musculoskeletal pain	1	1			1	1
Musculoskeletal stiffness	1	4	1	2		2
Myalgia	43	166	32	122	11	44
Neck pain	4	13	1	7	3	6
Pain in extremity	16	64	11	51	5	13
Periarthritis		2		2		
Rhabdomyolysis	1	2			1	2
Rheumatoid arthritis	1	2			1	2
Temporomand bular joint syndrome		1				1
	123	431	77	284	46	147

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute leukaemia		1		1
Polycythaemia vera		1		1
		2		2

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* AE=Adverse Event
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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	2	1	2		
Altered state of consciousness		6				6
Amnesia		5				5
Anosmia	1	2	1	2		
Aphasia	3	6			3	6
Autoimmune neuropathy	1	1			1	1
Autonomic nervous system imbalance	1	1			1	1
Balance disorder	2	4			2	4
Basilar artery occlusion		1				1
Bell's palsy	2	2			2	2
Brain injury	1	1			1	1
Burning sensation	4	10		4	4	6
Cerebellar embolism	1	1			1	1
Cerebral haemorrhage	1	2			1	2
Cerebral infarction	5	6			5	6
Cerebral ischaemia		1				1
Cerebral thrombosis	1	4			1	4
Cerebral vascular occlusion	1	1			1	1
Cerebral venous sinus thrombosis	1	1			1	1
Cerebrovascular accident	13	30			13	30
Clonic convulsion		1				1
Cognitive disorder		1				1
Coma		1				1
Coordination abnormal	2	5			2	5
Dementia		1				1
Depressed level of consciousness	2	13			2	13
Disturbance in attention	1	7	1	3		4
Dizziness	43	183	18	93	25	90
Dizziness exertional		1		1		
Dizziness postural	1	3			1	3
Dysaesthesia	1	3		1	1	2
Dysarthria	2	6			2	6

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysgeusia		4		2		2
Dysstasia		1				1
Embolic stroke	2	2			2	2
Epilepsy	2	4			2	4
Facial paralysis	1	5			1	5
Facial paresis	2	6	1	2	1	4
Generalised tonic-clonic seizure	1	5			1	5
Guillain-Barre syndrome		1				1
Haemorrhage intracranial	1	2			1	2
Haemorrhagic cerebral infarction	1	1			1	1
Headache	91	384	68	277	23	107
Head discomfort	3	7	2	5	1	2
Hemiparesis	3	9			3	9
Hemiplegia	1	3			1	3
Hyperaesthesia	1	1			1	1
Hypersomnia	1	5		1	1	4
Hypertonia		1				1
Hypoaesthesia	3	11		4	3	7
Hypokinesia	2	2	2	2		
Hypotonia		1		1		
Idiopathic intracranial hypertension		1				1
IIIrd nerve paresis		1				1
Ischaemic stroke	1	1			1	1
Lethargy	1	4	1	4		
Loss of consciousness	3	11			3	11
Memory impairment	1	2			1	2
Migraine	4	11	2	6	2	5
Monoparesis		2				2
Monoplegia		2				2
Motor dysfunction		1				1
Movement disorder	1	1	1	1		
Myelitis transverse	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nervous system disorder		1				1
Neuralgia		2		1		1
Neurological symptom	1	1			1	1
Neuropathy peripheral	1	1			1	1
Paraesthesia	11	48	4	26	7	22
Paraesthesia mucosal		1				1
Paralysis		1				1
Paresis		1				1
Parkinson's disease		1				1
Parosmia		1		1		
Partial seizures	1	1			1	1
Petit mal epilepsy	1	1			1	1
Presyncope	3	29		8	3	21
Radiculitis brachial	1	1			1	1
Restless arm syndrome	1	1			1	1
Restless legs syndrome	1	1			1	1
Seizure	3	7			3	7
Sensory disturbance	9	18	5	12	4	6
Sensory loss	1	3			1	3
Somnolence	4	16	3	11	1	5
Speech disorder	1	4		1	1	3
Subarachnoid haemorrhage	1	1			1	1
Syncope	9	27			9	27
Taste disorder		4		3		1
Tonic convulsion		1				1
Transient ischaemic attack	4	6			4	6
Tremor	3	22	3	9		13
Tunnel vision		2				2
Unresponsive to stimuli		1				1
VIth nerve paralysis		1				1
White matter lesion		1		1		
	274	1,011	113	484	161	527

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion missed	1	3	1	3
Abortion spontaneous	1	1	1	1
	2	4	2	4

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal dreams	1	1			1	1
Aggression		2				2
Anxiety	1	6		2	1	4
Confusional state	4	16		1	4	15
Delirium	1	9			1	9
Delusion		1				1
Depressed mood	2	2	2	2		
Derealisation		5		4		1
Disorientation	1	2			1	2
Eating disorder		1		1		
Hallucination	1	1			1	1
Hallucination, visual	2	3			2	3
Initial insomnia		1		1		
Insomnia	1	7		6	1	1
Middle insomnia	1	1	1	1		
Panic attack		1				1
Poor quality sleep		1		1		
Restlessness	2	11	2	8		3
Sleep disorder	1	4	1	4		
Thinking abnormal		1				1
	18	76	6	31	12	45

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury		4				4
Anti-glomerular basement membrane disease		1				1
Azotaemia		1				1
Dysuria		1				1
Haematuria		2		1		1
Micturition urgency		2				2
Renal colic		1		1		
Renal failure	1	5			1	5
Renal pain		1				1
Urinary incontinence	1	2			1	2
Urine odour abnormal		1				1
	2	21		2	2	19

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast pain		1		1		
Heavy menstrual bleeding	1	1	1	1		
Menstruation delayed	1	1	1	1		
Polymenorrhoea	1	1	1	1		
Postmenopausal haemorrhage		1				1
Vaginal discharge		1		1		
Vaginal haemorrhage		2		1		1
Vulvovaginal pain		1		1		
Vulvovaginal pruritus		1		1		
	3	10	3	8		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory distress syndrome		1				1
Acute respiratory failure		1				1
Aspiration		1				1
Asthma	1	6		1	1	5
Bronchospasm		3				3
Choking sensation		1				1
Chronic obstructive pulmonary disease	1	9			1	9
Cough	6	31	2	15	4	16
Dry throat		1		1		
Dysphonia	2	9	1	6	1	3
Dyspnoea	30	127	5	26	25	101
Dyspnoea at rest		1				1
Dyspnoea exertional		8		5		3
Emphysema		1				1
Epistaxis	1	5		1	1	4
Haemoptysis	2	2			2	2
Hyperventilation	1	7			1	7
Hypoxia		1				1
Idiopathic pulmonary fibrosis		1				1
Lung disorder		2				2
Lung infiltration	2	3			2	3
Nasal congestion		5		5		
Nasal discomfort		1				1
Nasal obstruction		1		1		
Nasal pruritus		3		1		2
Obliterative bronchiolitis		1				1
Obstructive airways disorder	1	4			1	4
Oropharyngeal discomfort		3		2		1
Oropharyngeal pain	3	24	2	19	1	5
Painful respiration		3		2		1
Pharyngeal haemorrhage	1	1			1	1
Pharyngeal oedema		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal paraesthesia	1	2	1	2		
Pharyngeal swelling	1	13		2	1	11
Pleural effusion		2				2
Pleurisy	1	1			1	1
Pleuritic pain		1		1		
Pneumonia aspiration		1				1
Pneumonitis		1				1
Productive cough	2	5		1	2	4
Prolonged expiration		1				1
Pulmonary arterial hypertension		1				1
Pulmonary congestion	1	1			1	1
Pulmonary embolism	10	33			10	33
Pulmonary fibrosis		2				2
Pulmonary oedema		6				6
Pulmonary pain		1		1		
Rales		1				1
Respiration abnormal		2				2
Respiratory acidosis		4				4
Respiratory alkalosis	1	1			1	1
Respiratory arrest	1	5			1	5
Respiratory disorder	1	1	1	1		
Respiratory distress	1	2			1	2
Respiratory failure	1	15			1	15
Rhinalgia		1		1		
Rhinorrhoea	1	8	1	6		2
Sneezing		6		6		
Sputum discoloured		1				1
Stridor		1				1
Tachypnoea		2				2
Throat irritation	2	12		5	2	7
Throat tightness		5		2		3
Tonsillar hypertrophy		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tracheal stenosis		1				1
Wheezing		1				1
Yawning		1		1		
	75	410	13	115	62	295

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	1	8			1	8
Cold sweat	5	11	2	6	3	5
Dermatitis allergic		2				2
Dry skin		1		1		
Eczema	1	2	1	2		
Erythema	8	44	4	25	4	19
Exfoliative rash	1	1	1	1		
Hand dermatitis		1		1		
Hyperhidrosis	2	17	2	10		7
Livedo reticularis		2				2
Night sweats		1		1		
Nodular rash	1	1	1	1		
Pain of skin	2	7	1	3	1	4
Palpable purpura	1	1			1	1
Petechiae	3	3			3	3
Photosensitivity reaction		1		1		
Pityriasis rosea	1	1	1	1		
Pruritus	10	50	7	34	3	16
Rash	10	48	8	33	2	15
Rash erythematous	2	20	2	13		7
Rash macular	1	3	1	3		
Rash morbilliform		1		1		
Rash papular	1	2		1	1	1
Rash pruritic	4	14	4	10		4
Rash vesicular		1		1		
Sensitive skin	1	1	1	1		
Skin burning sensation	1	2	1	1		1
Skin haemorrhage		1				1
Skin lesion		1		1		
Urticaria	18	52	8	27	10	25
	74	300	45	179	29	121

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Impaired work ability	1	1	1	1		
Loss of personal independence in daily activities	1	2			1	2
	2	3	1	1	1	2

System Organ Class

SOC Not Yet Coded

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysm rupture		1				1
Blood pressure fluctuation		1		1		
Circulatory collapse	2	3			2	3
Deep vein thrombosis	6	16			6	16
Flushing		11		5		6
Haematoma		1		1		
Haemodynamic instability		1				1
Haemorrhage		1				1
Hot flush	1	7		6	1	1
Hypertension	2	21		7	2	14
Hypotension	1	12		1	1	11
Infarction		1				1
Jugular vein thrombosis	1	1			1	1
Orthostatic hypotension	1	1	1	1		
Pallor		12		3		9
Peripheral coldness	2	5	1	1	1	4
Phlebitis deep		1				1
Thrombophlebitis	1	1			1	1
Thrombophlebitis superficial		1				1
Thrombosis	2	12			2	12
Vascular rupture	2	2	2	2		
Vasculitis	1	2		1	1	1
Vasodilatation		1				1
	22	115	4	29	18	86

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ECUADOR

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenitis		1		1
		1		1

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris		1				1
Autoimmune myocarditis	1	1			1	1
Pericarditis	2	2			2	2
Supraventricular extrasystoles	1	1			1	1
Tachycardia	1	1	1	1		
Ventricular extrasystoles	1	1			1	1
	6	7	1	1	5	6

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Eye pain		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Diarrhoea		4		4		
Dysphagia	1	1			1	1
Lip oedema		1		1		
Vomiting		1		1		
	2	8		6	2	2

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills		1		1		
Discomfort	2	6	2	6		
Drug ineffective	24	28			24	28
Face oedema		1		1		
Fatigue	1	3	1	3		
Feeling hot	1	1	1	1		
Malaise	2	2	1	1	1	1
Pain	2	3		1	2	2
Pyrexia	2	8	2	8		
Vaccination failure	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site oedema	1	1	1	1		
Vaccination site pain	1	7	1	7		
Vaccination site swelling	1	1	1	1		
Vaccination site urticaria	1	1	1	1		
	40	65	12	33	28	32

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	25	32	1	3	24	29
Influenza	1	1	1	1		
Laryngitis		2		2		
Nasopharyngitis	1	1	1	1		
Suspected COVID-19	1	2			1	2
Tracheitis		1		1		
	28	39	3	8	25	31

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Blood pressure increased		2		2
SARS-CoV-2 test positive		1		1
		3		3

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	2	1	2		
Limb discomfort		1		1		
Muscular weakness	1	1			1	1
Musculoskeletal disorder		1		1		
Myalgia	3	4	2	3	1	1
Neck pain	1	1			1	1
	6	10	3	7	3	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	2	4	1	3	1	1
Headache	1	2	1	2		
Head discomfort	1	1			1	1
Paraesthesia	1	1			1	1
Thrombotic stroke		1				1
Transient ischaemic attack	1	1			1	1
	6	10	2	5	4	5

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	2	2	2	2		
Depressed mood		1		1		
Insomnia	1	1			1	1
	3	4	2	3	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	1	2		1	1	1
Dysphonia	1	1			1	1
Lung infiltration		1		1		
Oropharyngeal pain	1	2		1	1	1
Respiratory disorder	1	1			1	1
Rhinorrhoea	2	2	1	1	1	1
Suffocation feeling	1	1			1	1
	7	10	1	4	6	6

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chronic pigmented purpura	1	1	1	1		
Erythema	1	1	1	1		
Hyperhidrosis	1	1			1	1
	3	3	2	2	1	1

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Sitting disability	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
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Country Where Event Occurred

EGYPT

System Organ Class

General disorders and administration site conditions

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Drug ineffective		1		1
		1		1

System Organ Class

Infections and infestations

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
COVID-19		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

EL SALVADOR

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Atypical pneumonia	1	1	1	1
Pneumonia	1	1	1	1
	2	2	2	2

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Back pain	1	1	1	1
	1	1	1	1

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cerebrovascular accident	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Insomnia	1	1	1	1
	1	1	1	1

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchospasm	1	1	1	1		
Pleural effusion	2	2			2	2
Pulmonary oedema	1	1			1	1
	4	4	1	1	3	3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ESTONIA

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	2	8	2	8
	2	8	2	8

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction		1				1
Angina pectoris	2	2			2	2
Arrhythmia	2	2			2	2
Atrial f brillation	1	1			1	1
Bradycardia		1				1
Cardiac arrest	1	1			1	1
Cardiac failure congestive		1				1
Hypertensive heart disease		1				1
Myocardial infarction	1	1			1	1
Palpitations		3		3		
Supraventricular tachycardia		1				1
Tachycardia		3		3		
Ventricular extrasystoles		1				1
	7	19		6	7	13

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorder		1		1		
Ear pain	1	2	1	2		
Tinnitus		2		1		1
	1	5	1	4		1

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blindness unilateral		1				1
Diplopia		1		1		
Lacrimation increased	1	1	1	1		
Ocular discomfort		1		1		
Photopsia		1		1		
Retinal vascular thrombosis		1				1
Vision blurred	1	2	1	2		
Visual impairment		1				1
	2	9	2	6		3

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	3		2	1	1
Abdominal pain upper		1				1
Diarrhoea	1	4		3	1	1
Dry mouth	1	1			1	1
Dyspepsia		1		1		
Dysphagia	1	3		1	1	2
Glossodynia	1	1	1	1		
Hypoaesthesia oral	1	3	1	3		
Lip swelling		1				1
Mouth swelling		1				1
Nausea	4	20	2	14	2	6
Paraesthesia oral		3		3		
Retching		1				1
Vomiting	3	5	1	3	2	2
	13	48	5	31	8	17

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	8	31	6	23	2	8
Chest discomfort		1		1		
Chest pain		5		3		2
Chills	5	28	5	27		1
Condition aggravated	2	3		1	2	2
Death		2				2
Disease recurrence		2		1		1
Drug ineffective	7	13			7	13
Extensive swelling of vaccinated limb		1		1		
Facial pain		2		2		
Fatigue	9	23	9	22		1
Feeling hot	1	3	1	3		
General physical health deterioration	1	1			1	1
Hypothermia		5				5
Influenza like illness		1		1		
Malaise	4	14	3	10	1	4
Pain		2		1		1
Peripheral swelling	2	3		1	2	2
Pyrexia	12	50	11	47	1	3
Vaccination failure	29	50			29	50
Vaccination site erythema	3	9	3	9		
Vaccination site extravasation		1		1		
Vaccination site induration	1	3	1	3		
Vaccination site oedema	2	8	2	8		
Vaccination site pain	8	42	8	42		
Vaccination site paraesthesia		1		1		
Vaccination site pruritus		1		1		
Vaccination site rash		2		2		
Vaccination site swelling	1	5	1	5		
	95	312	50	216	45	96

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic shock	1	1			1	1
Drug hypersensitivity		1				1
Hypersensitivity		4		1		3
Immunisation reaction		1				1
Type I hypersensitivity		1				1
Type IV hypersensitivity reaction		1				1
	1	9		1	1	8

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19	1	2			1	2
Bronchitis	1	1	1	1		
Cellulitis	1	1			1	1
COVID-19	34	61		1	34	60
COVID-19 pneumonia		1				1
Cystitis	1	1			1	1
Herpes zoster	1	1	1	1		
Oral herpes		2		2		
Pneumonia		1				1
Rhinitis	1	2	1	2		
Suspected COVID-19	1	2			1	2
Vaccine breakthrough infection		1				1
	41	76	3	7	38	69

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone contusion		1				1
Contusion		1				1
Exposure during pregnancy	1	6	1	6		
Exposure to SARS-CoV-2	1	1	1	1		
Fall	2	4		2	2	2
Fracture		1				1
Maternal exposure during pregnancy	3	6	3	5		1
Off label use		1		1		
Product use issue		1		1		
Road traffic accident		1		1		
Skull fractured base	1	1			1	1
Spinal cord injury		1				1
Subdural haematoma	1	1			1	1
Underdose		1		1		
Wound		1				1
	9	28	5	18	4	10

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood creatine phosphokinase increased		1		1		
Blood pressure increased	1	2	1	1		1
Body temperature decreased		1		1		
C-reactive protein increased		1		1		
Electrocardiogram ST segment depression	1	1			1	1
Heart rate increased		1				1
Pulse absent	1	1			1	1
	3	8	1	4	2	4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	2	4		2	2	2
Hypoglycaemia		1				1
Increased appetite		1		1		
	2	6		3	2	3

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	4	18	4	18		
Back pain		3		1		2
Bone pain		2		1		1
Joint range of motion decreased		1		1		
Joint stiffness		1		1		
Joint swelling		1		1		
Limb discomfort	1	1	1	1		
Muscle spasms		1		1		
Muscular weakness		3		3		
Musculoskeletal pain		1		1		
Musculoskeletal stiffness	1	2	1	1		1
Myalgia	9	25	9	24		1
Neck pain		2				2
Pain in extremity	4	12	4	12		
Tendon pain		1		1		
	19	74	19	67		7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute disseminated encephalomyelitis		1				1
Ageusia		2		2		
Altered state of consciousness	1	1			1	1
Balance disorder	2	4	2	4		
Basilar artery thrombosis	1	1			1	1
Bell's palsy	1	1			1	1
Cerebral haemorrhage		1				1
Cerebral infarction		1				1
Cerebrovascular accident		1				1
Cognitive disorder		1		1		
Demyelination		1				1
Dizziness	6	19	5	14	1	5
Dysgeusia	2	8	1	5	1	3
Facial nerve disorder		1		1		
Facial paralysis		1				1
Fine motor skill dysfunction	1	1	1	1		
Headache	14	53	14	49		4
Hypoaesthesia	1	5		4	1	1
Illrd nerve disorder		1				1
Ischaemic cerebral infarction	1	1			1	1
Loss of consciousness	1	2			1	2
Migraine with aura		1		1		
Myelitis transverse		1				1
Paraesthesia		18		15		3
Peripheral sensory neuropathy		1				1
Presyncope		1				1
Reversed hot-cold sensation	1	1	1	1		
Seizure		1				1
Somnolence	6	15	5	13	1	2
Speech disorder	1	2			1	2
Syncope	3	14			3	14
Tremor		2		2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Trigeminal nerve disorder		1				1
	42	165	29	113	13	52

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Haemorrhage in pregnancy		1		1
		1		1

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Syringe issue		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety		1				1
Immunisation anxiety related reaction		10		9		1
Insomnia	1	6	1	6		
Nervousness		1				1
Panic attack		1		1		
Restlessness		3		3		
	1	22	1	19		3

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Dysuria		1		1
Urinary retention		1		1
		2		2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphonia		1				1
Chronic obstructive pulmonary disease		1				1
Cough	3	6	3	6		
Dyspnoea	2	14	1	11	1	3
Dyspnoea exertional	1	1	1	1		
Epistaxis	1	1			1	1
Hypopnoea		1				1
Intranasal paraesthesia		1		1		
Laryngeal oedema	1	3			1	3
Nasal congestion		1		1		
Oropharyngeal discomfort		1				1
Oropharyngeal pain	5	8	5	8		
Pharyngeal hypoaesthesia		1		1		
Pharyngeal paraesthesia		1		1		
Pharyngeal swelling		1		1		
Pulmonary embolism	2	4			2	4
Pulmonary oedema		1				1
Respiration abnormal		1				1
Respiratory failure		3				3
Respiratory symptom		1		1		
Rhinorrhoea	3	6	3	6		
Sputum increased		1		1		
Throat irritation	1	1	1	1		
Throat tightness		1				1
	19	61	14	40	5	21

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat		1				1
Erythema	1	1	1	1		
Hyperhidrosis	3	6	2	5	1	1
Pruritus	2	3	2	3		
Psoriasis		1				1
Skin ulcer	1	1			1	1
Urticaria	1	1	1	1		
	8	14	6	10	2	4

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deep vein thrombosis		1				1
Femoral artery embolism	1	1			1	1
Flushing		1		1		
Haematoma		1		1		
Hot flush	1	1	1	1		
Hypertension	2	6	1	4	1	2
Hypotension	3	5	1	1	2	4
Pallor		1				1
Thrombophlebitis		1		1		
Thrombophlebitis superficial	1	1			1	1
	8	19	3	9	5	10

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

FINLAND

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acquired haemophilia		2				2
Immune thrombocytopenia		1				1
Increased tendency to bruise		1				1
Lymphadenitis	1	1			1	1
Lymphadenopathy	16	66	11	33	5	33
Lymph node pain		9		3		6
Neutropenia		1				1
Platelet disorder		1				1
Polycythaemia	1	1	1	1		
Splenic infarction	1	1			1	1
Thrombocytopenia	2	2			2	2
Thrombocytosis		1				1
	21	87	12	37	9	50

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction		2				2
Angina pectoris	2	2			2	2
Arrhythmia	9	30			9	30
Atrial fibrillation	4	11			4	11
Atrial flutter	1	1			1	1
Cardiac arrest		1				1
Cardiac disorder	3	3			3	3
Cardiac failure	2	9			2	9
Cardiac flutter		1				1
Cardiac hypertrophy		1				1
Cardiovascular disorder	1	1			1	1
Congestive cardiomyopathy		1				1
Coronary artery thrombosis		1				1
Extrasystoles	2	8		3	2	5
Myocardial infarction		2				2
Myocarditis		1				1
Palpitations	12	32	5	11	7	21
Right ventricular failure		2				2
Sinus tachycardia		2				2
Tachycardia	3	12		1	3	11
Ventricular fibrillation		1				1
	39	124	5	15	34	109

System Organ Class

Congenital, familial and genetic disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Porphyria		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness	1	1			1	1
Deafness bilateral	1	1			1	1
Deafness unilateral		3				3
Ear canal erythema		1		1		
Ear discomfort	1	5		3	1	2
Ear pain		7		6		1
Ear pruritus		1		1		
Hyperacusis	1	2			1	2
Hypoacusis	3	7	2	5	1	2
Meniere's disease	1	2			1	2
Sudden hearing loss		1				1
Tinnitus	6	12	2	6	4	6
Tympanic membrane hyperaemia		1		1		
Vertigo	3	8		1	3	7
Vertigo positional	1	2			1	2
	18	54	4	24	14	30

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accommodation disorder		1		1		
Amaurosis fugax	2	3			2	3
Asthenopia		2				2
Blepharitis		1				1
Blindness transient	1	1			1	1
Blindness unilateral	3	3			3	3
Chromatopsia	1	1			1	1
Conjunctival hyperaemia		1				1
Diplopia	2	4		2	2	2
Dry eye		1				1
Erythema of eyelid		2				2
Eye disorder		1				1
Eye haematoma		1				1
Eye irritation		1		1		
Eyelid irritation		1				1
Eyelid oedema	2	7	1	2	1	5
Eyelid ptosis		1				1
Eye movement disorder		1		1		
Eye oedema	2	2	1	1	1	1
Eye pain	2	11	2	5		6
Eye swelling	1	1			1	1
Gaze palsy		2				2
Iritis		1				1
Keratitis		1				1
Macular oedema	1	2			1	2
Mydriasis		1		1		
Ocular discomfort		1		1		
Ocular hyperaemia		2				2
Ophthalmic artery thrombosis	1	1			1	1
Ophthalmic vein thrombosis		1				1
Photophobia	2	5	1	2	1	3
Photopsia	1	3			1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pigmentary glaucoma		1				1
Retinal artery occlusion	1	1			1	1
Retinal haemorrhage		1				1
Retinal ischaemia	1	1			1	1
Retinal tear		1				1
Retinal vascular occlusion	1	2			1	2
Retinal vascular thrombosis		1				1
Retinal vein occlusion	1	1			1	1
Retinal vein thrombosis		2				2
Strabismus		1				1
Swelling of eyelid	1	3			1	3
Ulcerative keratitis		1				1
Vision blurred	2	6	2	3		3
Visual acuity reduced	1	2			1	2
Visual impairment	5	11	1	2	4	9
Vitreous detachment	1	1			1	1
	35	103	8	22	27	81

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	4	7	3	3	1	4
Abdominal distension		3		2		1
Abdominal pain	8	20	4	7	4	13
Abdominal pain lower	2	6		2	2	4
Abdominal pain upper	6	11	2	2	4	9
Abdominal symptom		2		1		1
Anal incontinence	1	1			1	1
Cheilitis		1		1		
Crohn's disease		1				1
Diarrhoea	17	36	7	15	10	21
Dry mouth		3				3
Dyspepsia		1				1
Dysphagia		9		2		7
Flatulence		1		1		
Gastric disorder		1		1		
Gastrointestinal necrosis		1				1
Gingival swelling		1		1		
Glossodynia	2	3	1	1	1	2
Haematochezia		1				1
Hypoaesthesia oral	5	18	3	8	2	10
Hypoaesthesia teeth		1		1		
Intestinal ischaemia	2	3			2	3
Lip exfoliation	1	1			1	1
Lip oedema	1	5		3	1	2
Lip pain		2		2		
Lip pruritus		1				1
Lip swelling	1	4		1	1	3
Mesenteric artery stenosis	1	1			1	1
Mesenteric artery thrombosis		1				1
Mesenteric vein thrombosis	2	2			2	2
Mouth haemorrhage		1				1
Mouth swelling	1	3			1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	41	120	21	47	20	73
Noninfective sialoadenitis		1				1
Oedema mouth	1	1			1	1
Oral discomfort	1	3	1	3		
Oral disorder		1				1
Oral mucosal blistering		2		2		
Oral pruritus	1	5			1	5
Palatal swelling	1	1			1	1
Paraesthesia oral	8	26	1	10	7	16
Rectal haemorrhage		1				1
Rectal ulcer		1				1
Salivary gland enlargement		1				1
Salivary hypersecretion		1				1
Stiff tongue	1	2			1	2
Stomatitis	1	1			1	1
Swollen tongue	5	7	1	1	4	6
Tongue discolouration		1				1
Tongue discomfort		3		1		2
Tongue disorder		1				1
Tongue erythema		1				1
Tongue oedema		4				4
Tongue pruritus	2	2			2	2
Toothache		1		1		
Vomiting	12	48	6	16	6	32
	128	387	50	135	78	252

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	25	81	11	22	14	59
Axillary pain	4	18	4	10		8
Cardiac death	1	1			1	1
Chest discomfort	6	23		5	6	18
Chest pain	2	12		2	2	10
Chills	32	76	23	39	9	37
Condition aggravated	4	8			4	8
Death	4	17			4	17
Discomfort		4		1		3
Disease recurrence	4	9	1	1	3	8
Drug ineffective		2				2
Drug interaction	2	2			2	2
Exercise tolerance decreased		2				2
Extensive swelling of vaccinated limb		2		2		
Face oedema	4	16	2	3	2	13
Facial pain		4		2		2
Fatigue	53	177	27	67	26	110
Feeling abnormal	11	25	3	5	8	20
Feeling cold	13	28	7	10	6	18
Feeling drunk		1				1
Feeling hot	6	31	3	12	3	19
Foaming at mouth		1				1
Gait deviation	1	1			1	1
Gait disturbance	3	11		2	3	9
Gait inability	1	2			1	2
General physical health deterioration	11	39	1	3	10	36
Hypothermia		4				4
Illness		1				1
Inflammation	1	2	1	1		1
Influenza like illness		3				3
Irritability postvaccinal		1		1		
Localised oedema	3	7	2	4	1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Loss of control of legs		3				3
Malaise	35	94	14	30	21	64
Nodule		3		2		1
Obstruction		2				2
Oedema		1		1		
Oedema peripheral	2	12	1	5	1	7
Pain	6	36	2	5	4	31
Peripheral swelling	4	6	1	2	3	4
Pyrexia	75	230	45	89	30	141
Secretion discharge		2		1		1
Sensation of foreign body	7	16	1	3	6	13
Sluggishness	1	1			1	1
Sudden death		3				3
Swelling	1	9		4	1	5
Swelling face	1	5		1	1	4
Thirst	4	4	2	2	2	2
Vaccination failure	1	2			1	2
Vaccination site bruising	1	3	1	1		2
Vaccination site erythema	7	40	5	26	2	14
Vaccination site haematoma		5		5		
Vaccination site hyperaesthesia	2	8		1	2	7
Vaccination site hypersensitivity	1	1			1	1
Vaccination site hypoaesthesia	1	3		1	1	2
Vaccination site induration	1	6		4	1	2
Vaccination site joint movement impairment		1		1		
Vaccination site macule		1		1		
Vaccination site mass	2	7	2	3		4
Vaccination site movement impairment	5	13	2	3	3	10
Vaccination site oedema	4	23	3	20	1	3
Vaccination site pain	23	89	16	50	7	39
Vaccination site paraesthesia	1	1	1	1		
Vaccination site plaque	1	2	1	2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pruritus		7		5		2
Vaccination site rash		1		1		
Vaccination site reaction		4		2		2
Vaccination site swelling		7		2		5
Vaccination site urticaria		1		1		
Vaccination site warmth	6	21	6	15		6
	383	1,284	188	482	195	802

System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute hepatic failure	1	1			1	1
Cholelithiasis		1				1
Hepatic steatosis	1	1	1	1		
Jaundice		1				1
Portal vein thrombosis	1	1			1	1
	3	5	1	1	2	4

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	1	3			1	3
Anaphylactic reaction	10	26			10	26
Anaphylactic shock	2	5			2	5
Food allergy		2				2
Hypersensitivity	9	26	2	3	7	23
Immune-mediated adverse reaction	1	1			1	1
Type IV hypersensitivity reaction		1		1		
	23	64	2	4	21	60

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appendicitis		1				1
Appendicitis perforated	1	1			1	1
Asymptomatic COVID-19	1	1			1	1
Atypical pneumonia	1	1			1	1
Bacterial infection	1	1			1	1
Borrelia infection		1				1
Bronchiolitis		1				1
Bronchitis		2				2
Corneal infection		1				1
COVID-19		3				3
Cystitis		1				1
Disseminated varicella zoster virus infection	2	2			2	2
Diverticulitis		2				2
Encephalitis		2				2
Erysipelas	3	5			3	5
Escherichia infection	1	1			1	1
Eye infection		1				1
Gastrointestinal viral infection		1				1
Haemorrhagic fever with renal syndrome	1	1			1	1
Herpes ophthalmic		1				1
Herpes simplex	1	1	1	1		
Herpes virus infection	1	2		1	1	1
Herpes zoster	7	19	3	9	4	10
Herpes zoster cutaneous disseminated	1	2			1	2
Herpes zoster oticus		1				1
Human herpesvirus 6 infection	1	1			1	1
Infection		2				2
Infectious mononucleosis	1	1			1	1
Influenza		3		1		2
Klebsiella infection	1	1			1	1
Mumps	1	1			1	1
Nasopharyngitis	1	10		1	1	9

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral herpes		1		1		
Paronychia	1	1	1	1		
Perichondritis		1		1		
Peritonitis	1	1			1	1
Pneumonia	3	14			3	14
Pseudomonal sepsis		1				1
Pyelonephritis	3	5			3	5
Respiratory tract infection		1				1
Rhinitis		2				2
Sepsis	1	1			1	1
Sialoadenitis		1				1
Sinusitis	1	1			1	1
Subcutaneous abscess		1				1
Urinary tract infection	3	10		1	3	9
Vaccination site abscess		1				1
Vaginal infection		1				1
Vestibular neuronitis		1				1
Viral infection		2				2
	39	120	5	17	34	103

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Back injury	1	1			1	1
Concussion	1	1			1	1
Contusion	2	4	1	2	1	2
Fall	7	19		1	7	18
Fracture	1	1			1	1
Head injury	3	5		1	3	4
Hip fracture		1				1
Inappropriate schedule of product administration	6	7	6	7		
Incorrect route of product administration		11		11		
Joint injury	1	2			1	2
Limb injury		2				2
Maternal exposure during pregnancy		1		1		
Muscle strain		1				1
Neck injury	1	1			1	1
Off label use	5	8	5	8		
Poor quality product administered	1	13	1	13		
Post procedural haemorrhage		1				1
Product preparation error		12		12		
Product use issue		1		1		
Skull fractured base		1				1
Traumatic intracranial haemorrhage	1	1			1	1
Wrong technique in product usage process		1		1		
	30	95	13	58	17	37

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased		1				1
Anti factor VIII ant body positive		2				2
Bacterial test positive		3				3
Biopsy muscle abnormal	1	1			1	1
Blood alkaline phosphatase increased		1				1
Blood bilirubin increased		1				1
Blood cholesterol increased	1	1			1	1
Blood creatine increased		1				1
Blood creatinine increased		1				1
Blood glucose decreased		1				1
Blood glucose increased	3	4			3	4
Blood lactic acid decreased		1		1		
Blood potassium decreased	1	1			1	1
Blood pressure decreased	6	15	4	5	2	10
Blood pressure diastolic decreased		1				1
Blood pressure diastolic increased		2				2
Blood pressure increased	19	43	6	9	13	34
Blood pressure systolic decreased		1				1
Blood pressure systolic increased	1	1			1	1
Blood uric acid increased		1				1
Body temperature decreased	1	3	1	1		2
Body temperature fluctuation		1				1
Body temperature increased	1	3		1	1	2
Breath sounds abnormal	2	4		1	2	3
Chest X-ray abnormal		1				1
Coma scale abnormal		2				2
C-reactive protein	1	1			1	1
C-reactive protein abnormal	1	1			1	1
C-reactive protein increased	6	20	3	6	3	14
CSF immunoglobulin increased		1				1
CSF protein increased		1				1
Electrocardiogram ST segment depression		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Electrocardiogram T wave inversion		1				1
Eosinophil count increased		1				1
Fibrin D dimer increased		2		2		
Glomerular filtration rate decreased	1	1	1	1		
Grip strength decreased	1	2			1	2
Haemoglobin decreased		2				2
Heart rate abnormal	1	1			1	1
Heart rate decreased		2		1		1
Heart rate increased	14	36	3	5	11	31
Heart rate irregular	3	8		1	3	7
Inflammatory marker increased	1	2			1	2
International normalised ratio decreased		3		1		2
Laboratory test abnormal	1	1			1	1
Lymph nodes scan abnormal		1				1
Oxygen saturation decreased		3				3
Peak expiratory flow rate decreased		3				3
Platelet count decreased	1	1			1	1
Red blood cell sedimentation rate increased		1				1
Red blood cells urine		1				1
Red blood cells urine positive		1				1
Respiratory rate decreased		1				1
Respiratory rate increased	1	2			1	2
Rinne tuning fork test abnormal		1		1		
SARS-CoV-2 test negative	4	8	2	3	2	5
Synovial fluid white blood cells positive		1				1
Troponin I increased		1				1
Urine porphobilinogen increased		1				1
Weber tuning fork test abnormal		1		1		
Weight decreased		1		1		
Weight increased	1	1			1	1
White blood cell count decreased	1	1	1	1		
White blood cell count increased		3				3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
White blood cells urine		1				1
White blood cells urine positive		1				1
	74	219	21	42	53	177

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	1	10	1	1		9
Dehydration	1	2	1	1		1
Feeding disorder		1				1
Fluid intake reduced		1				1
Fluid retention	1	1			1	1
Food aversion		1				1
Gout	2	2			2	2
Hyperlactacidaemia		1				1
Hypernatraemia		1				1
Hypokalaemia	1	6			1	6
Hyponatraemia		1				1
Hypophagia		1				1
Ketoacidosis	1	1			1	1
	7	29	2	2	5	27

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ankylosing spondylitis		1				1
Arthralgia	25	93	12	36	13	57
Arthritis		1				1
Arthritis reactive		2				2
Autoimmune arthritis		1				1
Back pain	5	24	3	13	2	11
Bone pain		3		1		2
Cervical spinal stenosis		1				1
CREST syndrome		1				1
Flank pain	1	4	1	1		3
Groin pain		1				1
Intervertebral disc disorder		1		1		
Joint effusion		1				1
Joint range of motion decreased	2	5	1	3	1	2
Joint stiffness	1	2		1	1	1
Joint swelling	1	2		1	1	1
Limb discomfort	2	4	1	3	1	1
Mobility decreased	2	6		1	2	5
Muscle disorder		1				1
Muscle fatigue	1	3	1	1		2
Muscle rigidity	1	1			1	1
Muscle spasms	7	13	1	2	6	11
Muscle tightness		2		1		1
Muscle twitching	4	13	2	5	2	8
Muscular weakness	4	31	1	4	3	27
Musculoskeletal discomfort		1				1
Musculoskeletal disorder		2		1		1
Musculoskeletal pain		3		1		2
Musculoskeletal stiffness	4	19	1	9	3	10
Myalgia	43	146	28	56	15	90
Myokymia	1	1			1	1
Neck pain	8	23	3	7	5	16

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nuchal rigidity	1	3		2	1	1
Osteoarthritis		1		1		
Pain in extremity	37	129	16	50	21	79
Pain in jaw	1	1			1	1
Polyarthritis		1				1
Polymyalgia rheumatica	2	3			2	3
Rheumatoid arthritis		1				1
Spinal disorder	1	1			1	1
Spinal pain	1	3		1	1	2
Tendon pain		2				2
Trismus		1		1		
	155	558	71	203	84	355

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Malignant lymphoid neoplasm		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	2			1	2
Amnesia	1	2			1	2
Amputation stump pain	1	1	1	1		
Anaesthesia		1		1		
Anosmia	3	3	1	1	2	2
Aphasia	2	4			2	4
Areflexia		1				1
Balance disorder	3	5	1	1	2	4
Bell's palsy	3	4			3	4
Burning sensation	5	14	1	4	4	10
Carotid artery thrombosis	1	1			1	1
Central nervous system inflammation		1				1
Cerebral artery thrombosis		1				1
Cerebral haematoma	1	1			1	1
Cerebral haemorrhage	1	2			1	2
Cerebral infarction	10	22			10	22
Cerebral thrombosis	2	2			2	2
Cerebrovascular accident		2				2
Cerebrovascular disorder	1	2			1	2
Clumsiness	2	4		2	2	2
Cognitive disorder		3		1		2
Coordination abnormal	1	2		1	1	1
Dementia Alzheimer's type		4				4
Demyelination		1				1
Depressed level of consciousness	1	7			1	7
Disturbance in attention	1	2			1	2
Dizziness	38	103	14	30	24	73
Dizziness postural	1	1			1	1
Dysarthria		11		1		10
Dysgeusia	3	6	1	2	2	4
Dyskinesia		1		1		
Dysmetria		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysstasia		2				2
Electric shock sensation		2		1		1
Embolic cerebellar infarction	1	1			1	1
Embolic cerebral infarction	1	1			1	1
Epilepsy	1	5			1	5
Facial paralysis	3	16			3	16
Facial paresis	3	5	1	1	2	4
Fine motor skill dysfunction	1	1			1	1
Headache	78	214	40	82	38	132
Head discomfort	3	11	1	4	2	7
Hemianaesthesia	4	23			4	23
Hemihyperaesthesia		1				1
Hemiparaesthesia		3				3
Hemiparesis	3	9			3	9
Hemiplegia		2				2
Hyperaesthesia	1	5	1	1		4
Hypersomnia		2		1		1
Hypoaesthesia	20	60	9	23	11	37
Hypogeusia	1	1	1	1		
Hyporeflexia		1				1
Hyposmia		1		1		
Hypotonia	1	4			1	4
IVth nerve paralysis	1	1			1	1
Lacunar infarction	1	1			1	1
Lethargy	1	3			1	3
Loss of consciousness	9	16			9	16
Memory impairment	3	5		1	3	4
Mental impairment		2				2
Migraine	2	14	1	2	1	12
Migraine with aura		1				1
Monoparesis	1	2			1	2
Movement disorder	1	2			1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Multiple sclerosis relapse	2	2			2	2
Muscle spasticity		2				2
Myelitis transverse	1	1			1	1
Narcolepsy		1				1
Neuralgia	4	17	2	6	2	11
Neuritis		1				1
Neurological symptom		2				2
Opisthotonus		1				1
Paraesthesia	12	46	5	15	7	31
Paraparesis		1				1
Paresis		1				1
Petit mal epilepsy	1	2			1	2
Post herpetic neuralgia	1	1	1	1		
Presyncope		5		1		4
Radiculopathy	1	1			1	1
Reduced facial expression		1		1		
Seizure	3	7			3	7
Sensory disturbance		1		1		
Sensory loss		1				1
Slow speech		1				1
Somnolence	8	14	2	3	6	11
Speech disorder	3	6			3	6
Stupor		1				1
Syncope	7	22			7	22
Taste disorder	1	1			1	1
Tension headache	1	1			1	1
Thrombotic cerebral infarction		1				1
Transient aphasia		2				2
Transient ischaemic attack	3	6			3	6
Tremor	5	20	1	3	4	17
Trigeminal palsy		1				1
Unresponsive to stimuli	1	3			1	3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	276	807	84	195	192	612

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion spontaneous		1		1
		1		1

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product quality issue		1		1
Product temperature excursion issue	1	1	1	1
	1	2	1	2

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* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	2	3			2	3
Apathy	1	1			1	1
Confusional state	6	12	1	3	5	9
Delirium		1				1
Delusion		2		2		
Depressed mood	1	1			1	1
Derealisation	1	2		1	1	1
Disorganised speech	1	1			1	1
Eating disorder		1		1		
Fear		1		1		
Hallucination	1	2			1	2
Hallucination, auditory		2				2
Hallucination, visual	2	2			2	2
Helplessness		1		1		
Illusion	1	1			1	1
Impaired reasoning		1				1
Inappropriate affect	1	1			1	1
Initial insomnia	1	2			1	2
Insomnia	6	17	2	5	4	12
Irritability	1	3			1	3
Middle insomnia		7		3		4
Nightmare	2	2			2	2
Poor quality sleep		1				1
Self-injurious ideation		1				1
Sleep disorder	1	1	1	1		
Stress		1				1
Suicidal ideation	1	1			1	1
	29	71	4	18	25	53

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anuria		2				2
Bladder dysfunction	1	1			1	1
Dysuria		2		1		1
Haematuria		1				1
Nephrolithiasis	1	1			1	1
Renal disorder		1		1		
Renal failure	1	2			1	2
Tubulointerstitial nephritis	1	1			1	1
Urinary incontinence	1	1			1	1
Urinary retention		1				1
Urogenital haemorrhage		1				1
	5	14		2	5	12

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast cyst	1	2	1	1		1
Breast pain		1				1
Breast swelling		1				1
Breast tenderness		1				1
Female genital tract fistula		1				1
Heavy menstrual bleeding	2	2	2	2		
Menstrual disorder		1				1
Vulvovaginal inflammation		1				1
	3	10	3	3		7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory failure		1				1
Aphonia	2	5		1	2	4
Apnoea	1	4			1	4
Aspiration		1				1
Asthma	1	2			1	2
Atelectasis	1	1			1	1
Choking sensation		1				1
Chronic obstructive pulmonary disease		1				1
Cough	12	33		3	12	30
Dysphonia	9	13	2	4	7	9
Dyspnoea	25	106	5	14	20	92
Dyspnoea exertional		4				4
Emphysema	1	1			1	1
Epistaxis		4		1		3
Hyperventilation	2	3	1	1	1	2
Hypopnoea		1				1
Increased bronchial secretion	1	1			1	1
Increased upper airway secretion	1	7			1	7
Laryngeal pain		1				1
Lung disorder		2				2
Nasal congestion	2	7	1	3	1	4
Nasal oedema		2				2
Nasal pruritus		1		1		
Oropharyngeal discomfort	1	6		1	1	5
Oropharyngeal oedema		2		1		1
Oropharyngeal pain	8	25	3	13	5	12
Painful respiration		1				1
Paranasal sinus discomfort		1				1
Pharyngeal hypoaesthesia		4		1		3
Pharyngeal oedema	4	11		1	4	10
Pharyngeal paraesthesia	1	4		1	1	3
Pharyngeal swelling	5	11	1	1	4	10

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pleural effusion	1	1			1	1
Pneumonia aspiration		1				1
Productive cough		3				3
Pulmonary embolism	4	14			4	14
Pulmonary haemorrhage		1				1
Pulmonary infarction		1				1
Pulmonary oedema		1				1
Pulmonary pain	1	7		1	1	6
Rales		1				1
Respiratory arrest		2				2
Respiratory tract congestion	1	1			1	1
Respiratory tract irritation		1				1
Rhinorrhoea	5	8	3	5	2	3
Rhonchi	1	2			1	2
Sinus disorder		1				1
Sneezing	1	2	1	1		1
Snoring		1				1
Sputum discoloured		1				1
Stertor	1	1			1	1
Stridor		2				2
Suffocation feeling		2				2
Throat irritation	5	16	1	4	4	12
Throat tightness	3	8			3	8
Wheezing	2	8		1	2	7
	102	353	18	59	84	294

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne	1	1			1	1
Blister	1	4		2	1	2
Cold sweat	1	4		1	1	3
Eczema		2				2
Erythema	10	48	3	15	7	33
Erythema multiforme		1				1
Fixed eruption		2		2		
Hyperhidrosis	7	18	3	6	4	12
Night sweats	1	2	1	2		
Pain of skin	3	8	2	3	1	5
Papule	2	3	1	2	1	1
Photosensitivity reaction	1	2			1	2
Pruritus	17	32	8	17	9	15
Rash	8	20	3	6	5	14
Rash erythematous		5		2		3
Rash macular	2	6	1	2	1	4
Rash papular	1	1			1	1
Rash pruritic		4		3		1
Rash vesicular	4	4	3	3	1	1
Scab		1				1
Skin burning sensation	2	2	1	1	1	1
Skin discolouration	2	2			2	2
Skin mass	1	1			1	1
Skin reaction		1		1		
Skin sensitisation		1				1
Skin striae		1				1
Skin ulcer	1	1			1	1
Skin warm		2		1		1
Urticaria	14	40	8	15	6	25
	79	219	34	84	45	135

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden		1				1
Impaired work ability	3	19		1	3	18
Loss of personal independence in daily activities	4	6	1	1	3	5
	7	26	1	2	6	24

System Organ Class

Surgical and medical procedures

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Mechanical ventilation		1		1
Mesenteric artery stent insertion	1	1	1	1
Resuscitation		1		1
Small intestinal resection	1	1	1	1
Thrombolysis	1	1	1	1
	3	5	3	5

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortitis		1				1
Arteriosclerosis	1	1			1	1
Blood pressure fluctuation	4	5	1	1	3	4
Circulatory collapse		2				2
Cyanosis	1	2			1	2
Deep vein thrombosis	10	14			10	14
Flushing		8		2		6
Giant cell arteritis	1	2			1	2
Haematoma	1	6		3	1	3
Haemodynamic instability		1				1
Haemorrhage	1	1			1	1
Hot flush		2				2
Hypertension	4	12	1	2	3	10
Hypotension		3				3
Pallor	1	7	1	2		5
Pelvic venous thrombosis		1				1
Peripheral coldness	1	2			1	2
Peripheral embolism		1				1
Thrombophlebitis superficial	6	7	2	2	4	5
Thrombosis		4				4
Venous thrombosis	1	3			1	3
Venous thrombosis limb	3	3			3	3
	35	88	5	12	30	76

* I=Interval, C=Cumulative
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Country Where Event Occurred

FRANCE

090177e19749cf15\Approved\Approved On: 14-Jun-2021 14:01 (GMT)

- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acquired haemophilia		2				2
Agranulocytosis		2				2
Anaemia	10	22	2	4	8	18
Anaemia macrocytic		1				1
Aplastic anaemia		1				1
Autoimmune haemolytic anaemia		1				1
Bicytopenia	2	2			2	2
Blood loss anaemia		1				1
Disseminated intravascular coagulation		1				1
Eosinophilia	1	6			1	6
Febrile bone marrow aplasia	1	1			1	1
Haemoglobinaemia	1	1			1	1
Haemolysis	1	1			1	1
Haemolytic anaemia		2				2
Haemorrhagic diathesis		1				1
Haemorrhagic disorder		1				1
Hypergammaglobulinaemia	1	1	1	1		
Hyperleukocytosis	4	22			4	22
Immune thrombocytopenia	12	22			12	22
Iron deficiency anaemia		1				1
Leukocytosis	1	4		2	1	2
Leukopenia	1	6			1	6
Lymphadenitis	5	18	1	10	4	8
Lymphadenopathy	38	158	28	82	10	76
Lymphadenopathy mediastinal		1		1		
Lymph node pain	1	7		2	1	5
Lymphopenia	8	25	3	9	5	16
Microcytic anaemia	2	2	1	1	1	1
Monocytosis	2	4	1	2	1	2
Myelocytosis		1				1
Neutropenia	4	13			4	13
Neutrophilia	1	3	1	3		

* I=Interval, C=Cumulative

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System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Normochromic anaemia		1				1
Normochromic normocytic anaemia		1		1		
Normocytic anaemia		1				1
Pancytopenia	2	6			2	6
Sickle cell anaemia with crisis	1	1			1	1
Splenic infarction		1				1
Splenic vein thrombosis	1	1			1	1
Thrombocytopenia	24	53			24	53
Thrombocytopenic purpura	1	2			1	2
Thrombocytosis	1	2		1	1	1
	126	403	38	119	88	284

* I=Interval, C=Cumulative
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System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome	9	29			9	29
Acute myocardial infarction	1	6			1	6
Angina pectoris	5	18			5	18
Angina unstable		2				2
Aortic valve calcification		1				1
Aortic valve incompetence		4				4
Arrhythmia	31	100			31	100
Arrhythmia supraventricular		5				5
Arteriosclerosis coronary artery	1	2	1	1		1
Atrial fibrillation	55	161			55	161
Atrial flutter	2	8		1	2	7
Atrial thrombosis	1	2			1	2
Atrioventricular block	2	9		1	2	8
Atrioventricular block complete	4	7			4	7
Atrioventricular block first degree	1	1			1	1
Atrioventricular block second degree	1	2			1	2
Bradyarrhythmia	1	1	1	1		
Bradycardia	10	59			10	59
Bundle branch block		1				1
Bundle branch block left	1	6		1	1	5
Bundle branch block right	1	8		3	1	5
Cardiac arrest	9	32			9	32
Cardiac discomfort		3		1		2
Cardiac disorder		3		1		2
Cardiac failure	22	109			22	109
Cardiac failure acute	1	6			1	6
Cardiac failure congestive		3				3
Cardiac fibrillation		2				2
Cardiac flutter	1	3			1	3
Cardiac tamponade		1				1
Cardiogenic shock	4	9			4	9
Cardiomegaly	2	3			2	3

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System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiomyopathy		1				1
Cardiopulmonary failure	3	6			3	6
Cardio-respiratory arrest	14	52			14	52
Cardio-respiratory distress		2				2
Cardiovascular disorder	2	6	1	1	1	5
Conduction disorder		1				1
Congestive cardiomyopathy		1				1
Coronary artery disease	1	3	1	1		2
Coronary artery insufficiency		1				1
Coronary artery occlusion	3	4			3	4
Coronary artery stenosis	2	6			2	6
Defect conduction intraventricular		1				1
Degenerative mitral valve disease	1	1			1	1
Dilatation ventricular	1	1	1	1		
Extrasystoles	4	25	1	7	3	18
Foetal heart rate disorder	1	1			1	1
Heart valve incompetence	1	1	1	1		
Hepatojugular reflux		1		1		
Intracardiac thrombus	1	3			1	3
Ischaemic cardiomyopathy		1				1
Left atrial dilatation	3	4	1	1	2	3
Left ventricular dilatation		2		2		
Left ventricular dysfunction	1	2	1	1		1
Left ventricular failure	2	5			2	5
Left ventricular hypertrophy	1	3	1	1		2
Mitral valve calcification		2				2
Mitral valve disease		1				1
Mitral valve incompetence	1	5			1	5
Mitral valve stenosis		1				1
Myocardial infarction	17	53			17	53
Myocardial ischaemia	1	6			1	6
Myocardial necrosis		1				1

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System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myocarditis	7	15			7	15
Palpitations	28	94	10	36	18	58
Pericardial effusion	8	16			8	16
Pericardial haemorrhage		1				1
Pericarditis	18	43			18	43
Pleuropericarditis	3	3			3	3
Right ventricular dilatation	1	2	1	1		1
Right ventricular failure	1	1			1	1
Sinus arrest		1				1
Sinus arrhythmia	1	1	1	1		
Sinus bradycardia	2	4			2	4
Sinus tachycardia	2	21	2	6		15
Stress cardiomyopathy	1	4			1	4
Supraventricular extrasystoles	3	8	2	2	1	6
Supraventricular tachyarrhythmia		1				1
Supraventricular tachycardia	4	14			4	14
Tachyarrhythmia	6	13	1	4	5	9
Tachycardia	81	322	19	79	62	243
Tachycardia paroxysmal		1				1
Tricuspid valve incompetence	1	2			1	2
Ventricular arrhythmia	1	2			1	2
Ventricular extrasystoles	3	18		4	3	14
Ventricular failure		1				1
Ventricular fibrillation	3	8			3	8
Ventricular hypokinesia	2	4			2	4
Ventricular tachycardia	5	12			5	12
	406	1,421	46	160	360	1261

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* AE=Adverse Event

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aplasia		1				1
Arteriovenous malformation	1	1			1	1
Block vertebra	1	1			1	1
Cystic lymphangioma		1				1
Factor II mutation		1		1		
Familial mediterranean fever	1	2			1	2
Hyperglycinaemia		1				1
Hypertrophic cardiomyopathy		2				2
Macroglossia		3				3
Spine malformation	1	1			1	1
Trisomy 21	1	1			1	1
	5	15		1	5	14

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* AE=Adverse Event
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System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute vestibular syndrome	1	7		1	1	6
Auditory disorder		1				1
Conductive deafness	1	1			1	1
Deafness	5	13			5	13
Deafness neurosensory		2				2
Deafness unilateral	3	13			3	13
Ear discomfort		2		1		1
Ear disorder		2		2		
Ear haemorrhage	1	2		1	1	1
Ear pain	4	25	1	9	3	16
Ear swelling		3		1		2
Hyperacusis		1		1		
Hypoacusis	2	11		2	2	9
Inner ear disorder		2		1		1
Meniere's disease	1	2			1	2
Otolithiasis		1				1
Paraesthesia ear		1				1
Presbycusis		1		1		
Sudden hearing loss	2	9			2	9
Tinnitus	27	75	14	28	13	47
Vertigo	60	182	25	63	35	119
Vertigo positional	3	14	1	1	2	13
Vestibular disorder	2	7	1	2	1	5
	112	377	42	114	70	263

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System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adrenal insufficiency		1				1
Adrenal mass		1		1		
Adrenocortical insufficiency acute	1	2			1	2
Autoimmune thyroiditis	2	6			2	6
Basedow's disease		1				1
Diabetes insipidus	1	2			1	2
Goitre	1	2		1	1	1
Hypercalcaemia of malignancy		1		1		
Hyperthyroidism		5				5
Hypothyroidism	2	3			2	3
Thyroid disorder		1		1		
Thyroiditis	1	1			1	1
Thyroiditis subacute	1	1			1	1
Thyroid mass	1	2	1	2		
	10	29	1	6	9	23

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal sensation in eye		1		1		
Accommodation disorder		1				1
Age-related macular degeneration		1				1
Amaurosis	1	3			1	3
Amaurosis fugax	1	3			1	3
Blepharitis	1	1			1	1
Blindness	3	5			3	5
Blindness cortical	1	1			1	1
Blindness transient		1				1
Blindness unilateral	1	5			1	5
Cataract		1				1
Choroidal neovascularisation	1	1			1	1
Conjunctival haemorrhage	4	19			4	19
Conjunctival hyperaemia		1		1		
Conjunctival irritation		1		1		
Conjunctival oedema		1		1		
Detachment of retinal pigment epithelium	1	1			1	1
Diplopia	8	23		2	8	21
Dry eye		4		3		1
Dyschromatopsia	1	1			1	1
Endocrine ophthalmopathy		1				1
Erythema of eyelid		2		1		1
Exophthalmos		1				1
Eye discharge		1				1
Eye disorder		1				1
Eye haemorrhage	1	7			1	7
Eye inflammation	1	1			1	1
Eye irritation	3	6	1	3	2	3
Eyelid disorder	1	2	1	1		1
Eyelid function disorder		1				1
Eyelid haematoma		1		1		
Eyelid irritation		1		1		

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid myoclonus		1				1
Eyelid oedema	2	20	2	8		12
Eyelid ptosis		3		1		2
Eye movement disorder	3	4	1	2	2	2
Eye oedema	1	3		1	1	2
Eye pain	6	17	5	11	1	6
Eye swelling	2	6		1	2	5
Gaze palsy		2				2
Glaucoma	1	2			1	2
Hyperaesthesia eye	1	1	1	1		
Hypermetropia	1	1			1	1
Hypoaesthesia eye	1	1	1	1		
Iridocyclitis	1	2			1	2
Lacrimation increased	1	8	1	5		3
Macular oedema		1				1
Metamorphopsia	1	3	1	2		1
Miosis		1				1
Mydriasis		5		2		3
Noninfective chorioretinitis		1				1
Ocular discomfort	3	8	2	6	1	2
Ocular hyperaemia	2	8	1	1	1	7
Ocular myasthenia		1				1
Ocular vascular disorder		1				1
Optic ischaemic neuropathy		2				2
Optic neuropathy	1	1			1	1
Orbital haematoma	1	2			1	2
Papilloedema	1	1			1	1
Parophthalmia		1				1
Periorbital oedema	1	2			1	2
Periorbital pain		2		1		1
Periorbital swelling		1				1
Photophobia	1	13	1	3		10

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Photopsia	2	6		1	2	5
Punctate keratitis	1	1			1	1
Pupils unequal		1		1		
Retinal artery occlusion	3	8			3	8
Retinal artery thrombosis	1	1			1	1
Retinal detachment	3	3			3	3
Retinal fovea disorder		1				1
Retinal haemorrhage	3	3			3	3
Retinal infarction	1	1			1	1
Retinal vein occlusion	1	8			1	8
Retinal vein thrombosis	2	2	1	1	1	1
Scleral disorder		1				1
Scleritis	2	3			2	3
Strabismus	1	1			1	1
Subretinal haematoma	1	1			1	1
Swelling of eyelid	1	2	1	1		1
Uveitis	1	2			1	2
Vision blurred	14	36	6	12	8	24
Visual acuity reduced	2	7			2	7
Visual acuity reduced transiently		1				1
Visual brightness		1				1
Visual field defect	3	6			3	6
Visual impairment	13	32	8	11	5	21
Vitreous detachment	1	1			1	1
Vitreous floaters	1	2			1	2
	117	356	34	89	83	267

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		3		2		1
Abdominal distension	2	10	1	6	1	4
Abdominal mass	1	2	1	2		
Abdominal pain	37	131	20	56	17	75
Abdominal pain lower		3		2		1
Abdominal pain upper	19	56	8	21	11	35
Abdominal rigidity		2				2
Abdominal wall haematoma	1	1			1	1
Abnormal faeces		1		1		
Acute abdomen		1				1
Aerophagia		1				1
Anaesthesia oral	2	4	2	2		2
Anal incontinence	1	1	1	1		
Aphthous ulcer	2	8	1	4	1	4
Colitis		3		1		2
Colitis ulcerative	1	2			1	2
Constipation	11	20	10	18	1	2
Crohn's disease		1				1
Diarrhoea	59	252	29	95	30	157
Diarrhoea haemorrhagic	1	6			1	6
Diverticulum intestinal	1	3		1	1	2
Dry mouth	4	11	3	6	1	5
Dyspepsia	4	11	1	2	3	9
Dysphagia	16	40	7	14	9	26
Enlarged uvula		1				1
Enteritis	1	1			1	1
Enterocolitis haemorrhagic	1	2			1	2
Eructation	1	5	1	1		4
Faecaloma	1	3			1	3
Faecal vomiting		2				2
Faeces discoloured	1	2	1	2		
Faeces soft		2		2		

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Flatulence	2	4	2	3		1
Functional gastrointestinal disorder	1	5			1	5
Gastric ulcer	2	2			2	2
Gastric ulcer haemorrhage	1	1			1	1
Gastric volvulus		1				1
Gastritis	1	2			1	2
Gastritis erosive		1				1
Gastrointestinal disorder	11	23	11	15		8
Gastrointestinal haemorrhage	1	4			1	4
Gastrointestinal hypermotility		1		1		
Gastrointestinal inflammation		1				1
Gastrointestinal motility disorder		3		2		1
Gastrointestinal pain	1	7		4	1	3
Gastrointestinal sounds abnormal		1		1		
Gastrointestinal wall thickening		1		1		
Gastroesophageal reflux disease	1	5	1	3		2
Gingival bleeding	2	3	2	2		1
Gingival discomfort		2		1		1
Gingival pain	1	1	1	1		
Glossitis		2		1		1
Glossodynia	2	4	1	3	1	1
Haematemesis		7				7
Haematochezia	1	6			1	6
Haemorrhoids		1				1
Haemorrhoids thrombosed	1	2			1	2
Hyperchlorhydria	1	1	1	1		
Hypoaesthesia oral	1	8		1	1	7
Intestinal ischaemia	2	7			2	7
Intestinal obstruction	1	3			1	3
Lip blister	1	1	1	1		
Lip dry	2	2	2	2		
Lip erosion		1				1

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lip erythema	1	1	1	1		
Lip haematoma		1				1
Lip haemorrhage		1				1
Lip oedema	3	22	1	6	2	16
Lip pain	1	3			1	3
Lip pruritus	1	2	1	1		1
Lip swelling	6	13	4	5	2	8
Melaena	3	4			3	4
Mesenteric artery thrombosis	1	1			1	1
Mesenteric vein thrombosis	2	3			2	3
Mouth haemorrhage	2	4	2	3		1
Mouth ulceration		3		3		
Mucous stools	1	2		1	1	1
Nausea	120	488	75	206	45	282
Necrotising colitis		1				1
Noninfective gingivitis		2		1		1
Obstruction gastric		1				1
Odynophagia	2	6		3	2	3
Oedema mouth	1	2			1	2
Oedematous pancreatitis	1	1			1	1
Oesophageal discomfort	1	1			1	1
Oesophageal pain		1				1
Oesophageal spasm		1				1
Oral blood blister		1				1
Oral discomfort	1	2	1	2		
Oral disorder		1		1		
Oral dysaesthesia		3		2		1
Oral pain	2	4	2	4		
Oral pruritus	1	4	1	2		2
Palatal disorder	1	1	1	1		
Palatal oedema	1	6	1	1		5
Pancreatic cyst	1	1			1	1

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pancreatic steatosis	1	1	1	1		
Pancreatitis	5	7			5	7
Pancreatitis acute	8	16			8	16
Paraesthesia oral	9	28	6	13	3	15
Peptic ulcer		1				1
Pneumoperitoneum		1				1
Proctitis	1	2	1	2		
Proctitis haemorrhagic	1	1			1	1
Rectal haemorrhage	4	12			4	12
Salivary gland disorder		1		1		
Salivary hypersecretion	4	7	3	4	1	3
Splenic artery aneurysm	1	1			1	1
Stomatitis		2		1		1
Subileus	1	3			1	3
Swollen tongue	3	9	1	3	2	6
Thrombosis mesenteric vessel		1				1
Tongue coated		2				2
Tongue discolouration	1	2			1	2
Tongue discomfort		1				1
Tongue disorder		1				1
Tongue dry		1				1
Tongue haematoma		2		2		
Tongue movement disturbance		1				1
Tongue oedema	3	11		3	3	8
Tongue pruritus	1	1			1	1
Tongue spasm	1	1	1	1		
Toothache	1	3	1	2		1
Tooth loss	1	1			1	1
Uvulitis		1				1
Visceral venous thrombosis	1	1			1	1
Volvulus of small bowel	1	1			1	1
Vomiting	82	302	51	107	31	195

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vomiting projectile	2	2			2	2
	488	1,718	263	665	225	1053

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Application site warmth		1		1		
Asthenia	208	873	138	362	70	511
Axillary pain	6	19	4	12	2	7
Chest discomfort	26	85	8	33	18	52
Chest pain	58	183	17	41	41	142
Chills	80	352	58	159	22	193
Condition aggravated	33	98	7	21	26	77
Crepitations		3		2		1
Crying	1	1	1	1		
Death	15	122			15	122
Deformity		1		1		
Discomfort	23	80	14	30	9	50
Disease progression	1	2			1	2
Disease recurrence	34	106	1	5	33	101
Drug ineffective	91	298	1	2	90	296
Drug interaction	1	3	1	2		1
Extensive swelling of vaccinated limb		12		10		2
Face oedema	6	47	2	7	4	40
Facial pain	2	8	2	3		5
Fatigue	107	466	73	240	34	226
Fat tissue increased		1		1		
Feeling abnormal	9	31	7	18	2	13
Feeling cold	7	31	3	13	4	18
Feeling drunk	2	11	1	4	1	7
Feeling hot	11	38	7	17	4	21
Feeling jittery	1	1	1	1		
Feeling of body temperature change	1	5	1	3		2
Foaming at mouth		1				1
Gait disturbance	13	39	9	20	4	19
Gait inability	5	15	3	5	2	10
Generalised oedema		1				1
General physical health deterioration	23	78	7	17	16	61

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
High-pitched crying		1		1		
Hyperthermia	26	89	7	26	19	63
Hypothermia	4	20			4	20
Ill-defined disorder		1				1
Illness	3	7	3	4		3
Induration	1	4	1	2		2
Inflammation	18	51	8	22	10	29
Inflammatory pain		2				2
Influenza like illness	147	626	69	157	78	469
Inhibitory drug interaction		1		1		
Injected limb mobility decreased	10	37	5	9	5	28
Injection site erythema		5		5		
Injection site haematoma	1	1	1	1		
Injection site haemorrhage	1	1	1	1		
Injection site hyperaesthesia		1		1		
Injection site oedema		1		1		
Injection site pain	1	7	1	7		
Injection site paraesthesia		1		1		
Injection site pruritus		3		3		
Injection site rash		1				1
Injection site reaction		2		1		1
Injection site swelling		1		1		
Lithiasis		1		1		
Localised oedema	1	9		3	1	6
Local reaction		3		3		
Malaise	96	443	35	137	61	306
Mass		1				1
Moaning		1				1
Mucosal discolouration		1				1
Mucosal pain		1		1		
Multiple organ dysfunction syndrome	3	9			3	9
Necrosis	1	2			1	2

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
No adverse event		2
Oedema	6	17
Oedema mucosal	1	1
Oedema peripheral	24	68
Pain	52	238
Peripheral swelling	13	35
Polyp		1
Polyserositis		1
Pre-existing condition improved	1	1
Pyrexia	215	822
Rebound effect		1
Secretion discharge	1	1
Sense of oppression	1	3
Shoulder injury related to vaccine administration	1	2
Sluggishness		2
Sudden death	14	70
Swelling	3	10
Swelling face	7	15
Systemic inflammatory response syndrome	1	3
Tenderness		1
Terminal state		1
Therapeutic response unexpected	1	3
Thirst		8
Ulcer	1	1
Vaccination failure	141	273
Vaccination site bruising	1	2
Vaccination site coldness		1
Vaccination site dermatitis		1
Vaccination site discharge		1
Vaccination site discolouration		1
Vaccination site discomfort	1	2
Vaccination site dysaesthesia		2

Spontaneous			
Nonserious		Serious	
I	C	I	C
	2		
3	7	3	10
1	1		
12	21	12	47
26	105	26	133
7	14	6	21
	1		
			1
1	1		
136	344	79	478
			1
1	1		
		1	3
		1	2
	2		
		14	70
3	7		3
3	6	4	9
1	1		2
	1		
			1
1	3		
	4		4
		1	1
		141	273
1	2		
	1		
	1		
			1
			1
1	1		1
	1		1

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site eczema		1				1
Vaccination site erythema	18	71	13	48	5	23
Vaccination site exfoliation		1				1
Vaccination site granuloma		1				1
Vaccination site haematoma	3	16	1	7	2	9
Vaccination site haemorrhage		3		2		1
Vaccination site hyperaesthesia	1	2			1	2
Vaccination site hypersensitivity	1	19	1	19		
Vaccination site hypoaesthesia		1				1
Vaccination site induration	3	22	3	17		5
Vaccination site inflammation	11	37	7	16	4	21
Vaccination site joint inflammation		1				1
Vaccination site joint movement impairment		1				1
Vaccination site joint pain	1	4	1	2		2
Vaccination site lymphadenopathy		2		1		1
Vaccination site macule	1	1	1	1		
Vaccination site mass		3		2		1
Vaccination site movement impairment	5	23	2	9	3	14
Vaccination site nodule		3		1		2
Vaccination site oedema	3	22	2	9	1	13
Vaccination site pain	107	487	88	282	19	205
Vaccination site papule		1		1		
Vaccination site paraesthesia	4	14	3	8	1	6
Vaccination site plaque		1				1
Vaccination site pruritus	7	31	7	18		13
Vaccination site rash		5		2		3
Vaccination site reaction	10	30	6	18	4	12
Vaccination site recall reaction		1		1		
Vaccination site swelling	10	33	8	22	2	11
Vaccination site thrombosis		1				1
Vaccination site urticaria	2	4	2	3		1
Vaccination site warmth		18		9		9

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular stent stenosis	1	1			1	1
Vascular stent thrombosis		1				1
	1,750	6,798	839	2445	911	4353

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System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmune hepatitis		1				1
Biliary colic	1	1	1	1		
Cholecystitis		3				3
Cholecystitis acute	1	1			1	1
Cholelithiasis	2	2	1	1	1	1
Cholestasis	7	12			7	12
Cholestatic liver injury	2	3			2	3
Hepatic cyst		1				1
Hepatic cytolysis	8	22			8	22
Hepatic failure	1	1			1	1
Hepatic function abnormal	1	3		2	1	1
Hepatic haematoma		1				1
Hepatic infarction	1	2			1	2
Hepatic lesion		1		1		
Hepatic pain	1	2		1	1	1
Hepatic steatosis	2	4	2	3		1
Hepatitis	1	2			1	2
Hepatitis acute	2	4			2	4
Hepatitis cholestatic		2				2
Hepatocellular injury	2	5			2	5
Hepatomegaly	3	5	1	1	2	4
Hyperbilirubinaemia	1	5			1	5
Jaundice		4				4
Jaundice cholestatic		1				1
Liver disorder	1	1			1	1
Liver injury	2	3			2	3
Mixed liver injury	1	1			1	1
Portal hypertension	1	1			1	1
Portal vein phlebitis	1	1			1	1
Portal vein thrombosis	5	6			5	6
	47	101	5	10	42	91

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System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		6		3		3
Anaphylactic reaction	11	50			11	50
Anaphylactic shock	5	18			5	18
Anaphylactoid reaction	1	3			1	3
Anaphylactoid shock	1	1			1	1
Anti-neutrophil cytoplasmic antibody positive vasculitis		1				1
Drug hypersensitivity		2				2
Haemophagocytic lymphohistiocytosis		4				4
Hypersensitivity	19	93	3	29	16	64
Hypogammaglobulinaemia	2	3			2	3
Immune reconstitution inflammatory syndrome	1	1			1	1
Immunodeficiency		1				1
Serum sickness		1				1
Transplant rejection	1	1			1	1
Type I hypersensitivity	2	5			2	5
Type II hypersensitivity		1				1
Type III immune complex mediated reaction	1	2			1	2
	44	193	3	32	41	161

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abscess		1		1		
Abscess of salivary gland	1	1			1	1
Acute sinusitis		1		1		
Aerococcus urinae infection		1				1
Appendicitis	4	6			4	6
Appendicitis perforated		1				1
Asymptomatic COVID-19	3	34		3	3	31
Atypical pneumonia		1				1
Bacteraemia	1	1			1	1
Bacterial infection		1				1
Bacterial pyelonephritis		1				1
Bacterial sepsis		2				2
Bacteriuria	1	1			1	1
Blastocystis infection		1				1
Bone abscess		1				1
Breast abscess		1				1
Bronchiolitis		2				2
Bronchitis	9	20	3	6	6	14
Cellulitis		1				1
Chorioretinitis	1	1			1	1
Citrobacter infection		1				1
Conjunctivitis	2	9	2	5		4
Conjunctivitis bacterial		1				1
Coronavirus infection		3		2		1
COVID-19	205	625	7	74	198	551
COVID-19 pneumonia	18	40			18	40
Cystitis	1	2			1	2
Cystitis klebsiella		1				1
Cytomegalovirus infection		2				2
Dacryocystitis	1	1			1	1
Dermo-hypodermatitis		6				6
Diarrhoea infectious		2				2

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disseminated varicella zoster virus infection	1	1			1	1
Diverticulitis		2				2
Ear infection		2				2
Encephalitis	4	6			4	6
Encephalitis viral		1				1
Enterococcal infection		1				1
Epstein-Barr virus infection		1				1
Epstein-Barr virus infection reactivation	2	3			2	3
Erysipelas	6	16			6	16
Escherichia bacteraemia		1				1
Escherichia infection		1				1
Escherichia pyelonephritis	1	1			1	1
Escherichia urinary tract infection	3	6			3	6
Gangrene		1				1
Gastroenteritis	4	7	1	2	3	5
Genital herpes		2				2
Genital herpes zoster		1				1
Gingivitis		1				1
Hepatic cyst infection		1				1
Hepatitis B		1				1
Hepatitis E	2	2			2	2
Hepatitis infectious mononucleosis		1				1
Hepatitis viral		1				1
Herpangina		1		1		
Herpes ophthalmic	1	4			1	4
Herpes pharyngitis		1				1
Herpes simplex	4	8	3	5	1	3
Herpes virus infection	1	2	1	2		
Herpes zoster	136	245	87	125	49	120
Herpes zoster cutaneous disseminated	1	2			1	2
Herpes zoster meningoencephalitis		2				2
Herpes zoster meningoradiculitis	1	1			1	1

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes zoster reactivation	2	3	2	3		
Impetigo	1	1			1	1
Infection	3	11	1	4	2	7
Infectious mononucleosis		1				1
Influenza	23	77	12	25	11	52
Klebsiella infection		2				2
Labyrinthitis	1	1	1	1		
Lactobacillus infection		1				1
Large intestine infection		2				2
Laryngitis		2				2
Liver abscess	1	1			1	1
Lower respiratory tract infection		1				1
Lung abscess	1	2			1	2
Lyme disease		2				2
Lymphangitis	1	3			1	3
Mastitis	1	1			1	1
Mediastinitis	1	1			1	1
Meningitis		2				2
Meningitis aseptic	3	5			3	5
Meningoencephalitis herpetic	1	3			1	3
Mononucleosis syndrome		1				1
Moraxella infection		1				1
Myelitis	1	2			1	2
Nasal herpes		1				1
Nasopharyngitis	5	14	4	11	1	3
Ophthalmic herpes zoster	24	47	1	1	23	46
Oral fungal infection		1		1		
Oral herpes	3	5	3	4		1
Oropharyngeal candidiasis		1				1
Otitis externa	1	4	1	3		1
Parotitis	2	3			2	3
Peritonitis	3	3			3	3

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngitis	3	5	2	4	1	1
Pneumococcal sepsis		1				1
Pneumonia	6	40			6	40
Pneumonia bacterial	1	5			1	5
Pneumonia moraxella		1				1
Pneumonia mycoplasmal	1	1			1	1
Pneumonia pneumococcal		1				1
Pneumonia respiratory syncytial viral	1	1			1	1
Pneumonia viral	1	1			1	1
Pseudomonal bacteraemia	1	1			1	1
Pseudomonal sepsis	1	1			1	1
Pulmonary sepsis	1	2			1	2
Pulpitis dental		1				1
Pyelonephritis	5	10			5	10
Pyelonephritis acute	2	2			2	2
Rash pustular		1				1
Respiratory tract infection	2	5			2	5
Respiratory tract infection bacterial		1				1
Rhinitis	4	12	4	9		3
Sepsis	4	14			4	14
Septic shock	3	9			3	9
Sialoadenitis		1				1
Sinusitis	2	5	1	1	1	4
Staphylococcal bacteraemia		3				3
Staphylococcal sepsis		1				1
Superinfection	3	4	1	1	2	3
Superinfection bacterial		1				1
Superinfection viral		1				1
Suspected COVID-19	6	14		2	6	12
Tonsillitis	3	5			3	5
Tooth abscess		2		1		1
Tooth infection		1		1		

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Toxocariasis		1				1
Toxoplasmosis		1		1		
Urinary tract candidiasis		1				1
Urinary tract infection	5	13	2	3	3	10
Urinary tract infection bacterial		3				3
Urosepsis		1				1
Vaccination site abscess		2		1		1
Vaccination site cellulitis		1				1
Vaccination site infection		1				1
Varicella zoster virus infection	1	1			1	1
Vestibular neuronitis	5	13			5	13
Vestibulitis		1				1
Viral infection	2	6		3	2	3
Viral pharyngitis	2	2			2	2
	557	1,503	139	307	418	1196

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental exposure to product	1	1	1	1		
Accidental overdose		2		2		
Arteriovenous fistula thrombosis	1	2			1	2
Brain contusion		1				1
Burn oesophageal	2	2	1	1	1	1
Burn oral cavity		2				2
Cerebral hyperperfusion syndrome		1				1
Chest injury	2	3			2	3
Chillblains	10	13	10	12		1
Circumstance or information capable of leading to medication error		1		1		
Contraindicated product administered		1				1
Contusion	5	7	3	5	2	2
Epicondylitis	2	2	1	1	1	1
Exposure during pregnancy	4	6	1	2	3	4
Exposure to SARS-CoV-2		1				1
Exposure via breast milk		4		3		1
Exposure via skin contact		1		1		
Extradural haematoma		1				1
Eye contusion		1		1		
Eye injury		2				2
Eyelid injury	1	1			1	1
Face injury	3	5			3	5
Facial bones fracture	1	3			1	3
Fall	43	135	12	29	31	106
Femoral neck fracture		1				1
Femur fracture		4				4
Foot fracture	1	1			1	1
Fracture		1				1
Frostbite		1		1		
Hand fracture	1	1			1	1
Head injury	6	25		1	6	24

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Humerus fracture		1				1
Inappropriate schedule of product administration	11	30	11	28		2
Incorrect dose administered	4	9	3	8	1	1
Incorrect route of product administration	5	21	5	20		1
Injury	1	1	1	1		
Intercepted product preparation error		1		1		
Jaw fracture	1	1			1	1
Joint dislocation		1				1
Joint injury		1				1
Ligament sprain	1	2			1	2
Lip injury	1	1			1	1
Maternal exposure during pregnancy	13	16	7	9	6	7
Maternal exposure timing unspecified	2	3	1	2	1	1
Medication error		1		1		
Nasal injury	1	1			1	1
Neck injury		1				1
Nerve injury	1	2			1	2
Occupational exposure to product		2		2		
Off label use	10	37	9	35	1	2
Overdose	12	22	12	22		
Pelvic fracture	2	3			2	3
Periorbital haematoma	2	3	2	2		1
Pneumocephalus	1	1			1	1
Poor quality product administered	190	374	190	374		
Post lumbar puncture syndrome	1	1	1	1		
Post vaccination syndrome	1	1			1	1
Product administered at inappropriate site	3	5	3	4		1
Product administration error		1				1
Product label confusion		1		1		
Product preparation error	34	39	34	39		
Product preparation issue	5	24	5	24		
Product storage error	6	7	6	7		

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product use issue	2	18	1	17	1	1
Radius fracture	1	1			1	1
Recalled product administered		1		1		
Rib fracture	2	5			2	5
Road traffic accident		6		1		5
Skin abrasion	1	1	1	1		
Spinal compression fracture		2				2
Sternal fracture		1				1
Subcutaneous haematoma	1	1	1	1		
Subdural haematoma	3	6			3	6
Sunburn		1				1
Tendon rupture		1				1
Thermal burns of eye		1				1
Tongue injury		1		1		
Toxicity to various agents		2				2
Transcription medication error		1		1		
Underdose	8	29	8	29		
Vaccination complication	2	8		3	2	5
Vascular graft thrombosis	3	3			3	3
Vasoplegia syndrome	1	2			1	2
Wound	1	2	1	1		1
Wrist fracture	2	2			2	2
Wrong patient received product		1		1		
Wrong product administered	1	1	1	1		
Wrong technique in product usage process	1	5	1	5		
	420	948	333	705	87	243

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Activated partial thromboplastin time abnormal		1				1
Activated partial thromboplastin time prolonged	2	3			2	3
Activated partial thromboplastin time shortened		1				1
Alanine aminotransferase increased	2	7		4	2	3
Anticoagulation drug level below therapeutic		2		1		1
Antinuclear ant body positive	1	2	1	1		1
Aortic bruit		1		1		
Aspartate aminotransferase increased	1	6		4	1	2
Bacterial test positive		2		1		1
Beta 2 microglobulin increased		1		1		
Bilirubin conjugated increased		1		1		
Blood albumin decreased		1		1		
Blood alkaline phosphatase increased	1	5		4	1	1
Blood bicarbonate decreased		1				1
Blood bilirubin abnormal		1		1		
Blood bilirubin increased	2	3	1	2	1	1
Blood bilirubin unconjugated increased		1		1		
Blood calcium decreased		1		1		
Blood chloride increased	1	1			1	1
Blood cholesterol increased	1	1			1	1
Blood creatine phosphokinase increased		1				1
Blood creatinine abnormal		1				1
Blood creatinine decreased		1				1
Blood creatinine increased	4	6	2	4	2	2
Blood culture positive		1				1
Blood fibrinogen increased	2	2	2	2		
Blood folate decreased		1				1
Blood glucose decreased	1	1			1	1
Blood glucose fluctuation		1		1		
Blood glucose increased	2	10		6	2	4
Blood immunoglobulin G decreased	1	1	1	1		
Blood immunoglobulin G increased	1	1	1	1		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood lactate dehydrogenase increased	3	5	2	4	1	1
Blood lactic acid increased	1	1			1	1
Blood osmolarity increased	1	1	1	1		
Blood parathyroid hormone increased		1		1		
Blood potassium increased		1		1		
Blood pressure abnormal	1	4	1	2		2
Blood pressure decreased	8	31	6	11	2	20
Blood pressure diastolic decreased	1	4		2	1	2
Blood pressure increased	26	55	11	18	15	37
Blood pressure systolic decreased	1	4	1	3		1
Blood pressure systolic increased	1	8		1	1	7
Blood sodium decreased		1		1		
Blood sodium increased		3		1		2
Blood thyroid stimulating hormone decreased		1		1		
Blood thyroid stimulating hormone increased		5		3		2
Blood urea increased	2	2	1	1	1	1
Blood uric acid increased		1		1		
Blood urine present	2	3	2	3		
Body temperature decreased		3		1		2
Body temperature increased	4	15	4	6		9
Brain natriuretic peptide increased	1	5		2	1	3
Brain scan abnormal		1				1
Breath sounds abnormal	2	3	2	2		1
Carcinoembryonic antigen increased		1				1
Chest X-ray abnormal	1	3			1	3
Coma scale abnormal		1				1
C-reactive protein increased	16	67	6	30	10	37
Creatinine renal clearance decreased	1	2	1	1		1
Cryoglobulins present	1	1	1	1		
Culture urine positive		1		1		
Cytomegalovirus test positive		1		1		
Ejection fraction abnormal	1	1			1	1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ejection fraction decreased	2	3	1	1	1	2
Electrocardiogram abnormal	1	2			1	2
Electrocardiogram PR prolongation		1				1
Electrocardiogram QRS complex prolonged	2	3			2	3
Electrocardiogram QRS complex shortened		1				1
Electrocardiogram QT interval abnormal		1				1
Electrocardiogram repolarisation abnormality	1	3			1	3
Electrocardiogram ST segment depression		1				1
Electrocardiogram ST segment elevation	2	3			2	3
Electrocardiogram ST-T segment abnormal		1				1
Electrocardiogram T wave abnormal		1		1		
Electrocardiogram T wave inversion		2				2
Electroencephalogram abnormal		1				1
Eosinophil count increased		1		1		
Epstein-Barr virus test positive	1	2		1	1	1
Escherichia test positive		2		2		
Fibrin D dimer increased	11	17	1	1	10	16
Gamma-glutamyltransferase increased	2	12		8	2	4
Gastric pH decreased		1		1		
Glomerular filtration rate decreased	3	8	1	2	2	6
Glycosylated haemoglobin increased	2	3	1	2	1	1
Haemoglobin decreased		8		4		4
Heart rate decreased	5	13	2	7	3	6
Heart rate increased	7	24	4	12	3	12
Heart rate irregular		5				5
Heart sounds abnormal	2	6	2	3		3
Hepatic enzyme abnormal	1	1			1	1
Hepatic enzyme increased	1	4	1	2		2
Herpes simplex test positive	1	2		1	1	1
High density lipoprotein decreased	1	1	1	1		
Hormone level abnormal		1				1
Immunoglobulins increased	2	3	2	3		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inflammatory marker increased	1	1			1	1
International normalised ratio abnormal		3		1		2
International normalised ratio increased	5	12	2	3	3	9
Iron binding capacity total abnormal	1	1			1	1
Laboratory test abnormal	1	2	1	1		1
Left ventricular end-diastolic pressure increased		1				1
Leukocyte alkaline phosphatase increased	1	1			1	1
Lipase increased		2		2		
Liver function test abnormal	2	2	1	1	1	1
Liver function test increased	1	2			1	2
Low density lipoprotein increased	1	2			1	2
Lumbar puncture	1	1			1	1
Lymphocyte count decreased		2		1		1
Mean cell volume decreased		2		1		1
Monoclonal immunoglobulin increased		1				1
Muscle strength abnormal		1				1
Myocardial necrosis marker increased		2				2
Nerve conduction studies abnormal		1		1		
Neurological examination abnormal		1				1
Neutrophil count abnormal		1				1
Neutrophil count decreased	1	4	1	2		2
Neutrophil count increased	1	6		4	1	2
Nitrite urine present		1		1		
N-terminal prohormone brain natriuretic peptide increased	4	9	3	4	1	5
Oxygen saturation abnormal		1				1
Oxygen saturation decreased	40	153	11	23	29	130
Oxygen saturation increased		1				1
Parvovirus B19 test positive	1	1			1	1
PCO2 increased	1	1			1	1
Physical examination abnormal	1	1	1	1		
Platelet count decreased	1	5	1	3		2

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Platelet count increased	2	3	1	1	1	2
Procalcitonin increased	2	3		1	2	2
Prohormone brain natriuretic peptide increased	1	1			1	1
Prostatic specific antigen increased	1	1			1	1
Protein C increased		1				1
Prothrombin level abnormal		1				1
Prothrombin time prolonged	1	1			1	1
Prothrombin time shortened		2		1		1
Pulmonary arterial pressure increased	1	3	1	1		2
Pulse abnormal		1		1		
Pulse absent	2	5		2	2	3
Red blood cell count decreased	1	1	1	1		
Red blood cell sedimentation rate increased		2		2		
Red blood cells urine positive		1				1
Respiratory rate decreased	1	2			1	2
Respiratory rate increased		3		2		1
Rheumatoid factor increased		1				1
Rheumatoid factor positive	1	1	1	1		
Romberg test positive		1		1		
SARS-CoV-2 ant body test negative		14		14		
SARS-CoV-2 ant body test positive	1	5	1	5		
SARS-CoV-2 test false positive		1		1		
SARS-CoV-2 test positive	4	35		9	4	26
Scan abdomen abnormal	1	1			1	1
Scan abnormal	1	1			1	1
Serology negative		1		1		
Serum ferritin increased	2	3		1	2	2
Sputum abnormal		1				1
Thyroxine free decreased		1		1		
Transaminases increased	1	2			1	2
Tri-iodothyronine free decreased		1		1		
Troponin abnormal	1	1			1	1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Troponin increased	6	20	2	6	4	14
Ultrasound scan abnormal	1	1			1	1
Varicella virus test positive	1	2			1	2
Venous oxygen saturation decreased		2				2
Von Willebrand's factor activity decreased		1				1
Weight decreased	5	19	3	5	2	14
Weight increased	5	9	3	4	2	5
White blood cell count decreased	2	7	2	4		3
White blood cell count increased	2	6	1	3	1	3
	253	834	100	310	153	524

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal loss of weight	2	2			2	2
Acidosis hyperchloraemic		1				1
Adult failure to thrive	1	2			1	2
Cachexia	1	1			1	1
Cell death		4				4
Decreased appetite	33	101	18	47	15	54
Dehydration	10	37		8	10	29
Diabetes mellitus	5	14			5	14
Diabetes mellitus inadequate control	3	15			3	15
Diabetic ketoacidosis	1	5			1	5
Diabetic ketosis	1	2			1	2
Diabetic metabolic decompensation	1	3			1	3
Dyslipidaemia	1	3	1	3		
Failure to thrive		1				1
Feeding disorder	5	5			5	5
Fluid overload	2	2	1	1	1	1
Fluid retention		1				1
Folate deficiency	3	3	2	2	1	1
Food aversion		2		1		1
Food craving		1				1
Food refusal	1	1	1	1		
Gout	2	6	1	3	1	3
Hypercalcaemia		1		1		
Hyperchloraemia		1				1
Hypercholesterolaemia		1		1		
Hyperferritinaemia	2	3	1	1	1	2
Hyperglycaemia	4	16	2	7	2	9
Hyperhomocysteinaemia	1	1	1	1		
Hyperkalaemia	3	10			3	10
Hyperlactacidaemia	2	3			2	3
Hypermetabolism	1	1			1	1
Hypernatraemia	3	10	1	4	2	6

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertriglyceridaemia	2	2	1	1	1	1
Hyperuricaemia	1	2		1	1	1
Hypervitaminosis B12		1				1
Hypoalbuminaemia	3	4	1	1	2	3
Hypocalcaemia	2	3			2	3
Hypoglycaemia	4	16	1	3	3	13
Hypokalaemia	3	10			3	10
Hyponatraemia	5	6	2	3	3	3
Hypophagia		1		1		
Hypophosphataemia	1	1	1	1		
Hypovitaminosis	1	1	1	1		
Insulin-requiring type 2 diabetes mellitus		1				1
Ketoacidosis	1	1			1	1
Lactic acidosis	1	3			1	3
Malnutrition	4	8	1	3	3	5
Metabolic acidosis	4	4			4	4
Polydipsia		2		1		1
Tetany	1	2			1	2
Type 1 diabetes mellitus		2				2
Type 2 diabetes mellitus		1				1
Vitamin D deficiency		2		1		1
	121	332	37	98	84	234

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amyotrophy		1				1
Ankylosing spondylitis	3	8			3	8
Antisynthetase syndrome		1				1
Arthralgia	72	279	44	126	28	153
Arthritis	3	14		4	3	10
Arthritis reactive		4				4
Arthropathy		1		1		
Axillary mass	1	1	1	1		
Back pain	17	66	9	28	8	38
Bone pain	1	7	1	2		5
Bone swelling	2	4	1	3	1	1
Bursal fluid accumulation		1		1		
Bursal haematoma	1	2			1	2
Bursitis	1	5		1	1	4
Camptocormia	1	1	1	1		
Chondrocalcinosis	1	2			1	2
Enthesopathy	2	2			2	2
Extremity contracture	1	1			1	1
Facial asymmetry	1	3			1	3
Flank pain	1	3		1	1	2
Foot deformity		1		1		
Groin pain		1		1		
Haemarthrosis	1	3			1	3
Haematoma muscle	1	3			1	3
Immunoglobulin G4 related disease	1	1			1	1
Intervertebral disc compression		1				1
Intervertebral disc disorder		1		1		
Intervertebral disc protrusion		1		1		
Joint ankylosis	1	2	1	1		1
Joint effusion	2	6	1	2	1	4
Joint range of motion decreased	2	4			2	4
Joint stiffness	1	6		1	1	5

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Joint swelling	3	12
Joint warmth		1
Limb discomfort	11	24
Mobility decreased	4	19
Muscle contracture		7
Muscle discomfort	1	1
Muscle disorder		1
Muscle fatigue	1	5
Muscle hypertrophy	1	1
Muscle rigidity	1	2
Muscle spasms	14	32
Muscle tightness	3	5
Muscle twitching	4	4
Muscular weakness	11	46
Musculoskeletal chest pain	3	10
Musculoskeletal discomfort		1
Musculoskeletal disorder	1	3
Musculoskeletal pain	3	6
Musculoskeletal stiffness	24	120
Myalgia	114	453
Myalgia intercostal		1
Myokymia		1
Myositis		3
Neck mass	1	1
Neck pain	19	47
Oligoarthritis	1	1
Osteoarthritis	2	7
Pain in extremity	75	214
Pain in jaw	4	15
Pathological fracture	1	1
Periarthritis	1	5
Polyarthritis	4	7

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	6	1	6
			1
6	14	5	10
1	7	3	12
	3		4
		1	1
	1		
1	3		2
		1	1
1	2		
8	15	6	17
3	5		
1	1	3	3
4	15	7	31
3	5		5
	1		
1	2		1
	3	3	3
15	38	9	82
87	217	27	236
			1
	1		
	1		2
1	1		
11	22	8	25
		1	1
	3	2	4
42	100	33	114
2	4	2	11
		1	1
		1	5
		4	7

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Polychondritis		1				1
Polymyalgia rheumatica	6	8			6	8
Psoriatic arthropathy		1				1
Rhabdomyolysis	1	6			1	6
Rheumatic disorder		2		1		1
Rheumatic fever		1				1
Rheumatoid arthritis	9	21			9	21
Rotator cuff syndrome	1	3	1	2		1
Sjogren's syndrome		3				3
SLE arthritis		1				1
Spinal osteoarthritis	1	2		1	1	1
Spinal pain		4		1		3
Spondylitis		1				1
Spondyloarthropathy		1		1		
Synovial cyst	4	6	3	3	1	3
Synovitis	1	1			1	1
Systemic lupus erythematosus		1				1
Temporomandibular joint syndrome		1		1		
Tendon disorder	2	4	1	1	1	3
Tendonitis	5	13	2	4	3	9
Tendon pain	1	3	1	3		
Tenosynovitis	1	2		1	1	1
Torticollis	1	4	1	2		2
Trismus		2		2		
	457	1,584	257	670	200	914

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myeloid leukaemia		2				2
B-cell lymphoma		1				1
Benign breast neoplasm		1		1		
Fibroma		1		1		
Lipoma		2				2
Lung cancer metastatic	1	1			1	1
Malignant peritoneal neoplasm	2	2			2	2
Meningioma	1	1			1	1
Metastases to peritoneum		1				1
Monoclonal gammopathy		2				2
Myelodysplastic syndrome		1				1
Myelofibrosis		1				1
Neoplasm		1				1
Ovarian cancer	1	1			1	1
Ovarian neoplasm	1	1			1	1
Phaeochromocytoma		1				1
Pituitary tumour benign	1	1	1	1		
Thymoma	1	1			1	1
Tumour perforation		1				1
	8	23	1	3	7	20

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* AE=Adverse Event
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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute polyneuropathy	1	1			1	1
Ageusia	7	19	5	13	2	6
Agnosia		1				1
Alexia		1				1
Allodynia	1	1	1	1		
Altered state of consciousness	2	16			2	16
Amnesia	6	13	1	2	5	11
Amnesic disorder	1	3			1	3
Anaesthesia		1				1
Anosmia	4	12	2	6	2	6
Anterograde amnesia	1	2			1	2
Aphasia	14	39	2	8	12	31
Areflexia	1	1			1	1
Ataxia	3	13	2	7	1	6
Aura		2				2
Balance disorder	13	39	7	13	6	26
Bell's palsy	3	4			3	4
Bradykinesia	1	1	1	1		
Brain hypoxia		1				1
Brain oedema	3	3			3	3
Brain stem haemorrhage		1				1
Brain stem stroke	1	1			1	1
Burning sensation	10	30	5	14	5	16
Carotid arteriosclerosis	1	1			1	1
Carotid artery occlusion	1	4			1	4
Carotid artery stenosis	1	2			1	2
Carotid artery thrombosis		3				3
Central nervous system lesion		1				1
Cerebellar ataxia		1		1		
Cerebellar haematoma		1				1
Cerebellar infarction	1	3			1	3
Cerebellar stroke	2	3			2	3

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* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebellar syndrome	3	6			3	6
Cerebral amyloid angiopathy	2	3			2	3
Cerebral arteriosclerosis	1	2	1	1		1
Cerebral artery stenosis		1				1
Cerebral atrophy	1	3			1	3
Cerebral disorder	1	2	1	1		1
Cerebral haematoma	2	10			2	10
Cerebral haemorrhage	2	12			2	12
Cerebral infarction	6	16			6	16
Cerebral ischaemia	1	2			1	2
Cerebral thrombosis		2				2
Cerebral venous thrombosis	2	4			2	4
Cerebrovascular accident	34	81			34	81
Cervical cord compression		1				1
Cervical radiculopathy	3	5	1	2	2	3
Cervicobrachial syndrome	2	5	1	2	1	3
Circadian rhythm sleep disorder		1		1		
Clonic convulsion	1	1			1	1
Clonus	1	3		1	1	2
Clumsiness	2	3	2	2		1
Cluster headache		1				1
Cognitive disorder	5	9	2	4	3	5
Coma	4	19			4	19
Complex regional pain syndrome		1		1		
Coordination abnormal	1	3	1	2		1
Cranial nerve paralysis	1	1			1	1
Dementia	1	4			1	4
Demyelination		1				1
Depressed level of consciousness	4	21			4	21
Diabetic coma		1				1
Diabetic hyperosmolar coma	1	2			1	2
Diplegia		1				1

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbance in attention	7	18	5	8	2	10
Dizziness	82	272	45	105	37	167
Dizziness postural	1	4	1	1		3
Droling		2		2		
Drop attacks	1	2			1	2
Dropped head syndrome		1				1
Dysaesthesia	6	20	2	9	4	11
Dysarthria	11	31	6	9	5	22
Dysgeusia	16	41	13	23	3	18
Dysgraphia	1	3	1	1		2
Dyskinesia	5	9	1	3	4	6
Dysmetria	1	2			1	2
Dysstasia	3	12	1	3	2	9
Electric shock sensation	3	7	2	3	1	4
Embolic stroke	1	5			1	5
Encephalopathy	1	1			1	1
Epilepsy	15	43			15	43
Extensor plantar response		1				1
Extrapyramidal disorder		3		1		2
Facial neuralgia	1	1			1	1
Facial paralysis	57	169			57	169
Facial paresis	1	7		3	1	4
Febrile convulsion	2	3			2	3
Fine motor skill dysfunction		1		1		
Focal dyscognitive seizures		2				2
Formication	2	12	1	5	1	7
Generalised onset non-motor seizure		1				1
Generalised tonic-clonic seizure	5	16			5	16
Gross motor delay		1				1
Guillain-Barre syndrome	4	9			4	9
Haemorrhagic stroke	4	23			4	23
Haemorrhagic transformation stroke	3	4			3	4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache	285	973	181	435	104	538
Head discomfort	3	9	2	6	1	3
Hemianaesthesia		1				1
Hemianopia		3				3
Hemianopia homonymous		3				3
Hemiapraxia		1				1
Hemiataxia	1	1			1	1
Hemiparaesthesia	1	4			1	4
Hemiparesis	9	25			9	25
Hemiplegia	7	26			7	26
Hippocampal atrophy		2		1		1
Hoffmann's sign		1		1		
Horner's syndrome		1				1
Hyperaesthesia	7	16	4	8	3	8
Hyperpathia	1	1	1	1		
Hypersomnia	1	7	1	4		3
Hypertensive encephalopathy	2	3			2	3
Hypertonia		2				2
Hypoaesthesia	26	69	11	30	15	39
Hypokinesia		5		1		4
Hypotonia	2	10	1	3	1	7
Hypoxic-ischaemic encephalopathy	1	1			1	1
IIIrd nerve paralysis	2	4			2	4
Incoherent	2	8	1	4	1	4
Intercostal neuralgia		1				1
Intracranial aneurysm	1	1			1	1
Intracranial artery dissection	1	1			1	1
Intracranial haematoma		1				1
Intracranial pressure increased		1				1
Ischaemic stroke	81	162			81	162
IVth nerve paralysis	1	1			1	1
Lacunar infarction		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lacunar stroke		2				2
Language disorder	2	5	1	1	1	4
Lethargy	2	2	2	2		
Leukoencephalopathy		5				5
Loss of consciousness	52	153			52	153
Memory impairment		9		2		7
Meningeal disorder	1	2	1	1		1
Meningoradiculitis		1				1
Meningorrhagia		1				1
Mental impairment	2	5			2	5
Migraine	8	38	7	19	1	19
Migraine with aura		4		3		1
Mononeuropathy multiplex	1	2			1	2
Monoparesis	3	8	3	4		4
Monoplegia	4	8	1	1	3	7
Motor dysfunction	15	34	8	10	7	24
Movement disorder	3	9	3	5		4
Multiple sclerosis	2	2			2	2
Multiple sclerosis relapse	1	1			1	1
Muscle contractions involuntary		3		1		2
Muscle spasticity	1	1			1	1
Myasthenia gravis	3	5			3	5
Myasthenia gravis crisis		2				2
Myoclonus	2	7			2	7
Nerve compression		1		1		
Nervous system disorder	4	10	1	2	3	8
Neuralgia	14	55	7	20	7	35
Neuralgic amyotrophy	3	4			3	4
Neuritis		3		2		1
Neuroleptic malignant syndrome	1	1			1	1
Neurological decompensation	1	3		1	1	2
Neurological symptom	2	3	1	1	1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuromuscular pain		2		1		1
Neuromyelitis optica spectrum disorder	1	1			1	1
Neuromyopathy		2				2
Neuropathy peripheral	5	9			5	9
Normal pressure hydrocephalus		1				1
Nystagmus	2	6	1	3	1	3
Occipital neuralgia	4	7	1	1	3	6
Ophthalmic migraine		3		1		2
Optic neuritis	1	2			1	2
Paraesthesia	62	206	31	73	31	133
Paralysis	5	11			5	11
Paraplegia	1	1			1	1
Paresis		3				3
Parkinsonism		2				2
Parkinson's disease	1	2			1	2
Parosmia	1	4		3	1	1
Partial seizures		6				6
Peripheral sensorimotor neuropathy	1	1			1	1
Peripheral sensory neuropathy		1				1
Persistent postural-perceptual dizziness		1				1
Petit mal epilepsy		8				8
Polyneuropathy	2	7			2	7
Posterior reversible encephalopathy syndrome		1				1
Post herpetic neuralgia	1	1	1	1		
Presyncope	21	61	9	24	12	37
Progressive supranuclear palsy		1				1
Psychomotor hyperactivity		1				1
Psychomotor skills impaired	3	7	2	4	1	3
Quadrantanopia	1	1			1	1
Quadriparesis	1	2			1	2
Quadriplegia		2				2
Radial nerve palsy		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Radiculitis brachial	1	1			1	1
Retrograde amnesia		1				1
Sciatica	3	6	3	4		2
Sedation		1		1		
Seizure	9	34			9	34
Seizure anoxic		1				1
Sensorimotor disorder		4		1		3
Sensory disturbance	3	10	1	3	2	7
Sensory loss	2	13	1	5	1	8
Somnolence	13	55	6	24	7	31
Speech disorder	10	30	4	6	6	24
Spinal cord infarction		2				2
Spinal cord ischaemia		1				1
Status epilepticus	1	9			1	9
Status migrainosus		1				1
Stupor	1	1	1	1		
Subarachnoid haemorrhage	1	4			1	4
Sudden onset of sleep		2				2
Syncope	16	55			16	55
Taste disorder		1		1		
Temporal lobe epilepsy		1				1
Tension headache	2	3	1	1	1	2
Thermohypoaesthesia		1		1		
Thrombotic stroke	1	1			1	1
Tongue biting	2	5		1	2	4
Tongue paralysis		1				1
Tonic clonic movements		7				7
Tonic convulsion		2				2
Transient aphasia	1	1			1	1
Transient global amnesia	3	5	1	1	2	4
Transient ischaemic attack	35	71			35	71
Tremor	25	84	15	31	10	53

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Trigeminal neuralgia	2	4	1	1	1	3
Ulnar nerve palsy		1				1
Unresponsive to stimuli		2				2
Vagus nerve disorder		1				1
Vascular encephalopathy		1				1
Vlth nerve paralysis	2	4			2	4
Vocal cord paralysis	1	1			1	1
White matter lesion		1				1
	1,200	3,704	429	1023	771	2681

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion spontaneous	6	15			6	15
Arrested labour	1	1			1	1
Foetal growth restriction	1	1			1	1
Morning sickness		1		1		
Premature baby	2	2	1	1	1	1
Small for dates baby		1				1
Umbilical cord thrombosis	1	1			1	1
Uterine contractions abnormal	1	1			1	1
Uterine contractions during pregnancy	1	1			1	1
	13	24	1	2	12	22

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Liquid product physical issue	4	4	4	4
Needle issue		3		3
Product complaint		15		15
Product contamination physical	2	3	2	3
Product physical issue	6	7	6	7
Product quality issue	1	2	1	2
Product temperature excursion issue	143	305	143	305
Syringe issue	1	1	1	1
	157	340	157	340

* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour		3		2		1
Affective disorder	1	2		1	1	1
Aggression	1	7		1	1	6
Agitation	5	24		6	5	18
Anxiety	10	32	6	14	4	18
Anxiety disorder		1		1		
Apathy	2	9	1	5	1	4
Behaviour disorder	2	12		1	2	11
Bipolar disorder		1				1
Bradyphrenia		2				2
Bruxism	1	1	1	1		
Catatonia	1	1			1	1
Clinomania		1		1		
Communication disorder	2	2			2	2
Confusional state	19	67	1	9	18	58
Daydreaming		2				2
Decreased interest		1				1
Delirium	1	9			1	9
Delusion		4		2		2
Depressed mood	1	1	1	1		
Depression		2		1		1
Disinhibition		1				1
Disorientation	6	30	1	8	5	22
Dysphemia		3				3
Eating disorder		2		1		1
Emotional distress		1		1		
Enuresis		1				1
Euphoric mood	1	2	1	2		
Fear		2		1		1
Fear of death		1				1
Generalised anxiety disorder		1				1
Hallucination	2	15			2	15

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hallucination, auditory		5				5
Hallucination, olfactory		1				1
Hallucinations, mixed	1	3			1	3
Hallucination, visual	2	13			2	13
Hostility		1				1
Illusion		1				1
Initial insomnia		1				1
Insomnia	16	76	8	34	8	42
Irritability		2		1		1
Listless		1				1
Logorrhoea		1				1
Loss of libido		1		1		
Major depression	2	3			2	3
Mental disorder	1	1			1	1
Mental fatigue		1				1
Middle insomnia	2	10		3	2	7
Mood altered	1	1			1	1
Mutism		2		1		1
Near death experience		3				3
Nervousness		1				1
Nightmare	1	3	1	2		1
Oppositional defiant disorder	1	1			1	1
Panic attack		2		1		1
Persecutory delusion		2		1		1
Persistent depressive disorder		1				1
Phonophobia		2		1		1
Pseudodementia		1				1
Psychomotor retardation		1				1
Restlessness	2	13	1	6	1	7
Sleep disorder	6	18	4	8	2	10
Sleep disorder due to general medical condition, insomnia type	1	4	1	3		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sleep talking		1		1		
Staring		1				1
Stereotypy		2				2
Stress	1	7		5	1	2
Suicidal ideation	1	2			1	2
Tension	4	9	3	6	1	3
	97	441	30	133	67	308

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	13	36			13	36
A buminuria		1				1
Anuria	1	3			1	3
Bladder dilatation	1	2	1	1		1
Bladder disorder	1	1	1	1		
Bladder dysfunction	1	1	1	1		
Calculus bladder	1	1	1	1		
Chromaturia		2		1		1
Chronic kidney disease	4	5			4	5
Costovertebral angle tenderness		1				1
Dysuria	1	7	1	3		4
Glomerulonephritis		1				1
Haematuria	4	10	1	1	3	9
Haemoglobinuria		1				1
Incontinence	1	2			1	2
Ketonuria	1	1			1	1
Leukocyturia	4	8	1	4	3	4
Nephropathy		1				1
Nephrotic syndrome	3	4			3	4
Nocturia		1		1		
Oliguria	1	2		1	1	1
Pollakiuria	2	4	2	4		
Prerenal failure		3				3
Proteinuria	2	5	1	2	1	3
Renal artery stenosis		1				1
Renal artery thrombosis	1	1			1	1
Renal colic	3	5	1	1	2	4
Renal cyst		1				1
Renal cyst haemorrhage		1				1
Renal disorder	1	1			1	1
Renal failure	7	26			7	26
Renal impairment	1	4			1	4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal infarct	1	2			1	2
Renal pain		2				2
Renal tubular necrosis	1	1			1	1
Urinary incontinence	4	11	2	3	2	8
Urinary retention	1	5			1	5
Urinary tract discomfort		1		1		
Urine odour abnormal		2		2		
	61	167	13	28	48	139

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal uterine bleeding	1	1	1	1		
Amenorrhoea	1	2	1	1		1
Benign prostatic hyperplasia	2	4	2	3		1
Breast haematoma	1	1			1	1
Breast induration		1				1
Breast mass		1				1
Breast pain		4		1		3
Breast swelling	1	2		1	1	1
Erectile dysfunction		3				3
Genital haemorrhage		1				1
Gynaecomastia	1	1	1	1		
Heavy menstrual bleeding	1	2	1	1		1
Intermenstrual bleeding	1	3			1	3
Menstruation delayed	3	4	3	3		1
Oedema genital		1				1
Pelvic haematoma	1	1	1	1		
Pelvic pain		4				4
Polymenorrhoea	2	2	2	2		
Priapism		1				1
Prostatitis		4		2		2
Testicular pain		1		1		
Uterine spasm	1	1			1	1
Vaginal haemorrhage		1				1
Vulval haemorrhage	1	1			1	1
	17	47	12	18	5	29

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute pulmonary oedema	7	30			7	30
Acute respiratory distress syndrome	9	26			9	26
Acute respiratory failure	2	18			2	18
Aphonia		3				3
Apnoea	1	3			1	3
Asphyxia	1	2			1	2
Aspiration	1	5			1	5
Asthma	4	18	1	2	3	16
Asthmatic crisis	8	16			8	16
Atelectasis		1				1
Bronchial obstruction		1				1
Bronchial secretion retention		1		1		
Bronchiectasis	1	1			1	1
Bronchopneumopathy		4		1		3
Bronchospasm	4	12	1	1	3	11
Choking	2	7			2	7
Choking sensation	2	3	1	2	1	1
Chronic obstructive pulmonary disease	1	16		2	1	14
Cough	23	114	17	49	6	65
Dry throat		2		1		1
Dysphonia	3	15	2	7	1	8
Dyspnoea	101	296	34	67	67	229
Dyspnoea at rest	1	8			1	8
Dyspnoea exertional	10	34	3	9	7	25
Emphysema		1				1
Eosinophilic bronchitis		1				1
Epistaxis	23	49	6	15	17	34
Haemoptysis		5				5
Haemothorax		1				1
Hypercapnia		2				2
Hypersensitivity pneumonitis	1	1			1	1
Hyperventilation	2	5		2	2	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypocapnia	1	1	1	1		
Hypoventilation	1	2			1	2
Hypoxia	8	31			8	31
Idiopathic pulmonary fibrosis	1	1			1	1
Increased bronchial secretion		3				3
Interstitial lung disease	6	11			6	11
Laryngeal discomfort	5	10	1	2	4	8
Laryngeal dyspnoea		2				2
Laryngeal oedema	4	16			4	16
Laryngeal stenosis	2	2			2	2
Laryngitis allergic		1				1
Laryngospasm	1	1			1	1
Larynx irritation		1				1
Lower respiratory tract congestion	2	7			2	7
Lung disorder	9	44	1	7	8	37
Lung opacity	1	3			1	3
Nasal congestion	5	9	2	5	3	4
Nasal discomfort	1	1			1	1
Neonatal respiratory acidosis	1	1			1	1
Nocturnal dyspnoea	1	2	1	1		1
Obstructive airways disorder		1		1		
Organising pneumonia	1	1			1	1
Oropharyngeal discomfort	3	7	2	5	1	2
Oropharyngeal oedema		1				1
Oropharyngeal pain	10	28	10	25		3
Oropharyngeal swelling		1				1
Orthopnoea	1	4	1	1		3
Painful respiration	2	3			2	3
Pharyngeal disorder		1				1
Pharyngeal oedema	1	2			1	2
Pharyngeal paraesthesia	4	10	4	6		4
Pharyngeal swelling	1	2	1	2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pleural effusion	9	16
Pleurisy	1	2
Pneumonia aspiration	4	32
Pneumonitis	1	5
Pneumothorax	1	4
Productive cough	3	11
Pulmonary alveolar haemorrhage		1
Pulmonary arterial hypertension	3	5
Pulmonary artery dilatation		1
Pulmonary congestion	1	3
Pulmonary embolism	137	249
Pulmonary hypertension		1
Pulmonary infarction	3	7
Pulmonary oedema	2	15
Pulmonary pain		2
Rales	4	17
Respiration abnormal		2
Respiratory acidosis		1
Respiratory alkalosis	2	5
Respiratory arrest	1	3
Respiratory depression		4
Respiratory disorder	6	20
Respiratory distress	8	47
Respiratory failure	3	16
Respiratory fatigue		1
Respiratory tract congestion		1
Respiratory tract oedema		1
Rhinalgia		1
Rhinorrhoea	4	19
Rhonchi		3
Sinus disorder		1
Sinus pain		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	3	8	13
1	1		1
		4	32
	1	1	4
		1	4
2	5	1	6
			1
		3	5
			1
		1	3
		137	249
			1
		3	7
		2	15
	1		1
4	5		12
			2
			1
1	1	1	4
		1	3
			4
1	2	5	18
		8	47
		3	16
			1
			1
			1
2	7	2	12
	1		2
			1
			1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sleep apnoea syndrome	1	3		1	1	2
Snoring	1	2	1	2		
Stertor		1				1
Stridor	1	1			1	1
Suffocation feeling	3	9	2	3	1	6
Tachypnoea	2	18	2	4		14
Throat irritation	2	11	2	7		4
Throat tightness	4	9	4	4		5
Tonsillar hypertrophy		1		1		
Tracheal pain	1	1			1	1
Upper-airway cough syndrome		1				1
Upper respiratory tract congestion	1	1	1	1		
Wheezing	1	8	1	2		6
	489	1,474	114	267	375	1207

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne		2		2		
Acute febrile neutrophilic dermatosis		1				1
Acute generalised exanthematous pustulosis	1	1			1	1
Angioedema	18	76	1	1	17	75
Blister	1	5		1	1	4
Blood blister	1	1			1	1
Cold sweat	4	13	2	7	2	6
Cutaneous lupus erythematosus		1				1
Cutaneous vasculitis	2	4			2	4
Decubitus ulcer		3		1		2
Dermal cyst		2		1		1
Dermatitis allergic	1	1			1	1
Dermatitis bullous	3	6			3	6
Dermatitis exfoliative generalised		2				2
Dermatomyositis		2				2
Dermatosis	1	1	1	1		
Drug eruption	2	3		1	2	2
Drug reaction with eosinophilia and systemic symptoms		1				1
Dry skin	1	2		1	1	1
Dyshidrotic eczema		2		2		
Ecchymosis	6	6	3	3	3	3
Eczema	1	6		2	1	4
Eczema nummular		1				1
Erythema	31	121	21	57	10	64
Erythema multiforme	2	5			2	5
Erythema nodosum		3		1		2
Erythrosis	1	1	1	1		
Guttate psoriasis		1		1		
Hair colour changes		1		1		
Henoch-Schonlein purpura		1		1		
Hyperhidrosis	19	90	8	28	11	62

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypersensitivity vasculitis		1				1
Lichenoid keratosis	1	1			1	1
Lichen planus		1				1
Livedo reticularis	5	15	4	7	1	8
Lividity		1				1
Macule		1		1		
Madarosis		1				1
Neutrophilic dermatosis		1				1
Night sweats	2	9	1	4	1	5
Pain of skin		6		2		4
Papule		3		2		1
Peau d'orange		1		1		
Pemphigoid	1	5			1	5
Pernio-like erythema		2		2		
Petechiae	7	15	4	9	3	6
Photosensitivity reaction		1		1		
Piloerection		1				1
Pruritus	34	112	19	49	15	63
Psoriasis		3		1		2
Purpura	11	20	2	4	9	16
Rash	23	84	11	38	12	46
Rash erythematous	6	25	2	8	4	17
Rash macular		7		1		6
Rash maculo-papular	9	25	2	9	7	16
Rash papular		7		3		4
Rash pruritic	5	17	2	7	3	10
Rash vesicular		3		1		2
Skin discolouration	1	4		2	1	2
Skin disorder		1		1		
Skin exfoliation	1	2	1	1		1
Skin fissures		1				1
Skin hyperpigmentation		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin induration		1				1
Skin lesion	3	10	1	4	2	6
Skin mass		2		1		1
Skin necrosis	1	2			1	2
Skin plaque	1	5	1	4		1
Skin reaction	2	7	2	5		2
Skin tightness	1	1	1	1		
Skin ulcer		2		1		1
Skin warm	2	5	1	4	1	1
Symmetrical drug-related intertriginous and flexural exanthema	1	1			1	1
Target skin lesion		1				1
Toxic skin eruption	2	4			2	4
Urticaria	34	100	19	41	15	59
Urticaria chronic		1				1
Urticarial vasculitis	1	1			1	1
Vascular purpura	10	18	2	4	8	14
Yellow skin		1		1		
	259	904	112	333	147	571

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden	2	3		1	2	2
Impaired driving ability	1	2			1	2
Impaired work ability	6	27	1	4	5	23
Loss of personal independence in daily activities	8	17	2	4	6	13
Walking disability		2				2
	17	51	3	9	14	42

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Surgical and medical procedures

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bed rest		1				1
Dermabrasion		1		1		
Thrombolysis		1				1
		3		1		2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated hypertension		1		1		
Air embolism		1				1
Aneurysm	1	1			1	1
Aneurysm ruptured	1	2			1	2
Aortic aneurysm	1	1	1	1		
Aortic arteriosclerosis	2	3	1	1	1	2
Aortic dilatation	1	1			1	1
Aortic dissection	1	3			1	3
Aortic stenosis	1	2			1	2
Arterial disorder	1	2			1	2
Arterial occlusive disease	1	1			1	1
Arterial thrombosis	2	4			2	4
Arteriosclerosis	2	4	1	1	1	3
Arteritis	1	1			1	1
Artery dissection	2	2			2	2
Axillary vein thrombosis		1		1		
Blood pressure fluctuation	3	9		3	3	6
Blood pressure inadequately controlled	2	3			2	3
Blue toe syndrome		1		1		
Capillary fragility	1	1			1	1
Capillary leak syndrome	1	1			1	1
Circulatory collapse	1	7			1	7
Claudication of jaw muscles		1				1
Cyanosis	4	14	2	4	2	10
Deep vein thrombosis	107	152			107	152
Dependent rubor		1				1
Embolism	1	2			1	2
Embolism venous		1				1
Extremity necrosis	1	3		1	1	2
Flushing	5	21	3	8	2	13
Giant cell arteritis	3	11			3	11
Haematoma	8	25	1	4	7	21

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* AE=Adverse Event

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System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemodynamic instability	1	3		2	1	1
Haemorrhage		1				1
Hot flush	11	61	6	30	5	31
Hypertension	208	691	26	93	182	598
Hypertensive crisis	35	185			35	185
Hypertensive urgency		1				1
Hypoperfusion		2		1		1
Hypotension	33	173	6	35	27	138
Hypotensive crisis		1				1
Hypovolaemic shock		2				2
Infarction	1	5			1	5
Intermittent claudication	1	1			1	1
Ischaemia		1				1
Ischaemic limb pain		1				1
Jugular vein distension		1				1
Jugular vein thrombosis	2	4			2	4
Labile blood pressure	1	2			1	2
Lymphoedema	2	6	1	4	1	2
Malignant hypertension		1				1
Microangiopathy	1	1			1	1
Microembolism		1				1
Orthostatic hypertension	1	1			1	1
Orthostatic hypotension	1	5		1	1	4
Pallor	7	32	3	5	4	27
Pelvic venous thrombosis	2	2			2	2
Peripheral arterial occlusive disease	1	1			1	1
Peripheral artery occlusion	1	1			1	1
Peripheral artery thrombosis	5	8			5	8
Peripheral coldness	6	16	4	11	2	5
Peripheral embolism		1				1
Peripheral ischaemia	6	15	3	3	3	12
Peripheral venous disease	1	3	1	2		1

* I=Interval, C=Cumulative

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System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Phlebitis	13	28	2	8	11	20
Phlebitis superficial	2	4	1	3	1	1
Raynaud's phenomenon	2	5	2	4		1
Shock	4	9			4	9
Shock haemorrhagic	1	3			1	3
Subclavian vein thrombosis	1	2			1	2
Superior vena cava syndrome		1				1
Systolic hypertension	2	3			2	3
Thrombophlebitis	11	20	2	3	9	17
Thrombophlebitis superficial	24	38	1	6	23	32
Thrombosed varicose vein		1				1
Thrombosis	16	28			16	28
Varicose vein		1		1		
Vascular occlusion	1	1			1	1
Vascular pain	1	2	1	2		
Vascular rupture	1	1			1	1
Vascular stenosis		1				1
Vasculitis	5	7	3	4	2	3
Vasoconstriction		1		1		
Vasodilatation		1		1		
Vein rupture		2				2
Vena cava thrombosis		2				2
Venous thrombosis	4	7			4	7
Venous thrombosis limb	5	12	1	2	4	10
Withdrawal hypertension	1	3		1	1	2
	575	1,695	72	249	503	1446

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Country Where Event Occurred

FRENCH GUIANA

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cerebral venous sinus thrombosis	1	1	1	1
Ischaemic stroke	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

FRENCH POLYNESIA

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cardiopulmonary failure		1		1
		1		1

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Asthenia	1	3	1	3
Hyperthermia		1		1
	1	4	1	4

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Staphylococcal sepsis		1		1
		1		1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Oxygen saturation decreased		1		1
		1		1

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Arthralgia		1		1
		1		1

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Apraxia	1	1	1	1
Dysstasia	1	2	1	2
Facial paralysis	1	1	1	1
Hyperaesthesia		1		1
Memory impairment		1		1
Movement disorder		1		1
	3	7	3	7

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Confusional state		1		1
		1		1

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute respiratory distress syndrome		1		1
Dyspnoea	1	2	1	2
Haemoptysis		1		1
Pulmonary embolism		1		1
	1	5	1	5

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Dermatitis bullous		1		1
Dermatosis		1		1
Toxic epidermal necrolysis		1		1
		3		3

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Country Where Event Occurred
FRENCH SOUTHERN TERRITORIES

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Death		1		1
		1		1

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Country Where Event Occurred

GAMBIA

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Oedema peripheral		1		1
		1		1

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Blood creatinine increased		1		1
		1		1

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypertension		1		1
		1		1

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Country Where Event Occurred

GEORGIA

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Pneumonia		1		1
Sepsis		1		1
		2		2

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Poor quality product administered	1	1	1	1
	1	1	1	1

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Liquid product physical issue	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

GERMANY

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- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Agranulocytosis		1						1
Anaemia	3	6			2	3	1	3
Blood disorder		1						1
Coagulopathy	2	4			1	1	1	3
Disseminated intravascular coagulation		1						1
Eosinophilia		1						1
Evans syndrome		1						1
Factor VIII inhibition		1						1
Haemolytic uraemic syndrome	1	2					1	2
Haemorrhagic diathesis	2	2					2	2
Immune thrombocytopenia	4	13					4	13
Leukocytosis		1						1
Leukopenia	4	5					4	5
Lymphadenitis	5	11			4	8	1	3
Lymphadenopathy	75	150		1	74	145	1	5
Lymphatic disorder	2	2			2	2		
Lymph node pain	23	44			23	44		
Lymphocytic infiltration		1						1
Lymphopenia	1	5				1	1	4
Microcytic anaemia		2						2
Monocytosis		1						1
Neutropenia		2						2
Normocytic anaemia	1	1					1	1
Pancytopenia	1	3					1	3
Polycythaemia	1	1					1	1
Splenomegaly	1	1					1	1
Spontaneous haematoma	1	1					1	1
Thrombocytopenia	11	19					11	19
Thrombotic microangiopathy	1	1					1	1
	139	284		1	106	204	33	80

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute coronary syndrome		5						5
Acute myocardial infarction	6	27					6	27
Acute right ventricular failure		1						1
Angina pectoris	11	27					11	27
Aortic valve stenosis		1						1
Arrhythmia	21	62		1			21	62
Atrial fibrillation	5	27					5	27
Atrial flutter		1				1		
Atrial tachycardia		1						1
Atrioventricular block complete		5						5
Atrioventricular block first degree		1				1		
Bradyarrhythmia		1						1
Bradycardia	1	7					1	7
Bundle branch block right		2						2
Cardiac aneurysm		1						1
Cardiac arrest	7	27					7	27
Cardiac discomfort	1	3			1	2		1
Cardiac disorder	2	2			1	1	1	1
Cardiac failure	4	44					4	44
Cardiac failure acute	2	3					2	3
Cardiac failure congestive	1	5					1	5
Cardiac fibrillation		2						2
Cardiac hypertrophy	2	2			1	1	1	1
Cardiac valve disease	1	1					1	1
Cardiac ventricular thrombosis	1	1					1	1
Cardiogenic shock	4	11					4	11
Cardiomyopathy	2	3					2	3
Cardiopulmonary failure		1						1
Cardio-respiratory arrest		2						2
Cardiovascular disorder	19	59			15	41	4	18
Cardiovascular insufficiency	3	11					3	11
Coronary artery disease	3	4					3	4

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* AE=Adverse Event

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System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Coronary artery dissection		1						1
Coronary artery stenosis		1						1
Coronary artery thrombosis	1	2					1	2
Cor pulmonale	1	2					1	2
Extrasystoles		2				1		1
Hypertensive heart disease	1	1					1	1
Intracardiac thrombus	2	2					2	2
Ischaemic cardiomyopathy		1						1
Left ventricular failure		1						1
Myocardial infarction	19	29					19	29
Myocardial ischaemia		1						1
Myocarditis	26	39					26	39
Palpitations	23	84		4	21	60	2	24
Pericardial effusion	2	4					2	4
Pericarditis	1	2					1	2
Right ventricular failure	1	2					1	2
Sinus tachycardia	1	7			1	2		5
Stress cardiomyopathy	1	1					1	1
Supraventricular extrasystoles		4				2		2
Supraventricular tachycardia	1	3			1	2		1
Tachyarrhythmia	1	5				1	1	4
Tachycardia	27	126		6	22	70	5	56
Tachycardia induced cardiomyopathy		1						1
Ventricle rupture	1	1					1	1
Ventricular extrasystoles	1	3				1	1	2
Ventricular fibrillation	2	6					2	6
Ventricular tachycardia	1	3					1	3
	209	684		11	63	186	146	498

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* AE=Adverse Event

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Huntington's disease	1	4	1	1		3
Klippel-Trenaunay syndrome	1	1			1	1
	2	5	1	1	1	4

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness	2	9			2	9
Deafness bilateral		1				1
Deafness transitory		1				1
Deafness unilateral	1	3			1	3
Ear congestion	1	1	1	1		
Ear discomfort	5	9	4	6	1	3
Ear pain	6	13	5	12	1	1
Ear swelling	1	1	1	1		
Hyperacusis		1		1		
Hypoacusis	5	7	4	5	1	2
Motion sickness	1	1	1	1		
Presbycusis		1				1
Sudden hearing loss	2	11			2	11
Tinnitus	13	23	11	17	2	6
Vertigo	3	14	2	12	1	2
	40	96	29	56	11	40

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Autoimmune thyroiditis		2		2
Basedow's disease	1	2	1	2
Hyperthyroidism		2		2
Hypothyroidism	1	2	1	2
Thyroiditis acute		1		1
	2	9	2	9

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Age-related macular degeneration	1	1					1	1
Amaurosis fugax		1						1
Asthenopia		1				1		
Blepharitis		1				1		
Blindness	1	1					1	1
Blindness transient	1	1					1	1
Blindness unilateral		1						1
Conjunctival haemorrhage	1	3					1	3
Conjunctival hyperaemia		1						1
Dark circles under eyes		1				1		
Diplopia	2	8			1	4	1	4
Dry age-related macular degeneration		1						1
Dry eye	1	3			1	3		
Endocrine ophthalmopathy	1	1					1	1
Episcleritis		1				1		
Eye discharge	1	1			1	1		
Eye disorder	1	1					1	1
Eye haemorrhage	2	6					2	6
Eye infarction	1	1					1	1
Eye inflammation	1	1			1	1		
Eye irritation	5	11			5	10		1
Eyelid exfoliation	1	1			1	1		
Eyelid function disorder	1	1					1	1
Eyelid haematoma	1	1			1	1		
Eyelid irritation	1	1			1	1		
Eyelid oedema		4				1		3
Eyelid ptosis	1	1			1	1		
Eye oedema	1	1			1	1		
Eye pain	6	12			6	12		
Eye pruritus	3	12			3	6		6
Eye swelling	5	10			5	9		1
Hypoaesthesia eye	1	1			1	1		

* I=Interval, C=Cumulative

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Iridocyclitis		2
Keratoconus		1
Lacrimation increased	3	12
Macular degeneration		
Macular hole		
Ocular discomfort	4	9
Ocular hyperaemia	4	10
Ocular myasthenia	1	1
Oculogyric crisis		1
Open angle glaucoma	1	1
Ophthalmic vein thrombosis	5	9
Optic atrophy	1	1
Optic ischaemic neuropathy		1
Optic nerve disorder		
Optic neuropathy		1
Papilloedema		1
Photophobia	3	3
Photopsia		2
Pupillary disorder		1
Pupils unequal		1
Retinal artery occlusion	1	2
Retinal detachment	1	1
Retinal disorder		1
Retinal tear		2
Retinal vein thrombosis	2	3
Retinopathy		1
Sudden visual loss		1
Swelling of eyelid	4	7
Vision blurred		11
Visual acuity reduced	2	3
Visual field defect	2	5
Visual impairment	13	43

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
		3	9		3
1	1				
1	1				
		4	8		1
		4	8		2
				1	1
					1
				1	1
				5	9
				1	1
					1
1	1				
					1
					1
		3	3		
			2		
			1		
					1
				1	2
				1	1
					1
					2
				2	3
					1
					1
		4	6		1
			6		5
		1	1	1	2
		1	2	1	3
		11	20	2	23

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* AE=Adverse Event

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vitreous disorder	87	230	3	3	60	123	27	107

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* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	2	7			1	6	1	1
Abdominal distension	1	2			1	2		
Abdominal pain	21	51		1	19	37	2	14
Abdominal pain lower	8	15			8	13		2
Abdominal pain upper	9	27			7	19	2	8
Abnormal faeces	10	24			10	23		1
Acute abdomen		3						3
Anaesthesia oral	1	1			1	1		
Anorectal disorder		1						1
Aphthous ulcer	1	2			1	1		1
Ascites	1	2					1	2
Autoimmune pancreatitis	1	1					1	1
Bowel movement irregularity		1				1		
Colitis ulcerative	2	6					2	6
Constipation	3	5			3	5		
Defaecation urgency		1				1		
Diarrhoea	63	189		11	56	158	7	31
Diarrhoea haemorrhagic	3	3					3	3
Dry mouth	4	16			4	11		5
Dyspepsia		4				4		
Dysphagia	4	26				12	4	14
Enteritis	1	3			1	1		2
Eructation	1	1			1	1		
Faecaloma	1	1					1	1
Faeces discoloured		1				1		
Flatulence	1	7		1	1	6		1
Frequent bowel movements	1	1			1	1		
Functional gastrointestinal disorder		1				1		
Gastric dilatation	1	1			1	1		
Gastric disorder	1	1			1	1		
Gastritis	1	2			1	2		
Gastrointestinal disorder	1	3			1	2		1

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastrointestinal haemorrhage	2	2
Gastrointestinal inflammation	1	1
Gastrointestinal motility disorder		1
Gastrointestinal necrosis		3
Gastrointestinal pain	3	6
Gingival bleeding		3
Gingival pain	1	1
Gingival swelling	1	3
Glossitis	1	1
Haematemesis		4
Haematochezia	4	8
Hypoaesthesia oral	5	18
Ileus		1
Ileus paralytic	1	3
Intestinal haemorrhage	1	2
Intestinal infarction	1	2
Intestinal ischaemia	1	3
Intestinal obstruction		2
Large intestine perforation	1	1
Lip oedema		2
Lip pain	1	1
Lip swelling	5	15
Mesenteric vascular occlusion	1	1
Mesenteric vein thrombosis	2	6
Mouth haemorrhage		1
Mouth swelling	1	4
Nausea	137	339
Obstructive pancreatitis		1
Odynophagia	1	2
Oesophageal irritation		1
Oral discomfort	4	5
Oral mucosa erosion		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
		1	1		
			1		
					3
	1	3	3		3
			1		2
		1	1		
		1	2		1
		1	1		
					4
				4	8
		4	14	1	4
					1
				1	3
				1	2
				1	2
				1	3
					2
				1	1
			1		1
		1	1		
		5	6		9
				1	1
				2	6
			1		
		1	1		3
	35	129	289	8	50
					1
	1	1	2		
					1
		4	5		
			1		

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Oral mucosal blistering		1				1		
Oral mucosal eruption		1				1		
Oral mucosal erythema	2	2			2	2		
Oral pain		1						1
Palatal swelling		1						1
Pancreatitis acute	1	2					1	2
Pancreatitis necrotising	1	1					1	1
Paraesthesia oral	10	32			8	26	2	6
Rectal polyp		1				1		
Retching	1	7				5	1	2
Salivary gland enlargement		2				2		
Salivary hypersecretion	2	2			2	2		
Stomatitis		3						3
Subileus		2				1		1
Swollen tongue	5	24			4	13	1	11
Tongue coated	1	2			1	2		
Tongue discomfort	3	5			2	4	1	1
Tongue disorder	2	4			1	3	1	1
Tongue oedema		2						2
Tongue pruritus		1						1
Toothache		1				1		
Trichoglossia	2	3			1	2	1	1
Upper gastrointestinal haemorrhage		2						2
Visceral venous thrombosis		1						1
Vomiting	44	144		8	34	96	10	48
	392	1,100		58	326	804	66	296

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute phase reaction		1				1		
Adverse event	2	2			2	2		
Application site erythema	1	1			1	1		
Application site pain	1	1			1	1		
Application site vesicles		1						1
Application site warmth	1	1			1	1		
Asthenia	110	276			101	236	9	40
Axillary pain	6	16			6	15		1
Brain death		2						2
Cardiac death		1						1
Chest discomfort	17	33			13	23	4	10
Chest pain	18	46			15	33	3	13
Chills	263	536	1	26	254	498	9	38
Condition aggravated	9	23			3	9	6	14
Crepitations		1						1
Crying	1	1			1	1		
Death	60	266					60	266
Discomfort	5	6		3	5	5		1
Disease progression		1						1
Disease recurrence	4	17			1	6	3	11
Drug ineffective	81	354				1	81	353
Drug interaction	3	8			2	5	1	3
Effusion		1						1
Enanthema	1	2			1	1		1
Exercise tolerance decreased	1	1		1			1	1
Face oedema	2	5			2	4		1
Facial discomfort	3	3			3	3		
Facial pain	1	4			1	4		
Fatigue	356	818	1	56	349	777	7	41
Feeling abnormal	8	24			7	21	1	3
Feeling cold	37	75			36	68	1	7
Feeling drunk		1				1		

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Feeling hot	16	53
Feeling jittery		
Feeling of body temperature change	5	16
Gait disturbance	16	29
Gait inability	1	3
General physical health deterioration	7	68
Hunger	1	2
Hyperpyrexia	1	2
Hyperthermia		1
Hypothermia		4
Illness	4	10
Impaired healing		1
Induration	1	2
Inflammation	5	8
Influenza like illness	89	170
Injected limb mobility decreased	1	3
Injection site discomfort		1
Injection site hypoaesthesia	1	1
Injection site pain	4	7
Injection site swelling	2	2
Local reaction	8	26
Loss of control of legs	1	1
Malaise	74	189
Multimorbidity		1
Multi-organ disorder		1
Multiple organ dysfunction syndrome		9
Necrosis		1
No adverse event	1	3
Nodule		1
Oedema		4
Oedema peripheral	2	7
Organ failure		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		15	38	1	15
	1				
		5	16		
		9	15	7	14
		1	2		1
		4	21	3	47
		1	2		
				1	2
					1
					4
		4	9		1
					1
		1	2		
		4	4	1	4
		88	164	1	6
		1	3		
			1		
		1	1		
		4	7		
		2	2		
		7	21	1	5
				1	1
	50	70	157	4	32
					1
					1
					9
					1
		1	3		
			1		
			1		3
		2	5		2
					1

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pain	41	108
Performance status decreased	5	9
Peripheral swelling	17	40
Physical deconditioning	1	1
Pseudoallergic reaction		2
Pyrexia	292	673
Sensation of blood flow		1
Sensation of foreign body	1	20
Sense of oppression		1
Sudden cardiac death	2	5
Sudden death	12	39
Swelling	8	31
Swelling face	13	38
Systemic inflammatory response syndrome		1
Tenderness	4	5
Therapeutic response unexpected	7	16
Thirst	3	6
Vaccination failure	9	46
Vaccination site bruising		4
Vaccination site dermatitis		1
Vaccination site discolouration		1
Vaccination site discomfort	8	16
Vaccination site dysaesthesia	1	2
Vaccination site erythema	32	73
Vaccination site granuloma		1
Vaccination site haematoma	1	10
Vaccination site haemorrhage		3
Vaccination site hyperaesthesia		4
Vaccination site hypersensitivity		2
Vaccination site hypoaesthesia		1
Vaccination site induration	3	11
Vaccination site inflammation	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		39	88	2	20
		4	6	1	3
		14	30	3	10
		1	1		
			1		1
	26	281	572	11	101
			1		
		1	6		14
			1		
				2	5
				12	39
		7	26	1	5
	3	13	25		13
					1
		4	5		
		7	16		
	1	3	6		
				9	46
			4		
			1		
			1		
		8	16		
		1	2		
	1	31	68	1	5
			1		
		1	9		1
			3		
			4		
			2		
					1
		3	11		
	1	1	1		

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site irritation		1				1		
Vaccination site joint movement impairment		3				2		1
Vaccination site joint pain	1	3			1	3		
Vaccination site lymphadenopathy	4	8			4	8		
Vaccination site movement impairment	5	16			5	16		
Vaccination site oedema		1				1		
Vaccination site pain	272	792		53	270	776	2	16
Vaccination site papule		1				1		
Vaccination site paraesthesia	1	7			1	7		
Vaccination site pruritus	14	28			14	27		1
Vaccination site rash	4	8			4	7		1
Vaccination site reaction	13	26			13	24		2
Vaccination site swelling	43	109		12	43	104		5
Vaccination site urticaria	1	4			1	3		1
Vaccination site warmth	19	43		1	19	41		2
	2,069	5,377	2	235	1819	4120	250	1257

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System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholelithiasis		1		1		
Hepatic cirrhosis		1				1
Hepatic failure		4				4
Hepatic pain		1		1		
Hepatitis	2	2			2	2
Hepatitis cholestatic		2				2
Jaundice		3		2		1
Liver disorder		1				1
Ocular icterus		1		1		
	2	16		5	2	11

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Allergic oedema		3				1		2
Allergy to vaccine	4	9			2	4	2	5
Anaphylactic reaction	18	109					18	109
Anaphylactic shock	10	26		1			10	26
Anaphylactoid reaction		2						2
Autoimmune disorder	3	4					3	4
Drug hypersensitivity	1	1					1	1
Hypersensitivity	30	122		4	23	57	7	65
Immunisation reaction			1	1				
Reaction to excipient		1				1		
Seasonal allergy	2	3			2	3		
Type IV hypersensitivity reaction	1	5				4	1	1
	69	285	1	6	27	70	42	215

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* AE=Adverse Event

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abscess		1						1
Abscess limb		1						1
Abscess neck		1						1
Abscess rupture	1	1					1	1
Appendicitis				1				
Asymptomatic COVID-19	5	12			1	2	4	10
Atypical pneumonia		1						1
Beta haemolytic streptococcal infection	1	1					1	1
Blister infected		1				1		
Borrelia infection	2	2					2	2
Breast abscess	1	1					1	1
Bronchitis	1	5			1	3		2
Bronchitis bacterial		2						2
Cellulitis		1						1
Conjunctivitis	2	7			2	4		3
Coronavirus infection	1	12				8	1	4
COVID-19	124	575		1	42	166	82	409
COVID-19 pneumonia	1	22					1	22
Creutzfeldt-Jakob disease		2						2
Cystitis	2	3			2	3		
Diverticulitis	3	5					3	5
Encephalitis		3						3
Epstein-Barr virus infection reactivation		3						3
Erysipelas	5	9					5	9
Erythema migrans	1	1			1	1		
Escherichia infection		1						1
Eye infection	1	1			1	1		
Febrile infection		3						3
Genital herpes	2	3			2	3		
Gingivitis	1	3			1	1		2
Haematoma infection		1						1
Herpes dermatitis		1				1		

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Herpes ophthalmic	1	1
Herpes simplex		3
Herpes simplex encephalitis		1
Herpes simplex reactivation		1
Herpes virus infection	1	2
Herpes zoster	103	152
Herpes zoster infection neurological		2
Herpes zoster meningitis	2	4
Herpes zoster meningoencephalitis	1	1
Herpes zoster oticus		3
Herpes zoster reactivation		1
Hordeolum		1
Infection	2	10
Infection susceptibility increased	1	1
Infective exacerbation of chronic obstructive airways disease		2
Influenza	16	24
Intestinal gangrene		1
Localised infection		1
Lyme disease	1	1
Lymphangitis	1	2
Mastitis	1	1
Meningitis	1	2
Meningitis aseptic		1
Meningitis viral		1
Meningoencephalitis herpetic	2	2
Mycoplasma infection		1
Myelitis	1	3
Myocarditis infectious		1
Myocarditis septic		1
Nasopharyngitis	23	56
Ophthalmic herpes simplex	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			2		1
					1
					1
		1	2		
		94	131	9	21
					2
				2	4
				1	1
					3
			1		
			1		
	1	1	4	1	6
				1	1
					2
		16	22		2
					1
			1		
				1	1
				1	2
				1	2
					1
					1
				2	2
			1		
				1	3
					1
					1
	1	23	50		6
				1	1

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ophthalmic herpes zoster	3	5
Oral candidiasis		1
Oral fungal infection		1
Oral herpes	5	9
Otitis media		1
Pathogen resistance		1
Peritonitis		1
Pharyngitis		2
Pharyngitis bacterial	1	1
Pneumonia	14	52
Pneumonia bacterial		2
Pneumonia streptococcal	1	1
Pneumonia viral		1
Postoperative wound infection	1	1
Pulmonary sepsis		2
Pustule	5	11
Pyelonephritis acute	1	1
Rash pustular	2	3
Respiratory tract infection		6
Respiratory tract infection viral		1
Rhinitis	4	7
SARS-CoV-2 sepsis		1
Sepsis	2	5
Septic arthritis staphylococcal		1
Septic shock	1	4
Sialoadenitis		1
Sinusitis	2	4
Soft tissue infection		1
Staphylococcal sepsis		2
Subcutaneous abscess		1
Superinfection bacterial		3
Suspected COVID-19	4	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	5
					1
					1
		5	8		1
			1		
					1
					1
			2		
				1	1
				14	52
					2
				1	1
					1
				1	1
					2
	1	5	9		2
				1	1
		2	3		
					6
			1		
		4	7		
					1
				2	5
					1
				1	4
					1
		2	4		
					1
					2
					1
					3
		2	2	2	6

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tonsillitis	1	1			1	1		
Tonsillitis bacterial		2						2
Upper respiratory tract infection		5				1		4
Urinary tract infection		3				1		2
Urosepsis		1						1
Vaccination site abscess	2	2					2	2
Vaccination site pustule		1				1		
Varicella		1				1		
Varicella zoster virus infection	1	2			1	2		
Vestibular neuronitis	1	2				1	1	1
Viral rash		2				2		
Vulvitis		1						1
Vulvovaginal mycotic infection	1	2			1	1		1
	364	1,135		5	211	457	153	678

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accidental exposure to product	1	2			1	2		
Accidental overdose		14				11		3
Booster dose missed	1	1			1	1		
Cardiac procedure complication	1	1					1	1
Cerebral ventricle collapse		1						1
Cervical vertebral fracture	1	1					1	1
Circumstance or information capable of leading to medication error	1	3			1	3		
Contusion	3	7				1	3	6
Cranio-cerebral injury		1						1
Epicondylitis	1	1			1	1		
Expired product administered	1	1			1	1		
Exposure during pregnancy	8	10			8	10		
Exposure via breast milk	6	14			6	14		
Exposure via skin contact	1	1			1	1		
Fall	10	31			2	4	8	27
Femoral neck fracture		1						1
Femur fracture		2						2
Fracture		1						1
Head injury		3						3
Inadequate aseptic technique in use of product		1				1		
Inappropriate schedule of product administration	16	45			16	45		
Incomplete course of vaccination	2	6			2	6		
Incorrect dose administered	4	7			4	7		
Incorrect route of product administration	34	110			33	108	1	2
Intentional product misuse		2				2		
Limb injury	1	1			1	1		
Maternal exposure before pregnancy	1	2			1	2		
Maternal exposure during pregnancy	32	69			30	66	2	3
Maternal exposure timing unspecified		1				1		
Medication error		1				1		
Muscle strain				1				

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nerve injury	1	1
Occupational exposure to product		1
Off label use	16	53
Overdose	4	6
Pelvic fracture		1
Peroneal nerve injury		1
Poisoning		1
Poor quality product administered	21	62
Product administered at inappropriate site	2	3
Product administered to patient of inappropriate age		1
Product administration error	2	2
Product dose omission issue		3
Product preparation error	1	4
Product preparation issue	2	10
Product prescribing error	1	1
Product storage error	10	12
Product use issue	7	27
Respiratory fume inhalation disorder		1
Rib fracture	1	1
Scratch		2
Skin abrasion		1
Skin laceration		1
Subdural haematoma		1
Tendon rupture		1
Thermal burn	1	1
Toxicity to various agents		1
Ulnar nerve injury	1	1
Underdose	3	24
Vaccination complication	6	10
Wound	1	2
Wrong product administered	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		
		16	53		
		4	4		2
					1
					1
					1
		21	60		2
		2	3		
			1		
		2	2		
			2		1
		1	4		
		2	10		
		1	1		
		10	12		
		6	26	1	1
					1
				1	1
			2		
					1
					1
					1
		1	1		
		3	24		
		4	4	2	6
		1	2		
		2	4		

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Wrong technique in product usage process	2	5			2	5		
	209	586		1	188	511	21	75

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Alanine aminotransferase increased	1	3
Amino acid level decreased		1
Antibody test abnormal		3
Antibody test negative	1	1
Aspartate aminotransferase increased	3	5
Blood calcium decreased		3
Blood calcium increased		1
Blood cholesterol increased		1
Blood count abnormal	1	2
Blood creatine phosphokinase increased	4	6
Blood creatine phosphokinase MB increased		1
Blood creatinine increased		1
Blood glucose abnormal		1
Blood glucose decreased	1	5
Blood glucose fluctuation		3
Blood glucose increased	1	4
Blood immunoglobulin M increased		1
Blood lactate dehydrogenase increased	2	4
Blood methaemoglobin present		1
Blood potassium decreased		4
Blood potassium increased	1	1
Blood pressure abnormal	1	3
Blood pressure decreased	4	20
Blood pressure immeasurable	1	3
Blood pressure increased	12	46
Blood pressure systolic increased	1	2
Blood sodium decreased		2
Blood test abnormal	1	2
Blood thyroid stimulating hormone increased		1
Blood uric acid increased	2	2
Blood urine present		2
Body temperature decreased	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		2
			1		
			3		
				1	1
		2	3	1	2
			2		1
			1		
			1		
		1	1		1
		2	3	2	3
			1		
					1
			1		
			2	1	3
			2		1
			3	1	1
			1		
		1	1	1	3
			1		
			1		3
				1	1
		1	3		
	1		6	4	14
				1	3
	2	8	26	4	20
				1	2
			1		1
		1	2		
			1		
		2	2		
					2
		1	3		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Body temperature fluctuation	1	1
Body temperature increased	52	111
Capillary nail refill test abnormal		2
Carbon dioxide decreased		1
Chest X-ray abnormal		1
Coagulation time prolonged		1
Complement factor C3 increased		1
Coronavirus test positive	1	3
C-reactive protein increased	7	19
CSF cell count increased	1	1
CSF protein increased	1	1
Digestive enzyme abnormal		1
Eastern Cooperative Oncology Group performance status worsened		1
Electrocardiogram QT prolonged		1
Electrocardiogram ST segment depression	1	2
Electrocardiogram T wave inversion		1
Electroencephalogram abnormal	1	1
Eosinophil count decreased		1
Fibrin D dimer increased	4	8
Gamma-glutamyltransferase increased	2	3
General physical condition abnormal		9
Glomerular filtration rate decreased		2
Glycosylated haemoglobin increased	1	1
Granulocyte count increased		1
Haematocrit decreased		2
Haematocrit increased	1	1
Haematology test abnormal	1	1
Haemoglobin decreased	1	6
Haemoglobin increased	1	1
Heart rate decreased	2	4
Heart rate increased	10	24

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
1	1	52	101		10
			1		1
					1
			1		
			1		
			1	1	2
		5	13	2	6
				1	1
				1	1
			1		
			1		
					1
				1	2
					1
		1	1		
			1		
		3	6	1	2
		2	2		1
					9
			2		
		1	1		
			1		
			2		
				1	1
				1	1
		1	3		3
				1	1
		1	1	1	3
		7	15	3	9

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Heparin-induced thrombocytopenia test positive		1
Hepatic enzyme increased	1	5
HIV test positive		1
Immature granulocyte count increased		1
Inflammatory marker increased	2	3
International normalised ratio decreased		1
International normalised ratio increased	1	2
Intraocular pressure increased	1	2
Lipase increased	1	2
Lipids increased	1	2
Liver function test abnormal	1	1
Liver function test increased		2
Low density lipoprotein increased		1
Lymphocyte count decreased		2
Lymphocyte count increased	1	1
Mean cell volume decreased	1	1
Misleading laboratory test result	1	1
Monocyte count decreased		1
Monocyte count increased	1	2
Muscle strength abnormal		1
Myoglobin blood increased		1
Natural killer T cell count decreased		1
Neutrophil count increased		1
Oxygen saturation decreased	4	19
Platelet count decreased	5	8
Platelet count increased	2	2
Platelet function test abnormal	1	1
PO2 decreased		1
Prostatic specific antigen increased	1	1
Protein urine present		1
Pulse absent		1
Pulse waveform abnormal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2	1	3
					1
			1		
		2	2		1
			1		
		1	2		
			1	1	1
		1	1		1
		1	2		
		1	1		
					2
			1		
			2		
				1	1
		1	1		
		1	1		
			1		
		1	2		
			1		
					1
			1		
			1		
		3	5	1	14
		1	2	4	6
				2	2
		1	1		
					1
		1	1		
			1		
					1
			1		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Quality of life decreased	1	1			1	1		
Red blood cell count decreased		2				2		
Red blood cell count increased	1	1					1	1
Red blood cell sedimentation rate increased	1	3			1	3		
Red cell distribution width decreased	2	2			1	1	1	1
Renal function test abnormal	1	1			1	1		
Respiratory rate decreased		1				1		
Respiratory rate increased	1	4			1	4		
SARS-CoV-2 ant body test		1				1		
SARS-CoV-2 ant body test negative	2	22			2	21		1
SARS-CoV-2 ant body test positive	5	37			4	35	1	2
SARS-CoV-2 test false positive		4				4		
SARS-CoV-2 test positive	5	50			3	33	2	17
Sensory level abnormal		4				3		1
Transaminases increased	3	6			2	4	1	2
Tryptase increased		1						1
Tumour marker increased	1	1					1	1
Urea urine	1	1			1	1		
Weight decreased	4	6			2	2	2	4
Weight increased	1	2			1	2		
White blood cell count decreased	2	5			1	4	1	1
White blood cell count increased	1	5			1	3		2
	183	582	1	4	131	391	52	191

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acidosis		1				1
Decreased appetite	14	38	13	31	1	7
Dehydration	3	9	3	4		5
Diabetes mellitus	1	3			1	3
Diabetes mellitus inadequate control		1				1
Diet refusal		6				6
Electrolyte depletion		1		1		
Electrolyte imbalance		1				1
Fluid retention		1		1		
Food refusal		3		1		2
Gout		1		1		
Hypercalcaemia		2				2
Hyperglycaemia	1	3	1	1		2
Hyperkalaemia		1				1
Hypernatraemia	1	1			1	1
Hypoglycaemia		2		2		
Hypokalaemia	1	1			1	1
Hyponatraemia	1	7		3	1	4
Hypophagia		2				2
Increased appetite	1	1	1	1		
Iron deficiency	1	1	1	1		
Lipid metabolism disorder		1		1		
Marasmus		1				1
Metabolic acidosis		1				1
Metabolic disorder		1				1
Obesity	2	2	2	2		
Overweight	1	1	1	1		
Polydipsia		1				1
Tetany		1				1
Type 1 diabetes mellitus		2				2
Type 2 diabetes mellitus	1	1			1	1
	28	98	22	51	6	47

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arthralgia	77	193
Arthritis		1
Arthritis reactive		1
Arthropathy	1	2
Back pain	25	51
Bone pain	11	34
Bursitis		2
Fibromyalgia	3	3
Fistula		1
Flank pain	1	2
Groin pain	1	2
Jaw clicking		1
Joint effusion	1	1
Joint range of motion decreased	3	7
Joint stiffness	2	2
Joint swelling	2	5
Limb deformity	1	1
Limb discomfort	44	81
Mobility decreased	5	23
Muscle discomfort	1	2
Muscle mass		1
Muscle spasms	10	22
Muscle swelling	1	2
Muscle tightness	3	6
Muscle twitching	2	14
Muscular weakness	17	35
Musculoskeletal chest pain	1	7
Musculoskeletal discomfort	1	3
Musculoskeletal disorder	1	2
Musculoskeletal pain	2	6
Musculoskeletal stiffness	5	8
Myalgia	131	349

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	22	75	177	2	16
					1
					1
		1	1		1
		25	48		3
		11	32		2
	1		1		1
		3	3		
					1
		1	2		
		1	2		
					1
		1	1		
		2	5	1	2
		2	2		
		2	3		2
		1	1		
		42	72	2	9
		4	17	1	6
		1	2		
			1		
		8	15	2	7
		1	2		
	1	2	5	1	1
		2	11		3
		15	26	2	9
		1	3		4
		1	3		
		1	2		
		2	4		2
		4	7	1	1
	35	128	330	3	19

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Myofascial spasm	1	1			1	1		
Myosclerosis		2						2
Myositis	1	3			1	2		1
Neck pain	25	53			24	50	1	3
Nuchal rigidity	1	3			1	2		1
Oligoarthritis		1						1
Osteoporosis		1				1		
Pain in extremity	295	625			286	589	9	36
Pain in jaw	1	3			1	3		
Polyarthritis	1	2					1	2
Polymyalgia rheumatica		2						2
Polymyositis	1	1					1	1
Rhabdomyolysis	2	5					2	5
Rheumatic disorder	1	3			1	2		1
Rheumatoid arthritis	6	8					6	8
Spinal disorder	1	2			1	1		1
Spinal pain	5	8			5	6		2
Systemic lupus erythematosus		1						1
Temporomand bular joint syndrome		1				1		
Tendonitis	1	2			1	1		1
Tendon pain	2	3			2	2		1
Tenosynovitis	1	2			1	2		
Trismus	2	2			1	1	1	1
Vertebral wedging		1						1
Weight bearing difficulty	1	2			1	1		1
	700	1,607		59	664	1443	36	164

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myeloid leukaemia		2		1		1
Breast cancer	2	2			2	2
Breast cancer recurrent	1	1			1	1
Chronic lymphocytic leukaemia	1	1			1	1
Histiocytosis	1	1			1	1
Leukaemia		1				1
Malignant melanoma		1				1
Malignant pleural effusion		1				1
Neoplasm		1				1
Neoplasm malignant	1	1			1	1
Pituitary tumour benign	1	1			1	1
Skin cancer	1	1			1	1
	8	14		1	8	13

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ageusia	5	17			5	16		1
Allodynia		1				1		
Altered state of consciousness		6		1				6
Amnesia	3	10			1	2	2	8
Amnesic disorder		1						1
Anaesthesia		1						1
Anosmia	2	9			2	8		1
Aphasia	3	21			2	7	1	14
Ataxia		7						7
Autonomic nervous system imbalance		2				1		1
Balance disorder	7	9			7	8		1
Basal ganglia haemorrhage		1						1
Basal ganglia infarction		1						1
Basilar artery occlusion		1						1
Basilar artery thrombosis		2						2
Bell's palsy	2	4					2	4
Brain injury		1						1
Brain oedema	1	4					1	4
Brain stem infarction	2	3					2	3
Brain stem ischaemia	2	2					2	2
Burning sensation	5	24			4	14	1	10
Burning sensation mucosal	1	1			1	1		
Carotid artery occlusion		1						1
Cerebellar ataxia		1						1
Cerebellar syndrome		2						2
Cerebral artery embolism	1	1					1	1
Cerebral artery occlusion	1	1					1	1
Cerebral atrophy		1						1
Cerebral haemorrhage	11	26					11	26
Cerebral infarction	9	23					9	23
Cerebral ischaemia	1	7					1	7
Cerebral thrombosis	1	3					1	3

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* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebral venous sinus thrombosis	15	22
Cerebral venous thrombosis		2
Cerebrovascular accident	21	69
Cerebrovascular disorder	2	3
Cervical radiculopathy	1	1
Chronic inflammatory demyelinating polyradiculoneuropathy		1
Clonus		1
Cluster headache		1
Cognitive disorder	1	4
Coma	1	3
Coordination abnormal	1	2
Cranial nerve disorder		2
Dementia	1	8
Dementia of the Alzheimer's type, with delirium		1
Demyelinating polyneuropathy	1	1
Depressed level of consciousness	1	10
Disturbance in attention	16	56
Dizziness	141	395
Dizziness postural		2
Dysaesthesia	3	12
Dysarthria	2	8
Dysgeusia	7	21
Dysgraphia	1	2
Dyskinesia	1	2
Dyslalia		1
Dysstasia	1	3
Electric shock sensation		1
Embolic cerebral infarction	1	2
Embolic stroke		1
Encephalitis autoimmune	1	2
Epilepsy	5	36

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				15	22
					2
				21	69
				2	3
		1	1		
					1
			1		1
		1	2		2
				1	3
		1	1		1
			2		
				1	8
					1
				1	1
			1	1	9
		16	43		13
	41	130	310	11	85
			1		1
		3	7		5
		1	2	1	6
		6	17	1	4
		1	2		
		1	1		1
					1
			2	1	1
			1		
				1	2
					1
				1	2
				5	36

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Essential tremor		1
Extrapyramidal disorder		2
Facial nerve disorder		2
Facial paralysis	15	52
Facial paresis	18	51
Fine motor skill dysfunction	1	1
Formication	2	3
Freezing phenomenon	1	1
Generalised tonic-clonic seizure		3
Guillain-Barre syndrome	5	7
Headache	458	1,068
Head discomfort	7	18
Hemiataxia	1	1
Hemiparaesthesia		3
Hemiparesis	7	27
Hemiplegia		4
Hyperaesthesia	3	9
Hypersomnia	3	8
Hypertonia		2
Hypoaesthesia	28	75
Hypogeusia	1	1
Hypokinesia	1	2
Hyporesponsive to stimuli		1
Hyposmia	1	1
Hypotonia	10	26
Idiopathic intracranial hypertension		2
IIIrd nerve paresis	1	2
Intracranial aneurysm		1
Ischaemic cerebral infarction		4
Ischaemic stroke	1	6
IVth nerve disorder		1
IVth nerve paresis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		1
			1		1
				15	52
		6	23	12	28
		1	1		
		2	3		
				1	1
					3
				5	7
1	57	440	973	18	95
		4	13	3	5
				1	1
					3
				7	27
					4
		3	8		1
		3	6		2
			1		1
	2	23	60	5	15
				1	1
		1	2		
					1
				1	1
		8	18	2	8
					2
				1	2
					1
					4
				1	6
					1
					1

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Language disorder	1	3
Lhermitte's sign		1
Loss of consciousness	9	34
Memory impairment		5
Meningism		3
Mental impairment	1	2
Migraine	15	25
Migraine with aura	1	1
Migraine without aura	1	1
Miller Fisher syndrome	1	1
Monoparesis	2	5
Monoplegia	3	7
Motor dysfunction		1
Movement disorder	10	22
Multiple sclerosis	2	4
Multiple sclerosis relapse	1	5
Muscle contractions involuntary		1
Muscle spasticity	1	2
Myasthenia gravis		1
Myoclonus		2
Nervous system disorder	3	8
Neuralgia	20	30
Neuralgic amyotrophy		5
Neuritis		4
Neurological symptom	1	1
Neuropathy peripheral	1	3
Nystagmus		1
Occipital neuralgia		1
Optic neuritis	1	3
Orthostatic intolerance		2
Paraesthesia	42	133
Paralysis	3	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
			1		
				9	34
			2		3
			1		2
				1	2
		14	22	1	3
		1	1		
		1	1		
				1	1
		1	2	1	3
				3	7
					1
		7	13	3	9
1	1			2	4
1	1			1	5
					1
		1	1		1
					1
			1		1
		1	2	2	6
		20	30		
			1		4
			3		1
		1	1		
				1	3
					1
			1		
				1	3
			1		1
	3	36	89	6	44
				3	7

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Paresis		7
Paresis cranial nerve	1	1
Parkinsonian rest tremor		1
Parkinsonism		1
Parkinson's disease	1	3
Parosmia	5	8
Partial seizures		2
Petit mal epilepsy		1
Pleocytosis		3
Polyneuropathy	1	7
Post herpetic neuralgia	1	1
Postictal state		1
Presyncope	5	21
Psychogenic seizure	1	1
Psychomotor hyperactivity		2
Psychomotor skills impaired	1	1
Pyramidal tract syndrome		1
Quadriparesis		2
Radiculopathy		2
Reduced facial expression	1	1
Resting tremor		1
Retrograde amnesia		2
Reversible cerebral vasoconstriction syndrome		1
Seizure	7	41
Sensorimotor disorder	1	1
Sensory disturbance	20	46
Sensory loss		2
Slow speech	1	1
Somnolence	32	66
Speech disorder	2	9
Spinal cord ischaemia		1
Status epilepticus		7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		4
				1	1
			1		
					1
				1	3
		4	6	1	2
					2
					1
			1		2
1	1			1	7
		1	1		
					1
		5	15		6
				1	1
					2
		1	1		
					1
					2
			1		1
		1	1		
					1
			1		1
					1
				7	41
		1	1		
		18	40	2	6
			1		1
		1	1		
		24	44	8	22
		1	4	1	5
					1
					7

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Stupor		1						1
Subarachnoid haemorrhage		3						3
Sudden onset of sleep		1						1
Superior sagittal sinus thrombosis	1	2					1	2
Syncope	18	84		1			18	84
Taste disorder	2	9			2	7		2
Tension headache		2				1		1
Thalamic infarction		1						1
Tonic convulsion		1						1
Transient aphasia		1						1
Transient global amnesia	1	3				1	1	2
Transient ischaemic attack	2	7					2	7
Tremor	9	44			3	20	6	24
Trigeminal nerve paresis	1	1					1	1
Trigeminal neuralgia	1	3			1	3		
Trigeminal neuritis	1	1			1	1		
Unresponsive to stimuli	1	11					1	11
Vascular dementia		1						1
Vascular encephalopathy		1						1
Vlth nerve paralysis		1						1
	1,081	3,002	4	108	821	1890	260	1112

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion missed		1		1
Abortion spontaneous		4		4
Pregnancy with contraceptive device		1		1
Premature separation of placenta	1	1	1	1
	1	7	1	7

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Embedded device		1				1
Liquid product physical issue	3	3	3	3		
Product complaint		1		1		
Product leakage		1		1		
Product quality issue	1	3	1	3		
Product supply issue		2		2		
Product temperature excursion issue	9	45	9	43		2
Suspected counterfeit product		1		1		
	13	57	13	54		3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour	1	1	1	1		
Acute stress disorder		2				2
Aggression		3				3
Agitation		5		1		4
Anger	1	1	1	1		
Anxiety	4	11	4	8		3
Apathy	2	11	2	6		5
Automatism		1				1
Bradyphrenia	1	1	1	1		
Chronic idiopathic pain syndrome	1	1	1	1		
Communication disorder		1		1		
Confusional state	5	21	3	7	2	14
Delirium	1	7			1	7
Delusion		2				2
Depressed mood	2	3	2	2		1
Depression	2	8	2	7		1
Depressive symptom	1	1	1	1		
Disorientation	2	10		4	2	6
Dysphemia	1	1	1	1		
Eating disorder		2		2		
Emotional disorder		1				1
Enuresis	1	1			1	1
Euphoric mood	1	1	1	1		
Fear	1	2	1	1		1
Feeling of despair		1		1		
Hallucination	4	8			4	8
Hallucination, auditory		1				1
Hallucinations, mixed		1				1
Hallucination, visual	2	2			2	2
Initial insomnia	1	3	1	3		
Insomnia	15	26	14	24	1	2
Lack of spontaneous speech	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Listless	2	5	2	4		1
Mental disorder	1	5	1	3		2
Middle insomnia		3		3		
Mood altered	1	1	1	1		
Nervousness		1		1		
Panic attack	1	5		1	1	4
Panic disorder		1		1		
Panic reaction	1	2	1	2		
Paranoia		1				1
Personality change		8		1		7
Phobia	1	1	1	1		
Poor quality sleep	2	9	2	7		2
Psychological factor affecting medical condition		1				1
Psychomotor retardation	1	2	1	1		1
Restlessness	9	22	7	17	2	5
Sleep disorder	9	20	9	20		
Somatic symptom disorder		1				1
Sopor		1				1
Stress	3	6	3	5		1
Suicidal ideation	1	1			1	1
Tension	1	2	1	2		
Thinking abnormal	1	1	1	1		
	84	240	67	146	17	94

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	6	21			6	21
Bladder discomfort	1	3	1	3		
Bladder dysfunction		1				1
Bladder irritation	1	1	1	1		
Bladder pain	1	2	1	2		
Chronic kidney disease		2				2
Cystitis haemorrhagic		1				1
Diabetic nephropathy	1	1	1	1		
Dysuria	1	3	1	1		2
Glomerulonephritis minimal lesion		1				1
Haematuria	1	2	1	2		
Incontinence	2	3	1	1	1	2
Micturition disorder		1		1		
Micturition urgency		1		1		
Nephrolithiasis		1				1
Nephrotic syndrome		1				1
Oliguria		1				1
Pollakiuria	2	4	2	4		
Polyuria		1				1
Proteinuria	1	2	1	1		1
Renal disorder	1	3	1	1		2
Renal failure	3	16			3	16
Renal impairment		1				1
Renal pain	2	6	2	4		2
Urinary incontinence	2	2	1	1	1	1
Urinary retention		1				1
Urinary tract inflammation		1				1
Urine odour abnormal		1		1		
	25	84	14	25	11	59

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Amenorrhoea	1	1					1	1
Aspermia	1	1			1	1		
Breast inflammation	1	1					1	1
Breast pain	2	4		1	1	3	1	1
Breast swelling	1	1					1	1
Cervix haematoma uterine		1						1
Dysmenorrhoea	4	4			4	4		
Endometriosis	1	1			1	1		
Erectile dysfunction	3	3					3	3
Genital haemorrhage		1						1
Heavy menstrual bleeding	7	8			6	7	1	1
Menstrual disorder	3	9			3	9		
Menstruation irregular	3	4			2	3	1	1
Pelvic pain		2				2		
Polymenorrhoea	1	1			1	1		
Prostatitis	1	1			1	1		
Vaginal haemorrhage	1	1			1	1		
Vulvovaginal discomfort		1						1
Vulvovaginal pain		1						1
Vulvovaginal swelling		1				1		
	30	47		1	21	34	9	13

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acute respiratory distress syndrome	1	6
Acute respiratory failure	1	5
Aspiration		4
Asthma	7	28
Bronchial disorder		1
Bronchial irritation	1	1
Bronchial obstruction		2
Bronchitis chronic		1
Bronchospasm	1	7
Chronic obstructive pulmonary disease	1	9
Cough	25	82
Diaphragmalgia		1
Dry throat	1	2
Dysphonia	2	14
Dyspnoea	59	226
Dyspnoea at rest	1	3
Dyspnoea exertional	8	22
Emphysema		1
Epistaxis	4	11
Haemoptysis	2	6
Haemothorax		1
Hyperventilation	1	12
Hypoventilation		1
Hypoxia		3
Increased upper airway secretion		1
Irregular breathing		2
Laryngeal obstruction		1
Laryngeal oedema	1	7
Laryngospasm		1
Lower respiratory tract congestion		1
Lung disorder	1	3
Lung infiltration		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	6
				1	5
					4
		6	18	1	10
			1		
		1	1		
					2
			1		
			2	1	5
		1	2		7
	1	23	63	2	19
			1		
		1	2		
		2	10		4
	2	37	106	22	120
				1	3
		7	12	1	10
					1
	1	3	8	1	3
		2	5		1
					1
		1	5		7
					1
					3
			1		
					2
					1
				1	7
					1
			1		
		1	3		
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nasal congestion	3	9
Nasal discomfort	1	1
Obstructive airways disorder		3
Organising pneumonia	2	2
Oropharyngeal blistering	1	3
Oropharyngeal discomfort		1
Oropharyngeal pain	22	48
Oropharyngeal swelling		1
Orthopnoea		2
Painful respiration	4	6
Pharyngeal erythema	1	1
Pharyngeal hypoaesthesia		2
Pharyngeal inflammation	1	2
Pharyngeal oedema		1
Pharyngeal paraesthesia		1
Pharyngeal swelling	1	13
Pleural effusion	2	4
Pleurisy		1
Pleuritic pain		1
Pneumonia aspiration		3
Pneumonitis	2	2
Productive cough	2	2
Pulmonary artery thrombosis	1	2
Pulmonary embolism	52	116
Pulmonary fibrosis		1
Pulmonary haemorrhage	1	2
Pulmonary hypertension		1
Pulmonary infarction	2	4
Pulmonary oedema	1	5
Pulmonary pain	4	6
Pulmonary sarcoidosis		1
Pulmonary thrombosis	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	8		1
		1	1		
					3
				2	2
				1	3
			1		
	1	22	45		3
					1
					2
		3	5	1	1
		1	1		
			2		
		1	2		
					1
			1		
	1		3	1	10
				2	4
					1
			1		
					3
				2	2
		2	2		
				1	2
				52	116
					1
				1	2
					1
				2	4
				1	5
		3	4	1	2
					1
				2	2

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Pulmonary vasculitis		1						1
Rales		1						1
Respiration abnormal	2	5			2	5		
Respiratory arrest	1	2					1	2
Respiratory disorder	3	3			3	3		
Respiratory distress	11	105					11	105
Respiratory failure	3	24					3	24
Respiratory symptom		1				1		
Respiratory tract inflammation		1						1
Respiratory tract oedema		1						1
Rhinalgia	1	3			1	3		
Rhinitis allergic		1						1
Rhinorrhoea	8	33			8	30		3
Rhonchi		2						2
Sinus congestion	1	3			1	3		
Sleep apnoea syndrome	2	2			1	1	1	1
Sneezing		8				7		1
Snoring		2				2		
Stridor	2	8					2	8
Suffocation feeling	1	1			1	1		
Tachypnoea	1	5				1	1	4
Throat clearing	1	1			1	1		
Throat irritation	4	21		1	4	20		1
Throat tightness	3	30			3	16		14
Tonsillar disorder	1	1			1	1		
Tonsillar hypertrophy		1				1		
Wheezing		6				2		4
	267	987		7	147	416	120	571

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acne	2	3			2	3		
Acute febrile neutrophilic dermatosis		2						2
Acute generalised exanthematous pustulosis		1						1
Alopecia	1	4			1	2		2
Alopecia areata		1				1		
Angioedema	6	40					6	40
Blister		7				5		2
Blood blister	2	2			2	2		
Circumoral oedema		1				1		
Cold sweat	3	15			3	8		7
Cutaneous vasculitis		3						3
Dermatitis	1	1					1	1
Dermatitis allergic	4	14			4	10		4
Dermatitis atopic		1				1		
Dermatitis bullous	1	2					1	2
Dermatitis contact	1	1			1	1		
Drug eruption	2	4			2	3		1
Dry skin	1	2			1	2		
Eczema	5	16			4	14	1	2
Eczema asteatotic	1	1			1	1		
Erythema	30	101		2	28	78	2	23
Erythema multiforme		1						1
Guttate psoriasis	1	1			1	1		
Hair disorder	1	1			1	1		
Hand dermatitis	1	1			1	1		
Hyperhidrosis	27	62		1	22	52	5	10
Hypersensitivity vasculitis		3						3
Koebner phenomenon	1	1			1	1		
Livedo reticularis		1				1		
Neurodermatitis	2	6			2	6		
Night sweats	6	12			6	12		
Onychoclasia		1				1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pain of skin	3	6
Pemphigus		2
Perioral dermatitis		1
Petechiae	6	18
Photosensitivity reaction	1	2
Prurigo		1
Pruritus	40	113
Pruritus allergic		2
Psoriasis	1	3
Purpura		1
Rash	44	128
Rash erythematous	5	11
Rash macular	6	12
Rash maculo-papular	3	9
Rash papular	1	3
Rash pruritic	12	26
Rash vesicular	6	10
Rosacea		1
Sensitive skin	2	3
Skin burning sensation	6	11
Skin discolouration	6	10
Skin disorder	1	2
Skin exfoliation		3
Skin haemorrhage	2	3
Skin irritation		1
Skin lesion		1
Skin necrosis	1	2
Skin reaction	3	4
Skin sensitisation	1	1
Skin swelling		2
Skin ulcer		1
Skin warm		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	6		
					2
			1		
		3	8	3	10
		1	2		
			1		
	2	38	84	2	29
			1		1
		1	2		1
					1
	4	40	83	4	45
		5	10		1
		5	11	1	1
		3	8		1
		1	3		
		10	21	2	5
		6	10		
					1
		2	3		
		6	9		2
		6	9		1
		1	1		1
			3		
		1	1	1	2
			1		
					1
				1	2
		3	4		
		1	1		
			2		
			1		
			1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Urticaria	23	66		1	22	50	1	16
Urticaria physical	1	1			1	1		
	273	773		10	242	546	31	227

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden		2		1		1
Impaired driving ability	1	1	1	1		
Impaired work ability	1	3	1	2		1
Loss of personal independence in daily activities	2	4	2	4		
	4	10	4	8		2

System Organ Class

Surgical and medical procedures

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cranial nerve decompression		1				1
Ileectomy		1				1
Medical induction of coma	1	1			1	1
Menstrual cycle management	2	2	2	2		
Resuscitation		1				1
Thrombectomy		1				1
	3	7	2	2	1	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Aortic aneurysm		3
Aortic arteriosclerosis	1	1
Aortic dissection		2
Arterial disorder	2	2
Arterial occlusive disease	3	4
Arterial thrombosis		2
Arteriosclerosis		2
Axillary vein thrombosis	1	1
Blood pressure fluctuation	1	6
Bloody discharge		1
Circulatory collapse	17	67
Cyanosis	5	14
Deep vein thrombosis	31	64
Embolism	1	2
Embolism arterial		1
Femoral artery embolism		1
Flushing	19	60
Giant cell arteritis	1	2
Haematoma	7	18
Haemorrhage	5	12
Hot flush	7	21
Hypertension	20	93
Hypertensive crisis	2	21
Hypertensive emergency		1
Hypotension	13	57
Infarction		2
Internal haemorrhage		1
Ischaemia	1	4
Jugular vein thrombosis	4	4
Lymphoedema	4	6
Microembolism		1
Microscopic polyangiitis		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
		1	1		
					2
		1	1	1	1
				3	4
					2
			1		1
				1	1
			5	1	1
			1		
	1			17	67
		3	6	2	8
				31	64
				1	2
					1
					1
		18	37	1	23
				1	2
		6	11	1	7
				5	12
		6	18	1	3
	3	12	38	8	55
				2	21
					1
		9	29	4	28
					2
					1
				1	4
				4	4
		3	5	1	1
					1
					2

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Orthostatic hypotension		2				2		
Pallor	1	9			1	3		6
Pelvic venous thrombosis	2	4					2	4
Peripheral circulatory failure	2	11			2	6		5
Peripheral coldness	6	9			6	9		
Peripheral embolism		3				1		2
Peripheral ischaemia		1						1
Peripheral vascular disorder	12	45		1	12	24		21
Phlebitis		1				1		
Poor peripheral circulation	1	1			1	1		
Raynaud's phenomenon		2				2		
Secondary hypertension		1				1		
Shock		3						3
Shock haemorrhagic		1						1
Subclavian artery thrombosis		1						1
Subclavian vein thrombosis	2	4					2	4
Thrombophlebitis	1	4			1	3		1
Thrombophlebitis superficial	5	8			2	4	3	4
Thrombosis	18	34					18	34
Varicophlebitis	1	1					1	1
Varicose vein		1				1		
Vascular occlusion		1						1
Vasculitis	1	5				1	1	4
Venous occlusion		1						1
Venous thrombosis	6	10					6	10
Venous thrombosis in pregnancy		1						1
Venous thrombosis limb	14	17			2	2	12	15
	217	659		5	86	214	131	445

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

GREECE

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia		1				1
Granulocytopenia	1	1			1	1
Haemolysis	1	1			1	1
Leukocytosis		2		1		1
Lymphadenitis	5	28	5	11		17
Lymphadenopathy	12	51	10	31	2	20
Lymph node pain	3	8	3	7		1
Lymphopenia		1		1		
Paratracheal lymphadenopathy		1				1
Thrombocytopenia	1	1			1	1
	23	95	18	51	5	44

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome	1	1			1	1
Acute myocardial infarction	3	6			3	6
Angina pectoris	1	2			1	2
Arrhythmia	2	12			2	12
Atrial fibrillation	7	14			7	14
Bradycardia	2	4			2	4
Cardiac arrest	4	12			4	12
Cardiac discomfort		1				1
Cardiac failure		1				1
Cardiac valve disease		1				1
Coronary artery stenosis	1	2			1	2
Coronary artery thrombosis		1				1
Extrasystoles		5		3		2
Left ventricular hypertrophy		1				1
Myocardial infarction	4	8			4	8
Myocarditis	3	4			3	4
Palpitations	4	33	4	18		15
Pericarditis	1	1			1	1
Supraventricular tachycardia	1	1			1	1
Systolic dysfunction	1	1			1	1
Tachyarrhythmia	1	1			1	1
Tachycardia	12	75	8	37	4	38
Ventricular arrhythmia		1				1
Ventricular fibrillation	1	1			1	1
	49	189	12	58	37	131

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypertrophic cardiomyopathy		1		1
		1		1

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness	1	2			1	2
Deafness unilateral		2				2
Ear pain	1	5		2	1	3
Hypoacusis		1				1
Inner ear disorder	1	1	1	1		
Tinnitus	1	10		6	1	4
Vertigo	4	16	3	11	1	5
	8	37	4	20	4	17

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Goitre		1				1
Thyroid cyst		1				1
Thyroiditis		2		1		1
Thyroiditis acute		1				1
		5		1		4

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blepharitis		1		1		
Blepharospasm		1		1		
Blindness	1	1			1	1
Conjunctival hyperaemia		2		2		
Diplopia	1	4			1	4
Dry eye		2		2		
Episcleritis		1				1
Eye haemorrhage		1				1
Eye irritation	1	3	1	3		
Eyelid irritation		1				1
Eyelid oedema		5		4		1
Eyelid ptosis	1	3			1	3
Eyelids pruritus		2		1		1
Eye oedema		1				1
Eye pain		1				1
Eye pruritus	1	3		1	1	2
Eye swelling		1				1
Iridocyclitis		1				1
Lacrimation increased	2	3	2	3		
Ocular hyperaemia		4		1		3
Ophthalmic artery thrombosis	1	2			1	2
Ophthalmoplegia	1	1			1	1
Papilloedema		1				1
Periorbital oedema		2		2		
Periorbital swelling		1		1		
Photophobia		1				1
Pupillary reflex impaired	1	1			1	1
Pupils unequal	1	1			1	1
Retinal artery thrombosis	1	1			1	1
Retinal vein thrombosis	1	1			1	1
Scleritis		1				1
Uveitis		5				5

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
			1	3	2	2
Vision blurred	3	5				
Visual impairment	1	3		1	1	2
	17	67	4	26	13	41

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal distension	1	2		1	1	1
Abdominal pain	8	20	5	11	3	9
Abdominal pain upper	4	12	2	9	2	3
Constipation		1		1		
Defaecation urgency		1				1
Diarrhoea	10	37	8	25	2	12
Dry mouth		9		7		2
Dyspepsia		5		3		2
Dysphagia	4	29	1	8	3	21
Enlarged uvula	1	4			1	4
Epigastric discomfort		1				1
Eructation		5		3		2
Flatulence		2				2
Gastrointestinal disorder	1	11	1	10		1
Gastrointestinal haemorrhage		1				1
Gastrointestinal hypermotility		1				1
Gastrointestinal pain	1	1	1	1		
Glossodynia		2				2
Haematochezia		1				1
Hypoaesthesia oral	9	37	7	19	2	18
Impaired gastric emptying		1				1
Lip oedema	3	12	1	4	2	8
Lip pain		2				2
Lip swelling	4	8	3	6	1	2
Mouth swelling	1	1	1	1		
Mouth ulceration		2		2		
Nausea	6	52	3	34	3	18
Oral discomfort		1		1		
Oral disorder	1	1			1	1
Oral mucosal erythema		1		1		
Pancreatitis		2				2

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Parotid gland enlargement		2		1		1
Salivary gland enlargement		1				1
Salivary gland pain		2		2		
Stomatitis	1	1			1	1
Swollen tongue	2	3	1	2	1	1
Teething		1				1
Tongue discomfort		1				1
Tongue oedema	1	6			1	6
Tongue ulceration		1		1		
Toothache	1	1	1	1		
Vomiting	8	33	4	16	4	17
	67	318	39	171	28	147

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	15	55	12	36	3	19
Axillary pain	1	3	1	2		1
Brain death		2				2
Chest discomfort	1	9		2	1	7
Chest pain	9	27	4	11	5	16
Chills	25	114	22	65	3	49
Condition aggravated	1	5	1	1		4
Crying		1		1		
Death	5	10			5	10
Discomfort		7		4		3
Disease recurrence	2	6			2	6
Drowning		1				1
Drug ineffective	11	33			11	33
Drug interaction		1				1
Face oedema		5		2		3
Fatigue	49	154	41	100	8	54
Feeling abnormal		1				1
Feeling cold		3		3		
Feeling drunk		1				1
Feeling hot	2	7	1	4	1	3
Fibrosis	1	1			1	1
Gait disturbance	2	12		5	2	7
Gait inability	1	3	1	1		2
Hyperpyrexia	1	1			1	1
Hypothermia	2	4			2	4
Illness		2		1		1
Impaired self-care		1				1
Inflammation		4		1		3
Influenza like illness		2		2		
Injection site erythema	1	1	1	1		
Injection site hypoaesthesia		1		1		
Injection site mass	1	1	1	1		

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* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site pain	4	5	4	5		
Localised oedema	1	4		1	1	3
Local reaction		2		2		
Malaise	11	44	10	30	1	14
Mucosal dryness		1				1
No adverse event	1	4	1	4		
Oedema	1	5		2	1	3
Oedema peripheral	2	6	2	4		2
Pain	13	43	6	22	7	21
Peripheral swelling	5	7	4	6	1	1
Pyrexia	88	263	73	179	15	84
Sensation of foreign body		1				1
Sudden death		3				3
Swelling	4	9	2	4	2	5
Swelling face		4		1		3
Terminal state		1				1
Therapeutic response unexpected	1	5	1	5		
Thirst		1		1		
Vaccination failure		4				4
Vaccination site bruising	2	3	2	3		
Vaccination site discomfort		5		5		
Vaccination site erythema	2	7	2	5		2
Vaccination site haemorrhage		1		1		
Vaccination site hyperaesthesia		1		1		
Vaccination site hypoaesthesia		4		3		1
Vaccination site induration		1		1		
Vaccination site inflammation	1	2	1	2		
Vaccination site irritation	1	2	1	1		1
Vaccination site lymphadenopathy		1				1
Vaccination site movement impairment		1		1		
Vaccination site oedema	3	10	3	9		1
Vaccination site pain	84	182	82	167	2	15

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pruritus	2	4	2	3		1
Vaccination site rash	2	4	1	3	1	1
Vaccination site reaction		1		1		
Vaccination site swelling		1		1		
Vaccination site warmth		3		2		1
	358	1,123	282	719	76	404

System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholecystitis	1	1			1	1
Cholelithiasis		1				1
Cholestasis	1	1			1	1
Hepatic function abnormal	1	1	1	1		
Hepatic pain	1	1	1	1		
Hepatitis		1				1
Hepatorenal syndrome	1	1			1	1
Hyperbilirubinaemia	1	1			1	1
Jaundice	2	2			2	2
Portal vein thrombosis	1	1			1	1
	9	11	2	2	7	9

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		4		1		3
Anaphylactic reaction	4	19			4	19
Anaphylactic shock		7				7
Anaphylactoid reaction		2				2
Hypersensitivity	5	41	1	16	4	25
Reaction to excipient		1				1
Sarcoidosis		1				1
	9	75	1	17	8	58

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abscess	1	1	1	1		
Asymptomatic COVID-19		5				5
Atypical pneumonia	1	1			1	1
Conjunctivitis		1		1		
COVID-19	12	47	2	12	10	35
Diverticulitis		1				1
Encephalitis	1	1			1	1
Gastroenteritis		1				1
Genital herpes zoster		1				1
Herpes dermatitis		1				1
Herpes ophthalmic		2				2
Herpes simplex reactivation		1		1		
Herpes zoster	6	23	4	13	2	10
Hordeolum		1		1		
Infection	1	2	1	2		
Influenza	1	1	1	1		
Listeriosis	1	1			1	1
Lower respiratory tract infection		1				1
Meningomyelitis herpes		1				1
Myelitis		2				2
Nasopharyngitis		1		1		
Ophthalmic herpes zoster	1	1			1	1
Oral herpes		4		3		1
Parotitis		1		1		
Pharyngeal abscess	1	1			1	1
Pharyngitis		1		1		
Pneumonia	1	2			1	2
Respiratory tract infection		3				3
Rhinitis		1		1		
Sputum purulent		1				1
Suspected COVID-19	3	5	2	3	1	2
Tonsillitis		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urinary tract infection		3		1		2
Viral infection		2		2		
	30	122	11	46	19	76

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accident	1	1			1	1
Arteriovenous graft thrombosis		1				1
Circumstance or information capable of leading to medication error		2		2		
Contusion	2	3	2	3		
Expired product administered		1		1		
Exposure via breast milk		1		1		
Fall	2	8	1	3	1	5
Femur fracture	1	2			1	2
Incomplete course of vaccination		1		1		
Incorrect route of product administration	3	7	3	7		
Injury		1		1		
Limb injury		1		1		
Lower limb fracture	1	1			1	1
Maternal exposure during pregnancy	1	5	1	5		
Muscle injury		1		1		
Muscle strain		1		1		
Occupational exposure to product		1		1		
Off label use		4		4		
Overdose		1		1		
Poor quality product administered		4		4		
Product preparation error		1		1		
Product use issue		3		3		
Tooth fracture	1	1	1	1		
Underdose	1	1	1	1		
Wrong technique in product usage process	1	3	1	3		
	14	56	10	46	4	10

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Activated partial thromboplastin time prolonged	1	1	1	1		
Alanine aminotransferase increased		2		2		
Amylase decreased	1	1	1	1		
Aspartate aminotransferase increased		1		1		
Audiogram abnormal		1		1		
Auscultation		1		1		
Blood calcium decreased		1		1		
Blood creatine phosphokinase increased	1	2	1	2		
Blood creatine phosphokinase MB increased	1	1	1	1		
Blood creatinine decreased	1	1	1	1		
Blood fibrinogen increased	1	1	1	1		
Blood gases abnormal		1				1
Blood glucose abnormal		3		2		1
Blood glucose decreased	1	1	1	1		
Blood glucose increased	1	2	1	2		
Blood iron decreased		1		1		
Blood lactate dehydrogenase increased	1	1	1	1		
Blood magnesium increased	1	1	1	1		
Blood parathyroid hormone increased	1	1	1	1		
Blood phosphorus decreased	1	1	1	1		
Blood potassium decreased	1	2	1	2		
Blood pressure abnormal		2				2
Blood pressure decreased		7		3		4
Blood pressure diastolic increased		2		2		
Blood pressure increased	15	70	11	37	4	33
Blood pressure systolic		1				1
Blood pressure systolic abnormal		1				1
Blood pressure systolic decreased	1	1	1	1		
Blood pressure systolic increased		5		1		4
Blood sodium increased	1	1	1	1		
Blood triglycerides increased		1				1
Blood urea increased		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Body temperature decreased	1	1	1	1		
Body temperature increased	1	1	1	1		
Carbohydrate antigen 125 increased		1		1		
Carcinoembryonic antigen increased		1				1
C-reactive protein increased	3	5	3	5		
CSF polymorphonuclear cell count increased		1				1
Ear, nose and throat examination abnormal		1		1		
Electrocardiogram repolarisation abnormality		1				1
Electromyogram abnormal		1		1		
Eosinophil count decreased	1	1	1	1		
Fibrin D dimer increased	1	3	1	2		1
Gamma-glutamyltransferase increased		1				1
Gastric pH decreased	1	1			1	1
Glycosylated haemoglobin decreased		1		1		
Haematocrit decreased	1	3	1	2		1
Haemoglobin decreased	1	2	1	2		
Heart rate abnormal		1				1
Heart rate decreased		5				5
Heart rate increased	1	25		16	1	9
Heart rate irregular		1				1
Immunoglobulins increased		1				1
International normalised ratio decreased	1	1	1	1		
Lymph node palpable	1	1	1	1		
Lymphocyte count decreased	1	1	1	1		
Neutrophil count decreased	1	1			1	1
Oxygen saturation abnormal		1				1
Oxygen saturation decreased		8		1		7
Platelet count decreased	1	1	1	1		
Platelet count increased		1		1		
Protein total decreased	1	2	1	2		
Prothrombin time prolonged	1	2	1	2		
Pulse abnormal		2		1		1

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* AE=Adverse Event

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulse absent		1				1
Red blood cell count decreased	1	1	1	1		
SARS-CoV-2 ant body test positive		2		2		
SARS-CoV-2 test positive	1	2		1	1	1
Transaminases increased	1	1	1	1		
Troponin increased	1	1	1	1		
Urine analysis abnormal	1	1	1	1		
White blood cell count decreased	1	2		1	1	1
White blood cell count increased	1	1	1	1		
	55	210	46	125	9	85

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cachexia		4				4
Decreased appetite	2	6	1	4	1	2
Dehydration		1				1
Diabetes mellitus inadequate control		4				4
Eating disorder symptom		1		1		
Feeding disorder		1		1		
Hypoalbuminaemia		1		1		
Hypoglycaemia	1	5		3	1	2
Hypokalaemia		2				2
Hyponatraemia		3		1		2
Insulin resistance		1				1
Polydipsia		1		1		
	3	30	1	12	2	18

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ankylosing spondylitis		1				1
Arthralgia	25	95	22	56	3	39
Arthritis		1		1		
Arthritis enteropathic		1				1
Back pain	4	14	3	11	1	3
Bone pain	5	10	5	8		2
Bursitis		2		1		1
Fibromyalgia		1		1		
Foot deformity		1				1
Intervertebral disc degeneration		1		1		
Intervertebral disc protrusion	1	2		1	1	1
Jaw disorder	1	1	1	1		
Joint effusion		1				1
Joint range of motion decreased		1		1		
Joint stiffness		1				1
Joint swelling	1	2	1	2		
Limb discomfort	2	6	1	3	1	3
Limb mass	2	2	2	2		
Mastication disorder	1	1	1	1		
Mobility decreased	3	3	1	1	2	2
Muscle discomfort		1				1
Muscle fatigue		1		1		
Muscle spasms	4	9	1	2	3	7
Muscle tightness	1	3	1	2		1
Muscular weakness	2	14	1	5	1	9
Musculoskeletal chest pain		1		1		
Musculoskeletal discomfort	2	3	2	3		
Musculoskeletal stiffness		3		2		1
Myalgia	52	168	48	119	4	49
Neck mass	1	1	1	1		
Neck pain	1	7	1	5		2
Osteoarthritis	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in extremity	24	64	21	55	3	9
Pain in jaw		2		1		1
Polyarthrits		1				1
Psoriatic arthropathy		1				1
Rheumatoid arthritis		2				2
Sjogren's syndrome		1				1
Soft tissue swelling		2		1		1
Spinal pain		3				3
Temporomand bular joint syndrome		2		2		
Tendon pain	1	1			1	1
Trismus		1		1		
	134	439	114	293	20	146

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Leukaemia		1				1
Neoplasm progression	1	1	1	1		
Pancreatic carcinoma	1	1			1	1
Skin papilloma	1	1			1	1
	3	4	1	1	2	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	2	3	1	1	1	2
Anosmia		2		1		1
Aphasia		1				1
Ataxia	1	1			1	1
Autonomic nervous system imbalance		1				1
Balance disorder	1	3		1	1	2
Bell's palsy	2	4			2	4
Burning sensation	6	38	5	28	1	10
Burning sensation mucosal		1				1
Carotid artery occlusion		1				1
Carpal tunnel syndrome	1	1	1	1		
Cerebral haemorrhage	3	4			3	4
Cerebral ischaemia	1	2			1	2
Cerebral venous thrombosis		1				1
Cerebrovascular accident	4	8			4	8
Cervical radiculopathy		1				1
Cholinergic syndrome		4				4
Clonus		1				1
Coma	1	2			1	2
Complex regional pain syndrome		5		1		4
Cranial nerve palsies multiple	1	1			1	1
Diplegia	1	4			1	4
Disturbance in attention		1				1
Dizziness	20	105	17	69	3	36
Dizziness postural	1	1			1	1
Dysarthria	1	4	1	1		3
Dysgeusia	9	24	9	17		7
Dyskinesia	2	7	2	6		1
Dysstasia		4		1		3
Electric shock sensation	1	2	1	2		
Embolic stroke	1	1			1	1
Epilepsy		1				1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial paralysis	1	5			1	5
Facial paresis	4	16	2	4	2	12
Fine motor skill dysfunction		1				1
Formication	1	1			1	1
Guillain-Barre syndrome		7				7
Headache	62	197	51	137	11	60
Head discomfort	3	7	3	7		
Hemianaesthesia	1	1			1	1
Hemiparesis	1	4			1	4
Hydrocephalus	1	1			1	1
Hypoaesthesia	24	108	15	59	9	49
Hyporeflexia		1				1
Hypotonia	2	8	1	4	1	4
Intercostal neuralgia		1		1		
Ischaemic cerebral infarction	1	2			1	2
Ischaemic stroke	1	2			1	2
Lethargy	3	8	3	6		2
Loss of consciousness	2	11			2	11
Memory impairment		2				2
Meningism		1		1		
Mental impairment	1	1			1	1
Migraine	2	10	1	7	1	3
Miller Fisher syndrome	1	1			1	1
Monoparesis		2				2
Monoplegia	1	1			1	1
Movement disorder		1		1		
Myoclonus	1	1			1	1
Nervous system disorder	1	1			1	1
Neuralgia		1				1
Neuritis		1				1
Neuritis cranial		1				1
Neuropathy peripheral		2				2

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nystagmus		1		1		
Paraesthesia		3		1		2
Paralysis	1	3			1	3
Paraparesis		1				1
Paresis		2				2
Parosmia	1	2	1	1		1
Petit mal epilepsy		1				1
Polyneuropathy		3				3
Post herpetic neuralgia		1				1
Presyncope	1	14		5	1	9
Reflexes abnormal		1				1
Sciatica		1				1
Seizure		1				1
Sensory loss		1				1
Somnolence	5	25	5	19		6
Speech disorder		5		2		3
Syncope	4	17			4	17
Taste disorder		3				3
Tension headache	1	1	1	1		
Thrombotic stroke	1	1			1	1
Transient ischaemic attack	2	3			2	3
Tremor		18		12		6
Trigeminal neuralgia	1	2	1	1		1
Trigeminal neuritis	1	1			1	1
	191	757	121	399	70	358

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System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion spontaneous		1		1
		1		1

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Liquid product physical issue		4		4		
Product quality issue		1		1		
Thrombosis in device	1	1			1	1
	1	6		5	1	1

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aggression		1				1
Agitation		1				1
Anxiety		2		2		
Body dysmorphic disorder		1				1
Bruxism	1	1			1	1
Communication disorder		1		1		
Confusional state	2	12	1	3	1	9
Depression	1	2		1	1	1
Disorientation	1	3	1	2		1
Dysphoria		4				4
Eating disorder		1				1
Insomnia		6		4		2
Irritability		1		1		
Middle insomnia		1		1		
Nervousness		1				1
Panic attack	1	1	1	1		
Panic reaction		1				1
Poor quality sleep		1		1		
Restlessness		1		1		
Stress		1		1		
Tension		2		2		
	6	45	3	21	3	24

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* AE=Adverse Event
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System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	1			1	1
Haematuria	1	2			1	2
Pollakiuria		1		1		
Polyuria		1		1		
Renal failure		1				1
Renal impairment		1				1
Urinary incontinence		2		1		1
	2	9		3	2	6

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast pain		1		1		
Breast swelling	1	1	1	1		
Cervix erythema		1				1
Dysmenorrhoea	1	1	1	1		
Heavy menstrual bleeding	1	2			1	2
Intermenstrual bleeding	1	2	1	2		
Menstruation delayed	1	2	1	2		
Menstruation irregular	1	3	1	2		1
Polymenorrhoea	2	2	2	2		
Priapism	1	1			1	1
	9	16	7	11	2	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory distress syndrome		1				1
Acute respiratory failure	1	2			1	2
Aphonia	1	1			1	1
Aspiration		1				1
Asthma	1	1			1	1
Asthmatic crisis		1				1
Bronchial hyperreactivity		1				1
Bronchospasm	1	11	1	1		10
Catarrh	1	3	1	3		
Choking sensation		1				1
Cough	4	34	2	15	2	19
Dry throat	1	13		3	1	10
Dysphonia	1	17	1	5		12
Dyspnoea	10	57	6	21	4	36
Epistaxis	2	4	2	4		
Haemoptysis		2		1		1
Hiccups	1	1	1	1		
Laryngeal oedema		6				6
Laryngeal pain		1				1
Laryngospasm		5				5
Nasal congestion		2		2		
Nasal pruritus		1		1		
Oropharyngeal discomfort		2		2		
Oropharyngeal pain	4	17	3	10	1	7
Pharyngeal oedema	1	2		1	1	1
Pharyngeal swelling	1	1			1	1
Pleural effusion	1	1			1	1
Productive cough	1	1			1	1
Pulmonary embolism	3	5			3	5
Pulmonary fibrosis		1				1
Pulmonary mass		1				1
Pulmonary oedema	1	2			1	2

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* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary pain	1	1			1	1
Pulmonary thrombosis		2				2
Respiratory failure		1				1
Rhinitis allergic		1		1		
Rhinorrhoea	1	3	1	2		1
Sputum increased		1				1
Suffocation feeling	1	1	1	1		
Tachypnoea		2		2		
Throat irritation		12		8		4
Throat tightness		1				1
Tonsillar hypertrophy		1				1
Wheezing		1		1		
	39	226	19	85	20	141

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne	2	3	2	3		
Alopecia		1		1		
Angioedema		15				15
Blister	1	5	1	5		
Circumoral oedema		1				1
Cold sweat	1	2			1	2
Dermatitis allergic	2	5			2	5
Dermatomyositis		1				1
Eczema	1	2	1	2		
Erythema	11	76	8	51	3	25
Granuloma annulare		1		1		
Hyperhidrosis	5	31	2	15	3	16
Hypersensitivity vasculitis		1				1
Lichenoid keratosis		1		1		
Livedo reticularis		1		1		
Mechanical urticaria		1		1		
Nail discolouration		2		2		
Onycholysis		1		1		
Petechiae		2		1		1
Pruritus	16	80	11	46	5	34
Pruritus allergic		1				1
Psoriasis		1		1		
Purpura	1	2			1	2
Rash	8	81	6	37	2	44
Rash erythematous	1	3	1	3		
Rash macular	1	3	1	3		
Rash maculo-papular	3	7	2	3	1	4
Rash morbilliform	1	1	1	1		
Rash papular	2	3	1	1	1	2
Rash pruritic	2	14	2	10		4
Skin burning sensation	2	5	2	4		1
Skin irritation		1		1		

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* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin lesion	1	2	1	1		1
Skin reaction		1				1
Urticaria	9	15	7	11	2	4
Vitiligo	1	1	1	1		
	71	373	50	208	21	165

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Impaired work ability		1				1
Loss of personal independence in daily activities		1		1		
Walking disability		1				1
Water pollution		1				1
		4		1		3

System Organ Class

Surgical and medical procedures

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Central nervous system stimulation		1		1
		1		1

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* AE=Adverse Event
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System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arteriosclerosis		1				1
Blood pressure fluctuation		1		1		
Blood pressure inadequately controlled		1		1		
Capillary disorder		1		1		
Cyanosis		3		2		1
Deep vein thrombosis	3	7			3	7
Diastolic hypertension		1				1
Flushing	2	33	1	14	1	19
Haematoma	1	2	1	1		1
Haemodynamic instability	1	1			1	1
Hot flush	1	3	1	1		2
Hypertension	8	45	5	22	3	23
Hypertensive crisis		15				15
Hypertensive emergency		1				1
Hypotension	2	22		6	2	16
Lymphoedema		1				1
Orthostatic hypotension		2		1		1
Pallor		3		2		1
Peripheral coldness	1	10	1	3		7
Peripheral venous disease		1		1		
Raynaud's phenomenon		1				1
Shock		1				1
Thrombosis	7	10			7	10
Vasculitis		1				1
Vasoconstriction		1				1
Venous thrombosis	2	2			2	2
Venous thrombosis limb		1				1
	28	171	9	56	19	115

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

GUINEA

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Headache		1		1
		1		1

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypertension		1		1
		1		1

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Country Where Event Occurred

HAITI

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vertigo		1		1
		1		1

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia		1		1
		1		1

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dizziness		1		1
Dyskinesia		1		1
		2		2

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Country Where Event Occurred
HOLY SEE (VATICAN CITY STATE)

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Periorbital oedema		1		1
		1		1

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia		1		1
Extensive swelling of vaccinated limb		1		1
Injected limb mobility decreased		1		1
Oedema peripheral		2		2
Vaccination site pain		1		1
		6		6

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pain in extremity		1		1
		1		1

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Country Where Event Occurred

HONDURAS

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Illness	2	2	2	2
	2	2	2	2

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19	2	2	2	2
	2	2	2	2

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* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

HONG KONG

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy		2		2
		2		2

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac arrest	2	2			2	2
Coronary artery disease	2	4			2	4
Myocardial infarction	1	1			1	1
Myocardial ischaemia		1				1
Palpitations	17	33	5	10	12	23
Tachycardia	2	2			2	2
	24	43	5	10	19	33

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival haemorrhage	1	1			1	1
Swelling of eyelid	2	2	2	2		
	3	3	2	2	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		2				2
Dysphagia	1	1	1	1		
Lip swelling	1	1	1	1		
Nausea	2	5	2	3		2
Vomiting		2		1		1
	4	11	4	6		5

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		3		2		1
Axillary pain	1	1	1	1		
Chest discomfort	6	14	3	7	3	7
Chest pain	8	17	2	4	6	13
Chills	1	1	1	1		
Death	1	1			1	1
Fatigue		3		3		
Injection site pain		1		1		
Malaise	1	2		1	1	1
Pain	1	1	1	1		
Pyrexia	3	5	2	3	1	2
Swelling	1	1	1	1		
Swelling face	1	1			1	1
Tenderness	1	1	1	1		
Vaccination site erythema	1	2	1	2		
Vaccination site hypoaesthesia	1	1			1	1
Vaccination site pain		3		2		1
Vaccination site pruritus		1		1		
Vaccination site swelling		1		1		
	27	60	13	32	14	28

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	1	3	1	2		1
Anaphylactic reaction		1				1
Anaphylactoid reaction	1	2			1	2
Drug hypersensitivity		1				1
Hypersensitivity	1	5		2	1	3
	3	12	1	4	2	8

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute haemorrhagic conjunctivitis	1	1	1	1		
Lower respiratory tract infection	1	1			1	1
Pneumonia	1	1			1	1
	3	3	1	1	2	2

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Contusion		1		1
Fall		2		2
Injury		1		1
Lip injury		1		1
		5		5

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased	4	11	2	7	2	4
	4	11	2	7	2	4

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite		1		1
		1		1

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	3		2	1	1
Back pain		1				1
Muscle twitching		1		1		
Muscular weakness		1				1
Musculoskeletal chest pain	1	1	1	1		
Musculoskeletal stiffness	1	2	1	2		
Myalgia	1	2	1	2		
Neck pain	1	1			1	1
	5	12	3	8	2	4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphasia		1		1		
Bell's palsy	13	15			13	15
Burning sensation		1		1		
Cerebrovascular accident	1	2			1	2
Coma	2	2			2	2
Dizziness	21	48	8	20	13	28
Epilepsy	1	1			1	1
Facial paralysis		1				1
Headache	4	9	1	4	3	5
Hypoaesthesia	7	20		5	7	15
Ischaemic stroke		1				1
Loss of consciousness	9	20			9	20
Migraine		1		1		
Movement disorder		1		1		
Neuralgia		1		1		
Paraesthesia		1		1		
Paralysis		1				1
Paresis		1				1
Presyncope	4	6		1	4	5
Seizure	11	17			11	17
Syncope	13	21			13	21
Transient ischaemic attack	1	1			1	1
Tremor		1		1		
	87	173	9	37	78	136

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion spontaneous		1		1
		1		1

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea	5	10	2	4	3	6
Hyperventilation	1	3			1	3
Lung opacity	1	1			1	1
Pharyngeal swelling		1		1		
	7	15	2	5	5	10

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermatitis allergic	1	1	1	1		
Erythema	1	1			1	1
Hyperhidrosis		2		2		
Pruritus	2	3		1	2	2
Rash	12	29	3	14	9	15
Rash pruritic	1	1	1	1		
Urticaria	1	2	1	1		1
	18	39	6	20	12	19

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic dissection	1	1			1	1
Essential hypertension	1	2			1	2
Hypertension	10	24	4	7	6	17
Hypertensive crisis	1	1			1	1
	13	28	4	7	9	21

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

HUNGARY

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia	1	2			1	2
Eosinophilia	1	1	1	1		
Lymphadenitis	2	5	1	4	1	1
Lymphadenopathy	14	52	12	43	2	9
Lymph node pain	4	15	4	14		1
Monocytosis		1				1
Thrombocytopenia	1	1			1	1
	23	77	18	62	5	15

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	2			1	2
Angina pectoris	2	7			2	7
Arrhythmia	1	2			1	2
Atrial fibrillation	2	6			2	6
Atrioventricular block complete	1	1			1	1
Bezold-Jarisch reflex		1		1		
Bradycardia	4	5			4	5
Cardiac arrest	4	4			4	4
Cardiac disorder	1	3			1	3
Cardiac failure	6	13			6	13
Cardiac failure congestive	1	1			1	1
Cardiogenic shock	1	1			1	1
Cardiomegaly		2		1		1
Cardiopulmonary failure	5	6			5	6
Cardiovascular disorder	1	2			1	2
Cardiovascular insufficiency	1	1			1	1
Extrasystoles	1	2	1	1		1
Ischaemic cardiomyopathy	1	1			1	1
Left ventricular failure	1	2			1	2
Myocardial infarction	2	2			2	2
Palpitations	6	14	6	12		2
Pericarditis		1				1
Pulseless electrical activity		1				1
Sinus tachycardia	1	1			1	1
Tachycardia	4	13	1	6	3	7
Tricuspid valve incompetence		1				1
	47	95	8	21	39	74

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear discomfort		3		2		1
Ear pain	1	4	1	4		
Ear pruritus		3		3		
Ear swelling		1				1
Tinnitus	1	6	1	6		
	2	17	2	15		2

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmune thyroiditis		1				1
Hyperthyroidism	2	2			2	2
Thyroiditis subacute		1		1		
	2	4		1	2	3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenopia	1	2	1	2		
Blepharospasm		1		1		
Blindness		1				1
Dark circles under eyes		1		1		
Dry eye		3		3		
Eye disorder	1	1	1	1		
Eye haemorrhage	2	4			2	4
Eye inflammation		2		1		1
Eye irritation		2		2		
Eyelid oedema		1		1		
Eye movement disorder	1	1	1	1		
Eye oedema		2				2
Eye pain	1	4	1	4		
Eye pruritus	1	2		1	1	1
Lacrimation increased		4		4		
Macular oedema		1				1
Meibomian gland dysfunction		1		1		
Ocular hyperaemia	1	1			1	1
Photopsia		1		1		
Retinal artery thrombosis	1	1			1	1
Retinal vascular thrombosis	1	1			1	1
Retinal vein thrombosis	1	1			1	1
Swelling of eyelid		2		2		
Uveitis		1				1
Vision blurred	1	3	1	3		
Visual impairment		2		1		1
	12	46	5	30	7	16

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	2	1	2		
Abdominal distension		3		3		
Abdominal pain	5	11	3	9	2	2
Abdominal pain upper		4		4		
Anal incontinence		1				1
Aphthous ulcer		1		1		
Constipation		1		1		
Defaecation urgency		1		1		
Diarrhoea	10	34	7	29	3	5
Diarrhoea haemorrhagic		1				1
Dry mouth	2	4	2	3		1
Dyspepsia		2		2		
Dysphagia	1	13		3	1	10
Enteritis		1				1
Frequent bowel movements	1	1	1	1		
Functional gastrointestinal disorder		1		1		
Gastric disorder	1	1	1	1		
Gastritis erosive		1				1
Gastrointestinal disorder	1	1	1	1		
Gastrointestinal haemorrhage		1				1
Gastrooesophageal reflux disease		1		1		
Gingival pain		1		1		
Glossitis	1	2	1	2		
Glossodynia	1	2		1	1	1
Haematemesis	1	1			1	1
Haematochezia	1	2			1	2
Hypoaesthesia oral	2	10	1	7	1	3
Ileus	1	1			1	1
Ileus paralytic	1	1			1	1
Lip disorder	1	1			1	1
Lip oedema		1				1
Lip swelling		3		1		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Megacolon		1				1
Melaena		1				1
Mouth swelling		2		1		1
Nausea	28	75	26	69	2	6
Noninfective gingivitis		1		1		
Odynophagia		1		1		
Oesophageal haemorrhage	1	1			1	1
Oesophageal varices haemorrhage	1	1			1	1
Pancreatitis acute	1	1			1	1
Retching		2		2		
Salivary gland enlargement		1		1		
Swollen tongue		1		1		
Tongue oedema	1	1			1	1
Toothache		1		1		
Tooth disorder		1				1
Vomiting	5	19	5	16		3
	68	221	49	168	19	53

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	30	101	27	82	3	19
Axillary pain	2	6	2	6		
Chest discomfort	4	12	4	11		1
Chest pain	5	17	3	13	2	4
Chills	22	84	21	82	1	2
Condition aggravated	3	11	2	5	1	6
Death	12	18			12	18
Discomfort		1		1		
Disease recurrence	4	5	2	2	2	3
Drug ineffective	25	54			25	54
Drug interaction	1	2	1	2		
Face oedema		3		1		2
Facial pain	1	2	1	2		
Fatigue	22	71	22	70		1
Feeling abnormal	2	14	2	12		2
Feeling cold		2		2		
Feeling hot	3	12	3	10		2
Feeling of body temperature change	1	2	1	2		
Foaming at mouth		1				1
Gait disturbance	1	5		4	1	1
Gait inability	1	1			1	1
General physical health deterioration	1	2		1	1	1
General symptom	1	1	1	1		
Illness		3		3		
Induration		1		1		
Inflammation	2	5	2	5		
Influenza like illness		4		4		
Injected limb mobility decreased	1	1	1	1		
Injection site pain	1	1	1	1		
Injection site urticaria		1		1		
Injection site warmth	1	1	1	1		
Localised oedema		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Local reaction		2
Malaise	17	64
Mucosal inflammation		1
Multiple organ dysfunction syndrome	2	2
Oedema peripheral		3
Pain	4	12
Performance status decreased	1	1
Peripheral swelling	6	14
Potentiating drug interaction		1
Pyrexia	53	162
Sensation of foreign body		7
Sudden death	5	5
Swelling	1	3
Swelling face	2	5
Therapeutic response unexpected		2
Thirst	1	4
Vaccination failure	4	8
Vaccination site coldness	1	2
Vaccination site discolouration	1	2
Vaccination site discomfort	2	3
Vaccination site erythema	7	36
Vaccination site haematoma		1
Vaccination site haemorrhage		1
Vaccination site hypoaesthesia	1	2
Vaccination site induration		2
Vaccination site inflammation		1
Vaccination site joint movement impairment	1	1
Vaccination site lymphadenopathy	1	1
Vaccination site macule		1
Vaccination site mass	1	2
Vaccination site movement impairment	2	7
Vaccination site nodule		4

Spontaneous			
Nonserious		Serious	
I	C	I	C
	2		
17	61		3
			1
		2	2
	1		2
4	12		
1	1		
6	12		2
	1		
45	145	8	17
	2		5
		5	5
1	3		
	3	2	2
	2		
1	3		1
		4	8
1	2		
1	2		
2	3		
7	36		
	1		
	1		
1	2		
	2		
	1		
		1	1
1	1		
	1		
1	2		
2	7		
	4		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site oedema	1	2	1	2		
Vaccination site pain	25	88	25	87		1
Vaccination site paraesthesia		1		1		
Vaccination site pruritus	3	8	3	8		
Vaccination site rash	1	2	1	2		
Vaccination site swelling	7	27	7	27		
Vaccination site vesicles	1	2	1	2		
Vaccination site warmth	2	7	2	7		
	299	944	228	776	71	168

System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Biliary tract disorder		1				1
Cholecystitis		1				1
Congestive hepatopathy	1	1			1	1
Hepatic function abnormal	1	1	1	1		
	2	4	1	1	1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic oedema	1	1			1	1
Allergy to vaccine		1				1
Anaphylactic reaction	2	5			2	5
Anaphylactic shock	1	2			1	2
Drug hypersensitivity		2		2		
Hypersensitivity	1	12		8	1	4
Immune-mediated adverse reaction	1	1	1	1		
Sarcoidosis	1	1			1	1
Type IV hypersensitivity reaction		1				1
	7	26	1	11	6	15

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchitis		2		1		1
Cellulitis		1				1
Clostridium difficile infection	1	1			1	1
COVID-19	34	73	3	8	31	65
COVID-19 pneumonia	14	15			14	15
Cystitis	1	1	1	1		
Erysipelas		1				1
Herpes virus infection		1		1		
Herpes zoster	5	15	5	15		
Influenza		1		1		
Nasopharyngitis	5	7	5	7		
Ophthalmic herpes zoster		1				1
Oral herpes	1	2	1	2		
Pelvic inflammatory disease	1	1			1	1
Pharyngitis		1		1		
Pneumonia	4	8			4	8
Post-acute COVID-19 syndrome	1	2		1	1	1
Progressive multifocal leukoencephalopathy	1	1			1	1
Pulpitis dental		1		1		
Sepsis	1	1			1	1
Sinusitis		1		1		
Suspected COVID-19	4	5	1	1	3	4
Upper respiratory tract infection		2		2		
Urinary tract infection	1	1	1	1		
Urosepsis	1	1			1	1
Vaginal infection	1	1	1	1		
	76	147	18	45	58	102

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cartilage injury		1				1
Craniofacial fracture		1				1
Exposure during pregnancy	1	4	1	4		
Exposure to SARS-CoV-2	1	1	1	1		
Exposure via breast milk	47	85	46	84	1	1
Fall		5		1		4
Femoral neck fracture		1				1
Head injury	1	1			1	1
Heat stroke	1	1	1	1		
Inappropriate schedule of product administration		1		1		
Incorrect product formulation administered		1		1		
Incorrect route of product administration	2	4	1	3	1	1
Lower limb fracture		1				1
Maternal exposure during breast feeding		1		1		
Maternal exposure during pregnancy		2		1		1
Muscle strain		2		2		
Off label use	49	92	49	92		
Overdose		1		1		
Poor quality product administered		1		1		
Product administered at inappropriate site		1		1		
Product use in unapproved indication		1		1		
Product use issue	49	91	49	91		
Vaccination complication	1	2	1	2		
Wound		3		2		1
Wound complication		1		1		
	152	305	149	292	3	13

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased		1		1		
Antibody test negative		1		1		
Antibody test normal		1		1		
Aspartate aminotransferase increased		1		1		
Bilirubin conjugated increased	1	1			1	1
Blood bilirubin increased	1	1			1	1
Blood glucose decreased		1		1		
Blood glucose increased		4		3		1
Blood pressure ambulatory increased		1		1		
Blood pressure decreased	2	7	1	5	1	2
Blood pressure increased	10	33	6	19	4	14
Blood pressure systolic increased		1				1
Blood test abnormal	1	1	1	1		
Blood thyroid stimulating hormone decreased		1		1		
Body temperature increased		2		2		
Fibrin D dimer increased	1	2			1	2
Full blood count abnormal		1				1
Gamma-glutamyltransferase increased		1		1		
Glomerular filtration rate decreased		1		1		
Heart rate decreased		1		1		
Heart rate increased	10	21	6	15	4	6
Heart rate irregular		1		1		
Hepatic enzyme abnormal	1	1			1	1
Hepatic enzyme increased		1		1		
Iodine uptake decreased		1		1		
Liver function test increased	1	1	1	1		
Lymphocyte count decreased		1		1		
Monocyte count increased		1		1		
Oxygen consumption increased		1		1		
Oxygen saturation decreased	1	3	1	2		1
Pulmonary arterial pressure increased		1				1
Red blood cell sedimentation rate increased		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
SARS-CoV-2 ant body test negative		1		1		
SARS-CoV-2 ant body test positive		2		2		
SARS-CoV-2 test positive	4	13		5	4	8
Serum ferritin increased		1		1		
Thyroxine free increased		1		1		
Total lung capacity decreased	1	1	1	1		
Tri-iodothyronine free increased		1		1		
Urine output increased	1	1	1	1		
Weight decreased	3	4	1	1	2	3
White blood cell count decreased	1	1	1	1		
	39	123	20	80	19	43

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cachexia	2	2			2	2
Decreased appetite	7	16	7	15		1
Dehydration	1	2			1	2
Feeding disorder		2				2
Food aversion	1	1	1	1		
Hypoglycaemia		1		1		
Increased appetite	1	1	1	1		
Metabolic acidosis		1				1
Overfeeding of infant		1		1		
Type 1 diabetes mellitus	1	1			1	1
	13	28	9	19	4	9

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	21	41	21	37		4
Arthritis reactive		1				1
Arthropathy		1		1		
Axillary mass		1		1		
Back pain	8	16	7	15	1	1
Bone pain	2	4	2	4		
Bursitis		1		1		
Intervertebral disc protrusion		1		1		
Joint range of motion decreased	1	2	1	2		
Joint swelling	2	2	2	2		
Limb discomfort	1	2	1	2		
Mastication disorder		1		1		
Mobility decreased	1	2	1	2		
Muscle fatigue		1		1		
Muscle spasms	3	4	2	3	1	1
Muscle tightness		1		1		
Muscle twitching		2		1		1
Muscular weakness	5	13	5	13		
Musculoskeletal chest pain		2		2		
Musculoskeletal stiffness	3	7	2	5	1	2
Myalgia	23	71	23	70		1
Neck pain	3	5	3	5		
Pain in extremity	27	90	24	85	3	5
Periarthritis		1		1		
Polyarthritis		2				2
Rheumatoid arthritis	1	1			1	1
Sjogren's syndrome		1				1
Spinal osteoarthritis		1		1		
Tenosynovitis	1	1	1	1		
	102	278	95	258	7	20

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
B-cell type acute leukaemia		1		1
Bronchial neoplasm	1	1	1	1
Lung neoplasm	1	1	1	1
Neoplasm	1	1	1	1
Neoplasm malignant	1	1	1	1
Neoplasm progression	1	2	1	2
	5	7	5	7

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	3	1	3		
Akinesia	1	1			1	1
Anosmia		4		4		
Ataxia	1	2		1	1	1
Balance disorder	2	2	2	2		
Bell's palsy	1	2			1	2
Brain injury	1	1			1	1
Burning sensation	2	12	2	11		1
Cerebral infarction		1				1
Cerebral ischaemia		1				1
Cerebrovascular accident	2	4			2	4
Cervical neuritis		1		1		
Cholinergic syndrome	1	1			1	1
Coordination abnormal		1		1		
Dementia	1	2			1	2
Disturbance in attention		2		1		1
Dizziness	23	67	19	57	4	10
Dysarthria	1	1			1	1
Dysgeusia	2	10	2	9		1
Dysstasia	1	1			1	1
Facial neuralgia	1	1	1	1		
Facial paralysis		2				2
Facial paresis	3	6	3	5		1
Guillain-Barre syndrome		1				1
Headache	42	134	41	126	1	8
Head discomfort	1	2	1	2		
Hemiparesis		1				1
Hyperaesthesia		3		3		
Hypertensive encephalopathy	1	1			1	1
Hypoaesthesia	13	35	9	28	4	7
Hypokinesia	1	2			1	2
Hyporeflexia		2		2		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypotonia		1				1
Ischaemic stroke	2	3			2	3
Lethargy	1	6	1	5		1
Lhermitte's sign		1		1		
Loss of consciousness	4	9			4	9
Memory impairment		2		1		1
Migraine	2	8	2	7		1
Monoplegia		2				2
Movement disorder	2	2	1	1	1	1
Myelopathy		1				1
Nervous system disorder	2	2	1	1	1	1
Neuralgia	1	4	1	3		1
Paraesthesia	1	5	1	3		2
Paralysis		1				1
Paraplegia	1	1			1	1
Peripheral nerve paresis		1				1
Polyneuropathy		1				1
Presyncope	3	3	3	3		
Radiculopathy		1		1		
Sciatica		1				1
Sensory loss		1		1		
Sleep deficit	1	1	1	1		
Somnolence	3	16	3	13		3
Speech disorder	2	3	1	2	1	1
Status epilepticus	1	1			1	1
Syncope	6	13			6	13
Taste disorder		1		1		
Tension headache		1		1		
Thrombotic stroke		1				1
Transient ischaemic attack	1	2			1	2
Tremor	6	17	5	13	1	4
Vascular dementia	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
White matter lesion		1		1		
	142	423	101	316	41	107

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion		1		1
Abortion missed		2		2
Foetal death	1	1	1	1
	1	4	1	4

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Liquid product physical issue		1		1
Product complaint		1		1
Suspected counterfeit product		1		1
		3		3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour		1		1		
Aggression		1				1
Anxiety		1		1		
Bradyphrenia		1		1		
Bruxism	1	1	1	1		
Confusional state	1	5		2	1	3
Depressed mood		1		1		
Depression		2		2		
Dysphemia		1				1
Fear of death	2	4	2	4		
Feeling of despair	1	2	1	2		
Initial insomnia	1	1	1	1		
Insomnia	2	11	2	11		
Irritability	1	2	1	2		
Lack of spontaneous speech	1	1	1	1		
Listless		1				1
Mood altered		2		2		
Panic attack		1		1		
Poor quality sleep	2	3	1	2	1	1
Psychiatric symptom		2				2
Restlessness	1	3		2	1	1
Sleep disorder	1	5	1	5		
Sleep disorder due to general medical condition, insomnia type	1	1	1	1		
Stress	1	3	1	3		
Tension		2		2		
	16	58	13	48	3	10

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	1			1	1
Anuria	1	2			1	2
Chromaturia		2		2		
Dysuria	1	1	1	1		
Haematuria		1				1
Incontinence	1	1	1	1		
Micturition urgency	1	2	1	2		
Pollakiuria		1				1
Renal cyst		1		1		
Renal impairment	1	2			1	2
Renal pain		2		2		
Urinary incontinence		1		1		
Urinary tract inflammation	1	1	1	1		
Urinary tract pain		1		1		
	7	19	4	12	3	7

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adnexa uteri pain		1		1		
Breast discomfort		2		2		
Breast mass		1				1
Heavy menstrual bleeding	1	1	1	1		
Lactation disorder		1		1		
Menstruation delayed	1	2	1	2		
Menstruation irregular	2	3	2	3		
Nipple pain		1		1		
Polymenorrhoea	1	1	1	1		
Prostatomegaly	1	1	1	1		
Vaginal discharge		1		1		
	6	15	6	14		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory distress syndrome	2	2			2	2
Acute respiratory failure		2				2
Asphyxia	2	6			2	6
Bronchospasm	1	1			1	1
Catarrh	1	1	1	1		
Choking		1				1
Chronic obstructive pulmonary disease		1		1		
Cough	7	20	2	13	5	7
Dry throat	1	1	1	1		
Dysphonia	1	6		2	1	4
Dyspnoea	19	38	6	15	13	23
Dyspnoea exertional	1	3	1	2		1
Emphysema		1				1
Epistaxis		1		1		
Haemoptysis		1				1
Laryngeal oedema		1				1
Lung disorder	1	1	1	1		
Nasal congestion	2	4	2	4		
Oropharyngeal pain	3	20	2	16	1	4
Painful respiration	1	2		1	1	1
Paranasal sinus discomfort		1		1		
Pharyngeal oedema	2	3	1	2	1	1
Pharyngeal swelling		3		2		1
Pneumonitis	1	1			1	1
Productive cough	1	3	1	3		
Pulmonary embolism	6	7			6	7
Pulmonary oedema	2	2			2	2
Respiratory arrest	1	1			1	1
Respiratory disorder		1		1		
Respiratory distress	1	3			1	3
Respiratory failure	4	5			4	5
Respiratory muscle weakness	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory symptom	1	1	1	1		
Rhinorrhoea	5	14	5	14		
Stridor		1				1
Tachypnoea	1	2			1	2
Throat irritation	2	3	2	3		
Throat tightness	3	6	1	2	2	4
Tonsillar hypertrophy		1		1		
Wheezing		1				1
	73	173	27	88	46	85

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecia		1		1		
Angioedema	1	3			1	3
Blister		2		2		
Capillaritis		1		1		
Cold sweat		3		3		
Cutaneous symptom		1				1
Decubitus ulcer		1				1
Dermal cyst	1	1	1	1		
Dermatitis allergic		1		1		
Dermatitis herpetiformis		1		1		
Eczema		1		1		
Eczema infantile	1	1	1	1		
Erythema	4	21	3	19	1	2
Erythema multiforme		1				1
Hyperhidrosis	5	13	4	11	1	2
Night sweats		1		1		
Oedema blister		1				1
Pain of skin	2	7	2	7		
Petechiae	1	2		1	1	1
Pityriasis rosea		1		1		
Pruritus	6	18	5	16	1	2
Rash	4	15	4	12		3
Rash erythematous		8		7		1
Rash macular	1	3		2	1	1
Rash maculo-papular		3		2		1
Rash pruritic	1	8		6	1	2
Rash vesicular		1		1		
Sensitive skin	1	4	1	4		
Skin burning sensation	1	8	1	7		1
Skin discolouration	2	3	1	2	1	1
Skin disorder	1	2	1	2		
Skin haemorrhage	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin hypertrophy		1		1		
Skin lesion		1		1		
Skin sensitisation		1		1		
Skin swelling	1	1	1	1		
Skin ulcer	1	2	1	1		1
Skin warm		1		1		
Urticaria	9	18	7	14	2	4
	44	163	34	134	10	29

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arteriosclerosis	1	2			1	2
Blood pressure fluctuation	5	9	4	6	1	3
Circulatory collapse	4	7			4	7
Cyanosis	1	2			1	2
Deep vein thrombosis	3	6			3	6
Flushing	1	5	1	4		1
Haematoma		4		1		3
Haemorrhage	1	3			1	3
Hot flush	1	6	1	5		1
Hyperaemia		1		1		
Hypertension	2	5	1	3	1	2
Hypertensive crisis	1	2			1	2
Hypotension	1	8		2	1	6
Hypovolaemic shock	1	1			1	1
Lymphoedema		1		1		
Pallor		5		4		1
Peripheral coldness		3		3		
Peripheral venous disease		1				1
Poor peripheral circulation		1		1		
Shock	1	1			1	1
Thrombophlebitis	1	3		1	1	2
Thrombophlebitis superficial	1	2			1	2
Thrombosis	1	1			1	1
Varicose vein		2		2		
Vascular pain	1	1	1	1		
Vasculitis		1		1		
Vasoconstriction		1				1
Vasodilatation	1	1			1	1
Vein disorder		1		1		
White coat hypertension		1		1		
	28	87	8	38	20	49

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ICELAND

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	1	6	1	6
	1	6	1	6

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction		2				2
Arrhythmia	2	2			2	2
Atrial f brillation		1				1
Bradycardia		1				1
Cardiac failure		2				2
Myocardial infarction		1				1
Palpitations	1	1	1	1		
Tachycardia	1	3	1	2		1
Ventricular tachycardia		1				1
	4	14	2	3	2	11

System Organ Class

Congenital, familial and genetic disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anencephaly		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear pain		1		1
		1		1

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular discomfort		1		1
Periorbital swelling		1		1
Visual impairment		1		1
		3		3

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anal incontinence		1		1
Dry mouth		1		1
Gastrointestinal pain		1		1
Nausea	6	18	6	18
Noninfective sialoadenitis		1		1
Salivary gland enlargement		1		1
Vomiting	2	3	2	3
	8	26	8	26

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		7		7		
Axillary pain		3		3		
Chest discomfort	1	3	1	3		
Chest pain	1	4		2	1	2
Chills	6	19	6	19		
Death		6				6
Discomfort	1	3	1	3		
Disease progression		1				1
Disease recurrence		1		1		
Fatigue	2	19	2	18		1
Feeling abnormal	1	4	1	4		
Feeling cold		2		2		
Feeling hot		1		1		
Influenza like illness	1	2	1	2		
Injection site pain		2		2		
Injection site swelling	1	1	1	1		
Malaise	7	32	7	27		5
Oedema peripheral		1		1		
Pain	1	3		2	1	1
Peripheral swelling		1				1
Pyrexia	15	57	14	52	1	5
Sluggishness		1		1		
Sudden death	1	3			1	3
Swelling		1		1		
Thirst		1		1		
Vaccination site erythema		6		6		
Vaccination site inflammation		3		3		
Vaccination site irritation	1	1	1	1		
Vaccination site pain	9	30	9	30		
Vaccination site reaction		1		1		
Vaccination site swelling		3		3		
Vaccination site warmth	1	3	1	3		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	49	225	45	200	4	25

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic reaction	1	1	1	1
	1	1	1	1

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nasopharyngitis	1	6	1	6		
Pneumonia		4				4
Sepsis		1				1
	1	11	1	6		5

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Contusion		1				1
Exposure via breast milk	1	1			1	1
Fall		1		1		
Maternal exposure during pregnancy		2		2		
Off label use	1	5	1	5		
Product use in unapproved indication		2		2		
Product use issue	1	4	1	4		
	3	16	2	14	1	2

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased		1				1
Blood pressure increased	1	2	1	2		
Breath sounds abnormal		1				1
Electrocardiogram QT prolonged	1	1			1	1
Fibrin D dimer increased		1				1
Heart rate increased	3	5	3	5		
Hepatic enzyme increased		2		1		1
Oxygen saturation decreased		2				2
	5	15	4	8	1	7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite		4		4		
Fluid overload		1				1
		5		4		1

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	2	7	2	7		
Arthritis	1	2	1	2		
Back pain	1	4		3	1	1
Bone pain	1	3	1	3		
Joint stiffness		1		1		
Joint swelling		2		2		
Limb discomfort		1		1		
Muscle twitching		2		2		
Muscular weakness	1	2	1	2		
Myalgia	13	38	13	38		
Neck pain	1	1	1	1		
Pain in extremity	4	12	4	10		2
	24	75	23	72	1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphasia	1	3		1	1	2
Balance disorder		1				1
Bell's palsy	1	1			1	1
Cerebrovascular accident		1				1
Depressed level of consciousness		1				1
Dizziness	5	15	5	15		
Dysgeusia	1	2	1	2		
Dyspraxia	1	1			1	1
Headache	15	52	15	52		
Head discomfort	1	2	1	2		
Hypersomnia		1		1		
Hypoaesthesia	3	8	2	7	1	1
Loss of consciousness		3				3
Memory impairment		1		1		
Migraine		1		1		
Motor dysfunction		1				1
Presyncope	1	1	1	1		
Sensory loss		1		1		
Speech disorder	1	1			1	1
Syncope	1	3			1	3
Transient ischaemic attack		2				2
Tremor	1	2	1	2		
	32	104	26	86	6	18

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Confusional state		1				1
Delirium		3				3
Disorientation	1	1			1	1
Dysphoria	1	1			1	1
Insomnia		2		2		
Personality change		1				1
Poor quality sleep		1		1		
Sleep disorder	1	2	1	1		1
	3	12	1	4	2	8

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urinary incontinence		1		1		
Urine flow decreased		1				1
		2		1		1

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breast inflammation		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma		1				1
Chronic obstructive pulmonary disease		1				1
Cough		5		4		1
Dry throat		1		1		
Dyspnoea	1	7	1	5		2
Hypercapnia		1				1
Hypoxia		2				2
Lung infiltration		1				1
Oropharyngeal pain		6		6		
Painful respiration		1		1		
Pharyngeal swelling		1		1		
Pneumonia aspiration		1				1
Productive cough		1		1		
Pulmonary embolism	1	1			1	1
Pulmonary oedema		1				1
Pulmonary pain	1	2	1	2		
Respiration abnormal		1				1
Respiratory arrest		1				1
Respiratory failure		1				1
Rhinorrhoea		3		3		
Throat tightness	1	1	1	1		
	4	40	3	25	1	15

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat	1	2	1	2		
Erythema		5		5		
Hyperhidrosis		3		2		1
Pruritus	1	6	1	6		
Rash	1	4	1	4		
Sensitive skin		2		2		
Skin burning sensation		1		1		
Skin discolouration		1		1		
Urticaria	1	1	1	1		
	4	25	4	24		1

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysm		1				1
Deep vein thrombosis		1				1
Hot flush		1		1		
Hypertension		1		1		
Hypoperfusion		1				1
Hypotension	1	1	1	1		
Pallor		2		2		
Peripheral artery thrombosis		1				1
Peripheral embolism		1				1
	1	10	1	5		5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

INDIA

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Myocardial infarction	1	1	1	1
	1	1	1	1

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Vomiting		1		1
		1		1

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Asthenia		1		1
Drug ineffective	3	4	3	4
Fatigue		1		1
Pain		1		1
Vaccination site pain		1		1
	3	8	3	8

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19	3	4	3	4
COVID-19 pneumonia	1	1	1	1
	4	5	4	5

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration		1		1
Off label use		1		1
		2		2

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Oxygen saturation decreased		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Dizziness		1		1
Headache		1		1
Loss of consciousness		1		1
		3		3

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Suspected counterfeit product		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
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Country Where Event Occurred

IRAQ

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	1	1	1	1
	1	1	1	1

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Myocardial infarction	1	1	1	1
	1	1	1	1

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Nausea		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Chest pain	1	1			1	1
Drug ineffective	1	1			1	1
Fatigue		1		1		
Gait disturbance	1	1	1	1		
Pyrexia	2	4	2	4		
Vaccination site pain	1	3	1	3		
	7	12	5	10	2	2

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	5	5	4	4	1	1
Mastitis	1	1			1	1
	6	6	4	4	2	2

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Oxygen saturation decreased	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite		1		1
		1		1

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Limb discomfort	1	1	1	1
Myalgia		1		1
Pain in extremity	1	1	1	1
	2	3	2	3

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebrovascular accident	2	2			2	2
Headache		1		1		
Lacunar infarction	1	1			1	1
Paraesthesia	1	1	1	1		
Tremor	1	1	1	1		
	5	6	2	3	3	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Insomnia		1		1
		1		1

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cough		1		1
		1		1

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hyperhidrosis	1	1	1	1
	1	1	1	1

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Deep vein thrombosis	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

IRELAND

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia		1				1
Lymphadenopathy	11	36	1	5	10	31
Lymph node pain	3	10	2	2	1	8
Neutropenia	1	2			1	2
	15	49	3	7	12	42

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute cardiac event		1				1
Acute myocardial infarction	2	2			2	2
Angina pectoris	1	1			1	1
Arrhythmia	2	2			2	2
Atrial fibrillation		1				1
Atrial tachycardia	1	1			1	1
Bradycardia		1				1
Cardiac arrest	1	4			1	4
Cardiac failure		1				1
Cardiac failure congestive		1				1
Cardiac flutter	1	1			1	1
Cardio-respiratory arrest	1	1			1	1
Coronary artery occlusion		1				1
Coronary artery thrombosis		1				1
Myocardial infarction		2				2
Myocardial ischaemia		1				1
Myocarditis	2	3			2	3
Palpitations	6	23	1	3	5	20
Pericardial effusion	1	1			1	1
Pericarditis	2	2			2	2
Pulseless electrical activity	1	1			1	1
Supraventricular extrasystoles	1	1			1	1
Supraventricular tachycardia		3				3
Tachycardia	5	26		1	5	25
Ventricular extrasystoles	1	1			1	1
	28	83	1	4	27	79

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness		2				2
Deafness unilateral	1	1			1	1
Ear discomfort		1				1
Ear pain	3	6	1	2	2	4
Paraesthesia ear	1	1			1	1
Tinnitus	2	6		2	2	4
Tympanic membrane perforation	1	1			1	1
Vertigo	4	8	2	4	2	4
	12	26	3	8	9	18

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Thyroiditis acute	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenopia	1	1			1	1
Blepharospasm		1				1
Blindness		1				1
Blindness transient		1				1
Dark circles under eyes		1				1
Diplopia		3		1		2
Dry eye	1	3			1	3
Erythema of eyelid		1				1
Excessive eye blinking		1				1
Eye discharge		1				1
Eye irritation	1	3		1	1	2
Eyelid ptosis		1				1
Eyelid rash	1	1			1	1
Eyelids pruritus		1				1
Eye movement disorder		3				3
Eye pain	2	6			2	6
Eye pruritus	2	4		1	2	3
Eye swelling		3		1		2
Lacrimation decreased		1				1
Lacrimation increased		1				1
Mydriasis		1		1		
Periorbital discomfort		1		1		
Periorbital oedema		1		1		
Periorbital swelling		1				1
Photophobia		2				2
Photopsia		1				1
Pupils unequal		1		1		
Swelling of eyelid	2	4		1	2	3
Uveitis	1	1			1	1
Vision blurred	3	6	1	2	2	4
Visual field defect	1	1	1	1		
Visual impairment		4		1		3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vitreous floaters	1	4	1	1		3
	16	66	3	14	13	52

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* I=Interval, C=Cumulative
 * AE=Adverse Event
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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	4	9	2	5	2	4
Abdominal distension	1	4		1	1	3
Abdominal pain	4	10		1	4	9
Abdominal pain lower	1	1	1	1		
Abdominal pain upper	4	10	2	4	2	6
Anal incontinence	1	1			1	1
Breath odour		1				1
Cheilitis		1				1
Colitis ulcerative	1	1			1	1
Constipation	1	2	1	1		1
Dental paraesthesia	1	1	1	1		
Diarrhoea	14	34	7	10	7	24
Dry mouth		1				1
Dyspepsia	1	1	1	1		
Dysphagia	1	3			1	3
Eructation	1	1	1	1		
Faeces discoloured		1				1
Faeces pale		1				1
Flatulence		2		1		1
Frequent bowel movements	1	1	1	1		
Gastric disorder		1				1
Gastrointestinal sounds abnormal	1	1	1	1		
Gastrooesophageal reflux disease		1				1
Glossodynia		1		1		
Haematemesis		1				1
Haematochezia		1				1
Hyperaesthesia teeth	1	1	1	1		
Hypoaesthesia oral	3	13	2	3	1	10
Irritable bowel syndrome		1				1
Lip discolouration		1				1
Lip dry		1				1
Lip swelling	2	13	1	1	1	12

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Melaena		1				1
Nausea	47	146	21	46	26	100
Oral hyperaesthesia	1	1			1	1
Oral pain	1	1			1	1
Oral pruritus		1		1		
Pancreatitis relapsing		1				1
Paraesthesia oral	5	16	2	6	3	10
Rectal haemorrhage	1	1			1	1
Retching		4				4
Salivary hypersecretion		2		2		
Swollen tongue	1	7			1	7
Tongue disorder		1				1
Tongue movement disturbance		1				1
Tongue rough	1	1			1	1
Toothache	2	2	1	1	1	1
Upper gastrointestinal haemorrhage		1				1
Vomiting	21	63	6	13	15	50
Vomiting projectile	1	1	1	1		
	124	373	53	105	71	268

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	21	74	4	16	17	58
Axillary pain	4	12	2	4	2	8
Chest discomfort	4	23	1	4	3	19
Chest pain	11	30	2	4	9	26
Chills	43	98	21	30	22	68
Condition aggravated	7	8	5	5	2	3
Cyst		1				1
Death	2	11			2	11
Decreased activity		1				1
Discomfort	3	14		1	3	13
Disease recurrence	1	6			1	6
Drug ineffective	7	12			7	12
Extensive swelling of vaccinated limb		1		1		
Facial pain	4	6	2	3	2	3
Fatigue	66	174	37	75	29	99
Feeling abnormal	10	23	4	7	6	16
Feeling cold	1	11	1	3		8
Feeling drunk		2				2
Feeling hot	12	30	6	8	6	22
Feeling jittery	1	1			1	1
Feeling of body temperature change	4	7	2	2	2	5
Gait disturbance	1	6			1	6
Gait inability		3		1		2
General physical health deterioration	1	5			1	5
Hangover		1		1		
Hyperpyrexia		1				1
Illness		3		2		1
Inflammation	1	3			1	3
Influenza like illness	8	23	6	12	2	11
Injected limb mobility decreased	2	4	1	2	1	2
Injection site movement impairment		1				1
Injection site pain	1	4		1	1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injury associated with device		2		2		
Loss of control of legs	1	2			1	2
Malaise	31	76	15	24	16	52
Mass		1				1
No adverse event		1		1		
Pain	31	97	15	30	16	67
Peripheral swelling	5	12	1	1	4	11
Pyrexia	65	167	29	53	36	114
Sensation of foreign body		2				2
Sudden death		3				3
Swelling	2	10	1	3	1	7
Swelling face	2	10	1	2	1	8
Tenderness	1	4			1	4
Thirst	2	3	1	1	1	2
Vaccination failure		1				1
Vaccination site bruising	1	2	1	1		1
Vaccination site discharge		1		1		
Vaccination site discolouration		1				1
Vaccination site discomfort		2		1		1
Vaccination site erythema	7	16	3	5	4	11
Vaccination site induration	2	2	1	1	1	1
Vaccination site inflammation	2	3	1	2	1	1
Vaccination site irritation		1				1
Vaccination site joint movement impairment		1				1
Vaccination site mass	3	6	2	2	1	4
Vaccination site movement impairment	1	1			1	1
Vaccination site pain	18	54	8	28	10	26
Vaccination site paraesthesia		2		1		1
Vaccination site pruritus	5	10	1	2	4	8
Vaccination site rash	1	1			1	1
Vaccination site reaction	1	1	1	1		
Vaccination site swelling	5	10	1	2	4	8

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site urticaria		1		1		
Vaccination site warmth	3	8	3	4		4
	404	1,113	179	351	225	762

System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hepatic pain	1	1	1	1
Jaundice		1		1
	1	2	1	2

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		2				2
Anaphylactic reaction	2	11			2	11
Anaphylactic shock		1				1
Anaphylactoid reaction	1	1			1	1
Hypersensitivity	1	8	1	2		6
Type III immune complex mediated reaction		1				1
Type IV hypersensitivity reaction		1				1
	4	25	1	2	3	23

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal infection		1				1
Cellulitis	1	5			1	5
Complicated appendicitis		1				1
Conjunctivitis		1		1		
COVID-19	7	18	1	1	6	17
Disseminated varicella zoster virus infection	1	1			1	1
Ear infection		1				1
Encephalitis		1				1
Eye infection	1	1			1	1
Furuncle		1				1
Herpes zoster	2	4	1	1	1	3
Herpes zoster oticus	1	1			1	1
Herpes zoster reactivation		1				1
Hordeolum	1	2			1	2
Infection		1		1		
Influenza	1	3	1	2		1
Kidney infection	1	1			1	1
Localised infection	1	1	1	1		
Lower respiratory tract infection	1	2			1	2
Mastitis		2				2
Nasopharyngitis	2	2	2	2		
Oral herpes		4		2		2
Otitis media	1	1			1	1
Pneumonia	3	5			3	5
Pulmonary sepsis		1				1
Respiratory tract infection		3				3
Rhinitis		2				2
Sinusitis	1	2			1	2
Suspected COVID-19	2	4	1	2	1	2
Upper respiratory tract infection		1		1		
Urinary tract infection	1	2		1	1	1
Vaccination site cellulitis	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Varicella zoster virus infection	1	1			1	1
Viral labyrinthitis	1	1	1	1		
	31	79	8	16	23	63

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* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental exposure to product		3		3		
Accidental overdose		1		1		
Chillblains	1	2			1	2
Circumstance or information capable of leading to medication error		1		1		
Contusion	1	2	1	2		
Epicondylitis	1	1			1	1
Expired product administered		1		1		
Exposure during pregnancy	2	4	1	3	1	1
Exposure via breast milk		6		5		1
Exposure via skin contact		2		2		
Extra dose administered	1	1	1	1		
Face injury		1				1
Fall	6	7			6	7
Head injury	2	2			2	2
Inappropriate schedule of product administration	3	8	3	8		
Incorrect dose administered	6	9	5	8	1	1
Injury	1	2			1	2
Maternal exposure during breast feeding		2		2		
Maternal exposure during pregnancy	3	11	2	9	1	2
Nerve injury	1	2			1	2
Off label use	3	13	3	13		
Overdose	1	1	1	1		
Poor quality product administered	1	13	1	13		
Product preparation error	2	3	1	2	1	1
Product preparation issue	4	11	4	11		
Product use issue	1	6	1	6		
Road traffic accident		1				1
Skin laceration		1		1		
Underdose	1	11	1	11		
Vaccination error		1		1		
Wound		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Wrong technique in product usage process		11		11		
	41	141	25	117	16	24

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* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased		1				1
Angiotensin converting enzyme increased		1				1
Aspiration joint	1	1	1	1		
Blood bilirubin increased		1				1
Blood glucose fluctuation		1				1
Blood lactic acid increased		1				1
Blood pH decreased		1				1
Blood pressure decreased	1	1			1	1
Blood pressure diastolic increased		1				1
Blood pressure increased		10				10
Blood pressure systolic increased	1	2		1	1	1
Blood sodium decreased		1				1
Blood urine present		1				1
Body temperature decreased		1				1
Body temperature increased		2		1		1
Carbon dioxide increased		1				1
Corneal reflex decreased		1				1
C-reactive protein increased	1	3	1	1		2
Electrocardiogram change	1	1			1	1
Eosinophil count increased		1				1
Haemoglobin decreased		1				1
Heart rate decreased		1				1
Heart rate increased	6	17	2	3	4	14
Heart rate irregular		3				3
Liver function test increased		1				1
Oxygen saturation decreased	2	11			2	11
Platelet count decreased		2				2
Pulse abnormal		2				2
Quality of life decreased		1				1
Red blood cell sedimentation rate increased	1	1	1	1		
Respiratory rate decreased		3				3
Respiratory rate increased	1	3			1	3

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
SARS-CoV-2 test positive		1				1
Tidal volume decreased		1				1
Troponin increased	1	2			1	2
Urine output decreased	1	1			1	1
Weight decreased		1				1
Weight increased	1	1			1	1
White blood cell count decreased	1	1			1	1
White blood cell count increased		1		1		
	19	88	5	9	14	79

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal loss of weight	1	1			1	1
Decreased appetite	12	24	3	5	9	19
Dehydration		2		1		1
Diabetes mellitus inadequate control	1	1			1	1
Feeding disorder	2	3			2	3
Fluid intake reduced	1	1			1	1
Hypoglycaemia		2				2
Metabolic acidosis		1				1
Tetany	1	1	1	1		
	18	36	4	7	14	29

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ankylosing spondylitis	1	1			1	1
Arthralgia	41	88	17	33	24	55
Arthritis	2	2			2	2
Axillary mass		2		1		1
Back pain	11	31	3	7	8	24
Bone pain	3	9	1	2	2	7
Flank pain		4				4
Groin pain	1	1			1	1
Intervertebral disc disorder	1	1	1	1		
Jaw disorder	1	1	1	1		
Joint range of motion decreased		1				1
Joint stiffness	1	6	1	2		4
Joint swelling	1	3			1	3
Joint warmth	1	1			1	1
Limb discomfort	6	13	5	7	1	6
Mobility decreased	4	8	1	1	3	7
Muscle fatigue		1		1		
Muscle spasms	2	8	1	3	1	5
Muscle tightness	1	2	1	1		1
Muscle twitching	1	8		1	1	7
Muscular weakness	3	9			3	9
Musculoskeletal chest pain	1	3			1	3
Musculoskeletal discomfort	1	2	1	1		1
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	5	15	2	8	3	7
Myalgia	42	99	24	36	18	63
Myokymia		1				1
Neck mass		1				1
Neck pain	8	18	5	7	3	11
Pain in extremity	26	81	18	38	8	43
Pain in jaw	3	4	2	3	1	1
Periarthritis		1				1

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* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rheumatoid arthritis	1	1			1	1
Spinal pain	1	1			1	1
Weight bearing difficulty	1	2			1	2
	171	430	85	155	86	275

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Skin papilloma		1		1
		1		1

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* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	3	8	1	3	2	5
Amnesia	1	1			1	1
Anosmia	1	3		1	1	2
Aphasia	2	4			2	4
Balance disorder	2	3	2	3		
Bell's palsy	6	17			6	17
Brain injury	1	1			1	1
Burning sensation	3	9		1	3	8
Cerebral disorder		1				1
Cerebral infarction	1	2			1	2
Cerebrovascular accident	5	8			5	8
Cerebrovascular insufficiency		1				1
Cluster headache		1		1		
Coma		1				1
Depressed level of consciousness	1	3			1	3
Disturbance in attention	1	5		2	1	3
Dizziness	41	107	13	27	28	80
Dizziness postural	1	1			1	1
Dysarthria	2	6	1	1	1	5
Dysgeusia	6	12	5	7	1	5
Dyskinesia	1	2		1	1	1
Dysstasia		2				2
Encephalopathy		1				1
Epilepsy		1				1
Facial nerve disorder		1		1		
Facial neuralgia	1	1			1	1
Facial paralysis	5	11			5	11
Facial paresis	1	2			1	2
Formication		1				1
Generalised tonic-clonic seizure	1	1			1	1
Headache	92	241	44	74	48	167
Hemiparaesthesia	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hemiparesis	1	4			1	4
Hyperaesthesia		1				1
Hypersomnia	4	5	1	1	3	4
Hypoaesthesia	15	44	8	17	7	27
Hypotonia		2				2
IVth nerve paralysis		1				1
Lethargy	11	22	3	4	8	18
Loss of consciousness	4	14			4	14
Memory impairment	1	3			1	3
Migraine	8	15	5	7	3	8
Migraine with aura		1				1
Myelitis transverse		1				1
Nerve compression		1				1
Nervous system disorder		1				1
Neuralgia	2	6			2	6
Neuritis cranial		1				1
Neuropathy peripheral		1				1
Normal pressure hydrocephalus		1				1
Nystagmus		1				1
Paraesthesia	20	61	10	20	10	41
Presyncope	3	11	2	6	1	5
Psychomotor hyperactivity		1				1
Sciatica	2	2	1	1	1	1
Seizure	2	5			2	5
Seizure like phenomena	1	1			1	1
Sensory disturbance	3	4	1	2	2	2
Sensory loss		2				2
Sinus headache	1	1			1	1
Somnolence	4	10	1	2	3	8
Speech disorder	1	3	1	2		1
Sudden onset of sleep		1				1
Syncope	16	37			16	37

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tardive dyskinesia		1				1
Taste disorder		2				2
Tension headache		1				1
Thrombotic stroke	1	1			1	1
Tongue biting		1				1
Tonic clonic movements		1				1
Transient ischaemic attack	2	5			2	5
Tremor	3	13	1	2	2	11
Trigeminal nerve disorder		2				2
Trigeminal neuralgia	1	2			1	2
Unresponsive to stimuli	2	6			2	6
	287	758	100	186	187	572

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion spontaneous	1	4	1	4
Abortion threatened	1	1	1	1
Retroplacental haematoma	1	1	1	1
	3	6	3	6

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product leakage	1	1	1	1
Product packaging quantity issue		1		1
Product temperature excursion issue	1	2	1	2
Suspected product quality issue		5		5
Syringe issue	2	2	2	2
	4	11	4	11

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation	2	3	1	1	1	2
Anxiety	4	9	3	3	1	6
Confusional state	4	11	1	1	3	10
Delirium	1	1			1	1
Depressed mood		1				1
Depression	2	2	1	1	1	1
Disorientation	1	5			1	5
Eating disorder	1	1	1	1		
Emotional distress	2	4			2	4
Hallucination		1				1
Insomnia	16	32	6	7	10	25
Irritability		1				1
Mood swings		1				1
Negative thoughts		1				1
Nervousness		2		1		1
Panic attack		3				3
Poor quality sleep		1		1		
Restlessness	1	1			1	1
Sleep disorder	2	3			2	3
Stress		1		1		
Thinking abnormal	1	1	1	1		
	37	85	14	18	23	67

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chromaturia		3		1		2
Micturition urgency		1		1		
Pollakiuria		1				1
Urinary incontinence	1	3			1	3
Urinary retention		1				1
Urine odour abnormal		1		1		
	1	10		3	1	7

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amenorrhoea		1				1
Breast mass		1				1
Breast pain		4				4
Breast swelling		4				4
Breast tenderness		1		1		
Heavy menstrual bleeding	2	3	2	3		
Intermenstrual bleeding		3				3
Menstrual disorder	1	3		1	1	2
Menstruation irregular	1	1			1	1
Oligomenorrhoea		1		1		
Polymenorrhoea	1	1	1	1		
Vaginal haemorrhage		3				3
	5	26	3	7	2	19

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory distress syndrome	1	1			1	1
Aspiration		1				1
Asthma		2				2
Choking sensation		1		1		
Cough	6	17	4	5	2	12
Dry throat		2				2
Dysphonia	1	2			1	2
Dyspnoea	11	34		1	11	33
Dyspnoea at rest		2				2
Dyspnoea exertional	2	4			2	4
Epistaxis		3		1		2
Hyperventilation		1				1
Hypopnoea	1	3			1	3
Hypoxia		1				1
Nasal congestion	1	4	1	2		2
Nasal discomfort		1		1		
Oropharyngeal discomfort	1	2	1	1		1
Oropharyngeal pain	3	13	1	3	2	10
Paranasal sinus discomfort		1				1
Pharyngeal hypoaesthesia		1		1		
Pharyngeal paraesthesia		5		3		2
Pharyngeal swelling	2	5	1	1	1	4
Pneumonitis		1				1
Productive cough	1	1			1	1
Pulmonary embolism	1	3			1	3
Pulmonary pain	1	1			1	1
Rales		1				1
Respiration abnormal		1				1
Respiratory arrest	3	3			3	3
Respiratory distress		1				1
Respiratory failure		1				1
Sinus congestion		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sinus pain	1	2	1	1		1
Sneezing	1	2	1	2		
Stridor		3				3
Throat irritation		4		2		2
Throat tightness		4		1		3
Upper-airway cough syndrome	1	1	1	1		
Wheezing		7				7
	38	143	11	27	27	116

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* AE=Adverse Event
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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	1	5			1	5
Blister		1				1
Cold sweat	2	7	2	3		4
Decubitus ulcer	1	1			1	1
Dermatitis	1	3	1	2		1
Dermatitis allergic	1	2			1	2
Dry skin	1	1	1	1		
Eczema		1				1
Erythema	3	10	1	4	2	6
Erythema nodosum	1	1			1	1
Exfoliative rash	1	1			1	1
Hyperhidrosis	8	30	1	3	7	27
Night sweats	2	5	2	4		1
Photosensitivity reaction	1	1			1	1
Pruritus	14	34	7	13	7	21
Psoriasis	2	2	2	2		
Purpura	1	1			1	1
Rash	23	50	8	15	15	35
Rash erythematous	4	12		1	4	11
Rash macular	2	4	1	1	1	3
Rash papular	1	1			1	1
Rash pruritic	3	7	1	3	2	4
Rash vesicular	1	1	1	1		
Sensitive skin		1				1
Skin burning sensation	1	3	1	1		2
Skin discolouration		2		1		1
Skin disorder	1	1			1	1
Skin exfoliation		1				1
Skin tightness		1				1
Skin warm		1				1
Skin wrinkling		1				1
Urticaria	7	24	4	8	3	16

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria chronic	1	1			1	1
Urticarial vasculitis		1				1
Urticaria papular		1		1		
	84	219	33	64	51	155

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden	5	6			5	6
Impaired driving ability		3				3
Impaired work ability	20	40	6	8	14	32
Loss of personal independence in daily activities	8	13		2	8	11
	33	62	6	10	27	52

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aneurysm	1	1	1	1		
Angiopathy	1	1			1	1
Aortic aneurysm		1				1
Bloody discharge		1				1
Cyanosis	3	6	1	2	2	4
Deep vein thrombosis	1	7			1	7
Flushing	2	8	1	1	1	7
Hot flush	2	2	1	1	1	1
Hypertension	8	25	2	3	6	22
Hypotension	1	11		3	1	8
Orthostatic hypotension		1				1
Pallor	1	12	1	4		8
Peripheral coldness	3	3	2	2	1	1
Thrombosis		2				2
	23	81	9	17	14	64

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ISRAEL

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia	1	3		1	1	2
Autoimmune haemolytic anaemia		1				1
Disseminated intravascular coagulation		1				1
Haemolytic anaemia		1				1
Immune thrombocytopenia		2				2
Leukocytosis		7				7
Leukopenia		1				1
Lymphadenopathy	3	23	3	19		4
Lymphocytosis		1		1		
Lymphopenia		1				1
Neutropenia		1				1
Pancytopenia		1				1
Thrombocytopenia		1				1
	4	44	3	21	1	23

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction		4				4
Angina pectoris		4				4
Arrhythmia	1	5			1	5
Atrial fibrillation	1	9			1	9
Atrioventricular block	1	1			1	1
Bradycardia	1	1			1	1
Cardiac arrest		12				12
Cardiac disorder		2				2
Cardiac dysfunction	1	1			1	1
Cardiac failure	1	8			1	8
Cardiac failure chronic		1				1
Cardiac flutter		1				1
Cardiac tamponade		1				1
Cardiogenic shock		1				1
Cardiomegaly	1	1			1	1
Conduction disorder	1	1	1	1		
Myocardial infarction		7				7
Myocarditis	14	84			14	84
Palpitations	2	14	2	12		2
Pericardial effusion	5	7			5	7
Pericarditis	3	46			3	46
Pulseless electrical activity		1				1
Right ventricular enlargement		1		1		
Sinus bradycardia	1	1			1	1
Sinus tachycardia	1	3	1	2		1
Tachycardia	1	9		5	1	4
Ventricular fibrillation		2				2
	35	228	4	21	31	207

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Congenital, familial and genetic disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Syndactyly		1		1
		1		1

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness		3				3
Deafness neurosensory		4				4
Deafness unilateral		3				3
Ear discomfort	1	7	1	5		2
Ear pain	3	8	3	8		
Hyperacusis	1	1	1	1		
Hypoacusis	1	3	1	2		1
Sudden hearing loss		4				4
Tinnitus	2	13	2	6		7
Vertigo	1	9	1	5		4
	9	55	9	27		28

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Basedow's disease		1				1
Ovulation delayed	1	1	1	1		
	1	2	1	1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenopia		1		1		
Blindness transient		1				1
Conjunctival disorder		1				1
Dyschromatopsia		1		1		
Eye haemorrhage		1				1
Eye irritation	1	3	1	2		1
Eyelid function disorder		1		1		
Eyelid oedema		1		1		
Eye pain	4	11	4	8		3
Eye swelling	1	5	1	2		3
Lacrimation increased		2		1		1
Ocular discomfort	2	3	1	2	1	1
Ocular hyperaemia		1		1		
Photopsia		1		1		
Pupil fixed		1				1
Uveitis		2				2
Vision blurred	1	7	1	7		
	9	43	8	28	1	15

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain	2	10	2	9		1
Abdominal pain upper		4		4		
Abnormal faeces	1	1	1	1		
Anaesthesia oral		1		1		
Anal haemorrhage		2		2		
Anorectal discomfort		1		1		
Aphthous ulcer		1		1		
Cheilitis		1		1		
Constipation	1	1	1	1		
Diarrhoea	4	26	4	24		2
Dry mouth		1		1		
Dyspepsia	1	7	1	7		
Dysphagia		6		4		2
Eosinophilic oesophagitis		1		1		
Faeces soft	2	2	2	2		
Gastric haemorrhage		1				1
Gastrointestinal necrosis		1				1
Gingival bleeding		1				1
Gingival pain		1		1		
Haematemesis	1	2			1	2
Haematochezia		1				1
Hypoaesthesia oral		13		11		2
Hypoaesthesia teeth		1		1		
Impaired gastric emptying	1	1			1	1
Lip disorder		1		1		
Lip pruritus		2		2		
Lip swelling	1	4	1	3		1
Nausea	19	70	16	61	3	9
Odynophagia	1	4	1	3		1
Oedema mouth		1				1
Oral discomfort		2		2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral pain		1		1		
Pancreatitis		1				1
Pancreatitis acute	1	1			1	1
Pancreatitis chronic	1	1			1	1
Paraesthesia oral	1	17	1	15		2
Swollen tongue		4				4
Tongue discomfort		1		1		
Tongue oedema		1				1
Toothache	1	3	1	3		
Tooth loss	1	1	1	1		
Vomiting	11	31	8	24	3	7
	50	234	40	191	10	43

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Adverse event		1
Asthenia	56	188
Axillary pain	1	2
Brain death		1
Cardiac death		1
Chest discomfort	4	11
Chest pain	12	44
Chills	43	121
Condition aggravated	1	4
Crying	1	3
Death	2	33
Decreased activity	1	1
Discomfort	4	8
Disease recurrence		5
Drug ineffective	10	61
Extensive swelling of vaccinated limb		2
Facial pain	1	3
Fatigue	28	109
Feeling abnormal	8	26
Feeling cold	5	21
Feeling hot	3	9
Feeling of body temperature change		1
Gait disturbance		7
Generalised oedema	1	1
General physical health deterioration		4
Hangover		1
Hypothermia		1
Illness		2
Inflammation	1	5
Influenza like illness	4	17
Injection site erythema	1	1
Malaise	6	36

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		52	169	4	19
		1	2		
					1
					1
		2	7	2	4
		10	29	2	15
		42	115	1	6
		1	3		1
		1	2		1
				2	33
		1	1		
		4	8		
			3		2
	1			10	61
			2		
		1	2		1
		27	104	1	5
		7	18	1	8
		5	21		
		3	9		
			1		
			2		5
				1	1
					4
			1		
					1
			2		
			2	1	3
		4	17		
		1	1		
		5	29	1	7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Multiple organ dysfunction syndrome		1
Oedema		1
Oedema peripheral		2
Pain	22	64
Peripheral swelling	1	7
Pyrexia	59	173
Sudden cardiac death		1
Sudden death		1
Swelling		3
Swelling face	2	5
Systemic inflammatory response syndrome		10
Tenderness		1
Therapeutic response unexpected	9	15
Thirst		2
Vaccination failure	2	11
Vaccination site bruising		1
Vaccination site discomfort	1	2
Vaccination site erythema	6	18
Vaccination site haematoma	1	1
Vaccination site haemorrhage	1	1
Vaccination site hypersensitivity		2
Vaccination site induration	1	1
Vaccination site inflammation		1
Vaccination site joint movement impairment		1
Vaccination site lymphadenopathy		2
Vaccination site movement impairment	2	4
Vaccination site oedema	1	1
Vaccination site pain	38	145
Vaccination site paraesthesia		1
Vaccination site pruritus	2	3
Vaccination site reaction	1	2
Vaccination site swelling	4	18

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
			1		1
		20	54	2	10
		1	5		2
		56	149	3	24
					1
					1
			3		
		2	4		1
					10
			1		
		9	15		
			1		1
				2	11
			1		
		1	2		
		5	16	1	2
		1	1		
		1	1		
			2		
		1	1		
			1		
			1		
			2		
		2	4		
				1	1
		38	144		1
			1		
		2	3		
		1	2		
		3	16	1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site vesicles		1				1		
Vaccination site warmth	1	1			1	1		
	347	1,233		1	311	984	36	249

System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholelithiasis		1		1		
Drug-induced liver injury		1				1
Hepatic failure		1				1
Hepatic function abnormal		2				2
Hepatitis		1				1
Hepatitis acute		1				1
Hepatomegaly	1	1			1	1
Hyperbilirubinaemia		1				1
Jaundice		1		1		
Liver injury		1				1
	1	11		2	1	9

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		4		2		2
Anaphylactic reaction	1	7			1	7
Anaphylactic shock		2				2
Drug hypersensitivity		3		1		2
Hypersensitivity	3	18	2	7	1	11
	4	34	2	10	2	24

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Arthritis infective	1	1					1	1
Asymptomatic COVID-19		5						5
Conjunctivitis	1	1			1	1		
Coronavirus infection	3	6					3	6
COVID-19	9	72		1		10	9	62
Diverticulitis		1						1
Ear infection		1				1		
Encephalitis		1						1
Endocarditis		1						1
Eye infection		3				2		1
Gastroenteritis viral		1				1		
Gingivitis		1				1		
Herpes simplex		1				1		
Herpes virus infection	1	2			1	2		
Herpes zoster	4	28			3	23	1	5
Infection		1				1		
Infective tenosynovitis	1	1					1	1
Influenza	1	4			1	4		
Laryngitis bacterial		1						1
Localised infection		1						1
Nasopharyngitis	1	6			1	6		
Ophthalmic herpes zoster		2						2
Oral herpes	1	8			1	6		2
Osteomyelitis		1						1
Otitis media		1				1		
Pneumonia	1	6					1	6
Pneumonia pseudomonal	1	1					1	1
Pseudomonas infection		1						1
Pulpitis dental		1				1		
Sepsis		1						1
Septic shock		1						1
Streptococcal infection		1						1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Suspected COVID-19		1						1
Tonsillitis		1						1
Urinary tract infection	1	2				1	1	1
Urosepsis		1						1
Vaccination site cellulitis		2				1		1
Vestibular neuronitis		1						1
	26	171		1	8	63	18	108

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Cartilage injury		1						1
Contusion	1	3			1	2		1
Expired product administered	2	2			2	2		
Exposure during pregnancy	3	8			3	6		2
Exposure to contaminated water		1				1		
Exposure to SARS-CoV-2				1				
Exposure via breast milk	4	9			4	9		
Face injury		1						1
Fall		7				3		4
Foetal exposure during pregnancy		1						1
Head injury		1						1
Hip fracture		1						1
Inappropriate schedule of product administration	1	8			1	8		
Incomplete course of vaccination	1	2			1	2		
Incorrect dose administered		2				2		
Incorrect route of product administration	1	1			1	1		
Inflammation of wound		1				1		
Intentional dose omission		1				1		
Ligament sprain	1	1			1	1		
Limb injury		1				1		
Maternal exposure during pregnancy	7	12			6	11	1	1
Maternal exposure timing unspecified		1				1		
Off label use	2	9			2	9		
Overdose		5				5		
Pelvic fracture		1						1
Poor quality product administered	7	39			7	39		
Product administered at inappropriate site	1	4			1	4		
Product administered to patient of inappropriate age		2				2		
Product preparation error		4				4		
Product preparation issue		2				2		
Product use issue	3	8			3	8		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Recall phenomenon		2				2		
Rib fracture		1						1
Tooth injury		1				1		
Underdose		3				3		
Wrong technique in product usage process		3				3		
	34	149		1	33	134	1	15

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Activated partial thromboplastin time shortened		1				1
Alanine aminotransferase increased	1	1	1	1		
Amylase increased	1	1			1	1
Antinuclear ant body positive		1		1		
Antiphospholipid antibodies positive		1				1
Aspartate aminotransferase increased	1	1	1	1		
Blood chloride increased		2		1		1
Blood creatine phosphokinase increased	3	4			3	4
Blood creatinine abnormal		1		1		
Blood fibrinogen increased	1	1			1	1
Blood glucose increased		3		1		2
Blood immunoglobulin M increased		1		1		
Blood iron decreased	2	3			2	3
Blood lactate dehydrogenase increased		1				1
Blood phosphorus decreased	1	1			1	1
Blood pressure abnormal	1	2	1	1		1
Blood pressure decreased		2		1		1
Blood pressure increased	7	20	5	12	2	8
Blood pressure systolic increased		1		1		
Blood triglycerides increased	1	1			1	1
Body temperature decreased	1	4	1	4		
Body temperature increased	1	1	1	1		
C-reactive protein increased	3	7	1	3	2	4
Electrocardiogram abnormal		2		1		1
Electrocardiogram T wave inversion		1				1
Foetal heart rate abnormal		1				1
Glomerular filtration rate decreased		1				1
Heart rate increased	6	15	5	13	1	2
Heart rate irregular	1	1	1	1		
Hepatic enzyme increased		1				1
Hormone level abnormal	1	2	1	2		
Inflammatory marker increased		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
International normalised ratio decreased		1				1
International normalised ratio increased		2		1		1
Liver function test abnormal	1	1	1	1		
Liver function test increased		1		1		
Lymphocyte count decreased	1	1			1	1
Lymphocyte count increased		1		1		
Mean cell haemoglobin concentration decreased		1		1		
Mean cell haemoglobin decreased		3		2		1
Mean cell volume decreased		1		1		
Mean platelet volume increased		1		1		
Neutrophil count decreased		1		1		
Neutrophil count increased		1				1
Oxygen saturation decreased		2		1		1
Pulse abnormal		1				1
Red blood cell count increased		1		1		
Respiratory rate increased		1				1
SARS-CoV-2 ant body test negative		3		2		1
SARS-CoV-2 test positive		2				2
Transaminases increased	1	1			1	1
Troponin increased		2				2
Ultrasound breast abnormal	1	1			1	1
Urine sodium increased	1	1			1	1
Vitamin B12 decreased		1				1
Weight decreased	2	5	2	3		2
	39	122	21	64	18	58

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alcohol intolerance		1		1		
Decreased appetite	3	14	3	13		1
Diabetic ketoacidosis		1				1
Food craving		1		1		
Food refusal		1				1
Hyponatraemia		1				1
	3	19	3	15		4

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	17	55	14	45	3	10
Arthritis	1	2	1	2		
Arthritis reactive		1				1
Arthropathy		1		1		
Back pain	6	27	5	23	1	4
Bone pain	6	11	6	11		
Facial asymmetry		1		1		
Finger deformity	1	1			1	1
Joint noise		1		1		
Joint range of motion decreased	3	4	1	1	2	3
Joint swelling	1	4	1	3		1
Limb discomfort	1	3	1	3		
Mobility decreased	1	6	1	4		2
Muscle disorder		1		1		
Muscle rigidity		1		1		
Muscle spasms	3	6	3	6		
Muscle twitching		1		1		
Muscular weakness	4	12	3	7	1	5
Musculoskeletal chest pain	1	3	1	3		
Musculoskeletal discomfort		1		1		
Musculoskeletal disorder	2	2	1	1	1	1
Musculoskeletal stiffness	1	3		2	1	1
Myalgia	50	124	46	114	4	10
Myositis	1	1			1	1
Neck pain	6	16	2	11	4	5
Pain in extremity	27	84	25	78	2	6
Pain in jaw	2	5	2	5		
Psoriatic arthropathy		1				1
Rhabdomyolysis		1				1
	134	379	113	326	21	53

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Chronic lymphocytic leukaemia		1		1
Non-Hodgkin's lymphoma		1		1
		2		2

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		2		2		
Anaesthesia	1	1	1	1		
Anosmia		3		3		
Aphasia		2		1		1
Balance disorder		1		1		
Bell's palsy	1	18			1	18
Brain injury		1				1
Brain oedema		1				1
Burning sensation	2	3	2	2		1
Cerebellar haemorrhage		1				1
Cerebral haemorrhage		1				1
Cerebral ischaemia		1				1
Cerebrovascular accident		12				12
Chronic inflammatory demyelinating polyradiculoneuropathy		1				1
Depressed level of consciousness		1				1
Disturbance in attention	2	2	2	2		
Dizziness	23	70	23	60		10
Dysaesthesia		1		1		
Dysarthria		1				1
Dysgeusia	3	14	3	14		
Dyskinesia		6		4		2
Dysstasia	1	5	1	3		2
Electric shock sensation		1		1		
Epilepsy	1	2			1	2
Facial nerve disorder		1		1		
Facial paralysis	2	26			2	26
Facial paresis		2				2
Foetal movement disorder		1				1
Formication	1	4	1	4		
Generalised tonic-clonic seizure	1	1			1	1
Guillain-Barre syndrome	1	5			1	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache	58	180	58	170		10
Head discomfort		3		3		
Hemiparaesthesia		1				1
Hemiparesis	1	1			1	1
Hemiplegia		1				1
Hypersomnia		1		1		
Hypoaesthesia	10	51	10	47		4
IIIrd nerve paralysis		1				1
Ischaemic stroke		1				1
Loss of consciousness		12				12
Migraine	2	4	2	4		
Migraine with aura	1	1	1	1		
Monoplegia		1				1
Motor dysfunction		1				1
Movement disorder	1	6	1	5		1
Multiple sclerosis		3				3
Multiple sclerosis relapse		4				4
Muscle contractions involuntary		4		4		
Myasthenia gravis		2				2
Nervous system disorder	1	2	1	2		
Neuralgia		3		1		2
Neuralgic amyotrophy		3		2		1
Neuritis		1		1		
Noninfective encephalitis	1	1			1	1
Paraesthesia	15	63	14	53	1	10
Paralysis		4				4
Paraplegia		1				1
Parosmia	1	4	1	4		
Polyneuropathy		1				1
Presyncope	3	7	2	5	1	2
Psychomotor hyperactivity		1		1		
Reduced facial expression		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ruptured cerebral aneurysm		1				1
Seizure		17				17
Sensory disturbance	1	5	1	4		1
Sensory loss	1	4	1	2		2
Slow speech		1				1
Somnolence	1	4	1	4		
Speech disorder		8		4		4
Subarachnoid haemorrhage	1	1			1	1
Superior sagittal sinus thrombosis		1				1
Syncope	1	12			1	12
Taste disorder	1	3	1	3		
Tonic convulsion		1				1
Transient ischaemic attack	1	7			1	7
Tremor	2	12	2	11		1
Trigeminal neuralgia	1	1	1	1		
Unresponsive to stimuli		1				1
Vlth nerve paralysis		1				1
	143	641	130	434	13	207

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion missed	1	1			1	1
Abortion spontaneous		2				2
Foetal death		3				3
High risk pregnancy	1	1	1	1		
Premature labour		1				1
Still birth		1				1
Twin pregnancy		1		1		
Uterine contractions abnormal		1		1		
	2	11	1	3	1	8

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Liquid product physical issue	3	18	3	18
Product colour issue	1	1	1	1
Product complaint		1		1
Product deposit		1		1
Product packaging quantity issue		12		12
Product quality issue	2	2	2	2
Product temperature excursion issue	1	1	1	1
	7	36	7	36

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation		1		1		
Anger		1		1		
Anxiety	1	8	1	6		2
Bruxism	1	1			1	1
Confusional state	3	7	3	5		2
Depressed mood		5		4		1
Depression		2		1		1
Dysphemia		1				1
Emotional disorder	1	1	1	1		
Fear of injection	1	1	1	1		
Frustration tolerance decreased	1	1	1	1		
Hallucination		1				1
Hallucination, auditory		1				1
Initial insomnia		1		1		
Insomnia	5	12	4	11	1	1
Loss of libido		1		1		
Mental disorder	1	2	1	2		
Mood altered		1		1		
Mood swings	1	1	1	1		
Nervousness		1		1		
Nightmare	1	1	1	1		
Personality change		1		1		
Poor quality sleep	1	3	1	3		
Restlessness		2		1		1
Schizophrenia		1				1
Sleep attacks	1	1	1	1		
Sleep disorder		2		1		1
Sleep disorder due to general medical condition, insomnia type		1		1		
Stress		2		2		
Suicidal ideation		1				1
Thinking abnormal		1		1		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tic	2	2	2	2		
	20	68	18	53	2	15

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute kidney injury	2	4	2	4
Glomerulonephritis minimal lesion	2	2	2	2
Nephrolithiasis		1		1
Nephrotic syndrome	2	2	2	2
	6	9	6	9

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adnexa uteri pain		1		1		
Amenorrhoea	2	2	2	2		
Breast engorgement		1		1		
Breast inflammation		1		1		
Breast pain		1		1		
Breast tenderness		1		1		
Dysmenorrhoea	2	3	2	3		
Heavy menstrual bleeding	14	17	14	17		
Hypomenorrhoea	1	3	1	3		
Intermenstrual bleeding	7	8	7	8		
Menstrual disorder	9	11	8	10	1	1
Menstruation delayed	4	4	4	4		
Menstruation irregular	14	16	14	16		
Pelvic pain		1		1		
Polymenorrhoea	3	3	3	3		
Premenstrual syndrome	2	3	2	3		
Testicular pain		1		1		
Uterine haemorrhage		1				1
Uterine pain	1	2	1	2		
Vaginal haemorrhage	8	18	8	13		5
Vaginal ulceration	1	1	1	1		
Vulval ulceration	1	1	1	1		
	69	100	68	93	1	7

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory distress syndrome		1				1
Acute respiratory failure		1				1
Aphonia		1				1
Aspiration		1				1
Asthma		2		1		1
Atelectasis		1				1
Choking		4				4
Chronic obstructive pulmonary disease		2				2
Cough	6	19	5	15	1	4
Dry throat	1	1	1	1		
Dysphonia	1	1	1	1		
Dyspnoea	9	60	6	24	3	36
Dyspnoea exertional	1	4	1	4		
Eosinophilic pneumonia acute		1				1
Epistaxis	1	3			1	3
Hyperventilation		1		1		
Hypoventilation		1				1
Laryngeal inflammation		1		1		
Lung disorder		2		1		1
Lung infiltration		1				1
Nasal congestion	1	1	1	1		
Oropharyngeal discomfort		1		1		
Oropharyngeal pain	7	21	6	19	1	2
Pharyngeal paraesthesia		1		1		
Pharyngeal swelling		4		2		2
Pleural effusion	2	4	1	1	1	3
Pleurisy	1	1			1	1
Pleuritic pain		2		1		1
Pneumonia aspiration		2				2
Productive cough	1	2		1	1	1
Pulmonary congestion	1	1			1	1
Pulmonary embolism	1	7			1	7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary oedema		2				2
Respiratory arrest		2				2
Respiratory disorder		4		1		3
Respiratory distress		1				1
Rhinalgia		1		1		
Rhinorrhoea		4		4		
Sneezing		3		2		1
Suffocation feeling		3				3
Throat irritation	1	2	1	1		1
Throat tightness	1	2			1	2
Tracheal oedema		1				1
Wheezing	1	4	1	2		2
Yawning		2		1		1
	36	186	24	88	12	98

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecia	1	2	1	2		
Angioedema		4				4
Blister	1	2	1	1		1
Cold sweat	1	4	1	4		
Eczema	1	1	1	1		
Erythema	4	20	4	17		3
Erythema nodosum	1	1			1	1
Hyperhidrosis	1	12	1	12		
Mechanical urticaria		1		1		
Miliaria		1		1		
Night sweats	2	2	2	2		
Palmar erythema		1		1		
Pruritus	4	18	4	14		4
Purpura		2		1		1
Rash	11	30	10	23	1	7
Rash macular		2		2		
Rash maculo-papular		1		1		
Rash pruritic	2	3	2	3		
Rash vesicular		1				1
Skin burning sensation		3		3		
Skin discolouration		3		3		
Skin disorder		1		1		
Skin exfoliation		1		1		
Skin reaction		1		1		
Skin tightness	1	1	1	1		
Urticaria	1	9	1	5		4
Yellow skin	1	1	1	1		
	32	128	30	102	2	26

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Impaired quality of life		1		1
Loss of personal independence in daily activities	1	3	1	3
Walking disability	2	2	2	2
	3	6	3	6

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aneurysm ruptured	1	1			1	1
Arterial thrombosis		1				1
Blood pressure fluctuation	1	2			1	2
Circulatory collapse		1				1
Cyanosis	1	1	1	1		
Deep vein thrombosis	1	4			1	4
Erythromelalgia	1	1			1	1
Flushing	1	1	1	1		
Haemorrhage		2				2
Hot flush	4	4	4	4		
Hypertension	1	8		3	1	5
Hypotension	1	6	1	3		3
Pallor		2		2		
Peripheral artery occlusion		1				1
Peripheral coldness	1	6	1	6		
Peripheral ischaemia		1				1
Shock		1				1
Thrombosis	1	4			1	4
Vein discolouration		1		1		
	14	48	8	21	6	27

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

ITALY

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System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acquired haemophilia			1	1				
Anaemia	8	12	1	1	1	3	7	9
Anaemia macrocytic		1						1
Blood disorder	1	1					1	1
Bone marrow disorder	1	1					1	1
Bone marrow oedema		1						1
Coagulopathy		1						1
Haemolysis	1	1					1	1
Haemorrhagic diathesis	2	2					2	2
Immune thrombocytopenia	2	3		1			2	3
Leukocytosis	2	4		1		2	2	2
Leukopenia		5		1				5
Lymphadenitis	10	52			10	39		13
Lymphadenopathy	218	1,699	1	15	196	1497	22	202
Lymphadenopathy mediastinal	1	1					1	1
Lymphatic obstruction		1						1
Lymph node pain	17	131	1	6	16	114	1	17
Lymphocytosis	1	3			1	3		
Lymphopenia		3						3
Neutropenia	1	2		1			1	2
Neutrophilia		2						2
Paratracheal lymphadenopathy		1				1		
Platelet disorder	1	1					1	1
Splenomegaly		1						1
Spontaneous haematoma	1	1	1	1	1	1		
Thrombocytopenia	20	41	1	2			20	41
Thrombocytosis	1	1					1	1
Thrombotic thrombocytopenic purpura	1	1					1	1
	289	1,973	6	30	225	1660	64	313

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute coronary syndrome	3	11					3	11
Acute myocardial infarction	10	19					10	19
Angina pectoris	3	8					3	8
Angina unstable	1	1					1	1
Aortic valve calcification	1	1					1	1
Aortic valve stenosis		1						1
Arrhythmia	6	35					6	35
Arteriospasm coronary		1						1
Atrial fibrillation	14	38	1	1			14	38
Atrial flutter	1	6				1	1	5
Atrial tachycardia	1	3				2	1	1
Atrioventricular block	1	1	1	1			1	1
Atrioventricular block complete		1						1
Atrioventricular block first degree		1				1		
Atrioventricular block second degree	1	1			1	1		
Bradycardia	1	22	3	4			1	22
Bundle branch block right		1						1
Cardiac arrest	14	33					14	33
Cardiac disorder	1	3					1	3
Cardiac dysfunction	1	1					1	1
Cardiac failure	7	19	1	1			7	19
Cardiac failure congestive	1	4					1	4
Cardiac fibrillation		1						1
Cardiac valve disease	1	1					1	1
Cardiogenic shock		1						1
Cardiomegaly	1	1			1	1		
Cardiomyopathy	1	1					1	1
Cardiopulmonary failure	2	3					2	3
Cardio-respiratory arrest	5	13					5	13
Cardiovascular disorder		1				1		
Coronary artery disease	1	3					1	3
Coronary artery dissection		1						1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Coronary artery stenosis		2
Defect conduction intraventricular		1
Dilatation atrial		1
Extrasystoles	2	26
Hypertensive heart disease		3
Intracardiac thrombus	1	1
Left ventricular dysfunction		1
Left ventricular failure		1
Left ventricular hypertrophy		1
Mitral valve incompetence		4
Mitral valve stenosis		1
Myocardial infarction	5	10
Myocardial ischaemia	4	6
Myocarditis	3	9
Palpitations	12	58
Paroxysmal arrhythmia		1
Pericardial effusion	5	17
Pericarditis	7	18
Pleuropericarditis	1	2
Right ventricular dilatation		1
Right ventricular dysfunction	1	1
Sinus bradycardia		1
Sinus tachycardia		17
Supraventricular extrasystoles		2
Supraventricular tachycardia	1	3
Tachyarrhythmia	2	6
Tachycardia	96	511
Tachycardia paroxysmal	2	9
Tricuspid valve incompetence		2
Ventricular arrhythmia	1	3
Ventricular dysfunction	1	1
Ventricular extrasystoles	2	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
					1
1	1	1	16	1	10
					3
				1	1
			1		
					1
					1
					4
					1
				5	10
				4	6
				3	9
		8	36	4	22
					1
				5	17
				7	18
				1	2
			1		
				1	1
			1		
	1		9		8
			1		1
		1	2		1
1	1	1	5	1	1
3	8	56	318	40	193
	1		4	2	5
					2
				1	3
				1	1
			7	2	5

* I=Interval, C=Cumulative
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System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ventricular f brillation	1	3					1	3
Ventricular tachycardia		2						2
Wandering pacemaker		1						1
	225	975	11	19	69	408	156	567

System Organ Class

Congenital, familial and genetic disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Corneal dystrophy		1						1
Gilbert's syndrome	1	1			1	1		
Hypertrophic cardiomyopathy		1						1
Macroglossia	2	4	1	1			2	4
Thyroglossal cyst		1						1
	3	8	1	1	1	1	2	7

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Auditory disorder	1	4				2	1	2
Deafness	2	6					2	6
Deafness bilateral		1						1
Deafness neurosensory	3	5			1	1	2	4
Deafness unilateral	1	2					1	2
Ear discomfort	1	18			1	14		4
Ear disorder		3				2		1
Ear haemorrhage	1	2				1	1	1
Ear pain	12	58			5	38	7	20
Ear pruritus		6				6		
Ear swelling	2	5			1	3	1	2
Hyperacusis	1	5			1	4		1
Hypoacusis	4	17	1	1		4	4	13
Motion sickness		3				3		
Neurosensory hypoacusis		1	1	1				1
Otolithiasis	1	1					1	1
Paraesthesia ear		2				1		1
Sudden hearing loss	2	3					2	3
Tinnitus	12	50	1	1	8	31	4	19
Vertigo	64	489	4	7	50	392	14	97
Vertigo positional		3		1		2		1
Vestibular disorder		1						1
	107	685	7	11	67	504	40	181

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adrenomegaly	1	3	1	3		
Autoimmune thyroiditis		5				5
Basedow's disease	1	2			1	2
Goitre	2	4	2	3		1
Hyperthyroidism	1	3			1	3
Hypopituitarism	1	1	1	1		
Hypothyroidism	1	1			1	1
Thyroid disorder	1	2	1	2		
Thyroiditis acute	2	2			2	2
Thyroiditis subacute		3		3		
Thyroid mass	1	2	1	1		1
Thyroid pain		2		1		1
	11	30	6	14	5	16

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Accommodation disorder	1	3
Age-related macular degeneration		1
Amaurosis fugax	1	2
Arteriosclerotic retinopathy		1
Asthenopia		15
Binocular eye movement disorder		1
Blepharitis	1	1
Blepharospasm		4
Blindness	3	8
Blindness unilateral	2	3
Chorioretinopathy	1	1
Conjunctival haemorrhage	5	14
Conjunctival hyperaemia	2	7
Conjunctival irritation		4
Conjunctivitis allergic	1	2
Corneal bleeding		1
Corneal opacity	1	2
Dark circles under eyes	1	1
Diplopia	15	37
Dry eye	1	8
Eczema eyelids	1	1
Episcleritis		1
Erythema of eyelid		3
Exophthalmos	3	3
Extraocular muscle paresis		1
Eye allergy		1
Eye colour change		1
Eye discharge	1	1
Eye disorder		4
Eye haematoma	1	2
Eye haemorrhage	3	5
Eye irritation	13	84

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	2
					1
				1	2
					1
			13		2
					1
		1	1		
			3		1
				3	8
				2	3
				1	1
	2			5	14
		1	3	1	4
			2		2
			1	1	1
					1
				1	2
		1	1		
		4	20	11	17
		1	6		2
		1	1		
					1
			2		1
				3	3
					1
			1		
					1
		1	1		
			2		2
				1	2
				3	5
	1	13	76		8

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eyelid bleeding	1	1
Eyelid function disorder	1	2
Eyelid myoclonus		2
Eyelid oedema	3	31
Eyelid pain		2
Eyelid ptosis	6	16
Eyelid retraction		1
Eyelids pruritus	1	3
Eye movement disorder	1	3
Eye oedema	3	11
Eye pain	11	68
Eye paraesthesia	2	8
Eye pruritus	5	28
Eye swelling	3	12
Foreign body sensation in eyes		1
Gaze palsy	2	3
Glare		1
Glaucoma	1	1
Iridocyclitis		1
Lacrimation disorder		1
Lacrimation increased	8	35
Lagophthalmos		3
Lens disorder	1	1
Macular rupture		1
Maculopathy		2
Metamorphopsia	1	2
Miosis		1
Mydriasis	1	2
Ocular discomfort	5	13
Ocular hyperaemia	5	43
Oculogyric crisis	1	2
Optic disc haemorrhage	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1		1
					2
	1	2	17	1	14
			1		1
		1	6	5	10
					1
		1	3		
			1	1	2
		2	7	1	4
	1	8	54	3	14
		2	6		2
		2	14	3	14
		3	9		3
			1		
				2	3
			1		
				1	1
					1
					1
		5	26	3	9
			1		2
		1	1		
					1
					2
		1	1		1
			1		
		1	1		1
		4	12	1	1
		4	31	1	12
				1	2
				1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Optic ischaemic neuropathy		1
Optic neuropathy		1
Orbital haematoma		1
Orbital oedema		1
Papilloedema	1	3
Periorbital discomfort		1
Periorbital oedema	2	16
Periorbital pain		2
Periorbital swelling	4	17
Photophobia	6	46
Photopsia	3	11
Pupils unequal	2	2
Retinal artery embolism	1	1
Retinal artery occlusion	2	4
Retinal degeneration		1
Retinal detachment		2
Retinal disorder		1
Retinal drusen		1
Retinal ischaemia	1	1
Retinal oedema		1
Retinal vascular thrombosis		
Retinal vein occlusion	1	2
Retinal vein thrombosis	2	5
Scintillating scotoma	1	4
Scleral discolouration	2	3
Scleral hyperaemia		1
Strabismus	2	2
Swelling of eyelid		9
Uveitis		7
Vision blurred	21	83
Visual acuity reduced	2	4
Visual field defect	2	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
					1
				1	3
					1
		2	10		6
			2		
		3	14	1	3
		5	38	1	8
		2	6	1	5
		1	1	1	1
				1	1
				2	4
					1
					2
					1
					1
				1	1
					1
	1				
				1	2
				2	5
		1	4		
		2	2		1
			1		
				2	2
			7		2
					7
1	1	13	56	8	27
	1	1	2	1	2
		1	5	1	2

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Visual impairment	13	46		2	8	26	5	20
Vitreoretinal traction syndrome	1	2					1	2
Vitreous detachment	1	5		1			1	5
Vitreous disorder		3				1		2
Vitreous floaters	1	4					1	4
Vitreous haemorrhage		1						1
Vitritis		1						1
Xanthopsia		1						1
Xerophthalmia		2						2
	191	831	1	11	100	504	91	327

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	10	22			7	17	3	5
Abdominal distension	6	29			4	20	2	9
Abdominal migraine		1				1		
Abdominal pain	63	414	3	3	52	348	11	66
Abdominal pain lower	3	6			2	4	1	2
Abdominal pain upper	39	185	2	4	28	145	11	40
Abdominal rigidity		4				4		
Abdominal tenderness	1	1			1	1		
Acquired macroglossia		1						1
Acute abdomen		2						2
Anaesthesia oral		7				5		2
Anal erythema		1						1
Anal haemorrhage	1	1					1	1
Anal incontinence		3				1		2
Anal sphincter atony		1						1
Angular cheilitis		1				1		
Aphthous ulcer	3	19		1	3	17		2
Apical granuloma	1	1			1	1		
Aptyalism	1	3				2	1	1
Bowel movement irregularity	1	1			1	1		
Breath odour	1	2			1	2		
Burning mouth syndrome		2				1		1
Change of bowel habit	1	1					1	1
Colitis	3	4			2	3	1	1
Colitis ischaemic		1						1
Constipation	6	13			4	10	2	3
Defaecation urgency		1				1		
Dental discomfort	1	1			1	1		
Dental dysaesthesia	1	1					1	1
Diarrhoea	151	792	3	6	126	658	25	134
Diarrhoea haemorrhagic	1	2					1	2
Diverticulum	1	1					1	1

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dry mouth	18	109
Duodenal ulcer haemorrhage	1	1
Dysbiosis		1
Dyschezia		1
Dyspepsia	4	33
Dysphagia	19	124
Enteritis	1	3
Enterocolitis		1
Eructation	1	4
Faeces hard		1
Faeces pale	1	1
Faeces soft		2
Flatulence	4	11
Frequent bowel movements		4
Functional gastrointestinal disorder		1
Gastric dilatation		1
Gastritis	5	6
Gastrointestinal disorder	12	55
Gastrointestinal haemorrhage		1
Gastrointestinal hypermotility		1
Gastrointestinal motility disorder	1	2
Gastrointestinal pain	9	19
Gastrointestinal sounds abnormal	2	4
Gastroesophageal reflux disease	1	6
Gingival bleeding	4	7
Gingival discolouration		1
Gingival discomfort	1	1
Gingival oedema		2
Gingival pain		2
Gingival swelling		2
Glossitis		8
Glossodynia	2	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	15	80	3	29
				1	1
					1
					1
		4	29		4
2	5	8	65	11	59
1	1	1	3		
					1
			3	1	1
			1		
				1	1
			1		1
		3	10	1	1
			4		
			1		
			1		
		4	5	1	1
	1	12	50		5
					1
					1
		1	1		1
		8	17	1	2
		2	4		
		1	6		
			1	4	6
					1
	1	1	1		
			1		1
			2		
			1		1
			6		2
		2	4		3

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haematemesis	1	3
Haematochezia	3	5
Haemoperitoneum		1
Haemorrhoids	1	1
Haemorrhoids thrombosed	2	2
Hiatus hernia	1	1
Hypertrophy of tongue papillae	2	3
Hypoaesthesia oral	8	56
Impaired gastric emptying		1
Infantile vomiting		1
Inflammatory bowel disease	1	1
Intestinal congestion		1
Intestinal infarction	1	1
Intestinal ischaemia	2	6
Intestinal obstruction	1	2
Intestinal pseudo-obstruction		1
Intra-abdominal haemorrhage	1	1
Irritable bowel syndrome	1	1
Lip disorder		2
Lip dry		2
Lip erythema	1	5
Lip oedema	13	87
Lip pain		4
Lip pruritus	2	20
Lip swelling	9	46
Melaena	1	2
Mesenteric vein thrombosis	1	1
Mouth haemorrhage		2
Mouth swelling	1	7
Mouth ulceration		2
Mucous stools		1
Nausea	320	2,127

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1			1	3
				3	5
					1
		1	1		
				2	2
				1	1
		2	2		1
		5	43	3	13
					1
			1		
				1	1
			1		
				1	1
				2	6
				1	2
					1
				1	1
		1	1		
					2
			2		
		1	4		1
	1	8	51	5	36
			4		
			9	2	11
	1	5	30	4	16
				1	2
				1	1
			1		1
		1	4		3
			1		1
			1		
5	16	273	1800	47	327

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Noninfective gingivitis	1	3
Odynophagia	1	9
Oedema mouth	1	10
Oedematous pancreatitis		1
Oesophageal oedema		1
Oesophageal pain		2
Oesophageal spasm		2
Oral discomfort	8	32
Oral disorder	1	2
Oral dysaesthesia	2	8
Oral mucosal erythema		2
Oral pain	2	7
Oral pruritus	1	16
Palatal disorder		1
Palatal oedema	2	25
Palatal swelling		5
Palatal ulcer	1	1
Pancreatitis		4
Pancreatitis acute		1
Paraesthesia oral	44	304
Parotid gland enlargement		2
Peristalsis vis ble		1
Plicated tongue	1	2
Rectal haemorrhage	5	7
Regurgitation		1
Retching	6	43
Salivary gland pain		1
Salivary hypersecretion	1	11
Scalloped tongue	1	1
Stomatitis	2	7
Submaxillary gland enlargement		1
Swollen tongue	7	48

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		1
	1	1	6		3
	1	1	7		3
					1
					1
			1		1
					2
	1	6	25	2	7
		1	2		
		1	7	1	1
			1		1
		2	5		2
		1	8		8
			1		
		1	15	1	10
			3		2
		1	1		
					4
					1
1	4	28	202	16	102
			1		1
			1		
		1	1		1
				5	7
					1
1	1	5	31	1	12
			1		
			8	1	3
		1	1		
			4	2	3
			1		
		4	24	3	24

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tongue blistering	1	1			1	1		
Tongue coated		2				2		
Tongue discolouration	1	4			1	3		1
Tongue discomfort		13				11		2
Tongue disorder		3				2		1
Tongue dry	1	8			1	6		2
Tongue eruption		1				1		
Tongue erythema		3				2		1
Tongue geographic	1	1			1	1		
Tongue movement disturbance		1						1
Tongue oedema	9	48		1	5	21	4	27
Tongue pruritus	3	16			2	10	1	6
Tongue ulceration		3				2		1
Toothache	1	5				4	1	1
Volvulus		1						1
Vomiting	125	621	3	10	79	435	46	186
Vomiting projectile		3				1		2
	983	5,637	22	61	737	4358	246	1279

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* AE=Adverse Event
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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Administration site erythema		3
Administration site induration	1	1
Administration site joint pain	1	1
Administration site movement impairment		2
Administration site oedema		19
Administration site pain	3	89
Administration site paraesthesia		2
Administration site pruritus		3
Administration site rash		1
Administration site reaction		7
Administration site swelling		4
Administration site warmth		1
Application site coldness		1
Application site oedema		2
Application site paraesthesia		1
Asthenia	422	2,458
Axillary pain	30	183
Breakthrough pain		2
Catheter site pain		2
Chest discomfort	21	104
Chest pain	58	197
Chills	401	2,561
Chronic fatigue syndrome	2	2
Condition aggravated	6	29
Crying	1	4
Cyst		1
Death	7	17
Discomfort	14	36
Disease progression	2	2
Disease recurrence	8	32
Drug ineffective	79	191
Drug interaction		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		
		1	1		
		1	1		
			1		1
			19		
		3	89		
			2		
			3		
			1		
			6		1
			4		
			1		
			1		
			2		
			1		
5	16	358	2114	64	344
	6	28	168	2	15
			1		1
			2		
2	4	15	64	6	40
5	6	24	110	34	87
	7	349	2219	52	342
		2	2		
1	1	1	7	5	22
1	1	1	3		1
			1		
				7	17
		11	28	3	8
				2	2
	1	2	6	6	26
2	3	1	1	78	190
1	1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Effusion		1
Enanthema		1
Extensive swelling of vaccinated limb		6
Extravasation		1
Face oedema	11	54
Facial discomfort		4
Facial pain	1	15
Fatigue	381	2,699
Feeling abnormal	8	39
Feeling cold	33	243
Feeling drunk		1
Feeling hot	36	223
Feeling jittery		6
Feeling of body temperature change	2	16
Foaming at mouth	1	3
Gait disturbance	14	52
Gait inability	3	10
Generalised oedema		1
General physical health deterioration	2	7
General symptom	1	1
Gravitational oedema	1	1
Hyperpyrexia	22	252
Hyperthermia	6	42
Hypothermia	6	27
Idiosyncratic drug reaction	1	1
Illness	10	18
Induration	1	11
Inflammation	1	14
Inflammatory pain		2
Influenza like illness	30	177
Infusion site joint swelling		1
Infusion site lymphadenopathy		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
			4		2
			1		
2	2	6	23	5	31
			4		
			8	1	7
2	7	320	2411	61	288
		8	31		8
	1	28	215	5	28
			1		
		25	161	11	62
			4		2
		1	10	1	6
				1	3
1	1	8	27	6	25
			2	3	8
			1		
			1	2	6
		1	1		
		1	1		
1	5			22	252
		6	33		9
		1	1	5	26
		1	1		
		9	14	1	4
		1	11		
		1	10		4
			1		1
	1	29	160	1	17
			1		
			1		

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Infusion site pain		4
Infusion site paraesthesia		1
Injected limb mobility decreased	2	32
Injection site discharge		1
Injection site discomfort	1	3
Injection site erythema	5	174
Injection site haematoma	1	10
Injection site haemorrhage		2
Injection site hyperaesthesia		1
Injection site hypersensitivity		3
Injection site hypoaesthesia		3
Injection site induration		13
Injection site inflammation		2
Injection site joint erythema		2
Injection site joint pain	1	4
Injection site joint swelling		1
Injection site lymphadenopathy		2
Injection site muscle weakness		2
Injection site oedema	2	309
Injection site pain	60	2,064
Injection site paraesthesia		13
Injection site pruritus		49
Injection site rash	1	5
Injection site reaction		28
Injection site swelling	1	63
Injection site urticaria		34
Injection site warmth	1	11
Instillation site bruise		1
Localised oedema	6	36
Local reaction	3	12
Loss of control of legs		1
Malaise	210	1,665

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			4		
			1		
	1	1	30	1	2
			1		
		1	3		
		5	174		
		1	10		
			2		
			1		
			3		
			3		
			13		
			2		
			2		
		1	4		
			1		
			2		
			2		
		2	309		
		59	2061	1	3
			13		
			49		
		1	5		
			28		
		1	63		
			33		1
		1	11		
			1		
	1	5	29	1	7
		3	12		
					1
7	10	179	1514	31	151

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mucosal dryness		3
Mucosal hyperaemia		1
Mucosal inflammation		1
Mucosal ulceration		1
Multi-organ disorder	1	1
Multiple organ dysfunction syndrome		3
No adverse event	1	3
Nodule		1
Non-cardiac chest pain		1
Non-pitting oedema		2
Obstruction		1
Oedema	9	41
Oedema mucosal	1	4
Oedema peripheral	16	60
Pain	125	761
Performance status decreased	1	1
Peripheral swelling	33	136
Pneumatosis		1
Puncture site induration		4
Puncture site pain		2
Pyrexia	1,027	6,037
Secretion discharge	1	2
Sensation of foreign body	4	27
Sense of oppression		7
Sluggishness	1	2
Stenosis	2	2
Sudden death	6	24
Swelling	25	106
Swelling face	12	67
Temperature intolerance		2
Temperature regulation disorder	1	1
Tenderness	1	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		
					1
			1		
					1
				1	1
	1				3
		1	3		
			1		
					1
			1		1
			1		
		8	35	1	6
				1	4
4	6	6	38	10	22
1	2	110	651	15	110
		1	1		
1	1	26	107	7	29
					1
			4		
			2		
11	50	884	5068	143	969
		1	1		1
		2	15	2	12
1	1		4		3
		1	1		1
				2	2
	1			6	24
		18	84	7	22
	1	6	41	6	26
			2		
		1	1		
		1	9		1

* I=Interval, C=Cumulative
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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Therapeutic response unexpected	2	3
Thirst	2	9
Thirst decreased	1	1
Vaccination failure	99	188
Vaccination site anaesthesia		1
Vaccination site bruising	1	5
Vaccination site dermatitis		1
Vaccination site discharge		1
Vaccination site discolouration		1
Vaccination site discomfort	5	9
Vaccination site eczema		1
Vaccination site erythema	52	191
Vaccination site extravasation		2
Vaccination site haematoma	5	18
Vaccination site hyperaesthesia		1
Vaccination site hypersensitivity	1	2
Vaccination site hypoaesthesia		14
Vaccination site induration	15	33
Vaccination site inflammation	5	17
Vaccination site irritation		1
Vaccination site ischaemia		1
Vaccination site joint erythema		3
Vaccination site joint inflammation		1
Vaccination site joint movement impairment	1	9
Vaccination site joint pain	4	16
Vaccination site joint swelling	4	26
Vaccination site joint warmth		1
Vaccination site lymphadenopathy	2	27
Vaccination site mass	2	5
Vaccination site movement impairment	2	31
Vaccination site nerve damage	1	1
Vaccination site nodule		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3		
		2	9		
		1	1		
5	7		6	99	182
					1
			3	1	2
					1
			1		
			1		
		5	9		
			1		
		45	145	7	46
			1		1
		5	18		
					1
		1	1		1
			12		2
		14	28	1	5
		5	14		3
			1		
					1
			3		
			1		
		1	8		1
		4	16		
		4	26		
			1		
		2	22		5
		2	5		
		2	30		1
		1	1		
			2		

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site oedema	45	442		1	44	422	1	20
Vaccination site pain	772	3,730		7	735	3471	37	259
Vaccination site pallor		1				1		
Vaccination site paraesthesia	11	44			8	34	3	10
Vaccination site phlebitis		1				1		
Vaccination site pruritus	21	79			15	62	6	17
Vaccination site rash	4	17			4	14		3
Vaccination site reaction	20	105			20	97		8
Vaccination site swelling	76	264		2	70	210	6	54
Vaccination site ulcer	1	1					1	1
Vaccination site urticaria	6	35			6	26		9
Vaccination site vesicles		5				4		1
Vaccination site warmth	5	38		1	5	28		10
Vessel puncture site swelling		1				1		
Xerosis		1						1
	4,353	27,141	53	156	3572	23200	781	3941

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System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Autoimmune hepatitis	1	1					1	1
Biliary colic		1						1
Cholangitis		1						1
Cholecystitis acute		1						1
Cholelithiasis		2				1		1
Gallbladder disorder	1	1					1	1
Hepatic pain		3				3		
Hepatic steatosis	1	1					1	1
Hepatitis acute	1	3					1	3
Hepatitis cholestatic	1	1					1	1
Hyperbilirubinaemia		1						1
Hypertransaminaemia		2	1	1				2
Jaundice	3	6				1	3	5
Jaundice cholestatic		1						1
Liver disorder	1	1					1	1
Portal hypertension	1	1					1	1
Portal vein thrombosis	2	2					2	2
	12	29	1	1		5	12	24

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* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Allergic reaction to excipient		1						1
Allergy to vaccine	4	14	1	1	1	4	3	10
Anamnestic reaction	1	1			1	1		
Anaphylactic reaction	10	85	1	4			10	85
Anaphylactic shock	3	18		1			3	18
Anaphylactoid reaction	2	6					2	6
Autoimmune disorder	3	3					3	3
Drug hypersensitivity		7				1		6
Food allergy		1						1
Hypersensitivity	17	87	3	6	7	35	10	52
Immune-mediated adverse reaction	1	1					1	1
Immune system disorder		1				1		
Immunodeficiency common variable	1	1					1	1
Reaction to excipient		1						1
Sarcoidosis	1	2					1	2
Seasonal allergy		1						1
Sensitisation		1				1		
Type I hypersensitivity	5	13					5	13
Type IV hypersensitivity reaction		1						1
	48	245	5	12	9	43	39	202

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abscess	1	2			1	1		1
Abscess limb		1				1		
Acarodermatitis	1	1					1	1
Adenoviral conjunctivitis		1				1		
Appendicitis	1	1					1	1
Asymptomatic COVID-19	33	60			5	6	28	54
Blister infected		1				1		
Breast abscess		1						1
Bronchitis	2	5			2	3		2
Bursitis infective		1						1
Clostridial infection	1	1					1	1
Complicated appendicitis	1	1					1	1
Conjunctivitis	10	37			5	24	5	13
COVID-19	175	390	7	9	26	66	149	324
COVID-19 pneumonia	11	21		2			11	21
Cystitis	3	8			3	7		1
Disseminated varicella zoster virus infection		1						1
Diverticulitis		1						1
Dysentery	15	192	2	8			15	192
Ear infection		11				9		2
Encephalitis	2	4					2	4
Enterococcal infection		1						1
Epididymitis	1	1					1	1
Erysipelas	2	4	1	1			2	4
Escherichia sepsis	1	1					1	1
Eye infection		1						1
Folliculitis		1				1		
Fungal infection		1				1		
Furuncle		1				1		
Gastroenteritis	1	9			1	8		1
Genital herpes zoster		1						1
Gingivitis		4				4		

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Herpes ophthalmic	2	9
Herpes simplex	3	9
Herpes simplex encephalitis		1
Herpes virus infection	5	16
Herpes zoster	51	96
Herpes zoster cutaneous disseminated	1	1
Herpes zoster infection neurological	2	3
Herpes zoster oticus	1	3
Herpes zoster reactivation	3	4
HIV infection		1
Infected cyst		1
Infection	1	3
Influenza	13	46
Injection site infection	1	13
Intervertebral discitis		1
Klebsiella infection	1	1
Labyrinthitis	1	10
Listeriosis		1
Liver abscess	1	1
Localised infection	1	1
Lymphangitis		10
Lymph node abscess		1
Mastitis	1	7
Myelitis	1	1
Myringitis		1
Nasal herpes	1	3
Nasopharyngitis	31	90
Necrotising fasciitis	1	2
Ophthalmic herpes simplex		2
Ophthalmic herpes zoster	2	5
Oral candidiasis	1	2
Oral herpes	10	66

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	9
		3	8		1
					1
		3	11	2	5
	1	43	67	8	29
				1	1
				2	3
				1	3
		3	3		1
					1
					1
		1	2		1
		13	43		3
		1	13		
					1
				1	1
			5	1	5
					1
				1	1
				1	1
					10
					1
				1	7
				1	1
					1
		1	3		
		24	69	7	21
				1	2
					2
				2	5
			1	1	1
		9	50	1	16

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* AE=Adverse Event

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Orchitis		1
Otitis externa		1
Otitis media		1
Otitis media acute	1	1
Parainfluenzae virus infection	1	1
Peritonsillar abscess		1
Pharyngitis	3	16
Pharyngitis streptococcal	1	1
Pharyngotonsillitis	1	1
Pneumonia	7	24
Pneumonia bacterial	1	3
Pneumonia legionella		1
Pseudomembranous colitis	1	1
Pustule		4
Q fever		9
Rash pustular	1	1
Respiratory tract infection	1	2
Rhinitis	10	33
Root canal infection		1
Scarlet fever		
Sepsis	3	6
Septic shock	2	6
Severe acute respiratory syndrome		3
Sinusitis	1	3
Soft tissue infection		1
Subcutaneous abscess		1
Superinfection bacterial		2
Suspected COVID-19	6	9
Tonsillitis		4
Tooth infection		1
Tracheitis	1	4
Upper respiratory tract infection		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
					1
		1	1		
				1	1
					1
	1	2	11	1	5
		1	1		
				1	1
				7	24
				1	3
					1
				1	1
			2		2
					9
		1	1		
1	1	8	25	2	8
			1		
	1				
				3	6
				2	6
					3
		1	2		1
					1
					1
					2
				6	9
			3		1
			1		
		1	3		1
					1

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Urinary tract infection	3	5				2	3	3
Urinary tract infection bacterial		1						1
Urosepsis		1						1
Vaccination site cellulitis		1						1
Vaccination site infection	1	1			1	1		
Vaginal infection		2				2		
Varicella	1	1			1	1		
Vascular device infection	1	1					1	1
Vestibular neuronitis	2	7				2	2	5
Viral corneal ulcer		1						1
Viral infection	1	1					1	1
Virologic failure	1	1			1	1		
Vulvovaginal candidiasis	1	2			1	2		
	448	1,346	11	24	163	472	285	874

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accidental overdose	2	2			1	1	1	1
Arthropod sting		2				2		
Back injury	1	1					1	1
Barotrauma		1				1		
Burn oral cavity		1						1
Central cord syndrome		1						1
Cerebral ventricle collapse		1						1
Chest injury			1	1				
Chillblains	1	7				5	1	2
Circumstance or information capable of leading to medication error		1				1		
Cold burn		2				2		
Contraindicated product administered		1						1
Contusion	4	11			2	8	2	3
Craniocerebral injury	2	2					2	2
Electric shock		1						1
Epicondylitis		2				2		
Exposure during pregnancy	8	10			8	10		
Exposure to SARS-CoV-2		2				2		
Exposure via breast milk	4	10			4	7		3
Extra dose administered	1	1					1	1
Face injury	1	3					1	3
Facial bones fracture	1	2					1	2
Fall	14	29	2	2	3	4	11	25
Femur fracture	1	1					1	1
Foreign body in throat		1						1
Head injury		2	1	1				2
Heat stroke		4				3		1
Inappropriate schedule of product administration	8	22			8	21		1
Incomplete course of vaccination	1	1			1	1		
Incorrect dosage administered		1				1		
Incorrect dose administered	2	7			2	7		

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* AE=Adverse Event

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Incorrect route of product administration	7	36
Injection related reaction		1
Injury	1	5
Intentional product misuse		1
Intentional product use issue	1	1
Jaw fracture		1
Joint dislocation		1
Ligament sprain	1	1
Limb injury	1	1
Maternal exposure before pregnancy		1
Maternal exposure during pregnancy	10	27
Maternal exposure timing unspecified		1
Medication error		1
Muscle strain		1
Nerve injury		1
Occupational exposure to product	1	2
Off label use	24	53
Overdose	25	73
Pelvic fracture	1	1
Poor quality product administered	7	9
Post-traumatic neck syndrome	1	1
Product administered at inappropriate site		8
Product administered to patient of inappropriate age	1	2
Product administration error	5	7
Product dose omission issue		1
Product label confusion		1
Product preparation error	5	5
Product preparation issue	4	9
Product use in unapproved indication	1	1
Product use issue	11	28
Rib fracture	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		7	36		
			1		
			3	1	2
			1		
		1	1		
					1
					1
				1	1
				1	1
			1		
		10	26		1
					1
			1		
			1		
			1		
		1	2		
		23	50	1	3
		23	68	2	5
				1	1
		7	9		
		1	1		
			8		
		1	2		
		5	7		
			1		
			1		
		5	5		
		4	9		
		1	1		
		11	26		2
				1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Scratch	1	1			1	1		
Skin laceration	1	5				2	1	3
Skull fractured base	1	1					1	1
Spinal compression fracture	1	1					1	1
Stoma site pain		1						1
Subcutaneous haematoma		1						1
Subdural haematoma	1	2					1	2
Thermal burns of eye		1						1
Traumatic fracture		1						1
Underdose	3	15			3	15		
Upper limb fracture		1						1
Vaccination complication	39	159		2	39	144		15
Vaccination error		1				1		
Wound	1	2	1	1			1	2
Wrong product administered	5	5			5	5		
Wrong technique in product usage process	2	4			2	4		
	214	615	5	7	179	512	35	103

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* AE=Adverse Event

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Activated partial thromboplastin time shortened	1	1
Alanine aminotransferase increased	1	4
A bumin CSF increased	1	1
Alpha globulin increased		1
Alpha tumour necrosis factor increased		1
Amylase increased	1	5
Antibody test abnormal		2
Antinuclear ant body positive		1
Anti-thyroid antibody positive		2
Aspartate aminotransferase increased	1	1
Basophil percentage increased		1
Blood alcohol increased	1	1
Blood alkaline phosphatase increased		1
Blood bilirubin increased		1
Blood calcium decreased		1
Blood creatinine increased	2	3
Blood fibrinogen increased	1	3
Blood glucose abnormal	1	2
Blood glucose decreased		1
Blood glucose increased	2	5
Blood lactate dehydrogenase increased		1
Blood potassium decreased		1
Blood pressure abnormal	3	5
Blood pressure decreased	7	24
Blood pressure diastolic increased	1	2
Blood pressure increased	40	152
Blood pressure systolic decreased		1
Blood pressure systolic increased		9
Blood thyroid stimulating hormone increased	1	3
Blood urea increased	1	1
Body temperature abnormal	1	2
Body temperature decreased	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	3		1
				1	1
			1		
					1
			2	1	3
			2		
					1
			2		
		1	1		
			1		
				1	1
					1
			1		
		1	2	1	1
		1	3		
				1	2
			1		
		1	3	1	2
					1
			1		
		2	4	1	1
	1	5	15	2	9
			1	1	1
4	4	18	84	22	68
			1		
			4		5
			2	1	1
		1	1		
		1	2		
		1	3	1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Body temperature fluctuation	1	1
Body temperature increased	6	50
Breath sounds		2
Breath sounds abnormal	2	5
Cardiac murmur	1	1
Cardio-ankle vascular index		1
Chest expansion decreased		1
Coagulation factor increased		1
Coagulation test abnormal	1	1
Coma scale abnormal		1
C-reactive protein abnormal	1	3
C-reactive protein increased	3	11
Electrocardiogram abnormal		4
Electrocardiogram change	1	1
Electrocardiogram repolarisation abnormality		1
Electrocardiogram T wave inversion		
Eosinophil count decreased		1
Eosinophil count increased		1
Fibrin D dimer increased	7	15
Full blood count abnormal	1	1
Full blood count increased		1
Gamma-glutamyltransferase increased		1
Grip strength decreased		2
Haematocrit decreased	1	2
Haemoglobin decreased	3	7
Haptoglobin increased		1
Heart rate abnormal		1
Heart rate decreased	2	8
Heart rate increased	5	30
Heart rate irregular		2
Hepatic enzyme increased	1	1
Hepatitis A antibody positive		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
1	2	6	45		5
			1		1
			1	2	4
				1	1
			1		
			1		
					1
		1	1		
					1
		1	2		1
		2	6	1	5
			1		3
				1	1
					1
	1				
					1
					1
1	1	4	8	3	7
		1	1		
			1		
					1
			1		1
		1	2		
		1	3	2	4
					1
					1
			3	2	5
		4	16	1	14
					2
	1			1	1
			1		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hepatitis B antibody positive		1
Hormone level abnormal	1	1
Inspiratory capacity abnormal		1
International normalised ratio increased	3	6
Intraocular pressure increased	1	1
Laboratory test abnormal		1
Lipase increased	1	6
Lymph node palpable		3
Lymphocyte count decreased		1
Lymphocyte count increased	1	2
Magnetic resonance imaging head abnormal	1	1
Mean cell haemoglobin concentration decreased		1
Mean cell haemoglobin decreased		1
Mean cell volume increased		1
Monocyte count decreased		1
Monocyte count increased		1
Muscle strength abnormal	1	1
Myocardial necrosis marker increased		1
Neutrophil count increased		2
Neutrophil percentage increased		1
Occult blood positive	2	2
Oxygen saturation abnormal		
Oxygen saturation decreased	20	81
Parvovirus B19 test positive		1
Platelet count decreased	2	3
Platelet count increased	1	2
PO2 decreased		1
Procalcitonin increased	1	2
Protein C increased	1	1
Pulse abnormal		1
Pulse volume decreased		2
Quality of life decreased	6	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
			1		
			1	3	5
		1	1		
					1
			3	1	3
			3		
			1		
		1	1		1
				1	1
			1		
			1		
					1
			1		
		1	1		
					1
			1		1
					1
		1	1	1	1
	1				
2	3	2	13	18	68
			1		
			1	2	2
		1	1		1
					1
		1	2		
				1	1
					1
			1		1
		2	5	4	8

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Red blood cell count decreased		1						1
Red blood cell count increased		1				1		
Red blood cell sedimentation rate increased	1	5			1	2		3
Red cell distribution width increased		1				1		
Respiratory rate increased		2				1		1
SARS-CoV-2 ant body test		2						2
SARS-CoV-2 ant body test negative		6				5		1
SARS-CoV-2 ant body test positive	1	8				6	1	2
SARS-CoV-2 test		2						2
SARS-CoV-2 test false positive		1				1		
SARS-CoV-2 test negative	1	2				1	1	1
SARS-CoV-2 test positive	13	37	4	4	6	10	7	27
Seroconversion test negative	1	5				3	1	2
Serratia test positive		1						1
Shift to the left	1	1			1	1		
Sinus rhythm		1				1		
Stenotrophomonas test positive		1						1
Thyroglobulin increased		1						1
Thyroid hormones increased		1						1
Transaminases increased	1	3				1	1	2
Troponin		1						1
Troponin I increased		1						1
Troponin increased	2	3					2	3
Troponin T increased		3						3
Urine output decreased	1	3					1	3
Vitamin D decreased	1	1			1	1		
Weight decreased	1	6				2	1	4
White blood cell count decreased	1	2			1	2		
White blood cell count increased	1	4				1	1	3
	172	652	12	18	76	320	96	332

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acidosis	1	1					1	1
Appetite disorder	1	1			1	1		
Decreased appetite	31	135	1	2	20	102	11	33
Dehydration	3	8					3	8
Diabetes mellitus	1	1					1	1
Electrolyte imbalance		1						1
Feeding disorder		1						1
Fluid retention		4				2		2
Food aversion		1				1		
Haemochromatosis		1				1		
Histamine intolerance		1				1		
Hypercholesterolaemia		1						1
Hypercreatininaemia		1						1
Hyperglycaemia	4	12				3	4	9
Hypoglycaemia	1	6				4	1	2
Hypokalaemia		3						3
Hyponatraemia	1	2	1	1			1	2
Hypovolaemia		1						1
Impaired fasting glucose	1	1					1	1
Lactic acidosis	1	1					1	1
Lactose intolerance	1	1			1	1		
Metabolic acidosis	1	2					1	2
Polydipsia	1	4			1	4		
Tetany		2				1		1
Type 1 diabetes mellitus		1						1
Vitamin B12 deficiency	1	1			1	1		
Vitamin D deficiency		1				1		
	49	195	2	3	24	123	25	72

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ankylosing spondylitis	1	1
Arthralgia	458	3,398
Arthritis	5	10
Arthritis reactive		
Arthropathy	1	1
Autoimmune arthritis	1	1
Axillary mass		1
Back disorder		1
Back pain	49	233
Bone pain	39	229
Bursitis	1	1
Connective tissue disorder		1
Connective tissue inflammation		1
Dactylitis		1
Enthesopathy	1	4
Extremity contracture		1
Facial asymmetry	2	4
Fasciitis		1
Fibromyalgia	1	3
Flank pain	2	8
Groin pain	3	8
Haematoma muscle	1	1
Hand deformity		1
Intervertebral disc degeneration	1	1
Joint ankylosis		1
Joint contracture		1
Joint effusion		2
Joint hyperextension		1
Joint instability		1
Joint lock	2	5
Joint range of motion decreased	3	15
Joint stiffness		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
1	11	396	3029	62	369
		2	6	3	4
	1				
				1	1
				1	1
			1		
					1
	3	39	185	10	48
		34	188	5	41
				1	1
					1
			1		
					1
			1	1	3
			1		
				2	4
			1		
		1	2		1
		2	8		
	2	1	6	2	2
		1	1		
			1		
				1	1
			1		
			1		
			1		
			1		
			1		
		1	3	1	2
		1	6	2	9
			2		

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Joint swelling	4	10
Joint warmth		2
Limb discomfort	17	84
Mastication disorder		2
Mobility decreased	4	14
Muscle contracture		11
Muscle discomfort	1	2
Muscle disorder		1
Muscle fatigue		7
Muscle oedema		5
Muscle rigidity	8	27
Muscle spasms	10	70
Muscle swelling		3
Muscle tightness	1	7
Muscle twitching	3	12
Muscular weakness	25	116
Musculoskeletal chest pain	3	33
Musculoskeletal discomfort		2
Musculoskeletal disorder	1	5
Musculoskeletal pain	57	507
Musculoskeletal stiffness	11	49
Myalgia	573	4,058
Myalgia intercostal		2
Myokymia		1
Myositis	3	7
Neck pain	35	179
Nuchal rigidity		22
Osteitis	1	1
Osteoarthritis	1	1
Osteoarthropathy		1
Pain in extremity	269	1,477
Pain in jaw	2	14

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	6		4
					2
		14	72	3	12
			1		1
		3	10	1	4
	1		8		3
		1	2		
			1		
			5		2
			3		2
		5	19	3	8
	1	7	54	3	16
			1		2
		1	5		2
		2	9	1	3
		11	78	14	38
		2	24	1	9
			1		1
		1	4		1
	1	52	439	5	68
		8	31	3	18
	13	520	3689	53	369
			1		1
			1		
	1	2	3	1	4
	2	25	142	10	37
			14		8
		1	1		
		1	1		
			1		
4	6	227	1300	42	177
		2	9		5

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Plantar fasciitis		1				1		
Polyarthritis		4						4
Polymyalgia rheumatica	1	2					1	2
Posture abnormal	1	1					1	1
Psoriatic arthropathy		3						3
Reynold's syndrome	1	1					1	1
Rhabdomyolysis	1	2					1	2
Rheumatic disorder		2				1		1
Rheumatoid arthritis		5						5
Sacroiliitis		1				1		
Sjogren's syndrome		1						1
Spinal pain	6	32			5	30	1	2
Systemic lupus erythematosus		2						2
Temporomand bular joint syndrome	1	4			1	3		1
Tendon disorder	1	1			1	1		
Tendonitis	1	3				2	1	1
Tendon pain	1	3				1	1	2
Tenosynovitis		2				1		1
Torticollis	3	11			3	11		
Trigger finger		1				1		
Trismus	2	2			2	2		
	1,619	10,755	5	42	1379	9437	240	1318

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angiomyolipoma		1				1
Benign hydatidiform mole	1	1			1	1
Brain neoplasm		1				1
Hypergammaglobulinaemia benign monoclonal	1	1			1	1
Leukaemia		1				1
Lipoma	1	1	1	1		
Lung cancer metastatic	1	1			1	1
Lung neoplasm malignant		1				1
Monoclonal gammopathy	1	1			1	1
Myeloid leukaemia	1	1			1	1
Neoplasm	1	1	1	1		
Non-Hodgkin's lymphoma	1	1			1	1
Oncologic complication	1	1	1	1		
Rosai-Dorfman syndrome	1	1			1	1
Squamous cell carcinoma	1	1			1	1
Testicular neoplasm		1				1
Uterine leiomyoma	1	1			1	1
Yolk sac tumour site unspecified	1	1			1	1
	13	18	3	3	10	15

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute motor axonal neuropathy		1						1
Acute polyneuropathy	1	2					1	2
Ageusia	18	56	2	4	10	37	8	19
Akathisia		1				1		
Akinesia		1						1
Allodynia		2				1		1
Altered pitch perception		1				1		
Altered state of consciousness	1	4					1	4
Amnesia	13	22			4	10	9	12
Anaesthesia	4	43			4	38		5
Anosmia	18	46	2	4	13	32	5	14
Anterograde amnesia		2						2
Apallic syndrome	1	1					1	1
Aphasia	18	40	2	3		2	18	38
Areflexia	2	2					2	2
Ataxia	2	5					2	5
Aura	2	5			2	5		
Balance disorder	10	39	1	3	4	23	6	16
Band sensation		6	1	1		4		2
Basilar artery occlusion	1	1					1	1
Bell's palsy	15	41	1	2			15	41
Bradykinesia	2	7	1	1	2	4		3
Brain compression		1						1
Brain oedema		1						1
Brain stem haemorrhage		1						1
Brain stem stroke		1						1
Burning sensation	10	38			8	28	2	10
Carotid arteriosclerosis	1	1					1	1
Carotid artery dissection		2						2
Carotid artery occlusion	1	1					1	1
Carotid artery stenosis	1	1					1	1
Carotid artery thrombosis	2	2					2	2

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cauda equina syndrome	1	1
Central nervous system lesion	2	3
Central nervous system vasculitis	2	2
Central pain syndrome		1
Cerebellar ataxia		1
Cerebellar haemorrhage	1	2
Cerebellar stroke	1	1
Cerebral artery embolism	1	1
Cerebral artery occlusion	1	3
Cerebral artery thrombosis		1
Cerebral disorder		1
Cerebral haematoma	1	2
Cerebral haemorrhage	14	25
Cerebral infarction	1	3
Cerebral ischaemia	10	22
Cerebral thrombosis	1	2
Cerebral venous sinus thrombosis	2	3
Cerebral venous thrombosis	1	2
Cerebrovascular accident	13	30
Cerebrovascular disorder		
Cerebrovascular insufficiency	1	1
Cervical radiculopathy		2
Cervicobrachial syndrome	3	12
Circadian rhythm sleep disorder		1
Clonic convulsion	3	3
Clonus		6
Cluster headache		3
Cognitive disorder	1	3
Coma	4	8
Convulsions local		1
Coordination abnormal	1	2
Cramp-fasciculation syndrome		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1	1	2
				2	2
			1		
					1
				1	2
				1	1
				1	1
				1	3
					1
					1
				1	2
				14	25
				1	3
				10	22
2	2			1	2
1	1			2	3
				1	2
1	2			13	30
1	1				
				1	1
			1		1
		1	8	2	4
			1		
				3	3
			2		4
			3		
	1	1	2		1
				4	8
					1
	1			1	2
			1		1

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cranial nerve disorder	2	5
Cranial nerve paralysis	5	6
Dementia Alzheimer's type		1
Demyelinating polyneuropathy		2
Demyelination		1
Depressed level of consciousness	13	59
Diplegia		4
Disturbance in attention	5	37
Dizziness	109	527
Dizziness postural	1	1
Drooling		2
Dysaesthesia	9	39
Dysarthria	16	27
Dysgeusia	24	167
Dysgraphia	2	4
Dyskinesia	2	6
Dyslalia	1	2
Dyslexia		1
Dysmetria		2
Dyspraxia	1	1
Dysstasia	7	11
Dystonia		1
Electric shock sensation	1	2
Embolic stroke	1	2
Encephalopathy		2
Epilepsy	8	21
Facial nerve disorder		6
Facial neuralgia		4
Facial paralysis	21	67
Facial paresis	13	47
Facial spasm	1	4
Febrile convulsion		13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	2	3
				5	6
					1
					2
					1
	1			13	59
					4
	1	2	23	3	14
	3	77	375	32	152
				1	1
			1		1
		5	29	4	10
5	6	1	3	15	24
	3	21	146	3	21
		1	2	1	2
		1	3	1	3
				1	2
					1
					2
				1	1
1	1	3	4	4	7
					1
		1	2		
				1	2
					2
1	1			8	21
			3		3
			2		2
	1			21	67
1	1	4	21	9	26
			2	1	2
			7		6

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Focal dyscognitive seizures		1
Generalised tonic-clonic seizure	2	6
Gliositis		1
Guillain-Barre syndrome	4	8
Haemorrhagic cerebral infarction		1
Haemorrhagic stroke	4	5
Headache	1,136	5,800
Head discomfort	7	30
Hemianaesthesia	2	11
Hemianopia	1	2
Hemianopia heteronymous		1
Hemianopia homonymous	1	2
Hemidysaesthesia	1	5
Hemihyperaesthesia	1	2
Hemiparaesthesia	6	32
Hemiparesis	11	37
Hemiplegia	5	15
Hepatic encephalopathy		
Hydrocephalus		1
Hyperaesthesia	3	18
Hyperkinesia		1
Hyperreflexia	1	2
Hypersomnia	1	6
Hypertonia	1	4
Hypoaesthesia	23	175
Hypogeusia	1	2
Hypoglossal nerve disorder		1
Hypoglycaemic unconsciousness	1	1
Hypokinesia	1	5
Hyporeflexia	1	3
Hyporesponsive to stimuli	1	5
Hyposmia	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				2	6
			1		
				4	8
					1
				4	5
10	31	1027	5138	109	662
		7	26		4
				2	11
				1	2
					1
				1	2
				1	5
				1	2
				6	32
				11	37
				5	15
1	1				
					1
		3	16		2
			1		
				1	2
		1	6		
1	1		3	1	1
	2	17	136	6	39
		1	2		
					1
				1	1
			2	1	3
		1	1		2
			3	1	2
			2	1	2

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypotonia		11
Hypotonic-hyporesponsive episode		1
IIIrd nerve disorder		1
IIIrd nerve paralysis	1	3
Intracranial pressure increased	1	1
Intraventricular haemorrhage		2
Ischaemic stroke	13	25
IVth nerve disorder		1
IVth nerve paralysis	1	1
Lacunar stroke		1
Language disorder		1
Lateropulsion		1
Lethargy	3	7
Loss of consciousness	36	132
Memory impairment	1	7
Meningeal disorder		1
Mental impairment	1	4
Migraine	30	242
Migraine with aura	3	7
Miller Fisher syndrome	1	1
Mononeuritis	2	2
Monoparesis	10	13
Monoplegia	2	9
Motor dysfunction	4	36
Movement disorder	3	24
Multiple sclerosis	2	4
Multiple sclerosis relapse	2	2
Muscle contractions involuntary	3	13
Myasthenia gravis		3
Myasthenia gravis crisis	1	3
Myoclonus		5
Narcolepsy		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			7		4
			1		
					1
				1	3
				1	1
					2
1	1			13	25
					1
				1	1
					1
			1		
					1
		2	6	1	1
				36	132
			2	1	5
			1		
				1	4
2	4	26	201	4	41
		3	7		
				1	1
		1	1	1	1
		9	11	1	2
				2	9
1	1		22	4	14
1	1		10	3	14
				2	4
				2	2
		1	9	2	4
					3
				1	3
			1		4
					3

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nerve compression	1	3
Nervous system disorder	4	7
Neuralgia	11	39
Neuralgic amyotrophy		1
Neuritis	1	11
Neurological symptom	2	4
Neurologic neglect syndrome		1
Neuromuscular pain	2	2
Neuropathy peripheral	3	18
Neurotoxicity		1
Normal pressure hydrocephalus	1	1
Nystagmus	1	4
Occipital neuralgia		1
Ophthalmic migraine		1
Optic neuritis	1	7
Paraesthesia	152	913
Paraesthesia mucosal	1	2
Paralysis		5
Paraparesis	1	6
Paresis	1	7
Paresis cranial nerve		2
Parosmia	2	15
Partial seizures	1	3
Peripheral nerve palsy	1	1
Peripheral paralysis	2	2
Peripheral sensorimotor neuropathy		1
Peripheral sensory neuropathy		1
Petit mal epilepsy	1	3
Polyneuropathy	1	2
Polyneuropathy in malignant disease	1	1
Post herpetic neuralgia		1
Presyncope	31	196

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		1
				4	7
	1	8	26	3	13
	1		1		
		1	8		3
1	2		1	2	3
					1
		1	1	1	1
				3	18
					1
				1	1
				1	4
					1
					1
				1	7
6	10	110	668	42	245
		1	1		1
					5
				1	6
		1	3		4
			1		1
		1	10	1	5
				1	3
		1	1		
				2	2
					1
			1		
				1	3
				1	2
				1	1
					1
2	3	12	108	19	88

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Psychomotor hyperactivity	4	8
Psychomotor skills impaired		1
Quadripareisis	2	3
Radial nerve palsy	1	1
Radiculitis brachial		3
Radiculopathy		4
Reduced facial expression		1
Restless legs syndrome		3
Retrograde amnesia		2
Sciatica	5	12
Sciatic nerve neuropathy	1	1
Sedation		7
Seizure	7	19
Seizure like phenomena		1
Senile dementia	1	1
Sensorimotor disorder		1
Sensory disturbance	5	9
Sensory loss	3	12
Sinus headache		1
Slow speech		1
Somnolence	55	315
Speech disorder	9	29
Spinal epidural haematoma	1	1
Status epilepticus	1	2
Stupor		15
Subarachnoid haemorrhage	2	5
Sudden onset of sleep		2
Syncope	47	181
Taste disorder	7	30
Tension headache	2	13
Thalamus haemorrhage	1	1
Thrombotic stroke	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	5	2	3
					1
				2	3
				1	1
			3		
			3		1
					1
					3
			1		1
		3	9	2	3
		1	1		
			5		2
				7	19
					1
				1	1
					1
		4	5	1	4
			4	3	8
			1		
					1
	2	45	264	10	51
	1	1	7	8	22
				1	1
				1	2
			8		7
				2	5
					2
6	10			47	181
		4	19	3	11
		2	11		2
				1	1
				1	1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tongue biting	3	3					3	3
Tongue paralysis		1						1
Tonic clonic movements		2						2
Tonic convulsion		1						1
Transient ischaemic attack	7	12					7	12
Tremor	37	192	2	4	23	113	14	79
Trigeminal nerve disorder		8				4		4
Trigeminal neuralgia	1	9				6	1	3
Trigeminal neuritis		1						1
Trigeminal palsy	1	1					1	1
Unresponsive to stimuli		3						3
Vertebral artery occlusion	1	1					1	1
Vertebrobasilar insufficiency	1	1					1	1
Vertigo CNS origin	1	1					1	1
VIth nerve paralysis		2						2
VIth nerve paresis		1				1		
Vocal cord paralysis		2						2
	2,195	10,544	57	120	1487	7750	708	2794

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion		2				2
Abortion missed	1	1			1	1
Abortion spontaneous	2	7			2	7
Ectopic pregnancy		1				1
Foetal death	1	1			1	1
Foetal growth restriction		1				1
Morning sickness		1		1		
	4	14		1	4	13

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Device issue		1		1		
Product leakage	1	1	1	1		
Undersensing		1				1
	1	3	1	2		1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal behaviour		1				1		
Abnormal dreams	1	1			1	1		
Aggression			1	1				
Agitation	7	37		1	3	23	4	14
Anxiety	9	46			4	30	5	16
Anxiety disorder due to a general medical condition		1				1		
Apathy	1	4			1	2		2
Behaviour disorder	1	1					1	1
Bradyphrenia		3	1	1		2		1
Compulsions		1						1
Confusional state	34	169	4	10	16	102	18	67
Delirium	2	3					2	3
Delirium febrile	1	1					1	1
Delusion	2	4				1	2	3
Depersonalisation/derealisation disorder		1				1		
Depressed mood	1	2			1	2		
Depression	3	5			1	3	2	2
Discouragement	1	1			1	1		
Disorientation	5	33	2	4	1	15	4	18
Dissociation		2				2		
Distract bility	1	1			1	1		
Drug abuse		1						1
Dysphemia		1						1
Eating disorder	1	1					1	1
Emotional disorder	1	2			1	2		
Emotional distress	1	1			1	1		
Enuresis	1	1					1	1
Euphoric mood	1	4			1	4		
Fear-related avoidance of activities	1	1			1	1		
Feeling of despair	1	1			1	1		
Flat affect		3				2		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hallucination	6	15
Hallucination, auditory		3
Hallucination, olfactory		2
Hallucinations, mixed		1
Hallucination, visual		6
Immunisation anxiety related reaction		1
Inappropriate affect		1
Initial insomnia	2	25
Insomnia	51	322
Irritability	4	14
Logorrhoea	1	2
Loss of libido		1
Mental disorder		2
Middle insomnia	1	12
Mood altered	2	4
Mood swings	1	2
Nervousness	2	6
Nightmare	3	4
Organic brain syndrome		1
Panic attack	3	10
Panic reaction		2
Persecutory delusion	1	1
Poor quality sleep	1	2
Psychiatric decompensation	1	1
Psychogenic pseudosyncope	1	1
Psychotic disorder		1
Restlessness	5	16
Sleep disorder	1	19
Soliloquy		1
Sopor	2	13
Stress	1	2
Suicidal ideation	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
2	2			6	15
1	1				3
					2
					1
					6
			1		
			1		
		1	21	1	4
		39	283	12	39
		2	9	2	5
				1	2
			1		
			1		1
			10	1	2
		2	3		1
			1	1	1
		2	5		1
		2	3	1	1
					1
		2	6	1	4
			2		
				1	1
			1	1	1
		1	1		
		1	1		
					1
		5	12		4
		1	17		2
			1		
1	3		4	2	9
			1	1	1
				1	1

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tension	1	4			1	3		1
Terminal insomnia		3				3		
Thought blocking		1						1
	167	835	12	23	94	590	73	245

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* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute kidney injury	3	7		1			3	7
Anuria	1	6	1	1			1	6
Azotaemia	1	3					1	3
Bladder dysfunction		1						1
Bladder obstruction		1						1
Bladder spasm	1	1					1	1
Chromaturia	2	4			1	2	1	2
Chronic kidney disease	1	1					1	1
Cystitis haemorrhagic	1	6					1	6
Dysuria	1	11				3	1	8
Glomerulonephritis		1						1
Haematuria	1	9				4	1	5
Incontinence	1	4			1	2		2
Micturition disorder		1				1		
Micturition urgency	2	4			2	2		2
Nephropathy	1	1					1	1
Neurogenic bladder		1						1
Nocturia		1				1		
Oliguria		3						3
Pollakiuria		5				3		2
Polyuria	4	9			3	6	1	3
Proteinuria	1	3			1	3		
Renal colic	3	3					3	3
Renal failure	6	9					6	9
Renal impairment	2	3					2	3
Renal infarct	1	1					1	1
Renal pain	4	16			2	13	2	3
Strangury			1	1				
Urinary incontinence	2	8			1	3	1	5
Urinary retention	2	6					2	6
Urine flow decreased		1				1		
Urine odour abnormal		1				1		

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* AE=Adverse Event

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System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
	41	131	2	3	11	45	30	86

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* AE=Adverse Event
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System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adnexa uteri pain	1	2	1	2		
Amenorrhoea	6	8	4	6	2	2
Breast cyst		1		1		
Breast discomfort		3		2		1
Breast disorder	1	1			1	1
Breast enlargement		2		2		
Breast inflammation	1	1	1	1		
Breast oedema		5		4		1
Breast pain	5	23	4	16	1	7
Breast swelling	1	4	1	2		2
Endometriosis		1				1
Erectile dysfunction	5	9			5	9
Female sexual dysfunction		1		1		
Genital discomfort		1				1
Genital pain	1	1	1	1		
Genital rash	1	1	1	1		
Haematospermia	1	1			1	1
Heavy menstrual bleeding	13	18	10	11	3	7
Intermenstrual bleeding	1	8	1	5		3
Menstrual disorder	10	11	9	10	1	1
Menstruation delayed	5	5	5	5		
Menstruation irregular	15	16	15	16		
Nipple disorder	1	1	1	1		
Nipple pain		1		1		
Oligomenorrhoea	1	1			1	1
Ovarian cyst	1	1	1	1		
Ovulation pain	1	1			1	1
Pelvic pain	1	3	1	3		
Penile erythema		1		1		
Perineal pain		1		1		
Polymenorrhoea	6	6	6	6		
Premenstrual pain		2		2		

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pruritus genital		2		2		
Scrotal erythema		1				1
Testicular pain	2	2			2	2
Vaginal haemorrhage	2	5		2	2	3
Vulvovaginal burning sensation		1		1		
Vulvovaginal pain		1		1		
	82	153	62	108	20	45

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acute pulmonary oedema	1	3
Acute respiratory distress syndrome		2
Acute respiratory failure	4	14
Allergic cough		1
Allergic respiratory symptom		1
Aphonia	3	13
Apnoea		1
Asphyxia	1	2
Aspiration	1	1
Asthma	4	31
Asthma exercise induced		1
Asthmatic crisis	3	15
Atelectasis	1	2
Bronchial disorder	1	1
Bronchial wall thickening		1
Bronchiectasis		1
Bronchitis chronic	1	1
Bronchospasm	7	43
Bronchostenosis	1	2
Catarrh	2	10
Choking		2
Choking sensation	1	6
Chronic obstructive pulmonary disease		1
Chronic respiratory failure		1
Cough	68	285
Diaphragmalgia		1
Diaphragmatic disorder	1	1
Diaphragmatic spasm		2
Dry throat	1	9
Dysaesthesia pharynx		2
Dysphonia	11	61
Dyspnoea	117	494

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
					2
				4	14
					1
					1
		2	7	1	6
					1
				1	2
				1	1
		2	13	2	18
					1
1	4			3	15
				1	2
		1	1		
					1
					1
		1	1		
	1	2	14	5	29
				1	2
		1	6	1	4
					2
			2	1	4
					1
					1
3	4	38	161	30	124
			1		
				1	1
			1		1
		1	7		2
			2		
	1	4	26	7	35
9	16	44	195	73	299

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dyspnoea at rest	1	4
Dyspnoea exertional	5	20
Emphysema		2
Epiglottic oedema		1
Epistaxis	14	35
Glottal incompetence		1
Grunting		1
Hiccups		1
Hypercapnia	2	3
Hyperventilation		10
Hypoxia	6	14
Increased upper airway secretion		2
Increased viscosity of bronchial secretion		1
Interstitial lung disease	5	11
Intranasal hypoaesthesia		1
Intranasal paraesthesia		2
Laryngeal discomfort		2
Laryngeal dyspnoea		4
Laryngeal obstruction		2
Laryngeal oedema	14	91
Laryngeal pain	1	2
Laryngeal stenosis		1
Laryngospasm	3	20
Larynx irritation		1
Lung disorder		1
Lung opacity	2	2
Mediastinal disorder	1	1
Nasal congestion	18	36
Nasal discomfort	3	7
Nasal obstruction	3	6
Nasal oedema	1	3
Nasal pruritus		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	4
1	1	2	11	3	9
					2
					1
		7	24	7	11
					1
					1
			1		
				2	3
	1		4		6
				6	14
			1		1
					1
				5	11
			1		
			2		
			1		1
					4
					2
				14	91
		1	2		
					1
		1	6	2	14
			1		
					1
		1	1	1	1
		1	1		
		10	24	8	12
		2	6	1	1
		3	5		1
		1	1		2
			1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nocturnal dyspnoea	2	2
Obstructive airways disorder	2	6
Oropharyngeal discomfort	3	28
Oropharyngeal oedema		2
Oropharyngeal pain	34	159
Oropharyngeal plaque		1
Oropharyngeal spasm		1
Oropharyngeal swelling	1	4
Orthopnoea		1
Painful respiration		1
Pharyngeal disorder		2
Pharyngeal erythema	2	9
Pharyngeal hypoaesthesia		2
Pharyngeal mass	2	4
Pharyngeal oedema	2	13
Pharyngeal paraesthesia	5	30
Pharyngeal swelling	1	17
Pleural effusion	2	11
Pleurisy	1	2
Pneumonia aspiration	1	1
Pneumonitis	3	7
Pneumothorax		1
Productive cough	1	5
Pulmonary air leakage	1	1
Pulmonary artery thrombosis	2	2
Pulmonary congestion	1	2
Pulmonary embolism	46	69
Pulmonary hypertension	1	2
Pulmonary hypoperfusion		1
Pulmonary infarction		1
Pulmonary mass		1
Pulmonary microemboli		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2		
			1	2	5
		2	19	1	9
					2
	1	29	127	5	32
					1
					1
		1	3		1
					1
			1		
			1		1
			3		
			1		
	1		2	2	11
		4	13	1	17
		1	7		10
		1	2	1	9
		1	1		1
				1	1
				3	7
					1
				1	5
		1	1		
				2	2
				1	2
4	6		1	46	68
				1	2
					1
					1
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pulmonary oedema	1	4
Pulmonary pain		3
Pulmonary thrombosis	2	2
Rales	1	5
Respiration abnormal	1	1
Respiratory acidosis	1	1
Respiratory alkalosis	1	1
Respiratory arrest		3
Respiratory depression	1	2
Respiratory disorder	2	19
Respiratory distress	3	27
Respiratory failure	17	36
Respiratory fatigue	3	12
Respiratory tract haemorrhage		1
Respiratory tract oedema	2	6
Rhinalgia	1	4
Rhinitis allergic	1	3
Rhinorrhoea	12	39
Rhonchi		1
Sinus pain	1	4
Sneezing	4	9
Stertor		1
Stridor	1	5
Suffocation feeling	3	11
Tachypnoea	6	33
Throat irritation	11	71
Throat tightness	16	124
Tonsillar erythema		1
Tonsillar hypertrophy	2	8
Tonsillar inflammation	1	1
Tracheal pain		2
Upper airway obstruction	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	4
			2		1
				2	2
			1	1	4
		1	1		
				1	1
				1	1
					3
				1	2
		2	7		12
	1			3	27
1	1			17	36
		1	3	2	9
					1
				2	6
		1	3		1
		1	3		
		8	28	4	11
			1		
			2	1	2
		3	7	1	2
					1
			1	1	4
		1	5	2	6
		2	17	4	16
		9	41	2	30
1	3	7	56	9	68
			1		
		2	8		
		1	1		
			1		1
				1	3

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Upper respiratory tract inflammation		2				1		1
Use of accessory respiratory muscles		7				2		5
Vasomotor rhinitis		1				1		
Vocal cord dysfunction		1						1
Wheezing	7	22			2	11	5	11
	523	2,165	20	41	210	922	313	1243

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acne	1	1			1	1		
Alopecia	2	6			1	2	1	4
Angioedema	15	72					15	72
Blister	5	16			3	11	2	5
Brow ptosis		1				1		
Bullous haemorrhagic dermatosis	1	1					1	1
Butterfly rash		2				1		1
Circumoral oedema	1	6			1	6		
Circumoral swelling		2						2
Cold sweat	6	37			3	21	3	16
Cold urticaria		1				1		
Dermal cyst	1	3			1	3		
Dermatitis	4	12			2	9	2	3
Dermatitis acneiform	2	2			2	2		
Dermatitis allergic	1	10			1	6		4
Dermatitis atopic		2				2		
Dermatitis bullous	4	16		1			4	16
Dermatitis exfoliative		1						1
Dermatitis exfoliative generalised		2						2
Dermatitis herpetiformis		3				1		2
Dermatitis psoriasiform		1				1		
Drug eruption		1				1		
Dry skin	1	7				1	1	6
Ecchymosis	7	13			2	4	5	9
Eczema	4	5			3	4	1	1
Eczema asteatotic	1	1			1	1		
Eczema nummular		1				1		
Erythema	75	486	5	7	55	348	20	138
Erythema multiforme	2	7					2	7
Erythema nodosum	1	7				4	1	3
Erythematotelangiectatic rosacea		1				1		
Guttate psoriasis		1						1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haemorrhage subcutaneous		1
Hand dermatitis	1	3
Hidradenitis		1
Hyperhidrosis	37	268
Hypersensitivity vasculitis		1
Idiopathic urticaria		1
Lichen sclerosus	1	1
Lipodystrophy acquired		1
Livedo reticularis	1	2
Macule	1	1
Madarosis		1
Mechanical urticaria	1	9
Neurodermatitis		1
Night sweats	4	27
Pain of skin	1	7
Palpable purpura		2
Panniculitis		1
Papule	1	7
Pemphigoid	1	2
Penile ulceration		1
Perioral dermatitis		1
Petechiae	10	18
Photosensitivity reaction	3	6
Piloerection		1
Pityriasis rosea		6
Prurigo		1
Pruritus	75	529
Pruritus allergic		1
Psoriasis	1	4
Purpura	2	3
Pustular psoriasis		1
Rash	59	378

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	3		
					1
	1	27	203	10	65
					1
			1		
				1	1
					1
	1		1	1	1
				1	1
					1
	2		5	1	4
			1		
		4	26		1
		1	6		1
			1		1
					1
		1	5		2
				1	2
			1		
			1		
	1	2	8	8	10
		3	4		2
					1
			5		1
			1		
2	4	56	412	19	117
			1		
			2	1	2
1	2			2	3
					1
	3	49	267	10	111

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rash erythematous	7	34
Rash macular	8	21
Rash maculo-papular	1	9
Rash maculovesicular		1
Rash morbilliform	1	3
Rash papular	2	9
Rash papulosquamous		1
Rash pruritic	10	56
Rash scarlatiniform		1
Rash vesicular	2	10
Rosacea		1
Scab		2
Seborrhoeic dermatitis		1
Sensitive skin	1	3
Skin burning sensation	2	19
Skin discolouration	3	10
Skin discomfort	1	2
Skin exfoliation	1	5
Skin hypertrophy	2	3
Skin induration	1	2
Skin irritation	3	6
Skin lesion	2	11
Skin mass	1	3
Skin oedema		2
Skin reaction	7	37
Skin striae		1
Skin swelling	1	2
Skin tightness		4
Skin warm		5
Telangiectasia	1	1
Toxic skin eruption		2
Umbilical haematoma		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	6	23	1	11
		7	17	1	4
		1	8		1
			1		
			2	1	1
		2	7		2
			1		
		9	37	1	19
			1		
		2	8		2
					1
			1		1
			1		
			2	1	1
			15	2	4
		2	5	1	5
		1	2		
			3	1	2
		1	2	1	1
		1	1		1
		3	5		1
		1	7	1	4
		1	3		
			2		
		6	27	1	10
			1		
		1	1		1
			2		2
			2		3
		1	1		
					2
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Urticaria	57	406	1	1	46	293	11	113
Urticaria chronic		1				1		
Urticaria papular	1	2				1	1	1
Urticaria physical		1				1		
Urticaria thermal		1				1		
Urticaria vesiculosa		1						1
Vascular purpura		2				1		1
Vascular skin disorder	1	1					1	1
Vasculitic rash		2				1		1
Yellow skin		2				2		
	449	2,701	9	24	311	1876	138	825

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden		1		1		
Immobile		1				1
Immobilisation prolonged	1	1			1	1
Impaired quality of life	7	11	2	5	5	6
Impaired work ability		1				1
Loss of personal independence in daily activities	2	7		4	2	3
Partner stress		1		1		
Sitting disability		1		1		
	10	24	2	12	8	12

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Surgical and medical procedures

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardioversion	1	1	1	1		
Immunisation	1	2	1	2		
Injection		1		1		
Joint stabilisation	1	1	1	1		
Limb immobilisation	1	2		1	1	1
Mechanical ventilation	1	1			1	1
Menstrual cycle management		1		1		
Venous arterialisation	1	1			1	1
	6	10	3	7	3	3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Aneurysm ruptured		1						1
Angiopathy		1						1
Aortic arteriosclerosis	1	1					1	1
Aortic dilatation		1				1		
Aortic dissection		1						1
Arterial occlusive disease	2	2					2	2
Arterial thrombosis	1	1	1	1			1	1
Arteriosclerosis	3	4			1	1	2	3
Arteriovenous fistula		1						1
Blood pressure fluctuation	1	8				4	1	4
Bloody discharge		1						1
Capillary fragility	2	4			1	2	1	2
Circulatory collapse	2	6					2	6
Cyanosis	5	17			1	3	4	14
Deep vein thrombosis	37	54		1			37	54
Diastolic hypertension		1				1		
Diastolic hypotension		1						1
Embolism	3	6	1	1			3	6
Embolism venous		1						1
Endothelial dysfunction	1	1			1	1		
Essential hypertension			1	1				
Fibromuscular dysplasia		1						1
Flushing	18	159	2	2	15	133	3	26
Haematoma	8	23			1	11	7	12
Haemodynamic instability	1	1					1	1
Haemorrhage	2	4					2	4
Haemorrhagic infarction	1	2					1	2
Hot flush	27	120			20	96	7	24
Hyperaemia	3	11			1	6	2	5
Hypertension	39	180	1	2	16	85	23	95
Hypertensive crisis	29	116		2			29	116
Hypoperfusion	1	1			1	1		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypotension	32	183
Hypotensive crisis	1	8
Infarction		1
Intermittent claudication	2	3
Internal haemorrhage	1	1
Ischaemia	7	11
Lymphoedema		9
Orthostatic hypotension		5
Pallor	6	31
Peripheral artery thrombosis		1
Peripheral coldness	6	27
Peripheral embolism		1
Peripheral ischaemia	2	4
Peripheral venous disease	1	2
Phlebitis	2	9
Phlebitis superficial	1	3
Post thrombotic syndrome	1	1
Raynaud's phenomenon	2	4
Shock	2	6
Spider vein		1
Subclavian vein thrombosis	1	1
Systolic hypertension		1
Takayasu's arteritis	1	1
Thromboangiitis obliterans		1
Thrombophlebitis	11	16
Thrombophlebitis superficial	8	17
Thrombosis	15	24
Vascular calcification	1	1
Vascular rupture		1
Vasculitis	5	15
Vasculitis necrotising	1	3
Vasoconstriction		8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
2	5	14	96	18	87
				1	8
					1
			1	2	2
				1	1
				7	11
			7		2
			4		1
2	3	5	21	1	10
					1
1	2	2	18	4	9
					1
				2	4
		1	2		
		2	7		2
			1	1	2
				1	1
			2	2	2
1	1			2	6
			1		
				1	1
					1
				1	1
					1
		9	12	2	4
	1	2	3	6	14
1	1			15	24
		1	1		
					1
		2	9	3	6
		1	1		2
			3		5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vasodilatation		3				1		2
Vena cava thrombosis	1	1					1	1
Venous occlusion	1	1					1	1
Venous thrombosis	8	12			2	2	6	10
Venous thrombosis limb	6	8		2	1	2	5	6
Withdrawal hypertension	1	1			1	1		
	313	1,157	13	25	101	540	212	617

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

JAPAN

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia	3	9		4	3	5
Blood disorder	1	1	1	1		
Disseminated intravascular coagulation	1	2			1	2
Haemolytic anaemia	1	1			1	1
Haemorrhagic disorder	1	1			1	1
Hypochromic anaemia	1	1			1	1
Leukopenia		1				1
Lymphadenitis	2	3	2	3		
Lymphadenopathy	25	37	20	30	5	7
Lymph node pain	4	6	3	4	1	2
Thrombocytopenia	1	1			1	1
Thrombocytopenic purpura	1	2			1	2
Thrombotic thrombocytopenic purpura	1	1			1	1
	42	66	26	42	16	24

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome		2				2
Acute myocardial infarction	8	9			8	9
Angina pectoris	3	4			3	4
Angina unstable		1				1
Arrhythmia	11	21			11	21
Arrhythmia supraventricular	1	1			1	1
Atrial f brillation	2	3			2	3
Atrial tachycardia	1	2			1	2
Atrioventricular block complete	2	2			2	2
Bradycardia	11	19		1	11	18
Bundle branch block right	1	2	1	2		
Cardiac arrest	8	8			8	8
Cardiac discomfort		1		1		
Cardiac failure	7	12			7	12
Cardiac failure acute	4	5			4	5
Cardiac failure chronic		1				1
Cardiac failure congestive	1	1			1	1
Cardiac hypertrophy	1	1	1	1		
Cardiac tamponade	2	3			2	3
Cardiomyopathy	2	2			2	2
Cardio-respiratory arrest	23	30			23	30
Cardiovascular disorder	2	5	1	4	1	1
Coronary artery occlusion	1	1			1	1
Coronary artery stenosis	2	2			2	2
Extrasystoles	2	3	1	2	1	1
Myocardial infarction	6	8			6	8
Myocardial ischaemia	3	3			3	3
Myocardial rupture	1	1			1	1
Myocarditis	2	6			2	6
Palpitations	178	322	88	165	90	157
Pericardial effusion	2	2			2	2
Pericarditis	1	3			1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulseless electrical activity	1	1			1	1
Sinus bradycardia		1		1		
Sinus tachycardia	12	16	2	4	10	12
Stress cardiomyopathy	1	1			1	1
Supraventricular extrasystoles	2	2	1	1	1	1
Supraventricular tachyarrhythmia	1	1			1	1
Supraventricular tachycardia	2	2	1	1	1	1
Tachyarrhythmia	1	1	1	1		
Tachycardia	83	131	35	54	48	77
Ventricular extrasystoles	1	4	1	3		1
Ventricular fibrillation	2	3			2	3
Ventricular hypokinesia		1				1
Ventricular tachycardia	2	2			2	2
	396	652	133	241	263	411

System Organ Class

Congenital, familial and genetic disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Atrial septal defect	1	1			1	1
Cerebral palsy	1	1			1	1
Colour blindness		1		1		
	2	3		1	2	2

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autophony		1		1		
Deafness	6	8			6	8
Deafness neurosensory	3	4			3	4
Ear discomfort	11	18	8	12	3	6
Ear pain	1	1	1	1		
Ear pruritus	1	2			1	2
Ear swelling	1	2	1	1		1
Eustachian tube dysfunction	1	1	1	1		
Hypoacusis	3	5	1	2	2	3
Meniere's disease	2	2			2	2
Motion sickness		2		1		1
Otorrhoea		1				1
Sudden hearing loss	2	11			2	11
Tinnitus	7	12	3	6	4	6
Vertigo	17	30	7	10	10	20
Vertigo positional	1	1	1	1		
	56	101	23	36	33	65

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diabetes insipidus	1	1			1	1
Hyperthyroidism	1	1			1	1
Hypothyroidism		1				1
Primary hyperaldosteronism	1	2		1	1	1
Thyroiditis acute	1	1			1	1
Thyroiditis subacute	1	1	1	1		
	5	7	1	2	4	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal sensation in eye	4	9	1	4	3	5
Asthenopia	3	4	3	3		1
Blepharospasm	6	9	4	4	2	5
Blindness unilateral	1	1			1	1
Chromatopsia		1				1
Conjunctival haemorrhage	1	3			1	3
Conjunctival hyperaemia	13	31	5	14	8	17
Conjunctival oedema	2	2	2	2		
Diplopia		2		1		1
Erythema of eyelid	6	7	4	4	2	3
Erythroptosis	1	1	1	1		
Excessive eye blinking	1	2	1	1		1
Eye discharge	1	1	1	1		
Eye disorder	3	8	2	3	1	5
Eye haemorrhage	2	3			2	3
Eyelid function disorder		1				1
Eyelid irritation	1	2	1	1		1
Eyelid oedema	9	30	5	15	4	15
Eyelid pain	1	1			1	1
Eyelid ptosis	1	3			1	3
Eyelid rash	2	2			2	2
Eyelids pruritus	2	2	1	1	1	1
Eye movement disorder	4	6	3	3	1	3
Eye oedema	2	3	2	2		1
Eye pain	4	7	3	4	1	3
Eye pruritus	12	24	5	12	7	12
Eye swelling	1	4		1	1	3
Foreign body sensation in eyes	2	2	2	2		
Gaze palsy	1	5			1	5
Glare	2	2	2	2		
Lacrimation increased	8	13	2	5	6	8
Lid margin discharge		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mydriasis		1		1		
Ocular hyperaemia	13	34	8	23	5	11
Optic atrophy		1				1
Orbital oedema	1	1			1	1
Periorbital oedema		1				1
Periorbital swelling	2	8	1	4	1	4
Photophobia	1	1			1	1
Photopsia	8	12	4	7	4	5
Pupils unequal		1		1		
Retinal haemorrhage	3	5			3	5
Retinal vein occlusion	2	2			2	2
Scleral haemorrhage	1	1			1	1
Scleritis		1				1
Strabismus	1	1			1	1
Swelling of eyelid	10	23	6	13	4	10
Uveitis	1	1			1	1
Vision blurred	5	10	2	6	3	4
Visual acuity reduced	1	1			1	1
Visual brightness	1	1			1	1
Visual field defect	1	2	1	2		
Visual impairment	19	26	11	15	8	11
Vitreous floaters		1		1		
	166	327	83	160	83	167

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	19	46	6	19	13	27
Abdominal distension	4	5	1	2	3	3
Abdominal pain	59	108	33	57	26	51
Abdominal pain lower	5	8	3	4	2	4
Abdominal pain upper	16	27	9	14	7	13
Abdominal symptom	1	2			1	2
Abdominal tenderness	2	2	2	2		
Acute abdomen	1	1			1	1
Allergic gastroenteritis	1	1			1	1
Anal incontinence		1		1		
Ascites		1				1
Bowel movement irregularity	1	1	1	1		
Cheilitis		1		1		
Colitis		1				1
Colitis ischaemic	1	2			1	2
Colitis ulcerative	2	3			2	3
Diarrhoea	108	173	64	100	44	73
Diverticulum		1				1
Diverticulum intestinal haemorrhagic	1	1			1	1
Dry mouth		3		1		2
Duodenal ulcer	1	1			1	1
Dyschezia	1	1			1	1
Dyspepsia		3		1		2
Dysphagia	8	13	2	3	6	10
Enteritis		1				1
Enterocolitis	3	7			3	7
Epigastric discomfort	1	4		2	1	2
Eructation		1		1		
Faeces discoloured	1	1			1	1
Faeces soft	3	8	2	6	1	2
Flatulence	2	2			2	2
Frequent bowel movements		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastric ulcer	2	2			2	2
Gastric ulcer haemorrhage	2	2			2	2
Gastrointestinal disorder	6	9	3	3	3	6
Gastrointestinal haemorrhage	1	2			1	2
Gastrointestinal hypermotility		3				3
Gastrointestinal hypomotility	1	1			1	1
Gastrointestinal motility disorder	1	2		1	1	1
Gastrointestinal mucosal disorder		1				1
Gastrointestinal necrosis	1	1			1	1
Gastrointestinal oedema	3	4			3	4
Gastrooesophageal reflux disease	1	1			1	1
Gingival bleeding	1	1			1	1
Glossodynia	2	3	2	3		
Haematemesis	1	1			1	1
Haematochezia	6	11			6	11
Hypoaesthesia oral	30	52	17	31	13	21
Ileus paralytic	1	2			1	2
Intestinal ischaemia	1	1			1	1
Intestinal ulcer	1	1			1	1
Lip discolouration	1	1			1	1
Lip erythema		1				1
Lip haemorrhage	1	1	1	1		
Lip oedema	3	5	1	2	2	3
Lip pruritus	2	5	1	2	1	3
Lip swelling	9	23	2	10	7	13
Melaena	2	4			2	4
Mesenteric arterial occlusion	1	1			1	1
Mesenteric artery thrombosis	1	1			1	1
Mouth swelling	1	6	1	5		1
Mucous stools	1	1	1	1		
Nausea	411	662	185	305	226	357
Odynophagia	1	2	1	1		1

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* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oedema mouth	2	3			2	3
Oral discomfort	12	23	7	14	5	9
Oral disorder	1	1	1	1		
Oral mucosa erosion		1		1		
Oral mucosa haematoma		1		1		
Oral mucosal blistering		1		1		
Oral mucosal roughening	1	1	1	1		
Oral pain		1		1		
Oral pruritus	9	14	3	5	6	9
Palatal oedema	1	1			1	1
Pancreatitis acute	1	1			1	1
Paraesthesia oral	13	22	5	12	8	10
Parotid gland enlargement	1	1	1	1		
Rectal tenesmus		1				1
Retching	1	1			1	1
Salivary gland calculus	1	1	1	1		
Salivary gland pain	2	2	2	2		
Salivary hypersecretion	3	4	1	1	2	3
Stomatitis	3	5	2	4	1	1
Submaxillary gland enlargement		1		1		
Swollen tongue	1	1	1	1		
Thrombosis mesenteric vessel	1	1			1	1
Tongue discomfort	1	1			1	1
Tongue disorder		1				1
Tongue erythema	2	2	1	1	1	1
Tongue oedema	1	2	1	2		
Tongue pruritus	1	1	1	1		
Toothache	1	2	1	2		
Upper gastrointestinal haemorrhage		1				1
Vomiting	149	258	56	106	93	152
	944	1,600	423	741	521	859

* I=Interval, C=Cumulative

* AE=Adverse Event

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site movement impairment		1		1		
Asthenia	51	83	21	34	30	49
Axillary pain	6	9	6	8		1
Cardiac death		1				1
Chest discomfort	49	81	20	36	29	45
Chest pain	9	18	3	6	6	12
Chills	166	274	115	180	51	94
Condition aggravated	8	14	1	2	7	12
Death	5	6			5	6
Discomfort	15	34	11	22	4	12
Disease recurrence	8	10	1	2	7	8
Drowning		1				1
Drug ineffective	17	24			17	24
Enanthema	1	1			1	1
Face oedema	13	24	2	7	11	17
Facial pain		4		2		2
Fatigue	63	78	53	63	10	15
Feeling abnormal	248	418	119	208	129	210
Feeling cold	40	62	17	25	23	37
Feeling drunk	2	2	2	2		
Feeling hot	83	142	42	76	41	66
Feeling jittery		1				1
Foaming at mouth	1	1	1	1		
Gait disturbance	14	25	6	8	8	17
Gait inability		1				1
Generalised oedema		1				1
General physical health deterioration	4	5	1	1	3	4
General symptom	1	1	1	1		
Glassy eyes	1	1			1	1
Hyperpyrexia	1	5			1	5
Hyperthermia	6	10	3	5	3	5
Hypothermia	2	4			2	4

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Induration	2	4	2	4		
Inflammation	2	3	1	2	1	1
Injected limb mobility decreased	2	7	2	7		
Injection site erythema	1	2	1	1		1
Injection site hypoaesthesia	1	2	1	2		
Injection site muscle weakness		1		1		
Injection site pain		3		3		
Injection site pruritus	1	3		2	1	1
Injection site rash		1		1		
Injection site swelling		1		1		
Injection site vesicles		1				1
Injection site warmth		1		1		
Injury associated with device	1	1			1	1
Local reaction		1		1		
Malaise	357	611	242	420	115	191
Mass	1	1	1	1		
Mucosal disorder		1		1		
Mucosal haemorrhage		1		1		
Mucosal inflammation	1	1			1	1
Multi-organ disorder		2		1		1
Multiple organ dysfunction syndrome	1	1			1	1
No adverse event	1	1	1	1		
Oedema	6	10	2	2	4	8
Oedema mucosal	3	4	1	1	2	3
Oedema peripheral	9	12	6	7	3	5
Pain	84	125	53	85	31	40
Peripheral swelling	16	23	10	17	6	6
Physical deconditioning	10	21	3	10	7	11
Puncture site pain	1	2		1	1	1
Pyrexia	475	819	323	579	152	240
Sensation of blood flow		1		1		
Sensation of foreign body	19	27	6	13	13	14

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Shoulder injury related to vaccine administration		1
Stenosis	1	3
Sudden cardiac death	2	2
Sudden death	2	2
Swelling	26	42
Swelling face	17	37
Temperature intolerance		1
Tenderness		1
Thirst	8	16
Vaccination failure		1
Vaccination site bruising	4	5
Vaccination site coldness	2	3
Vaccination site discolouration		1
Vaccination site discomfort	3	3
Vaccination site erythema	36	63
Vaccination site haematoma	1	1
Vaccination site haemorrhage	4	7
Vaccination site hypoaesthesia	6	10
Vaccination site induration	7	10
Vaccination site joint discomfort		1
Vaccination site joint pain	1	1
Vaccination site lymphadenopathy	1	1
Vaccination site mass	3	4
Vaccination site movement impairment	4	13
Vaccination site necrosis		2
Vaccination site pain	268	451
Vaccination site papule	1	2
Vaccination site paraesthesia	2	5
Vaccination site pruritus	27	49
Vaccination site rash	5	11
Vaccination site reaction	1	4
Vaccination site swelling	77	103

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
		1	3
		2	2
		2	2
21	32	5	10
11	19	6	18
			1
			1
3	8	5	8
			1
4	4		1
1	2	1	1
	1		
3	3		
29	47	7	16
1	1		
3	5	1	2
4	7	2	3
5	8	2	2
	1		
1	1		
1	1		
2	3	1	1
2	8	2	5
			2
209	367	59	84
1	2		
1	4	1	1
19	37	8	12
5	11		
	3	1	1
66	85	11	18

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site urticaria	4	10	2	7	2	3
Vaccination site vesicles		1				1
Vaccination site warmth	12	17	9	11	3	6
	2,333	3,920	1483	2535	850	1385

System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bile duct stone	1	1			1	1
Biliary dilatation	1	1			1	1
Cholecystitis	1	1			1	1
Drug-induced liver injury	1	1			1	1
Gallbladder enlargement	1	1			1	1
Hepatic function abnormal	7	14	2	4	5	10
Hepatitis	1	1			1	1
Hepatitis acute	3	3			3	3
Liver disorder		1				1
Portal vein embolism	1	1			1	1
Portal vein thrombosis	1	1			1	1
	18	26	2	4	16	22

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic reaction to excipient		2				2
Allergy to vaccine	8	19	3	11	5	8
Anaphylactic reaction	442	1,160	1	4	441	1156
Anaphylactic shock	21	45			21	45
Anaphylactoid reaction	3	13			3	13
Drug hypersensitivity	7	14	2	4	5	10
Hypersensitivity	84	137	24	51	60	86
Immune system disorder	1	1			1	1
Immunisation reaction	2	2	1	1	1	1
Oral allergy syndrome	1	1	1	1		
Reaction to excipient		2				2
Sensitisation	1	1			1	1
Serum sickness		1				1
Type I hypersensitivity	2	10			2	10
Type IV hypersensitivity reaction	2	3	1	2	1	1
	574	1,411	33	74	541	1337

* I=Interval, C=Cumulative
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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute endocarditis		1				1
Appendicitis	1	1			1	1
Asymptomatic COVID-19		2				2
Bronchitis	2	2	2	2		
Bronchitis bacterial	1	1			1	1
Cellulitis	3	7			3	7
Coronavirus infection	2	2			2	2
COVID-19	32	40	12	14	20	26
COVID-19 pneumonia	1	1			1	1
Cystitis	4	4	1	1	3	3
Diverticulitis		2				2
Eczema herpeticum		1				1
Encephalitis	2	2			2	2
Enteritis infectious		1				1
Gastroenteritis		1		1		
Gastroenteritis bacterial		1				1
Gastroenteritis viral	1	1	1	1		
Gingivitis	1	1	1	1		
Herpes simplex	3	3	3	3		
Herpes virus infection	1	2			1	2
Herpes zoster	11	14	9	10	2	4
Herpes zoster oticus		2				2
Hordeolum	1	1			1	1
Infection		1		1		
Lymphadenitis bacterial		1				1
Meningitis	1	4			1	4
Meningitis aseptic	2	9			2	9
Muscle abscess	1	1			1	1
Myelitis		1				1
Nasopharyngitis	6	8	4	6	2	2
Norovirus infection	1	1	1	1		
Oral herpes	2	2	1	1	1	1

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* AE=Adverse Event

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Parotitis	1	3	1	3		
Peritonitis		1				1
Pharyngitis	4	4	4	4		
Pharyngitis bacterial	1	2			1	2
Pneumonia	7	10			7	10
Pneumonia viral		1				1
Pyelonephritis	2	2			2	2
Sepsis	1	1			1	1
Septic shock	2	2			2	2
Sialoadenitis		1				1
Sputum purulent		2				2
Streptococcal infection		1				1
Suspected COVID-19	2	3	1	1	1	2
Urinary tract infection	4	4			4	4
Urinary tract infection bacterial	1	1	1	1		
Vestibular neuronitis		1				1
Viral infection		1				1
Viral pericarditis		1				1
	104	162	42	51	62	111

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accident		1				1
Accidental overdose	1	1	1	1		
Autonomic dysreflexia	2	2			2	2
Brain herniation	3	3			3	3
Chillblains	3	3	2	2	1	1
Contusion	2	2	2	2		
Exposure during pregnancy	2	3		1	2	2
Exposure via breast milk	1	1	1	1		
Fall	23	32	7	12	16	20
Foreign body in respiratory tract	1	1			1	1
Foreign body in throat		2				2
Fracture		1		1		
Head injury	1	1			1	1
Inappropriate schedule of product administration	4	5	4	5		
Incorrect dose administered	2	5	2	5		
Incorrect route of product administration	3	8	3	8		
Maternal exposure during pregnancy		1		1		
Muscle strain		1		1		
Occupational exposure to product	1	1	1	1		
Off label use	4	5	4	5		
Overdose		1		1		
Parasympathetic nerve injury	1	1			1	1
Product administered at inappropriate site	4	5	4	5		
Product preparation error	1	1	1	1		
Product preparation issue		2		2		
Radiation pneumonitis	1	1	1	1		
Road traffic accident		1		1		
Scratch	1	1	1	1		
Skin abrasion		1				1
Skin laceration	1	1			1	1
Spinal column injury		1		1		
Subdural haematoma	1	1			1	1

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* AE=Adverse Event

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sunburn		1		1		
Tracheal obstruction		2				2
Underdose	1	6	1	6		
Vaccination complication		2		1		1
Vascular injury		1		1		
Wrong technique in product usage process		1				1
	64	109	35	68	29	41

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased		1				1
Antiphospholipid antibodies positive		1				1
Blood alkaline phosphatase decreased		1		1		
Blood creatine phosphokinase increased	3	4		1	3	3
Blood creatinine decreased		1		1		
Blood creatinine increased	1	1			1	1
Blood glucose decreased		1				1
Blood glucose increased	1	1	1	1		
Blood pressure abnormal	5	8		1	5	7
Blood pressure ambulatory abnormal	1	1			1	1
Blood pressure decreased	68	108	12	34	56	74
Blood pressure diastolic decreased	5	6	2	3	3	3
Blood pressure diastolic increased	2	4	1	2	1	2
Blood pressure immeasurable	4	5	1	2	3	3
Blood pressure increased	298	441	74	137	224	304
Blood pressure measurement		1		1		
Blood pressure systolic		1		1		
Blood pressure systolic decreased	5	5	3	3	2	2
Blood pressure systolic increased	17	27	7	12	10	15
Blood urea increased	1	1			1	1
Body temperature abnormal		1		1		
Body temperature decreased	2	2	2	2		
Body temperature increased	15	24	9	18	6	6
Breath sounds abnormal	4	6	1	1	3	5
Coma scale abnormal		1				1
C-reactive protein increased	4	5	2	2	2	3
CSF cell count increased	1	1			1	1
CSF protein increased		1				1
Electrocardiogram change	1	1			1	1
Electrocardiogram P wave abnormal	1	1	1	1		
Electrocardiogram QRS complex shortened	1	1			1	1
Electrocardiogram ST segment elevation	2	2			2	2

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Electrocardiogram T wave inversion	1	1			1	1
Enzyme level increased	1	1			1	1
Fibrin D dimer increased	1	1	1	1		
Fibrin degradation products increased		1				1
Gamma-glutamyltransferase increased	1	1	1	1		
General physical condition abnormal	1	1			1	1
Glucose urine present	1	1	1	1		
Grip strength decreased	2	8	1	5	1	3
Heart rate decreased	11	16	2	5	9	11
Heart rate increased	67	105	27	49	40	56
Hepatic enzyme increased	1	1			1	1
HIV antibody positive		2		2		
Imaging procedure abnormal	1	1			1	1
Inflammatory marker increased	1	1	1	1		
Liver function test abnormal	1	1			1	1
Lymphocyte count increased	1	1	1	1		
Lymphocyte percentage decreased		1		1		
Monocyte percentage increased		1		1		
Oxygen saturation decreased	42	62	8	13	34	49
Oxygen saturation immeasurable	1	1			1	1
Oxygen saturation increased	1	2			1	2
Platelet aggregation abnormal	1	1	1	1		
Platelet count decreased	2	5	1	1	1	4
Protein total decreased		1		1		
Protein urine present	1	2		1	1	1
Pulse abnormal	6	8	2	2	4	6
Radial pulse abnormal	2	6	1	2	1	4
Radial pulse increased		1				1
Red blood cells urine positive	1	1			1	1
Respiratory rate decreased		2		1		1
Respiratory rate increased	6	11	2	3	4	8
Serum ferritin increased	1	1	1	1		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sinus rhythm	1	3			1	3
Thyroid function test abnormal	1	1	1	1		
Troponin increased	1	1			1	1
Urinary occult blood	1	1			1	1
Urinary occult blood positive	3	3			3	3
Urine analysis abnormal	1	1			1	1
Urine output decreased	1	1			1	1
White blood cell count decreased	3	4	2	2	1	2
White blood cell count increased	4	6	1	2	3	4
White blood cells urine positive	1	1			1	1
	614	936	171	324	443	612

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* AE=Adverse Event
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System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acidosis	1	2			1	2
Decreased appetite	38	55	19	26	19	29
Dehydration	9	13	1	2	8	11
Diabetes mellitus	2	2			2	2
Electrolyte imbalance	1	1	1	1		
Feeding disorder	9	14	5	6	4	8
Fluid intake reduced	1	1			1	1
Hyperglycaemia		1		1		
Hypoglycaemia	2	2			2	2
Hypokalaemia	2	5			2	5
Hyponatraemia	1	1	1	1		
Hypophagia	3	5	1	2	2	3
Marasmus	2	2			2	2
Polydipsia	1	1	1	1		
Tetany	2	3	1	1	1	2
	74	108	30	41	44	67

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* AE=Adverse Event
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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	158	227	119	167	39	60
Arthritis	7	10	4	5	3	5
Arthritis reactive	1	2			1	2
Arthropathy	1	1			1	1
Back pain	26	42	17	29	9	13
Bone pain	1	1			1	1
Coccydynia	1	1	1	1		
Fibromyalgia	1	1	1	1		
Groin pain	1	2			1	2
Haemarthrosis		1				1
Joint range of motion decreased	4	11	3	6	1	5
Joint swelling	4	6	4	6		
Joint warmth	1	1	1	1		
Limb discomfort	18	33	11	22	7	11
Mobility decreased	7	13	5	9	2	4
Muscle atrophy		1		1		
Muscle fatigue	2	2	1	1	1	1
Muscle spasms	14	26	7	12	7	14
Muscle swelling	2	2	1	1	1	1
Muscle tightness	8	12	4	7	4	5
Muscle twitching	4	6	2	3	2	3
Muscular weakness	41	75	17	28	24	47
Musculoskeletal chest pain		1		1		
Musculoskeletal discomfort	4	8	3	6	1	2
Musculoskeletal disorder	1	1			1	1
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	12	18	7	11	5	7
Myalgia	152	253	132	217	20	36
Myopathy	1	1	1	1		
Myositis	2	4	1	2	1	2
Neck pain	11	19	6	9	5	10
Pain in extremity	68	115	51	88	17	27

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Posture abnormal	1	1			1	1
Rheumatoid arthritis	2	2			2	2
Rotator cuff syndrome	1	1			1	1
Sjogren's syndrome	1	1			1	1
Soft tissue atrophy		1				1
Systemic lupus erythematosus	1	1			1	1
	560	904	400	636	160	268

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acoustic neuroma		1		1
Acute lymphocytic leukaemia		1		1
Bile duct cancer	1	1	1	1
Brain neoplasm		1		1
Breast cancer		1		1
Lymphoma	1	2	1	2
Neoplasm	1	1	1	1
	3	8	3	8

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute disseminated encephalomyelitis	4	4			4	4
Altered state of consciousness	26	37			26	37
Amnesia	6	8	3	3	3	5
Anaesthesia dolorosa		1				1
Aphasia	5	6	1	1	4	5
Apraxia		1				1
Areflexia	1	1			1	1
Autonomic nervous system imbalance		1				1
Autonomic neuropathy		1				1
Balance disorder	1	2			1	2
Basilar artery occlusion	1	1			1	1
Bradykinesia	1	1			1	1
Brain compression		1				1
Brain oedema		1		1		
Brain stem haemorrhage	1	2			1	2
Brain stem infarction	2	2			2	2
Burning sensation	8	11	4	5	4	6
Carotid artery dissection	1	1			1	1
Carotid artery stenosis	1	1			1	1
Cerebellar ataxia	1	1			1	1
Cerebral artery embolism	1	1			1	1
Cerebral artery stenosis	1	1			1	1
Cerebral congestion		1				1
Cerebral haemorrhage	20	26			20	26
Cerebral infarction	20	25			20	25
Cerebral mass effect	1	1			1	1
Cerebral venous sinus thrombosis	1	2			1	2
Cerebral venous thrombosis	1	1			1	1
Cerebral ventricular rupture	1	1			1	1
Cerebrovascular accident	1	1			1	1
Cerebrovascular disorder	2	2			2	2
Cholinergic syndrome		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Clonic convulsion	1	1			1	1
Clonus	1	1	1	1		
Coma	2	2			2	2
Complex regional pain syndrome	1	4			1	4
Convulsions local	1	2			1	2
Cubital tunnel syndrome	1	1			1	1
Decreased vibratory sense		2				2
Dementia	1	1			1	1
Dementia Alzheimer's type	1	1			1	1
Depressed level of consciousness	37	64	1	1	36	63
Disturbance in attention	1	2	1	1		1
Dizziness	181	309	83	158	98	151
Dizziness postural	10	18	8	13	2	5
Dysaesthesia	2	5	1	2	1	3
Dysarthria	3	3			3	3
Dysgeusia	9	11	7	8	2	3
Dyskinesia	6	7	3	3	3	4
Dyslalia		1		1		
Dysstasia	17	18	5	5	12	13
Embolic cerebral infarction	1	1			1	1
Embolic stroke	1	1			1	1
Epilepsy	6	7			6	7
Facial paralysis	16	31			16	31
Febrile convulsion	1	1			1	1
Guillain-Barre syndrome	6	12	1	1	5	11
Haemorrhagic cerebral infarction	1	1			1	1
Headache	442	723	283	464	159	259
Head discomfort	35	63	21	38	14	25
Hemiparesis	1	2			1	2
Hemiplegia	6	8			6	8
Hyperaesthesia	1	3	1	1		2
Hyperreflexia	2	3	1	1	1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertonia	1	2		1	1	1
Hypoaesthesia	169	278	99	163	70	115
Hypokinesia		1		1		
Hyporeflexia	1	1			1	1
Hypotonia		1				1
Illrd nerve paralysis		1				1
Incoherent	1	1	1	1		
Intention tremor	1	1			1	1
Intracranial aneurysm	3	4			3	4
Intraventricular haemorrhage	2	2			2	2
Lacunar infarction		1				1
Lethargy		1				1
Loss of consciousness	44	72			44	72
Memory impairment	3	5	2	3	1	2
Migraine	3	5			3	5
Monoparesis	2	2			2	2
Monoplegia	4	4			4	4
Movement disorder	12	18	9	11	3	7
Multiple sclerosis		1				1
Nervous system disorder	1	1	1	1		
Neuralgia	4	4	1	1	3	3
Neuritis		1		1		
Neurological symptom	5	6	1	1	4	5
Neuropathy peripheral	38	65			38	65
Nystagmus	5	6	2	2	3	4
Opisthotonus		1				1
Optic neuritis	1	1			1	1
Orthostatic intolerance		1				1
Paraesthesia	25	43	14	27	11	16
Paralysis	5	7			5	7
Paresis	2	2			2	2
Parosmia	4	5	1	2	3	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paroxysmal sympathetic hyperactivity	1	1			1	1
Peripheral nerve palsy	2	2	2	2		
Peripheral nerve paresis		1				1
Petit mal epilepsy		2				2
Postural tremor		1				1
Presyncope	91	150	38	82	53	68
Putamen haemorrhage	3	3			3	3
Quadripareisis	1	1			1	1
Reduced facial expression		1				1
Restless legs syndrome	1	1	1	1		
Ruptured cerebral aneurysm	2	2			2	2
Sciatica	1	1	1	1		
Sedation	1	1	1	1		
Seizure	20	39		1	20	38
Sensory disturbance	22	28	11	16	11	12
Sensory loss	1	1	1	1		
Slow response to stimuli		1				1
Slow speech	1	1	1	1		
Somnolence	31	48	18	28	13	20
Speech disorder	3	5	1	2	2	3
Subarachnoid haemorrhage	15	22			15	22
Sympathicotonia	1	3	1	2		1
Syncope	13	28			13	28
Taste disorder	7	8	4	5	3	3
Tension headache		1				1
Thalamic infarction	1	1			1	1
Thalamus haemorrhage	1	1			1	1
Thrombotic cerebral infarction	1	1			1	1
Tongue paralysis	1	1			1	1
Tonic convulsion	1	1			1	1
Transient global amnesia	1	1			1	1
Transient ischaemic attack	2	2			2	2

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tremor	51	78	23	30	28	48
Trigeminal nerve disorder	1	4	1	1		3
Trigeminal neuralgia	1	2		1	1	1
Ulnar nerve palsy	1	1			1	1
Unresponsive to stimuli		2				2
Vagus nerve disorder		1				1
Vertebral artery dissection		2				2
Vlth nerve disorder		1				1
White matter lesion	1	1			1	1
	1,518	2,452	660	1098	858	1354

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Needle issue	1	3	1	3
Product container issue	1	1	1	1
Product leakage		2		2
	2	6	2	6

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour	1	1	1	1		
Affective disorder		1		1		
Agitation	1	2		1	1	1
Anxiety	12	23	6	10	6	13
Anxiety disorder	3	3			3	3
Bradyphrenia		1				1
Burnout syndrome	1	1	1	1		
Communication disorder	1	1			1	1
Completed suicide	2	2			2	2
Confusional state	2	3	2	3		
Daydreaming		1				1
Delirium	1	2			1	2
Depressed mood	2	2			2	2
Derealisation	1	1	1	1		
Disorientation	1	1			1	1
Dissociative disorder	2	3	2	3		
Dysphoria	40	48	17	20	23	28
Eating disorder	1	3	1	1		2
Emotional distress	1	1	1	1		
Fear	1	1			1	1
Hallucination	1	1			1	1
Hallucination, visual	2	3			2	3
Illusion	5	6	4	4	1	2
Insomnia	9	11	6	8	3	3
Irritability	1	1			1	1
Listless	1	4		3	1	1
Mental disorder	2	2	1	1	1	1
Middle insomnia	1	2	1	1		1
Mood altered	1	1			1	1
Mutism		1				1
Nightmare	1	1	1	1		
Panic attack	4	5	1	1	3	4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Panic disorder	2	2			2	2
Poor quality sleep	2	3	2	3		
Posturing	1	1	1	1		
Restlessness	3	3			3	3
Sleep disorder	1	2			1	2
Sleep disorder due to general medical condition, insomnia type		1				1
Somatic symptom disorder	2	4	1	3	1	1
Speech sound disorder	1	2		1	1	1
Stress		3		2		1
Tearfulness	1	1	1	1		
Tension	7	9	4	5	3	4
Tic	1	1			1	1
Trance		1		1		
	122	172	55	79	67	93

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	1			1	1
Bilirubinuria		1				1
Calculus urinary	1	2	1	2		
Chromaturia	4	4	2	2	2	2
Dysuria	2	3			2	3
Glomerulonephritis	1	1			1	1
Haematuria	4	4			4	4
Nephropathy	1	1	1	1		
Nephrotic syndrome	1	2			1	2
Oliguria	1	1			1	1
Pollakiuria	2	4			2	4
Polyuria	2	2	1	1	1	1
Proteinuria	1	1			1	1
Renal disorder	1	1			1	1
Renal impairment	1	1			1	1
Urinary incontinence	1	1			1	1
Urinary retention	3	5			3	5
Urine abnormality	1	2			1	2
	28	37	5	6	23	31

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysmenorrhoea	1	1	1	1		
Female reproductive tract disorder	1	1	1	1		
Genital haemorrhage	3	3			3	3
Heavy menstrual bleeding	3	3	2	2	1	1
Intermenstrual bleeding	2	2	1	1	1	1
Menstrual disorder	2	2	2	2		
Menstruation irregular	1	1	1	1		
Ovarian haemorrhage	1	1			1	1
Postmenopausal haemorrhage	1	1			1	1
Prostatitis		1				1
Prostatomegaly		1				1
Uterine haemorrhage	1	1			1	1
Vaginal discharge	1	1	1	1		
Vaginal haemorrhage	3	3			3	3
	20	22	9	9	11	13

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory distress syndrome		3				3
Allergic pharyngitis	1	1			1	1
Aphonia	1	2		1	1	1
Apnoea	5	8			5	8
Apnoeic attack		1				1
Asphyxia	3	3			3	3
Aspiration	1	1			1	1
Asthma	77	132	22	41	55	91
Asthmatic crisis	1	1			1	1
Bronchial disorder	1	1			1	1
Bronchial obstruction		1				1
Bronchospasm	8	10	1	1	7	9
Bronchostenosis	1	4			1	4
Choking	2	3			2	3
Choking sensation	5	6	2	2	3	4
Chronic obstructive pulmonary disease	2	2	1	1	1	1
Chronic respiratory disease	1	1	1	1		
Cough	196	411	69	135	127	276
Cough variant asthma	1	2	1	1		1
Dry throat	1	3		2	1	1
Dysphonia	27	56	13	27	14	29
Dyspnoea	233	424	69	136	164	288
Epistaxis	2	4	2	2		2
Grunting		2		1		1
Haemoptysis		1				1
Hiccups	1	1			1	1
Hyperventilation	40	62	8	16	32	46
Hypopnoea	1	2	1	1		1
Hypoventilation		1				1
Hypoxia	3	6			3	6
Interstitial lung disease	3	4			3	4
Irregular breathing	1	2			1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Laryngeal discomfort	11	18	4	8	7	10
Laryngeal obstruction	1	2			1	2
Laryngeal oedema	8	14	2	3	6	11
Laryngeal pain		1		1		
Laryngospasm		1				1
Larynx irritation	3	6	1	2	2	4
Lung infiltration		1				1
Nasal congestion	14	18	10	10	4	8
Nasal mucosal disorder	1	2	1	1		1
Nasal obstruction	7	12	2	3	5	9
Nasal oedema	2	2	1	1	1	1
Nasal pruritus	1	2	1	1		1
Obstructive airways disorder	4	7			4	7
Oropharyngeal discomfort	185	363	73	144	112	219
Oropharyngeal pain	25	59	16	41	9	18
Orthopnoea	1	1			1	1
Pharyngeal disorder		1				1
Pharyngeal erythema	1	2		1	1	1
Pharyngeal hypoaesthesia	1	1	1	1		
Pharyngeal inflammation	1	1	1	1		
Pharyngeal oedema	8	8	4	4	4	4
Pharyngeal paraesthesia	4	7	1	3	3	4
Pharyngeal stenosis	3	5			3	5
Pharyngeal swelling	9	19	2	7	7	12
Pleural effusion		1				1
Pneumonia aspiration	4	4			4	4
Pneumothorax		2				2
Productive cough	6	13	4	8	2	5
Prolonged expiration	1	1			1	1
Pulmonary artery thrombosis	2	3			2	3
Pulmonary embolism	4	6			4	6
Pulmonary oedema	1	1			1	1

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* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary thrombosis	1	1			1	1
Respiration abnormal	3	3			3	3
Respiratory acidosis	1	1	1	1		
Respiratory alkalosis	1	2		1	1	1
Respiratory arrest	4	4			4	4
Respiratory disorder	9	17	3	5	6	12
Respiratory distress	3	14		1	3	13
Respiratory failure	5	5			5	5
Respiratory symptom	1	7		1	1	6
Rhinalgia	1	1	1	1		
Rhinorrhoea	30	55	16	31	14	24
Sneezing	7	14	4	8	3	6
Sputum discoloured		1		1		
Sputum increased	2	2			2	2
Sputum retention	2	3	1	2	1	1
Status asthmaticus	1	1			1	1
Stridor	1	8	1	4		4
Suffocation feeling	1	3		1	1	2
Tachypnoea	14	27	5	13	9	14
Throat clearing	1	1	1	1		
Throat irritation	52	90	26	46	26	44
Throat tightness	44	75	13	27	31	48
Tonsillar disorder		1		1		
Tonsillar hypertrophy	1	1	1	1		
Tracheal stenosis	1	3			1	3
Upper airway obstruction		1				1
Upper respiratory tract inflammation	2	2	2	2		
Use of accessory respiratory muscles	1	1			1	1
Vocal cord disorder		1				1
Wheezing	40	74	11	15	29	59
Yawning	1	7	1	5		2
	1,156	2,171	401	776	755	1395

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute febrile neutrophilic dermatosis		1				1
Alopecia	1	1	1	1		
Angioedema	4	13		2	4	11
Blister	2	3	2	2		1
Capillaritis		1		1		
Circumoral oedema	1	1			1	1
Circumoral swelling	2	2			2	2
Cold sweat	34	74	11	30	23	44
Cutaneous symptom	2	6		2	2	4
Dermatitis	2	4	1	3	1	1
Dermatitis allergic	8	14	6	10	2	4
Dermatitis atopic	1	4	1	3		1
Dermatitis bullous	1	1			1	1
Dermatitis contact		1		1		
Drug eruption	8	17	3	9	5	8
Dry skin	2	4		2	2	2
Eczema	11	20	3	10	8	10
Erythema	306	565	118	267	188	298
Erythema ab igne		1		1		
Erythema multiforme	3	5			3	5
Haemorrhage subcutaneous	9	17			9	17
Hand dermatitis	1	1			1	1
Henoch-Schonlein purpura	5	6	3	4	2	2
Hyperhidrosis	59	105	31	53	28	52
Livedo reticularis		1		1		
Mucocutaneous disorder		1		1		
Mucocutaneous rash	1	1			1	1
Nail discolouration	1	1			1	1
Neutrophilic dermatosis		1		1		
Night sweats		1		1		
Oculomucocutaneous syndrome	7	15			7	15
Pain of skin	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Palmar erythema	3	4		1	3	3
Papule	1	2		1	1	1
Pemphigoid	1	1			1	1
Petechiae	2	2	2	2		
Pigmentation disorder		1		1		
Piloerection	1	3	1	1		2
Prurigo	2	2	1	1	1	1
Pruritus	372	680	144	324	228	356
Purpura	6	8	6	8		
Rash	241	431	103	214	138	217
Rash erythematous	25	36	13	20	12	16
Rash macular	2	2	1	1	1	1
Rash papular	3	4	1	2	2	2
Rash pruritic	5	6	4	5	1	1
Scar pain	1	1	1	1		
Skin discolouration	1	1	1	1		
Skin discomfort	1	1			1	1
Skin disorder		1		1		
Skin erosion	1	1	1	1		
Skin exfoliation	2	2	1	1	1	1
Skin fissures		1		1		
Skin haemorrhage	1	1			1	1
Skin plaque		1				1
Skin reaction	1	1	1	1		
Toxic skin eruption	2	6			2	6
Urticaria	224	450	86	230	138	220
	1,370	2,538	548	1224	822	1314

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* AE=Adverse Event

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System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Immobile	1	1			1	1
Impaired driving ability	1	1			1	1
Impaired work ability	2	2	2	2		
Physical disability	1	1	1	1		
Sitting disability		1		1		
	5	6	3	4	2	2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aneurysm	1	2			1	2
Aneurysm ruptured	2	2			2	2
Angiopathy	1	1			1	1
Aortic dissection	3	5			3	5
Arterial occlusive disease	1	1	1	1		
Blood pressure fluctuation	1	3	1	2		1
Circulatory collapse		4				4
Cyanosis	7	11	1	3	6	8
Deep vein thrombosis	2	4			2	4
Diastolic hypotension		1				1
Embolism venous	1	2			1	2
Flushing	46	83	17	35	29	48
Haematoma	2	2			2	2
Haemorrhage	4	6			4	6
Hot flush	55	102	29	58	26	44
Hyperaemia	2	4	1	1	1	3
Hypertension	34	57	7	12	27	45
Hypertensive emergency	2	4			2	4
Hypertensive urgency		1				1
Hypotension	3	3	1	1	2	2
Infarction	1	1			1	1
Internal haemorrhage	15	28	1	1	14	27
Lymphoedema		1				1
Orthostatic hypotension	1	2			1	2
Pallor	59	81	19	27	40	54
Peripheral circulatory failure	1	3			1	3
Peripheral coldness	31	60	15	34	16	26
Peripheral vascular disorder	1	1			1	1
Phlebitis		1		1		
Poor peripheral circulation	1	1	1	1		
Post thrombotic syndrome		1				1
Raynaud's phenomenon		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Shock	7	12			7	12
Shock haemorrhagic	1	1			1	1
Shock symptom	1	2			1	2
Thrombophlebitis superficial		1		1		
Thrombosis	1	3			1	3
Vascular occlusion	1	1			1	1
Vasculitis	4	5	4	5		
Vasodilatation		2		2		
Vasospasm		1				1
	292	507	98	186	194	321

* I=Interval, C=Cumulative
* AE=Adverse Event
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Country Where Event Occurred

JORDAN

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Haematemesis		1				1
Mesenteric vein thrombosis		1				1
Tongue disorder		1		1		
		4		1		3

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	2	1	1		1
Chills		1		1		
Condition aggravated		1				1
Drug ineffective	1	1			1	1
Fatigue	1	5	1	5		
Feeling cold	1	1	1	1		
Influenza like illness		1		1		
Injection site pain		1		1		
Pain		2		2		
Pyrexia	1	2	1	2		
Swelling		2		1		1
Swelling face		1		1		
Vaccination failure		1				1
Vaccination site pain	1	3	1	3		
	6	24	5	19	1	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	2	5		1	2	4
COVID-19 pneumonia		1				1
Gangrene		1				1
Influenza		1		1		
Pneumonia		1				1
	2	9		2	2	7

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Accidental overdose	1	1	1	1
Animal attack		1		1
Scratch	1	1	1	1
	2	3	2	3

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased		1				1
Inflammatory marker increased	1	1	1	1		
Weight decreased		1		1		
	1	3	1	2		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia		1		1
Muscle spasms		1		1
Myalgia	1	4	1	4
Pain in extremity		3		3
	1	9	1	9

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anosmia		1		1		
Burning sensation	1	1	1	1		
Cerebral thrombosis		1				1
Cerebrovascular accident		1				1
Dizziness		1		1		
Dysgeusia		1		1		
Headache	1	3	1	3		
Loss of consciousness		1				1
Syncope		2				2
	2	12	2	7		5

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Confusional state		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Testicular swelling		1		1
		1		1

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma		1		1		
Cough		1		1		
Dyspnoea		1				1
Hypoxia		1				1
Increased bronchial secretion		1				1
Increased viscosity of upper respiratory secretion		1				1
Lung disorder		1				1
Obstructive airways disorder		1				1
Respiratory failure		1				1
Sputum retention		1				1
Tachypnoea		1				1
		11		2		9

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne	1	1	1	1		
Erythema		1				1
Pruritus	2	2	2	2		
	3	4	3	3		1

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* I=Interval, C=Cumulative
* AE=Adverse Event
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Country Where Event Occurred
KOREA, REPUBLIC OF (SOUTH KOREA)

System Organ Class

Blood and lymphatic system disorders

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	1	1	1	1
	1	1	1	1

System Organ Class

General disorders and administration site conditions

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Swelling	1	1	1	1
	1	1	1	1

System Organ Class

Musculoskeletal and connective tissue disorders

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Joint swelling		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Brain oedema	1	1	1	1
Cerebral infarction	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

KUWAIT

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy	1	2		1	1	1
Splenomegaly		1		1		
	1	3		2	1	1

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Ear pain	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Axillary pain	1	1			1	1
Fatigue		2		2		
Pain		1		1		
Peripheral swelling		1		1		
Polyp		1		1		
Pyrexia		2		2		
Swelling		1		1		
Tenderness		2		2		
Vaccination site pain		1		1		
Vaccination site swelling		1		1		
	1	13		12	1	1

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19		2		2
		2		2

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Maternal exposure during pregnancy	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphocyte percentage increased		1		1
Mean cell haemoglobin concentration increased		1		1
		2		2

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1			1	1
Back pain	1	1			1	1
Muscle tightness	1	1			1	1
Musculoskeletal chest pain	1	1			1	1
Musculoskeletal stiffness		1		1		
Myalgia		1		1		
Neck pain		1		1		
Pain in extremity		1		1		
	4	8		4	4	4

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache		2		2		
Hypoaesthesia	1	1			1	1
Paraesthesia	1	1			1	1
	2	4		2	2	2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breast pain	1	1	1	1
	1	1	1	1

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthma		1		1
		1		1

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hyperhidrosis	1	1	1	1
	1	1	1	1

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* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

LATVIA

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenitis		2		1		1
Lymphadenopathy	3	25	3	21		4
Lymph node pain		6		3		3
	3	33	3	25		8

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris		1				1
Arrhythmia		2				2
Atrial f brillation		1				1
Bradycardia		1				1
Bundle branch block left		1				1
Extrasystoles		1				1
Palpitations		3				3
Tachycardia		7		1		6
		17		1		16

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness		1				1
Ear discomfort		1				1
Ear pain		2		1		1
Hyperacusis	1	1	1	1		
Hypoacusis		1		1		
Vertigo		4		4		
	1	10	1	7		3

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypothyroidism		1		1
		1		1

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal sensation in eye		1		1		
Blepharitis		1		1		
Conjunctival haemorrhage		1				1
Diplopia		1				1
Eye pain	2	14	1	13	1	1
Lacrimation increased		2		1		1
Photophobia	2	5	2	4		1
Vision blurred		1				1
	4	26	3	20	1	6

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		5		5		
Abdominal pain lower	1	2	1	2		
Abdominal pain upper		2				2
Diarrhoea	1	7	1	7		
Dry mouth		2		1		1
Glossodynia	1	1	1	1		
Nausea	5	30	5	29		1
Oral discomfort		1		1		
Palatal swelling		1		1		
Paraesthesia oral	2	4	2	2		2
Stomatitis		1				1
Tongue spasm		1				1
Toothache		1		1		
Vomiting		7		6		1
	10	65	10	56		9

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	3	28	3	24		4
Axillary pain	1	1	1	1		
Chest discomfort		1				1
Chest pain		2		2		
Chills	7	61	7	61		
Condition aggravated		2		1		1
Death	1	1			1	1
Disease recurrence		2				2
Drug ineffective	2	5			2	5
Face oedema		1				1
Fatigue	11	81	9	71	2	10
Feeling hot		2		2		
Gait disturbance		2		2		
Generalised oedema		1				1
Illness		2		2		
Influenza like illness		1		1		
Malaise	1	4	1	4		
Oedema mucosal		1				1
Oedema peripheral		1				1
Pain	2	6	2	5		1
Peripheral swelling		1		1		
Pyrexia	16	97	16	82		15
Swelling face	2	2	1	1	1	1
Thirst		2		1		1
Vaccination failure	1	4			1	4
Vaccination site discolouration		1		1		
Vaccination site erythema		12		10		2
Vaccination site haematoma		1				1
Vaccination site hyperaesthesia	1	1	1	1		
Vaccination site hypoaesthesia		1				1
Vaccination site inflammation		1		1		
Vaccination site lymphadenopathy		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site mass		2				2
Vaccination site oedema	1	9	1	7		2
Vaccination site pain	12	85	12	81		4
Vaccination site pruritus		4		3		1
Vaccination site rash		2				2
Vaccination site reaction		2		2		
Vaccination site swelling	1	2	1	2		
Vaccination site warmth	1	6	1	5		1
	63	441	56	375	7	66

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Bacille Calmette-Guerin scar reactivation		1		1		
Hypersensitivity	1	1	1	1		
	1	3	1	2		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19	1	1			1	1
COVID-19	2	11		3	2	8
Herpes zoster		1				1
Nasopharyngitis		1		1		
Oral herpes	1	1	1	1		
	4	15	1	5	3	10

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposure during pregnancy		2		1		1
Head injury	1	1			1	1
Inappropriate schedule of product administration	1	2	1	2		
Off label use		2		2		
Product use issue		1		1		
	2	8	1	6	1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood creatine phosphokinase increased		1		1		
Blood pressure decreased		1		1		
Blood pressure increased		3		1		2
Body temperature decreased		1		1		
Body temperature increased	11	60	11	59		1
C-reactive protein increased		3		3		
Glomerular filtration rate decreased		1		1		
Heart rate increased		2		1		1
Neutrophil count increased		1		1		
Pulse volume decreased		1		1		
SARS-CoV-2 test positive		1				1
	11	75	11	70		5

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite	1	8	1	8
Increased appetite		1		1
	1	9	1	9

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	8	59	7	54	1	5
Back pain		2		2		
Bone pain		2		2		
Joint range of motion decreased		1		1		
Joint stiffness		2		1		1
Muscle spasms	1	3	1	2		1
Muscular weakness	1	6	1	3		3
Musculoskeletal discomfort	1	3	1	3		
Musculoskeletal stiffness	2	4	2	3		1
Myalgia	12	70	11	65	1	5
Neck pain		3		2		1
Pain in extremity	3	11	3	9		2
Rhabdomyolysis		1				1
Somatic dysfunction		1				1
	28	168	26	147	2	21

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anosmia		1				1
Bell's palsy		1				1
Burning sensation		4		1		3
Coordination abnormal		1		1		
Disturbance in attention		8		5		3
Dizziness	1	22		17	1	5
Dysgeusia		4		2		2
Facial paresis		2				2
Generalised tonic-clonic seizure		1				1
Headache	14	93	12	82	2	11
Head discomfort		1		1		
Hyperaesthesia		7		4		3
Hypoaesthesia		1				1
Loss of proprioception		1				1
Mental impairment		1				1
Migraine	1	3		1	1	2
Neuralgia		3				3
Paraesthesia	2	9	1	2	1	7
Peripheral sensory neuropathy		1				1
Presyncope		1				1
Restless legs syndrome		1		1		
Somnolence	1	10	1	8		2
Syncope	1	3			1	3
Transient ischaemic attack		1				1
Tunnel vision		1				1
Vertebrobasilar stroke		1				1
	20	182	14	125	6	57

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion missed		1		1
		1		1

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety		2				2
Bradyphrenia		1		1		
Confusional state		1		1		
Depressed mood		1		1		
Depression		1		1		
Initial insomnia		3		3		
Insomnia	1	3		1	1	2
Sleep disorder		2		2		
Sleep disorder due to general medical condition, insomnia type		1		1		
	1	15		11	1	4

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Costovertebral angle tenderness		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Menstrual disorder	1	1	1	1
Polymenorrhoea	1	2	1	2
	2	3	2	3

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma		2		1		1
Cough	1	9	1	9		
Dysphonia		2		2		
Dyspnoea	1	7	1	4		3
Dyspnoea exertional		2		2		
Epistaxis		1				1
Nasal congestion	2	4	2	4		
Nasal oedema		1		1		
Oropharyngeal pain		6		5		1
Pharyngeal oedema		1		1		
Pharyngeal paraesthesia	1	1	1	1		
Respiratory distress		1				1
Rhinorrhoea		2		1		1
Throat irritation		4		4		
Throat tightness	1	1	1	1		
Upper respiratory tract congestion		1		1		
	6	45	6	37		8

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat		2		1		1
Dermatitis allergic	1	1	1	1		
Dry skin		1		1		
Erythema	1	3	1	2		1
Hyperhidrosis	4	11	4	11		
Night sweats		1		1		
Pruritus	1	4	1	2		2
Purpura		2				2
Rash		4		3		1
Rash macular		1		1		
Rash maculo-papular	1	1	1	1		
Rash pruritic		3		3		
Sensitive skin	1	1	1	1		
Skin burning sensation		1				1
Skin tightness		1				1
Urticaria	1	2		1	1	1
Urticaria papular	1	1			1	1
Vasculitic rash		1		1		
	11	41	9	30	2	11

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Flushing	1	1	1	1		
Hot flush	1	4	1	3		1
Hypertension		3		2		1
Hypertensive crisis		2				2
Hypotension		1		1		
Peripheral coldness	1	3	1	2		1
Thrombosis	1	1			1	1
	4	15	3	9	1	6

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

LEBANON

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Thrombocytopenia	1	1	1	1
	1	1	1	1

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Extrasystoles		1				1
Tachycardia		2		2		
		3		2		1

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid ptosis	1	1			1	1
Vision blurred		1		1		
	1	2		1	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Diarrhoea		1		1		
Irritable bowel syndrome		1		1		
Vomiting	1	1			1	1
	1	4		3	1	1

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse event	1	1	1	1		
Chest discomfort		1		1		
Chest pain	1	1	1	1		
Chills		6		5		1
Death		11				11
Drug ineffective	3	7			3	7
Fatigue	1	3		2	1	1
Feeling cold		1		1		
Inflammation	1	1	1	1		
Malaise		1		1		
Pain		1		1		
Pyrexia		6		5		1
Swelling face	1	1	1	1		
Vaccination failure	1	5			1	5
Vaccination site pain		1		1		
	9	47	4	21	5	26

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic reaction to excipient		1		1		
Anaphylactic reaction		1				1
Hypersensitivity		1				1
		3		1		2

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	4	18		4	4	14
Influenza		1		1		
Pyelonephritis		1				1
	4	20		5	4	15

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Incorrect route of product administration		2		2
		2		2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite		1		1
Dehydration		1		1
		2		2

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia		1		1
Back pain		2		2
Limb discomfort		1		1
Muscle twitching		1		1
Muscular weakness	1	1	1	1
Myalgia	1	3	1	3
Pain in extremity		2		2
	2	11	2	11

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphasia	1	1			1	1
Bell's palsy		1				1
Cerebrovascular accident		1				1
Dizziness		1		1		
Dysarthria	1	1	1	1		
Facial paresis		1				1
Headache	1	5		4	1	1
Hypoaesthesia	1	2	1	2		
Loss of consciousness		1				1
Neurological symptom	2	2			2	2
Paraesthesia	1	5	1	5		
Paralysis	1	1			1	1
Sciatica		1		1		
Speech disorder		1		1		
	8	24	3	15	5	9

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product container issue	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Confusional state	1	1	1	1		
Insomnia		1		1		
Lack of spontaneous speech	1	1			1	1
Mood altered		1		1		
Panic attack		1		1		
	2	5	1	4	1	1

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Menstruation delayed	4	4	4	4
	4	4	4	4

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysphonia		1				1
Dyspnoea		2		2		
Lung disorder		1				1
Oropharyngeal pain		2		2		
Respiratory tract oedema		1				1
Rhinorrhoea		2		2		
Throat irritation		2		2		
Throat tightness		1				1
		12		8		4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermatitis allergic		1		1		
Erythema		1				1
Hyperhidrosis		1		1		
Pruritus		1				1
Rash		2				2
Urticaria		1		1		
		7		3		4

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Embolism venous	1	1			1	1
Flushing		1		1		
Hypertension	1	6	1	4		2
Hypotension		1		1		
	2	9	1	6	1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

LIECHTENSTEIN

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Herpes zoster	1	1	1	1
	1	1	1	1

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Incorrect dose administered		1		1
Wrong product administered	1	1	1	1
	1	2	1	2

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Neuralgia	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

LITHUANIA

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemolytic anaemia		1				1
Lymphadenopathy	1	8	1	7		1
Lymph node pain		1				1
Lymphopenia	1	1	1	1		
	2	11	2	8		3

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris	1	5			1	5
Arrhythmia	3	4			3	4
Atrial fibrillation	1	1			1	1
Cardiac arrest	1	1			1	1
Cardiogenic shock		1				1
Extrasystoles	1	1	1	1		
Palpitations	2	2			2	2
Tachycardia	4	6	2	3	2	3
	13	21	3	4	10	17

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorder	1	1			1	1
Ear pain	2	4	2	4		
Hypoacusis		1		1		
Tinnitus		2		1		1
	3	8	2	6	1	2

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry eye		1		1		
Eye disorder	1	2	1	2		
Eye irritation	1	2	1	2		
Eyelid function disorder		1				1
Eye pain		5		5		
Eye swelling	1	1	1	1		
Lacrimation increased		3		2		1
Photophobia	1	1	1	1		
Visual impairment		1		1		
	4	17	4	15		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	2		1	1	1
Abdominal pain upper		3		2		1
Chronic gastritis		1		1		
Diarrhoea	1	7	1	5		2
Diverticulum		1		1		
Dry mouth	2	2	1	1	1	1
Dyspepsia		1		1		
Dysphagia	1	2			1	2
Flatulence		1		1		
Hypoaesthesia oral		1				1
Lip swelling		1		1		
Nausea	7	21	7	17		4
Paraesthesia oral	1	1	1	1		
Swollen tongue	1	1	1	1		
Tongue dry	1	1			1	1
Tongue movement disturbance	1	1			1	1
Vomiting	2	8	2	4		4
	18	55	13	37	5	18

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	12	41	7	30	5	11
Axillary pain		5		4		1
Chest discomfort	1	2	1	1		1
Chest pain		1		1		
Chills	3	22	3	20		2
Condition aggravated	1	3	1	1		2
Death	1	4			1	4
Discomfort	1	1	1	1		
Fatigue	2	8	2	7		1
Feeling abnormal	2	3	1	2	1	1
Feeling drunk		1		1		
Feeling hot	1	3		1	1	2
Feeling of body temperature change		1		1		
Gait disturbance	1	2			1	2
Induration	1	1			1	1
Injected limb mobility decreased		1		1		
Injection site pain		1		1		
Local reaction		1				1
Malaise	2	5	1	2	1	3
Mucosal disorder		1		1		
Non-cardiac chest pain		1		1		
Pain	1	3	1	2		1
Peripheral swelling	3	7	2	5	1	2
Pyrexia	10	41	10	40		1
Sensation of foreign body		1				1
Swelling	2	2	1	1	1	1
Swelling face	1	2		1	1	1
Vaccination failure		1				1
Vaccination site erythema	3	15	3	14		1
Vaccination site induration		1		1		
Vaccination site inflammation		1		1		
Vaccination site mass	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	8	30	7	28	1	2
Vaccination site pruritus		1		1		
Vaccination site reaction		1		1		
Vaccination site swelling		10		9		1
Vaccination site warmth		3		2		1
	57	228	42	183	15	45

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic reaction		2		2
Anaphylactic shock		1		1
Hypersensitivity	1	2	1	2
	1	5	1	5

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chronic sinusitis		1		1		
COVID-19		1		1		
COVID-19 pneumonia		1				1
Herpes simplex		1		1		
Lymph node abscess	6	15			6	15
Nasopharyngitis	3	6	3	6		
Peritonitis		1				1
Peritonsillar abscess		1				1
Pneumonia	1	2			1	2
	10	29	3	9	7	20

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose		1				1
Exposure during pregnancy		1		1		
Off label use		1		1		
Overdose		1		1		
Product preparation issue		1				1
Product use issue		1		1		
Thermal burns of eye	1	1			1	1
Underdose		1		1		
Vaccination complication		1		1		
	1	9		6	1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure abnormal		1		1		
Blood pressure ambulatory increased		1		1		
Blood pressure decreased	1	3			1	3
Blood pressure increased	2	9		2	2	7
Body temperature increased	2	6	1	4	1	2
Heart rate increased	1	9		5	1	4
Heart rate irregular		1		1		
Lymph node palpable		1				1
Pulse abnormal	1	1			1	1
Respiratory rate increased	1	1			1	1
	8	33	1	14	7	19

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite	1	3	1	3
	1	3	1	3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	5	20	5	19		1
Back pain		2		2		
Bone pain	2	8	2	8		
Facial asymmetry		1				1
Groin pain	1	1	1	1		
Joint swelling	1	1			1	1
Limb discomfort	1	1	1	1		
Mobility decreased		1		1		
Muscle spasms		1		1		
Muscle twitching		1		1		
Muscular weakness	1	3	1	3		
Musculoskeletal chest pain	1	1	1	1		
Musculoskeletal stiffness		1		1		
Myalgia	3	24	3	22		2
Myositis		1		1		
Neck pain		3		3		
Pain in extremity	6	24	5	22	1	2
Polymyositis		1				1
Tendon pain		1		1		
	21	96	19	88	2	8

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Balance disorder		1		1		
Bell's palsy		1				1
Cognitive disorder		1				1
Convulsions local		1				1
Coordination abnormal		1				1
Depressed level of consciousness	1	2			1	2
Dizziness	6	19	5	14	1	5
Dysgeusia		1		1		
Dyspraxia	1	1	1	1		
Epilepsy		1				1
Facial nerve disorder		1		1		
Facial paralysis		4				4
Haemorrhagic stroke	1	1			1	1
Headache	9	42	9	35		7
Head discomfort	1	2	1	2		
Hypoaesthesia	1	10		8	1	2
Loss of consciousness	3	7			3	7
Memory impairment	1	2	1	2		
Mental impairment	1	1			1	1
Neuralgia		1				1
Paraesthesia	2	6	1	4	1	2
Paralysis	1	1			1	1
Paresis		1				1
Seizure		5				5
Slow response to stimuli		1		1		
Somnolence	1	6	1	6		
Speech disorder	1	1			1	1
Syncope	2	8			2	8
Taste disorder		1				1
Tremor	3	8		4	3	4
	35	138	19	80	16	58

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	1	2	1	1		1
Apathy		1		1		
Confusional state		1		1		
Disorientation		2				2
Insomnia	2	4	2	4		
Irritability		1				1
Panic attack	1	1			1	1
Stress		1		1		
	4	13	3	8	1	5

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Urinary incontinence		1		1
		1		1

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Heavy menstrual bleeding	1	1	1	1
Menstrual disorder	1	1	1	1
Menstruation delayed	1	1	1	1
	3	3	3	3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	1	5	1	5		
Dyspnoea	6	11	4	7	2	4
Epistaxis	1	1	1	1		
Nasal congestion	1	3		2	1	1
Oropharyngeal pain	1	2	1	2		
Pharyngeal disorder	1	1			1	1
Pulmonary embolism	1	1			1	1
Pulmonary oedema		1				1
Rhinorrhoea	1	2	1	2		
Sneezing		1		1		
Throat tightness	1	1			1	1
Tonsillar hypertrophy		1		1		
	14	30	8	21	6	9

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blister	1	1			1	1
Cold sweat	2	3		1	2	2
Erythema		3		2		1
Hyperhidrosis	2	4	1	3	1	1
Night sweats	1	1	1	1		
Pain of skin		1		1		
Pruritus	3	6	2	5	1	1
Rash	4	5	2	3	2	2
Rash maculo-papular	1	2		1	1	1
Rash papular		1				1
Sensitive skin		1		1		
Skin discolouration	1	1			1	1
Skin mass		1				1
Urticaria	2	2	1	1	1	1
	17	32	7	19	10	13

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure fluctuation	1	3	1	2		1
Deep vein thrombosis		1				1
Hot flush		1		1		
Hypertension	1	3		1	1	2
Hypertensive crisis		1				1
Hypotension	1	2			1	2
Pallor	2	3			2	3
Peripheral coldness	1	2		1	1	1
Phlebitis	1	1			1	1
Thrombophlebitis	1	1			1	1
Thrombosis	1	2			1	2
	9	20	1	5	8	15

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

LUXEMBOURG

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenitis	1	1	1	1		
Lymphadenopathy	4	9	1	5	3	4
Lymph node pain	1	1			1	1
	6	11	2	6	4	5

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute coronary syndrome		1		1
Arrhythmia		2		2
Atrial f brillation		1		1
Cardiac arrest	1	1	1	1
Palpitations		3		3
Tachycardia	1	5	1	5
	2	13	2	13

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness	1	1			1	1
Tinnitus		1				1
Vertigo	1	2	1	2		
	2	4	1	2	1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diplopia		1				1
Eyelid oedema		2		1		1
Eye movement disorder		1				1
Eye pain		1				1
Eye swelling	1	1			1	1
Uveitis	1	1			1	1
	2	7		1	2	6

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1				1
Abdominal pain upper		2				2
Diarrhoea		7		1		6
Dry mouth		2				2
Lip pain	1	1	1	1		
Nausea	4	15	4	5		10
Paraesthesia oral		1		1		
Rectal haemorrhage		1				1
Tongue ulceration		1				1
Vomiting		4				4
	5	35	5	8		27

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	2	5		1	2	4
Chest discomfort	3	6			3	6
Chest pain	1	3		1	1	2
Chills	5	21	3	6	2	15
Drug ineffective		1				1
Face oedema		2				2
Facial pain	1	1	1	1		
Fatigue	16	43	11	13	5	30
Feeling abnormal		1				1
Feeling cold	1	1			1	1
Feeling hot		1				1
Gait disturbance	1	1			1	1
General physical health deterioration		1				1
Hyperthermia		2		1		1
Illness	1	1	1	1		
Inflammation	1	1			1	1
Injected limb mobility decreased		1				1
Injection site reaction		1		1		
Malaise	3	13	2	3	1	10
Pain	2	3	1	1	1	2
Peripheral swelling	1	4	1	3		1
Pyrexia	13	31	8	10	5	21
Swelling		1				1
Swelling face	1	3		1	1	2
Therapeutic response unexpected		1		1		
Vaccination site induration	1	1	1	1		
Vaccination site pain	5	8	3	3	2	5
Vaccination site reaction	8	31	8	24		7
Vaccination site swelling	1	1	1	1		
	67	190	41	73	26	117

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic oedema		1		1		
Anaphylactic reaction	1	1			1	1
Hypersensitivity		3				3
	1	5		1	1	4

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctivitis		1				1
COVID-19		1				1
COVID-19 pneumonia		1				1
Herpes zoster		1		1		
Influenza		6		2		4
Nasopharyngitis		1		1		
Oral herpes		1		1		
Pneumonia	1	2			1	2
Sepsis		1				1
Tonsillitis bacterial	1	1			1	1
Urinary tract infection		1		1		
	2	17		6	2	11

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chillblains		1		1		
Fall		2				2
Subdural haematoma	1	1			1	1
Vaccination complication	1	6		1	1	5
	2	10		2	2	8

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased		1				1
C-reactive protein	1	1	1	1		
C-reactive protein increased	2	2	1	1	1	1
Haemoglobin decreased		1				1
Heart rate increased		1				1
Oxygen saturation decreased		1				1
Pulse abnormal		1				1
SARS-CoV-2 ant body test negative		1				1
Weight decreased	1	1			1	1
	4	10	2	2	2	8

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	1	2			1	2
Feeding disorder		1				1
Hypernatraemia		1				1
Tetany		1		1		
Vitamin B12 deficiency		1				1
	1	6		1	1	5

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	7	23	3	7	4	16
Back pain	1	2	1	2		
Bone pain	1	1			1	1
Joint swelling	1	1			1	1
Limb discomfort	1	1			1	1
Muscular weakness	1	2			1	2
Musculoskeletal stiffness		2				2
Myalgia	10	36	5	11	5	25
Neck pain	3	5		1	3	4
Pain in extremity	3	9	3	5		4
	28	82	12	26	16	56

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Altered state of consciousness		1				1
Carotid arteriosclerosis	1	1	1	1		
Cerebral haemorrhage		1				1
Cerebrovascular accident	1	1			1	1
Cervical radiculopathy	1	1			1	1
Coma	1	1			1	1
Dizziness	1	7	1	1		6
Dysaesthesia		1				1
Dysgeusia		1				1
Epilepsy		3				3
Facial paralysis	1	1			1	1
Formication		1				1
Generalised tonic-clonic seizure	1	1			1	1
Headache	16	52	10	16	6	36
Hemiparaesthesia		1				1
Hemiparesis	1	1			1	1
Hypersomnia	1	2		1	1	1
Hypoaesthesia		1				1
Hypotonia	1	1	1	1		
Loss of consciousness	1	3			1	3
Migraine		1				1
Paraesthesia	1	4			1	4
Paresis		1				1
Presyncope	2	3	2	2		1
Somnolence		1				1
Speech disorder	1	1			1	1
Tremor		3		1		2
Vlth nerve paralysis		1				1
	31	97	15	23	16	74

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety		3		2		1
Apathy	1	1			1	1
Bradyphrenia		1				1
Confusional state	2	2			2	2
Fear of injection		1		1		
Insomnia	2	3	1	1	1	2
Panic attack		1		1		
Panic reaction	1	1	1	1		
	6	13	2	6	4	7

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute kidney injury		1		1
Urinary incontinence		1		1
		2		2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthmatic crisis		1				1
Cough		1				1
Dysphonia		2				2
Dyspnoea	3	8			3	8
Dyspnoea exertional	2	3			2	3
Epistaxis	1	2	1	1		1
Hypoxia		1				1
Laryngeal discomfort		1				1
Lung disorder		1				1
Oropharyngeal discomfort	1	2			1	2
Pharyngeal paraesthesia	1	1			1	1
Pneumonia aspiration	1	1			1	1
Productive cough		1				1
Pulmonary embolism	1	4			1	4
Pulmonary pain		1				1
Respiratory failure		1				1
Throat tightness		1				1
Wheezing		2				2
	10	34	1	1	9	33

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermatitis allergic		1				1
Dermatitis bullous		1				1
Dry skin		1				1
Erythema	2	2			2	2
Erythema nodosum		1				1
Hyperhidrosis		2				2
Pruritus	2	8	1	2	1	6
Psoriasis	1	1	1	1		
Rash	1	4			1	4
Skin haemorrhage		1				1
Skin plaque	1	1	1	1		
Urticaria	1	2	1	2		
	8	25	4	6	4	19

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure fluctuation	1	1	1	1		
Claudication of jaw muscles	1	1			1	1
Deep vein thrombosis	2	3			2	3
Haematoma	1	2		1	1	1
Hot flush		1				1
Hypertension	2	9		1	2	8
Hypertensive crisis	1	1			1	1
Hypotension	3	7	2	2	1	5
Lymphoedema	1	1			1	1
Pallor		1				1
Peripheral coldness		1				1
Phlebitis	1	1			1	1
Venous thrombosis limb	1	1			1	1
	14	30	3	5	11	25

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

MACAO

System Organ Class

Cardiac disorders

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Acute coronary syndrome		1		1
		1		1

System Organ Class

Nervous system disorders

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Bell's palsy	1	1	1	1
Facial paralysis	3	3	3	3
	4	4	4	4

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred
MACEDONIA, THE FORMER YUGOSLAV

System Organ Class

Eye disorders

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Eye oedema	1	1	1	1
	1	1	1	1

System Organ Class

Gastrointestinal disorders

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Lip oedema	1	1	1	1
	1	1	1	1

System Organ Class

General disorders and administration site conditions

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Asthenia		1		1
Malaise	2	4	2	4
Pyrexia	3	4	3	4
Vaccination site pain	1	2	1	2
	6	11	6	11

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypersensitivity	1	1	1	1
	1	1	1	1

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	1			1	1
Nasopharyngitis		1		1		
Pneumonia	1	1			1	1
	2	3		1	2	2

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Incorrect route of product administration		1		1
		1		1

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Body temperature increased	1	3	1	3
	1	3	1	3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia		1		1
Myalgia	2	3	2	3
	2	4	2	4

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache	1	4	1	4		
Loss of consciousness		1				1
	1	5	1	4		1

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Rhinorrhoea		1		1
		1		1

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Rash maculo-papular		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

MALAYSIA

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Disseminated intravascular coagulation	1	1	1	1
	1	1	1	1

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cardiac disorder	1	1	1	1
	1	1	1	1

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1			1	1
Abdominal pain upper	1	1			1	1
Constipation		1		1		
Gastrointestinal necrosis	1	1			1	1
Intestinal ischaemia	1	1			1	1
Nausea	1	1			1	1
Saliva altered	1	1	1	1		
Vomiting	1	1			1	1
	7	8	1	2	6	6

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		1		1		
Death	1	2			1	2
Fatigue		1		1		
Malaise	1	2		1	1	1
No adverse event	4	5	4	5		
Perforation	1	1			1	1
Pyrexia		1		1		
Vaccination site erythema		1		1		
Vaccination site pain	1	3	1	3		
Vaccination site swelling	1	1	1	1		
Vaccination site warmth		1		1		
	9	19	6	15	3	4

System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hepatic function abnormal	1	1	1	1
	1	1	1	1

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactoid reaction	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal sepsis	1	1			1	1
Cellulitis		1				1
COVID-19		1		1		
Septic shock	1	1			1	1
	2	4		1	2	3

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Contusion	1	1	1	1
Maternal exposure during pregnancy	2	3	2	3
	3	4	3	4

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood uric acid increased	1	1			1	1
Platelet count decreased	1	1	1	1		
	2	2	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Musculoskeletal stiffness		1		1
		1		1

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amnesia	1	1	1	1		
Cerebral infarction	1	1			1	1
Dizziness		1		1		
Haemorrhagic stroke	1	1			1	1
Haemorrhagic transformation stroke	1	1			1	1
Headache		2		2		
Hypoaesthesia		1		1		
Loss of consciousness	1	1			1	1
Memory impairment	1	1	1	1		
Neuropathy peripheral		2				2
Seizure		1				1
Speech disorder	1	1			1	1
	7	14	2	6	5	8

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product complaint	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Renal impairment	1	1	1	1
	1	1	1	1

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Heavy menstrual bleeding	1	1	1	1
	1	1	1	1

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bronchospasm	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hair texture abnormal		1		1		
Pityriasis rosea		1		1		
Rash	1	1	1	1		
Rash erythematous		1		1		
Rash papular		1		1		
Skin discolouration	1	1	1	1		
Skin necrosis		1				1
Urticaria	1	1	1	1		
	3	8	3	7		1

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Labile blood pressure	1	1	1	1
Thrombosis	1	1	1	1
	2	2	2	2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

MALTA

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy	3	5	3	5		
Normochromic normocytic anaemia		1		1		
Nucleated red cells		1		1		
Thrombocytopenia	2	3			2	3
	5	10	3	7	2	3

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arrhythmia	1	1			1	1
Atrial f brillation	1	2			1	2
Cardiac arrest		2				2
Cardiac failure	1	1			1	1
Cardiac failure congestive	2	2			2	2
Palpitations		5		1		4
Pericardial effusion	1	1			1	1
Sinus tachycardia		1				1
Tachycardia		4				4
	6	19		1	6	18

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness	1	1			1	1
Ear swelling		2		2		
Tinnitus	2	2			2	2
Vertigo	1	1	1	1		
	4	6	1	3	3	3

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Goitre		1		1
		1		1

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye swelling		1				1
Ocular hyperaemia		1		1		
Periorbital swelling	1	2		1	1	1
Retinal vein occlusion		1				1
Vision blurred		2				2
	1	7		2	1	5

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		2		2		
Defaecation urgency		1		1		
Diarrhoea	1	4	1	3		1
Dysphagia		1				1
Haematemesis		1				1
Lip swelling	1	2	1	1		1
Mouth ulceration		1		1		
Nausea	2	8	2	5		3
Oral pain		1		1		
Paraesthesia oral		2		2		
Swollen tongue		1				1
Tongue ulceration		1		1		
Toothache		1		1		
Vomiting	1	4	1	3		1
	5	31	5	22		9

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	4	1	3		1
Chest discomfort		2				2
Chest pain		2		1		1
Chills	5	13	5	13		
Discomfort	1	1	1	1		
Drug ineffective	1	5			1	5
Fatigue	3	19	3	17		2
Feeling abnormal		1		1		
Feeling of body temperature change		1				1
Gait disturbance		1		1		
Gait inability		1		1		
Hypothermia		1				1
Impaired healing	1	1			1	1
Influenza like illness	1	2	1	2		
Malaise	1	7	1	7		
Pain	3	10	3	10		
Peripheral swelling		1		1		
Pyrexia	6	27	6	25		2
Swelling		3				3
Swelling face		5		2		3
Ulcer		1		1		
Vaccination failure	1	5			1	5
Vaccination site discomfort		1		1		
Vaccination site erythema		1		1		
Vaccination site induration		1		1		
Vaccination site movement impairment		1		1		
Vaccination site pain	4	16	4	16		
Vaccination site pruritus		2		2		
Vaccination site rash		1		1		
Vaccination site urticaria		2		1		1
	28	138	25	110	3	28

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		8				8
Hypersensitivity	2	10	2	6		4
	2	18	2	6		12

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthritis infective		1				1
COVID-19	2	11		1	2	10
COVID-19 pneumonia		2				2
Fungal skin infection		1		1		
Sepsis	1	3			1	3
Septic shock		1				1
Urinary tract infection	1	2		1	1	1
Urosepsis		1				1
	4	22		3	4	19

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inappropriate schedule of product administration	1	1	1	1		
Off label use		2		2		
Overdose		1		1		
Product administered at inappropriate site		1		1		
Product use issue		1		1		
Traumatic haemorrhage	1	1			1	1
	2	7	1	6	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Activated partial thromboplastin time prolonged		2		2		
Activated partial thromboplastin time ratio increased		1		1		
Alanine aminotransferase increased		1		1		
Basophil count increased		1		1		
Blood alkaline phosphatase increased		2		2		
Blood calcium decreased		1		1		
Blood creatinine increased		1		1		
Blood glucose increased		1		1		
Blood magnesium decreased		1		1		
Blood osmolarity increased		1		1		
Blood phosphorus decreased		1		1		
Blood urea increased		2		2		
C-reactive protein increased		3		3		
Eosinophil count decreased		1		1		
Grip strength decreased	1	1	1	1		
Haematocrit decreased		3		3		
Haemoglobin decreased		3		3		
Heart rate increased		2		1		1
Immature granulocyte count increased		1		1		
International normalised ratio increased		1		1		
Lymphocyte count decreased		3		3		
Mean cell haemoglobin concentration decreased		1		1		
Mean cell haemoglobin concentration increased		1		1		
Mean cell volume increased		1		1		
Mean platelet volume decreased		1		1		
Monocyte count decreased		1		1		
Monocyte count increased		1		1		
Neutrophil count increased		3		3		
Oxygen saturation decreased		1		1		
Platelet count decreased		1		1		
Platelet count increased		2		2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Prothrombin time prolonged		1		1		
Red blood cell count decreased		3		3		
Red cell distribution width increased		2		2		
Reticulocyte count increased		1		1		
White blood cell count increased		1		1		
	1	54	1	53		1

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite		1		1
Dehydration		1		1
		2		2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	3	7	3	7		
Arthritis reactive	1	1			1	1
Bone pain		2		2		
Limb discomfort	3	5	3	4		1
Mobility decreased		1		1		
Muscle spasms		1		1		
Muscle twitching		1		1		
Musculoskeletal stiffness	1	3	1	3		
Myalgia	2	11	2	11		
Neck pain		3		3		
Pain in extremity	3	12	3	10		2
Soft tissue swelling	1	1	1	1		
	14	48	13	44	1	4

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Neoplasm progression		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Altered state of consciousness	2	3			2	3
Bell's palsy		3				3
Burning sensation		2		1		1
Cerebellar atrophy		1				1
Cerebral atrophy		2				2
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident	1	2			1	2
Dizziness		4		4		
Dysgeusia		2		1		1
Facial paralysis		2				2
Fine motor skill dysfunction	1	1	1	1		
Generalised tonic-clonic seizure		1				1
Headache	3	9	3	9		
Hemiplegia	1	1			1	1
Hypoaesthesia	1	5	1	4		1
Lethargy	3	14	1	12	2	2
Loss of consciousness		2				2
Migraine		1		1		
Paraesthesia	3	8	3	8		
Parosmia		1		1		
Somnolence		3		3		
Speech disorder	1	1	1	1		
Syncope		4				4
Taste disorder		1		1		
Tremor		1				1
	17	75	10	47	7	28

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fear of injection		1		1
Insomnia	2	3	2	3
Panic reaction		1		1
Restlessness	1	1	1	1
	3	6	3	6

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute kidney injury	2	4	2	4
Renal failure	1	1	1	1
Urinary retention	1	1	1	1
	4	6	4	6

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma		2				2
Bronchospasm		3				3
Cough		3		2		1
Dysphonia		3				3
Dyspnoea	1	7			1	7
Hypoxia	1	4			1	4
Oropharyngeal pain		1		1		
Pulmonary artery thrombosis	1	1			1	1
Pulmonary embolism	1	2			1	2
Respiratory arrest		2				2
Respiratory depression		1				1
Respiratory distress		3				3
Respiratory failure	1	2			1	2
Tachypnoea	1	4			1	4
Throat tightness		1				1
Use of accessory respiratory muscles		2				2
Wheezing		2				2
	6	43		3	6	40

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema		2				2
Erythema	1	9	1	6		3
Hyperhidrosis	1	3	1	3		
Night sweats		1		1		
Pigmentation disorder	1	1	1	1		
Pruritus	1	9	1	5		4
Rash	2	9	2	5		4
Rash erythematous		3		1		2
Rash pruritic		2				2
Urticaria	1	3	1	2		1
	7	42	7	24		18

System Organ Class

Surgical and medical procedures

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Injection		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deep vein thrombosis	3	4			3	4
Flushing		3		1		2
Hot flush		3		3		
Hypertension		3		1		2
Peripheral coldness	1	2	1	2		
Poor peripheral circulation		1		1		
Thrombosis		1				1
	4	17	1	8	3	9

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

MEXICO

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemolytic anaemia		1				1
Haemorrhagic disorder	2	12			2	12
Leukopenia		3				3
Lymphadenitis	1	3	1	3		
Lymphadenopathy	88	179	81	163	7	16
Lymph node pain	2	3	2	3		
Lymphopenia	1	3	1	2		1
Monocytosis	1	1	1	1		
Splenomegaly		1		1		
Thrombocytopenia	1	3			1	3
Thrombocytopenic purpura	1	4		2	1	2
	97	213	86	175	11	38

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction		2				2
Angina pectoris		1				1
Angina unstable	1	1			1	1
Arrhythmia		8				8
Atrial fibrillation	1	3			1	3
Bradycardia	2	21			2	21
Cardiac failure	1	1			1	1
Cardio-respiratory arrest	1	3			1	3
Cardiovascular disorder		1		1		
Myocardial infarction		2				2
Palpitations	19	44	15	36	4	8
Pericardial disease		1		1		
Sinus tachycardia		4		2		2
Tachyarrhythmia		1		1		
Tachycardia	554	1,010	480	834	74	176
Tachycardia paroxysmal	1	1	1	1		
	580	1,104	496	876	84	228

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Auricular swelling	1	2	1	2		
Deafness		1				1
Deafness bilateral	1	1			1	1
Deafness unilateral		2				2
Ear discomfort	1	6	1	6		
Ear disorder	2	3	2	3		
Ear pain	14	23	11	19	3	4
Ear pruritus	1	1	1	1		
External ear inflammation		1		1		
Hyperacusis	1	1	1	1		
Hypoacusis	1	4	1	4		
Inner ear inflammation	1	1	1	1		
Tinnitus	20	34	20	31		3
Tympanic membrane disorder		1		1		
Tympanic membrane perforation	1	1			1	1
Vertigo	44	78	33	61	11	17
	88	160	72	131	16	29

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal sensation in eye	1	1	1	1		
Asthenopia	1	1	1	1		
Blepharitis	1	2	1	2		
Blepharospasm	1	2	1	2		
Blindness		1				1
Blindness transient		1				1
Conjunctival disorder	1	1			1	1
Conjunctival haemorrhage	1	6			1	6
Conjunctival hyperaemia	4	8	4	7		1
Conjunctival irritation	1	1	1	1		
Diplopia		2		2		
Eye discharge	1	2	1	2		
Eye disorder	1	4	1	4		
Eye haemorrhage	2	2			2	2
Eye inflammation	1	2		1	1	1
Eye irritation	13	27	13	27		
Eyelid irritation	1	1	1	1		
Eyelid oedema	21	29	16	22	5	7
Eyelid pain	1	2		1	1	1
Eyelid ptosis	1	6	1	6		
Eyelid rash		1		1		
Eyelid sensory disorder	1	2	1	2		
Eyelids pruritus		1		1		
Eye movement disorder		1				1
Eye oedema	2	2	1	1	1	1
Eye pain	47	68	43	63	4	5
Eye paraesthesia	1	1	1	1		
Eye pruritus	3	7	3	7		
Eye swelling	1	4	1	3		1
Foreign body sensation in eyes		1		1		
Lacrimation increased	8	21	8	21		
Metamorphopsia	1	2	1	2		

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular discomfort	2	4	2	4		
Ocular hyperaemia	3	14	2	12	1	2
Periorbital oedema	1	2	1	2		
Photophobia	18	23	16	21	2	2
Photopsia	12	18	10	14	2	4
Pupillary disorder	1	1	1	1		
Swelling of eyelid	1	1	1	1		
Vision blurred	49	80	40	66	9	14
Visual acuity reduced	2	2			2	2
Visual field defect	1	1	1	1		
Visual impairment	3	4	1	2	2	2
Xerophthalmia		1				1
	210	363	176	307	34	56

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	6	2	5		1
Abdominal distension	4	6	4	6		
Abdominal pain	270	444	245	396	25	48
Abdominal pain lower	1	2	1	2		
Abdominal pain upper	6	15	6	14		1
Abdominal symptom		1		1		
Abnormal faeces	4	9	4	7		2
Anaesthesia oral	1	1	1	1		
Aphthous ulcer		2		2		
Bowel movement irregularity	1	2	1	2		
Cheilitis	4	5	3	4	1	1
Colitis	2	4	2	4		
Constipation	2	2	1	1	1	1
Diarrhoea	356	586	313	505	43	81
Diarrhoea haemorrhagic		1				1
Diverticulum intestinal		1				1
Dry mouth	29	51	27	42	2	9
Dyspepsia		2		2		
Dysphagia	14	31	6	19	8	12
Epigastric discomfort		1		1		
Eructation	2	2	2	2		
Faeces discoloured	1	2	1	2		
Faeces soft	1	1	1	1		
Flatulence	2	2	2	2		
Frequent bowel movements	1	2	1	2		
Gastritis		4		4		
Gastrointestinal disorder	3	4	3	3		1
Gastrointestinal haemorrhage		1				1
Gastrointestinal hypermotility	1	2	1	2		
Gastrointestinal hypomotility		1		1		
Gastrointestinal motility disorder		3		3		
Gastrointestinal pain	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastroesophageal reflux disease	1	2	1	2		
Gingival bleeding	1	2		1	1	1
Gingival hypertrophy	1	1	1	1		
Gingival pain		1		1		
Gingival swelling		1		1		
Glossitis	2	2			2	2
Glossodynia	1	2	1	2		
Haematochezia	1	20			1	20
Hypoaesthesia oral	26	41	23	35	3	6
Intussusception		13				13
Lip discolouration		1		1		
Lip disorder		2		2		
Lip oedema	12	19	8	15	4	4
Lip pain	1	2	1	2		
Lip pruritus	1	1	1	1		
Melaena		1				1
Mouth haemorrhage		1				1
Mouth swelling		1				1
Mucous stools		1		1		
Nausea	1,112	1,678	994	1472	118	206
Noninfective gingivitis		1		1		
Odynophagia	100	162	93	144	7	18
Oedema mouth	1	1	1	1		
Oral discomfort	3	4	1	1	2	3
Oral disorder		2		1		1
Oral dysaesthesia		1		1		
Oral mucosal eruption	1	1	1	1		
Oral pruritus	4	4	3	3	1	1
Paraesthesia oral	41	73	30	52	11	21
Parotid gland enlargement		1		1		
Reflux gastritis	2	2	2	2		
Retching	1	1	1	1		

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Salivary hypersecretion	11	13	11	12		1
Stomatitis		1		1		
Swollen tongue	1	3	1	3		
Tongue oedema	1	4	1	3		1
Tongue pruritus	2	2	2	2		
Toothache		2		2		
Vomiting	310	543	256	437	54	106
	2,345	3,810	2061	3243	284	567

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Application site hypoaesthesia	1	1	1	1		
Application site induration	1	1	1	1		
Application site oedema	1	1	1	1		
Application site pain	9	9	9	9		
Asthenia	1,539	2,376	1402	2136	137	240
Atrophy		1		1		
Axillary pain	10	17	9	16	1	1
Chest discomfort	41	62	38	54	3	8
Chest pain	95	189	79	154	16	35
Chills	1,061	1,616	993	1471	68	145
Condition aggravated	1	6		2	1	4
Crying	39	71	37	66	2	5
Death	1	4			1	4
Decreased activity	2	3	1	2	1	1
Discharge		1		1		
Discomfort	111	158	105	147	6	11
Disease recurrence		5		3		2
Drug ineffective	9	39			9	39
Face oedema	6	13	5	12	1	1
Facial discomfort	1	1	1	1		
Facial pain	2	2	2	2		
Fatigue	1,076	1,721	968	1538	108	183
Feeling abnormal	3	10	3	8		2
Feeling cold	11	18	10	16	1	2
Feeling drunk		1		1		
Feeling hot	32	49	30	42	2	7
Feeling of body temperature change	1	2	1	2		
Fibrosis		1		1		
Gait disturbance	13	19	6	12	7	7
Gait inability	1	1	1	1		
Generalised oedema	4	5	3	4	1	1
General physical health deterioration	6	18	4	16	2	2

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
General symptom		1
Granuloma	2	2
Hunger		2
Hyperpyrexia		1
Hyperthermia	34	50
Hypothermia	2	19
Illness	1	1
Induration	292	458
Inflammation	284	434
Influenza like illness	2	5
Injection site erythema	1	1
Injection site haematoma	1	1
Injection site haemorrhage		1
Injection site hypoaesthesia	2	2
Injection site inflammation	1	1
Injection site pain	10	11
Injection site pruritus	1	1
Injection site reaction	2	2
Irritability postvaccinal	1	4
Localised oedema	4	7
Local reaction	165	220
Malaise	184	289
Mass		1
Mucosal dryness		2
Nodule	295	479
Obstruction	1	1
Oedema	373	595
Oedema peripheral	12	29
Oral administration complication		1
Pain	1,687	2,423
Peripheral swelling	4	8
Pyrexia	879	1,420

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
2	2		
	2		
			1
32	47	2	3
		2	19
1	1		
282	435	10	23
259	394	25	40
2	5		
1	1		
1	1		
	1		
2	2		
1	1		
10	11		
1	1		
2	2		
1	4		
4	7		
162	214	3	6
161	253	23	36
	1		
	2		
283	450	12	29
1	1		
330	515	43	80
9	25	3	4
	1		
1595	2240	92	183
4	6		2
805	1286	74	134

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* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Screaming		1
Secretion discharge		1
Sensation of foreign body	25	43
Sudden infant death syndrome		1
Swelling	8	18
Swelling face	2	5
Temperature intolerance	1	3
Temperature regulation disorder	2	3
Tenderness	2	6
Therapeutic response unexpected	4	4
Thirst	2	6
Vaccination failure	1	1
Vaccination site bruising	1	1
Vaccination site dermatitis	1	1
Vaccination site discolouration	1	1
Vaccination site discomfort	4	11
Vaccination site erythema	35	60
Vaccination site haematoma	1	3
Vaccination site haemorrhage	3	5
Vaccination site hyperaesthesia	3	8
Vaccination site hypersensitivity	13	50
Vaccination site hypoaesthesia	7	10
Vaccination site induration	30	65
Vaccination site inflammation	20	40
Vaccination site joint movement impairment	4	5
Vaccination site joint pain		1
Vaccination site movement impairment	11	18
Vaccination site nodule	17	34
Vaccination site oedema	43	61
Vaccination site pain	729	1,075
Vaccination site papule	2	2
Vaccination site paraesthesia	14	18

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	1		
19	25	6	18
			1
7	15	1	3
2	4		1
1	3		
2	3		
1	5	1	1
4	4		
2	5		1
		1	1
1	1		
		1	1
1	1		
4	11		
32	55	3	5
1	3		
2	3	1	2
3	8		
11	48	2	2
7	10		
28	58	2	7
19	37	1	3
4	5		
	1		
11	18		
17	32		2
40	55	3	6
689	1018	40	57
1	1	1	1
14	18		

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* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pruritus	24	31	20	26	4	5
Vaccination site rash	5	8	3	5	2	3
Vaccination site reaction	13	34	12	32	1	2
Vaccination site swelling	14	20	14	20		
Vaccination site warmth	28	43	27	42	1	1
	9,387	14,590	8660	13206	727	1384

System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deficiency of bile secretion		1				1
Hepatic function abnormal		1		1		
Hepatic pain		1		1		
Hyperbilirubinaemia		1				1
Jaundice		2				2
Ocular icterus	1	1	1	1		
	1	7	1	3		4

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		7		6		1
Anaphylactic reaction		27				27
Anaphylactic shock	3	48			3	48
Anaphylactoid reaction		1				1
Drug hypersensitivity		3				3
Hypersensitivity	15	56	10	42	5	14
Sensitisation		2		2		
Type I hypersensitivity		1				1
	18	145	10	50	8	95

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abscess	7	15	6	13	1	2
Asymptomatic COVID-19		1				1
Atypical pneumonia		1				1
Bronchitis	1	1	1	1		
Cellulitis	10	54			10	54
Conjunctivitis	12	24	12	24		
COVID-19	37	100	23	56	14	44
COVID-19 pneumonia	1	7			1	7
Cystitis		1		1		
Disseminated Bacillus Calmette-Guerin infection	1	13			1	13
Ear infection		3		3		
Encephalitis	1	1			1	1
Enterococcal infection	1	1			1	1
Furuncle	1	1	1	1		
Gastroenteritis		2		1		1
Herpes virus infection	1	1	1	1		
Herpes zoster	4	6	4	6		
Infection	1	1	1	1		
Influenza	5	10	4	9	1	1
Lymphangitis		1				1
Measles		1				1
Meningitis		2				2
Mumps	1	1	1	1		
Myelitis		1				1
Nasal abscess		1				1
Nasopharyngitis	4	11	2	7	2	4
Oral candidiasis	1	3		2	1	1
Oral herpes		1		1		
Otitis externa		1		1		
Otitis media	1	2	1	2		
Otitis media acute		1		1		
Parotitis	1	3	1	3		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngitis	1	2	1	1		1
Pharyngotonsillitis	1	1			1	1
Pneumonia	8	31			8	31
Pneumonia bacterial	1	1			1	1
Pustule	1	1	1	1		
Pyelonephritis		1				1
Respiratory tract infection viral		1		1		
Rhinitis	5	8	5	8		
Sepsis		1				1
Septic shock		1				1
Sinusitis	1	1	1	1		
Sputum purulent		1				1
Suspected COVID-19	10	16	7	10	3	6
Sweating fever		1				1
Tonsillitis bacterial	1	1			1	1
Urinary tract infection	1	3	1	3		
Vaccination site abscess		3		3		
Vaccination site cellulitis	2	26	2	16		10
Varicella	1	1	1	1		
Vestibular neuronitis		1				1
	124	374	77	180	47	194

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose	1	1			1	1
Burn oral cavity		1				1
Circumstance or information capable of leading to medication error	1	1	1	1		
Contusion	1	4	1	4		
Counterfeit product administered	1	5	1	5		
Expired product administered	2	4	2	4		
Exposure during pregnancy	2	5	2	5		
Exposure to SARS-CoV-2		1		1		
Exposure via breast milk		1		1		
Eye injury	21	40	18	32	3	8
Fall	2	8	1	4	1	4
Foreign body in throat		1				1
Hip fracture		1				1
Inappropriate schedule of product administration	2	13	2	13		
Incorrect dose administered	1	1	1	1		
Incorrect route of product administration	8	9	8	9		
Joint injury	1	2		1	1	1
Maternal exposure during pregnancy	1	15	1	15		
Off label use	15	27	15	27		
Overdose	2	3	2	3		
Palate injury		1		1		
Peroneal nerve injury		1				1
Poor quality product administered	2	4	2	4		
Product administered at inappropriate site	1	1	1	1		
Product use issue	14	22	14	22		
Scratch	1	1	1	1		
Skeletal injury		1		1		
Skin injury		1		1		
Thermal burn		1				1
Thermal burns of eye		2				2
Toxicity to various agents		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Traumatic lung injury		2		2		
Vaccination complication	2	4	2	3		1
Vaccination error	2	2	1	1	1	1
Vascular injury	1	1	1	1		
Wrong product administered	1	3	1	3		
Wrong technique in device usage process	1	1	1	1		
Wrong technique in product usage process	3	9	2	8	1	1
	89	201	81	176	8	25

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* AE=Adverse Event
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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased		1		1		
Antibody test abnormal		2		2		
Antibody test negative		3		3		
Aspartate aminotransferase increased		1				1
Blood glucose abnormal	2	2	1	1	1	1
Blood glucose decreased		1				1
Blood glucose increased	4	7	2	5	2	2
Blood pressure abnormal	25	28	15	18	10	10
Blood pressure ambulatory abnormal	1	1			1	1
Blood pressure ambulatory increased	1	1	1	1		
Blood pressure decreased	3	5	3	3		2
Blood pressure diastolic increased	2	3	1	2	1	1
Blood pressure increased	134	184	84	114	50	70
Blood pressure systolic increased	6	6	3	3	3	3
Body temperature abnormal	1	1			1	1
Body temperature decreased		1		1		
Body temperature fluctuation		1				1
Body temperature increased	259	422	236	381	23	41
Chest X-ray abnormal	1	1	1	1		
Coagulation time prolonged		1				1
C-reactive protein abnormal	1	1	1	1		
C-reactive protein increased		1		1		
Faecal volume decreased	1	1	1	1		
General physical condition abnormal	1	2	1	1		1
Heart rate abnormal	2	4	2	4		
Heart rate decreased		1		1		
Heart rate increased	10	24	4	17	6	7
Heart rate irregular		1				1
Immunology test abnormal		1		1		
Inspiratory capacity abnormal	1	1	1	1		
Mean cell haemoglobin concentration decreased		1		1		
Mean cell haemoglobin decreased		1		1		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mean cell volume decreased		1		1		
Mean platelet volume decreased		1		1		
Monocyte count increased		1		1		
Muscle strength abnormal	3	4	2	3	1	1
Neutrophil count increased		2		2		
Oxygen saturation abnormal	1	10	1	6		4
Oxygen saturation decreased	32	73	12	37	20	36
Platelet count decreased		1				1
Platelet count increased		3		3		
Pulse absent	1	1			1	1
Respiratory rate increased	2	3	2	3		
SARS-CoV-2 ant body test negative	1	3	1	3		
SARS-CoV-2 test positive	3	7	3	5		2
Transaminases increased		2				2
Vascular test abnormal		1		1		
Vestibular function test abnormal	1	1			1	1
White blood cell count increased		1				1
	499	826	378	632	121	194

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	118	211	112	195	6	16
Dehydration	3	8	3	6		2
Diabetes mellitus		1				1
Diabetic ketoacidosis		1				1
Dyslipidaemia		1		1		
Eating disorder symptom	2	2	2	2		
Electrolyte imbalance		1				1
Feeding intolerance	1	1	1	1		
Hyperglycaemia	1	5	1	3		2
Hypernatraemia		1				1
Hypoglycaemia	6	7	2	2	4	5
Increased appetite	1	1	1	1		
Polydipsia	1	1			1	1
	133	241	122	211	11	30

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1,138	1,753	1057	1603	81	150
Arthritis	2	3	1	2	1	1
Arthropathy	1	1	1	1		
Axillary mass		1		1		
Back pain	55	89	47	78	8	11
Bone disorder	1	1	1	1		
Bone pain	3	5	2	3	1	2
Flank pain		1		1		
Groin pain		1		1		
Jaw disorder	1	1	1	1		
Joint range of motion decreased	1	2	1	2		
Joint stiffness		1		1		
Joint swelling		1		1		
Limb discomfort	10	14	10	13		1
Mastication disorder	1	1			1	1
Masticatory pain		1		1		
Mobility decreased	24	40	23	39	1	1
Muscle atrophy		1		1		
Muscle contracture	1	3	1	3		
Muscle fatigue	1	4	1	4		
Muscle rigidity	2	3	1	2	1	1
Muscle spasms	11	22	11	21		1
Muscle tightness	1	3	1	3		
Muscular weakness	30	56	20	35	10	21
Musculoskeletal chest pain	3	4	3	4		
Musculoskeletal discomfort	2	2	2	2		
Musculoskeletal pain	2	2	2	2		
Musculoskeletal stiffness	2	4	1	3	1	1
Myalgia	1,362	2,081	1268	1907	94	174
Myalgia intercostal		1		1		
Myopathy		1		1		
Neck pain	21	45	21	45		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Osteoarthritis	5	5	5	5		
Pain in extremity	142	225	136	214	6	11
Pain in jaw	1	3		1	1	2
Sacroiliitis		1				1
Soft tissue swelling	1	1	1	1		
Spinal pain	3	3	3	3		
Synovial cyst	1	3	1	3		
Systemic lupus erythematosus		1				1
Trismus	1	1	1	1		
	2,829	4,391	2623	4011	206	380

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Diffuse large B-cell lymphoma		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Advanced sleep phase	1	1	1	1		
Ageusia	4	11	2	8	2	3
Akathisia		1		1		
Allodynia	1	3	1	3		
Altered state of consciousness	1	1			1	1
Amnesia	2	3	2	2		1
Anaesthesia	1	1			1	1
Anosmia	36	63	36	60		3
Aphasia		2		2		
Areflexia	1	1			1	1
Asterixis		1				1
Ataxia		1		1		
Aura		1				1
Axonal neuropathy		1				1
Balance disorder	3	8	2	5	1	3
Bell's palsy	1	8			1	8
Bradykinesia	1	1			1	1
Brain oedema		1				1
Brain stem ischaemia		2				2
Burning sensation	9	16	9	12		4
Cerebral haematoma		1				1
Cerebral infarction		1				1
Cerebral ischaemia		1				1
Cerebral small vessel ischaemic disease	1	1			1	1
Cerebrovascular accident		3				3
Chorea	1	1			1	1
Clonic convulsion		1				1
Cogwheel rigidity	1	1	1	1		
Coordination abnormal	1	1	1	1		
Demyelinating polyneuropathy		1				1
Demyelination		3				3
Depressed level of consciousness	3	10			3	10

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diplegia		1				1
Disturbance in attention		2		2		
Dizziness	1,233	1,945	1105	1687	128	258
Dizziness postural	1	2	1	2		
Dysaesthesia	8	13	8	12		1
Dysarthria	5	8	2	5	3	3
Dysgeusia	35	64	35	60		4
Dyskinesia	2	3	2	3		
Dyslalia	2	3	1	1	1	2
Dysstasia	3	5	3	4		1
Dystonia		2				2
Electric shock sensation	1	2	1	1		1
Encephalitis post immunisation		1				1
Epilepsy		2				2
Extensor plantar response	1	1			1	1
Facial nerve disorder		2		2		
Facial paralysis	4	26			4	26
Facial paresis		3		3		
Facial spasm		1		1		
Febrile convulsion	14	45	9	31	5	14
Generalised tonic-clonic seizure	1	9			1	9
Glabellar reflex abnormal		1		1		
Guillain-Barre syndrome	7	16			7	16
Headache	2,789	3,982	2561	3594	228	388
Head discomfort	4	6	3	5	1	1
Hemiparaesthesia	3	11			3	11
Hemiparesis	3	14			3	14
Hemiplegia		2				2
Hyperaesthesia	3	10	3	10		
Hyperreflexia		1		1		
Hypersomnia	1	3	1	3		
Hypoaesthesia	66	106	55	83	11	23

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypokinesia	15	24	12	20	3	4
Hyposmia	1	3	1	3		
Hypotonia	2	5	1	4	1	1
Intracranial aneurysm		1				1
Ischaemic stroke	1	2			1	2
Lacunar stroke	1	1			1	1
Lateropulsion		1				1
Lethargy	5	8	4	5	1	3
Loss of consciousness	5	24			5	24
Memory impairment	1	1	1	1		
Migraine	5	6	5	6		
Mononeuropathy		2				2
Monoparesis	3	6	3	4		2
Monoplegia		1				1
Motor dysfunction	1	2	1	2		
Movement disorder	8	15	6	10	2	5
Muscle contractions involuntary	2	7	2	5		2
Muscle spasticity	1	2			1	2
Myelitis transverse		1				1
Myoclonic epilepsy		1				1
Myoclonus	2	3	2	3		
Narcolepsy		1				1
Nerve degeneration		1				1
Nervous system disorder		2				2
Neuralgia	1	2	1	2		
Neuritis		5		2		3
Neuropathy peripheral	2	4			2	4
Nystagmus	3	4	2	3	1	1
Optic neuritis	1	1			1	1
Paraesthesia	185	317	161	261	24	56
Paraesthesia mucosal		1				1
Paralysis	9	35			9	35

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraparesis		2				2
Paresis	4	6	4	6		
Parosmia		1		1		
Partial seizures	1	1			1	1
Patient elopement	2	3	2	3		
Peripheral motor neuropathy		1				1
Petit mal epilepsy		1				1
Presyncope	2	6	2	4		2
Radiculitis brachial		1				1
Radiculopathy		2				2
Reflexes abnormal		1		1		
Ruptured cerebral aneurysm		1				1
Sciatica		1				1
Sciatic nerve neuropathy		1				1
Seizure	14	83			14	83
Sensory disturbance	3	4	3	4		
Sensory loss	1	4		2	1	2
Sleep deficit	1	1	1	1		
Slow response to stimuli		2		2		
Slow speech	1	2		1	1	1
Somnolence	33	56	32	53	1	3
Speech disorder	2	4	1	3	1	1
Subarachnoid haemorrhage		2				2
Syncope	9	89			9	89
Taste disorder	1	2	1	2		
Tension headache	2	3	1	2	1	1
Tongue paralysis	2	3			2	3
Tremor	22	46	20	42	2	4
Vascular headache	1	1	1	1		
	4,609	7,263	4115	6067	494	1196

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product colour issue		1		1
Product complaint		1		1
Product supply issue		1		1
Suspected counterfeit product	2	6	2	6
	2	9	2	9

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Affect lability		1		1		
Aggression		2		2		
Agitation	7	8	5	6	2	2
Anxiety	45	88	37	67	8	21
Bruxism	1	1			1	1
Confusional state	2	6	2	5		1
Conversion disorder		2		2		
Delirium		1				1
Depression	1	1	1	1		
Disorientation	4	12	4	10		2
Eating disorder		1		1		
Emotional disorder	1	1	1	1		
Fear	1	1	1	1		
Feeling of despair	3	6	3	6		
Hallucination	1	1			1	1
Hallucination, visual		3				3
Initial insomnia	1	1	1	1		
Insomnia	11	16	10	14	1	2
Irritability	121	233	108	199	13	34
Laziness		1		1		
Listless	1	1	1	1		
Mood altered	1	1			1	1
Mutism	1	1			1	1
Near death experience		1				1
Nervousness	5	11	5	10		1
Panic attack	1	2	1	2		
Persistent depressive disorder		1		1		
Phonophobia	1	1	1	1		
Restlessness		1		1		
Sleep disorder	1	2			1	2
Sleep inertia		1				1
Stress		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tic	1	1	1	1		
	211	411	182	336	29	75

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Choluria	1	3	1	1		2
Chromaturia	1	1	1	1		
End stage renal disease		1				1
Pollakiuria	1	1	1	1		
Urinary incontinence	1	3	1	3		
Urinary retention	1	1			1	1
	5	10	4	6	1	4

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast pain	4	5	3	4	1	1
Dysmenorrhoea	1	2	1	2		
Genital paraesthesia		1		1		
Genital tract inflammation		1		1		
Intermenstrual bleeding		1		1		
Menstrual disorder		1		1		
Menstruation irregular	1	1	1	1		
Pelvic discomfort		1				1
Pelvic pain	1	3	1	3		
Vaginal haemorrhage	3	4		1	3	3
	10	20	6	15	4	5

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphonia	5	7	5	7		
Apnoeic attack	1	1			1	1
Asphyxia	1	1			1	1
Asthma	3	5	3	5		
Asthmatic crisis	1	3			1	3
Bronchial disorder		2		2		
Bronchospasm	37	110	26	64	11	46
Catarrh		1		1		
Choking		1				1
Choking sensation		1				1
Cough	461	777	414	681	47	96
Dry throat	5	7	5	6		1
Dysphonia	13	21	8	14	5	7
Dyspnoea	116	733	80	546	36	187
Dyspnoea at rest		1				1
Dyspnoea exertional	3	9	1	7	2	2
Epiglottic oedema		2				2
Epistaxis	6	16	6	13		3
Haemoptysis		1		1		
Hyperoxia	1	1	1	1		
Hypopnoea	1	1	1	1		
Hypoventilation		2				2
Hypoxia	8	9			8	9
Laryngeal discomfort	1	1	1	1		
Laryngeal inflammation		1				1
Laryngeal obstruction		1				1
Laryngeal oedema		7				7
Laryngospasm	1	5	1	3		2
Larynx irritation		1				1
Lung disorder		1		1		
Nasal congestion	22	39	22	39		
Nasal discomfort	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nasal dryness	2	2	2	2		
Nasal obstruction	1	3		2	1	1
Nasal oedema	1	1	1	1		
Nasal pruritus	1	3	1	3		
Nasal turbinate hypertrophy	1	1	1	1		
Obstructive airways disorder	2	3			2	3
Oropharyngeal discomfort	7	17	7	12		5
Oropharyngeal pain	520	860	482	786	38	74
Painful respiration		2		2		
Pharyngeal disorder	2	5	2	5		
Pharyngeal erythema	3	4	3	4		
Pharyngeal hypoaesthesia	1	2			1	2
Pharyngeal inflammation	1	3	1	1		2
Pharyngeal oedema	1	6	1	1		5
Pharyngeal paraesthesia	5	10	5	7		3
Pharyngeal swelling	4	4			4	4
Pharyngeal ulceration		1		1		
Pleural effusion		1		1		
Pneumonitis		1		1		
Productive cough	10	13	7	9	3	4
Pulmonary embolism	1	1			1	1
Pulmonary oedema		1				1
Pulmonary pain	1	2	1	2		
Rales	2	3	1	2	1	1
Respiration abnormal	1	1	1	1		
Respiratory acidosis	1	1			1	1
Respiratory arrest		2				2
Respiratory disorder	1	4	1	3		1
Respiratory distress	92	697			92	697
Respiratory failure		3				3
Rhinalgia		1		1		
Rhinorrhoea	496	772	465	721	31	51

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sneezing	9	11	7	9	2	2
Sputum discoloured		1		1		
Stridor	2	4	1	1	1	3
Suffocation feeling	4	7	4	6		1
Tachypnoea	7	20	4	9	3	11
Throat irritation	21	35	20	32	1	3
Throat tightness	2	5		2	2	3
Tonsillar hypertrophy	1	1			1	1
Upper-airway cough syndrome		1		1		
Upper airway obstruction		1				1
Wheezing	3	9	2	4	1	5
	1,893	4,294	1595	3028	298	1266

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne	1	3	1	3		
Angioedema	1	11			1	11
Blister	5	9	5	7		2
Circumoral oedema	2	2	1	1	1	1
Cold sweat	1	2	1	2		
Dermatitis	1	1	1	1		
Dermatitis allergic	1	3	1	3		
Dermatitis exfoliative generalised	1	1			1	1
Dermatosis	2	4	1	3	1	1
Dry skin	1	1	1	1		
Ecchymosis	1	4	1	3		1
Erythema	294	486	267	432	27	54
Erythema multiforme		1				1
Hyperhidrosis	76	123	66	98	10	25
Livedo reticularis	2	5		3	2	2
Macule	3	3	3	3		
Mechanical urticaria	3	4	1	2	2	2
Nail discolouration		1		1		
Night sweats		2		1		1
Pain of skin	3	7	3	7		
Palmar erythema	1	2	1	2		
Papule		2		2		
Petechiae	4	9	4	6		3
Photosensitivity reaction	3	4	3	4		
Pigmentation disorder		1		1		
Piloerection	1	1	1	1		
Prurigo	1	3	1	3		
Pruritus	369	555	310	459	59	96
Purpura	11	14	9	11	2	3
Rash	246	419	193	324	53	95
Rash erythematous	2	4	2	3		1
Rash macular	1	5	1	4		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash maculo-papular	2	7	1	5	1	2
Rash papular	2	2	2	2		
Rash pruritic	5	5	5	5		
Scab	1	2	1	1		1
Sensitive skin	1,702	2,277	1613	2118	89	159
Skin burning sensation		2		2		
Skin discolouration	2	4	2	4		
Skin disorder		1		1		
Skin exfoliation		1		1		
Skin haemorrhage		1		1		
Skin lesion	1	4	1	4		
Skin mass	1	2	1	2		
Skin plaque	2	2	1	1	1	1
Skin reaction		1				1
Skin sensitisation	38	40	38	40		
Skin swelling		1		1		
Stasis dermatitis		1		1		
Stevens-Johnson syndrome		5				5
Toxic epidermal necrolysis		1				1
Urticaria	13	27	9	21	4	6
	2,806	4,078	2552	3601	254	477

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden	1	1			1	1
Fasting		1		1		
Impaired quality of life	1	1	1	1		
Impaired work ability	1	1	1	1		
Loss of personal independence in daily activities	4	6	3	4	1	2
	7	10	5	7	2	3

System Organ Class

Surgical and medical procedures

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Analgesic therapy	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure fluctuation	6	6	6	6		
Cyanosis	5	10	2	6	3	4
Deep vein thrombosis	1	1			1	1
Embolism		2				2
Flushing	19	29	19	27		2
Haematoma		2		2		
Haemorrhage	1	27			1	27
Hot flush	5	9	5	9		
Hyperaemia	9	15	9	14		1
Hypertension	234	338	144	204	90	134
Hypertensive crisis	12	81			12	81
Hypertensive emergency	1	3			1	3
Hypertensive urgency	1	1			1	1
Hypotension	37	63	19	33	18	30
Hypovolaemic shock		31				31
Infarction	1	1			1	1
Lymphoedema	1	1	1	1		
Pallor	5	14	3	10	2	4
Peripheral coldness	3	11	3	10		1
Peripheral vascular disorder		1				1
Prehypertension	2	2	2	2		
Raynaud's phenomenon		2		2		
Secondary hypertension	2	2	2	2		
Shock	1	5			1	5
Thrombophlebitis superficial	1	1			1	1
Thrombosis	4	7			4	7
Varicophlebitis	1	1	1	1		
Varicose vein	1	1			1	1
Vasculitis	1	1	1	1		
Vasodilatation	1	2		1	1	1
Vasospasm	1	1	1	1		
White coat hypertension	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	357	672	219	333	138	339

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

MONACO

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Drug ineffective		1		1
		1		1

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19		1		1
		1		1

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Speech disorder		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

NETHERLANDS

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia	1	2	1	2		
Blood loss anaemia		1				1
Coagulopathy	1	2		1	1	1
Coombs negative haemolytic anaemia		1				1
Immune thrombocytopenia		1				1
Increased tendency to bruise		1		1		
Leukocytosis	1	1	1	1		
Leukopenia	1	2			1	2
Lymphadenitis	1	2	1	2		
Lymphadenopathy	34	162	34	161		1
Lymph node pain	2	8	2	8		
Normocytic anaemia	1	1	1	1		
Pancytopenia		1				1
Splenic infarction		1				1
Thrombocytopenia	16	20	2	2	14	18
	58	206	42	179	16	27

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute cardiac event		1						1
Acute coronary syndrome	2	3					2	3
Acute myocardial infarction	4	12					4	12
Angina pectoris	2	10					2	10
Angina unstable		1						1
Aortic valve stenosis		4						4
Arrhythmia	20	39	1	1			20	39
Atrial fibrillation	14	40		1	1	1	13	39
Atrial flutter		2				1		1
Atrioventricular block complete		1						1
Bradycardia	1	5					1	5
Bundle branch block right	2	3				1	2	2
Cardiac arrest	5	23					5	23
Cardiac asthma		7						7
Cardiac discomfort		1				1		
Cardiac disorder	1	7				1	1	6
Cardiac failure	10	40					10	40
Cardiac failure acute	1	5					1	5
Cardiac failure congestive		1						1
Cardiac fibrillation	2	2					2	2
Cardiac flutter	1	1					1	1
Cardiac tamponade	1	1					1	1
Cardiac ventricular thrombosis		1						1
Cardiogenic shock		3						3
Cardiopulmonary failure		1						1
Cardiovascular disorder		2						2
Coronary artery disease	1	2					1	2
Coronary artery stenosis		1						1
Dilatation atrial		1						1
Extrasystoles	2	3			2	3		
Left ventricular dysfunction		1						1
Left ventricular failure		1						1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Left ventricular hypertrophy		2				1		1
Myocardial calcification	1	1			1	1		
Myocardial infarction	15	35					15	35
Palpitations	12	61			8	49	4	12
Pericarditis		3						3
Right ventricular failure		2						2
Sinus bradycardia		1						1
Sinus tachycardia		4				3		1
Stress cardiomyopathy	1	1					1	1
Supraventricular tachycardia	1	3			1	2		1
Tachycardia	4	21			3	16	1	5
Torsade de pointes	1	1					1	1
Ventricular extrasystoles	1	1					1	1
Ventricular f brillation	1	4					1	4
Ventricular tachycardia	3	3					3	3
	109	368	1	2	16	80	93	288

System Organ Class

Congenital, familial and genetic disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Haemophilia		1		1
Macroglossia	1	1	1	1
	1	2	1	2

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* AE=Adverse Event
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System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Auricular swelling		1				1		
Deafness	3	4					3	4
Deafness neurosensory		1						1
Deafness transitory		1						1
Deafness unilateral	1	4					1	4
Ear discomfort		3				3		
Ear pain	5	9			5	9		
Hyperacusis		1				1		
Hypoacusis		1				1		
Meniere's disease		5						5
Paraesthesia ear		1				1		
Sudden hearing loss	1	7					1	7
Tinnitus	2	12	1	2	1	10	1	2
Vertigo	6	23			5	20	1	3
Vertigo positional		1				1		
	18	74	1	2	11	47	7	27

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Adrenal disorder		1		1
Hyperthyroidism	2	2	2	2
Hypothyroidism	1	1	1	1
Pituitary apoplexy		1		1
Secondary adrenocortical insufficiency		1		1
Thyroid mass	1	1	1	1
	4	7	4	7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accommodation disorder		2				2		
Amaurosis fugax		1						1
Blepharospasm	1	1			1	1		
Blindness	1	8		1			1	8
Blindness transient	1	1					1	1
Blindness unilateral	1	4					1	4
Conjunctival haemorrhage	2	4	1	1			2	4
Conjunctival oedema		1						1
Dark circles under eyes		1				1		
Diplopia	1	12				9	1	3
Dry eye	1	5			1	5		
Endocrine ophthalmopathy		1						1
Episcleritis		1				1		
Eye disorder	1	3				2	1	1
Eye haematoma		1						1
Eye haemorrhage	1	3					1	3
Eye inflammation	2	2			1	1	1	1
Eye irritation	5	6			5	6		
Eyelid ptosis		2				2		
Eye movement disorder		1				1		
Eye pain	1	6			1	5		1
Eye pruritus	1	5			1	5		
Eye swelling	2	8			2	7		1
Eye symptom		1				1		
Gaze palsy		1						1
Halo vision		1				1		
Iridocyclitis	1	2					1	2
Lacrimation increased		3				3		
Macular degeneration		1						1
Night blindness		1				1		
Ocular discomfort	1	2			1	2		
Ocular hyperaemia	1	6			1	4		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ocular myasthenia		1						1
Ocular vascular disorder	1	1					1	1
Optic nerve infarction		1						1
Oscillopsia		1				1		
Papilloedema	1	1					1	1
Periorbital discomfort	1	1			1	1		
Periorbital oedema		1				1		
Periorbital swelling		2				2		
Photophobia	1	3			1	3		
Pupillary disorder		1				1		
Pupillary reflex impaired	1	1					1	1
Retinal artery embolism	1	1					1	1
Retinal artery occlusion	2	4					2	4
Retinal detachment		1						1
Retinal vein occlusion	2	3					2	3
Swelling of eyelid	2	9			2	8		1
Vision blurred	2	18			2	18		
Visual acuity reduced		1				1		
Visual field defect	2	2					2	2
Visual impairment	4	18			2	8	2	10
	44	168	1	2	22	104	22	64

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	6	20	5	17	1	3
Abdominal distension		2		2		
Abdominal pain	8	23	8	21		2
Abdominal pain lower		1		1		
Abdominal pain upper	7	22	5	20	2	2
Abnormal faeces		1				1
Acute abdomen		1				1
Anal haemorrhage	1	1			1	1
Anal sphincter hypertonia		1		1		
Aphthous ulcer		2		2		
Colitis ulcerative	1	1			1	1
Constipation	1	4	1	3		1
Crohn's disease		1				1
Defaecation urgency	2	2	2	2		
Diarrhoea	22	82	20	77	2	5
Diarrhoea haemorrhagic	1	1			1	1
Dry mouth	1	6		5	1	1
Dyspepsia	1	5	1	5		
Dysphagia	10	32	6	13	4	19
Enterocolitis		1				1
Eructation	1	2	1	2		
Faeces discoloured		2		2		
Faeces hard	1	1	1	1		
Frequent bowel movements		1		1		
Gastric haemorrhage		1				1
Gastrointestinal disorder	2	3	1	2	1	1
Gastrointestinal haemorrhage	2	8			2	8
Gastrointestinal obstruction		1				1
Gastrointestinal pain	2	2	2	2		
Gastrooesophageal reflux disease		1		1		
Gingival bleeding	1	1	1	1		
Gingival pain		1		1		

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* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Glossitis	1	1	1	1		
Glossodynia	3	5	2	4	1	1
Haematemesis		1				1
Haematochezia	1	2			1	2
Haemorrhoids		1		1		
Hiatus hernia	2	3	1	1	1	2
Hyperaesthesia teeth		1		1		
Hyperchlorhydria		1		1		
Hypoaesthesia oral	2	6	2	5		1
Hypoaesthesia teeth	1	1			1	1
Ileus	1	1			1	1
Intestinal haemorrhage		2				2
Intestinal ischaemia	2	4			2	4
Intestinal obstruction		1				1
Irritable bowel syndrome	1	1	1	1		
Lip blister		1		1		
Lip oedema	1	1	1	1		
Lip swelling	5	10	1	4	4	6
Melaena		1				1
Mesenteric artery thrombosis		1				1
Mesenteric vein thrombosis	1	1			1	1
Mouth swelling		3		1		2
Nausea	172	884	165	839	7	45
Odynophagia		1		1		
Oral discomfort	1	2	1	2		
Oral disorder		1		1		
Oral mucosal blistering		3		2		1
Oral mucosal erythema		1				1
Oral pain		1		1		
Oral pruritus	1	2	1	1		1
Palatal disorder	1	1	1	1		
Paraesthesia oral	6	37	5	34	1	3

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rectal haemorrhage		3				3
Rectal prolapse		1				1
Regurgitation		1		1		
Retching		3		1		2
Salivary gland pain		1		1		
Salivary hypersecretion	1	2	1	1		1
Small intestinal obstruction		1				1
Stiff tongue		1		1		
Stomatitis	1	2	1	2		
Swollen tongue	8	20	1	7	7	13
Thrombosis mesenteric vessel		1				1
Tongue discolouration		1		1		
Tongue discomfort		2		2		
Tongue disorder	1	5		2	1	3
Tongue erythema	1	1	1	1		
Tongue oedema	1	2			1	2
Toothache	2	3	2	3		
Uvulitis		1		1		
Vomiting	22	92	17	66	5	26
	309	1,358	259	1176	50	182

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Asthenia	6	24
Axillary pain	8	29
Brain death		1
Cardiac death	2	6
Chest discomfort	8	31
Chest pain	11	57
Chills	224	1,179
Condition aggravated	7	22
Crying	1	2
Death	4	36
Discomfort	1	7
Disease recurrence	3	13
Drug ineffective	12	26
Drug interaction	1	1
Exercise tolerance decreased	2	2
Extensive swelling of vaccinated limb	5	291
Face oedema	1	2
Facial pain	1	5
Fatigue	371	1,689
Feeling abnormal	7	24
Feeling cold	2	11
Feeling drunk		2
Feeling hot	6	27
Feeling jittery		4
Feeling of body temperature change		1
Gait disturbance	3	16
Gait inability	2	6
General physical health deterioration	1	16
Hangover		1
Hernia	1	1
Hernia pain		1
Hunger		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	19		5
		8	29		
					1
				2	6
		5	22	3	9
		8	42	3	15
		215	1148	9	31
		3	8	4	14
		1	2		
				4	36
			5	1	2
			2	3	11
				12	26
				1	1
		2	2		
		5	290		1
				1	2
		1	4		1
		360	1625	11	64
		7	22		2
		2	10		1
			2		
		5	23	1	4
			4		
			1		
		1	11	2	5
		1	3	1	3
		1	5		11
			1		
		1	1		
			1		
			1		

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyperpyrexia	11	82
Hypothermia	2	6
Ill-defined disorder		1
Illness	1	2
Inflammation		5
Influenza like illness	3	11
Injected limb mobility decreased	2	10
Injection site discomfort		1
Injection site erythema	1	4
Injection site haematoma	1	1
Injection site induration		1
Injection site inflammation	2	8
Injection site pain	3	15
Injection site pruritus		4
Injection site swelling		7
Injection site warmth	1	8
Localised oedema	1	1
Loss of control of legs	2	3
Malaise	359	1,753
Mucosal dryness		1
Multiple organ dysfunction syndrome		2
Nodule		1
Oedema	1	6
Oedema peripheral	5	10
Organ failure	1	1
Pain	13	61
Peripheral swelling	6	19
Prolapse		1
Puncture site pain		1
Pyrexia	182	921
Sensation of blood flow	1	1
Sensation of foreign body	1	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				11	82
				2	6
					1
		1	1		1
			3		2
		2	9	1	2
		2	10		
			1		
		1	4		
		1	1		
			1		
		2	8		
		3	15		
			4		
			7		
		1	8		
				1	1
				2	3
		339	1632	20	121
			1		
					2
			1		
			3	1	3
		3	5	2	5
				1	1
		13	56		5
		6	16		3
			1		
			1		
1	1	165	833	17	88
		1	1		
		1	4		2

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* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sudden cardiac death	3	7
Sudden death	6	20
Swelling	3	18
Swelling face	3	21
Symptom recurrence		1
Thirst		2
Thirst decreased		1
Vaccination failure	8	10
Vaccination site bruising	6	43
Vaccination site coldness		1
Vaccination site discolouration	1	2
Vaccination site discomfort	6	18
Vaccination site erythema	90	503
Vaccination site haematoma	27	114
Vaccination site haemorrhage		1
Vaccination site induration	9	38
Vaccination site inflammation	156	547
Vaccination site irritation	1	1
Vaccination site lymphadenopathy	1	1
Vaccination site movement impairment		2
Vaccination site pain	302	1,312
Vaccination site pallor		1
Vaccination site papule		1
Vaccination site paraesthesia		2
Vaccination site pruritus	37	196
Vaccination site rash		3
Vaccination site reaction	1	8
Vaccination site swelling	112	613
Vaccination site urticaria		1
Vaccination site warmth	107	583
Vascular stent thrombosis		1
	2,168	10,560

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	7
				6	20
		3	18		
		2	14	1	7
					1
			2		
					1
				8	10
		6	43		
			1		
		1	2		
		6	18		
		90	502		1
		26	113	1	1
			1		
		9	38		
		156	547		
		1	1		
		1	1		
			2		
		300	1307	2	5
					1
			1		
			2		
		37	196		
			3		
		1	8		
		112	611		2
			1		
		107	583		
					1
1	1	2031	9924	137	636

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System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholecystitis		1				1
Cholelithiasis	1	1			1	1
Hepatic failure		2				2
Hepatic pain		1		1		
Hepatic steatosis	1	1			1	1
Hepatitis	1	2			1	2
Hepatitis acute		1				1
Hepatitis cholestatic		1				1
Jaundice		4		1		3
Portal vein thrombosis	1	1			1	1
	4	15		2	4	13

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Allergy to vaccine		2		1		1		1
Amyloidosis	1	1					1	1
Anamnestic reaction		1						1
Anaphylactic reaction	2	17					2	17
Anaphylactic shock	1	5					1	5
Decreased immune responsiveness		1						1
Drug hypersensitivity	1	2					1	2
Food allergy	1	2				1	1	1
Haemophagocytic lymphohistiocytosis		1						1
Hypersensitivity	14	38			7	21	7	17
Immune system disorder	1	2			1	1		1
	21	72		1	8	24	13	48

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abscess		1						1
Appendicitis		1						1
Asymptomatic COVID-19	1	1					1	1
Bacterial infection		1						1
Beta haemolytic streptococcal infection	1	1					1	1
Bronchitis		1						1
Candida infection		1						1
COVID-19	29	58			10	16	19	42
COVID-19 pneumonia		2						2
Cystitis	4	14			3	9	1	5
Dacryocystitis		1						1
Diverticulitis	2	2					2	2
Encephalitis enteroviral		1						1
Endocarditis		1						1
Erysipelas	5	9					5	9
Escherichia urinary tract infection		1						1
Eye infection	1	1					1	1
Gastroenteritis		1						1
Gastroenteritis viral		1				1		
Hepatitis C		1						1
Herpes ophthalmic		3						3
Herpes simplex		1				1		
Herpes virus infection		1				1		
Herpes zoster	68	76			68	73		3
Herpes zoster reactivation	3	4			2	2	1	2
Infection	1	5			1	1		4
Infection susceptibility increased		1						1
Influenza	1	1			1	1		
Joint abscess		1						1
Kidney infection		1						1
Laryngitis		1				1		
Localised infection		1						1

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Lyme disease	1	1					1	1
Lymphangitis	1	3					1	3
Mastitis	1	1					1	1
Meningitis		1						1
Nasopharyngitis	7	30			7	29		1
Oophoritis		1						1
Ophthalmic herpes zoster		1						1
Oral bacterial infection		1						1
Oral herpes	3	5			3	5		
Osteomyelitis	1	1					1	1
Pharyngitis	1	1			1	1		
Pneumonia	17	46	1	1			17	46
Pneumonia bacterial		1						1
Pulmonary sepsis	1	1					1	1
Pyelonephritis		1						1
Respiratory tract infection		2						2
Respiratory tract infection viral		1						1
Rhinitis		2				2		
Sepsis		2						2
Sialoadenitis		2						2
Soft tissue infection		1						1
Staphylococcal infection	1	1					1	1
Suspected COVID-19	1	3				1	1	2
Tinea versicolour	1	1			1	1		
Tonsillitis	2	2			2	2		
Urinary tract infection	2	10			2	5		5
Urosepsis	1	5					1	5
Vestibular neuritis		1						1
Viral infection		2						2
Wound infection		1						1
	157	327	1	1	101	152	56	175

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- * AE=Adverse Event
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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Chest injury		2						2
Chillblains		3				3		
Circumstance or information capable of leading to medication error		1				1		
Concussion		1						1
Contusion	4	9			3	6	1	3
Epidural haemorrhage	1	1					1	1
Exposure during pregnancy	1	3				2	1	1
Exposure to SARS-CoV-2	1	2			1	2		
Exposure via breast milk		2				2		
Eye contusion		1				1		
Facial bones fracture		1						1
Fall	7	35		1	3	14	4	21
Fracture		1						1
Hand fracture		1						1
Head injury		2						2
Hip fracture		2						2
Inappropriate schedule of product administration	7	15			7	15		
Incorrect dose administered	1	1			1	1		
Incorrect route of product administration		1				1		
Intentional product use issue		1				1		
Ligament sprain	1	1			1	1		
Limb injury		2				1		1
Maternal exposure during pregnancy		5				3		2
Muscle strain	2	9			2	8		1
Occupational exposure to product		1				1		
Off label use	5	13			5	13		
Pelvic fracture		1						1
Periorbital haematoma	1	1			1	1		
Poor quality product administered		1				1		
Post concussion syndrome		1				1		
Product administered at inappropriate site	1	1			1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Product label confusion		1				1		
Product preparation error		2				2		
Product preparation issue	1	2			1	2		
Product storage error		1				1		
Scrotal injury		1				1		
Skin abrasion	1	1			1	1		
Skull fracture	1	1					1	1
Spinal cord injury	1	1					1	1
Subdural haematoma		2						2
Traumatic haematoma		1						1
Upper limb fracture		1						1
Wound	1	2			1	2		
Wound haemorrhage		1				1		
Wrist fracture		1						1
	37	139		1	28	91	9	48

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Activated partial thromboplastin time prolonged	1	1			1	1
Activated partial thromboplastin time shortened		1		1		
Alanine aminotransferase decreased		1		1		
Alanine aminotransferase increased	2	3	1	2	1	1
Amylase increased		1		1		
Aspartate aminotransferase increased	2	4		2	2	2
Bacterial test positive		1				1
Basophil count decreased		1		1		
Blood alcohol decreased		1		1		
Blood alkaline phosphatase increased		2		2		
Blood bicarbonate decreased		2		2		
Blood bilirubin increased		4		4		
Blood calcium decreased		1		1		
Blood cholesterol abnormal		1		1		
Blood cholesterol increased	2	5	2	5		
Blood creatine phosphokinase increased		1		1		
Blood creatinine decreased	1	1	1	1		
Blood creatinine increased	3	8	2	7	1	1
Blood fibrinogen decreased	1	1			1	1
Blood glucose decreased		3		3		
Blood glucose fluctuation	1	4	1	4		
Blood glucose increased	6	14	4	11	2	3
Blood lactate dehydrogenase increased	1	2		1	1	1
Blood lactic acid increased	1	2		1	1	1
Blood potassium decreased		2		2		
Blood pressure abnormal		1		1		
Blood pressure decreased	2	9	2	4		5
Blood pressure increased	1	12		7	1	5
Blood pressure systolic increased	1	4	1	2		2
Blood sodium decreased		2		2		
Blood sodium increased	1	1			1	1
Blood urea abnormal		1		1		

* I=Interval, C=Cumulative

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood urea increased	3	8	2	7	1	1
Blood uric acid increased		1		1		
Body temperature decreased	2	6	2	4		2
Body temperature increased	20	144	20	139		5
Brain natriuretic peptide increased	1	2	1	2		
Breath sounds abnormal	1	1	1	1		
Calcium ionised decreased	1	1	1	1		
Coagulation factor VIII level increased	1	1	1	1		
Complement factor C1 increased	1	1	1	1		
Complement factor C3 increased	1	1	1	1		
Complement factor increased	1	1	1	1		
C-reactive protein increased	2	14	1	10	1	4
Electrocardiogram QT prolonged	1	1			1	1
Electrocardiogram ST segment abnormal		1				1
Eosinophil count decreased		2		2		
Fibrin D dimer increased	1	4		2	1	2
Gamma-glutamyltransferase increased	1	4	1	4		
Gastric pH decreased		1		1		
Glomerular filtration rate decreased	1	5	1	5		
Haematocrit decreased	1	6	1	6		
Haematocrit increased	1	2		1	1	1
Haemoglobin abnormal		1		1		
Haemoglobin decreased	3	13	2	9	1	4
Heart rate abnormal	1	2	1	2		
Heart rate decreased	2	6	2	5		1
Heart rate increased	9	26	8	18	1	8
Heart rate irregular	1	3		2	1	1
High density lipoprotein increased	1	1	1	1		
Human epidermal growth factor receptor decreased		1				1
Inflammatory marker increased	1	2	1	1		1
International normalised ratio fluctuation		1				1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
International normalised ratio increased	2	5	1	2	1	3
Low density lipoprotein increased	1	1	1	1		
Lymph nodes scan abnormal		1		1		
Lymphocyte count decreased		2		1		1
Mean cell haemoglobin concentration increased	1	1	1	1		
Mean cell haemoglobin increased	1	1	1	1		
Mean cell volume increased		1		1		
Monocyte count increased		1		1		
Neutrophil count decreased		1				1
Neutrophil count increased	2	5	2	5		
Oxygen saturation abnormal		3		1		2
Oxygen saturation decreased	4	26	1	4	3	22
Platelet count decreased	1	6		4	1	2
Platelet count increased		2		2		
PO2 increased	1	1			1	1
Prothrombin time prolonged	1	2		1	1	1
Prothrombin time ratio increased		1		1		
Pulmonary arterial pressure increased		1				1
Red blood cell count decreased	1	4	1	4		
Red blood cell sedimentation rate increased	1	1	1	1		
Respiratory rate decreased		2		2		
Respiratory rate increased	1	6		2	1	4
SARS-CoV-2 ant body test positive		1		1		
SARS-CoV-2 test positive	1	4	1	1		3
Serum ferritin abnormal		1				1
Total cholesterol/HDL ratio decreased	1	1	1	1		
Troponin I increased	1	1			1	1
Troponin increased		2		1		1
Urine output decreased		2		2		
Weight decreased		6		4		2
Weight increased		1		1		
White blood cell count decreased		1		1		

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* AE=Adverse Event

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
White blood cell count increased	3	5	2	4	1	1
	107	459	77	353	30	106

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* AE=Adverse Event
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System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal loss of weight		1		1		
Cachexia		3				3
Decreased appetite	8	30	7	22	1	8
Dehydration	2	8		2	2	6
Diabetes mellitus inadequate control		2				2
Electrolyte imbalance		1				1
Feeding disorder	1	4		2	1	2
Fluid intake reduced		3		1		2
Fluid retention	2	5	2	3		2
Glucose tolerance impaired		1		1		
Hypercalcaemia	2	2			2	2
Hyperglycaemia	2	3	2	2		1
Hyperkalaemia	2	3			2	3
Hypernatraemia		2				2
Hypertriglyceridaemia		1				1
Hypoglycaemia	2	6	1	3	1	3
Hypokalaemia		1				1
Hyponatraemia	1	2	1	2		
Hypophagia	1	7		1	1	6
Iron deficiency	1	1			1	1
Metabolic acidosis		1		1		
Starvation	1	1			1	1
Type 1 diabetes mellitus		1				1
Underweight		1		1		
Vitamin B12 deficiency	1	1	1	1		
	26	91	14	43	12	48

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ankylosing spondylitis	1	1			1	1
Arthralgia	135	769	132	753	3	16
Arthritis		3		1		2
Back pain	7	18	6	16	1	2
Bursitis		1		1		
Flank pain	1	2		1	1	1
Haemarthrosis		1				1
Hand deformity		1				1
Joint stiffness		1		1		
Joint swelling	3	3	3	3		
Limb discomfort	6	19	6	17		2
Mobility decreased	1	4		2	1	2
Muscle discomfort	1	1	1	1		
Muscle disorder	1	2	1	2		
Muscle rigidity		1		1		
Muscle spasms	6	17	2	12	4	5
Muscle tightness		1		1		
Muscle twitching	1	3	1	2		1
Muscular weakness	11	25	6	15	5	10
Musculoskeletal chest pain	1	3	1	2		1
Musculoskeletal discomfort	1	4	1	4		
Musculoskeletal disorder		2		1		1
Musculoskeletal pain	6	25	6	25		
Musculoskeletal stiffness	4	15	4	15		
Myalgia	398	1,768	397	1745	1	23
Neck pain	4	12	4	10		2
Pain in extremity	31	121	29	114	2	7
Pain in jaw	2	10	1	8	1	2
Polymyalgia rheumatica	1	1			1	1
Rheumatic disorder		1		1		
Rheumatoid arthritis	3	5			3	5
Soft tissue swelling		1				1

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Spinal osteoarthritis		1		1		
Systemic lupus erythematosus	1	1			1	1
Tendonitis	1	2	1	2		
Torticollis	1	2		1	1	1
Trismus	1	1	1	1		
	629	2,848	603	2759	26	89

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Leukaemia	1	1	1	1
Metastases to lung	1	1	1	1
Myelodysplastic syndrome	1	2	1	2
Plasma cell leukaemia	1	1	1	1
Renal neoplasm		1		1
	4	6	4	6

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ageusia		10				10		
Allodynia	1	2			1	2		
Altered state of consciousness		1						1
Amnesia	2	4			2	2		2
Anosmia	1	7			1	7		
Apallic syndrome		2						2
Aphasia	5	19			2	5	3	14
Apraxia	1	2					1	2
Ataxia		2						2
Autonomic nervous system imbalance		2						2
Balance disorder	1	10			1	7		3
Basilar artery thrombosis	1	3					1	3
Bell's palsy	5	9					5	9
Bradykinesia		2				2		
Burning sensation	1	8			1	8		
Carotid arteriosclerosis		1						1
Carotid artery dissection	1	1					1	1
Carotid artery thrombosis	1	2					1	2
Cerebellar haematoma		1						1
Cerebellar infarction		1						1
Cerebellar ischaemia		1						1
Cerebral amyloid angiopathy		1						1
Cerebral artery thrombosis	2	2					2	2
Cerebral atrophy	1	2					1	2
Cerebral haemorrhage	9	20					9	20
Cerebral infarction	35	58	1	1			35	58
Cerebral ischaemia	2	4					2	4
Cerebral thrombosis	1	5					1	5
Cerebral venous sinus thrombosis	1	2					1	2
Cerebrovascular accident	14	44		1			14	44
Cerebrovascular disorder		2				1		1
Cervical radiculopathy		1				1		

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chorea		1
Cognitive disorder	2	4
Coma	2	2
Coma hepatic		1
Consciousness fluctuating		1
Coordination abnormal		5
Dementia		3
Dementia Alzheimer's type		1
Depressed level of consciousness	4	19
Diplegia	1	1
Disturbance in attention	3	8
Dizziness	47	205
Dysarthria		10
Dysgeusia	2	24
Dysgraphia		2
Dyskinesia	1	1
Dysstasia	1	3
Electric shock sensation		2
Encephalitis autoimmune		1
Epilepsy	5	39
Facial neuralgia	1	2
Facial paralysis	3	14
Facial paresis		4
Febrile convulsion		2
Generalised tonic-clonic seizure		6
Guillain-Barre syndrome	2	3
Headache	400	1,787
Head discomfort	2	7
Hemianaesthesia		1
Hemianopia	2	2
Hemiparaesthesia	1	1
Hemiparesis	4	14

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		2	3		1
				2	2
					1
					1
			3		2
					3
					1
1	1			4	19
				1	1
		3	8		
		44	188	3	17
			3		7
		2	24		
			1		1
		1	1		
			1	1	2
			2		
					1
				5	39
		1	2		
				3	14
			2		2
			2		
					6
				2	3
		395	1757	5	30
		1	5	1	2
					1
				2	2
				1	1
				4	14

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hemiplegia	2	6
Horner's syndrome	1	1
Hydrocephalus		1
Hyperaesthesia		3
Hypersomnia	1	4
Hypoaesthesia	7	19
Hypokinesia	1	2
Hyporesponsive to stimuli		1
Intention tremor		1
Intracranial pressure increased	1	2
Ischaemic cerebral infarction	5	29
Ischaemic stroke	1	3
IVth nerve paralysis		1
Lacunar infarction		1
Lethargy		1
Loss of consciousness	10	42
Memory impairment	1	4
Mental impairment		4
Migraine	4	9
Monoparesis	2	4
Monoplegia		1
Movement disorder		4
Multiple sclerosis		2
Muscle contractions involuntary		2
Myelitis transverse	1	1
Myelopathy		1
Myoclonus		1
Neuralgia	2	6
Neuritis		1
Neurologic neglect syndrome	2	3
Neuropathy peripheral	4	9
Nystagmus		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	6
				1	1
					1
			2		1
		1	4		
		4	15	3	4
		1	2		
			1		
					1
				1	2
				5	29
				1	3
			1		
					1
			1		
1	1			10	42
		1	4		
					4
		4	8		1
				2	4
					1
			2		2
					2
			2		
				1	1
					1
			1		
		2	6		
					1
				2	3
				4	9
			1		

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Optic neuritis		1
Paraesthesia	28	67
Paralysis	2	7
Paresis		2
Parkinson's disease		2
Parosmia	1	4
Periventricular leukomalacia	1	1
Peroneal nerve palsy		2
Polyneuropathy chronic	1	1
Posterior reversible encephalopathy syndrome		1
Postictal state		1
Presyncope	2	22
Quadriplegia		1
Reduced facial expression		1
Resting tremor		1
Restless legs syndrome	1	1
Sciatica		1
Seizure	2	12
Sensory disturbance	1	2
Slow speech		1
Somnolence	5	23
Speech disorder	4	14
Spinal cord compression		1
Spinal epidural haemorrhage		1
Spinal meningeal cyst		1
Status epilepticus		3
Subarachnoid haemorrhage	2	2
Syncope	24	111
Taste disorder	1	7
Thunderclap headache		1
Tongue biting	1	1
Transient aphasia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		23	60	5	7
				2	7
			1		1
					2
		1	4		
				1	1
			1		1
		1	1		
					1
			1		
		2	19		3
					1
					1
			1		
		1	1		
					1
				2	12
		1	2		
			1		
		3	12	2	11
		2	6	2	8
					1
					1
					1
					3
				2	2
1	2			24	111
		1	7		
					1
		1	1		
					1

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Transient global amnesia		1				1		
Transient ischaemic attack	31	80		1			31	80
Transverse sinus thrombosis	1	1					1	1
Tremor	3	19			2	16	1	3
Trigeminal nerve disorder		1				1		
Trigeminal neuralgia	1	1			1	1		
Unresponsive to stimuli	1	9					1	9
Vascular parkinsonism	1	1					1	1
Vertebrobasilar stroke	2	2					2	2
	729	2,989	4	7	509	2234	220	755

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion missed		2		2
Abortion spontaneous	2	13	2	13
Anembryonic gestation		2		2
	2	17	2	17

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product packaging quantity issue	1	1	1	1
	1	1	1	1

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour	1	2			1	2
Abnormal dreams		3		3		
Affect lability	1	3	1	3		
Agitation	1	2	1	2		
Anxiety	5	16	4	14	1	2
Apathy		2		1		1
Bradyphrenia		3		2		1
Catatonia		2		1		1
Confusional state	9	33	5	16	4	17
Conversion disorder		1				1
Decreased interest	1	1	1	1		
Delirium	6	29			6	29
Delirium febrile		1				1
Delusion		1		1		
Depressed mood		4		4		
Depression		6		4		2
Depression suicidal	1	1			1	1
Derealisation		2		2		
Disorganised speech		1		1		
Disorientation		2		1		1
Dissociation		1		1		
Emotional disorder		1				1
Emotional distress		1		1		
Emotional poverty		1				1
Fear		2		1		1
Hallucination	4	8			4	8
Hallucination, olfactory	2	2			2	2
Hallucination, visual	1	2			1	2
Imperception		1				1
Insomnia	2	8	2	8		
Listless	4	9	4	9		
Mental disorder	2	2	1	1	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mood altered		2		2		
Mutism		2				2
Nightmare		1		1		
Panic attack		1		1		
Personality disorder		1		1		
Poor quality sleep	1	2	1	2		
Psychotic symptom		2				2
Restlessness	3	10	3	9		1
Sleep disorder		1		1		
Somnambulism		2		2		
Suicidal ideation		1				1
Suspiciousness		1		1		
Thinking abnormal	1	2	1	2		
	45	181	24	99	21	82

* I=Interval, C=Cumulative
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System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	2	3			2	3
Azotaemia		2				2
Cystitis noninfective		1				1
Glomerulonephritis minimal lesion	1	2			1	2
Incontinence	1	5		1	1	4
Nephrolithiasis		3				3
Nephrotic syndrome	1	3			1	3
Oliguria		1		1		
Pollakiuria		2		2		
Polyuria		1		1		
Renal artery thrombosis	1	1			1	1
Renal disorder		2		2		
Renal failure	3	6			3	6
Renal impairment	3	6			3	6
Renal infarct		1				1
Renal ischaemia	1	1			1	1
Urinary incontinence	2	5	1	3	1	2
Urinary retention		5				5
	15	50	1	10	14	40

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast disorder female		1		1		
Breast pain		1		1		
Dysmenorrhoea	1	2	1	2		
Erectile dysfunction	1	2			1	2
Genital discomfort	1	1	1	1		
Genital paraesthesia		1		1		
Heavy menstrual bleeding	1	1	1	1		
Intermenstrual bleeding	2	2	2	2		
Menstrual disorder	6	6	6	6		
Menstruation delayed	2	2	2	2		
Menstruation irregular	3	3	3	3		
Pelvic pain		2		2		
Polymenorrhoea	1	1	1	1		
Postmenopausal haemorrhage		2				2
Vaginal haemorrhage	1	2	1	2		
Vulvovaginal pain		1		1		
	19	30	18	26	1	4

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute respiratory failure		1						1
Aphonia	2	4			2	2		2
Aspiration		1						1
Asthma	2	6			2	3		3
Bronchiectasis	1	1					1	1
Bronchospasm	1	2					1	2
Choking		1						1
Choking sensation		2						2
Chronic obstructive pulmonary disease	2	6				1	2	5
Cough	11	35			9	30	2	5
Diaphragmalgia		1				1		
Dry throat		1				1		
Dysphonia	2	6					2	6
Dyspnoea	42	179	1	2	27	99	15	80
Dyspnoea at rest	3	5					3	5
Dyspnoea exertional	1	7			1	4		3
Emphysema	1	1			1	1		
Epistaxis	4	20	1	1	4	13		7
Haemoptysis		3				2		1
Hyperventilation		6				3		3
Hypopnoea		1				1		
Hypoxia	2	17					2	17
Increased upper airway secretion		1						1
Interstitial lung disease		1						1
Lung disorder		6				2		4
Nasal congestion	5	8			5	7		1
Nasal discomfort		1				1		
Nasal dryness		1				1		
Nasal inflammation		1				1		
Nocturnal dyspnoea	1	1			1	1		
Obstructive airways disorder	1	1					1	1
Oropharyngeal blistering		1						1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oropharyngeal discomfort	1	3
Oropharyngeal pain	12	43
Painful respiration	2	4
Pharyngeal erythema		1
Pharyngeal oedema	1	2
Pharyngeal paraesthesia		2
Pharyngeal swelling	6	21
Pleural effusion	1	4
Pneumonia aspiration	1	12
Productive cough	1	3
Pulmonary embolism	34	68
Pulmonary haemorrhage		1
Pulmonary hypertension		1
Pulmonary infarction	2	5
Pulmonary mass	1	2
Pulmonary oedema	1	3
Pulmonary pain	1	4
Respiration abnormal		1
Respiratory disorder		3
Respiratory failure	3	12
Respiratory symptom	1	1
Respiratory tract irritation		2
Respiratory tract oedema		1
Rhinitis allergic	1	1
Rhinorrhoea	2	8
Sneezing	1	5
Snoring	1	2
Sputum discoloured	1	1
Sputum increased		1
Stridor	3	7
Tachypnoea		4
Throat irritation	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	1	1
		11	41	1	2
		1	3	1	1
					1
				1	2
					2
		2	8	4	13
		1	1		3
				1	12
		1	2		1
				34	68
					1
1	1				1
				2	5
				1	2
				1	3
		1	4		
					1
			2		1
				3	12
		1	1		
			2		
					1
		1	1		
		2	8		
		1	5		
		1	2		
		1	1		
			1		
			1	3	6
			3		1
		1	2	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Throat tightness	3	10			1	5	2	5
Wheezing		1				1		
	163	570	3	4	78	270	85	300

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acne		1				1		
Angioedema	6	20					6	20
Blister	2	5			2	4		1
Cold sweat	2	10			2	7		3
Cutaneous vasculitis	2	4					2	4
Dandruff		1				1		
Dermatitis	1	2			1	2		
Dermatitis allergic	1	2			1	2		
Dermatitis bullous	1	3					1	3
Dry skin	1	1			1	1		
Ecchymosis		3				1		2
Eczema	1	4			1	4		
Erythema	15	56			14	48	1	8
Erythema nodosum		1						1
Henoch-Schonlein purpura	1	1					1	1
Hidradenitis		1				1		
Hyperhidrosis	7	38			7	34		4
Ingrowing nail		1				1		
Livedo reticularis		1						1
Night sweats	3	6			3	6		
Pain of skin	1	7			1	7		
Panniculitis		1						1
Pemphigoid	1	2					1	2
Petechiae		4				4		
Piloerection		1				1		
Pityriasis rosea		1				1		
Pruritus	18	48		1	16	43	2	5
Psoriasis	2	2			2	2		
Purpura		1				1		
Rash	11	39		1	11	34		5
Rash erythematous	4	15			4	15		
Rash macular	2	3			2	3		

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* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Rash maculo-papular		1				1		
Rash papular	3	6			3	6		
Rash pruritic	5	12			5	11		1
Rash vesicular	1	1			1	1		
Sensitive skin		3				3		
Skin burning sensation		3				3		
Skin discolouration	1	7			1	5		2
Skin discomfort		1				1		
Skin exfoliation	1	1			1	1		
Skin induration		1				1		
Skin irritation	3	4			3	4		
Skin swelling		1				1		
Skin warm		1				1		
Toxic skin eruption	1	2					1	2
Trichodynia	1	1			1	1		
Urticaria	8	28			6	21	2	7
	106	358		2	89	285	17	73

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden		2		1		1
Loss of personal independence in daily activities	2	5	2	4		1
	2	7	2	5		2

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System Organ Class

SOC Not Yet Coded

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
		1		1
		1		1

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* AE=Adverse Event
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System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Aneurysm		1						1
Aortic aneurysm	1	1					1	1
Aortic arteriosclerosis	1	2			1	1		1
Aortic dissection		1						1
Aortic thrombosis	1	1					1	1
Arterial thrombosis		1						1
Bleeding varicose vein	1	1					1	1
Blood pressure fluctuation	3	3			2	2	1	1
Circulatory collapse	3	8					3	8
Cyanosis		3				1		2
Deep vein thrombosis	20	46					20	46
Embolism		1						1
Embolism arterial	1	1					1	1
Flushing	2	5			2	5		
Giant cell arteritis		2						2
Haematoma		4				3		1
Haemodynamic instability	2	3			1	1	1	2
Haemorrhage	2	4					2	4
Hot flush		6				5		1
Hypertension	16	53			7	26	9	27
Hypertensive crisis		1						1
Hypertensive urgency		1						1
Hypotension	11	31		1	6	14	5	17
Hypovolaemic shock		1						1
Infarction		2						2
Lymphoedema	1	1			1	1		
Pallor	3	18			3	11		7
Peripheral coldness	1	9			1	7		2
Raynaud's phenomenon		1				1		
Secondary hypertension		1						1
Shock	1	3					1	3
Thrombophlebitis	2	8			1	5	1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Thrombophlebitis superficial	3	5			1	1	2	4
Thrombosis	4	25					4	25
Varicose vein	1	1			1	1		
Vascular calcification	1	1					1	1
Vasculitis		3				3		
	81	259		1	27	88	54	171

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Country Where Event Occurred

NEW ZEALAND

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Nausea	1	2	1	2
	1	2	1	2

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Chest discomfort	1	1			1	1
Drug ineffective		1				1
Influenza like illness	1	2			1	2
Reactogenicity event		1				1
	3	6	1	1	2	5

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypersensitivity	20	25	20	25
	20	25	20	25

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Asymptomatic COVID-19		1		1
		1		1

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposure to SARS-CoV-2		1				1
Product administration error	1	1	1	1		
	1	2	1	1		1

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate increased	2	2	1	1	1	1
	2	2	1	1	1	1

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypoglycaemia		3		3
		3		3

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Musculoskeletal stiffness	1	1			1	1
Myalgia	1	1			1	1
	3	3	1	1	2	2

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cerebrovascular accident	1	1	1	1
Headache	1	1	1	1
Seizure	1	1	1	1
	3	3	3	3

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Thrombosis	1	1	1	1
	1	1	1	1

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Country Where Event Occurred
NORTHERN MARIANA ISLANDS

System Organ Class

General disorders and administration site conditions

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Chest discomfort		1		1
Chills		1		1
Fatigue		1		1
		3		3

System Organ Class

Injury, poisoning and procedural complications

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration		2		2
		2		2

System Organ Class

Musculoskeletal and connective tissue disorders

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Arthralgia		1		1
Pain in extremity		1		1
		2		2

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* AE=Adverse Event
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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dizziness		1		1
Headache		1		1
		2		2

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Disorientation		1		1
Poor quality sleep		1		1
		2		2

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Country Where Event Occurred

NORWAY

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eosinophilia		1				1
Febrile neutropenia	1	1			1	1
Immune thrombocytopenia	2	4			2	4
Increased tendency to bruise		1				1
Iron deficiency anaemia	1	1			1	1
Leukocytosis	1	3		1	1	2
Lymphadenitis		2		1		1
Lymphadenopathy	1	5	1	4		1
Lymph node pain	1	1	1	1		
Lymphocytosis		1		1		
Monocytosis	1	1	1	1		
Neutropenia	2	3			2	3
Neutrophilia	1	1	1	1		
Pancytopenia		1				1
Splenic infarction	1	1			1	1
Thrombocytopenia	2	7			2	7
	14	34	4	10	10	24

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome		1				1
Acute myocardial infarction	6	11			6	11
Angina pectoris		2				2
Arrhythmia	4	6			4	6
Arteriosclerosis coronary artery		1				1
Atrial fibrillation	4	8			4	8
Atrial flutter	1	2			1	2
Atrioventricular block	1	1			1	1
Atrioventricular block first degree		1				1
Bradycardia	2	7			2	7
Cardiac arrest	4	7			4	7
Cardiac disorder	1	1			1	1
Cardiac failure	1	5			1	5
Cardiac fibrillation		1				1
Cardiomegaly		1				1
Cardio-respiratory arrest		1				1
Cardiovascular disorder		1				1
Coronary artery occlusion		1				1
Coronary artery thrombosis	1	1			1	1
Cor pulmonale acute	1	1			1	1
Extrasystoles		1				1
Intracardiac thrombus		2				2
Left ventricular failure		1				1
Myocardial infarction	3	5			3	5
Nodal rhythm		1				1
Palpitations	9	16	3	7	6	9
Pericardial effusion	1	3			1	3
Pericardial haemorrhage		1				1
Pericarditis	5	11			5	11
Right ventricular failure	1	1			1	1
Sinoatrial block	1	2			1	2
Supraventricular extrasystoles		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia	8	18	1	7	7	11
Ventricular extrasystoles		2		1		1
Ventricular tachycardia		1				1
	54	126	4	15	50	111

System Organ Class

Congenital, familial and genetic disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Neurofibromatosis	1	1	1	1
	1	1	1	1

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Auditory disorder		1		1		
Ear discomfort		3		3		
Ear pain		2		2		
Ear swelling		1		1		
Sudden hearing loss	1	1			1	1
Vertigo	1	4		1	1	3
Vertigo positional		1				1
	2	13		8	2	5

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* AE=Adverse Event
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System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Basedow's disease		1		1
Hyperthyroidism		1		1
Hypothyroidism	1	1	1	1
	1	3	1	3

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blepharospasm		1		1		
Blindness	1	2			1	2
Blindness transient	1	1			1	1
Diplopia		3		1		2
Eye disorder	1	1	1	1		
Eye haemorrhage	1	3			1	3
Eye irritation	1	1	1	1		
Eyelid oedema	1	1	1	1		
Eye pain		2		2		
Eye swelling	1	1	1	1		
Iridocyclitis		2				2
Lacrimation increased	1	1	1	1		
Myopia		1				1
Ocular hyperaemia	1	3	1	2		1
Orbital oedema		1				1
Photophobia	1	4	1	3		1
Pupil fixed		2				2
Retinal artery occlusion	1	1			1	1
Retinal vein occlusion	1	1			1	1
Swelling of eyelid		2		1		1
Vision blurred	1	4	1	1		3
Visual field defect	1	1			1	1
Visual impairment	3	7	1	3	2	4
	17	46	9	19	8	27

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	3		2	1	1
Abdominal pain	7	21	4	12	3	9
Abdominal pain upper	5	20	2	7	3	13
Abdominal wall haemorrhage		1				1
Anal incontinence		1				1
Coating in mouth	1	1			1	1
Colitis	1	1			1	1
Constipation		2		1		1
Defaecation disorder		1				1
Defaecation urgency	1	1	1	1		
Diarrhoea	7	37	3	20	4	17
Diarrhoea haemorrhagic	1	1			1	1
Dry mouth		6		5		1
Duodenitis		1				1
Dysphagia		7		2		5
Faeces discoloured	1	3		1	1	2
Flatulence		1		1		
Gastric disorder		1				1
Gastric haemorrhage		1				1
Gastritis		1		1		
Gastrointestinal haemorrhage	2	4			2	4
Gastrointestinal necrosis		1				1
Haematemesis		2				2
Haematochezia	1	1			1	1
Hypoaesthesia oral	4	9	3	6	1	3
Intestinal ischaemia		1				1
Intra-abdominal haematoma	1	1			1	1
Lip pruritus	1	2			1	2
Lip swelling	4	4	2	2	2	2
Melaena		1				1
Mesenteric artery embolism		1				1
Mouth haemorrhage		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mouth swelling	1	2			1	2
Mouth ulceration		1				1
Nausea	34	114	16	68	18	46
Odynophagia	1	1			1	1
Oral mucosa haematoma		1				1
Oral pruritus	2	4			2	4
Pancreatitis	1	1			1	1
Paraesthesia oral	4	6	3	4	1	2
Rectal haemorrhage		2				2
Retching	2	9		3	2	6
Swollen tongue	8	8	2	2	6	6
Tongue disorder	1	1			1	1
Tongue pruritus	1	1			1	1
Vomiting	17	59	7	22	10	37
	110	349	43	160	67	189

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	2	17	1	7	1	10
Axillary pain		3		2		1
Chest discomfort	3	9	1	6	2	3
Chest pain	13	33		7	13	26
Chills	14	50	11	34	3	16
Concomitant disease aggravated		2				2
Condition aggravated	2	9		2	2	7
Crepitations	1	1	1	1		
Death	3	30			3	30
Decreased activity		1		1		
Discomfort		7		5		2
Disease recurrence	3	9	1	2	2	7
Drug ineffective	3	5			3	5
Drug interaction	1	5		3	1	2
Face oedema		1				1
Fatigue	47	171	36	129	11	42
Feeling abnormal		5		4		1
Feeling cold	3	6	3	6		
Feeling drunk		1		1		
Feeling hot	7	16	3	9	4	7
Feeling of body temperature change		1		1		
Foaming at mouth		1		1		
Gait disturbance	1	3		1	1	2
General physical health deterioration	7	76		18	7	58
General symptom		1				1
Hunger	1	1	1	1		
Hyperpyrexia		1				1
Hypothermia		2				2
Illness	1	2	1	2		
Inflammation	1	2	1	1		1
Influenza like illness	7	17	6	12	1	5
Injection site muscle weakness		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site pain	1	4	1	4		
Irritability postvaccinal		1				1
Local reaction		1				1
Malaise	20	62	9	40	11	22
Moaning		1				1
Oedema peripheral		5		2		3
Pain	9	28	3	16	6	12
Peripheral swelling	2	10	1	6	1	4
Pyrexia	43	155	32	98	11	57
Secretion discharge		2				2
Sensation of foreign body	1	1			1	1
Stenosis		1				1
Sudden cardiac death		1				1
Sudden death	2	10			2	10
Swelling	3	4	1	1	2	3
Swelling face	1	6	1	3		3
Systemic inflammatory response syndrome	2	2			2	2
Tenderness		2		2		
Terminal state		1				1
Therapeutic product effect decreased		1		1		
Thirst	1	3	1	2		1
Ulcer	1	1	1	1		
Vaccination failure	13	15			13	15
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	4	14	4	13		1
Vaccination site haemorrhage	1	1	1	1		
Vaccination site hypoaesthesia		1		1		
Vaccination site movement impairment	1	2	1	1		1
Vaccination site oedema		1		1		
Vaccination site pain	15	53	15	46		7
Vaccination site paraesthesia		2		2		
Vaccination site pruritus	2	6	2	5		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site rash		1		1		
Vaccination site reaction	1	5		3	1	2
Vaccination site swelling	8	14	7	10	1	4
Vaccination site warmth	1	4	1	3		1
	253	911	148	521	105	390

System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Autoimmune hepatitis	1	1	1	1
Cholecystitis		1		1
Hepatic cyst		1		1
	1	3	1	3

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		2				2
Anaphylactic reaction	19	31			19	31
Anaphylactic shock	1	1			1	1
Hypersensitivity	7	15	1	3	6	12
Immune-mediated adverse reaction	1	2			1	2
Immune system disorder	1	1			1	1
Serum sickness	1	1			1	1
	30	53	1	3	29	50

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal infection		1				1
Appendicitis		2				2
Arthritis bacterial		1				1
Asymptomatic COVID-19	4	4			4	4
Bacterial sepsis		1				1
Bronchitis		1		1		
Cellulitis	1	1			1	1
Conjunctivitis		1		1		
COVID-19	12	17	1	2	11	15
COVID-19 pneumonia	2	2			2	2
Disseminated varicella zoster virus infection	1	1			1	1
Diverticulitis		1				1
Encephalitis brain stem	1	1			1	1
Erysipelas	2	5			2	5
Fungal infection	1	1			1	1
Gastroenteritis		1				1
Herpes simplex reactivation		1		1		
Herpes zoster	14	14	13	13	1	1
Infection	10	18	1	2	9	16
Infective exacerbation of chronic obstructive airways disease		1				1
Influenza		2		2		
Lower respiratory tract infection		1				1
Lymphangitis		1				1
Mastitis	1	1			1	1
Nasopharyngitis		2		1		1
Neuroborreliosis		1				1
Ophthalmic herpes zoster	1	3			1	3
Pneumonia	4	29			4	29
Pneumonia bacterial		1				1
Pyelonephritis		1				1
Respiratory tract infection		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sepsis		4				4
Soft tissue infection	1	1			1	1
Staphylococcal sepsis		1				1
Urinary tract infection		6		5		1
Urosepsis		2				2
Vaccine breakthrough infection		1				1
Vestibular neuronitis	1	1			1	1
	56	134	15	28	41	106

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* AE=Adverse Event
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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arteriovenous fistula thrombosis		2				2
Brain herniation	1	1			1	1
Concussion		2				2
Contusion	1	4	1	2		2
Exposure during pregnancy	1	2	1	2		
Exposure to SARS-CoV-2	1	1	1	1		
Face injury	1	1			1	1
Fall	4	27	1	6	3	21
Femoral neck fracture		2				2
Femur fracture		1				1
Fracture		1				1
Frostbite	3	4	2	2	1	2
Head injury		2				2
Inappropriate schedule of product administration		4		4		
Incomplete course of vaccination	2	2			2	2
Incorrect dose administered		5		5		
Incorrect route of product administration	2	6	2	6		
Intercepted product preparation error		1		1		
Maternal exposure during pregnancy		1		1		
Multiple fractures		1				1
Off label use	6	10	6	10		
Poor quality product administered	5	12	5	12		
Product administered at inappropriate site		1		1		
Product preparation error		2		2		
Product preparation issue		8		8		
Rib fracture	1	1			1	1
Road traffic accident	2	2			2	2
Skin laceration		1				1
Subdural haematoma		1				1
Subdural haemorrhage		1				1
Tooth avulsion		1				1
Transfusion reaction		1		1		

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* AE=Adverse Event

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Underdose		1		1		
Vaccination error		1		1		
Wrong technique in product usage process		1		1		
	30	114	19	67	11	47

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased		1		1		
Antinuclear ant body increased		1		1		
Anti-thyroid antibody		1		1		
Bacterial test positive		1		1		
Blood 25-hydroxycholecalciferol decreased		1		1		
Blood bilirubin increased		1		1		
Blood calcium decreased		1		1		
Blood creatinine increased	1	1			1	1
Blood glucose decreased		1		1		
Blood glucose fluctuation		3		3		
Blood glucose increased	2	4	1	3	1	1
Blood magnesium increased		1		1		
Blood phosphorus decreased		1		1		
Blood potassium decreased	1	2		1	1	1
Blood pressure decreased	4	17	2	5	2	12
Blood pressure diastolic decreased		1		1		
Blood pressure diastolic increased	1	1			1	1
Blood pressure increased	8	11	3	5	5	6
Blood pressure systolic decreased		1				1
Blood pressure systolic increased	2	4			2	4
Body temperature decreased		1		1		
Body temperature fluctuation		1				1
Body temperature increased		2		1		1
Breath sounds abnormal		1				1
Cardiac murmur	1	1	1	1		
CD4 lymphocytes decreased	1	1			1	1
C-reactive protein abnormal	1	1			1	1
C-reactive protein increased	9	39	3	11	6	28
Fibrin D dimer increased	3	3			3	3
Forced expiratory flow	1	1			1	1
Grip strength decreased		2				2
Haemoglobin decreased		3				3

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* AE=Adverse Event

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate decreased	3	4	2	2	1	2
Heart rate increased	6	24	3	11	3	13
Heart rate irregular	1	4		2	1	2
Inflammatory marker increased		1				1
International normalised ratio increased		2				2
Low density lipoprotein increased		1		1		
Lymphocyte count decreased	1	1			1	1
N-terminal prohormone brain natriuretic peptide increased		2				2
Oxygen saturation decreased	3	22		2	3	20
Platelet count increased	1	1			1	1
Red blood cell sedimentation rate increased		2		1		1
Respiratory rate decreased		1		1		
Respiratory rate increased	1	12		5	1	7
Salmonella test positive		1				1
Troponin I increased		1		1		
Troponin increased		1				1
Weight decreased	1	2	1	2		
White blood cell count decreased	1	1			1	1
White blood cell count increased		3		2		1
	53	197	16	72	37	125

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal weight gain	1	1	1	1		
Decreased appetite	3	18	1	8	2	10
Dehydration	2	5	2	3		2
Diabetes mellitus inadequate control		1				1
Electrolyte imbalance		1				1
Food refusal		1				1
Hyperglycaemia		2		1		1
Hyperkalaemia		1				1
Hypernatraemia		1				1
Hyponatraemia		2				2
Hypophagia		4				4
Marasmus		1				1
	6	38	4	13	2	25

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* AE=Adverse Event
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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	20	50	13	38	7	12
Arthritis	1	3		1	1	2
Arthritis reactive		1				1
Axillary mass		1				1
Back pain	3	17	2	10	1	7
Bone pain	2	4		1	2	3
Bursitis	1	1			1	1
Enthesopathy	1	1			1	1
Joint swelling	2	3	1	2	1	1
Limb discomfort		4		3		1
Mobility decreased		1		1		
Muscle rigidity		1				1
Muscle spasms	3	9	1	2	2	7
Muscle twitching		1		1		
Muscular weakness	2	9	1	3	1	6
Musculoskeletal pain		2		2		
Musculoskeletal stiffness	2	10	2	7		3
Myalgia	26	70	18	51	8	19
Neck pain	2	11	2	9		2
Pain in extremity	14	30	10	23	4	7
Polymyalgia rheumatica	1	1			1	1
Tendon pain		1		1		
	80	231	50	155	30	76

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* AE=Adverse Event
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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Adenoma benign		1		1
Metastases to peritoneum		1		1
		2		2

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Altered state of consciousness	1	8			1	8
Amnesia		3		1		2
Apallic syndrome		1				1
Aphasia		5				5
Autonomic nervous system imbalance		1				1
Balance disorder	2	9	1	3	1	6
Bell's palsy	2	3			2	3
Brain injury	1	1			1	1
Brain oedema	1	1			1	1
Brain stem infarction	1	1			1	1
Brain stem stroke		1				1
Burning sensation	2	5	1	3	1	2
Carotid arteriosclerosis		1		1		
Carotid artery occlusion		1				1
Cerebellar haemorrhage	1	1			1	1
Cerebellar infarction		1				1
Cerebral artery embolism	1	2			1	2
Cerebral artery thrombosis	1	2			1	2
Cerebral haemorrhage	3	13			3	13
Cerebral infarction	3	12			3	12
Cerebral thrombosis	1	3			1	3
Cerebral venous thrombosis	1	1			1	1
Cerebrovascular accident	8	30			8	30
Cerebrovascular disorder		1				1
Cognitive disorder	2	5	1	2	1	3
Coma		1				1
Coordination abnormal		3		1		2
Dementia		2				2
Dementia Alzheimer's type		1				1
Demyelinating polyneuropathy		1				1
Depressed level of consciousness	2	9			2	9
Disturbance in attention	1	3	1	3		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	26	87	10	43	16	44
Drooling		1		1		
Dysarthria		7		2		5
Dysgeusia	3	7	2	5	1	2
Dyskinesia		1				1
Embolic cerebral infarction		1				1
Epilepsy		5				5
Facial paralysis	2	5			2	5
Facial paresis	3	12	2	5	1	7
Generalised tonic-clonic seizure	1	2			1	2
Guillain-Barre syndrome		1				1
Headache	52	152	37	113	15	39
Hemianopia		1				1
Hemiparesis	3	8			3	8
Hemiplegia	2	6			2	6
Hyperaesthesia		2				2
Hypersomnia	1	2	1	2		
Hypoaesthesia	6	15	5	12	1	3
Hypogeusia	2	3	2	3		
Hypokinesia	1	3	1	2		1
Hyposmia	1	2	1	2		
Ischaemic stroke		3				3
Lethargy	3	10	2	5	1	5
Loss of consciousness	8	21			8	21
Memory impairment	1	5	1	5		
Mental impairment		1				1
Migraine		4		2		2
Migraine with aura		1				1
Monoparesis		1				1
Monoplegia		1				1
Motor dysfunction		1		1		
Multiple sclerosis	2	2			2	2

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle contractions involuntary	1	2	1	2		
Muscle spasticity		1				1
Neuralgia	1	1			1	1
Neuropathy peripheral		2				2
Nystagmus		1				1
Paraesthesia	7	16	5	10	2	6
Paralysis	1	2			1	2
Paresis		1		1		
Parosmia		1		1		
Postictal state		1		1		
Presyncope	2	11	1	3	1	8
Psychomotor hyperactivity		2		1		1
Radiculopathy	1	1			1	1
Reversible cerebral vasoconstriction syndrome	1	1			1	1
Seizure	2	3			2	3
Sleep paralysis	1	1	1	1		
Somnolence	4	21	3	12	1	9
Speech disorder	1	8		2	1	6
Spinal vascular disorder	1	1			1	1
Status epilepticus		1				1
Status migrainosus		1				1
Syncope	8	41			8	41
Taste disorder	1	1	1	1		
Thrombotic stroke	1	2			1	2
Transient ischaemic attack	2	7			2	7
Tremor	5	13	2	5	3	8
Unresponsive to stimuli		4				4
VIIIth nerve paralysis		1				1
	191	653	82	257	109	396

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion spontaneous	1	2	1	2
	1	2	1	2

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product temperature excursion issue	5	12	5	12
	5	12	5	12

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour		1				1
Abnormal dreams		1		1		
Aggression		2		1		1
Agitation		1				1
Anxiety	3	6		1	3	5
Apathy		2				2
Communication disorder		1		1		
Confusional state	6	37	2	12	4	25
Delirium	1	7			1	7
Delusion	1	2			1	2
Depressed mood		1		1		
Disorientation	2	3			2	3
Fear	1	1			1	1
Fear of death		1		1		
Hallucination	2	8			2	8
Hallucination, auditory		2				2
Hallucinations, mixed		1				1
Hallucination, visual	6	7			6	7
Insomnia	1	2	1	2		
Listless	1	2	1	2		
Mania		1				1
Middle insomnia		1		1		
Nightmare		1		1		
Panic attack		1		1		
Paranoia		1				1
Personality change		1				1
Psychiatric symptom	1	1	1	1		
Psychological trauma	1	1			1	1
Restlessness	4	17		5	4	12
Sleep disorder	1	4		1	1	3
Sleep disorder due to general medical condition, insomnia type	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Somnambulism	1	1	1	1		
Time perception altered		1		1		
	33	120	7	35	26	85

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	2	5			2	5
Chronic kidney disease		1				1
Glomerulonephritis chronic		1				1
Glomerulonephritis minimal lesion		1				1
Incontinence		1				1
Kidney fibrosis		1				1
Nephrolithiasis		1				1
Nocturia	1	1	1	1		
Prerenal failure	1	1			1	1
Renal cyst		1				1
Renal failure		2				2
Renal impairment		1				1
Tubulointerstitial nephritis		1				1
Urinary incontinence	1	3		1	1	2
Urinary retention		2				2
	5	23	1	2	4	21

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast enlargement		1		1		
Breast pain		1		1		
Breast tenderness	1	1	1	1		
Heavy menstrual bleeding	1	1	1	1		
Menstrual discomfort	1	1			1	1
Menstrual disorder	1	1	1	1		
Vaginal haemorrhage	1	1			1	1
	5	7	3	5	2	2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory failure	1	1			1	1
Apnoea	1	4			1	4
Apnoeic attack		1				1
Aspiration		1				1
Asthma	3	5	1	2	2	3
Atelectasis		1				1
Bronchospasm	1	1			1	1
Chronic obstructive pulmonary disease		6				6
Cough	11	32	4	16	7	16
Cystic lung disease		1		1		
Dysphonia	4	8	1	5	3	3
Dyspnoea	41	116	8	34	33	82
Dyspnoea at rest	1	2			1	2
Dyspnoea exertional	1	1	1	1		
Emphysema		1		1		
Epistaxis	2	5	2	4		1
Grunting	1	1			1	1
Haemothorax		1				1
Hypercapnia		1				1
Hyperventilation	5	12		4	5	8
Hypoxia	1	5			1	5
Increased bronchial secretion		3		1		2
Increased viscosity of upper respiratory secretion		1		1		
Interstitial lung disease		1				1
Intranasal hypoaesthesia		1		1		
Intranasal paraesthesia		1		1		
Lung consolidation		1				1
Lung infiltration	1	1	1	1		
Lung opacity		3				3
Mediastinal haemorrhage		1				1
Nasal congestion	4	9	2	7	2	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nasal pruritus		1				1
Obstructive airways disorder	2	4	1	1	1	3
Oropharyngeal discomfort	1	1			1	1
Oropharyngeal pain	4	16	2	10	2	6
Oropharyngeal swelling		1				1
Painful respiration	3	4		1	3	3
Paranasal sinus discomfort		1		1		
Pharyngeal paraesthesia	2	3			2	3
Pharyngeal swelling	3	6		1	3	5
Pleural effusion	1	3			1	3
Pleurisy		1				1
Pneumonia aspiration		3				3
Pneumonitis		2				2
Productive cough	2	7	1	1	1	6
Pulmonary congestion		1				1
Pulmonary embolism	31	44			31	44
Pulmonary infarction	2	2			2	2
Pulmonary necrosis		1				1
Pulmonary oedema		1				1
Pulmonary pain	1	1			1	1
Pulmonary thrombosis		1				1
Rales		4		2		2
Respiration abnormal		1				1
Respiratory acidosis		1				1
Respiratory alkalosis		1				1
Respiratory arrest	1	5			1	5
Respiratory disorder		1				1
Respiratory distress	1	1			1	1
Respiratory failure	4	14			4	14
Respiratory symptom	1	1			1	1
Respiratory tract congestion		1				1
Rhinorrhoea	2	9	2	9		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sneezing		1		1		
Snoring		1				1
Sputum increased		1		1		
Stridor	1	3			1	3
Tachypnoea		3		1		2
Throat clearing		1		1		
Throat irritation	3	6		1	3	5
Throat tightness	11	14	1	1	10	13
Upper respiratory tract congestion	1	1			1	1
Upper respiratory tract irritation	1	1			1	1
Wheezing	4	7	1	1	3	6
	160	410	28	113	132	297

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	4	7			4	7
Blister	1	1			1	1
Cold sweat	5	19		5	5	14
Cutaneous vasculitis	1	1			1	1
Decubitus ulcer		1		1		
Dermatitis allergic		1				1
Drug reaction with eosinophilia and systemic symptoms		1				1
Dry skin		1		1		
Ecchymosis		1				1
Eczema		1				1
Erythema	8	22	3	13	5	9
Erythema multiforme	1	1			1	1
Exfoliative rash		1				1
Haemorrhage subcutaneous		2				2
Hyperhidrosis	5	12	2	9	3	3
Hypersensitivity vasculitis	1	1			1	1
Livedo reticularis		1		1		
Mechanical urticaria	1	1			1	1
Night sweats	1	2	1	2		
Pain of skin	1	3	1	2		1
Petechiae	3	8	1	2	2	6
Pruritus	11	28	5	11	6	17
Psoriasis	1	2		1	1	1
Purpura	1	1			1	1
Rash	10	24	2	12	8	12
Rash erythematous	5	8		2	5	6
Rash macular	2	2	1	1	1	1
Rash maculo-papular	1	1			1	1
Rash papular	1	1	1	1		
Rash pruritic	4	9	4	6		3
Skin discolouration	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin haemorrhage		2		2		
Skin warm	1	1	1	1		
Urticaria	18	29	11	14	7	15
	88	197	33	87	55	110

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden		7		2		5
Immobile		1				1
Impaired driving ability	1	1			1	1
Loss of personal independence in daily activities		2				2
Wa king aid user	1	1	1	1		
	2	12	1	3	1	9

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysm	1	1			1	1
Aortic arteriosclerosis		1		1		
Aortic stenosis		1				1
Arterial haemorrhage		1				1
Brachiocephalic vein thrombosis	1	1			1	1
Circulatory collapse	1	5			1	5
Cyanosis		2				2
Deep vein thrombosis	12	18			12	18
Flushing	3	7	2	5	1	2
Giant cell arteritis		1				1
Haematoma		2				2
Haemorrhage		3				3
Hot flush		1		1		
Hypertension	5	11	2	6	3	5
Hypotension	2	19	1	2	1	17
Inferior vena caval occlusion		1				1
Jugular vein thrombosis	1	1			1	1
Malignant hypertension		2				2
Orthostatic hypotension	1	3		1	1	2
Pallor	2	14	1	5	1	9
Pelvic venous thrombosis	2	2			2	2
Peripheral coldness	1	4	1	3		1
Shock		1				1
Thrombophlebitis	1	4	1	3		1
Thrombophlebitis superficial		3		1		2
Thrombosis	1	2			1	2
Vena cava thrombosis	1	1			1	1
	35	112	8	28	27	84

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

OMAN

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea		1		1
Gastritis		1		1
		2		2

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug ineffective	1	1			1	1
Fatigue		1		1		
Pain		1		1		
Pyrexia		1		1		
Therapeutic response unexpected		1		1		
	1	5		4	1	1

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration		1		1
		1		1

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headache		1		1
		1		1

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product supply issue		1		1
		1		1

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Thrombosis	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
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Country Where Event Occurred
PALESTINIAN TERRITORY, OCCUPIED

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Thirst	1	1	1	1
	1	1	1	1

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dyspnoea	1	1	1	1
	1	1	1	1

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* I=Interval, C=Cumulative
* AE=Adverse Event
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Country Where Event Occurred

PANAMA

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenitis	2	2	2	2
Lymphadenopathy	2	3	2	3
	4	5	4	5

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arrhythmia	1	1			1	1
Bradycardia	1	1			1	1
Palpitations	4	5	4	5		
Tachycardia	5	5	5	5		
	11	12	9	10	2	2

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear pain	1	1	1	1
Tinnitus	1	1	1	1
Vertigo	2	2	2	2
	4	4	4	4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Eye pain	1	1	1	1
Periorbital oedema	1	1	1	1
Photopsia	1	1	1	1
Vision blurred	1	1	1	1
	4	4	4	4

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Diarrhoea	9	9	8	8	1	1
Dysphagia		1		1		
Flatulence		1		1		
Haematochezia	1	1			1	1
Hypoaesthesia oral	2	3	2	2		1
Lip dry		1		1		
Lip oedema	3	3	3	3		
Nausea	10	10	9	9	1	1
Odynophagia	1	1	1	1		
Salivary hypersecretion	1	1	1	1		
Vomiting	5	5	4	4	1	1
	33	37	29	32	4	5

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	16	21	13	18	3	3
Axillary pain	1	1	1	1		
Chest discomfort	3	3	3	3		
Chest pain	5	5	4	4	1	1
Chills	18	19	18	19		
Discomfort	1	1	1	1		
Disease progression	1	1	1	1		
Disease recurrence	1	1			1	1
Drug ineffective	2	2			2	2
Fatigue	7	8	7	8		
Feeling cold	1	1	1	1		
Feeling hot	9	9	8	8	1	1
Gait disturbance		1				1
Influenza like illness		1		1		
Irritability postvaccinal	3	3	2	2	1	1
Local reaction	6	8	4	6	2	2
Malaise	8	9	7	8	1	1
Oedema	3	3	3	3		
Pain	13	13	13	13		
Pyrexia	33	35	31	32	2	3
Vaccination site erythema	3	3	3	3		
Vaccination site oedema	2	2	2	2		
Vaccination site pain	14	18	14	17		1
Vaccination site papule	1	1	1	1		
Vaccination site pruritus	2	2	2	2		
Vaccination site reaction	8	9	8	9		
Vaccination site warmth	1	1	1	1		
	162	181	148	164	14	17

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	11	13	10	12	1	1
Anaphylactic reaction	2	3			2	3
Hypersensitivity	7	9	6	8	1	1
	20	25	16	20	4	5

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	6	6	4	4	2	2
Herpes zoster	1	1	1	1		
Vaccination site cellulitis	1	1	1	1		
	8	8	6	6	2	2

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Incorrect route of product administration	9	10	9	10
Off label use	1	1	1	1
Overdose		1		1
Product use issue	1	1	1	1
	11	13	11	13

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Blood pressure increased	1	1	1	1
	1	1	1	1

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperglycaemia	2	2	1	1	1	1
	2	2	1	1	1	1

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	8	9	8	9		
Back pain	6	6	5	5	1	1
Bone pain	1	1	1	1		
Muscular weakness	1	1			1	1
Musculoskeletal stiffness	1	1	1	1		
Myalgia	11	11	10	10	1	1
Neck pain	3	3	3	3		
Osteitis	1	1	1	1		
Pain in extremity	3	3	3	3		
	35	36	32	33	3	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	2	2	2	2		
Anosmia	2	2	2	2		
Balance disorder	1	1	1	1		
Burning sensation	1	1	1	1		
Dizziness	21	21	19	19	2	2
Dysgeusia	2	2	2	2		
Dyskinesia		1		1		
Guillain-Barre syndrome	1	1			1	1
Headache	47	48	45	46	2	2
Hemiparesis		1				1
Hypoaesthesia	4	4	4	4		
Hypotonia	1	2		1	1	1
Hypotonic-hyporesponsive episode	3	5	1	2	2	3
Migraine		1		1		
Monoparesis	1	1	1	1		
Paraesthesia	8	9	7	7	1	2
Presyncope	5	5	4	4	1	1
Sciatica	1	1	1	1		
Seizure	4	4			4	4
Somnolence	1	1	1	1		
Syncope		3				3
	105	116	91	96	14	20

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation	3	3	3	3		
Confusional state		1		1		
Depressed mood	1	1			1	1
Irritability	1	2		1	1	1
	5	7	3	5	2	2

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Urinary incontinence	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthmatic crisis	1	1			1	1
Bronchospasm	2	2			2	2
Cough	9	9	7	7	2	2
Dry throat		1		1		
Dysphonia	1	1	1	1		
Dyspnoea	7	8	4	4	3	4
Nasal congestion	2	2	2	2		
Nasal oedema	1	1	1	1		
Oropharyngeal pain	4	4	4	4		
Pulmonary pain		1				1
Pulmonary thrombosis	1	1			1	1
Rhinorrhoea	4	4	4	4		
	32	35	23	24	9	11

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	1	1			1	1
Cold sweat	1	1	1	1		
Erythema	3	4	3	4		
Hyperhidrosis	5	5	5	5		
Papule	2	2	2	2		
Photosensitivity reaction		1		1		
Pigmentation disorder	1	1	1	1		
Pruritus	15	15	7	7	8	8
Rash	18	18	11	11	7	7
Rash erythematous		1				1
Rash pruritic		7				7
Urticaria	1	1	1	1		
	47	57	31	33	16	24

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Flushing	1	1	1	1		
Haematoma	1	1	1	1		
Hot flush	1	1	1	1		
Hypertension	8	9	5	6	3	3
Hypertensive crisis	3	3			3	3
Hypertensive emergency	1	1			1	1
Hypotension	3	3	3	3		
Pallor	2	3	1	2	1	1
	20	22	12	14	8	8

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

PERU

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal pain	2	2	2	2
Diarrhoea	1	1	1	1
Nausea	2	2	2	2
Tongue discomfort	1	1	1	1
	6	6	6	6

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Application site acne	1	1	1	1		
Chest discomfort	1	1	1	1		
Chest pain	1	2	1	2		
Chills	2	2	2	2		
Discomfort		2		2		
Drug ineffective	3	4			3	4
Fatigue	2	3	2	3		
General physical health deterioration	1	1			1	1
Hunger	1	1	1	1		
Pain		1		1		
Pyrexia	1	7	1	7		
Vaccination site hypoaesthesia	1	1	1	1		
Vaccination site pain	3	5	3	5		
Vaccination site pruritus	1	1	1	1		
	18	32	14	27	4	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	3		1	1	2
COVID-19 pneumonia	1	1			1	1
Otitis media	1	1	1	1		
Pharyngitis streptococcal	1	1	1	1		
Suspected COVID-19	1	1			1	1
	5	7	2	3	3	4

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposure via breast milk		2		2
Off label use		2		2
Product use issue		2		2
		6		6

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate increased	1	2	1	2		
Oxygen saturation decreased	1	1			1	1
	2	3	1	2	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Food intolerance	1	1	1	1
	1	1	1	1

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	2	1	2
Back pain	2	3	2	3
Pain in extremity	2	4	2	4
	5	9	5	9

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headache	5	10	5	10
Paraesthesia	1	1	1	1
Tremor	1	1	1	1
	7	12	7	12

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory failure	1	1			1	1
Bronchial disorder	1	1			1	1
Dysphonia	1	1	1	1		
Epistaxis		1				1
Nasal dryness		1		1		
Oropharyngeal pain	1	2	1	2		
Pharyngeal inflammation	1	1	1	1		
	5	8	3	5	2	3

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hyperhidrosis		1		1
		1		1

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertension	2	2	1	1	1	1
Hypotension	1	1	1	1		
	3	3	2	2	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

PHILIPPINES

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea	1	1	1	1
	1	1	1	1

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills	1	1	1	1		
Drug ineffective	1	1			1	1
Fatigue	1	1	1	1		
Feeling cold	1	1	1	1		
Gait inability	1	1	1	1		
Pain	4	4	4	4		
Pyrexia	5	5	5	5		
Therapeutic response unexpected	1	1	1	1		
Thirst	1	1	1	1		
Vaccination site discomfort	1	1	1	1		
Vaccination site movement impairment	3	3	3	3		
Vaccination site pain	9	9	9	9		
Vaccination site swelling	1	1	1	1		
	30	30	29	29	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19	1	1			1	1
Sinusitis	1	1	1	1		
	2	2	1	1	1	1

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Blood pressure increased	7	7	7	7
Body temperature increased	1	1	1	1
	8	8	8	8

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	2	2	2	2
Pain in extremity	1	1	1	1
	3	3	3	3

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dizziness	1	1	1	1
Headache	2	2	2	2
Somnolence	1	1	1	1
	4	4	4	4

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	1	1	1	1		
Dyspnoea	2	2	1	1	1	1
Rhinorrhoea	1	1	1	1		
	4	4	3	3	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

POLAND

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia	1	2			1	2
Coagulopathy		2		1		1
Haemorrhagic diathesis		1				1
Hypercoagulation	1	1			1	1
Immune thrombocytopenia	1	1			1	1
Lymphadenopathy	8	71	8	35		36
Lymph node pain	1	41	1	11		30
Thrombocytopenia		1				1
	12	120	9	47	3	73

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	4			1	4
Arrhythmia	3	12			3	12
Atrial fibrillation	3	6			3	6
Atrial flutter		2				2
Bradyarrhythmia		1				1
Bradycardia		2				2
Cardiac arrest	7	18			7	18
Cardiac disorder	1	1	1	1		
Cardiac fibrillation	1	1			1	1
Cardiogenic shock		2				2
Cardiovascular disorder		3		1		2
Coronary artery thrombosis		1				1
Extrasystoles		1				1
Myocardial hypoxia		2				2
Myocardial infarction	2	4			2	4
Myocarditis		1				1
Palpitations	5	13	3	5	2	8
Supraventricular extrasystoles		1				1
Tachyarrhythmia		1				1
Tachycardia	8	37	4	8	4	29
Ventricular extrasystoles		1				1
Ventricular tachycardia	2	2			2	2
	33	116	8	15	25	101

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness	1	3			1	3
Deafness unilateral		1				1
Ear discomfort	1	1	1	1		
Ear pain		1		1		
Ear swelling		1				1
Hyperacusis		1		1		
Hypoacusis	1	1	1	1		
Inner ear disorder	1	1			1	1
Sudden hearing loss		1				1
Tinnitus	5	11	4	9	1	2
Vertigo		6		1		5
	9	28	6	14	3	14

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Goitre		1		1
Thyroiditis		1		1
Thyroid pain		1		1
		3		3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blindness	1	1			1	1
Cataract	1	1			1	1
Conjunctival hyperaemia		3		1		2
Conjunctival pallor		1				1
Episcleritis	1	1			1	1
Eye disorder	1	2	1	2		
Eye irritation	1	1	1	1		
Eyelid oedema		1				1
Eyelids pruritus		1				1
Eye pain	4	15	3	5	1	10
Eye pruritus		1				1
Hypoaesthesia eye		2				2
Iritis	1	2		1	1	1
Lacrimation increased	1	8	1	1		7
Lagophthalmos		1		1		
Ocular hyperaemia	1	2			1	2
Photophobia	6	8	5	6	1	2
Vision blurred	2	3	1	2	1	1
Visual acuity reduced	1	2			1	2
Visual field defect		2		2		
Visual impairment	8	13	6	8	2	5
	29	71	18	30	11	41

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal distension	1	2	1	1		1
Abdominal pain	1	19	1	10		9
Abdominal pain lower		2		1		1
Abdominal pain upper	3	8	2	5	1	3
Anal incontinence		4		1		3
Aphthous ulcer		1		1		
Constipation	1	1	1	1		
Defaecation urgency	1	1	1	1		
Diarrhoea	10	45	9	29	1	16
Dry mouth		3		2		1
Dysphagia		3				3
Epigastric discomfort		1				1
Eructation	1	1	1	1		
Faeces soft		1				1
Flatulence		2		1		1
Gastric disorder	1	1	1	1		
Gastritis	1	1			1	1
Gastrointestinal disorder	1	3		1	1	2
Gastrointestinal haemorrhage		1				1
Gingival swelling		1		1		
Haematemesis		2				2
Hyperaesthesia teeth		1		1		
Hypoaesthesia oral	6	15	5	8	1	7
Lip blister		1				1
Lip pruritus		1				1
Lip swelling	1	3	1	1		2
Melaena		1				1
Nausea	28	88	26	62	2	26
Oesophageal spasm	1	1	1	1		
Pancreatitis acute		2				2
Paraesthesia oral	3	4	3	3		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Retching		1		1		
Swollen tongue	1	4	1	1		3
Tongue oedema		1				1
Toothache		2		1		1
Vomiting	8	45	6	22	2	23
	70	274	61	159	9	115

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse reaction		1		1		
Asthenia	45	196	39	123	6	73
Axillary pain	3	9	2	8	1	1
Cardiac death		1				1
Chest discomfort	2	8	2	7		1
Chest pain	7	16	6	7	1	9
Chills	33	126	32	89	1	37
Condition aggravated		1				1
Crying		1		1		
Death	3	20			3	20
Decreased activity		1		1		
Discomfort		2		2		
Disease progression		1				1
Disease recurrence		2				2
Drug ineffective	24	77			24	77
Exercise tolerance decreased		2		2		
Extensive swelling of vaccinated limb		1		1		
Face oedema	1	3	1	1		2
Facial pain	1	1	1	1		
Fatigue	23	54	22	48	1	6
Feeling abnormal	18	28	17	26	1	2
Feeling cold	2	21	2	12		9
Feeling hot	1	14	1	11		3
Feeling of body temperature change	1	1	1	1		
Feeling of relaxation		1				1
Gait disturbance	2	6	1	4	1	2
Gait inability	2	3	1	1	1	2
General physical health deterioration	2	4			2	4
Hyperpyrexia		2				2
Hypothermia		1				1
Illness	1	2	1	2		
Inflammation		4		3		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Influenza like illness	7	17
Injection site pain		3
Injection site swelling		1
Localised oedema	1	2
Malaise	33	93
Oedema		4
Oedema peripheral	2	6
Pain	8	21
Peripheral swelling	8	13
Pyrexia	72	298
Sensation of foreign body		1
Sluggishness		1
Sudden cardiac death		1
Sudden death		2
Swelling	5	11
Swelling face	2	5
Temperature intolerance		1
Therapeutic response unexpected		4
Thirst		2
Vaccination failure	3	17
Vaccination site abscess sterile		2
Vaccination site discolouration	1	1
Vaccination site discomfort		1
Vaccination site erythema	12	32
Vaccination site extravasation	1	4
Vaccination site haemorrhage	1	1
Vaccination site hypersensitivity	1	3
Vaccination site hypertrophy	1	1
Vaccination site hypoaesthesia	1	1
Vaccination site induration		3
Vaccination site inflammation		1
Vaccination site macule		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
7	16		1
	3		
	1		
1	1		1
25	70	8	23
	1		3
1	2	1	4
7	17	1	4
6	8	2	5
61	176	11	122
			1
			1
			1
			2
4	8	1	3
2	2		3
	1		
	4		
	2		
		3	17
			2
		1	1
			1
10	24	2	8
1	3		1
1	1		
	1	1	2
1	1		
		1	1
	3		
	1		
	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site movement impairment	1	4	1	4		
Vaccination site oedema	1	7	1	4		3
Vaccination site pain	49	160	46	144	3	16
Vaccination site paraesthesia		1		1		
Vaccination site pruritus	1	12	1	12		
Vaccination site rash		1				1
Vaccination site reaction	3	62	2	15	1	47
Vaccination site scab		1		1		
Vaccination site swelling	5	23	3	18	2	5
Vaccination site vesicles		1		1		
Vaccination site warmth	2	8	2	7		1
	392	1,444	312	906	80	538

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic reaction to excipient		2		2		
Allergy to vaccine	1	3	1	1		2
Anaphylactic reaction	1	14			1	14
Anaphylactic shock	1	13			1	13
Decreased immune responsiveness	1	1	1	1		
Drug hypersensitivity		2				2
Hypersensitivity	3	28	1	4	2	24
Immune system disorder	1	1	1	1		
Reaction to excipient	1	2	1	2		
	9	66	5	11	4	55

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abscess	1	1	1	1		
Asymptomatic COVID-19	1	10		1	1	9
COVID-19	40	116	8	16	32	100
COVID-19 pneumonia	1	2			1	2
Cystitis		1		1		
Erysipelas		1				1
Herpes virus infection		3		3		
Herpes zoster	4	5	4	5		
Infection	1	4	1	3		1
Influenza	1	2	1	2		
Labyrinthitis		2				2
Nasopharyngitis	4	7	4	7		
Oral candidiasis		1		1		
Oral herpes	1	2	1	2		
Parotitis		1		1		
Pneumonia	5	13			5	13
Pneumonia viral		2				2
Pulpitis dental		1		1		
Respiratory tract infection		1				1
Rhinitis		3				3
Rotavirus infection	1	1	1	1		
Sepsis		1				1
Sinusitis	1	2	1	2		
Suspected COVID-19	1	5		1	1	4
Vaccination site infection		1		1		
Vestibular neuritis		1		1		
Viral infection		1		1		
	62	190	22	51	40	139

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental exposure to product	1	1	1	1		
Brachial plexus injury		1				1
Circumstance or information capable of leading to medication error		1		1		
Contraindicated product administered	1	1	1	1		
Contusion	3	10	3	4		6
Exposure during pregnancy		4		4		
Exposure via breast milk	1	9	1	9		
Exposure via skin contact	1	1	1	1		
Fall	1	6	1	1		5
Head injury		1				1
Inappropriate schedule of product administration	2	7	2	7		
Incorrect dose administered	2	3	2	3		
Incorrect route of product administration	4	10	4	10		
Joint injury		1				1
Maternal exposure during breast feeding		1		1		
Maternal exposure during pregnancy	1	3	1	3		
Muscle injury		1				1
Nerve injury	1	1	1	1		
Off label use	2	16	2	15		1
Poor quality product administered	1	5	1	5		
Product administered at inappropriate site		1		1		
Product label confusion		2		2		
Product preparation error		1		1		
Product use issue	2	12	2	11		1
Underdose	2	2	2	2		
Vaccination complication		2		2		
Wrong product administered	3	3	3	3		
	28	106	28	89		17

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased		2				2
Antibody test abnormal		10		10		
Aspartate aminotransferase increased		2				2
Basophil count decreased		1		1		
Blood creatine phosphokinase increased		3		1		2
Blood glucose increased	1	3	1	1		2
Blood pressure abnormal	1	4	1	2		2
Blood pressure decreased	2	25		5	2	20
Blood pressure diastolic increased		1				1
Blood pressure increased	10	35	4	7	6	28
Blood smear test abnormal		1		1		
Blood thyroid stimulating hormone decreased		1				1
Blood urine present		1		1		
Body temperature decreased	1	2		1	1	1
Body temperature fluctuation		1		1		
Body temperature increased	11	22	9	15	2	7
Bone density decreased		1		1		
Breath sounds abnormal	1	2			1	2
C-reactive protein increased		4		2		2
Eosinophil count decreased		1		1		
Fibrin D dimer increased		1				1
Grip strength decreased		1		1		
Heart rate abnormal	1	2	1	2		
Heart rate increased	9	21	5	10	4	11
Heart rate irregular	1	1	1	1		
International normalised ratio increased		1		1		
Lymphocyte count decreased		1		1		
Monocyte count decreased		1		1		
Neutrophil count increased		1		1		
Oxygen saturation decreased	2	16	1	4	1	12
PCO2 abnormal		1				1
Prostatic specific antigen increased		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Protein urine present	1	2	1	2		
Pulse abnormal	1	1			1	1
SARS-CoV-2 ant body test negative		1				1
SARS-CoV-2 ant body test positive		1		1		
SARS-CoV-2 test positive	2	3	1	2	1	1
Transaminases increased		1				1
White blood cell count increased	1	2	1	1		1
	45	181	26	78	19	103

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	7	20	7	13		7
Electrolyte imbalance		1		1		
Metabolic acidosis		1				1
Type 2 diabetes mellitus	1	2			1	2
	8	24	7	14	1	10

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	21	102	19	68	2	34
Arthritis		1		1		
Arthropathy	5	7	5	7		
Axillary mass		1		1		
Back pain	7	22	7	20		2
Bone pain	4	22	3	14	1	8
Bursitis		1		1		
Cervical spinal stenosis		1				1
Decreased nasolabial fold		1		1		
Extremity contracture	1	2	1	2		
Intervertebral disc protrusion		1				1
Joint effusion		1		1		
Joint range of motion decreased		2		2		
Joint stiffness	1	2	1	2		
Joint swelling	2	7	1	3	1	4
Limb discomfort	1	2		1	1	1
Mobility decreased	3	4	3	3		1
Muscle disorder	1	1	1	1		
Muscle spasms	1	3	1	3		
Muscle tightness		2		2		
Muscular weakness	5	11	3	5	2	6
Musculoskeletal pain		3		1		2
Musculoskeletal stiffness		4		4		
Myalgia	34	159	31	107	3	52
Neck pain		10		6		4
Pain in extremity	45	121	43	101	2	20
Pain in jaw	1	2	1	2		
Psoriatic arthropathy		1				1
Rhabdomyolysis		1				1
Rheumatic disorder	1	1			1	1
Rheumatoid arthritis	1	1			1	1
Spinal pain	2	7	2	5		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Synovial disorder		1		1		
Systemic lupus erythematosus		1				1
	136	508	122	365	14	143

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bladder cancer		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	2	11	2	9		2
Altered state of consciousness	3	6	1	1	2	5
Amnesia	1	1	1	1		
Anosmia		11		9		2
Aphasia		3		1		2
Balance disorder	4	7	4	6		1
Bell's palsy	1	1			1	1
Brain oedema		1				1
Brain stem stroke		1				1
Brain stem syndrome		1				1
Burning sensation		3		3		
Cerebellar stroke	1	1			1	1
Cerebral disorder	1	1			1	1
Cerebral haematoma		2				2
Cerebral haemorrhage		1				1
Cerebrovascular accident	1	5			1	5
Chorea		1		1		
Cognitive disorder		1		1		
Coma		1				1
Depressed level of consciousness	1	3			1	3
Disturbance in attention	4	10	3	7	1	3
Dizziness	26	72	26	48		24
Dysarthria	1	3	1	1		2
Dysgeusia	3	10	3	5		5
Dyskinesia	1	1	1	1		
Dysstasia	1	2	1	2		
Encephalopathy		2				2
Facial paralysis	2	14			2	14
Febrile convulsion		8				8
Fine motor skill dysfunction	1	1	1	1		
Formication	1	2			1	2
Generalised tonic-clonic seizure		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Guillain-Barre syndrome		1				1
Haemorrhagic stroke	1	2			1	2
Headache	52	188	48	135	4	53
Head discomfort	1	3	1	3		
Hemiparesis		1				1
Hyperaesthesia		7		3		4
Hypoaesthesia	16	48	11	24	5	24
Hypotonia		3				3
Hypotonic-hyporesponsive episode	1	26		4	1	22
Ischaemic stroke		1				1
Lethargy		2		1		1
Loss of consciousness	5	33			5	33
Memory impairment	3	6	3	5		1
Migraine	2	4	2	4		
Monoparesis	1	2			1	2
Monoplegia	1	1			1	1
Motor dysfunction	1	1	1	1		
Movement disorder		3		2		1
Multiple sclerosis relapse		1				1
Neuralgia	3	3	3	3		
Neuritis cranial		1				1
Neuropathy peripheral		1				1
Olfactory nerve disorder	1	1	1	1		
Optic neuritis		1				1
Paraesthesia	7	22	6	14	1	8
Paralysis		2				2
Paraparesis		3				3
Paresis		2		1		1
Parkinsonism	1	1			1	1
Parosmia	1	5	1	3		2
Presyncope	5	13	4	6	1	7
Radicular pain		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Radiculitis brachial		1		1		
Sciatica		2		1		1
Seizure	6	30			6	30
Sensory disturbance	2	5			2	5
Sensory loss	1	1	1	1		
Sinus headache		1				1
Somnolence	9	21	7	15	2	6
Speech disorder	3	12	2	5	1	7
Speech disorder developmental	1	1	1	1		
Spinal cord compression		1				1
Stupor		1				1
Syncope	7	35			7	35
Taste disorder	2	7	2	6		1
Tension headache	1	2	1	2		
Transient ischaemic attack		1				1
Tremor	3	10	2	6	1	4
Trigeminal nerve disorder		1		1		
Trigeminal nerve paresis	1	1			1	1
Trigeminal neuralgia	1	3		1	1	2
Trigeminal neuritis		1				1
Ulnar nerve palsy		1		1		
	194	715	141	349	53	366

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Needle issue		1		1
Product contamination physical		1		1
Product leakage	1	1	1	1
Product supply issue	2	2	2	2
Product temperature excursion issue		1		1
Syringe issue	1	1	1	1
	4	7	4	7

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation		1				1
Anxiety	1	7	1	5		2
Confusional state	4	10	3	5	1	5
Delirium	1	3			1	3
Depressed mood	1	1	1	1		
Derealisation	1	1	1	1		
Disorientation	1	3	1	1		2
Distract bility		1		1		
Eating disorder		1		1		
Fear	1	1			1	1
Hallucination, olfactory		1				1
Helplessness		1				1
Initial insomnia		1		1		
Insomnia	9	18	8	17	1	1
Mental disorder	1	2	1	2		
Middle insomnia		1		1		
Mood altered	1	2	1	2		
Mutism		1		1		
Nervousness	1	3	1	2		1
Nightmare		1		1		
Poor quality sleep		1		1		
Psychological trauma		1		1		
Psychomotor retardation	1	1			1	1
Restlessness		1				1
Sleep disorder	1	2	1	1		1
Stress		1				1
	24	67	19	45	5	22

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury		2				2
Anuria		5				5
Bladder disorder	1	1	1	1		
Chromaturia	1	2	1	1		1
Dysuria	1	1	1	1		
Glomerulonephritis chronic	1	1			1	1
Haematuria		2		1		1
Hydronephrosis		1				1
Myoglobinuria		1				1
Oliguria		1		1		
Pollakiuria	2	2	2	2		
Renal disorder	1	1			1	1
Renal failure	1	3			1	3
Renal pain		1		1		
Urinary incontinence		3				3
Urinary tract inflammation		1				1
	8	28	5	8	3	20

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adnexa uteri pain		1		1		
Breast disorder	1	1	1	1		
Breast enlargement		1		1		
Breast pain		2		1		1
Dysmenorrhoea	1	1	1	1		
Menstrual disorder	3	3	3	3		
Menstruation irregular	1	1	1	1		
Prostatitis		1				1
Suppressed lactation		2		1		1
	6	13	6	10		3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory distress syndrome	1	1			1	1
Acute respiratory failure	1	1			1	1
Allergic respiratory symptom		2				2
Apnoea		2				2
Asphyxia		1				1
Asthma		8				8
Asthmatic crisis		1				1
Bronchial oedema		1				1
Choking		1				1
Choking sensation	1	2	1	1		1
Cough	8	26	7	14	1	12
Dysphonia	1	4		3	1	1
Dyspnoea	15	57	6	16	9	41
Dyspnoea at rest		1				1
Dyspnoea exertional	1	3		1	1	2
Emphysema		1		1		
Epistaxis	1	3	1	3		
Haemoptysis	1	3		1	1	2
Hiccups	1	1	1	1		
Hypopnoea		2				2
Hypoxia		1				1
Increased upper airway secretion		1		1		
Irregular breathing		1				1
Laryngeal oedema		1				1
Laryngeal pain	1	1	1	1		
Laryngospasm		8				8
Lung disorder		2		2		
Lung opacity		1		1		
Nasal congestion		2		1		1
Oropharyngeal pain	1	7	1	5		2
Painful respiration		1		1		
Pharyngeal erythema	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal hypoaesthesia		2				2
Pharyngeal swelling		2		1		1
Pleural effusion		1		1		
Pulmonary calcification		1		1		
Pulmonary congestion		1				1
Pulmonary embolism	1	1			1	1
Pulmonary mass	1	2	1	2		
Pulmonary oedema	1	4			1	4
Pulmonary pain		1				1
Respiration abnormal		1		1		
Respiratory arrest		2				2
Respiratory disorder		2				2
Respiratory failure	2	7			2	7
Respiratory tract oedema		1				1
Rhinorrhoea	1	11	1	9		2
Sinus pain	1	1	1	1		
Suffocation feeling	1	1	1	1		
Tachypnoea		3				3
Throat irritation	1	2		1	1	1
Throat tightness		2		1		1
Tonsillar hypertrophy		1		1		
Tracheal oedema		1				1
Wheezing	1	1	1	1		
	44	199	24	75	20	124

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecia	1	1	1	1		
Angioedema	1	13			1	13
Blister		1				1
Cold sweat	1	2			1	2
Dermatitis allergic	1	2			1	2
Ecchymosis	2	3			2	3
Erythema	7	20	5	9	2	11
Erythema multiforme	1	4			1	4
Haemorrhage subcutaneous		1				1
Hyperhidrosis	7	29	6	19	1	10
Lividity	2	6			2	6
Macule		1				1
Night sweats	2	3	2	3		
Pain of skin	2	4	2	3		1
Petechiae	3	7	1	2	2	5
Pruritus	5	13	5	8		5
Rash	2	17		4	2	13
Rash erythematous	1	4	1	2		2
Rash macular	2	3	1	2	1	1
Rash morbilliform	1	2			1	2
Rash papular	2	6	1	3	1	3
Rash pruritic	2	4	2	4		
Rash rubelliform	1	3			1	3
Rash vesicular		2				2
Skin disorder	1	1	1	1		
Skin exfoliation		1				1
Skin hypertrophy		1		1		
Skin lesion	1	2	1	1		1
Skin mass		1		1		
Skin warm	1	1			1	1
Urticaria	2	14	1	4	1	10
Yellow skin	1	2	1	1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	52	174	31	69	21	105

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Illiteracy		1				1
Loss of personal independence in daily activities	1	1	1	1		
Wa king disability		2		1		1
	1	4	1	2		2

System Organ Class

SOC Not Yet Coded

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angiopathy		1				1
Aortic aneurysm rupture		1				1
Arterial thrombosis	1	1			1	1
Arteriosclerosis		2		1		1
Bleeding varicose vein		1				1
Blood pressure fluctuation	2	4	1	1	1	3
Circulatory collapse	1	2			1	2
Cyanosis		4				4
Deep vein thrombosis	1	1			1	1
Embolism arterial	1	1			1	1
Embolism venous	1	1			1	1
Essential hypertension		1				1
Flushing		3		2		1
Haematoma		1		1		
Hot flush	1	5	1	4		1
Hypertension	3	10		1	3	9
Hypotension	1	6	1	2		4
Lymphoedema	1	1	1	1		
Pallor	2	12	1	2	1	10
Peripheral coldness	1	3	1	2		1
Phlebitis		1		1		
Shock		1				1
Shock symptom		1				1
Subclavian vein thrombosis		1				1
Thrombophlebitis	1	2	1	2		
Thrombophlebitis superficial	2	2	1	1	1	1
Thrombosis	4	12			4	12
Vein discolouration	1	1	1	1		
Vein disorder		1		1		
Venous thrombosis		1				1
	24	84	9	23	15	61

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

PORTUGAL

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia		1		1		
Leukaemoid reaction		1				1
Leukocytosis		1				1
Lymphadenitis	2	14	1	6	1	8
Lymphadenopathy	49	285	35	73	14	212
Lymph node pain	3	6	3	3		3
Myelosuppression		1				1
Necrotic lymphadenopathy		1				1
Neutrophilia		1				1
Pancytopenia		1				1
Thrombocytopenia		1				1
Thrombocytopenic purpura	1	1			1	1
Thrombotic microangiopathy		1				1
	55	315	39	83	16	232

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction		4				4
Angina pectoris		1				1
Arrhythmia	5	11			5	11
Atrial fibrillation	1	3			1	3
Atrioventricular block complete		2				2
Atrioventricular block second degree	1	1			1	1
Bradycardia	2	11			2	11
Cardiac disorder		1				1
Cardiac failure		1				1
Cardio-respiratory arrest	1	6			1	6
Extrasystoles	1	3		1	1	2
Myocardial infarction		1				1
Myocarditis		2				2
Palpitations	7	27	3	7	4	20
Pericardial effusion		1				1
Pericarditis	1	2			1	2
Postural orthostatic tachycardia syndrome		1				1
Sinus tachycardia		2				2
Supraventricular extrasystoles	1	1			1	1
Tachyarrhythmia		3				3
Tachycardia	16	80	11	24	5	56
Ventricular extrasystoles	1	2	1	1		1
	37	166	15	33	22	133

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autophony		1				1
Deafness		1				1
Deafness neurosensory	1	2			1	2
Deafness transitory		1				1
Deafness unilateral	1	3			1	3
Ear congestion	1	1			1	1
Ear pain	2	7	1	2	1	5
Hypoacusis	1	4			1	4
Paraesthesia ear	1	1			1	1
Sudden hearing loss		2				2
Tinnitus	3	9	1	2	2	7
Vertigo	12	31	5	8	7	23
Vertigo positional		1				1
	22	64	7	12	15	52

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypothyroidism		1		1
Thyroiditis		1		1
Thyroid mass		1		1
		3		3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenopia		1				1
Blepharospasm	1	1	1	1		
Blindness		2				2
Blindness unilateral	2	3			2	3
Choroiditis		1				1
Conjunctival haemorrhage		1				1
Conjunctival irritation		1				1
Corneal degeneration		1				1
Corneal opacity		1				1
Diplopia	2	3		1	2	2
Dry eye		1		1		
Episcleritis		1				1
Exophthalmos		1				1
Eye disorder	1	3		1	1	2
Eye haemorrhage	2	2			2	2
Eye irritation		5		4		1
Eyelid myokymia		1				1
Eyelid oedema	1	5			1	5
Eyelid sensory disorder		1		1		
Eyelids pruritus	1	1			1	1
Eye movement disorder		1				1
Eye pain	3	6	2	5	1	1
Eye paraesthesia		1				1
Eye pruritus	1	2	1	1		1
Eye swelling	1	2			1	2
Lacrimation increased		1				1
Ocular discomfort		2		2		
Ocular hyperaemia	1	3	1	1		2
Ophthalmic artery thrombosis	1	1			1	1
Photophobia		6		2		4
Retinal artery occlusion	1	1			1	1
Retinal haemorrhage		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling of eyelid	2	2	1	1	1	1
Vision blurred	7	15	3	7	4	8
Visual acuity reduced	1	2		1	1	1
Visual impairment	3	7	1	1	2	6
Vitreous floaters		1				1
	31	90	10	30	21	60

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	11	2	5		6
Abdominal distension		1				1
Abdominal pain	9	39	5	11	4	28
Abdominal pain lower		1				1
Abdominal pain upper	4	18	2	6	2	12
Abdominal symptom	1	1	1	1		
Abnormal faeces		1				1
Aphthous ulcer		4		1		3
Chapped lips	1	1	1	1		
Cheilitis		1		1		
Constipation		1				1
Crohn's disease		1				1
Diarrhoea	25	120	16	38	9	82
Dry mouth	2	10	2	4		6
Dyspepsia		5		1		4
Dysphagia		11		1		10
Eructation		2		2		
Faeces soft		1				1
Flatulence		3		1		2
Functional gastrointestinal disorder		3				3
Gastric disorder		1				1
Gastrointestinal disorder	4	4	2	2	2	2
Gastrointestinal pain		1				1
Glossodynia		2		2		
Hypoaesthesia oral	2	17	1	6	1	11
Intestinal obstruction	1	1			1	1
Lip erythema	1	1			1	1
Lip oedema	2	15		1	2	14
Lip pruritus		1				1
Lip swelling		3				3
Nausea	76	335	46	101	30	234
Odynophagia	4	22	2	6	2	16

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oedema mouth		3				3
Oesophageal disorder		1				1
Oesophageal pain		1				1
Oral discomfort	1	3	1	3		
Oral disorder		1				1
Oral pain		1				1
Palatal disorder		1				1
Pancreatitis		1				1
Paraesthesia oral	5	27	4	9	1	18
Salivary hypersecretion		2		2		
Stiff tongue		1				1
Stomatitis		3		2		1
Swollen tongue	1	1			1	1
Terminal ileitis		1				1
Tongue coated		1				1
Tongue discomfort	1	3			1	3
Tongue disorder		2		1		1
Tongue dry		3		1		2
Tongue eruption		2				2
Tongue oedema		17		3		14
Tongue pruritus		1				1
Tongue rough		1		1		
Trichoglossia		1		1		
Upper gastrointestinal haemorrhage		1				1
Vomiting	27	103	16	25	11	78
	169	820	101	239	68	581

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site bruise		1		1		
Administration site swelling		2		2		
Administration site warmth		1		1		
Application site hyperaesthesia	1	1	1	1		
Asthenia	23	173	17	39	6	134
Axillary pain	11	45	9	18	2	27
Chest discomfort	3	17	2	6	1	11
Chest pain	8	39	4	7	4	32
Chills	48	265	39	75	9	190
Condition aggravated	3	13	2	5	1	8
Crying		2		1		1
Death	1	9			1	9
Discomfort	8	15	7	9	1	6
Disease recurrence	1	2			1	2
Drug ineffective	4	73			4	73
Drug interaction		2				2
Face oedema	6	30	2	6	4	24
Facial pain	2	2	1	1	1	1
Fatigue	53	282	42	81	11	201
Feeling abnormal		2		1		1
Feeling cold	4	20	2	5	2	15
Feeling hot	14	43	10	18	4	25
Feeling of body temperature change		1				1
Foreign body reaction	1	1			1	1
Gait disturbance		2				2
Gait inability	1	5	1	3		2
General symptom		1				1
Hyperthermia	2	15	1	4	1	11
Hypothermia		3				3
Illness		1		1		
Inflammation		4				4
Influenza like illness	1	3	1	2		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injected limb mobility decreased		2		1		1
Injection site erythema		2		2		
Injection site pain	1	5	1	5		
Injection site swelling	1	1	1	1		
Localised oedema	3	10	2	3	1	7
Malaise	23	135	18	46	5	89
Moaning	1	1			1	1
Nodule	1	2	1	2		
Non-cardiac chest pain		1		1		
Oedema	1	10	1	3		7
Oedema mucosal		1				1
Oedema peripheral	7	23	1	5	6	18
Pain	25	94	18	35	7	59
Peripheral swelling	1	8		2	1	6
Puncture site haematoma		1				1
Pyrexia	121	619	102	185	19	434
Sensation of foreign body		2		1		1
Sluggishness	1	1	1	1		
Sudden cardiac death		1				1
Sudden death	1	1			1	1
Swelling	2	15	1	4	1	11
Swelling face	2	3			2	3
Systemic inflammatory response syndrome		1				1
Tenderness	1	1	1	1		
Vaccination failure	7	64			7	64
Vaccination site discolouration		1				1
Vaccination site discomfort		3		2		1
Vaccination site eczema		2		1		1
Vaccination site erythema	19	88	17	38	2	50
Vaccination site haematoma		6		3		3
Vaccination site haemorrhage		1		1		
Vaccination site hypersensitivity	1	1	1	1		

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* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site hypoaesthesia		1				1
Vaccination site induration	9	21	9	12		9
Vaccination site inflammation	1	17	1	4		13
Vaccination site injury		1				1
Vaccination site joint inflammation		1				1
Vaccination site joint movement impairment	1	4	1	1		3
Vaccination site joint pain		1				1
Vaccination site lymphadenopathy	1	3	1	1		2
Vaccination site mass	1	1	1	1		
Vaccination site movement impairment	3	9	1	2	2	7
Vaccination site nodule	2	3	2	3		
Vaccination site oedema	24	102	22	44	2	58
Vaccination site pain	161	679	142	362	19	317
Vaccination site paraesthesia	1	4	1	3		1
Vaccination site pruritus	5	34	5	12		22
Vaccination site rash	2	8	2	4		4
Vaccination site reaction		8		4		4
Vaccination site swelling	11	43	10	17	1	26
Vaccination site urticaria		1				1
Vaccination site warmth	12	33	10	18	2	15
	648	3,155	515	1119	133	2036

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* AE=Adverse Event
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System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholangitis		1				1
Cholestasis		1				1
Drug-induced liver injury		1				1
Hepatic mass	1	1	1	1		
Hepatitis		1				1
Jaundice	1	2			1	2
Liver injury	1	1			1	1
	3	8	1	1	2	7

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		3				3
Anaphylactic reaction	6	28			6	28
Anaphylactic shock		2				2
Anaphylactoid reaction		2				2
Anti-neutrophil cytoplasmic antibody positive vasculitis	1	1			1	1
Drug hypersensitivity		1				1
Hypersensitivity	3	16		4	3	12
Immune system disorder		1		1		
	10	54		5	10	49

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adenopathy syphilitic		2				2
Asymptomatic COVID-19	1	31		2	1	29
Bacterial infection		1				1
COVID-19	43	191	37	70	6	121
COVID-19 pneumonia	1	5			1	5
Escherichia bacteraemia		1				1
Gonorrhoea		1				1
Herpes zoster	6	8	2	3	4	5
Herpes zoster cutaneous disseminated	1	1			1	1
Impetigo		1				1
Influenza		7		1		6
Mastitis	1	3			1	3
Meningitis viral		1				1
Myelitis		1				1
Nasopharyngitis	2	3	2	2		1
Ophthalmic herpes simplex		1				1
Oral candidiasis		2				2
Oral herpes	2	4	2	2		2
Pharyngitis		1				1
Pneumonia	2	4			2	4
Pyelonephritis		1				1
Respiratory tract infection		1				1
Rhinitis		2		1		1
Sepsis		1				1
Sinusitis		2		2		
Suspected COVID-19	1	1	1	1		
Tonsillitis		1				1
Tonsillitis bacterial		1				1
Tooth abscess		1		1		
Urinary tract infection	1	7	1	1		6
Urinary tract infection bacterial		1				1
Vaccination site abscess		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site cellulitis	1	1	1	1		
Varicella		1				1
Vestibular neuronitis	1	1	1	1		
	63	292	47	89	16	203

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* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chillblains		1		1		
Contraindicated product administered		1		1		
Contusion	2	3			2	3
Exposure during pregnancy	2	11	2	10		1
Exposure to SARS-CoV-2		1				1
Exposure via breast milk	3	13	3	13		
Fall	2	6	1	3	1	3
Head injury		1				1
Inappropriate schedule of product administration	3	9	3	8		1
Incomplete course of vaccination	1	1	1	1		
Incorrect dose administered	1	3	1	3		
Incorrect route of product administration	6	25	6	25		
Maternal exposure during pregnancy	2	7	2	7		
Occupational exposure to SARS-CoV-2		1		1		
Off label use	6	21	6	21		
Overdose	19	42	18	40	1	2
Patella fracture		1				1
Procedural haemorrhage		1				1
Procedural nausea		1				1
Product administered at inappropriate site	2	4	2	4		
Product preparation issue	1	1	1	1		
Product use issue	4	17	4	17		
Scar		1		1		
Underdose	1	1	1	1		
Vaccination complication	1	5	1	2		3
Wound		1		1		
	56	179	52	161	4	18

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amylase increased		1				1
Blood creatinine increased	1	1	1	1		
Blood glucose fluctuation		1		1		
Blood glucose increased		1				1
Blood potassium decreased	1	1			1	1
Blood pressure decreased		2				2
Blood pressure diastolic decreased		1		1		
Blood pressure diastolic increased		1				1
Blood pressure increased	6	15	2	3	4	12
Blood pressure systolic increased		1		1		
Blood thyroid stimulating hormone increased		1				1
Body temperature abnormal		1				1
Body temperature decreased		1				1
Body temperature increased	1	8	1	3		5
Computerised tomogram thorax abnormal		1		1		
Dermatologic examination abnormal	1	1			1	1
Electrocardiogram ST segment depression	1	1	1	1		
Fibrin D dimer increased		2		2		
Haemoglobin decreased	1	1	1	1		
Heart rate decreased	1	2			1	2
Heart rate increased	6	11	5	6	1	5
Inspiratory capacity decreased		2				2
International normalised ratio decreased		1		1		
International normalised ratio increased		1				1
Lipase increased		1				1
Liver function test abnormal	1	1			1	1
Lymph node palpable		2		1		1
Magnetic resonance imaging head abnormal		1		1		
Monocyte count increased		1		1		
Oxygen saturation decreased	2	14			2	14
Platelet count increased		1		1		
PO2 decreased		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
SARS-CoV-2 test positive	8	17	6	6	2	11
Thyroid function test abnormal		1		1		
Transaminases increased		1				1
Weight decreased		1		1		
White blood cell count increased	1	1	1	1		
	31	102	18	35	13	67

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acidosis		1				1
Decreased appetite	6	41	2	7	4	34
Food refusal		1				1
Hyperglycaemia		5		1		4
Hyperlactacidaemia		1				1
Hypoglycaemia	3	6	1	1	2	5
Hypokalaemia		3				3
Polydipsia		5				5
	9	63	3	9	6	54

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	56	250	44	62	12	188
Arthritis		1				1
Arthritis reactive		1				1
Axillary mass	1	2			1	2
Back pain	8	30	5	8	3	22
Bone pain		2		1		1
Bursitis		1				1
Facial asymmetry		1				1
Groin pain		1				1
Joint microhaemorrhage	1	1			1	1
Joint range of motion decreased		5		1		4
Joint swelling		2				2
Limb discomfort	2	6		2	2	4
Limb mass		1		1		
Mobility decreased	2	10	1	4	1	6
Muscle fatigue		5		2		3
Muscle rigidity		1				1
Muscle spasms		3		1		2
Muscle tightness		1				1
Muscle twitching		1				1
Muscular weakness	7	22	4	5	3	17
Musculoskeletal discomfort		1				1
Musculoskeletal disorder	1	3	1	1		2
Musculoskeletal pain	2	2	2	2		
Musculoskeletal stiffness	2	7	1	1	1	6
Myalgia	191	884	165	289	26	595
Myalgia intercostal		1				1
Neck mass		1		1		
Neck pain	9	21	6	10	3	11
Pain in extremity	18	90	13	35	5	55
Pain in jaw	1	2	1	1		1
Posture abnormal	2	2			2	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rhabdomyolysis	1	2			1	2
Soft tissue haemorrhage		1		1		
Spinal pain		1				1
Synovial cyst	3	12	3	3		9
Tenosynovitis		1		1		
Trismus		1				1
	307	1,379	246	432	61	947

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Lymphoproliferative disorder		1		1
Meningioma		1		1
		2		2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	2	4	2	2		2
Allodynia		1				1
Altered state of consciousness		2				2
Amnesia		1		1		
Anosmia	3	6	3	3		3
Aphasia	1	2			1	2
Ataxia	1	1			1	1
Aura		1		1		
Autonomic nervous system imbalance		1				1
Balance disorder	4	9	2	2	2	7
Bell's palsy	2	5			2	5
Burning sensation	1	8	1	2		6
Cerebral artery occlusion	1	1			1	1
Cerebral artery thrombosis	1	1			1	1
Cerebral infarction	2	2			2	2
Cerebral thrombosis	1	1			1	1
Cerebral venous sinus thrombosis		2				2
Cerebrovascular accident	9	17			9	17
Cholinergic syndrome		1				1
Conus medullaris syndrome		1				1
Coordination abnormal	2	2	1	1	1	1
Depressed level of consciousness	1	2			1	2
Disturbance in attention	1	2	1	1		1
Dizziness	38	177	22	52	16	125
Dizziness postural		2				2
Drooling		1		1		
Dysarthria	1	6		1	1	5
Dysgeusia	5	29	4	18	1	11
Dyskinesia		1				1
Dyslexia		1				1
Dysstasia		1				1
Dystonia	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Electric shock sensation	1	1			1	1
Embolic stroke	1	2			1	2
Extrapyramidal disorder		1				1
Facial nerve disorder		1				1
Facial paralysis	1	8			1	8
Facial paresis	1	3			1	3
Facial spasm		2		1		1
Febrile convulsion		1				1
Generalised tonic-clonic seizure	1	4			1	4
Haemorrhagic stroke	3	3			3	3
Haemorrhagic transformation stroke		1				1
Headache	168	769	139	262	29	507
Head discomfort	2	6	1	2	1	4
Hemianaesthesia		1				1
Hemidysaesthesia		1				1
Hemiparaesthesia		2				2
Hemiparesis	1	2			1	2
Hemiplegia		1				1
Hydrocephalus		1				1
Hyperaesthesia	2	4	1	1	1	3
Hypoaesthesia	11	30	1	9	10	21
Hypokinesia	2	2	2	2		
Hyposmia		1				1
Hypotonic-hyporesponsive episode		1				1
Infant irritability		1		1		
Intercostal neuralgia		1				1
Ischaemic stroke	7	11			7	11
Lacunar stroke		2				2
Lethargy		4		1		3
Loss of consciousness	1	4			1	4
Migraine		9		3		6
Motor dysfunction		4				4

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Movement disorder	2	6	1	3	1	3
Muscle contractions involuntary	1	4		1	1	3
Myoclonus	2	5	2	2		3
Neuralgia		1				1
Neurological symptom	1	1	1	1		
Neuropathy peripheral		2				2
Nystagmus		4				4
Orthostatic intolerance	1	1			1	1
Paraesthesia	25	114	19	46	6	68
Paralysis	1	3			1	3
Parkinson's disease	1	1			1	1
Parosmia	1	1			1	1
Peripheral nerve lesion	1	1	1	1		
Presyncope	11	51	7	17	4	34
Sciatica		1				1
Seizure	1	9			1	9
Sensory disturbance		1				1
Sensory loss		7		2		5
Somnolence	15	87	11	44	4	43
Speech disorder		4		1		3
Status epilepticus		1				1
Stroke in evolution		1				1
Syncope	3	31			3	31
Taste disorder	1	10	1	3		7
Tension headache	1	3	1	2		1
Tongue paralysis	1	1			1	1
Tonic clonic movements		1				1
Transient ischaemic attack	1	2			1	2
Tremor	8	52	5	12	3	40
Trigeminal neuralgia		1		1		
Trigeminal palsy		1				1
Vertebral artery occlusion	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	358	1,585	229	503	129	1082

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion	1	1	1	1
Abortion spontaneous	1	3	1	3
	2	4	2	4

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation		2				2
Anxiety	4	15	3	9	1	6
Apathy		1				1
Behaviour disorder	1	1			1	1
Bradyphrenia	1	3			1	3
Confusional state	2	4	2	2		2
Depressed mood		1				1
Disorientation	1	4		1	1	3
Emotional distress	1	1			1	1
Fear of injection	1	1			1	1
Hallucination		1				1
Insomnia	9	34	7	14	2	20
Irritability		1		1		
L bido decreased		1		1		
Mental fatigue		1				1
Mood altered		1				1
Nervousness		2				2
Phonophobia		1				1
Poor quality sleep		2				2
Restlessness		1		1		
Sleep disorder	1	6	1	1		5
	21	84	13	30	8	54

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury		2				2
Bladder disorder		1				1
Chronic kidney disease		1				1
Dysuria		1				1
Haemoglobinuria		1				1
Leukocyturia		1		1		
Oliguria		2		1		1
Proteinuria		1		1		
Renal colic		1				1
Renal pain	1	1			1	1
Renal tubular necrosis		1				1
	1	13		3	1	10

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amenorrhoea		1		1		
Breast discomfort		1				1
Breast pain		5		2		3
Breast swelling		3		2		1
Gynaecomastia		1				1
Intermenstrual bleeding	1	2	1	1		1
Menstrual disorder		1		1		
Nipple disorder		1		1		
Perineal pain		1				1
Suppressed lactation		1		1		
Vaginal haemorrhage		2				2
Vulvovaginal burning sensation		2		1		1
Vulvovaginal swelling		1				1
	1	22	1	10		12

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute pulmonary oedema		1				1
Aphonia		1				1
Apnoea		1				1
Atelectasis		1		1		
Bradypnoea		1				1
Bronchial hyperreactivity	1	1			1	1
Bronchospasm		7				7
Choking sensation		1				1
Cough	13	67	8	18	5	49
Dry throat		2		1		1
Dysphonia	2	11	1	3	1	8
Dyspnoea	12	58	6	12	6	46
Dyspnoea at rest		3				3
Dyspnoea exertional	1	3			1	3
Epistaxis	1	9		4	1	5
Haemoptysis		1				1
Hyperventilation		1				1
Hypopnoea		1				1
Hypoxia	1	1			1	1
Laryngeal oedema	2	15			2	15
Lung infiltration		1				1
Nasal congestion	3	9	1	2	2	7
Nasal discomfort		1		1		
Nasal dryness		1		1		
Nasal obstruction	1	2	1	1		1
Nasal oedema		1		1		
Oropharyngeal discomfort	1	19	1	8		11
Oropharyngeal oedema	1	3		1	1	2
Oropharyngeal pain	7	22	6	10	1	12
Orthopnoea		2				2
Painful respiration		1				1
Pharyngeal cyst		2				2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal erythema		1				1
Pharyngeal hypoaesthesia		3		1		2
Pharyngeal inflammation		2		1		1
Pharyngeal oedema		1				1
Pharyngeal paraesthesia		5				5
Pharyngeal swelling	1	2			1	2
Pleuritic pain		2				2
Pneumonia aspiration		2				2
Productive cough	1	4	1	1		3
Pulmonary embolism	7	11			7	11
Respiratory disorder		1				1
Respiratory distress		3				3
Respiratory failure		1				1
Respiratory tract congestion		1				1
Rhinalgia		1		1		
Rhinorrhoea	10	33	9	17	1	16
Sneezing	1	4	1	2		2
Suffocation feeling	1	1			1	1
Tachypnoea	1	4	1	1		3
Throat irritation	4	17	3	8	1	9
Throat tightness	2	11	1	2	1	9
Tonsillar hypertrophy		1				1
Tonsillar inflammation		1		1		
Upper-airway cough syndrome		1				1
Wheezing		5		1		4
	74	368	40	100	34	268

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne		1				1
Alopecia	1	1	1	1		
Angioedema	1	12			1	12
Blister	1	1	1	1		
Circumoral oedema		1				1
Cold sweat	1	5			1	5
Cutaneous vasculitis	1	2			1	2
Dermatitis	1	1			1	1
Dermatitis allergic	1	2			1	2
Dermatitis bullous	1	1			1	1
Dermatitis exfoliative	2	3			2	3
Dermatitis exfoliative generalised		1				1
Drug reaction with eosinophilia and systemic symptoms	1	1			1	1
Dry skin		1				1
Ecchymosis	3	4	1	1	2	3
Eczema		2				2
Erythema	12	45	7	16	5	29
Erythema nodosum		1				1
Hyperhidrosis	10	40	5	11	5	29
Macule	1	2			1	2
Miliaria	1	1	1	1		
Nail pigmentation	1	1			1	1
Night sweats		3				3
Palmar-plantar erythrodysesthesia syndrome		1				1
Papule	4	4	3	3	1	1
Perioral dermatitis	1	1			1	1
Petechiae	3	5	2	2	1	3
Pigmentation disorder	1	1	1	1		
Piloerection		4				4
Pityriasis rosea		2				2
Pruritus	17	64	12	21	5	43

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Purpura	3	8	1	2	2	6
Rash	12	86	5	23	7	63
Rash erythematous	3	8	2	5	1	3
Rash macular	1	14	1	2		12
Rash maculo-papular		7		2		5
Rash maculovesicular	1	1			1	1
Rash papular		4		2		2
Rash pruritic	2	13	2	8		5
Rash vesicular		1				1
Sensitive skin		2		1		1
Skin burning sensation		2				2
Skin exfoliation		2				2
Skin lesion	1	3			1	3
Skin reaction		2				2
Skin warm	1	8	1	2		6
Telangiectasia	1	1			1	1
Urticaria	11	29	6	9	5	20
Urticaria cholinergic		2		2		
Urticaria papular		1				1
	101	408	52	116	49	292

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aborted pregnancy		1				1
Bedridden		2				2
Impaired work ability		2		1		1
Loss of personal independence in daily activities		5				5
		10		1		9

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Surgical and medical procedures

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Axillary lymphadenectomy		1		1
		1		1

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arteriosclerosis		1		1		
Blood pressure fluctuation		1				1
Cyanosis		2				2
Deep vein thrombosis	6	9			6	9
Diastolic hypertension		1				1
Embolism	1	2			1	2
Embolism venous	1	3			1	3
Flushing	2	20	1	6	1	14
Haematoma	6	10	1	2	5	8
Hot flush	1	5	1	1		4
Hyperaemia		1				1
Hypertension	7	46	1	5	6	41
Hypertensive crisis	4	9			4	9
Hypoperfusion		1				1
Hypotension	7	33	3	4	4	29
Lymphoedema		1				1
Pallor	4	17	1	3	3	14
Peripheral artery occlusion		1				1
Peripheral artery stenosis		1				1
Peripheral coldness	1	6			1	6
Phlebitis	2	3			2	3
Shock		1				1
Takayasu's arteritis		1				1
Thrombophlebitis	2	5	1	1	1	4
Thrombophlebitis superficial	1	1			1	1
Thrombosis	2	4			2	4
Vasculitis	2	4			2	4
Venous occlusion	1	1			1	1
Venous thrombosis	1	1			1	1
	51	191	9	23	42	168

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

PUERTO RICO

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenitis		1		1
Lymphadenopathy	1	8	1	8
	1	9	1	9

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Palpitations		1		1		
Sinus arrhythmia		1				1
Tachycardia		3		3		
		5		4		1

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Blepharospasm		1		1
Eyelid oedema	1	1	1	1
Photophobia		2		2
	1	4	1	4

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal discomfort		4		4
Abdominal pain	1	3	1	3
Diarrhoea	1	4	1	4
Dry mouth		1		1
Dyspepsia		1		1
Flatulence		1		1
Gingival bleeding		1		1
Nausea	1	8	1	8
Oral discomfort		1		1
	3	24	3	24

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		2		2		
Axillary pain		1		1		
Chest discomfort	1	2		1	1	1
Chest pain	1	3		2	1	1
Chills	1	8	1	8		
Death		1				1
Discomfort		1		1		
Face oedema	1	1	1	1		
Facial pain		1		1		
Fatigue	1	17	1	17		
Feeling cold		1				1
Gait disturbance		1		1		
Illness		1				1
Inflammation		1		1		
Malaise		1		1		
Nodule		1		1		
Oedema	1	1	1	1		
Pain		6		6		
Peripheral swelling		3		3		
Pyrexia	1	19	1	19		
Sensation of blood flow	1	1	1	1		
Swelling		1		1		
Swelling face		4		4		
Thirst		1		1		
Vaccination site discomfort		1		1		
Vaccination site erythema		1		1		
Vaccination site induration	1	2	1	2		
Vaccination site inflammation		1		1		
Vaccination site pain		7		7		
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	1	6	1	6		
Vaccination site warmth	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	12	99	10	94	2	5

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19		1		1		
Herpes zoster		1		1		
Oral herpes		1		1		
Pneumonia		1				1
Urinary tract infection		1				1
		5		3		2

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Contraindicated product administered	1	1	1	1
Inappropriate schedule of product administration		3		3
Maternal exposure during pregnancy		1		1
Off label use		1		1
Poor quality product administered		10		10
Product administered at inappropriate site		1		1
Product dose omission issue	1	1	1	1
	2	18	2	18

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Antibody test abnormal		1		1		
Antinuclear ant body positive		1		1		
Blood pressure increased		1		1		
Blood test abnormal		1		1		
Heart rate decreased		1				1
Heart rate increased		1		1		
Red blood cell sedimentation rate increased		1		1		
		7		6		1

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite		1		1
Dehydration		1		1
		2		2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	9	1	9		
Back pain		1		1		
Bone disorder		1		1		
Bone pain		1		1		
Joint range of motion decreased		1		1		
Joint swelling		2		2		
Limb discomfort		2		2		
Muscle spasms	2	4		2	2	2
Muscular weakness	1	1			1	1
Musculoskeletal discomfort		1		1		
Musculoskeletal stiffness		1		1		
Myalgia	1	11	1	11		
Neck pain	1	2	1	2		
Pain in extremity	1	10	1	10		
	7	47	4	44	3	3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Balance disorder		1		1		
Burning sensation		3		3		
Cerebrovascular accident		1				1
Dizziness		5		4		1
Dizziness postural		1		1		
Dysgeusia		1		1		
Dyskinesia		1				1
Electric shock sensation		1		1		
Facial paralysis	1	4			1	4
Headache	3	25	2	24	1	1
Head discomfort		1		1		
Hypoaesthesia	1	9		7	1	2
Migraine		1				1
Movement disorder		1		1		
Neuralgia		1		1		
Paraesthesia	3	5	1	3	2	2
Somnolence		3		3		
Speech disorder		1		1		
Syncope	1	1			1	1
Taste disorder		2		2		
	9	68	3	54	6	14

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Depression		1		1
Insomnia		1		1
Sleep disorder		1		1
Stress		1		1
		4		4

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vaginal haemorrhage	1	1	1	1
	1	1	1	1

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysphonia		1		1		
Dyspnoea	1	3	1	2		1
Oropharyngeal pain	1	1	1	1		
Pharyngeal swelling	1	1			1	1
Productive cough		1		1		
Rhinorrhoea		1		1		
	3	8	2	6	1	2

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermatitis		1		1		
Erythema		3		3		
Hyperhidrosis		1				1
Night sweats		1				1
Pruritus		2		2		
Rash		5		5		
Urticaria		1		1		
		14		12		2

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Loss of personal independence in daily activities		2		2
		2		2

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deep vein thrombosis		1				1
Flushing		2		2		
Haematoma		1		1		
Hot flush	1	1			1	1
Hypertension	1	4	1	3		1
Hypotension	1	1			1	1
Thrombosis		1				1
	3	11	1	6	2	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

QATAR

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia	1	3		1	1	2
	1	3		1	1	2

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Vertigo		1		1
		1		1

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Ocular hyperaemia		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspepsia		2		2		
Nausea		1				1
		3		2		1

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		2		1		1
Drug ineffective		1				1
Feeling cold		1		1		
Feeling hot		1				1
Gait disturbance		1		1		
Pyrexia	1	3		1	1	2
Vaccination failure		1				1
	1	10		4	1	6

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic shock		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19		3		1		2
Herpes zoster		2		2		
Rhinovirus infection		1				1
		6		3		3

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposure during pregnancy		1		1
Overdose		1		1
Product preparation error		1		1
Product use issue		1		1
		4		4

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased		1		1		
C-reactive protein increased		1				1
Heart rate decreased		1		1		
Heart rate increased		1		1		
Inflammatory marker increased		1				1
Neutrophil count increased		1				1
Platelet count increased		1				1
Pulse abnormal	1	1			1	1
Red blood cell sedimentation rate increased		1				1
White blood cell count increased		1				1
	1	10		3	1	7

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Starvation		1		1
		1		1

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Back pain		1				1
Myalgia		1		1		
Neck pain		1				1
Pain in extremity		1				1
		4		1		3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbance in attention		1		1		
Dizziness		2				2
Dysgeusia		1		1		
Facial paralysis		1				1
Headache		2		2		
Muscle spasticity		1				1
Neuralgia		1		1		
Presyncope		1				1
Syncope		1				1
		11		5		6

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Confusional state		1		1
Depressed mood		1		1
Middle insomnia		1		1
Mood altered		1		1
Sleep disorder		1		1
		5		5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Sexual dysfunction	1	1	1	1
	1	1	1	1

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cough		1		1
Dyspnoea	1	2	1	2
	1	3	1	3

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema		2		1		1
Hyperhidrosis		1				1
Rash		1				1
		4		1		3

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* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypertension		1		1
Hypotension		1		1
Peripheral coldness		1		1
		3		3

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ROMANIA

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coagulopathy	1	1			1	1
Hypercoagulation	1	1			1	1
Lymphadenitis	3	11	1	5	2	6
Lymphadenopathy	26	60	15	33	11	27
Lymph node pain	1	2		1	1	1
Lymphopenia		1				1
Paratracheal lymphadenopathy		1				1
	32	77	16	39	16	38

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome		1				1
Acute myocardial infarction	1	1			1	1
Angina pectoris	2	5			2	5
Arrhythmia	1	6			1	6
Atrial fibrillation		1				1
Atrioventricular block		1				1
Bradycardia	16	16			16	16
Cardiac arrest		1				1
Cardiac fibrillation		1				1
Cardio-respiratory arrest	1	3			1	3
Cardiovascular disorder	2	2			2	2
Myocardial infarction	1	2			1	2
Myocardial ischaemia		1				1
Palpitations	4	14	1	2	3	12
Pericarditis	1	2			1	2
Sinus tachycardia		2				2
Stress cardiomyopathy	1	1			1	1
Supraventricular tachycardia		2				2
Tachyarrhythmia		1				1
Tachycardia	6	32	1	10	5	22
Ventricular arrhythmia	1	1			1	1
Ventricular extrasystoles		1		1		
Ventricular tachycardia	1	1			1	1
	38	98	2	13	36	85

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness unilateral	1	1			1	1
Ear congestion	1	1			1	1
Ear discomfort	1	2	1	2		
Ear pain	1	3		1	1	2
Hypoacusis	1	5			1	5
Paraesthesia ear		1		1		
Tinnitus	3	7		1	3	6
Vertigo	3	28	2	7	1	21
Vestibular disorder	1	2		1	1	1
	12	50	3	13	9	37

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmune thyroiditis	1	1			1	1
Goitre		1				1
Hypothyroidism		1				1
Thyroiditis subacute		1		1		
	1	4		1	1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angle closure glaucoma		1				1
Blepharitis		1				1
Blindness unilateral	1	1			1	1
Cataract		1				1
Diplopia	1	3		1	1	2
Eye haemorrhage		2				2
Eyelid oedema	1	3		1	1	2
Eyelid ptosis		2		1		1
Eye pain	1	3			1	3
Eye pruritus	1	2		1	1	1
Hypoaesthesia eye		1				1
Lid sulcus deepened	1	1			1	1
Metamorphopsia		1				1
Mydriasis	16	16	10	10	6	6
Ocular discomfort		3		2		1
Ocular hyperaemia		1		1		
Ocular vascular disorder	1	1			1	1
Photophobia	1	2	1	1		1
Vision blurred	2	5			2	5
Visual acuity reduced		1				1
Visual field defect	1	2	1	1		1
Visual impairment	4	9		1	4	8
	31	62	12	20	19	42

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal pain	4	13	2	5	2	8
Abdominal pain upper	4	6	1	2	3	4
Diarrhoea	5	21	3	9	2	12
Dry mouth	2	5			2	5
Dysphagia	4	8	2	3	2	5
Eructation		1				1
Faeces soft	1	2	1	1		1
Flatulence		1				1
Hypoaesthesia oral	3	7			3	7
Irritable bowel syndrome	1	1			1	1
Lip dry		1				1
Lip oedema	1	7		2	1	5
Lip swelling	1	3		1	1	2
Mouth swelling		1				1
Nausea	26	96	11	42	15	54
Odynophagia	1	2	1	2		
Oedematous pancreatitis		1				1
Oesophageal oedema	1	1			1	1
Oral pigmentation		1		1		
Paraesthesia oral	2	4	2	4		
Rectal haemorrhage		1				1
Stomatitis		2				2
Swollen tongue	2	3	1	1	1	2
Teething		1				1
Tongue oedema		1				1
Tongue spasm		1				1
Vomiting	9	30	5	10	4	20
	67	222	29	83	38	139

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site pain		4		3		1
Administration site reaction		4		4		
Administration site swelling		1		1		
Asthenia	16	56	12	40	4	16
Axillary pain	2	6	2	4		2
Chest discomfort	4	9		4	4	5
Chest pain	9	23	3	6	6	17
Chills	60	174	33	89	27	85
Condition aggravated		4		1		3
Crying		1		1		
Death	2	11			2	11
Discomfort	1	3	1	3		
Disease recurrence	1	3	1	1		2
Drug ineffective	8	98			8	98
Extensive swelling of vaccinated limb		1				1
Face oedema		2				2
Facial pain		2		1		1
Fatigue	41	120	28	84	13	36
Feeling abnormal	2	7	1	4	1	3
Feeling cold		5		2		3
Feeling hot	1	6	1	3		3
Foaming at mouth		1				1
Gait disturbance	1	3			1	3
General physical health deterioration	2	5	1	4	1	1
Hyperpyrexia	5	6			5	6
Illness	1	2	1	1		1
Induration	1	1	1	1		
Inflammation	3	5	1	3	2	2
Influenza like illness		8		8		
Injected limb mobility decreased	1	5	1	5		
Localised oedema		1				1
Local reaction		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Malaise	26	54
Mucosal dryness		1
No adverse event		1
Nodule	2	2
Oedema		3
Oedema peripheral	5	8
Pain	13	27
Peripheral swelling	1	2
Pyrexia	85	226
Sensation of foreign body	3	3
Sluggishness	1	1
Swelling	2	4
Swelling face	3	4
Systemic inflammatory response syndrome		1
Thirst	2	6
Vaccination failure	1	16
Vaccination site discolouration	1	2
Vaccination site discomfort	1	4
Vaccination site erythema	4	31
Vaccination site granuloma		1
Vaccination site haemorrhage	1	1
Vaccination site induration	3	8
Vaccination site inflammation	2	4
Vaccination site joint movement impairment		3
Vaccination site lymphadenopathy	1	3
Vaccination site macule		1
Vaccination site movement impairment		7
Vaccination site nodule		2
Vaccination site oedema	2	5
Vaccination site pain	60	205
Vaccination site papule		1
Vaccination site paraesthesia		2

Spontaneous			
Nonserious		Serious	
I	C	I	C
11	23	15	31
			1
	1		
1	1	1	1
	2		1
1	1	4	7
10	21	3	6
1	1		1
51	128	34	98
		3	3
		1	1
	2	2	2
1	1	2	3
			1
		2	6
		1	16
1	2		
1	4		
4	28		3
	1		
		1	1
2	6	1	2
1	2	1	2
	1		2
1	3		
	1		
	4		3
	2		
1	4	1	1
50	161	10	44
	1		
	1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pruritus	1	5	1	5		
Vaccination site reaction	1	26	1	26		
Vaccination site swelling	7	14	6	13	1	1
Vaccination site urticaria		1		1		
Vaccination site warmth	1	2	1	2		
	390	1,265	233	723	157	542

System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hepatic cytolysis		1				1
Jaundice	2	2	1	1	1	1
	2	3	1	1	1	2

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		1		1		
Anaphylactic reaction	6	15			6	15
Anaphylactic shock	5	10			5	10
Anaphylactoid reaction		2				2
Autoimmune disorder		1				1
Hypersensitivity	5	30		21	5	9
	16	59		22	16	37

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19		2				2
Bronchitis		1				1
Coronavirus infection		1				1
COVID-19	13	195	5	15	8	180
Herpes simplex	1	1	1	1		
Herpes zoster	6	8	3	4	3	4
Nasal vestibulitis		1				1
Pharyngitis		1		1		
Pneumonia	1	2			1	2
Rhinitis	2	2	1	1	1	1
Sialoadenitis		1				1
Suspected COVID-19	2	7	1	2	1	5
Sweating fever		1				1
Toxocariasis		1				1
Viral infection		1				1
	25	225	11	24	14	201

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental exposure to product	1	1	1	1		
Burn of internal organs		1				1
Circumstance or information capable of leading to medication error		3		3		
Contusion	4	5		1	4	4
Craniocerebral injury	1	1			1	1
Exposure during pregnancy	1	2	1	2		
Exposure to SARS-CoV-2		1		1		
Exposure via breast milk	3	4	3	4		
Fall	3	3	1	1	2	2
Inappropriate schedule of product administration	4	6	4	6		
Incomplete course of vaccination		1		1		
Incorrect route of product administration	15	23		5	15	18
Intercepted medication error		1		1		
Joint dislocation	1	1			1	1
Limb injury		1				1
Maternal exposure during pregnancy		3		3		
Medication error		3		3		
Off label use	6	11	6	11		
Overdose		1		1		
Poor quality product administered	1	1	1	1		
Product preparation error	1	13	1	13		
Product preparation issue		9		9		
Product use issue	3	6	3	6		
Underdose		3		3		
Vaccination complication	1	1			1	1
Vaccination error	1	1			1	1
Wrong product administered		2		2		
Wrong technique in product usage process	3	20	3	20		
	49	128	24	98	25	30

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased	1	1			1	1
Aspartate aminotransferase increased	1	1			1	1
Blood fibrinogen increased		1		1		
Blood glucose decreased		1				1
Blood glucose increased		1				1
Blood pressure abnormal	1	4	1	3		1
Blood pressure decreased		1				1
Blood pressure diastolic increased		1				1
Blood pressure increased	6	15	1	4	5	11
Blood pressure systolic increased		3		1		2
Blood uric acid increased		1		1		
Body temperature abnormal	1	3	1	3		
Body temperature increased	1	3	1	2		1
C-reactive protein increased	1	1	1	1		
Gastric pH decreased		1		1		
General physical condition abnormal		2		2		
Heart rate abnormal	1	2		1	1	1
Heart rate decreased	1	3			1	3
Heart rate increased	12	31	4	6	8	25
Herpes virus test		1		1		
High density lipoprotein decreased		1		1		
Laboratory test abnormal		2		2		
Lipase increased		1		1		
Listeria test positive		1		1		
Lymph node palpable		1		1		
Mean cell haemoglobin increased		1		1		
Nitrite urine present		1		1		
Oxygen saturation abnormal		1				1
Oxygen saturation decreased		5		1		4
Protein urine present		1		1		
Pulse abnormal		4		2		2
Pulse volume decreased		2		2		

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Red blood cells urine positive		1		1		
Rheumatoid factor increased	1	1	1	1		
SARS-CoV-2 ant body test negative		7		7		
SARS-CoV-2 ant body test positive	1	8	1	8		
SARS-CoV-2 test positive		9		3		6
Toxoplasma serology positive		1		1		
Transaminases increased		1		1		
Urine ketone body present		1		1		
Weight decreased		1				1
Weight increased		1				1
White blood cell count decreased	1	1	1	1		
White blood cells urine positive		1		1		
	29	131	12	66	17	65

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	4	14	3	7	1	7
Dehydration	2	3			2	3
Diabetes mellitus		1				1
Feeding disorder	1	1	1	1		
Hyperglycaemia	2	5		1	2	4
Hyperkalaemia		2				2
Hypocalcaemia		1				1
Hypoglycaemia	2	2			2	2
Metabolic acidosis	1	2			1	2
Tetany	1	1	1	1		
Type 2 diabetes mellitus		1				1
	13	33	5	10	8	23

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	22	78	10	43	12	35
Back disorder		1		1		
Back pain	5	15	3	6	2	9
Bone pain	4	14	1	4	3	10
Facial asymmetry	1	1	1	1		
Intervertebral disc protrusion	1	1			1	1
Jaw disorder		1				1
Joint ankylosis		1				1
Joint instability	1	1			1	1
Joint stiffness		1				1
Joint swelling	2	2			2	2
Mobility decreased	1	3		1	1	2
Muscle contracture		2		1		1
Muscle discomfort	1	1			1	1
Muscle rigidity		1				1
Muscle spasms	1	2			1	2
Muscle swelling		1		1		
Muscle tightness	1	1	1	1		
Muscle twitching	1	1			1	1
Muscular weakness	2	8	1	6	1	2
Musculoskeletal chest pain		1				1
Musculoskeletal disorder	1	1	1	1		
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	1	2	1	1		1
Myalgia	71	198	45	111	26	87
Myositis	1	1			1	1
Neck pain	1	2		1	1	1
Osteoarthritis	1	1	1	1		
Osteoporosis	1	1	1	1		
Pain in extremity	23	71	12	51	11	20
Rheumatic disorder		1		1		
Spinal pain		2		1		1

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* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Synovial cyst	1	1			1	1
Tendon pain		1				1
	145	420	79	235	66	185

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acoustic neuroma		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		5		3		2
Anosmia	2	6	1	3	1	3
Aphasia	1	1			1	1
Balance disorder	2	6		1	2	5
Burning sensation	4	8	2	3	2	5
Cerebral small vessel ischaemic disease		1				1
Cerebrovascular accident	3	8			3	8
Cervical radiculopathy	1	1	1	1		
Cognitive disorder	1	1			1	1
Coma		2				2
Coma hepatic		1				1
Dementia		1				1
Depressed level of consciousness		1				1
Disturbance in attention	1	5	1	2		3
Dizziness	35	94	17	42	18	52
Dysgeusia		2				2
Dysstasia	2	3			2	3
Encephalopathy	1	1			1	1
Facial nerve disorder	1	1			1	1
Facial neuralgia		1				1
Facial paralysis	2	12			2	12
Facial paresis	5	10	2	4	3	6
Guillain-Barre syndrome	1	2			1	2
Headache	74	235	51	140	23	95
Head discomfort	1	3	1	1		2
Hemianaesthesia		1				1
Hemiparaesthesia		1				1
Hemiparesis	3	4			3	4
Hemiplegia		1				1
Horner's syndrome		1				1
Hyperaesthesia	2	3	2	3		
Hypersomnia	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia	16	37	6	14	10	23
Hypokinesia		1		1		
Hypotonia		1				1
Hypoxic-ischaemic encephalopathy		1				1
Incoherent	1	1	1	1		
Intracranial pressure increased	1	2			1	2
Ischaemic stroke	1	2			1	2
Lethargy	2	3	1	2	1	1
Loss of consciousness	9	17			9	17
Memory impairment		1				1
Migraine	3	6		1	3	5
Monoparesis	1	1			1	1
Monoplegia		1				1
Movement disorder		1				1
Muscle contractions involuntary	1	3	1	2		1
Myoclonus	1	3			1	3
Nervous system disorder		3		3		
Neuralgia		1				1
Neuritis	1	1			1	1
Neurological symptom		3				3
Neuronal neuropathy		1				1
Neuropathy peripheral	2	4			2	4
Nystagmus		1		1		
Optic neuritis	1	2			1	2
Paraesthesia	13	47	5	17	8	30
Paralysis		1				1
Paraplegia	1	2			1	2
Paresis	1	1			1	1
Parkinson's disease		1				1
Parosmia		3		1		2
Presyncope		6		4		2
Sciatica	1	1	1	1		

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* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Seizure	3	6			3	6
Sensory disturbance	1	1			1	1
Sensory loss		1		1		
Somnolence	19	52	13	30	6	22
Speech disorder	1	2			1	2
Syncope	33	67			33	67
Taste disorder		3		2		1
Tremor	6	12		2	6	10
	262	726	107	287	155	439

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion spontaneous	1	2	1	2
	1	2	1	2

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Liquid product physical issue	1	1	1	1
Product quality issue		1		1
Syringe issue		1		1
	1	3	1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aggression	1	1			1	1
Agitation	1	2	1	1		1
Anxiety	1	14		4	1	10
Bruxism	1	1	1	1		
Confusional state	3	4	1	2	2	2
Delirium	1	1			1	1
Disorientation	2	3	2	2		1
Emotional disorder	2	2	2	2		
Emotional distress		1		1		
Fear		1		1		
Hallucination	1	1			1	1
Insomnia	6	13	5	7	1	6
Mental disorder	1	1			1	1
Mental status changes		1				1
Mood altered	1	1			1	1
Organic brain syndrome		1				1
Panic attack	1	4		3	1	1
Panic reaction	1	1			1	1
Sleep disorder		1				1
Sleep talking	1	1	1	1		
Stress	1	1	1	1		
	25	56	14	26	11	30

* I=Interval, C=Cumulative

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System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematuria	1	1	1	1		
Nephrogenic diabetes insipidus	1	1			1	1
Nephropathy		1				1
Pollakiuria		1				1
Polyuria	1	4			1	4
Renal pain	2	5			2	5
Urinary incontinence	2	3	2	2		1
	7	16	3	3	4	13

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adnexa uteri pain		1				1
Amenorrhoea		1		1		
Breast inflammation	1	3	1	1		2
Breast pain	4	8	2	3	2	5
Dysmenorrhoea	1	1	1	1		
Heavy menstrual bleeding	1	1	1	1		
Intermenstrual bleeding	1	1	1	1		
Menometrorrhagia	1	1			1	1
Menstrual disorder		2		1		1
Menstruation irregular	4	5	4	4		1
Pelvic pain		1				1
Suppressed lactation		1		1		
	13	26	10	14	3	12

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute pulmonary oedema		2				2
Aphonia		1		1		
Apnoea		1				1
Asphyxia	1	3			1	3
Asthma		1				1
Asthmatic crisis		1				1
Bronchospasm		6		2		4
Catarrh	1	1	1	1		
Cough	5	17	1	7	4	10
Dry throat	2	2			2	2
Dysphonia	1	3		2	1	1
Dyspnoea	10	30		3	10	27
Dyspnoea exertional		1				1
Epiglottic oedema		1				1
Epistaxis		1		1		
Irregular breathing	1	1			1	1
Laryngeal oedema		2				2
Laryngospasm		1				1
Lung disorder		1		1		
Nasal congestion	2	3	1	1	1	2
Nasal discomfort		2		2		
Nasal dryness	1	4		1	1	3
Nasal oedema		1				1
Obstructive airways disorder		1				1
Oropharyngeal discomfort		2				2
Oropharyngeal pain	4	6	1	1	3	5
Pleurisy		1				1
Productive cough		1				1
Pulmonary embolism	1	1			1	1
Pulmonary infarction	1	1			1	1
Rales		1				1
Respiration abnormal		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory disorder		2		1		1
Respiratory distress		3				3
Respiratory failure	1	2			1	2
Rhinalgia		1				1
Rhinorrhoea	2	7	2	6		1
Stridor		1		1		
Suffocation feeling	5	9		1	5	8
Tachypnoea		1				1
Throat irritation	1	1			1	1
Throat tightness		1		1		
Use of accessory respiratory muscles		1		1		
Wheezing		2		1		1
	39	132	6	35	33	97

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* AE=Adverse Event
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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema		5				5
Blister		1				1
Circumoral oedema		1				1
Cold sweat		4		2		2
Dermatitis allergic	2	7		1	2	6
Drug eruption		2				2
Dry skin	1	1			1	1
Erythema	7	28	3	15	4	13
Erythema nodosum		2		1		1
Hyperhidrosis	20	39	18	24	2	15
Intertrigo	1	1	1	1		
Lividity		1				1
Night sweats	1	3		1	1	2
Pain of skin	2	4	1	1	1	3
Petechiae		1				1
Photosensitivity reaction		1				1
Pruritus	1	13		6	1	7
Rash	5	20	3	13	2	7
Rash erythematous		4				4
Rash pruritic	1	6		3	1	3
Rash vesicular		1				1
Scar pain		1		1		
Skin burning sensation		1				1
Skin discolouration		2		2		
Skin exfoliation	1	1			1	1
Skin hypertrophy		1				1
Skin irritation	1	3	1	1		2
Skin plaque		1				1
Urticaria	7	23	5	11	2	12
Urticaria papular		1		1		
	50	179	32	84	18	95

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* AE=Adverse Event

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System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hearing disability	1	1			1	1
Immobile		1				1
Impaired work ability		1				1
Loss of personal independence in daily activities		2		2		
Sitting disability		1				1
Walking disability	1	1	1	1		
	2	7	1	3	1	4

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure fluctuation	2	5			2	5
Circulatory collapse	1	1			1	1
Cyanosis		3		1		2
Deep vein thrombosis		3				3
Flushing		1		1		
Haemorrhage	2	2			2	2
Hot flush		1		1		
Hyperaemia		1				1
Hypertension	24	72	4	12	20	60
Hypertensive crisis		2				2
Hypotension	22	29	16	17	6	12
Infarction		1				1
Orthostatic hypotension	1	1			1	1
Pallor	16	20	15	16	1	4
Peripheral arterial occlusive disease		1				1
Peripheral coldness		2		1		1
Peripheral venous disease	1	1			1	1
Raynaud's phenomenon		1				1
Shock		1				1
Systolic hypertension		1				1
Thrombophlebitis	1	1			1	1
Thrombophlebitis superficial	1	2		1	1	1
Thrombosis	3	4			3	4
	74	156	35	50	39	106

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Country Where Event Occurred

SAUDI ARABIA

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acquired haemophilia		1				1
Lymphadenopathy	1	4	1	4		
	1	5	1	4		1

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cardiac arrest		1		1
		1		1

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	2		1	1	1
Abdominal pain upper		1				1
Mouth ulceration		1		1		
Nausea		1		1		
Retching	1	1	1	1		
Stomatitis	1	1			1	1
Vomiting		3				3
	3	10	1	4	2	6

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		2		2		
Axillary pain		1		1		
Chills		2		2		
Death	2	2			2	2
Drug ineffective	2	2			2	2
Fatigue	1	8	1	7		1
Feeling hot		1		1		
Gait disturbance		2		1		1
Gait inability		1				1
Malaise		2		2		
Pain		6		5		1
Pyrexia		7		6		1
Temperature intolerance		1		1		
Vaccination site erythema		1		1		
Vaccination site pain	1	7	1	7		
Vaccination site pruritus		1		1		
Vaccination site swelling		1		1		
	6	47	2	38	4	9

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic shock		1		1
		1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	3	6	1	4	2	2
Herpes zoster		1		1		
Infection		1		1		
Nasopharyngitis		1		1		
Vaginal infection	1	2	1	2		
	4	11	2	9	2	2

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Accidental overdose		1		1
Exposure via breast milk	2	2	2	2
Extra dose administered	1	1	1	1
Inappropriate schedule of product administration		1		1
Off label use	2	2	2	2
Overdose	1	1	1	1
Product administered to patient of inappropriate age	1	1	1	1
Product preparation issue		1		1
Product use issue	2	2	2	2
	9	12	9	12

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased	1	1	1	1		
C-reactive protein increased		1		1		
Heart rate decreased		1				1
Red blood cell sedimentation rate increased		1		1		
Weight decreased	1	1	1	1		
	2	5	2	4		1

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite	1	1	1	1
Poor feeding infant	2	2	2	2
	3	3	3	3

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	4	1	4		
Mastication disorder		1		1		
Mobility decreased		4		3		1
Musculoskeletal stiffness		1		1		
Myalgia		7		6		1
Pain in extremity	1	5	1	3		2
Pain in jaw		1		1		
	2	23	2	19		4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Lymphoma		1		1
		1		1

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Carotid artery stenosis		1				1
Cerebral haemorrhage	1	1			1	1
Cerebrovascular accident	1	1			1	1
Disturbance in attention	1	1	1	1		
Dizziness	2	4	2	3		1
Dysstasia		1				1
Headache	3	9	3	9		
Hypoaesthesia	1	1	1	1		
Movement disorder		1		1		
Sciatica		2		2		
Seizure		2				2
Somnolence		1		1		
Syncope		3				3
Tremor		1		1		
	9	29	7	19	2	10

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* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion	1	1	1	1
	1	1	1	1

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Sleep disorder		1		1
		1		1

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pollakiuria		1		1
		1		1

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heavy menstrual bleeding	1	1	1	1		
Menstruation irregular	1	2	1	2		
Vaginal haemorrhage	1	1			1	1
	3	4	2	3	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Epistaxis	1	1	1	1		
Oropharyngeal pain		1		1		
Pulmonary embolism		1				1
Respiration abnormal	1	1	1	1		
Rhinorrhoea		1		1		
	2	5	2	4		1

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperhidrosis		4		3		1
Night sweats		1		1		
Pain of skin		1		1		
		6		5		1

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Sitting disability		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hot flush		1		1		
Hypertension	1	1	1	1		
Hypotension		1				1
Peripheral coldness		2		2		
	1	5	1	4		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

SERBIA

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Leukopenia	1	1			1	1
Lymphadenitis	1	2	1	1		1
Lymphadenopathy	4	7	4	6		1
	6	10	5	7	1	3

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myocardial infarction		1				1
Myocarditis		1				1
Palpitations		2		2		
Tachycardia	1	4		1	1	3
	1	8		3	1	5

System Organ Class

Congenital, familial and genetic disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Huntington's disease		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness		1				1
Deafness unilateral		1				1
Tinnitus		1		1		
Vertigo		1		1		
		4		2		2

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blepharospasm		1				1
Eyelid oedema		1		1		
Eyelid ptosis		1				1
Eye pain		1		1		
Lacrimation increased		1		1		
Photophobia		1		1		
Swelling of eyelid	1	2	1	2		
Vision blurred		2		1		1
	1	10	1	7		3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Diarrhoea	2	4	2	4		
Dry mouth		1		1		
Haematemesis		1				1
Hypoaesthesia oral		2		1		1
Lip disorder		1		1		
Lip pruritus		1		1		
Lip swelling		1		1		
Nausea	6	24	5	20	1	4
Oedema mouth		1		1		
Pancreatitis acute		1				1
Paraesthesia oral	2	3		1	2	2
Swollen tongue		1		1		
Tongue oedema		1				1
Vomiting	1	5	1	4		1
	11	48	8	37	3	11

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	10	1	9		1
Axillary pain		2		1		1
Chest discomfort		2		2		
Chest pain	1	4	1	2		2
Chills	4	15	3	11	1	4
Death		1				1
Disease recurrence		1		1		
Drug ineffective	2	5			2	5
Face oedema		1				1
Fatigue	14	26	14	25		1
Feeling abnormal		1		1		
Feeling cold	1	2	1	2		
Feeling hot		2		2		
Influenza like illness		2		2		
Localised oedema		1		1		
Malaise	4	25	4	22		3
No adverse event		1		1		
Oedema mucosal		1				1
Oedema peripheral	1	3	1	3		
Pain		3		2		1
Peripheral swelling		1				1
Pyrexia	23	60	23	54		6
Swelling		2		1		1
Thirst	1	1	1	1		
Vaccination failure		1				1
Vaccination site erythema	2	6	2	6		
Vaccination site haematoma		1				1
Vaccination site induration		1		1		
Vaccination site lymphadenopathy	1	1	1	1		
Vaccination site oedema		2		2		
Vaccination site pain	10	26	10	26		
Vaccination site pruritus		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site reaction		1		1		
Vaccination site swelling		1		1		
	65	213	62	182	3	31

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactoid reaction		1				1
Hypersensitivity	1	3	1	2		1
	1	4	1	2		2

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abscess		1				1
Conjunctivitis		1		1		
COVID-19	6	17	4	11	2	6
COVID-19 pneumonia		1				1
Herpes zoster	1	2	1	2		
Infection	1	1	1	1		
Lymphangitis	1	1			1	1
Nasopharyngitis		1		1		
Pneumonia		1				1
	9	26	6	16	3	10

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposure during pregnancy		1		1		
Exposure via breast milk		1		1		
Fall		2		1		1
Inappropriate schedule of product administration	1	2	1	2		
Maternal exposure during pregnancy		1		1		
Off label use		1		1		
Overdose		1				1
Vaccination complication	2	7	1	6	1	1
Wrong product administered		1		1		
	3	17	2	14	1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood bilirubin increased	1	1	1	1		
Blood calcium decreased	1	1	1	1		
Blood creatinine increased	1	1	1	1		
Blood iron decreased	1	1	1	1		
Blood lactate dehydrogenase increased		1				1
Blood pressure increased		2		1		1
Body temperature increased	9	23	8	21	1	2
C-reactive protein increased	1	3	1	2		1
Fibrin D dimer increased		1		1		
Gamma-glutamyltransferase increased	1	1	1	1		
Heart rate increased		1		1		
Inflammatory marker increased		1		1		
Intraocular pressure increased		1				1
Monocyte count increased		1		1		
Oxygen saturation decreased		1				1
Red blood cell count increased		1		1		
Red blood cell sedimentation rate increased		1				1
SARS-CoV-2 ant body test negative		1		1		
SARS-CoV-2 test positive		3		1		2
	15	46	14	36	1	10

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite	1	2	1	2
	1	2	1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	8	18	7	16	1	2
Back pain	2	3	2	2		1
Bone pain		2		2		
Joint stiffness		2		1		1
Muscular weakness	1	3		2	1	1
Musculoskeletal stiffness		1		1		
Myalgia	12	27	11	25	1	2
Myositis		1				1
Neck pain	1	2			1	2
Pain in extremity	6	20	6	20		
Pain in jaw		1		1		
	30	80	26	70	4	10

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Tumour pseudoprogression	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	5	1	4		1
Anosmia	1	4	1	4		
Balance disorder		1				1
Burning sensation		1		1		
Dizziness	2	8	2	7		1
Dysgeusia		1				1
Facial paralysis		1				1
Facial paresis		1				1
Guillain-Barre syndrome	2	2			2	2
Headache	17	40	16	36	1	4
Head discomfort	1	1	1	1		
Hyperaesthesia		1		1		
Hypoaesthesia		2		2		
Ischaemic stroke		1				1
Loss of consciousness	1	2			1	2
Movement disorder		1		1		
Optic neuritis		1				1
Paraesthesia	1	4		3	1	1
Paraesthesia mucosal	1	1			1	1
Seizure	1	1			1	1
Somnolence	1	4	1	3		1
Syncope	1	5			1	5
Tremor		2		2		
	30	90	22	65	8	25

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product supply issue	1	1	1	1
	1	1	1	1

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety		2		2		
Confusional state	1	2	1	2		
Fear		1				1
Fear of death		1		1		
Insomnia		2		1		1
Irritability		1		1		
Nervousness		1				1
Sleep disorder	1	2	1	2		
	2	12	2	9		3

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Heavy menstrual bleeding	2	2	2	2
	2	2	2	2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asphyxia		2				2
Bronchospasm		2		1		1
Cough	4	7	3	4	1	3
Dyspnoea		4		1		3
Hypopnoea		1				1
Laryngeal discomfort	1	1			1	1
Lung disorder	1	1	1	1		
Nasal congestion	2	4	1	2	1	2
Oropharyngeal pain	1	3	1	3		
Pulmonary pain		2		1		1
Rhinorrhoea		1				1
Sneezing		1				1
Wheezing		1				1
	9	30	6	13	3	17

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	1	9	1	8		1
Hyperhidrosis		4		3		1
Pruritus	1	2	1	2		
Rash	2	5	2	4		1
Rash macular	1	3	1	1		2
Rash pruritic	1	1	1	1		
Skin burning sensation		2		1		1
Skin reaction		1				1
Urticaria	3	6	2	5	1	1
	9	33	8	25	1	8

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circulatory collapse	2	2			2	2
Haematoma		1		1		
Hypertension		8		2		6
Pallor	1	3		2	1	1
Phlebitis		1				1
Superficial vein prominence		1		1		
Thrombophlebitis		1				1
Thrombosis	1	2			1	2
	4	19		6	4	13

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

SINGAPORE

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bicytopenia		1				1
Eosinophilia		1				1
Lymphadenopathy		1		1		
		3		1		2

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Extrasystoles		1				1
Myocardial infarction		1				1
Palpitations		10		1		9
Postural orthostatic tachycardia syndrome		1				1
Sinus tachycardia		1				1
Tachycardia	1	5			1	5
	1	19		1	1	18

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness neurosensory		1				1
Dysacusis		1		1		
Vertigo		1		1		
		3		2		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hyperthyroidism		1		1
		1		1

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blepharospasm		1		1		
Diplopia	1	2			1	2
Dry eye		1				1
Eye colour change		1		1		
Eye disorder		1				1
Eye movement disorder		4				4
Eye pruritus		2		1		1
Eye swelling		2		1		1
Lacrimation increased		1				1
Periorbital swelling		6		1		5
Swelling of eyelid		1				1
Vision blurred		4		2		2
Visual impairment		2		1		1
	1	28		8	1	20

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		5				5
Abdominal tenderness		1				1
Diarrhoea		5		1		4
Dry mouth		1		1		
Dysphagia		2				2
Enlarged uvula		4				4
Gastroesophageal reflux disease		1				1
Lip swelling		4		1		3
Nausea		11		5		6
Odynophagia		1				1
Palatal oedema		2				2
Swollen tongue		1				1
Vomiting		9		2		7
		47		10		37

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		2		1		1
Chest discomfort		13		3		10
Chest pain		3				3
Chills		7		2		5
Disease progression		1		1		
Disease recurrence		1				1
Drug ineffective	1	1			1	1
Fatigue	5	10	5	9		1
Feeling abnormal	1	1	1	1		
Gait disturbance		1				1
Hunger		1		1		
Influenza like illness		1		1		
Injection site swelling		1		1		
Malaise		2				2
Oedema peripheral	1	2	1	2		
Pain	1	3	1	2		1
Peripheral swelling	1	2	1	1		1
Pyrexia	3	14	3	8		6
Secretion discharge		1		1		
Sensation of foreign body		5				5
Swelling face		1				1
Vaccination site bruising	1	1	1	1		
Vaccination site erythema	1	3	1	3		
Vaccination site hypoaesthesia		1				1
Vaccination site mass		1		1		
Vaccination site pain	2	6	2	4		2
Vaccination site paraesthesia		1				1
Vaccination site pruritus	1	3	1	3		
Vaccination site rash	1	3	1	2		1
Vaccination site reaction		1		1		
Vaccination site swelling	1	1	1	1		
Vaccination site urticaria	1	2	1	1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	21	96	20	51	1	45

System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hepatitis		1		1
		1		1

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		1				1
Anaphylactic reaction		17				17
Anaphylactic shock		5				5
Hypersensitivity		3		1		2
		26		1		25

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cellulitis		1				1
COVID-19	1	1			1	1
Gianotti-Crosti syndrome		1		1		
Herpes zoster	1	1	1	1		
Respiratory tract infection		1				1
Vestibular neuronitis		1				1
	2	6	1	2	1	4

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fall		2				2
Femoral neck fracture		1				1
Maternal exposure during pregnancy		1		1		
Nerve injury		1				1
Poor quality product administered		3		3		
Product preparation issue	1	1	1	1		
Skin abrasion		1				1
Vaccination complication		1				1
Wrong technique in product usage process	1	1	1	1		
	2	12	2	6		6

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased		1				1
Antineutrophil cytoplasmic antibody positive	1	1	1	1		
Aspartate aminotransferase increased		1				1
Blood alkaline phosphatase increased		1				1
Blood bilirubin increased		1				1
Blood pressure decreased		1				1
Blood pressure increased		6		2		4
Blood pressure systolic increased		3				3
Body temperature increased		1				1
Breath sounds abnormal		1				1
Complement factor C3 increased		1				1
Haematocrit increased		1				1
Haemoglobin increased		1				1
Heart rate increased		3				3
Oxygen saturation decreased		3				3
Pupillary light reflex tests abnormal		1				1
Respiratory rate decreased		1				1
Respiratory rate increased		1				1
Transaminases increased		2				2
Troponin increased		1				1
	1	32	1	3		29

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Decreased appetite		1		1
Dehydration		1		1
Feeding disorder		1		1
		3		3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		2				2
Arthritis		1				1
Facial asymmetry		1				1
Limb discomfort	1	1	1	1		
Muscular weakness		2				2
Musculoskeletal stiffness		1				1
Myalgia	1	5	1	4		1
Neck pain		1				1
Pain in extremity	2	6	2	5		1
Rheumatoid arthritis		1				1
Tenosynovitis		1				1
	4	22	4	10		12

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fibroma		1		1		
Pituitary tumour	1	1			1	1
	1	2		1	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bell's palsy		2				2
Cranial nerve disorder	1	1			1	1
Dizziness		22		7		15
Droling		1				1
Dysgeusia	1	2	1	2		
Dyskinesia		4				4
Dysstasia		1				1
Facial paralysis		1				1
Generalised tonic-clonic seizure		2				2
Headache		8		6		2
Head discomfort		1		1		
Hypoaesthesia		6		1		5
IIIrd nerve paralysis	1	1			1	1
IVth nerve paralysis	1	1			1	1
Lethargy		1		1		
Migraine		1				1
Optic neuritis		1				1
Parosmia		2		2		
Petit mal epilepsy		1				1
Radiculopathy		1				1
Seizure		4				4
Sensory disturbance		1				1
Somnolence		3		1		2
Status epilepticus		1				1
Syncope		5				5
Taste disorder		1		1		
Tongue biting		1				1
Tonic clonic movements		1				1
Tonic convulsion		1				1
Toxic neuropathy		1				1
Tremor		1		1		
Unresponsive to stimuli		3				3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vlth nerve paralysis		1				1
	4	84	1	23	3	61

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Ectopic pregnancy	1	1	1	1
	1	1	1	1

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product quality issue	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute psychosis		1				1
Confusional state		2				2
Insomnia	1	1	1	1		
Mental status changes		1				1
Sleep disorder		1		1		
Tic		1				1
	1	7	1	2		5

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute kidney injury		1		1
Haematuria		1		1
Proteinuria		1		1
Renal impairment		1		1
		4		4

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma		2				2
Cough		4				4
Dysphonia		9		1		8
Dyspnoea		22		1		21
Dyspnoea exertional		2		1		1
Laryngeal oedema		1				1
Oropharyngeal pain		2				2
Pharyngeal mass		1		1		
Pharyngeal swelling		2				2
Pneumonia aspiration		1				1
Pulmonary embolism		1				1
Rhinorrhoea		1				1
Throat irritation		4		2		2
Throat tightness		9		1		8
Upper respiratory tract congestion		1		1		
Wheezing		4		1		3
		66		9		57

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne		1		1		
Acute generalised exanthematous pustulosis		1				1
Angioedema		7				7
Cold sweat		1				1
Dermatitis bullous		1				1
Drug reaction with eosinophilia and systemic symptoms		1				1
Erythema		2				2
Erythema multiforme		1				1
Hand dermatitis		1		1		
Hyperhidrosis		2		1		1
Pruritus		5				5
Rash		17		7		10
Rash erythematous		1		1		
Rash macular	1	5	1	1		4
Rash maculo-papular		2		1		1
Rash papular		1				1
Rash pruritic		1				1
Skin lesion		1		1		
Urticaria	1	14	1	3		11
	2	65	2	17		48

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deep vein thrombosis		1				1
Flushing		3				3
Hypertension	1	6			1	6
Hypotension		5				5
Pallor		1				1
Peripheral coldness		1		1		
	1	17		1	1	16

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

SLOVAKIA

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenitis		1		1
Lymphadenopathy	7	19	7	19
Lymph node pain		1		1
	7	21	7	21

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction		1				1
Arrhythmia	1	2			1	2
Atrial f brillation		1				1
Bradycardia		1				1
Cardiac discomfort		1		1		
Cardiac failure		1				1
Cardiac failure chronic	1	1			1	1
Cardiac fibrillation		1				1
Coronary artery disease	1	1			1	1
Left ventricular hypertrophy	1	1			1	1
Myocardial ischaemia		1				1
Palpitations		7		7		
Sinus tachycardia		2				2
Tachycardia		10		7		3
	4	31		15	4	16

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness		1				1
Sudden hearing loss		2				2
Tinnitus		6		6		
Vertigo	1	15	1	14		1
	1	24	1	20		4

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diplopia		1		1		
Eye allergy		1		1		
Eye irritation	1	4	1	4		
Eyelid oedema	1	1	1	1		
Eyelid rash		1		1		
Eye oedema		3		1		2
Eye pain		2		2		
Eye pruritus		2		2		
Lacrimation increased		1		1		
Mydriasis		1		1		
Ocular discomfort		1		1		
Ocular hyperaemia		1		1		
Photophobia		2		2		
Vision blurred	1	4	1	4		
Visual impairment		1				1
	3	26	3	23		3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		3		2		1
Abdominal pain		2		1		1
Abdominal pain upper		2		2		
Angular cheilitis	1	1	1	1		
Diarrhoea	2	10	2	8		2
Dry mouth		3		2		1
Dysphagia	1	2	1	2		
Enlarged uvula		1		1		
Flatulence		1		1		
Lip oedema		1		1		
Nausea	7	39	7	36		3
Oral discomfort		1		1		
Pancreatitis acute		1				1
Paraesthesia oral		3		2		1
Rectal haemorrhage	1	1			1	1
Retching		2		2		
Tongue discolouration		1		1		
Tongue dry		1				1
Vomiting	1	9	1	6		3
	13	84	12	69	1	15

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	8	47	7	40	1	7
Axillary pain		4		4		
Chest discomfort	2	7	2	6		1
Chest pain	1	4	1	4		
Chills	13	94	12	87	1	7
Condition aggravated		1		1		
Drug ineffective	3	10			3	10
Face oedema	1	4	1	3		1
Fatigue	12	57	11	56	1	1
Feeling abnormal		1		1		
Feeling hot	1	9	1	9		
Feeling of body temperature change		1		1		
Gait disturbance		1		1		
Inflammation		1		1		
Influenza like illness	2	4	2	4		
Malaise	3	19	3	18		1
Oedema		1		1		
Oedema peripheral		1		1		
Pain		8		8		
Peripheral swelling		2		2		
Pyrexia	9	72	9	69		3
Thirst		2		2		
Tissue infiltration		1		1		
Vaccination failure	2	4			2	4
Vaccination site bruising	1	2	1	2		
Vaccination site dermatitis		1		1		
Vaccination site erythema	2	10	2	10		
Vaccination site hypersensitivity		1		1		
Vaccination site induration		3		3		
Vaccination site inflammation		1		1		
Vaccination site joint movement impairment		1		1		
Vaccination site movement impairment		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site oedema	2	14	2	14		
Vaccination site pain	23	96	23	95		1
Vaccination site pruritus	1	4	1	4		
Vaccination site swelling		2		1		1
Vaccination site urticaria		1		1		
Vaccination site warmth	1	2	1	2		
	87	494	79	457	8	37

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		2				2
Hypersensitivity		2		1		1
		4		1		3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19	1	2			1	2
Conjunctivitis		2		1		1
COVID-19	3	16		3	3	13
COVID-19 pneumonia	1	1			1	1
Erysipelas		1				1
Herpes zoster	1	1			1	1
Lymphangitis		1				1
Nasopharyngitis	2	2	2	2		
Pneumonia	1	1			1	1
Pyelonephritis	1	1			1	1
Rash pustular		1		1		
Rhinitis		2		2		
Urinary tract infection	1	1			1	1
Urosepsis	1	1			1	1
Viral infection		1				1
	12	34	2	9	10	25

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Brachial plexus injury		1				1
Brain contusion		1				1
Exposure via breast milk		1		1		
Extra dose administered		1		1		
Fall		2		1		1
Maternal exposure during pregnancy		3		3		
Off label use		2		2		
Product administered at inappropriate site		2		2		
Product administration error		1				1
Product use issue		1		1		
		15		11		4

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood glucose increased	1	3	1	3		
Blood pressure decreased	1	9	1	3		6
Blood pressure increased	2	22	1	8	1	14
Body temperature decreased	1	1			1	1
Body temperature fluctuation		1		1		
Body temperature increased	6	38	6	34		4
Heart rate decreased		1		1		
Heart rate increased		4		4		
Oxygen saturation decreased	1	1			1	1
SARS-CoV-2 ant body test positive		1				1
SARS-CoV-2 test positive		2		1		1
Tryptase decreased		1		1		
	12	84	9	56	3	28

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	1	6	1	6		
Dehydration		2		1		1
Insulin resistance		1				1
	1	9	1	7		2

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	5	38	5	37		1
Back pain		4		4		
Bone pain		2		2		
Limb discomfort		1		1		
Muscular weakness	1	3	1	2		1
Musculoskeletal chest pain		1		1		
Musculoskeletal discomfort		1		1		
Musculoskeletal stiffness		1		1		
Myalgia	9	54	9	54		
Neck pain		2		2		
Pain in extremity	15	64	15	64		
Synovitis		1		1		
Tendonitis		1		1		
	30	173	30	171		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Altered state of consciousness		2				2
Amnesia		1				1
Anosmia	1	1	1	1		
Aphasia		2		1		1
Balance disorder		1		1		
Burning sensation	1	4	1	4		
Cerebral ischaemia		1				1
Cervicobrachial syndrome		1				1
Dizziness	2	22	2	18		4
Dysaesthesia		1		1		
Dysarthria		1		1		
Dyskinesia		1		1		
Epilepsy		1				1
Facial paresis	1	2	1	1		1
Headache	12	80	12	79		1
Head discomfort		3		3		
Hypoaesthesia		1		1		
Loss of consciousness		3				3
Meningeal disorder	1	1			1	1
Migraine	2	3	2	3		
Movement disorder		2		2		
Paraesthesia	4	23	4	18		5
Presyncope	1	8	1	5		3
Somnolence		5		4		1
Speech disorder		1				1
Syncope		11				11
Tension headache		2		2		
Tonic convulsion		1				1
Tremor		1				1
	25	186	24	146	1	40

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal dreams		1		1		
Confusional state	1	1			1	1
Disorientation		1		1		
Insomnia	1	4	1	4		
Loss of libido	1	1	1	1		
Restlessness		2				2
	3	10	2	7	1	3

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Micturition urgency		1		1
Renal colic	1	1	1	1
	1	2	1	2

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Prostatitis	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asphyxia		1				1
Cough	2	10	2	10		
Dry throat		1		1		
Dyspnoea	3	12	2	8	1	4
Oropharyngeal pain		2		2		
Painful respiration	1	1	1	1		
Rhinalgia		1		1		
Sneezing	1	1	1	1		
Tachypnoea		1				1
Throat irritation		2		2		
Throat tightness		1		1		
Wheezing		1				1
	7	34	6	27	1	7

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema		2				2
Cold sweat		1		1		
Cutaneous vasculitis		1		1		
Dermatitis allergic		1		1		
Erythema	1	7	1	6		1
Hyperhidrosis	2	11	2	8		3
Pain of skin		1		1		
Petechiae		1		1		
Pruritus	1	5	1	4		1
Rash		5		5		
Rash papular		1		1		
Rash pruritic		2		2		
Rash vesicular		1		1		
Urticaria	3	4	3	3		1
	7	43	7	35		8

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Axillary vein thrombosis		1				1
Cyanosis		1				1
Flushing		1		1		
Hot flush	1	8	1	6		2
Hyperaemia	1	1	1	1		
Hypertension		4		3		1
Hypertensive crisis		1				1
Pallor		3		2		1
Peripheral coldness		3		3		
Subclavian vein stenosis		1				1
Subclavian vein thrombosis		1				1
Thrombosis		2				2
Venous thrombosis limb		2				2
	2	29	2	16		13

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

SLOVENIA

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia	1	2			1	2
Hypochromasia		1		1		
Lymphadenitis	1	2	1	2		
Lymphadenopathy		5		5		
Neutropenia		1				1
Thrombocytopenia		2				2
	2	13	1	8	1	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction		2				2
Angina pectoris		1				1
Arrhythmia		1				1
Atrial fibrillation		3				3
Atrial tachycardia		1				1
Bradycardia		4				4
Cardiac arrest	2	3			2	3
Cardiac failure		2				2
Cardiac failure congestive		1				1
Cardiac tamponade		1				1
Cardiomegaly		1				1
Cardiopulmonary failure		2				2
Extrasystoles		1				1
Mitral valve incompetence	1	1			1	1
Myocardial fibrosis		1				1
Myocardial infarction	2	4			2	4
Myocardial rupture		1				1
Sinus tachycardia		1				1
Tachycardia		4		3		1
Tricuspid valve incompetence	1	1			1	1
Ventricular extrasystoles		2		1		1
	6	38		4	6	34

System Organ Class

Congenital, familial and genetic disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Factor VIII deficiency	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear pain		1				1
Vertigo		11		5		6
		12		5		7

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Autoimmune thyroiditis		1		1
		1		1

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blindness unilateral		1				1
Eyelid disorder		1		1		
Eyelid oedema		1		1		
Eye pruritus		1		1		
Miosis		1				1
		5		3		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		3		3		
Abdominal pain lower		1		1		
Abdominal pain upper		1		1		
Diarrhoea	3	10	3	9		1
Diverticulum intestinal		1				1
Dry mouth		1		1		
Dysphagia		1		1		
Lip oedema		1				1
Lip swelling		1		1		
Nausea	3	11	2	7	1	4
Paraesthesia oral		3		1		2
Swollen tongue		2		2		
Tongue movement disturbance		1		1		
Tongue pruritus		2		2		
Vomiting		4		2		2
	6	44	5	33	1	11

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site pain	1	1	1	1		
Asthenia	2	6	1	4	1	2
Axillary pain		1				1
Chest discomfort		4		1		3
Chest pain	2	9	1	4	1	5
Chills		7		7		
Disease recurrence		1				1
Drug ineffective		1				1
Fatigue	4	29	4	24		5
Feeling abnormal		1		1		
Feeling cold	1	2	1	2		
Feeling hot		3		1		2
Gait disturbance		1				1
Gait inability		1				1
General physical health deterioration		1				1
Malaise	2	22	2	15		7
Oedema peripheral	1	3			1	3
Pain		2		2		
Peripheral swelling	1	1			1	1
Pyrexia	2	13	2	11		2
Sensation of foreign body	1	2			1	2
Sudden cardiac death		2				2
Sudden death		2				2
Vaccination failure		2				2
Vaccination site erythema		10		10		
Vaccination site oedema		4		4		
Vaccination site pain	8	59	8	54		5
Vaccination site pruritus		3		3		
Vaccination site rash	1	1	1	1		
Vaccination site swelling	1	3	1	3		
Vaccination site warmth		1				1
Vascular stent thrombosis		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	27	199	22	148	5	51

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Hypersensitivity	1	2		1	1	1
	1	3		1	1	2

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic bacteriuria		1				1
COVID-19		4				4
COVID-19 pneumonia		1				1
Herpes zoster	1	1			1	1
Infection	1	2	1	1		1
Lower respiratory tract infection		1				1
Nasopharyngitis		2		2		
Oral herpes		1				1
Pneumonia		2				2
Pneumonia bacterial		1				1
Sinusitis		1		1		
Suspected COVID-19		1				1
	2	18	1	4	1	14

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Contusion		1		1		
Fall		4		1		3
Head injury		1		1		
Inappropriate schedule of product administration		3		3		
Joint injury	1	1	1	1		
Maternal exposure during pregnancy		1		1		
Off label use		3		3		
Skin abrasion		1		1		
	1	15	1	12		3

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood creatine phosphokinase increased		1				1
Blood pressure increased		1		1		
Body temperature increased	4	15	3	12	1	3
Muscle strength abnormal	1	1			1	1
Myoglobin blood increased		1				1
Oxygen saturation decreased		3				3
Protein total increased		1		1		
Total lung capacity decreased		1				1
White blood cell count increased		1		1		
	5	25	3	15	2	10

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	1	1	1	1		
Decreased insulin requirement	1	1	1	1		
Dehydration	1	1	1	1		
Diabetes mellitus		1				1
Hypoglycaemia	1	1			1	1
Hypokalaemia		2		1		1
Metabolic acidosis		1				1
	4	8	3	4	1	4

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	2	7		5	2	2
Back pain	2	2	2	2		
Joint swelling	1	1			1	1
Muscular weakness		1		1		
Myalgia	4	16	3	13	1	3
Neck pain		1		1		
Osteopenia		1		1		
Pain in extremity	3	5	3	4		1
Polymyalgia rheumatica	1	1			1	1
Rhabdomyolysis		1				1
	13	36	8	27	5	9

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
B-cell lymphoma		1		1
B-cell type acute leukaemia		1		1
		2		2

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* AE=Adverse Event
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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphasia		2				2
Aura		1		1		
Basilar artery thrombosis		1				1
Bell's palsy		1				1
Brain injury		1				1
Cerebral haemorrhage		1				1
Cerebral ischaemia	1	1			1	1
Cerebral thrombosis		1				1
Cerebrovascular accident	2	3			2	3
Coordination abnormal		1				1
Dementia		1				1
Dizziness		6		3		3
Dysarthria		1				1
Dysgeusia		2		2		
Epilepsy		3				3
Guillain-Barre syndrome		2				2
Headache	8	31	6	25	2	6
Hemiparesis	1	1			1	1
Hypoaesthesia	1	3		1	1	2
Hyposmia		2		2		
Ischaemic cerebral infarction		1				1
Ischaemic stroke	1	2			1	2
Loss of consciousness	2	14			2	14
Memory impairment	1	1			1	1
Migraine		2		1		1
Migraine with aura		1				1
Monoparesis		1				1
Neurological symptom		1		1		
Paraesthesia	1	8		4	1	4
Paresis		1				1
Presyncope		1		1		
Quadriparesis		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Seizure	1	2			1	2
Sensory disturbance		2		1		1
Somnolence	2	10	2	7		3
Speech disorder	2	4		1	2	3
Subarachnoid haemorrhage		1				1
Syncope	1	6			1	6
Tongue biting		1				1
Transient ischaemic attack	2	3			2	3
Tremor	1	1	1	1		
Unresponsive to stimuli		3				3
Vertebral artery thrombosis		1				1
	27	133	9	51	18	82

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Confusional state	1	4		1	1	3
Insomnia		3		3		
Irritability		1				1
Mood altered		1				1
Nightmare		1		1		
Restlessness		1		1		
Soliloquy		1		1		
Thinking abnormal		1		1		
	1	13		8	1	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Renal failure		1		1
Urinary incontinence		1		1
		2		2

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Uterine spasm		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory failure		1				1
Bronchial disorder		1				1
Cough		1				1
Dyspnoea	1	8	1	2		6
Epistaxis	1	1			1	1
Haemoptysis	1	1			1	1
Hyperventilation		1				1
Oropharyngeal pain		1		1		
Pharyngeal erythema		1		1		
Pneumothorax spontaneous		1				1
Pulmonary embolism		3				3
Pulmonary hypertension	1	1			1	1
Pulmonary oedema		1				1
Respiratory acidosis		1				1
Suffocation feeling		1				1
Throat tightness		1		1		
Wheezing		1				1
	4	26	1	5	3	21

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema		1				1
Erythema	1	3		1	1	2
Night sweats		1				1
Pain of skin	1	1	1	1		
Pityriasis rosea		1		1		
Rash		2		1		1
Rash pruritic		2		2		
Skin burning sensation		1		1		
Skin disorder		1				1
Urticaria		1				1
	2	14	1	7	1	7

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bedridden		1		1
Immobile		2		2
Working disability		1		1
		4		4

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circulatory collapse		3				3
Deep vein thrombosis	2	4			2	4
Haematoma	1	1			1	1
Haemorrhage	1	1			1	1
Hot flush		1				1
Hypertension		5				5
Hypotension		1				1
Pelvic venous thrombosis	1	1			1	1
Peripheral coldness		1		1		
Superficial vein prominence		1				1
Thrombophlebitis superficial		1				1
	5	20		1	5	19

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

SOUTH AFRICA

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Palpitations	2	2	2	2
	2	2	2	2

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Tinnitus	1	1	1	1
	1	1	1	1

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Conjunctivitis allergic	1	1	1	1
Vision blurred	1	1	1	1
	2	2	2	2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal pain	1	1	1	1
Diarrhoea	1	1	1	1
Lip swelling	1	1	1	1
Vomiting	1	1	1	1
	4	4	4	4

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	2	2	2	2		
Chills	1	1	1	1		
Death	2	2			2	2
Fatigue	2	2	2	2		
Illness	1	1			1	1
Malaise	1	1	1	1		
Pain	4	4	4	4		
Pyrexia	1	1	1	1		
Swelling	1	1	1	1		
Vaccination site lymphadenopathy	1	1	1	1		
Vaccination site rash	1	1	1	1		
	17	17	14	14	3	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Heart rate increased	1	1	1	1
	1	1	1	1

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite	1	1	1	1
Dehydration	1	1	1	1
Feeding disorder	1	1	1	1
	3	3	3	3

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
Back pain	1	1	1	1
Bone pain	1	1	1	1
Groin pain	1	1	1	1
	4	4	4	4

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphasia	1	1			1	1
Cerebral venous thrombosis	1	1			1	1
Cerebrovascular accident	1	1			1	1
Dizziness	2	2	2	2		
Headache	6	6	6	6		
	11	11	8	8	3	3

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Erythema	1	1	1	1
Pruritus	1	1	1	1
	2	2	2	2

* I=Interval, C=Cumulative
* AE=Adverse Event
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Country Where Event Occurred

SPAIN

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agranulocytosis	1	1			1	1
Anaemia	5	7	3	3	2	4
Anisocytosis	1	1	1	1		
Atypical haemolytic uraemic syndrome		1				1
Autoimmune haemolytic anaemia		1				1
Coagulopathy	2	2			2	2
Coombs positive haemolytic anaemia		1				1
Haemorrhagic diathesis		1				1
Hilar lymphadenopathy	1	1	1	1		
Hyperfibrinogenaemia		1				1
Hypochromasia	1	1	1	1		
Hypochromic anaemia	1	1			1	1
Immune thrombocytopenia	5	11			5	11
Iron deficiency anaemia	2	2	1	1	1	1
Leukocytosis	3	5		1	3	4
Leukopenia		1				1
Lymphadenitis	6	21	5	11	1	10
Lymphadenopathy	79	218	62	110	17	108
Lymphadenopathy mediastinal	2	2	1	1	1	1
Lymph node pain	1	2			1	2
Lymphocytosis		1		1		
Lymphopenia	2	4	2	4		
Microcytosis	1	1	1	1		
Neutropenia	1	2			1	2
Neutrophilia	1	3		1	1	2
Normochromic normocytic anaemia		1		1		
Pancytopenia	2	4			2	4
Splenic vein thrombosis	1	1			1	1
Spontaneous haematoma		1				1
Thrombocytopenia	15	23			15	23
Thrombotic microangiopathy		1				1
Thrombotic thrombocytopenic purpura		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	133	324	78	138	55	186

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* AE=Adverse Event
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System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome	1	2			1	2
Acute myocardial infarction	12	19			12	19
Angina pectoris	3	5			3	5
Aortic valve calcification		1				1
Aortic valve incompetence	1	1			1	1
Arrhythmia	4	7			4	7
Arteriosclerosis coronary artery	1	1			1	1
Atrial f brillation	16	29			16	29
Atrioventricular block first degree		1		1		
Bradycardia	1	10			1	10
Bundle branch block left	1	2	1	1		1
Bundle branch block right	1	2			1	2
Cardiac amyloidosis	1	1			1	1
Cardiac arrest	3	7			3	7
Cardiac disorder		2		1		1
Cardiac failure	8	24			8	24
Cardiac failure acute	3	10			3	10
Cardiac failure congestive	3	6			3	6
Cardiac tamponade	1	2			1	2
Cardiogenic shock	1	1			1	1
Cardiomegaly	3	6	2	2	1	4
Cardio-respiratory arrest	12	25			12	25
Cardio-respiratory distress		1				1
Cardiovascular disorder	2	2	1	1	1	1
Coronary artery stenosis	1	1			1	1
Dilatation atrial		1				1
Dilatation ventricular	1	2			1	2
Extrasystoles	3	5	1	1	2	4
Hyperdynamic left ventricle		1				1
Left ventricular failure	1	1			1	1
Mitral valve calcification	1	1			1	1
Mitral valve incompetence	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mitral valve stenosis	1	1			1	1
Myocardial infarction		2				2
Myocardial ischaemia	1	3			1	3
Myocardial rupture		1				1
Myocarditis		4				4
Palpitations	10	34	5	10	5	24
Paroxysmal atrioventricular block	1	1			1	1
Pericardial effusion	1	1			1	1
Pericardial haemorrhage		1				1
Pericarditis	4	13			4	13
Pleuropericarditis	2	3			2	3
Pulseless electrical activity	1	1			1	1
Restrictive cardiomyopathy	1	1			1	1
Right ventricular dilatation	1	1			1	1
Right ventricular dysfunction	1	1			1	1
Right ventricular failure	1	1			1	1
Right ventricular hypertrophy	1	1			1	1
Sinus arrest		1				1
Sinus bradycardia	2	3	1	2	1	1
Sinus tachycardia	1	10		1	1	9
Supraventricular extrasystoles		1				1
Supraventricular tachycardia	1	3			1	3
Systolic dysfunction	2	2			2	2
Tachyarrhythmia		1				1
Tachycardia	19	93	10	26	9	67
Tachycardia paroxysmal		1				1
Tricuspid valve incompetence		1				1
Ventricular dysfunction	1	2	1	1		1
Ventricular enlargement		1				1
Ventricular extrasystoles		1				1
Ventricular fibrillation	1	2			1	2
Ventricular hypokinesia	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ventricular tachycardia	1	1			1	1
	141	374	22	47	119	327

System Organ Class

Congenital, familial and genetic disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypertrophic cardiomyopathy	1	1	1	1
Macroglossia		1		1
Myoclonic dystonia		2		2
	1	4	1	4

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness	2	3			2	3
Deafness unilateral		2				2
Ear discomfort	1	2			1	2
Ear pain	6	13	5	6	1	7
Hypoacusis	1	8	1	1		7
Meniere's disease		1				1
Misophonia		1				1
Neurosensory hypoacusis		1				1
Tinnitus	3	18	1	6	2	12
Vertigo	9	28	5	9	4	19
Vertigo positional		1				1
	22	78	12	22	10	56

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adrenal mass		1		1		
Autoimmune hypothyroidism		1				1
Autoimmune thyroiditis	1	1			1	1
Basedow's disease	1	1			1	1
Goitre	2	3	1	2	1	1
Hyperthyroidism		1				1
Hypothyroidism	1	2			1	2
Primary hyperthyroidism	1	1			1	1
Silent thyroiditis		1				1
Thyroiditis	1	1			1	1
Thyroiditis acute	1	1			1	1
Thyroid mass	1	1			1	1
	9	15	1	3	8	12

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accommodation disorder	1	1	1	1		
Amaurosis fugax		2				2
Anisometropia		1		1		
Asthenopia	1	4	1	1		3
Blepharitis		2		2		
Blepharospasm	2	4	2	3		1
Blindness	1	1			1	1
Blindness transient		1				1
Blindness unilateral		1				1
Chorioretinopathy		1				1
Conjunctival haemorrhage	3	11			3	11
Conjunctival hyperaemia		2				2
Diplopia	2	10		2	2	8
Dry eye	1	3	1	2		1
Dyschromatopsia		1				1
Episcleritis		1				1
Eye allergy	1	1	1	1		
Eye discharge		1				1
Eye disorder	1	1	1	1		
Eye haemorrhage		1				1
Eye inflammation	1	1	1	1		
Eye irritation	1	1	1	1		
Eyelid disorder	1	1	1	1		
Eyelid oedema	2	8	1	2	1	6
Eyelid pain	1	1			1	1
Eyelid ptosis	1	1	1	1		
Eyelids pruritus	1	1			1	1
Eye pain	4	12	3	5	1	7
Eye pruritus		5		2		3
Eye swelling	1	2			1	2
Floppy eyelid syndrome		1				1
Foreign body sensation in eyes		3		3		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gaze palsy		1				1
Giant papillary conjunctivitis		1				1
Hypoaesthesia eye	1	2	1	1		1
Iridocyclitis	1	2			1	2
Keratitis		2				2
Lacrimation increased		5		1		4
Macular oedema		1				1
Metamorphopsia	1	1	1	1		
Miosis		1				1
Noninfective conjunctivitis	1	1	1	1		
Ocular discomfort	1	1	1	1		
Ocular dysmetria		1		1		
Ocular hyperaemia	1	3			1	3
Ophthalmic vein thrombosis	1	1			1	1
Papilloedema	1	1	1	1		
Periorbital inflammation	1	1			1	1
Periorbital oedema	1	2		1	1	1
Periorbital pain		1				1
Periorbital swelling		1		1		
Photophobia	2	9	1	3	1	6
Photopsia		2		2		
Pupils unequal	1	1	1	1		
Retinal artery occlusion	1	3			1	3
Retinal artery thrombosis	1	1	1	1		
Retinal detachment	1	1	1	1		
Retinal vein occlusion		1				1
Retinal vein thrombosis	2	3			2	3
Scleritis		1				1
Sudden visual loss		1				1
Vision blurred	9	26	5	9	4	17
Visual acuity reduced		1				1
Visual field defect	3	3	2	2	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Visual impairment	2	5			2	5
Vitreous detachment		2				2
Vitreous floaters		1				1
Vogt-Koyanagi-Harada disease	1	1			1	1
	59	178	31	58	28	120

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* AE=Adverse Event
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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	7	14	5	10	2	4
Abdominal distension	2	5	1	4	1	1
Abdominal mass		1		1		
Abdominal pain	20	52	15	33	5	19
Abdominal pain lower	2	6	2	5		1
Abdominal pain upper	5	18	2	10	3	8
Abdominal symptom		1		1		
Abdominal wall haematoma	1	1			1	1
Abnormal faeces		1		1		
Anaesthesia oral	1	1	1	1		
Anal incontinence	2	4	1	2	1	2
Anal sphincter atony		3				3
Angular cheilitis		1		1		
Aphthous ulcer	4	10	3	6	1	4
Atrophic glossitis		1				1
Bowel movement irregularity	1	1	1	1		
Cheilitis		4				4
Colitis	1	2	1	2		
Colitis ischaemic	2	2			2	2
Colitis ulcerative		1				1
Constipation	1	9	1	6		3
Dental caries		1		1		
Diarrhoea	65	203	53	130	12	73
Diarrhoea haemorrhagic	1	3			1	3
Dry mouth	2	10	2	3		7
Duodenal ulcer haemorrhage		1				1
Dyspepsia	3	6	2	3	1	3
Dysphagia	8	25	4	8	4	17
Epigastric discomfort	1	2			1	2
Faecal vomiting	1	1			1	1
Faeces discoloured		1				1
Faeces soft		2		2		

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Flatulence	1	5	1	4		1
Gastric disorder		2		1		1
Gastritis		2		1		1
Gastrointestinal disorder	2	4	2	4		
Gastrointestinal haemorrhage	1	4			1	4
Gastrointestinal pain	1	1	1	1		
Gastrooesophageal reflux disease		2		1		1
Gingival bleeding	2	5		1	2	4
Gingival discolouration	1	1	1	1		
Gingival erythema	1	1			1	1
Gingival swelling	1	2	1	1		1
Glossitis		4				4
Glossodynia		1				1
Haematemesis	2	2			2	2
Haematochezia		1				1
Hiatus hernia	1	4	1	2		2
Hypoaesthesia oral	4	13	4	7		6
Ileus paralytic	1	3			1	3
Inflammatory bowel disease		2				2
Inguinal hernia	1	1			1	1
Intestinal angina	1	1			1	1
Intestinal ischaemia	1	3			1	3
Intestinal obstruction	1	4			1	4
Intra-abdominal haematoma	1	1			1	1
Lip blister		1		1		
Lip erythema		1				1
Lip oedema	5	17	1	3	4	14
Lip pruritus		5		3		2
Lip swelling	2	10		1	2	9
Melaena	1	4			1	4
Mesenteric artery thrombosis	1	1			1	1
Mesenteric panniculitis	1	1			1	1

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* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mesenteric vein thrombosis	3	3			3	3
Mouth haemorrhage	2	2			2	2
Mouth swelling	1	3			1	3
Mouth ulceration	1	2			1	2
Nausea	103	275	94	196	9	79
Noninfective gingivitis		1				1
Odynophagia	13	33	7	13	6	20
Oedema mouth		3		1		2
Oral discomfort	1	3		2	1	1
Oral disorder		1				1
Oral dysaesthesia	2	3	1	1	1	2
Oral mucosal blistering	1	2		1	1	1
Oral pain		1		1		
Oral pruritus		4		1		3
Palatal oedema	3	16			3	16
Palatal swelling		3		1		2
Pancreatitis chronic		1				1
Paraesthesia oral	8	28	6	9	2	19
Parotid gland enlargement		2		2		
Proctalgia		1		1		
Proctitis		1				1
Rectal discharge		1				1
Rectal haemorrhage	2	8			2	8
Rectal tenesmus		1				1
Salivary hypersecretion		1				1
Stomatitis	1	5	1	4		1
Swollen tongue	3	11			3	11
Thrombosis mesenteric vessel	1	1			1	1
Tongue coated		1				1
Tongue discomfort		1		1		
Tongue disorder	2	3	1	2	1	1
Tongue eruption	1	3		2	1	1

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* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue erythema		1				1
Tongue oedema	5	18		2	5	16
Tongue pruritus	1	7	1	3		4
Tongue ulceration	1	3	1	3		
Upper gastrointestinal haemorrhage		1				1
Uvulitis	1	3			1	3
Volvulus		1				1
Vomiting	65	196	49	115	16	81
	384	1,156	267	624	117	532

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site erythema		1		1		
Administration site pruritus		1		1		
Asthenia	72	203	58	116	14	87
Axillary pain	3	20	3	14		6
Cardiac death	1	1			1	1
Chest discomfort	7	30	5	10	2	20
Chest pain	15	55	8	17	7	38
Chills	77	200	72	144	5	56
Concomitant disease aggravated		4				4
Condition aggravated	16	37	3	6	13	31
Crying	1	1	1	1		
Death	4	11			4	11
Device related thrombosis	1	1			1	1
Discomfort	7	26	5	16	2	10
Disease recurrence	7	15		1	7	14
Drowning	1	3			1	3
Drug effective for unapproved indication	1	1	1	1		
Drug ineffective	12	65			12	65
Drug interaction	1	3		1	1	2
Drug intolerance	1	1	1	1		
Effusion	1	1			1	1
Exercise tolerance decreased	1	1	1	1		
Extensive swelling of vaccinated limb		3		3		
Face oedema	10	25	1	1	9	24
Facial pain	2	4	2	3		1
Fatigue	99	238	84	160	15	78
Feeling abnormal	6	14	6	10		4
Feeling cold	6	14	5	7	1	7
Feeling drunk		1		1		
Feeling hot	9	29	4	15	5	14
Feeling of body temperature change	1	1	1	1		
Gait disturbance	11	23	8	9	3	14

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* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gait inability		8
Generalised oedema	2	4
General physical health deterioration	7	17
Hyperpyrexia		1
Hyperthermia	1	2
Hypothermia	3	11
Ill-defined disorder		1
Illness	2	2
Induration	1	3
Inflammation	6	18
Influenza like illness	4	8
Injection site erythema		1
Injection site inflammation		1
Injection site joint erythema	1	1
Injection site pain	1	2
Injection site paraesthesia	1	1
Localised oedema		2
Local reaction	3	8
Malaise	134	344
Mass		2
Mucosal disorder	1	1
Mucosal dryness		1
Multiple organ dysfunction syndrome	2	7
Necrosis	1	2
No adverse event		1
Nodule		1
Oedema	4	9
Oedema peripheral	12	28
Pain	29	64
Peripheral swelling	8	16
Puncture site pain	1	1
Pyrexia	341	925

Spontaneous			
Nonserious		Serious	
I	C	I	C
	2		6
1	1	1	3
3	7	4	10
			1
1	1		1
		3	11
			1
2	2		
1	2		1
4	11	2	7
4	7		1
	1		
	1		
1	1		
1	2		
1	1		
			2
3	4		4
115	241	19	103
			2
1	1		
			1
		2	7
		1	2
	1		
	1		
3	6	1	3
6	9	6	19
24	44	5	20
3	7	5	9
1	1		
305	644	36	281

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* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sensation of foreign body	2	7
Sense of oppression		2
Shoulder injury related to vaccine administration		1
Sudden cardiac death		1
Sudden death	10	27
Swelling	9	12
Swelling face	4	10
Systemic inflammatory response syndrome	1	2
Temperature intolerance		1
Temperature regulation disorder	12	41
Tenderness	2	3
Therapeutic response unexpected	1	1
Thirst	1	2
Ulcer	1	1
Vaccination failure	17	41
Vaccination site discomfort	4	8
Vaccination site erosion		1
Vaccination site erythema	10	27
Vaccination site haematoma	3	10
Vaccination site haemorrhage		1
Vaccination site hyperaesthesia		2
Vaccination site hypersensitivity		1
Vaccination site hypoaesthesia		5
Vaccination site induration	9	17
Vaccination site inflammation	11	50
Vaccination site joint discomfort		1
Vaccination site joint erythema	4	19
Vaccination site joint inflammation		3
Vaccination site joint movement impairment	1	2
Vaccination site joint pain	3	3
Vaccination site joint swelling	1	3
Vaccination site lymphadenopathy	11	41

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1	1	6
			2
	1		
			1
		10	27
8	10	1	2
3	5	1	5
		1	2
	1		
10	25	2	16
2	2		1
1	1		
1	2		
1	1		
		17	41
4	6		2
	1		
8	18	2	9
2	3	1	7
	1		
	1		1
	1		
	2		3
8	14	1	3
9	38	2	12
	1		
4	13		6
	1		2
1	1		1
3	3		
1	3		
8	23	3	18

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site macule	2	2	2	2		
Vaccination site movement impairment	1	7	1	6		1
Vaccination site oedema	5	10	4	6	1	4
Vaccination site pain	102	306	95	239	7	67
Vaccination site paraesthesia	3	10	2	4	1	6
Vaccination site phlebitis	1	1			1	1
Vaccination site pruritus	2	15	1	8	1	7
Vaccination site rash		5		3		2
Vaccination site reaction	4	9	4	7		2
Vaccination site swelling	4	15	4	10		5
Vaccination site urticaria	1	1	1	1		
Vaccination site warmth	6	15	5	9	1	6
	1,186	3,268	943	2013	243	1255

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* AE=Adverse Event
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System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute hepatic failure		1				1
Autoimmune hepatitis		2				2
Bile duct stone	1	1			1	1
Biliary colic	1	3			1	3
Biliary cyst		1		1		
Cholangitis	1	1			1	1
Cholecystitis	1	1			1	1
Cholelithiasis	1	1			1	1
Cholestasis		1				1
Gallbladder enlargement		1				1
Granulomatous liver disease	1	2			1	2
Hepatic cyst	1	3	1	3		
Hepatic cytolysis	1	2			1	2
Hepatic failure		1				1
Hepatic function abnormal	1	1			1	1
Hepatic lesion	1	1			1	1
Hepatic steatosis		1				1
Hepatitis		1				1
Hepatitis acute		5				5
Hepatitis cholestatic		1				1
Hepatomegaly		1				1
Hypertransaminasaemia		4		1		3
Jaundice	1	1	1	1		
Ocular icterus	1	1	1	1		
Portal vein thrombosis	1	2			1	2
Portosplenomesenteric venous thrombosis	1	1			1	1
	14	41	3	7	11	34

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic oedema		2				2
Allergic reaction to excipient	1	2			1	2
Allergy to vaccine	3	12		1	3	11
Amyloidosis senile	1	1			1	1
Anamnestic reaction	1	1			1	1
Anaphylactic reaction	8	57			8	57
Anaphylactic shock		6				6
Bacille Calmette-Guerin scar reactivation		1		1		
Drug hypersensitivity	2	4	2	2		2
Food allergy		1				1
Haemophagocytic lymphohistiocytosis		1				1
Hypersensitivity	10	39	5	9	5	30
Immune system disorder		1				1
Immunisation reaction		1		1		
Immunodeficiency	1	1			1	1
Reaction to excipient		1				1
Reaction to preservatives	1	1	1	1		
Type IV hypersensitivity reaction		1				1
	28	133	8	15	20	118

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Appendicitis		3						3
Asymptomatic bacteriuria	1	1					1	1
Asymptomatic COVID-19	6	29				5	6	24
Bacteraemia	1	2					1	2
Bacterial disease carrier		1						1
Bacteriuria	2	2			2	2		
Biliary sepsis	1	1					1	1
Bronchitis	1	2			1	1		1
Bronchitis bacterial		1						1
Cellulitis	3	12					3	12
Cellulitis staphylococcal		1						1
Chronic sinusitis	1	1			1	1		
Citrobacter infection		1						1
Clostridium difficile colitis		1						1
COVID-19	28	127			5	32	23	95
COVID-19 pneumonia	5	18					5	18
Diverticulitis intestinal haemorrhagic	1	1					1	1
Ear infection		1						1
Eczema herpeticum		1						1
Encephalitis	1	6					1	6
Endocarditis	1	1					1	1
Enterococcal infection	1	2					1	2
Epididymitis	1	1					1	1
Epiglottitis		1						1
Epstein-Barr virus infection reactivation		1						1
Escherichia bacteraemia	1	1					1	1
Escherichia infection		2						2
Escherichia urinary tract infection	1	1					1	1
Fungal skin infection		1						1
Gastroenteritis	2	8			1	5	1	3
Genital herpes		1				1		
Gingivitis	2	3			1	2	1	1

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Herpes ophthalmic	1	4
Herpes simplex	1	4
Herpes virus infection	1	3
Herpes zoster	40	97
Herpes zoster cutaneous disseminated	2	4
Herpes zoster oticus	2	3
Herpes zoster reactivation	2	5
Infection		2
Infectious mononucleosis		1
Infective exacerbation of bronchiectasis		1
Influenza	4	11
Labyrinthitis		1
Large intestine infection		1
Laryngitis		1
Localised infection		1
Lower respiratory tract infection		1
Lymphangitis		3
Mastitis	1	1
Meningitis aseptic	1	1
Meningitis herpes		1
Meningoencephalitis herpetic	1	1
Morganella infection		1
Myelitis	1	2
Nasal herpes		1
Nasopharyngitis	4	7
Ophthalmic herpes zoster	5	7
Oral candidiasis	1	5
Oral herpes	3	14
Orchitis	1	1
Parotitis	1	4
Periorbital abscess		1
Persistent generalised lymphadenopathy		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	4
			1	1	3
		1	2		1
	1	14	24	26	73
				2	4
				2	3
		2	2		3
			1		1
					1
					1
		3	6	1	5
					1
					1
					1
					1
					3
				1	1
				1	1
					1
				1	1
					1
				1	2
					1
		4	7		
				5	7
		1	4		1
		2	7	1	7
				1	1
			1	1	3
					1
					1

* I=Interval, C=Cumulative

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pertussis		2
Pharyngitis		1
Pharyngotonsillitis		2
Pneumonia	4	18
Pneumonia bacterial	1	1
Post viral fatigue syndrome		1
Pseudomonal bacteraemia	1	1
Pulmonary sepsis		1
Pustule		1
Pyelonephritis		1
Respiratory tract infection	2	8
Rhinitis	1	8
Sepsis	2	4
Septic arthritis staphylococcal		1
Septic shock		2
Serratia infection	1	1
Severe acute respiratory syndrome		1
Sialoadenitis		1
Sinusitis		1
Staphylococcal infection		1
Subcutaneous abscess		1
Superinfection	1	1
Superinfection bacterial		1
Suspected COVID-19	1	2
Thrombophlebitis septic	1	1
Tonsillitis	1	3
Tracheitis	1	1
Tracheobronchitis bacterial	1	1
Tuberculosis		1
Upper respiratory tract infection		1
Urinary tract infection	5	19
Urinary tract infection bacterial		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
					2
				4	18
				1	1
					1
				1	1
					1
					1
					1
				2	8
		1	7		1
				2	4
					1
					2
				1	1
					1
			1		
					1
					1
		1	1		
					1
					1
				1	2
				1	1
				1	3
				1	1
				1	1
					1
					1
		2	5	3	14
					1

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Urinary tract infection pseudomonal		1						1
Urosepsis		1						1
Vaccination site abscess		1						1
Vaccination site cellulitis	1	3					1	3
Varicella zoster virus infection	2	2			1	1	1	1
Vestibular neuritis	1	2					1	2
Viral infection	1	1			1	1		
Viral keratouveitis		1						1
Viral rash		1						1
Vulvovaginal candidiasis	1	2			1	1		1
Yellow fever	1	1					1	1
Yersinia bacteraemia	1	1					1	1
Yersinia infection	1	1					1	1
	164	534		1	45	121	119	413

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose	1	1	1	1		
Alcohol poisoning		1				1
Brachial plexus injury		1				1
Chest injury		1				1
Complications of transplanted kidney	1	1			1	1
Conjunctival laceration		1		1		
Contusion	1	6		2	1	4
Craniocerebral injury	3	9			3	9
Exposure during pregnancy	2	7	2	6		1
Exposure via breast milk	4	11	4	9		2
Face injury		1				1
Facial bones fracture		2				2
Fall	8	26	2	9	6	17
Femur fracture		1				1
Foreign body in throat	1	2			1	2
Fracture		1				1
Head injury		4		1		3
Humerus fracture	1	1			1	1
Inappropriate schedule of product administration	8	19	8	19		
Incorrect dose administered	3	7	3	7		
Incorrect route of product administration	8	15	8	15		
Injury	1	3		1	1	2
Jaw fracture		1				1
Joint dislocation	1	1	1	1		
Joint injury	1	3			1	3
Ligament sprain		1		1		
Maternal exposure during pregnancy	4	9	4	8		1
Maternal exposure timing unspecified		1		1		
Medication error		1		1		
Mouth injury	1	1	1	1		
Muscle injury	1	1	1	1		
Muscle strain	1	1			1	1

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Off label use	11	25	11	25		
Overdose	2	11	2	11		
Patella fracture		1				1
Periorbital haematoma	1	2	1	1		1
Poor quality product administered	1	6	1	6		
Product administered at inappropriate site	1	1	1	1		
Product administration interrupted	1	1	1	1		
Product dose omission issue	1	1	1	1		
Product preparation error		5		5		
Product preparation issue	1	5	1	5		
Product use issue	4	12	4	12		
Rib fracture	2	3			2	3
Skeletal injury		1				1
Spinal cord injury		1				1
Subcutaneous haematoma		1				1
Subdural haematoma	1	1			1	1
Tongue injury	2	2	1	1	1	1
Tooth avulsion		1				1
Toxicity to various agents		1				1
Underdose	4	5	4	5		
Upper limb fracture		2		1		1
Vaccination complication	1	5		1	1	4
Vascular graft thrombosis	1	1			1	1
Vasoplegia syndrome	1	2			1	2
Wound	2	3	1	1	1	2
Wrong technique in product usage process	1	3	1	3		
	89	243	65	165	24	78

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Activated partial thromboplastin time prolonged		1				1
Activated partial thromboplastin time shortened	1	2	1	2		
Alanine aminotransferase increased	1	1	1	1		
Amino acid level increased	1	1	1	1		
Antibody test abnormal		1		1		
Antipsychotic drug level increased		1				1
AST/ALT ratio abnormal	2	2	2	2		
Autoantibody negative		1				1
Bacterial test		1				1
Base excess decreased		1		1		
Blood bicarbonate decreased		1				1
Blood bicarbonate increased		1		1		
Blood calcium decreased		1		1		
Blood chloride decreased		1		1		
Blood chloride increased	1	1	1	1		
Blood cholesterol decreased	1	1	1	1		
Blood creatine phosphokinase increased	2	2			2	2
Blood creatinine decreased	2	2	2	2		
Blood creatinine increased	1	2	1	2		
Blood fibrinogen decreased		1		1		
Blood fibrinogen increased	8	10	7	9	1	1
Blood gases abnormal		1				1
Blood glucose decreased	1	2	1	1		1
Blood glucose increased	8	10	6	7	2	3
Blood iron decreased	1	1			1	1
Blood lactate dehydrogenase increased	1	3	1	2		1
Blood lactic acid increased	2	2	2	2		
Blood parathyroid hormone increased	1	1	1	1		
Blood phosphorus increased	1	1			1	1
Blood potassium decreased	1	1	1	1		
Blood pressure abnormal		4		2		2
Blood pressure decreased	4	6	1	2	3	4

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure diastolic decreased	2	3	2	2		1
Blood pressure diastolic increased		1				1
Blood pressure increased	12	26	7	16	5	10
Blood pressure systolic increased	3	5	2	4	1	1
Blood sodium decreased		1		1		
Blood sodium increased	1	1	1	1		
Blood thyroid stimulating hormone increased		1		1		
Blood urea increased	7	8	7	7		1
Body temperature decreased	3	5	3	4		1
Body temperature increased	1	3		2	1	1
Breath sounds abnormal		1				1
Cardiac murmur	2	2	2	2		
Cardiothoracic ratio increased		1				1
Carotid bruit		2				2
Chest X-ray abnormal	1	1	1	1		
Clostridium test positive	1	1			1	1
Coma scale abnormal	1	1			1	1
Corneal reflex decreased		1				1
C-reactive protein increased	6	10	3	7	3	3
CSF protein increased	1	1			1	1
Cytomegalovirus test positive		1				1
Electrocardiogram abnormal	1	1			1	1
Electrocardiogram normal		1				1
Electrocardiogram QRS complex prolonged		1				1
Electrocardiogram QRS complex shortened		2				2
Electrocardiogram repolarisation abnormality		1				1
Electrocardiogram ST segment elevation		1				1
Electrocardiogram ST-T change		1				1
Electrocardiogram T wave inversion		1				1
Eosinophil count increased	1	1	1	1		
Epstein-Barr virus antibody positive		1				1
Fibrin D dimer increased	6	13	2	3	4	10

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fibrinolysis		1				1
Fibrinolysis abnormal	1	1			1	1
Foetal heart rate abnormal		1				1
Gamma-glutamyltransferase increased		1		1		
Glomerular filtration rate decreased	3	4	2	3	1	1
Glycosylated haemoglobin increased	1	1	1	1		
Haematocrit decreased	4	5	4	5		
Haemoglobin decreased	2	6	1	4	1	2
Haemoglobin increased		1		1		
Heart rate abnormal	1	1			1	1
Heart rate decreased		1				1
Heart rate increased	2	8	2	5		3
Heart rate irregular		1				1
Hepatic enzyme abnormal		1				1
Hepatitis B virus test positive		1		1		
Hormone level abnormal	1	1	1	1		
International normalised ratio increased	6	6	2	2	4	4
Lipase decreased		1		1		
Liver function test abnormal		1				1
Lymphocyte count decreased	5	6	5	6		
Lymphocyte count increased	1	2	1	2		
Lymphocyte percentage decreased		1		1		
Mean cell haemoglobin concentration decreased	2	3	2	3		
Mean cell volume decreased	1	1	1	1		
Mean platelet volume increased	1	1	1	1		
Neutrophil count decreased	2	2	1	1	1	1
Neutrophil count increased	6	10	6	10		
Neutrophil percentage increased	1	2	1	2		
N-terminal prohormone brain natriuretic peptide increased	1	2	1	1		1
Oxygen saturation decreased	9	26	2	4	7	22
PCO2 decreased		1		1		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
PCO2 increased	2	2	2	2		
Platelet count decreased	7	8	6	6	1	2
Platelet count increased	1	2	1	2		
PO2 decreased	1	4	1	4		
Positron emission tomogram		1				1
Procalcitonin increased	1	1			1	1
Prothrombin level decreased		1				1
Prothrombin level increased	1	1			1	1
Prothrombin time prolonged		3		2		1
Prothrombin time shortened	3	3	3	3		
Pulse abnormal		2				2
Red blood cell count abnormal	1	1			1	1
Red blood cell sedimentation rate increased		2		2		
Red cell distribution width increased	1	1	1	1		
Respiratory rate decreased		1				1
SARS-CoV-2 ant body test negative		2		2		
SARS-CoV-2 ant body test positive	1	5	1	4		1
SARS-CoV-2 test positive	1	8		6	1	2
Serology negative		1		1		
Serum ferritin abnormal	1	1			1	1
Serum ferritin increased	1	1	1	1		
Thyroxine decreased		1		1		
Transaminases increased	1	2			1	2
Transferrin abnormal	1	1			1	1
Troponin I increased	1	2			1	2
Troponin T increased	1	3	1	1		2
Urinary sediment abnormal		1		1		
Urinary sediment present		1		1		
Urine output decreased		1		1		
Venous pressure	1	1	1	1		
Vitamin B12 decreased	1	1	1	1		
Vitamin D decreased	1	1	1	1		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
White blood cell count decreased	1	2			1	2
White blood cell count increased	9	11	9	11		
X-ray abnormal		1				1
	178	347	124	210	54	137

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cachexia		1				1
Cell death		1				1
Decreased appetite	5	20	3	8	2	12
Dehydration	2	5	1	3	1	2
Diabetes mellitus	2	4			2	4
Diabetes mellitus inadequate control	1	3			1	3
Diabetic ketoacidosis		1				1
Diabetic metabolic decompensation		2				2
Electrolyte imbalance		1				1
Fluid overload		1				1
Folate deficiency		1		1		
Hypercholesterolaemia		1		1		
Hyperglycaemia	6	15	1	1	5	14
Hyperkalaemia	1	2			1	2
Hyperlactacidaemia	1	1			1	1
Hypernatraemia		3		1		2
Hyperuricaemia	1	1	1	1		
Hypocalcaemia	2	4	2	3		1
Hypoglycaemia	5	10	3	3	2	7
Hypokalaemia	2	3			2	3
Hypomagnesaemia	1	1			1	1
Hyponatraemia	1	4			1	4
Hypophagia	1	1	1	1		
Hypophosphataemia		1		1		
Hypoproteinaemia	1	1	1	1		
Insulin resistance		1				1
Iron deficiency	1	2	1	2		
Malnutrition	1	2	1	2		
Metabolic acidosis	1	1			1	1
Polydipsia	1	1			1	1
Vitamin D deficiency	2	3	2	3		
	38	98	17	32	21	66

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- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	74	205	64	144	10	61
Arthritis	3	5			3	5
Arthritis allergic		1				1
Arthritis reactive		2				2
Axillary mass	1	1	1	1		
Back pain	13	35	11	23	2	12
Bone disorder	1	1	1	1		
Bursitis		2				2
Costochondritis		1				1
Decreased nasolabial fold		1				1
Fibromyalgia	1	2			1	2
Groin pain	1	2	1	1		1
Haematoma muscle	2	5			2	5
Immobilisation syndrome		1		1		
Intervertebral disc disorder	1	1	1	1		
Jaw disorder		1		1		
Joint contracture		2		2		
Joint range of motion decreased	1	3	1	1		2
Joint swelling		1				1
Joint warmth		1				1
Limb discomfort	2	6	2	4		2
Mastication disorder	1	1	1	1		
Mobility decreased	1	13	1	4		9
Muscle contracture		5		4		1
Muscle fatigue		1		1		
Muscle rigidity	2	4	1	1	1	3
Muscle spasms	3	10	2	6	1	4
Muscle tightness	1	5	1	2		3
Muscular weakness	9	24	8	15	1	9
Musculoskeletal chest pain	1	3		2	1	1
Musculoskeletal discomfort	2	6	2	2		4
Musculoskeletal disorder	1	2			1	2

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal pain	11	49	7	19	4	30
Musculoskeletal stiffness	3	8	3	4		4
Myalgia	143	411	131	295	12	116
Myositis		4				4
Neck mass		1		1		
Neck pain	8	24	6	12	2	12
Nuchal rigidity		4				4
Osteoarthritis		1		1		
Pain in extremity	55	117	47	83	8	34
Pain in jaw		1		1		
Periarthritis	1	3			1	3
Polyarthritis	1	2			1	2
Psoriatic arthropathy		1				1
Rheumatoid arthritis	1	1			1	1
Rotator cuff syndrome	3	5	2	2	1	3
Scoliosis		1				1
SLE arthritis		1				1
Spinal osteoarthritis		1				1
Spinal pain		2				2
Systemic lupus erythematosus	1	2			1	2
Tendon disorder		1				1
Tendonitis	1	3		1	1	2
Tenosynovitis	1	2	1	1		1
Trismus	1	1	1	1		
Weight bearing difficulty	1	1			1	1
	352	1,000	296	639	56	361

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute leukaemia		1				1
Basal cell carcinoma	1	1			1	1
Castleman's disease	1	1			1	1
Chronic lymphocytic leukaemia		1				1
Colon neoplasm		1				1
Haemangioma	1	1	1	1		
Haemangioma of liver	1	1	1	1		
Kaposi's sarcoma AIDS related		1				1
Lipoma		1		1		
Neoplasm		2		1		1
Neoplasm progression	1	1	1	1		
Uterine leiomyoma	1	1	1	1		
	6	13	4	6	2	7

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acoustic neuritis		1				1
Ageusia	2	13	2	5		8
Akathisia	1	1	1	1		
Allodynia		1		1		
Altered state of consciousness	1	1			1	1
Amnesia		8		4		4
Anosmia	2	12	2	6		6
Anterograde amnesia	1	1			1	1
Apallic syndrome	1	1			1	1
Aphasia	4	12	1	2	3	10
Ataxia		1				1
Autoimmune demyelinating disease		1				1
Axonal neuropathy		1		1		
Balance disorder	4	20	1	7	3	13
Basal ganglia haematoma	1	1			1	1
Basal ganglia stroke	1	2			1	2
Basilar artery thrombosis		1				1
Bell's palsy	9	20			9	20
Brachial plexopathy	1	1	1	1		
Bradykinesia		2		1		1
Brain oedema		1				1
Bulbar palsy	1	1			1	1
Burning sensation	2	5	1	1	1	4
Burning sensation mucosal		1		1		
Carotid arteriosclerosis	1	1	1	1		
Carpal tunnel syndrome	1	1			1	1
Central nervous system lesion	1	1			1	1
Cerebellar ataxia	1	1	1	1		
Cerebellar infarction		1				1
Cerebellar stroke	1	1			1	1
Cerebellar syndrome		1				1
Cerebral arteriosclerosis	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral artery embolism	1	1			1	1
Cerebral disorder		1				1
Cerebral haematoma	1	4			1	4
Cerebral haemorrhage	2	8			2	8
Cerebral infarction	1	3			1	3
Cerebral ischaemia	1	2			1	2
Cerebral small vessel ischaemic disease	1	1			1	1
Cerebral thrombosis	1	1			1	1
Cerebral venous sinus thrombosis	2	3			2	3
Cerebral venous thrombosis		3				3
Cerebrovascular accident	6	15			6	15
Cerebrovascular disorder		1				1
Cervicobrachial syndrome		2		1		1
Circadian rhythm sleep disorder		1				1
Cognitive disorder	3	7	1	2	2	5
Coma	1	1			1	1
Coordination abnormal	1	3		1	1	2
Delayed ischaemic neurological deficit	1	1			1	1
Demyelination		2				2
Depressed level of consciousness	4	26			4	26
Disturbance in attention	3	10	3	4		6
Dizziness	86	262	64	146	22	116
Dizziness postural	4	7	4	6		1
Dysaesthesia	4	12	1	2	3	10
Dysarthria	7	14	4	7	3	7
Dysgeusia	11	23	8	14	3	9
Dyskinesia		1				1
Dyslexia		1				1
Dysstasia	1	2	1	2		
Dystonia		1				1
Embolic stroke	4	6			4	6
Encephalopathy		2				2

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Epilepsy	3	10			3	10
Essential tremor		2		1		1
Extensor plantar response		1		1		
Extrapyramidal disorder		1				1
Facial neuralgia		1		1		
Facial paralysis	17	54			17	54
Facial paresis	1	5	1	2		3
Febrile convulsion		5				5
Focal dyscognitive seizures	1	1			1	1
Formication	1	6	1	3		3
Fumbling	1	2			1	2
Generalised tonic-clonic seizure	5	12			5	12
Guillain-Barre syndrome	3	9			3	9
Haemorrhage intracranial	2	3			2	3
Haemorrhagic stroke	1	3			1	3
Haemorrhagic transformation stroke	1	1			1	1
Headache	262	702	229	471	33	231
Head discomfort		1				1
Hemianaesthesia	1	2			1	2
Hemidysaesthesia		1				1
Hemihyperaesthesia		1				1
Hemiparaesthesia	2	9			2	9
Hemiparesis	3	7			3	7
Hemiplegia	1	5			1	5
Hydrocephalus	1	1			1	1
Hyperaesthesia	1	5	1	3		2
Hypercapnic coma	1	1			1	1
Hypersomnia	2	3	2	2		1
Hypertensive encephalopathy		1				1
Hypertonia	1	1			1	1
Hypoaesthesia	13	46	8	17	5	29
Hypokinesia		2		1		1

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyporeflexia	1	2	1	1		1
Hyporesponsive to stimuli		1				1
Hyposmia	2	2			2	2
Hypotonia		1		1		
Incoherent	1	3	1	1		2
Infant irritability		1				1
Intracranial pressure increased	1	1	1	1		
Intraventricular haemorrhage	1	2			1	2
Ischaemic cerebral infarction		1				1
Ischaemic stroke	11	30			11	30
Lacunar infarction	1	1			1	1
Lacunar stroke		1				1
Lateral medullary syndrome	1	1			1	1
Lethargy		1				1
Leukoencephalopathy	1	2			1	2
Loss of consciousness	8	34			8	34
Memory impairment	2	3	2	2		1
Meningism		1				1
Mental impairment	2	8			2	8
Migraine	3	12	1	3	2	9
Migraine with aura		3		1		2
Migraine without aura		1				1
Mononeuritis	1	1			1	1
Mononeuropathy		1				1
Monoparesis	2	4	1	1	1	3
Monoplegia	1	4			1	4
Motor dysfunction	1	1			1	1
Movement disorder	2	5	2	3		2
Multiple sclerosis		1				1
Muscle contractions involuntary	1	6		3	1	3
Myoclonus		1				1
Nervous system disorder	1	3	1	1		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuralgia	2	7	2	4		3
Neuralgic amyotrophy		3				3
Neuropathy peripheral	2	7			2	7
Oculofacial paralysis		1				1
Optic neuritis	2	3			2	3
Paraesthesia	43	152	25	53	18	99
Paraesthesia mucosal		1				1
Paraparesis	1	3	1	1		2
Paresis		1		1		
Parosmia		1				1
Partial seizures		2				2
Partial seizures with secondary generalisation	1	1			1	1
Peripheral paralysis		1				1
Peripheral sensory neuropathy		1				1
Petit mal epilepsy	1	7			1	7
Post herpetic neuralgia	3	3			3	3
Presyncope	10	35	7	13	3	22
Psychomotor hyperactivity	1	6		2	1	4
Resting tremor	1	1			1	1
Restless legs syndrome	2	3	2	2		1
Seizure	5	17			5	17
Sensory disturbance	1	3	1	1		2
Sensory loss	3	12		4	3	8
Slow response to stimuli	1	1	1	1		
Slow speech		3		1		2
Somnolence	10	33	8	21	2	12
Spasmodic dysphonia		1		1		
Speech disorder	4	8	2	3	2	5
Status epilepticus	3	4			3	4
Stupor		1				1
Subarachnoid haemorrhage	4	5			4	5
Superior sagittal sinus thrombosis	1	1			1	1

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Syncope	18	93			18	93
Tension headache		7		4		3
Thalamic infarction		1				1
Thalamus haemorrhage	1	1			1	1
Thunderclap headache		1				1
Tonic clonic movements		1				1
Transient global amnesia	3	4			3	4
Transient ischaemic attack	3	11			3	11
Transverse sinus thrombosis	1	1			1	1
Tremor	11	24	9	11	2	13
Trigeminal neuralgia		2				2
Trigeminal neuritis	1	1	1	1		
Tunnel vision		1				1
Vestibular migraine		1				1
White matter lesion	1	3		1	1	2
	691	2,067	408	863	283	1204

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion missed	1	3	1	3
Abortion spontaneous		3		3
Anembryonic gestation	1	1	1	1
Cephalhaematoma		1		1
	2	8	2	8

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour	1	1			1	1
Acute psychosis		1				1
Agitation	2	8	1	2	1	6
Anxiety	8	17	4	12	4	5
Apathy		1				1
Bradyphrenia	1	8	1	4		4
Bruxism		1		1		
Claustrophobia	1	1	1	1		
Confusional state	7	23	4	9	3	14
Delirium		3				3
Delirium febrile		1				1
Delusion		1				1
Depressed mood		5		5		
Disorganised speech		1				1
Disorientation	7	20	3	8	4	12
Dyssomnia	1	1	1	1		
Eating disorder		1		1		
Echolalia	1	1	1	1		
Emotional disorder	1	1			1	1
Euphoric mood		3		1		2
Fear	1	1	1	1		
Gastrointestinal somatic symptom disorder		1		1		
Hallucination	3	7			3	7
Hallucination, auditory		1				1
Hallucinations, mixed		1				1
Hallucination, visual	1	3			1	3
Hypersexuality		1				1
Insomnia	4	13	3	8	1	5
Mental disorder		1				1
Middle insomnia	1	1	1	1		
Mood altered		1				1
Mutism	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nervousness	6	13	6	9		4
Panic attack	1	1	1	1		
Panic reaction		1				1
Persistent depressive disorder	2	3	1	1	1	2
Phonophobia		1				1
Poor quality sleep		1				1
Post-traumatic stress disorder	1	1			1	1
Psychotic disorder		1		1		
Restlessness	3	8	3	5		3
Sleep attacks	1	1	1	1		
Suicide attempt		1				1
Tic	1	4	1	1		3
	56	167	34	76	22	91

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* AE=Adverse Event
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System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	4	10			4	10
Anuria	1	2			1	2
Bladder spasm		2				2
Bladder sphincter atony		2				2
Chromaturia		1		1		
Chronic kidney disease	1	3			1	3
Dysuria	1	7	1	4		3
Haematuria	2	5	1	2	1	3
Micturition urgency		2				2
Nephrotic syndrome	1	1			1	1
Nocturia	1	1	1	1		
Pollakiuria		1				1
Polyuria	1	2			1	2
Prerenal failure		1				1
Renal cyst	1	3	1	3		
Renal failure	1	6			1	6
Renal impairment	4	7			4	7
Renal pain	1	1	1	1		
Urinary incontinence	1	2	1	2		
Urinary retention		2				2
	20	61	6	14	14	47

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adnexa uteri pain		1		1		
Amenorrhoea	3	4	1	1	2	3
Breast haematoma		1				1
Breast mass		1		1		
Breast oedema		1				1
Breast pain	3	3			3	3
Dysmenorrhoea		1		1		
Galactorrhoea	1	2			1	2
Genital blister		1		1		
Genital ulceration		1				1
Heavy menstrual bleeding	4	5	4	4		1
Intermenstrual bleeding	3	12	2	3	1	9
Menometrorrhagia	1	2			1	2
Menstrual disorder	8	8	8	8		
Menstruation delayed		2				2
Menstruation irregular	6	6	6	6		
Ovarian cyst		1				1
Pelvic pain		1		1		
Penile discomfort		1		1		
Polymenorrhoea		1		1		
Postmenopausal haemorrhage	3	3			3	3
Testicular pain		1		1		
Uterine haemorrhage		2				2
Vaginal discharge		1		1		
Vaginal haemorrhage	1	5		2	1	3
Vulval ulceration		1				1
	33	68	21	33	12	35

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute pulmonary oedema	1	2			1	2
Acute respiratory distress syndrome		1				1
Acute respiratory failure	5	18			5	18
Allergic cough	1	2	1	2		
Aphonia	4	11	2	4	2	7
Apnoea		1				1
Asphyxia		3				3
Aspiration	6	7			6	7
Asthma		4		1		3
Asthmatic crisis		2				2
Atelectasis	1	4	1	2		2
Bronchial hyperreactivity		2				2
Bronchiectasis		1				1
Bronchitis chronic	1	1	1	1		
Bronchospasm	1	19			1	19
Catarrh		2		1		1
Choking		2				2
Choking sensation	2	9		1	2	8
Chronic obstructive pulmonary disease	2	3	1	1	1	2
Chronic respiratory failure		2				2
Cough	20	66	13	31	7	35
Diaphragmalgia		1				1
Dry throat	1	4		2	1	2
Dysphonia	1	10		2	1	8
Dyspnoea	54	172	20	35	34	137
Dyspnoea at rest	1	2			1	2
Dyspnoea exertional	4	15	1	4	3	11
Dyspnoea paroxysmal nocturnal	1	1			1	1
Emphysema	1	1	1	1		
Epistaxis	5	10	1	3	4	7
Haemoptysis	1	3			1	3
Hyperventilation	1	2			1	2

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* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoventilation	2	2			2	2
Hypoxia	4	17			4	17
Increased bronchial secretion		1				1
Increased upper airway secretion	1	1	1	1		
Interstitial lung disease	1	3			1	3
Laryngeal discomfort	1	1			1	1
Laryngeal disorder		1				1
Laryngeal erythema		1				1
Laryngeal oedema	2	16			2	16
Laryngeal pain		1				1
Laryngospasm		2		1		1
Larynx irritation		1				1
Lung consolidation	1	1			1	1
Lung disorder		2				2
Lung infiltration	2	5	1	3	1	2
Nasal congestion	5	20	3	13	2	7
Nasal disorder		1		1		
Nasal obstruction	2	2	1	1	1	1
Nasal pruritus		1				1
Oropharyngeal discomfort	2	8	1	2	1	6
Oropharyngeal oedema		3				3
Oropharyngeal pain	11	23	8	13	3	10
Orthopnoea	3	4	2	2	1	2
Pharyngeal erythema		3				3
Pharyngeal hypoaesthesia		1				1
Pharyngeal inflammation	1	4		1	1	3
Pharyngeal lesion	1	1	1	1		
Pharyngeal oedema	1	5		1	1	4
Pharyngeal swelling		4				4
Pleural effusion	4	9	1	2	3	7
Pleuritic pain	1	4		1	1	3
Pneumonia aspiration	2	6			2	6

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* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonitis		1				1
Pneumothorax		1				1
Productive cough	1	5	1	3		2
Pulmonary embolism	47	87			47	87
Pulmonary haemorrhage		1				1
Pulmonary hypertension	2	4			2	4
Pulmonary infarction	2	5			2	5
Pulmonary oedema	2	2			2	2
Pulmonary thrombosis	1	5			1	5
Rales		1				1
Respiration abnormal		1				1
Respiratory acidosis	1	3			1	3
Respiratory alkalosis	2	2			2	2
Respiratory arrest		2				2
Respiratory disorder		4		1		3
Respiratory distress	6	29			6	29
Respiratory failure	6	17			6	17
Respiratory fatigue	1	1			1	1
Rhinalgia		1		1		
Rhinitis allergic	1	1	1	1		
Rhinorrhoea	7	19	5	14	2	5
Rhonchi	3	3	2	2	1	1
Sneezing	1	4		3	1	1
Stridor	1	2			1	2
Suffocation feeling		2				2
Tachypnoea	5	12	3	5	2	7
Throat irritation	9	29	7	14	2	15
Throat tightness	1	6	1	2		4
Wheezing		10		3		7
Yawning		1		1		
	260	798	81	184	179	614

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- * I=Interval, C=Cumulative
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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne	2	2	2	2		
Acute generalised exanthematous pustulosis		1				1
Alopecia		1				1
Androgenetic alopecia		1				1
Angioedema	3	38			3	38
Blister	2	5	2	3		2
Butterfly rash		1		1		
Circumoral oedema	1	1			1	1
Circumoral swelling	1	2		1	1	1
Cold sweat	1	5		2	1	3
Cutaneous vasculitis		1				1
Decubitus ulcer	1	1	1	1		
Dermatitis	2	2			2	2
Dermatitis allergic	3	11	2	3	1	8
Dermatitis atopic		1				1
Dermatitis bullous		3				3
Dermatitis contact		1				1
Drug eruption		1		1		
Dry skin	1	2	1	1		1
Dyshidrotic eczema	1	1	1	1		
Ecchymosis	1	2	1	1		1
Eczema	1	3	1	2		1
Epidermal necrosis		1				1
Erythema	23	79	13	36	10	43
Erythema multiforme		1				1
Erythema nodosum		1				1
Hyperhidrosis	8	25	5	10	3	15
Hypersensitivity vasculitis	1	2			1	2
Idiopathic angioedema		1				1
Lichen planus		1				1
Lividity		1				1
Mechanical urticaria		1				1

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* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neutrophilic dermatosis		1				1
Night sweats		5		2		3
Pain of skin	2	2	2	2		
Panniculitis	1	2			1	2
Papule		2		1		1
Pernio-like erythema		2		1		1
Petechiae	3	11	1	4	2	7
Pigmentation disorder		1		1		
Pityriasis rosea	1	5			1	5
Pruritus	36	120	24	48	12	72
Pruritus allergic	1	1	1	1		
Psoriasis		1				1
Purpura	2	3			2	3
Rash	22	85	10	29	12	56
Rash erythematous	3	12	2	2	1	10
Rash macular	5	6	4	4	1	2
Rash maculo-papular	1	6		2	1	4
Rash papular	2	7	2	2		5
Rash pruritic	1	12		2	1	10
Rash vesicular	1	2	1	2		
Scab		1		1		
Skin discomfort	1	1	1	1		
Skin disorder	1	1	1	1		
Skin exfoliation		2				2
Skin lesion	3	8	3	4		4
Skin necrosis		2				2
Skin odour abnormal		1				1
Skin reaction	2	5	2	3		2
Skin sensitisation	1	1	1	1		
Skin swelling	1	1	1	1		
Skin tightness	1	1	1	1		
Skin ulcer	1	5		3	1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stevens-Johnson syndrome	1	1			1	1
Systemic lupus erythematosus rash		1		1		
Toxic skin eruption	2	4			2	4
Urticaria	24	87	9	34	15	53
	171	607	95	219	76	388

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden		2				2
Contraindication to vaccination	1	1	1	1		
Loss of personal independence in daily activities	1	3	1	2		1
Walking disability	1	1			1	1
	3	7	2	3	1	4

System Organ Class

Surgical and medical procedures

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion induced		1				1
Limb immobilisation	3	4	3	3		1
	3	5	3	3		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute aortic syndrome	1	1			1	1
Angiopathy	1	1	1	1		
Aortic aneurysm	1	1			1	1
Aortic arteriosclerosis	3	3	2	2	1	1
Aortic dissection		1				1
Aortic elongation	1	1	1	1		
Aortic stenosis	1	1			1	1
Arterial thrombosis	1	1			1	1
Arteriosclerosis	3	3			3	3
Axillary vein thrombosis	1	1			1	1
Blood pressure fluctuation	1	1			1	1
Capillary fragility	1	1	1	1		
Circulatory collapse		1				1
Cyanosis		5		2		3
Deep vein thrombosis	33	49			33	49
Embolism venous	1	1			1	1
Essential hypertension		1				1
Flushing	6	11	4	6	2	5
Giant cell arteritis		1				1
Haematoma	6	15	3	8	3	7
Haemodynamic instability	2	2			2	2
Haemorrhage	1	4			1	4
Hot flush	1	4	1	2		2
Hyperaemia	1	2	1	2		
Hypertension	25	80	7	21	18	59
Hypertensive crisis	15	42			15	42
Hypertensive emergency		1				1
Hypertensive urgency		3				3
Hypotension	15	48	5	13	10	35
Hypovolaemic shock		1				1
Ischaemia	2	3	1	1	1	2
Jugular vein thrombosis	2	2			2	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
May-Thurner syndrome	1	1			1	1
Microangiopathy	1	1	1	1		
Neurogenic shock		1				1
Obstructive shock	1	1			1	1
Orthostatic hypotension	1	2	1	1		1
Pallor	4	11	2	4	2	7
Pelvic venous thrombosis	1	1			1	1
Peripheral artery thrombosis	1	2			1	2
Peripheral coldness	1	7	1	4		3
Peripheral embolism		1				1
Peripheral ischaemia	3	5	1	1	2	4
Peripheral vascular disorder	1	1			1	1
Peripheral venous disease	2	3	1	1	1	2
Phlebitis		2		1		1
Phlebitis superficial	1	3		1	1	2
Poor peripheral circulation	1	3	1	3		
Post thrombotic syndrome		1				1
Raynaud's phenomenon		5				5
Shock	1	2			1	2
Subclavian vein thrombosis	2	2			2	2
Thrombophlebitis	8	12		1	8	11
Thrombophlebitis superficial	7	14		1	7	13
Thrombosed varicose vein	1	1	1	1		
Thrombosis	3	5			3	5
Vasculitis		3				3
Vasodilatation	1	1			1	1
Venous haemorrhage	1	1			1	1
Venous thrombosis limb	4	9			4	9
	172	393	36	80	136	313

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

SWEDEN

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia	2	3			2	3
Coagulopathy		1				1
Haemolytic anaemia		2				2
Haemorrhagic diathesis		1				1
Immune thrombocytopenia	1	3			1	3
Increased tendency to bruise	1	1			1	1
Leukocytosis	1	2	1	1		1
Leukopenia	1	3			1	3
Lymphadenitis		1				1
Lymphadenopathy	12	35	11	24	1	11
Lymphadenopathy mediastinal		1		1		
Lymph node pain	11	19	11	17		2
Myelosuppression		1				1
Neutropenia	1	1			1	1
Pancytopenia		2				2
Spleen disorder		1				1
Splenic artery thrombosis	1	1			1	1
Spontaneous haematoma		1				1
Thrombocytopenia	9	23			9	23
Thrombocytopenic purpura		1				1
	40	103	23	43	17	60

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome	1	1			1	1
Acute left ventricular failure		1				1
Acute myocardial infarction	3	11			3	11
Angina pectoris	3	7			3	7
Arrhythmia	5	10	1	1	4	9
Arteriosclerosis coronary artery		1				1
Atrial fibrillation	6	16			6	16
Atrial flutter	1	3			1	3
Atrial thrombosis		1				1
Atrioventricular block complete		2				2
Bradycardia		1				1
Bundle branch block left		2		1		1
Bundle branch block right		1				1
Cardiac arrest	3	23			3	23
Cardiac discomfort	1	3			1	3
Cardiac disorder	1	5			1	5
Cardiac failure	3	20			3	20
Cardiac failure acute	1	3			1	3
Cardiac failure chronic		1				1
Cardiac fibrillation	1	2			1	2
Cardiac flutter	1	2			1	2
Cardiogenic shock		2				2
Cardiopulmonary failure		1				1
Cardiovascular disorder		1				1
Coronary artery disease	1	1			1	1
Coronary artery occlusion		1				1
Coronary artery stenosis		1				1
Coronary artery thrombosis	1	1			1	1
Cor pulmonale acute		1				1
Dilatation ventricular		1		1		
Extrasystoles	1	4	1	1		3
Intracardiac thrombus	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Left ventricular hypertrophy		1				1
Myocardial fibrosis		1				1
Myocardial infarction	13	27			13	27
Myocardial ischaemia		3				3
Myocardial rupture		1				1
Myocarditis	1	4			1	4
Palpitations	11	45	2	10	9	35
Pericardial effusion		3				3
Pericardial haemorrhage		1				1
Pericarditis		1				1
Sinus tachycardia	2	3			2	3
Stress cardiomyopathy	1	1			1	1
Supraventricular extrasystoles		1				1
Supraventricular tachycardia	1	2			1	2
Tachycardia	4	21	2	7	2	14
Ventricular fibrillation		2				2
Ventricular hypokinesia		1				1
Ventricular tachycardia		1				1
	67	250	6	21	61	229

System Organ Class

Congenital, familial and genetic disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Atrial septal defect		1		1
		1		1

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System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness	3	3			3	3
Deafness unilateral		2				2
Ear discomfort	2	4	1	1	1	3
Ear pain	2	5	1	1	1	4
Ear swelling		1				1
Hyperacusis		1				1
Hypoacusis	2	9			2	9
Paraesthesia ear		1				1
Sudden hearing loss		1				1
Tinnitus	8	24	1	1	7	23
Vertigo	1	5	1	2		3
Vertigo positional	1	2	1	2		
Vestibular disorder	1	1	1	1		
	20	59	6	8	14	51

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adrenal haemorrhage	1	1			1	1
Adrenocortical insufficiency acute		1				1
Basedow's disease	1	2			1	2
Goitre		2				2
Hyperparathyroidism primary		1		1		
	2	7		1	2	6

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal sensation in eye		1				1
Asthenopia		4				4
Blepharospasm	1	2			1	2
Blindness	4	7			4	7
Blindness transient		1				1
Blindness unilateral	1	1			1	1
Diplopia	2	3		1	2	2
Dry eye	1	1			1	1
Eye disorder		3				3
Eye haemorrhage		2				2
Eye inflammation	2	3	1	1	1	2
Eye irritation	2	5	1	1	1	4
Eyelids pruritus	1	1	1	1		
Eye pain	3	12	2	3	1	9
Eye pruritus		2				2
Eye swelling		2				2
Gaze palsy	1	1			1	1
Lacrimation increased		1				1
Miosis		1		1		
Myopia		1				1
Ocular discomfort	1	3	1	1		2
Ocular hyperaemia	2	2			2	2
Optic ischaemic neuropathy	1	1			1	1
Periorbital discomfort		1				1
Periorbital oedema		3				3
Periorbital pain		2		1		1
Periorbital swelling		2		1		1
Photophobia		4				4
Retinal artery occlusion		1				1
Retinal haemorrhage		1				1
Retinal tear	1	1			1	1
Retinal vascular thrombosis	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Retinal vein occlusion	1	2			1	2
Sudden visual loss		1				1
Vision blurred	5	13	2	3	3	10
Visual field defect	2	6			2	6
Visual impairment	4	13		1	4	12
Vitreous detachment	2	2			2	2
	38	113	8	15	30	98

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* AE=Adverse Event
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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	4	8	3	4	1	4
Abdominal distension	3	6		1	3	5
Abdominal pain	14	35	9	18	5	17
Abdominal pain lower		2				2
Abdominal pain upper	9	17	6	9	3	8
Abdominal symptom		1				1
Abdominal tenderness	1	1	1	1		
Abdominal wall haemorrhage		1				1
Aphthous ulcer	1	1	1	1		
Ascites		1				1
Chronic gastritis		1				1
Coeliac artery stenosis		1				1
Colitis	1	1			1	1
Colitis ulcerative	1	1			1	1
Constipation	1	3	1	3		
Diarrhoea	21	67	11	36	10	31
Diverticulum		1		1		
Dry mouth	4	6	3	3	1	3
Dyspepsia		1		1		
Dysphagia	1	16		4	1	12
Flatulence		1		1		
Gastric disorder		2		1		1
Gastric haemorrhage		1				1
Gastritis		1		1		
Gastrointestinal disorder	1	1			1	1
Gastrointestinal haemorrhage		1				1
Gastrointestinal pain		1		1		
Gastrooesophageal reflux disease	1	1	1	1		
Gingival bleeding	1	1			1	1
Gingival erythema	1	1			1	1
Gingival swelling	1	1			1	1
Glossodynia		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematemesis		4				4
Haematochezia		1				1
Hypoaesthesia oral	4	19		5	4	14
Infrequent bowel movements		1		1		
Intestinal haemorrhage		4				4
Intestinal ischaemia		3				3
Lip pain	1	1			1	1
Lip pruritus		2				2
Lip swelling		8		2		6
Lip ulceration		1		1		
Loose tooth		1				1
Mesenteric artery embolism		1				1
Mouth swelling	2	3			2	3
Mouth ulceration		1		1		
Nausea	65	172	39	86	26	86
Noninfective gingivitis	1	1	1	1		
Oesophageal ulcer haemorrhage		1				1
Oral discomfort		3				3
Oral mucosal blistering	3	5	3	3		2
Oral pain		1		1		
Oral pruritus		7		4		3
Palatal swelling		1				1
Paraesthesia oral	4	16	1	6	3	10
Retroperitoneal haemorrhage		1				1
Stomatitis	1	2	1	1		1
Swollen tongue	2	14		1	2	13
Tongue discomfort		2		1		1
Tongue erythema		1		1		
Tongue movement disturbance		1				1
Tongue pruritus		4				4
Toothache	1	1	1	1		
Upper gastrointestinal haemorrhage		1				1

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vomiting	27	91	13	27	14	64
	177	559	95	231	82	328

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* I=Interval, C=Cumulative
 * AE=Adverse Event
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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	19	57	14	25	5	32
Axillary pain	7	19	7	15		4
Cardiac death		1				1
Catheter site haemorrhage		1		1		
Chest discomfort	10	29	4	12	6	17
Chest pain	11	44	1	11	10	33
Chills	72	173	51	100	21	73
Chronic fatigue syndrome		1				1
Concomitant disease aggravated		1				1
Condition aggravated	6	27		4	6	23
Crepitations		2		1		1
Crying		1		1		
Death	4	46			4	46
Discomfort	2	11	1	4	1	7
Disease recurrence	3	17		3	3	14
Drug ineffective	2	13			2	13
Drug intolerance	1	1			1	1
Energy increased		1				1
Exercise tolerance decreased	1	1			1	1
Facial discomfort		1		1		
Facial pain		3				3
Fatigue	118	332	74	185	44	147
Feeling abnormal	3	18	2	8	1	10
Feeling cold	7	25	6	18	1	7
Feeling drunk	1	1	1	1		
Feeling hot	5	32	1	14	4	18
Feeling of body temperature change		3				3
Gait disturbance	9	13	1	2	8	11
Gait inability		2		1		1
Generalised oedema		2				2
General physical health deterioration	6	52	1	10	5	42
Hypothermia		3				3

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Illness	1	6	1	2		4
Inflammation	2	5			2	5
Influenza like illness	8	19	7	13	1	6
Injected limb mobility decreased	2	3	2	3		
Injection site pain	1	1	1	1		
Local reaction		1		1		
Malaise	37	92	21	51	16	41
Mass		1				1
Nodule	1	2	1	2		
Oedema peripheral	1	3		1	1	2
Pain	55	136	40	74	15	62
Peripheral swelling	17	39	4	9	13	30
Physical deconditioning		2		1		1
Pyrexia	160	423	130	253	30	170
Screaming		1		1		
Sensation of foreign body		1				1
Sense of oppression		1				1
Sensitivity to weather change	1	1			1	1
Sluggishness		1				1
Sudden death		6				6
Swelling	9	18	6	10	3	8
Swelling face	5	19		4	5	15
Systemic inflammatory response syndrome		1				1
Temperature regulation disorder		1		1		
Tenderness	3	6	2	3	1	3
Vaccination failure	6	12			6	12
Vaccination site bruising	1	3	1	2		1
Vaccination site discolouration	1	2			1	2
Vaccination site discomfort		1				1
Vaccination site erythema	20	53	12	32	8	21
Vaccination site haematoma	2	4			2	4
Vaccination site haemorrhage	3	4	1	2	2	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site hypoaesthesia		2		2		
Vaccination site induration	1	5	1	4		1
Vaccination site joint movement impairment		3		3		
Vaccination site joint pain	2	2			2	2
Vaccination site lymphadenopathy	1	2	1	1		1
Vaccination site mass		1		1		
Vaccination site movement impairment	5	12	4	10	1	2
Vaccination site nodule		2		2		
Vaccination site pain	102	230	85	186	17	44
Vaccination site paraesthesia	2	3	2	3		
Vaccination site phlebitis		1		1		
Vaccination site pruritus	11	21	3	10	8	11
Vaccination site rash	1	2	1	1		1
Vaccination site reaction	6	10	2	4	4	6
Vaccination site swelling	21	59	12	37	9	22
Vaccination site thrombosis		1				1
Vaccination site urticaria		1		1		
Vaccination site warmth	7	18	6	16	1	2
	782	2,176	510	1165	272	1011

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Biliary colic	1	2	1	2
Biliary dilatation		1		1
Biliary tract disorder		1		1
Cholecystitis		1		1
Gallbladder disorder		1		1
Gallbladder oedema		1		1
Hepatic pain	1	1	1	1
Hepatitis acute		1		1
Hydrocholecystis	1	1	1	1
Jaundice		1		1
Liver disorder		2		2
	3	13	3	13

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		3		1		2
Anaphylactic reaction	4	30			4	30
Anaphylactic shock	2	5			2	5
Anaphylactoid reaction		1				1
Graft versus host disease		1				1
Hypersensitivity	7	46		5	7	41
Immunisation reaction		1				1
Lung transplant rejection		1				1
	13	88		6	13	82

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal infection		1				1
Abscess limb	1	1			1	1
Appendicitis	2	2			2	2
Asymptomatic COVID-19		1				1
Atypical pneumonia	1	2			1	2
Bronchitis		1				1
Clostridium difficile colitis		1				1
COVID-19	16	62	7	31	9	31
COVID-19 pneumonia		1				1
Device related infection		1				1
Diverticulitis		1				1
Encephalitis		2				2
Erysipelas	1	7			1	7
Escherichia infection		1				1
Escherichia sepsis		1				1
Escherichia urinary tract infection		1				1
Furuncle		1				1
Gastroenteritis		1				1
Herpes ophthalmic		1				1
Herpes simplex		1				1
Herpes virus infection	1	1			1	1
Herpes zoster	6	20	2	5	4	15
Infection	2	15		2	2	13
Meningitis		1				1
Meningitis herpes		1				1
Myelitis		2				2
Nasopharyngitis	9	20	7	10	2	10
Necrotising fasciitis	1	1			1	1
Ophthalmic herpes zoster	1	2			1	2
Oral herpes		3		2		1
Oral viral infection		1				1
Pharyngitis		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonia	3	17			3	17
Pneumonia bacterial		1				1
Pneumonia pneumococcal		1				1
Pneumonia streptococcal		1				1
Post-acute COVID-19 syndrome	1	1	1	1		
Post viral fatigue syndrome		1		1		
Rhinitis		2		2		
Sepsis	3	10			3	10
Septic shock		2				2
Streptococcal bacteraemia		1				1
Suspected COVID-19		2		1		1
Tonsillitis	1	1			1	1
Upper respiratory tract infection		3				3
Urinary tract infection	3	14		6	3	8
Urosepsis		3				3
Vaccination site infection		1				1
Vestibular neuronitis	2	2			2	2
Viral infection		1		1		
	54	222	17	63	37	159

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Brain herniation		1				1
Circumstance or information capable of leading to medication error		29		29		
Concussion		1		1		
Contusion	4	6	1	1	3	5
Exposure via breast milk	1	1	1	1		
Face injury		1				1
Fall	9	25	3	6	6	19
Femoral neck fracture		1				1
Head injury	1	5		2	1	3
Heat stroke		1				1
Hip fracture		1				1
Inappropriate schedule of product administration	3	6	3	6		
Incorrect route of product administration		9		9		
Injury	1	1	1	1		
Ligament sprain	1	1			1	1
Limb injury	1	2			1	2
Lower limb fracture	1	1			1	1
Maternal exposure during pregnancy	3	3	2	2	1	1
Off label use	3	7	3	7		
Overdose		2		2		
Poor quality product administered	5	42	5	42		
Postoperative wound complication		1				1
Product administered at inappropriate site	1	3		2	1	1
Product administration error	1	1	1	1		
Product preparation issue	1	5	1	5		
Product use issue	1	2	1	2		
Rib fracture	1	2			1	2
Scapula fracture		1				1
Skin wound		1				1
Skull fracture	1	1			1	1
Subcutaneous haematoma	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Subdural haematoma	2	4			2	4
Tracheal haemorrhage		1				1
Underdose	2	7	2	7		
Vaccination complication	1	1			1	1
Wound		2		1		1
Wound necrosis		1				1
	45	180	24	127	21	53

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood albumin increased	1	1			1	1
Blood alkaline phosphatase increased		1				1
Blood bilirubin increased		1				1
Blood creatine increased	1	1	1	1		
Blood creatinine increased		5		3		2
Blood fibrinogen decreased		1				1
Blood glucose abnormal		1		1		
Blood glucose decreased	1	3	1	2		1
Blood glucose increased	2	5	1	2	1	3
Blood lactate dehydrogenase increased		1				1
Blood phosphorus decreased		1		1		
Blood potassium increased		2		1		1
Blood pressure abnormal		1				1
Blood pressure decreased	5	19	1	4	4	15
Blood pressure diastolic decreased		1		1		
Blood pressure diastolic increased	1	1	1	1		
Blood pressure increased	3	12	1	4	2	8
Blood pressure measurement	1	1			1	1
Blood pressure systolic increased		2		1		1
Body temperature decreased		2				2
Body temperature increased	2	7	2	5		2
Brain scan abnormal		1				1
Breath sounds abnormal		1				1
Cardiac murmur		1				1
C-reactive protein abnormal		1		1		
C-reactive protein decreased	1	1	1	1		
C-reactive protein increased	3	17	1	7	2	10
Electrocardiogram abnormal	2	2	1	1	1	1
Electrocardiogram ST segment elevation	1	3			1	3
Electrocardiogram ST-T segment depression	1	1			1	1
Electrocardiogram T wave inversion		1				1
Fibrin D dimer increased	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gamma-glutamyltransferase increased		1				1
Glomerular filtration rate decreased		2		1		1
Grip strength decreased	1	1			1	1
Haemoglobin decreased		2				2
Heart rate decreased	1	4	1	3		1
Heart rate increased	14	37	1	6	13	31
Heart rate irregular		4		3		1
Hepatic enzyme increased	2	3			2	3
Inflammatory marker increased	2	2			2	2
International normalised ratio increased		1				1
Lipids increased	1	1			1	1
Low density lipoprotein increased	1	1			1	1
N-terminal prohormone brain natriuretic peptide increased		1		1		
Oxygen saturation abnormal		1		1		
Oxygen saturation decreased	3	28		4	3	24
PCO2 increased		1		1		
Platelet count decreased	1	3		1	1	2
Procalcitonin decreased	1	1	1	1		
Procalcitonin increased		2				2
Pulse abnormal		3		2		1
Pulse pressure decreased		1		1		
Red blood cell sedimentation rate increased		1				1
Respiratory rate increased		8		1		7
Skin turgor decreased		1				1
Transaminases increased		1				1
Troponin abnormal	1	1			1	1
Troponin I increased	1	1			1	1
Troponin increased	1	2		1	1	1
Troponin T increased	1	1			1	1
Urine output decreased		2				2
Weight decreased	1	3		1	1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Weight increased		1				1
White blood cell count decreased	2	3	1	2	1	1
White blood cell count increased		2		2		
White blood cells urine positive		1		1		
	60	227	15	70	45	157

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acetonaemia	1	1			1	1
Cachexia		1				1
Decreased appetite	4	22	2	10	2	12
Dehydration		8		2		6
Electrolyte imbalance		1		1		
Feeding disorder		2		1		1
Fluid intake reduced		1				1
Fluid retention		2				2
Food refusal		1				1
Glucose tolerance impaired	1	1			1	1
Gout	1	2			1	2
Hypercalcaemia		1				1
Hyperglycaemia	1	2			1	2
Hypernatraemia		1				1
Hypoalbuminaemia		1		1		
Hypoglycaemia	1	5			1	5
Hypokalaemia		2				2
Hypophagia		2				2
Increased insulin requirement	1	1	1	1		
Lactic acidosis		1				1
Metabolic acidosis		1				1
Metabolic disorder		2		1		1
	10	61	3	17	7	44

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	54	103	35	58	19	45
Arthritis	3	7	3	3		4
Back pain	10	31	8	18	2	13
Bone disorder		1		1		
Bursitis		1				1
Fibromyalgia		1				1
Flank pain		1		1		
Jaw disorder		1				1
Joint instability	1	1			1	1
Joint lock		1				1
Joint range of motion decreased		2		1		1
Joint stiffness	1	6		3	1	3
Joint swelling	1	3	1	2		1
Limb discomfort	4	5	2	2	2	3
Mobility decreased	1	3		1	1	2
Muscle fatigue	1	2	1	1		1
Muscle spasms	3	18		5	3	13
Muscle tightness		1				1
Muscle twitching	2	8	2	2		6
Muscular weakness	8	35	2	6	6	29
Musculoskeletal chest pain		2				2
Musculoskeletal discomfort	1	2			1	2
Musculoskeletal stiffness	13	39	11	20	2	19
Myalgia	69	166	47	93	22	73
Neck pain	11	27	7	14	4	13
Osteoarthritis	3	3	1	1	2	2
Pain in extremity	84	201	54	128	30	73
Pain in jaw	2	5	1	2	1	3
Periarthritis		1				1
Polyarthritis		1				1
Polymyalgia rheumatica		1				1
Rheumatoid arthritis	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rotator cuff syndrome	1	1			1	1
Spinal pain	1	2	1	2		
Systemic lupus erythematosus		1				1
Tenosynovitis		1				1
Torticollis		1				1
	275	686	176	364	99	322

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Metastasis		1		1
Neoplasm progression	1	2	1	2
	1	3	1	3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	7		3	1	4
Akathisia	1	1			1	1
Akinesia		1				1
Allodynia		1		1		
Altered state of consciousness	2	4			2	4
Amnesia	1	6			1	6
Anosmia	2	9		3	2	6
Aphasia	1	4			1	4
Areflexia		1				1
Autonomic nervous system imbalance		1				1
Balance disorder	6	18	2	3	4	15
Ballismus	1	1			1	1
Basilar artery thrombosis		1				1
Bell's palsy	2	7			2	7
Brain injury	1	2			1	2
Brain stem syndrome		1				1
Burning sensation	4	5	3	3	1	2
Central pain syndrome		1				1
Cerebellar haemorrhage		1				1
Cerebellar infarction	1	1			1	1
Cerebellar syndrome		1				1
Cerebral artery embolism	2	4			2	4
Cerebral atrophy		1				1
Cerebral disorder	1	1			1	1
Cerebral haemorrhage	9	17			9	17
Cerebral infarction	6	12			6	12
Cerebral ischaemia	1	1			1	1
Cerebral microangiopathy		1				1
Cerebral small vessel ischaemic disease	1	1			1	1
Cerebral thrombosis	1	2			1	2
Cerebrovascular accident	18	39			18	39
Cerebrovascular disorder	2	3			2	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cognitive disorder	3	5			3	5
Coma	1	1			1	1
Coordination abnormal		3				3
Cranial nerve disorder		1				1
Dementia		1				1
Dementia Alzheimer's type		1				1
Depressed level of consciousness	1	21			1	21
Disturbance in attention	3	9	1	3	2	6
Dizziness	64	176	27	60	37	116
Dizziness exertional		1				1
Dysaesthesia		1		1		
Dysarthria	2	9		1	2	8
Dysgeusia		8		2		6
Dyskinesia	1	1			1	1
Dysstasia	3	6	2	2	1	4
Dystonia		1				1
Electric shock sensation		1		1		
Embolic cerebral infarction		1				1
Encephalopathy		1				1
Epilepsy	1	6			1	6
Facial neuralgia		1				1
Facial paralysis	4	15			4	15
Facial paresis	2	19			2	19
Formication	2	6	1	2	1	4
Generalised tonic-clonic seizure		1				1
Guillain-Barre syndrome		1				1
Haemorrhage intracranial		1				1
Headache	168	380	123	237	45	143
Head discomfort	5	14	2	5	3	9
Hemiparaesthesia		1				1
Hemiparesis	2	10			2	10
Hemiplegia	1	2			1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Horner's syndrome		1				1
Hyperaesthesia		1		1		
Hypersomnia	1	4		1	1	3
Hypoaesthesia	14	89	3	24	11	65
Hypokinesia	2	4			2	4
Hyposmia	1	1			1	1
Intention tremor		1				1
Intraventricular haemorrhage	1	1			1	1
Ischaemic stroke	7	16			7	16
Lacunar infarction	1	1			1	1
Lethargy		3		1		2
Loss of consciousness	2	18			2	18
Memory impairment	4	11	1	3	3	8
Meningism		1				1
Migraine	7	18	5	9	2	9
Mononeuritis	1	1			1	1
Monoparesis		1				1
Monoplegia		1				1
Motor dysfunction		1				1
Movement disorder	1	1			1	1
Multiple sclerosis		3				3
Muscle contractions involuntary		1				1
Muscle tone disorder		1				1
Nervous system disorder	1	1	1	1		
Neuralgia		3		2		1
Neuralgic amyotrophy		1				1
Neuritis		1				1
Neurological symptom	1	2			1	2
Neuropathy peripheral	1	4			1	4
Ophthalmic migraine	1	1			1	1
Paraesthesia	11	55	3	15	8	40
Paralysis		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraparesis	1	1			1	1
Paresis		1				1
Parkinson's disease		1				1
Parosmia	4	7	2	2	2	5
Peripheral motor neuropathy		1				1
Peripheral sensory neuropathy		1				1
Petit mal epilepsy		2				2
Polyneuropathy	2	3			2	3
Post stroke epilepsy		1				1
Presyncope		5		1		4
Reduced facial expression		1				1
Restless legs syndrome		2				2
Sciatica		2		1		1
Seizure	4	15			4	15
Seizure like phenomena		2				2
Sensory disturbance	2	4		1	2	3
Sensory loss	2	2	1	1	1	1
Sleep paralysis		2		1		1
Slow speech		1				1
Somnolence	6	16	4	8	2	8
Speech disorder	1	5		2	1	3
Spinal subdural haemorrhage	1	1			1	1
Status epilepticus		1				1
Stroke in evolution	1	1			1	1
Subarachnoid haemorrhage	2	6			2	6
Syncope	5	32			5	32
Taste disorder	3	7	2	3	1	4
Transient global amnesia	1	1			1	1
Transient ischaemic attack	8	17			8	17
Tremor	4	18	1	3	3	15
Trigeminal nerve paresis		1				1
Unresponsive to stimuli		3				3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular dementia		1				1
	431	1,274	184	407	247	867

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion spontaneous	1	2	1	2
	1	2	1	2

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product colour issue		36		36
Product temperature excursion issue	5	6	5	6
	5	42	5	42

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour	1	4		1	1	3
Abnormal dreams	1	2		1	1	1
Aggression	1	2			1	2
Agitation		3		1		2
Anxiety	4	19	3	9	1	10
Apathy	1	3			1	3
Confusional state	7	26	3	5	4	21
Daydreaming	1	1	1	1		
Delirium		1				1
Delusional disorder, unspecified type		1				1
Depressed mood		4		1		3
Depression	1	3	1	2		1
Depressive symptom	1	1			1	1
Derealisation		1				1
Disorganised speech		1				1
Disorientation		2		1		1
Dissociation		1				1
Eating disorder		1				1
Fear	1	1			1	1
Fear of death		1				1
Feeling of despair		1				1
Hallucination	2	6			2	6
Hallucination, auditory		1				1
Hallucination, visual		3				3
Helplessness		1				1
Hypersomnia-bulimia syndrome		1				1
Initial insomnia		1				1
Insomnia	2	11	2	6		5
Laziness	1	1	1	1		
Mania	1	1	1	1		
Mental fatigue	1	9	1	2		7
Nervousness	1	3	1	2		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuropsychiatric symptoms	1	1			1	1
Nightmare		4		1		3
Panic attack		2				2
Panic reaction		2				2
Paranoia	1	1			1	1
Personality change	1	1			1	1
Poor quality sleep		2		1		1
Psychotic disorder		3				3
Reading disorder		1				1
Sleep disorder	2	7	2	2		5
Sleep talking		1				1
Stress		2		2		
	32	144	16	40	16	104

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	7			1	7
Bladder dysfunction	1	1			1	1
Haematuria		1				1
Hypertonic bladder	1	1			1	1
Incontinence	1	2		1	1	1
Nephrolithiasis		1				1
Prerenal failure	1	1			1	1
Renal failure	1	3			1	3
Renal haemorrhage		1				1
Renal impairment		2				2
Renal infarct		1				1
Renal pain	3	5	3	4		1
Renal tubular necrosis		1				1
Urinary incontinence		1				1
Urinary retention		1				1
	9	29	3	5	6	24

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal uterine bleeding	1	1	1	1		
Adnexa uteri pain	1	1	1	1		
Amenorrhoea		1		1		
Breast cyst	1	1			1	1
Breast pain	1	2	1	1		1
Genital pain	1	1			1	1
Intermenstrual bleeding	1	2	1	1		1
Menstrual disorder	2	2	1	1	1	1
Menstruation irregular	1	1			1	1
Penile haemorrhage		1				1
Uterine inflammation		1		1		
Vaginal haemorrhage		1				1
	9	15	5	7	4	8

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory distress syndrome	1	1			1	1
Acute respiratory failure	1	1			1	1
Apnoea		2				2
Aspiration		1				1
Asthma	1	2			1	2
Atelectasis		1				1
Bronchial haemorrhage		1				1
Bronchospasm		1				1
Chronic obstructive pulmonary disease	2	7			2	7
Chronic respiratory failure		1				1
Cough	12	46	4	20	8	26
Dysphonia	1	11		5	1	6
Dyspnoea	38	146	8	24	30	122
Dyspnoea exertional	2	6	1	1	1	5
Epistaxis	6	13	2	5	4	8
Haemoptysis		2				2
Hiccups		1				1
Hydrothorax		1				1
Hyperventilation	2	5	1	1	1	4
Hypopnoea		1				1
Hypoxia		2				2
Idiopathic pulmonary fibrosis		1				1
Increased upper airway secretion		2		2		
Interstitial lung disease	1	1			1	1
Irregular breathing		1		1		
Laryngeal oedema		1				1
Lung disorder	1	3	1	1		2
Lung infiltration	2	3			2	3
Lung opacity	1	1			1	1
Nasal congestion	1	13		5	1	8
Nasal dryness	1	1	1	1		
Nasal oedema	1	2		1	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Obstructive airways disorder	1	4	1	1		3
Oropharyngeal discomfort		1		1		
Oropharyngeal pain	8	32	5	21	3	11
Oropharyngeal spasm		1				1
Oropharyngeal swelling	1	1			1	1
Painful respiration	2	4	1	3	1	1
Paranasal sinus haemorrhage		1		1		
Pharyngeal disorder		1				1
Pharyngeal erythema		2		1		1
Pharyngeal hypoaesthesia	1	4			1	4
Pharyngeal mass		1				1
Pharyngeal oedema		1				1
Pharyngeal paraesthesia		2				2
Pharyngeal swelling	9	24	3	6	6	18
Pleural effusion		5		1		4
Pleurisy		1				1
Pneumonia aspiration		3				3
Pneumothorax	1	1			1	1
Productive cough	2	7			2	7
Pulmonary artery thrombosis		1				1
Pulmonary embolism	35	84			35	84
Pulmonary fibrosis	2	2			2	2
Pulmonary haemorrhage	1	1			1	1
Pulmonary hypertension		1				1
Pulmonary infarction		1				1
Pulmonary oedema	3	12			3	12
Pulmonary pain	3	5	2	2	1	3
Pulmonary thrombosis	1	3			1	3
Respiration abnormal		1				1
Respiratory arrest	1	6			1	6
Respiratory disorder	3	5		1	3	4
Respiratory distress	1	16			1	16

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory failure	2	5			2	5
Respiratory symptom	1	1			1	1
Rhinalgia		2		1		1
Rhinorrhoea	6	26	4	21	2	5
Sinus congestion		1		1		
Sinus disorder		1		1		
Sneezing	4	5	3	4	1	1
Snoring	1	1			1	1
Tachypnoea		5		2		3
Throat irritation	6	18	4	7	2	11
Throat tightness		6		1		5
Upper respiratory tract congestion		1		1		
Wheezing	1	11		3	1	8
	170	598	41	147	129	451

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne	1	2	1	2		
Angioedema		6				6
Blister	1	3	1	2		1
Circumoral swelling	1	1			1	1
Cold sweat	3	14		3	3	11
Cutaneous vasculitis	1	1			1	1
Decubitus ulcer		1		1		
Dermatitis		2		1		1
Dermatitis bullous	1	1			1	1
Dermatitis psoriasiform	1	1			1	1
Drug eruption		3		2		1
Dry skin		1		1		
Dyshidrotic eczema	1	1			1	1
Ecchymosis	1	1			1	1
Eczema		2		1		1
Erythema	8	44	2	21	6	23
Haemorrhage subcutaneous	2	3			2	3
Hyperhidrosis	2	19		8	2	11
Livedo reticularis		1		1		
Nail discolouration		1				1
Night sweats	1	2		1	1	1
Pain of skin	4	7	3	4	1	3
Palpable purpura	1	1			1	1
Pemphigoid		2				2
Petechiae	2	7		1	2	6
Photosensitivity reaction	1	1	1	1		
Pruritus	16	48	9	19	7	29
Psoriasis		1		1		
Purpura		1				1
Rash	8	27	3	10	5	17
Rash erythematous	2	9		1	2	8
Rash macular	1	3		2	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash maculo-papular		1				1
Rash pruritic		4		2		2
Skin burning sensation		1				1
Skin discolouration	1	6		2	1	4
Skin disorder		1				1
Skin exfoliation	1	1			1	1
Skin reaction	1	2		1	1	1
Skin swelling	1	1			1	1
Skin tightness		1				1
Skin ulcer		4				4
Skin warm		1		1		
Solar dermatitis		1				1
Stevens-Johnson syndrome		1				1
Toxic epidermal necrolysis		1				1
Urticaria	13	52	10	24	3	28
	76	295	30	113	46	182

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden	1	2	1	1		1
Loss of personal independence in daily activities	1	3		1	1	2
Physical disability	1	1			1	1
Wa king aid user	1	1			1	1
	4	7	1	2	3	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angiopathy	1	1	1	1		
Aortic aneurysm	1	1			1	1
Aortic aneurysm rupture		1				1
Aortic arteriosclerosis		2		1		1
Aortic rupture	1	1			1	1
Arterial thrombosis		1				1
Arteriosclerosis	2	4			2	4
Blood pressure fluctuation	1	2			1	2
Circulatory collapse	1	7			1	7
Cyanosis		4		2		2
Deep vein thrombosis	13	36			13	36
Embolism	2	5			2	5
Embolism arterial		1				1
Flushing	2	5	1	1	1	4
Haematoma		6				6
Haemorrhage		5				5
Hot flush	1	4	1	2		2
Hypertension	6	23		3	6	20
Hypoperfusion		1				1
Hypotension	1	24	1	5		19
Hypovolaemic shock	1	1			1	1
Internal haemorrhage	1	1			1	1
Lymphoedema		1				1
Microscopic polyangiitis	1	1			1	1
Orthostatic hypotension	1	2			1	2
Pallor		8		4		4
Peripheral artery thrombosis	1	1			1	1
Peripheral coldness	2	6		1	2	5
Peripheral embolism	3	4			3	4
Phlebitis		1				1
Thrombophlebitis	5	10	1	2	4	8
Thrombophlebitis superficial		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thrombosis	9	21			9	21
Varicose vein	1	1	1	1		
Vasculitis		1				1
Vasodilatation		1		1		
Venous thrombosis		1				1
	57	196	6	24	51	172

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

SWITZERLAND

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia		1				1
Eosinophilia		1		1		
Immune thrombocytopenia		1				1
Leukopenia	1	1			1	1
Lymphadenopathy	9	13	8	9	1	4
Lymph node pain	2	3	2	2		1
Lymphopenia		1				1
Monocytosis	1	2		1	1	1
Neutrophilia		1				1
Sickle cell anaemia with crisis		1				1
Thrombocytopenia		2				2
	13	27	10	13	3	14

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction		2				2
Angina pectoris		1				1
Arrhythmia	1	5			1	5
Arteriosclerosis coronary artery		1				1
Atrial fibrillation	3	7			3	7
Atrioventricular block first degree	1	1			1	1
Atrioventricular block second degree	1	1			1	1
Bradycardia	4	4			4	4
Cardiac arrest		2				2
Cardiac disorder	1	1			1	1
Cardiac failure		5				5
Cardiac failure acute		2				2
Cardiac failure chronic		1				1
Cardiac failure congestive		1				1
Cardiac fibrillation		1				1
Cardiac valve disease		1				1
Cardiogenic shock	1	1			1	1
Cardio-respiratory arrest		1				1
Cardiovascular disorder		2				2
Extrasystoles	1	1			1	1
Left ventricular failure		1				1
Myocardial infarction		1				1
Myocarditis	1	1			1	1
Palpitations	1	5			1	5
Pericardial effusion		1				1
Sinus tachycardia		1				1
Stress cardiomyopathy		1				1
Supraventricular tachycardia	1	1			1	1
Tachycardia	4	19	1	3	3	16
Ventricular fibrillation		1				1
	20	73	1	3	19	70

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness unilateral	1	2			1	2
Ear discomfort	1	1	1	1		
Ear pain		1				1
Ear pruritus		1				1
Meniere's disease		1				1
Paraesthesia ear	1	1	1	1		
Sudden hearing loss		1				1
Tinnitus	1	2	1	1		1
Vertigo	6	10	2	3	4	7
Vertigo positional		1				1
	10	21	5	6	5	15

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blindness transient		1				1
Diplopia		1				1
Eye discharge	1	1			1	1
Eye disorder	1	1			1	1
Eye haematoma	1	1			1	1
Eye haemorrhage		1				1
Eyelid oedema		2				2
Eyelids pruritus	1	1	1	1		
Eye pain	1	2		1	1	1
Gaze palsy	1	1			1	1
Keratitis	1	1			1	1
Ocular hyperaemia	1	1			1	1
Periorbital swelling	1	1	1	1		
Photophobia	1	2	1	1		1
Swelling of eyelid	1	2	1	1		1
Visual field defect	1	1			1	1
Visual impairment		3				3
	12	23	4	5	8	18

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2		1		1
Abdominal pain	2	8	1	2	1	6
Abdominal pain lower		1				1
Abdominal pain upper	1	1	1	1		
Anal haemorrhage		1		1		
Aphthous ulcer	1	2	1	1		1
Ascites		1				1
Cheilitis	1	1	1	1		
Colitis microscopic	1	1			1	1
Colitis ulcerative	1	1			1	1
Crohn's disease	1	1			1	1
Diarrhoea	8	20	6	9	2	11
Diarrhoea haemorrhagic	1	1			1	1
Duodenal ulcer haemorrhage	1	1			1	1
Dysphagia	3	3	1	1	2	2
Epigastric discomfort	1	1	1	1		
Flatulence	1	1	1	1		
Gastric disorder		1				1
Gastritis		1				1
Gastrointestinal disorder		3		2		1
Gastrooesophageal reflux disease		2				2
Haematemesis		1				1
Hypoaesthesia oral		2		1		1
Lip oedema		1				1
Lip swelling	1	2	1	1		1
Mouth swelling	1	1			1	1
Nausea	16	38	11	17	5	21
Odynophagia	2	3	2	2		1
Oesophageal perforation		1				1
Pancreatitis		1				1
Paraesthesia oral	1	4		1	1	3
Salivary hypersecretion		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swollen tongue		1				1
Tongue dry	1	1			1	1
Tongue oedema		1				1
Upper gastrointestinal haemorrhage	1	1			1	1
Vomiting	6	27	4	7	2	20
	52	140	31	50	21	90

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	10	26	8	11	2	15
Atrophy		1				1
Chest discomfort		5				5
Chest pain	3	7	1	1	2	6
Chills	19	40	14	19	5	21
Condition aggravated	5	7	3	3	2	4
Death	2	8			2	8
Discomfort	1	3		1	1	2
Disease recurrence	2	5			2	5
Drug ineffective	1	8			1	8
Drug interaction	1	2	1	2		
Fatigue	28	52	18	29	10	23
Feeling cold		3		3		
Feeling hot	1	5		1	1	4
Gait disturbance	1	5	1	2		3
General physical health deterioration	1	9	1	4		5
Hyperthermia	1	2		1	1	1
Inflammation		3				3
Influenza like illness	5	9	4	6	1	3
Injection site discomfort	1	1	1	1		
Malaise	13	35	5	10	8	25
Oedema peripheral	1	4		1	1	3
Pain	4	12	3	6	1	6
Performance status decreased	1	2	1	1		1
Peripheral swelling	2	3			2	3
Pyrexia	34	81	25	35	9	46
Sense of oppression		2				2
Sudden death		4				4
Swelling face	2	4	1	3	1	1
Therapeutic response unexpected		2		2		
Vaccination failure	4	8			4	8
Vaccination site erythema	6	12	6	9		3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site haematoma	1	2	1	1		1
Vaccination site induration	2	3	2	2		1
Vaccination site lymphadenopathy		1				1
Vaccination site oedema		1		1		
Vaccination site pain	12	27	10	18	2	9
Vaccination site pruritus	4	6	4	5		1
Vaccination site rash	2	3	2	3		
Vaccination site reaction	3	4	3	3		1
Vaccination site swelling	3	5	3	3		2
Vaccination site urticaria	1	2	1	1		1
Vaccination site warmth	1	3	1	2		1
	178	427	120	190	58	237

System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cholecystitis acute		1		1
Cholestasis		2		2
Hepatic cirrhosis		1		1
Hepatocellular injury		1		1
Liver disorder		1		1
Liver injury		1		1
		7		7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	1	1			1	1
Anaphylactic reaction	4	18			4	18
Anaphylactic shock		1				1
Haemophagocytic lymphohistiocytosis		1				1
Hypersensitivity	6	28	1	5	5	23
Immune-mediated adverse reaction		1		1		
Type I hypersensitivity		1				1
Type II hypersensitivity		1				1
	11	52	1	6	10	46

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal infection		1				1
Appendicitis		1				1
Asymptomatic COVID-19		1		1		
Atypical pneumonia	1	1			1	1
Conjunctivitis bacterial		1				1
COVID-19	3	23		1	3	22
COVID-19 pneumonia	2	3			2	3
Cystitis		1				1
Encephalitis	2	3			2	3
Erysipelas		2				2
Erysipeloid		1				1
Genital herpes		1				1
Herpes virus infection	1	1			1	1
Herpes zoster	9	27	2	2	7	25
Infection		1		1		
Influenza	2	3	2	2		1
Lower respiratory tract infection	1	1			1	1
Myelitis		1				1
Nasopharyngitis		1				1
Ophthalmic herpes zoster	1	3			1	3
Oral herpes	1	2	1	1		1
Otitis media	1	1			1	1
Parotitis		1				1
Pneumonia		4				4
Pneumonia bacterial		1				1
Pneumonia pneumococcal		1				1
Pyelitis	1	1			1	1
Pyelonephritis	1	1			1	1
Rash pustular		1				1
Respiratory tract infection		1				1
Rhinitis		1		1		
Sepsis		2				2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Septic shock	1	2			1	2
Skin infection	1	1	1	1		
Superinfection bacterial	1	1			1	1
Tooth infection	1	1			1	1
Urinary tract infection		2				2
Urinary tract infection bacterial		1				1
Vaccination site cellulitis	1	1	1	1		
Varicella zoster virus infection		1				1
Viral infection		1		1		
	31	105	7	12	24	93

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest injury	1	1			1	1
Contusion	1	2	1	2		
Craniocerebral injury	1	3		1	1	2
Facial bones fracture	1	1			1	1
Fall	5	12	1	3	4	9
Head injury	2	2			2	2
Inappropriate schedule of product administration	1	2	1	2		
Incorrect route of product administration	4	11	4	10		1
Joint dislocation		1				1
Off label use	2	3	2	3		
Overdose	1	1	1	1		
Product administration error		1		1		
Rib fracture		1		1		
Road traffic accident		1				1
Scratch		2		2		
Skull fracture		1				1
Subdural haematoma		1				1
Tendon rupture	1	2	1	1		1
Traumatic haematoma	1	1			1	1
Underdose	1	3	1	3		
Wrong product administered		1		1		
Wrong technique in product usage process		1		1		
	22	54	12	32	10	22

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alanine aminotransferase increased		1		1		
Anti-myelin-associated glycoprotein antibodies positive		1				1
Blood alkaline phosphatase increased		1		1		
Blood glucose increased		1		1		
Blood pressure decreased		2		1		1
Blood pressure increased	3	8	1	2	2	6
Body temperature increased	1	2	1	2		
Cardiac murmur	1	1			1	1
Carotid bruit	1	1			1	1
C-reactive protein increased	3	7	1	2	2	5
CSF test abnormal		1				1
Electrocardiogram abnormal	1	1			1	1
Heart rate decreased		1				1
Heart rate increased	1	2	1	1		1
Iliac bruit	1	1			1	1
NIH stroke scale score decreased		1				1
Oxygen saturation decreased		3				3
Peak expiratory flow rate decreased		1				1
Platelet count increased		1		1		
SARS-CoV-2 ant body test negative		1		1		
Troponin increased	1	1			1	1
Tumour marker increased		2		2		
Weight decreased		1		1		
	13	42	4	16	9	26

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite		3		1		2
Dehydration		2				2
Diabetic ketoacidosis		1				1
Diabetic metabolic decompensation		1				1
Feeding disorder		2		1		1
Fluid overload		1				1
Gout		1				1
Hypercholesterolaemia	1	1			1	1
Hyperglycaemia		1				1
Hypokalaemia	1	1			1	1
Metabolic syndrome		1				1
	2	15		2	2	13

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	17	28	15	18	2	10
Back pain	2	5	1	3	1	2
Bone formation increased		1		1		
Bone pain		1		1		
Enthesopathy	1	1	1	1		
Facet joint syndrome	1	1	1	1		
Joint range of motion decreased	1	2	1	1		1
Joint swelling	2	3	1	1	1	2
Mobility decreased		1		1		
Muscle disorder		1				1
Muscle spasms		3				3
Muscle tightness	1	1			1	1
Muscular weakness	2	4			2	4
Musculoskeletal pain	1	2	1	2		
Musculoskeletal stiffness	2	3	2	2		1
Myalgia	26	46	19	26	7	20
Neck pain	5	6	4	4	1	2
Pain in extremity	12	23	8	13	4	10
Periarthritis	1	1			1	1
Rheumatoid arthritis		2				2
Spinal disorder	1	1	1	1		
Spinal pain	1	1			1	1
Synovitis	1	1	1	1		
Tendon pain		1		1		
	77	139	56	78	21	61

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Meningioma		1		1
		1		1

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Altered state of consciousness		1				1
Amnesia	1	3		2	1	1
Aphasia		4				4
Autonomic nervous system imbalance	1	1	1	1		
Balance disorder	3	3	2	2	1	1
Bell's palsy	1	1			1	1
Brain hypoxia		1				1
Burning sensation	2	2	2	2		
Central nervous system lesion		1				1
Cerebral infarction		1				1
Cerebrovascular accident	2	6			2	6
Coma		2				2
Dementia		1				1
Disturbance in attention	1	5	1	2		3
Dizziness	14	37	11	16	3	21
Dysaesthesia	3	5	1	1	2	4
Dysarthria		2				2
Dysgeusia		2		2		
Dyskinesia	1	1	1	1		
Embolic stroke		1				1
Encephalopathy	1	2			1	2
Epilepsy	1	7			1	7
Facial paralysis	6	9			6	9
Facial paresis		3				3
Generalised tonic-clonic seizure	2	4			2	4
Haemorrhagic stroke		1				1
Headache	41	75	31	44	10	31
Head discomfort	1	1	1	1		
Hemianaesthesia	2	2			2	2
Hemiparaesthesia	1	1			1	1
Hemiparesis	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hemiplegia		1				1
Hypertonia	1	1			1	1
Hypoglycaemic coma		1				1
Ischaemic cerebral infarction		3				3
Language disorder	1	1			1	1
Lethargy		1		1		
Loss of consciousness		3				3
Migraine	1	2	1	2		
Monoplegia		1				1
Multiple sclerosis relapse	1	1			1	1
Myoclonus	1	1			1	1
Nervous system disorder		1				1
Neuralgia	3	6	2	2	1	4
Neuralgic amyotrophy		2				2
Neuropathy peripheral	1	1			1	1
Paraesthesia	5	12	2	4	3	8
Paresis	1	1	1	1		
Pleocytosis		1				1
Polyneuropathy		1				1
Presyncope	4	11	1	1	3	10
Restless legs syndrome	2	2			2	2
Sedation		1				1
Seizure		1				1
Sensory disturbance	3	6			3	6
Somnolence	1	5			1	5
Speech disorder		1				1
Spinal cord ischaemia		1				1
Syncope	5	13			5	13
Transient ischaemic attack	1	3			1	3
Tremor	2	5	2	2		3
Trigeminal neuralgia		1				1
Vascular encephalopathy		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
White matter lesion		1		1		
	119	280	61	89	58	191

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute stress disorder	1	3			1	3
Agitation		1				1
Confusional state	2	5	1	1	1	4
Delirium		5				5
Depressed mood		1		1		
Disorientation		2				2
Dissociative disorder		1				1
Enuresis		1				1
Hallucination, visual		1				1
Illusion		1		1		
Immunisation anxiety related reaction		2				2
Insomnia	3	5	3	5		
Middle insomnia		1		1		
Paranoia		1				1
Psychiatric decompensation	1	1			1	1
Sleep disorder		1		1		
Tension	1	1			1	1
	8	33	4	10	4	23

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute kidney injury	1	4	1	4
Glomerulonephritis minimal lesion		1		1
Renal failure		2		2
Renal impairment		1		1
Urinary incontinence		1		1
Urinary retention	1	1	1	1
Urogenital haemorrhage		1		1
	2	11	2	11

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast haematoma		1				1
Breast pain		1				1
Heavy menstrual bleeding	1	1	1	1		
	1	3	1	1		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute pulmonary oedema		2				2
Aphonia	1	1	1	1		
Apnoea		1				1
Asthma	1	4			1	4
Bronchial hyperreactivity	1	1			1	1
Bronchial wall thickening	1	1	1	1		
Chronic obstructive pulmonary disease		2				2
Cough	5	12	5	7		5
Dysphonia		1		1		
Dyspnoea	9	28	2	6	7	22
Dyspnoea at rest	1	1			1	1
Dyspnoea exertional	1	1			1	1
Epistaxis	1	2	1	2		
Haemoptysis	1	1			1	1
Hyperventilation	1	5			1	5
Lung consolidation	1	1	1	1		
Lung disorder		1				1
Lung infiltration	1	1			1	1
Nasal congestion	1	1	1	1		
Obstructive airways disorder		1				1
Oropharyngeal oedema		1				1
Oropharyngeal pain	6	8	5	6	1	2
Pharyngeal paraesthesia		1				1
Pleural effusion		2		1		1
Pneumonia aspiration	1	2			1	2
Pulmonary congestion	1	1			1	1
Pulmonary embolism	5	10			5	10
Pulmonary fibrosis		1				1
Pulmonary infarction	1	1			1	1
Pulmonary oedema		1				1
Respiratory depression		1				1
Respiratory distress	1	3			1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory failure		3				3
Respiratory paralysis		1				1
Sinus disorder	1	1	1	1		
Tachypnoea		2				2
Throat irritation		1				1
Throat tightness	1	3			1	3
	43	111	18	28	25	83

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecia		1				1
Angioedema	4	13			4	13
Blister		1		1		
Cold sweat	1	2	1	1		1
Dermatitis allergic	1	2		1	1	1
Dermatitis bullous	1	1			1	1
Dermatitis psoriasiform	1	1	1	1		
Drug eruption		1				1
Eczema	1	1	1	1		
Erythema	3	11		2	3	9
Erythema annulare		1				1
Hair growth abnormal		1		1		
Hyperhidrosis	1	5	1	1		4
Livedo reticularis	1	1	1	1		
Pemphigoid	2	2			2	2
Petechiae	1	1			1	1
Pruritus	9	23	5	8	4	15
Purpura		1				1
Rash	9	20	6	11	3	9
Rash erythematous		2				2
Rash maculo-papular	1	3		1	1	2
Rash papular		1				1
Rash papulosquamous	1	1	1	1		
Rash pruritic	2	3	2	2		1
Skin disorder		1				1
Skin lesion	1	2	1	1		1
Skin reaction	3	4	3	3		1
Urticaria	4	10	2	3	2	7
	47	116	25	40	22	76

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Bedridden	1	1	1	1
Impaired work ability	1	2	1	2
Loss of personal independence in daily activities	1	1	1	1
	3	4	3	4

System Organ Class

Surgical and medical procedures

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Axillary lymphadenectomy		1		1
		1		1

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* AE=Adverse Event
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System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arteriosclerosis		1				1
Circulatory collapse	2	5			2	5
Deep vein thrombosis	3	6			3	6
Embolism		1				1
Extremity necrosis	1	1			1	1
Flushing		2				2
Hot flush	3	3			3	3
Hypertension	7	25	3	5	4	20
Hypertensive crisis	3	5			3	5
Hypertensive emergency		1				1
Hypotension	2	9	1	2	1	7
Lymphangiectasia		1				1
Pallor	2	4	2	2		2
Peripheral coldness		2				2
Peripheral vascular disorder		1				1
Peripheral venous disease	1	1	1	1		
Subclavian vein thrombosis	1	1			1	1
Thrombophlebitis superficial	1	1			1	1
Thrombosis	1	1			1	1
	27	71	7	10	20	61

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

THAILAND

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breast haematoma	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

TUNISIA

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vertigo		1		1
		1		1

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea	1	1	1	1
	1	1	1	1

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia		2		2
Chills		1		1
Face oedema	1	1	1	1
Fatigue		2		2
Influenza like illness		1		1
Injection site pain		1		1
Pyrexia		1		1
Vaccination site pain	1	3	1	3
	2	12	2	12

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19		1		1
Herpes zoster	4	4	4	4
Influenza	1	1	1	1
	5	6	5	6

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint range of motion decreased		1		1
Musculoskeletal stiffness		1		1
Myalgia		2		2
Pain in extremity	1	1	1	1
	1	5	1	5

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dizziness		2		2
Dysgeusia		1		1
Headache	1	2	1	2
Paraesthesia		1		1
	1	6	1	6

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cough		1		1
		1		1

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Skin swelling	1	1	1	1
	1	1	1	1

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypertension	1	2	1	2
Vasculitis	1	1	1	1
	2	3	2	3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

TURKEY

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	1	2	1	2
	1	2	1	2

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness	1	1			1	1
Hyperacusis	1	1	1	1		
Tinnitus	3	3	3	3		
	5	5	4	4	1	1

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Eye pain	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dry mouth	1	1	1	1
Dysphagia	1	1	1	1
Mouth ulceration	1	1	1	1
Nausea	3	4	3	4
Toothache		2		2
Vomiting		1		1
	6	10	6	10

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse event	1	1	1	1		
Asthenia	9	12	9	12		
Axillary pain	1	1	1	1		
Chest pain	2	2	1	1	1	1
Chills	4	5	3	4	1	1
Drug ineffective	1	2			1	2
Fatigue	3	5	3	5		
Feeling abnormal	1	1			1	1
Feeling cold	2	2	2	2		
Feeling hot	2	2	2	2		
Malaise	3	4	3	4		
Pain	3	3	3	3		
Peripheral swelling	2	2	2	2		
Pyrexia	10	13	9	12	1	1
Swelling	1	1	1	1		
Swelling face		1		1		
Vaccination site bruising	1	1	1	1		
Vaccination site hypoaesthesia	1	1	1	1		
Vaccination site pain	9	13	9	13		
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	2	2	2	2		
	59	75	54	69	5	6

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Hypersensitivity	3	3	2	2	1	1
	3	4	2	2	1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	4		2	1	2
Cytomegalovirus infection	1	1			1	1
Herpes zoster	1	2	1	2		
Influenza	1	1	1	1		
Meningitis		1				1
Nasopharyngitis	1	1	1	1		
Otitis media	1	1	1	1		
Suspected COVID-19		1		1		
Vaccination site cellulitis	1	1			1	1
	7	13	4	8	3	5

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Accidental overdose		1		1
Contusion	1	1	1	1
Incorrect dose administered		1		1
Incorrect route of product administration	2	2	2	2
Maternal exposure during pregnancy	1	2	1	2
Off label use	1	1	1	1
Overdose		1		1
Paternal exposure during pregnancy	1	1	1	1
Product preparation error		2		2
Product use issue	2	2	2	2
	8	14	8	14

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased	1	1	1	1		
Blood pressure systolic increased	1	1			1	1
Body temperature decreased	1	1	1	1		
Electrocardiogram abnormal	1	1			1	1
Heart rate increased	2	2	1	1	1	1
	6	6	3	3	3	3

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	6	8	5	7	1	1
Back pain	9	10	7	8	2	2
Bone pain	1	1	1	1		
Joint range of motion decreased	1	1	1	1		
Limb deformity	1	1	1	1		
Mastication disorder	1	1	1	1		
Muscle contracture	1	1	1	1		
Muscle spasms	1	1	1	1		
Myalgia	7	7	7	7		
Neck pain	1	1	1	1		
Pain in extremity	12	13	11	12	1	1
	41	45	37	41	4	4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Invasive ductal breast carcinoma		1		1
		1		1

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphasia	1	1			1	1
Burning sensation	2	2	2	2		
Concentric sclerosis	1	1			1	1
Depressed level of consciousness	1	1			1	1
Dizziness	6	8	6	8		
Guillain-Barre syndrome	1	1			1	1
Headache	19	24	17	22	2	2
Head discomfort	1	1	1	1		
Hypoaesthesia	6	6	6	6		
Hypokinesia	2	2	1	1	1	1
Paraesthesia	1	1	1	1		
Presyncope	2	2	1	1	1	1
Restless legs syndrome	1	1	1	1		
Seizure	1	1			1	1
Simple partial seizures	1	1			1	1
Somnolence	2	2	2	2		
Syncope	1	1			1	1
Tremor	1	1	1	1		
	50	57	39	46	11	11

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Nightmare	1	1	1	1
Sleep disorder	1	1	1	1
	2	2	2	2

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Renal pain	1	1	1	1
Urine abnormality	1	1	1	1
	2	2	2	2

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Pelvic pain	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough		1		1		
Dyspnoea	3	4	1	2	2	2
Oropharyngeal pain	2	3	2	3		
Rhinorrhoea	1	1	1	1		
Tonsillar hypertrophy		1		1		
	6	10	4	8	2	2

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blister	3	3	3	3		
Dry skin		1		1		
Erythema	4	6	4	6		
Hyperhidrosis	1	1	1	1		
Pruritus	6	7	5	6	1	1
Rash	3	3	3	3		
Rash erythematous	1	1	1	1		
Rash pruritic	2	2	2	2		
Sensitive skin	1	1	1	1		
Skin texture abnormal	1	1	1	1		
Urticaria		1		1		
	22	27	21	26	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertension	2	2	1	1	1	1
Hypotension	1	1	1	1		
Thrombosis	1	1			1	1
Vein disorder	1	1	1	1		
	5	5	3	3	2	2

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Country Where Event Occurred
TURKS AND CAICOS ISLANDS

System Organ Class

General disorders and administration site conditions

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Fatigue		1		1
		1		1

System Organ Class

Musculoskeletal and connective tissue disorders

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Myalgia		1		1
Neck mass		1		1
		2		2

System Organ Class

Nervous system disorders

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Generalised tonic-clonic seizure		1		1
Haemorrhagic stroke		1		1
Seizure		1		1
		3		3

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* AE=Adverse Event
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Country Where Event Occurred

UKRAINE

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypoaesthesia		1		1
		1		1

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Country Where Event Occurred

UNITED ARAB EMIRATES

System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythropenia		1				1
Lymphadenopathy	2	4	2	4		
Lymph node pain		1		1		
	2	6	2	5		1

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypoacusis		1		1
		1		1

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blindness unilateral		1				1
Ocular vascular disorder		1				1
Vision blurred		2		2		
		4		2		2

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* AE=Adverse Event
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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		4		4		
Nausea	1	7	1	6		1
Rectal haemorrhage		1				1
Vomiting		2		2		
	1	14	1	12		2

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		1		1		
Axillary pain	1	1	1	1		
Chest discomfort		1		1		
Chest pain		2				2
Chills		3		3		
Death		1				1
Drug ineffective	2	9			2	9
Fatigue		7		7		
Feeling abnormal		2		2		
Gait disturbance		1		1		
Injected limb mobility decreased		1		1		
Injection site pain		1		1		
Pain	1	4	1	4		
Pyrexia	1	12	1	12		
Sudden death		1				1
Swelling	1	2	1	1		1
Vaccination failure		1				1
Vaccination site pain	1	8	1	8		
	7	58	5	43	2	15

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic shock	1	1	1	1
	1	1	1	1

System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Babesiosis		1				1
COVID-19	3	13	1	3	2	10
Lyme disease		1				1
Nasopharyngitis		1		1		
Ophthalmic herpes zoster		1				1
Pneumonia		1				1
Suspected COVID-19		1				1
	3	19	1	4	2	15

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Head injury		1				1
Inappropriate schedule of product administration	1	2	1	2		
Maternal exposure timing unspecified		1		1		
Off label use		1		1		
Product use issue		1		1		
	1	6	1	5		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased		1				1
Heart rate increased	1	1	1	1		
SARS-CoV-2 ant body test negative		3		3		
	1	5	1	4		1

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite		1		1
		1		1

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia		2		2
Back pain		3		3
Bone pain		1		1
Fibromyalgia		1		1
Muscle fatigue		1		1
Myalgia		2		2
Pain in extremity		1		1
		11		11

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bell's palsy		1				1
Depressed level of consciousness		1				1
Dizziness	1	5	1	4		1
Dysgeusia		2		2		
Facial paralysis		1				1
Headache	3	10	3	9		1
Head discomfort	1	1	1	1		
Hypoaesthesia		1				1
Lethargy	1	1	1	1		
Loss of consciousness		1				1
Neuralgia		1		1		
Neurotoxicity		1				1
Paraesthesia		1		1		
Sciatica		2		2		
Sleep deficit		1		1		
Somnolence		1		1		
Syncope	1	1			1	1
Tremor		1		1		
	7	33	6	24	1	9

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Depressed mood		1		1
		1		1

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System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Erectile dysfunction		1		1
		1		1

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	1	2	1	2		
Dyspnoea	1	3	1	2		1
Hypoxia		1				1
Respiratory tract irritation		1		1		
Tachypnoea		1		1		
	2	8	2	6		2

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperhidrosis		1		1		
Pruritus		1		1		
Rash		3		2		1
Skin irritation		1		1		
Urticaria		1				1
		7		5		2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertension		2		1		1
Thrombosis		2				2
		4		1		3

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Country Where Event Occurred

UNITED KINGDOM

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* AE=Adverse Event

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System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal lymphadenopathy		2						2
Abnormal clotting factor	2	2			1	1	1	1
Acquired haemophilia	1	2					1	2
Anaemia	15	37			1	3	14	34
Anaemia megaloblastic		1						1
Anaemia vitamin B12 deficiency		2				1		1
Anisocytosis		2						2
Antiphospholipid syndrome	1	3					1	3
Aplasia pure red cell	1	1					1	1
Autoimmune anaemia	1	2					1	2
Autoimmune haemolytic anaemia	5	8					5	8
Autoimmune neutropenia		2						2
Blood disorder	2	2					2	2
Coagulopathy	2	11			1	2	1	9
Deficiency anaemia		1				1		
Disseminated intravascular coagulation		1						1
Eosinophilia	4	5			1	2	3	3
Evans syndrome		1						1
Haemolysis	4	6					4	6
Haemolytic anaemia	2	3					2	3
Haemorrhagic diathesis		2						2
Hilar lymphadenopathy	1	1					1	1
Hypercoagulation	1	2					1	2
Immune thrombocytopenia	23	61					23	61
Increased tendency to bruise	1	9				4	1	5
Intravascular haemolysis		1						1
Iron deficiency anaemia	1	4				1	1	3
Leukopenia		2						2
Lymphadenitis	19	74			14	34	5	40
Lymphadenopathy	774	3,105	3	7	292	1097	482	2008
Lymphatic disorder	1	3			1	2		1
Lymph node pain	165	634	2	3	51	181	114	453

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Lymphocytosis	1	4			1	1		3
Lymphopenia		4				2		2
Mast cell activation syndrome	1	5					1	5
Mastocytosis		1						1
Monocytosis		1				1		
Myelosuppression		1						1
Necrotic lymphadenopathy		2						2
Neutropenia	5	28					5	28
Neutrophilia		1						1
Pancytopenia		3						3
Platelet anisocytosis		1						1
Platelet disorder		1						1
Polychromasia		2						2
Pseudolymphoma		1						1
Purpura non-thrombocytopenic	1	1					1	1
Red blood cell abnormality	1	1			1	1		
Retroperitoneal lymphadenopathy	1	1					1	1
Spleen atrophy		1						1
Splenic infarction	1	1					1	1
Splenic vein thrombosis	1	1					1	1
Splenomegaly	1	4					1	4
Spontaneous haematoma	1	1					1	1
Thrombocytopenia	49	114					49	114
Thrombocytopenic purpura	2	2					2	2
Thrombocytosis		2				1		1
Thrombotic microangiopathy		1						1
Thrombotic thrombocytopenic purpura	1	6					1	6
White blood cell disorder		2						2
	1,092	4,185	5	10	364	1335	728	2850

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute cardiac event	1	4					1	4
Acute coronary syndrome	1	5					1	5
Acute myocardial infarction	2	21					2	21
Angina pectoris	9	49					9	49
Angina unstable		1						1
Arrhythmia	7	37					7	37
Arrhythmia supraventricular	1	8				1	1	7
Arteriosclerosis coronary artery		2						2
Arteriospasm coronary		1						1
Atrial fibrillation	22	130		1			22	130
Atrial flutter	4	9					4	9
Atrial tachycardia		3				1		2
Atrioventricular block	1	4					1	4
Atrioventricular block complete		2						2
Atrioventricular block second degree	1	1					1	1
Bradycardia	5	32					5	32
Bundle branch block		1						1
Bundle branch block right		3				1		2
Cardiac amyloidosis	1	1					1	1
Cardiac arrest	6	67					6	67
Cardiac discomfort		3				1		2
Cardiac disorder	9	19			2	4	7	15
Cardiac dysfunction	1	1					1	1
Cardiac failure	4	24					4	24
Cardiac failure acute		2						2
Cardiac failure chronic		1						1
Cardiac failure congestive		4						4
Cardiac flutter	21	69					21	69
Cardiac valve disease		1						1
Cardiogenic shock		2						2
Cardiomegaly	1	2				1	1	1
Cardiomyopathy	1	2					1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiopulmonary failure		1
Cardio-respiratory arrest		1
Cardiovascular disorder	1	4
Congestive cardiomyopathy		1
Coronary artery disease		6
Coronary artery occlusion	1	2
Coronary artery stenosis		1
Coronary artery thrombosis	1	2
Cor pulmonale		1
Extrasystoles	19	42
Hypertensive heart disease		5
Intracardiac thrombus	1	1
Left ventricular dysfunction	1	4
Left ventricular failure		2
Left ventricular hypertrophy		1
Microvascular coronary artery disease		2
Mitral valve incompetence	1	2
Mitral valve prolapse		1
Myocardial fibrosis		1
Myocardial haemorrhage		1
Myocardial infarction	24	110
Myocardial ischaemia	2	14
Myocardial oedema	1	3
Myocardial rupture		1
Myocarditis	7	22
Palpitations	178	877
Paroxysmal arrhythmia		1
Pericardial effusion	1	7
Pericardial haemorrhage	1	3
Pericarditis	9	24
Postural orthostatic tachycardia syndrome	3	10
Pulseless electrical activity		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				1	4
					1
					6
				1	2
					1
				1	2
					1
		3	6	16	36
					5
				1	1
				1	4
					2
					1
					2
				1	2
					1
					1
				24	110
				2	14
				1	3
					1
				7	22
	1	78	261	100	616
					1
				1	7
				1	3
				9	24
		1	2	2	8
					3

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Right ventricular dysfunction	1	1					1	1
Right ventricular enlargement		1				1		
Right ventricular failure		1						1
Sinus arrest		2						2
Sinus bradycardia	2	3			1	1	1	2
Sinus node dysfunction		1						1
Sinus tachycardia	1	26			1	11		15
Stress cardiomyopathy		2						2
Supraventricular extrasystoles		1						1
Supraventricular tachycardia	4	24			1	6	3	18
Tachyarrhythmia	2	2					2	2
Tachycardia	52	413		1	25	132	27	281
Tricuspid valve incompetence	1	1					1	1
Ventricular arrhythmia	2	4					2	4
Ventricular extrasystoles	6	17			1	2	5	15
Ventricular fibrillation		6						6
Ventricular flutter	1	1					1	1
Ventricular hypertrophy		2						2
Ventricular tachycardia	3	7					3	7
	424	2,182		3	113	431	311	1751

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Amegakaryocytic thrombocytopenia		1		1
Ankyloglossia congenital	1	1	1	1
Cerebral palsy	1	1	1	1
Congenital cystic lung		1		1
Dysmorphism		1		1
Ehlers-Danlos syndrome	1	2	1	2
Familial hemiplegic migraine		1		1
Familial periodic paralysis		1		1
Foetal malformation		1		1
Gastroschisis		1		1
Haemophilia		1		1
Heart disease congenital		2		2
Hereditary neuropathy with liability to pressure palsies		1		1
Hypertrophic cardiomyopathy		1		1
Moebius II syndrome	1	1	1	1
Retinitis pigmentosa		1		1
Spina bifida	1	1	1	1
Transposition of the great vessels	1	1	1	1
	6	20	6	20

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute vestibular syndrome		1				1		
Auditory disorder	1	7				1	1	6
Auricular swelling		4						4
Deafness	26	94					26	94
Deafness bilateral	3	5					3	5
Deafness neurosensory	4	15					4	15
Deafness transitory	1	3					1	3
Deafness unilateral	8	25					8	25
Ear canal erythema		1				1		
Ear congestion	3	8			1	2	2	6
Ear discomfort	14	58			7	23	7	35
Ear disorder	3	14			1	6	2	8
Ear haemorrhage	2	5			1	1	1	4
Ear pain	110	399			38	120	72	279
Ear pruritus	3	11			1	4	2	7
Ear swelling	9	24			6	8	3	16
Eustachian tube disorder	1	2					1	2
Eustachian tube dysfunction		2						2
Excessive cerumen production	1	3					1	3
External ear disorder	1	1					1	1
External ear inflammation	1	2			1	1		1
External ear pain		4				3		1
Hyperacusis	7	36				9	7	27
Hypoacusis	21	64			9	26	12	38
Inner ear disorder		4						4
Inner ear inflammation	2	3					2	3
Meniere's disease		8						8
Middle ear disorder	1	1					1	1
Middle ear effusion	1	2			1	1		1
Middle ear inflammation		1						1
Misophonia	2	3			1	1	1	2
Motion sickness	5	31			1	11	4	20

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Otorrhoea		1				1		
Red ear syndrome	1	1			1	1		
Sudden hearing loss	5	17					5	17
Tinnitus	175	525			45	115	130	410
Tympanic membrane hyperaemia		1						1
Vertigo	119	502		1	32	97	87	405
Vertigo labyrinthine	4	7			2	2	2	5
Vertigo positional	10	39				3	10	36
Vestibular disorder		3				1		2
	544	1,937		1	148	439	396	1498

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Addison's disease		1				1
Adrenal haemorrhage	1	1			1	1
Adrenocortical insufficiency acute	1	9			1	9
Anovulatory cycle	3	4	2	2	1	2
Autoimmune thyroid disorder	1	1			1	1
Basedow's disease		1				1
Goitre	1	6		2	1	4
Hyperparathyroidism	1	1			1	1
Hyperthyroidism	2	10			2	10
Hypothyroidism	1	11			1	11
Premature menarche		1		1		
Thyroid disorder		1				1
Thyroiditis	3	3	1	1	2	2
Thyroiditis subacute		1		1		
Thyroid pain		1				1
	14	52	3	7	11	45

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal sensation in eye		13				6		7
Age-related macular degeneration		1						1
Amaurosis fugax	1	1					1	1
Amblyopia		2				1		1
Angle closure glaucoma	1	1					1	1
Asthenopia	20	85			13	30	7	55
Autoimmune uveitis		1						1
Binocular eye movement disorder		1						1
Blepharitis	2	6				1	2	5
Blepharospasm	12	29			4	7	8	22
Blindness	8	47					8	47
Blindness transient	3	11					3	11
Blindness unilateral	1	8					1	8
Cataract	3	4					3	4
Central vision loss		2						2
Chalazion		2						2
Charles Bonnet syndrome		1						1
Chloropsia	1	1					1	1
Chorioretinopathy		1						1
Choroidal neovascularisation		3						3
Chromatopsia		1				1		
Conjunctival haemorrhage	4	22					4	22
Conjunctival hyperaemia		2						2
Conjunctival oedema		2						2
Corneal disorder		1						1
Corneal erosion		1						1
Cyanopsia		1						1
Dark circles under eyes	2	3			1	1	1	2
Diabetic eye disease		1				1		
Diplopia	17	78			1	19	16	59
Dry eye	16	57			9	24	7	33
Dyschromatopsia	1	2				1	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eczema eyelids		3
Episcleritis		4
Erythema of eyelid	1	5
Erythroptosis		2
Exophthalmos		1
Exposure keratitis		1
Extraocular muscle disorder		1
Extraocular muscle paresis	1	2
Eye allergy		2
Eye colour change	1	2
Eye discharge	4	13
Eye disorder	11	35
Eye haematoma	1	2
Eye haemorrhage	7	18
Eye inflammation	4	14
Eye irritation	16	63
Eyelid bleeding		1
Eyelid cyst		1
Eyelid disorder	2	6
Eyelid exfoliation	1	2
Eyelid function disorder	2	6
Eyelid irritation	1	3
Eyelid margin crusting		1
Eyelid oedema	1	5
Eyelid pain	2	9
Eyelid ptosis	3	18
Eyelid rash	1	6
Eyelid skin dryness	1	1
Eyelids pruritus	1	8
Eye movement disorder	4	14
Eye oedema		5
Eye pain	134	500

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		
			1		3
			1	1	4
			1		1
					1
			1		
					1
				1	2
			1		1
		1	1		1
		2	3	2	10
		3	10	8	25
				1	2
				7	18
			3	4	11
		7	17	9	46
					1
					1
		1	3	1	3
				1	2
		2	3		3
			1	1	2
			1		
			2	1	3
			2	2	7
		1	10	2	8
			2	1	4
				1	1
		1	3		5
		2	3	2	11
			3		2
		55	146	79	354

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye paraesthesia		1
Eye pruritus	29	117
Eye swelling	51	221
Eye symptom	1	2
Eye ulcer	1	2
Foreign body sensation in eyes	1	17
Glaucoma	1	5
Halo vision	4	5
Hypoaesthesia eye	4	9
Iridocyclitis	2	8
Iritis		3
Keratitis		3
Lacrimonial disorder		1
Lacrimonial structural disorder	1	1
Lacrimation increased	14	84
Lagophthalmos	1	3
Limbal swelling		1
Macular degeneration		2
Macular hole		1
Macular oedema	1	3
Macular rupture		1
Maculopathy		2
Metamorphopsia	3	12
Miosis	1	3
Mydriasis	4	8
Ocular discomfort	7	27
Ocular hyperaemia	26	111
Ocular hypertension		1
Ocular myasthenia		1
Ocular sarcoidosis		1
Ocular vascular disorder	3	4
Ophthalmic vein thrombosis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
	2	17	52	12	65
	2	14	63	37	158
		1	1		1
			1	1	1
		1	6		11
				1	5
		2	2	2	3
		3	4	1	5
				2	8
			1		2
			2		1
					1
				1	1
		7	24	7	60
			1	1	2
					1
					2
					1
				1	3
					1
					2
		1	2	2	10
		1	1		2
		2	3	2	5
		4	14	3	13
		12	41	14	70
					1
					1
					1
		2	2	1	2
				1	1

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ophthalmoplegia		3
Optic disc haemorrhage	1	1
Optic ischaemic neuropathy	1	2
Optic nerve disorder	1	2
Optic neuropathy		1
Orbital oedema		1
Orbital swelling	1	1
Oscillopsia		1
Papilloedema	3	5
Parophthalmia		1
Periorbital discomfort	1	1
Periorbital oedema	1	9
Periorbital pain		3
Periorbital swelling	18	66
Photophobia	41	198
Photopsia	18	56
Pupil fixed		1
Pupillary disorder		1
Pupillary reflex impaired		2
Pupils unequal		3
Retinal aneurysm		1
Retinal artery occlusion	4	6
Retinal artery thrombosis		1
Retinal detachment	1	2
Retinal disorder		1
Retinal exudates		2
Retinal fovea disorder		1
Retinal haemorrhage	1	3
Retinal tear	1	2
Retinal toxicity		1
Retinal vasculitis		1
Retinal vein occlusion	7	15

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
				1	1
				1	2
				1	2
					1
					1
				1	1
			1		
				3	5
					1
		1	1		
		1	2		7
			1		2
		10	22	8	44
		15	55	26	143
		6	16	12	40
					1
					1
			1		1
					3
					1
				4	6
					1
				1	2
			1		
					2
					1
				1	3
				1	2
					1
					1
				7	15

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Retinal vein thrombosis	1	2					1	2
Retinopathy		1						1
Scintillating scotoma	2	3			1	1	1	2
Scleral discolouration		4				2		2
Scleritis	1	3					1	3
Strabismus	1	3			1	2		1
Sudden visual loss	1	3					1	3
Swelling of eyelid	19	74			5	22	14	52
Ulcerative keratitis		4						4
Uveitis	2	12					2	12
Vision blurred	108	433			38	128	70	305
Visual acuity reduced	1	10				2	1	8
Visual brightness		1				1		
Visual field defect	4	13			1	3	3	10
Visual impairment	48	190			15	59	33	131
Visual snow syndrome		1						1
Vitreous detachment	8	18					8	18
Vitreous disorder	1	1					1	1
Vitreous floaters	13	29			5	11	8	18
Vitreous haemorrhage	2	4					2	4
Vitreous haze	1	1					1	1
Xanthopsia	1	1					1	1
	761	3,011		4	269	865	492	2146

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal adhesions		2						2
Abdominal discomfort	74	304	1	4	35	102	39	202
Abdominal distension	43	152			15	53	28	99
Abdominal mass		1						1
Abdominal migraine	1	2			1	1		1
Abdominal pain	121	553		2	48	175	73	378
Abdominal pain lower	17	50			3	11	14	39
Abdominal pain upper	212	869		2	71	245	141	624
Abdominal rigidity	1	7			1	3		4
Abdominal symptom		1						1
Abdominal tenderness	2	10				3	2	7
Abnormal faeces	1	11			1	7		4
Acute abdomen		4						4
Aerophagia	1	2			1	1		1
Anaesthesia oral	1	1			1	1		
Anal fissure		1						1
Anal haemorrhage		7						7
Anal hypoaesthesia	1	1					1	1
Anal incontinence	4	13		1	1	3	3	10
Anal pruritus		2				1		1
Anal sphincter atony		1						1
Angina bullosa haemorrhagica		1						1
Angular cheilitis		1						1
Anorectal discomfort		2				1		1
Anorectal swelling		1						1
Aphthous ulcer	2	15			1	4	1	11
Aptyalism		1				1		
Ascites		3						3
Bowel movement irregularity	2	5			1	2	1	3
Breath odour	2	12			2	7		5
Burning mouth syndrome	2	2					2	2
Cardiospasm	1	1					1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Change of bowel habit	1	3
Chapped lips		7
Cheilitis	3	10
Chronic gastritis		1
Coating in mouth	2	2
Coeliac disease	1	6
Colitis	6	18
Colitis ischaemic		1
Colitis microscopic		2
Colitis ulcerative	7	27
Constipation	18	98
Crohn's disease	4	20
Cyclic vomiting syndrome		1
Defaecation urgency		8
Dental caries		1
Dental discomfort	1	2
Dental paraesthesia	2	2
Diarrhoea	398	2,109
Diarrhoea haemorrhagic		11
Discoloured vomit		5
Diverticulum	1	2
Diverticulum intestinal		1
Dry mouth	50	234
Duodenal ulcer haemorrhage		1
Duodenal ulcer perforation		1
Duodenogastric reflux		2
Dyschezia		3
Dyspepsia	25	122
Dysphagia	42	170
Enlarged uvula	4	10
Enteritis	1	5
Epigastric discomfort		8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		1
			3		4
		1	5	2	5
					1
		1	1	1	1
				1	6
		1	2	5	16
					1
					2
	1			7	27
		6	21	12	77
				4	20
					1
					8
					1
				1	2
				2	2
1	5	201	679	197	1430
					11
			2		3
			1	1	1
					1
	1	24	89	26	145
					1
					1
			1		1
			2		1
		12	41	13	81
		19	57	23	113
		3	5	1	5
			1	1	4
			2		6

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Epiploic appendagitis	1	1
Eructation	5	25
Faecaloma		2
Faeces discoloured	2	20
Faeces hard		2
Faeces pale	1	5
Faeces soft	4	6
Flatulence	18	87
Food poisoning		3
Frequent bowel movements	4	23
Functional gastrointestinal disorder	1	4
Gastric antral vascular ectasia	2	4
Gastric dilatation		3
Gastric disorder	2	17
Gastric haemorrhage	1	3
Gastric ulcer	1	3
Gastric varices haemorrhage		1
Gastritis	6	22
Gastrointestinal disorder	3	15
Gastrointestinal haemorrhage	4	9
Gastrointestinal motility disorder		1
Gastrointestinal pain	11	57
Gastrointestinal sounds abnormal	2	15
Gastrointestinal wall thickening		1
Gastrooesophageal reflux disease	17	55
Gingival bleeding	5	17
Gingival blister	1	3
Gingival discomfort		3
Gingival disorder	1	5
Gingival erythema		2
Gingival pain	8	46
Gingival pruritus		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		3	6	2	19
					2
		2	11		9
					2
		1	3		2
		1	1	3	5
		9	28	9	59
					3
		2	5	2	18
				1	4
				2	4
					3
		2	8		9
				1	3
				1	3
					1
		2	4	4	18
			5	3	10
				4	9
			1		
		2	8	9	49
		1	4	1	11
			1		
		6	10	11	45
		1	6	4	11
		1	3		
			1		2
			2	1	3
			1		1
		2	10	6	36
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gingival swelling	4	13
Gingivitis ulcerative		2
Glossitis	2	7
Glossodynia	14	98
Haematemesis	2	20
Haematochezia	5	28
Haemoperitoneum		1
Haemorrhoids	3	13
Haemorrhoids thrombosed		1
Hiatus hernia	3	3
Hyperaesthesia teeth	6	11
Hyperchlorhydria	3	9
Hypoaesthesia oral	55	227
Hypoaesthesia teeth	1	2
Ileal perforation	1	1
Ileus paralytic		1
Impaired gastric emptying	3	5
Inflammatory bowel disease		1
Internal hernia		1
Intestinal angioedema	1	1
Intestinal haemorrhage		1
Intestinal infarction		1
Intestinal ischaemia		3
Intestinal mass		1
Intestinal obstruction		6
Intestinal perforation	1	3
Intestinal pseudo-obstruction		1
Irritable bowel syndrome	8	39
Large intestine perforation	1	1
Lip blister	2	14
Lip discolouration	1	2
Lip disorder		6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	4	11
					2
		1	4	1	3
		6	42	8	56
				2	20
			1	5	27
					1
		2	2	1	11
					1
		1	1	2	2
		3	5	3	6
		1	2	2	7
		32	110	23	117
			1	1	1
				1	1
					1
				3	5
					1
					1
				1	1
					1
					1
					3
					1
					6
				1	3
					1
		4	9	4	30
				1	1
			2	2	12
				1	2
			4		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lip dry	5	30
Lip erythema		4
Lip exfoliation	2	5
Lip haemorrhage		1
Lip oedema		3
Lip pain	5	33
Lip pruritus	1	6
Lip scab		1
Lip swelling	71	339
Lip ulceration		4
Malabsorption	1	1
Mallory-Weiss syndrome	1	3
Malocclusion	1	1
Melaena	1	7
Mesenteric vein thrombosis	2	5
Mouth cyst		3
Mouth haemorrhage	1	8
Mouth swelling	14	55
Mouth ulceration	29	143
Mucous stools	1	5
Nausea	1,115	6,109
Noninfective gingivitis	1	4
Noninfective sialoadenitis		1
Obstructive pancreatitis		2
Odynophagia	8	31
Oedema mouth	1	5
Oesophageal discomfort		1
Oesophageal pain		4
Oesophageal spasm		2
Oesophageal stenosis		1
Oesophageal varices haemorrhage		1
Oesophagitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			11	5	19
			2		2
		1	2	1	3
					1
					3
		1	13	4	20
			4	1	2
					1
	1	38	124	33	215
			2		2
				1	1
				1	3
				1	1
				1	7
				2	5
			2		1
			3	1	5
		4	15	10	40
1	1	17	53	12	90
				1	5
3	24	522	2191	593	3918
				1	4
					1
					2
		3	12	5	19
			1	1	4
			1		
			2		2
			1		1
					1
			1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral blood blister	2	7
Oral discharge		1
Oral discomfort	10	43
Oral disorder	4	14
Oral dysaesthesia		1
Oral lichen planus		2
Oral mucosa erosion		1
Oral mucosal blistering	2	18
Oral mucosal discolouration		1
Oral mucosal eruption	1	6
Oral mucosal erythema		4
Oral mucosal exfoliation		6
Oral mucosal roughening		2
Oral pain	22	86
Oral papule		1
Oral pruritus	2	15
Oral purpura		1
Overflow diarrhoea		1
Palatal oedema		2
Palatal swelling		3
Palatal ulcer		1
Pancreatic disorder		1
Pancreatitis	2	5
Pancreatitis acute	2	6
Pancreatitis necrotising		1
Paraesthesia oral	103	583
Parotid gland enlargement	2	5
Peptic ulcer haemorrhage	2	4
Plicated tongue		2
Pouchitis		1
Proctalgia	2	8
Proctitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	5		2
			1		
		5	15	5	28
		3	6	1	8
					1
					2
			1		
		1	11	1	7
					1
		1	4		2
			1		3
			3		3
					2
		11	32	11	54
					1
		1	6	1	9
					1
			1		
					2
					3
					1
					1
				2	5
				2	6
					1
	1	74	313	29	270
		1	2	1	3
				2	4
			1		1
					1
			3	2	5
			1		

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* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Proctitis ulcerative		1
Pylorospasm		1
Rectal discharge	4	5
Rectal haemorrhage	14	43
Rectal spasm		1
Reflux gastritis	1	4
Regurgitation		1
Retching	7	61
Retroperitoneal haemorrhage		1
Salivary duct obstruction		1
Salivary gland disorder	1	2
Salivary gland enlargement	1	5
Salivary gland pain	2	8
Salivary hypersecretion	9	29
Scalloped tongue	1	2
Small intestinal haemorrhage	2	5
Small intestinal obstruction		2
Steatorrhoea	1	3
Stiff tongue	1	3
Stomach mass	1	1
Stomatitis	5	32
Submaxillary gland enlargement		2
Swollen tongue	57	288
Teething	1	3
Tongue blistering	3	11
Tongue coated	3	8
Tongue cyst		1
Tongue discolouration	5	15
Tongue discomfort	5	25
Tongue disorder	7	35
Tongue dry	3	9
Tongue eruption		6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
		1	2	3	3
				14	43
			1		
		1	3		1
					1
		1	21	6	40
					1
					1
				1	2
				1	5
		2	3		5
		3	11	6	18
				1	2
				2	5
					2
			1	1	2
		1	2		1
				1	1
	1	2	13	3	19
			2		
		21	89	36	199
		1	2		1
		2	4	1	7
	1	1	4	2	4
					1
		1	6	4	9
		2	9	3	16
		2	9	5	26
		1	4	2	5
			2		4

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tongue erythema		4				2		2
Tongue exfoliation	1	1					1	1
Tongue haemorrhage		1				1		
Tongue movement disturbance	1	4			1	2		2
Tongue oedema		13				2		11
Tongue pruritus	2	10			1	3	1	7
Tongue rough		1				1		
Tongue spasm	1	3			1	1		2
Tongue ulceration	5	19			4	10	1	9
Toothache	14	56			2	13	12	43
Tooth discolouration	1	1					1	1
Tooth disorder		1				1		
Tooth erosion		1				1		
Trichoglossia	1	1					1	1
Upper gastrointestinal haemorrhage		3						3
Uvulitis		1				1		
Visceral venous thrombosis		1						1
Vomiting	314	1,748	1	5	131	527	183	1221
Vomiting projectile	7	36			1	7	6	29
	3,167	16,086	7	50	1404	5445	1763	10641

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Administration site bruise	1	1			1	1		
Administration site discomfort		1				1		
Administration site joint movement impairment		2						2
Adverse drug reaction	3	30			3	21		9
Adverse event	1	2			1	2		
Adverse reaction				1				
Alcohol interaction	1	3					1	3
Apparent death		1						1
Application site acne	1	1					1	1
Application site pain	1	1					1	1
Application site vesicles		1						1
Asthenia	264	1,223	4	5	96	382	168	841
Axillary pain	267	929			83	283	184	646
Capsular contracture associated with breast implant	1	1					1	1
Chest discomfort	126	628		1	54	194	72	434
Chest pain	233	1,006	1	5	66	232	167	774
Chills	794	4,763	7	25	401	1794	393	2969
Chronic fatigue syndrome	10	43		1	5	7	5	36
Condition aggravated	81	361		2	16	78	65	283
Crepitations	1	2			1	2		
Crying	9	47			5	15	4	32
Cyst	3	5			1	2	2	3
Death	12	117					12	117
Decreased activity	1	3				1	1	2
Discharge		2						2
Discomfort	67	219		1	29	88	38	131
Disease progression	2	5					2	5
Disease recurrence	84	311	1	2	19	42	65	269
Drug ineffective	75	657	1	2			75	657
Drug interaction	7	16			3	6	4	10
Drug withdrawal syndrome	2	3			1	1	1	2

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Effusion	1	1
Energy increased	1	5
Exercise tolerance decreased	2	12
Extensive swelling of vaccinated limb	2	11
Eye complication associated with device		1
Face oedema	1	13
Facial discomfort	2	13
Facial pain	23	141
Fatigue	1,939	9,864
Feeling abnormal	218	965
Feeling cold	158	826
Feeling drunk	9	50
Feeling hot	196	832
Feeling jittery	2	21
Feeling of body temperature change	62	258
Feeling of relaxation	1	2
Fever neonatal	1	1
Foaming at mouth		1
Gait disturbance	68	309
Gait inability	16	101
Generalised oedema		2
General physical health deterioration	4	17
Glassy eyes		1
Hangover	11	37
Hernia	1	1
Hunger	3	11
Hyperpyrexia	2	6
Hyperthermia	1	5
Hypothermia		22
Illness	190	848
Immediate post-injection reaction		1
Impaired healing		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1	1	4
		1	4	1	8
			6	2	5
					1
		1	5		8
			4	2	9
		9	45	14	96
23	108	850	3420	1089	6444
2	5	86	331	132	634
1	6	61	300	97	526
		4	17	5	33
1	1	92	399	104	433
			6	2	15
		28	98	34	160
				1	2
				1	1
					1
	1	20	66	48	243
	1	3	17	13	84
			1		1
		3	6	1	11
					1
		7	13	4	24
				1	1
		1	6	2	5
				2	6
				1	5
					22
	2	90	272	100	576
			1		
					2

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Impaired self-care		1
Implant site pain		1
Implant site swelling	1	1
Inadequate analgesia		1
Induration	1	6
Inflammation	34	142
Inflammatory pain	3	6
Influenza like illness	248	1,372
Inhibitory drug interaction	1	2
Injected limb mobility decreased	6	22
Injection site bruising	2	2
Injection site coldness		1
Injection site erythema	15	28
Injection site haemorrhage	1	1
Injection site hypoaesthesia	2	2
Injection site indentation	1	1
Injection site induration	1	1
Injection site inflammation	1	1
Injection site joint movement impairment		1
Injection site mass	5	7
Injection site muscle weakness		1
Injection site oedema		1
Injection site pain	42	101
Injection site paraesthesia	1	2
Injection site pruritus	6	10
Injection site rash	3	4
Injection site reaction		2
Injection site scab	1	1
Injection site swelling	7	16
Injection site urticaria		1
Injection site warmth	4	7
Injury associated with device		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
		1	1		
					1
			2	1	4
		12	49	22	93
		1	3	2	3
4	8	119	499	129	873
		1	1		1
		6	12		10
		2	2		
			1		
		13	24	2	4
		1	1		
		2	2		
				1	1
		1	1		
		1	1		
					1
		3	3	2	4
					1
			1		
		34	74	8	27
		1	2		
		6	9		1
		2	2	1	2
			1		1
		1	1		
		6	13	1	3
					1
		2	3	2	4
			1		

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Irritability postvaccinal	1	1
Localised oedema	5	15
Local reaction	7	31
Loss of control of legs	2	9
Malaise	638	3,420
Mass	11	31
Moaning		3
Mucosal disorder	1	1
Mucosal dryness	1	1
Mucosal haemorrhage	1	3
Multiple organ dysfunction syndrome	1	6
Necrosis	1	1
No adverse event	3	8
Nodule	1	12
Non-cardiac chest pain	1	5
Nonspecific reaction	1	1
No reaction on previous exposure to drug	1	3
Obstruction	1	1
Oedema	13	29
Oedema mucosal	1	1
Oedema peripheral	11	44
Pain	874	3,953
Perforation	1	1
Peripheral swelling	346	1,298
Physical deconditioning		1
Polyp		1
Potentiating drug interaction		1
Pre-existing condition improved		4
Prolapse		1
Puncture site bruise	1	3
Puncture site discharge		1
Puncture site swelling		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		3	7	2	8
		5	16	2	15
				2	9
5	16	291	1195	347	2225
		4	9	7	22
					3
		1	1		
				1	1
				1	3
				1	6
				1	1
		3	8		
		1	5		7
			1	1	4
		1	1		
		1	3		
				1	1
			5	13	24
		1	1		
		3	13	8	31
1	11	373	1551	501	2402
				1	1
	3	135	431	211	867
					1
					1
					1
			3		1
					1
		1	1		2
					1
			1		

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pyrexia	1,031	6,571
Screaming	2	6
Secretion discharge	1	6
Sensation of blood flow		2
Sensation of foreign body	6	33
Sensitivity to weather change		2
Serositis		2
Shoulder injury related to vaccine administration	1	4
Sluggishness		12
Soft tissue inflammation	1	1
Sudden death	4	24
Suprapubic pain		1
Swelling	293	1,050
Swelling face	111	455
Symptom recurrence	2	4
Systemic inflammatory response syndrome		2
Temperature intolerance	1	14
Temperature regulation disorder	4	15
Tenderness	66	226
Therapeutic product effect delayed		1
Therapeutic product effect increased		1
Therapeutic product ineffective		1
Therapeutic response unexpected	12	38
Thirst	43	164
Treatment noncompliance		1
Ulcer	1	6
Vaccination failure	1	10
Vaccination site bruising	26	136
Vaccination site calcification		1
Vaccination site coldness	1	3
Vaccination site cyst		1
Vaccination site discharge		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
7	30	497	2464	534	4107
		1	3	1	3
			1	1	5
					2
		4	10	2	23
					2
					2
				1	4
			4		8
		1	1		
				4	24
			1		
2	2	109	413	184	637
	1	44	131	67	324
		1	2	1	2
					2
			1	1	13
			4	4	11
1	4	41	140	25	86
					1
					1
					1
		12	29		9
		18	57	25	107
					1
			1	1	5
				1	10
1	1	15	68	11	68
					1
		1	1		2
					1
					1

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site discolouration	5	16
Vaccination site discomfort	20	97
Vaccination site dryness		2
Vaccination site eczema		1
Vaccination site erythema	155	807
Vaccination site haematoma		2
Vaccination site haemorrhage	4	29
Vaccination site hyperaesthesia	1	6
Vaccination site hypersensitivity	1	5
Vaccination site hypoaesthesia	4	27
Vaccination site induration	21	93
Vaccination site inflammation	13	75
Vaccination site irritation	4	12
Vaccination site joint discomfort		2
Vaccination site joint erythema	1	5
Vaccination site joint movement impairment	5	21
Vaccination site joint pain	5	18
Vaccination site joint swelling		2
Vaccination site joint warmth		1
Vaccination site lymphadenopathy	1	25
Vaccination site macule		2
Vaccination site mass	76	318
Vaccination site movement impairment	29	121
Vaccination site necrosis		3
Vaccination site nodule	1	2
Vaccination site oedema	4	16
Vaccination site pain	582	3,571
Vaccination site papule		1
Vaccination site paraesthesia	2	33
Vaccination site photosensitivity reaction	1	1
Vaccination site pruritus	81	328
Vaccination site rash	29	161

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	6	4	10
		10	52	10	45
			1		1
			1		
1	1	104	463	51	344
					2
		1	8	3	21
			2	1	4
		1	3		2
		1	11	3	16
		13	58	8	35
		9	45	4	30
		3	6	1	6
			2		
		1	3		2
		1	8	4	13
		4	10	1	8
			1		1
			1		
		1	10		15
			2		
1	2	40	153	36	165
		6	44	23	77
					3
		1	1		1
		3	7	1	9
1	10	358	1807	224	1764
					1
			15	2	18
		1	1		
1	1	62	208	19	120
		18	83	11	78

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site reaction	15	68	1	1	10	33	5	35
Vaccination site scab		3						3
Vaccination site scar		2				1		1
Vaccination site swelling	162	876			96	443	66	433
Vaccination site ulcer		1						1
Vaccination site urticaria	5	20			3	12	2	8
Vaccination site vesicles	1	12			1	4		8
Vaccination site warmth	83	410			54	216	29	194
Vascular stent thrombosis		1						1
Visceral pain		1				1		
Withdrawal syndrome	3	6				2	3	4
	10,192	51,398	67	260	4626	19187	5566	32211

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* AE=Adverse Event

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System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute hepatic failure	1	1			1	1
Autoimmune hepatitis	2	2			2	2
Bile duct stone		1				1
Biliary colic	1	2			1	2
Cholangitis		1				1
Cholelithiasis		3				3
Cholestasis	1	1			1	1
Congestive hepatopathy	1	2			1	2
Drug-induced liver injury		2				2
Gallbladder disorder		1				1
Hepatic artery embolism		1				1
Hepatic cirrhosis	1	2			1	2
Hepatic failure		1				1
Hepatic function abnormal		1				1
Hepatic haemorrhage	1	1			1	1
Hepatic lesion		1				1
Hepatic pain	2	11	1	2	1	9
Hepatic vascular thrombosis	1	1			1	1
Hepatic vein thrombosis	1	1			1	1
Hepatitis	1	7			1	7
Hepatomegaly		1				1
Immune-mediated hepatic disorder		1				1
Ischaemic hepatitis	1	1			1	1
Jaundice	5	13		1	5	12
Liver disorder	1	1			1	1
Liver injury		5				5
Liver tenderness	1	2			1	2
Periportal oedema	1	1			1	1
Portal vein thrombosis	1	2			1	2
Primary biliary cholangitis		1				1
	23	71	1	3	22	68

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- * AE=Adverse Event
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System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic oedema	2	8		1	2	7
Allergic reaction to excipient	1	5	1	1		4
Allergy to arthropod bite		2		1		1
Allergy to arthropod sting		1				1
Allergy to chemicals	2	2			2	2
Allergy to metals	1	1	1	1		
Allergy to vaccine	4	55	1	25	3	30
Anaphylactic reaction	38	307			38	307
Anaphylactic shock	7	25			7	25
Anaphylactoid reaction	3	17			3	17
Anaphylactoid shock	1	4			1	4
Atopy		1				1
Autoimmune disorder	7	22			7	22
Bacille Calmette-Guerin scar reactivation	3	10	1	4	2	6
Contrast media reaction		1				1
Corneal graft rejection	3	3			3	3
Decreased immune responsiveness		2				2
Drug hypersensitivity	2	18		3	2	15
Food allergy	2	8		1	2	7
Graft versus host disease		1				1
Hypersensitivity	86	368	30	103	56	265
Immune-mediated adverse reaction		2		1		1
Immune system disorder	10	25	2	3	8	22
Immunisation reaction	1	2			1	2
Immunodeficiency	1	4			1	4
Immunodeficiency common variable		1				1
Immunosuppression	1	1			1	1
Kidney transplant rejection		1				1
Multiple allergies	1	2			1	2
Oral allergy syndrome	1	2			1	2
Reaction to colouring		1				1
Reaction to excipient	2	6		1	2	5

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* AE=Adverse Event

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System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Reaction to preservatives		3				3
Rubber sensitivity		1				1
Sarcoidosis	2	11			2	11
Seasonal allergy	15	27	3	8	12	19
Sensitisation		2				2
Serum sickness		1				1
Serum sickness-like reaction		2				2
Solid organ transplant rejection	1	1			1	1
Systemic immune activation		2				2
Type I hypersensitivity		1				1
Type III immune complex mediated reaction		1				1
Type IV hypersensitivity reaction		6		1		5
	197	966	39	154	158	812

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal infection		1						1
Abscess	1	9				2	1	7
Abscess jaw		1						1
Abscess oral		3				1		2
Acarodermatitis		1						1
Acne pustular		2				1		1
African trypanosomiasis		2						2
Appendicitis	2	10					2	10
Appendicitis perforated		2						2
Arthritis bacterial		1						1
Arthritis viral		2				1		1
Asymptomatic COVID-19	2	21				2	2	19
Bacterial diarrhoea		1						1
Bacterial infection	3	5			1	1	2	4
Biliary sepsis		1						1
Blister infected		1				1		
Breast abscess	2	3					2	3
Breast cellulitis		1						1
Bronchitis	1	6				1	1	5
Bronchopulmonary aspergillosis		1						1
Campylobacter gastroenteritis	1	1					1	1
Candida infection	1	8				2	1	6
Cavernous sinus thrombosis		1						1
Cellulitis	14	113					14	113
Cholecystitis infective		1						1
Clostridium difficile colitis		1						1
Clostridium difficile infection		1						1
Complicated appendicitis	1	1					1	1
Conjunctivitis	3	26			1	7	2	19
Conjunctivitis bacterial		2						2
Conjunctivitis viral		1				1		
Coronavirus infection		3				1		2

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
COVID-19	97	689
COVID-19 pneumonia	1	29
Creutzfeldt-Jakob disease		2
Croup infectious	1	1
Cystitis	10	31
Cytomegalovirus infection reactivation		1
Dermatitis infected		3
Device related infection		1
Disseminated varicella zoster virus infection		1
Diverticulitis		4
Dysentery		1
Ear infection	7	36
Ear infection bacterial		1
Eczema herpeticum		2
Encephalitis	4	13
Encephalitis viral	1	3
Endocarditis	1	1
Endometritis	1	1
Epididymitis		2
Epiglottitis		2
Epstein-Barr virus infection		2
Erythema induratum	1	1
Escherichia bacteraemia	1	1
External ear cellulitis		1
Eye abscess		1
Eye infection	4	12
Eyelid infection	1	1
Febrile infection	1	1
Folliculitis		4
Fungal infection		1
Fungal skin infection		1
Furuncle	3	15

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	3	27	145	70	544
				1	29
					2
				1	1
		2	7	8	24
					1
			1		2
					1
					1
					4
					1
		2	10	5	26
					1
					2
				4	13
				1	3
				1	1
				1	1
					2
					2
					2
				1	1
				1	1
					1
					1
		3	3	1	9
				1	1
				1	1
			2		2
					1
					1
		2	4	1	11

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastroenteritis	2	18
Gastroenteritis norovirus		1
Gastroenteritis rotavirus		1
Gastroenteritis viral	1	7
Genital herpes	7	13
Genital herpes simplex	3	3
Gingival abscess		1
Gingivitis	2	5
Gonorrhoea		1
Hepatitis A		1
Hepatitis E	1	1
Hepatitis viral		3
Herpes ophthalmic		2
Herpes simplex	5	13
Herpes simplex encephalitis		1
Herpes simplex reactivation		2
Herpes virus infection	3	9
Herpes zoster	398	743
Herpes zoster meningoencephalitis		1
Herpes zoster oticus	5	9
Herpes zoster reactivation	7	12
HIV infection	1	1
Hordeolum	4	9
Impetigo	1	2
Infected cyst	1	1
Infected dermal cyst		1
Infected skin ulcer		1
Infection	23	98
Infectious mononucleosis	2	5
Infectious pleural effusion		1
Infective exacerbation of chronic obstructive airways disease		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3	1	15
					1
					1
		1	3		4
			2	7	11
		1	1	2	2
					1
		1	3	1	2
					1
					1
				1	1
					3
					2
		1	4	4	9
					1
			1		1
		1	2	2	7
		174	273	224	470
					1
				5	9
		6	6	1	6
				1	1
		2	3	2	6
				1	2
				1	1
					1
					1
		6	26	17	72
				2	5
					1
					1

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Infective pericardial effusion	1	1
Infective tenosynovitis	1	1
Influenza	123	653
Infusion site infection		1
Injection site cellulitis		1
Injection site pustule		1
Kidney infection	3	12
Klebsiella infection		1
Labyrinthitis	12	49
Laryngitis		3
Localised infection	1	17
Lower respiratory tract infection	15	106
Lower respiratory tract infection viral		1
Lymphangitis	1	5
Lymph gland infection	2	8
Lymph node abscess		1
Mastitis	3	20
Mastoiditis	1	1
Measles		2
Meningitis	1	5
Meningitis aseptic		1
Meningitis bacterial		1
Meningitis pneumococcal		1
Meningitis viral	2	4
Mumps	1	4
Myelitis		3
Nasal herpes	1	3
Nasopharyngitis	94	381
Necrotising fasciitis		2
Neutropenic sepsis		2
Ophthalmic herpes simplex	1	1
Ophthalmic herpes zoster	5	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
3	7	50	193	73	460
					1
					1
					1
				3	12
					1
		4	9	8	40
					3
		1	4		13
				15	106
					1
				1	5
		1	3	1	5
					1
				3	20
				1	1
					2
				1	5
					1
					1
				2	4
				1	4
					3
			2	1	1
		36	142	58	239
					2
					2
				1	1
				5	12

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral candidiasis	3	17
Oral herpes	37	106
Oral infection	1	1
Orchitis		3
Otitis externa		1
Parainfluenzae viral laryngotracheobronchitis		1
Paronychia	1	1
Parotitis	2	7
Periorbital cellulitis		2
Periorbital infection	1	1
Peritonitis		1
Pharyngeal pustule		1
Pharyngitis	1	10
Pharyngitis streptococcal	1	4
Pneumonia	12	66
Pneumonia bacterial		1
Pneumonia fungal		1
Pneumonia staphylococcal		1
Post procedural infection	1	1
Post viral fatigue syndrome	12	48
Prion disease		1
Prostatic abscess		1
Pulmonary sepsis		1
Pulmonary tuberculosis		1
Pulpitis dental		1
Pustule		4
Pyelonephritis		1
Q fever	2	9
Rash pustular	2	5
Rectal abscess		1
Relapsing fever		1
Respiratory tract infection	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	5	2	12
	1	19	46	18	60
				1	1
					3
					1
					1
		1	1		
		1	3	1	4
					2
				1	1
					1
			1		
		1	4		6
		1	1		3
				12	66
					1
					1
					1
		1	1		
	1	3	4	9	44
					1
					1
					1
					1
			1		3
					1
				2	9
				2	5
					1
					1
				1	5

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rhinitis	4	26
Scarlet fever		1
Secondary transmission		1
Sepsis	4	32
Sepsis syndrome		1
Septic pulmonary embolism		1
Septic shock	1	4
Severe acute respiratory syndrome		1
Sialoadenitis	1	3
Sinusitis	10	39
Skin infection	3	12
Soft tissue infection		1
Sputum purulent		1
Staphylococcal abscess		1
Staphylococcal infection		3
Staphylococcal sepsis		1
Streptococcal abscess		1
Streptococcal endocarditis	1	1
Streptococcal sepsis	1	1
Subcutaneous abscess		2
Suspected COVID-19	41	436
Sweating fever	5	59
Syphilis	1	1
Systemic candida		1
Tonsillitis	5	25
Tonsillitis bacterial	1	4
Tooth abscess	2	3
Tooth infection		1
Tracheitis		3
Upper respiratory tract infection		7
Urinary tract infection	14	90
Urinary tract infection bacterial		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	11	3	15
					1
					1
				4	32
					1
					1
				1	4
					1
				1	3
		6	9	4	30
		1	6	2	6
					1
					1
			1		
					3
					1
					1
				1	1
				1	1
			1		1
		22	170	19	266
				5	59
				1	1
					1
	1	3	7	2	18
				1	4
				2	3
					1
			1		2
			3		4
	1	5	15	9	75
					1

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Urosepsis		2						2
Vaccination site abscess		5				3		2
Vaccination site cellulitis	4	30			3	10	1	20
Vaccination site infection	1	26			1	8		18
Vaccination site pustule		1						1
Vaccine breakthrough infection		17						17
Varicella	5	11			1	3	4	8
Varicella zoster virus infection		1						1
Vestibular neuronitis	2	10					2	10
Vestibulitis	1	1					1	1
Viral infection	11	27				5	11	22
Viral labyrinthitis		5				3		2
Viral pericarditis		1						1
Viral pharyngitis	1	5					1	5
Viral rash	5	16			2	6	3	10
Viral sepsis	1	1					1	1
Viral tonsillitis		1						1
Viral upper respiratory tract infection		1						1
Virologic failure		1						1
Vulval abscess		1						1
Vulvovaginal candidiasis	2	11			1	3	1	8
Wound infection		1						1
	1,103	4,613	4	14	398	1205	705	3408

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accident	1	2				1	1	1
Accidental exposure to product	3	9			3	8		1
Accidental overdose		19				18		1
Airway burns		1						1
Alcohol poisoning		1						1
Ankle fracture		2						2
Arthropod bite	1	3				1	1	2
Atypical femur fracture		1						1
Back injury		1						1
Barotitis media	1	1			1	1		
Bite		1						1
Bone contusion		1				1		
Brachial plexus injury		1						1
Burn oesophageal		1						1
Burn oral cavity		1						1
Burns second degree	2	5				2	2	3
Cartilage injury	1	1					1	1
Chest crushing	1	4					1	4
Chest injury	1	4					1	4
Chillblains	6	35			4	25	2	10
Circumstance or information capable of leading to medication error		4				4		
Clavicle fracture	1	2			1	1		1
Concussion		2				1		1
Contraindicated product administered		2				1		1
Contraindicated product prescribed	1	2				1	1	1
Contusion	102	333		2	32	117	70	216
Corneal abrasion		1						1
Decreased embryo viability		1						1
Delayed recovery from anaesthesia	1	3				1	1	2
Dose calculation error		1				1		
Electric shock		4				2		2

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Epicondylitis	2	6
Expired product administered	1	8
Exposure during pregnancy	16	49
Exposure to extreme temperature		1
Exposure to SARS-CoV-2		3
Exposure via breast milk	20	122
Exposure via skin contact	3	3
Eye contusion	2	12
Eye injury	5	7
Face crushing		1
Face injury	1	5
Failed in vitro fertilisation		1
Fall	34	186
Femoral neck fracture	1	3
Femur fracture		1
Foetal exposure during pregnancy		2
Foreign body in gastrointestinal tract		1
Foreign body in mouth		1
Foreign body in urogenital tract	1	1
Fracture	1	2
Fractured skull depressed		1
Gastrointestinal stoma complication		1
Hand fracture		1
Head injury	7	43
Heart injury	2	9
Heat exhaustion	1	1
Heat illness	1	2
Heat oedema	1	5
Heat stroke	1	3
Hip fracture		2
Humerus fracture		1
Hyphaema		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2	1	4
		1	6		2
	1	12	39	4	10
					1
			1		2
		13	88	7	34
		3	3		
	1	1	6	1	6
		1	1	4	6
					1
			1	1	4
					1
		8	49	26	137
				1	3
					1
			1		1
					1
				1	1
				1	2
					1
					1
		2	14	5	29
				2	9
		1	1		
				1	2
			1	1	4
		1	2		1
					2
					1
					1

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Inappropriate schedule of product administration	532	1,042
Incision site pain		3
Incomplete course of vaccination		1
Incorrect dose administered	4	13
Incorrect route of product administration	8	52
Infusion related reaction	1	4
Injection related reaction	3	23
Injury	4	9
Injury corneal		1
Intentional product misuse		1
Intentional product use issue	1	2
Joint dislocation		1
Joint injury	1	8
Ligament sprain	4	9
Limb crushing injury	1	2
Limb injury	8	27
Lip injury	1	1
Lower limb fracture		2
Maternal exposure before pregnancy	1	3
Maternal exposure during breast feeding	12	26
Maternal exposure during pregnancy	36	121
Maternal exposure timing unspecified	3	6
Medication error	3	8
Meniscus injury		1
Mouth injury	1	2
Multiple injuries		1
Muscle injury		3
Muscle rupture	1	4
Muscle strain	7	22
Nail avulsion		1
Nasal injury	1	2
Neck injury		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
2	2	516	1010	16	32
					3
			1		
		4	12		1
		7	50	1	2
				1	4
			5	3	18
				4	9
					1
			1		
		1	2		
					1
		1	4		4
				4	9
				1	2
		2	6	6	21
		1	1		
					2
		1	1		2
		5	11	7	15
5	9	16	77	20	44
		3	6		
		2	4	1	4
			1		
				1	2
					1
			1		2
				1	4
		4	6	3	16
			1		
		1	1		1
					1

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nerve injury	1	20
Occupational exposure to product	1	3
Occupational exposure to SARS-CoV-2		1
Off label use	500	1,447
Overdose	5	28
Palate injury	1	1
Paternal exposure before pregnancy		1
Paternal exposure during pregnancy	1	1
Periorbital haematoma		1
Poisoning	1	4
Poor quality product administered	11	94
Post laminectomy syndrome		1
Post lumbar puncture syndrome		1
Postoperative ileus		1
Post procedural complication		3
Post procedural constipation		1
Procedural dizziness		4
Procedural nausea		3
Procedural pain	1	1
Product administered at inappropriate site	4	29
Product administered to patient of inappropriate age	10	27
Product administration error	3	5
Product dose omission issue		1
Product label confusion		1
Product preparation error	3	13
Product preparation issue	1	4
Product storage error	7	9
Product use issue	42	514
Reaction to previous exposure to any vaccine		1
Rectal injury		1
Retinal injury	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			6	1	14
		1	3		
			1		
2	2	483	1384	17	63
		4	26	1	2
				1	1
					1
		1	1		
					1
				1	4
		11	94		
					1
					1
					1
					3
			1		
			1		3
					3
				1	1
		4	25		4
		9	25	1	2
		2	3	1	2
					1
			1		
		3	12		1
		1	4		
		7	9		
		38	480	4	34
					1
					1
				1	3

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rib fracture	1	2
Road traffic accident	4	8
Scar	6	11
Sciatic nerve injury	1	1
Scratch	2	9
Sedation complication		1
Skin abrasion		8
Skin injury		1
Skin laceration		5
Skull fracture		1
Soft tissue injury		1
Spinal column injury		1
Spinal fracture	3	5
Splenic rupture		2
Stoma site discharge		1
Stoma site extravasation		1
Stoma site haemorrhage	1	2
Subcutaneous haematoma		1
Subdural haematoma	1	3
Subdural haemorrhage	1	2
Sunburn	2	5
Superficial injury of eye		1
Synovial rupture		1
Tendon injury	2	7
Tendon rupture	3	3
Thermal burn	3	12
Thermal burns of eye	1	6
Tongue injury		1
Tooth fracture		2
Toxic anterior segment syndrome	1	1
Toxicity to various agents		2
Traumatic haematoma	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
		2	3	2	5
		2	3	4	8
				1	1
		1	3	1	6
					1
			4		4
			1		
			2		3
					1
					1
					1
				3	5
					2
					1
			1		
				1	2
			1		
				1	3
				1	2
		1	2	1	3
					1
			1		
		1	1	1	6
				3	3
		1	4	2	8
				1	6
					1
					2
				1	1
	1				2
				2	2

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Traumatic haemorrhage		1						1
Traumatic intracranial haemorrhage		1						1
Ulnar nerve injury		4						4
Underdose	4	16			3	15	1	1
Upper limb fracture		6						6
Vaccination complication	5	29			1	10	4	19
Vaccination error	2	2			2	2		
Vascular injury	1	4					1	4
Venous injury		3						3
Vth nerve injury		1						1
Vulvovaginal injury	1	1					1	1
Wound	3	9			1	3	2	6
Wound complication	3	5			2	3	1	2
Wound haemorrhage		1						1
Wound secretion		2						2
Wrist fracture	1	2					1	2
Wrong product administered	15	21			15	20		1
Wrong technique in product usage process	3	8			3	7		1
	1,520	4,785	9	18	1248	3764	272	1021

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Activated partial thromboplastin time prolonged	6	11
Activated partial thromboplastin time shortened		2
Alanine aminotransferase increased	2	16
Ammonia abnormal		1
Amylase increased		1
Analgesic drug level		1
Antibody test positive		1
Anticoagulation drug level below therapeutic		1
Anticoagulation drug level increased		1
Antinuclear antibody	1	1
Antinuclear ant body increased	1	1
Anti-thyroid antibody positive		1
Aspartate aminotransferase increased		2
Bleeding time abnormal		1
Bleeding time prolonged	1	1
Blood albumin decreased		1
Blood alcohol decreased	1	1
Blood alkaline phosphatase increased		4
Blood bilirubin abnormal	1	1
Blood calcium decreased	1	1
Blood cholesterol increased	1	5
Blood count	1	1
Blood count abnormal		3
Blood creatine phosphokinase increased	1	5
Blood creatinine increased		2
Blood electrolytes increased		1
Blood fibrinogen decreased		1
Blood folate decreased	1	2
Blood follicle stimulating hormone increased	1	1
Blood glucose		2
Blood glucose abnormal	1	7
Blood glucose decreased	7	27

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	5	10
					2
		1	3	1	13
			1		
			1		
					1
			1		
					1
					1
				1	1
		1	1		
					1
					2
					1
				1	1
			1		3
				1	1
				1	1
				1	5
		1	1		
					3
			1	1	4
			1		1
			1		
					1
			1	1	1
				1	1
					2
			3	1	4
		1	6	6	21

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood glucose fluctuation		15
Blood glucose increased	9	74
Blood growth hormone abnormal		2
Blood heavy metal increased		1
Blood immunoglobulin E increased		1
Blood immunoglobulin G increased	1	2
Blood immunoglobulin M abnormal		1
Blood immunoglobulin M decreased	1	1
Blood immunoglobulin M increased		1
Blood iron decreased	1	2
Blood iron increased		2
Blood ketone body	1	1
Blood ketone body increased		1
Blood ketone body present		1
Blood lactate dehydrogenase increased		1
Blood lactic acid increased		5
Blood luteinising hormone abnormal		1
Blood magnesium decreased		1
Blood oestrogen increased		1
Blood pH		2
Blood pH abnormal	1	1
Blood pH increased	1	5
Blood phosphorus decreased		2
Blood potassium abnormal		1
Blood potassium decreased		6
Blood potassium increased	1	3
Blood pressure abnormal	5	12
Blood pressure decreased	10	57
Blood pressure diastolic decreased	1	3
Blood pressure diastolic increased		3
Blood pressure increased	40	235
Blood pressure measurement	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			4		11
			19	9	55
			2		
			1		
					1
			1	1	1
					1
				1	1
			1		
			1	1	1
			1		1
				1	1
					1
					1
			2		3
			1		
			1		
					1
					2
				1	1
			2	1	3
					2
					1
			2		4
			1	1	2
		1	5	4	7
		6	19	4	38
		1	3		
					3
		8	84	32	151
				1	1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood pressure normal	1	1
Blood pressure orthostatic abnormal		1
Blood pressure orthostatic decreased	1	2
Blood pressure systolic decreased		4
Blood pressure systolic increased	2	8
Blood prolactin increased		1
Blood sodium decreased	3	9
Blood test	1	1
Blood test abnormal	2	10
Blood testosterone increased		1
Blood thrombin		1
Blood thyroid stimulating hormone increased		2
Blood urea increased		2
Blood uric acid increased	1	1
Blood urine	3	5
Blood urine present	8	25
Blood viscosity increased		1
Body temperature	10	32
Body temperature abnormal	18	86
Body temperature decreased	12	46
Body temperature fluctuation	8	40
Body temperature increased	48	309
Breath sounds abnormal		2
Cardiac murmur	1	7
Cells in urine		1
Central venous pressure abnormal		1
Chest X-ray abnormal		1
Clostridium test positive		1
Clot retraction		1
Coagulation time prolonged	1	3
Coagulation time shortened	1	1
Coma scale abnormal		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
				1	2
					4
		1	4	1	4
			1		
		1	3	2	6
				1	1
				2	10
			1		
					1
			1		1
		1	1		
				3	5
		2	7	6	18
			1		
		6	20	4	12
		8	32	10	54
		5	13	7	33
		3	14	5	26
1	3	26	145	22	164
			1		1
			1	1	6
					1
			1		
			1		
					1
					1
				1	3
				1	1
					3

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Corneal reflex decreased		2
Coronavirus test positive	1	2
Cortisol decreased		2
C-reactive protein abnormal		1
C-reactive protein increased	7	35
Creatinine renal clearance decreased		1
Culture negative		1
Drug level decreased		1
Drug level fluctuating		1
Electrocardiogram abnormal	1	7
Electrocardiogram change		1
Electrocardiogram ST segment abnormal		1
Electrocardiogram ST segment elevation		3
Electrocardiogram T wave inversion	1	1
Eosinophil count increased		3
Epinephrine increased	1	3
Faecal calprotectin		1
Faecal calprotectin increased	3	4
False positive investigation result		1
Fibrin D dimer increased	8	21
Foetal heart rate abnormal	2	2
Forced expiratory volume increased		2
Foveal reflex abnormal		1
Full blood count abnormal		1
Full blood count increased		1
Gamma-glutamyltransferase increased	1	3
Glomerular filtration rate decreased	1	1
Glucose urine present		1
Grip strength		1
Grip strength decreased	9	31
Haematocrit increased		1
Haemoglobin decreased	4	14

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
		1	2		
					2
					1
		1	7	6	28
					1
					1
					1
					1
		1	2		5
			1		
					1
					3
				1	1
			1		2
		1	2		1
					1
		2	2	1	2
					1
			2	8	19
		1	1	1	1
					2
					1
					1
				1	3
				1	1
					1
					1
		2	9	7	22
					1
			4	4	10

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haemoglobin increased		2
Haptoglobin decreased		1
Heart rate	6	18
Heart rate abnormal	16	46
Heart rate decreased	7	43
Heart rate increased	101	475
Heart rate irregular	18	57
Heart sounds abnormal	1	2
Hepatic enzyme increased		4
Histamine level increased		1
Hormone level abnormal	4	6
Hysteroscopy	1	1
Immunology test	1	2
Inflammatory marker increased		7
International normalised ratio abnormal		3
International normalised ratio decreased	1	15
International normalised ratio fluctuation		1
International normalised ratio increased	1	35
Intraocular pressure increased	1	2
Iodine uptake increased		1
Laboratory test abnormal	1	1
Liver function test abnormal	9	20
Liver function test increased		10
Lymph node palpable	3	8
Lymph nodes scan abnormal		1
Lymphocyte count decreased		2
Lymphocyte count increased		1
Magnetic resonance imaging abnormal		1
Magnetic resonance imaging head abnormal		2
Mean cell volume decreased		1
Mini mental status examination abnormal		1
Myocardial necrosis marker increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
		4	7	2	11
	1	4	12	12	34
		3	8	4	35
		28	146	73	329
1	1	5	8	13	49
		1	1		1
			3		1
			1		
		2	2	2	4
				1	1
			1	1	1
			1		6
			1		2
			2	1	13
					1
			8	1	27
				1	2
					1
				1	1
			3	9	17
			2		8
		2	6	1	2
					1
					2
					1
					1
					2
					1
					1
					1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Natural killer T cell count increased		1
Neutrophil count abnormal	4	5
Neutrophil count decreased	2	6
Neutrophil count increased		1
Ophthalmological examination abnormal		1
Oxygen consumption decreased		1
Oxygen saturation	1	2
Oxygen saturation decreased	15	75
Peak expiratory flow rate		1
Peak expiratory flow rate abnormal		1
Peak expiratory flow rate decreased		3
pH urine		1
pH urine abnormal	1	1
pH urine increased		1
Plasma viscosity abnormal		1
Platelet count abnormal		1
Platelet count decreased	21	61
Platelet count increased		3
Polymerase chain reaction positive	7	11
Pregnancy test positive		1
Product residue present	1	2
Prostatic specific antigen increased	1	2
Protein urine present	1	1
Prothrombin time prolonged		1
Pulmonary function test		1
Pulse abnormal		8
Pulse pressure increased	1	1
Quality of life decreased		2
Radial pulse abnormal		1
Radioisotope uptake increased		1
Red blood cell sedimentation rate abnormal		1
Red blood cell sedimentation rate increased		6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		4	4		1
		2	4		2
			1		
			1		
			1		
				1	2
		1	8	14	67
					1
					1
					3
					1
				1	1
					1
					1
			1		
		7	14	14	47
					3
		3	6	4	5
			1		
		1	1		1
			1	1	1
				1	1
					1
					1
			2		6
		1	1		
					2
					1
					1
					6

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Renal function test abnormal	1	1
Respiratory rate	1	1
Respiratory rate decreased		4
Respiratory rate increased	11	41
Reticulocyte count decreased		1
Rheumatoid factor increased	1	2
SARS-CoV-2 ant body test		1
SARS-CoV-2 ant body test negative		12
SARS-CoV-2 ant body test positive		2
SARS-CoV-2 test		1
SARS-CoV-2 test false positive		1
SARS-CoV-2 test negative		3
SARS-CoV-2 test positive	8	54
Serum ferritin decreased	1	2
Serum ferritin increased		1
Sigmoidoscopy abnormal		1
Skin temperature	2	9
Skin test positive	1	1
Sputum abnormal		2
Stroke volume decreased	1	1
Swollen joint count increased		1
Temperature difference of extremities		4
Temperature perception test increased		1
Thyroid function test abnormal		1
Thyroxine free increased		2
Transaminases increased	1	2
Transferrin decreased		1
Tri-iodothyronine		1
Tri-iodothyronine decreased		2
Troponin	1	1
Troponin increased	2	10
Urine analysis abnormal		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1		
					4
		4	10	7	31
					1
				1	2
			1		
			8		4
			1		1
					1
			1		
			2		1
		1	11	7	43
				1	2
					1
					1
		2	4		5
		1	1		
					2
				1	1
					1
					4
					1
			1		
					2
				1	2
			1		
			1		
					2
				1	1
				2	10
			1		2

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Urine ketone body present	1	2					1	2
Urine output		3				1		2
Urine output decreased	2	8			1	3	1	5
Urine output increased	1	3				1	1	2
Viral test		1						1
Vital capacity		1						1
Vitamin B12 decreased		1						1
Vitamin D		1						1
Vitamin D decreased	1	1			1	1		
Weight decreased	19	64			4	13	15	51
Weight increased	1	6			1	2		4
White blood cell count abnormal		1						1
White blood cell count decreased	2	10			1	2	1	8
White blood cell count increased	4	19			1	5	3	14
White blood cells urine positive	1	1			1	1		
	549	2,580	2	5	170	787	379	1793

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal loss of weight	3	5					3	5
Abnormal weight gain	2	5			1	1	1	4
Acidosis		3				1		2
Alcohol intolerance		2						2
Appetite disorder		8				1		7
Body fat disorder		1				1		
Cachexia		1						1
Dairy intolerance	1	2					1	2
Decreased appetite	159	863	1	5	68	278	91	585
Decreased insulin requirement		1						1
Dehydration	21	97			6	29	15	68
Diabetes mellitus	7	28					7	28
Diabetes mellitus inadequate control	1	9					1	9
Diabetic complication		2						2
Diabetic ketoacidosis		8						8
Diabetic ketosis	1	1					1	1
Eating disorder symptom		2						2
Feeding disorder	14	67			9	34	5	33
Fluid imbalance		2				1		1
Fluid intake reduced		2						2
Fluid retention	7	18			1	3	6	15
Food aversion		5						5
Food craving	2	5				1	2	4
Food intolerance	2	5				1	2	4
Food refusal	1	5				1	1	4
Glucose tolerance impaired	1	2				1	1	1
Gluten sensitivity	1	1					1	1
Glycopenia		1				1		
Gout	14	42			3	3	11	39
Histamine intolerance		1						1
Hyperglycaemia	4	45				5	4	40
Hyperkalaemia		2						2

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyperphagia		1
Hypervolaemia		1
Hypocalcaemia		3
Hypoglycaemia	10	47
Hypokalaemia		1
Hypokalaemic syndrome		2
Hyponatraemia		6
Hyponatraemic syndrome		1
Hypophagia	5	20
Hypovitaminosis		3
Hypovolaemia		1
Increased appetite	2	4
Increased insulin requirement		1
Insulin resistance	2	5
Insulin resistant diabetes	1	1
Iron deficiency		3
Ketoacidosis		3
Lactose intolerance		1
Latent autoimmune diabetes in adults		1
Malnutrition		1
Metabolic acidosis		2
Overweight		1
Polydipsia	2	5
Poor feeding infant		1
Postprandial hypoglycaemia		1
Salt craving		1
Tetany		1
Type 1 diabetes mellitus	1	9
Type 2 diabetes mellitus		4
Underweight		2
Vitamin D deficiency		3
Weight loss poor		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					3
		3	9	7	38
					1
					2
					6
					1
		1	1	4	19
			1		2
					1
		1	2	1	2
					1
			1	2	4
				1	1
					3
					3
			1		
					1
					1
					2
					1
		1	2	1	3
					1
					1
					1
				1	9
					4
					2
					3
					1

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
	264	1,378	1	5	94	379	170	999

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* I=Interval, C=Cumulative
 * AE=Adverse Event
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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ankylosing spondylitis		6
Antisynthetase syndrome	1	1
Arthralgia	849	4,381
Arthritis	29	118
Arthritis reactive	4	18
Arthropathy	7	24
Axillary mass	36	122
Back disorder	1	1
Back pain	261	1,168
Bone disorder	3	4
Bone pain	41	235
Bone swelling	3	12
Bursitis	7	22
Chondritis		1
Coccydynia		2
Connective tissue disorder	1	1
Costochondritis	5	23
Crystal arthropathy		1
Drooping shoulder syndrome		1
Dupuytren's contracture		1
Enthesopathy		1
Epiphyses premature fusion		1
Facial asymmetry		1
Fibromyalgia	16	48
Finger deformity	1	2
Flank pain	5	26
Fracture pain	1	1
Gouty tophus		1
Groin pain	19	70
Haemarthrosis	2	6
Hand deformity		2
Hypermobility syndrome	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					6
		1	1		
7	30	326	1388	523	2993
		5	16	24	102
				4	18
		3	8	4	16
		15	44	21	78
		1	1		
	3	103	379	158	789
		2	2	1	2
	3	10	69	31	166
		1	6	2	6
		2	3	5	19
					1
			2		
				1	1
		2	3	3	20
					1
			1		
					1
			1		
	1	6	10	10	38
			1	1	1
			10	5	16
				1	1
					1
		8	25	11	45
				2	6
					2
				1	1

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Inguinal mass		1
Intervertebral disc compression		1
Intervertebral disc protrusion		2
Jaw clicking	2	3
Jaw disorder	2	3
Joint destruction		1
Joint effusion	3	17
Joint instability	1	1
Joint laxity		2
Joint lock		5
Joint microhaemorrhage		1
Joint noise	3	10
Joint range of motion decreased	46	162
Joint stiffness	26	136
Joint swelling	64	260
Joint vibration		1
Joint warmth		6
Ligament disorder	1	2
Ligamentitis		1
Limb deformity	1	1
Limb discomfort	180	750
Limb mass	8	31
Lordosis	1	1
Lupus-like syndrome		1
Mandibular mass	1	2
Mastication disorder	1	5
Medial tibial stress syndrome	1	2
Mobility decreased	40	226
Muscle atrophy	1	8
Muscle contracture	1	1
Muscle discomfort	2	4
Muscle disorder	2	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
			1		1
		1	1	1	2
				2	3
					1
		1	5	2	12
				1	1
					2
					5
					1
		1	2	2	8
	1	14	43	32	119
		7	27	19	109
		17	64	47	196
					1
			3		3
				1	2
					1
		1	1		
3	8	93	339	87	411
		1	10	7	21
				1	1
					1
		1	2		
				1	5
				1	2
		11	63	29	163
			2	1	6
		1	1		
			1	2	3
			2	2	4

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* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle fatigue	23	149
Muscle haemorrhage	1	1
Muscle mass	2	3
Muscle rigidity		9
Muscle spasms	110	399
Muscle swelling	2	13
Muscle tightness	8	50
Muscle twitching	24	108
Muscular weakness	99	527
Musculoskeletal chest pain	29	119
Musculoskeletal deformity		1
Musculoskeletal discomfort	19	76
Musculoskeletal disorder	10	29
Musculoskeletal pain	4	35
Musculoskeletal stiffness	150	650
Myalgia	896	5,194
Myalgia intercostal		1
Myofascial pain syndrome		5
Myopathy	4	4
Myosclerosis	1	1
Myositis	3	13
Neck mass	2	16
Neck pain	238	1,037
Nuchal rigidity	1	4
Osteitis	1	1
Osteoarthritis	8	25
Osteochondritis		1
Osteonecrosis of jaw		2
Osteopenia	1	1
Osteoporosis	1	2
Pain in extremity	1,370	5,767
Pain in jaw	43	172

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1	9	37	14	112
				1	1
		1	1	1	2
	1		1		8
2	3	42	118	68	281
			4	2	9
		2	16	6	34
		15	46	9	62
2	2	24	138	75	389
		7	25	22	94
					1
		8	30	11	46
		3	6	7	23
			8	4	27
1	3	66	224	84	426
5	32	481	2018	415	3176
					1
			2		3
				4	4
				1	1
			3	3	10
		1	6	1	10
	2	84	343	154	694
		1	1		3
				1	1
		2	5	6	20
			1		
					2
				1	1
				1	2
10	54	670	2337	700	3430
		19	53	24	119

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Palindromic rheumatism		1
Patellofemoral pain syndrome		1
Periarthritis	20	47
Plantar fasciitis		6
Polyarthritis	4	11
Polychondritis		2
Polymyalgia rheumatica	8	35
Polymyositis	2	3
Posture abnormal		2
Psoriatic arthropathy	2	14
Purple glove syndrome		1
Rhabdomyolysis		5
Rheumatic disorder		1
Rheumatoid arthritis	13	74
Rotator cuff syndrome	4	11
Sacroiliitis		4
Seronegative arthritis	1	1
Sjogren's syndrome	1	5
Soft tissue swelling	1	5
Spinal disorder		3
Spinal osteoarthritis		1
Spinal pain	8	40
Spinal stenosis		1
Spondylitis	2	3
Symphysiolysis		1
Synovial cyst	1	8
Synovitis		4
Systemic lupus erythematosus	3	14
Temporomand bular joint syndrome	2	6
Tendon disorder	2	2
Tendonitis	2	18
Tendon pain	2	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
	1	4	8	16	39
			1		5
				4	11
					2
				8	35
				2	3
			1		1
				2	14
					1
					5
					1
	1			13	74
		1	1	3	10
			1		3
				1	1
				1	5
		1	3		2
			1		2
					1
		3	11	5	29
					1
				2	3
					1
		1	2		6
					4
	1			3	14
			3	2	3
				2	2
		1	3	1	15
		1	3	1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tenosynovitis		1						1
Tenosynovitis stenosans		2						2
Torticollis		1						1
Trigger finger		4				1		3
Trismus	3	13			1	2	2	11
Vertebral lesion	1	2					1	2
Weight bearing difficulty	2	10				3	2	7
	4,814	22,739	31	147	2082	8004	2732	14735

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acoustic neuroma		2				2
Acrochordon		1				1
Acute leukaemia		1				1
Basal cell carcinoma		2				2
Benign lymph node neoplasm	1	1			1	1
Bladder neoplasm		1				1
Bone neoplasm	1	3		1	1	2
Brain neoplasm		2				2
Breast cancer	5	15			5	15
Breast cancer stage I	1	1			1	1
Breast cancer stage III		1				1
Chronic lymphocytic leukaemia	2	3			2	3
Chronic lymphocytic leukaemia recurrent	1	1			1	1
Colon cancer		1				1
Cranial nerve neoplasm benign	1	1			1	1
Essential thrombocythaemia		1				1
Follicular lymphoma	1	2			1	2
Gastric cancer		1				1
Gastrointestinal carcinoma		1				1
Haemangioma		1		1		
Hepatic cancer	1	1			1	1
Hepatocellular carcinoma	1	1			1	1
Hodgkin's disease	1	1			1	1
Invasive ductal breast carcinoma	1	1			1	1
Leukaemia		1				1
Lip neoplasm	1	1			1	1
Lipoma		1		1		
Lung neoplasm malignant		3				3
Lymphangioma		1				1
Lymphoma	2	13			2	13
Melanocytic naevus		1				1
Metastases to lymph nodes	1	8			1	8

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Metastasis		1				1
Metastatic neoplasm		1				1
Myelodysplastic syndrome		1				1
Neoplasm	3	7	2	3	1	4
Neoplasm malignant	1	5			1	5
Neoplasm progression	2	2	1	1	1	1
Neoplasm recurrence	1	1			1	1
Neoplasm skin		1				1
Non-Hodgkin's lymphoma		1				1
Oligodendroglioma		1				1
Pancreatic carcinoma		3				3
Pituitary tumour benign	1	1			1	1
Plasma cell myeloma		1				1
Primary gastrointestinal follicular lymphoma		1				1
Prostate cancer	1	1			1	1
Renal cancer		2				2
Sarcoma		1				1
Second primary malignancy		1				1
Skin cancer		1				1
Skin papilloma	1	1	1	1		
Squamous cell carcinoma	1	1			1	1
TEMPI syndrome		1				1
Thyroid neoplasm	1	1			1	1
Triple negative breast cancer	1	2			1	2
Uterine leiomyoma	4	4			4	4
	38	118	4	8	34	110

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* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute disseminated encephalomyelitis	1	3					1	3
Acute motor axonal neuropathy		1						1
Ageusia	38	193		1	21	77	17	116
Akathisia		1						1
Alexia		1				1		
Allodynia	3	8			2	2	1	6
Altered state of consciousness	2	11					2	11
Amnesia	14	63			4	13	10	50
Anosmia	15	94			10	38	5	56
Anticholinergic syndrome		1						1
Aphasia	11	43			3	10	8	33
Apraxia		1				1		
Areflexia	1	3					1	3
Ataxia	2	7			1	1	1	6
Atonic seizures		4						4
Aura	2	13			1	6	1	7
Autonomic nervous system imbalance	2	5					2	5
Axonal neuropathy		2						2
Balance disorder	76	274	1	2	27	63	49	211
Bell's palsy	47	263					47	263
Bradykinesia	3	9			1	2	2	7
Brain hypoxia		1						1
Brain injury	1	3					1	3
Brain oedema		2						2
Brain stem stroke		2						2
Brain stem syndrome		2						2
Bulbar palsy		1						1
Burning feet syndrome		1						1
Burning sensation	81	269			34	89	47	180
Carotid artery disease		1						1
Carotid artery dissection		1						1
Carotid artery occlusion	1	2					1	2

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Carotid artery thrombosis		1
Carpal tunnel syndrome	1	8
Cataplexy		2
Central nervous system lesion		1
Central nervous system vasculitis		1
Cerebellar haemorrhage	1	2
Cerebellar infarction		2
Cerebellar stroke		3
Cerebral artery embolism	1	2
Cerebral artery occlusion		1
Cerebral artery thrombosis	1	4
Cerebral congestion	1	1
Cerebral cyst	1	1
Cerebral disorder	1	4
Cerebral haemorrhage	8	32
Cerebral infarction	5	30
Cerebral small vessel ischaemic disease	1	1
Cerebral thrombosis		15
Cerebral venous sinus thrombosis	7	23
Cerebral venous thrombosis	2	4
Cerebrospinal fluid leakage		1
Cerebrovascular accident	51	248
Cerebrovascular disorder	1	1
Cervical radiculopathy		1
Cervicobrachial syndrome		2
Cervicogenic headache	1	3
Chorea		2
Clinically isolated syndrome	1	1
Clonic convulsion		2
Clonus	1	1
Clumsiness	2	7
Cluster headache	21	89

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			2	1	6
					2
			1		
					1
				1	2
					2
					3
				1	2
					1
				1	4
				1	1
				1	1
		1	3		1
				8	32
				5	30
				1	1
					15
				7	23
				2	4
					1
				51	248
				1	1
					1
					2
			1	1	2
					2
				1	1
					2
		1	1		
		1	1	1	6
1	1	5	22	16	67

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cognitive disorder	13	50
Cold-stimulus headache	3	8
Coma	1	5
Consciousness fluctuating		4
Coordination abnormal	5	41
Cranial nerve disorder		2
Cranial nerve palsies multiple		1
Dementia	1	11
Dementia Alzheimer's type		1
Dementia with Lewy bodies		1
Demyelination	2	6
Depressed level of consciousness	4	27
Diabetic coma		1
Diplegia	2	8
Disturbance in attention	63	245
Dizziness	846	3,969
Dizziness exertional	1	24
Dizziness postural	64	334
Dreamy state		2
Drooling	3	12
Dysaesthesia		2
Dysarthria	12	89
Dysdiadochokinesis		1
Dysgeusia	122	502
Dysgraphia	1	3
Dyskinesia	9	46
Dysstasia	13	80
Dystonia		8
Electric shock sensation	2	14
Embolic cerebral infarction		1
Embolic stroke		4
Encephalopathy		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	5	10	45
		1	2	2	6
				1	5
					4
			6	5	35
					2
					1
				1	11
					1
					1
				2	6
				4	27
					1
				2	8
	1	17	66	46	179
4	18	351	1350	495	2619
			2	1	22
	1	24	100	40	234
			1		1
		1	3	2	9
			1		1
		1	13	11	76
					1
	1	84	283	38	219
				1	3
		2	11	7	35
		1	22	12	58
					8
		1	9	1	5
					1
					4
					2

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Epilepsy	26	93
Epileptic aura		1
Epileptic encephalopathy		1
Essential tremor		1
Exertional headache		4
Extensor plantar response		1
Facial nerve disorder		2
Facial neuralgia	2	10
Facial paralysis	28	192
Facial paresis	5	44
Facial spasm	5	17
Febrile convulsion	3	11
Fine motor skill dysfunction	3	9
Focal dyscognitive seizures		1
Formication	5	22
Freezing phenomenon	1	4
Generalised tonic-clonic seizure	5	38
Gliosis		1
Guillain-Barre syndrome	9	35
Haemorrhage intracranial		5
Haemorrhagic stroke	2	8
Hand-arm vibration syndrome		2
Hand-eye coordination impaired		1
Headache	2,259	11,635
Head discomfort	37	166
Head titubation	2	3
Hemianopia		1
Hemianopia homonymous		2
Hemiparaesthesia		1
Hemiparesis	3	25
Hemiplegia	3	17
Hemiplegic migraine	1	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				26	93
					1
					1
			2		2
					1
			2		
		1	4	1	6
	2			28	192
		2	17	3	27
		2	8	3	9
		1	7	2	4
		2	3	1	6
					1
		1	5	4	17
		1	1		3
				5	38
					1
				9	35
					5
				2	8
					2
					1
12	56	1132	4415	1127	7220
		15	56	22	110
		1	1	1	2
					1
					2
					1
				3	25
				3	17
				1	6

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* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Horner's syndrome		1
Hydrocephalus	1	1
Hyperaesthesia	8	63
Hypergeusia	1	2
Hyperintensity in brain deep nuclei	1	2
Hyperreflexia		1
Hypersomnia	34	177
Hypertonia		2
Hypoaesthesia	257	1,020
Hypogeusia	1	2
Hypoglycaemic coma		1
Hypokinesia	23	76
Hyporeflexia		5
Hyporesponsive to stimuli	1	2
Hyposmia	2	7
Hypotonia	2	7
Idiopathic intracranial hypertension	2	4
IIIrd nerve disorder		2
IIIrd nerve paralysis		5
Inability to crawl		1
Incoherent	2	10
Infant irritability		2
Intracranial aneurysm		1
Intracranial pressure increased		1
Irregular sleep wake rhythm disorder		1
Ischaemic stroke	2	28
IVth nerve paralysis		1
Lacunar infarction		2
Lacunar stroke		1
Language disorder	1	3
Lateral medullary syndrome		1
Lennox-Gastaut syndrome		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
		4	28	4	35
		1	1		1
				1	2
					1
		10	62	24	115
					2
	5	117	383	140	637
		1	1		1
					1
		6	21	17	55
			2		3
				1	2
		2	4		3
			1	2	6
				2	4
					2
					5
					1
		1	4	1	6
			1		1
					1
			1		
				2	28
					1
					2
					1
				1	3
					1
					1

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lethargy	199	1,095
Lhermitte's sign		1
Limbic encephalitis	1	1
Locked-in syndrome		1
Long thoracic nerve palsy		1
Loss of consciousness	47	290
Loss of proprioception		1
Lower motor neurone lesion	1	1
Medication overuse headache	1	2
Memory impairment	14	72
Mental impairment	3	24
Migraine	239	1,076
Migraine with aura	18	80
Migraine without aura	3	7
Mononeuropathy		1
Monoparesis	9	30
Monoplegia	3	32
Morton's neuralgia		1
Motor dysfunction		6
Movement disorder	23	98
Multiple sclerosis	2	24
Multiple sclerosis relapse	2	19
Muscle contractions involuntary	4	13
Muscle spasticity	3	6
Muscle tone disorder		1
Myasthenia gravis	1	6
Myasthenia gravis crisis		2
Myelitis transverse	3	21
Myoclonus	1	9
Narcolepsy		2
Nerve compression	4	15
Nerve degeneration		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
2	9	84	403	115	692
					1
				1	1
					1
			1		
				47	290
					1
				1	1
		1	1		1
		5	21	9	51
	1			3	24
	5	77	258	162	818
	1	5	21	13	59
		1	1	2	6
					1
1	1	6	8	3	22
				3	32
					1
			1		5
		12	26	11	72
				2	24
				2	19
			3	4	10
		1	1	2	5
					1
				1	6
					2
				3	21
			2	1	7
					2
			3	4	12
					1

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nervous system disorder	2	12
Neuralgia	65	205
Neuritis	3	5
Neurological symptom	5	20
Neurologic neglect syndrome		2
Neuromuscular pain		1
Neuromyelitis optica spectrum disorder		1
Neuromyopathy		1
Neuropathy peripheral	12	55
New daily persistent headache		1
Noninfective encephalitis		1
Numb chin syndrome		1
Nystagmus	1	8
Occipital neuralgia	3	7
Ophthalmic migraine	4	12
Ophthalmoplegic migraine		1
Optic neuritis	5	15
Paraesthesia	330	1,394
Paralysis	13	56
Paraparesis		1
Paresis	1	3
Parkinsonian gait	1	1
Parkinsonism		4
Parkinson's disease	1	8
Parosmia	24	87
Partial seizures	3	13
Patient elopement		1
Peripheral sensory neuropathy	1	6
Peroneal nerve palsy		7
Persistent genital arousal disorder	1	1
Persistent postural-perceptual dizziness		3
Petit mal epilepsy		15

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			4	2	8
		18	53	47	152
			1	3	4
			1	5	19
					2
					1
					1
					1
				12	55
			1		
					1
					1
					8
				3	7
			1	4	11
			1		
				5	15
	3	168	573	162	821
	1			13	56
					1
				1	3
		1	1		
			1		3
				1	8
		20	43	4	44
				3	13
					1
		1	3		3
			2		5
		1	1		
			1		2
					15

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Phantom limb syndrome		2
Pineal gland cyst		1
Posterior revers ble encephalopathy syndrome		1
Post herpetic neuralgia	10	15
Postictal paralysis		1
Postictal state		1
Post stroke seizure		1
Presyncope	41	243
Primary cough headache	1	4
Primary headache associated with sexual activity		1
Psychogenic seizure	1	6
Psychomotor hyperactivity	3	12
Pudendal canal syndrome	1	1
Quadrantanopia		2
Radiculitis brachial	2	5
Radiculopathy		2
Reduced facial expression		4
Repetitive speech		1
Resting tremor	1	1
Restless legs syndrome	4	33
Retinal migraine	3	12
Reversed hot-cold sensation		1
Revers ble cerebral vasoconstriction syndrome		1
Sciatica	8	29
Sciatic nerve neuropathy	1	2
Sedation	1	5
Seizure	40	230
Seizure anoxic	1	1
Seizure cluster		4
Seizure like phenomena		1
Senile dementia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
					1
		4	6	6	9
					1
					1
					1
	1	23	104	18	139
		1	2		2
					1
			1	1	5
		1	4	2	8
				1	1
					2
			1	2	4
					2
			3		1
					1
		1	1		
		3	11	1	22
		1	3	2	9
					1
					1
		3	8	5	21
		1	1		1
			1	1	4
				40	230
				1	1
					4
					1
					1

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* AE=Adverse Event

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sensory disturbance	19	59
Sensory loss	7	41
Sensory overload	1	1
Serotonin syndrome		1
Sinus headache	27	141
Sleep deficit	1	7
Sleep paralysis	1	4
Slow response to stimuli		2
Slow speech		3
Somnolence	123	552
Speech disorder	18	73
Spinal cord disorder		1
Spinal cord infarction	1	1
Status epilepticus	8	30
Stiff leg syndrome		1
Stupor	1	2
Subacute inflammatory demyelinating polyneuropathy		1
Subarachnoid haemorrhage	1	8
Sudden onset of sleep	1	1
Superior sagittal sinus thrombosis		2
Syncope	129	673
Tardive dyskinesia		1
Taste disorder	32	135
Temporal lobe epilepsy		1
Tension headache	35	193
Thalamic infarction		1
Thoracic outlet syndrome	1	1
Thrombotic stroke	1	2
Thunderclap headache	2	4
Tongue biting	2	3
Tongue paralysis	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		8	27	11	32
			13	7	28
				1	1
					1
1	2	11	53	16	88
			2	1	5
		1	3		1
					2
					3
	1	59	201	64	351
	1	6	20	12	53
					1
				1	1
				8	30
					1
		1	1		1
					1
				1	8
				1	1
					2
	1	1	1	128	672
					1
		18	67	14	68
					1
	2	13	62	22	131
					1
				1	1
				1	2
				2	4
				2	3
				1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tonic clonic movements		3						3
Tonic convulsion	2	11					2	11
Transient global amnesia	2	6			1	1	1	5
Transient ischaemic attack	19	97					19	97
Tremor	153	860		3	63	251	90	609
Trigeminal nerve disorder		1				1		
Trigeminal neuralgia	8	23			2	5	6	18
Tumefactive multiple sclerosis		1						1
Tunnel vision	1	7					1	7
Typical aura without headache	2	4			1	1	1	3
Ulnar neuritis		1						1
Unresponsive to stimuli	5	43					5	43
Vascular dementia		4						4
Vascular headache	3	10				3	3	7
Vertebral artery stenosis		1						1
Vestibular migraine		8				1		7
Visual perseveration		1						1
Visuospatial deficit	1	1					1	1
Vlth nerve paralysis	2	6					2	6
Writer's cramp		1						1
	6,096	29,624	22	120	2522	9534	3574	20090

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abortion missed	3	4					3	4
Abortion spontaneous	13	64	2	2			13	64
Face presentation		1				1		
Foetal death	1	3					1	3
Foetal growth restriction	1	1					1	1
Foetal hypokinesia	1	1					1	1
Gestational diabetes	2	3			1	1	1	2
Haemorrhage in pregnancy		1						1
Morning sickness	2	10			1	1	1	9
Oligohydramnios		1						1
Postpartum haemorrhage	1	1					1	1
Pregnancy		4				3		1
Pregnancy after post coital contraception	1	1					1	1
Pregnancy with contraceptive device	1	2					1	2
Pregnancy with implant contraceptive	1	1					1	1
Premature baby		2						2
Premature delivery		1						1
Premature separation of placenta	1	1					1	1
Preterm premature rupture of membranes		2						2
Still birth	1	2					1	2
Umbilical cord abnormality	1	1					1	1
Uterine contractions abnormal		1						1
	30	108	2	2	2	6	28	102

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Device connection issue	1	1	1	1		
Device infusion issue		1				1
Device pacing issue		1				1
Device stimulation issue		1		1		
Liquid product physical issue		3		3		
Needle issue		2		1		1
Oversensing	2	9		1	2	8
Patient-device incompatibility	1	1	1	1		
Product complaint		3		1		2
Product contamination	1	1	1	1		
Product contamination physical		1		1		
Product leakage	1	1	1	1		
Product packaging quantity issue		4		4		
Product quality issue	1	1	1	1		
Product supply issue		1		1		
Product taste abnormal		1		1		
Product temperature excursion issue	1	72	1	72		
Syringe issue	2	2	2	2		
Thrombosis in device		2				2
Undersensing	1	1	1	1		
	11	109	9	94	2	15

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal behaviour	3	10			2	4	1	6
Abnormal dreams	20	79			13	47	7	32
Adjustment disorder with depressed mood		1						1
Affective disorder	1	2					1	2
Affect lability	1	5				1	1	4
Aggression	1	10				2	1	8
Agitated depression		1						1
Agitation	9	55			5	17	4	38
Alcoholic hangover		1						1
Alexithymia		1				1		
Anger		5				3		2
Anorgasmia	1	2			1	1		1
Anxiety	44	277			19	93	25	184
Apathy	5	21				5	5	16
Attention deficit hyperactivity disorder		2						2
Autism spectrum disorder	2	2					2	2
Autoscopy		6				1		5
Behaviour disorder		3						3
Binge eating		1						1
Bipolar disorder	3	4					3	4
Bipolar I disorder		1						1
Bradyphrenia	6	19			3	6	3	13
Bruxism	3	7			1	1	2	6
Bulimia nervosa		1						1
Catatonia		1						1
Communication disorder		7				2		5
Confusional arousal		1						1
Confusional state	83	433		1	18	81	65	352
Constricted affect		1						1
Conversion disorder	2	3					2	3
Cyclothymic disorder		1						1
Decreased interest	2	9			1	3	1	6

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Deja vu		1
Delirium	9	70
Delusion	1	6
Delusional perception	1	2
Depersonalisation/derealisation disorder		3
Depressed mood	47	139
Depression	22	95
Depression suicidal		2
Derealisation	1	6
Disorganised speech		4
Disorientation	34	146
Dissociation	2	20
Dissociative amnesia		1
Dissociative disorder		1
Dysphemia	3	7
Dysphoria		1
Dyssomnia		1
Eating disorder	4	27
Emotional disorder	9	30
Emotional distress	6	24
Enuresis	4	10
Euphoric mood	7	20
Exploding head syndrome	1	2
Factitious disorder		1
Fear	6	22
Fear of falling		2
Fear of injection		2
Feeling of despair	1	6
Flashback		2
Flat affect	1	4
Frustration tolerance decreased	2	3
Grief reaction		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				9	70
		1	3		3
				1	2
			1		2
		17	34	30	105
		3	7	19	88
					2
			1	1	5
			1		3
		7	27	27	119
		1	10	1	10
			1		
			1		
		1	2	2	5
					1
			1		
			4	4	23
		1	8	8	22
		1	6	5	18
			2	4	8
		2	7	5	13
				1	2
					1
		2	7	4	15
					2
			2		
				1	6
					2
			2	1	2
			1	2	2
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Habit cough	1	4
Hallucination	17	104
Hallucination, auditory	3	8
Hallucination, olfactory		4
Hallucinations, mixed		2
Hallucination, tactile		1
Hallucination, visual	6	16
Head banging	1	4
Homicidal ideation	1	1
Hypervigilance	1	2
Hypnagogic hallucination		2
Hypnopompic hallucination	1	1
Hypomania		1
Hyposomnia		1
Illusion		1
Immunisation anxiety related reaction		1
Inappropriate affect		2
Indifference	1	5
Initial insomnia	3	11
Insomnia	191	807
Intentional self-injury		3
Intrusive thoughts		2
Irritability	17	64
Lack of spontaneous speech		4
Laziness		1
Learning disability		1
Learning disorder	1	1
L bido decreased		1
L bido increased	1	2
Listless	2	10
Logorrhoea	1	3
Loss of libido	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	3
				17	104
				3	8
					4
					2
					1
				6	16
			2	1	2
		1	1		
				1	2
					2
				1	1
					1
			1		1
					2
		1	2		3
		2	6	1	5
	1	74	278	117	529
					3
			1		1
		8	22	9	42
			1		3
					1
					1
				1	1
					1
		1	2		
				2	10
				1	3
				1	4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Major depression		3
Mania		4
Mental disorder	1	11
Mental fatigue	17	80
Mental status changes		1
Middle insomnia	5	48
Mood altered	3	14
Mood disorder due to a general medical condition		1
Mood swings	9	19
Morose		3
Mutism	1	6
Near death experience		1
Negative thoughts		2
Nervousness	21	131
Neuropsychiatric symptoms		1
Nightmare	22	77
Obsessive-compulsive symptom		1
Osmophobia		1
Panic attack	8	40
Panic disorder		5
Panic reaction	4	18
Paramnesia		2
Paranoia	1	9
Perinatal depression	1	1
Personality change		4
Personality disorder	1	1
Phobia		1
Phonophobia		1
Poor quality sleep	30	126
Post-traumatic stress disorder	1	3
Pressure of speech		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
					4
			5	1	6
		4	16	13	64
					1
		4	21	1	27
		1	4	2	10
					1
		2	5	7	14
			2		1
			3	1	3
					1
					2
		7	39	14	92
			1		
		6	26	16	51
					1
					1
		4	12	4	28
			2		3
		1	5	3	13
					2
			1	1	8
				1	1
			1		3
				1	1
					1
			1		
	1	13	48	17	78
				1	3
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Psychiatric symptom		3
Psychotic behaviour		1
Psychotic disorder	1	10
Psychotic symptom		2
Purging		1
Reading disorder	1	2
Restlessness	19	93
Schizophrenia		1
Self-injurious ideation		2
Sense of a foreshortened future		4
Sleep attacks		2
Sleep disorder	54	256
Sleep disorder due to a general medical condition	3	18
Sleep disorder due to general medical condition, insomnia type	1	27
Sleep talking	1	2
Sleep terror	3	9
Social avoidant behaviour	2	3
Social fear		1
Somatic symptom disorder		2
Somnambulism	1	1
Staring		3
Stereotypy		1
Stress	7	33
Suicidal behaviour		1
Suicidal ideation	5	19
Suicide attempt	1	5
Suspiciousness	1	1
Tachyphrenia		2
Tearfulness	4	26
Tension	1	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		2
					1
			1	1	9
					2
					1
				1	2
		8	26	11	67
					1
					2
			2		2
					2
		21	110	33	146
			9	3	9
		1	10		17
		1	2		
		1	2	2	7
		1	1	1	2
					1
					2
				1	1
					3
					1
			8	7	25
					1
				5	19
				1	5
				1	1
					2
		2	8	2	18
			4	1	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Terminal insomnia	3	7			1	2	2	5
Thinking abnormal	7	23			4	8	3	15
Tic		2						2
Trance	1	1			1	1		
Vomiting psychogenic		1						1
	837	3,897		3	269	1100	568	2797

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	5	38			5	38
A buminuria		1				1
Anuria	1	4			1	4
Bladder discomfort		1		1		
Bladder disorder	3	9	1	1	2	8
Bladder dysfunction	1	2			1	2
Bladder irritation		1				1
Bladder pain	5	12			5	12
Chromaturia	8	31	1	13	7	18
Chronic kidney disease	1	8			1	8
Costovertebral angle tenderness		1		1		
Cystitis interstitial		2				2
Cystitis-like symptom		1				1
Dysuria	12	44	4	14	8	30
Genitourinary symptom		1				1
Glomerulonephritis		1				1
Glomerulonephritis minimal lesion		4				4
Glomerulonephritis rapidly progressive		1				1
Haematuria	6	24	1	4	5	20
Haemorrhage urinary tract		8				8
Hypertonic bladder		3		3		
IgA nephropathy	1	2			1	2
Incontinence	2	22		3	2	19
Kidney small		1				1
Loss of bladder sensation		2				2
Lupus nephritis	1	1			1	1
Micturition disorder		4		2		2
Micturition urgency	5	16	2	3	3	13
Nephritis	1	2			1	2
Nephrolithiasis	1	2			1	2
Nephrotic syndrome	3	12			3	12
Neurogenic bladder		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nocturia	1	2	1	2		
Oliguria		2				2
Pollakiuria	17	43	9	15	8	28
Polyuria	4	6	2	3	2	3
Proteinuria		3		1		2
Renal colic		1		1		
Renal cyst		2				2
Renal disorder	1	5			1	5
Renal failure	1	11			1	11
Renal haemorrhage		2				2
Renal impairment	5	17			5	17
Renal infarct	1	1			1	1
Renal injury	1	1			1	1
Renal mass	1	1			1	1
Renal pain	28	116	10	35	18	81
Renal vasculitis		1				1
Tubulointerstitial nephritis		1				1
Ureteric stenosis		1				1
Urethral stenosis		1				1
Urge incontinence	2	2			2	2
Urinary bladder haemorrhage		1				1
Urinary incontinence	9	48	4	12	5	36
Urinary retention	5	33			5	33
Urinary tract disorder	1	2	1	1		1
Urinary tract pain		1				1
Urine abnormality	4	8	2	5	2	3
Urine flow decreased	2	5		1	2	4
Urine odour abnormal	1	7		3	1	4
	140	586	38	124	102	462

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal uterine bleeding		1						1
Adenomyosis	1	1					1	1
Adnexa uteri pain	1	6					1	6
Amenorrhoea	26	40			15	17	11	23
Anisomastia		1				1		
Breast cyst		2				1		1
Breast discomfort	3	9			1	4	2	5
Breast disorder		1						1
Breast engorgement		1						1
Breast enlargement		3						3
Breast haematoma	1	1			1	1		
Breast inflammation	2	4			1	1	1	3
Breast mass	6	26			1	5	5	21
Breast milk discolouration		1				1		
Breast oedema		1						1
Breast pain	61	189			22	49	39	140
Breast swelling	17	60			2	17	15	43
Breast tenderness	12	29			6	10	6	19
Cervical dysplasia		1						1
Coital bleeding	1	1					1	1
Dysmenorrhoea	75	104			30	41	45	63
Endometriosis	6	10			1	2	5	8
Erectile dysfunction		15						15
Erection increased		2						2
Galactorrhoea		3						3
Genital haemorrhage	2	3					2	3
Genital lesion	1	2			1	2		
Genital pain	1	3			1	1		2
Genital rash	1	1					1	1
Genital tract inflammation		1				1		
Genital ulceration	1	2			1	1		1
Haemospermia		1						1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Heavy menstrual bleeding	195	264
Hypomenorrhoea	14	23
Infertility		1
Intermenstrual bleeding	29	40
Labia enlarged	1	1
Lactation disorder	1	3
Menometrorrhagia	1	1
Menopausal symptoms		4
Menstrual discomfort	1	2
Menstrual disorder	90	109
Menstruation delayed	124	166
Menstruation irregular	105	134
Nipple exudate bloody		1
Nipple pain	2	12
Nipple swelling		4
Oligomenorrhoea	3	6
Ovarian cyst		1
Ovarian haemorrhage	1	1
Ovarian vein thrombosis	1	1
Ovulation disorder	1	1
Ovulation pain	2	3
Pelvic discomfort		1
Pelvic haemorrhage	1	4
Pelvic pain	11	34
Penile oedema	1	1
Penile swelling		3
Penis disorder	1	1
Perineal pain	1	2
Polycystic ovaries	5	5
Polymenorrhoea	28	37
Postmenopausal haemorrhage	16	23
Premature menopause	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	98	119	97	145
		10	16	4	7
					1
		13	18	16	22
				1	1
				1	3
		1	1		
			2		2
				1	2
	1	64	72	26	37
1	1	100	113	24	53
	1	68	77	37	57
					1
		1	4	1	8
			2		2
		3	3		3
			1		
				1	1
				1	1
				1	1
		1	1	1	2
					1
				1	4
			6	11	28
		1	1		
			1		2
		1	1		
			1	1	1
		3	3	2	2
	1	16	20	12	17
				16	23
		1	1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Premature ovulation	1	1
Premenstrual dysphoric disorder	2	2
Premenstrual pain	2	2
Premenstrual syndrome	3	4
Prostatic disorder		1
Prostatic pain		1
Prostatitis		2
Prostatomegaly		3
Pruritus genital		1
Scrotal erythema		1
Scrotal exfoliation		1
Scrotal pain	1	5
Scrotal swelling		3
Semen discolouration		1
Suppressed lactation		2
Testicular pain	5	13
Testicular swelling	1	6
Testicular torsion		1
Testis discomfort		2
Uterine haemorrhage	2	5
Uterine pain	1	3
Uterine polyp	1	1
Uterine prolapse	1	1
Uterine spasm		1
Vaginal cyst		2
Vaginal discharge	3	5
Vaginal disorder		2
Vaginal haemorrhage	55	105
Vaginal ulceration		1
Vulval haemorrhage		4
Vulval oedema		1
Vulval ulceration	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				2	2
		1	1	1	1
		3	3		1
			1		
					1
					2
			2		1
			1		
					1
					1
		1	3		2
					3
					1
					2
		2	5	3	8
			3	1	3
					1
			1		1
				2	5
				1	3
				1	1
				1	1
			1		
					2
		1	2	2	3
			1		1
		15	26	40	79
					1
					4
			1		
		1	2		

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vulvovaginal burning sensation		1						1
Vulvovaginal dryness	1	1					1	1
Vulvovaginal pain	2	7				2	2	5
Vulvovaginal pruritus		1				1		
Vulvovaginal rash		1				1		
Vulvovaginal swelling		1						1
Vulvovaginal ulceration		3						3
	936	1,616	1	5	489	676	447	940

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acute pulmonary oedema		1
Acute respiratory distress syndrome		1
Acute respiratory failure		2
Allergic cough		5
Allergic sinusitis		1
Alveolitis		1
Aphonia	11	37
Apnoea		2
Apnoeic attack	2	2
Asphyxia	1	1
Aspiration		6
Asthma	31	167
Asthma late onset		1
Atelectasis		1
Bronchial disorder		1
Bronchial secretion retention		1
Bronchiectasis	4	9
Bronchospasm	4	12
Catarrh	2	8
Choking	4	14
Choking sensation	1	6
Chronic obstructive pulmonary disease	3	16
Cough	161	951
Cough decreased		1
Cough variant asthma	1	1
Cyanosis central		1
Diaphragmalgia	2	6
Diaphragmatic disorder		1
Dry lung syndrome	1	1
Dry throat	17	82
Dysphonia	15	79
Dyspnoea	346	1,707

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					2
					5
					1
					1
	1	5	11	6	26
					2
				2	2
				1	1
					6
		8	30	23	137
					1
					1
					1
			1		
				4	9
		1	3	3	9
		1	5	1	3
				4	14
			1	1	5
		1	1	2	15
1	4	70	330	91	621
			1		
				1	1
					1
		1	2	1	4
					1
				1	1
	2	9	37	8	45
1	1	7	27	8	52
	1	100	377	246	1330

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dyspnoea at rest	2	7
Dyspnoea exertional	20	77
Emphysema	1	3
Epiglottic oedema		1
Epistaxis	65	272
Haemoptysis	7	28
Hiccups	2	4
Hyperactive pharyngeal reflex		1
Hypercapnia		1
Hyperoxia		1
Hypersensitivity pneumonitis		1
Hyperventilation	8	21
Hypopnoea	14	47
Hypoventilation		2
Hypoxia		19
Increased bronchial secretion		1
Increased upper airway secretion		6
Increased viscosity of bronchial secretion		1
Increased viscosity of upper respiratory secretion	1	6
Interstitial lung disease	1	3
Intranasal hypoaesthesia		1
Intranasal paraesthesia	1	4
Irregular breathing	1	11
Laryngeal disorder		1
Laryngeal obstruction		1
Laryngeal pain		3
Laryngospasm		1
Lung consolidation		2
Lung disorder	2	11
Lung infiltration		2
Lung opacity		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	7
		2	19	18	58
		1	1		2
					1
		31	95	34	177
		1	4	6	24
				2	4
					1
					1
					1
					1
		5	11	3	10
		2	4	12	43
					2
					19
					1
			2		4
					1
			1	1	5
				1	3
					1
		1	4		
			2	1	9
					1
					1
			1		2
					1
					2
		1	3	1	8
			1		1
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mouth breathing		3
Nasal congestion	27	122
Nasal crusting	1	1
Nasal discharge discolouration		1
Nasal discomfort	8	34
Nasal disorder		3
Nasal dryness	3	10
Nasal obstruction		3
Nasal odour	1	4
Nasal oedema	4	9
Nasal pruritus		5
Neonatal pneumothorax		1
Neonatal respiratory distress		1
Nocturnal dyspnoea	1	3
Obstructive airways disorder	4	6
Oropharyngeal blistering	3	13
Oropharyngeal discomfort	6	46
Oropharyngeal oedema		1
Oropharyngeal pain	229	1,049
Oropharyngeal plaque		1
Oropharyngeal spasm		1
Orthopnoea	1	5
Painful respiration	5	37
Paranasal sinus discomfort		11
Paranasal sinus hypersecretion		1
Paranasal sinus inflammation		1
Pharyngeal disorder	2	3
Pharyngeal enanthema		1
Pharyngeal erythema	1	6
Pharyngeal haemorrhage	2	3
Pharyngeal hypoaesthesia	2	12
Pharyngeal inflammation		8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
	1	11	43	16	79
		1	1		
			1		
		5	14	3	20
			2		1
		1	4	2	6
			2		1
			1	1	3
		1	3	3	6
			1		4
					1
					1
		1	1		2
				4	6
				3	13
		2	18	4	28
					1
2	5	123	404	106	645
			1		
					1
			1	1	4
		1	6	4	31
			5		6
					1
					1
		1	1	1	2
					1
			2	1	4
				2	3
		1	6	1	6
			1		7

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pharyngeal leukoplakia		1
Pharyngeal mass	1	1
Pharyngeal oedema	1	10
Pharyngeal paraesthesia	4	34
Pharyngeal swelling	32	151
Pharyngeal ulceration	2	9
Pleural effusion	2	12
Pleural rub	1	1
Pleurisy	2	15
Pleuritic pain	4	16
Pneumonia aspiration	1	8
Pneumonitis	3	16
Pneumothorax	2	3
Pneumothorax spontaneous		1
Productive cough	17	86
Pulmonary artery dilatation		1
Pulmonary artery thrombosis		1
Pulmonary cavitation	1	1
Pulmonary congestion	1	5
Pulmonary embolism	63	214
Pulmonary fibrosis	1	3
Pulmonary haemorrhage		1
Pulmonary hypertension		2
Pulmonary infarction	1	5
Pulmonary mass	1	1
Pulmonary oedema	3	19
Pulmonary pain	7	49
Pulmonary sarcoidosis		2
Pulmonary thrombosis	5	19
Rales	1	4
Respiration abnormal	3	26
Respiratory acidosis	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
			1	1	9
		3	15	1	19
		9	37	23	114
		1	2	1	7
				2	12
		1	1		
		1	1	1	14
		1	3	3	13
				1	8
			1	3	15
				2	3
					1
1	1	7	26	10	60
					1
					1
				1	1
				1	5
				63	214
				1	3
					1
					2
				1	5
				1	1
				3	19
			10	7	39
			1		1
	1			5	19
				1	4
		3	9		17
				1	2

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory arrest		13
Respiratory depression		1
Respiratory disorder	6	30
Respiratory distress	2	11
Respiratory failure	1	8
Respiratory muscle weakness		1
Respiratory symptom	3	6
Respiratory tract congestion	1	2
Respiratory tract irritation	2	6
Respiratory tract oedema	1	4
Reversible airways obstruction		1
Rhinalgia	2	10
Rhinitis allergic		3
Rhinorrhoea	66	284
Sinonasal obstruction	1	6
Sinus congestion	6	24
Sinus disorder	4	10
Sinus pain	12	67
Sleep apnoea syndrome	2	7
Sneezing	31	136
Snoring	1	3
Sputum discoloured	1	5
Sputum increased	2	3
Stridor	2	14
Suffocation feeling		1
Tachypnoea	3	25
Throat clearing	1	5
Throat irritation	26	129
Throat tightness	23	175
Tonsillar cyst		1
Tonsillar disorder	1	3
Tonsillar erythema		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1				13
					1
		1	7	5	23
				2	11
				1	8
					1
	1	1	1	2	5
				1	2
		1	3	1	3
				1	4
					1
		1	5	1	5
			1		2
	5	32	103	34	181
			2	1	4
		4	9	2	15
		1	1	3	9
		5	20	7	47
				2	7
	1	13	56	18	80
			1	1	2
		1	2		3
				2	3
			1	2	13
			1		
			6	3	19
				1	5
		12	46	14	83
		9	50	14	125
			1		
		1	2		1
			1		1

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tonsillar haemorrhage		1						1
Tonsillar hypertrophy	5	27			3	13	2	14
Tonsillar inflammation	1	5				3	1	2
Tonsillar ulcer		1						1
Tracheal inflammation		1				1		
Tracheal pain		1				1		
Upper-airway cough syndrome	3	8				2	3	6
Upper airway obstruction		2						2
Upper respiratory tract congestion	1	6			1	2		4
Vocal cord disorder		1						1
Wheezing	46	219			13	56	33	163
Yawning	2	11			1	3	1	8
	1,449	7,068	5	25	521	2000	928	5068

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acne	8	21			4	8	4	13
Acute febrile neutrophilic dermatosis		1						1
Adiposis dolorosa	1	1					1	1
Alopecia	18	46			2	6	16	40
Alopecia areata	3	5					3	5
Alopecia totalis		1						1
Androgenetic alopecia		1						1
Angioedema	16	123					16	123
Blister	59	167			26	59	33	108
Blister rupture		1				1		
Blood blister	5	19			1	3	4	16
Butterfly rash		3				1		2
Chronic spontaneous urticaria	1	2					1	2
Circumoral swelling		1				1		
Cold sweat	45	317			14	99	31	218
Cold urticaria		1				1		
Cutaneous sarcoidosis		2						2
Cutaneous symptom		1						1
Cutaneous vasculitis	3	5					3	5
Decubitus ulcer		2						2
Dermal cyst	1	2			1	1		1
Dermatitis	13	51			7	21	6	30
Dermatitis acneiform		1						1
Dermatitis allergic	9	67			5	23	4	44
Dermatitis atopic	2	10			1	2	1	8
Dermatitis bullous	1	8					1	8
Dermatitis contact	3	6					3	6
Dermatitis diaper		1				1		
Dermatitis exfoliative		2						2
Dermatitis exfoliative generalised	1	2					1	2
Dermatomyositis	2	5					2	5
Dermatosis		1				1		

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* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Drug eruption	1	8
Dry skin	30	88
Dyshidrotic eczema	2	6
Eczema	17	64
Eczema asteatotic	1	2
Eczema nummular		1
Eczema weeping		1
Ephelides		1
Erythema	228	976
Erythema annulare		2
Erythema multiforme	4	21
Erythema nodosum	3	9
Excessive granulation tissue		1
Exfoliative rash	3	9
Fingerprint loss	1	1
Fixed eruption		1
Fracture blisters		1
Granuloma skin		1
Guttate psoriasis	1	3
Haemorrhage subcutaneous		5
Hair colour changes	1	2
Hair disorder		1
Hair texture abnormal	1	4
Henoch-Schonlein purpura	1	1
Hidradenitis		1
Hirsutism	1	1
Hyperhidrosis	182	1,007
Ingrown hair	1	1
Itching scar		6
Lichenoid keratosis		2
Lichen planus	2	2
Lichen sclerosus	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		5
		11	35	19	53
				2	6
	1	4	15	13	49
				1	2
			1		
			1		
			1		
	2	131	499	97	477
					2
				4	21
			1	3	8
					1
				3	9
		1	1		
			1		
			1		
				1	3
					5
			1	1	1
			1		
			1	1	3
				1	1
					1
				1	1
1	2	62	313	120	694
				1	1
			4		2
					2
				2	2
				1	1

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Livedo reticularis	1	17
Macule		4
Madarosis	1	2
Mechanical urticaria	1	2
Mechanic's hand	1	1
Miliaria	8	41
Nail discolouration		5
Nail pigmentation		1
Nail ridging		1
Night sweats	58	275
Onychalgia	2	2
Onychoclasia		2
Pain of skin	40	165
Palmar erythema	1	5
Palmoplantar pustulosis	1	1
Papule	7	24
Parapsoriasis	1	1
Peau d'orange		1
Pemphigoid	1	9
Pemphigus	2	4
Perioral dermatitis		1
Petechiae	12	47
Photosensitivity reaction	8	36
Pigmentation disorder	3	7
Piloerection	3	11
Pityriasis	2	7
Pityriasis lichenoides et varioliformis acuta	2	3
Pityriasis rosea	5	17
Plantar erythema		1
Progressive macular hypomelanosis	1	1
Pruritus	422	1,633
Pseudofolliculitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	5		12
			2		2
				1	2
		1	2		
				1	1
		3	17	5	24
			2		3
					1
					1
	3	31	118	27	157
		1	1	1	1
			1		1
1	1	19	53	21	112
			2	1	3
				1	1
		4	9	3	15
		1	1		
			1		
				1	9
				2	4
			1		
		4	18	8	29
		3	9	5	27
		2	4	1	3
		3	3		8
		1	4	1	3
		1	2	1	1
		2	8	3	9
					1
				1	1
2	3	254	775	168	858
					1

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Psoriasis	11	42
Purpura	4	23
Pustular psoriasis	1	2
Rash	492	1,678
Rash erythematous	118	496
Rash macular	62	237
Rash maculo-papular	7	31
Rash morbilliform	8	16
Rash neonatal	1	1
Rash papular	40	135
Rash pruritic	118	450
Rash vesicular	16	45
Red man syndrome		1
Rosacea	5	8
Scab	6	12
Scar pain	2	5
Scleroderma associated digital ulcer		1
Seborrhoea	1	2
Seborrhoeic dermatitis	1	1
Sensitive skin	16	85
Skin burning sensation	24	93
Skin depigmentation		2
Skin discharge		2
Skin discolouration	12	67
Skin discomfort	1	1
Skin disorder	5	20
Skin erosion	4	12
Skin exfoliation	13	49
Skin fissures	2	5
Skin haemorrhage	2	7
Skin hyperpigmentation	1	1
Skin hypertrophy		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	11	9	31
		1	10	3	13
		1	1		1
	1	286	801	206	877
	3	60	218	58	278
		40	131	22	106
		4	13	3	18
		3	6	5	10
		1	1		
		25	65	15	70
		77	195	41	255
		10	20	6	25
					1
			1	5	7
		3	7	3	5
		2	4		1
					1
		1	1		1
				1	1
		9	38	7	47
	2	14	34	10	59
					2
					2
		4	21	8	46
				1	1
		1	4	4	16
		3	5	1	7
		5	16	8	33
		1	2	1	3
			2	2	5
		1	1		
			1		

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* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin indentation	2	2
Skin induration		4
Skin irritation	8	50
Skin laxity		1
Skin lesion	17	39
Skin lesion inflammation	1	1
Skin mass	2	10
Skin odour abnormal	5	8
Skin plaque		1
Skin reaction	12	39
Skin sensitisation	2	13
Skin striae	1	1
Skin swelling	11	42
Skin tightness	6	31
Skin ulcer	3	9
Skin warm	15	106
Skin weeping	1	6
Skin wrinkling		2
Solar dermatitis	1	1
Solar lentigo	1	2
Solar urticaria	1	1
Splinter haemorrhages		1
Stevens-Johnson syndrome	2	5
Systemic lupus erythematosus rash	1	6
Telangiectasia		1
Toxic epidermal necrolysis		2
Toxic skin eruption		1
Trichodynia		1
Urticaria	123	586
Urticaria chronic	1	5
Urticaria contact	1	1
Urticarial vasculitis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2		
			3		1
		7	19	1	31
					1
1	1	8	18	9	21
				1	1
		2	5		5
			3	5	5
					1
		6	20	6	19
		2	5		8
				1	1
		6	23	5	19
		3	14	3	17
				3	9
	1	6	41	9	65
				1	6
			1		1
				1	1
				1	2
				1	1
					1
				2	5
			1	1	5
					1
	1				2
					1
					1
		73	262	50	324
				1	5
				1	1
				1	1

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* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Urticaria papular	2	4			1	2	1	2
Urticaria thermal	1	3			1	3		
Vasculitic rash	1	8				2	1	6
Vitiligo		1						1
Yellow skin	1	8				5	1	3
	2,451	9,968	5	21	1273	4184	1178	5784

System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden	7	28	5	8	2	20
Breast prosthesis user		1		1		
Excessive exercise	1	1			1	1
Hair dye user	1	1			1	1
Immobile	4	11			4	11
Impaired driving ability	2	19	1	8	1	11
Impaired quality of life	1	4		1	1	3
Impaired work ability	11	28	3	7	8	21
Joint prosthesis user		1				1
Loss of personal independence in daily activities	38	168	9	50	29	118
Menopause	6	7	3	3	3	4
Non-tobacco user		1		1		
Physical disability	1	2			1	2
Sight disability	1	2	1	1		1
Sitting disability	1	3		1	1	2
Wa king aid user	1	1			1	1
Wa king disability	1	1			1	1
Water pollution		1				1
	76	280	22	81	54	199

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

SOC Not Yet Coded

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
	20	42	20	42
	20	42	20	42

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* AE=Adverse Event
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System Organ Class

Surgical and medical procedures

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abscess drainage		1				1
Airway secretion clearance therapy		1				1
Anaphylaxis prophylaxis		1				1
Asthma prophylaxis		1				1
Axillary lymphadenectomy		1				1
Bed rest		1				1
COVID-19 immunisation		4		1		3
Dermal filler injection		1		1		
Diabetic diet		1				1
Gastrointestinal surgery		1				1
Immunisation		2				2
Limb immobilisation	2	7	1	5	1	2
Limb operation		1				1
Mass excision		1		1		
Menstrual cycle management	1	1	1	1		
Migraine prophylaxis		1				1
Multiple sclerosis relapse prophylaxis		1				1
Nerve block	1	1			1	1
Prophylaxis of nausea and vomiting	1	2	1	1		1
Splenic artery embolisation		1				1
Therapeutic procedure		1		1		
Tooth extraction		1				1
Weight loss diet		1				1
Wheat-free diet		1				1
Wound drainage	1	1			1	1
	6	36	3	11	3	25

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Achenbach syndrome		1				1		
Acute aortic syndrome	1	1					1	1
Aneurysm		1						1
Angiopathy	1	1					1	1
Aortic aneurysm		1						1
Aortic aneurysm rupture	1	2					1	2
Aortic arteriosclerosis		1						1
Aortic dissection		1						1
Aortic embolus		2						2
Aortic stenosis		2						2
Aortic thrombosis	1	1					1	1
Arterial disorder		1						1
Arterial occlusive disease		2						2
Arterial rupture		1						1
Arterial stenosis	2	3					2	3
Arterial thrombosis	1	4			1	1		3
Arteritis	1	2					1	2
Behcet's syndrome		5						5
Blood pressure fluctuation	8	18			3	5	5	13
Bloody discharge		1						1
Blue toe syndrome	3	9			1	3	2	6
Circulatory collapse	3	54					3	54
CT hypotension complex		2						2
Cyanosis	6	31			2	11	4	20
Deep vein thrombosis	47	145		1			47	145
Diastolic hypertension		1						1
Embolism	26	68					26	68
Embolism venous	1	1					1	1
Essential hypertension		3						3
Extremity necrosis		1						1
Femoral artery embolism	1	1					1	1
Flushing	54	268		1	28	117	26	151

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Giant cell arteritis		5
Granulomatosis with polyangiitis	1	1
Haematoma	3	16
Haemodynamic instability		1
Haemorrhage	58	129
Haemorrhagic infarction		1
Hot flush	93	422
Hypertension	68	374
Hypertensive crisis	3	8
Hypertensive urgency		1
Hypoperfusion		1
Hypotension	37	211
Hypovolaemic shock		1
Infarction		4
Intermittent claudication	1	1
Internal haemorrhage	4	5
Ischaemia	3	5
Jugular vein thrombosis		3
Labile blood pressure		2
Labile hypertension	1	1
Lymphangiopathy		1
Lymphoedema	17	65
MAGIC syndrome		1
Malignant hypertension	1	3
Microembolism		1
Neurogenic shock	1	16
Orthostatic hypertension	1	2
Orthostatic hypotension		10
Pallor	34	154
Pelvic venous thrombosis	1	3
Peripheral arterial occlusive disease	1	1
Peripheral artery occlusion	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					5
				1	1
		1	5	2	11
					1
	2			58	129
					1
		42	168	51	254
	1	17	98	51	276
				3	8
					1
					1
		15	57	22	154
					1
					4
				1	1
				4	5
				3	5
			1		2
					2
				1	1
					1
1	2	7	19	10	46
					1
				1	3
					1
				1	16
				1	2
			3		7
		19	64	15	90
				1	3
				1	1
				1	1

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System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Peripheral circulatory failure	1	4
Peripheral coldness	57	217
Peripheral embolism		1
Peripheral ischaemia	4	9
Peripheral vascular disorder		1
Peripheral vein stenosis		1
Peripheral vein thrombus extension		1
Peripheral venous disease	1	1
Phlebitis	6	19
Phlebitis superficial	2	2
Poor peripheral circulation	2	4
Poor venous access	1	1
Prehypertension		1
Raynaud's phenomenon	8	30
Secondary hypertension	1	1
Shock	4	17
Shock symptom		1
Subclavian vein thrombosis		2
Superficial vein prominence		1
Systolic hypertension		2
Thrombophlebitis	2	11
Thrombophlebitis superficial	2	8
Thrombosis	62	173
Varicose vein		6
Vascular pain	2	6
Vasculitis	6	32
Vasoconstriction		2
Vasodilatation	1	11
Vasospasm		1
Vein discolouration		1
Vein disorder	5	12
Vein rupture		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	4
	1	24	75	33	142
					1
		1	3	3	6
			1		
					1
					1
				1	1
		1	6	5	13
				2	2
			2	2	2
				1	1
			1		
		3	10	5	20
				1	1
				4	17
					1
					2
			1		
					2
			3	2	8
			3	2	5
2	3			62	173
			2		4
			2	2	4
		1	7	5	25
					2
			2	1	9
			1		
			1		
		1	3	4	9
					2

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System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vena cava embolism		1						1
Vena cava thrombosis		1						1
Venous haemorrhage		1						1
Venous thrombosis		5						5
Venous thrombosis limb		1						1
	653	2,675	3	11	167	676	486	1999

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Country Where Event Occurred
UNITED STATES

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System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal clotting factor		2						2
Anaemia	5	16			4	10	1	6
Anaemia vitamin B12 deficiency		1				1		
Antiphospholipid syndrome	1	1					1	1
Autoimmune haemolytic anaemia	1	3					1	3
Blood disorder	2	11			1	8	1	3
B-lymphocyte abnormalities	1	1			1	1		
Bone marrow disorder	2	3			2	3		
Coagulopathy	2	13			1	3	1	10
Coombs negative haemolytic anaemia	1	2					1	2
Disseminated intravascular coagulation	1	3					1	3
Eosinophilia		2				1		1
Febrile neutropenia	1	2					1	2
Haemolysis		1						1
Haemolytic anaemia		6						6
Haemorrhagic diathesis	1	1					1	1
Heparin-induced thrombocytopenia		1						1
Immune thrombocytopenia	6	27					6	27
Increased tendency to bruise	2	4			1	3	1	1
Leukocytosis		6				2		4
Lymphadenitis	5	28			3	23	2	5
Lymphadenopathy	256	1,437		1	232	1345	24	92
Lymph node pain	47	278			43	259	4	19
Lymphocytosis		1				1		
Lymphopenia		1						1
Mast cell activation syndrome	1	1					1	1
Microangiopathic haemolytic anaemia		1						1
Neutropenia	2	6					2	6
Neutropenia neonatal		1						1
Neutrophilia		1				1		
Normocytic anaemia		1				1		
Nucleated red cells	1	1			1	1		

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System Organ Class

Blood and lymphatic system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Pancytopenia	1	5					1	5
Platelet disorder		4				2		2
Polycythaemia		1				1		
Red blood cell abnormality		1						1
Sickle cell anaemia with crisis		2						2
Spleen disorder	1	2			1	1		1
Splenic infarction		1						1
Splenic vein thrombosis	1	2					1	2
Splenomegaly		4				2		2
Thrombocytopenia	10	40					10	40
Thrombocytopenic purpura	1	1					1	1
Thrombotic microangiopathy		1						1
Thrombotic thrombocytopenic purpura	2	2					2	2
	354	1,929		1	290	1669	64	260

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System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acute coronary syndrome		2
Acute myocardial infarction	2	9
Angina pectoris	21	55
Angina unstable		1
Aortic valve disease		1
Arrhythmia	15	76
Arrhythmia supraventricular		1
Arteriosclerosis coronary artery		1
Arteriospasm coronary		4
Atrial fibrillation	32	154
Atrial flutter		8
Atrioventricular block	2	4
Atrioventricular block complete	1	3
Atrioventricular block second degree		1
Bradycardia		7
Bundle branch block left		1
Cardiac amyloidosis	1	1
Cardiac arrest	9	48
Cardiac discomfort	1	6
Cardiac disorder	14	71
Cardiac dysfunction	1	1
Cardiac failure	1	6
Cardiac failure chronic		1
Cardiac failure congestive	3	13
Cardiac fibrillation	1	3
Cardiac flutter	13	50
Cardiac tamponade	3	3
Cardiac valve disease		3
Cardiac valve sclerosis		1
Cardiac ventricular thrombosis	1	2
Cardiogenic shock		3
Cardiomegaly	3	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
				2	9
				21	55
					1
					1
				15	76
					1
			1		
					4
1	1			32	154
			3		5
		1	1	1	3
				1	3
					1
					7
					1
				1	1
				9	48
		1	5		1
		7	42	7	29
				1	1
				1	6
					1
				3	13
				1	3
				13	50
				3	3
			2		1
					1
				1	2
					3
		3	3		

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System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiomyopathy		5
Cardio-respiratory arrest		5
Cardiovascular disorder	4	10
Congestive cardiomyopathy	1	2
Coronary artery disease		2
Coronary artery dissection	1	1
Coronary artery occlusion		1
Coronary artery thrombosis	2	2
Cor pulmonale acute		2
Dilatation ventricular		1
Extrasystoles	3	15
Heart valve incompetence		2
Hypertensive heart disease		1
Intracardiac thrombus		2
Left ventricular dysfunction	1	1
Left ventricular hypertrophy	1	1
Mitral valve disease		1
Mitral valve incompetence	1	2
Mitral valve prolapse		1
Myocardial infarction	40	141
Myocarditis	26	47
Nodal rhythm		1
Palpitations	133	627
Pericardial disease		1
Pericardial effusion	10	22
Pericarditis	25	46
Postural orthostatic tachycardia syndrome	5	15
Prinzmetal angina		2
Pulseless electrical activity	1	2
Right ventricular dilatation		1
Right ventricular dysfunction		1
Sinus arrhythmia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					5
					5
		2	7	2	3
				1	2
					2
				1	1
					1
				2	2
					2
					1
		3	14		1
			1		1
					1
					2
				1	1
		1	1		
					1
				1	2
					1
			2	40	139
		1	2	25	45
			1		
1	1	111	500	22	127
					1
				10	22
				25	46
	1	1	4	4	11
					2
				1	2
			1		
					1
		1	1		

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System Organ Class

Cardiac disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Sinus bradycardia		3				1		2
Sinus tachycardia	3	12			2	6	1	6
Supraventricular extrasystoles	1	6				3	1	3
Supraventricular tachycardia	4	14			2	5	2	9
Tachycardia	28	346			15	219	13	127
Tachycardia foetal		1						1
Torsade de pointes		1						1
Tricuspid valve incompetence		1						1
Ventricular arrhythmia	1	3					1	3
Ventricular extrasystoles	3	24			2	13	1	11
Ventricular fibrillation		4						4
Ventricular hypertrophy		1						1
Ventricular tachycardia		4						4
	419	1,927	2	3	153	838	266	1089

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* AE=Adverse Event

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anomalous pulmonary venous connection		1				1
Cerebral palsy		3				3
Congenital anomaly	1	1			1	1
Dermoid cyst		1				1
Ductus arteriosus premature closure		1				1
Factor V Leiden mutation		1				1
Foetal cystic hygroma	1	2			1	2
Hereditary haemorrhagic telangiectasia		1		1		
Huntington's disease		1		1		
Hyperreflexia	1	1	1	1		
Macroglossia		2				2
Methylenetetrahydrofolate reductase gene mutation		1		1		
Osteogenesis imperfecta		1				1
Porphyria acute		1				1
Retinitis pigmentosa		1				1
Syndactyly	1	1			1	1
Tourette's disorder		1				1
Type V hyperlipidaemia		2				2
Von Willebrand's disease		1				1
Williams syndrome	1	1			1	1
	5	25	1	4	4	21

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* AE=Adverse Event
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System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Auditory disorder		1				1		
Auricular swelling		2				1		1
Cerumen impaction		1				1		
Conductive deafness		1						1
Deafness	38	119				1	38	118
Deafness bilateral	4	7					4	7
Deafness neurosensory	5	19					5	19
Deafness transitory		4						4
Deafness unilateral	15	56	1	1		1	15	55
Dysacusis	1	2				1	1	1
Ear congestion	4	15			2	9	2	6
Ear discomfort	45	145			36	126	9	19
Ear disorder	5	28			5	23		5
Ear haemorrhage	1	3				1	1	2
Ear pain	61	239			54	212	7	27
Ear pruritus	6	27			4	23	2	4
Ear swelling	8	31			7	27	1	4
Eustachian tube disorder		1				1		
Eustachian tube dysfunction	1	4			1	3		1
Eustachian tube obstruction	1	1			1	1		
Excessive cerumen production		4				3		1
External ear disorder		1				1		
External ear pain	1	3			1	3		
Hyperacusis	6	32			6	29		3
Hypoacusis	35	112			25	92	10	20
Inner ear disorder		3				2		1
Inner ear inflammation	1	3				2	1	1
Mastoid disorder		2				1		1
Meniere's disease	1	7					1	7
Middle ear effusion		2				2		
Motion sickness		12				11		1
Otorrhoea	1	2			1	2		

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Ear and labyrinth disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Paraesthesia ear		1				1		
Red ear syndrome	1	3			1	3		
Sudden hearing loss	4	12					4	12
Tinnitus	170	531			127	400	43	131
Vertigo	93	415			82	347	11	68
Vertigo positional	1	10			1	7		3
Vestibular disorder	4	7			3	5	1	2
	513	1,868	1	1	357	1343	156	525

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System Organ Class

Endocrine disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adrenal disorder		3		2		1
Adrenal insufficiency		2				2
Adrenocortical insufficiency acute		2				2
Autoimmune thyroid disorder		1				1
Autoimmune thyroiditis	1	7			1	7
Basedow's disease	1	4			1	4
Endocrine disorder	1	1	1	1		
Goitre	4	9	2	5	2	4
Hyperparathyroidism		1		1		
Hyperthyroidism	2	4			2	4
Hypopituitarism	1	1	1	1		
Hypothyroidism	2	8			2	8
Thyroid disorder	4	14	2	11	2	3
Thyroiditis	2	3	2	3		
Thyroiditis acute		1				1
Thyroiditis subacute	1	5	1	5		
Thyroid mass	1	4	1	2		2
Thyroid pain	2	6	2	6		
Thyrotoxic crisis		3				3
	22	79	12	37	10	42

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* AE=Adverse Event

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal sensation in eye	3	13			3	13		
Altered visual depth perception		1				1		
Amaurosis fugax		1						1
Angle closure glaucoma		1						1
Anterior chamber cell		1						1
Asthenopia	6	34			6	32		2
Binocular eye movement disorder		1						1
Blepharitis		2				2		
Blepharochalasis		1				1		
Blepharospasm	3	18			3	18		
Blindness	20	56					20	56
Blindness transient	4	16					4	16
Blindness unilateral	1	13					1	13
Cataract	8	14					8	14
Cataract nuclear		1						1
Chalazion		1				1		
Chloropsia	1	1					1	1
Chromatopsia		3				3		
Ciliary muscle spasm		1				1		
Computer vision syndrome		1				1		
Conjunctival haemorrhage		10						10
Conjunctival hyperaemia		1						1
Conjunctival irritation		1				1		
Conjunctival oedema		1				1		
Conjunctivitis allergic		3				3		
Corneal disorder		1						1
Corneal infiltrates		1						1
Corneal oedema		1				1		
Cyanopsia	1	1					1	1
Diplopia	10	48			6	32	4	16
Dry eye	14	47			14	44		3
Dyschromatopsia		1				1		

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Endocrine ophthalmopathy	1	3
Episcleritis		2
Erythema of eyelid	1	13
Erythroptosis	1	1
Excessive ocular convergence		1
Exophthalmos	1	4
Extraocular muscle disorder	1	2
Extraocular muscle paresis		3
Eye allergy		2
Eye colour change	1	4
Eye discharge	5	21
Eye disorder	10	74
Eye haematoma	1	1
Eye haemorrhage	9	45
Eye inflammation	2	11
Eye irritation	16	72
Eyelid disorder	2	10
Eyelid function disorder		4
Eyelid haematoma		1
Eyelid irritation		4
Eyelid margin crusting		1
Eyelid oedema	1	7
Eyelid pain	1	14
Eyelid ptosis	3	18
Eyelid rash	1	2
Eyelid sensory disorder		2
Eyelids pruritus	2	10
Eyelid vascular disorder		1
Eye movement disorder	2	14
Eye oedema	4	14
Eye pain	35	186
Eye paraesthesia		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
			2		
		1	10		3
		1	1		
					1
				1	4
		1	2		
					3
			2		
		1	2		2
		5	21		
		8	62	2	12
				1	1
				9	45
		1	7	1	4
		13	65	3	7
		2	9		1
			2		2
			1		
			3		1
			1		
		1	7		
		1	13		1
		2	11	1	7
		1	2		
			2		
		2	8		2
			1		
		2	9		5
		4	13		1
		33	170	2	16
			1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye pruritus	19	109
Eye swelling	44	213
Eye ulcer		1
Foreign body sensation in eyes	3	8
Glare		2
Glaucoma	2	9
Heterophoria		1
Hypermetropia		1
Hypoaesthesia eye	2	12
Iridocyclitis		3
Iritis	1	3
Keratic precipitates		2
Keratitis		3
Lacrimonial disorder	1	2
Lacrimation decreased		1
Lacrimation increased	22	93
Macular degeneration		5
Macular hole		1
Macular oedema		1
Maculopathy	1	2
Meibomian gland dysfunction		1
Metamorphopsia	1	2
Miosis	1	3
Mydriasis	5	11
Myopia		1
Necrotising retinitis		1
Ocular discomfort	12	57
Ocular hyperaemia	19	113
Ocular ischaemic syndrome	1	1
Ocular vascular disorder	3	6
Ophthalmic vein thrombosis	1	1
Ophthalmoplegia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		16	93	3	16
		34	165	10	48
			1		
		3	8		
			2		
		1	2	1	7
					1
			1		
		1	10	1	2
					3
		1	3		
					2
			1		2
		1	2		
					1
		22	86		7
					5
					1
					1
				1	2
					1
				1	2
		1	3		
		5	11		
			1		
					1
		12	52		5
		18	99	1	14
				1	1
			2	3	4
				1	1
				1	1

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Optic ischaemic neuropathy		3
Optic nerve disorder		1
Orbital oedema		1
Periorbital discomfort		1
Periorbital disorder		2
Periorbital oedema		2
Periorbital pain		2
Periorbital swelling	9	49
Photophobia	17	78
Photopsia	4	21
Pupil fixed		1
Pupillary disorder		2
Pupils unequal		1
Retinal aneurysm	1	1
Retinal artery occlusion		3
Retinal detachment	2	5
Retinal disorder		1
Retinal haemorrhage		1
Retinal tear		3
Retinal vascular thrombosis		2
Retinal vein occlusion	4	10
Retinopathy hypertensive		1
Scleral discolouration		1
Scleral haemorrhage		1
Scleritis	1	4
Strabismus	1	7
Sudden visual loss		2
Swelling of eyelid	16	65
Ulcerative keratitis	1	1
Uveitis		5
Vision blurred	75	313
Visual acuity reduced	1	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
					1
					1
			1		
			2		
			1		1
			1		1
		6	40	3	9
		16	73	1	5
		3	15	1	6
					1
			2		
					1
				1	1
					3
		1	1	1	4
			1		
					1
					3
			1		1
				4	10
					1
			1		
					1
				1	4
		1	3		4
					2
		11	55	5	10
				1	1
1	1				5
		65	250	10	63
			6	1	2

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Visual field defect	1	14			1	11		3
Visual impairment	40	165			29	124	11	41
Vitreous degeneration		2						2
Vitreous detachment	4	7					4	7
Vitreous floaters	6	18			5	13	1	5
Xanthopsia		1				1		
	493	2,320	1	1	364	1727	129	593

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	86	385			81	367	5	18
Abdominal distension	23	90			19	80	4	10
Abdominal mass	1	2				1	1	1
Abdominal pain	70	328			53	267	17	61
Abdominal pain lower	6	31			4	23	2	8
Abdominal pain upper	113	496			101	449	12	47
Abdominal rigidity		7				6		1
Abdominal symptom		1				1		
Abdominal tenderness	1	2			1	2		
Abdominal wall haematoma		1						1
Abdominal wall haemorrhage		1						1
Abnormal faeces	5	14			4	11	1	3
Achlorhydria		1				1		
Anal haemorrhage	1	4			1	3		1
Anal incontinence	2	14			1	12	1	2
Anal pruritus		2				2		
Anal skin tags		1				1		
Angular cheilitis		1				1		
Anorectal discomfort		3				3		
Aphthous ulcer	6	16			4	14	2	2
Appendix disorder		2				1		1
Apyalism		2				2		
Barrett's oesophagus		1						1
Bile acid malabsorption		1				1		
Bowel movement irregularity	4	24			4	23		1
Breath odour	1	4			1	3		1
Burning mouth syndrome		1				1		
Cardiospasm		4				3		1
Chapped lips	1	6			1	6		
Cheilitis	3	8			3	7		1
Coeliac disease	2	2					2	2
Colitis	4	15			2	10	2	5

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Colitis ischaemic	1	4
Colitis microscopic	2	3
Colitis ulcerative	2	9
Constipation	12	77
Crohn's disease	4	9
Defaecation disorder		1
Defaecation urgency	2	7
Dental caries	1	3
Dental discomfort		9
Dental paraesthesia		3
Diarrhoea	285	1,580
Diarrhoea haemorrhagic	4	20
Diverticulum intestinal		1
Dry mouth	29	161
Dumping syndrome		1
Duodenogastric reflux	1	3
Dyschezia	2	2
Dyspepsia	23	113
Dysphagia	51	254
Enlarged uvula	2	14
Enteritis	1	2
Enterocolitis haemorrhagic	1	1
Enterovesical fistula	1	1
Eosinophilic oesophagitis	1	2
Epigastric discomfort		2
Erosive oesophagitis		1
Eructation	3	23
Faecaloma		1
Faeces discoloured	3	22
Faeces pale		1
Faeces soft	2	13
Flatulence	11	64

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	4
				2	3
2	2			2	9
		11	71	1	6
1	1			4	9
			1		
		2	7		
		1	3		
			9		
			3		
	1	259	1450	26	130
				4	20
					1
		26	141	3	20
			1		
		1	3		
		1	1	1	1
		22	108	1	5
	1	28	170	23	84
		1	8	1	6
				1	2
				1	1
				1	1
			1	1	1
			2		
					1
		3	22		1
					1
		2	19	1	3
			1		
		2	10		3
		9	60	2	4

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Food poisoning	2	7
Frequent bowel movements		9
Functional gastrointestinal disorder		5
Gastric dilatation		1
Gastric disorder	5	34
Gastric haemorrhage		3
Gastric ulcer		2
Gastritis	3	11
Gastrointestinal disorder	15	71
Gastrointestinal haemorrhage	2	12
Gastrointestinal hypomotility		2
Gastrointestinal inflammation	1	2
Gastrointestinal motility disorder	1	3
Gastrointestinal oedema		1
Gastrointestinal pain	7	36
Gastrointestinal sounds abnormal	2	9
Gastrointestinal tract irritation		3
Gastroesophageal reflux disease	10	52
Gingival bleeding	1	13
Gingival blister	1	3
Gingival discolouration		1
Gingival discomfort	2	6
Gingival disorder	2	3
Gingival erythema		5
Gingival pain	5	20
Gingival recession		1
Gingival swelling		17
Gingival ulceration		1
Glossitis	3	12
Glossodynia	13	51
Haematemesis	4	15
Haematochezia	18	70

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	7		
			8		1
			5		
			1		
		4	31	1	3
					3
					2
		2	9	1	2
		14	63	1	8
				2	12
			1		1
		1	2		
		1	3		
					1
		7	33		3
		2	9		
			3		
		8	48	2	4
		1	11		2
		1	2		1
					1
		2	5		1
		2	3		
			5		
		5	18		2
			1		
			15		2
			1		
		2	11	1	1
		12	48	1	3
				4	15
1	1			18	70

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haemorrhoidal haemorrhage		1
Haemorrhoids	2	12
Hiatus hernia	1	3
Hyperaesthesia teeth	2	6
Hyperchlorhydria		1
Hypoaesthesia oral	51	290
Hypoaesthesia teeth		2
Ileus		1
Impaired gastric emptying	3	5
Infantile vomiting		2
Inflammatory bowel disease		2
Infrequent bowel movements		1
Intestinal haemorrhage		2
Intestinal ischaemia		1
Intestinal obstruction	1	3
Intestinal perforation		1
Intra-abdominal haematoma		1
Irritable bowel syndrome	4	13
Large intestinal haemorrhage		1
Large intestinal obstruction		1
Large intestine perforation		1
Large intestine polyp		1
Lip blister	2	17
Lip discolouration	2	4
Lip disorder	4	16
Lip dry	2	8
Lip erythema	1	7
Lip exfoliation	2	3
Lip haemorrhage		1
Lip oedema		8
Lip pain	7	16
Lip pruritus	1	19

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		2	9		3
			2	1	1
		2	6		
					1
		40	230	11	60
			2		
					1
				3	5
			2		
					2
			1		
1	1				2
					1
				1	3
					1
					1
		4	11		2
					1
					1
			1		
			11	2	6
		2	3		1
		3	15	1	1
		2	6		2
		1	6		1
		2	3		
					1
			5		3
		6	15	1	1
		1	12		7

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lip swelling	63	284
Lip ulceration		1
Lower gastrointestinal haemorrhage		2
Melaena		2
Mesenteric artery aneurysm		1
Mesenteric panniculitis		1
Mesenteric vein thrombosis		1
Mouth cyst	1	1
Mouth haemorrhage	2	9
Mouth swelling	10	50
Mouth ulceration	6	22
Mucous stools		7
Nausea	672	3,826
Noninfective gingivitis	2	6
Odynophagia	3	28
Oedema mouth		1
Oesophageal achalasia		1
Oesophageal disorder	1	3
Oesophageal irritation	1	1
Oesophageal pain	2	5
Oesophageal spasm	1	1
Oesophageal stenosis		1
Oesophagitis	1	2
Oral blood blister	2	4
Oral discomfort	12	55
Oral disorder	5	25
Oral dysaesthesia		1
Oral lichen planus		1
Oral mucosal blistering	8	21
Oral mucosal discolouration	1	1
Oral mucosal eruption	3	9
Oral mucosal erythema	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		40	199	23	85
			1		
					2
					2
					1
					1
					1
		1	1		
		2	7		2
		7	35	3	15
		6	21		1
			7		
1	2	621	3497	51	329
		2	6		
		3	23		5
					1
			1		
			1	1	2
		1	1		
		1	4	1	1
		1	1		
					1
		1	2		
		2	2		2
		9	47	3	8
		4	21	1	4
					1
			1		
		7	19	1	2
		1	1		
			5	3	4
			3	1	2

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral mucosal exfoliation		1
Oral mucosal roughening		1
Oral pain	11	48
Oral pruritus	7	31
Palatal disorder		2
Palatal swelling	2	11
Pancreatic cyst		1
Pancreatic disorder		4
Pancreatitis	3	14
Pancreatitis acute	3	10
Pancreatitis haemorrhagic	1	1
Pancreatitis relapsing		1
Paraesthesia oral	34	330
Parotid duct obstruction		1
Parotid gland enlargement	1	1
Plicated tongue	1	2
Proctalgia	1	3
Rectal discharge		1
Rectal haemorrhage	4	17
Rectal tenesmus		1
Reflux gastritis	1	2
Regurgitation	1	3
Retching	10	66
Saliva discolouration		1
Salivary gland disorder		2
Salivary gland enlargement	2	4
Salivary gland mass	1	1
Salivary gland pain	2	4
Salivary hypersecretion	3	16
Small intestinal haemorrhage		1
Small intestinal obstruction		3
Stiff tongue		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
		11	45		3
		5	21	2	10
			1		1
		1	8	1	3
			1		
			2		2
				3	14
				3	10
				1	1
					1
		24	263	10	67
					1
		1	1		
		1	2		
		1	3		
			1		
				4	17
			1		
		1	2		
		1	3		
	1	6	54	4	12
					1
			1		1
		1	3	1	1
				1	1
		2	4		
		3	12		4
					1
					3
					1

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Stomatitis	15	48
Strawberry tongue		1
Submaxillary gland enlargement	1	1
Swollen tongue	36	235
Teeth brittle		1
Teething	1	1
Tongue blistering	5	13
Tongue coated	1	5
Tongue cyst		1
Tongue discolouration	3	11
Tongue discomfort	11	46
Tongue disorder	8	39
Tongue dry	1	7
Tongue eruption		4
Tongue erythema	3	11
Tongue haematoma		1
Tongue haemorrhage		1
Tongue movement disturbance		3
Tongue oedema	1	3
Tongue pruritus	5	23
Tongue rough	1	1
Tongue spasm		1
Tongue ulceration	3	10
Toothache	18	89
Tooth discolouration		1
Tooth disorder	1	21
Tooth loss		1
Upper gastrointestinal haemorrhage		1
Uvulitis		1
Volvulus		1
Vomiting	265	1,312
Vomiting projectile		13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		12	41	3	7
			1		
				1	1
	1	20	137	16	98
			1		
		1	1		
		5	12		1
		1	4		1
			1		
		3	9		2
		9	40	2	6
		8	31		8
		1	7		
			2		2
		2	10	1	1
			1		
			1		
			2		1
			1	1	2
		3	17	2	6
		1	1		
			1		
		1	7	2	3
		18	82		7
			1		
		1	20		1
					1
					1
			1		
					1
1	2	219	1104	46	208
			13		

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System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
	2,219	11,678	7	13	1851	9961	368	1717

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 * AE=Adverse Event
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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Adhesion		1						1
Administration site bruise	1	3			1	3		
Administration site erythema		1				1		
Administration site irritation		1				1		
Administration site joint erythema		1				1		
Administration site pain		1				1		
Administration site pruritus		1				1		
Administration site reaction		1				1		
Adverse drug reaction	1	3			1	3		
Adverse event	7	21			6	20	1	1
Adverse reaction		3				3		
Alcohol interaction	2	2			1	1	1	1
Application site acne	1	1			1	1		
Application site erythema		1				1		
Application site haemorrhage		1						1
Application site pain		1				1		
Application site swelling		1				1		
Asthenia	313	1,627		1	278	1417	35	210
Axillary pain	34	212			32	205	2	7
Brain death		2						2
Breakthrough pain	1	1			1	1		
Calcinosis	1	1			1	1		
Chest discomfort	114	589			95	449	19	140
Chest pain	189	684			124	474	65	210
Chills	916	5,512	1	1	864	5207	52	305
Chronic fatigue syndrome	2	3			2	3		
Complication associated with device		2						2
Condition aggravated	140	534	1	1	99	403	41	131
Crepitations	2	4			2	4		
Crying	7	44			6	38	1	6
Cyst		4				3		1
Cyst rupture		1				1		

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Death	22	138
Death neonatal		1
Decreased activity		1
Deformity		1
Discharge		1
Discomfort	55	242
Disease progression	1	4
Disease recurrence	35	164
Drowning		1
Drug effective for unapproved indication		6
Drug ineffective	381	2,025
Drug interaction	8	41
Drug intolerance	1	2
Enanthema		1
Energy increased	2	19
Exercise tolerance decreased	1	5
Extensive swelling of vaccinated limb		1
Face oedema	2	11
Facial discomfort	5	18
Facial pain	16	96
Fatigue	1,148	6,367
Feeling abnormal	354	1,603
Feeling cold	66	362
Feeling drunk	9	36
Feeling hot	118	653
Feeling jittery	5	39
Feeling of body temperature change	28	104
Feeling of relaxation	2	3
Fever neonatal		2
Foaming at mouth	1	3
Gait disturbance	103	446
Gait inability	37	135

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1			22	138
					1
			1		
			1		
			1		
		50	226	5	16
			2	1	2
		21	93	14	71
					1
			6		
7	11	2	2	379	2023
		7	32	1	9
			1	1	1
			1		
		2	19		
			4	1	1
			1		
		1	7	1	4
		5	18		
		14	84	2	12
	3	1079	6039	69	328
		333	1484	21	119
		62	330	4	32
		9	32		4
		109	574	9	79
		5	34		5
		25	94	3	10
		2	3		
					2
			2	1	1
		71	337	32	109
		18	76	19	59

* I=Interval, C=Cumulative

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
General physical health deterioration	2	9
Glassy eyes		8
Granuloma		1
Hangover	7	26
Hernia	2	3
Hunger	3	14
Hyperpyrexia	2	12
Hyperthermia		3
Hypothermia	4	12
Idiosyncratic drug reaction		1
III-defined disorder	1	4
Illness	175	749
Impaired healing	1	7
Impaired self-care		1
Implant site nodule		1
Implant site pain	1	1
Induration	3	9
Inflammation	40	143
Inflammatory pain	1	3
Influenza like illness	117	624
Infusion site mobility decreased		1
Inhibitory drug interaction		1
Injected limb mobility decreased	3	12
Injection site bruising		9
Injection site discolouration		2
Injection site discomfort		11
Injection site erythema	12	103
Injection site extravasation	1	5
Injection site haematoma		2
Injection site haemorrhage	1	8
Injection site hypoaesthesia		1
Injection site indentation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2	1	7
			7		1
					1
		7	24		2
		1	1	1	2
		3	14		
				2	12
			3		
				4	12
			1		
		1	4		
	1	157	683	18	66
		1	6		1
					1
			1		
		1	1		
		3	8		1
		35	129	5	14
		1	3		
		109	585	8	39
			1		
			1		
		3	12		
			9		
			2		
			11		
		12	103		
		1	5		
			1		1
		1	8		
			1		
			1		

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site induration		3
Injection site inflammation		1
Injection site injury		1
Injection site joint pain		3
Injection site mass	1	12
Injection site nodule		3
Injection site oedema		1
Injection site pain	33	385
Injection site papule		1
Injection site paraesthesia		3
Injection site pruritus	2	35
Injection site rash	3	30
Injection site reaction		9
Injection site scab		1
Injection site swelling	6	76
Injection site urticaria	1	8
Injection site vesicles		1
Injection site warmth	2	22
Instillation site pain		1
Instillation site warmth	1	1
Irritability postvaccinal		1
Localised oedema	1	6
Local reaction		1
Loss of control of legs		4
Malaise	374	2,103
Mass	23	75
Moaning	1	4
Mucosal disorder	2	8
Mucosal dryness	1	3
Mucosal inflammation	1	2
Mucosal pain	1	1
Mucosa vesicle		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		
			1		
			1		
			3		
		1	12		
			3		
			1		
		32	382	1	3
			1		
			3		
		2	35		
		3	30		
			9		
			1		
		6	76		
		1	7		1
			1		
		2	22		
			1		
		1	1		
			1		
		1	5		1
			1		
					4
		339	1949	35	154
		20	68	3	7
		1	3		1
		2	6		2
		1	3		
			1	1	1
		1	1		
					1

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Multi-organ disorder		3
Multiple organ dysfunction syndrome	1	4
Necrosis		1
No adverse event	11	63
Nodule	6	24
Non-cardiac chest pain		1
Non-pitting oedema		1
Nonspecific reaction		1
Oedema	3	23
Oedema mucosal	1	1
Oedema peripheral	7	27
Organ failure		1
Pain	910	5,018
Pelvic mass		2
Peripheral swelling	188	796
Physical deconditioning		1
Polyserositis		1
Potentiating drug interaction	6	37
Pre-existing condition improved	2	10
Pyrexia	1,010	5,590
Reactogenicity event		1
Screaming	1	7
Secretion discharge	8	28
Sensation of blood flow		3
Sensation of foreign body	3	52
Sensitivity to weather change	1	6
Shoulder injury related to vaccine administration	1	3
Sluggishness	9	46
Stenosis		1
Sudden cardiac death		2
Sudden death		3
Suprapubic pain	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		1
				1	4
					1
		11	63		
		6	22		2
			1		
					1
			1		
		3	20		3
		1	1		
		5	20	2	7
					1
1	2	825	4694	85	324
					2
	1	148	696	40	100
			1		
					1
		6	37		
		2	10		
1	1	929	5201	81	389
			1		
		1	5		2
		5	22	3	6
			1		2
		3	41		11
		1	6		
			2	1	1
		9	44		2
					1
					2
					3
				1	1

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Swelling	125	577
Swelling face	104	496
Symptom recurrence		1
Systemic inflammatory response syndrome	2	5
Temperature intolerance	1	13
Temperature regulation disorder	2	5
Tenderness	22	110
Therapeutic product effect decreased	2	2
Therapeutic product effect delayed		1
Therapeutic product effect incomplete		1
Therapeutic product effect prolonged		1
Therapeutic response decreased	1	1
Therapeutic response increased		1
Therapeutic response unexpected	21	105
Thirst	17	84
Thirst decreased		1
Ulcer	4	10
Ulcer haemorrhage	1	2
Unevaluable event		2
Vaccination failure	59	184
Vaccination site bruising	20	99
Vaccination site coldness		9
Vaccination site cyst	1	1
Vaccination site dermatitis	1	2
Vaccination site discharge	3	7
Vaccination site discolouration	11	36
Vaccination site discomfort	17	75
Vaccination site dryness	1	2
Vaccination site erythema	87	584
Vaccination site exfoliation	1	2
Vaccination site extravasation	2	15
Vaccination site haematoma		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		104	501	21	76
		71	372	33	124
			1		
				2	5
		1	11		2
		2	5		
		22	105		5
		2	2		
			1		
					1
			1		
		1	1		
			1		
		21	105		
		15	78	2	6
			1		
		3	8	1	2
				1	2
			2		
	1		1	59	183
		20	95		4
			9		
		1	1		
		1	1		1
		3	7		
		11	35		1
		16	71	1	4
		1	2		
		83	557	4	27
		1	2		
		2	15		
			3		1

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site haemorrhage	18	81
Vaccination site hyperaesthesia	1	2
Vaccination site hypersensitivity	1	5
Vaccination site hypoaesthesia	5	32
Vaccination site induration	6	61
Vaccination site inflammation	2	26
Vaccination site injury		4
Vaccination site irritation	2	12
Vaccination site joint erythema		2
Vaccination site joint movement impairment	3	18
Vaccination site joint pain	3	15
Vaccination site joint swelling		2
Vaccination site lymphadenopathy	1	19
Vaccination site macule		5
Vaccination site mass	35	161
Vaccination site movement impairment	7	61
Vaccination site nerve damage	1	1
Vaccination site nodule	5	17
Vaccination site oedema	1	8
Vaccination site pain	471	3,189
Vaccination site pallor		1
Vaccination site papule	1	4
Vaccination site paraesthesia	4	35
Vaccination site pruritus	48	299
Vaccination site rash	34	157
Vaccination site reaction	11	53
Vaccination site scab	2	6
Vaccination site scar	2	5
Vaccination site streaking		1
Vaccination site swelling	91	577
Vaccination site thrombosis		1
Vaccination site ulcer		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		14	73	4	8
		1	2		
		1	5		
		4	28	1	4
		6	59		2
		2	24		2
			4		
		2	12		
			1		1
		3	15		3
		3	13		2
			1		1
		1	18		1
			5		
		32	151	3	10
		5	58	2	3
		1	1		
		4	15	1	2
		1	6		2
	2	457	3099	14	90
			1		
		1	4		
		3	31	1	4
		46	281	2	18
		31	145	3	12
1	1	10	50	1	3
		2	6		
		2	5		
			1		
		87	551	4	26
					1
			1		

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site urticaria	6	60			6	55		5
Vaccination site vesicles	3	18			3	18		
Vaccination site warmth	33	250			29	235	4	15
Vessel puncture site bruise		1				1		
Vessel puncture site haemorrhage		1				1		
Vessel puncture site injury		1				1		
	8,431	45,776	12	27	7172	39870	1259	5906

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System Organ Class

Hepatobiliary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute hepatic failure		2				2
Biliary colic	2	3	2	3		
Biliary tract disorder		2		1		1
Cholecystitis	1	3			1	3
Cholelithiasis	2	6		2	2	4
Cholelithiasis obstructive		1				1
Cholestasis		3				3
Gallbladder disorder	1	10	1	5		5
Gallbladder oedema		1				1
Gallbladder polyp		1		1		
Hepatic cirrhosis		1				1
Hepatic cyst		2		1		1
Hepatic failure	1	3			1	3
Hepatic function abnormal		1				1
Hepatic haemorrhage		1				1
Hepatic lesion		1				1
Hepatic mass		1		1		
Hepatic necrosis		1				1
Hepatic pain	3	6	2	3	1	3
Hepatic steatosis		2		2		
Hepatitis		4				4
Hepatitis acute		3				3
Hepatitis cholestatic		1				1
Hepatomegaly	1	4		2	1	2
Hyperbilirubinaemia		1				1
Jaundice	1	14		5	1	9
Liver disorder		4		2		2
Liver injury		5		1		4
Liver tenderness		1		1		
Ocular icterus	1	3	1	3		
Portal vein thrombosis	3	9			3	9
	16	100	6	33	10	67

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System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Allergic reaction to excipient	2	7			2	6		1
Allergy to animal	1	1			1	1		
Allergy to arthropod sting	1	3				2	1	1
Allergy to chemicals	1	2			1	2		
Allergy to vaccine	22	101			10	62	12	39
Amyloidosis		1						1
Anaphylactic reaction	41	381				1	41	380
Anaphylactic shock	6	32					6	32
Anaphylactoid reaction		5						5
Anti-neutrophil cytoplasmic antibody positive vasculitis	1	1					1	1
Atopy	1	1			1	1		
Autoimmune disorder	8	29					8	29
Contrast media allergy		1				1		
Corneal graft rejection		1						1
Cytokine storm		1						1
Decreased immune responsiveness	3	4			2	3	1	1
Drug hypersensitivity	10	70			5	60	5	10
Food allergy	4	10			3	8	1	2
Haemophagocytic lymphohistiocytosis		1						1
Hypersensitivity	142	546			95	385	47	161
Hypogammaglobulinaemia		1						1
Immune system disorder	15	51			11	38	4	13
Immunisation reaction		1						1
Immunodeficiency	4	11	2	2			4	11
Immunosuppression		1						1
Multiple allergies		2				2		
Multisystem inflammatory syndrome in children	1	1					1	1
Reaction to excipient	3	13			2	9	1	4
Reaction to preservatives		2				2		
Rubber sensitivity		1				1		
Sarcoidosis	1	3					1	3

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System Organ Class

Immune system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Seasonal allergy	7	23			7	23		
Sensitisation	1	3			1	3		
Serum sickness		2						2
Systemic immune activation		1						1
Type I hypersensitivity	1	1					1	1
Type III immune complex mediated reaction		1						1
Type IV hypersensitivity reaction	1	3			1	3		
	277	1,319	2	2	142	613	135	706

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal abscess		1						1
Abdominal infection		2						2
Abscess		3				2		1
Acarodermatitis	1	3				1	1	2
Amniotic cavity infection		1						1
Anal abscess	2	2					2	2
Anal infection		1				1		
Appendicitis	20	64					20	64
Appendicitis perforated	1	8					1	8
Arthritis infective	1	1					1	1
Arthropod infestation		1						1
Asymptomatic COVID-19	13	64			1	16	12	48
Atypical pneumonia	1	2					1	2
Bacteraemia	1	4					1	4
Bacterial disease carrier		1				1		
Bacterial infection	5	11			4	8	1	3
Bacterial pyelonephritis		1						1
Bacterial vaginosis	1	3			1	3		
Bacteriuria		1						1
Body tinea		1				1		
Breast abscess		1				1		
Breast cellulitis	1	1					1	1
Bronchitis	7	38			5	28	2	10
Campylobacter infection	1	1					1	1
Candida infection	2	7			2	7		
Cardiac valve vegetation		1						1
Cellulitis	17	57					17	57
Cellulitis gangrenous		1						1
Cholecystitis infective		1						1
Chronic sinusitis	1	2			1	2		
Clostridium difficile colitis		1						1
Clostridium difficile infection	3	5					3	5

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Coccidioidomycosis	1	3
Complicated appendicitis		1
Conjunctivitis	4	18
Conjunctivitis bacterial	1	1
Conjunctivitis viral	2	3
Corneal infection		1
Coronavirus infection	1	2
COVID-19	637	2,825
COVID-19 pneumonia	7	51
Cystitis	8	30
Cystitis bacterial	1	2
Cystitis escherichia		1
Cytomegalovirus infection reactivation	2	2
Dermatophytosis of nail		1
Diabetic foot infection		1
Disseminated varicella zoster vaccine virus infection	1	1
Disseminated varicella zoster virus infection		1
Diverticulitis	2	27
Dysentery		4
Ear infection	11	34
Ear infection bacterial		1
Ear infection viral		1
Ebola disease		1
Encephalitis	3	9
Endocarditis		2
Epididymitis	1	1
Epstein-Barr viraemia		1
Epstein-Barr virus infection	2	2
Epstein-Barr virus infection reactivation		1
Escherichia bacteraemia		1
Escherichia infection	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
					1
		3	17	1	1
				1	1
		1	2	1	1
					1
			1	1	1
6	11	216	804	421	2021
2	2			7	51
		6	22	2	8
				1	2
					1
				2	2
			1		
			1		
				1	1
					1
		1	1	1	26
					4
		11	30		4
					1
			1		
					1
				3	9
					2
				1	1
			1		
		1	1	1	1
					1
					1
				1	2

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Escherichia urinary tract infection		1
Eye infection		8
Eyelid infection		1
Flea infestation	1	1
Folliculitis		4
Fungal infection	3	13
Fungal peritonitis		1
Fungal skin infection		1
Furuncle	1	5
Gangrene		1
Gastric infection		1
Gastritis bacterial		1
Gastroenteritis		2
Gastroenteritis viral	1	16
Gastrointestinal bacterial infection	1	1
Gastrointestinal infection	1	2
Gastrointestinal viral infection		1
Genital herpes	2	8
Genital herpes simplex		2
Gingival abscess	2	2
Gingivitis	4	8
Haemorrhagic varicella syndrome		1
Helicobacter infection		1
Hepatitis C	2	2
Hepatitis D		1
Herpes dermatitis	1	1
Herpes ophthalmic	1	1
Herpes simplex	3	18
Herpes simplex gastritis	1	1
Herpes simplex reactivation		3
Herpes virus infection	5	17
Herpes zoster	274	492

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			8		
			1		
		1	1		
			4		
		3	12		1
					1
			1		
		1	5		
					1
					1
					1
			1		1
		1	12		4
				1	1
			1	1	1
			1		
			5	2	3
			2		
		2	2		
		4	8		
					1
					1
				2	2
					1
		1	1		
				1	1
		1	15	2	3
				1	1
			3		
		5	16		1
		238	416	36	76

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Herpes zoster infection neurological	1	1
Herpes zoster oticus	3	7
Herpes zoster reactivation	5	6
HIV infection		1
Hordeolum		10
Impetigo	1	1
Infection	9	47
Infection parasitic		1
Infection reactivation	1	1
Infectious mononucleosis	3	10
Influenza	35	162
Injection site abscess		1
Injection site cellulitis	1	1
Injection site infection		2
Intervertebral discitis		1
Kidney infection	6	22
Labyrinthitis	1	5
Large intestine infection		1
Laryngitis	6	16
Lip infection		1
Localised infection	3	15
Lower respiratory tract infection	1	9
Lower respiratory tract infection bacterial	1	1
Lung abscess	1	1
Lyme disease	3	6
Lymphangitis		1
Lymph gland infection		3
Mastitis	2	8
Measles	3	5
Meningitis	2	8
Meningitis aseptic		2
Meningitis bacterial	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
1	1			3	7
		5	6		
			1		
			9		1
				1	1
		4	30	5	17
			1		
		1	1		
		2	8	1	2
		32	151	3	11
			1		
		1	1		
			2		
					1
				6	22
			1	1	4
					1
		5	13	1	3
			1		
		2	13	1	2
				1	9
				1	1
				1	1
				3	6
					1
			2		1
				2	8
				3	5
		1	1	1	7
					2
				1	1

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Meningitis viral		7
Mumps		1
Myelitis	1	1
Nail infection		1
Nasopharyngitis	90	424
Neurological infection	1	1
Nipple infection		1
Omphalitis		1
Ophthalmic herpes simplex		1
Ophthalmic herpes zoster	5	6
Oral candidiasis	1	7
Oral fungal infection		3
Oral herpes	30	96
Oral viral infection		2
Orchitis		2
Oropharyngeal candidiasis		1
Osteomyelitis		3
Otitis media	1	3
Parotitis	1	2
Pelvic inflammatory disease		1
Periodontitis		1
Periorbital cellulitis		1
Peritonitis	1	1
Pertussis	1	2
Pharyngeal abscess	2	2
Pharyngitis	1	12
Pharyngitis streptococcal	6	14
Pneumocystis jirovecii pneumonia		1
Pneumonia	32	141
Pneumonia bacterial	1	3
Pneumonia staphylococcal		1
Pneumonia viral	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					7
			1		
				1	1
			1		
		88	414	2	10
				1	1
			1		
					1
					1
				5	6
		1	7		
			3		
		28	88	2	8
			2		
			1		1
			1		
					3
		1	3		
		1	2		
					1
			1		
					1
				1	1
				1	2
				2	2
			9	1	3
		4	11	2	3
					1
1	1		2	32	139
				1	3
					1
				1	4

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Post-acute COVID-19 syndrome	2	2
Postoperative wound infection		1
Post procedural infection		1
Post viral fatigue syndrome		1
Prostate infection	1	2
Pseudomonas infection		1
Pustule	1	12
Rash pustular	2	4
Respiratory tract infection	1	9
Retinitis		1
Rhinitis		6
Rhinovirus infection		2
Root canal infection		2
Rubella		1
Scrotal infection		1
Sepsis	3	24
Septic shock	1	1
Serratia infection	1	1
Sialoadenitis		4
Sinusitis	19	115
Sinusitis bacterial		2
Skin bacterial infection	1	2
Skin infection		2
Sputum purulent	1	1
Staphylococcal bacteraemia		1
Staphylococcal infection	1	8
Staphylococcal skin infection		1
Streptobacillus infection	1	2
Streptococcal infection	1	7
Streptococcal urinary tract infection	1	1
Subcutaneous abscess		3
Suspected COVID-19	67	183

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
					1
					1
			1		
				1	2
					1
			6	1	6
			2	2	2
				1	9
					1
			5		1
			2		
			2		
			1		
					1
				3	24
				1	1
				1	1
					4
		17	103	2	12
					2
		1	1		1
			1		1
				1	1
					1
			1	1	7
					1
				1	2
		1	6		1
				1	1
			1		2
		26	70	41	113

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Sweating fever		1						1
Syphilis		1						1
Tetanus		1						1
Tinea infection	1	1			1	1		
Tinea pedis		1				1		
Tongue fungal infection		1				1		
Tonsillitis	2	6			1	5	1	1
Tonsillitis streptococcal	1	1					1	1
Tooth abscess	4	9			3	7	1	2
Tooth infection	3	14			3	13		1
Tracheitis	1	2			1	2		
Tuberculosis		2						2
Upper respiratory tract infection	2	12			2	12		
Urinary tract infection	28	128			19	91	9	37
Urinary tract infection bacterial		4						4
Urosepsis		1						1
Vaccination site cellulitis	2	18				4	2	14
Vaccination site infection		9				9		
Vaccination site pustule	1	3			1	3		
Vaginal infection		2				1		1
Varicella	1	5			1	5		
Varicella zoster virus infection	1	2			1	2		
Vestibular neuronitis	1	4				1	1	3
Viral infection	13	24			11	19	2	5
Viral myelitis	1	1					1	1
Viral myocarditis	1	2					1	2
Viral rash		2				2		
Viral sepsis	1	1					1	1
Viral upper respiratory tract infection		3				2		1
Vulvovaginal mycotic infection	1	4			1	4		
Wound infection		1						1
	1,499	5,714	10	15	776	2644	723	3070

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accident	2	9			1	4	1	5
Accidental exposure to product	4	49			4	49		
Accidental exposure to product by child	1	1			1	1		
Accidental overdose	10	56			10	53		3
Accidental underdose		5				5		
Animal bite		3				3		
Ankle fracture		3						3
Arthropod bite	3	12			3	12		
Arthropod sting		5				5		
Autonomic dysreflexia	1	1					1	1
Back injury	6	12			4	9	2	3
Bite		3				3		
Bone contusion	1	1			1	1		
Booster dose missed		3				3		
Burn oesophageal		1				1		
Burn oral cavity	1	2					1	2
Burns third degree	2	2					2	2
Cartilage injury		1				1		
Chest injury	1	4					1	4
Chillblains	2	10			2	9		1
Circumstance or information capable of leading to device use error		7				7		
Circumstance or information capable of leading to medication error	54	975			52	973	2	2
Cold burn	1	1					1	1
Compression fracture	1	1					1	1
Concussion	5	18			1	6	4	12
Contraindicated product administered		6				6		
Contusion	65	230			54	204	11	26
Counterfeit product administered		1				1		
Cranial nerve injury	1	1					1	1
Dental restoration failure	1	3			1	3		

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Discontinued product administered		1
Dose calculation error		1
Ear injury		1
Electric shock	1	1
Epicondylitis	1	3
Expired product administered	28	87
Exposure during pregnancy	23	82
Exposure to SARS-CoV-2	12	105
Exposure to toxic agent		1
Exposure via breast milk	13	119
Exposure via eye contact	1	4
Exposure via skin contact	2	36
Extra dose administered	2	6
Eye contusion	2	14
Eye injury	1	5
Face injury		11
Facial bones fracture		4
Fall	70	293
Femur fracture		2
Foetal exposure during pregnancy	1	3
Foot fracture	2	5
Foreign body aspiration		1
Foreign body in eye		1
Foreign body in throat		4
Fracture		1
Frostbite		1
Gallbladder injury		1
Gastrointestinal injury		1
Gastrointestinal stoma complication		1
Gun shot wound	1	1
Hair injury	1	2
Hand fracture		5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
			1		
		1	1		
		1	3		
		27	86	1	1
		20	71	3	11
		11	94	1	11
			1		
		11	114	2	5
		1	4		
		2	36		
		2	6		
		2	14		
			3	1	2
			7		4
					4
1	1	42	175	28	118
					2
		1	2		1
			1	2	4
					1
			1		
					4
					1
			1		
			1		
			1		
				1	1
		1	2		
					5

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Head injury	22	66
Heart injury		7
Heat illness		2
Hip fracture	3	13
Humerus fracture	1	1
Hypobarism		1
Iliotibial band syndrome		1
Inappropriate schedule of product administration	192	1,198
Incision site haemorrhage		1
Incomplete course of vaccination	1	19
Incorrect dosage administered		5
Incorrect dose administered	28	94
Incorrect dose administered by device		1
Incorrect dose administered by product		1
Incorrect product administration duration		2
Incorrect route of product administration	17	164
Injury	3	17
Intentional dose omission		10
Intentional overdose		1
Intentional product misuse	1	10
Intentional product use issue	1	2
Intercepted medication error		2
Joint dislocation	2	9
Joint injury	9	31
Lack of vaccination site rotation	1	1
Ligament injury	1	4
Ligament rupture	2	3
Ligament sprain	1	12
Limb injury	7	51
Lip injury	3	9
Liver contusion		1
Lower limb fracture		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1	14	36	8	30
					7
			2		
				3	13
				1	1
					1
			1		
		187	1192	5	6
					1
		1	19		
			5		
		27	91	1	3
			1		
			1		
			2		
		17	159		5
		2	10	1	7
			10		
			1		
		1	10		
		1	2		
			2		
		1	2	1	7
		7	27	2	4
		1	1		
		1	4		
		2	2		1
		1	12		
1	1	7	49		2
		3	7		2
					1
			1		3

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System Organ Class

Injury, poisoning and procedural complications

	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
<i>Preferred Term</i>		
Maternal exposure before pregnancy	1	2
Maternal exposure during breast feeding	2	4
Maternal exposure during pregnancy	29	162
Maternal exposure timing unspecified	4	9
Medication error	1	12
Meniscus injury		2
Mouth injury	2	7
Multiple fractures		1
Muscle contusion	1	1
Muscle injury	2	5
Muscle rupture	2	3
Muscle strain	11	27
Nasal injury	1	5
Neck injury	1	6
Nerve injury	12	31
Neurological procedural complication	1	1
Occupational exposure to product	1	11
Occupational exposure to SARS-CoV-2	1	7
Off label use	156	891
Overdose	535	797
Paternal exposure timing unspecified	1	1
Pelvic fracture	1	2
Peripheral nerve injury		2
Phrenic nerve injury		1
Poisoning		3
Poor quality product administered	277	653
Post concussion syndrome	1	1
Post lumbar puncture syndrome		1
Post procedural complication		1
Post procedural haemorrhage		1
Post procedural oedema		1
Post-traumatic neck syndrome	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
		2	4		
		23	147	6	15
		3	8	1	1
		1	12		
			1		1
		1	6	1	1
					1
		1	1		
		1	4	1	1
				2	3
		10	23	1	4
			4	1	1
		1	6		
		6	20	6	11
		1	1		
		1	11		
		1	6		1
		153	883	3	8
		533	793	2	4
		1	1		
				1	2
					2
					1
					3
		277	653		
		1	1		
			1		
	1				1
					1
			1		
		1	1		3

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Prescr bed overdose		1
Procedural haemorrhage		1
Procedural pain		2
Procedural site reaction		1
Product administered at inappropriate site	16	113
Product administered to patient of inappropriate age	13	33
Product administration error	9	43
Product communication issue		1
Product confusion		2
Product dispensing issue		1
Product dose omission in error		2
Product dose omission issue	36	196
Product label confusion		1
Product preparation error	66	209
Product preparation issue	356	573
Product prescribing error	2	12
Product storage error	89	156
Product substitution error		1
Product use complaint		1
Product use in unapproved indication		1
Product use issue	51	481
Radial nerve injury	1	1
Radiation injury	1	1
Rib fracture		5
Road traffic accident	8	14
Scar	4	14
Scratch	7	28
Skeletal injury		1
Skin abrasion	2	4
Skin injury	2	6
Skin laceration	5	20

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
			1		1
					1
		16	110		3
		13	33		
		9	41		2
			1		
			2		
			1		
			2		
		36	195		1
			1		
		66	207		2
		356	570		3
		2	12		
		89	156		
			1		
			1		
			1		
		50	475	1	6
				1	1
		1	1		
					5
		4	6	4	8
		4	9		5
		6	24	1	4
			1		
		2	4		
		1	5	1	1
		3	11	2	9

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Soft tissue injury	1	2
Spinal compression fracture		1
Spinal fracture	1	1
Splenic rupture	1	1
Splinter		1
Stoma site haemorrhage	1	2
Stoma site pruritus		1
Subdural haematoma		1
Subdural haemorrhage		1
Sunburn	5	13
Superficial injury of eye		1
Suture related complication		1
Tendon rupture	2	2
Thermal burn	3	7
Thermal burns of eye	1	1
Thoracic vertebral fracture		1
Tibia fracture		1
Tongue injury		2
Tooth fracture	2	6
Tooth injury	2	8
Toxicity to various agents	1	2
Tracheal deviation		1
Tracheal obstruction		1
Transplant failure		1
Traumatic haemorrhage		1
Underdose	57	281
Upper limb fracture	2	8
Vaccination complication	1	8
Vaccination error	1	6
Vascular injury	3	3
Wound	1	12
Wound complication		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	1
					1
				1	1
				1	1
			1		
				1	2
			1		
					1
					1
		4	11	1	2
			1		
					1
		1	1	1	1
		3	6		1
				1	1
					1
			2		
		2	5		1
		1	4	1	4
				1	2
					1
					1
					1
		56	279	1	2
			1	2	7
1	2	1	7		1
		1	6		
		1	1	2	2
			8	1	4
			1		

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Wound haemorrhage	2	9			1	6	1	3
Wound secretion		1						1
Wrist fracture		1						1
Wrong dose		1				1		
Wrong product administered	28	80			27	79	1	1
Wrong schedule		13				13		
Wrong technique in device usage process		2				2		
Wrong technique in product usage process	28	137			27	134	1	3
	2,473	9,175	4	6	2331	8669	142	506

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Activated partial thromboplastin time prolonged		2
Alanine aminotransferase		1
Alanine aminotransferase abnormal		1
Alanine aminotransferase decreased		2
Alanine aminotransferase increased	6	17
A bumin globulin ratio decreased		2
Allergy test positive		1
Ammonia increased		1
Amphetamines positive	1	1
Amylase increased		1
Anion gap abnormal		1
Anion gap decreased		1
Anion gap increased		2
Antibody test abnormal	1	7
Antibody test negative	1	6
Antibody test positive	1	1
Anti Kell antibody test positive		1
Antinuclear ant body positive	2	2
Anti-thyroid antibody positive	1	1
Aspartate aminotransferase		1
Aspartate aminotransferase decreased		1
Aspartate aminotransferase increased	4	14
Bacterial test positive	2	3
Band neutrophil count increased		1
Basophil count abnormal		1
Basophil count increased		1
Bilirubin urine present		1
Biopsy		1
Blast cell count increased		1
Blood albumin decreased		4
Blood albumin increased		1
Blood alcohol increased	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
			1		
			1		
			1		1
		3	11	3	6
			2		
			1		
					1
		1	1		
			1		
			1		
			1		
			1		1
		1	7		
			5	1	1
		1	1		
			1		
		1	1	1	1
		1	1		
			1		
			1		
		1	10	3	4
		2	3		
					1
			1		
			1		
			1		
			1		
					1
			4		
			1		
		1	1	1	1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood alkaline phosphatase		1
Blood alkaline phosphatase increased	1	3
Blood bilirubin abnormal		1
Blood bilirubin decreased		2
Blood bilirubin increased	1	9
Blood calcium decreased	1	4
Blood calcium increased	1	4
Blood chloride decreased		4
Blood chloride increased		3
Blood cholesterol		2
Blood cholesterol abnormal		4
Blood cholesterol decreased		1
Blood cholesterol increased	6	16
Blood chromium increased		1
Blood copper increased		2
Blood count abnormal	1	7
Blood creatine increased		3
Blood creatine phosphokinase abnormal		1
Blood creatine phosphokinase increased		7
Blood creatinine abnormal		1
Blood creatinine decreased		2
Blood creatinine increased	1	12
Blood electrolytes decreased	1	2
Blood fibrinogen decreased		1
Blood folate decreased		1
Blood folate increased		1
Blood follicle stimulating hormone increased		1
Blood glucose	1	1
Blood glucose abnormal	3	12
Blood glucose decreased	10	46
Blood glucose fluctuation		3
Blood glucose increased	18	116

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	3		
					1
			2		
		1	6		3
		1	3		1
		1	3		1
			3		1
			3		
			2		
			4		
			1		
		5	15	1	1
					1
			2		
		1	6		1
			2		1
			1		
			2		5
					1
			1		1
		1	10		2
				1	2
			1		
			1		
			1		
					1
		1	1		
		2	9	1	3
		8	31	2	15
			3		
		10	84	8	32

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood immunoglobulin E increased		1
Blood immunoglobulin G		1
Blood immunoglobulin G abnormal		1
Blood immunoglobulin G decreased		2
Blood immunoglobulin G increased	1	2
Blood immunoglobulin M abnormal		1
Blood immunoglobulin M increased	2	3
Blood insulin increased		1
Blood iron decreased		6
Blood iron increased		1
Blood ketone body increased		1
Blood lactate dehydrogenase increased	1	1
Blood lactic acid decreased		1
Blood lactic acid increased		4
Blood magnesium decreased	1	4
Blood osmolarity decreased		1
Blood parathyroid hormone decreased	1	1
Blood phosphorus decreased		1
Blood phosphorus increased	1	1
Blood potassium decreased	2	24
Blood potassium increased		5
Blood pressure abnormal	10	40
Blood pressure decreased	15	86
Blood pressure diastolic decreased		4
Blood pressure diastolic increased		4
Blood pressure increased	65	424
Blood pressure measurement		2
Blood pressure orthostatic increased		1
Blood pressure systolic increased	4	17
Blood sodium decreased	2	12
Blood sodium increased	1	1
Blood test abnormal	1	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
			1		
			2		
			1	1	1
			1		
		2	3		
			1		
			3		3
			1		
					1
		1	1		
			1		
			1		3
				1	4
			1		
		1	1		
					1
		1	1		
		1	12	1	12
			2		3
		8	32	2	8
		10	53	5	33
			3		1
			3		1
		36	254	29	170
			2		
			1		
		2	7	2	10
		2	8		4
		1	1		
		1	7		2

* I=Interval, C=Cumulative

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood testosterone decreased		1
Blood thyroid stimulating hormone abnormal	1	1
Blood thyroid stimulating hormone decreased	2	3
Blood thyroid stimulating hormone increased	1	6
Blood triglycerides abnormal		1
Blood triglycerides decreased		2
Blood triglycerides increased	1	5
Blood urea decreased		1
Blood urea increased		4
Blood uric acid increased		2
Blood urine		3
Blood urine present	14	43
Blood zinc decreased	1	1
B-lymphocyte count decreased		1
Body height decreased	5	36
Body mass index increased	1	1
Body temperature		2
Body temperature abnormal	11	45
Body temperature decreased	3	40
Body temperature fluctuation	4	12
Body temperature increased	30	193
Bone density abnormal		1
Brain natriuretic peptide increased	1	2
Breath sounds abnormal		4
Capillary nail refill test abnormal		2
Carbohydrate antigen 125 increased		1
Carbon dioxide increased		1
Carcinoembryonic antigen increased	1	1
Cardiac murmur		1
CD4 lymphocytes decreased	1	1
Cell marker decreased		1
Chest X-ray abnormal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	1		
		1	1	1	2
			4	1	2
			1		
			2		
		1	3		2
			1		
			2		2
			1		1
			3		
		12	33	2	10
		1	1		
			1		
		5	35		1
		1	1		
			2		
		10	41	1	4
		2	35	1	5
		4	12		
		26	183	4	10
			1		
			1	1	1
			4		
			2		
			1		
			1		
				1	1
				1	1
					1
					1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Coagulation time prolonged		1
Computerised tomogram normal		1
Corneal reflex decreased		2
Coronavirus test positive		2
C-reactive protein increased	3	22
Crystal urine		1
CSF glucose increased	1	1
CSF oligoclonal band present		1
CSF protein increased	1	3
Culture urine positive		1
Cytogenetic analysis abnormal	1	1
Differential white blood cell count abnormal		1
Double stranded DNA antibody positive	1	1
Drug screen positive		1
Ejection fraction abnormal		1
Ejection fraction decreased	1	6
Electrocardiogram abnormal	5	16
Electrocardiogram PR shortened		1
Electrocardiogram QT prolonged		3
Electrocardiogram ST segment depression		1
Electrocardiogram ST segment elevation	2	4
Electrocardiogram T wave abnormal		1
Electrocardiogram T wave peaked		1
Eosinophil count decreased		1
Eosinophil count increased		6
Epinephrine increased		1
Epstein-Barr virus antibody		1
Epstein-Barr virus antibody positive	1	3
Epstein-Barr virus antigen positive		1
Exercise electrocardiogram abnormal	1	2
Faecal calprotectin decreased	1	1
Faecal calprotectin increased	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
			1		1
					2
		2	15	1	7
			1		
				1	1
					1
				1	3
			1		
				1	1
					1
				1	1
			1		
			1		
				1	6
		1	10	4	6
					1
					3
					1
				2	4
			1		
			1		
					1
			2		4
			1		
			1		
			2	1	1
			1		
		1	1		1
		1	1		
		1	1		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
False negative investigation result		1
False positive investigation result		1
Fibrin D dimer increased	7	22
Fibroblast growth factor 23	1	1
Fibroblast growth factor 23 increased	1	1
Foetal heart rate abnormal		1
Foetal heart rate decreased		1
Full blood count		1
Full blood count abnormal		3
Gastric pH decreased		2
Glomerular filtration rate abnormal		1
Glomerular filtration rate decreased	2	9
Glycosylated haemoglobin decreased	1	1
Glycosylated haemoglobin increased	1	5
Granulocytes abnormal		2
Grip strength decreased	2	17
Haematocrit decreased		4
Haematocrit increased		2
Haematology test abnormal		1
Haemoglobin abnormal		1
Haemoglobin decreased	5	24
Haemoglobin increased		2
Haemoglobin urine present	1	1
Haptoglobin increased		1
Heart rate		1
Heart rate abnormal	8	43
Heart rate decreased	12	45
Heart rate increased	190	918
Heart rate irregular	13	74
Heart rate normal		1
Hepatic enzyme abnormal	1	4
Hepatic enzyme increased	5	21

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
		5	14	2	8
		1	1		
		1	1		
					1
					1
			1		
			2		1
			2		
			1		
			5	2	4
		1	1		
			1	1	4
			1		1
		2	16		1
			3		1
			2		
			1		
					1
		3	12	2	12
			2		
		1	1		
			1		
			1		
		8	36		7
		7	28	5	17
		141	721	49	197
		9	57	4	17
			1		
				1	4
		1	12	4	9

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hepatitis A virus test positive		1
Herpes simplex test positive	1	1
Histamine level increased		3
HIV test false positive	1	4
HIV test negative		1
HIV test positive	1	1
Hormone level abnormal		2
Human chorionic gonadotropin increased	1	1
Immunoglobulins abnormal		2
Immunoglobulins decreased		2
Inflammatory marker increased	4	6
Influenza A virus test positive		1
Influenza B virus test positive		1
Inspiratory capacity decreased	2	3
International normalised ratio decreased		6
International normalised ratio increased	1	10
Intraocular pressure increased		5
Intraocular pressure test abnormal	1	2
Investigation abnormal	1	1
Laboratory test abnormal	1	6
Laboratory test normal		1
Lipase decreased		1
Lipase increased		3
Lipids abnormal		1
Lipids increased		2
Liver function test abnormal		3
Liver function test increased	2	6
Low density lipoprotein increased	2	5
Lumbar puncture abnormal		1
Lymph node palpable		4
Lymphoblast count		1
Lymphocyte count abnormal		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	1		
			2		1
		1	4		
					1
		1	1		
			1		1
				1	1
			2		
			2		
		2	4	2	2
			1		
			1		
		2	3		
			4		2
		1	6		4
			4		1
		1	2		
		1	1		
		1	5		1
			1		
			1		
			2		1
			1		
			2		
			1		2
		1	5	1	1
		2	5		
					1
			4		
			1		
			2		1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lymphocyte count decreased	4	10
Lymphocyte count increased	2	6
Mammogram abnormal		1
Mast cell degranulation present		1
Mean cell haemoglobin decreased	1	1
Mean cell haemoglobin increased	1	1
Mean cell volume increased	2	3
Mean platelet volume decreased	1	3
Metabolic function test abnormal		3
Metamyelocyte count increased		1
Monocyte count abnormal		1
Monocyte count increased		6
Myelocyte count increased		1
Myocardial necrosis marker increased	5	10
Myocardial strain		1
Neurological examination normal		1
Neutrophil count abnormal		2
Neutrophil count decreased	4	10
Neutrophil count increased	1	7
Nitrite urine present		1
Norepinephrine increased		1
Orthostatic heart rate response increased		1
Oxygen consumption		1
Oxygen consumption decreased	1	3
Oxygen saturation		2
Oxygen saturation abnormal	2	12
Oxygen saturation decreased	18	93
Pancreatic enzymes increased		1
PCO2 decreased		1
Physical examination abnormal		1
Platelet count abnormal		1
Platelet count decreased	17	71

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	8	2	2
		1	4	1	2
			1		
			1		
		1	1		
		1	1		
		2	3		
		1	3		
			2		1
					1
			1		
			4		2
					1
				5	10
					1
			1		
					2
		3	7	1	3
		1	5		2
			1		
			1		
			1		
			1	1	2
			2		
		2	12		
		5	39	13	54
			1		
					1
					1
			1		
1	1	8	30	9	41

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Platelet count increased	3	12
PO2 decreased		2
Prostate examination abnormal	1	1
Prostatic specific antigen increased		1
Protein total decreased		4
Protein total increased		3
Protein urine	1	1
Protein urine present		1
Prothrombin level increased		1
Prothrombin time prolonged		4
Pulmonary arterial pressure abnormal		1
Pulse abnormal	3	20
Pulse absent		4
Pulse pressure decreased		1
Pulse pressure increased	2	3
Pulse volume decreased		1
Quality of life decreased		3
Radial pulse abnormal	1	1
Red blood cell count abnormal		2
Red blood cell count decreased	5	14
Red blood cell count increased	1	3
Red blood cell sedimentation rate abnormal		1
Red blood cell sedimentation rate increased	6	13
Red blood cells urine positive		1
Red cell distribution width decreased		1
Red cell distribution width increased		1
Renal function test abnormal	1	1
Respiratory rate decreased	1	9
Respiratory rate increased	4	30
Retinogram abnormal	1	1
SARS-CoV-1 test positive		3
SARS-CoV-2 ant body test		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	7	1	5
			1		1
		1	1		
			1		
			4		
			2		1
				1	1
			1		
					1
			3		1
					1
		2	12	1	8
					4
					1
		2	3		
			1		
			2		1
				1	1
			2		
		2	7	3	7
		1	3		
			1		
		5	8	1	5
			1		
			1		
					1
		1	1		
		1	7		2
		4	16		14
				1	1
			3		
			1		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
SARS-CoV-2 ant body test negative		54
SARS-CoV-2 ant body test positive	1	18
SARS-CoV-2 test		2
SARS-CoV-2 test false positive		4
SARS-CoV-2 test negative	1	7
SARS-CoV-2 test positive	29	312
Sensory level abnormal		2
Serum ferritin decreased		2
Serum ferritin increased		1
Sinus rhythm		1
Skin temperature		1
Skin turgor decreased		1
Streptococcus test positive	1	4
Synovial fluid analysis abnormal	1	1
Thyroid function test abnormal		4
Thyroid hormones increased		2
Thyroxine decreased		1
Thyroxine free increased	1	1
T-lymphocyte count decreased	1	1
T-lymphocyte count increased		1
Total lung capacity decreased		1
Transaminases decreased		1
Transaminases increased	2	6
Tri-iodothyronine decreased		1
Tri-iodothyronine increased	1	1
Troponin abnormal		1
Troponin I decreased		1
Troponin I increased		1
Troponin increased	12	36
Tryptase decreased		1
Tryptase increased		1
Tuberculin test positive		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			50		4
		1	17		1
			2		
			3		1
		1	7		
		14	74	15	238
			2		
					2
			1		
			1		
			1		
					1
			1	1	3
				1	1
			4		
			2		
			1		
		1	1		
				1	1
			1		
			1		
					1
		1	3	1	3
			1		
				1	1
					1
			1		
			1		
		1	5	11	31
			1		
			1		
			1		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tumour marker abnormal		1						1
Tumour marker decreased		1				1		
Tumour marker increased	1	1					1	1
Urine analysis abnormal	2	9			2	9		
Urine leukocyte esterase positive		2				2		
Urine output decreased	2	8			2	8		
Urine output increased		3				3		
Urobilinogen urine increased		1				1		
Vascular test abnormal	1	1					1	1
Viral test positive		1				1		
Vital functions abnormal	2	2			1	1	1	1
Vitamin B12 decreased		3				1		2
Vitamin B12 increased		1				1		
Vitamin D decreased		7				6		1
Weight abnormal		1				1		
Weight decreased	45	160			35	126	10	34
Weight increased	8	32			8	31		1
White blood cell count abnormal	1	3				2	1	1
White blood cell count decreased	8	27	1	1	5	19	3	8
White blood cell count increased	17	59			11	37	6	22
White blood cells urine	2	2			2	2		
White blood cells urine positive		2				2		
X-ray abnormal	1	1			1	1		
	766	4,034	2	2	508	2743	258	1291

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal loss of weight	1	1	1	1		
Acetonaemia		1		1		
Acidosis		1				1
Appetite disorder		7		7		
Decreased appetite	117	575	107	520	10	55
Dehydration	37	168	18	94	19	74
Diabetes mellitus	3	19			3	19
Diabetes mellitus inadequate control	2	7			2	7
Diabetic ketoacidosis		1				1
Diet refusal	1	2			1	2
Dyslipidaemia		1		1		
Eating disorder symptom		3		3		
Electrolyte imbalance	1	3			1	3
Failure to thrive	1	1			1	1
Feeding disorder	23	82	17	67	6	15
Fluid imbalance		1				1
Fluid intake reduced		6		4		2
Fluid overload	1	2	1	1		1
Fluid retention	2	16	1	11	1	5
Food aversion	1	4	1	4		
Food craving	1	1	1	1		
Food intolerance	1	2	1	2		
Gout	8	36	4	30	4	6
Hypercholesterolaemia	1	1	1	1		
Hyperglycaemia	2	8	1	3	1	5
Hyperlipidaemia		1				1
Hypernatraemia		1				1
Hyperphagia	1	2	1	2		
Hypocalcaemia		1				1
Hypoglycaemia	2	16	2	10		6
Hypokalaemia	1	6			1	6
Hypokalaemic syndrome		1		1		

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypomagnesaemia		1				1
Hyponatraemia		1		1		
Hyponatraemic syndrome		1		1		
Hypophagia	2	10	2	7		3
Increased appetite	4	9	4	9		
Insulin resistance		1				1
Insulin resistant diabetes		1				1
Iron deficiency	2	3	2	3		
Lactic acidosis		2		1		1
Lactose intolerance	1	1	1	1		
Latent autoimmune diabetes in adults		1				1
Malnutrition	1	2		1	1	1
Metabolic acidosis		1		1		
Obesity		1		1		
Oligodipsia		1				1
Overweight	1	5	1	4		1
Polydipsia		2		2		
Poor feeding infant		1		1		
Shock hypoglycaemic	1	1			1	1
Starvation	1	1			1	1
Tetany		2				2
Type 1 diabetes mellitus	1	3			1	3
Type 2 diabetes mellitus	1	2			1	2
Underweight	1	1	1	1		
Vitamin D deficiency		5		4		1
Weight fluctuation	1	7	1	7		
	224	1,043	169	809	55	234

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Aneurysmal bone cyst	1	1
Ankylosing spondylitis	1	2
Arthralgia	476	2,623
Arthritis	30	116
Arthritis reactive	1	2
Arthropathy	9	44
Axillary mass	7	37
Back disorder	13	27
Back pain	214	907
Bone development abnormal		1
Bone disorder		5
Bone pain	39	175
Bone swelling		9
Bursa disorder		1
Bursitis	6	18
Cervical spinal stenosis	1	1
Chondritis		1
Coccydynia	2	4
Costochondritis	4	9
Degenerative bone disease	1	2
Dupuytren's contracture		1
Extremity contracture	1	3
Facet joint syndrome		1
Facial asymmetry	1	2
Fasciitis		2
Fibromyalgia	8	22
Finger deformity	1	3
Fistula		2
Flank pain	2	21
Foot deformity	1	4
Groin pain	10	32
Growing pains	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				1	2
	1	432	2444	44	179
		21	100	9	16
				1	2
		8	42	1	2
		7	34		3
		11	25	2	2
		189	793	25	114
			1		
			4		1
		35	159	4	16
			7		2
			1		
		6	14		4
				1	1
			1		
		2	4		
		2	5	2	4
		1	2		
					1
		1	3		
			1		
		1	2		
					2
		8	20		2
		1	3		
			2		
			16	2	5
		1	4		
		8	26	2	6
		1	1		

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haemarthrosis	1	1
Hand deformity		1
Head deformity		2
Immune-mediated arthritis		1
Intervertebral disc degeneration		2
Intervertebral disc protrusion	1	8
Jaw clicking		3
Jaw cyst		1
Jaw disorder	3	12
Joint adhesion	1	1
Joint contracture	1	1
Joint effusion	2	7
Joint instability		4
Joint lock	1	11
Joint noise	3	5
Joint range of motion decreased	15	87
Joint stiffness	18	67
Joint swelling	46	199
Joint warmth	1	2
Knee deformity		1
Ligament disorder		1
Ligamentitis	1	1
Ligament pain	1	2
Limb deformity		1
Limb discomfort	62	318
Limb mass	4	20
Loose body in joint		1
Lupus-like syndrome	1	1
Lupus myositis		1
Mastication disorder	1	13
Mixed connective tissue disease	1	2
Mobility decreased	29	134

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
			1		1
					1
			2		
			4	1	4
			3		
			1		
	1	3	11		1
		1	1		
		1	1		
		2	6		1
			1		3
			10	1	1
		2	4	1	1
		12	72	3	15
		16	61	2	6
		37	170	9	29
		1	2		
			1		
					1
				1	1
			1	1	1
			1		
		61	292	1	26
		4	18		2
					1
				1	1
					1
		1	11		2
				1	2
		20	104	9	30

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Morphoea	1	1
Muscle atrophy	1	4
Muscle contracture		2
Muscle discomfort	3	25
Muscle disorder	2	27
Muscle fatigue	6	29
Muscle haemorrhage	1	1
Muscle mass		1
Muscle rigidity	4	10
Muscle spasms	99	434
Muscle swelling	5	15
Muscle tightness	31	144
Muscle twitching	32	109
Muscular weakness	76	380
Musculoskeletal chest pain	17	76
Musculoskeletal discomfort	19	105
Musculoskeletal disorder	7	25
Musculoskeletal pain	6	32
Musculoskeletal stiffness	95	414
Myalgia	411	2,568
Myokymia		2
Myopathy	1	1
Myosclerosis	1	1
Myositis	7	11
Neck deformity	1	1
Neck mass	8	23
Neck pain	129	676
Nose deformity		2
Nuchal rigidity		3
Osteitis	1	1
Osteoarthritis	1	11
Osteochondritis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			3	1	1
			2		
		3	25		
		1	22	1	5
		4	26	2	3
				1	1
			1		
		4	7		3
		87	371	12	63
		5	13		2
		27	124	4	20
		31	95	1	14
		45	271	31	109
		15	68	2	8
		16	95	3	10
		7	18		7
		6	26		6
		84	377	11	37
	1	383	2417	28	151
			2		
				1	1
				1	1
		6	7	1	4
		1	1		
		7	22	1	1
		114	601	15	75
			2		
			2		1
		1	1		
		1	11		
			1		

* I=Interval, C=Cumulative

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Osteolysis	1	1
Osteopenia	1	1
Osteoporosis		3
Pain in extremity	1,020	4,966
Pain in jaw	26	133
Periarthritis	2	5
Plantar fasciitis		2
Polyarthritis		1
Polychondritis		1
Polymyalgia rheumatica	1	9
Polymyositis		1
Posture abnormal	1	3
Psoriatic arthropathy		6
Rhabdomyolysis	5	8
Rheumatic disorder	1	2
Rheumatoid arthritis	10	52
Rotator cuff syndrome	4	6
Sacroiliitis		1
Scleroderma		2
Scoliosis	1	1
Seronegative arthritis		2
Sinus tarsi syndrome		1
Sjogren's syndrome	2	6
Snapping hip syndrome		1
Soft tissue disorder		2
Soft tissue swelling	1	3
Spinal disorder		4
Spinal osteoarthritis		2
Spinal pain	8	43
Spinal stenosis	1	4
Spondylitis	2	4
Still's disease		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1		
			3		
	3	943	4710	77	256
	1	23	116	3	17
		2	4		1
			2		
					1
					1
				1	9
					1
		1	3		
1	1				6
				5	8
		1	2		
5	6			10	52
		3	4	1	2
			1		
					2
		1	1		
					2
			1		
				2	6
			1		
			2		
		1	3		
			2		2
			2		
		7	38	1	5
			3	1	1
		2	2		2
1	1				1

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Synovial cyst	1	2			1	2		
Synovitis		1				1		
Systemic lupus erythematosus	2	13	1	1			2	13
Systemic scleroderma		1						1
Temporomandibular joint syndrome		4				2		2
Tendon discomfort		1				1		
Tendonitis	7	19			3	14	4	5
Tendon pain	1	7				5	1	2
Tenosynovitis		2				2		
Torticollis		1				1		
Trigger finger	2	10			1	9	1	1
Trismus	1	12			1	9		3
Undifferentiated connective tissue disease		1						1
Weight bearing difficulty	2	4			2	3		1
Winged scapula		1				1		
	3,091	15,481	8	16	2739	14056	352	1425

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myeloid leukaemia		4				4
Adenoma benign		1		1		
Basal cell carcinoma		1				1
Blast cell crisis		1				1
Bone neoplasm		2		1		1
Brain cancer metastatic		1				1
Brain neoplasm	1	1			1	1
Breast cancer	1	3			1	3
Breast cancer metastatic		1				1
Cardiac neoplasm unspecified		1				1
Chronic lymphocytic leukaemia	1	3			1	3
Chronic myeloid leukaemia recurrent		1				1
Colon cancer		1				1
Cutaneous T-cell lymphoma	1	1			1	1
Ear neoplasm		1		1		
Endometrial cancer	1	2			1	2
Good syndrome		1				1
Haemangioma		1				1
Inflammatory carcinoma of the breast	1	1			1	1
Leukaemia	1	6			1	6
Leukaemia recurrent		1				1
Lipoma		2		1		1
Lung carcinoma cell type unspecified recurrent	1	1			1	1
Lung carcinoma cell type unspecified stage I		1				1
Lung neoplasm malignant		3				3
Lymphoma	1	5			1	5
Malignant melanoma	1	1			1	1
Melanocytic naevus	1	1	1	1		
Melanoma recurrent		2				2
Metastases to meninges		1				1
Monoclonal gammopathy		1		1		
Neoplasm	1	10	1	9		1

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neoplasm malignant	5	16			5	16
Neoplasm progression	1	4		1	1	3
Neoplasm recurrence	1	1	1	1		
Neoplasm skin	1	4	1	4		
Non-Hodgkin's lymphoma		2				2
Ovarian cancer		1				1
Pancreatic carcinoma metastatic	1	1			1	1
Pituitary tumour benign		1				1
Plasma cell myeloma	1	2			1	2
POEMS syndrome	1	1			1	1
Prostate cancer		5				5
Salivary gland neoplasm	1	1			1	1
Schwannoma		1				1
Skin cancer	2	2			2	2
Thyroid cancer	1	2			1	2
Tumour pain	2	2			2	2
Uterine leiomyoma	1	1			1	1
	30	110	4	21	26	89

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acoustic neuritis		2				1		1
Acute disseminated encephalomyelitis		2						2
Adrenergic syndrome		1				1		
Ageusia	45	261			41	237	4	24
Agnosia	1	1			1	1		
Allodynia		1				1		
Altered state of consciousness		7						7
Amnesia	19	64			14	46	5	18
Anaesthesia		3				3		
Anosmia	31	211			28	187	3	24
Aphasia	14	53			8	26	6	27
Apraxia	1	1			1	1		
Arachnoid cyst		1						1
Areflexia	1	3				1	1	2
Ataxia	2	8				3	2	5
Aura	2	5			2	4		1
Autonomic nervous system imbalance	2	6				2	2	4
Autonomic neuropathy	1	2					1	2
Balance disorder	51	218			40	173	11	45
Basal ganglia haemorrhage		3						3
Basal ganglia infarction		1						1
Basal ganglia stroke		2						2
Basilar artery thrombosis	1	1					1	1
Bell's palsy	85	348				4	85	344
Brachial plexopathy		3				1		2
Bradykinesia	3	8			3	8		
Brain injury	1	8					1	8
Brain oedema	7	12					7	12
Brain stem haemorrhage	1	2					1	2
Brain stem infarction	1	2					1	2
Brain stem stroke		1						1
Brain stem syndrome		2						2

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Brown-Sequard syndrome	1	1
Burning sensation	121	409
Burning sensation mucosal	1	2
Carotid artery occlusion		1
Carpal tunnel syndrome	3	8
Central nervous system lesion	1	3
Central pain syndrome		1
Cerebellar ataxia		1
Cerebellar haemorrhage	1	1
Cerebellar stroke		3
Cerebral arteriosclerosis	1	1
Cerebral artery embolism		1
Cerebral artery occlusion	1	3
Cerebral artery stenosis	1	1
Cerebral atrophy	1	1
Cerebral disorder	8	18
Cerebral haematoma	1	1
Cerebral haemorrhage	6	23
Cerebral infarction		3
Cerebral thrombosis	8	17
Cerebral venous sinus thrombosis	1	5
Cerebrospinal fluid leakage		1
Cerebrovascular accident	67	241
Cerebrovascular disorder		1
Cervical radiculopathy	1	3
Cervicobrachial syndrome		1
Cervicogenic vertigo	1	1
Chorea		1
Chronic inflammatory demyelinating polyradiculoneuropathy	1	3
Circadian rhythm sleep disorder		3
Clonus	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		92	334	29	75
		1	2		
					1
		2	6	1	2
			1	1	2
			1		
			1		
				1	1
					3
				1	1
					1
				1	3
				1	1
				1	1
		7	16	1	2
				1	1
				6	23
					3
				8	17
				1	5
					1
				67	241
					1
		1	2		1
			1		
		1	1		
					1
				1	3
			2		1
			1	1	1

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Clumsiness	1	6
Cluster headache		4
Cognitive disorder	14	50
Cold-stimulus headache		1
Coma	3	7
Complex regional pain syndrome		1
Consciousness fluctuating		1
Coordination abnormal	6	18
Cranial nerve disorder		2
Cranial nerve paralysis		1
Dementia	3	21
Dementia Alzheimer's type	1	3
Demyelinating polyneuropathy		3
Demyelination	1	1
Depressed level of consciousness		14
Diabetic coma		1
Diabetic neuropathy		1
Diplegia	3	5
Disturbance in attention	22	100
Dizziness	641	3,271
Dizziness exertional	2	4
Dizziness postural	7	48
Dreamy state		1
Drooling	1	9
Dropped head syndrome		1
Dysaesthesia	3	10
Dysarthria	25	71
Dysgeusia	55	355
Dysgraphia		4
Dyskinesia	9	52
Dyslexia	1	2
Dysstasia	26	121

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	5		1
			3		1
		12	35	2	15
			1		
				3	7
			1		
					1
		4	11	2	7
			1		1
					1
				3	21
				1	3
					3
				1	1
					14
					1
			1		
				3	5
		20	83	2	17
2	3	555	2830	86	441
		2	4		
		6	43	1	5
			1		
		1	8		1
					1
		3	9		1
		17	42	8	29
		48	331	7	24
			3		1
		9	44		8
		1	2		
		20	81	6	40

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dystonia	2	9
Electric shock sensation	10	26
Embolic stroke	3	5
Encephalomalacia		1
Encephalopathy	1	4
Epilepsy	2	4
Essential tremor	1	1
Exaggerated startle response	1	2
Facial nerve disorder		6
Facial neuralgia	1	5
Facial paralysis	19	115
Facial paresis	2	19
Facial spasm	2	6
Febrile convulsion		2
Fine motor skill dysfunction		5
Formication	2	18
Freezing phenomenon	1	7
Generalised tonic-clonic seizure	8	17
Gross motor delay	1	1
Guillain-Barre syndrome	11	38
Haemorrhage intracranial	1	2
Haemorrhagic stroke	1	7
Hand-eye coordination impaired		1
Headache	1,524	7,734
Head discomfort	63	226
Head titubation	1	4
Hemianaesthesia		
Hemiparesis	7	26
Hemiplegia	2	9
Hemiplegic migraine	1	1
Hyperaesthesia	7	41
Hyperreflexia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	9
		8	24	2	2
				3	5
					1
				1	4
				2	4
		1	1		
		1	2		
			2		4
		1	4		1
			2	19	113
		1	12	1	7
			2	2	4
					2
			4		1
		2	16		2
		1	7		
				8	17
				1	1
				11	38
				1	2
				1	7
					1
		1443	7252	81	482
		58	199	5	27
		1	4		
1	1				
1	1			7	26
				2	9
		1	1		
		5	38	2	3
			1		

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypersomnia	27	151
Hypertonia		3
Hypoaesthesia	274	1,150
Hypogeusia	2	14
Hypokinesia	5	40
Hyporeflexia		1
Hyporesponsive to stimuli		2
Hyposmia		6
Hypotonia		4
Hypoxic-ischaemic encephalopathy		1
Idiopathic intracranial hypertension	1	2
IIIrd nerve paralysis	2	5
Immune-mediated neuropathy	1	1
Incoherent	3	15
Infant irritability		4
Intellectual disability	1	1
Intracranial aneurysm		3
Intracranial hypotension	1	1
Intracranial mass		1
Intracranial pressure increased	1	5
Intraventricular haemorrhage		1
Irregular sleep wake rhythm disorder		2
Ischaemic cerebral infarction		1
Ischaemic stroke	4	16
IVth nerve paralysis		2
Lacunar infarction		1
Lacunar stroke		1
Lethargy	76	365
Loss of consciousness	137	471
Loss of proprioception		1
Lumbar radiculopathy		2
Memory impairment	35	111

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		23	137	4	14
			2		1
		220	921	54	229
		2	13		1
		3	31	2	9
					1
			1		1
			6		
			4		
					1
				1	2
				2	5
				1	1
		1	6	2	9
			3		1
				1	1
					3
		1	1		
					1
				1	5
					1
			2		
					1
				4	16
					2
					1
					1
		73	338	3	27
1	1	2	3	135	468
					1
			2		
		30	93	5	18

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Meningeal disorder		1
Meningism		1
Meningitis noninfective		1
Mental impairment	16	65
Meralgia paraesthetica		1
Metabolic encephalopathy		1
Migraine	95	461
Migraine with aura	2	8
Migraine without aura		1
Mononeuropathy		1
Mononeuropathy multiplex	1	1
Monoparesis		1
Monoplegia	8	16
Motor dysfunction	6	19
Movement disorder	54	183
Multiple sclerosis	9	20
Multiple sclerosis relapse	3	9
Muscle contractions involuntary	3	11
Muscle spasticity	1	4
Myasthenia gravis		4
Myelitis transverse	5	17
Myelopathy		1
Myoclonus	1	6
Narcolepsy		2
Nerve compression	1	25
Nervous system disorder	14	37
Neuralgia	31	136
Neuralgic amyotrophy	3	6
Neuritis	4	8
Neurological symptom	7	22
Neuromyelitis optica spectrum disorder		2
Neuropathy peripheral	26	106

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
					1
				16	65
					1
					1
		72	392	23	69
		2	6		2
			1		
					1
				1	1
					1
				8	16
		4	10	2	9
		44	155	10	28
				9	20
				3	9
		2	8	1	3
		1	3		1
					4
				5	17
					1
			1	1	5
					2
		1	21		4
		10	26	4	11
		25	111	6	25
		2	3	1	3
		3	7	1	1
		2	12	5	10
					2
		2	2	24	104

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Noninfective encephalitis	2	7
Nystagmus	2	7
Occipital neuralgia	1	4
Oculofacial paralysis		1
Ophthalmic migraine	3	12
Optic neuritis	1	8
Oromandibular dystonia		1
Orthostatic intolerance		1
Paraesthesia	230	1,186
Paraesthesia mucosal		1
Paralysis	22	66
Paraplegia		2
Paresis		1
Parkinsonism	1	3
Parkinson's disease	2	6
Parosmia	19	79
Paroxysmal sympathetic hyperactivity		1
Patient elopement	1	2
Peripheral paralysis		1
Peripheral sensory neuropathy	1	4
Peroneal nerve palsy	2	8
Phantom limb syndrome		1
Polyneuropathy		3
Post herpetic neuralgia	2	4
Postictal state		2
Post-traumatic neuralgia		1
Presyncope	40	205
Primary headache associated with sexual activity		1
Psychomotor hyperactivity	1	9
Radial nerve palsy		1
Radiculitis brachial	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	7
		2	5		2
		1	3		1
					1
		2	11	1	1
				1	8
			1		
			1		
		193	1001	37	185
			1		
			2	22	64
					2
					1
			1	1	2
				2	6
		14	69	5	10
					1
		1	2		
					1
			1	1	3
		1	4	1	4
			1		
					3
		1	3	1	1
			1		1
			1		
		26	149	14	56
					1
		1	7		2
			1		
				2	4

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Reduced facial expression	1	4
Repetitive speech	1	1
Restless legs syndrome	1	14
Ruptured cerebral aneurysm	1	3
Sciatica	7	32
Sciatic nerve neuropathy		1
Sedation		10
Seizure	73	212
Seizure like phenomena	3	7
Senile dementia	1	1
Sensorimotor disorder		1
Sensory disturbance	8	38
Sensory loss	10	32
Serotonin syndrome		1
Sinus headache	3	37
Sleep deficit	1	7
Sleep paralysis		2
Slow response to stimuli	1	2
Slow speech	1	4
Small fibre neuropathy	1	3
Somnolence	102	460
Speech disorder	33	159
Speech disorder developmental	2	2
Spinal cord disorder	2	6
Status epilepticus	1	1
Status migrainosus	1	1
Stupor	1	1
Subarachnoid haemorrhage	1	7
Superior sagittal sinus thrombosis		1
Syncope	100	398
Tardive dyskinesia	2	3
Taste disorder	19	125

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	3
		1	1		
		1	13		1
				1	3
		3	21	4	11
			1		
			9		1
				73	212
				3	7
				1	1
					1
		7	35	1	3
		7	20	3	12
					1
		3	37		
		1	7		
			2		
		1	2		
		1	4		
			1	1	2
		96	424	6	36
		17	100	16	59
		2	2		
				2	6
				1	1
				1	1
		1	1		
				1	7
					1
1	1	3	4	97	394
				2	3
		17	111	2	14

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System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tension headache	5	25			5	23		2
Thalamic infarction		1						1
Thoracic outlet syndrome		1				1		
Thrombotic stroke	1	3					1	3
Thunderclap headache		1						1
Tongue biting		2				1		1
Tongue paralysis		4						4
Tonic clonic movements		1						1
Transient global amnesia		2				2		
Transient ischaemic attack	11	49					11	49
Transverse sinus stenosis		1						1
Transverse sinus thrombosis	1	1					1	1
Tremor	126	623	1	2	104	502	22	121
Trigeminal nerve disorder		5				3		2
Trigeminal neuralgia	2	13			1	7	1	6
Trigeminal neuritis		1				1		
Tunnel vision	3	21					3	21
Unresponsive to stimuli	4	33					4	33
Vagus nerve disorder		1						1
Vascular dementia		1						1
Vertebral artery dissection		1						1
Vestibular migraine		1				1		
Vibratory sense increased		1				1		
VIIIth nerve lesion		1						1
VIth nerve paralysis	1	7					1	7
Vocal cord paralysis		1						1
Vocal cord paresis		1				1		
White matter lesion		2						2
	4,717	22,109	7	9	3502	17104	1215	5005

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion		1				1
Abortion missed		1				1
Abortion spontaneous	19	49			19	49
Abortion threatened	1	1			1	1
Cervical incompetence	1	1			1	1
Ectopic pregnancy	1	1			1	1
Foetal death	3	7			3	7
Foetal growth restriction	3	4			3	4
Foetal hypokinesia		2				2
Morning sickness		1				1
Postpartum disorder		1		1		
Pre-eclampsia	1	1			1	1
Premature baby	2	8			2	8
Premature delivery		1				1
Premature labour		2				2
Premature rupture of membranes	1	2			1	2
Uterine contractions during pregnancy		2		1		1
	32	85		2	32	83

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Product issues

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Device breakage		1				1
Device issue		1		1		
Device leakage		1		1		
Lead dislodgement	1	1			1	1
Liquid product physical issue		11		11		
Needle issue	2	16	2	15		1
Oversensing		2		2		
Product colour issue		5		5		
Product complaint	1	7	1	7		
Product compounding quality issue		1		1		
Product container issue		2		2		
Product expiration date issue	1	1	1	1		
Product formulation issue		1				1
Product label issue	1	1	1	1		
Product leakage	4	20	4	20		
Product lot number issue		1		1		
Product odour abnormal		1		1		
Product packaging issue	1	1	1	1		
Product packaging quantity issue		4		4		
Product quality issue	3	20	3	20		
Product supply issue	7	41	7	41		
Product temperature excursion issue	143	348	143	348		
Suspected counterfeit product		2		2		
Syringe issue	1	8	1	8		
	165	497	164	493	1	4

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Abnormal behaviour	5	16
Abnormal dreams	6	43
Abnormal sleep-related event	1	1
Abulia	1	1
Acute stress disorder	1	1
Affective disorder		2
Affect lability	1	3
Aggression	3	10
Agitation	6	32
Anger	10	21
Anhedonia		1
Anxiety	88	369
Anxiety disorder		2
Apathy	1	9
Attention deficit hyperactivity disorder	2	2
Autism spectrum disorder		1
Autoscopy	1	5
Behaviour disorder		2
Belligerence		1
Bipolar disorder	1	2
Bradyphrenia	1	10
Bruxism	1	2
Catatonia		2
Change in sustained attention		1
Claustrophobia		1
Communication disorder	2	8
Completed suicide	2	3
Confusional state	37	202
Conversion disorder		1
Coprolalia	1	1
Daydreaming		3
Decreased interest	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	11	1	5
		6	39		4
		1	1		
		1	1		
		1	1		
			2		
		1	1		2
		1	6	2	4
		5	30	1	2
		10	18		3
			1		
		82	332	6	37
			1		1
		1	8		1
		2	2		
					1
		1	4		1
					2
					1
				1	2
		1	7		3
		1	2		
			1		1
			1		
		1	4	1	4
				2	3
		26	145	11	57
			1		
		1	1		
			3		
		1	3		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Delirium	7	40
Delirium febrile		1
Delusion	1	7
Delusional disorder, unspecified type	1	1
Delusional perception	1	5
Depersonalisation/derealisation disorder		3
Depressed mood	16	53
Depression	17	51
Derealisation		1
Discouragement		1
Disorganised speech	1	3
Disorientation	24	111
Dissociation		5
Distract bility	2	2
Disturbance in social behaviour		2
Dysphemia	5	14
Eating disorder	24	81
Emotional disorder	6	25
Emotional distress	3	9
Enuresis	1	2
Euphoric mood	3	18
Fear	6	43
Fear of death	1	2
Fear of falling	1	2
Fear of injection		2
Flat affect	2	2
Frustration tolerance decreased	8	24
Generalised anxiety disorder		3
Hallucination	19	67
Hallucination, auditory	1	10
Hallucination, visual	3	17
Head banging	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	7	39
					1
		1	4		3
				1	1
		1	4		1
			3		
	1	15	50	1	3
		14	42	3	9
			1		
			1		
		1	1		2
		14	71	10	40
			4		1
		2	2		
			2		
		3	8	2	6
		20	63	4	18
		6	23		2
		2	6	1	3
		1	2		
		3	17		1
		5	38	1	5
		1	1		1
		1	2		
			2		
		2	2		
		8	23		1
			3		
		1	1	18	66
				1	10
				3	17
		1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hostility	1	2
Hydrophobia		1
Hypersexuality	1	1
Hypersomnia-bulimia syndrome	1	1
Hypervigilance		2
Illness anxiety disorder		1
Illusion	1	1
Impatience	1	1
Imperception		1
Impulsive behaviour		1
Inappropriate affect		1
Initial insomnia	1	10
Insomnia	155	650
Intentional self-injury	1	1
Intrusive thoughts		1
Irritability	15	47
Lack of spontaneous speech	2	5
Laziness	1	5
Listless		4
Major depression	1	4
Mania	2	5
Mental disorder	5	23
Mental fatigue	1	4
Mental status changes	3	10
Middle insomnia	5	46
Mood altered	3	7
Mood swings		4
Mutism		4
Near death experience	16	42
Neglect of personal appearance		1
Nervousness	42	185
Nightmare	9	48

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		1
			1		
		1	1		
				1	1
			2		
			1		
		1	1		
		1	1		
			1		
			1		
			1		
			9	1	1
		137	582	18	68
				1	1
			1		
		12	42	3	5
		1	1	1	4
		1	5		
			4		
				1	4
		2	4		1
		4	18	1	5
		1	4		
		2	8	1	2
		5	44		2
		3	7		
			2		2
			3		1
				16	42
			1		
		40	174	2	11
		9	45		3

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Obsessive-compulsive personality disorder	1	1
Obsessive thoughts		1
Panic attack	18	57
Panic disorder	2	8
Panic reaction	3	22
Paranoia	4	14
Paranoid personality disorder		1
Personality change	1	5
Poor quality sleep	12	66
Post-traumatic stress disorder		2
Posturing		1
Pressure of speech		2
Psychiatric symptom		1
Psychotic disorder	2	7
Reading disorder	2	2
Restlessness	4	60
Schizophrenia		1
Self-injurious ideation		1
Sitophobia		1
Sleep attacks		1
Sleep disorder	35	163
Sleep disorder due to a general medical condition	4	13
Sleep disorder due to general medical condition, insomnia type	1	4
Sleep talking		2
Sleep terror	1	2
Soliloquy	2	2
Somatic symptom disorder		3
Somnambulism	1	2
Speech sound disorder		1
Staring	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
		15	45	3	12
		2	8		
		3	21		1
		4	13		1
			1		
		1	3		2
		12	65		1
			2		
					1
			1		1
			1		
		2	4		3
		2	2		
		3	52	1	8
					1
			1		
			1		
			1		
		33	155	2	8
		4	13		
		1	4		
			2		
		1	2		
		2	2		
			3		
		1	2		
			1		
			1	1	4

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* AE=Adverse Event

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Stress	12	54			11	51	1	3
Substance abuse		1						1
Suicidal behaviour	1	1					1	1
Suicidal ideation	10	22			1	1	9	21
Suicide attempt		1						1
Tachyphrenia		6				6		
Tearfulness		2				2		
Tension	4	11			3	10	1	1
Terminal insomnia		4				4		
Thanatophobia		1				1		
Thinking abnormal	14	55			12	50	2	5
Tic	3	7			2	5	1	2
	731	3,105		1	586	2507	145	598

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System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	2	13		1	2	12
Bladder discomfort	1	4	1	3		1
Bladder disorder	1	7		6	1	1
Bladder dysfunction		1		1		
Bladder hypertrophy	1	1			1	1
Bladder pain		3		3		
Bladder spasm		1		1		
Chromaturia	7	25	6	24	1	1
Chronic kidney disease		5				5
Costovertebral angle tenderness		1		1		
Dysuria	7	33	4	26	3	7
Glomerulonephritis minimal lesion		1				1
Haematuria	3	12		4	3	8
Haemorrhage urinary tract	8	14			8	14
Hydronephrosis		1				1
IgA nephropathy	1	1			1	1
Incontinence	2	9	1	5	1	4
Micturition disorder	1	4	1	2		2
Micturition frequency decreased		1		1		
Micturition urgency	2	10	1	7	1	3
Nephritis	2	2			2	2
Nephrolithiasis	9	32			9	32
Nephropathy	1	6	1	2		4
Nephrotic syndrome		1				1
Nocturia		4		3		1
Oliguria		1		1		
Pollakiuria	8	47	6	45	2	2
Polyuria	1	12	1	10		2
Proteinuria		3		2		1
Renal atrophy		2				2
Renal cyst	1	3	1	2		1
Renal disorder	5	24	1	13	4	11

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* AE=Adverse Event

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System Organ Class

Renal and urinary disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal failure	8	22			8	22
Renal haemorrhage		1				1
Renal impairment	6	15			6	15
Renal infarct		1				1
Renal injury		1				1
Renal pain	13	42	10	35	3	7
Renal tubular disorder		1				1
Renal tubular injury		1				1
Stress urinary incontinence	1	2	1	2		
Ureteric stenosis		1				1
Urethral disorder		1		1		
Urethral haemorrhage		1				1
Urethritis noninfective	1	1	1	1		
Urge incontinence		2		2		
Urinary bladder haemorrhage	1	2			1	2
Urinary incontinence	9	35	7	27	2	8
Urinary retention	6	13			6	13
Urinary tract disorder		2		2		
Urine abnormality	1	5	1	5		
Urine odour abnormal	4	6	4	5		1
	113	439	48	243	65	196

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System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal uterine bleeding	1	1			1	1
Abnormal withdrawal bleeding		1		1		
Adnexa uteri pain		3		3		
Amenorrhoea	4	5	4	5		
Anisomastia		1		1		
Breast cyst		1		1		
Breast discharge		4		4		
Breast discomfort	3	9	3	8		1
Breast disorder	1	6		5	1	1
Breast engorgement		1		1		
Breast enlargement	1	1	1	1		
Breast haematoma		1		1		
Breast induration	1	3	1	3		
Breast mass	1	15	1	13		2
Breast milk discolouration		1		1		
Breast pain	26	97	23	91	3	6
Breast swelling	6	23	6	22		1
Breast tenderness	8	17	8	16		1
Dysmenorrhoea	17	31	14	27	3	4
Dyspareunia		1		1		
Endometrial thickening		1		1		
Endometriosis	1	2			1	2
Erectile dysfunction	2	12			2	12
Erection increased		1				1
Female reproductive tract disorder	1	1			1	1
Galactostasis	1	1	1	1		
Genital haemorrhage		1				1
Genital lesion		1		1		
Genital rash		1		1		
Genital swelling		1		1		
Genital ulceration		1		1		
Haemospermia		1		1		

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System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heavy menstrual bleeding	50	86	36	68	14	18
Hypomenorrhoea		1		1		
Infertility female		1				1
Intermenstrual bleeding	11	26	10	23	1	3
Menopausal symptoms		1		1		
Menstrual discomfort		1		1		
Menstrual disorder	39	66	35	60	4	6
Menstruation delayed	12	16	10	13	2	3
Menstruation irregular	44	69	41	66	3	3
Nipple exudate bloody		1		1		
Nipple pain	1	10	1	10		
Nipple swelling		4		4		
Oligomenorrhoea	5	5	4	4	1	1
Orchitis noninfective		1		1		
Ovarian cyst	2	3	2	2		1
Ovarian cyst ruptured	1	1			1	1
Ovarian disorder		1				1
Ovarian enlargement		1		1		
Ovarian vein thrombosis	1	1			1	1
Ovulation disorder	1	1	1	1		
Pelvic discomfort		1		1		
Pelvic pain	4	19	3	17	1	2
Penile erythema	1	1	1	1		
Penile haemorrhage	1	2			1	2
Penile rash	1	1	1	1		
Penile swelling	1	1	1	1		
Penis disorder	1	2	1	2		
Polymenorrhoea	8	11	7	10	1	1
Postmenopausal haemorrhage	13	21			13	21
Premenstrual syndrome	2	8	2	8		
Prostatic disorder	1	1	1	1		
Prostatitis	1	1			1	1

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* AE=Adverse Event

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System Organ Class

Reproductive system and breast disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Prostatomegaly		1		1		
Pruritus genital		1				1
Scrotal dermatitis		1		1		
Scrotal disorder		1		1		
Scrotal erythema		1		1		
Scrotal inflammation		1		1		
Scrotal pain		2		2		
Suppressed lactation		1		1		
Testicular disorder	2	2	2	2		
Testicular pain	5	9	5	8		1
Testicular swelling	2	5	2	4		1
Uterine disorder	1	1	1	1		
Uterine haemorrhage	5	7			5	7
Uterine inflammation		1				1
Uterine pain	2	3	2	2		1
Uterine spasm		1		1		
Vaginal discharge		2		2		
Vaginal disorder		1		1		
Vaginal haemorrhage	19	51	13	35	6	16
Vaginal lesion	1	2		1	1	1
Varicocele		1		1		
Vulval disorder		1		1		
Vulvovaginal burning sensation	2	3	1	1	1	2
Vulvovaginal discomfort	1	1			1	1
Vulvovaginal dryness	1	1	1	1		
Vulvovaginal erythema	1	1	1	1		
Vulvovaginal pain	4	6	3	4	1	2
Vulvovaginal pruritus	1	2	1	1		1
Vulvovaginal rash	1	2	1	1		1
Vulvovaginal swelling	2	4	1	2	1	2
Withdrawal bleed		1		1		
	325	728	253	590	72	138

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acute pulmonary oedema		1
Acute respiratory distress syndrome		3
Acute respiratory failure	1	3
Agonal respiration	1	1
Allergic cough	1	2
Allergic respiratory disease		1
Allergic sinusitis		2
Aphonia	10	40
Apnoea	2	4
Asphyxia		1
Aspiration	2	4
Asthma	27	119
Asthma exercise induced		1
Atelectasis	3	10
Bronchial disorder		1
Bronchial oedema		1
Bronchospasm	1	34
Choking	1	22
Choking sensation	1	14
Chronic obstructive pulmonary disease	4	17
Cough	212	1,023
Diaphragmalgia	2	5
Diaphragmatic disorder		2
Diaphragmatic paralysis		1
Dry throat	11	59
Dysphonia	22	166
Dyspnoea	352	1,613
Dyspnoea at rest		3
Dyspnoea exertional	6	31
Emphysema	1	3
Epistaxis	40	160
Grunting		10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					3
1	1			1	3
				1	1
		1	2		
			1		
			2		
		7	26	3	14
				2	4
					1
				2	4
		22	92	5	27
			1		
		1	3	2	7
			1		
		1	19		15
	1			1	22
			9	1	5
	1	3	8	1	9
	1	186	891	26	132
		2	5		
			2		
					1
		11	54		5
		17	117	5	49
	2	232	1054	120	559
					3
		3	22	3	9
		1	2		1
		36	129	4	31
			8		2

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haemoptysis	6	30
Hiccups	1	10
Hydrothorax	1	1
Hyperactive pharyngeal reflex		1
Hyperventilation	14	45
Hypopnoea	4	18
Hypoxia	2	17
Increased bronchial secretion		1
Increased upper airway secretion	1	10
Increased viscosity of bronchial secretion	1	2
Increased viscosity of upper respiratory secretion		3
Intranasal hypoaesthesia		1
Intranasal paraesthesia	1	4
Irregular breathing		2
Laryngeal discomfort		1
Laryngeal oedema		5
Laryngeal pain	2	4
Laryngospasm		4
Lower respiratory tract congestion	1	4
Lung disorder	10	37
Lung hyperinflation		2
Lung infiltration		4
Lung opacity		4
Meconium aspiration syndrome	1	1
Mediastinal mass	1	1
Nasal congestion	77	426
Nasal crusting		1
Nasal discharge discolouration		1
Nasal discomfort	8	38
Nasal disorder	1	8
Nasal dryness	4	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	16	5	14
		1	9		1
				1	1
			1		
		11	35	3	10
		4	13		5
				2	17
			1		
			6	1	4
		1	1		1
			2		1
			1		
		1	4		
			2		
			1		
					5
		2	4		
			1		3
		1	4		
		5	28	5	9
			2		
			1		3
			3		1
				1	1
		1	1		
		74	397	3	29
			1		
			1		
		6	33	2	5
		1	7		1
		4	9		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nasal mucosal disorder		1
Nasal oedema	2	21
Nasal pruritus	3	8
Nocturnal dyspnoea	1	1
Obstructive airways disorder	3	10
Organising pneumonia	1	2
Oropharyngeal blistering	2	5
Oropharyngeal cobble stone mucosa		1
Oropharyngeal discomfort	21	100
Oropharyngeal pain	131	740
Oropharyngeal plaque	1	1
Oropharyngeal spasm	1	4
Oropharyngeal swelling		2
Orthopnoea		1
Painful respiration	2	18
Paranasal sinus discomfort	13	48
Paranasal sinus hypersecretion	3	10
Paranasal sinus hyposecretion		1
Pharyngeal disorder	2	9
Pharyngeal enanthema		2
Pharyngeal erythema	1	19
Pharyngeal haemorrhage		2
Pharyngeal hypoaesthesia	2	21
Pharyngeal inflammation	1	6
Pharyngeal mass		6
Pharyngeal oedema	1	11
Pharyngeal paraesthesia	3	32
Pharyngeal swelling	49	245
Pharyngeal ulceration	1	2
Pleural effusion	7	17
Pleurisy	4	10
Pleuritic pain	1	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	14	1	7
		3	7		1
		1	1		
		1	2	2	8
				1	2
				2	5
			1		
		16	84	5	16
		121	690	10	50
		1	1		
				1	4
			1		1
					1
			10	2	8
		10	45	3	3
		3	10		
			1		
		2	8		1
			2		
		1	18		1
					2
		1	14	1	7
			5	1	1
			5		1
			5	1	6
		2	23	1	9
		32	146	17	99
		1	2		
		1	3	6	14
		1	4	3	6
			5	1	2

* I=Interval, C=Cumulative

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pneumonia aspiration	2	7
Pneumonitis	5	10
Pneumothorax	3	7
Productive cough	12	75
Pulmonary artery occlusion		1
Pulmonary artery thrombosis		1
Pulmonary congestion	3	25
Pulmonary embolism	41	127
Pulmonary fibrosis		7
Pulmonary hypertension		2
Pulmonary infarction	1	3
Pulmonary mass		4
Pulmonary oedema	11	31
Pulmonary pain	18	43
Pulmonary thrombosis	21	55
Pulmonary venous thrombosis		1
Respiration abnormal	3	16
Respiratory arrest	3	18
Respiratory disorder	7	48
Respiratory disorder neonatal		1
Respiratory distress	2	56
Respiratory failure		11
Respiratory symptom		6
Respiratory tract congestion	5	44
Respiratory tract inflammation		1
Respiratory tract irritation		3
Respiratory tract oedema	1	8
Restrictive pulmonary disease		1
Rhinalgia	5	17
Rhinitis allergic	2	6
Rhinorrhoea	74	480
Sinus congestion	5	44

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	7
		3	4	2	6
				3	7
		10	68	2	7
					1
					1
			1	3	24
				41	127
1	1				7
	1				2
				1	3
			2		2
		1	2	10	29
		17	35	1	8
				21	55
					1
		3	15		1
				3	18
		5	29	2	19
					1
				2	56
					11
			4		2
		4	39	1	5
			1		
			2		1
				1	8
					1
		5	16		1
		2	5		1
		74	457		23
		4	41	1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sinus disorder	11	71
Sinus pain	7	28
Sleep apnoea syndrome		2
Sneezing	37	182
Snoring		3
Sputum discoloured	1	10
Sputum increased		1
Status asthmaticus		1
Stridor		10
Suffocation feeling		2
Tachypnoea		36
Throat clearing	1	11
Throat irritation	52	274
Throat lesion	2	2
Throat tightness	59	324
Tonsillar disorder	1	5
Tonsillar erythema		1
Tonsillar hypertrophy	3	10
Tonsillar inflammation	1	3
Tonsillar ulcer		1
Tonsillolith	1	2
Tracheal stenosis	1	1
Tracheomalacia		1
Upper-airway cough syndrome	2	28
Upper airway obstruction		3
Upper respiratory tract congestion	9	48
Use of accessory respiratory muscles		6
Vocal cord disorder	1	4
Vocal cord dysfunction		1
Vocal cord inflammation	1	1
Wheezing	25	149
Yawning	3	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		10	66	1	5
		7	28		
			1		1
		34	174	3	8
			2		1
			5	1	5
			1		
					1
			5		5
			2		
			23		13
		1	7		4
		45	216	7	58
		2	2		
		34	184	25	140
			3	1	2
			1		
		1	8	2	2
		1	3		
			1		
		1	2		
				1	1
					1
		2	26		2
					3
		9	45		3
			3		3
				1	4
			1		
				1	1
		19	100	6	49
		3	3		

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
	1,534	7,799	2	8	1131	5773	403	2026

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* I=Interval, C=Cumulative
 * AE=Adverse Event
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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acne	10	35			9	33	1	2
Acute febrile neutrophilic dermatosis		2						2
Alopecia	9	46			9	40		6
Alopecia areata	1	3			1	3		
Alopecia universalis		2				2		
Angioedema	10	80			1	1	9	79
Angiokeratoma		1				1		
Angiolymphoid hyperplasia with eosinophilia		1				1		
Blister	34	128			25	102	9	26
Blister rupture	1	1			1	1		
Blood blister	3	11			3	8		3
Butterfly rash		3				2		1
Circumoral swelling	2	5			2	5		
Cold sweat	32	168			31	152	1	16
Cold urticaria	1	1			1	1		
Cutaneous lupus erythematosus		1						1
Cutaneous vasculitis	2	7				1	2	6
Dermatitis	7	30			6	26	1	4
Dermatitis acneiform	1	4				3	1	1
Dermatitis allergic	2	13			1	10	1	3
Dermatitis atopic	1	5			1	5		
Dermatitis bullous	1	1					1	1
Dermatitis contact	3	14			3	14		
Dermatitis diaper		1						1
Dermatitis exfoliative		1						1
Dermatomyositis		3						3
Diabetic wound		1						1
Diffuse alopecia		1						1
Drug eruption		5				4		1
Dry skin	20	57			19	52	1	5
Ecchymosis	1	6			1	6		
Eczema	9	25			7	22	2	3

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Erythema	171	839
Erythema marginatum		1
Erythema multiforme	3	10
Erythema nodosum	2	4
Erythrodermic psoriasis	1	1
Granuloma annulare		1
Granuloma skin		1
Haemorrhage subcutaneous	1	3
Haemorrhagic urticaria		1
Hair disorder		1
Hair growth abnormal		1
Hair texture abnormal	1	1
Henoch-Schonlein purpura	2	4
Hidradenitis		2
Hyperhidrosis	172	817
Hypersensitivity vasculitis		2
Hypertrichosis		1
Idiopathic urticaria	1	1
Keratosis pilaris	1	3
Lichenoid keratosis		1
Lichen planus		1
Lichen sclerosus		1
Livedo reticularis	1	8
Macule	1	6
Madarosis		1
Mechanical urticaria	1	2
Miliaria	3	11
Nail discolouration	1	7
Night sweats	26	162
Onychalgia		1
Onychoclasia		2
Pain of skin	19	62

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		147	721	24	118
			1		
				3	10
		1	3	1	1
		1	1		
			1		
					1
				1	3
					1
			1		
			1		
		1	1		
				2	4
			2		
		155	727	17	90
					2
			1		
				1	1
		1	3		
					1
			1		
			1		
			4	1	4
		1	6		
			1		
		1	2		
		3	11		
		1	6		1
		25	151	1	11
			1		
			2		
		18	57	1	5

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Palmar erythema		8
Palpable purpura		1
Panniculitis	1	1
Papule	4	8
Peau d'orange	1	1
Pemphigoid	3	5
Pemphigus	1	3
Perivascular dermatitis		1
Petechiae	5	36
Photosensitivity reaction	8	27
Pigmentation disorder		4
Piloerection	6	17
Pityriasis		1
Pityriasis rosea	2	5
Plantar erythema		2
Post inflammatory pigmentation change		1
Pruritus	341	1,576
Pseudofolliculitis	1	1
Psoriasis	5	22
Purpura	3	10
Rash	371	1,681
Rash erythematous	50	231
Rash macular	49	195
Rash maculo-papular	4	20
Rash morbilliform	4	16
Rash neonatal		1
Rash papular	18	82
Rash pruritic	64	252
Rash vesicular	6	29
Rosacea	1	7
Scab	10	21
Seborrhoea		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			7		1
			1		
				1	1
		3	7	1	1
		1	1		
				3	5
				1	3
			1		
		2	21	3	15
1	1	7	22	1	5
			3		1
		6	16		1
			1		
		2	5		
			2		
			1		
		286	1367	55	209
		1	1		
		5	20		2
		2	8	1	2
		313	1446	58	235
		43	194	7	37
		46	172	3	23
		4	19		1
		2	9	2	7
			1		
		17	76	1	6
		52	217	12	35
		6	25		4
			6	1	1
		8	18	2	3
			1		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sensitive skin	9	37
Skin atrophy	1	1
Skin burning sensation	21	73
Skin depigmentation	1	4
Skin discharge	1	1
Skin discolouration	27	113
Skin discomfort		3
Skin disorder	20	77
Skin erosion	1	2
Skin exfoliation	12	46
Skin fissures	1	5
Skin haemorrhage	1	11
Skin hyperpigmentation	1	3
Skin hypertrophy	2	3
Skin indentation		3
Skin irritation	11	38
Skin laxity		2
Skin lesion	9	37
Skin mass	7	16
Skin odour abnormal	1	5
Skin oedema		1
Skin reaction	7	21
Skin sensitisation	2	4
Skin swelling	5	19
Skin texture abnormal		1
Skin tightness	2	13
Skin ulcer	1	5
Skin warm	4	15
Skin weeping	3	3
Skin wrinkling	1	3
Solar lentigo		1
Splinter haemorrhages		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		7	35	2	2
		1	1		
		16	66	5	7
		1	4		
		1	1		
		24	91	3	22
			3		
		19	68	1	9
		1	2		
		9	40	3	6
		1	4		1
			9	1	2
		1	3		
		2	3		
			3		
		10	37	1	1
			2		
		8	35	1	2
		6	14	1	2
		1	5		
			1		
		6	16	1	5
		2	4		
		4	16	1	3
			1		
		2	11		2
		1	5		
		4	15		
		2	2	1	1
		1	3		
					1
			1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Stevens-Johnson syndrome	3	6					3	6
Sticky skin		1				1		
Trichorrhexis	1	1			1	1		
Urticaria	295	998			243	801	52	197
Urticaria chronic	2	3			1	2	1	1
Urticaria thermal		1				1		
Vasculitic rash	1	2			1	2		
Yellow skin	1	6			1	4		2
	1,969	8,472	1	1	1659	7182	310	1290

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System Organ Class

Social circumstances

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden	12	50	9	42	3	8
Caffeine consumption		1		1		
Contraindication to medical treatment		1		1		
Contraindication to vaccination		11		11		
Disability		2		1		1
Drug abuser	1	1			1	1
Exercise lack of		1		1		
Hearing disability	1	4		3	1	1
Immobile	5	11			5	11
Impaired driving ability	5	25	4	20	1	5
Impaired quality of life		1				1
Impaired work ability	9	29	7	24	2	5
Job dissatisfaction		1		1		
Loss of employment		1		1		
Loss of personal independence in daily activities	54	206	38	166	16	40
Menopause		2		2		
Sitting disability	1	8	1	7		1
Tanning		1		1		
Tobacco user	1	1	1	1		
Urinary assistance device user		1		1		
Wa king aid user	2	7	2	6		1
Wa king disability	4	9	1	5	3	4
Water pollution		1		1		
	95	375	63	296	32	79

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

SOC Not Yet Coded

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
	1	5	1	5
	1	5	1	5

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* AE=Adverse Event
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System Organ Class

Surgical and medical procedures

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal operation		1		1		
Appendectomy		1		1		
Asthma prophylaxis		2		1		1
Bed rest	1	6	1	6		
Contraceptive diaphragm		1		1		
Cooling therapy		1		1		
COVID-19 immunisation		4		4		
Drainage	4	6	4	6		
Emergency care	1	1	1	1		
Endodontic procedure	1	1	1	1		
Haemodialysis		1		1		
Hernia repair		1				1
Hospitalisation		1				1
Hysterectomy		1				1
Immunisation		3		3		
Joint stabilisation		1				1
Knee operation		1				1
Limb immobilisation	1	1	1	1		
Local anaesthesia		1		1		
Sinus operation		1		1		
Skin lesion removal		1		1		
Spinal fusion surgery		1				1
Surgery	1	1	1	1		
Tooth extraction		4		4		
Wound closure		1		1		
	9	44	9	37		7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Aneurysm	1	4					1	4
Aneurysm ruptured		1						1
Angiopathy		5				4		1
Aortic arteriosclerosis		1				1		
Aortic disorder		1						1
Aortitis		1						1
Arterial occlusive disease		1						1
Arterial stenosis	2	2					2	2
Arterial thrombosis		1						1
Arteriosclerosis		2						2
Artery dissection	1	1					1	1
Blood pressure fluctuation	10	42			8	32	2	10
Blue toe syndrome		3						3
Capillary disorder		1				1		
Capillary fragility		1				1		
Circulatory collapse	1	7					1	7
Cyanosis	4	28			2	18	2	10
Deep vein thrombosis	39	111					39	111
Diastolic hypotension		1						1
Embolism		2						2
Essential hypertension		1				1		
Fibromuscular dysplasia	1	1					1	1
Flushing	39	390			30	314	9	76
Haematoma		14				13		1
Haemorrhage	37	101				2	37	99
Hot flush	47	219			44	200	3	19
Hyperaemia		1				1		
Hypertension	86	404		1	44	227	42	177
Hypertensive crisis		5						5
Hypertensive emergency		4						4
Hypotension	33	126			19	64	14	62
Hypovolaemic shock		2						2

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Infarction	2	2
Internal haemorrhage	1	6
Ischaemia	1	1
Jugular vein thrombosis	1	1
Kawasaki's disease	1	1
Labile blood pressure	1	1
Labile hypertension		1
Lymphoedema	3	18
Malignant hypertension		1
May-Thurner syndrome		1
Microembolism		2
Obstructive shock		1
Orthostatic hypertension	1	1
Orthostatic hypotension	1	9
Pallor	17	89
Peripheral arterial occlusive disease		1
Peripheral artery thrombosis	2	4
Peripheral coldness	20	118
Peripheral ischaemia		2
Peripheral vascular disorder		3
Peripheral venous disease	2	7
Phlebitis		4
Phlebitis superficial	1	3
Poor peripheral circulation	1	9
Poor venous access		1
Raynaud's phenomenon	4	11
Shock	2	19
Shock symptom	1	5
Subclavian vein thrombosis	1	1
Superficial vein prominence		2
Systolic hypertension		1
Thrombophlebitis		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
				1	6
				1	1
				1	1
				1	1
				1	1
			1		
		3	18		
					1
					1
					2
					1
				1	1
			4	1	5
		15	68	2	21
					1
			1	2	3
		15	104	5	14
			1		1
			3		
		2	6		1
			4		
		1	3		
			6	1	3
			1		
		3	9	1	2
				2	19
				1	5
				1	1
			1		1
			2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Thrombophlebitis superficial	2	14			1	7	1	7
Thrombosis	139	310	1	2			139	310
Varicose vein	2	8			2	7		1
Vascular occlusion		1						1
Vascular pain		3				2		1
Vascular rupture	1	2			1	2		
Vasculitis	3	5			2	4	1	1
Vasodilatation	2	3			2	3		
Vein discolouration	1	4			1	4		
Vein disorder	7	15			7	14		1
Vein rupture		1						1
Vein wall hypertrophy	1	1					1	1
Venous thrombosis limb	1	3					1	3
	523	2,182	1	3	202	1154	321	1028

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

UNITED STATES MINOR OUTLYING ISLA

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal pain upper		1		1
Diarrhoea		1		1
		2		2

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vaccination site pain		1		1
		1		1

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pain in extremity		1		1
		1		1

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dizziness		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

URUGUAY

System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fatigue	1	1	1	1
Inflammation		1		1
Pain	1	2	1	2
Pyrexia	1	1	1	1
	3	5	3	5

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Maternal exposure during pregnancy	2	2	2	2
	2	2	2	2

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Synovial cyst		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headache	1	1	1	1
Paraesthesia	1	1	1	1
	2	2	2	2

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pruritus	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

APPENDIX 2.5.2: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per Age Group by Preferred Term per Country

Cumulative Reporting Period: Through 31-MAY-2021

Interval Reporting Period: 30-APR-2021 Through 31-MAY-2021

Total Number of Cases: 47,174 (Interval) / 167,956 (Cumulative)

Total Number of Adverse Events (PT): 174,177 (Interval) / 631,356 (Cumulative)

MedDRA Version: v.24.0J

Country Where Event Occurred

AFGHANISTAN

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills		1		1		
Erythema		1		1		
Facial paralysis		1				1
Feeling of body temperature change		1		1		
Muscle tightness		1		1		
Paraesthesia		1		1		
Pruritus		1		1		
Rash		1		1		
Swelling face		1		1		
		9		8		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ALBANIA

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Off label use		1		1
Product use issue		1		1
		2		2

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19		2		2
		2		2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

AMERICAN SAMOA

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills		1		1
Pain		1		1
		2		2

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Feeling cold	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ANDORRA

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product administered to patient of inappropriate age		1		1

1

1

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ANGOLA

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inappropriate schedule of product administration		1		1		
Nasopharyngitis		1				1
Pyrexia		1				1
Swollen tongue		1				1
Vomiting		1				1
		5		1		4

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ARGENTINA

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19	1	1	1	1
Influenza	1	1	1	1
	2	2	2	2

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	1			1	1
Diabetes mellitus	1	1			1	1
Drug ineffective	1	1			1	1
Gait disturbance	1	1	1	1		
Gait inability	1	1	1	1		
Intervertebral disc protrusion	1	1			1	1
Lung disorder	1	1	1	1		
Malaise	1	1	1	1		
Mobility decreased	1	1	1	1		
Pain	1	1	1	1		
Pruritus	1	1	1	1		
Pulmonary thrombosis	1	1			1	1
Pyrexia	1	1	1	1		
Thyroid disorder	1	1	1	1		
	14	14	9	9	5	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	1	1	1	1		
Diabetes mellitus		1				1
Hypersensitivity		1		1		
Hypertension	1	1	1	1		
Injection site erythema	1	1	1	1		
Intentional product misuse		1		1		
Rash papular	1	1	1	1		
SARS-CoV-2 ant body test negative		1		1		
	4	8	4	7		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood immunoglobulin G decreased		1		1		
Blood immunoglobulin M decreased		1		1		
Blood pressure increased	1	1			1	1
Circumstance or information capable of leading to medication error		1		1		
Cognitive disorder	1	1			1	1
Confusional state	1	1			1	1
COVID-19	1	1	1	1		
Dizziness	1	1			1	1
Drug ineffective	1	1			1	1
Headache	1	1			1	1
Hot flush	1	1			1	1
Hyperhidrosis	1	1			1	1
Memory impairment	1	1			1	1
Motor dysfunction	1	1			1	1
Nausea	1	1			1	1
Pain in extremity		1		1		
Pyrexia	1	1			1	1
Suspected COVID-19	1	1			1	1
Thunderclap headache	1	1			1	1
Vertigo	1	1			1	1
	16	20	1	5	15	15

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

AUSTRALIA

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposure via breast milk		1		1		
Respiratory distress		1				1
Wheezing		1		1		
		3		2		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	2	1	2		
Adrenocortical insufficiency acute		1				1
Anaphylactic reaction	2	6			2	6
Angioedema	1	1			1	1
Anxiety		1				1
Apnoea		1				1
Arthralgia	2	5	2	5		
Arthritis	1	1	1	1		
Blood thyroid stimulating hormone increased	1	1	1	1		
Cellulitis	1	1			1	1
Chest pain	1	2	1	2		
Chills	2	8	2	8		
Contusion	1	1	1	1		
Cough	1	4	1	4		
Cyanosis		1		1		
Diarrhoea		2		2		
Dizziness	1	10	1	9		1
Dyspnoea	4	5	4	5		
Erythema		2		2		
Extensive swelling of vaccinated limb	1	1	1	1		
Eye discharge		1		1		
Eye pain		1		1		
Eye pruritus	1	1	1	1		
Facial paresis	1	1	1	1		
Fatigue	4	12	4	12		
Feeling abnormal		1		1		
Feeling of body temperature change		1		1		
Flushing		1		1		
Hallucination		1				1
Headache	9	25	9	25		
Heart rate increased	1	1	1	1		
Hyperhidrosis		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia oral	1	1	1	1		
Hypoglycaemia		1		1		
Hypotension	1	2	1	2		
Influenza like illness		1		1		
Insomnia		1		1		
Joint stiffness		1		1		
Lethargy	6	12	6	12		
Limb discomfort	1	1	1	1		
Loss of consciousness		1				1
Lymphadenopathy		3		3		
Malaise	1	3	1	3		
Myalgia	3	13	3	13		
Nausea	3	12	3	11		1
Neutrophil count decreased		1		1		
Ocular hyperaemia		1		1		
Oropharyngeal pain	1	2	1	2		
Pain		1		1		
Pain in extremity		2		2		
Paraesthesia		2		2		
Paraesthesia oral	1	1	1	1		
Pericarditis	1	1			1	1
Presyncope	1	5	1	3		2
Pruritus	1	2	1	2		
Pyrexia	6	14	6	14		
Rash	4	5	4	5		
Rash pruritic	1	1	1	1		
Rectal haemorrhage		1				1
Rhinorrhoea		1		1		
Seizure		1				1
Sinus tachycardia		1		1		
Somatic symptom disorder		1				1
Somnolence		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling	2	2	2	2		
Syncope	5	9			5	9
Systemic lupus erythematosus	1	1			1	1
Tachycardia	1	1	1	1		
Throat tightness	2	3	2	3		
Urticaria	2	3	2	3		
Vaccination site bruising		1		1		
Vaccination site erythema		1		1		
Vaccination site pain		5		5		
Vaccination site reaction	2	10	2	10		
Vaccination site swelling	1	4	1	4		
Vomiting		2		2		
White blood cell count decreased		1		1		
	84	242	73	211	11	31

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	4	7	4	6		1
Ageusia	2	2	2	2		
Anaphylactic reaction	5	11			5	11
Angioedema	3	4			3	4
Anxiety		3		1		2
Aphasia	1	1	1	1		
Appendicitis		1				1
Arthralgia	10	21	10	21		
Asthenia	3	4	3	4		
Back pain		1		1		
Balance disorder		1				1
Bell's palsy	1	1			1	1
Blood pressure increased		2		1		1
Body temperature increased		2		2		
Bradycardia	1	1			1	1
Burning sensation	1	1	1	1		
Cardiac arrest		1				1
Cerebral venous sinus thrombosis	1	1			1	1
Chest discomfort	4	7	4	7		
Chest pain	3	4	3	4		
Chills	8	15	8	15		
Condition aggravated	2	2	1	1	1	1
Conjunctival haemorrhage	2	2			2	2
Contusion		2		2		
Cough	8	12	8	12		
COVID-19		1		1		
Deafness neurosensory	1	1			1	1
Deafness unilateral	1	1			1	1
Decreased appetite		1		1		
Deep vein thrombosis	5	7			5	7
Demyelination	1	2			1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea	5	5	5	5		
Dizziness	6	14	6	12		2
Dry throat		1		1		
Dysarthria		1				1
Dysphagia		1		1		
Dyspnoea	8	11	8	10		1
Ear pain	1	1	1	1		
Endometriosis	1	1			1	1
Erythema	2	3	2	3		
Extensive swelling of vaccinated limb		1		1		
Eye pruritus		1		1		
Face oedema		1		1		
Facial pain		1		1		
Facial paralysis		1				1
Fatigue	7	21	7	21		
Febrile neutropenia	1	1			1	1
Feeling abnormal		1				1
Feeling hot	2	3	2	3		
Feeling of body temperature change		1		1		
Flushing	1	5	1	5		
Gastrointestinal disorder	1	1	1	1		
Haematemesis		1				1
Haemorrhage	1	1			1	1
Hallucination	1	1			1	1
Hallucination, tactile		1				1
Headache	23	49	23	49		
Herpes zoster	1	1	1	1		
Hyperaldosteronism	1	1			1	1
Hyperhidrosis	2	5	2	5		
Hypertension	2	5	2	5		
Hypoaesthesia	1	3	1	3		
Injection site hypersensitivity	1	1	1	1		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lethargy	13	17	13	17		
Liver function test abnormal	1	1	1	1		
Loss of consciousness	1	1			1	1
Lower respiratory tract infection	1	1			1	1
Lymphadenopathy	1	3	1	3		
Malaise	1	5	1	4		1
Migraine	1	3	1	3		
Monoplegia	1	2			1	2
Multiple sclerosis		1				1
Multiple sclerosis relapse		1				1
Muscle tightness		2		2		
Musculoskeletal stiffness		1		1		
Myalgia	14	31	14	31		
Nausea	6	14	6	14		
Neck pain	1	2	1	2		
Nerve injury		1		1		
Nystagmus	1	1	1	1		
Odynophagia		1		1		
Oedema	1	1	1	1		
Oropharyngeal pain	1	3	1	3		
Pain	1	3	1	3		
Pain in extremity	2	4	2	4		
Pallor	1	1	1	1		
Palpitations		1		1		
Paraesthesia	2	9	2	9		
Paraesthesia oral	1	2	1	2		
Petit mal epilepsy	1	1			1	1
Pharyngeal swelling	1	1	1	1		
Pharyngitis	1	1	1	1		
Photophobia		1		1		
Photosensitivity reaction		1		1		
Platelet count increased	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Presyncope		4		4		
Pruritus	4	7	3	6	1	1
Pulmonary embolism	1	2			1	2
Pupil fixed		1				1
Pyrexia	15	29	15	29		
Rash	9	15	9	15		
Rash macular		1				1
Renal impairment	1	1			1	1
Respiratory rate increased		1				1
Rhinorrhoea	1	1	1	1		
Sensation of foreign body		1		1		
Sensory disturbance		1		1		
Sepsis	1	2			1	2
Skin sensitisation		1		1		
Sweating fever	1	1			1	1
Swelling	2	2	2	2		
Swollen tongue	1	1	1	1		
Syncope	11	17			11	17
Tachycardia	1	2	1	2		
Throat irritation	2	3	2	3		
Throat tightness	1	2	1	2		
Thrombocytopenia	1	1			1	1
Thrombophlebitis		1		1		
Thrombosis	2	2			2	2
Thunderclap headache	1	1	1	1		
Transient ischaemic attack		1				1
Tremor		1		1		
Trigeminal neuralgia		1		1		
Urticaria	3	5	3	5		
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema		1		1		
Vaccination site pain	3	10	3	10		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site reaction	9	24	9	24		
Vaccination site swelling		1		1		
Vaccination site vesicles		1		1		
Vision blurred	1	2	1	2		
Visual acuity reduced	1	1	1	1		
Visual impairment		1		1		
Vomiting	1	7	1	6		1
Wheezing		2		2		
	265	545	215	453	50	92

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain	1	5	1	5		
Abdominal pain lower		1		1		
Ageusia		2		2		
Anaphylactic reaction	2	9			2	9
Anxiety		1				1
Aphonia	1	1	1	1		
Arrhythmia		1				1
Arthralgia	1	6	1	6		
Asthenia		1		1		
Back pain	1	1	1	1		
Blood pressure increased	1	3	1	2		1
Cellulitis	1	1			1	1
Chest discomfort	2	4	2	3		1
Chest pain	1	2	1	2		
Chills	2	6	2	6		
Circumstance or information capable of leading to medication error		1		1		
Cold sweat		2		2		
Confusional state		1		1		
Conjunctival haemorrhage	1	1			1	1
Cough	2	4	2	4		
Crying		1		1		
Deafness		1				1
Deep vein thrombosis	1	1			1	1
Depressed mood		1		1		
Diarrhoea	2	3	2	3		
Dizziness		7		5		2
Dry throat		1		1		
Dysphonia		1		1		
Dyspnoea	3	5	3	4		1
Ear pain	1	2	1	2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Epilepsy	1	1			1	1
Eye pain		2		2		
Facial paralysis		1				1
Fatigue	5	9	5	9		
Feeling abnormal		1		1		
Feeling cold		1		1		
Feeling hot	1	4	1	3		1
Feeling jittery		1		1		
Feeling of body temperature change		1		1		
Fibrin D dimer increased	1	1	1	1		
Flushing		1		1		
Gait disturbance		1		1		
Headache	7	21	7	19		2
Hyperhidrosis		2		2		
Hypertension		8		7		1
Hypoaesthesia	1	3	1	3		
Hypoaesthesia oral	1	2	1	1		1
Illness		1		1		
Inadequate aseptic technique in use of product		1		1		
Incontinence		1		1		
Inflammation		1		1		
Influenza like illness	1	2	1	2		
Joint swelling		1		1		
Laryngitis		1		1		
Lethargy	3	10	3	9		1
Lower respiratory tract infection	1	1			1	1
Lymphadenopathy	1	4	1	4		
Malaise	2	3	2	3		
Myalgia	3	9	3	9		
Nausea	1	7	1	7		
Neck pain	1	2	1	2		
Nephrolithiasis	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nervousness		1		1		
Ocular discomfort		1		1		
Oral herpes		1		1		
Oropharyngeal pain		1		1		
Orthostatic tremor		1		1		
Oxygen saturation decreased		1		1		
Pain	1	2	1	2		
Pain in extremity	1	1	1	1		
Palpitations		2		2		
Paraesthesia		5		5		
Paraesthesia oral	2	4	2	3		1
Pharyngeal swelling	1	1	1	1		
Poor quality product administered		1		1		
Presyncope		3		3		
Pruritus	1	3	1	3		
Pyrexia	2	7	2	7		
Rash	2	5	2	5		
Rhinorrhoea	1	4	1	4		
Rhinovirus infection		1		1		
Scar		1		1		
Seizure	2	2			2	2
Seizure like phenomena	1	1			1	1
Sinus congestion	1	1	1	1		
Swollen tongue		1				1
Syncope	3	5			3	5
Tachycardia		3		1		2
Tachypnoea		1		1		
Throat irritation	1	1	1	1		
Throat tightness		1				1
Thrombophlebitis		1		1		
Thrombosis	2	2			2	2
Tinnitus		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tonsillitis		1		1		
Tremor		1		1		
Urticaria	1	1	1	1		
Vaccination site discomfort		1		1		
Vaccination site erythema		1		1		
Vaccination site hypersensitivity	1	1	1	1		
Vaccination site pain	1	5	1	5		
Vaccination site pruritus		1		1		
Vaccination site reaction	3	10	3	10		
Venous thrombosis		1		1		
Vertigo		1		1		
Vertigo positional		1				1
Visual impairment		1		1		
Vomiting		1		1		
Wheezing	2	3	2	3		
	83	278	67	232	16	46

* I=Interval, C=Cumulative
* AE=Adverse Event
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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	2	1	2		
Adverse event following immunisation	1	1			1	1
Altered state of consciousness		1				1
Anaemia	1	1	1	1		
Asthenia		1		1		
Bicytopenia	1	1			1	1
Blood pressure increased	1	1	1	1		
Cardiac arrest		1				1
Cellulitis	1	1			1	1
Cerebral haemorrhage	1	1			1	1
Chest pain	2	2	1	1	1	1
Chills	1	2	1	2		
Cold sweat		1		1		
Concomitant disease aggravated	1	2			1	2
Condition aggravated		2				2
Confusional state	1	1	1	1		
Consciousness fluctuating		1				1
Contusion		1				1
Cough		1		1		
Death	3	3			3	3
Deep vein thrombosis	2	2			2	2
Depressed level of consciousness		2				2
Diarrhoea		1		1		
Dizziness	1	1	1	1		
Dyskinesia		1		1		
Dysphagia		1				1
Dyspnoea	2	2			2	2
Dysuria	1	1	1	1		
Facial paralysis		1				1
Fall	1	2	1	1		1
Fatigue	2	3	2	3		
Gait disturbance	1	1	1	1		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
General physical health deterioration		2				2
Haemorrhage	1	1			1	1
Headache	2	4	2	4		
Hypertension		1		1		
Hypotension	1	2		1	1	1
Joint swelling	1	1	1	1		
Lethargy	1	2	1	2		
Loss of consciousness	1	3			1	3
Lymphocyte count increased	1	1	1	1		
Malaise	1	1	1	1		
Mouth ulceration	1	1	1	1		
Myalgia		1				1
Nausea		4		4		
Oxygen saturation decreased	1	1	1	1		
Peripheral swelling	1	1			1	1
Pneumonia aspiration	1	1			1	1
Productive cough	1	1	1	1		
Pulmonary embolism	1	1			1	1
Pupil fixed		1				1
Pyrexia	3	7	2	3	1	4
Rash		3		2		1
Rectal haemorrhage	2	2			2	2
Respiratory failure	1	1			1	1
Respiratory rate increased	1	1	1	1		
Seizure	1	1			1	1
Sepsis	1	2			1	2
Somnolence	1	2			1	2
Splenomegaly	1	1	1	1		
Swelling	1	1	1	1		
Tachycardia	2	3	1	1	1	2
Tachypnoea		1				1
Thrombocytopenia	2	2			2	2

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tremor	1	2	1	2		
Unresponsive to stimuli		1				1
Urinary tract infection	1	1			1	1
Vaccination site erythema		1				1
Vaccination site pain		1				1
Vaccination site reaction	1	1	1	1		
Vaccination site swelling		1				1
Vision blurred	1	1	1	1		
Vomiting		2		2		
Weight decreased		1				1
Wheezing	1	1	1	1		
	61	115	31	54	30	61

* I=Interval, C=Cumulative
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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose		2		2		
Acute coronary syndrome		1				1
Acute kidney injury	1	2			1	2
Acute pulmonary oedema		1				1
Adverse event following immunisation	2	4			2	4
Agitation	1	1			1	1
Anaphylactic reaction	1	2			1	2
Anxiety		1				1
Aphasia		1				1
Areflexia		1				1
Arrhythmia	1	1			1	1
Aspiration		1				1
Body temperature decreased	1	1			1	1
Body temperature increased	1	1			1	1
Bradycardia	1	1			1	1
Cardiac arrest	2	5			2	5
Cardiogenic shock	2	2			2	2
Cerebral haemorrhage		1				1
Cerebrovascular accident	2	4			2	4
Circulatory collapse		1				1
Cognitive disorder		1				1
Cold sweat		2				2
Coma scale abnormal	2	3			2	3
Concomitant disease progression	5	5			5	5
Condition aggravated		1				1
Confusional state		2		1		1
Contusion	2	2	1	1	1	1
Cough		4		2		2
Cyanosis	1	2			1	2
Death	9	14			9	14
Decreased appetite		2				2
Deep vein thrombosis	3	3			3	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Depressed level of consciousness	3	5			3	5
Diabetic ketoacidosis		1				1
Disease progression	1	2	1	1		1
Disseminated intravascular coagulation	1	1			1	1
Dizziness	1	1	1	1		
Drooling		1				1
Dysarthria	1	3			1	3
Dysphagia		1				1
Dyspnoea	6	13	2	2	4	11
Facial paralysis		1				1
Fall	4	7		1	4	6
Fatigue	1	3	1	2		1
Fine motor skill dysfunction	1	1			1	1
Flushing		1		1		
Foaming at mouth		1				1
General physical health deterioration	1	3			1	3
Heart rate increased		1				1
Hyperglycaemia		1				1
Hyperglycaemic hyperosmolar nonketotic syndrome		1				1
Hyperhidrosis		1				1
Hypertension		2		2		
Hypophagia	1	2			1	2
Hyporesponsive to stimuli		1				1
Hypotension	3	5	1	1	2	4
Hypoxia	1	2			1	2
Incoherent	1	1			1	1
Intestinal obstruction	1	1			1	1
Ischaemic stroke		2				2
Lethargy	1	2			1	2
Lip swelling		1		1		
Loss of consciousness	3	6			3	6

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* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lower respiratory tract infection	1	1			1	1
Malaise	1	6			1	6
Monoplegia		1				1
Multiple organ dysfunction syndrome		1				1
Mydriasis		2				2
Myocardial infarction	1	2			1	2
Nausea	2	3	1	2	1	1
Oedema peripheral	1	2			1	2
Oropharyngeal pain		1		1		
Oxygen saturation decreased	2	6	2	2		4
Pain	2	2			2	2
Pallor	1	1			1	1
Pelvic fracture		1				1
Peripheral swelling	1	1			1	1
Pneumonia	1	10			1	10
Pneumonia aspiration	2	4			2	4
Pneumothorax	1	1			1	1
Product preparation error		2		2		
Pulmonary congestion		1				1
Pulmonary embolism	1	2			1	2
Pulmonary sepsis		1				1
Pupil fixed		1				1
Pupils unequal		1				1
Pyrexia	1	5		2	1	3
Rales		1				1
Respiratory distress		1				1
Respiratory failure		3				3
Respiratory rate increased		1				1
Rhinorrhoea		2		2		
Seizure	2	3			2	3
Sepsis	2	2			2	2
Septic shock		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Somnolence		2		1		1
Subdural haemorrhage	1	1			1	1
Swelling face		1		1		
Terminal state	3	3			3	3
Throat tightness	1	1	1	1		
Tremor		1		1		
Unresponsive to stimuli	3	9			3	9
Urinary incontinence		1				1
Urosepsis		2				2
Urticaria	2	2	2	2		
Vaccination site bruising	1	1	1	1		
Vaccination site pain	1	2	1	2		
Vaccination site reaction	2	2	2	2		
Vision blurred	1	1			1	1
Vomiting	2	12	1	3	1	9
Wheezing	1	2			1	2
	108	264	18	43	90	221

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	9	16	9	16		
Abdominal pain upper		1		1		
Abdominal sepsis	1	1			1	1
Abdominal tenderness		1		1		
Abortion spontaneous	2	2			2	2
Acute kidney injury		1				1
Acute macular outer retinopathy	1	1			1	1
Ageusia	2	2	2	2		
Agitation		1		1		
Amaurosis fugax	1	1			1	1
Anal haemorrhage		1		1		
Anaphylactic reaction	16	52			16	52
Angina pectoris	1	1			1	1
Angioedema	7	9			7	9
Anosmia	1	1	1	1		
Anxiety		2		2		
Aphonia	2	2	2	2		
Aphthous ulcer	1	1	1	1		
Apnoea	1	1			1	1
Arrhythmia	1	2			1	2
Arthralgia	35	65	35	65		
Asthenia	1	6	1	6		
Asthma	6	7	6	7		
Atrioventricular block complete	1	1			1	1
Axillary pain		1		1		
Back pain	2	4	2	4		
Balance disorder	1	2	1	2		
Bell's palsy	5	7			5	7
Blister	1	1	1	1		
Blood blister	1	1	1	1		
Blood creatine phosphokinase increased		1				1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood disorder		1		1		
Blood pressure decreased		2		2		
Blood pressure immeasurable	1	1			1	1
Blood pressure increased	3	5	3	5		
Bradycardia	2	6			2	6
Brain stem stroke	2	2			2	2
Bronchitis	1	1	1	1		
Bronchospasm	1	2	1	2		
Burning sensation	1	2	1	2		
Cardiac fibrillation	1	1			1	1
Cellulitis		2				2
Cerebrovascular accident	3	8			3	8
Chest discomfort	16	25	16	25		
Chest pain	4	11	4	11		
Chills	22	47	22	46		1
Chronic obstructive pulmonary disease	1	1	1	1		
Circumstance or information capable of leading to medication error	1	1	1	1		
Cold sweat	2	7	2	6		1
Concomitant disease progression	1	1	1	1		
Confusional state	1	3	1	3		
Conjunctival haemorrhage		2				2
Contusion	1	5	1	5		
Cough	42	63	42	63		
COVID-19	1	2			1	2
Deafness	1	3			1	3
Deafness neurosensory	1	1			1	1
Deafness unilateral		2				2
Death	1	2			1	2
Decreased appetite	2	6	1	5	1	1
Deep vein thrombosis	12	13			12	13
Delirium		2				2

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Depressed level of consciousness	1	2			1	2
Dermatitis allergic		1		1		
Dermatitis bullous	1	1			1	1
Diabetes mellitus		1				1
Diabetic ketoacidosis	1	1			1	1
Diarrhoea	10	19	10	19		
Disorientation		2		2		
Dizziness	24	48	24	47		1
Drug ineffective	1	2			1	2
Dry eye	1	1	1	1		
Dry mouth	1	2	1	2		
Dry throat	1	1	1	1		
Dysgeusia	3	5	3	5		
Dysphagia	1	2		1	1	1
Dysphonia	3	5	3	5		
Dyspnoea	52	69	51	65	1	4
Ear pain	1	1	1	1		
Epistaxis	2	3	2	3		
Erythema	4	10	4	10		
Extensive swelling of vaccinated limb	3	4	3	3		1
Eye pain		1		1		
Eye pruritus		1		1		
Eye swelling	1	1	1	1		
Face oedema	1	1	1	1		
Facial paralysis	2	5			2	5
Facial paresis	1	6	1	2		4
Fall	2	3	2	3		
Fatigue	42	81	42	81		
Feeling abnormal	1	3	1	3		
Feeling cold	1	1	1	1		
Feeling hot	2	6	2	6		
Feeling of body temperature change	1	2	1	2		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling of despair	1	1	1	1		
Fibrin D dimer increased	2	2	2	2		
Flushing	10	17	10	17		
Foaming at mouth	1	1	1	1		
Food refusal		1		1		
Gait disturbance	2	4	2	4		
Gastrointestinal haemorrhage		1				1
Generalised tonic-clonic seizure	3	3			3	3
Haemorrhage	1	1			1	1
Haemorrhage intracranial	1	1			1	1
Hallucination	1	2			1	2
Hangover	1	1	1	1		
Headache	77	146	77	146		
Head discomfort		1		1		
Heart rate increased	2	5	2	5		
Heart rate irregular		1				1
Hemiparesis	1	2			1	2
Hemiplegia	1	1			1	1
Herpes zoster		2		2		
Hot flush	4	7	4	7		
Hyperhidrosis	1	8	1	8		
Hyperkalaemia	1	1			1	1
Hypersensitivity	4	8	4	8		
Hypertension	8	22	8	22		
Hyperthyroidism	2	4			2	4
Hypoaesthesia	3	7	3	7		
Hypoaesthesia oral	1	1	1	1		
Hypopnoea		2		2		
Hypotension	1	10	1	9		1
Hypoxia		2				2
Influenza like illness	4	7	4	7		
Injected limb mobility decreased		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site discomfort	1	1	1	1		
Injection site pain		2		2		
Injection site reaction		2		2		
Insomnia	2	5	2	5		
Iridocyclitis		1				1
Lacunar infarction	1	1			1	1
Laryngitis	1	1	1	1		
Lethargy	54	82	54	82		
Limb discomfort	2	4	2	4		
Lip oedema	1	1	1	1		
Lip swelling	7	9	7	9		
Liver function test increased		1		1		
Liver injury		1				1
Localised oedema		1		1		
Local reaction	1	1	1	1		
Loss of consciousness		3				3
Lower respiratory tract infection	9	9			9	9
Lymphadenopathy	10	22	10	21		1
Lymph node pain	1	1	1	1		
Lymphoedema	1	1	1	1		
Malaise	6	13	6	13		
Maternal exposure during pregnancy	1	1	1	1		
Menstruation irregular	2	2	1	1	1	1
Migraine	2	4	2	4		
Migraine with aura		1		1		
Miliaria	1	1	1	1		
Mobility decreased		1		1		
Multiple organ dysfunction syndrome	1	1			1	1
Multiple sclerosis	1	2			1	2
Muscle injury	1	1	1	1		
Muscle spasms		2		2		
Muscle twitching		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscular weakness	1	2	1	2		
Musculoskeletal stiffness	1	2	1	2		
Myalgia	72	114	72	114		
Myalgia intercostal	1	1	1	1		
Myocardial infarction	1	1			1	1
Myokymia	1	1	1	1		
Nasal congestion	7	10	7	10		
Nasal pruritus	1	1	1	1		
Nasopharyngitis	1	3	1	3		
Nausea	35	81	35	80		1
Neck pain		2		2		
Nervousness		1				1
Neuropathy peripheral		1				1
Night sweats		2		2		
Occipital neuralgia		1		1		
Ocular hyperaemia	1	4	1	4		
Off label use		2		2		
Oral contusion	1	1	1	1		
Oral herpes	1	1	1	1		
Oropharyngeal pain	19	30	19	30		
Oxygen saturation decreased	1	1	1	1		
Oxygen saturation immeasurable	1	1			1	1
Pain	3	7	3	7		
Pain in extremity	5	10	5	10		
Pain in jaw	1	1	1	1		
Pallor		2		1		1
Palpitations	5	13	5	13		
Pancreatitis		1				1
Panic reaction		1		1		
Paraesthesia	2	13	2	13		
Paraesthesia ear		1		1		
Paraesthesia oral	5	13	5	13		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pelvic pain	1	1	1	1		
Peripheral circulatory failure		1				1
Peripheral coldness		1		1		
Peripheral swelling	1	2	1	2		
Peritonsillar abscess	1	1			1	1
Petechiae	1	1	1	1		
Pharyngeal swelling	1	3	1	1		2
Pharyngitis	1	1	1	1		
Photophobia	1	3	1	3		
Pleuritic pain		2		2		
Pneumonia	3	5			3	5
Pneumonia aspiration		1				1
Pneumonia viral		1				1
Postural orthostatic tachycardia syndrome	1	1	1	1		
Presyncope	2	14	2	14		
Product use issue		3		3		
Pruritus	12	24	12	24		
Pulmonary congestion	2	2			2	2
Pulmonary embolism	1	4			1	4
Pulmonary oedema		1				1
Pyrexia	54	91	53	90	1	1
Rales	1	1	1	1		
Rash	47	62	47	61		1
Rash erythematous		1		1		
Rash maculo-papular	1	1	1	1		
Rash pruritic	4	7	4	7		
Rectal haemorrhage		2				2
Renal impairment	1	1			1	1
Respiratory symptom	1	1	1	1		
Respiratory tract infection		1				1
Restlessness	1	1	1	1		
Retching	2	3	2	3		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Retinal artery occlusion		1				1
Rhinorrhoea	6	13	6	13		
Rotator cuff syndrome	1	1	1	1		
Seizure	4	12			4	12
Sensitive skin		1		1		
Sensory loss		1		1		
Sepsis	1	2			1	2
Sinus congestion	1	1	1	1		
Sinusitis	1	1	1	1		
Sinus pain		1		1		
Soft tissue inflammation		1		1		
Somnolence	3	5	3	5		
Speech disorder		1		1		
Speech disorder developmental	1	1	1	1		
Spinal pain		1		1		
Stridor	2	2	2	2		
Swelling	4	7	4	7		
Swelling face	2	4	2	4		
Swelling of eyelid	1	1	1	1		
Swollen tongue	5	8	5	8		
Syncope	28	55			28	55
Tachycardia	16	27	16	27		
Tachypnoea		1		1		
Taste disorder	1	1	1	1		
Tendon rupture	1	1	1	1		
Thirst	1	1	1	1		
Throat irritation	8	15	8	15		
Throat tightness	5	8	5	7		1
Thrombocytopenia	4	4			4	4
Thrombosis	4	4			4	4
Thrombotic stroke	1	1			1	1
Tinnitus	1	3	1	3		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue oedema	1	1	1	1		
Tonsillitis	1	1	1	1		
Transient ischaemic attack	1	2			1	2
Transverse sinus thrombosis	1	1			1	1
Tremor	1	7	1	7		
Unresponsive to stimuli	1	3			1	3
Urticaria	16	29	16	29		
Vaccination site bruising		1		1		
Vaccination site cellulitis		1		1		
Vaccination site discomfort	2	2	2	2		
Vaccination site erythema		3		3		
Vaccination site hypersensitivity	1	1	1	1		
Vaccination site pain	8	20	8	20		
Vaccination site pruritus		1		1		
Vaccination site rash	1	1	1	1		
Vaccination site reaction	44	64	44	64		
Vaccination site swelling	1	3	1	3		
Vaccination site warmth		1		1		
Vaginal haemorrhage	1	1	1	1		
Vasculitis	1	1	1	1		
Vasoconstriction		1		1		
Vertigo		3		3		
Vision blurred	4	5	4	5		
Visual impairment		1		1		
Vomiting	11	25	11	24		1
Wheezing	7	9	7	9		
	1,138	2,112	987	1801	151	311

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

AUSTRIA

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blepharospasm	1	1	1	1		
Dizziness		1				1
Dyspnoea exertional		1				1
Facial paresis		1				1
Fatigue	1	1	1	1		
Hypotension		1				1
Malaise		1		1		
Myalgia	1	1	1	1		
Nausea		1				1
Off label use		2		2		
Product use issue		2		2		
Pyrexia		1		1		
Rash		1				1
Sinus tachycardia		1				1
Tachycardia		1				1
Vaccination site pain	1	1	1	1		
	4	18	4	10		8

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain lower		1				1
Abdominal pain upper	1	1			1	1
Ageusia	1	1	1	1		
Amenorrhoea		1				1
Anaemia		1				1
Angina pectoris		2				2
Anosmia	1	1	1	1		
Anxiety		1		1		
Arrhythmia	1	1			1	1
Arthralgia	12	16	12	15		1
Asthenia		7		5		2
Asymptomatic COVID-19	1	4			1	4
Back pain	1	2	1	1		1
Blood creatine phosphokinase increased		2				2
Blood glucose decreased	1	1			1	1
Blood pressure increased		1				1
Body temperature increased	2	2	2	2		
Bradycardia		2				2
Cardiac arrest		1				1
Cardiovascular disorder		1		1		
Chest discomfort	1	3			1	3
Chest pain		1		1		
Chills	7	20	7	17		3
Circulatory collapse	2	6			2	6
Clonus		1				1
Confusional state		1				1
Cough	1	3	1	3		
COVID-19	3	6		2	3	4
Dermatitis allergic		1				1
Diarrhoea	2	5	2	5		
Diarrhoea haemorrhagic		1				1
Diplopia		1		1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbance in attention		2				2
Dizziness	7	17	7	13		4
Drug eruption		1				1
Drug ineffective	1	1			1	1
Dry mouth		2		1		1
Dysaesthesia		2				2
Dysarthria		1				1
Dyspnoea		8		2		6
Dyspnoea exertional		2				2
Ear discomfort		1		1		
Electrocardiogram change		1				1
Electrocardiogram ST segment elevation		1				1
Electrocardiogram ST-T change		1				1
Epilepsy	1	1			1	1
Epistaxis	1	2	1	2		
Erythema		2		2		
Eye pruritus		1		1		
Eye swelling	1	1	1	1		
Fatigue	16	29	15	24	1	5
Febrile convulsion	1	2		1	1	1
Feeling cold		1				1
Feeling hot		1				1
Feeling jittery		1		1		
Flushing		3				3
Foreign body aspiration		1				1
Gait disturbance		1		1		
Headache	28	53	27	47	1	6
Head discomfort		1				1
Heart rate increased		1				1
Hemianaesthesia		1				1
Hemiparaesthesia	2	3			2	3
Hemiparesis		1				1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hot flush		2				2
Hyperchromic anaemia		1				1
Hyperhidrosis		1		1		
Hyperreflexia		1				1
Hypersensitivity		1				1
Hypertension		4				4
Hypertensive crisis		1				1
Hypertonia		1				1
Hyperventilation	1	1			1	1
Hypoaesthesia		4		2		2
Hypoaesthesia oral		2		1		1
Hypoglycaemia	2	2			2	2
Hypotension		2		1		1
Hypothermia	1	1			1	1
Ileus	1	1			1	1
Impaired work ability	1	3		1	1	2
Inappropriate schedule of product administration	2	2	2	2		
Incorrect route of product administration		1		1		
Influenza like illness	2	5	2	5		
Injection site bruising		1		1		
Injection site pain		1		1		
Injection site paraesthesia		1		1		
Intermenstrual bleeding		1				1
Leukopenia		1				1
Loss of consciousness	1	2			1	2
Lymphadenopathy	4	11	3	7	1	4
Lymph node pain	3	5	3	4		1
Lymphocyte count increased		1		1		
Memory impairment		1				1
Migraine		1				1
Migraine with aura	1	1	1	1		
Mouth haemorrhage		1				1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle contractions involuntary		2				2
Muscle rigidity	1	1	1	1		
Muscle spasms	1	2		1	1	1
Muscle spasticity		1				1
Muscular weakness		2				2
Musculoskeletal stiffness	1	1			1	1
Myalgia	8	11	8	10		1
Myelosuppression		1				1
Myocarditis		1				1
Nausea	15	22	14	20	1	2
Neck pain		2		2		
Neurological symptom		1				1
Off label use	2	2	2	2		
Oropharyngeal pain	2	6	2	6		
Pain	1	5	1	4		1
Painful respiration		1		1		
Pain in extremity	4	14	4	13		1
Pallor		1				1
Palpitations	1	4	1	3		1
Pancytopenia		1				1
Paraesthesia	1	8			1	8
Paraesthesia oral	1	1			1	1
Parosmia		1		1		
Peripheral swelling		2		2		
Petechiae		2				2
Pharyngeal swelling		3				3
Pneumothorax spontaneous		1				1
Poor peripheral circulation		1		1		
Presyncope	2	2	2	2		
Pruritus		2				2
Pruritus allergic		1				1
Pulmonary function test decreased		1		1		

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* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia	23	43	21	37	2	6
Rash		6				6
Rash macular		1				1
Rash pruritic		2		1		1
Respiratory disorder	1	1			1	1
Restlessness		1		1		
Retrograde amnesia	1	1	1	1		
Rhinitis		2		2		
Rhinorrhoea	1	1	1	1		
SARS-CoV-2 test positive		1				1
Sensation of foreign body	1	3			1	3
Sense of oppression		1				1
Sensory level abnormal		2				2
Somnolence	2	5	2	5		
Speech disorder		1				1
Splenomegaly		1		1		
Spontaneous haematoma		1				1
Swelling		3		3		
Swelling face		1				1
Swollen tongue		1				1
Syncope	2	6			2	6
Tachycardia	1	5			1	5
Taste disorder		1		1		
Throat irritation		1				1
Thrombocytopenia		1				1
Tonsillitis	1	1	1	1		
Tonsillitis bacterial	1	1			1	1
Troponin T increased		2				2
Urticaria		3		1		2
Vaccination failure	3	7			3	7
Vaccination site anaesthesia		1				1
Vaccination site erythema	1	5	1	4		1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site hypoaesthesia		2		1		1
Vaccination site induration	2	3	1	1	1	2
Vaccination site lymphadenopathy		2		2		
Vaccination site movement impairment	1	1	1	1		
Vaccination site pain	19	32	18	30	1	2
Vaccination site paraesthesia		1				1
Vaccination site pruritus	1	1	1	1		
Vaccination site reaction	2	3	1	2	1	1
Vaccination site swelling	6	10	6	9		1
Vaccination site warmth	1	3	1	2		1
Ventricular f brillation		1				1
Vertigo	1	5	1	4		1
Vomiting	2	7		5	2	2
	227	597	181	370	46	227

* I=Interval, C=Cumulative
* AE=Adverse Event
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	5	1	2	1	3
Abdominal pain upper		1		1		
Accommodation disorder	1	1	1	1		
Activated partial thromboplastin time prolonged		1				1
Acute disseminated encephalomyelitis	1	4			1	4
Acute macular outer retinopathy		1				1
Administration site hypoaesthesia		1		1		
Ageusia	2	4	2	4		
Agitation		1		1		
Alanine aminotransferase increased		1		1		
Allergy to vaccine	2	2	1	1	1	1
Alopecia	1	3	1	3		
Altered visual depth perception		1		1		
Amnesia		1		1		
Anaphylactic reaction		8				8
Anaphylactic shock		3				3
Anaphylactoid reaction		1				1
Angina pectoris	1	3			1	3
Anosmia		1		1		
Anxiety		1				1
Apathy		1		1		
Aphasia	2	2	1	1	1	1
Application site pain		1		1		
Arrhythmia	1	5			1	5
Arthralgia	42	72	41	59	1	13
Arthritis	1	1	1	1		
Aspartate aminotransferase increased		1		1		
Asthenia	6	13	5	12	1	1
Asthma		1				1
Asymptomatic COVID-19	6	10			6	10
Autoimmune thyroiditis		1				1
Axillary pain		2		1		1

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Back pain	2	6		2	2	4
Balance disorder	2	3	2	3		
Beta globulin increased		1		1		
Blepharospasm	1	1	1	1		
Blister		1				1
Blood albumin decreased		1		1		
Blood creatine phosphokinase increased		1		1		
Blood creatine phosphokinase MB increased		1		1		
Blood creatinine increased		1		1		
Blood glucose increased		1		1		
Blood pressure abnormal		1				1
Blood pressure increased	2	8	2	5		3
Blood pressure systolic increased		1				1
Blood sodium decreased		1		1		
Blood urea increased		1		1		
Body temperature abnormal	1	1	1	1		
Body temperature increased	2	13	1	12	1	1
Bone pain		1		1		
Burning sensation		3		2		1
Bursitis		1		1		
Cardiovascular disorder	4	10	4	9		1
Cerebrovascular accident	1	1			1	1
Chapped lips		1				1
Chest discomfort	1	6		1	1	5
Chest pain	3	9	1	4	2	5
Chillblains	1	1			1	1
Chills	30	72	29	53	1	19
Circulatory collapse	5	18			5	18
Coagulation factor increased	1	1			1	1
Concomitant disease aggravated		1				1
Condition aggravated		2		1		1
Confusional state		3		1		2

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Contusion		1				1
Cough	3	7	1	5	2	2
COVID-19	23	30	2	3	21	27
C-reactive protein increased		2		1		1
Cutaneous vasculitis	1	1			1	1
Deafness	1	1			1	1
Decreased appetite	1	2	1	2		
Deep vein thrombosis	1	1			1	1
Defaecation urgency		1		1		
Dehydration		1		1		
Dermatitis allergic	1	2			1	2
Diarrhoea	9	21	8	17	1	4
Discomfort	2	2	1	1	1	1
Disorganised speech		1		1		
Disturbance in attention	2	5	2	5		
Dizziness	22	59	17	43	5	16
Drug ineffective	7	11			7	11
Dry mouth	1	6		4	1	2
Dry throat		1		1		
Dysacusis	1	1	1	1		
Dysaesthesia	3	7	1	2	2	5
Dyschromatopsia	1	1			1	1
Dysgeusia	1	5	1	2		3
Dysgraphia		1		1		
Dysphagia		5		1		4
Dyspnoea	10	27	3	7	7	20
Dyspnoea exertional	2	7		1	2	6
Dysuria		1		1		
Ear infection		1				1
Ear pain		2		2		
Ear pruritus	1	1	1	1		
Ear swelling	1	1	1	1		

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eczema	1	1	1	1		
Electrocardiogram abnormal		1		1		
Endocrine ophthalmopathy		1				1
Epilepsy		1				1
Epistaxis		3		2		1
Epstein-Barr virus infection	1	1			1	1
Erythema	1	8	1	4		4
Exercise tolerance decreased		1		1		
External ear pain		1				1
Extrasystoles	1	3		1	1	2
Eye haemorrhage		1				1
Eyelid oedema		1				1
Eye pain	1	4		2	1	2
Eye swelling		1		1		
Face oedema		1				1
Facial pain	1	1			1	1
Facial paralysis	2	5			2	5
Facial paresis		5				5
Facial spasm		1				1
Fall		2		1		1
Fatigue	62	120	59	105	3	15
Fear of disease	1	1			1	1
Feeling abnormal		5		5		
Feeling cold	2	6	2	3		3
Feeling drunk		2		2		
Feeling hot		4		1		3
Feeling of body temperature change		1		1		
Fibrin D dimer increased		1		1		
Flushing	1	4			1	4
Formication	1	2		1	1	1
Gait disturbance	3	6	3	4		2
Gastrointestinal disorder		2		2		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal motility disorder		1		1		
Generalised oedema		1		1		
General physical health deterioration	2	3	2	2		1
Glossodynia		1				1
Glossopharyngeal nerve disorder		1				1
Grunting		1		1		
Guillain-Barre syndrome	1	1			1	1
Haematuria		2				2
Haemorrhage		1				1
Hand dermatitis		1		1		
Hangover		1		1		
Headache	77	159	73	126	4	33
Head discomfort		1		1		
Heart rate increased	1	3	1	3		
Heavy menstrual bleeding	1	2			1	2
Helplessness	1	1	1	1		
Hemianaesthesia		1				1
Hemidysaesthesia		2				2
Hemiparaesthesia		1				1
Hepatic pain		1		1		
Hereditary angioedema with normal C1 esterase inhibitor		1				1
Herpes zoster	3	7	3	6		1
Hot flush		3		2		1
Hyperhidrosis	2	5	2	4		1
Hypersensitivity	3	14	1	1	2	13
Hypersomnia		1		1		
Hypertension	2	7	1	2	1	5
Hypertensive crisis		2				2
Hyperventilation		2		1		1
Hypoacusis	3	4	2	2	1	2
Hypoaesthesia	4	22	2	8	2	14

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia oral	2	8	2	4		4
Hypoglossal nerve paresis		1				1
Hypokalaemia		1				1
Hypokinesia		1		1		
Hypotension	1	3	1	1		2
Hypothermia	2	2			2	2
Hypotonia		1		1		
Idiopathic angioedema		1				1
Immune thrombocytopenia		1				1
Impaired work ability	4	9	1	4	3	5
Inappropriate schedule of product administration	1	2	1	2		
Incorrect route of product administration		3		3		
Inflammation	1	1			1	1
Influenza like illness	1	1	1	1		
Injected limb mobility decreased		1				1
Injection site pain		1		1		
Injury		1				1
Insomnia		4		3		1
Intermenstrual bleeding	1	1	1	1		
Intervertebral disc protrusion		1				1
Joint range of motion decreased		1				1
Joint swelling		4		2		2
Lacrimation increased		1		1		
Laryngeal oedema		1				1
Laryngeal pain		1				1
Leukopenia		2				2
Lip dry		2		1		1
Lip erythema		1				1
Lip pruritus		1				1
Lip swelling		5				5
Lividity		1		1		
Localised oedema		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Loss of consciousness		4				4
Lung disorder		1		1		
Lymphadenopathy	10	29	9	17	1	12
Lymph node pain	4	6	4	6		
Lymphopenia		1		1		
Malaise	4	10	4	8		2
Mania		1				1
Mean platelet volume decreased		1		1		
Memory impairment		3		2		1
Meningism		1				1
Menstruation irregular	2	3	1	1	1	2
Migraine	1	5		3	1	2
Monoparesis	1	3			1	3
Monoplegia	1	3			1	3
Mouth swelling		1				1
Movement disorder		1		1		
Multiple sclerosis	1	3			1	3
Muscle atrophy		1		1		
Muscle contractions involuntary		1		1		
Muscle disorder		1				1
Muscle spasms		5		3		2
Muscle twitching	1	2	1	2		
Muscular weakness		8		2		6
Musculoskeletal chest pain		1				1
Musculoskeletal disorder	1	2	1	1		1
Myalgia	41	65	41	57		8
Myocardial infarction		1				1
Myocarditis		2				2
Narcolepsy		1				1
Nasal congestion	1	1	1	1		
Nasopharyngitis	1	1	1	1		
Nausea	26	62	24	44	2	18

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neck pain	4	6	4	6		
Neoplasm malignant		1				1
Nerve conduction studies abnormal		1				1
Neuralgia		2				2
Neuralgic amyotrophy		1				1
Neuritis		1				1
Night sweats	1	2	1	1		1
Nuchal rigidity		1		1		
Obstructive airways disorder		1		1		
Occipital neuralgia		1		1		
Ocular hyperaemia		1		1		
Oedema		1				1
Oedema peripheral		2				2
Off label use	1	5	1	5		
Onychoclasia		1		1		
Optic neuritis	1	1			1	1
Oral discomfort		2				2
Oral herpes	1	1	1	1		
Oral pruritus		2				2
Oral pustule		1		1		
Oropharyngeal pain	4	8	2	5	2	3
Oxygen saturation decreased		3		1		2
Pain	3	12	3	9		3
Pain in extremity	15	54	14	42	1	12
Pain of skin	1	3		1	1	2
Palatal swelling		1				1
Pallor		2		1		1
Palmar erythema		1				1
Palpitations	4	18	3	8	1	10
Panic attack		1				1
Paraesthesia	7	30	3	13	4	17
Paraesthesia oral	2	4	2	2		2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paralysis	1	1			1	1
Paresis		1				1
Performance status decreased		1		1		
Pericardial effusion		2				2
Periorbital swelling		1				1
Peripheral coldness		1		1		
Peripheral embolism	1	1			1	1
Peripheral swelling	1	6		1	1	5
Peroneal nerve palsy		1				1
Petechiae	1	3		1	1	2
Pharyngeal swelling	1	2	1	1		1
Phobic postural vertigo	1	1	1	1		
Photophobia	1	3		2	1	1
Platelet count increased		1		1		
Pleural effusion		1				1
Pneumonia	1	2			1	2
Pollakiuria		1		1		
Poor quality product administered		1		1		
Presyncope	1	13	1	4		9
Product preparation error		1		1		
Product use issue		3		3		
Prurigo		1				1
Pruritus	4	24	1	6	3	18
Psychotic disorder		1				1
Pulmonary embolism	1	3			1	3
Pupils unequal		1				1
Pustule		1		1		
Pyrexia	76	134	72	106	4	28
Rash	5	21	4	10	1	11
Rash macular		2		1		1
Rash morbilliform		1				1
Rash papular	1	1			1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash pruritic	1	5	1	1		4
Rash pustular		1				1
Red blood cell sedimentation rate increased		1		1		
Reduced facial expression		1		1		
Renal pain		2				2
Respiratory disorder		1		1		
Respiratory distress		1				1
Respiratory rate decreased	1	1	1	1		
Restlessness		3		2		1
Rhabdomyolysis		1				1
Rhinitis	1	1			1	1
Rhinitis allergic		1				1
SARS-CoV-2 ant body test negative		1				1
SARS-CoV-2 test positive	9	10	1	1	8	9
Sciatica	1	1			1	1
Seizure		1				1
Sensation of foreign body	1	4	1	1		3
Sensory disturbance		1				1
Serum ferritin decreased		1		1		
Shock		1				1
Sinus tachycardia		1				1
Skin burning sensation		1				1
Skin discolouration		1				1
Skin exfoliation		2		1		1
Skin indentation		1		1		
Skin reaction		1		1		
Skin tightness		1				1
Sleep attacks		1		1		
Sleep disorder due to general medical condition, hypersomnia type		1		1		
Somatic symptom disorder		1				1
Somnolence	4	20	2	14	2	6

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Speech disorder	1	2	1	1		1
Spinal pain		3		2		1
Splenic vein thrombosis		1				1
Strabismus		1		1		
Stress		1		1		
Swelling		3		1		2
Swelling face	1	5	1	2		3
Swollen tongue	1	9		2	1	7
Syncope	2	11			2	11
Syringe issue		1		1		
Tachycardia	4	11	1	3	3	8
Tachycardia paroxysmal		1				1
Taste disorder	1	2	1	1		1
Tension		1		1		
Thinking abnormal		1		1		
Thirst		1		1		
Throat irritation	1	5	1	3		2
Throat tightness		4				4
Thrombocytopenia		1				1
Tinnitus	3	4	1	2	2	2
Tongue discomfort		2				2
Tonsillitis bacterial		1				1
Toothache		1				1
Transferrin increased		1		1		
Tremor	2	4	1	3	1	1
Trichoglossia		1		1		
Trigeminal neuralgia		2				2
Troponin increased		1				1
Underdose		1		1		
Urinary tract infection		1				1
Urticaria		8				8
Urticaria pressure		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Use of accessory respiratory muscles		1		1		
Vaccination failure	21	29			21	29
Vaccination site discolouration		2				2
Vaccination site dysaesthesia		1				1
Vaccination site erythema	4	10	4	5		5
Vaccination site haematoma	1	1	1	1		
Vaccination site hypoaesthesia		4		2		2
Vaccination site induration	2	5	2	4		1
Vaccination site inflammation	1	2	1	1		1
Vaccination site joint pain	1	1	1	1		
Vaccination site lymphadenopathy	5	10	5	7		3
Vaccination site movement impairment		4		4		
Vaccination site pain	42	96	42	85		11
Vaccination site paraesthesia		1		1		
Vaccination site pruritus	2	6	2	3		3
Vaccination site pustule		1		1		
Vaccination site rash		1		1		
Vaccination site reaction	2	5	2	5		
Vaccination site swelling	13	21	13	17		4
Vaccination site urticaria	1	2	1	1		1
Vaccination site warmth		3		2		1
Vasculitis		1				1
Ventricular extrasystoles		1				1
Vertigo	4	14	4	10		4
Vestibular neuronitis		1				1
Viral infection		1		1		
Viral rash		1				1
Vision blurred	1	6	1	5		1
Visual acuity reduced	1	1			1	1
Visual field defect	1	4		1	1	3
Visual impairment	2	6	1	2	1	4
Vomiting	7	15	7	12		3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Weight bearing difficulty		1		1		
White blood cell count increased		2		2		
White blood cells urine		1				1
	789	2,118	597	1269	192	849

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1		1		
Abdominal pain		1				1
Abdominal pain lower		1				1
Abdominal pain upper		1		1		
Ageusia		1		1		
Alanine aminotransferase increased	1	1			1	1
Analgesic drug level above therapeutic		1				1
Anaphylactic reaction	3	3			3	3
Anaphylactic shock		1				1
Anaphylactoid reaction		1				1
Angina pectoris	2	3			2	3
Anxiety		1		1		
Aphasia		2		1		1
Aphonia		1				1
Arrhythmia		1				1
Arthralgia	18	36	18	29		7
Arthritis infective	1	1			1	1
Aspartate aminotransferase increased	1	1			1	1
Asthenia	1	7	1	7		
Asthma		1				1
Asymptomatic COVID-19	2	3			2	3
Atelectasis		1				1
Atrial fibrillation	1	1			1	1
Back pain		3		1		2
Balance disorder		1				1
Basilar migraine		1				1
Bedridden		1		1		
Bell's palsy		1				1
Biliary colic		1				1
Blepharospasm		1				1
Blood fibrinogen increased	1	1	1	1		
Blood glucose fluctuation	1	2			1	2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood lactate dehydrogenase increased		1		1		
Blood pressure abnormal		1				1
Blood pressure fluctuation	1	1			1	1
Blood pressure increased		3		1		2
Body temperature increased	1	1	1	1		
Bone marrow oedema		1				1
Bone pain	2	2	2	2		
Bronchial obstruction		1				1
Bundle branch block right		1				1
Burning feet syndrome	1	1	1	1		
Bursitis		1				1
Cardiomyopathy		1				1
Cardiovascular disorder	1	4	1	4		
Cerebellar stroke		1				1
Cerebral venous sinus thrombosis	1	2			1	2
Cerebrovascular accident	1	1			1	1
Chest discomfort	1	2		1	1	1
Chest pain	3	4			3	4
Chills	16	43	15	35	1	8
Chronic obstructive pulmonary disease	1	2	1	1		1
Circulatory collapse	2	4			2	4
Coagulopathy		1				1
Coma	1	1			1	1
Concomitant disease aggravated		1				1
Concomitant disease progression		1				1
Condition aggravated	1	2			1	2
Confusional state	1	1	1	1		
Conjunctival haemorrhage		2				2
Conjunctivitis		1				1
Coronary artery thrombosis	1	1			1	1
Cough	2	5	1	3	1	2
COVID-19	9	12	1	2	8	10

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
C-reactive protein increased	1	1	1	1		
Death		1				1
Decreased appetite		2		2		
Deep vein thrombosis		1				1
Delirium		1				1
Depressed level of consciousness		1				1
Depression	1	1			1	1
Diarrhoea	3	11	3	9		2
Diarrhoea haemorrhagic		1				1
Diplopia		1				1
Discomfort		1		1		
Disease progression		1				1
Disorientation	1	3	1	2		1
Disturbance in attention	1	3	1	1		2
Dizziness	5	20	4	14	1	6
Drug ineffective	5	6			5	6
Dry mouth		1		1		
Dysgeusia	2	6	1	4	1	2
Dysphagia		2		2		
Dyspnoea	5	11			5	11
Dyspnoea exertional	1	1			1	1
Ear discomfort		1		1		
Eczema		2		1		1
Epilepsy		1				1
Erysipelas		1				1
Erythema		6		4		2
Escherichia infection	1	1			1	1
Escherichia sepsis	1	1			1	1
Eye irritation		1				1
Eyelid ptosis		1				1
Eye pruritus		1		1		
Face oedema		2		1		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial paralysis	2	2			2	2
Facial paresis		4				4
Faecal calprotectin increased		1				1
Fatigue	32	64	31	56	1	8
Feeling abnormal	1	3	1	1		2
Feeling cold	1	1	1	1		
Feeling hot		2		2		
Feeling of body temperature change		1		1		
Fibrin D dimer increased	1	1	1	1		
Flank pain		1				1
Flatulence		1		1		
Flushing		4		1		3
Gait disturbance		1				1
Gastrointestinal hypermotility		1		1		
Gingivitis		1		1		
Haematoma		1				1
Headache	32	72	30	59	2	13
Heart rate increased		1				1
Hepatic pain		1				1
Herpes simplex reactivation	1	1			1	1
Herpes zoster	2	4	1	2	1	2
Herpes zoster cutaneous disseminated		1				1
Histamine intolerance		1				1
Hyperaesthesia		1				1
Hyperhidrosis		1		1		
Hypersensitivity	1	5		1	1	4
Hypertension	1	2			1	2
Hypertensive crisis	2	6			2	6
Hypoaesthesia		2		2		
Hypoaesthesia oral		1		1		
Hypogeusia		2		1		1
Hypoglycaemia		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyposmia		1				1
Hypotension	1	4	1	1		3
Hypotonia		1		1		
Hypoxia	1	1			1	1
Illness		1				1
Immunisation anxiety related reaction	1	1			1	1
Impaired driving ability		1				1
Impaired healing	1	1	1	1		
Impaired quality of life		1				1
Impaired work ability	1	5		1	1	4
Incorrect route of product administration	1	2	1	2		
Inflammation		1				1
Inflammatory bowel disease	1	1			1	1
Influenza like illness		2		1		1
Insomnia		2		1		1
Intentional overdose		1				1
International normalised ratio fluctuation	1	1			1	1
Intraocular pressure increased		1				1
Laryngospasm		1				1
Leukopenia		1				1
Limb discomfort		1				1
Lip swelling		1				1
Locked-in syndrome		1				1
Loss of consciousness	1	3			1	3
Loss of personal independence in daily activities		1				1
Lymphadenopathy	2	7	2	4		3
Lymph node pain		1		1		
Lymph node palpable		1		1		
Malaise	3	6	3	5		1
Mechanical ventilation	1	1			1	1
Memory impairment		1				1
Migraine		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mouth swelling		1				1
Movement disorder		1		1		
Muscle spasms	1	2		1	1	1
Muscular weakness		1		1		
Myalgia	18	38	17	30	1	8
Myocardial infarction	2	2			2	2
Myocarditis	1	1			1	1
Myosclerosis	1	1			1	1
Nausea	9	32	6	22	3	10
Neck pain	1	3	1	2		1
Necrosis	1	1			1	1
Neuralgia		1		1		
Neuropathy peripheral		1				1
Night sweats		1		1		
Nuchal rigidity		1				1
Ocular hyperaemia		1		1		
Oedema mucosal		1		1		
Off label use		1		1		
Opiates positive		1				1
Oral herpes	2	2			2	2
Oral mucosal erythema		1				1
Oropharyngeal pain		2				2
Oxygen saturation abnormal	1	1	1	1		
Oxygen saturation decreased		1				1
Pain	2	4	2	3		1
Painful respiration	1	1			1	1
Pain in extremity	6	17	6	14		3
Pallor		1		1		
Palpitations		2		1		1
Panic reaction		1		1		
Paraesthesia		9		5		4
Paraesthesia oral		2		1		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Parosmia		1		1		
Peripheral coldness		2		1		1
Peripheral swelling		1		1		
Personality change		1				1
Petechiae	1	1			1	1
Pharyngeal swelling		2		1		1
Photophobia		2		2		
Pneumonia aspiration		1				1
Presyncope		6		2		4
Product administered at inappropriate site		1		1		
Product use issue		1		1		
Prohormone brain natriuretic peptide increased	1	1	1	1		
Pruritus		7		1		6
Pulmonary congestion	1	1			1	1
Pulmonary embolism	1	3			1	3
Pulmonary pain	1	1			1	1
Pyrexia	34	70	31	53	3	17
Radial nerve palsy		1				1
Radiculopathy		1				1
Rash	1	7	1	2		5
Rash macular		1				1
Rash pruritic		1		1		
Rash pustular		2		1		1
Renal pain		1				1
Respiratory distress	1	1			1	1
Respiratory failure		1				1
Resuscitation	1	1			1	1
Retinal tear		1				1
Rheumatoid arthritis		1				1
Road traffic accident		1				1
Ruptured cerebral aneurysm		1				1
SARS-CoV-2 ant body test negative		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
SARS-CoV-2 test positive	4	4			4	4
Sciatica	1	1			1	1
Seizure	1	1			1	1
Sensation of foreign body		1				1
Serum ferritin increased	1	2		1	1	1
Shift to the left		1				1
Sinus congestion		1		1		
Skin lesion		1				1
Sleep disorder	1	2	1	1		1
Somnolence	2	4	2	3		1
Speech disorder		1		1		
Spinal pain		1				1
Status epilepticus		1				1
Stomatitis		1		1		
Subarachnoid haemorrhage		1				1
Sudden hearing loss		2				2
Suspected COVID-19		1				1
Swelling		2		1		1
Swelling face		3		1		2
Swelling of eyelid		1				1
Swollen tongue		1				1
Syncope	3	6			3	6
Tachycardia	1	3			1	3
Tachypnoea		1		1		
Taste disorder		1		1		
Tendon disorder		1		1		
Tension headache		2		1		1
Thinking abnormal		1				1
Throat irritation		1		1		
Throat tightness	1	1			1	1
Tinnitus		3		2		1
Tongue discomfort		2		1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Toxicity to various agents		1				1
Transaminases increased		2		1		1
Tremor		1				1
Trismus	1	1			1	1
Troponin I increased		1				1
Tunnel vision	1	3	1	1		2
Urinary tract infection	1	1			1	1
Urticaria	1	3			1	3
Vaccination failure	5	7			5	7
Vaccination site abscess	1	1			1	1
Vaccination site erythema	4	5	3	4	1	1
Vaccination site haemorrhage		1		1		
Vaccination site hypoaesthesia		1		1		
Vaccination site joint pain		2		1		1
Vaccination site lymphadenopathy	3	3	3	3		
Vaccination site movement impairment	2	3	2	2		1
Vaccination site pain	21	38	20	33	1	5
Vaccination site pruritus	2	2	1	1	1	1
Vaccination site rash		1		1		
Vaccination site swelling	4	8	3	6	1	2
Vaccination site urticaria		1		1		
Vaccination site warmth		1		1		
Vaginal haemorrhage		1				1
Venous thrombosis limb		1				1
Vertigo	2	7	1	3	1	4
Vision blurred	1	2	1	1		1
Visual impairment	1	6			1	6
Vitreous detachment	1	1			1	1
Vitreous haemorrhage		1				1
Vomiting	2	10	2	6		4
Weight bearing difficulty	1	1			1	1
Wrong technique in product usage process		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	353	961	234	539	119	422

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Accommodation disorder	1	1	1	1		
Acute coronary syndrome		2				2
Agitation	1	2	1	2		
Angioedema		1				1
Anti-platelet ant body		1				1
Anxiety		1				1
Arrhythmia	1	2			1	2
Arterial occlusive disease		1				1
Arterial thrombosis	1	1			1	1
Arteriosclerosis coronary artery		1				1
Arthralgia	3	5	1	1	2	4
Arthritis	1	1	1	1		
Aspiration		1				1
Asthenia	1	6		2	1	4
Atrial fibrillation		3				3
Autoimmune disorder		1				1
Autoimmune haemolytic anaemia		1				1
Bacterial sepsis		1				1
Balance disorder		1				1
Basal ganglia stroke		1				1
Benign prostatic hyperplasia	1	1			1	1
Bleeding time prolonged	1	1			1	1
Blister	1	1	1	1		
Blood creatine phosphokinase increased		1		1		
Blood glucose fluctuation	1	1			1	1
Blood pressure increased		1		1		
Body temperature increased		1		1		
Bradycardia		1				1
Bradykinesia		2		1		1
Brain natriuretic peptide increased		1				1
Breast pain		1		1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchitis		1				1
Cachexia		1				1
Cardiac failure acute		1				1
Cardiomegaly	1	1			1	1
Cardiopulmonary failure		1				1
Cardiovascular disorder		1				1
Central nervous system infection		1				1
Cerebral haemorrhage		1				1
Cerebral infarction		1				1
Cerebral ischaemia		1				1
Cerebrovascular accident		2				2
Chest discomfort		1				1
Chest pain		1				1
Chills		3		2		1
Chromaturia	1	1			1	1
Chronic obstructive pulmonary disease		1				1
Circulatory collapse	1	3			1	3
Confusional state		1				1
Coronary artery stenosis		1				1
Cough	1	1	1	1		
COVID-19	9	12			9	12
COVID-19 pneumonia	1	3			1	3
C-reactive protein increased		1		1		
Daydreaming		1				1
Death	1	7			1	7
Decreased appetite	3	5	2	3	1	2
Deep vein thrombosis	7	8			7	8
Dermatitis bullous		1				1
Diplopia	1	1			1	1
Disease recurrence		1				1
Disorientation		1		1		
Dizziness		5		2		3

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug eruption		1				1
Drug ineffective	6	8			6	8
Dysarthria	1	1			1	1
Dysphagia		1				1
Dyspnoea	3	7	1	1	2	6
Dyspnoea exertional		1		1		
Dysstasia		1				1
Epididymal tenderness	1	1			1	1
Extrasystoles		1				1
Facial asymmetry		1				1
Facial bones fracture		1				1
Facial paresis	2	3			2	3
Faeces pale	1	1			1	1
Fall	1	4			1	4
Fatigue	6	13	3	8	3	5
Feeling cold		1				1
Fibrin D dimer increased		1				1
Gait disturbance		1		1		
Generalised tonic-clonic seizure		1				1
General physical health deterioration	2	6			2	6
Genital discomfort	1	1	1	1		
Groin pain		1		1		
Haematemesis		1				1
Haemolytic anaemia	1	1			1	1
Haemorrhage intracranial	1	1			1	1
Haemorrhage subcutaneous	1	1			1	1
Headache	2	6			2	6
Head banging		1				1
Head injury		1				1
Hemiataxia	1	1			1	1
Hemiparesis	1	2			1	2
Herpes simplex encephalitis		1				1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes zoster	2	4	2	3		1
Hypereosinophilic syndrome	1	1			1	1
Hyperglycaemia		1				1
Hyperkalaemia	1	1			1	1
Hypersomnia	1	2	1	2		
Hypertension	1	2			1	2
Hypertensive crisis	1	2			1	2
Hyponatraemia	1	1			1	1
Hypotension	1	5	1	3		2
Incorrect route of product administration	1	3	1	3		
Infection	1	2			1	2
Inflammatory marker increased	1	1			1	1
Influenza		1		1		
Influenza like illness		1		1		
Intraventricular haemorrhage		1				1
Ischaemic cerebral infarction		1				1
Jaundice	1	1			1	1
Joint swelling		2				2
Loss of personal independence in daily activities		1				1
Lymphadenopathy	1	2		1	1	1
Lymph node pain		1		1		
Malaise	1	2			1	2
Mesenteric vein thrombosis	1	1			1	1
Movement disorder		1				1
Multiple organ dysfunction syndrome		1				1
Musculoskeletal disorder		1				1
Myalgia		2		1		1
Myocardial infarction	2	2			2	2
Nausea	1	3	1	2		1
Nervous system disorder		1				1
Oedema genital	1	1			1	1
Ophthalmoplegia	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral disorder		1		1		
Oral mucosa erosion		1		1		
Oxygen saturation decreased		1				1
Pain	1	1			1	1
Pain in extremity	1	4		1	1	3
Pain in jaw	1	1	1	1		
Palpitations		1				1
Pancreatitis	1	1			1	1
Performance status decreased	1	1			1	1
Peripheral swelling	1	2			1	2
Petit mal epilepsy		1				1
Pharyngeal lesion		1		1		
Phlebitis superficial	1	1			1	1
Pleurisy		1				1
Pneumonia	1	2			1	2
Pneumonia aspiration		2				2
Post herpetic neuralgia		1				1
Presyncope	2	3			2	3
Pruritus	1	1			1	1
Pulmonary embolism	7	14			7	14
Pulmonary infarction		1				1
Pulpitis dental	1	1			1	1
Pupillary reflex impaired		1				1
Pyrexia	2	16		5	2	11
Rash	2	3			2	3
Rash erythematous	1	1			1	1
Respiratory acidosis		1				1
Respiratory failure	1	2			1	2
Restlessness		1		1		
Retching		1		1		
Retinal artery occlusion	1	2			1	2
Retinal vein thrombosis	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
SARS-CoV-2 ant body test negative		1				1
SARS-CoV-2 test positive	1	3			1	3
Seizure		1				1
Sepsis		1				1
Sinus tachycardia		1				1
Somnolence		2		1		1
Speech disorder		1				1
Status epilepticus	1	1			1	1
Strabismus	1	1			1	1
Sudden cardiac death	1	1			1	1
Supraventricular tachycardia		1				1
Swelling	1	1			1	1
Syncope		2				2
Systemic inflammatory response syndrome		1				1
Tachycardia	1	1			1	1
Thalamic infarction	1	1			1	1
Thrombocytopenia	1	3			1	3
Transient ischaemic attack	1	1			1	1
Troponin T increased		1				1
Urinary retention	1	1			1	1
Urticaria	1	3			1	3
Uterine abscess	1	1			1	1
Vaccination failure	4	4			4	4
Vaccination site induration	1	1	1	1		
Vaccination site pain		4		3		1
Vaccination site pruritus	1	1	1	1		
Vaccination site rash		1				1
Vaccination site swelling	1	2	1	1		1
Vaginal haemorrhage		1				1
Vascular occlusion	1	1			1	1
Venous thrombosis limb		1		1		
Vertigo		4				4

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Visual impairment	2	2			2	2
Vitreous haemorrhage		1				1
Vomiting		1		1		
	141	369	24	76	117	293

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1				1
Acute kidney injury		1				1
Acute left ventricular failure		1				1
Acute myocardial infarction	1	2			1	2
Ageusia	1	1			1	1
Agranulocytosis		1				1
Allodynia		1		1		
Anaemia	3	4			3	4
Anaphylactic shock		2				2
Angina pectoris		1				1
Angioedema		1				1
Anosmia	1	1			1	1
Anxiety	1	1	1	1		
Aphasia		2				2
Apnoea		1				1
Arrhythmia	2	3			2	3
Arthralgia	1	4	1	1		3
Asthenia	5	11	2	5	3	6
Asymptomatic COVID-19	6	7	1	1	5	6
Atelectasis	1	1	1	1		
Atrial f brillation		4				4
Back pain		1				1
Blindness unilateral	1	1			1	1
Blood glucose increased		1				1
Blood lactate dehydrogenase increased	1	1			1	1
Blood lactic acid increased	1	1			1	1
Blood pressure abnormal		1				1
Blood pressure decreased	1	3		1	1	2
Blood pressure immeasurable		1				1
Blood pressure increased	1	1	1	1		
Body temperature increased		2		1		1
Bradycardia		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breath sounds		1		1		
Breath sounds abnormal		1				1
Bundle branch block left		1				1
Cachexia		1				1
Cardiac arrest		3				3
Cardiac death		1				1
Cardiac failure	3	12			3	12
Cardiopulmonary failure	1	2			1	2
Cardio-respiratory arrest		2				2
Cardiovascular disorder	1	1	1	1		
Cerebral artery occlusion		1				1
Cerebral haemorrhage		1				1
Cerebral infarction		2				2
Cerebral venous sinus thrombosis	1	1			1	1
Cerebrovascular accident	3	8			3	8
Chest discomfort		1		1		
Chest pain		5		1		4
Chills	1	4			1	4
Choking		1				1
Cholestasis		1				1
Chromaturia	1	1	1	1		
Chronic kidney disease		1				1
Circulatory collapse		3				3
Cognitive disorder	1	1			1	1
Cold sweat		1				1
Colitis		1				1
Concussion		1				1
Condition aggravated	3	3	1	1	2	2
Confusional state	1	3	1	1		2
Cough	1	3	1	2		1
COVID-19	21	36	1	1	20	35
COVID-19 pneumonia	4	6			4	6

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Craniocerebral injury		1				1
C-reactive protein increased	2	3	1	1	1	2
Cyanosis	1	1			1	1
Death	1	11			1	11
Decreased appetite	1	2	1	2		
Deep vein thrombosis	4	10			4	10
Dehydration		1				1
Device related infection		1				1
Diarrhoea	1	3		1	1	2
Diarrhoea haemorrhagic		1				1
Diffuse alveolar damage	1	1			1	1
Diplopia	1	1			1	1
Disease recurrence	2	3			2	3
Disseminated varicella zoster virus infection		1				1
Dizziness	1	4	1	3		1
Dizziness postural		1		1		
Drug ineffective	12	19			12	19
Dysarthria		1				1
Dyskinesia		1				1
Dysphagia		2				2
Dyspnoea	6	15			6	15
Dyspnoea at rest	2	2			2	2
Dysstasia		1		1		
Eczema		1				1
Emphysema		1				1
Epilepsy		2				2
Escherichia sepsis		1				1
Eye contusion		1				1
Eyelid contusion		1				1
Eyelid oedema	1	1	1	1		
Eyelid ptosis	1	1			1	1
Eye movement disorder		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Face oedema		1				1
Facial paralysis	1	3			1	3
Facial paresis	2	2			2	2
Fall	1	4	1	1		3
Fatigue	6	19	3	11	3	8
Febrile convulsion	2	2			2	2
Feeling hot		2		1		1
Feeling jittery	1	1			1	1
Fibrin D dimer increased	2	2	2	2		
Flushing		1				1
Gait disturbance	2	4	1	3	1	1
Gastroenteritis		1		1		
Generalised tonic-clonic seizure		2				2
General physical health deterioration	4	12		2	4	10
Guillain-Barre syndrome	1	1			1	1
Haematemesis		1				1
Haematoma		1				1
Hallucination		1				1
Headache	3	6	2	5	1	1
Heart rate decreased		2				2
Hemiparesis	3	4			3	4
Hemiplegia	1	2			1	2
Herpes zoster	5	6	3	3	2	3
Hyperglycaemia		1				1
Hyperhidrosis	2	2			2	2
Hyperkalaemia	1	1			1	1
Hypernatraemia		1				1
Hypertension		1				1
Hypertensive crisis	1	3			1	3
Hypertensive emergency	1	2			1	2
Hyperventilation		1				1
Hypoaesthesia	1	1			1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyponatraemia	2	2			2	2
Hypophagia		1				1
Hypopnoea		1				1
Hypotonia		2		1		1
Immobilisation syndrome	1	1			1	1
Inappropriate schedule of product administration		1		1		
Incontinence		1				1
Incorrect route of product administration		2		2		
Infection		1				1
Inflammatory marker increased	2	2			2	2
Influenza like illness	1	1	1	1		
Insomnia	1	1			1	1
Interleukin level increased		1				1
Ischaemic cardiomyopathy	1	1			1	1
Ischaemic stroke		1				1
Joint effusion	1	1			1	1
Lack of spontaneous speech		1				1
Language disorder		1		1		
Left ventricular failure		2				2
Leukocytosis		2				2
Leukoencephalopathy		1				1
Leukopenia	2	2			2	2
Lip oedema	1	1	1	1		
Listless	1	1			1	1
Loss of consciousness		1				1
Loss of personal independence in daily activities	1	1			1	1
Low density lipoprotein increased	1	1			1	1
Lung infiltration		1				1
Lymph node pain	1	2	1	1		1
Lymphocyte count increased		1				1
Lymphocytosis		1				1
Lymphoedema	1	1			1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise		2				2
Marasmus	1	2			1	2
Memory impairment	1	1			1	1
Meningitis bacterial		1				1
Mitral valve incompetence	1	1			1	1
Mouth ulceration	1	1			1	1
Multiple organ dysfunction syndrome	1	3			1	3
Muscle spasms		1				1
Muscular weakness	1	1			1	1
Myalgia	1	4	1	3		1
Myasthenia gravis	1	1			1	1
Myocardial infarction		2				2
Myocarditis	1	2			1	2
Myoclonus		1				1
Nausea		9		5		4
Neutropenia		1				1
Ocular myasthenia	1	1			1	1
Oculofacial paralysis	1	1			1	1
Oedema peripheral	1	1			1	1
Off label use	1	2	1	2		
Organising pneumonia	1	1			1	1
Oxygen saturation		1				1
Oxygen saturation decreased	1	3		1	1	2
Oxygen saturation immeasurable		1				1
Pain	1	4		1	1	3
Pain in extremity	1	4			1	4
Pain in jaw	1	1	1	1		
Pallor		3				3
Palpitations		1				1
Pancytopenia	1	1			1	1
Praesthesia		2				2
Praesthesia oral		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paralysis	1	1			1	1
Pelvic venous thrombosis	1	1			1	1
Pemphigus		1				1
Pericarditis		1				1
Peripheral swelling	3	4	2	2	1	2
Platelet count decreased		1		1		
Pleural effusion	3	5			3	5
Pneumonia		7				7
Pneumonia aspiration		1				1
Pneumonia bacterial		1				1
Presyncope		1				1
Productive cough		1		1		
Product use issue	1	1	1	1		
Pruritus	1	3			1	3
Psoriasis		1				1
Pulmonary embolism	5	16			5	16
Pulmonary hypertensive crisis		1				1
Pulmonary infarction	2	3			2	3
Pulmonary oedema		2				2
Pyrexia	7	16	4	8	3	8
Rales		2		1		1
Rash		2				2
Rash macular		1				1
Renal failure	1	3			1	3
Renal function test abnormal	1	1	1	1		
Respiratory depression		1				1
Respiratory disorder	2	2			2	2
Respiratory failure	3	3			3	3
Respiratory rate decreased		1				1
Respiratory symptom	1	1	1	1		
Restlessness	1	1			1	1
Retching		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rib fracture		1				1
SARS-CoV-2 test positive	6	7			6	7
Seizure		3				3
Sensory disturbance		1				1
Sepsis	1	2			1	2
Septic shock		1				1
Skin laxity		1		1		
Sleep disorder	1	1			1	1
Somnolence	3	7		1	3	6
Sopor		1				1
Speech disorder		1				1
Subcutaneous haematoma		1				1
Subdural haemorrhage		1				1
Syncope	1	5			1	5
Tachycardia		2				2
Tachypnoea	1	1			1	1
Thalamic infarction		1				1
Thrombocytopenia	2	2			2	2
Thrombophlebitis	1	2			1	2
Thrombosed varicose vein		1				1
Thrombosis	1	5			1	5
Thrombosis mesenteric vessel		1				1
Transaminases increased	1	1			1	1
Transient ischaemic attack		1				1
Tremor	1	2			1	2
Type I hypersensitivity		1				1
Unresponsive to stimuli	1	5			1	5
Urinary retention		1				1
Urine ketone body present		1		1		
Urticaria	5	6			5	6
Vaccination complication		1				1
Vaccination failure	17	20	1	1	16	19

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site erythema	3	5	3	5		
Vaccination site inflammation	2	2	1	1	1	1
Vaccination site pain		1		1		
Vaccination site rash		1		1		
Vaccination site reaction		1		1		
Vaccination site swelling		2		2		
Vaginal discharge		1		1		
Varicophlebitis	1	1			1	1
Vascular encephalopathy		1				1
Venous thrombosis limb	1	4			1	4
Vertigo	1	2			1	2
Vertigo positional	1	1			1	1
Vomiting	1	8		4	1	4
Wound haemorrhage		1				1
Wrong technique in product usage process		1		1		
	267	671	49	121	218	550

* I=Interval, C=Cumulative
* AE=Adverse Event
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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1				1
Aneurysm ruptured		1				1
Antibody test abnormal		1		1		
Antiphospholipid syndrome		1				1
Apathy		1		1		
Arteriosclerosis		1				1
Arteriosclerosis coronary artery		1				1
Arthralgia	3	3	3	3		
Asthenia	1	3	1	3		
Asymptomatic COVID-19	1	1			1	1
Atrial fibrillation		1				1
Back pain		2		1		1
Blood creatine phosphokinase MB increased		1				1
Blood glucose decreased	1	1			1	1
Blood glucose increased	1	1	1	1		
Blood pressure decreased		1				1
Body temperature increased		1				1
Bronchiolitis		1				1
Cardiac hypertrophy		1				1
Cardiomegaly		1		1		
Cardiovascular disorder	1	2	1	2		
Cerebral haemorrhage		1				1
Chest discomfort		1				1
Chills	5	7	5	7		
Circulatory collapse	1	1			1	1
Complication associated with device		1		1		
Congestive hepatopathy		1				1
Conjunctival hyperaemia	1	1	1	1		
Coronavirus infection		1				1
Cough		1				1
COVID-19	1	17		1	1	16
Diarrhoea	3	5	3	4		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	2	2	2	2		
Drug ineffective		17				17
Dysgeusia	1	1	1	1		
Dyspnoea	1	3	1	2		1
Dyspnoea exertional		1				1
Emphysema		1		1		
Exposure during pregnancy		1		1		
Extrasystoles	1	1	1	1		
Facial paralysis		1				1
Fatigue	6	12	5	10	1	2
Feeling abnormal	1	1	1	1		
Feeling hot	1	1	1	1		
Feeling of body temperature change	1	1	1	1		
Fluid retention	1	1	1	1		
Gastrointestinal pain		1				1
Headache	5	13	5	12		1
Head discomfort	1	1	1	1		
Heavy menstrual bleeding	1	1	1	1		
Helicobacter infection		1				1
Hepatic steatosis		1		1		
Herpes zoster	1	1	1	1		
Hirsutism		1		1		
Impaired work ability		1				1
Incorrect dose administered		1		1		
Influenza like illness	1	6	1	5		1
Intervertebral disc protrusion	1	1			1	1
Joint swelling	1	1	1	1		
Lymphadenopathy		2		2		
Lymphoedema	1	1			1	1
Mass	1	1	1	1		
Maternal exposure during pregnancy		1		1		
Muscle spasms		1				1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	1	2	1	1		1
Myocarditis	1	1			1	1
Nasopharyngitis		1		1		
Nausea	3	5	3	5		
Neutralising antibodies negative		1		1		
Oropharyngeal pain	1	2		1	1	1
Oropharyngeal swelling	1	1	1	1		
Pain in extremity	6	11	6	10		1
Palpitations		1				1
Paraesthesia		1		1		
Performance status decreased		2		1		1
Periorbital swelling	1	1	1	1		
Peripheral swelling	1	1	1	1		
Platelet count decreased	1	1			1	1
Pneumonia		1				1
Pneumonia bacterial		1				1
Presyncope	1	2	1	1		1
Pruritus	1	2	1	2		
Pulmonary congestion		1				1
Pulmonary embolism		1				1
Pulmonary oedema		1				1
Pyrexia	3	8	3	8		
Renal disorder		1		1		
SARS-CoV-2 test positive	1	1			1	1
Skin irritation	1	1	1	1		
Skin striae		1		1		
Somnolence	1	1	1	1		
Subarachnoid haemorrhage		1				1
Suspected COVID-19	1	2	1	1		1
Tachycardia	1	1	1	1		
Therapeutic response unexpected	1	1	1	1		
Tongue discomfort	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Underdose	1	1	1	1		
Urticaria		1		1		
Vaccination failure	2	2			2	2
Vaccination site erythema		1		1		
Vaccination site movement impairment		1		1		
Vaccination site pain	3	6	3	6		
Vaccination site pruritus		1		1		
Vaccination site reaction	1	1	1	1		
Vomiting	1	1	1	1		
Weight increased	1	1	1	1		
Wrong technique in product usage process		1		1		
	84	220	71	135	13	85

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

BAHRAIN

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Anosmia	1	1	1	1		
COVID-19	1	1			1	1
Drug ineffective	1	1			1	1
Fatigue	1	1	1	1		
Headache		1		1		
Myalgia		1		1		
Oropharyngeal pain	1	1	1	1		
Vaccination site pain		1		1		
	6	9	4	7	2	2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	1			1	1
Anaphylactic reaction	1	1			1	1
Axillary pain		1				1
Cerebral artery occlusion	1	1			1	1
Cerebrovascular accident	2	2			2	2
Chest pain	1	1			1	1
Chills		3		2		1
Dysarthria	1	1			1	1
Dyspnoea	1	2	1	1		1
Guillain-Barre syndrome	1	1			1	1
Headache	3	3	1	1	2	2
Heart rate increased		1				1
Hot flush		1		1		
Hyperhidrosis	1	2			1	2
Hypoaesthesia	3	3	1	1	2	2
Lymphadenopathy		1		1		
Muscle spasms		1				1
Muscular weakness	2	2	2	2		
Myalgia		1		1		
Nausea	1	2		1	1	1
Neck pain		1		1		
Pain		2		1		1
Paraesthesia		1				1
Photophobia	1	1			1	1
Pruritus		1		1		
Pyrexia		3		2		1
Sensory loss	1	1	1	1		
Swelling		1				1
Troponin increased	1	1			1	1
Vomiting	1	1			1	1
	23	44	6	17	17	27

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	1			1	1
Headache	1	1	1	1		
Nasal congestion	1	1	1	1		
Secretion discharge	1	1	1	1		
	4	4	3	3	1	1

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Atrioventricular block	1	1			1	1
Cough	1	1	1	1		
Fatigue	1	1	1	1		
Pyrexia	1	1	1	1		
	4	4	3	3	1	1

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	1	1	1	1		
Headache	1	1	1	1		
Limb discomfort	1	1	1	1		
Pyrexia	1	1	1	1		
Syncope	1	1			1	1
	5	5	4	4	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

BELGIUM

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased		1				1
Cerebrovascular accident	1	1			1	1
Exposure via breast milk	2	3	2	3		
Maternal exposure during pregnancy	1	1			1	1
Pyrexia	1	1	1	1		
Screaming	1	1	1	1		
Syncope		1				1
	6	9	4	5	2	4

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	2			1	2
Abdominal distension		1		1		
Abdominal pain	1	3			1	3
Abdominal pain upper	4	4	4	4		
Acute macular outer retinopathy		1				1
Alanine aminotransferase increased		1		1		
Anaphylactic reaction		4				4
Angina pectoris	1	2			1	2
Apathy		1				1
Appendicitis		2				2
Arthralgia	18	52	8	9	10	43
Aspartate aminotransferase increased		1		1		
Asthenia	7	15	6	8	1	7
Asthenopia	1	1			1	1
Autoimmune disorder	1	2			1	2
Aversion	1	1	1	1		
Axillary mass		1				1
Axillary pain	9	13	8	8	1	5
Back pain	3	6	3	3		3
Blood pressure decreased		2				2
Blood pressure increased		1				1
Blood test abnormal		1				1
Body temperature fluctuation		1				1
Body temperature increased	2	4	2	2		2
Bone pain		1				1
Bradycardia		1				1
Burning sensation	2	3	1	2	1	1
Cardiac arrest		2				2
Cardiovascular disorder	1	6		1	1	5
Chest discomfort		3		1		2
Chest pain	5	6	3	3	2	3
Chills	32	138	14	22	18	116

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coagulopathy	1	3			1	3
Condition aggravated		1				1
Contusion	1	3			1	3
Cough		1				1
COVID-19		2		1		1
C-reactive protein increased	1	1	1	1		
Crying		1				1
Cyanosis		1				1
Deafness unilateral		1				1
Decreased appetite	2	4	1	2	1	2
Deep vein thrombosis	1	1			1	1
Dermatitis	1	1	1	1		
Diarrhoea	7	12	3	4	4	8
Diarrhoea haemorrhagic		1				1
Disorientation		1				1
Disturbance in attention		1		1		
Dizziness	2	11	2	3		8
Drug ineffective		1				1
Dry mouth		1				1
Dysgeusia	1	2	1	2		
Dyspepsia	1	1	1	1		
Dysphagia		1		1		
Dyspnoea	4	11	3	3	1	8
Dyspnoea exertional		1				1
Eczema	1	1	1	1		
Endolymphatic hydrops		1				1
Epilepsy		1				1
Epistaxis		1				1
Erythema	4	5	4	4		1
Extensive swelling of vaccinated limb	4	4			4	4
Eye pain		5		2		3
Eye swelling		1				1

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* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial nerve disorder	1	1			1	1
Facial paralysis	1	5			1	5
Facial paresis	1	1			1	1
Fatigue	52	178	28	42	24	136
Feeding disorder	1	1			1	1
Feeling abnormal	1	2	1	1		1
Feeling cold	2	5	2	4		1
Feeling hot	3	4	3	4		
Feeling of body temperature change	3	6	3	3		3
Fibrin D dimer increased		1				1
Gamma-glutamyltransferase increased		1		1		
Gastric dilatation	1	1			1	1
Gastric disorder		1				1
Gastrointestinal pain	2	2	1	1	1	1
Generalised tonic-clonic seizure		1				1
Haematoma		1				1
Hallucination	1	2			1	2
Hangover	1	1	1	1		
Headache	73	209	48	62	25	147
Heart rate increased	2	7	2	4		3
Hepatic enzyme increased		1		1		
Hepatitis		1				1
Herpes ophthalmic		1				1
Herpes zoster		1		1		
Hunger	1	1	1	1		
Hyperaesthesia	1	2	1	1		1
Hyperhidrosis	7	10	7	7		3
Hypersensitivity		4				4
Hypersomnia		1				1
Hyperventilation		2				2
Hypoaesthesia	3	4	1	2	2	2
Hypoaesthesia oral		1		1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypothermia		1				1
Illness		2		2		
Inflammation	1	1			1	1
Influenza	2	2	1	1	1	1
Influenza like illness	9	33	7	10	2	23
Injection site reaction		4		1		3
Injection site swelling	1	1	1	1		
Insomnia	4	9	2	4	2	5
Joint range of motion decreased	1	2	1	1		1
Joint stiffness		1				1
Ketoacidosis		3				3
Lacrimation increased		1				1
Laryngeal discomfort	1	1			1	1
Laryngeal oedema		1				1
Limb discomfort	3	4	3	3		1
Lipase increased	1	1	1	1		
Liver disorder	1	1			1	1
Localised infection		1				1
Loss of consciousness		2				2
Lung disorder		1				1
Lymphadenitis		1				1
Lymphadenopathy	8	17	8	10		7
Lymph node pain		3				3
Malaise	17	80	6	10	11	70
Middle insomnia	3	3	3	3		
Migraine		4				4
Muscle contracture		1				1
Muscle fatigue		1				1
Muscle strain	1	4	1	1		3
Muscular weakness	2	2	2	2		
Musculoskeletal discomfort		1				1
Musculoskeletal stiffness	22	40	21	30	1	10

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	49	156	30	38	19	118
Nasal congestion	1	1	1	1		
Nausea	39	119	19	23	20	96
Neck pain	3	6	3	3		3
Nervous system disorder		4				4
Night sweats	2	2	2	2		
Noninfective encephalitis	1	1			1	1
Ocular discomfort	1	3	1	3		
Odynophagia		1		1		
Off label use		1		1		
Oropharyngeal pain		3		2		1
Pain	8	13	6	6	2	7
Painful respiration		2				2
Pain in extremity	14	25	9	15	5	10
Pain of skin	1	2	1	1		1
Palpitations	3	7	1	3	2	4
Pancreatitis	1	1			1	1
Paraesthesia	2	4		1	2	3
Paraesthesia oral	1	2		1	1	1
Parosmia		1		1		
Pericarditis	1	1			1	1
Peripheral swelling	2	10	2	3		7
Petechiae	1	1			1	1
Pharyngeal inflammation	1	1			1	1
Pharyngitis	1	1			1	1
Photopsia		1				1
Poor quality sleep	1	3	1	2		1
Presyncope		3		1		2
Product use issue		1		1		
Pruritus		1		1		
Psychomotor hyperactivity	1	1			1	1
Pulmonary arterial hypertension		1				1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary embolism		1				1
Pyelonephritis		2				2
Pyrexia	53	164	38	51	15	113
Rash		1		1		
Rash erythematous		2		1		1
Renal disorder		2				2
Renal pain		1				1
Respiratory arrest		1				1
Respiratory disorder	1	8			1	8
Retinal pigment epitheliopathy	1	1			1	1
Rhinitis	1	2	1	1		1
Rhinorrhoea		2		1		1
Scleral discolouration		1				1
Seizure		4				4
Sensitive skin	1	2	1	1		1
Skin burning sensation		1				1
Skin disorder		6				6
Skin sensitisation		1				1
Sleep disorder		1		1		
Somnolence	1	3	1	1		2
Swelling	1	1	1	1		
Swelling of eyelid		1				1
Swollen tongue		1				1
Syncope	2	5			2	5
Synovial cyst	1	1	1	1		
Tachycardia	1	6	1	1		5
Tachypnoea	1	1			1	1
Tendonitis	1	1			1	1
Tension headache	1	1	1	1		
Thirst	1	1	1	1		
Tinnitus		1				1
Tonsillitis		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tremor	3	6	3	3		3
Type III immune complex mediated reaction	1	1			1	1
Unresponsive to stimuli		1				1
Urosepsis		1				1
Vaccination site discolouration	1	1	1	1		
Vaccination site discomfort	2	2	2	2		
Vaccination site erythema	8	13	6	10	2	3
Vaccination site induration	2	2	1	1	1	1
Vaccination site inflammation	1	1			1	1
Vaccination site lymphadenopathy		2				2
Vaccination site oedema	1	1	1	1		
Vaccination site pain	25	49	23	31	2	18
Vaccination site pruritus	1	2	1	1		1
Vaccination site reaction	16	67	4	11	12	56
Vaccination site swelling	2	5	1	2	1	3
Vaccination site warmth	2	5	2	4		1
Vaginal haemorrhage		1				1
Vasodilatation	1	1			1	1
Vertigo	5	8	5	5		3
Vision blurred	1	2	1	1		1
Visual field defect	1	2			1	2
Visual impairment	1	3			1	3
Vomiting	4	17	1	1	3	16
White blood cell count decreased	1	1			1	1
	634	1,853	398	559	236	1294

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	3	1	3		
Abdominal distension	1	2	1	1		1
Abdominal pain	2	6	1	1	1	5
Abdominal pain upper	7	12	1	2	6	10
Abdominal symptom		1		1		
Abnormal dreams	1	2			1	2
Ageusia	1	1	1	1		
Agitation		1				1
Allergic reaction to excipient		1				1
Altered state of consciousness		2				2
Anaphylactic reaction	1	13			1	13
Anaphylactic shock		3				3
Angioedema		4				4
Anosmia	1	1	1	1		
Anxiety		4		1		3
Aphonia	1	1	1	1		
Aphthous ulcer	1	4	1	1		3
Arrhythmia		1				1
Arthralgia	26	104	10	15	16	89
Arthritis		1				1
Asthenia	8	22	5	9	3	13
Asthenopia		2		2		
Asthma	1	3	1	1		2
Asymptomatic COVID-19		1				1
Autoimmune disorder		1				1
Axillary pain	3	4	1	1	2	3
Back pain	11	13	5	5	6	8
Balance disorder		2				2
Bell's palsy	2	3			2	3
Biliary colic		1				1
Blood pressure abnormal		1				1
Blood pressure decreased		3				3

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased		3		1		2
Body temperature increased	2	5	2	3		2
Bone pain	1	3	1	1		2
Bradycardia		4				4
Bradypnoea		1				1
Brain injury		1				1
Breast pain		3		1		2
Breath odour		1				1
Bronchospasm	1	2			1	2
Burning sensation	1	3			1	3
Cardiac arrest		1				1
Cardiovascular disorder	1	18		3	1	15
Carpal tunnel syndrome	1	1			1	1
Cerebrovascular accident		2				2
Chest discomfort		4				4
Chest pain	1	13	1	5		8
Chills	62	211	30	45	32	166
Coagulopathy	3	7		2	3	5
Coccydynia	1	1	1	1		
Cold sweat		1				1
Condition aggravated	1	1			1	1
Confusional state	1	1			1	1
Contusion	1	2	1	2		
Cough	2	10		2	2	8
COVID-19	3	12	1	3	2	9
Crying		1				1
Cyanosis		2				2
Deafness		1				1
Decreased appetite	3	9	1	1	2	8
Deep vein thrombosis	2	3			2	3
Dehydration		1				1
Depressed level of consciousness		2				2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diaphragmalgia	1	2	1	1		1
Diarrhoea	3	16	1	3	2	13
Diplopia		1				1
Discomfort	2	3			2	3
Disease recurrence		1				1
Disorientation	1	1			1	1
Disturbance in attention	1	1			1	1
Diverticulitis	1	1			1	1
Dizziness	7	30	5	9	2	21
Dizziness postural		1				1
Drug ineffective	2	6			2	6
Dry mouth		1				1
Dysacusis		1				1
Dysgeusia	1	4	1	2		2
Dysphonia	2	2	2	2		
Dyspnoea	5	19	4	5	1	14
Dyspnoea exertional		2				2
Ear pain		5		1		4
Eczema	2	2	1	1	1	1
Endolymphatic hydrops		1				1
Epicondylitis	1	1			1	1
Epilepsy	1	1			1	1
Epistaxis	1	1	1	1		
Erythema	2	8	1	1	1	7
Exercise tolerance decreased		2				2
Expired product administered		2		1		1
Extensive swelling of vaccinated limb	5	11			5	11
Eye pain	1	1	1	1		
Eye swelling	1	2	1	1		1
Face oedema		2		1		1
Facial asymmetry		1				1
Facial paralysis	1	6			1	6

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial paresis		2				2
Facial spasm		2		2		
Faeces discoloured		1				1
Fall	1	1			1	1
Fasciitis	1	1			1	1
Fatigue	84	272	40	62	44	210
Feeling abnormal	6	10	2	3	4	7
Feeling cold	3	9	2	3	1	6
Feeling hot	4	7	3	4	1	3
Feeling of body temperature change	2	5	2	2		3
Fibrin D dimer increased	1	1	1	1		
Flatulence		2		2		
Flushing		1				1
Gait inability	1	1			1	1
Gastric dilatation		1		1		
Gastroenteritis viral	1	1			1	1
Gastrointestinal disorder	2	3	2	2		1
Gastrointestinal pain	2	4			2	4
Gastrooesophageal reflux disease	1	2	1	1		1
Generalised tonic-clonic seizure	1	1			1	1
General physical health deterioration		2		1		1
Haematoma	1	1	1	1		
Hallucination		2				2
Hangover	1	1			1	1
Headache	96	310	53	88	43	222
Head discomfort	1	1			1	1
Heart rate decreased		1				1
Heart rate increased		2		1		1
Heart rate irregular		1		1		
Hemianaesthesia		1				1
Hemiparaesthesia		1				1
Hemiparesis		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes simplex		1				1
Herpes zoster		1		1		
Herpes zoster meningoradiculitis	1	1			1	1
Hot flush		7				7
Hyperhidrosis	7	12	6	8	1	4
Hypersensitivity		5				5
Hypersomnia	1	2	1	1		1
Hypertension		13		1		12
Hypertensive crisis		1				1
Hyperventilation		1		1		
Hypoaesthesia	1	5	1	2		3
Hypoglycaemia		1				1
Hypotension	1	7	1	1		6
Hypothermia		1				1
Impaired work ability		1		1		
Incorrect dose administered		1		1		
Infection		2		2		
Influenza	5	8	4	6	1	2
Influenza like illness	23	46	16	20	7	26
Injection site discomfort		1		1		
Injection site hypersensitivity		1				1
Injection site pain		1		1		
Injection site reaction		1				1
Insomnia	3	12		2	3	10
Jaw disorder		1		1		
Joint swelling		1				1
Leukocyturia		1		1		
Limb discomfort	2	5	1	1	1	4
Lip swelling		1				1
Liver disorder		1		1		
Loss of consciousness		4				4
Loss of personal independence in daily activities	1	2		1	1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenitis		1		1		
Lymphadenopathy	8	24	5	7	3	17
Lymph node pain	2	6	1	1	1	5
Lymphoedema		1				1
Malaise	27	129	11	18	16	111
Microangiopathic haemolytic anaemia	1	1			1	1
Middle insomnia	1	1			1	1
Migraine	6	11	3	3	3	8
Migraine with aura		1				1
Mobility decreased	2	4	2	3		1
Muscle contractions involuntary		1				1
Muscle disorder	1	1			1	1
Muscle fatigue		1		1		
Muscle spasms	1	1	1	1		
Muscle strain	3	8	2	3	1	5
Muscle tightness	1	1	1	1		
Muscular weakness		1				1
Musculoskeletal chest pain		2		1		1
Musculoskeletal discomfort	1	1	1	1		
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	9	28	6	19	3	9
Myalgia	84	240	47	63	37	177
Mydriasis		1		1		
Myocarditis	1	1			1	1
Myosclerosis		1				1
Nasal congestion		1		1		
Nasopharyngitis	2	2			2	2
Nausea	40	163	19	30	21	133
Neck pain	4	10	4	4		6
Nerve injury	1	1	1	1		
Nervous system disorder	2	12		1	2	11
Neuralgia		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuritis		1				1
Neurogenic shock		1				1
Neuropathic muscular atrophy	1	1			1	1
Nightmare		1				1
Night sweats	1	3			1	3
Oedema peripheral		1				1
Off label use	2	5	2	5		
Oral herpes		2				2
Oral pruritus		1				1
Oropharyngeal discomfort	1	1	1	1		
Oropharyngeal pain	1	8		3	1	5
Orthostatic hypotension	2	2	2	2		
Orthostatic intolerance		1				1
Oxygen saturation decreased		3		1		2
Pain	7	14	3	6	4	8
Painful respiration		1				1
Pain in extremity	24	52	15	32	9	20
Pain in jaw		1				1
Pallor		1				1
Palpitations		8		2		6
Paraesthesia	5	13	4	8	1	5
Paraesthesia oral	1	3	1	1		2
Parapharyngeal space infection		1				1
Pericardial effusion	1	1			1	1
Pericarditis	1	1			1	1
Peripheral motor neuropathy		1				1
Peripheral swelling	2	20	2	6		14
Petechiae	1	1	1	1		
Pharyngeal swelling		1				1
Phlebitis	1	1			1	1
Photophobia		1				1
Pleuritic pain	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonia		2				2
Pneumonitis		1				1
Poor quality sleep	2	3	2	3		
Presyncope	1	5	1	1		4
Product administered at inappropriate site		1				1
Product use issue	2	5	2	5		
Pruritus	3	11	1	2	2	9
Pruritus allergic		1				1
Pulmonary embolism	1	1			1	1
Pyrexia	62	206	34	52	28	154
Rash	4	9	3	5	1	4
Rash erythematous		1		1		
Rash macular	1	2	1	1		1
Rash maculo-papular	1	1	1	1		
Rash pruritic		1				1
Respiratory disorder	1	20	1	2		18
Respiratory distress		1				1
Restless legs syndrome		1		1		
Retching		1				1
Retinal vein occlusion	1	1			1	1
Retinal vein thrombosis	1	1	1	1		
Rhinorrhoea	1	4		1	1	3
Scarlet fever		1				1
Seizure		1				1
Sense of oppression		2		1		1
Sensitive skin	1	3	1	2		1
Sensory disturbance		2		2		
Serum ferritin increased		1		1		
Sinus headache		1				1
Sinusitis	1	2	1	1		1
Skin disorder	7	18	3	4	4	14
Skin haemorrhage	1	1	1	1		

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sleep deficit		1
Sleep disorder		3
Sleep disorder due to general medical condition, insomnia type	1	1
Sneezing		1
Somnolence	3	5
Speech disorder		1
Spinal pain		2
Sudden hearing loss		1
Suffocation feeling		1
Suppressed lactation		1
Swelling	1	2
Swelling face		1
Swollen tongue		4
Syncope	1	8
Tachyarrhythmia		1
Tachycardia	1	16
Tachypnoea		1
Taste disorder	2	3
Tension	1	1
Tetany		1
Therapeutic response unexpected		1
Thinking abnormal		1
Thirst	1	3
Thoracic outlet syndrome		1
Throat tightness		1
Thrombocytopenia	2	3
Thrombophlebitis		1
Thrombosis		2
Tinnitus	1	5
Tongue discomfort		1
Tonsillar inflammation		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
			3
		1	1
	1		
		3	5
	1		
	2		
			1
			1
			1
		1	2
			1
	1		3
		1	8
			1
1	2		14
			1
1	2	1	1
		1	1
			1
	1		
			1
	1	1	2
			1
		2	3
			1
			2
	1	1	4
			1
			1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tonsillitis		1				1
Tremor	1	4	1	1		3
Troponin increased	1	1			1	1
Urticaria	2	5	2	2		3
Vaccination failure		1				1
Vaccination site discomfort	2	2	1	1	1	1
Vaccination site erythema	3	10	2	7	1	3
Vaccination site haematoma		1				1
Vaccination site induration	2	4	2	4		
Vaccination site joint pain	1	1			1	1
Vaccination site movement impairment	1	4		1	1	3
Vaccination site pain	18	47	11	19	7	28
Vaccination site pruritus	1	2	1	1		1
Vaccination site reaction	26	119	6	15	20	104
Vaccination site swelling	2	7	2	6		1
Vaccination site warmth	1	3		1	1	2
Vaginal haemorrhage	1	1	1	1		
Vasculitis		1		1		
Venous thrombosis limb	1	1			1	1
Ventricular tachycardia		1				1
Vertigo	2	17	2	4		13
Vertigo positional	1	1	1	1		
Vestibular neuronitis		1				1
Vision blurred		4		1		3
Visual field defect		1				1
Visual impairment	1	4	1	3		1
Vomiting	6	20	4	6	2	14
Weight decreased		1				1
Wheezing		2				2
White blood cell count decreased		1		1		
Wrong product administered		1		1		
	878	2,956	453	784	425	2172

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	3		1	1	2
Abdominal pain upper	1	3		1	1	2
Ageusia		1		1		
Allergic reaction to excipient		1		1		
Allergy to vaccine		1				1
Altered state of consciousness		2				2
Anaphylactic reaction	1	8			1	8
Anaphylactic shock		1				1
Anaphylactoid reaction		1				1
Anosmia		1				1
Anxiety		2				2
Aphasia		2				2
Appendicitis	1	1			1	1
Arthralgia	19	57	7	12	12	45
Arthritis		2				2
Arthropathy	1	1	1	1		
Asthenia	6	12	1	2	5	10
Asthma exercise induced		1				1
Autoimmune disorder	1	4			1	4
Axillary pain	2	3	1	1	1	2
Back pain	1	3		1	1	2
Balance disorder		4				4
Blindness		3				3
Blood glucose decreased		1		1		
Blood glucose increased		1		1		
Blood pressure decreased	1	2	1	1		1
Blood pressure increased	1	4			1	4
Blood pressure systolic increased		1		1		
Blood test abnormal	1	1	1	1		
Body temperature decreased		1				1
Body temperature increased		3		1		2
Bone pain		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Brain contusion	1	1			1	1
Bronchospasm		1				1
Bundle branch block left		1				1
Burning sensation		2		1		1
Cardiac arrest		1				1
Cardiac failure		1				1
Cardiovascular disorder	2	14	1	4	1	10
Cerebral thrombosis		1				1
Cerebrovascular accident		2				2
Chest discomfort	2	6	1	2	1	4
Chest injury	1	1			1	1
Chest pain	2	7	1	3	1	4
Chillblains		1				1
Chills	28	100	9	12	19	88
Circadian rhythm sleep disorder	1	1	1	1		
Coagulopathy	2	7	1	1	1	6
Cough	1	2			1	2
COVID-19	5	9	2	3	3	6
Death		1				1
Decreased appetite		2				2
Deep vein thrombosis	1	3			1	3
Delirium		1				1
Delusion	1	1			1	1
Depressed level of consciousness		2				2
Dermo-hypodermatitis		1				1
Diabetic complication		1				1
Diarrhoea	4	7			4	7
Diplopia	1	1			1	1
Discomfort	2	4		1	2	3
Disturbance in attention		1				1
Dizziness	3	19	2	7	1	12
Drug administered in wrong device		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug ineffective	2	3			2	3
Dry mouth		1				1
Dry throat		1				1
Dysgeusia	4	7	1	1	3	6
Dyskinesia	1	1			1	1
Dyspepsia	1	1	1	1		
Dysphagia	1	2			1	2
Dysphonia		2				2
Dyspnoea	5	15		1	5	14
Dyspnoea exertional		2				2
Dyspraxia		1				1
Dysstasia	2	2	2	2		
Dystonia		1				1
Ear discomfort	1	2		1	1	1
Ear infection	1	1	1	1		
Ear pain	1	2	1	1		1
Electric shock sensation		1				1
Endocrine ophthalmopathy		1				1
Epilepsy		5				5
Epistaxis		1				1
Erythema	2	9	1	3	1	6
Exercise tolerance decreased		1				1
Extensive swelling of vaccinated limb	2	4		1	2	3
Eye swelling		1				1
Face oedema		1		1		
Facial bones fracture		1				1
Facial pain		1				1
Facial paralysis	1	4			1	4
Facial paresis		2				2
Fall	1	3		1	1	2
Fatigue	52	141	20	32	32	109
Feeling abnormal	1	4		2	1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling cold	1	1			1	1
Feeling drunk	1	2	1	2		
Feeling hot	4	6	2	3	2	3
Feeling of body temperature change	1	1			1	1
Fibrin D dimer increased		1				1
Folate deficiency	1	1	1	1		
Gait disturbance		1				1
Gastritis	1	1			1	1
Gastrointestinal disorder		1				1
Gastrointestinal pain	1	1	1	1		
General physical health deterioration		1				1
Haematoma	1	1			1	1
Haemorrhage		1				1
Headache	47	134	20	29	27	105
Heart rate decreased		1				1
Heart rate increased	1	4		1	1	3
Hemiparaesthesia	1	1			1	1
Hepatic pain	1	1	1	1		
Hepatitis	1	2			1	2
Herpes virus infection		1				1
Herpes zoster	5	8	5	7		1
Hot flush	2	7		3	2	4
Hyperacusis		1				1
Hyperferritinaemia	1	1			1	1
Hyperhidrosis	1	5			1	5
Hyperresponsive to stimuli	1	1			1	1
Hypersensitivity	1	7		3	1	4
Hypertension		8				8
Hyperventilation		1				1
Hypoaesthesia	4	6	4	4		2
Hypotension	2	3	2	2		1
Hypothermia		1				1

* I=Interval, C=Cumulative
* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Incorrect route of product administration		2		2		
Infection		1				1
Inflammation		1				1
Influenza	1	1			1	1
Influenza like illness	6	20	2	3	4	17
Injection site erythema		1				1
Injection site haematoma		1		1		
Injection site pain		1		1		
Injection site reaction		2		1		1
Insomnia		3		1		2
Joint range of motion decreased	1	1			1	1
Laryngitis		1				1
Laryngospasm		1				1
Lethargy		2				2
Limb discomfort	1	3		1	1	2
Lip swelling		1				1
Liver disorder	1	3		1	1	2
Loss of consciousness		1				1
Loss of personal independence in daily activities	1	1			1	1
Lymphadenopathy	3	7	2	2	1	5
Malaise	21	82	5	11	16	71
Mastication disorder	1	1			1	1
Memory impairment		2		1		1
Meniere's disease	1	1			1	1
Migraine	1	3			1	3
Migraine with aura		1				1
Mobility decreased		1				1
Movement disorder	1	1	1	1		
Mumps	1	1	1	1		
Muscle strain	2	4	1	1	1	3
Muscle tightness		1				1
Muscular weakness	2	4	2	2		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal chest pain		1		1		
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	2	9	1	2	1	7
Myalgia	27	91	8	17	19	74
Myocarditis	1	1			1	1
Nasal congestion	2	2	1	1	1	1
Nasopharyngitis	2	2	1	1	1	1
Nausea	23	72	8	12	15	60
Neck pain	2	4	1	1	1	3
Nervous system disorder	2	10	1	3	1	7
Neuropathy peripheral		1				1
Noninfective gingivitis	1	1	1	1		
Oedema peripheral	1	1			1	1
Ophthalmic herpes zoster	1	1			1	1
Oral herpes	2	3	1	1	1	2
Oropharyngeal pain	1	3	1	1		2
Oxygen saturation decreased	1	6			1	6
Pain	2	7	1	2	1	5
Painful respiration	1	1	1	1		
Pain in extremity	10	17	3	5	7	12
Pain in jaw	1	1	1	1		
Pain of skin		2				2
Pallor		2				2
Palmoplantar pustulosis		1		1		
Palpitations	1	1			1	1
Papule		1		1		
Paraesthesia	5	11	5	7		4
Paraesthesia oral		2				2
Parosmia	1	2	1	1		1
Parotid gland enlargement	1	1			1	1
Pelvic pain	1	1	1	1		
Pericarditis		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral coldness	1	1			1	1
Peripheral swelling	2	9	1	1	1	8
Pharyngeal swelling		4				4
Phlebitis		1				1
Photophobia		1				1
Polyuria	1	1			1	1
Poor quality sleep		1				1
Presyncope	1	1	1	1		
Procedural pain		1				1
Pruritus		10		4		6
Pulmonary embolism	2	3			2	3
Pyrexia	30	95	16	26	14	69
Rash	3	7	2	3	1	4
Rash maculo-papular		1				1
Rash papular	1	1	1	1		
Renal disorder		1				1
Renal failure		1				1
Renal pain		1				1
Respiratory disorder	1	9		1	1	8
Respiratory rate increased		1				1
Restlessness		1				1
Retching		1				1
Rhinitis allergic	1	1			1	1
Rhinolaryngitis	1	1	1	1		
Rhinorrhoea	2	3	1	1	1	2
Salivary gland pain	1	1			1	1
SAPHO syndrome		1				1
SARS-CoV-2 ant body test positive		1		1		
Seizure		4				4
Sense of oppression		4		2		2
Septic shock		1				1
Sinusitis	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sinus pain		1				1
Skin disorder	7	19	4	7	3	12
Skin mass		1				1
Skin odour abnormal	1	1	1	1		
Sleep disorder	1	1			1	1
Sleep disorder due to a general medical condition		1		1		
Sneezing	1	1	1	1		
Somnolence	1	3			1	3
Speech disorder	2	2			2	2
Sudden death		1				1
Supraventricular tachycardia		1				1
Swelling	1	1	1	1		
Swelling face		1				1
Swollen tongue		3				3
Syncope	1	8			1	8
Tachycardia	1	6	1	2		4
Thirst	1	1	1	1		
Throat tightness		1				1
Tinnitus		1				1
Tooth disorder	1	1	1	1		
Tremor	1	6	1	1		5
Trigeminal neuralgia	1	1			1	1
Troponin increased		1				1
Urticaria	1	3	1	1		2
Vaccination failure	1	1			1	1
Vaccination site bruising	1	1	1	1		
Vaccination site discomfort		1		1		
Vaccination site erythema	1	8		1	1	7
Vaccination site hypersensitivity		1				1
Vaccination site hypertrophy		1				1
Vaccination site induration	1	6	1	2		4

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site inflammation		1		1		
Vaccination site lymphadenopathy	1	1			1	1
Vaccination site movement impairment	1	1	1	1		
Vaccination site pain	11	27	7	10	4	17
Vaccination site pruritus	1	1			1	1
Vaccination site rash		1		1		
Vaccination site reaction	22	67	7	12	15	55
Vaccination site swelling	1	8		1	1	7
Vaccination site warmth	2	6	1	1	1	5
Vasculitis		1				1
Vasodilatation	1	1	1	1		
Vein disorder	1	1	1	1		
Vertigo		6		4		2
Vision blurred		4		3		1
Visual impairment		1				1
Vitamin B complex deficiency	1	1	1	1		
Vomiting	3	9			3	9
Weight decreased	1	1			1	1
Wheezing		1				1
Yellow skin		1				1
	506	1,582	202	361	304	1221

* I=Interval, C=Cumulative
* AE=Adverse Event
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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal pain	1	2			1	2
Abdominal pain upper	1	1			1	1
Acute kidney injury		1				1
Acute pulmonary oedema		1				1
Acute respiratory failure		2				2
Aggression	1	1			1	1
Agitation	1	1	1	1		
Allodynia		1				1
Anal incontinence		1		1		
Anaphylactic reaction		6				6
Angina pectoris	1	1			1	1
Angioedema	1	1			1	1
Apathy		1		1		
Arrhythmia	1	3			1	3
Arthralgia	15	23	4	5	11	18
Asthenia	1	4			1	4
Atrial fibrillation		2				2
Auditory disorder	1	1	1	1		
Back pain	2	2	1	1	1	1
Balance disorder	2	2			2	2
Blepharospasm	1	1			1	1
Blood pressure abnormal		1		1		
Blood pressure decreased	1	3	1	2		1
Blood pressure increased	2	3			2	3
Body temperature increased	1	4		2	1	2
Breath odour		1				1
Bronchitis	1	1			1	1
Cardiac arrest		2				2
Cardiac disorder		1				1
Cardiac failure		1				1
Cardiogenic shock		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiomegaly	1	2			1	2
Cardio-respiratory arrest		2				2
Cardiovascular disorder	3	8	1	1	2	7
Cerebral haemorrhage		1				1
Cerebrovascular accident	1	1			1	1
Chest pain	4	6			4	6
Chills	17	37	2	6	15	31
Coagulopathy	8	9	1	1	7	8
Condition aggravated	1	1			1	1
Conjunctival hyperaemia	1	1			1	1
Constipation		1				1
Coronary artery thrombosis		1				1
Cough	2	5		2	2	3
COVID-19	8	19	1	1	7	18
COVID-19 pneumonia		1				1
C-reactive protein increased	2	4		1	2	3
Death	5	6			5	6
Decreased appetite	1	3		2	1	1
Decreased vibratory sense		1				1
Deep vein thrombosis	1	2			1	2
Delirium	1	1			1	1
Diarrhoea	1	2			1	2
Diplopia	1	1			1	1
Disturbance in attention	1	1			1	1
Dizziness	2	4			2	4
Drug ineffective	5	11			5	11
Drug resistance		1				1
Dysaesthesia		1				1
Dysgeusia		2				2
Dysphagia		2		1		1
Dysphonia	2	2	1	1	1	1
Dyspnoea	7	11	1	1	6	10

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea exertional	1	1	1	1		
Epilepsy	2	3			2	3
Erysipelas		1				1
Erythema	2	4		1	2	3
Erythema multiforme	1	1			1	1
Extensive swelling of vaccinated limb	3	4			3	4
Facial pain		1		1		
Facial paralysis	3	3			3	3
Facial paresis	1	1			1	1
Faecal vomiting		1				1
Fall	1	3			1	3
Fatigue	30	54	7	13	23	41
Feeling abnormal	1	3			1	3
Feeling cold	1	1			1	1
Fibrin D dimer increased	1	1			1	1
Flatulence	1	1			1	1
Gait disturbance		1				1
Gastric dilatation		1				1
Gastrointestinal disorder	1	1			1	1
Generalised tonic-clonic seizure		1				1
General physical health deterioration	1	4			1	4
Haematoma		1		1		
Haematuria	2	2	1	1	1	1
Haemorrhagic stroke		1				1
Haemorrhagic transformation stroke	1	1			1	1
Headache	26	48	5	12	21	36
Hemiplegia	1	1			1	1
Herpes zoster	3	3	2	2	1	1
Hot flush	1	1			1	1
Hyperaesthesia	1	1			1	1
Hyperhidrosis	2	2	1	1	1	1
Hypersensitivity	2	3			2	3

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypersomnia	1	1	1	1		
Hypertension	3	7	1	2	2	5
Hypoaesthesia	1	2			1	2
Hypoglycaemia	1	2			1	2
Hyporeflexia		1				1
Hyporesponsive to stimuli		1				1
Hypotension		3				3
Illness		1		1		
Inflammation		1		1		
Influenza		1				1
Influenza like illness	4	9	3	3	1	6
Insomnia		3				3
Intestinal obstruction		1				1
Iridocyclitis	1	1			1	1
Irritability		1				1
Ischaemic stroke	1	1			1	1
Joint range of motion decreased		1				1
Lacrimation increased	1	1			1	1
Lactic acidosis		1				1
Limb discomfort	1	1			1	1
Lip swelling		1		1		
Loss of consciousness	3	3			3	3
Lymphadenopathy	1	1	1	1		
Malaise	15	32	4	6	11	26
Middle insomnia	1	1	1	1		
Migraine		1				1
Mobility decreased		1				1
Multiple organ dysfunction syndrome		1				1
Muscle spasms		2				2
Muscular weakness		2		1		1
Musculoskeletal stiffness	1	6	1	4		2
Myalgia	19	37	5	10	14	27

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* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nasopharyngitis	2	2			2	2
Nausea	14	32	3	6	11	26
Neck pain	1	1	1	1		
Nerve compression	1	1			1	1
Nervous system disorder	4	6	1	1	3	5
Neuralgia		1				1
Neutrophilia		1				1
Oropharyngeal pain	1	2		1	1	1
Oxygen saturation abnormal		1				1
Oxygen saturation decreased	1	6			1	6
Pain	2	3	2	3		
Pain in extremity	6	8	1	2	5	6
Palpitations	2	2			2	2
Paraesthesia	1	1			1	1
Paralysis	1	1			1	1
Parkinson's disease		2				2
Pericardial effusion		1				1
Pericarditis	1	1			1	1
Peripheral swelling		2				2
Peripheral venous disease	1	1			1	1
Pharyngeal inflammation	1	1	1	1		
Photophobia	1	1			1	1
Pleural effusion		1				1
Pneumonia	1	2			1	2
Pneumonitis		1				1
Polyneuropathy		1				1
Presyncope		1		1		
Productive cough	1	1			1	1
Prohormone brain natriuretic peptide increased		1				1
Pruritus	2	2			2	2
Pulmonary embolism	5	6			5	6
Pulmonary oedema		1				1

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* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia	17	38	4	8	13	30
Rales		1				1
Rectal haemorrhage	1	1			1	1
Renal failure		1				1
Renal pain	1	1			1	1
Respiratory acidosis		1				1
Respiratory disorder	3	7			3	7
Respiratory distress		1				1
Respiratory tract infection		1				1
Retching		1				1
Rhinorrhoea	2	2	1	1	1	1
Salivary hypersecretion	1	3		1	1	2
SARS-CoV-2 test positive		1				1
Seizure	2	3			2	3
Sensation of foreign body		2		1		1
Sense of oppression	1	1	1	1		
Sensitive skin		1				1
Sinus tachycardia		1				1
Skin disorder	5	7	1	2	4	5
Sleep disorder		1				1
Speech disorder		1		1		
Stress cardiomyopathy		1		1		
Subdural haematoma	1	1			1	1
Sudden death	1	5			1	5
Swelling face		1		1		
Swelling of eyelid	1	1			1	1
Syncope		2				2
Tachycardia	1	1			1	1
Taste disorder	1	1			1	1
Thirst	1	1			1	1
Throat tightness		1				1
Thrombocytopenia	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thrombophlebitis superficial	1	1	1	1		
Thrombosis	4	5			4	5
Thrombotic stroke	1	1			1	1
Tongue oedema	1	1			1	1
Tracheitis	1	1	1	1		
Trigeminal neuralgia	1	1			1	1
Troponin T increased		1				1
Vaccination failure		1				1
Vaccination site erythema		3		3		
Vaccination site induration		1		1		
Vaccination site movement impairment	1	1			1	1
Vaccination site pain	3	4	2	3	1	1
Vaccination site reaction	22	31	5	6	17	25
Vaccination site swelling		1		1		
Venous thrombosis	1	1			1	1
Vertigo	1	2			1	2
Vestibular disorder	1	1			1	1
Visual impairment	3	3			3	3
Vitamin D deficiency		1				1
Vomiting	3	7	1	1	2	6
	385	764	75	147	310	617

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Abdominal pain upper		1				1
Acute kidney injury	3	5			3	5
Acute psychosis		1				1
Acute respiratory failure		2				2
Agitation		5		1		4
Altered state of consciousness		1				1
Amnesia		1				1
Angina pectoris	1	2			1	2
Angle closure glaucoma		1				1
Anxiety		2		1		1
Aphasia	4	4			4	4
Arrhythmia		1				1
Arthralgia	7	9	2	3	5	6
Asthenia		2		1		1
Atrial fibrillation		1				1
Atrioventricular block complete		2				2
Back pain	2	2			2	2
Bedridden	1	1			1	1
Blood alkaline phosphatase increased	1	1			1	1
Blood lactic acid increased		2				2
Blood pressure abnormal		1				1
Blood pressure decreased		1				1
Blood urine present		1				1
Body temperature increased		1		1		
Bradycardia		4				4
Bronchial disorder		1				1
Burning sensation	1	1			1	1
Cardiac arrest		3				3
Cardiac discomfort	1	1			1	1
Cardiac disorder		1				1
Cardiac failure		2				2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiogenic shock		1				1
Cardio-respiratory arrest	1	2			1	2
Cardiovascular disorder		16		1		15
Carotid artery occlusion	2	2			2	2
Carotid artery thrombosis	1	1			1	1
Cerebral ischaemia		1				1
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident	4	10			4	10
Chest discomfort	1	1			1	1
Chest pain		1				1
Cheyne-Stokes respiration		1				1
Chills	5	13		3	5	10
Cholelithiasis	1	1			1	1
Chromaturia	1	1			1	1
Coagulopathy	8	12	2	3	6	9
Cold sweat		1				1
Coma		1				1
Concussion		1				1
Confusional state		5		2		3
Contusion	1	1	1	1		
Cough	1	3			1	3
COVID-19	12	29	1	3	11	26
COVID-19 pneumonia		2				2
C-reactive protein increased	1	3		1	1	2
Cutaneous vasculitis	1	1			1	1
Cyanosis	1	1			1	1
Death	3	5			3	5
Decreased appetite	3	4	1	2	2	2
Deep vein thrombosis	3	3			3	3
Depressed level of consciousness		5				5
Diarrhoea		3		1		2
Disorientation		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	2	4	1	2	1	2
Drug ineffective	6	16			6	16
Dry skin		1				1
Dyspnoea	2	11			2	11
Dyspnoea exertional	1	1			1	1
Dysstasia		2				2
Epilepsy	1	4			1	4
Erythema	1	2	1	1		1
Eschar		1				1
Extensive swelling of vaccinated limb	2	2			2	2
Extrasystoles	1	1			1	1
Eye movement disorder		1				1
Eye pain		1		1		
Facial paresis	1	2			1	2
Faeces discoloured	1	1			1	1
Fall		7		1		6
Fatigue	11	28	4	13	7	15
Feeling cold	1	1			1	1
Fibrin D dimer increased	1	2			1	2
Gait disturbance	1	1			1	1
Generalised tonic-clonic seizure		1				1
General physical health deterioration	1	12			1	12
Glaucoma		1				1
Haematoma	1	1	1	1		
Haemophagocytic lymphohistiocytosis	1	1			1	1
Haemoptysis	1	1			1	1
Haemorrhage intracranial		1				1
Hallucination		1				1
Hallucination, visual		1				1
Headache	9	17	4	7	5	10
Heart rate increased		1				1
Hemiparesis	1	2			1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hemiplegia	4	6			4	6
Hepatic cytolysis	1	1			1	1
Hepatic failure		1				1
Herpes ophthalmic		2				2
Hyperhidrosis	1	1			1	1
Hypersensitivity	1	1			1	1
Hypertension	2	6			2	6
Hyperthermia		1		1		
Hypoglycaemia	1	2	1	1		1
Hypokalaemia		1				1
Hyponatraemia		1				1
Hypotension		5				5
Hypovolaemic shock		1				1
Hypoxia		1				1
Illness	1	1	1	1		
Illusion		1				1
Inappropriate schedule of product administration	1	2	1	2		
Inflammation	1	1			1	1
Influenza like illness		3		2		1
Injection site pain	1	1	1	1		
Injection site reaction	1	2	1	2		
Injection site warmth	1	1	1	1		
Insomnia	1	1			1	1
International normalised ratio increased	1	1			1	1
Intestinal dilatation		1				1
Intestinal ischaemia		2				2
Ischaemic cerebral infarction	1	1			1	1
Ischaemic stroke	2	2			2	2
Lacrimation increased		1		1		
Lactic acidosis		1				1
Leukocytosis	1	2			1	2
Lip swelling	1	2	1	1		1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Livedo reticularis		1				1
Liver disorder	2	2			2	2
Liver function test abnormal		3				3
Local reaction	1	1	1	1		
Loss of consciousness	2	3			2	3
Lower respiratory tract congestion		1				1
Lung infiltration		1				1
Malaise	10	30	3	8	7	22
Metabolic acidosis		1				1
Monoplegia	2	2			2	2
Motor dysfunction	1	1			1	1
Multiple organ dysfunction syndrome		1				1
Muscle spasms	1	1			1	1
Muscle strain	2	2			2	2
Myalgia	9	14	4	7	5	7
Myocardial infarction		1				1
Nausea	6	17	2	5	4	12
Neck pain	1	2	1	1		1
Nerve injury	1	1			1	1
Nervous system disorder	5	14		2	5	12
Neurogenic shock		1				1
Neutropenia		1				1
N-terminal prohormone brain natriuretic peptide increased		1				1
Ocular hyperaemia		1		1		
Oral herpes		2		1		1
Oropharyngeal pain	1	1	1	1		
Oxygen saturation decreased		11				11
Pain		1				1
Pain in extremity	2	3	1	1	1	2
Pancreatitis acute	1	1			1	1
Paresis		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Patient elopement		1				1
Peripheral coldness		1				1
Peripheral swelling	5	6	4	4	1	2
Phlebitis superficial	2	2			2	2
Platelet count decreased	1	1			1	1
Pleural effusion		1				1
Pneumonia		1				1
Pneumonia aspiration	1	2			1	2
Pneumonia bacterial		1				1
Pneumonitis		1				1
Presyncope		2				2
Productive cough	1	2			1	2
Pruritus	1	1	1	1		
Pulmonary embolism	4	10			4	10
Pulmonary infarction		1				1
Pulmonary oedema		2				2
Pyrexia	13	38	8	19	5	19
Rales		1				1
Rash erythematous	1	1	1	1		
Rash macular		1				1
Red blood cell sedimentation rate increased		1		1		
Renal disorder	2	4			2	4
Renal failure		1				1
Respiration abnormal		2				2
Respiratory arrest	1	1			1	1
Respiratory disorder	1	13		1	1	12
Respiratory distress		2				2
Respiratory failure	1	2			1	2
Respiratory tract infection		2				2
Restlessness		2		1		1
Retching		1				1
Rhythm idioventricular		1				1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sedation		2				2
Seizure		1				1
Sepsis		1				1
Septic shock		1				1
Skin disorder	3	5			3	5
Sneezing	1	2		1	1	1
Somnolence		2				2
Speech disorder	1	1			1	1
Spinal pain	1	1			1	1
Staring		1				1
Sudden death	3	14			3	14
Swelling face	1	2	1	1		1
Syncope	1	7			1	7
Tachycardia		1				1
Tachypnoea		1				1
Thrombocytopenia	3	4			3	4
Transient ischaemic attack	1	1			1	1
Tremor		1		1		
Troponin increased		2				2
Tumour thrombosis	1	1			1	1
Unresponsive to stimuli		2				2
Urinary retention		1				1
Urinary tract infection		1		1		
Urticaria	2	2			2	2
Vaccination site erythema	2	13	2	12		1
Vaccination site haematoma	1	3	1	3		
Vaccination site induration	2	4	2	4		
Vaccination site pain		2		2		
Vaccination site pruritus		1		1		
Vaccination site reaction	9	18	5	10	4	8
Vaccination site swelling		3		3		
Vision blurred		1		1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vomiting		3		1		2
Weight decreased	1	1	1	1		
Wrong product administered		1		1		
	255	720	64	162	191	558

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	1	1	1	1		
Anaphylactic reaction		4				4
Anaphylactic shock		1				1
Angina pectoris		1				1
Anxiety		1				1
Apathy		1				1
Arthralgia	17	35	7	11	10	24
Arthritis		1		1		
Asthenia	2	5	1	2	1	3
Asymptomatic COVID-19		24				24
Autoimmune disorder		1				1
Axillary pain	1	1	1	1		
Back pain	4	5	4	5		
Balance disorder		2				2
Blood pressure decreased	3	3	2	2	1	1
Body temperature increased	1	1	1	1		
Bone pain	1	2			1	2
Bone swelling	1	1	1	1		
Bradycardia		1				1
Bronchospasm		1				1
Burning sensation		1				1
Cardiovascular disorder		2				2
Cerebral thrombosis		1				1
Cerebrovascular accident		1				1
Chest discomfort		2				2
Chest pain	2	5	2	2		3
Chills	22	52	11	14	11	38
Coagulopathy	1	2			1	2
Condition aggravated		1		1		
Cough	1	3	1	1		2
COVID-19	13	62		11	13	51

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cutaneous vasculitis		1				1
Deafness		1				1
Decreased appetite		1				1
Deep vein thrombosis	1	2			1	2
Depressed level of consciousness		1				1
Depressive symptom	1	1	1	1		
Diarrhoea	3	6	2	3	1	3
Discomfort		1				1
Disease recurrence		1				1
Dizziness	8	11	8	8		3
Drug ineffective	13	60			13	60
Dry mouth	1	1	1	1		
Dry throat		1		1		
Dysgeusia		1		1		
Dyspepsia		1				1
Dysphagia		1				1
Dyspnoea	1	11	1	3		8
Ear discomfort		1		1		
Ear pain	1	1			1	1
Eczema		1		1		
Electric shock sensation		1				1
Erysipelas	1	1			1	1
Erythema	3	6	3	5		1
Exposure via breast milk		1		1		
Exposure via skin contact		1		1		
Eye irritation		1				1
Eye pain	1	1			1	1
Facial paresis		1				1
Fatigue	30	72	16	25	14	47
Feeling abnormal	3	4	3	4		
Feeling cold		1				1
Feeling hot	2	2	2	2		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling of body temperature change	3	3	3	3		
Fluid retention	1	1	1	1		
Food allergy		1				1
Formication		1				1
Gait disturbance		1				1
Gastrointestinal pain		1				1
Gingival pain		1				1
Headache	54	98	43	50	11	48
Head discomfort		1				1
Heart rate increased	1	2	1	1		1
Hemiplegia		1				1
Herpes zoster	2	2	2	2		
Hot flush	1	1	1	1		
Hyperacusis		1				1
Hyperaesthesia teeth		1				1
Hyperglycaemia	2	2			2	2
Hyperhidrosis	5	5	4	4	1	1
Hypersensitivity		5				5
Hypertension	1	8	1	2		6
Hyperthermia		1		1		
Hyperventilation	1	1	1	1		
Hypoacusis		1				1
Hypoaesthesia		1				1
Hypoglycaemia		2				2
Hypotension	1	3		1	1	2
Hypothermia		1				1
Illness	1	3	1	2		1
Immobile		1				1
Incorrect route of product administration	78	125	78	125		
Inflammation		1				1
Influenza	4	4	4	4		
Influenza like illness	18	22	17	19	1	3

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site pain		1		1		
Injection site reaction		1				1
Insomnia	3	4	3	4		
Lethargy		1		1		
Lip swelling		1				1
Liver disorder		1				1
Loss of consciousness		1				1
Lymphadenopathy	6	11	4	5	2	6
Lymph node pain	1	2	1	1		1
Malaise	12	39	8	13	4	26
Maternal exposure during pregnancy	2	4	2	4		
Migraine	5	8	3	3	2	5
Muscle strain	1	2	1	2		
Muscular weakness	1	1	1	1		
Musculoskeletal stiffness	7	8	6	7	1	1
Myalgia	37	75	24	32	13	43
Nasopharyngitis	1	3	1	1		2
Nausea	20	46	14	19	6	27
Neck pain	4	6	4	6		
Nervous system disorder	1	6	1	2		4
Neuralgia		1				1
Noninfective gingivitis		1				1
Occupational exposure to product		1		1		
Ocular hyperaemia	1	1	1	1		
Off label use	1	1	1	1		
Oral herpes	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Oxygen saturation decreased		1				1
Pain	4	5	3	4	1	1
Pain in extremity	12	17	12	13		4
Palpitations	1	3		1	1	2
Papule		1				1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia	3	4	3	4		
Paraesthesia oral		1				1
Paralysis		1				1
Peripheral swelling	2	8	2	4		4
Petechiae		1		1		
Pharyngeal erythema		1				1
Pharyngeal swelling		1				1
Phlebitis	1	1	1	1		
Photophobia		1				1
Polyuria	1	1	1	1		
Posture abnormal		1		1		
Presyncope		2				2
Product preparation issue		1		1		
Product use issue	1	1	1	1		
Pruritus	2	7	2	4		3
Pyrexia	42	77	33	44	9	33
Rash		1		1		
Rash erythematous	1	2	1	2		
Renal pain		1				1
Respiratory disorder		7		1		6
Rhinorrhoea		1		1		
SARS-CoV-2 ant body test negative	1	1			1	1
Seizure		1				1
Sensory loss		1				1
Sepsis		1				1
Skin discolouration	1	1	1	1		
Skin disorder	1	5	1	1		4
Skin reaction	1	1	1	1		
Sleep disorder		1		1		
Sneezing		2				2
Somnolence	1	3	1	2		1
Speech disorder		1		1		

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Spinal pain	1	1	1	1		
Stomatitis		1				1
Subcutaneous abscess	1	1	1	1		
Sudden death	1	1			1	1
Suspected COVID-19		1				1
Swelling		1				1
Swelling face		1				1
Syncope	1	5			1	5
Syringe issue		1		1		
Tachycardia	1	4			1	4
Thrombocytopenia	1	1			1	1
Tinnitus		1				1
Transient ischaemic attack		1				1
Tremor	1	1			1	1
Underdose		1		1		
Upper airway obstruction		1				1
Urticaria		1				1
Vaccination failure		15				15
Vaccination site erythema	5	7	5	7		
Vaccination site haematoma		2		1		1
Vaccination site induration	2	3	2	3		
Vaccination site movement impairment	2	3	1	1	1	2
Vaccination site pain	6	17	6	14		3
Vaccination site reaction	12	25	5	7	7	18
Vaccination site swelling	2	5	2	3		2
Vaginal abscess	1	1			1	1
Vertigo	1	4	1	1		3
Vision blurred	2	2	2	2		
Visual acuity reduced	1	1			1	1
Vomiting	7	10	5	5	2	5
Vulval abscess	1	1			1	1
Wrong technique in product usage process	77	112	77	112		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	619	1,350	475	689	144	661

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Country Where Event Occurred

BERMUDA

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills		1		1
Diarrhoea		1		1
Feeling cold		1		1
Night sweats		1		1
Paraesthesia		1		1
Pyrexia		1		1
		6		6

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Ear congestion		1		1		
Ear discomfort		1		1		
Erythema		1				1
Lymphadenopathy	1	1	1	1		
Pain		1				1
Pain in extremity	1	1	1	1		
Peripheral swelling	1	2	1	1		1
Sudden visual loss		1				1
	4	10	4	6		4

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Balance disorder		1		1		
Dizziness		1		1		
Dyspnoea		1				1
Rash		1		1		
		4		3		1

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Maternal exposure during pregnancy	1	1	1	1
	1	1	1	1

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* AE=Adverse Event
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Country Where Event Occurred

BOLIVIA

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cough	1	1	1	1
Oropharyngeal pain	1	1	1	1
Tachycardia	1	1	1	1
	3	3	3	3

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased	1	1	1	1		
Dizziness	1	1	1	1		
Feeling hot	1	1	1	1		
Heart rate increased	1	1	1	1		
Hypertension	1	1			1	1
Pancreatitis	1	1			1	1
	6	6	4	4	2	2

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

BOSNIA AND HERZEGOVINA

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Axillary pain	1	1	1	1
Lymphadenopathy	1	1	1	1
Oedema	1	1	1	1
	3	3	3	3

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19		1		1
		1		1

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Country Where Event Occurred

BRAZIL

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Maternal exposure during pregnancy	1	1	1	1
Premature baby	1	1	1	1
	2	2	2	2

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills	1	1	1	1		
COVID-19	1	1	1	1		
Diarrhoea	1	1	1	1		
Fatigue	1	1	1	1		
Headache	1	1	1	1		
Hypersensitivity	1	1			1	1
Pain in extremity	1	1	1	1		
Papule	1	1			1	1
Pruritus	1	1			1	1
Rash	1	1			1	1
Urticaria	1	1			1	1
Vaccination site pain	1	1	1	1		
	12	12	7	7	5	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Ageusia	1	1	1	1		
Arthralgia	1	1	1	1		
Asthenia	2	2	2	2		
Back pain	2	2	2	2		
Blood glucose increased	1	1	1	1		
Body temperature increased	1	1	1	1		
Burning sensation	1	1	1	1		
Cardio-respiratory arrest	1	1			1	1
Chest discomfort	1	1	1	1		
Chills	7	7	7	7		
Cough	1	1	1	1		
COVID-19	1	1	1	1		
Decreased appetite	1	1	1	1		
Diarrhoea	3	3	3	3		
Dizziness	1	1	1	1		
Dyspnoea	1	1			1	1
Erythema	1	1	1	1		
Fatigue	6	6	6	6		
Feeling abnormal	1	1	1	1		
Haemorrhage	1	1			1	1
Headache	7	7	7	7		
Head discomfort	1	1	1	1		
Hyperhidrosis	1	1	1	1		
Hypersensitivity	1	1	1	1		
Hypoaesthesia oral	1	1	1	1		
Hypokinesia	1	1	1	1		
Hypotension	1	1	1	1		
Influenza like illness	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Lymphocyte count decreased	1	1	1	1		
Lymphopenia	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise	1	1	1	1		
Maternal exposure during pregnancy	1	1			1	1
Mobility decreased	1	1	1	1		
Myalgia	7	7	7	7		
Nausea	4	4	4	4		
Neutrophil count decreased	1	1	1	1		
Overdose	2	2	2	2		
Pain	2	2	2	2		
Pain in extremity	4	4	4	4		
Pain in jaw	1	1	1	1		
Peripheral coldness	1	1	1	1		
Pleural effusion	1	1			1	1
Pollakiuria	1	1	1	1		
Premature labour	1	1			1	1
Product administered at inappropriate site	1	1	1	1		
Pruritus	2	2	2	2		
Pyrexia	6	6	6	6		
Rash	1	1	1	1		
Somnolence	1	1	1	1		
Swelling face	1	1	1	1		
Tachycardia	1	1	1	1		
Thrombosis	1	1			1	1
Tremor	1	1	1	1		
Vaccination site haematoma	1	1	1	1		
Vaccination site pain	8	8	8	8		
Vaccination site swelling	2	2	2	2		
Visual impairment	1	1	1	1		
White blood cell count decreased	1	1	1	1		
	109	109	102	102	7	7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Anxiety	1	1	1	1		
Asthenia	4	4	4	4		
Chills	2	2	2	2		
Dizziness	2	2	2	2		
Dry mouth	1	1	1	1		
Dyskinesia	1	1	1	1		
Epistaxis	1	1	1	1		
Fatigue	3	3	2	2	1	1
Headache	7	7	7	7		
Head discomfort	1	1	1	1		
Incorrect dose administered	1	1	1	1		
Influenza like illness	2	2	2	2		
Lymphadenopathy	2	2	2	2		
Malaise	3	3	3	3		
Menstrual disorder	1	1	1	1		
Myalgia	2	2	2	2		
Nasal congestion	1	1	1	1		
Nausea	2	2	2	2		
Oropharyngeal pain	1	1	1	1		
Overdose	1	1	1	1		
Pain	6	6	6	6		
Pain in extremity	5	5	5	5		
Pyrexia	7	7	6	6	1	1
SARS-CoV-2 test positive	1	1			1	1
Sleep disorder	1	1	1	1		
Sluggishness	2	2	2	2		
Somnolence	2	2	2	2		
Therapeutic response unexpected	1	1	1	1		
Tremor	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site mass	1	1	1	1		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	9	9	8	8	1	1
	77	77	73	73	4	4

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation	1	1	1	1		
Eyelid oedema	1	1	1	1		
Eyelid pain	1	1	1	1		
Eye pain	1	1	1	1		
Eye swelling	1	1	1	1		
Heart rate increased	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination site haemorrhage	1	1			1	1
Vaccination site inflammation	1	1			1	1
Vaccination site mass	1	1			1	1
Vaccination site pain	1	1			1	1
	11	11	7	7	4	4

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	2	2	2		
Appetite disorder	1	1	1	1		
Arthralgia	3	3	3	3		
Asthenia	1	1	1	1		
Asthenopia	1	1	1	1		
Back pain	1	1	1	1		
Bone pain	1	1	1	1		
Burning sensation	1	1	1	1		
Chills	6	6	6	6		
Contusion	1	1	1	1		
Cough	4	4	4	4		
COVID-19	1	1			1	1
Decreased appetite	1	1	1	1		
Diarrhoea	1	1	1	1		
Drug ineffective	2	2			2	2
Dry mouth	2	2	2	2		
Dry throat	1	1	1	1		
Dysphonia	1	1	1	1		
Dyspnoea	1	1	1	1		
Erythema	2	2	2	2		
Exposure during pregnancy	1	1			1	1
Exposure via breast milk	1	1	1	1		
Fatigue	3	3	3	3		
Feeling abnormal	1	1	1	1		
Feeling hot	1	1	1	1		
Foetal death	1	1			1	1
Gait disturbance	1	1	1	1		
Headache	11	11	11	11		
Hyperhidrosis	1	1	1	1		
Hypersensitivity	3	3	3	3		
Influenza like illness	1	1	1	1		
Insomnia	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Limb discomfort	2	2	2	2		
Lymphadenopathy	1	1	1	1		
Malaise	2	2	2	2		
Maternal exposure during pregnancy	2	2	2	2		
Maternal exposure timing unspecified	1	1	1	1		
Myalgia	2	2	2	2		
Nasal congestion	1	1	1	1		
Nausea	3	3	3	3		
Neck pain	1	1	1	1		
Off label use	1	1	1	1		
Overdose	1	1	1	1		
Pain	5	6	5	6		
Painful respiration	1	1	1	1		
Pain in extremity	7	7	7	7		
Peripheral swelling	1	1	1	1		
Polymenorrhoea	1	1	1	1		
Poor quality product administered	1	1	1	1		
Productive cough	1	1	1	1		
Product preparation error	1	1	1	1		
Product use issue	1	1	1	1		
Pruritus	1	1	1	1		
Pyrexia	8	8	8	8		
Rhinitis	1	1	1	1		
Rhinorrhoea	1	1	1	1		
SARS-CoV-2 test positive	1	1	1	1		
Seizure	1	1			1	1
Speech disorder	1	1	1	1		
Suspected COVID-19	1	1			1	1
Tachycardia	1	1	1	1		
Thirst	2	2	2	2		
Throat irritation	2	2	2	2		
Vaccination site bruising	1	1	1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site haemorrhage	1	1	1	1		
Vaccination site pain	9	9	9	9		
Vomiting	1	1	1	1		
Wrong technique in product usage process	1	1	1	1		
	129	130	122	123	7	7

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* I=Interval, C=Cumulative
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Country Where Event Occurred

BULGARIA

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	4	1	4		
Asthenia		2		2		
Blood pressure fluctuation		1		1		
Body temperature abnormal		1		1		
Body temperature increased	2	3	2	3		
Chills		1		1		
Condition aggravated		1		1		
COVID-19		1				1
Deafness unilateral		1				1
Decreased appetite	1	1	1	1		
Discomfort		1		1		
Disturbance in attention	1	1	1	1		
Dizziness	1	3	1	3		
Drug eruption		1		1		
Drug ineffective		1				1
Dry mouth		1		1		
Dyspnoea		1		1		
Epistaxis	1	1	1	1		
Erythema	1	2	1	2		
Eye irritation	1	1	1	1		
Fatigue	1	5	1	5		
Feeling abnormal	1	1	1	1		
Headache	2	5	2	5		
Heart rate increased		1		1		
Herpes zoster	1	1	1	1		
HIV test positive		1		1		
Hot flush		1		1		
Hypertension	1	1	1	1		
Injection site swelling		1		1		
Lacrimation increased	1	1	1	1		
Lymphadenopathy		1		1		
Lymphocyte count decreased		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise		3		3		
Muscle spasms	1	1	1	1		
Myalgia	1	5	1	5		
Nausea	2	5	2	5		
Neuralgia	1	2	1	2		
Oropharyngeal pain	1	1	1	1		
Pain		1		1		
Pain in extremity	2	5	2	5		
Palpitations		1		1		
Panic attack		2		2		
Paraesthesia		3		3		
Pyrexia	1	5	1	5		
Rash	1	1	1	1		
Renal pain		1		1		
Seizure		1				1
Spinal pain		1		1		
Swelling		1		1		
Tremor		1		1		
Urticaria	1	1	1	1		
Vaccination site erythema		1		1		
Vaccination site pain	5	9	5	9		
Vaccination site swelling		1		1		
Vertigo	1	2	1	1		1
	33	103	33	98		5

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Agitation		2		2		
Allergy to vaccine		1		1		
Anaphylactoid reaction		1				1
Anti-thyroid antibody positive		1				1
Application site erythema	1	1	1	1		
Application site swelling	1	1	1	1		
Arthralgia	3	13	1	11	2	2
Asthenia	2	13	2	11		2
Axillary pain		1		1		
Back pain	2	3	1	2	1	1
Blood fibrinogen increased	1	1			1	1
Blood pressure ambulatory increased	1	2	1	1		1
Blood pressure inadequately controlled		1		1		
Blood pressure increased	1	4	1	3		1
Body temperature abnormal	1	1	1	1		
Body temperature increased	11	24	10	22	1	2
Bone pain		1		1		
Breast pain	1	2	1	2		
Chest discomfort	1	1	1	1		
Chest pain		1		1		
Chills	7	23	6	20	1	3
Circulatory collapse		1				1
Coccydynia	1	1			1	1
Confusional state	1	1	1	1		
Cough	1	3	1	3		
COVID-19	2	5	1	3	1	2
COVID-19 pneumonia		2				2
Cystitis	1	1			1	1
Diarrhoea		1		1		
Discomfort	1	1	1	1		
Disturbance in attention		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	1	6	1	6		
Drug ineffective	1	2			1	2
Dysphagia	1	1	1	1		
Dyspnoea		4		3		1
Epigastric discomfort		1		1		
Erythema	1	3	1	3		
Eye pain	2	3	2	3		
Facial bones fracture		1				1
Fatigue	7	21	7	21		
Feeling hot		1		1		
Gait disturbance		1		1		
Grip strength decreased		1		1		
Headache	12	38	12	36		2
Head discomfort		1		1		
Heart alternation		1		1		
Hyperhidrosis	1	4	1	3		1
Hypersensitivity	1	1			1	1
Hypertension	1	2	1	1		1
Hypoaesthesia	2	2	2	2		
Hypothermia		1				1
Influenza like illness	3	3	3	3		
Injection site pain	1	4	1	4		
Injection site swelling		1		1		
Joint injury		1				1
Jugular vein distension		1				1
Lacrimation increased		1		1		
Leukopenia		1				1
Limb discomfort		1		1		
Lip swelling	1	2	1	1		1
Lymphadenopathy	4	11	3	10	1	1
Lymph node pain		2		2		
Malaise	2	6	2	6		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mastication disorder		1		1		
Meningism		1		1		
Movement disorder		1		1		
Muscle spasms	1	1	1	1		
Muscular weakness	1	1	1	1		
Musculoskeletal stiffness	2	4	1	2	1	2
Myalgia	7	22	7	22		
Nasopharyngitis		2		2		
Nausea	3	7	3	7		
Neck pain	1	2	1	2		
Oedema peripheral	1	1	1	1		
Oropharyngeal discomfort	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Overdose		2		2		
Pain		1		1		
Painful respiration		1		1		
Pain in extremity	5	11	3	9	2	2
Palpitations	1	3	1	2		1
Paraesthesia	1	4		2	1	2
Paranasal sinus discomfort		1		1		
Peripheral swelling	1	1	1	1		
Photophobia		1		1		
Pneumonia		1				1
Polymenorrhoea	1	1	1	1		
Poor peripheral circulation	1	1	1	1		
Pruritus	1	3		1	1	2
Pyrexia	7	18	7	17		1
Rash	1	2		1	1	1
Rash erythematous	1	1			1	1
Rash macular		1				1
Rash papular	1	1			1	1
Sensitive skin	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Somnolence	1	1	1	1		
Sweating fever		1				1
Swelling		2		2		
Swelling face	1	1	1	1		
Swollen tongue		1				1
Syncope		2				2
Tachycardia		3		1		2
Thirst		1		1		
Tinnitus		2		2		
Tremor		3		2		1
Trismus		1		1		
Urticaria	1	3		1	1	2
Vaccination site erythema	3	10	3	8		2
Vaccination site induration	1	2	1	1		1
Vaccination site oedema		1		1		
Vaccination site pain	12	44	11	42	1	2
Vaccination site paraesthesia	1	2	1	2		
Vaccination site pruritus	1	1	1	1		
Vaccination site reaction		1				1
Vaccination site swelling	3	12	3	11		1
Vasospasm		1				1
Ventricular extrasystoles		1				1
Vertigo		6		4		2
Vomiting	1	3	1	3		
	147	450	125	378	22	72

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris		1				1
Anosmia		1		1		
Antibody test abnormal		1		1		
Arthralgia	1	8	1	8		
Arthritis		1		1		
Asthenia	1	1	1	1		
Axillary pain	1	1	1	1		
Back pain	1	2	1	2		
Blood glucose increased	1	3		1	1	2
Blood pressure decreased		1				1
Blood pressure increased		4		3		1
Body temperature increased	4	10	4	10		
Bronchitis		1		1		
Chills	2	7	2	7		
Condition aggravated		1		1		
Conjunctivitis allergic		1		1		
Cough	1	1	1	1		
COVID-19	1	6	1	2		4
Dental discomfort		1		1		
Diarrhoea	1	1	1	1		
Dizziness		1		1		
Drug ineffective		4				4
Drug interaction	1	1			1	1
Dry mouth		1		1		
Dysphonia		1		1		
Dyspnoea	2	2	2	2		
Erythema		2		2		
Extrasystoles		2		2		
Eye pain		1		1		
Facial paralysis		1				1
Fatigue	2	8	2	8		
Fear	1	1	1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gait disturbance		1		1		
Headache	4	14	3	13	1	1
Heart rate increased	1	1	1	1		
Herpes simplex		1		1		
Hyperglycaemia	1	1			1	1
Hypersensitivity	1	1			1	1
Hypertension	1	2		1	1	1
Influenza like illness		2		2		
Injection site pain		1		1		
Injection site swelling		1		1		
Interstitial lung disease		1				1
Lacrimation increased		1		1		
Limb discomfort		1		1		
Lymphadenopathy	1	7	1	6		1
Malaise		2		2		
Mobility decreased		1		1		
Mouth swelling	1	1			1	1
Movement disorder		1				1
Musculoskeletal stiffness	1	1	1	1		
Myalgia	2	10	2	10		
Myelitis transverse		1				1
Nasopharyngitis		1		1		
Nausea		4		4		
Neuromyelitis optica spectrum disorder		1				1
Oedema peripheral		2		2		
Oropharyngeal pain		3		3		
Pain		1		1		
Pain in extremity	1	3	1	3		
Palpitations		1		1		
Paraesthesia	2	2	2	2		
Peripheral sensory neuropathy		1		1		
Peripheral swelling	1	3		2	1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Photophobia	1	1	1	1		
Pneumonia	1	1			1	1
Presyncope		1		1		
Productive cough		1		1		
Pyrexia	7	13	7	13		
Rash	2	4	2	4		
Rash erythematous		1		1		
Rash pruritic		1		1		
Renal pain	1	1	1	1		
Rheumatoid arthritis		1				1
Rheumatoid factor increased		1				1
Rheumatoid factor positive		1		1		
Sinusitis		1		1		
Tachycardia	1	1	1	1		
Tracheitis		1		1		
Urticaria	1	1			1	1
Vaccination site erythema	2	10	2	10		
Vaccination site extravasation		1		1		
Vaccination site induration		1		1		
Vaccination site pain	1	15	1	15		
Vaccination site reaction		1		1		
Vaccination site swelling	1	9	1	9		
Vertigo		2		2		
Vomiting	1	1	1	1		
	56	223	46	193	10	30

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		1		1		
Arthralgia	1	7	1	7		
Asthenia		3		3		
Back pain		2		2		
Blood pressure diastolic decreased		1		1		
Body temperature increased	1	5	1	4		1
Chills		4		3		1
Cold sweat		1		1		
Cough		2		2		
COVID-19		2				2
Decreased appetite		2		1		1
Diarrhoea		1		1		
Discomfort		1		1		
Dizziness	1	7	1	6		1
Dizziness postural		1		1		
Drug ineffective		2				2
Dyspnoea		1				1
Erectile dysfunction		1				1
Eye pain	1	1	1	1		
Facial paralysis		2				2
Fatigue	1	3	1	3		
Feeling cold		1		1		
Gait disturbance		1				1
Haematoma		1				1
Headache	1	3	1	2		1
Head discomfort		1				1
Heart rate irregular		1		1		
Hyperhidrosis		2		1		1
Insomnia		1		1		
Lethargy		1		1		
Malaise	1	2	1	2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia		5		5		
Nausea		3		2		1
Oropharyngeal pain	1	2	1	2		
Pain		1		1		
Pallor		1		1		
Paraesthesia		2		2		
Paraesthesia oral		1		1		
Peripheral coldness		1		1		
Pruritus	1	2	1	2		
Pyrexia	1	5	1	4		1
Rash		1		1		
Rhinorrhoea		2		2		
SARS-CoV-2 test positive		1				1
Throat irritation		1		1		
Tremor		1		1		
Urticaria		1		1		
Vaccination site erythema	1	2	1	1		1
Vaccination site pain	4	13	4	13		
Vaccination site swelling		1				1
Vasodilatation		1		1		
Vertigo		3		2		1
Vomiting	1	2	1	2		
	16	117	16	94		23

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Abdominal pain upper		1				1
Asthenia	1	1	1	1		
Decreased appetite	1	1	1	1		
Epistaxis		1		1		
Gait disturbance	1	1	1	1		
Headache		1				1
Iron deficiency anaemia	1	1	1	1		
Vertigo	1	1	1	1		
Vomiting		1				1
	5	10	5	6		4

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		1		1		
Anosmia		1		1		
Arrhythmia		1				1
Arthralgia	2	4	2	4		
Asthenia		2		2		
Back pain	2	2	2	2		
Body temperature increased	2	2	2	2		
Chills		1		1		
Communication disorder	1	1	1	1		
Cough	1	1	1	1		
COVID-19	1	4			1	4
C-reactive protein increased		1				1
Decreased appetite	1	1	1	1		
Discomfort	1	1	1	1		
Dizziness	2	2	2	2		
Drug ineffective	1	4			1	4
Dyspnoea	1	1	1	1		
Erythema	1	1	1	1		
Fatigue	3	4	3	4		
Gastrointestinal disorder		1		1		
Groin abscess		1				1
Headache	2	2	2	2		
Hypersensitivity	2	2	1	1	1	1
Hypertension		1		1		
Hypoaesthesia		1		1		
Inappropriate schedule of product administration		1		1		
Insomnia	1	1	1	1		
Joint swelling	1	1	1	1		
Joint warmth	1	1	1	1		
Lymphadenopathy		2		2		
Lymph node pain		2		2		
Malaise	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal pain		1		1		
Myalgia	2	4	2	4		
Nausea	1	1	1	1		
Off label use		1		1		
Pain		1		1		
Pain in extremity	1	3	1	3		
Pyrexia	2	8	2	8		
Somnolence	1	1	1	1		
Swelling face	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site oedema	1	1	1	1		
Vaccination site pain		1		1		
Vision blurred	1	1	1	1		
	38	77	35	65	3	12

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

CANADA

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea	1	1	1	1		
Dysphonia	1	1	1	1		
Ear infection		1				1
Exposure via breast milk	11	26	11	26		
Fatigue		1		1		
Irritability		1		1		
Nasopharyngitis		1		1		
Pyrexia		2		1		1
Rhinorrhoea		1		1		
Roseola		1		1		
Sleep disorder		1		1		
	13	37	13	35		2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal distension		1		1		
Abdominal pain	1	2	1	2		
Abdominal pain upper	1	1	1	1		
Affect lability	1	1	1	1		
Ageusia		1		1		
Amenorrhoea	1	1	1	1		
Anaphylactic reaction		2				2
Anxiety		1		1		
Arthralgia	4	8	4	8		
Asthenia	1	4	1	4		
Back pain	2	4	2	3		1
Bedridden	1	1			1	1
Bell's palsy		2				2
Beta haemolytic streptococcal infection		1				1
Blister	1	1			1	1
Blood glucose decreased	1	1			1	1
Blood glucose increased		1		1		
Blood pressure decreased	1	2	1	2		
Blood pressure orthostatic abnormal	1	1			1	1
Body temperature increased	2	2	2	2		
Bradyphrenia	1	1	1	1		
Breast pain	1	1	1	1		
Breast tenderness		1		1		
Burning sensation	1	1	1	1		
Cardiac flutter		1				1
Chest discomfort		1				1
Chest pain	3	5	3	4		1
Chillblains	1	1	1	1		
Chills	5	10	5	10		
Condition aggravated		1				1
Confusional state	2	2	1	1	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctivitis	1	1	1	1		
Contusion	1	1	1	1		
Costochondritis	1	1	1	1		
Cough		1		1		
COVID-19	1	2	1	1		1
Crying	1	1	1	1		
Decreased appetite		2		2		
Depressed level of consciousness	1	1			1	1
Dermatitis		1				1
Diarrhoea	2	5	1	4	1	1
Disease recurrence		1				1
Distract bility		1		1		
Disturbance in attention		1		1		
Dizziness	9	14	7	12	2	2
Drug ineffective		1				1
Dysgeusia		1		1		
Dysmenorrhoea		1		1		
Dysphagia		2		2		
Dyspnoea	3	6	3	6		
Ear discomfort		1		1		
Erythema	1	3	1	2		1
Exposure during pregnancy	1	5	1	5		
Eyelid function disorder		1				1
Eye pain		1		1		
Facial pain		1		1		
Fatigue	10	23	9	22	1	1
Feeling abnormal	2	4	2	4		
Feeling hot	2	3	2	3		
Flushing		2		2		
Gait disturbance	1	1	1	1		
Galactostasis	1	1	1	1		
Gastroenteritis viral		1		1		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemoglobin decreased	1	1			1	1
Headache	9	19	9	19		
Head discomfort	2	2	2	2		
Heart rate increased	3	4	2	3	1	1
Heart rate irregular	1	1			1	1
Heavy menstrual bleeding	4	5	2	2	2	3
Herpes zoster	6	8	5	7	1	1
Hot flush		1		1		
Hyperaesthesia		1				1
Hyperhidrosis	2	2	2	2		
Hypoacusis		2		2		
Hypoaesthesia	4	7	3	5	1	2
Hypoaesthesia eye		1		1		
Hypoaesthesia oral	1	1			1	1
Hypopnoea	1	1	1	1		
Hypotension	1	2		1	1	1
Impaired quality of life	1	1	1	1		
Impaired work ability		1		1		
Inflammation	1	1	1	1		
Influenza like illness		2		2		
Injection site erythema	1	1	1	1		
Injection site haemorrhage	1	1	1	1		
Insomnia		1		1		
Joint stiffness	1	1	1	1		
Joint warmth	1	1	1	1		
Lip swelling		1		1		
Liver function test increased		1				1
Loss of consciousness		1				1
Lung disorder		1				1
Lymphadenopathy	2	5	2	5		
Malaise	3	7	2	6	1	1
Mastitis	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Maternal exposure before pregnancy		2		2		
Maternal exposure during pregnancy		3		3		
Menstrual disorder	1	2		1	1	1
Menstruation delayed	1	1	1	1		
Menstruation irregular	6	6	5	5	1	1
Micturition urgency	1	1	1	1		
Migraine		3		3		
Mobility decreased		1		1		
Motion sickness	1	1	1	1		
Movement disorder	1	1	1	1		
Multiple organ dysfunction syndrome	1	1			1	1
Multiple sclerosis		1				1
Muscle spasms	1	2		1	1	1
Muscle tightness	1	2	1	2		
Muscle twitching		1		1		
Muscular weakness	1	3		1	1	2
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	1	2	1	2		
Myalgia	4	11	4	11		
Nausea	9	16	9	16		
Neck pain	1	3	1	3		
Neurogenic shock	1	1			1	1
Neurological symptom		1				1
Ocular hyperaemia	1	1			1	1
Odynophagia		1		1		
Off label use	4	10	4	10		
Ophthalmic herpes zoster	1	1			1	1
Oropharyngeal pain	1	5	1	5		
Overdose		1		1		
Pain	4	7	4	7		
Pain in extremity	7	15	7	15		
Pain in jaw		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pallor	2	2	2	2		
Palpitations	2	4		2	2	2
Paraesthesia	1	4	1	3		1
Paraesthesia oral	1	1			1	1
Penis disorder		1				1
Peripheral coldness		1				1
Peripheral swelling	1	1	1	1		
Photophobia	1	1	1	1		
Platelet count decreased	1	1			1	1
Polydipsia		1		1		
Polyuria		1		1		
Postural orthostatic tachycardia syndrome	1	1			1	1
Presyncope	1	1	1	1		
Product use issue	4	8	4	8		
Pruritus		2		1		1
Psychotic disorder due to a general medical condition		1				1
Pulmonary embolism	2	2			2	2
Pulmonary pain		1				1
Pyrexia	4	15	4	15		
Rash	2	7	2	7		
Rash pruritic		1		1		
Rash pustular		1		1		
Renal failure	1	1			1	1
Rheumatoid arthritis	1	1			1	1
Scar	1	1			1	1
Seizure		1				1
Sensory disturbance		1				1
Sensory loss		1		1		
Shock	1	1			1	1
Sinus disorder	1	1	1	1		
Skin burning sensation		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Speech disorder	1	2	1	2		
Swelling		1		1		
Swelling face		1		1		
Swollen tongue		2		2		
Syncope	4	4			4	4
Tachycardia		1		1		
Taste disorder		1		1		
Temporomand bular joint syndrome		1		1		
Testicular retraction		1				1
Thirst	2	2	2	2		
Threatened labour		1		1		
Thrombosis	3	3			3	3
Tremor		1		1		
Type IV hypersensitivity reaction		1		1		
Underdose		1		1		
Urinary incontinence		1				1
Urticaria	4	6	4	5		1
Vaccination site discomfort		1		1		
Vaccination site erythema		1		1		
Vaccination site hypersensitivity	1	1	1	1		
Vaccination site inflammation		1		1		
Vaccination site pain	7	16	7	16		
Vaccination site rash		1		1		
Vaccination site swelling	1	3	1	3		
Vaccination site urticaria	1	1	1	1		
Vaginal haemorrhage	1	1	1	1		
Venous thrombosis limb	1	1			1	1
Vertigo		2		1		1
Vision blurred	1	2		1	1	1
Visual acuity reduced	1	1	1	1		
Visual impairment		1				1
Vomiting	1	4	1	4		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term

Vomiting projectile

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
175	396	49	87

224

483

175

396

49

87

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Abdominal pain lower	1	2	1	2		
Abdominal pain upper	3	6	2	5	1	1
Abnormal sensation in eye	1	1			1	1
Abortion spontaneous		3				3
Affect lability		1		1		
Ageusia		1		1		
Agitation	1	1	1	1		
Alanine aminotransferase decreased		1		1		
Anal incontinence	1	1			1	1
Anaphylactic reaction		8				8
Anaphylactic shock		2				2
Angioedema		1				1
Angiopathy		1		1		
Anosmia	1	2	1	2		
Anxiety	3	9	1	6	2	3
Aphthous ulcer		1		1		
Arrhythmia	2	2			2	2
Arthralgia	5	20	4	16	1	4
Arthritis	1	1			1	1
Asthenia	1	8	1	6		2
Autoimmune disorder	1	2			1	2
Axillary mass	1	1	1	1		
Axillary pain		3		3		
Back pain	4	5	4	4		1
Balance disorder	1	1	1	1		
Bell's palsy	2	5			2	5
Blister	1	1			1	1
Blood creatinine abnormal		1		1		
Blood glucose decreased	1	2	1	1		1
Blood immunoglobulin G increased		1		1		
Blood iron decreased	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased		1				1
Body temperature increased	1	2	1	2		
Breast pain	1	2	1	1		1
Burning sensation	3	4	1	2	2	2
Cardiac flutter	1	1			1	1
Carotid artery dissection		1				1
Carotid artery thrombosis		1				1
Cerebrovascular accident		1				1
Chest discomfort	3	12	1	7	2	5
Chest pain	5	9	5	9		
Chills	9	29	8	28	1	1
Cognitive disorder	1	1	1	1		
Cold sweat	1	3		1	1	2
Condition aggravated	1	5	1	2		3
Confusional state	1	1	1	1		
Conjunctival haemorrhage	1	1			1	1
Conjunctivitis		1		1		
Connective tissue disorder		1				1
Contusion		3		2		1
Cough	2	6	2	6		
COVID-19	1	5		1	1	4
COVID-19 pneumonia		1				1
C-reactive protein increased		1		1		
Deafness unilateral		1				1
Decreased appetite	3	4	1	2	2	2
Defaecation urgency	1	1	1	1		
Dehydration	1	1	1	1		
Depressed level of consciousness		1				1
Depressed mood	1	1			1	1
Depression		2		2		
Dermatitis infected		1		1		
Dermatochalasis		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea	3	12	2	10	1	2
Discomfort	1	2		1	1	1
Disease recurrence	1	3			1	3
Disturbance in attention	2	3	2	3		
Dizziness	12	30	9	23	3	7
Dizziness postural	1	1	1	1		
Drug ineffective	2	3			2	3
Drug interaction		1				1
Drug level increased		1		1		
Dry eye		1		1		
Dry mouth		1		1		
Dysgeusia		2		2		
Dysmenorrhoea	4	5	4	5		
Dysphagia	1	3	1	3		
Dyspnoea	1	13		10	1	3
Ear discomfort		2		2		
Ear pain	1	1	1	1		
Ear pruritus	1	1	1	1		
Ear swelling	2	2	2	2		
Ectopic pregnancy		1				1
Eczema		1		1		
Electric shock sensation	1	1			1	1
Erythema	3	7	2	4	1	3
Erythema multiforme		1				1
Euphoric mood	1	1	1	1		
Exposure during pregnancy	3	7	3	7		
Extrasystoles		1		1		
Eye haemorrhage	1	1			1	1
Eyelid ptosis		1				1
Eye movement disorder	1	1			1	1
Eye pain	3	3	2	2	1	1
Eye swelling		3		2		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Face oedema		1				1
Facial pain	2	4	1	3	1	1
Fatigue	27	68	21	56	6	12
Fear		1		1		
Feeling abnormal	5	8	4	7	1	1
Feeling cold		2		1		1
Feeling drunk		1		1		
Feeling hot	3	8	3	7		1
Feeling of body temperature change		1		1		
Fibrin D dimer increased	1	1			1	1
Fibromyalgia		1		1		
Fluid retention		3		3		
Flushing	2	3	1	1	1	2
Frequent bowel movements	1	1	1	1		
Frustration tolerance decreased	1	1			1	1
Fungal skin infection		1		1		
Gait disturbance	1	2	1	1		1
Gastric disorder		1		1		
Gastrointestinal disorder	1	2	1	2		
Gastrooesophageal reflux disease		1		1		
Gestational diabetes		1				1
Grip strength decreased		1		1		
Haematemesis		1				1
Haematochezia		1				1
Haemoglobin increased		1		1		
Haemorrhage	1	1			1	1
Headache	23	68	16	55	7	13
Head discomfort	1	1	1	1		
Heart rate decreased		1				1
Heart rate increased	3	6	1	2	2	4
Heavy menstrual bleeding	10	10	8	8	2	2
Hepatic enzyme increased		1				1

* I=Interval, C=Cumulative

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes zoster	4	7	3	5	1	2
Hot flush	1	2	1	1		1
Hunger	2	2	1	1	1	1
Hyperaesthesia	1	2	1	2		
Hyperaesthesia teeth	1	1			1	1
Hyperhidrosis	6	8	5	6	1	2
Hypersensitivity	1	5		2	1	3
Hypersomnia		1		1		
Hypertension	1	8		2	1	6
Hypertensive crisis		1				1
Hypoaesthesia	10	22	7	12	3	10
Hypoaesthesia eye	1	1	1	1		
Hypoaesthesia oral		4				4
Hypomenorrhoea	1	1	1	1		
Hypotension	1	4	1	2		2
Illness	1	2	1	2		
Impaired driving ability	1	1	1	1		
Inappropriate schedule of product administration	2	7	2	7		
Incomplete course of vaccination		1		1		
Incorrect route of product administration		1		1		
Inflammation		1		1		
Influenza like illness		4		3		1
Injection site pain		5		5		
Injection site scar		1		1		
Insomnia	2	3	1	2	1	1
Intermenstrual bleeding	2	2	2	2		
Intraocular pressure increased	1	1			1	1
Joint noise		1		1		
Joint range of motion decreased		1		1		
Joint swelling		2		1		1
Language disorder	1	1	1	1		
Laryngospasm		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lethargy		1		1		
Leukoplakia		1		1		
Limb discomfort	2	3	2	3		
Lip swelling	2	2	1	1	1	1
Loss of consciousness	4	5			4	5
Lymphadenopathy	3	19	3	16		3
Lymph node pain		1		1		
Malaise	7	13	6	12	1	1
Maternal exposure before pregnancy		1		1		
Maternal exposure during pregnancy	1	11	1	11		
Mean cell haemoglobin concentration increased		1		1		
Meningitis aseptic		1				1
Menstrual disorder	5	5	4	4	1	1
Menstruation delayed		1		1		
Menstruation irregular	10	12	10	12		
Mental disorder	1	1	1	1		
Migraine	2	7	2	6		1
Migraine with aura		1				1
Miosis	1	1	1	1		
Mobility decreased	1	2		1	1	1
Monocyte percentage increased		1		1		
Multiple sclerosis	1	1			1	1
Muscle injury		1		1		
Muscle rigidity	1	1	1	1		
Muscle spasms	3	4	2	2	1	2
Muscular weakness	4	7	3	6	1	1
Musculoskeletal stiffness		4		4		
Myalgia	3	24	3	21		3
Myocarditis		2				2
Nasal congestion		1		1		
Nasopharyngitis		2		2		
Nausea	13	32	10	25	3	7

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neck mass	1	1	1	1		
Neck pain		3		3		
Necrosis		1				1
Neuralgia		2				2
Neurogenic shock	1	1			1	1
Neuropathy peripheral	2	2			2	2
Neutropenia	1	1			1	1
Night sweats		1		1		
No adverse event		1		1		
Ocular discomfort	1	1			1	1
Ocular hyperaemia		1		1		
Oedema peripheral		1		1		
Off label use	12	29	12	28		1
Ophthalmic herpes zoster	1	1			1	1
Optic nerve disorder	1	1	1	1		
Oral herpes	1	2		1	1	1
Oropharyngeal pain	3	7	3	7		
Overdose		3		3		
Oversensing	1	1	1	1		
Oxygen saturation decreased		1				1
Pain	6	20	5	18	1	2
Pain in extremity	18	37	16	31	2	6
Pain in jaw		1		1		
Pain of skin		1		1		
Palatal swelling	1	1	1	1		
Pallor		2		1		1
Palmar erythema	1	1			1	1
Palpitations	3	4	1	2	2	2
Paraesthesia	6	20	3	11	3	9
Paraesthesia oral	2	9	1	5	1	4
Pelvic pain	1	1			1	1
Pericarditis	1	2			1	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Periorbital swelling		1		1		
Peripheral coldness	2	2	1	1	1	1
Peripheral swelling	1	4	1	2		2
Petechiae		1		1		
Pharyngeal hypoaesthesia	1	3	1	2		1
Pharyngeal paraesthesia		1				1
Pharyngeal swelling	1	4	1	3		1
Photosensitivity reaction	1	1	1	1		
Pneumonia		1				1
Polymenorrhoea	3	4	3	4		
Poor quality sleep	1	1			1	1
Premenstrual pain	1	1	1	1		
Presyncope	1	5	1	4		1
Product administered at inappropriate site	1	4	1	4		
Product preparation issue		2		2		
Product supply issue		1		1		
Product use issue	11	27	11	26		1
Pruritus	4	14	1	9	3	5
Pulmonary congestion	1	1			1	1
Pulmonary embolism		2				2
Pulmonary infarction		1				1
Pulse volume decreased		2		1		1
Pyrexia	11	31	10	29	1	2
Rash	3	12	1	9	2	3
Rash erythematous	1	2	1	1		1
Rash macular		2		2		
Rash papular		1				1
Rash pruritic	1	2			1	2
Raynaud's phenomenon		1				1
Rectal haemorrhage		1				1
Rectal polyp		1				1
Reflexes abnormal		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory distress		1				1
Rheumatoid arthritis		1				1
Rhinorrhoea		1				1
SARS-CoV-2 test positive	1	1			1	1
Seizure		1				1
Seizure like phenomena	1	1			1	1
Sensitisation	1	1	1	1		
Sensory loss	2	2	1	1	1	1
Sepsis		1				1
Sinus pain		1		1		
Skin burning sensation		1		1		
Skin discolouration	1	2	1	2		
Skin disorder	1	2	1	2		
Skin lesion		1		1		
Skin reaction		2		2		
Sleep disorder	3	4	2	3	1	1
Small fibre neuropathy	1	1	1	1		
Sneezing		1		1		
Somnolence	4	4	4	4		
Speech disorder	1	1	1	1		
Spinal pain	1	1	1	1		
Stomatitis	1	1	1	1		
Stress	2	3	2	3		
Superior sagittal sinus thrombosis		1				1
Swelling	2	5	1	3	1	2
Swelling face	2	6	1	3	1	3
Swelling of eyelid	1	3	1	3		
Swollen tongue		3		1		2
Syncope		8				8
Synovitis	1	1			1	1
Systemic lupus erythematosus		1				1
Tachycardia	3	11	1	5	2	6

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachypnoea		2		2		
Tendon disorder	1	1			1	1
Tendonitis		2		2		
Testicular pain		1		1		
Therapeutic response unexpected	1	2	1	2		
Thirst		1		1		
Throat irritation		2		2		
Throat tightness		2		1		1
Thrombosis	2	5			2	5
Tinnitus	3	5	2	3	1	2
Tongue discomfort	1	1			1	1
Tongue disorder		4		3		1
Transient ischaemic attack		1				1
Tremor	2	3	1	2	1	1
Troponin increased		1		1		
Type I hypersensitivity		1				1
Urinary incontinence	1	1			1	1
Urticaria	3	17	3	14		3
Vaccination failure		1				1
Vaccination site cellulitis	1	1	1	1		
Vaccination site discomfort		2		1		1
Vaccination site erythema	1	4		3	1	1
Vaccination site hyperaesthesia	1	1	1	1		
Vaccination site hypoaesthesia	1	1	1	1		
Vaccination site induration	2	3	1	2	1	1
Vaccination site joint movement impairment		1		1		
Vaccination site mass		2		2		
Vaccination site movement impairment		1		1		
Vaccination site pain	17	40	15	37	2	3
Vaccination site paraesthesia	1	1	1	1		
Vaccination site rash		1		1		
Vaccination site swelling		3		3		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site urticaria		1				1
Vaccination site warmth	1	3		2	1	1
Vaginal discharge		1		1		
Vaginal haemorrhage	5	7		2	5	5
Venous bruit	1	1	1	1		
Vertebral artery dissection		1				1
Vertigo		2		2		
Viral rash		1		1		
Vision blurred	3	6	2	4	1	2
Vomiting	3	5	3	4		1
Vulval disorder		1				1
Vulvitis		1		1		
Weight decreased	1	1			1	1
Weight increased		1		1		
Wheezing		2		2		
White blood cell count increased	1	1	1	1		
	491	1,314	347	951	144	363

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	3	1	2	1	1
Abdominal pain upper	1	2	1	2		
Abnormal dreams		1		1		
Acne		1		1		
Ageusia		1		1		
Alanine aminotransferase increased		1		1		
Amyloidosis	1	1			1	1
Anaphylactic reaction	2	9			2	9
Aneurysm	1	1			1	1
Angioedema	2	2			2	2
Anxiety	1	1			1	1
Arrhythmia	1	3			1	3
Arthralgia	7	18	5	16	2	2
Arthritis	2	2	2	2		
Asthenia	4	8	3	7	1	1
Asthma	1	2		1	1	1
Asymptomatic COVID-19		1				1
Ataxia	1	2		1	1	1
Atrial fibrillation	1	1			1	1
Axillary mass		1		1		
Axillary pain	1	4	1	4		
Balance disorder	1	2	1	2		
Bell's palsy		1				1
Blindness transient	1	1			1	1
Blood glucose decreased		1				1
Blood pressure increased		2		2		
Blood pressure systolic increased	1	1	1	1		
Breast swelling		1		1		
Bronchospasm		1				1
Burning sensation	1	1	1	1		
Cardiac flutter		1				1
Cardiovascular disorder		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral haemorrhage	1	1			1	1
Cerumen impaction		1		1		
Chest discomfort	1	3		1	1	2
Chest pain	1	1	1	1		
Chills	7	19	6	17	1	2
Choking	1	1			1	1
Cold sweat		1		1		
Colitis ischaemic	1	1			1	1
Colitis ulcerative		1				1
Coma	1	1			1	1
Communication disorder	1	1			1	1
Condition aggravated	1	3		1	1	2
Confusional state	1	1	1	1		
Constipation	1	1	1	1		
Contusion		2		1		1
Cough	1	4	1	1		3
Deafness	1	1			1	1
Death	1	1			1	1
Deep vein thrombosis		1				1
Defaecation urgency		1		1		
Dehydration		1		1		
Delirium		1				1
Diabetes mellitus		1				1
Diarrhoea	4	8	3	6	1	2
Diplopia		2		1		1
Discomfort	1	2	1	2		
Disease recurrence	2	5	2	3		2
Disturbance in attention		2		2		
Diverticulitis	1	1			1	1
Dizziness	11	18	7	13	4	5
Drug hypersensitivity		1		1		
Drug interaction		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug level increased		1				1
Dry mouth	1	3	1	2		1
Dysgeusia	3	8	2	7	1	1
Dyskinesia		1		1		
Dysphagia	1	5		3	1	2
Dysphonia		3		2		1
Dyspnoea	5	13	2	4	3	9
Ear discomfort	1	3		2	1	1
Ear pruritus	1	1	1	1		
Ear swelling		1		1		
Eating disorder	1	1	1	1		
Electric shock sensation		2				2
Epistaxis		1		1		
Erythema	3	6	3	6		
Excessive cerumen production		1		1		
Eyelids pruritus	1	1	1	1		
Eye movement disorder	1	1			1	1
Eye pain	1	1			1	1
Eye pruritus	1	1	1	1		
Eye swelling	1	2	1	2		
Face oedema	1	1			1	1
Facial paralysis		1				1
Fall		1				1
Fatigue	17	39	14	32	3	7
Feeling abnormal	3	4	3	4		
Feeling cold		1				1
Feeling drunk	1	1			1	1
Feeling hot	3	5	3	5		
Fluid retention	1	1	1	1		
Flushing	3	4	3	4		
Gait disturbance	4	4	4	4		
Gastric ulcer		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal pain	1	2	1	2		
Gout	2	2	2	2		
Hand deformity	1	1	1	1		
Headache	12	44	10	41	2	3
Head discomfort	1	2	1	2		
Heart rate decreased	1	2	1	1		1
Heart rate increased	1	3	1	2		1
Heavy menstrual bleeding		1		1		
Hepatic enzyme increased		1				1
Herpes ophthalmic	1	1			1	1
Herpes zoster	4	5	4	5		
Hiatus hernia		1		1		
Hiccups	1	1			1	1
Hot flush	1	2	1	2		
Hyperacusis	1	1	1	1		
Hyperaesthesia		1		1		
Hyperaesthesia teeth	1	2	1	2		
Hyperhidrosis	3	5	3	4		1
Hypersensitivity	3	3	2	2	1	1
Hypersomnia		1		1		
Hypertension	2	6	1	2	1	4
Hypoacusis	1	1	1	1		
Hypoaesthesia	5	8	4	5	1	3
Hypoaesthesia oral	1	3	1	2		1
Hypotension	3	4	2	2	1	2
Idiopathic angioedema	1	1			1	1
Illness	1	1	1	1		
Impaired driving ability	1	1	1	1		
Inappropriate schedule of product administration	1	6	1	6		
Incoherent	1	1	1	1		
Incontinence		1				1
Incorrect dose administered	1	1	1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Infection		1		1		
Influenza like illness		1				1
Infusion site warmth		1		1		
Injection site bruising	1	1	1	1		
Injection site erythema		1		1		
Injection site pain	1	2	1	2		
Insomnia	1	2	1	2		
IVth nerve paralysis		1				1
Joint swelling	2	4	1	2	1	2
Lacrimation increased		1		1		
Laryngeal oedema	1	1			1	1
Lethargy	1	3	1	3		
Limb discomfort	1	1	1	1		
Lip disorder		1		1		
Lip oedema	1	1	1	1		
Lip pain		1		1		
Lip swelling	1	2			1	2
Loss of consciousness		1				1
Loss of personal independence in daily activities	1	4	1	3		1
Lymphadenopathy	3	9	3	7		2
Lymph node pain		2		2		
Lymphoedema	1	1	1	1		
Malaise	4	11	3	9	1	2
Mass		1		1		
Menstrual disorder	1	1	1	1		
Mental impairment	1	2			1	2
Migraine	1	1	1	1		
Mobility decreased	1	1			1	1
Mouth swelling	2	3	1	1	1	2
Movement disorder	1	2	1	2		
Muscle spasms		1		1		
Muscle twitching		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal chest pain	1	1	1	1		
Musculoskeletal pain		1		1		
Musculoskeletal stiffness	1	3	1	3		
Myalgia	3	15	3	15		
Myocarditis	1	1			1	1
Myositis	1	1	1	1		
Nasal congestion		1				1
Nausea	6	22	3	16	3	6
Neck pain		3		2		1
Nervousness	1	2	1	1		1
Neuralgia	1	1	1	1		
Neurological symptom	1	1	1	1		
Nightmare	1	1			1	1
Ocular discomfort	1	1	1	1		
Odynophagia	1	1	1	1		
Oesophageal disorder		1				1
Oesophagitis		1				1
Off label use	1	5	1	5		
Oral candidiasis		1		1		
Oral discomfort		2		2		
Oral mucosal blistering		1		1		
Oropharyngeal pain		1		1		
Osteoarthritis	1	1	1	1		
Overdose		1		1		
Pain	6	14	6	12		2
Pain in extremity	12	24	10	20	2	4
Pain of skin		1		1		
Palpitations		1		1		
Panic reaction	1	1	1	1		
Paraesthesia	4	9	4	6		3
Paraesthesia oral	2	6	1	5	1	1
Parvovirus infection		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pericardial effusion		1				1
Periorbital swelling	1	2	1	2		
Peripheral coldness	1	2	1	2		
Peripheral swelling	3	9	2	8	1	1
Petechiae		1		1		
Pharyngeal oedema	1	1	1	1		
Pharyngeal swelling	1	3		1	1	2
Phlebitis	1	1			1	1
Photophobia	1	1	1	1		
Photosensitivity reaction	2	2	1	1	1	1
Pleural effusion		1				1
Postmenopausal haemorrhage	1	1			1	1
Presyncope		3		1		2
Product administered at inappropriate site		2		2		
Productive cough		1				1
Product supply issue		1		1		
Product use issue		1		1		
Pruritus	1	7		5	1	2
Psychomotor hyperactivity	1	1			1	1
Purpura		2		2		
Pyrexia	5	17	4	14	1	3
Rash	4	11	3	10	1	1
Rash erythematous	1	4		3	1	1
Rash macular	1	1	1	1		
Rash maculo-papular		1		1		
Rash pruritic	1	3		1	1	2
Rash vesicular	1	1			1	1
Respiratory rate increased	1	1			1	1
Rheumatoid arthritis		1				1
Rhinorrhoea	2	2	1	1	1	1
Sinus pain	1	1			1	1
Skin burning sensation	2	2	2	2		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin discolouration	1	1	1	1		
Skin induration	1	1	1	1		
Sleep disorder	1	2	1	2		
Somnolence	2	5	1	2	1	3
Speech disorder		1		1		
Splenitis		1				1
Stress		1		1		
Sudden death	1	1			1	1
Sudden hearing loss	1	1			1	1
Swelling	3	4	2	3	1	1
Swelling face	4	6	4	5		1
Swelling of eyelid	1	1	1	1		
Swollen tongue	1	2		1	1	1
Syncope	1	1			1	1
Tachycardia	1	4		2	1	2
Taste disorder		1		1		
Tenderness		1		1		
Tendon disorder		1		1		
Tension headache		1		1		
Therapeutic product effect decreased	1	1	1	1		
Throat irritation		1		1		
Throat tightness	3	9		2	3	7
Thrombocytopenia		2				2
Thrombosis	1	3			1	3
Thyroid disorder		1		1		
Tinnitus	3	11	2	7	1	4
Tongue disorder		1		1		
Tongue oedema	1	1	1	1		
Tongue pruritus		1		1		
Toothache	1	1			1	1
Toxicity to various agents		1				1
Tremor		4		3		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Type I hypersensitivity		1				1
Urinary retention	1	1			1	1
Urinary tract infection	1	1			1	1
Urticaria	2	8	2	7		1
Uveitis		1				1
Vaccination failure		1				1
Vaccination site erythema	1	1			1	1
Vaccination site induration		1		1		
Vaccination site lymphadenopathy		1		1		
Vaccination site mass	1	1	1	1		
Vaccination site pain	5	17	3	14	2	3
Vaccination site pruritus		1		1		
Vaccination site reaction	1	3	1	3		
Vaccination site swelling	2	3	1	2	1	1
Vaccination site urticaria		1		1		
Vaccination site warmth	1	2		1	1	1
Vascular anastomosis	1	1			1	1
Vertigo	5	5	1	1	4	4
Vision blurred	1	2	1	2		
Visual impairment		1		1		
Vitreous detachment		1				1
Vitreous floaters		1		1		
Vomiting	4	11	3	7	1	4
Weight decreased	1	1	1	1		
Wheezing	2	3			2	3
Wrong product administered		1		1		
	339	825	227	584	112	241

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2		2		
Abdominal pain		1		1		
Abdominal pain lower		1		1		
Abdominal pain upper	1	2	1	2		
Acne	1	1	1	1		
Ageusia	1	1	1	1		
Alanine aminotransferase increased		2		1		1
Anaphylactic reaction	1	3			1	3
Aneurysm		1				1
Angioedema	1	2			1	2
Anosmia	1	1	1	1		
Aphthous ulcer		1		1		
Arrhythmia	2	2			2	2
Arthralgia	9	11	5	7	4	4
Arthritis	4	4	1	1	3	3
Arthritis reactive	1	1			1	1
Aspartate aminotransferase increased		1				1
Asthenia	3	5	3	5		
Atrial fibrillation		2				2
Autoimmune disorder	1	1			1	1
Axillary pain	1	1	1	1		
Back pain	2	6		4	2	2
Balance disorder	1	3	1	2		1
Bell's palsy	1	4			1	4
Bladder spasm		1		1		
Blood cholesterol decreased		1		1		
Blood creatine phosphokinase increased		1				1
Blood pressure decreased		2				2
Blood pressure fluctuation	1	1			1	1
Blood pressure increased		1		1		
Blood urine present		2		2		
Bradycardia		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchitis		1		1		
Burning sensation	5	6	5	6		
Candida infection	1	1	1	1		
Cardiac failure		1				1
Cardiac flutter	1	2			1	2
Cerebrovascular accident	4	5			4	5
Chapped lips		1		1		
Chest discomfort		2		1		1
Chest pain	3	3	1	1	2	2
Chills	2	8	1	7	1	1
Chronic obstructive pulmonary disease		1				1
Cold sweat		1		1		
Condition aggravated	4	7	2	2	2	5
Contusion	3	3	2	2	1	1
Conversion disorder	1	1			1	1
Cough	2	6	2	6		
COVID-19		2				2
C-reactive protein increased	1	2	1	1		1
Cystitis		1		1		
Deafness	1	2			1	2
Deafness neurosensory	1	1			1	1
Deafness unilateral	2	2			2	2
Decreased appetite		2		2		
Deep vein thrombosis	1	1			1	1
Dehydration	1	1	1	1		
Depressed level of consciousness		1				1
Dermatitis	1	1	1	1		
Diarrhoea	4	7	4	6		1
Discomfort	1	2	1	2		
Disease recurrence	2	3		1	2	2
Disseminated varicella zoster virus infection	1	1			1	1
Disturbance in attention	1	3		1	1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	6	18	4	12	2	6
Dizziness postural	1	1	1	1		
Drug ineffective		1				1
Drug interaction	2	2	1	1	1	1
Dry mouth		1		1		
Dysarthria		1				1
Dysgeusia		3		3		
Dysphagia	1	3	1	2		1
Dysphonia	1	2	1	2		
Dyspnoea	2	8	2	7		1
Dysstasia		1		1		
Dysuria		1		1		
Encephalitis autoimmune	1	1			1	1
Eructation		1		1		
Erythema	3	8	2	6	1	2
Eye irritation		1				1
Eyelid sensory disorder		1		1		
Eye pruritus	1	2	1	2		
Eye swelling	1	1	1	1		
Fall	1	2	1	1		1
Fatigue	8	25	7	22	1	3
Fear	1	1	1	1		
Feeling abnormal	2	6	1	5	1	1
Feeling cold	1	3	1	3		
Feeling hot	3	3	3	3		
Feeling of body temperature change		1		1		
Fibrin D dimer increased	1	1	1	1		
Flatulence		2		2		
Gait disturbance	4	5	4	4		1
Gastroenteritis		1		1		
Generalised tonic-clonic seizure		1				1
Haematocrit decreased		1		1		

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* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemoglobin decreased		2		2		
Haemorrhage urinary tract		3				3
Headache	11	29	9	26	2	3
Head discomfort	2	2	2	2		
Heart rate decreased		1		1		
Heart rate increased		1				1
Hemiparesis		1				1
Herpes simplex	1	2			1	2
Herpes zoster	8	9	8	8		1
Herpes zoster oticus		1				1
Hot flush	1	2	1	2		
Hypersensitivity	4	10	4	8		2
Hypersomnia		2		2		
Hypertension	4	6	1	2	3	4
Hyperuricaemia		1		1		
Hypoaesthesia	7	16	4	10	3	6
Hypoaesthesia oral	2	4	2	3		1
Hypokinesia		1		1		
Hypoxia		1				1
Iliac artery occlusion		1				1
Illness		1		1		
Inappropriate schedule of product administration	1	2	1	2		
Incorrect dose administered		1		1		
Incorrect route of product administration		1		1		
Inflammation	1	1	1	1		
Injection site pain		1		1		
Insomnia	2	3	1	2	1	1
Ischaemic stroke	1	2	1	1		1
Joint stiffness	1	1	1	1		
Joint swelling	3	3	2	2	1	1
Joint warmth	1	1			1	1
Labyrinthitis	1	1			1	1

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lacrimation increased		2		2		
Lateral medullary syndrome	1	1			1	1
Lethargy	2	3	2	3		
Limb discomfort	3	3	2	2	1	1
Lip blister		1		1		
Lip haemorrhage		1		1		
Lip pain		1		1		
Lip swelling	2	5	2	5		
Loss of consciousness	1	5			1	5
Loss of personal independence in daily activities		1		1		
Lung disorder		1				1
Lymphocyte count decreased		1		1		
Malaise	4	8	4	8		
Mean cell haemoglobin		1		1		
Mean cell volume increased		1		1		
Melaena		1				1
Micturition urgency		1		1		
Migraine	1	2	1	2		
Monocyte count increased		1		1		
Monoparesis		1				1
Movement disorder	1	1	1	1		
Mucosal discolouration		1		1		
Mucosal disorder		1		1		
Multiple sclerosis relapse		1				1
Muscle twitching	3	3	3	3		
Muscular weakness	2	3	1	2	1	1
Musculoskeletal discomfort	1	1	1	1		
Musculoskeletal stiffness	2	5	2	5		
Myalgia	6	12	4	10	2	2
Myelocyte count increased		1		1		
Myocardial infarction	1	1			1	1
Nasopharyngitis	1	1	1	1		

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* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	6	16	6	14		2
Neck pain	2	4	2	4		
Needle issue		1		1		
Nervous system disorder		1				1
Neuropathy peripheral	1	1			1	1
Off label use		2		2		
Oral discomfort		1		1		
Oral herpes		1		1		
Oral pain		1		1		
Oropharyngeal discomfort		1		1		
Overdose		2		2		
Pain	4	12	4	11		1
Pain in extremity	8	15	7	14	1	1
Pain in jaw		1				1
Palpitations	2	4	2	3		1
Paraesthesia	5	10	3	6	2	4
Paraesthesia oral		1				1
Paralysis		1				1
Paraparesis		1				1
Pericardial effusion	1	1			1	1
Pericarditis	1	1			1	1
Peripheral arterial occlusive disease		1		1		
Peripheral artery thrombosis	1	1			1	1
Peripheral swelling	6	7	3	4	3	3
Pharyngeal hypoaesthesia		1		1		
Platelet count decreased		1		1		
Platelet count increased	1	1	1	1		
Pleural effusion	1	1			1	1
Pneumonia		1				1
Pneumonia aspiration		1				1
Poor peripheral circulation		1		1		
Portal vein thrombosis	1	1			1	1

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* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Productive cough		2		2		
Product preparation error		1		1		
Product preparation issue		1		1		
Product supply issue	1	1	1	1		
Product use issue		1		1		
Pruritus	7	14	4	9	3	5
Pulmonary embolism	1	2			1	2
Pyrexia	4	12	2	9	2	3
Rash	1	3	1	3		
Rash erythematous		2		2		
Rash macular	1	1	1	1		
Rash pruritic	1	3		2	1	1
Red blood cell count decreased		1		1		
Respiratory disorder		1		1		
Respiratory failure		1				1
Restless arm syndrome	1	1	1	1		
Restless legs syndrome	1	1	1	1		
Retinal vascular thrombosis	1	1			1	1
Rheumatoid arthritis		1				1
Rhinorrhoea		4		4		
Scleral disorder	1	1	1	1		
Screaming		1		1		
Seasonal allergy	1	1	1	1		
Secretion discharge		2		2		
Seizure		1				1
Sensory loss		1		1		
Sepsis		1				1
Shoulder injury related to vaccine administration		1		1		
Skin burning sensation	2	2	2	2		
Skin exfoliation	1	2		1	1	1
Skin warm		1		1		
Sluggishness	1	1	1	1		

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* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sneezing	1	3	1	3		
Somnolence		1				1
Speech disorder	2	2	2	2		
Spinal pain	2	2	1	1	1	1
Stevens-Johnson syndrome		1				1
Stomatitis		1		1		
Suicidal ideation		1				1
Suspected COVID-19		1		1		
Swelling	2	4	2	4		
Swelling face	1	3		1	1	2
Swollen tongue	1	1	1	1		
Syncope	1	6			1	6
Synovitis	1	1			1	1
Tachycardia	2	3	1	1	1	2
Tachypnoea		1		1		
Tenderness		1		1		
Therapeutic response unexpected		2		2		
Thirst		2		2		
Thrombophlebitis	1	1			1	1
Thrombosis	6	7	1	1	5	6
Thyroiditis	1	1	1	1		
Tinnitus	1	2		1	1	1
Tremor	1	2	1	2		
Trigeminal nerve disorder	1	1			1	1
Troponin increased		1		1		
Upper-airway cough syndrome		1		1		
Urinary tract infection		1		1		
Urticaria	6	10	4	7	2	3
Vaccination failure		1				1
Vaccination site bruising	1	1	1	1		
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema		2		2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	3	9	3	9		
Vaccination site swelling		2		2		
Vaccination site urticaria		1				1
Vaccination site warmth		2		2		
Ventricular tachycardia		1				1
Vertigo	4	6	3	5	1	1
Vision blurred	1	2			1	2
Visual impairment	1	1			1	1
Vitamin B12 increased	1	2	1	1		1
Vomiting	1	8	1	5		3
Weight decreased	1	1	1	1		
Wheezing		1		1		
White blood cell count increased	1	1	1	1		
White coat hypertension		1				1
	307	714	203	495	104	219

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		3		2		1
Acute kidney injury		1				1
Agitation		1		1		
Aphasia		1		1		
Arrhythmia		1				1
Arthralgia	1	4		2	1	2
Arthritis	1	2		1	1	1
Asthenia		10		6		4
Atrial fibrillation		2				2
Balance disorder		1				1
Bell's palsy		2				2
Blood pressure decreased	1	2	1	1		1
Blood pressure fluctuation		1		1		
Blood urine		1		1		
Bursitis		1		1		
Cardiac arrest	1	1			1	1
Cardiac disorder		1				1
Cellulitis		1				1
Cerebral artery occlusion	1	1			1	1
Cerebral haemorrhage	1	1			1	1
Cerebrovascular accident	3	5			3	5
Change of bowel habit		1		1		
Chills	1	6	1	5		1
Chromaturia		1		1		
Confusional state		1		1		
COVID-19		2				2
Deafness	1	2			1	2
Death		1				1
Decreased appetite		2		1		1
Diarrhoea		4		4		
Disease recurrence	1	1			1	1
Disseminated varicella zoster virus infection		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	2	4	2	3		1
Dizziness postural		1		1		
Drug ineffective		2				2
Dry throat		1		1		
Dyskinesia	1	1	1	1		
Dyspnoea		4		2		2
Dysuria		1				1
Eyelid disorder		1		1		
Faeces soft		1		1		
Fall		4		1		3
Fatigue	1	3	1	2		1
Feeling abnormal	1	3	1	3		
Gait disturbance		1		1		
Gastric ulcer		1				1
Gout	2	2	1	1	1	1
Haemorrhage urinary tract		1				1
Hallucination	1	1			1	1
Headache	4	6	4	6		
Heart rate increased		1		1		
Herpes zoster	1	3	1	2		1
Hip fracture		1				1
Hypertension		1				1
Hypoacusis		1		1		
Hypoaesthesia	1	2	1	2		
Hypotension	1	3	1	3		
Impaired quality of life		1		1		
Inappropriate schedule of product administration	1	6	1	6		
Inflammatory pain	1	1			1	1
Influenza like illness		1		1		
Insomnia	2	3	2	3		
Joint swelling		1		1		
Lack of spontaneous speech		1		1		

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* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lethargy		1		1		
Ligament sprain		1		1		
Limb discomfort	1	2	1	2		
Lip swelling		1		1		
Livedo reticularis	1	1	1	1		
Loss of consciousness	1	2			1	2
Lung disorder		1				1
Lymphadenopathy		1		1		
Lymphoedema	2	2	2	2		
Malaise		2		2		
Memory impairment		1		1		
Myalgia		2		1		1
Myocardial infarction		2				2
Nausea		4		4		
Night sweats		1				1
Off label use	1	2	1	2		
Pain	2	6	2	5		1
Pain in extremity	1	1			1	1
Pallor		1		1		
Paraesthesia	3	3	3	3		
Pneumonia	1	1			1	1
Pruritus		1		1		
Pulmonary embolism	1	1			1	1
Pulmonary oedema		1				1
Pyrexia	2	5	2	4		1
Rash		3		2		1
Rash macular	1	2	1	2		
Rash maculo-papular		2		1		1
Rash papular		1		1		
Respiratory failure		1				1
Rib fracture		1				1
Road traffic accident		1				1

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* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Seizure		1				1
Skin injury		1		1		
Skin laceration		1		1		
Somnolence		3		2		1
Stress		1		1		
Swollen tongue		2		2		
Syncope	1	2			1	2
Therapeutic response unexpected		1		1		
Thrombosis	1	1			1	1
Transient ischaemic attack		1				1
Unresponsive to stimuli	1	1			1	1
Urticaria		3		2		1
Vaccination site bruising		1		1		
Vaccination site pain	1	1	1	1		
Varicella		1		1		
Vital functions abnormal		1				1
Vomiting	1	3	1	3		
	53	211	33	131	20	80

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Abdominal pain upper	1	1	1	1		
Accidental exposure to product		1		1		
Accidental overdose	1	1	1	1		
Adverse event	1	1	1	1		
Ageusia		1		1		
Allergy to vaccine		1		1		
Anaphylactic reaction	1	22			1	22
Anaphylactic shock	2	3			2	3
Anger	1	1	1	1		
Aphasia		1		1		
Arrhythmia	2	2			2	2
Arthralgia	2	3	2	3		
Arthritis		1		1		
Asthenia	2	3	2	3		
Back pain	1	1	1	1		
Bell's palsy		2				2
Blood pressure decreased	1	1			1	1
Breast pain		1		1		
Chest pain	1	1	1	1		
Chills	3	6	3	6		
Circumstance or information capable of leading to medication error		3		3		
Coeliac disease		1				1
Cognitive disorder		1		1		
Coma	1	1			1	1
Confusional state		1		1		
Contusion	1	2		1	1	1
COVID-19	8	45	2	2	6	43
Deafness	1	1			1	1
Decreased appetite		1		1		
Diarrhoea	1	5		4	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disease recurrence		1		1		
Disturbance in attention		1		1		
Dizziness	3	11	1	8	2	3
Drug ineffective	6	44			6	44
Dyspnoea	1	1	1	1		
Ear pruritus		1		1		
Eosinophil count increased		1		1		
Erythema		2		2		
Exposure during pregnancy		4		2		2
Exposure via breast milk	3	7	3	7		
Eyelid oedema		1				1
Eyelids pruritus		1				1
Eye pain	1	1			1	1
Eye swelling	1	1			1	1
Facial paralysis		1				1
Faeces discoloured		1		1		
Fatigue	6	14	6	14		
Feeling abnormal	2	4	2	4		
Feeling hot		1		1		
Foetal growth restriction		3				3
Headache	5	10	4	8	1	2
Heart rate increased		1		1		
Heavy menstrual bleeding		1		1		
Herpes zoster	2	2	2	2		
Hyperhidrosis	1	1	1	1		
Hypersensitivity	1	9	1	1		8
Hypertension		3		3		
Hypoaesthesia	2	2			2	2
Hypopnoea		1		1		
Hypotension		1		1		
Illness	1	1			1	1
Impaired work ability		1		1		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Inappropriate schedule of product administration		32
Incomplete course of vaccination		1
Incorrect dose administered		2
Influenza like illness		1
Injection site erythema		1
Insomnia	1	1
Intentional product misuse		1
Intermenstrual bleeding	1	1
Joint stiffness	1	1
Lethargy		1
Limb discomfort	2	2
Lip pruritus		1
Lip swelling		1
Livedo reticularis	1	1
Lymphadenopathy	2	3
Malaise		6
Maternal exposure before pregnancy		1
Maternal exposure during pregnancy		6
Maternal exposure timing unspecified		2
Menstruation irregular	2	2
Migraine	2	2
Monocyte count increased		1
Muscular weakness		1
Musculoskeletal chest pain	1	1
Musculoskeletal stiffness		1
Myalgia	1	3
Myocardial infarction	2	2
Nausea	4	7
Neck pain	1	2
Neutrophil count decreased		1
No adverse event	2	3
Oedema		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	32		
	1		
	2		
	1		
	1		
1	1		
	1		
1	1		
		1	1
	1		
1	1	1	1
	1		
			1
1	1		
1	2	1	1
	6		
			1
	6		
	2		
2	2		
2	2		
	1		
	1		
1	1		
	1		
1	3		
		2	2
3	6	1	1
1	2		
	1		
2	3		
			1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Off label use	2	40	2	40		
Overdose		5		5		
Pain	1	4	1	4		
Pain in extremity	3	7	3	7		
Pallor	1	1	1	1		
Paraesthesia	2	3	1	2	1	1
Pericarditis	2	2			2	2
Periorbital swelling		1		1		
Peripheral swelling		1		1		
Polymenorrhoea	3	3	3	3		
Postpartum haemorrhage		1		1		
Product complaint		4		4		
Product container issue		1		1		
Product preparation error	1	3	1	3		
Product preparation issue		11		11		
Product quality issue		1		1		
Product use issue	1	11	1	11		
Pruritus	1	3	1	2		1
Pulmonary embolism	1	1			1	1
Pyrexia	5	10	5	10		
Rash	2	5	1	4	1	1
Rash papular	1	1	1	1		
Rash pruritic	1	1	1	1		
Respiratory disorder	1	1			1	1
Rheumatoid arthritis		1				1
Rhinorrhoea		1		1		
SARS-CoV-2 test positive		1				1
Somnolence		1		1		
Suspected COVID-19		2		1		1
Swelling	1	1			1	1
Swelling face		1		1		
Syncope	1	2			1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Taste disorder		1		1		
Therapeutic response unexpected	1	3	1	3		
Thrombosis		1				1
Tinnitus	1	1	1	1		
Tongue pruritus		1		1		
Underdose		12		12		
Urticaria	2	3		1	2	2
Vaccination site erythema	1	1	1	1		
Vaccination site nodule	1	1			1	1
Vaccination site oedema		3		3		
Vaccination site pain	3	6	2	5	1	1
Vaccination site rash		1		1		
Vaccination site swelling		1		1		
Vaccination site urticaria		2		2		
Vaginal haemorrhage		1		1		
Vertigo	1	1			1	1
Vision blurred	1	1			1	1
Vitreous floaters	1	1			1	1
Vomiting	3	5	1	3	2	2
Weight decreased		2		2		
White blood cell count decreased		1		1		
Wrong product administered	1	1	1	1		
	136	523	83	343	53	180

* I=Interval, C=Cumulative
* AE=Adverse Event
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Country Where Event Occurred

CAYMAN ISLANDS

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite		1		1
Dyspepsia		1		1
Fatigue		1		1
Headache		1		1
Irritability		1		1
Muscle spasms		1		1
Muscle twitching		1		1
Palpitations		1		1
		8		8

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Back pain	1	1	1	1
Pain in extremity	1	1	1	1
	2	2	2	2

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Back pain	5	5	5	5
Pain in extremity	5	5	5	5
	10	10	10	10

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

CHILE

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris		1				1
Blood glucose increased		1				1
Cough		1		1		
Exposure via breast milk	1	2	1	2		
Fall		1				1
Fatigue		1		1		
Headache	1	2	1	2		
Head injury		1				1
Malaise		1		1		
Myalgia		1		1		
Nasal congestion		1		1		
Seizure		1				1
Vaccination site pain	1	2	1	2		
Wound haemorrhage		1				1
	3	17	3	11		6

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Aphasia		1				1
Arthralgia		2		2		
Asthenia	1	1	1	1		
Back pain		1		1		
Breast pain		1		1		
Chills	1	3	1	3		
Complement factor C3 decreased		1		1		
C-reactive protein decreased		1		1		
Diarrhoea		1		1		
Dysgeusia		1				1
Dyspnoea	1	2	1	1		1
Erythema nodosum		1				1
Eye discharge		1		1		
Eye movement disorder		1				1
Face oedema		1				1
Fatigue		2		2		
Feeling abnormal		1		1		
Gait disturbance		2		1		1
Gait inability		1				1
Headache	1	4	1	4		
Hemiparesis		1				1
Herpes zoster	1	1	1	1		
Loss of consciousness		1				1
Loss of personal independence in daily activities		1		1		
Lymphadenopathy		1		1		
Lymph node pain		1		1		
Malaise	2	3	2	3		
Maternal exposure during pregnancy		1		1		
Monocyte count decreased		1		1		
Muscular weakness		1		1		
Myalgia	1	4	1	4		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	1	2	1	2		
Pain	1	2	1	2		
Paraesthesia		1		1		
Peripheral swelling		1		1		
Pyrexia	1	4	1	4		
Rhabdomyolysis		1				1
SARS-CoV-2 ant body test negative		1		1		
Seizure		1				1
Tongue movement disturbance		1				1
Toothache		1		1		
Vaccination site pain	1	3	1	2		1
Vasculitis		1				1
Venous thrombosis		1				1
Vomiting		1		1		
Wrong product administered		1		1		
	12	68	12	51		17

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Abdominal pain upper		1		1		
Anaphylactic reaction		2				2
Angioedema		1				1
Arrhythmia		1				1
Arthralgia	2	6	2	5		1
Arthritis	1	2			1	2
Asthenia		1		1		
Axillary pain	1	1	1	1		
Back pain	1	2	1	2		
Blood pressure fluctuation		1		1		
Breast engorgement		1		1		
Breast pain	1	1	1	1		
Breast swelling	1	1	1	1		
Burning sensation	1	1	1	1		
Chest discomfort	1	1	1	1		
Chest pain		2		1		1
Chills	1	5	1	4		1
Choking		1				1
Contusion	1	1	1	1		
Costochondritis	1	1	1	1		
COVID-19		1				1
Cyst		1		1		
Depressed mood	3	3	3	3		
Dermatitis acneiform	1	1	1	1		
Diarrhoea		4		4		
Discomfort	1	2	1	2		
Disease recurrence		1		1		
Dizziness		2		2		
Drug ineffective		1				1
Dry skin		1		1		
Dysbiosis		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspepsia	1	1	1	1		
Dyspnoea		2				2
Erythema	1	1			1	1
Eye inflammation	1	1			1	1
Eyelid oedema	1	1			1	1
Eyelids pruritus	1	1			1	1
Eye pruritus		1				1
Eye swelling	1	2			1	2
Facial paralysis		1				1
Fatigue	1	8	1	8		
Feeling cold	1	3	1	3		
Flatulence	1	1	1	1		
Galactostasis		1		1		
Glossitis		1		1		
Headache	5	13	5	12		1
Head discomfort		1		1		
Hemiparaesthesia		1				1
Hyperaesthesia		2		2		
Hyperhidrosis		1		1		
Hypersensitivity		5		5		
Hyperventilation		1				1
Hypoaesthesia		3		2		1
Hypotension		1				1
Inappropriate schedule of product administration		1		1		
Incorrect route of product administration		1		1		
Internal haemorrhage		1				1
Joint swelling		2		1		1
Laboratory test interference	1	1	1	1		
Loss of consciousness		1				1
Lymphadenitis	1	1	1	1		
Lymphadenopathy	2	5	2	4		1
Lymph node pain		2		2		

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise	2	6	2	6		
Muscle discomfort		1		1		
Muscle spasms		3		3		
Musculoskeletal pain		1		1		
Myalgia		6		5		1
Myocardial infarction	1	1			1	1
Myocardial ischaemia	1	1			1	1
Nasal congestion		1		1		
Nausea	1	4	1	4		
Neck pain		1		1		
Neuralgia		1				1
Nipple pain	1	1	1	1		
Ocular discomfort	1	1			1	1
Ocular hyperaemia		1				1
Oedema	1	1			1	1
Off label use		2		2		
Pain		2		1		1
Pain in extremity	1	3	1	3		
Pallor		1				1
Paraesthesia		5		4		1
Peripheral swelling		1				1
Pharyngeal swelling	1	1			1	1
Photophobia		1				1
Product use issue		1		1		
Pruritus	1	2		1	1	1
Pyrexia	4	11	4	10		1
Rash	1	3		1	1	2
Rash papular	1	1			1	1
Rash pruritic		1				1
Respiratory disorder	1	1	1	1		
Respiratory distress		1				1
Rhinorrhoea		1		1		

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensory loss		1		1		
Skin burning sensation		1		1		
Skin discomfort	1	1	1	1		
Splenic rupture		1				1
Splenomegaly		1				1
Stenosis		1		1		
Swelling	1	1			1	1
Swelling face	1	2			1	2
Swollen tongue		1		1		
Syncope		1				1
Synovial cyst		1		1		
Tachycardia		1				1
Therapeutic response unexpected	1	1	1	1		
Thirst	1	1	1	1		
Urticaria	1	2			1	2
Vaccination site pain	5	9	5	7		2
Vaccination site paraesthesia		1		1		
Vein disorder	1	1	1	1		
Vestibular disorder		1		1		
Vomiting	1	2	1	2		
	66	219	49	156	17	63

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* AE=Adverse Event
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Abdominal pain upper		2		1		1
Abnormal faeces		1		1		
Asthenia	1	1	1	1		
Chills		2		2		
Decreased appetite		2		2		
Diarrhoea		1		1		
Dizziness	1	1	1	1		
Drug-induced liver injury		1				1
Erythema		1		1		
Fatigue		1		1		
Fear of disease	1	1	1	1		
General physical health deterioration	1	1	1	1		
Headache		4		4		
Hepatic enzyme increased		1				1
Hepatic steatosis		1		1		
Hypersensitivity		1		1		
Hypertension		1		1		
Injected limb mobility decreased	1	1	1	1		
Insomnia	1	2	1	2		
Loss of personal independence in daily activities	2	2	2	2		
Malaise		2		2		
Myalgia		4		4		
Nausea		3		2		1
Neck pain		1		1		
Overdose		1		1		
Oxygen saturation decreased		1		1		
Pain	1	3	1	3		
Pain in extremity	1	2	1	2		
Pancreatitis		1				1
Product preparation error		1		1		
Pruritus		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia		3		3		
Skin burning sensation		1		1		
Transaminases increased		1		1		
Urine analysis abnormal		1				1
Vaccination site discomfort		1		1		
Vaccination site pain	1	3	1	3		
	11	59	11	53		6

* I=Interval, C=Cumulative
* AE=Adverse Event
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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain upper	2	5	2	5		
Adverse event	1	1	1	1		
Allergy to vaccine	1	1	1	1		
Angioedema		1				1
Anxiety		1		1		
Arthralgia		2		2		
Asthenia		1		1		
Aversion		1		1		
Axillary mass		1		1		
Axillary pain		1		1		
Back pain	2	3	2	3		
Blood glucose decreased		1		1		
Blood pressure increased	1	2	1	2		
Blood test abnormal		1		1		
Bone pain		2		2		
Bronchitis	1	1	1	1		
Burning sensation		2		2		
Chest discomfort		2		2		
Chest pain	1	3	1	2		1
Chills		4		4		
Circumstance or information capable of leading to medication error	1	1	1	1		
Cold sweat		1		1		
Colitis		1		1		
Contusion		2		2		
Coronavirus infection		1		1		
Cough	1	3	1	2		1
COVID-19	1	1	1	1		
Crying		1				1
Decreased appetite	1	1	1	1		
Depressed mood		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermatitis allergic		5		4		1
Diarrhoea		3		3		
Discomfort	1	2	1	2		
Discouragement		1		1		
Dizziness	2	5	2	5		
Dry mouth		1				1
Dyspepsia	1	1	1	1		
Dyspnoea	1	4	1	4		
Ear discomfort		1		1		
Emotional distress		1		1		
Erythema	1	3	1	3		
Eye irritation		1		1		
Eye pain		1		1		
Eye swelling		1		1		
Face oedema		1				1
Fatigue	3	10	3	10		
Fear	1	2	1	2		
Feeling abnormal	2	2	2	2		
Feeling cold	1	3	1	3		
Gait disturbance		2		2		
Guillain-Barre syndrome		2				2
Haemorrhoids	1	1	1	1		
Headache	6	32	6	31		1
Hemiplegia		1				1
Hot flush	1	2	1	2		
Hypersensitivity	2	4	2	4		
Hypertension		1		1		
Hypertonia		1		1		
Hypoaesthesia	1	2	1	2		
Inappropriate schedule of product administration	1	2	1	2		
Incomplete course of vaccination		9		9		
Inflammation		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Insomnia	1	3	1	3		
Limb discomfort		1		1		
Localised oedema		1				1
Loss of personal independence in daily activities		1		1		
Lymphadenitis	1	1	1	1		
Lymphadenopathy	1	4	1	4		
Malaise	4	14	4	13		1
Mass		1		1		
Maternal exposure timing unspecified		1		1		
Mental disorder		1		1		
Mobility decreased	1	1	1	1		
Muscle spasms	1	1	1	1		
Musculoskeletal chest pain		1		1		
Myalgia	1	16	1	15		1
Nausea	2	10	2	9		1
Oedema peripheral		1		1		
Off label use	1	2	1	2		
Oropharyngeal pain		2		1		1
Pain	1	10	1	10		
Pain in extremity	6	14	6	14		
Panic attack		1		1		
Panic reaction	1	2	1	2		
Paraesthesia		1				1
Peripheral swelling		2		2		
Polydipsia		1		1		
Proctalgia	1	1	1	1		
Product supply issue	1	2	1	2		
Product use issue	1	2	1	2		
Pruritus	1	1	1	1		
Pyrexia	4	21	4	20		1
Respiratory disorder		1				1
Rhinorrhoea		2		2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin swelling	1	1	1	1		
Somnolence		3		3		
Stress		1		1		
Suspected COVID-19		1				1
Tachycardia	1	4	1	3		1
Therapeutic response unexpected		1		1		
Thirst	1	1	1	1		
Throat irritation		3		3		
Tinnitus		1		1		
Type 2 diabetes mellitus		1		1		
Urticaria		1		1		
Vaccination site erythema		3		3		
Vaccination site inflammation		4		4		
Vaccination site mass		1		1		
Vaccination site pain		12		12		
Vaccination site pruritus		1		1		
Vaccination site swelling		1		1		
Vomiting		1				1
Wheezing	1	1	1	1		
Wrong product administered		1		1		
	71	324	71	302		22

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

COLOMBIA

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* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic shock		1				1
Arthralgia		1		1		
Asphyxia		1				1
Asthenia		2		1		1
Bone pain		1		1		
Chills	1	3	1	2		1
Cough		1		1		
Decreased appetite		1		1		
Discomfort		1				1
Dizziness	1	1	1	1		
Dyspnoea		1		1		
Erythema		2		2		
Eye pain		1		1		
Fatigue		1				1
Gait inability		1		1		
Headache	1	4	1	4		
Lymphadenopathy		1		1		
Malaise		1		1		
Myalgia		1		1		
Nausea		2		2		
Ocular hyperaemia		1		1		
Oropharyngeal pain		1		1		
Oxygen saturation decreased		1		1		
Paraesthesia		1		1		
Pharyngeal erythema		1		1		
Puncture site pain		1		1		
Pyrexia	1	2	1	2		
Respiratory distress		1				1
Secretion discharge		1		1		
Sneezing		1		1		
Urticaria		1		1		
Vaccination site pain		2		2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term

Vertigo

Interval Total #
Spontaneous AE

4

Cumulative Total #
Spontaneous AE

1

43

Spontaneous			
Nonserious		Serious	
I	C	I	C
4	35		1
			8

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* I=Interval, C=Cumulative
* AE=Adverse Event
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Aphthous ulcer	1	1	1	1		
Arthralgia	3	5	3	5		
Asthenia	1	2	1	2		
Asymptomatic COVID-19		1				1
Axillary mass	1	1			1	1
Axillary pain	1	1			1	1
Bone pain	1	1	1	1		
Bowel movement irregularity	1	1			1	1
Burning sensation	1	1	1	1		
Chills	1	3	1	3		
Cough	1	3	1	2		1
COVID-19	2	3	1	2	1	1
Diarrhoea	1	2	1	2		
Discomfort	1	1	1	1		
Dizziness	4	6	3	5	1	1
Drug ineffective	1	1			1	1
Dysgeusia	1	1			1	1
Dyspnoea		2		1		1
Erythema	1	1	1	1		
Exposure during pregnancy		1		1		
Eye pain	1	1	1	1		
Fatigue	1	1	1	1		
Feeling hot		1		1		
Gait disturbance	1	1	1	1		
Headache	5	12	5	10		2
Herpes zoster	1	1	1	1		
Hypertension		2		1		1
Hypokinesia	1	1	1	1		
Influenza like illness		1		1		
Joint swelling	1	1	1	1		
Lip dry	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy	1	1	1	1		
Lymph node palpable	1	1	1	1		
Malaise	2	7	2	6		1
Musculoskeletal pain	1	1	1	1		
Myalgia	3	4	3	4		
Nasal congestion	1	1	1	1		
Nausea	2	2	1	1	1	1
Neck pain	2	2	2	2		
Odynophagia	2	2	2	2		
Oropharyngeal pain		1		1		
Pain in extremity	1	1	1	1		
Papule	1	1	1	1		
Pharyngitis	1	1	1	1		
Pyrexia	2	4	2	3		1
Rash		2		1		1
Sedation	1	1			1	1
Swelling	1	1	1	1		
Tachycardia		1		1		
Tinnitus	1	1	1	1		
Tremor	1	1			1	1
Urticaria		1		1		
Vaccination site pain	2	2	2	2		
Vomiting	1	3	1	3		
	62	104	51	83	11	21

* I=Interval, C=Cumulative
* AE=Adverse Event
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain upper		1		1		
Anal rash	1	1	1	1		
Anaphylactic reaction	1	1			1	1
Arthralgia	1	1	1	1		
Asthenia	1	1	1	1		
Back pain		1		1		
Burning sensation	1	1	1	1		
Chills	2	2	2	2		
Cough		2		2		
COVID-19	1	1			1	1
Diplopia	1	1			1	1
Drug hypersensitivity		1		1		
Dyspnoea		1		1		
Erythema	1	2	1	2		
Fatigue	1	1	1	1		
General physical health deterioration	1	1	1	1		
Headache	1	3	1	3		
Hypersensitivity	2	3	1	2	1	1
Hypoaesthesia		1		1		
Inflammation	1	1	1	1		
Influenza		1		1		
Lymphadenopathy	1	2	1	2		
Malaise		1		1		
Mobility decreased	1	1			1	1
Muscle spasms	1	2	1	2		
Myalgia	1	1	1	1		
Myocardial infarction	1	1			1	1
Oedema		1		1		
Oropharyngeal pain	1	1	1	1		
Oxygen saturation decreased	1	1			1	1
Pain	2	4	2	4		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia		1		1		
Pharyngeal oedema	1	1			1	1
Pneumonia	1	1			1	1
Pruritus allergic	1	1	1	1		
Rash	2	2	1	1	1	1
Rhinitis allergic	1	1	1	1		
Rhinorrhoea		1		1		
Swelling face	1	1	1	1		
Vaccination site pain	1	1	1	1		
Vision blurred	1	1			1	1
	35	55	24	44	11	11

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphonia	1	1	1	1		
Asphyxia	1	1			1	1
Asthenopia	1	1	1	1		
Blister		1		1		
Body temperature decreased	1	1	1	1		
Bone pain	1	1	1	1		
Burning sensation		1		1		
Candida infection		1		1		
Cardiac disorder	1	1			1	1
Chills	1	2	1	2		
Choking sensation	1	1			1	1
COVID-19	1	2	1	2		
Death		1				1
Dyspnoea	1	1	1	1		
Erythema		1		1		
Fatigue	1	1	1	1		
Gingivitis		1		1		
Hypersensitivity		2		2		
Leukocytosis		1		1		
Lung disorder	1	1			1	1
Malaise	1	2	1	2		
Off label use		1		1		
Oral candidiasis		1		1		
Oropharyngeal pain	1	1	1	1		
Oxygen saturation decreased	1	1			1	1
Pharyngeal swelling	1	1	1	1		
Product use issue		1		1		
Pruritus		1		1		
Pyrexia		1		1		
Renal disorder	1	1			1	1
Stomatitis		1		1		
Vertigo	2	2	2	2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vomiting	1	1	1	1		
		1		1		
	20	39	14	32	6	7

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19 pneumonia	1	1	1	1
Drug ineffective	1	1	1	1
	2	2	2	2

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* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Anaphylactic reaction		2				2
Anxiety		1				1
Arthralgia		3		3		
Arthritis	1	1	1	1		
Asthenia	1	2	1	2		
Asymptomatic COVID-19	2	2			2	2
Blister	1	1	1	1		
Blood pressure increased		1		1		
Body temperature decreased	1	1	1	1		
Chest pain		1		1		
Chills		2		2		
Cough	1	2	1	2		
COVID-19	11	13	6	6	5	7
Cyanosis		1		1		
Diarrhoea	1	2	1	1		1
Discomfort	3	3	2	2	1	1
Dizziness	1	2	1	2		
Drug ineffective	6	7			6	7
Dry mouth	1	1	1	1		
Dry throat	1	1	1	1		
Dysphonia		1		1		
Dyspnoea	1	1			1	1
Eye inflammation	1	1	1	1		
Eye pain	1	1	1	1		
Facial paralysis	1	1			1	1
Fatigue	1	1	1	1		
Feeling hot		2		2		
Headache	5	7	5	7		
Herpes virus infection	1	1	1	1		
Herpes zoster	2	2	2	2		
Hyperhidrosis		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypersensitivity	1	2
Inappropriate schedule of product administration	1	2
Influenza		1
Insomnia	1	1
Limb discomfort	1	1
Malaise	3	5
Myalgia	1	3
Neuralgia	1	1
Oxygen saturation abnormal	1	1
Oxygen saturation decreased		1
Pain	2	2
Pain in extremity	2	2
Paraesthesia	1	2
Post herpetic neuralgia	1	1
Product use issue	1	1
Pruritus	1	1
Pyrexia	2	4
Rash	3	6
Seizure		1
Skin discolouration		1
Skin plaque		1
Suffocation feeling		1
Suspected COVID-19	1	1
Syncope		1
Tachycardia	1	1
Thirst	1	1
Thrombophlebitis	1	1
Thrombosed varicose vein	1	1
Underdose		1
Urticaria		2
Vaccination failure	1	1
Vaccination site erythema		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1	1	1
1	2		
	1		
1	1		
1	1		
3	5		
1	3		
1	1		
		1	1
	1		
2	2		
2	2		
1	2		
1	1		
1	1		
2	4		
2	4	1	2
			1
	1		
	1		
	1		
1	1		
			1
1	1		
1	1		
1	1		
1	1		
	1		
	2		
		1	1
	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	1	6	1	6		
Vertigo	1	1	1	1		
Vomiting	2	3	2	2		1
	78	131	58	100	20	31

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Country Where Event Occurred

COSTA RICA

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Abortion spontaneous		1				1
Adnexa uteri pain		1		1		
Anaphylactic shock		1				1
Application site inflammation		1		1		
Application site pain		1		1		
Arthralgia	1	2	1	2		
Asthenia	1	3	1	3		
Axillary pain		1		1		
Burning sensation		2		2		
Chills	2	4	2	4		
Condition aggravated		1		1		
COVID-19	2	3		1	2	2
Dermatitis allergic		2		1		1
Diarrhoea	1	1	1	1		
Dizziness	1	1	1	1		
Drug ineffective	1	1			1	1
Dyspnoea		1		1		
Dysstasia	1	1	1	1		
Encephalopathy		1				1
Erythema		1		1		
Eye pain	1	1	1	1		
Eye pruritus		1		1		
Fatigue	3	7	3	7		
Feeling abnormal	1	1	1	1		
Feeling cold	1	1	1	1		
Feeling hot		1		1		
Headache	5	12	5	12		
Head discomfort		1		1		
Hyperhidrosis	1	1	1	1		
Hyperthermia		1		1		
Hyposmia		1		1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Impaired work ability	1	1			1	1
Incorrect route of product administration		2		2		
Infection		2		2		
Lethargy		1		1		
Limb discomfort		3		3		
Lymph node pain		1		1		
Malaise	1	2	1	2		
Migraine	2	2	2	2		
Mobility decreased	1	1	1	1		
Multiple organ dysfunction syndrome	1	1			1	1
Muscle spasms		1		1		
Muscle tightness	1	1	1	1		
Myalgia	1	6	1	6		
Nasal congestion		1		1		
Nausea	1	2	1	2		
Neck pain		1		1		
Nervous system disorder		1		1		
Ocular hyperaemia		2		2		
Odynophagia		1		1		
Oropharyngeal pain		1		1		
Oxygen saturation decreased		1				1
Pain	3	4	3	4		
Pain in extremity	2	9	2	9		
Peripheral coldness		1		1		
Pruritus		2		2		
Pyrexia	4	7	4	7		
Rash		2		2		
Rash papular		1		1		
Seizure		1				1
Skin lesion		1		1		
Sleep disorder		1		1		
Somnolence		2		2		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia		1		1		
Throat irritation		1		1		
Throat tightness		1				1
Urticaria		1		1		
Vaccination failure	1	1			1	1
Vaccination site discomfort		1		1		
Vaccination site mass		1		1		
Vaccination site pain	2	19	2	19		
Vaccination site urticaria		1		1		
	44	151	38	138	6	13

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1				1
Abdominal pain	1	2	1	2		
Abdominal pain upper		4		1		3
Anaphylactic reaction		1				1
Anaphylactic shock		1				1
Application site pain	2	2	2	2		
Arthralgia	2	7	2	7		
Asthenia	2	5	2	3		2
Axillary pain	1	1	1	1		
Back pain		2		2		
Bacterial test positive	1	1	1	1		
Blood cholesterol increased	1	1	1	1		
Bone pain		1		1		
Bowel movement irregularity	1	1	1	1		
Chest discomfort		1				1
Chest pain		1				1
Chills	1	7	1	5		2
Cold sweat		1		1		
Colitis	1	1	1	1		
Condition aggravated		1				1
Contusion		1				1
Cough	1	4	1	4		
COVID-19		2		1		1
Deafness		1				1
Diarrhoea	1	4	1	2		2
Discomfort		1				1
Dizziness	2	5	2	3		2
Dry mouth		1				1
Dysgeusia		2		1		1
Dyspepsia		2				2
Dysphonia		2		2		
Dyspnoea	1	3	1	2		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear discomfort		1		1		
Ear pain	1	1	1	1		
Energy increased		1		1		
Epistaxis		1				1
Euphoric mood		1		1		
Extensive swelling of vaccinated limb		1		1		
Eye pain	1	1	1	1		
Eye pruritus		1		1		
Face oedema	1	1	1	1		
Fall		1				1
Fatigue	9	18	9	16		2
Feeling abnormal		2		2		
Feeling cold		1		1		
Feeling hot	2	2	2	2		
Gastritis		1				1
Gingival bleeding		1		1		
Gingival disorder		1		1		
Gingival pain		1		1		
Gingivitis		1		1		
Haemorrhage		1				1
Headache	9	23	9	20		3
Heart rate increased	1	2			1	2
Heart rate irregular		1		1		
High density lipoprotein decreased	1	1	1	1		
Hyperaesthesia	1	1	1	1		
Hyperhidrosis	3	5	3	4		1
Hypertension		1				1
Hypoaesthesia	1	2	1	2		
Immune thrombocytopenia		1				1
Influenza	1	1	1	1		
Influenza like illness		1				1
Insomnia		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint swelling		1		1		
Lethargy		1		1		
Limb discomfort		1		1		
Low density lipoprotein increased	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Malaise	2	6	2	6		
Migraine		2		1		1
Miosis		1				1
Mobility decreased		1		1		
Muscle spasms		2		2		
Myalgia	5	14	5	13		1
Nasal discomfort	1	1	1	1		
Nasopharyngitis		1		1		
Nausea		3		2		1
Ocular hyperaemia		1		1		
Oropharyngeal discomfort		1				1
Oropharyngeal pain		1		1		
Oxygen saturation decreased		1		1		
Pain	7	10	7	10		
Pain in extremity	4	12	4	12		
Paraesthesia	1	3	1	3		
Peripheral swelling		1		1		
Petechiae		1				1
Photopsia		1		1		
Platelet count abnormal		1				1
Pruritus		3		3		
Pyrexia	2	11	2	11		
Rash	1	2	1	2		
Rash macular	1	1	1	1		
Red blood cell sedimentation rate increased		1		1		
Respiratory disorder		1				1
Respiratory distress		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory symptom	1	1	1	1		
Respiratory tract congestion		1		1		
Sensation of foreign body		1		1		
Sleep disorder		1		1		
Somnolence	2	4	2	4		
Swelling	1	1	1	1		
Tachycardia	1	3	1	3		
Tachypnoea		2		2		
Thirst		2				2
Throat clearing		1		1		
Throat irritation		1		1		
Tooth disorder		1		1		
Vaccination site erythema	1	1	1	1		
Vaccination site induration	1	1	1	1		
Vaccination site nodule		1		1		
Vaccination site pain	7	18	7	18		
Vaccination site swelling	1	1	1	1		
Vaccination site warmth	1	1	1	1		
Vasculitis		1		1		
Vision blurred	1	2	1	2		
Vomiting	1	3	1	2		1
	93	286	92	233	1	53

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Back pain		1		1		
Chills	1	2	1	2		
COVID-19	1	1			1	1
Diarrhoea	2	3	2	3		
Discomfort	1	1	1	1		
Eye pain		1		1		
Fatigue	1	2	1	2		
Headache	1	3	1	3		
Lymphadenopathy		1		1		
Malaise	1	1	1	1		
Migraine	1	2	1	2		
Musculoskeletal chest pain		1		1		
Myalgia		2		2		
Pain	2	3	2	3		
Pain in extremity	2	3	2	3		
Pain of skin	1	1	1	1		
Pyrexia		1		1		
Rash	1	1	1	1		
Toothache	1	1	1	1		
Vaccination failure	1	1			1	1
Vaccination site pain	1	4	1	4		
	18	37	16	35	2	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Arthralgia		1		1		
Asthenia		1		1		
Cerebrovascular accident		2				2
Cough		1		1		
COVID-19	2	3			2	3
Death		1				1
Diarrhoea		2		2		
Dizziness	1	3	1	2		1
Drug ineffective	1	1			1	1
Dyspnoea		1		1		
Fatigue	1	3	1	3		
Feeling abnormal		1				1
Headache	1	3	1	3		
Hepatic enzyme increased		1				1
Hypothermia		1				1
Infarction	1	1			1	1
Influenza		1		1		
Joint range of motion decreased		1				1
Lacrimation increased	1	1	1	1		
Malaise		1				1
Mobility decreased		1				1
Muscle contracture		1		1		
Myalgia		3		2		1
Myocardial infarction		1				1
Nausea		2		1		1
Oxygen saturation abnormal		1				1
Pain	2	3	2	3		
Pain in extremity		3		3		
Pruritus		1		1		
Pyrexia		3		1		2
Rash	1	2	1	2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal disorder	1	1			1	1
Splenomegaly		1				1
Syncope		1				1
Thrombophlebitis	1	1	1	1		
Thrombosis	1	1			1	1
Urticaria		1		1		
Vaccination complication		1		1		
Vaccination failure	1	2			1	2
Vaccination site pain	3	9	3	9		
Vertigo	1	1	1	1		
Vomiting		1				1
	20	72	13	44	7	28

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		1		1		
Cardiac arrest	1	1			1	1
Death	1	2			1	2
Dizziness		1		1		
Drug reaction with eosinophilia and systemic symptoms	1	1			1	1
Dry eye		1		1		
Erythema	1	1	1	1		
Erythema of eyelid		1		1		
Eyelid irritation		1		1		
Feeling cold		1		1		
Headache	1	1	1	1		
Hypersensitivity		1		1		
Mouth swelling		1		1		
Myocardial infarction		1				1
Nausea		1		1		
Pain		1		1		
Pain in extremity		2		2		
Peripheral swelling	1	2	1	2		
Pruritus	1	2	1	2		
Pyrexia		1		1		
Swelling face		1		1		
Vaccination site erythema		1		1		
Vomiting		1		1		
	7	27	4	22	3	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adnexa uteri pain		1		1		
Aphonia		1		1		
Aphthous ulcer		1		1		
Arthralgia		1		1		
Asthenia		3		3		
Axillary pain		1		1		
Back pain	1	1	1	1		
Blood pressure increased		1		1		
Breast discomfort		1		1		
Bronchospasm		1		1		
Cerebrovascular accident		1				1
Chills	1	4	1	4		
Communication disorder		1		1		
Constipation		2		2		
Contusion		1		1		
COVID-19	3	10			3	10
Depression		1		1		
Diarrhoea	1	4	1	4		
Discomfort	1	3	1	3		
Dizziness		2		2		
Drug ineffective	2	7			2	7
Drug reaction with eosinophilia and systemic symptoms	1	1			1	1
Dysgeusia		1		1		
Dyspnoea		4		3		1
Ecchymosis		1		1		
Epistaxis		1		1		
Exposure via breast milk	1	1	1	1		
Eye allergy		1		1		
Eye inflammation		1		1		
Faeces soft		1		1		
Fatigue	3	19	3	19		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling abnormal		1		1		
Feeling cold		2		2		
Fibrin D dimer increased		1		1		
Flatulence		1		1		
Gastric disorder		1		1		
Gastritis		1		1		
Gastrointestinal pain		1		1		
Gastrointestinal sounds abnormal		1		1		
Headache	5	16	5	16		
Hypersomnia		1		1		
Hypertensive crisis		1				1
Immunology test abnormal		1		1		
Impaired work ability		1		1		
Incoherent		1		1		
Influenza	1	1	1	1		
Influenza like illness	1	1	1	1		
Intentional product use issue		1		1		
Ischaemia		1		1		
Loss of personal independence in daily activities		2		2		
Lung disorder		2		1		1
Lymphadenopathy		2		2		
Lymphangitis		1				1
Lymph node pain		1		1		
Malaise		1		1		
Migraine		1		1		
Myalgia	1	5	1	5		
Nausea		3		3		
Oropharyngeal pain		2		2		
Oxygen saturation decreased		2				2
Pain	2	11	2	11		
Pain in extremity		10		10		
Peripheral swelling		1		1		

* I=Interval, C=Cumulative
* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Petechiae		1		1		
Platelet count abnormal		1				1
Pleural effusion		1				1
Pleuritic pain		1		1		
Pneumonitis		1				1
Poor quality product administered		1		1		
Pyrexia	2	10	2	10		
Rash		1		1		
Renal disorder		1		1		
Rhinorrhoea	1	2	1	2		
SARS-CoV-2 ant body test negative		1		1		
Skin burning sensation		1		1		
Skin discolouration		1		1		
Somnolence	1	1	1	1		
Suspected COVID-19		1		1		
Tinnitus		2		2		
Tremor		1		1		
Vaccination failure	1	2			1	2
Vaccination site induration		1		1		
Vaccination site movement impairment		1		1		
Vaccination site pain	1	11	1	11		
Venous thrombosis		1				1
Vertigo	1	1	1	1		
Vomiting		1		1		
	31	203	24	172	7	31

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred
CROATIA

090177e19749cf15\Approved\Approved On: 14-Jun-2021 14:01 (GMT)

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1			1	1
Arthralgia	1	3	1	3		
Asthenia	2	6	2	5		1
Axillary mass	1	1	1	1		
Axillary pain	1	1	1	1		
Blister		1				1
Body temperature increased	1	4	1	4		
Chest discomfort		1				1
Chills	3	11	3	10		1
Choking sensation		1				1
Cold sweat		2		1		1
COVID-19	2	3		1	2	2
C-reactive protein increased	1	1	1	1		
Dermatitis allergic		1				1
Diarrhoea	2	2	2	2		
Disturbance in attention		1		1		
Dizziness		2		1		1
Dizziness postural	1	1	1	1		
Dysgeusia		1				1
Dysphagia		1				1
Dyspnoea		2				2
Erythema	1	3	1	1		2
Extensive swelling of vaccinated limb	1	2			1	2
Eye pain		1		1		
Facial paresis		1				1
Fatigue	3	7	3	6		1
Feeling abnormal		1				1
Feeling cold		1		1		
Feeling hot		2		1		1
Headache	5	22	4	18	1	4
Herpes zoster	1	1	1	1		
Hyperhidrosis		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Immune system disorder		1		1		
Insomnia		1		1		
Loss of consciousness	1	1			1	1
Lymphadenopathy		1				1
Lymph node pain		1				1
Malaise		3		3		
Muscle tightness		1		1		
Muscular weakness		1		1		
Myalgia	3	12	3	10		2
Myosclerosis		1				1
Nasopharyngitis	1	2		1	1	1
Nausea	2	7	2	7		
Neck pain		1		1		
Pain		3		3		
Pain in extremity	1	3	1	3		
Pallor		1				1
Palpitations		1				1
Panic attack		1				1
Paraesthesia		3		1		2
Pharyngeal paraesthesia		1				1
Presyncope		1				1
Pruritus	1	3			1	3
Pyrexia	6	19	6	16		3
Rash	1	2			1	2
Rash macular	1	1	1	1		
Rash maculo-papular		2				2
Salivary hypersecretion		1				1
Sleep paralysis		1		1		
Sleep terror		1		1		
Somnolence	1	1	1	1		
Spinal pain		1		1		
Tension headache	1	1	1	1		

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Throat tightness		1				1
Tongue oedema		2				2
Tremor		2		1		1
Type I hypersensitivity		3				3
Urticaria	1	3	1	1		2
Vaccination failure	2	2			2	2
Vaccination site erythema		2		1		1
Vaccination site joint movement impairment		1		1		
Vaccination site oedema		3		2		1
Vaccination site pain	4	23	4	19		4
Vaccination site swelling	1	4	1	3		1
Vertigo		1				1
Vomiting	1	3	1	3		
	55	219	44	148	11	71

* I=Interval, C=Cumulative
* AE=Adverse Event
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		2		2		
Abortion spontaneous		1				1
Ageusia	2	2			2	2
Allergy to chemicals		1		1		
Altered state of consciousness		1				1
Anaphylactic shock		1				1
Angioedema		1				1
Anosmia	2	3			2	3
Anxiety	1	1	1	1		
Aphthous ulcer		1		1		
Application site oedema		1		1		
Arrhythmia		2				2
Arthralgia	1	10	1	9		1
Arthritis	1	1			1	1
Arthritis reactive		1				1
Asthenia	5	18	4	14	1	4
Asymptomatic COVID-19	1	1			1	1
Axillary pain	1	2	1	1		1
Back pain		3		2		1
Bell's palsy		1				1
Blood pressure increased		5		3		2
Body temperature increased	3	11	3	10		1
Bone pain	2	7	2	7		
Bronchospasm		1				1
Burning sensation	1	2	1	1		1
Catarrh		1				1
Chest discomfort		3				3
Chest pain		1		1		
Chills	6	35	5	28	1	7
Condition aggravated		1				1
Confusional state	2	4	2	3		1
Conjunctivitis allergic		1				1

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coordination abnormal	1	1	1	1		
Cough	2	3			2	3
COVID-19	9	13		1	9	12
Cyanosis		1				1
Deafness bilateral		1				1
Decreased appetite	1	4	1	4		
Dermatitis allergic		1		1		
Diaphragmatic spasm		1				1
Diarrhoea	1	3	1	3		
Discomfort		1		1		
Disorientation	1	1	1	1		
Disturbance in attention	1	1	1	1		
Dizziness	1	5		3	1	2
Drug ineffective	1	1			1	1
Dry mouth		1		1		
Dyskinesia		1				1
Dyspnoea		6		3		3
Dyspnoea exertional		1		1		
Ear canal erythema		1				1
Ear pain		2				2
Ear pruritus		1				1
Encephalitis post immunisation		1				1
Epilepsy		1				1
Erythema	2	12	2	3		9
Exposure during pregnancy		1		1		
Extensive swelling of vaccinated limb	1	12			1	12
Extrapyramidal disorder		1				1
Eyelid function disorder		1				1
Eyelid oedema		2		1		1
Eyelid pain		1		1		
Eyelid ptosis		2				2
Facial nerve disorder		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial pain		1		1		
Facial paresis	1	5			1	5
Fatigue	15	35	13	29	2	6
Fear		1				1
Feeding disorder		1		1		
Feeling abnormal	1	2	1	2		
Feeling hot		8		5		3
Flushing	1	1	1	1		
Gait disturbance	1	1	1	1		
Gastrointestinal pain		1		1		
Gingival bleeding		1		1		
Haematoma		1		1		
Headache	16	58	14	44	2	14
Head discomfort		1				1
Heart rate increased		1				1
Heavy menstrual bleeding	1	1	1	1		
Hot flush		2		1		1
Hyperaesthesia		1		1		
Hyperhidrosis		6		4		2
Hypersensitivity		1				1
Hypertension	1	7	1	2		5
Hypoacusis		1		1		
Hypoaesthesia		4		2		2
Hypoaesthesia oral		1				1
Hypogeusia		1		1		
Hypokinesia		1				1
Hypotension		2		1		1
Influenza like illness	1	1	1	1		
Insomnia		3		3		
Irritable bowel syndrome		1		1		
Joint effusion		1				1
Lacrimation increased		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lip disorder		1				1
Lip oedema		2				2
Lip swelling		1				1
Livedo reticularis		1				1
Localised oedema		1		1		
Loss of consciousness		3				3
Lymphadenitis		2		1		1
Lymphadenopathy	3	10	3	9		1
Lymph node pain	2	4	2	4		
Malaise	4	14	3	12	1	2
Menstrual disorder		1		1		
Moaning		1				1
Monoparesis	1	2	1	1		1
Muscle contractions involuntary		1		1		
Muscle spasms		2		1		1
Muscular weakness		2		1		1
Musculoskeletal stiffness		1				1
Myalgia	11	37	10	33	1	4
Nasal congestion	2	2			2	2
Nasopharyngitis	1	2		1	1	1
Nausea	4	20	4	16		4
Neck pain	2	6	2	5		1
Neuritis		1		1		
Neurological symptom		1		1		
Nystagmus		1				1
Ocular hyperaemia		1		1		
Oedema mouth		1				1
Oedema peripheral		1				1
Off label use		1		1		
Oral herpes	1	1	1	1		
Oral mucosal erythema		1		1		
Oral pain		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oropharyngeal pain	1	4		3	1	1
Pain	2	3	2	3		
Pain in extremity	4	14	4	12		2
Pain of skin		1				1
Pallor		1				1
Palpitations		7		4		3
Panic attack		1				1
Paraesthesia	3	12	2	8	1	4
Paraesthesia oral	1	4		1	1	3
Paresis		1				1
Parosmia	1	1			1	1
Peripheral coldness		1		1		
Peripheral swelling	1	3		2	1	1
Pleural effusion		1				1
Pneumonia		1				1
Polymenorrhoea	1	2	1	2		
Presyncope		2		1		1
Product use issue		1		1		
Pruritus	4	13	4	6		7
Pulmonary embolism		1				1
Pulmonary pain		1		1		
Pulse absent		1				1
Pyrexia	11	52	9	40	2	12
Rash	2	9	2	2		7
Rash erythematous		1				1
Rash macular		3				3
Rash maculo-papular	1	3	1	1		2
Rash pruritic	1	1	1	1		
Rectal haemorrhage		1				1
Renal pain		1		1		
Respiratory symptom	1	1			1	1
Restlessness		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Retching		1
Rhinorrhoea	1	2
Sensation of foreign body		1
Sensory loss		1
Serum sickness		1
Skin burning sensation		3
Skin oedema		1
Skin sensitisation		1
Skin tightness		2
Sneezing		1
Snoring		1
Somnolence		3
Swollen tongue		1
Syncope		1
Synovitis		1
Tachycardia		8
Tachypnoea		1
Tension		1
Thirst	1	1
Tinnitus		3
Tongue oedema		1
Tremor	1	7
Trismus	1	1
Type I hypersensitivity		10
Urticaria	3	4
Use of accessory respiratory muscles		1
Vaccination failure	9	12
Vaccination site erythema	5	27
Vaccination site haematoma		2
Vaccination site hypersensitivity		1
Vaccination site induration		4
Vaccination site joint erythema		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
		1	2
	1		
			1
			1
	1		2
	1		
	1		
			2
			1
			1
	1		2
			1
			1
	2		6
			1
	1		
		1	1
	1		2
			1
	5	1	2
1	1		
			10
3	3		1
			1
		9	12
5	20		7
	2		
	1		
	3		1
	1		

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site lymphadenopathy		2		2		
Vaccination site mass		1				1
Vaccination site movement impairment		1				1
Vaccination site oedema	1	7	1	5		2
Vaccination site pain	12	67	12	58		9
Vaccination site pruritus	1	4	1	4		
Vaccination site reaction		1		1		
Vaccination site swelling	3	15	3	12		3
Vertigo	2	5	2	4		1
Vision blurred		1				1
Visual impairment	1	2	1	1		1
Vomiting	1	7	1	5		2
Wheezing		1				1
Wrong technique in product usage process		1		1		
	194	860	142	543	52	317

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Anaemia		1				1
Anaphylactic reaction		2				2
Anaphylactic shock		1				1
Angina pectoris		1				1
Angioedema		1				1
Arrhythmia		4				4
Arthralgia	1	5	1	5		
Asthenia	2	11	1	10	1	1
Asthma		1				1
Asymptomatic COVID-19	2	2			2	2
Atrial f brillation		1				1
Back pain		2		1		1
Blood creatine phosphokinase increased		1		1		
Blood pressure decreased		1		1		
Blood pressure increased		9		1		8
Body temperature increased	2	4	1	3	1	1
Bone pain		2		2		
Breast pain		1		1		
Breath sounds abnormal		1				1
Bronchospasm		2				2
Burning sensation	1	3			1	3
Chest discomfort	1	2		1	1	1
Chest pain	4	7	1	3	3	4
Chills	3	15	3	15		
Condition aggravated		1				1
Contusion	1	1			1	1
Cough		5		3		2
COVID-19	2	6		1	2	5
Death		1				1
Decreased appetite		1		1		
Deep vein thrombosis		2				2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Defaecation urgency		1		1		
Dermatitis	1	1			1	1
Diarrhoea		2		1		1
Dizziness	1	5	1	5		
Drug ineffective	2	2			2	2
Dry eye		1				1
Dry mouth		1				1
Dysarthria		1		1		
Dysgeusia		1		1		
Dyspepsia		1		1		
Dysphagia		1				1
Dysphonia		1				1
Dyspnoea	1	7		1	1	6
Dyspnoea exertional	1	1			1	1
Ear pain		1		1		
Eructation		1		1		
Erythema	1	8		2	1	6
Extensive swelling of vaccinated limb		9				9
Eye haematoma		1				1
Eye haemorrhage		1				1
Eye opacity		1		1		
Eye pain		2		2		
Face oedema	1	1			1	1
Facial paresis		2				2
Fall	1	1			1	1
Fatigue	2	9	1	7	1	2
Feeling abnormal		1		1		
Fibromyalgia		1				1
Gastritis		1		1		
Headache	4	23	3	17	1	6
Heart rate increased	1	2		1	1	1
Hemiparesis		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hemiplegia		1				1
Hyperhidrosis		2		1		1
Hypertension		1				1
Hypertensive crisis		1				1
Hypoaesthesia		1		1		
Hypoaesthesia oral		1		1		
Illness		1		1		
Incorrect dose administered		1				1
Incorrect route of product administration		1		1		
Increased appetite		1		1		
Insomnia	1	1	1	1		
Lacrimation increased		1		1		
Lip oedema	1	1			1	1
Loss of consciousness	1	2			1	2
Lymphadenopathy		1		1		
Lymph node pain	1	1	1	1		
Lymphopenia		1		1		
Malaise	1	6		4	1	2
Memory impairment		1		1		
Migraine		1		1		
Motor dysfunction	1	1			1	1
Movement disorder	1	1			1	1
Multi-organ disorder		1				1
Muscle contractions involuntary		1				1
Muscle spasms		1		1		
Muscular weakness	1	2		1	1	1
Musculoskeletal stiffness		1		1		
Myalgia	4	14	4	14		
Nasal congestion		1		1		
Nausea		6		5		1
Neck pain	1	2	1	2		
Night sweats		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular discomfort		2		2		
Oedema peripheral		1		1		
Oropharyngeal discomfort		1		1		
Oropharyngeal pain		1		1		
Overdose		1		1		
Oxygen saturation decreased	1	1			1	1
Pain	2	4	1	3	1	1
Pain in extremity	3	12	2	7	1	5
Pallor		1				1
Palpitations		3		1		2
Paraesthesia		1				1
Paraesthesia oral		3		1		2
Peripheral coldness		2				2
Peripheral swelling	1	1			1	1
Pharyngeal swelling		1		1		
Photophobia	1	1	1	1		
Pneumonia		2				2
Poor peripheral circulation		1				1
Product preparation error		1		1		
Psoriasis		1		1		
Pulmonary embolism	2	3			2	3
Pyrexia	3	32	3	22		10
Rales		1				1
Rash		5		2		3
Rash erythematous		1		1		
Respiratory tract oedema		1				1
Retching		2		2		
Rheumatoid factor positive		1		1		
Rhinorrhoea		3		3		
Sensory disturbance	1	2			1	2
Sensory loss	1	1			1	1
Sinusitis	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin discolouration		1				1
Skin hypertrophy		1				1
Skin reaction		1				1
Somnolence		1		1		
Spinal pain	1	1			1	1
Stridor		2				2
Suffocation feeling		1				1
Swelling face		1				1
Swollen tongue		1				1
Syncope	1	4			1	4
Tachycardia		5		4		1
Tachypnoea		1				1
Throat tightness		1				1
Thrombocytopenia		1				1
Thrombophlebitis		1				1
Thrombosis		1				1
Tinnitus	1	2		1	1	1
Tongue disorder		1				1
Tongue oedema	1	1			1	1
Tremor	1	4	1	4		
Type I hypersensitivity		5				5
Underdose		1				1
Urine odour abnormal		1		1		
Urticaria		1				1
Use of accessory respiratory muscles		1				1
Vaccination error		1		1		
Vaccination failure	2	5			2	5
Vaccination site erythema		11		9		2
Vaccination site haematoma		1		1		
Vaccination site induration		1				1
Vaccination site lymphadenopathy		1		1		
Vaccination site oedema	1	2	1	2		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	1	22	1	20		2
Vaccination site pruritus		1				1
Vaccination site swelling		3		1		2
Vaccination site warmth		1		1		
Viral infection		1		1		
Vitreous detachment		1				1
Vomiting		2		2		
Wheezing		2				2
	73	439	29	241	44	198

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aptyalism		1				1
Arthralgia	1	3	1	1		2
Asthenia		1		1		
Asymptomatic COVID-19	6	6			6	6
Balance disorder		1				1
Blood creatine phosphokinase increased		1		1		
Blood creatinine increased	1	1			1	1
Blood glucose increased		1		1		
Blood pressure decreased		1		1		
Blood pressure increased		2		1		1
Body temperature increased	1	3	1	2		1
Bone pain	1	1			1	1
Bronchospasm		1				1
Capillary fragility		1		1		
Cardiac failure acute		1				1
Cardio-respiratory arrest		1				1
Cerebral artery thrombosis		1				1
Cerebral haemorrhage		1				1
Cerebral infarction		1				1
Cerebrovascular accident		1				1
Chest pain	1	2			1	2
Chills		1		1		
Coma		1				1
Conjunctival haemorrhage		3				3
Cough	1	3	1	2		1
COVID-19	1	3			1	3
Cyanosis		1				1
Deafness unilateral		1				1
Death		1				1
Diabetes mellitus		1				1
Dizziness		1		1		
Drug eruption	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug ineffective		1				1
Dry mouth		1				1
Dysphagia		1				1
Dyspnoea	2	3			2	3
Erythema		1				1
Extensor plantar response		1		1		
Facial paresis		1				1
Fall		1				1
Gait disturbance	1	1			1	1
Headache	1	4	1	3		1
Head titubation		1				1
Hemiparesis		1				1
Hepatic enzyme abnormal	1	1			1	1
Hypersensitivity		2				2
Hypertension	1	2			1	2
Hypoacusis		1				1
Intraocular pressure increased		1		1		
Ischaemic stroke		1				1
Loss of consciousness		1				1
Loss of personal independence in daily activities		1				1
Muscular weakness		1				1
Myalgia		2				2
Myocardial infarction	1	1			1	1
Neutrophil count increased		1		1		
Pain in extremity	1	1			1	1
Pyrexia		1				1
Rash	1	1			1	1
Rash maculo-papular	1	1			1	1
Respiratory distress		1				1
Respiratory rate decreased		1		1		
Speech disorder		1				1
Stress cardiomyopathy		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swollen tongue		1				1
Tachycardia	1	1	1	1		
Throat tightness		1				1
Tinnitus		1		1		
Tremor	1	1	1	1		
Type I hypersensitivity		1				1
Unresponsive to stimuli		1				1
Urinary tract infection		1				1
Urticaria		1				1
Vaccination failure	7	8			7	8
Vaccination site erythema		1		1		
Vaccination site pain		3		2		1
Vaccination site paraesthesia	1	1	1	1		
Vaccination site swelling		1		1		
Vertigo		1		1		
White blood cell count increased		1		1		
	34	114	7	30	27	84

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Asthenia		4				4
Asymptomatic COVID-19	17	17			17	17
Atrial fibrillation		1				1
Balance disorder		1				1
Blood glucose increased		1				1
Blood pressure increased		1				1
Cardiac arrest		1				1
Cardiac disorder		1				1
Cardiac failure	1	4			1	4
Cardiac failure congestive		1				1
Cardiomyopathy		1				1
Cerebral haemorrhage		1				1
Cerebrovascular disorder		1				1
Chest discomfort		1				1
Chest pain		1				1
Chills	1	1	1	1		
Communication disorder		1				1
Confusional state	1	1			1	1
COVID-19	20	28			20	28
Cyanosis		2				2
Death		1				1
Decreased appetite		1				1
Deep vein thrombosis	1	1			1	1
Diarrhoea		1				1
Disorientation		1				1
Dizziness	1	2			1	2
Drug ineffective		1				1
Dyspnoea	1	5			1	5
Ear infection		1				1
Erythema	1	1			1	1
Escherichia urinary tract infection		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fall		2				2
Fatigue		1				1
Gait disturbance	1	3			1	3
General physical health deterioration		1				1
Haemorrhage subcutaneous		1				1
Heart rate increased		1		1		
Hypersensitivity		1				1
Hypertension		2				2
Hypopnoea		1				1
Hyporesponsive to stimuli		1				1
Hypotension		2				2
Hypoxia		1				1
Ischaemic cerebral infarction		1				1
Loss of consciousness	1	1			1	1
Loss of personal independence in daily activities		1				1
Malaise		1				1
Melaena		1				1
Multiple organ dysfunction syndrome	1	1			1	1
Myalgia	1	1	1	1		
Nausea		2				2
Oedema peripheral	1	2			1	2
Overdose	1	1	1	1		
Oxygen saturation decreased		1				1
Palpitations		1				1
Peripheral swelling		1				1
Pneumonia klebsiella		1				1
Pneumonia staphylococcal		1				1
Product preparation error	1	1	1	1		
Pulmonary embolism	1	1			1	1
Pyrexia	1	3	1	2		1
Sepsis syndrome	1	1			1	1
Snoring		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Speech disorder		1				1
Swelling face		1				1
Tinnitus		1				1
Transient ischaemic attack	1	2			1	2
Type I hypersensitivity		1				1
Urinary incontinence		1				1
Vaccination failure	38	45			38	45
Vaccination site pain	1	1	1	1		
Vertigo	1	1			1	1
Vomiting		3				3
Wheezing		1				1
	95	186	6	9	89	177

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arrhythmia		1				1
Arthralgia		1		1		
Asthenia	1	1	1	1		
Blood glucose increased		1		1		
Bronchitis		1				1
Chills	2	2	2	2		
COVID-19	1	1			1	1
Drug ineffective	1	1			1	1
Dyspnoea	1	1	1	1		
Facial paresis		1		1		
Fatigue	1	2	1	2		
Headache	1	1	1	1		
Heart rate increased	1	1	1	1		
Hypertension		1				1
Insomnia		2		2		
Joint swelling		1		1		
Myalgia	1	1	1	1		
Nausea	1	1	1	1		
Organic brain syndrome		1				1
Pain in extremity	1	1	1	1		
Paraesthesia	1	1	1	1		
Pyrexia	2	4	2	4		
Respiratory failure		1				1
Vaccination site erythema		2		2		
Vaccination site induration		2		2		
Vaccination site pain	1	4	1	4		
Vaccination site swelling	1	1	1	1		
	17	38	15	31	2	7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

CYPRUS

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Axillary pain		1		1		
Chills		1		1		
Headache		2		2		
Head titubation		1		1		
Hyperhidrosis		1		1		
Myalgia		1		1		
Oxygen saturation decreased		1		1		
Pain in extremity		1		1		
Pallor		1		1		
Pyrexia		1		1		
Syncope		2				2
Tremor		1		1		
Vaccination site oedema		1		1		
Vomiting		1		1		
		17		14		3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Amenorrhoea	1	1	1	1		
Arthralgia	2	5	2	5		
Asthenia	3	5	3	5		
Axillary pain		1		1		
Back pain		1		1		
Body temperature increased	1	2	1	2		
Bone pain		1		1		
Bradycardia		1				1
Cerebrovascular accident		1				1
Chest pain	1	1	1	1		
Chills	3	8	3	8		
Cold sweat	1	1	1	1		
Condition aggravated		1		1		
Contusion		1		1		
COVID-19		2		1		1
Dermatitis atopic		1		1		
Dizziness	2	5	2	5		
Drug ineffective		1				1
Dyspnoea	4	5	2	3	2	2
Ear pain		1		1		
Eczema		1		1		
Epistaxis		1				1
Eyelid ptosis		1		1		
Eye pain		1		1		
Facial paresis		3				3
Fatigue	1	2	1	2		
Feeling of relaxation	1	1	1	1		
Generalised tonic-clonic seizure		1				1
Headache	1	9	1	9		
Hyperhidrosis	1	3	1	3		
Hypersensitivity		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia	1	2	1	1		1
Hypoaesthesia oral		1				1
Hypotension		2				2
Inappropriate schedule of product administration		1		1		
Insomnia		1		1		
Jaw disorder	1	1	1	1		
Lymphadenopathy		4		4		
Malaise		3		3		
Migraine		1		1		
Muscle spasms	1	1	1	1		
Musculoskeletal stiffness	1	1	1	1		
Myalgia	2	10	2	10		
Nausea		5		5		
Neck pain		1		1		
Oedema	1	1	1	1		
Off label use		1		1		
Oropharyngeal discomfort	1	1	1	1		
Pain in extremity	1	1	1	1		
Product use issue		1		1		
Pyrexia		5		5		
SARS-CoV-2 ant body test negative		1				1
Somnolence	2	2	2	2		
Swelling face	1	1	1	1		
Syncope		1				1
Tachycardia	3	3	3	3		
Thirst	1	1	1	1		
Tongue rough	1	1	1	1		
Vaccination site pain	1	8	1	8		
Vaccination site swelling		1		1		
Vomiting		2		2		
	41	135	39	118	2	17

* I=Interval, C=Cumulative
* AE=Adverse Event

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Angina pectoris		1				1
Arthralgia	1	3	1	3		
Asthenia	1	1	1	1		
Cervix oedema		1		1		
Chest pain		1		1		
Chills	4	7	4	7		
Condition aggravated	1	1	1	1		
Cough	2	2	2	2		
COVID-19		1				1
Dizziness	1	3	1	3		
Drug ineffective		1				1
Drug interaction		1		1		
Dry mouth	1	1	1	1		
Dysaesthesia		1				1
Dyspnoea	1	3	1	3		
Ear discomfort		1		1		
Erythema		1		1		
Eye disorder		1		1		
Face oedema		1		1		
Facial paralysis		1				1
Facial paresis	1	1	1	1		
Fatigue	1	4	1	4		
Headache	5	7	5	7		
Herpes zoster	1	1	1	1		
Hyperhidrosis	1	1	1	1		
Hypertension		1				1
Hypoacusis		1		1		
Hypoaesthesia eye		1				1
Hypoaesthesia oral		1				1
Inflammation		1		1		
Influenza like illness		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site pain		1		1		
Lymphadenopathy		1		1		
Malaise	1	3	1	3		
Mobility decreased		1		1		
Muscle contracture		1		1		
Myalgia	5	11	5	11		
Myocardial infarction		1				1
Nasal congestion		1		1		
Nasopharyngitis	1	1	1	1		
Nausea		2		2		
Oropharyngeal pain	1	1	1	1		
Overdose		1		1		
Pain		1		1		
Peripheral swelling		1		1		
Pyrexia	3	7	3	7		
Rash		1		1		
Respiratory distress		1				1
Sinus congestion	1	1	1	1		
Tachyarrhythmia		1				1
Tachycardia		2		1		1
Therapeutic response unexpected		1		1		
Upper respiratory tract congestion	1	1	1	1		
Vaccination site oedema		2		2		
Vaccination site pain	1	2	1	2		
Vasculitis		1		1		
Vertigo		1		1		
Vision blurred	1	1	1	1		
Vomiting	1	1	1	1		
	37	104	37	91		13

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury		1				1
Acute respiratory distress syndrome		1				1
Aortic aneurysm		1				1
Arthralgia		2		2		
Asthenia		1		1		
Asymptomatic COVID-19	1	1			1	1
Bacterial sepsis		1				1
Balance disorder		1		1		
Blood pressure increased		1				1
Chills		1		1		
Confusional state		1		1		
COVID-19	1	4			1	4
Death		1				1
Dehydration		1				1
Diarrhoea		1		1		
Discomfort		1		1		
Drug ineffective	2	4			2	4
Dysgeusia		1		1		
Dysphagia		1		1		
Dyspnoea		1		1		
Facial paresis		1				1
Fatigue		3		3		
Gait disturbance		1		1		
Gastrointestinal infection		1				1
Headache	1	1	1	1		
Herpes zoster	2	2	2	2		
Hypoaesthesia	1	2	1	2		
Hypoaesthesia oral		1		1		
Hypotension		1				1
Inappropriate schedule of product administration		1		1		
Insomnia	1	2	1	2		
Lymphadenopathy		1				1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise		2		2		
Multiple organ dysfunction syndrome		1				1
Myalgia		3		3		
Nausea		1		1		
Off label use		1		1		
Pharyngeal oedema		1		1		
Pulmonary embolism		1				1
Pulmonary oedema		1				1
Pyrexia	1	4	1	4		
Respiratory tract oedema		1				1
Shock		1				1
Swollen tongue		1		1		
Unresponsive to stimuli		1				1
Vaccination site pain	1	2	1	2		
Vasculitis		1				1
Viral sepsis		1				1
Vomiting		2		1		1
	11	69	7	40	4	29

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		1		1		
Asthenia		2		2		
Confusional state		1		1		
COVID-19		6				6
C-reactive protein increased		1		1		
Diarrhoea		1		1		
Dizziness		1		1		
Drug ineffective		1				1
Dyspnoea		3		1		2
Face oedema		1				1
Facial paresis		2				2
Fatigue		3		3		
Fibrin D dimer increased		1		1		
Gait disturbance		1		1		
Gait inability		1		1		
Gastric haemorrhage		1				1
Guillain-Barre syndrome		1				1
Headache		1		1		
Hypertension		1		1		
Hyponatraemia		2		2		
Malaise		1		1		
Muscular weakness		2		1		1
Myalgia		2		2		
Myelitis		1				1
Myocardial infarction		1				1
Nausea		1		1		
Oxygen saturation decreased		2				2
Pulmonary embolism		5				5
Pyrexia		1		1		
Rash erythematous		1		1		
Sialoadenitis		1				1
Sluggishness		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urinary retention		1				1
Vaccination failure		1				1
Vomiting		1		1		
		54		27		27

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Adverse event	1	1	1	1		
Arthralgia	1	10	1	10		
Asthenia	2	2	2	2		
Back pain		1		1		
Chills	1	8	1	8		
Contusion		1		1		
COVID-19	2	3			2	3
Dizziness		1		1		
Drug ineffective		1				1
Dysgeusia		1		1		
Facial paralysis		1				1
Fatigue	2	7	2	7		
Headache		5		5		
Hypoaesthesia		3		3		
Influenza		1		1		
Influenza like illness	1	3	1	3		
Insomnia		1		1		
Lymphadenopathy	1	1	1	1		
Malaise		6		6		
Migraine		1		1		
Myalgia	3	14	3	14		
Nasopharyngitis		1		1		
Nausea		1		1		
Pain		2		2		
Paraesthesia		1		1		
Pyrexia	2	6	2	6		
Rash		1		1		
Swollen tongue		1		1		
Vaccination failure	1	1			1	1
Vaccination site pain	2	9	2	9		
Vaccination site swelling		1		1		

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vomiting		1		1		
	19	98	16	92	3	6

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Country Where Event Occurred

CZECH REPUBLIC

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	2	1	2		
Abdominal pain lower	1	1	1	1		
Acute respiratory failure		1				1
Alopecia	1	1			1	1
Anaesthesia oral		1				1
Anaphylactic reaction		3				3
Angina pectoris		1				1
Angioedema		1				1
Anxiety		1		1		
Arthralgia	9	30	9	27		3
Asthenia	7	14	6	10	1	4
Autoimmune haemolytic anaemia	1	1			1	1
Axillary pain	1	1	1	1		
Back pain	3	6	3	6		
Bell's palsy		1				1
Blister		1				1
Blood pressure increased	1	1	1	1		
Blood pressure systolic increased		1		1		
Bradycardia		1				1
Burning sensation		1				1
Chest pain		1				1
Chills	16	37	15	32	1	5
Choking sensation		1				1
Circulatory collapse		1				1
Clumsiness	1	1	1	1		
Cough	1	2	1	1		1
COVID-19	1	3			1	3
C-reactive protein increased	1	1	1	1		
Decreased appetite	1	2	1	1		1
Dermatitis allergic		1				1
Diarrhoea	1	5	1	5		
Disorientation	1	1	1	1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbance in attention	2	2	1	1	1	1
Dizziness	1	7		4	1	3
Drug ineffective		2				2
Drug interaction	1	1	1	1		
Dry mouth		1				1
Dry skin		1				1
Dysphagia		1				1
Dyspnoea	5	12		2	5	10
Dysstasia		1				1
Ear discomfort	1	3		1	1	2
Eczema		1				1
Enterococcal infection		1				1
Erythema		3		2		1
Eyelid oedema	2	2			2	2
Eye movement disorder		1		1		
Eye pain		1		1		
Facial paresis	2	2			2	2
Fatigue	11	33	11	30		3
Feeling abnormal	1	1	1	1		
Feeling hot	1	5	1	4		1
Flushing	1	2		1	1	1
Formication	2	2	1	1	1	1
Gastric ulcer		1				1
Grunting		1				1
Headache	13	41	13	39		2
Heart rate increased	1	1	1	1		
Heavy menstrual bleeding	2	2	1	1	1	1
Hot flush	2	7	2	4		3
Hyperaesthesia		1		1		
Hyperhidrosis		1		1		
Hyperpyrexia	1	1			1	1
Hypersensitivity		8		3		5

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertension		2		1		1
Hyperventilation	1	1			1	1
Hypoacusis		1				1
Hypoaesthesia	1	1			1	1
Hypoaesthesia oral		1				1
Hypogeusia	1	1	1	1		
Hypotension		1		1		
Immunoglobulins increased		1		1		
Incorrect route of product administration	1	1	1	1		
Influenza		1		1		
Influenza like illness	5	11	4	9	1	2
Insomnia	1	2	1	1		1
Irritability		1		1		
Joint range of motion decreased		1		1		
Joint swelling		1		1		
Joint warmth		1		1		
Limb discomfort	1	1			1	1
Lip swelling		1				1
Loss of consciousness	1	3			1	3
Lymphadenopathy	5	11	4	8	1	3
Lymph node pain	1	2		1	1	1
Malaise	2	5	2	5		
Maternal exposure during pregnancy		1		1		
Menstrual disorder		1		1		
Mental impairment	1	1			1	1
Migraine		1		1		
Motor dysfunction	1	1	1	1		
Mucosal disorder		1				1
Multiple organ dysfunction syndrome		1				1
Muscle spasms		1				1
Muscle strain	1	1	1	1		
Muscle twitching	1	2	1	2		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscular weakness		1		1		
Musculoskeletal disorder		1		1		
Musculoskeletal stiffness		2		2		
Myalgia	10	30	10	27		3
Nasal congestion	1	2		1	1	1
Nausea	5	12	5	10		2
Neck pain	1	3	1	2		1
Neuropathy peripheral		1				1
Oedema peripheral	1	2			1	2
Oligomenorrhoea	1	1			1	1
Oropharyngeal pain	1	1	1	1		
Oxygen saturation decreased		1				1
Pain	1	4		1	1	3
Pain in extremity	7	11	6	10	1	1
Pallor		5		3		2
Palpitations	1	1	1	1		
Paraesthesia	6	9	5	6	1	3
Paraesthesia oral		1				1
Paresis		1				1
Peripheral coldness	1	2	1	2		
Peripheral nerve palsy		1				1
Peripheral swelling	1	2			1	2
Pharyngeal oedema		1				1
Pharyngeal swelling		1				1
Photopsia		1				1
Photosensitivity reaction		1		1		
Premature menarche	1	1	1	1		
Presyncope	1	2		1	1	1
Product administered at inappropriate site		1		1		
Pruritus		6		1		5
Pulmonary embolism		1				1
Pyrexia	17	52	15	39	2	13

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash	1	6		2	1	4
Rash macular		2				2
Rash pruritic	1	4			1	4
Rash pustular		1		1		
Reduced facial expression	1	1	1	1		
Respiratory depression		1				1
Respiratory disorder		1				1
Respiratory tract oedema	1	1			1	1
Rhinorrhoea	1	3	1	2		1
SARS-CoV-2 ant body test negative		1				1
Seizure		1				1
Shock		1				1
Skin burning sensation		2				2
Skin disorder		1				1
Somnolence		3		2		1
Swelling face		3				3
Syncope		3				3
Tachycardia		5		2		3
Tachypnoea		1				1
Tension headache		1		1		
Throat tightness	1	1			1	1
Tongue oedema		1				1
Toothache	1	1	1	1		
Tremor	2	2	2	2		
Urticaria		1				1
Vaccination failure	1	1			1	1
Vaccination site erythema	3	11	3	6		5
Vaccination site haematoma		1				1
Vaccination site induration		1		1		
Vaccination site oedema	2	6	1	2	1	4
Vaccination site pain	13	30	13	26		4
Vaccination site pruritus	1	4	1	4		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site rash		2		1		1
Vaccination site reaction		1		1		
Vaccination site swelling		5		1		4
Vaccination site urticaria		1				1
Vaccination site warmth		2				2
Vertigo		3		1		2
Vestibular neuronitis		1				1
Vision blurred	2	3	2	3		
Vomiting	2	6	2	6		
Wound	1	1	1	1		
	211	625	166	412	45	213

* I=Interval, C=Cumulative
* AE=Adverse Event
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		3		1		2
Abdominal pain		4		1		3
Abdominal pain lower	1	1	1	1		
Abdominal pain upper	2	4	2	3		1
Acute vestibular syndrome		1				1
Ageusia	1	5		2	1	3
Airway burns		2				2
Akinesia		1				1
Allergy to vaccine		4		1		3
Alopecia		2		1		1
Altered state of consciousness		1				1
Amenorrhoea	1	1			1	1
Anal incontinence		1		1		
Anaphylactic reaction		8				8
Angioedema		1				1
Anosmia	1	6		3	1	3
Antibody test abnormal		1		1		
Anxiety	2	5	1	2	1	3
Aphonia		1				1
Apnoea		1				1
Application site coldness		1				1
Application site erythema		1				1
Arrhythmia		2				2
Arthralgia	36	102	33	82	3	20
Arthritis	1	1			1	1
Asthenia	12	44	11	37	1	7
Asthma	1	2			1	2
Axillary mass		1		1		
Axillary pain	3	9	2	8	1	1
Back pain	4	14	4	12		2
Biliary colic	1	1	1	1		
Blepharospasm	1	1			1	1

* I=Interval, C=Cumulative
* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blindness		1				1
Blood pressure increased	1	7	1	3		4
Blood pressure systolic increased		2		1		1
Body temperature decreased		1		1		
Body temperature increased	5	8	5	7		1
Bone pain	1	2	1	2		
Borrelia infection		1				1
Bradycardia		1				1
Bradyphrenia	1	1	1	1		
Breast pain	1	4	1	2		2
Breast swelling		2		1		1
Bundle branch block right	1	1			1	1
Burning sensation	3	5	1	3	2	2
Burning sensation mucosal		2		2		
Bursitis	1	1			1	1
Cerebral venous sinus thrombosis		1				1
Chest discomfort	3	8	1	2	2	6
Chest pain	5	13		5	5	8
Chills	52	132	52	120		12
Circulatory collapse		4				4
Cognitive disorder	1	1			1	1
Cold sweat		1		1		
Condition aggravated	1	1			1	1
Conductive deafness		1				1
Confusional state	1	2	1	2		
Conjunctivitis allergic		1		1		
Cough	5	11	4	10	1	1
COVID-19	2	16	2	6		10
C-reactive protein increased		3		1		2
Cytomegalovirus test positive		1		1		
Deafness	1	1			1	1
Deafness neurosensory	1	1			1	1

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	1	6	1	5		1
Deep vein thrombosis	3	5			3	5
Defect conduction intraventricular	1	1			1	1
Depression		2				2
Dermatitis		1				1
Dermatitis allergic	3	8	1	2	2	6
Dermatitis atopic	1	1			1	1
Diarrhoea	5	22	4	18	1	4
Diplopia	1	2			1	2
Discomfort	1	2		1	1	1
Disease recurrence		3		1		2
Disorientation	1	1			1	1
Disturbance in attention	2	5	2	4		1
Dizziness	6	23	3	14	3	9
Drug hypersensitivity		2		1		1
Drug ineffective		3				3
Drug interaction		1				1
Dry mouth	1	3	1	2		1
Dysaesthesia	1	2			1	2
Dysgeusia	1	4	1	3		1
Dyskinesia		1				1
Dysmenorrhoea	1	1			1	1
Dyspepsia		5		2		3
Dysphagia	1	8	1	2		6
Dyspnoea	7	33	2	9	5	24
Dysuria	1	1	1	1		
Ear discomfort	2	5	1	2	1	3
Ear pain	2	3	2	3		
Eczema	2	2			2	2
Eczema herpeticum		1				1
Endolymphatic hydrops	1	1			1	1
Epistaxis	2	3	1	2	1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	1	15		8	1	7
Erythema nodosum		1				1
Extrasystoles		1		1		
Eye disorder		1		1		
Eye irritation	2	4	2	2		2
Eyelid oedema		1				1
Eye pain	4	8	3	6	1	2
Eye pruritus		1		1		
Eye swelling		1				1
Face oedema		1				1
Facial paralysis		2				2
Facial paresis		3				3
Fatigue	52	148	52	132		16
Febrile convulsion		1				1
Feeling abnormal	1	3		2	1	1
Feeling cold		3		3		
Feeling hot	2	9		2	2	7
Feeling of body temperature change	1	1	1	1		
Fibrin D dimer increased	1	1	1	1		
Flatulence	1	3	1	3		
Fluid intake reduced		1		1		
Flushing		2				2
Foetal death		1				1
Formication		1		1		
Frequent bowel movements		1		1		
Gastroenteritis		1		1		
Gastrointestinal hypermotility		1				1
Gastrooesophageal reflux disease		1				1
Gaze palsy		1				1
Generalised oedema		1		1		
General physical health deterioration	1	2			1	2
Grip strength decreased	1	1			1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Groin pain		1		1		
Guillain-Barre syndrome		1				1
Haematochezia		2				2
Haematoma		1				1
Haemoptysis		1				1
Haemorrhage		1				1
Hallucinations, mixed		1				1
Headache	53	151	49	128	4	23
Head discomfort		1				1
Heart rate decreased		1		1		
Heart rate increased	2	3	2	2		1
Heavy menstrual bleeding	1	1	1	1		
Herpes simplex		1				1
Herpes zoster	5	6			5	6
Hordeolum		1				1
Hot flush	2	8	1	6	1	2
Hyperacusis		1				1
Hyperaemia		1		1		
Hyperglycaemia		1				1
Hyperhidrosis	3	11	3	8		3
Hypersensitivity	4	20	2	5	2	15
Hypersomnia		2				2
Hypertension	2	14		5	2	9
Hyperventilation	2	3	2	3		
Hypoacusis		2		2		
Hypoaesthesia	1	8		5	1	3
Hypoaesthesia oral		1		1		
Hypokinesia		1		1		
Hypophagia		1		1		
Hypotension	1	10	1	4		6
Illusion		1		1		
Impaired work ability		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inappropriate schedule of product administration	1	3	1	3		
Incorrect route of product administration		1		1		
Inflammation		1		1		
Inflammatory marker increased	1	1	1	1		
Influenza like illness	19	61	19	51		10
Injection site erythema		1				1
Insomnia	4	9	4	8		1
Intermenstrual bleeding	3	3	2	2	1	1
Intestinal haemorrhage	1	1			1	1
Joint instability		1				1
Joint range of motion decreased	1	3	1	3		
Joint stiffness		1		1		
Joint swelling	3	4	2	3	1	1
Lacrimation increased	1	2	1	1		1
Laryngospasm		1				1
Leukocytosis	1	1	1	1		
Ligament sprain		1				1
Limb discomfort		3		1		2
Limb immobilisation		1		1		
Lip dry		1		1		
Lip swelling	1	3			1	3
Localised oedema		4				4
Loss of consciousness		5				5
Loss of personal independence in daily activities		1		1		
Lymphadenitis		3		1		2
Lymphadenopathy	18	62	14	35	4	27
Lymph node pain	7	18	5	13	2	5
Lymphoedema		1		1		
Malaise	4	17	4	16		1
Mass		2		1		1
Menstrual disorder	2	2	1	1	1	1
Menstruation delayed		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Menstruation irregular	8	8	5	5	3	3
Migraine	2	8	2	4		4
Mobility decreased		2		2		
Monoplegia		2				2
Mood swings	1	1			1	1
Movement disorder	2	2			2	2
Mucosal dryness		1				1
Multiple sclerosis		1				1
Multiple sclerosis relapse		1				1
Muscle spasms	4	5	3	3	1	2
Muscle spasticity		1		1		
Muscle twitching	1	2		1	1	1
Muscular weakness	2	8	2	6		2
Musculoskeletal chest pain		1		1		
Musculoskeletal pain		1		1		
Musculoskeletal stiffness	3	9	3	7		2
Myalgia	32	80	30	66	2	14
Mydriasis		1				1
Myelitis		1				1
Myocarditis		1				1
Myosclerosis		1				1
Nasal congestion	1	2		1	1	1
Nasal oedema		1		1		
Nausea	22	73	19	63	3	10
Neck pain		1		1		
Nervousness	2	2	1	1	1	1
Neuralgic amyotrophy	1	1			1	1
Night sweats	1	3	1	3		
Nodule		1				1
Nuchal rigidity	1	2		1	1	1
Nystagmus		1		1		
Oedema	1	2		1	1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oedema peripheral	1	4	1	2		2
Off label use	1	8	1	8		
Oral discomfort		1		1		
Oral herpes		1		1		
Oral mucosal blistering		1		1		
Oral pruritus	1	2	1	2		
Oropharyngeal discomfort		1				1
Oropharyngeal pain	1	8	1	6		2
Overdose	1	3	1	3		
Pain	4	13	3	11	1	2
Pain in extremity	32	74	30	65	2	9
Pain of skin		2		2		
Palatal swelling	1	3			1	3
Pallor		3		1		2
Palpitations	5	16	4	8	1	8
Panic attack	1	1			1	1
Panic reaction	1	1	1	1		
Paraesthesia	14	42	7	15	7	27
Paraesthesia mucosal		1				1
Paraesthesia oral	2	18		1	2	17
Paralysis		1				1
Paresis		1				1
Paresis cranial nerve		1				1
Parosmia		1				1
Peripheral coldness		5		4		1
Peripheral swelling	2	6	1	3	1	3
Petechiae		1				1
Pharyngeal oedema		1				1
Pharyngeal swelling		3				3
Photophobia		4		3		1
Photopsia		1		1		
Photosensitivity reaction	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pigmentation disorder	1	1	1	1		
Pneumobilia	1	1			1	1
Polymenorrhoea	1	1			1	1
Poor quality product administered		1		1		
Presyncope	3	11		1	3	10
Product administered at inappropriate site		2		2		
Productive cough		1		1		
Product preparation error		1		1		
Product use issue		5		5		
Pruritus	2	18		5	2	13
Pulmonary embolism	2	3			2	3
Pulmonary sensitisation		2		1		1
Puncture site erythema	1	1	1	1		
Puncture site oedema		1		1		
Pyrexia	66	168	61	121	5	47
Rash	7	34	3	12	4	22
Rash macular		5		1		4
Rash maculo-papular	2	3			2	3
Rash pruritic	1	3	1	2		1
Reduced facial expression	1	1			1	1
Renal pain		1		1		
Respiratory distress		1				1
Respiratory failure		1				1
Respiratory tract oedema		2				2
Restlessness		1		1		
Retching	2	8	2	5		3
Rhinalgia		1		1		
Rhinitis		2		2		
Rhinorrhoea	2	5	2	4		1
Salivary hypersecretion		1				1
SARS-CoV-2 ant body test negative		1				1
SARS-CoV-2 test positive		2		1		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Seizure	2	5			2	5
Sensation of foreign body		4				4
Shock		1				1
Sinus tachycardia	1	1	1	1		
Skin burning sensation	1	3	1	3		
Skin discolouration		1		1		
Skin disorder		1				1
Skin exfoliation		2		1		1
Skin reaction		1		1		
Somnolence	2	11	2	6		5
Sopor		1				1
Spinal disorder	1	1	1	1		
Spinal pain	2	4	2	2		2
Subarachnoid haemorrhage	1	1			1	1
Suicidal ideation	1	1			1	1
Supraventricular tachycardia		1				1
Swelling	1	5		3	1	2
Swelling face	1	10		1	1	9
Swelling of eyelid	2	2			2	2
Swollen tongue		4				4
Syncope	2	7			2	7
Tachycardia	2	15	1	9	1	6
Tachypnoea		2				2
Taste disorder		1				1
Tension headache		2		1		1
Throat irritation		4		2		2
Throat tightness	1	7	1	3		4
Thrombophlebitis superficial		1				1
Tinnitus	2	10		3	2	7
Tongue discomfort		2		1		1
Tongue oedema		1				1
Toothache		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tooth infection		1				1
Transverse sinus thrombosis		1				1
Tremor	1	8		6	1	2
Troponin I increased		1				1
Urinary incontinence		1				1
Urinary tract inflammation		1				1
Urticaria	4	11		1	4	10
Urticarial dermatitis	1	1	1	1		
Vaccination complication		2		1		1
Vaccination failure		5				5
Vaccination site atrophy		1		1		
Vaccination site bruising		1				1
Vaccination site discomfort		2		1		1
Vaccination site erythema	8	51	7	31	1	20
Vaccination site haematoma	2	3	2	3		
Vaccination site hypersensitivity	1	1	1	1		
Vaccination site induration	2	7	2	4		3
Vaccination site joint movement impairment		2		1		1
Vaccination site joint pain	1	1	1	1		
Vaccination site joint swelling	1	1			1	1
Vaccination site mass	1	3	1	1		2
Vaccination site movement impairment	3	9	2	6	1	3
Vaccination site oedema	6	29	6	17		12
Vaccination site pain	46	124	44	99	2	25
Vaccination site papule		1				1
Vaccination site paraesthesia	1	2		1	1	1
Vaccination site pruritus	1	10	1	6		4
Vaccination site rash	3	6	2	3	1	3
Vaccination site reaction		2		2		
Vaccination site swelling	5	25	5	17		8
Vaccination site urticaria		1		1		
Vaccination site warmth	3	11	3	8		3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular pain	1	1	1	1		
Vertigo	7	29	4	19	3	10
Vertigo positional	1	1			1	1
Viral infection		1		1		
Vision blurred	5	13	2	6	3	7
Visual field defect		2				2
Visual impairment		1				1
Vomiting	5	29	5	21		8
	785	2,589	611	1677	174	912

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal pain	1	7	1	4		3
Abdominal pain upper	1	3	1	2		1
Abscess of salivary gland		1				1
Acne	1	1			1	1
Acute kidney injury	1	1			1	1
Acute myocardial infarction		1				1
Allergy to vaccine		1				1
Anaphylactic reaction		4				4
Angina pectoris		2				2
Anosmia		1				1
Anuria		1				1
Anxiety		3		2		1
Apathy	1	3	1	2		1
Aphasia		1				1
Aphthous ulcer		2				2
Arthralgia	31	66	30	51	1	15
Asthenia	5	24	5	14		10
Asymptomatic COVID-19	1	1			1	1
Atrial flutter		1				1
Attention deficit hyperactivity disorder		1		1		
Axillary pain	1	4	1	2		2
Back pain	2	3	2	3		
Bell's palsy		1				1
Blood pressure decreased		1				1
Blood pressure increased	1	3		2	1	1
Blood pressure systolic increased	1	1			1	1
Body temperature fluctuation	1	1	1	1		
Body temperature increased	1	4	1	2		2
Bone pain	1	3	1	2		1
Breast pain	1	1	1	1		
Bronchospasm		2		1		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burning sensation		1				1
Cerebrovascular accident		1				1
Chest discomfort	1	9	1	4		5
Chest pain	1	3		1	1	2
Chills	30	66	29	61	1	5
Circulatory collapse		2				2
Cold sweat	1	1	1	1		
Concussion	1	1	1	1		
Contusion	1	1	1	1		
Coordination abnormal		1				1
Cough	2	14	2	12		2
Cough decreased	1	1	1	1		
COVID-19	7	17		2	7	15
COVID-19 pneumonia		3				3
C-reactive protein increased	1	1	1	1		
Deafness neurosensory		1				1
Deafness unilateral		1				1
Decreased appetite	1	5	1	4		1
Deep vein thrombosis	2	2			2	2
Dehydration	1	1	1	1		
Depression		1		1		
Dermatitis		1		1		
Dermatitis allergic		2				2
Diarrhoea	5	15	5	10		5
Disease recurrence		1				1
Disturbance in attention		3				3
Diverticulitis		1				1
Dizziness	3	8	2	7	1	1
Drug eruption		2				2
Drug ineffective	5	10			5	10
Dry eye		1				1
Dry mouth	1	3		2	1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry skin		1				1
Dysgeusia		1				1
Dyspepsia		1				1
Dysphagia		1				1
Dysphonia		1		1		
Dyspnoea	3	19		4	3	15
Ear discomfort		2		1		1
Ear pain	1	3	1	3		
Ear swelling		1				1
Embolism	1	1			1	1
Epistaxis	1	4	1	2		2
Erythema		8		3		5
Eye haemorrhage	1	2			1	2
Eye inflammation		1		1		
Eye irritation		2				2
Eyelid function disorder		1				1
Eyelid oedema	1	3			1	3
Eye pain	2	4	2	3		1
Eye pruritus		1		1		
Eye swelling		1				1
Facial pain		1				1
Facial paralysis	1	3			1	3
Facial paresis		2				2
Fatigue	44	95	43	81	1	14
Fear		1		1		
Fear of death		1		1		
Feeling abnormal		2		1		1
Feeling hot	2	4	1	3	1	1
Feeling of body temperature change	1	1	1	1		
Flatulence		1				1
Flushing		1		1		
Food intolerance		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Functional gastrointestinal disorder		1		1		
Gait disturbance		1				1
Gastrointestinal necrosis	1	1			1	1
Gingival bleeding	1	1	1	1		
Gingival pain		1		1		
Grunting		1		1		
Haematuria	1	1	1	1		
Headache	36	77	35	68	1	9
Head discomfort	1	1	1	1		
Heart rate increased		1		1		
Herpes dermatitis		1				1
Herpes zoster	2	5			2	5
Hot flush		4		2		2
Hypercoagulation	1	1			1	1
Hyperglycaemia		2		1		1
Hyperhidrosis	2	10	2	9		1
Hypersensitivity	4	12		3	4	9
Hypertension	5	11		1	5	10
Hypoaesthesia	1	2			1	2
Hypoaesthesia oral		1				1
Hypokalaemia		2				2
Hypotension	3	7	1	2	2	5
Hypoxia		1				1
Ileus	1	1			1	1
Immune system disorder		1				1
Inappropriate schedule of product administration		2		2		
Incorrect route of product administration		2		2		
Infection		1		1		
Influenza	2	2	2	2		
Influenza like illness	14	35	12	25	2	10
Injected limb mobility decreased		2		2		
Insomnia	1	7	1	6		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ischaemic stroke	1	2			1	2
Joint range of motion decreased		1				1
Joint stiffness		1				1
Joint swelling		2		2		
Lagophthalmos		1		1		
Laryngeal oedema		1				1
Leukocytosis		1		1		
Leukopenia		1				1
Ligament pain		1		1		
Lip oedema		1				1
Lip swelling		1				1
Livedo reticularis		1		1		
Localised oedema	1	1	1	1		
Loss of consciousness	2	7			2	7
Loss of personal independence in daily activities	1	1			1	1
Lymphadenitis		1				1
Lymphadenopathy	6	29	5	13	1	16
Lymph node pain		2		2		
Malaise	7	13	7	11		2
Migraine	1	4	1	3		1
Migraine with aura		1		1		
Movement disorder	1	1			1	1
Muscle atrophy		1				1
Muscle spasms		2		1		1
Muscular weakness	1	5	1	4		1
Musculoskeletal chest pain		1		1		
Musculoskeletal disorder	1	1	1	1		
Musculoskeletal stiffness	2	3	2	3		
Myalgia	19	54	19	42		12
Myocardial infarction	1	2			1	2
Nasal congestion		2		2		
Nasal discomfort		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nasal dryness		1		1		
Nausea	17	36	15	28	2	8
Neck pain	3	7	3	6		1
Necrosis ischaemic	1	1			1	1
Nervousness		1				1
Neutropenia		1				1
Nodule	1	1	1	1		
Ocular discomfort	1	3	1	1		2
Ocular hyperaemia		1		1		
Oedema		1		1		
Oedema mouth		1				1
Oedema peripheral		3		1		2
Off label use		1		1		
Oral discomfort		2				2
Oral herpes		1				1
Oropharyngeal discomfort		1		1		
Oropharyngeal pain	1	3	1	3		
Overdose	1	2	1	2		
Pain	7	9	7	9		
Pain in extremity	32	53	32	43		10
Palpitations		5		2		3
Paraesthesia	10	28	2	10	8	18
Paraesthesia oral	2	8			2	8
Paralysis		1				1
Paraparesis		1				1
Parosmia		1		1		
Peripheral coldness		3		3		
Peripheral swelling	1	5	1	2		3
Pharyngeal swelling	1	3			1	3
Photophobia		1		1		
Pneumonia		1				1
Presyncope	2	5			2	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product preparation error		1		1		
Pruritus	3	10	2	5	1	5
Pulmonary embolism	1	1			1	1
Pulmonary pain		1				1
Pulpitis dental		1				1
Pulse abnormal		1		1		
Purpura		1				1
Pyrexia	48	108	42	74	6	34
Radiculitis brachial		1				1
Rash	3	11	1	4	2	7
Rash erythematous		1				1
Rash macular	2	3	1	1	1	2
Rash maculo-papular		1				1
Rash pruritic	2	4			2	4
Red blood cell sedimentation rate increased		1		1		
Renal transplant failure		1				1
Respiratory depression		1				1
Respiratory failure	1	1			1	1
Respiratory tract oedema	1	1			1	1
Retching		2		1		1
Rhinalgia		1		1		
Rhinitis		2		2		
Rhinorrhoea		5		5		
SARS-CoV-2 test positive		1		1		
Sciatica	1	1			1	1
Seizure		2				2
Sensation of foreign body		2		1		1
Shock		1				1
Sinus pain		1		1		
Sinus tachycardia		1				1
Skin burning sensation	1	2			1	2
Skin mass		1		1		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sleep deficit		1				1
Sleep disorder		1				1
Sneezing		2		2		
Somnolence	3	7	3	6		1
Spinal disorder		1				1
Spinal pain	1	4	1	2		2
Sputum purulent		1				1
Swelling	1	1	1	1		
Swelling face	2	4	1	1	1	3
Swollen tongue		2				2
Syncope	3	7			3	7
Tachycardia		13		5		8
Tachypnoea		3		1		2
Tendon pain		1				1
Tetany	1	1			1	1
Thirst		2		2		
Throat tightness	2	5			2	5
Thrombosis	1	1			1	1
Tinnitus		3		1		2
Tongue erythema	1	1	1	1		
Tongue oedema	1	3			1	3
Toothache		2		1		1
Tracheal pain	1	1	1	1		
Tremor	1	5		1	1	4
Urinary incontinence		1				1
Urinary tract infection		1				1
Urticaria	1	3		1	1	2
Vaccination complication		1		1		
Vaccination failure	1	3			1	3
Vaccination site atrophy		1				1
Vaccination site bruising		1		1		
Vaccination site discomfort	1	2	1	2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site erythema	10	31	8	17	2	14
Vaccination site extravasation		1		1		
Vaccination site haematoma		1				1
Vaccination site hyperaesthesia	2	2	2	2		
Vaccination site induration		1				1
Vaccination site joint pain		2		2		
Vaccination site lymphadenopathy		1		1		
Vaccination site oedema	3	10	3	7		3
Vaccination site pain	57	88	56	79	1	9
Vaccination site paraesthesia		1		1		
Vaccination site pruritus	1	2	1	2		
Vaccination site reaction		3		1		2
Vaccination site swelling	8	10	7	9	1	1
Vaccination site urticaria		1				1
Vaccination site warmth		2		2		
Vascular pain		1				1
Ventricular tachycardia		1				1
Vertigo	3	11	2	6	1	5
Vision blurred	1	6			1	6
Vomiting	6	18	6	12		6
Wheezing		1				1
	548	1,487	437	923	111	564

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1			1	1
Abdominal pain		2		2		
Abdominal pain lower		1		1		
Abdominal pain upper	1	2	1	2		
Acne		1		1		
Ageusia		1		1		
Akathisia		1		1		
Allergic oedema		1				1
Allergy to vaccine		1				1
Altered state of consciousness		3				3
Amnesia	1	1			1	1
Anaphylactic reaction		2				2
Anosmia		2		2		
Apathy	1	2		1	1	1
Aphthous ulcer		1				1
Application site erythema		1		1		
Arrhythmia	1	2			1	2
Arthralgia	33	46	29	39	4	7
Asthenia	8	17	7	14	1	3
Asthma	1	2		1	1	1
Asymptomatic COVID-19	1	1	1	1		
Atrial fibrillation	1	3			1	3
Auditory disorder	1	1			1	1
Axillary pain	3	3	2	2	1	1
Back pain	5	12	3	9	2	3
Bacterial rhinitis		1				1
Bacterial test positive		1		1		
Balance disorder	4	4	2	2	2	2
Bladder pain	1	1			1	1
Blister		1				1
Blood glucose fluctuation	1	1	1	1		
Blood glucose increased		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased	3	3	2	2	1	1
Blood pressure fluctuation	1	2		1	1	1
Blood pressure increased	2	4	2	2		2
Blood pressure systolic increased		1				1
Blood urea increased		1		1		
Blood urine	1	1			1	1
Blood urine present		1		1		
Body temperature increased	1	3	1	3		
Bradycardia	1	1			1	1
Bradyphrenia		1		1		
Brain oedema		1				1
Breast pain	1	1			1	1
Breast swelling	1	1			1	1
Bronchitis		1				1
Bundle branch block right		1				1
Burning sensation	1	2	1	2		
Cardiac arrest		2				2
Cardiac failure	1	2			1	2
Cardiac failure acute	1	1			1	1
Cardiomegaly	1	1	1	1		
Cardio-respiratory arrest		1				1
Cerebrovascular accident		6				6
Chest pain	3	4	1	1	2	3
Chills	29	46	28	44	1	2
Circumoral swelling	1	1			1	1
Coma		1				1
Communication disorder	1	2			1	2
Confusional state	2	4		1	2	3
Constipation		1		1		
Cough	8	13	6	10	2	3
COVID-19	18	24	7	8	11	16
COVID-19 pneumonia	1	2			1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cranial nerve palsies multiple		1				1
C-reactive protein increased	1	1			1	1
Deafness unilateral		1				1
Death	1	1			1	1
Decreased appetite	3	12	2	9	1	3
Deep vein thrombosis	5	5			5	5
Dehydration		1		1		
Diarrhoea	2	7	1	4	1	3
Diplopia	1	1	1	1		
Disease progression	1	1			1	1
Disease recurrence		2				2
Disorientation	1	1			1	1
Dizziness	12	14	10	12	2	2
Dizziness postural		1				1
Drug eruption	1	1			1	1
Drug hypersensitivity		1				1
Drug ineffective	5	6			5	6
Dry mouth	2	3	2	2		1
Dry throat		1		1		
Dysarthria		1				1
Dyspepsia		3		3		
Dysphagia	1	1	1	1		
Dyspnoea	9	20	4	6	5	14
Dyspnoea exertional	1	2		1	1	1
Dysstasia	1	1	1	1		
Dysuria	1	1	1	1		
Ear discomfort		2		2		
Ear pain	1	1	1	1		
Epilepsy		1				1
Epistaxis	1	2		1	1	1
Erythema	2	8	2	6		2
Extensive swelling of vaccinated limb	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye haemorrhage		2				2
Eye irritation	1	1	1	1		
Eyelid oedema	1	1			1	1
Eye pain	1	2	1	2		
Eye swelling		1		1		
Face oedema		1				1
Facial asymmetry		1				1
Facial pain	1	1			1	1
Facial paralysis		1				1
Fall	1	3			1	3
Fatigue	67	93	66	85	1	8
Feeling abnormal	2	3		1	2	2
Feeling hot		1		1		
Flatulence		1		1		
Formication	1	2	1	2		
Gait disturbance	3	5			3	5
Gait inability	1	2		1	1	1
Gastrointestinal pain		1		1		
Generalised onset non-motor seizure	1	1			1	1
Genital pain	1	1			1	1
Gingival bleeding	1	1			1	1
Glaucoma		1				1
Groin pain	1	1			1	1
Haematoma	1	2			1	2
Haemorrhage	1	1			1	1
Hangover	1	1	1	1		
Headache	32	46	31	45	1	1
Heart rate irregular		1		1		
Hemiparesis		1				1
Hepatic infarction	1	1			1	1
Herpes virus infection		1		1		
Herpes zoster	4	6			4	6

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* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes zoster reactivation	1	1			1	1
Hot flush		1				1
Hyperaesthesia	1	1	1	1		
Hyperglycaemia	1	3			1	3
Hyperhidrosis	4	7	4	7		
Hyperlipidaemia		1		1		
Hypersensitivity	3	11	2	4	1	7
Hypersomnia		1				1
Hypertension	4	13		1	4	12
Hypertensive crisis	1	1			1	1
Hypoacusis	2	2			2	2
Hypoaesthesia	1	3	1	1		2
Hypoglycaemia		1				1
Hypokalaemia		1				1
Hypokinesia		1		1		
Hypomagnesaemia		1		1		
Hypotension	2	6			2	6
Inappropriate schedule of product administration		1		1		
Increased bronchial secretion	1	1	1	1		
Induration		1		1		
Inflammation	1	1			1	1
Inflammatory marker increased	1	1			1	1
Influenza	1	1	1	1		
Influenza like illness	22	35	20	29	2	6
Insomnia	2	4	1	2	1	2
Intermenstrual bleeding	1	1			1	1
Intermittent claudication	1	1	1	1		
Ischaemic stroke	1	3			1	3
Joint effusion		1				1
Joint range of motion decreased	2	2	1	1	1	1
Joint stiffness	1	1			1	1
Joint swelling	1	1	1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Laboratory test abnormal		1		1		
Lacrimation increased		1		1		
Lethargy		1		1		
Leukocytosis		1		1		
Ligament sprain	1	1			1	1
Limb discomfort	1	1			1	1
Lip swelling	2	5		1	2	4
Loss of consciousness	4	5			4	5
Lymphadenitis	1	2			1	2
Lymphadenopathy	4	6	2	4	2	2
Lymph node pain	1	1	1	1		
Malaise	6	10	6	8		2
Memory impairment	2	2			2	2
Mental fatigue	1	1	1	1		
Micturition disorder	1	1	1	1		
Micturition urgency	1	1			1	1
Middle insomnia	1	1	1	1		
Migraine		1				1
Mineral metabolism disorder	1	1			1	1
Mobility decreased	3	5		2	3	3
Monoparesis		1				1
Movement disorder	1	2			1	2
Mucosal haemorrhage	1	1			1	1
Muscle tightness		1		1		
Muscle twitching		1				1
Muscular weakness	3	4	1	1	2	3
Musculoskeletal chest pain	1	1			1	1
Musculoskeletal stiffness	1	4	1	2		2
Myalgia	26	32	24	29	2	3
Myoclonic epilepsy	1	1			1	1
Myositis		1				1
Narcolepsy		2				2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nasal congestion	1	1			1	1
Nasopharyngitis	1	1	1	1		
Nausea	15	28	13	24	2	4
Neuralgia	1	2			1	2
Neuropathy peripheral		3				3
Oedema		1		1		
Oedema peripheral	2	3			2	3
Off label use		2		2		
Oral discomfort		1		1		
Oral herpes	1	1			1	1
Oropharyngeal pain	2	2	2	2		
Overdose		1		1		
Oxygen saturation decreased		2				2
Pain	6	10	5	8	1	2
Pain in extremity	28	40	21	32	7	8
Palpitations	2	3	1	1	1	2
Paraesthesia	7	15		1	7	14
Paraesthesia oral	2	6			2	6
Peripheral swelling	2	5	1	3	1	2
Petechiae		1				1
Pharyngeal paraesthesia		1				1
Pneumonia	1	3			1	3
Polyarthrits		1				1
Poor quality product administered		65		65		
Poor quality sleep	1	1	1	1		
Productive cough	1	2	1	1		1
Product preparation error		65		65		
Product use issue		1		1		
Pruritus	3	10		3	3	7
Pulmonary embolism	1	2			1	2
Pulmonary hypoperfusion	1	1			1	1
Pulmonary oedema		1				1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia	45	71	34	54	11	17
Rash	4	10	3	6	1	4
Rash macular		2				2
Rash papular	1	1			1	1
Rash pruritic	4	6	3	4	1	2
Renal colic	1	1			1	1
Renal failure		1				1
Renal impairment		1				1
Renal infarct	1	1			1	1
Renal mass	1	1			1	1
Renal pain	1	2		1	1	1
Respiration abnormal		1				1
Respiratory failure		1				1
Restlessness	1	2	1	1		1
Retching	1	1	1	1		
Retinal artery thrombosis	1	1			1	1
Rheumatoid arthritis	1	2			1	2
Rhinitis	2	4	2	3		1
Rhinorrhoea		2		2		
Salivary gland pain	1	1	1	1		
Scab		2		2		
Scratch	1	1			1	1
Seizure		1				1
Sinus bradycardia		1		1		
Sleep disorder	1	1	1	1		
Somnolence	3	9	3	6		3
Speech disorder	1	1			1	1
Sputum discoloured		1				1
Stridor		1		1		
Sudden death		2				2
Swelling		1		1		
Swelling face	1	5		1	1	4

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* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling of eyelid		1				1
Syncope	1	7			1	7
Tachycardia	1	4		1	1	3
Throat irritation		1				1
Throat tightness		1				1
Thrombocytopenia	2	2			2	2
Thrombosis	4	4			4	4
Tinnitus	1	1			1	1
Tongue discomfort		1				1
Tongue oedema		2				2
Toothache	2	3	1	2	1	1
Tremor		1				1
Underdose	1	1	1	1		
Urinary straining	1	1			1	1
Urinary tract infection		1				1
Urinary tract inflammation		1		1		
Urosepsis	1	1			1	1
Urticaria	2	2			2	2
Vaccination failure	1	3			1	3
Vaccination site cellulitis		1				1
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	7	9	4	5	3	4
Vaccination site hypersensitivity	2	3	1	1	1	2
Vaccination site induration	2	4	2	3		1
Vaccination site joint movement impairment		1				1
Vaccination site mass		1				1
Vaccination site oedema	2	4	2	4		
Vaccination site pain	52	64	52	63		1
Vaccination site pruritus	2	5	1	3	1	2
Vaccination site pustule		1		1		
Vaccination site swelling	4	7	4	7		
Vaccination site warmth	1	2	1	2		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Venous thrombosis	1	1			1	1
Venous thrombosis limb		1				1
Vertigo	4	8	3	6	1	2
Vision blurred	3	6	1	1	2	5
Visual impairment	2	2			2	2
Vomiting	3	10	2	7	1	3
Wheezing		1		1		
White blood cell count decreased	1	1	1	1		
Yellow skin		1				1
	691	1,348	466	880	225	468

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		3		1		2
Abdominal pain lower		1				1
Abdominal pain upper	1	3	1	3		
Abnormal dreams		2		2		
Acquired haemophilia	1	1			1	1
Acute kidney injury		1				1
Acute myocardial infarction		1				1
Acute respiratory failure		1				1
Altered state of consciousness		1				1
Amnesia		1				1
Anaemia		3		1		2
Anaphylactic reaction		1				1
Anaphylactoid reaction		1				1
Aneurysm		1				1
Angina pectoris		1				1
Anxiety	1	4	1	4		
Aortic arteriosclerosis		1				1
Aortic stenosis		1				1
Apathy	2	5	1	1	1	4
Aphasia		3		1		2
Aphthous ulcer		1				1
Arrhythmia	1	3			1	3
Arteriosclerosis		2				2
Arthralgia	14	30	12	23	2	7
Arthritis	1	1			1	1
Asthenia	5	18	3	11	2	7
Atrial f brillation		3				3
Back pain	3	4	3	4		
Bacterial sepsis	1	1			1	1
Balance disorder		1				1
Basal ganglia haemorrhage		1				1

* I=Interval, C=Cumulative
* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blindness		1				1
Blood chloride increased		1		1		
Blood glucose increased		1		1		
Blood lactic acid increased		1		1		
Blood pressure abnormal		1				1
Blood pressure decreased		1				1
Blood pressure diastolic increased		1		1		
Blood pressure fluctuation	1	2	1	1		1
Blood pressure increased	3	7	1	3	2	4
Blood urine present		1		1		
Bone pain	1	1			1	1
Bradycardia		2				2
Bradyphrenia		1				1
Brain oedema		2				2
Breast pain		1		1		
Bronchitis chronic		1		1		
Cardiac arrest		1				1
Cardiac disorder		1				1
Cardiac failure		3				3
Cardiac failure congestive		1				1
Cardiac hypertrophy		1				1
Cardiomyopathy		1				1
Cardio-respiratory arrest		1				1
Carpal tunnel syndrome		1				1
Cerebral atrophy		1				1
Cerebral haemorrhage		1				1
Cerebral ischaemia		1				1
Cerebral thrombosis		1				1
Cerebrovascular accident		7				7
Chest discomfort		4		2		2
Chest pain		3		2		1
Chills	9	25	9	22		3

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circulatory collapse		2				2
Clostridium difficile colitis	1	1			1	1
Coagulopathy		1				1
Cognitive disorder		1				1
Coma	1	1			1	1
Concussion		1				1
Condition aggravated	1	2		1	1	1
Confusional state	2	7	1	1	1	6
Conjunctivitis	1	1	1	1		
Constipation		2		1		1
Contusion		3				3
Coordination abnormal	1	1			1	1
Cor pulmonale		1				1
Cough	2	9	2	5		4
COVID-19	3	11		1	3	10
COVID-19 pneumonia	1	4			1	4
C-reactive protein increased	1	3	1	2		1
Cyanosis		1				1
Cystitis noninfective		1		1		
Deafness		1				1
Deafness neurosensory		1				1
Death		3				3
Decreased activity		2		2		
Decreased appetite		14		10		4
Deep vein thrombosis	2	2			2	2
Dehydration		1				1
Delirium		3				3
Dementia		1				1
Dermatitis allergic		1				1
Diarrhoea	2	9	1	5	1	4
Disorganised speech		1				1
Disorientation	1	8	1	3		5

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	5	12	4	10	1	2
Drug eruption		2				2
Drug ineffective	1	5			1	5
Duodenal ulcer		1				1
Dysarthria		2		1		1
Dysphagia	1	1			1	1
Dysphemia		1				1
Dysphonia	1	1	1	1		
Dyspnoea	2	13		2	2	11
Dyspnoea at rest		1				1
Dyspnoea exertional		1				1
Dysuria		1				1
Ear discomfort		1				1
Ear infection	1	1			1	1
Ear pain	1	1			1	1
Ear pruritus		1				1
Eating disorder		2		1		1
Electrocardiogram abnormal		2		1		1
Epilepsy		1				1
Epistaxis		2				2
Erysipelas		2				2
Erythema		3		2		1
Escherichia infection		1				1
Eye irritation	1	1			1	1
Eyelid oedema		1				1
Eye pruritus		1				1
Eye swelling		1		1		
Facial paralysis		2				2
Fall	1	9		3	1	6
Fatigue	28	51	27	44	1	7
Feeling abnormal		1		1		
Feeling cold	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling hot		2		1		1
Femur fracture	1	1			1	1
Flank pain		1		1		
Flushing	1	1			1	1
Formication		1				1
Gait disturbance		6		2		4
Gait inability		3		1		2
Gallbladder disorder		1		1		
Gastric ulcer		1				1
Gastrointestinal disorder		2		2		
Gastrointestinal necrosis		1				1
General physical health deterioration	2	10	1	4	1	6
Glomerular filtration rate decreased		1		1		
Gout		1		1		
Haemarthrosis	1	1			1	1
Haematoma	2	4		1	2	3
Haemoglobin decreased	1	1	1	1		
Haemorrhage intracranial		1				1
Hallucination	1	2			1	2
Headache	13	23	13	22		1
Head discomfort		1		1		
Heart rate increased	1	4			1	4
Heart rate irregular		1		1		
Hemiparesis		1				1
Hemiplegia		2				2
Hepatic function abnormal		1				1
Hepatic infarction		1				1
Hepatitis		1				1
Herpes simplex		1				1
Herpes zoster	1	8			1	8
Humerus fracture		1				1
Hyperhidrosis		5		4		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperphagia		1		1		
Hyperpyrexia		1				1
Hypersensitivity	1	6	1	3		3
Hypersomnia	1	2	1	1		1
Hypertension		7		1		6
Hypoacusis		1				1
Hypoaesthesia	1	3			1	3
Hypoglycaemia		1		1		
Hypokalaemia		3				3
Hypokinesia		1		1		
Hypophagia	1	1			1	1
Hypotension	1	6			1	6
Hypotonia		1		1		
Hypotonic-hyporesponsive episode		1				1
Hypoxia		1				1
Immune thrombocytopenia	1	1			1	1
Inappropriate schedule of product administration		1		1		
Incontinence	1	1	1	1		
Incorrect route of product administration		1		1		
Induration	1	1			1	1
Inflammation		1				1
Influenza like illness	7	18	3	10	4	8
Insomnia	3	7	3	5		2
International normalised ratio increased		2		1		1
Intestinal infarction		1				1
Intraocular pressure increased	1	1	1	1		
Irritability	1	1	1	1		
Ischaemic stroke	1	1			1	1
Jaundice		1		1		
Joint swelling	1	3		1	1	2
Jugular vein distension		1		1		
Klebsiella infection	1	2			1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lacrimation increased	1	2	1	2		
Language disorder		1				1
Leukopenia		1				1
Localised oedema		1				1
Logorrhoea		1		1		
Loss of consciousness		2				2
Lymphadenopathy	2	5	2	3		2
Lymph node pain		1				1
Malaise	2	5	2	4		1
Mean cell haemoglobin concentration increased	1	1	1	1		
Mean cell haemoglobin decreased	1	1	1	1		
Melaena		1				1
Memory impairment	2	3			2	3
Mental disorder		1		1		
Mental impairment	1	1			1	1
Mesenteric arterial occlusion		1				1
Mesenteric vascular insufficiency		1				1
Mobility decreased	2	2	1	1	1	1
Monoparesis	1	2	1	1		1
Monoplegia	1	1			1	1
Multiple organ dysfunction syndrome		1				1
Muscle spasms	1	2	1	2		
Muscle twitching		1				1
Muscular weakness	1	4		2	1	2
Musculoskeletal disorder	1	1	1	1		
Myalgia	11	15	9	13	2	2
Myocardial infarction		2				2
Nasal congestion	1	1			1	1
Nasopharyngitis	2	3	2	3		
Nausea	4	16	4	13		3
Nephrosclerosis		1				1
Nervousness		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neutrophil count increased	1	1	1	1		
Night sweats		2		1		1
Nystagmus		1		1		
Oedema peripheral	3	7	2	5	1	2
Oropharyngeal pain	1	3	1	3		
Oxygen saturation decreased		3		2		1
Pain	3	10	2	6	1	4
Pain in extremity	16	27	10	19	6	8
Pallor		1		1		
Palpitations		3				3
Pancreatic infarction		1				1
Paraesthesia	6	8	3	4	3	4
Patient uncooperative		1		1		
Pemphigoid	1	1			1	1
Peripheral coldness	1	2			1	2
Peripheral swelling	2	4	1	2	1	2
Peripheral venous disease		1				1
Petechiae		1				1
Platelet count decreased	1	1			1	1
Pneumoconiosis		1				1
Pneumonia		3				3
Pneumonitis		1				1
Polyarthrits		2				2
Poor peripheral circulation	1	1			1	1
Posture abnormal		1		1		
Procalcitonin increased	1	1	1	1		
Productive cough		2				2
Prolonged expiration		1		1		
Prostate cancer		1				1
Pruritus	1	7	1	3		4
Psychomotor hyperactivity		1				1
Pulmonary embolism	2	3			2	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary pain		1		1		
Pyrexia	18	56	14	37	4	19
Quadripareisis		1				1
Radiculopathy		1				1
Rash	2	7		1	2	6
Rash erythematous		2				2
Rash macular		1				1
Rash maculo-papular		2				2
Rash pruritic		4		1		3
Rash vesicular		1		1		
Renal cyst		1				1
Renal disorder		1		1		
Renal failure		2				2
Renal impairment		1				1
Respiratory acidosis		1		1		
Respiratory failure		3				3
Respiratory tract oedema		1				1
Restlessness	1	4	1	4		
Rheumatoid arthritis		1				1
Rhinitis		2		2		
Rhinorrhoea	4	4	4	4		
Right ventricular dilatation		1				1
SARS-CoV-2 test positive		1				1
Sensory loss	1	1			1	1
Sepsis		2				2
Sitting disability		1				1
Skin burning sensation		1		1		
Skin discolouration	1	1			1	1
Skin laceration		1				1
Skin warm	1	1			1	1
Sleep disorder		1		1		
Sleep talking		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Somnolence	2	6	2	6		
Speech disorder		4		2		2
Spinal pain	2	2	1	1	1	1
Splenic infarction		1				1
Splenic infection		1				1
Starvation	1	1			1	1
Stridor		1		1		
Sudden death		1				1
Supraventricular extrasystoles		1		1		
Swelling	1	2			1	2
Swelling face		6				6
Swelling of eyelid		1				1
Syncope		4				4
Tachycardia	2	3		1	2	2
Tachypnoea		2				2
Tenderness		2		1		1
Tension headache		1				1
Thirst		1		1		
Thrombocytopenia		1				1
Thrombophlebitis	1	1			1	1
Thrombosis		1				1
Tinnitus		2				2
Tongue oedema		2				2
Transient ischaemic attack		2				2
Tremor	1	5		1	1	4
Truncus coeliacus thrombosis		1				1
Urinary tract disorder	1	1	1	1		
Urinary tract infection		2		1		1
Urinary tract infection enterococcal		1				1
Urinary tract inflammation		1				1
Urogenital infection bacterial		1				1
Urosepsis		1				1

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* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria		1				1
Vaccination failure	1	3			1	3
Vaccination site anaesthesia		1				1
Vaccination site bruising	1	1	1	1		
Vaccination site discomfort	1	2	1	2		
Vaccination site erythema	3	7	3	4		3
Vaccination site mass		1		1		
Vaccination site movement impairment	1	1			1	1
Vaccination site oedema	3	5	3	5		
Vaccination site pain	20	28	20	27		1
Vaccination site pruritus	3	5	3	5		
Vaccination site swelling	2	5	2	3		2
Vaccination site urticaria		1				1
Vena cava thrombosis		1				1
Ventricular tachycardia		1				1
Vertigo		4		3		1
Vision blurred	1	1			1	1
Visual acuity reduced	1	1			1	1
Visual impairment		2		1		1
Vomiting		13		10		3
Weight decreased		1		1		
Wheezing		1		1		
White blood cell count decreased	1	1			1	1
White blood cell count increased	1	1	1	1		
White coat hypertension		1		1		
	306	1,022	203	508	103	514

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal dreams	1	1	1	1		
Abortion spontaneous		1				1
Alanine aminotransferase increased	1	1	1	1		
Amnesia		1				1
Angina pectoris	3	3			3	3
Anosmia		1		1		
Apathy		1				1
Aphasia		1		1		
Arthralgia	5	16	5	15		1
Aspartate aminotransferase increased	1	1	1	1		
Asthenia	4	11	4	11		
Axillary pain		1		1		
Back pain	2	3	1	2	1	1
Balance disorder	1	1	1	1		
Blood pressure increased		1		1		
Bradycardia		1				1
Burning sensation		1		1		
Chest discomfort	1	3	1	3		
Chest pain	2	3	1	2	1	1
Chills	3	16	3	15		1
Choking	1	1			1	1
Circulatory collapse		1				1
Cold sweat		1		1		
Condition aggravated		1				1
Confusional state		1		1		
Cough		3		3		
COVID-19	2	9		3	2	6
Decreased appetite		1		1		
Decreased interest		1		1		
Diarrhoea	1	1	1	1		
Diplopia		2		2		
Drug ineffective	1	2			1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea	2	5	1	2	1	3
Exposure via breast milk		1		1		
Eye pain		2		2		
Facial pain		1		1		
Fatigue	4	16	4	15		1
Feeling abnormal		1		1		
Feeling hot		1		1		
Hallucination		1				1
Headache	5	15	5	15		
Herpes ophthalmic	1	1			1	1
Herpes zoster	1	1			1	1
Hot flush		1		1		
Hypersensitivity		1		1		
Hypokinesia	1	1	1	1		
Inappropriate schedule of product administration		1		1		
Influenza like illness	3	3	3	3		
Insomnia		1		1		
Intermenstrual bleeding		1		1		
Local reaction		1		1		
Loss of consciousness	1	1			1	1
Loss of personal independence in daily activities		1		1		
Lymphadenopathy	2	3	1	1	1	2
Malaise	2	2	2	2		
Migraine		1		1		
Mucosal dryness		1		1		
Myalgia	1	3	1	2		1
Nasal congestion		1		1		
Nausea	2	2	2	2		
Oedema peripheral		1		1		
Oesophageal irritation		1		1		
Orbital oedema		1				1
Oropharyngeal discomfort		1		1		

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oropharyngeal pain	1	1	1	1		
Pain		3		3		
Pain in extremity		5		5		
Pain in jaw		1		1		
Pain of skin		1				1
Palpitations	1	2		1	1	1
Paraesthesia	2	3	1	2	1	1
Paraesthesia oral		1		1		
Paralysis		1				1
Peripheral ischaemia	1	1			1	1
Peripheral swelling		1		1		
Petechiae		1				1
Pleurisy	1	1			1	1
Poor quality product administered		17		17		
Poor quality sleep	1	1	1	1		
Presyncope	1	1			1	1
Product preparation error		16		16		
Product preparation issue		1		1		
Pruritus		1		1		
Pyrexia	5	21	4	18	1	3
Rhinorrhoea		2		2		
Sleep disorder		1		1		
Somnolence		2		2		
Spinal pain	2	3	2	3		
Swelling		1		1		
Swelling face		1		1		
Syncope	1	1			1	1
Toothache		1		1		
Tremor	1	1	1	1		
Vaccination complication		1		1		
Vaccination failure		2				2
Vaccination site discolouration		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site erythema	2	3	1	2	1	1
Vaccination site induration	2	4	1	3	1	1
Vaccination site lymphadenopathy	1	1	1	1		
Vaccination site oedema	2	3	2	3		
Vaccination site pain	2	11	2	11		
Vaccination site swelling		1		1		
Vertigo	2	5	1	4	1	1
Viral infection		1				1
	82	292	58	240	24	52

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

DENMARK

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma		1				1
Dyspnoea		1				1
Erythema		1		1		
Oxygen saturation decreased		1				1
Peripheral swelling		1		1		
Vaccination site pain		1		1		
		6		3		3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Abdominal pain upper		3		1		2
Abnormal dreams	1	1			1	1
Abortion spontaneous	1	1			1	1
Anaphylactic shock	2	2			2	2
Angioedema		1				1
Anxiety	1	2		1	1	1
Arthralgia		10		7		3
Arthritis reactive		1				1
Asthenia		1				1
Asthma	1	1			1	1
Axillary pain		1		1		
Blood lactic acid increased	1	1	1	1		
Blood pressure increased		3		2		1
Blood prolactin increased	1	1	1	1		
Breath sounds abnormal		1				1
Bursitis		1				1
Cerebrovascular accident		1				1
Chest discomfort		3		2		1
Chest pain	1	3		1	1	2
Chills	3	14	1	8	2	6
Circulatory collapse	1	1			1	1
Cold sweat	1	2	1	2		
Cough		5		4		1
COVID-19		1				1
C-reactive protein increased		1				1
Decreased appetite	1	1	1	1		
Deep vein thrombosis		1				1
Derealisation		1		1		
Diarrhoea		4		2		2
Diplopia		2				2
Discomfort		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disease recurrence	1	2		1	1	1
Dizziness	3	26	1	12	2	14
Drug ineffective		1				1
Dyspepsia		1		1		
Dysphagia		1				1
Dysphonia		1		1		
Dyspnoea	2	9	1	3	1	6
Dyspnoea exertional		1		1		
Eating disorder		1		1		
Eczema		1		1		
Epilepsy	1	1			1	1
Erythema		1		1		
Eye pain		2		2		
Face oedema		1				1
Fall		1				1
Fatigue	5	26	4	20	1	6
Feeling cold	1	4		1	1	3
Feeling hot	1	2	1	2		
Feeling of body temperature change		2				2
Flushing		1				1
Gastroesophageal reflux disease		1		1		
Generalised tonic-clonic seizure	1	2			1	2
General physical health deterioration		2				2
Hallucination, visual	1	1			1	1
Headache	11	66	9	49	2	17
Heart rate increased		1		1		
Hot flush		1		1		
Hyperacusis		1				1
Hyperaesthesia	1	1			1	1
Hyperchlorhydria		1		1		
Hyperhidrosis	1	1	1	1		
Hypersensitivity	1	5	1	1		4

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypersomnia		1		1		
Hypertension	1	2		1	1	1
Hyperventilation		2				2
Hypoacusis		2		2		
Hypoaesthesia		1				1
Hypokalaemia	1	2			1	2
Hypokinesia	1	1	1	1		
Hypotonia		1		1		
Idiopathic intracranial hypertension		1				1
Inappropriate schedule of product administration		1		1		
Incorrect route of product administration		1				1
Infection	1	1			1	1
Influenza		2		1		1
Influenza like illness		3		3		
Joint swelling		1				1
Lethargy		1		1		
Limb discomfort		2		1		1
Loss of consciousness	1	3			1	3
Lymphadenitis		1				1
Lymphadenopathy	2	9	2	7		2
Lymphangitis		1				1
Malaise	4	21	1	10	3	11
Maternal exposure during pregnancy	2	2	2	2		
Migraine		1		1		
Muscle spasms	2	2	1	1	1	1
Muscle tightness		1				1
Muscular weakness		3		2		1
Myalgia	5	29	3	22	2	7
Myelitis transverse	1	1			1	1
Nasal congestion		1		1		
Nausea	6	28	3	16	3	12
Neck pain	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neurological symptom	1	1			1	1
Obstructive airways disorder		1				1
Odynophagia		2		2		
Off label use		1		1		
Oral mucosal blistering		1		1		
Oropharyngeal pain		8		8		
Pain	2	4	2	2		2
Pain in extremity	3	10	3	8		2
Pain of skin	1	2	1	1		1
Palpable purpura	1	1			1	1
Palpitations	1	5	1	3		2
Panic attack		1				1
Paraesthesia	1	3	1	2		1
Paraesthesia oral	1	2	1	1		1
Pericarditis		1				1
Periorbital swelling	1	1			1	1
Peripheral coldness	1	1			1	1
Peripheral swelling	1	1	1	1		
Petechiae	2	2			2	2
Pharyngeal swelling	1	2		1	1	1
Photophobia		1				1
Photopsia		1				1
Platelet count decreased	2	2	1	1	1	1
Pneumonia	1	1			1	1
Presyncope	2	5			2	5
Product use issue		1		1		
Pruritus		2		1		1
Pulmonary embolism	1	1			1	1
Pyrexia	9	46	6	33	3	13
Rash	1	5		3	1	2
Rash erythematous		2				2
Rash pruritic		2				2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal colic		1		1		
Respiratory distress	1	1			1	1
Respiratory failure	1	1			1	1
Restlessness	1	1	1	1		
Rhinalgia		1		1		
Rhinorrhoea		2		1		1
Seizure		2				2
Sensitive skin	1	1	1	1		
Sensory disturbance	1	3	1	3		
Sleep disorder	1	1	1	1		
Somnolence		1		1		
Stomatitis		1		1		
Stridor		1				1
Swelling		1		1		
Swelling face		2				2
Syncope	2	4			2	4
Tachycardia	1	2	1	1		1
Temporomandibular joint syndrome		1				1
Tenderness	1	5	1	4		1
Throat irritation	2	2			2	2
Throat tightness		1		1		
Thrombosis		1				1
Tinnitus		1		1		
Tongue discomfort	1	1			1	1
Tongue pruritus	1	1			1	1
Tremor	1	4	1	3		1
Tunnel vision		1				1
Urticaria	2	6	1	2	1	4
Vaccination site abscess		1				1
Vaccination site discolouration	1	2	1	1		1
Vaccination site erythema	2	12	2	11		1
Vaccination site haematoma	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site induration		1		1		
Vaccination site nodule		1		1		
Vaccination site pain	5	41	5	37		4
Vaccination site pruritus		3		3		
Vaccination site rash		1				1
Vaccination site reaction		1		1		
Vaccination site swelling	3	18	3	16		2
Vaccination site thrombosis		1				1
Vaccination site warmth	1	5	1	5		
Vaginal discharge		1		1		
Vaginal haemorrhage		1		1		
Vision blurred		3				3
Visual impairment		1				1
Vlth nerve paralysis		1				1
Vomiting	2	9		7	2	2
Vulvovaginal pain		1		1		
Vulvovaginal pruritus		1		1		
White blood cell count increased	1	1	1	1		
Yawning		1		1		
	139	647	75	396	64	251

* I=Interval, C=Cumulative
* AE=Adverse Event
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2		2		
Abdominal distension		1		1		
Abdominal lymphadenopathy	1	1	1	1		
Abdominal pain	2	10	1	7	1	3
Abdominal pain lower	1	1	1	1		
Abdominal pain upper		2		1		1
Abortion missed	1	3			1	3
Acute myocardial infarction		1				1
Acute respiratory distress syndrome		1				1
Ageusia		1		1		
Allergy to vaccine		1				1
Anaphylactic reaction		11				11
Anaphylactic shock		3				3
Angioedema	1	2			1	2
Anosmia		1		1		
Aphasia	1	1			1	1
Appendicitis		1				1
Arthralgia	16	33	12	22	4	11
Arthritis reactive	1	1			1	1
Asthenia	1	7	1	3		4
Asthma		3		1		2
Atrial fibrillation		3				3
Axillary pain	1	2	1	2		
Back pain	1	2	1	2		
Bell's palsy	1	1			1	1
Blindness	1	1			1	1
Blood bilirubin decreased		1		1		
Blood glucose increased		1		1		
Blood potassium decreased		1		1		
Blood pressure abnormal		1				1
Blood pressure decreased	3	5	1	1	2	4
Blood pressure fluctuation		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased		5		1		4
Body temperature increased		1		1		
Burning sensation		4		3		1
Cardiovascular disorder		1				1
Cerebral vascular occlusion	1	1			1	1
Cerebral venous sinus thrombosis	1	1			1	1
Cerebrovascular accident	1	3			1	3
Chest discomfort	1	10		4	1	6
Chest pain	2	5		1	2	4
Chills	5	30	2	23	3	7
Choking sensation		1				1
Chorioretinitis		1				1
Cold sweat		5		3		2
Colitis		1		1		
Condition aggravated	1	2	1	1		1
Conjunctival hyperaemia		1		1		
Coordination abnormal		2				2
Coronary artery thrombosis		1				1
Cough	2	15	2	8		7
C-reactive protein increased	1	5		1	1	4
Death		1				1
Decreased appetite		1		1		
Deep vein thrombosis	1	2			1	2
Depressed level of consciousness		1				1
Derealisation		2		2		
Dermatitis allergic		1				1
Diarrhoea	5	21	2	14	3	7
Diplopia	1	1			1	1
Discomfort	1	8		2	1	6
Disease recurrence		1		1		
Disorientation		1				1
Disturbance in attention		2		1		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	18	79	10	49	8	30
Dizziness exertional		1		1		
Dizziness postural		1				1
Dry eye		1		1		
Dry mouth		2		1		1
Dry skin		1		1		
Dry throat		1		1		
Dysaesthesia		1		1		
Dysgeusia		2		1		1
Dysphagia		4		2		2
Dysphonia		2		1		1
Dyspnoea	6	26	1	9	5	17
Dyspnoea at rest		1				1
Dyspnoea exertional		2		1		1
Electrocardiogram ST segment depression		1				1
Epistaxis		1				1
Erythema	2	16	2	10		6
Exfoliative rash	1	1	1	1		
Extravasation	1	1			1	1
Eyelid oedema		1		1		
Eye pain		3		3		
Eye pruritus		4		4		
Eye swelling		1		1		
Facial pain		1		1		
Facial paralysis	1	2			1	2
Fatigue	17	95	12	70	5	25
Feeling abnormal		2		2		
Feeling cold	1	6	1	5		1
Feeling drunk		1		1		
Feeling hot		15		9		6
Feeling of body temperature change	1	1	1	1		
Flushing		5		1		4

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastroesophageal reflux disease		1		1		
Generalised tonic-clonic seizure		1				1
General physical health deterioration		1				1
Groin pain		1		1		
Haematology test abnormal		1				1
Haemoconcentration	1	1	1	1		
Hand dermatitis		1		1		
Headache	35	159	27	124	8	35
Head discomfort	1	2	1	1		1
Heart rate decreased		2		2		
Heart rate increased		8		5		3
Heavy menstrual bleeding	1	1	1	1		
Hemiplegia	1	1			1	1
Hepatic cyst		1		1		
Hepatic vein thrombosis	1	1			1	1
Herpes simplex meningoencephalitis	1	1			1	1
Hot flush	1	2		1	1	1
Hyperhidrosis		6		2		4
Hypersensitivity	2	17	1	6	1	11
Hypertension		7		3		4
Hyperthyroidism	1	1			1	1
Hyperventilation		3				3
Hypoacusis		2				2
Hypoaesthesia	1	5		3	1	2
Hypoglycaemia		1		1		
Hypokalaemia		1				1
Hypokinesia	1	1	1	1		
Hypotension		1				1
Incorrect route of product administration	1	1	1	1		
Infection	2	2			2	2
Influenza	1	3	1	2		1
Influenza like illness	3	14	3	9		5

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Initial insomnia		1		1		
Injected limb mobility decreased		1		1		
Injection site pain		1		1		
Insomnia		5		5		
Intracardiac thrombus		1				1
Joint swelling	1	1			1	1
Lacrimation increased		1		1		
Lethargy		1		1		
Leukopenia	1	2			1	2
Limb discomfort		4		2		2
Lip pruritus		1				1
Lip swelling	1	4	1	1		3
Loss of consciousness	1	2			1	2
Lymphadenitis		1		1		
Lymphadenopathy	1	15	1	11		4
Lymph node pain	1	5	1	5		
Lymphopenia		1				1
Malaise	9	56	8	38	1	18
Maternal exposure during pregnancy	1	2			1	2
Meniere's disease		1				1
Menstruation delayed	1	1	1	1		
Migraine	2	6	1	2	1	4
Mobility decreased		1		1		
Monoplegia		1				1
Motor dysfunction		1				1
Mouth swelling		1				1
Muscle discomfort		1		1		
Muscle fatigue		2		2		
Muscle spasms	2	4		1	2	3
Muscle tightness	1	1	1	1		
Muscle twitching		1				1
Muscular weakness		4		1		3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal discomfort		1				1
Musculoskeletal stiffness		1				1
Myalgia	17	69	14	54	3	15
Mydriasis		1		1		
Myelitis		1				1
Myocarditis		1				1
Nasal congestion		3		3		
Nasal discomfort		1				1
Nasal obstruction		1		1		
Nasal pruritus		2		1		1
Nasopharyngitis	2	4	2	4		
Nausea	14	75	13	57	1	18
Neck pain	1	5		4	1	1
Neuralgia		1		1		
Night sweats		1		1		
Obliterative bronchiolitis		1				1
Odynophagia		1				1
Oedema mucosal		1				1
Off label use		3		3		
Oral discomfort		1				1
Oral fungal infection		1		1		
Oropharyngeal discomfort		3		2		1
Oropharyngeal pain	1	7	1	5		2
Pain	4	15	4	11		4
Painful respiration		1				1
Pain in extremity	4	21	1	18	3	3
Pain of skin		2		2		
Pallor		8		2		6
Palpitations	3	18	2	10	1	8
Paraesthesia	3	24	2	14	1	10
Paraesthesia oral	1	9	1	6		3
Pericarditis		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Periorbital swelling		1				1
Peripheral swelling	1	4		1	1	3
Pharyngeal paraesthesia	1	1	1	1		
Pharyngeal swelling		5		1		4
Photophobia		1				1
Photopsia		2		1		1
Pityriasis rosea	1	1	1	1		
Pleurisy	1	1			1	1
Pleuritic pain		1		1		
Pneumonia	1	3			1	3
Polymenorrhoea	1	1	1	1		
Postmenopausal haemorrhage		1				1
Presyncope		13		5		8
Productive cough		1		1		
Product use issue		3		3		
Pruritus	5	29	5	20		9
Pulmonary embolism	1	3			1	3
Pulse abnormal		1				1
Pyrexia	30	116	26	89	4	27
Rash	5	23	5	15		8
Rash erythematous	2	14	2	10		4
Rash pruritic	2	7	2	6		1
Renal pain		1				1
Respiratory failure		3				3
Respiratory tract infection bacterial		1				1
Restlessness	1	4	1	4		
Rhinitis		1		1		
Rhinorrhoea	1	2	1	2		
Seasonal allergy		1		1		
Seizure		2				2
Sensation of foreign body		2				2
Sensory disturbance	4	7	3	6	1	1

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensory loss		1				1
Sinus tachycardia		2		2		
Sleep disorder		1		1		
Sneezing		3		3		
Subarachnoid haemorrhage	1	1			1	1
Swelling	2	5	2	5		
Swelling face	1	8	1	3		5
Swelling of eyelid		1		1		
Swollen tongue		6		1		5
Syncope	3	9			3	9
Tachycardia	1	5			1	5
Tachypnoea		1				1
Taste disorder		2		1		1
Tenderness	2	4	2	4		
Throat irritation		8		4		4
Throat tightness		2				2
Thrombocytopenia	2	2			2	2
Thrombosis		2				2
Tinnitus		2				2
Tongue pruritus		2				2
Tonic convulsion		1				1
Tonsillar hypertrophy		1		1		
Transient ischaemic attack		1				1
Transplant failure		1				1
Tremor	1	9	1	4		5
Upper respiratory tract infection		1		1		
Urinary incontinence		1				1
Urticaria	6	20	4	13	2	7
Vaccination complication		2		1		1
Vaccination site discomfort		1		1		
Vaccination site erythema	3	17	3	16		1
Vaccination site haematoma	1	3		2	1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site haemorrhage	1	2	1	2		
Vaccination site induration		1		1		
Vaccination site inflammation		3		3		
Vaccination site lymphadenopathy		1		1		
Vaccination site movement impairment	1	2	1	2		
Vaccination site pain	22	120	20	111	2	9
Vaccination site paraesthesia		3		3		
Vaccination site pruritus		5		4		1
Vaccination site rash	3	7	3	5		2
Vaccination site swelling	3	26	3	23		3
Vaccination site warmth		10		9		1
Vaginal haemorrhage		1				1
Vascular rupture	1	1	1	1		
Vasodilatation		1				1
Visual impairment		1		1		
Vomiting	7	19	3	11	4	8
Wheezing		1				1
Wound complication		1		1		
	347	1,774	238	1156	109	618

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1			1	1
Abdominal pain	1	3	1	3		
Abdominal pain upper	2	3	1	2	1	1
Abdominal wall abscess		1				1
Acute coronary syndrome	1	1			1	1
Acute myocardial infarction		1				1
Adrenal insufficiency		1				1
Adrenocortical insufficiency acute	1	1			1	1
Ageusia	1	1	1	1		
Alanine aminotransferase increased		1		1		
Altered state of consciousness		1				1
Amnesia		2				2
Anaphylactic reaction		4				4
Anaphylactic shock		3				3
Angioedema		2				2
Anosmia	1	1	1	1		
Anxiety		3				3
Arthralgia	8	28	8	21		7
Arthritis		1		1		
Asthenia		4		1		3
Asthma		1				1
Atrial fibrillation		2				2
Auricular swelling		1		1		
Autoimmune neuropathy	1	1			1	1
Autonomic nervous system imbalance	1	1			1	1
Axillary pain		2		2		
Back pain		6		5		1
Blood iron decreased		1		1		
Blood lactate dehydrogenase abnormal		1		1		
Blood pressure systolic increased		2				2
Blood test abnormal	1	1	1	1		
Body temperature increased		5		4		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bradycardia		1				1
Breast pain		1		1		
Bronchitis		1				1
Burning sensation		2		1		1
Cardiac arrest		1				1
Cardiogenic shock		1				1
Cardiovascular symptom	1	1			1	1
Cerebral thrombosis		1				1
Cerebrovascular accident	1	1			1	1
Chest discomfort	2	10	1	2	1	8
Chest pain	2	6	1	2	1	4
Chills	5	26	5	19		7
Chronic obstructive pulmonary disease		1				1
Clonic convulsion		1				1
Condition aggravated		2				2
Confusional state	1	1			1	1
Coronary artery thrombosis		1				1
Cough	1	4		2	1	2
COVID-19		3		1		2
C-reactive protein increased		5		1		4
Crying		1				1
Cystitis		1		1		
Decreased appetite	2	3	1	2	1	1
Deep vein thrombosis	1	4			1	4
Depressed mood	1	1	1	1		
Derealisation		2		1		1
Dermatitis allergic		1				1
Diarrhoea	2	10	2	8		2
Discomfort	1	3		2	1	1
Disease progression	1	1			1	1
Disturbance in attention		2		1		1
Dizziness	7	46	5	21	2	25

* I=Interval, C=Cumulative

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness postural		1				1
Dry mouth		3		3		
Dysaesthesia	1	2			1	2
Dysarthria		1				1
Dysgeusia		2		1		1
Dysphagia		2				2
Dysphonia		2		1		1
Dyspnoea	4	30	1	7	3	23
Dyspnoea exertional		4		2		2
Dysuria		1				1
Ear discomfort	1	2	1	2		
Ear pruritus		1				1
Electrocardiogram QT prolonged		1				1
Epistaxis		1		1		
Erysipelas	1	2			1	2
Erythema	2	15	1	8	1	7
Eye irritation		1		1		
Eyelid ptosis		1				1
Eye pain		2		2		
Eye pruritus		1				1
Facial paresis		1				1
Faeces soft		1		1		
Fall		1				1
Fatigue	18	65	14	49	4	16
Feeling abnormal		1				1
Feeling cold	1	4	1	4		
Feeling hot	1	8		1	1	7
Feeling of body temperature change		1				1
Fibrin D dimer increased		2		1		1
Flatulence	1	2		1	1	1
Flushing		3		3		
Functional gastrointestinal disorder	1	1			1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gait disturbance		1				1
Gastrointestinal sounds abnormal	1	1			1	1
Generalised tonic-clonic seizure		1				1
General symptom	1	1	1	1		
Glossodynia		1		1		
Groin pain		1		1		
Haematoma		1		1		
Haemolysis		1				1
Haemorrhage		1				1
Headache	24	109	22	84	2	25
Head discomfort	1	4	1	4		
Head injury		1				1
Heart rate abnormal		1		1		
Heart rate increased	2	5	1	4	1	1
Herpes zoster	1	1	1	1		
Hot flush		1		1		
Hyperacusis	1	2		1	1	1
Hyperhidrosis	1	3	1	2		1
Hypersensitivity		3				3
Hypersomnia		2				2
Hypertension		6		3		3
Hyperventilation	1	2			1	2
Hypoaesthesia	1	2			1	2
Hypoaesthesia oral		2				2
Hypophagia		1		1		
Hypotension		3				3
Idiopathic pulmonary fibrosis		1				1
IIIrd nerve paresis		1				1
Immune-mediated hepatitis		1				1
Immune thrombocytopenia		1				1
Impaired work ability	1	1	1	1		
Inappropriate schedule of product administration		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Infection		2		2		
Influenza		3		1		2
Influenza like illness	2	7	2	6		1
Inner ear disorder	1	1	1	1		
Insomnia	1	1			1	1
Ischaemic stroke	1	1			1	1
Joint range of motion decreased	1	1	1	1		
Joint stiffness		1				1
Joint swelling	1	5	1	3		2
Joint warmth		1		1		
Lacrimation increased		1		1		
Lethargy	1	1	1	1		
Limb discomfort		2		1		1
Lip swelling		2				2
Loss of consciousness		3				3
Lymphadenopathy		4		2		2
Malaise	3	40	1	21	2	19
Memory impairment		1				1
Migraine	2	4	1	3	1	1
Mobility decreased	1	2	1	2		
Monoplegia		1				1
Movement disorder	1	1	1	1		
Multimorbidity		1				1
Muscle fatigue		1		1		
Muscle spasms		2		2		
Muscle twitching		1		1		
Muscular weakness		4		2		2
Musculoskeletal chest pain	1	1	1	1		
Myalgia	13	46	10	34	3	12
Nasal congestion		1		1		
Nasal pruritus		1				1
Nasopharyngitis		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	11	54	8	38	3	16
Neck pain	1	3	1	3		
Nervous system disorder		1				1
Neuralgia		1				1
Neuropathy peripheral	1	1			1	1
Neutrophil count increased		1		1		
Obstructive airways disorder		1				1
Ocular hyperaemia		1		1		
Oedema peripheral		2		1		1
Oesophageal spasm		1		1		
Off label use		3		3		
Oral discomfort		1		1		
Oral mucosal eruption		1		1		
Oral pruritus		1		1		
Oropharyngeal pain	1	6	1	5		1
Oxygen saturation decreased		5		1		4
Pain	1	10	1	10		
Painful respiration		1		1		
Pain in extremity	8	25	7	21	1	4
Pain of skin		1				1
Pallor		1				1
Palpitations	1	7		5	1	2
Paraesthesia	2	14	1	8	1	6
Paraesthesia mucosal		1				1
Paraesthesia oral	1	6	1	3		3
Periarthritis		2		2		
Periorbital swelling		2		1		1
Peripheral coldness	1	3	1	1		2
Peripheral swelling	1	5	1	4		1
Pharyngeal oedema		1				1
Pharyngeal paraesthesia		1		1		
Pharyngeal swelling		5				5

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngitis		1				1
Photophobia		3		1		2
Photosensitivity reaction		1		1		
Pleural effusion		1				1
Pneumonia	1	2			1	2
Poor quality sleep		1		1		
Presyncope		8		3		5
Productive cough		2				2
Product use issue		3		3		
Pruritus	2	11	1	8	1	3
Pulmonary embolism	2	7			2	7
Pulmonary pain		1		1		
Pyrexia	12	74	9	52	3	22
Rash		9		6		3
Rash erythematous		4		3		1
Rash macular		1		1		
Rash morbilliform		1		1		
Rash papular	1	2		1	1	1
Rash pruritic		2		1		1
Rash vesicular		1		1		
Respiration abnormal		1				1
Respiratory alkalosis	1	1			1	1
Respiratory arrest		1				1
Respiratory failure		1				1
Restless arm syndrome	1	1			1	1
Restless legs syndrome	1	1			1	1
Restlessness		3		2		1
Rheumatoid factor increased		1				1
Rhinorrhoea		2		2		
Salivary gland enlargement		1		1		
Salivary gland pain		1		1		
Salivary hypersecretion		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Seizure	1	1			1	1
Sensory disturbance	1	4	1	3		1
Sepsis		1				1
Skin burning sensation		1				1
Sleep disorder		1		1		
Sneezing		3		3		
Somnolence		2		1		1
Speech disorder		1				1
Sputum discoloured		1				1
Sudden cardiac death		1				1
Sudden death		1				1
Swelling	1	3		2	1	1
Swelling face		5		3		2
Swelling of eyelid		1				1
Swollen tongue		4		1		3
Syncope		5				5
Tachycardia		2		1		1
Taste disorder		1		1		
Tenderness	1	4	1	2		2
Throat irritation		2		1		1
Throat tightness		2		1		1
Thrombocytopenia		2				2
Thrombosis		2				2
Tinnitus	1	3	1	3		
Tongue discomfort		1		1		
Toxicity to various agents		1				1
Tracheal stenosis		1				1
Tremor		3		1		2
Tunnel vision		1				1
Type I hypersensitivity		1				1
Urticaria	2	10	1	7	1	3
Vaccination site discomfort		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site erythema	7	13	7	13		
Vaccination site hypoaesthesia		1		1		
Vaccination site inflammation		1		1		
Vaccination site irritation	1	3	1	2		1
Vaccination site movement impairment		1		1		
Vaccination site pain	13	62	13	58		4
Vaccination site paraesthesia	1	1	1	1		
Vaccination site pruritus	1	2	1	2		
Vaccination site rash		1		1		
Vaccination site swelling	6	12	6	12		
Vaccination site warmth	2	4	2	4		
Vasculitis	1	1			1	1
Vertigo		2		1		1
Viral infection		1		1		
Visual impairment	1	1			1	1
Vomiting	2	11	1	6	1	5
White blood cell count increased		2		2		
Wound infection		1				1
	234	1,214	164	741	70	473

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	5	2	2		3
Abdominal pain lower		1				1
Abdominal pain upper		1				1
Abdominal tenderness		1				1
Acute coronary syndrome	1	1			1	1
Acute kidney injury		1				1
Acute myocardial infarction	2	3			2	3
Allergy to vaccine	2	2			2	2
Altered state of consciousness		2				2
Anaphylactic reaction		2				2
Angina pectoris		1				1
Angioedema		1				1
Anti-glomerular basement membrane disease		1				1
Anxiety		1		1		
Aphasia	1	1			1	1
Appendicitis		1				1
Arthralgia	8	13	2	5	6	8
Asthenia	2	3	1	1	1	2
Azotaemia		1				1
Back pain	1	2		1	1	1
Balance disorder	1	3			1	3
Bell's palsy	1	1			1	1
Beta haemolytic streptococcal infection	1	1			1	1
Blindness	1	1			1	1
Blood albumin decreased		1		1		
Blood chloride increased		1		1		
Blood creatinine increased		1				1
Blood glucose increased		1		1		
Blood lactic acid increased		1		1		
Blood pressure decreased		1		1		
Blood pressure increased	1	1			1	1
Blood urea decreased		1				1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bradycardia	1	3			1	3
Brain injury	1	1			1	1
Bronchospasm		2				2
Burning sensation	4	4			4	4
Calcium ionised increased		1		1		
Cardiac arrest	5	8			5	8
Cardiac failure		1				1
Cardiogenic shock		1				1
Cardiovascular disorder		1				1
Cerebral haemorrhage	1	2			1	2
Cerebral infarction	3	4			3	4
Cerebrovascular accident	8	14			8	14
Chest discomfort	1	2			1	2
Chest pain	5	8			5	8
Chills	3	6	2	3	1	3
Chronic obstructive pulmonary disease	1	6			1	6
Circulatory collapse	1	1			1	1
Cold sweat	3	3	1	1	2	2
Colitis		1				1
Condition aggravated		2				2
Confusional state	1	4			1	4
Conjunctival oedema	1	1			1	1
Coordination abnormal	2	3			2	3
Cough	3	5		1	3	4
COVID-19		4		2		2
C-reactive protein abnormal		1				1
C-reactive protein increased	1	2	1	1		1
Death		3				3
Decreased appetite		2				2
Deep vein thrombosis	4	7			4	7
Dehydration	2	3			2	3
Delirium		3				3

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Depressed level of consciousness	2	4			2	4
Depressed mood	1	1	1	1		
Diarrhoea	7	10	1	1	6	9
Diplopia	1	2			1	2
Discomfort	2	3	2	2		1
Disseminated intravascular coagulation		1				1
Disturbance in attention	1	1	1	1		
Dizziness	10	14	2	3	8	11
Dizziness postural	1	1			1	1
Drug ineffective		1				1
Dysarthria	1	3			1	3
Dysphagia		1				1
Dysphonia	1	3		2	1	1
Dyspnoea	14	29		1	14	28
Eczema	1	1	1	1		
Embolic stroke	1	1			1	1
Encephalitis	1	1			1	1
Endocarditis bacterial	1	1			1	1
Endophthalmitis	1	1			1	1
Epilepsy	1	3			1	3
Epistaxis		1				1
Erythema	2	4		1	2	3
Extensive swelling of vaccinated limb	1	1			1	1
Eyelid ptosis		1				1
Eye pain	1	1			1	1
Eye swelling	1	1			1	1
Face oedema		1				1
Facial paresis	2	3	1	2	1	1
Fall	4	6	1	1	3	5
Fatigue	14	31	5	14	9	17
Feeling abnormal	1	1			1	1
Feeling cold		3		1		2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling hot	3	4	2	2	1	2
Femoral neck fracture	1	1			1	1
Fluid intake reduced	1	2			1	2
Foaming at mouth		2		1		1
Gait disturbance	1	3		1	1	2
Gait inability	1	1			1	1
Gastric ulcer		1				1
Gastrointestinal necrosis		1				1
Gastroesophageal reflux disease		1				1
Generalised tonic-clonic seizure		1				1
General physical health deterioration		4				4
Glomerular filtration rate decreased		1				1
Guillain-Barre syndrome		1				1
Haemoglobin decreased	1	2	1	1		1
Haemoptysis	2	2			2	2
Haemorrhage intracranial	1	2			1	2
Headache	14	30	5	12	9	18
Head injury	1	1	1	1		
Heart rate decreased	1	1	1	1		
Heart rate increased		2				2
Heart rate irregular		1				1
Hemiparesis	1	5			1	5
Herpes zoster	3	5	3	4		1
Hyperhidrosis		3		2		1
Hypermetabolism	1	1	1	1		
Hypersensitivity	3	4	1	2	2	2
Hypersomnia	1	2			1	2
Hypertension		1				1
Hypoaesthesia	1	2			1	2
Hyponatraemia	1	1			1	1
Hypophagia	1	1			1	1
Hypotension	1	5		1	1	4

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Illness		1		1		
Inappropriate schedule of product administration		1		1		
Infarction		1				1
Influenza		3		3		
Influenza like illness	3	7	1	3	2	4
Intestinal ischaemia		1				1
Intracardiac thrombus	1	1			1	1
Joint stiffness		1		1		
Jugular vein thrombosis	1	1			1	1
Lacrimation increased		1		1		
Lethargy		1		1		
Limb discomfort		2		1		1
Livedo reticularis		1				1
Loss of personal independence in daily activities		1				1
Lung disorder		1				1
Lung infiltration	2	2			2	2
Lymphadenopathy		2		1		1
Malaise	7	23	3	7	4	16
Memory impairment	1	1			1	1
Meningitis	1	1			1	1
Mesenteric artery thrombosis		1				1
Metabolic acidosis		1				1
Metabolic alkalosis		1		1		
Micturition urgency		1				1
Mobility decreased		1				1
Monoparesis		1				1
Muscle spasms	1	2			1	2
Muscle twitching	2	2	1	1	1	1
Muscular weakness	5	7	1	1	4	6
Musculoskeletal stiffness	1	2	1	2		
Myalgia	5	13	3	8	2	5
Myocardial ischaemia	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	11	19	5	7	6	12
Neck pain	1	2			1	2
Neutrophil count increased		1		1		
Nodular rash	1	1	1	1		
Obstructive airways disorder	1	1			1	1
Oedema	1	2			1	2
Oedema peripheral	1	5		2	1	3
Off label use		1		1		
Oropharyngeal pain	1	2		1	1	1
Orthostatic hypotension	1	1	1	1		
Oxygen saturation decreased		1				1
Pain	2	4	1	1	1	3
Pain in extremity	1	6		3	1	3
Pain of skin	1	2			1	2
Pallor		2		1		1
Palpitations	1	1			1	1
Pancreatitis acute		1				1
Paraesthesia	5	5			5	5
Paraesthesia oral	1	2			1	2
Paresis		1				1
Parkinson's disease		1				1
Partial seizures	1	1			1	1
Periorbital swelling	1	1			1	1
Peripheral coldness		1				1
Peripheral swelling		2				2
Petechiae	1	1			1	1
Petit mal epilepsy	1	1			1	1
Pharyngeal haemorrhage	1	1			1	1
Pharyngeal swelling		1				1
Platelet count abnormal		1				1
Platelet count decreased	1	1	1	1		
Pneumonia	1	6			1	6

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonia bacterial		1				1
Pneumonitis		1				1
Polycythaemia vera		1				1
Presyncope	1	3			1	3
Productive cough	2	2			2	2
Prolonged expiration		1				1
Protein total decreased	1	1	1	1		
Pruritus	3	5	1	3	2	2
Pulmonary arterial hypertension		1				1
Pulmonary embolism	6	13			6	13
Pulmonary fibrosis		1				1
Pulmonary oedema		3				3
Pyrexia	7	23	2	11	5	12
Radiculitis brachial	1	1			1	1
Rash	4	9	3	7	1	2
Rash macular	1	1	1	1		
Rash pruritic	1	1	1	1		
Renal failure	1	2			1	2
Respiratory acidosis		2				2
Respiratory distress		1				1
Respiratory failure		3				3
Restlessness		1				1
Rhabdomyolysis	1	1			1	1
Rheumatoid arthritis		1				1
Rhinorrhoea		2		1		1
Scratch	1	1			1	1
Seizure	2	2			2	2
Sensory disturbance	3	4			3	4
Sensory loss	1	2			1	2
Septic embolus	1	1			1	1
Skin abrasion		1				1
Skin burning sensation	1	1	1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sleep disorder		1		1		
Somnolence	2	7	1	5	1	2
Speech disorder		2		1		1
Splenic infarction		1				1
Staphylococcal infection		1				1
Strabismus	1	1			1	1
Sudden death		1				1
Swelling face		1				1
Swollen tongue		1				1
Syncope	3	5			3	5
Tachypnoea		1				1
Tenderness		2		1		1
Therapeutic response unexpected	1	1	1	1		
Thrombocytopenia		1				1
Thrombophlebitis	1	1			1	1
Thrombophlebitis superficial		1				1
Thrombosis	2	4			2	4
Tinnitus	1	1			1	1
Tooth infection	1	1			1	1
Transient ischaemic attack	3	4			3	4
Tremor		2				2
Urinary tract infection		1				1
Urosepsis		1				1
Urticaria	4	9	1	2	3	7
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema		5		4		1
Vaccination site haematoma		1		1		
Vaccination site haemorrhage	1	1			1	1
Vaccination site movement impairment	1	1	1	1		
Vaccination site pain	12	20	9	16	3	4
Vaccination site swelling		3		2		1
Vaccination site warmth		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vasculitis		1		1		
Ventricular f brillation	1	1			1	1
Ventricular tachycardia		1				1
Vertigo		1				1
Vision blurred	2	2			2	2
Visual field defect	1	1			1	1
Visual impairment	1	1			1	1
Vomiting	5	11	1	2	4	9
Weight increased		1		1		
White blood cell count increased	1	1	1	1		
White blood cells urine positive	1	1			1	1
Wound		1				1
	1	1	1	1		
	340	762	85	206	255	556

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		4		1		3
Abdominal pain upper	1	3		1	1	2
Acute kidney injury		3				3
Acute leukaemia		1				1
Acute myocardial infarction		2				2
Acute respiratory failure		1				1
Aggression		2				2
Altered state of consciousness		3				3
Amnesia		3				3
Anaemia		2		1		1
Anaphylactic reaction		3				3
Angioedema		2				2
Aortic aneurysm rupture		1				1
Aphasia	1	4			1	4
Appendicitis		1				1
Arthralgia	1	3	1	1		2
Aspiration		1				1
Asthenia		11		3		8
Atrial fibrillation	1	5			1	5
Atrial flutter		2				2
Back pain		1				1
Bacteraemia		1				1
Bacterial infection		1				1
Balance disorder	1	1			1	1
Basilar artery occlusion		1				1
Blood alkaline phosphatase increased		1		1		
Blood count abnormal		1		1		
Blood creatine phosphokinase increased		1				1
Blood creatinine abnormal	1	1			1	1
Blood potassium increased		1		1		
Blood pressure decreased	1	1	1	1		
Blood pressure increased	1	2			1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure systolic increased		1		1		
Blood sodium decreased		1		1		
Blood uric acid abnormal		1		1		
Body temperature increased		1		1		
Bradycardia		1				1
Bronchospasm		1				1
Carbon monoxide poisoning		1				1
Cardiac arrest		4				4
Cardiac disorder		1				1
Cardiac failure	1	2			1	2
Cardiogenic shock		1				1
Cerebellar embolism	1	1			1	1
Cerebral infarction	2	2			2	2
Cerebral ischaemia		1				1
Cerebral thrombosis	1	3			1	3
Cerebrovascular accident	3	11			3	11
Chest discomfort		1				1
Chest pain	1	8		2	1	6
Chills	3	5	1	1	2	4
Chronic obstructive pulmonary disease		2				2
Circulatory collapse		1				1
Cognitive disorder		1				1
Cold sweat	1	1			1	1
Coma		1				1
Condition aggravated		7				7
Confusional state	2	11		1	2	10
Conjunctival haemorrhage		1				1
Constipation	2	2	1	1	1	1
Contusion		1				1
Cough		2				2
COVID-19		13		1		12
C-reactive protein increased		6		3		3

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Death		12				12
Decreased appetite	1	5			1	5
Deep vein thrombosis		2				2
Dehydration	2	3			2	3
Delirium	1	6			1	6
Delusion		1				1
Dementia		1				1
Depressed level of consciousness		8				8
Diabetic complication		1				1
Diarrhoea	3	9	1	3	2	6
Diplopia	1	1			1	1
Discomfort	1	4	1	1		3
Disorientation	1	1			1	1
Disturbance in attention		2				2
Dizziness	5	18		8	5	10
Drug ineffective		6				6
Drug interaction		1				1
Dysarthria	1	2			1	2
Dysphagia	1	1			1	1
Dyspnoea	3	30	1	4	2	26
Dyspnoea exertional		1		1		
Dysstasia		1				1
Embolic stroke	1	1			1	1
Emphysema		1				1
Epistaxis	1	2			1	2
Erysipelas	1	1			1	1
Erythema	2	7	1	4	1	3
Eye pain	1	1	1	1		
Facial paralysis		3				3
Facial paresis		2				2
Fall		6				6
Fatigue	11	30	10	15	1	15

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling abnormal		2		1		1
Feeling cold	1	1			1	1
Feeling hot		3		3		
Femur fracture		1				1
Fibrin D dimer increased		1				1
Fluid intake reduced		2		1		1
Flushing		2		1		1
Gait disturbance		1				1
General physical health deterioration	1	10			1	10
Haematemesis		1				1
Haematochezia		1				1
Haematuria		2		1		1
Haemodynamic instability		1				1
Haemoglobin abnormal	1	1			1	1
Haemoglobin decreased		2				2
Haemorrhagic cerebral infarction	1	1			1	1
Haemorrhagic diathesis		1				1
Hallucination	1	1			1	1
Hallucination, visual	1	2			1	2
Headache	2	12		1	2	11
Head discomfort	1	1			1	1
Head injury		1				1
Heart rate decreased		1		1		
Heart rate increased	1	1			1	1
Hemiparesis	2	4			2	4
Hemiplegia		2				2
Herpes zoster	1	1	1	1		
Hot flush		3		3		
Hyperglycaemia		1				1
Hyperhidrosis		4		3		1
Hypersensitivity		1				1
Hypertension	1	5			1	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertonia		1				1
Hypoglycaemia		1				1
Hypophagia		1		1		
Hypotension		3				3
Hypothermia		2				2
Hypoxia		1				1
Ileus paralytic		1				1
Immune-mediated adverse reaction		1				1
Inappropriate schedule of product administration	1	3	1	3		
Incorrect route of product administration		2		2		
Infection	1	2			1	2
Influenza	1	2	1	1		1
Influenza like illness	1	3	1	3		
Insomnia		1		1		
Intracardiac thrombus	1	2			1	2
Joint swelling	1	1			1	1
Ketoacidosis		1				1
Leukocytosis		1		1		
Livedo reticularis		1				1
Liver function test increased		1		1		
Loss of consciousness	1	3			1	3
Loss of control of legs		1				1
Loss of personal independence in daily activities	1	1			1	1
Low density lipoprotein increased		1		1		
Lung disorder		1				1
Lung infiltration		1				1
Lymphadenopathy		1		1		
Lymphopenia		2		1		1
Malaise	5	24	1	8	4	16
Melaena		1				1
Micturition urgency		1				1
Middle insomnia	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mobility decreased		2				2
Monoparesis		1				1
Muscle discomfort		1				1
Muscle spasms		1				1
Muscular weakness	1	1			1	1
Musculoskeletal pain	1	1			1	1
Musculoskeletal stiffness		1				1
Myalgia	1	5		1	1	4
Myelosuppression		1				1
Myocardial infarction		1				1
Nausea	7	20	2	6	5	14
Neck pain		2				2
Obstructive airways disorder		1				1
Oedema	1	2			1	2
Oedema peripheral		1				1
Off label use	1	2	1	2		
Oral pruritus		1		1		
Oropharyngeal pain		1				1
Oxygen saturation decreased	1	2			1	2
Pain	1	5	1	3		2
Painful respiration		1		1		
Pain in extremity		2		1		1
Pallor		1				1
Palpitations	1	3			1	3
Pancreatitis acute	1	1			1	1
Pancytopenia		1				1
Paraesthesia		1		1		
Paralysis		1				1
Parosmia		1		1		
Pericarditis	1	1			1	1
Phlebitis deep		1				1
Pleural effusion		1				1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonia	5	17			5	17
Pneumonia aspiration		1				1
Pruritus		3		2		1
Pulmonary arterial pressure increased		1		1		
Pulmonary congestion	1	1			1	1
Pulmonary embolism		9				9
Pulmonary fibrosis		1				1
Pulmonary oedema		3				3
Pulse abnormal	1	1			1	1
Pyrexia	6	27	2	4	4	23
Rales		1				1
Rash		2		2		
Rash macular		1		1		
Rash pruritic	1	2	1	2		
Renal failure		3				3
Respiration abnormal		1				1
Respiratory acidosis		2				2
Respiratory arrest	1	4			1	4
Respiratory failure		7				7
Respiratory rate decreased		1				1
Respiratory rate increased	1	1	1	1		
Restlessness		2		1		1
Retinal vascular thrombosis		1				1
Rhabdomyolysis		1				1
Rheumatoid arthritis	1	1			1	1
SARS-CoV-2 test positive		1				1
Scratch		1				1
Sensation of foreign body		2				2
Sepsis		1				1
Septic shock		1				1
Severe acute respiratory syndrome		1				1
Sinus node dysfunction	1	1			1	1

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin haemorrhage		1				1
Skin lesion		1		1		
Somnolence	2	6	2	4		2
Speech disorder	1	1			1	1
Splenic haemorrhage		1				1
Stress cardiomyopathy		1				1
Sudden death		2				2
Swelling	1	2	1	1		1
Swelling face		3		1		2
Syncope	1	4			1	4
Systemic immune activation		2				2
Systemic inflammatory response syndrome		1				1
Taste disorder		1		1		
Tenderness		1		1		
Thinking abnormal		1				1
Thrombocytopenia		1				1
Thrombocytosis		1				1
Thrombosis		3				3
Transient ischaemic attack	1	1			1	1
Tremor	1	4	1	1		3
Troponin I increased		2		1		1
Troponin increased		2				2
Unresponsive to stimuli		1				1
Urinary incontinence	1	1			1	1
Urinary tract infection		2				2
Urinary tract infection bacterial		1				1
Urine odour abnormal		1				1
Urticaria	4	6	1	3	3	3
Vaccination site erythema	4	4	4	4		
Vaccination site haemorrhage	1	1			1	1
Vaccination site infection	1	1	1	1		
Vaccination site necrosis		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	7	9	7	9		
Vaccination site swelling	1	2	1	2		
Vision blurred		1		1		
Visual impairment	1	1	1	1		
Vomiting	4	20	1	5	3	15
White matter lesion		1		1		
	156	742	53	171	103	571

* I=Interval, C=Cumulative
* AE=Adverse Event
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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental exposure to product		1		1		
Anaphylactic reaction		3				3
Anencephaly	1	1			1	1
Arthralgia		1		1		
Chills		2		2		
Cleft palate	1	1			1	1
Congenital absence of cranial vault	1	1			1	1
Contusion		1		1		
COVID-19		1				1
Discomfort	2	2	2	2		
Drug ineffective		1				1
Dysphonia	1	1	1	1		
Dyspnoea	1	2	1	2		
Exposure via breast milk		1		1		
Exposure via skin contact		1		1		
Fatigue	2	4	2	4		
Feeling abnormal	2	2	2	2		
Gastrointestinal disorder		1		1		
General physical health deterioration	1	2	1	2		
Headache	5	8	5	7		1
Hepatic enzyme increased	1	2	1	2		
Hypoaesthesia		1		1		
Immunisation reaction	1	1	1	1		
Inappropriate schedule of product administration	1	1	1	1		
Incorrect route of product administration		1		1		
Influenza like illness	4	6	4	5		1
Lymphadenopathy	1	2	1	2		
Malaise	1	1			1	1
Maternal exposure during pregnancy	1	1			1	1
Myalgia	2	4	2	3		1
No adverse event	1	1	1	1		
Off label use	1	2	1	2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain	3	5	3	5		
Paraesthesia		1		1		
Product administration error		1		1		
Product preparation issue		1		1		
Product use issue		1		1		
Pyrexia	4	5	4	5		
Reaction to excipient		2				2
Respiratory disorder	1	1	1	1		
Underdose		2		2		
Urticaria		1				1
Vaccination site erythema	1	2	1	2		
Vaccination site pain	1	4	1	3		1
Vaccination site pruritus		1		1		
Vaccination site swelling	1	3	1	3		
Vaccination site warmth		1		1		
Vascular rupture	1	1	1	1		
Wrong product administered	1	1	1	1		
	44	93	39	76	5	17

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ECUADOR

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Blood pressure increased		1		1
Chills		1		1
Diarrhoea		2		2
Dizziness		2		2
Face oedema		1		1
Fatigue		1		1
Lip oedema		1		1
Vaccination site pain		1		1
Vomiting		1		1
		11		11

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	1	1	1	1		
Arthralgia	1	2	1	2		
Chronic pigmented purpura	1	1	1	1		
Cough		1		1		
COVID-19		2		1		1
Depressed mood		1		1		
Diarrhoea		1		1		
Discomfort		2		2		
Dizziness	2	2	1	1	1	1
Drug ineffective	1	1			1	1
Dysphagia	1	1			1	1
Eye pain		1		1		
Headache		1		1		
Insomnia	1	1			1	1
Limb discomfort		1		1		
Lung infiltration		1		1		
Muscular weakness	1	1			1	1
Myalgia	2	3	2	3		
Oropharyngeal pain		1		1		
Pain	1	1			1	1
Pericarditis	1	1			1	1
Pyrexia	1	4	1	4		
Rhinorrhoea	1	1	1	1		
SARS-CoV-2 test positive		1		1		
Sitting disability	1	1			1	1
Supraventricular extrasystoles	1	1			1	1
Suspected COVID-19	1	1			1	1
Vaccination site pain		2		2		
Ventricular extrasystoles	1	1			1	1
	19	39	8	27	11	12

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Autoimmune myocarditis	1	1			1	1
Cough	1	1			1	1
COVID-19		1		1		
Dysphonia	1	1			1	1
Erythema	1	1	1	1		
Fatigue	1	1	1	1		
Headache	1	1	1	1		
Head discomfort	1	1			1	1
Hyperhidrosis	1	1			1	1
Influenza	1	1	1	1		
Laryngitis		1		1		
Malaise	2	2	1	1	1	1
Myalgia	1	1			1	1
Neck pain	1	1			1	1
Oropharyngeal pain	1	1			1	1
Pain	1	1			1	1
Paraesthesia	1	1			1	1
Pericarditis	1	1			1	1
Respiratory disorder	1	1			1	1
Rhinorrhoea	1	1			1	1
Suffocation feeling	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site swelling	1	1	1	1		
Vaccination site urticaria	1	1	1	1		
	24	26	8	10	16	16

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	1	1	1	1		
COVID-19	2	2	1	1	1	1
Drug ineffective	1	1			1	1
Transient ischaemic attack	1	1			1	1
	5	5	2	2	3	3

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Thrombotic stroke		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris		1				1
Blood pressure increased		1		1		
COVID-19	23	27			23	27
Diarrhoea		1		1		
Discomfort	2	4	2	4		
Drug ineffective	22	26			22	26
Fatigue		1		1		
Feeling hot	1	1	1	1		
Laryngitis		1		1		
Lymphadenitis		1		1		
Musculoskeletal disorder		1		1		
Nasopharyngitis	1	1	1	1		
Pain		1		1		
Pyrexia	1	4	1	4		
Suspected COVID-19		1				1
Tachycardia	1	1	1	1		
Tracheitis		1		1		
Vaccination failure	1	1			1	1
Vaccination site oedema	1	1	1	1		
Vaccination site pain	1	4	1	4		
	54	80	8	24	46	56

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

EGYPT

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19		1		1
Drug ineffective		1		1
		2		2

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

EL SALVADOR

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Atypical pneumonia	1	1			1	1
Back pain	1	1	1	1		
Bronchospasm	1	1	1	1		
Cerebrovascular accident	1	1			1	1
Insomnia	1	1	1	1		
Pleural effusion	1	1			1	1
Pneumonia	1	1			1	1
Pulmonary oedema	1	1			1	1
	8	8	3	3	5	5

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Pleural effusion	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

ESTONIA

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cardiac arrest	1	1	1	1
Pulmonary embolism	1	1	1	1
	2	2	2	2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	3	1	3		
Asthenia	2	5	2	4		1
Asymptomatic COVID-19	1	1			1	1
Bradycardia		1				1
Chest pain		1		1		
Chills	1	7	1	7		
COVID-19		3				3
Dizziness	1	4	1	3		1
Dyspnoea		1		1		
Ear disorder		1		1		
Exposure during pregnancy		2		2		
Fatigue	2	6	2	6		
Feeling hot	1	2	1	2		
Flushing		1		1		
Headache	3	10	3	10		
Hyperhidrosis		1		1		
Hypertension	1	1	1	1		
Hypoaesthesia		1		1		
Hypopnoea		1				1
Hypotension		1				1
Immunisation reaction		1				1
Insomnia		1		1		
Intranasal paraesthesia		1		1		
Laryngeal oedema	1	1			1	1
Limb discomfort	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Malaise	1	4	1	2		2
Maternal exposure during pregnancy	3	5	3	5		
Migraine with aura		1		1		
Muscular weakness		1		1		
Musculoskeletal stiffness	1	1	1	1		
Myalgia		3		3		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	1	3	1	2		1
Oropharyngeal pain	1	2	1	2		
Pain in extremity		2		2		
Paraesthesia		3		3		
Paraesthesia oral		1		1		
Pharyngeal paraesthesia		1		1		
Pruritus	1	1	1	1		
Pyrexia	2	11	2	11		
Retching		1				1
Speech disorder		1				1
Syncope		2				2
Vaccination failure	1	4			1	4
Vaccination site erythema	1	3	1	3		
Vaccination site induration	1	1	1	1		
Vaccination site oedema		2		2		
Vaccination site pain	2	10	2	10		
Vaccination site swelling	1	1	1	1		
Visual impairment		1				1
Vomiting		1		1		
	32	125	29	102	3	23

* I=Interval, C=Cumulative
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		2		2		
Acute disseminated encephalomyelitis		1				1
Acute myocardial infarction		1				1
Anxiety		1				1
Aphonia		1				1
Arrhythmia	1	1			1	1
Arthralgia	2	8	2	8		
Asthenia	2	11	2	8		3
Asymptomatic COVID-19		1				1
Back pain		3		1		2
Balance disorder	2	3	2	3		
Bell's palsy	1	1			1	1
Blood creatine phosphokinase increased		1		1		
Body temperature decreased		1		1		
Chest pain		3		2		1
Chills	4	10	4	10		
Cognitive disorder		1		1		
COVID-19	9	19			9	19
Death		1				1
Demyelination		1				1
Diarrhoea		2		2		
Disease recurrence		1				1
Dizziness	3	9	3	8		1
Drug hypersensitivity		1				1
Drug ineffective	4	6			4	6
Dysgeusia	1	4	1	3		1
Dyspepsia		1		1		
Dysphagia		1				1
Dyspnoea		6		4		2
Dyspnoea exertional	1	1	1	1		
Dysuria		1				1
Ear pain		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposure during pregnancy	1	4	1	4		
Facial nerve disorder		1		1		
Facial pain		2		2		
Fall		1		1		
Fatigue	3	10	3	9		1
Feeling hot		1		1		
Fine motor skill dysfunction	1	1	1	1		
Fracture		1				1
Haemorrhage in pregnancy		1				1
Headache	7	26	7	24		2
Heart rate increased		1				1
Hyperhidrosis	1	3	1	3		
Hypersensitivity		1		1		
Hypertension		2		1		1
Hypoaesthesia		2		2		
Hypothermia		3				3
Immunisation anxiety related reaction		4		4		
Insomnia		3		3		
Lacrimation increased	1	1	1	1		
Laryngeal oedema		1				1
Lymphadenopathy		3		3		
Malaise	1	5	1	5		
Maternal exposure during pregnancy		1				1
Mouth swelling		1				1
Muscular weakness		1		1		
Musculoskeletal stiffness		1				1
Myalgia	6	12	6	12		
Myelitis transverse		1				1
Nasal congestion		1		1		
Nausea		5		4		1
Neck pain		2				2
Nervousness		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular discomfort		1		1		
Oropharyngeal pain	3	3	3	3		
Pain		2		1		1
Pain in extremity	3	6	3	6		
Paraesthesia		12		9		3
Paraesthesia oral		1		1		
Peripheral swelling		1		1		
Pharyngeal swelling		1		1		
Photopsia		1		1		
Pruritus		1		1		
Pulmonary oedema		1				1
Pyrexia	8	20	8	19		1
Rhinorrhoea	1	3	1	3		
Seizure		1				1
Somnolence	3	9	3	8		1
Spinal cord injury		1				1
Sputum increased		1		1		
Suspected COVID-19	1	1			1	1
Syncope		4				4
Syringe issue		1		1		
Tachycardia		3		3		
Tendon pain		1		1		
Thrombophlebitis		1		1		
Type I hypersensitivity		1				1
Underdose		1		1		
Urinary retention		1				1
Vaccination failure	6	15			6	15
Vaccination site erythema	1	3	1	3		
Vaccination site induration		1		1		
Vaccination site oedema	2	4	2	4		
Vaccination site pain	4	18	4	18		
Vaccination site paraesthesia		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pruritus		1		1		
Vaccination site rash		1		1		
Vaccination site swelling		2		2		
Ventricular extrasystoles		1				1
Vision blurred	1	2	1	2		
	84	336	62	237	22	99

* I=Interval, C=Cumulative
* AE=Adverse Event
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1				1
Arthralgia	1	4	1	4		
Asthenia	3	10	2	8	1	2
Blood pressure increased	1	2	1	1		1
Bone pain		1				1
Bronchitis	1	1	1	1		
Chest discomfort		1		1		
Chest pain		1				1
Chills		9		8		1
Chronic obstructive pulmonary disease		1				1
Cold sweat		1				1
Cough	2	4	2	4		
COVID-19	9	14			9	14
Decreased appetite		1		1		
Diplopia		1		1		
Disease recurrence		1		1		
Dizziness	1	5	1	3		2
Drug ineffective		2				2
Dysgeusia		2		1		1
Dysphagia		1		1		
Dyspnoea	1	2	1	2		
Ear pain	1	1	1	1		
Extensive swelling of vaccinated limb		1		1		
Fall	1	1			1	1
Fatigue	2	4	2	4		
Glossodynia	1	1	1	1		
Headache	3	10	3	8		2
Herpes zoster	1	1	1	1		
Hot flush	1	1	1	1		
Hyperhidrosis	1	1	1	1		
Hypersensitivity		3				3
Hypertension		2		2		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia oral		1		1		
Hypoglycaemia		1				1
Hypotension	1	2	1	1		1
Hypothermia		2				2
Illrd nerve disorder		1				1
Immunisation anxiety related reaction		5		4		1
Insomnia		1		1		
Ischaemic cerebral infarction	1	1			1	1
Laryngeal oedema		1				1
Lip swelling		1				1
Loss of consciousness	1	1			1	1
Lymphadenopathy		2		2		
Malaise	1	2	1	2		
Muscular weakness		1		1		
Myalgia	2	5	2	4		1
Nausea	1	8	1	6		2
Off label use		1		1		
Oral herpes		1		1		
Oropharyngeal discomfort		1				1
Oropharyngeal pain		1		1		
Pain in extremity		2		2		
Pallor		1				1
Palpitations		1		1		
Panic attack		1		1		
Paraesthesia		2		2		
Paraesthesia oral		1		1		
Peripheral sensory neuropathy		1				1
Pharyngeal hypoaesthesia		1		1		
Pneumonia		1				1
Presyncope		1				1
Product use issue		1		1		
Pyrexia	1	8	1	8		

* I=Interval, C=Cumulative

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiration abnormal		1				1
Respiratory failure		1				1
Restlessness		1		1		
Reversed hot-cold sensation	1	1	1	1		
Rhinitis	1	1	1	1		
Rhinorrhoea	2	2	2	2		
Skull fractured base	1	1			1	1
Somnolence	2	5	2	5		
Speech disorder	1	1			1	1
Subdural haematoma	1	1			1	1
Suspected COVID-19		1				1
Syncope	2	5			2	5
Throat irritation	1	1	1	1		
Throat tightness		1				1
Tinnitus		2		1		1
Tremor		1		1		
Trigeminal nerve disorder		1				1
Vaccination failure	9	13			9	13
Vaccination site erythema		1		1		
Vaccination site pain	1	6	1	6		
Vomiting	1	2	1	2		
	61	200	34	121	27	79

* I=Interval, C=Cumulative
* AE=Adverse Event
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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Ageusia		1		1		
Altered state of consciousness	1	1			1	1
Anaphylactic shock	1	1			1	1
Angina pectoris	2	2			2	2
Arrhythmia	1	1			1	1
Arthralgia		3		3		
Asthenia	1	3		2	1	1
Atrial fibrillation	1	1			1	1
Balance disorder		1		1		
Basilar artery thrombosis	1	1			1	1
Cardiac failure congestive		1				1
Cellulitis	1	1			1	1
Cerebral infarction		1				1
Condition aggravated	1	2		1	1	1
COVID-19	6	12		1	6	11
C-reactive protein increased		1		1		
Cystitis	1	1			1	1
Death		1				1
Decreased appetite	1	2		1	1	1
Deep vein thrombosis		1				1
Diarrhoea	1	2		1	1	1
Dizziness	1	1			1	1
Drug ineffective	1	2			1	2
Dry mouth	1	1			1	1
Dyspnoea		4		4		
Electrocardiogram ST segment depression	1	1			1	1
Epistaxis	1	1			1	1
Fatigue	2	3	2	3		
Femoral artery embolism	1	1			1	1
General physical health deterioration	1	1			1	1
Headache	1	4	1	4		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperhidrosis	1	1			1	1
Hypertension	1	1			1	1
Hypertensive heart disease		1				1
Hypoaesthesia	1	1			1	1
Hypotension	1	1			1	1
Immunisation anxiety related reaction		1		1		
Increased appetite		1		1		
Insomnia	1	1	1	1		
Joint range of motion decreased		1		1		
Joint stiffness		1		1		
Joint swelling		1		1		
Lymphadenopathy	1	1	1	1		
Malaise	1	1			1	1
Myalgia	1	3	1	3		
Nausea	2	3		1	2	2
Oropharyngeal pain		1		1		
Pain in extremity		1		1		
Palpitations		2		2		
Peripheral swelling	1	1			1	1
Pruritus	1	1	1	1		
Psoriasis		1				1
Pulmonary embolism	1	2			1	2
Pulse absent	1	1			1	1
Pyrexia	1	7		6	1	1
Respiratory failure		1				1
Respiratory symptom		1		1		
Restlessness		2		2		
Rhinorrhoea		1		1		
Skin ulcer	1	1			1	1
Somnolence	1	1			1	1
Supraventricular tachycardia		1				1
Thrombophlebitis superficial	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tremor		1		1		
Type IV hypersensitivity reaction		1				1
Urticaria	1	1	1	1		
Vaccination failure	5	9			5	9
Vaccination site erythema		1		1		
Vaccination site extravasation		1		1		
Vaccination site induration		1		1		
Vaccination site oedema		2		2		
Vaccination site pain		2		2		
Vaccination site rash		1		1		
Vaccination site swelling		2		2		
Vaccine breakthrough infection		1				1
Vomiting	1	1			1	1
	55	129	8	61	47	68

* I=Interval, C=Cumulative
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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		1		1		
Asthenia		2		1		1
Blindness unilateral		1				1
Bone contusion		1				1
Bone pain		1		1		
Cerebral haemorrhage		1				1
Cerebrovascular accident		1				1
Chills		2		2		
Condition aggravated	1	1			1	1
Contusion		1				1
Cough	1	2	1	2		
COVID-19	10	12			10	12
COVID-19 pneumonia		1				1
Decreased appetite	1	1			1	1
Drug ineffective	2	2			2	2
Dysgeusia	1	1			1	1
Dysphagia	1	1			1	1
Dyspnoea	1	1			1	1
Erythema	1	1	1	1		
Exposure to SARS-CoV-2	1	1	1	1		
Facial paralysis		1				1
Fall	1	2		1	1	1
Haematoma		1		1		
Headache		2		2		
Hypoaesthesia		1		1		
Hypoaesthesia oral	1	2	1	2		
Hypotension	1	1			1	1
Loss of consciousness		1				1
Malaise		2		1		1
Musculoskeletal pain		1		1		
Myalgia		1		1		
Myocardial infarction	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea		1		1		
Oropharyngeal pain	1	1	1	1		
Pain in extremity	1	1	1	1		
Paraesthesia		1		1		
Peripheral swelling	1	1			1	1
Pulmonary embolism		1				1
Pyrexia		3		2		1
Respiratory failure		1				1
Retinal vascular thrombosis		1				1
Rhinitis		1		1		
Road traffic accident		1		1		
Syncope	1	3			1	3
Vaccination failure	8	9			8	9
Vomiting	1	1			1	1
Wound		1				1
	37	78	6	27	31	51

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19		1				1
Drug ineffective		1				1
Dysgeusia		1		1		
Headache		1		1		
Influenza like illness		1		1		
Lymphadenopathy		1		1		
Muscle spasms		1		1		
Myalgia		1		1		
Oral herpes		1		1		
Pyrexia		1		1		
Vaccination site erythema	1	1	1	1		
Vaccination site pain	1	6	1	6		
	2	17	2	15		2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

FINLAND

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	3	2	2		1
Abdominal pain	1	4	1	2		2
Abdominal pain upper	1	2	1	1		1
Abortion spontaneous		1				1
Allergy to vaccine		1				1
Anaphylactic reaction	2	2			2	2
Ankylosing spondylitis		1				1
Appendicitis		1				1
Arrhythmia	1	2			1	2
Arthralgia	1	8	1	2		6
Asthenia	3	10	3	4		6
Axillary pain	1	5	1	3		2
Back pain		2				2
Bladder dysfunction	1	1			1	1
Blood glucose increased	1	1			1	1
Blood potassium decreased	1	1			1	1
Blood pressure decreased	1	2	1	1		1
Blood pressure diastolic increased		1				1
Blood pressure fluctuation	1	1			1	1
Blood pressure increased	3	5	2	3	1	2
Breast cyst		1				1
Breath sounds abnormal		1				1
Bronchitis		2				2
Burning sensation	1	3	1	1		2
Cervical spinal stenosis		1				1
Chest discomfort	1	4			1	4
Chest pain		2		1		1
Chills	4	9	4	5		4
Choking sensation		1				1
Confusional state		1				1
Cough		4				4
C-reactive protein increased		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea	1	3	1	3		
Disease recurrence		1				1
Disorganised speech	1	1			1	1
Dizziness	3	7	1	2	2	5
Dysarthria		1				1
Dysphagia		1				1
Dyspnoea	1	10			1	10
Dysuria		1				1
Erythema		4		1		3
Erythema of eyelid		1				1
Extrasystoles	1	1			1	1
Eyelid oedema		1				1
Eye pain		2				2
Face oedema		3		1		2
Facial pain		1				1
Facial paralysis		1				1
Fatigue	3	17	3	7		10
Feeling abnormal	1	3	1	2		1
Feeling cold	1	2	1	1		1
Feeling hot		6		2		4
Flank pain		2				2
General physical health deterioration		2				2
Grip strength decreased	1	1			1	1
Headache	11	31	6	9	5	22
Heart rate increased	1	6		1	1	5
Heart rate irregular		1				1
Heavy menstrual bleeding	1	1	1	1		
Hemianaesthesia		1				1
Herpes simplex	1	1	1	1		
Herpes zoster		3		1		2
Hyperaesthesia	1	2	1	1		1
Hyperhidrosis	2	3			2	3

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypersensitivity	1	5			1	5
Hypersomnia		1		1		
Hypertension	1	1	1	1		
Hypoaesthesia	4	16	1	3	3	13
Hypoaesthesia oral		2				2
Hypokalaemia		2				2
Hypothermia		1				1
Illness		1				1
Impaired work ability		2				2
Incorrect route of product administration		1		1		
Increased upper airway secretion		2				2
Influenza		1				1
Insomnia	1	2	1	1		1
Joint range of motion decreased		1				1
Joint stiffness		1		1		
Ketoacidosis	1	1			1	1
Limb discomfort	1	1	1	1		
Localised oedema		2		1		1
Loss of consciousness	1	3			1	3
Loss of control of legs		1				1
Lymphadenitis	1	1			1	1
Lymphadenopathy	4	14	4	8		6
Lymph node pain		2		1		1
Lymph nodes scan abnormal		1				1
Malaise	2	9		1	2	8
Malignant lymphoid neoplasm		1				1
Memory impairment	1	1			1	1
Migraine		4		1		3
Mobility decreased		1				1
Muscle fatigue		1				1
Muscle spasms	3	5	1	2	2	3
Muscle twitching	3	6	2	4	1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscular weakness		4				4
Musculoskeletal pain		1		1		
Musculoskeletal stiffness		3		2		1
Myalgia	6	22	3	6	3	16
Myocarditis		1				1
Narcolepsy		1				1
Nasal congestion		1				1
Nasal oedema		1				1
Nasopharyngitis	1	3			1	3
Nausea	5	16	3	6	2	10
Neck pain		2				2
Neuralgia		4		1		3
Night sweats		1		1		
Nuchal rigidity		1		1		
Oedema peripheral		1				1
Oral pruritus		1				1
Oropharyngeal oedema		1		1		
Oropharyngeal pain		2				2
Pain	1	4	1	2		2
Pain in extremity	6	20	5	9	1	11
Pain of skin		1				1
Pallor		1		1		
Palpitations		3				3
Paraesthesia	1	7		2	1	5
Paraesthesia oral	2	3			2	3
Pharyngeal hypoaesthesia		2				2
Pharyngeal oedema		4				4
Pharyngeal paraesthesia		1		1		
Pharyngeal swelling		1				1
Photophobia		1				1
Pneumonia		2				2
Presyncope		1				1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Productive cough		1				1
Pruritus	1	2	1	2		
Pulmonary pain	1	3			1	3
Pyrexia	11	36	7	14	4	22
Rash macular		1				1
Respiratory tract congestion	1	1			1	1
Salivary hypersecretion		1				1
SARS-CoV-2 test negative	1	2	1	1		1
Seizure	2	2			2	2
Sensation of foreign body	1	2		1	1	1
Sensory disturbance		1		1		
Somnolence	2	4	1	1	1	3
Stridor		1				1
Swollen tongue	1	1			1	1
Syncope	1	4			1	4
Tendon pain		1				1
Throat irritation		2				2
Thrombocytosis		1				1
Thrombophlebitis superficial	1	1			1	1
Tongue oedema		1				1
Tremor	1	3		1	1	2
Urticaria	2	5	1	2	1	3
Vaccination site abscess		1				1
Vaccination site bruising		1				1
Vaccination site erythema	1	8	1	4		4
Vaccination site haematoma		1		1		
Vaccination site hyperaesthesia		2				2
Vaccination site hypoaesthesia		1		1		
Vaccination site induration		2		1		1
Vaccination site mass		1				1
Vaccination site movement impairment	1	1	1	1		
Vaccination site oedema	1	6	1	5		1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	5	17	5	11		6
Vaccination site paraesthesia	1	1	1	1		
Vaccination site swelling		1				1
Vaccination site urticaria		1		1		
Vaccination site warmth		5		2		3
Vestibular neuronitis		1				1
Vision blurred		1				1
Visual impairment	1	1	1	1		
Vomiting	1	5			1	5
Wheezing		1				1
	139	549	77	171	62	378

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2				2
Abdominal distension		2		1		1
Abdominal pain	1	4	1	2		2
Abdominal pain lower		1				1
Abdominal pain upper	2	4			2	4
Abdominal symptom		1				1
Accommodation disorder		1		1		
Acute hepatic failure	1	1			1	1
Allergy to vaccine	1	2			1	2
Amaurosis fugax	1	1			1	1
Amnesia	1	1			1	1
Anaphylactic reaction	5	14			5	14
Anaphylactic shock	1	3			1	3
Angina pectoris	2	2			2	2
Anosmia	1	1			1	1
Anxiety	2	3			2	3
Aphonia	1	4		1	1	3
Apnoea		1				1
Arrhythmia	4	18			4	18
Arthralgia	14	51	8	19	6	32
Arthritis reactive		1				1
Asthenia	7	38	4	9	3	29
Asthenopia		1				1
Asymptomatic COVID-19	1	1			1	1
Axillary pain	2	10	2	6		4
Back injury	1	1			1	1
Back pain	2	14	2	9		5
Balance disorder	1	1	1	1		
Bell's palsy	1	2			1	2
Blister		3		2		1
Blood glucose increased	1	1			1	1
Blood pressure decreased	4	7	3	3	1	4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure fluctuation	2	3	1	1	1	2
Blood pressure increased	6	18	2	3	4	15
Blood pressure systolic decreased		1				1
Body temperature decreased		1				1
Body temperature fluctuation		1				1
Body temperature increased	1	2			1	2
Bone pain		2				2
Borrelia infection		1				1
Breast cyst	1	1	1	1		
Breast pain		1				1
Breast swelling		1				1
Breast tenderness		1				1
Burning sensation	1	4		1	1	3
Cardiac disorder	1	1			1	1
Central nervous system inflammation		1				1
Cerebral thrombosis	1	1			1	1
Chest discomfort	3	12		4	3	8
Chest pain		3				3
Chills	12	32	9	16	3	16
Chromatopsia	1	1			1	1
Clumsiness	1	3		2	1	1
Cognitive disorder		1				1
Cold sweat	1	3		1	1	2
Condition aggravated	1	2			1	2
Confusional state	2	4	1	2	1	2
Conjunctival hyperaemia		1				1
Contusion	1	2		1	1	1
Coordination abnormal		1		1		
Corneal infection		1				1
Cough	5	16		2	5	14
COVID-19		2				2
C-reactive protein increased		2		1		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
CSF immunoglobulin increased		1				1
Deafness	1	1			1	1
Deafness bilateral	1	1			1	1
Deafness unilateral		1				1
Decreased appetite	1	5	1	1		4
Deep vein thrombosis	1	2			1	2
Delusion		1		1		
Demyelination		1				1
Depressed level of consciousness	1	2			1	2
Derealisation	1	2		1	1	1
Diarrhoea	4	13	2	5	2	8
Diplopia	1	2		1	1	1
Discomfort		4		1		3
Diverticulitis		1				1
Dizziness	19	55	9	22	10	33
Drug ineffective		1				1
Drug interaction	2	2			2	2
Dry eye		1				1
Dry mouth		3				3
Dysarthria		2		1		1
Dysgeusia	2	5	1	2	1	3
Dyskinesia		1		1		
Dyspepsia		1				1
Dysphagia		1				1
Dysphonia	4	7	1	2	3	5
Dyspnoea	11	47	4	9	7	38
Dyspnoea exertional		3				3
Dysstasia		2				2
Dysuria		1		1		
Ear canal erythema		1		1		
Ear discomfort	1	3		2	1	1
Ear pain		5		5		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear pruritus		1		1		
Eczema		1				1
Electric shock sensation		2		1		1
Embolic cerebellar infarction	1	1			1	1
Encephalitis		1				1
Eosinophil count increased		1				1
Epilepsy		1				1
Epistaxis		1		1		
Erythema	8	31	2	10	6	21
Erythema of eyelid		1				1
Exercise tolerance decreased		2				2
Extensive swelling of vaccinated limb		2		2		
Extrasystoles		5		3		2
Eye haematoma		1				1
Eye infection		1				1
Eyelid irritation		1				1
Eyelid oedema		3				3
Eye movement disorder		1		1		
Eye oedema	1	1	1	1		
Eye pain	1	4	1	1		3
Face oedema	2	7	2	2		5
Facial pain		1				1
Facial paralysis	1	4			1	4
Facial paresis		1				1
Fall	2	5			2	5
Fatigue	22	75	14	28	8	47
Fear		1		1		
Feeling abnormal	6	11	2	3	4	8
Feeling cold	5	14	3	5	2	9
Feeling hot	4	15	2	5	2	10
Female genital tract fistula		1				1
Flank pain	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Flatulence		1		1		
Flushing		6		2		4
Food allergy		2				2
Food aversion		1				1
Fracture	1	1			1	1
Gait disturbance	1	3		1	1	2
Gait inability		1				1
Gastric disorder		1		1		
General physical health deterioration	1	6		1	1	5
Glossodynia	1	2	1	1		1
Haematochezia		1				1
Haematoma		2		2		
Haemorrhagic fever with renal syndrome	1	1			1	1
Hallucination	1	1			1	1
Hallucination, auditory		1				1
Hallucination, visual	1	1			1	1
Headache	26	94	16	36	10	58
Head discomfort	2	5	1	1	1	4
Head injury	1	3		1	1	2
Heart rate abnormal	1	1			1	1
Heart rate decreased		1				1
Heart rate increased	9	22	3	4	6	18
Heart rate irregular	3	4			3	4
Helplessness		1		1		
Hemianaesthesia	4	15			4	15
Hemiparaesthesia		1				1
Hepatic steatosis	1	1	1	1		
Herpes ophthalmic		1				1
Herpes virus infection	1	2		1	1	1
Herpes zoster		2		2		
Herpes zoster cutaneous disseminated		1				1
Herpes zoster oticus		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hot flush		1				1
Human herpesvirus 6 infection	1	1			1	1
Hyperacusis		1				1
Hyperaesthesia		3				3
Hyperhidrosis	1	9	1	4		5
Hypersensitivity	5	13	1	1	4	12
Hypersomnia		1				1
Hypertension	1	3			1	3
Hyperventilation	2	2	1	1	1	1
Hypoacusis	3	5	2	3	1	2
Hypoaesthesia	10	25	6	14	4	11
Hypoaesthesia oral	3	9	2	5	1	4
Hypoaesthesia teeth		1		1		
Hypokalaemia		3				3
Hypothermia		2				2
Impaired work ability	2	14		1	2	13
Inappropriate schedule of product administration	2	3	2	3		
Incorrect route of product administration		3		3		
Increased bronchial secretion	1	1			1	1
Increased upper airway secretion		1				1
Infectious mononucleosis	1	1			1	1
Inflammation		1				1
Influenza		1				1
Influenza like illness		3				3
Initial insomnia	1	2			1	2
Insomnia	2	7	1	4	1	3
International normalised ratio decreased		2		1		1
Irritability		2				2
Joint injury	1	1			1	1
Joint range of motion decreased	1	2	1	2		
Joint stiffness	1	1			1	1
Keratitis		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Laryngeal pain		1				1
Limb discomfort	1	3		2	1	1
Lip exfoliation	1	1			1	1
Lip oedema		1		1		
Lip pain		1		1		
Lip pruritus		1				1
Lip swelling	1	1			1	1
Localised oedema	3	5	2	3	1	2
Loss of consciousness	3	4			3	4
Loss of personal independence in daily activities	2	3	1	1	1	2
Lung disorder		1				1
Lymphadenopathy	7	36	5	17	2	19
Lymph node pain		5		2		3
Malaise	14	44	8	18	6	26
Meniere's disease		1				1
Menstrual disorder		1				1
Middle insomnia		6		3		3
Migraine	1	7	1	1		6
Mouth swelling		1				1
Multiple sclerosis relapse	1	1			1	1
Mumps	1	1			1	1
Muscle disorder		1				1
Muscle fatigue		1				1
Muscle spasms	1	4			1	4
Muscle spasticity		2				2
Muscle strain		1				1
Muscle tightness		2		1		1
Muscle twitching		4		1		3
Muscular weakness		13		2		11
Musculoskeletal discomfort		1				1
Musculoskeletal pain		1				1
Musculoskeletal stiffness	1	7	1	2		5

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	16	63	13	21	3	42
Mydriasis		1		1		
Myokymia	1	1			1	1
Nasal congestion	1	5		2	1	3
Nasal oedema		1				1
Nasopharyngitis		5		1		4
Nausea	16	57	9	22	7	35
Neck injury	1	1			1	1
Neck pain	2	8	1	1	1	7
Neuralgia	4	10	2	3	2	7
Neurological symptom		1				1
Neutropenia		1				1
Nightmare	1	1			1	1
Night sweats	1	1	1	1		
Nodule		2		2		
Ocular hyperaemia		2				2
Oedema mouth	1	1			1	1
Oedema peripheral	1	5	1	2		3
Off label use	2	2	2	2		
Oral discomfort	1	1	1	1		
Oral herpes		1		1		
Oral pruritus	1	4			1	4
Oropharyngeal discomfort	1	3			1	3
Oropharyngeal oedema		1				1
Oropharyngeal pain	1	9		4	1	5
Oxygen saturation decreased		1				1
Pain	2	20	1	3	1	17
Pain in extremity	15	64	7	26	8	38
Pain in jaw	1	1			1	1
Pain of skin		3		1		2
Pallor	1	4	1	1		3
Palpitations	7	24	4	10	3	14

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Papule	2	3	1	2	1	1
Paraesthesia	9	27	5	10	4	17
Paraesthesia oral	3	13	1	6	2	7
Paranasal sinus discomfort		1				1
Paraparesis		1				1
Peak expiratory flow rate decreased		1				1
Perichondritis		1		1		
Peripheral coldness		1				1
Pharyngeal hypoaesthesia		2		1		1
Pharyngeal oedema	2	3		1	2	2
Pharyngeal paraesthesia		1				1
Pharyngeal swelling	3	7			3	7
Photophobia	2	3	1	1	1	2
Photopsia	1	1			1	1
Presyncope		2		1		1
Pruritus	9	18	5	8	4	10
Pulmonary embolism	2	2			2	2
Pulmonary pain		4		1		3
Pyrexia	24	96	21	41	3	55
Rash	4	14	2	5	2	9
Rash erythematous		2		1		1
Rash macular	1	1	1	1		
Rash pruritic		2		2		
Rash vesicular	2	2	2	2		
Rectal ulcer		1				1
Red blood cell sedimentation rate increased		1				1
Respiratory arrest		1				1
Respiratory rate increased		1				1
Respiratory tract irritation		1				1
Rhinitis		2				2
Rhinorrhoea	2	4	1	2	1	2
Rhonchi	1	1			1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rinne tuning fork test abnormal		1		1		
SARS-CoV-2 test negative	1	2			1	2
Scab		1				1
Secretion discharge		1				1
Seizure	1	3			1	3
Sensation of foreign body	6	12	1	2	5	10
Sinus disorder		1				1
Sinus tachycardia		2				2
Skin burning sensation	1	1	1	1		
Skin discolouration	2	2			2	2
Skin mass	1	1			1	1
Skin reaction		1		1		
Skin sensitisation		1				1
Skin striae		1				1
Skin warm		1				1
Sneezing		1				1
Somnolence	1	2			1	2
Speech disorder		2				2
Spinal pain		1		1		
Sputum discoloured		1				1
Stiff tongue		1				1
Stridor		1				1
Suffocation feeling		1				1
Suicidal ideation	1	1			1	1
Swelling	1	4		2	1	2
Swelling face		1		1		
Swelling of eyelid	1	3			1	3
Swollen tongue	2	3	1	1	1	2
Syncope	5	14			5	14
Tachycardia	1	7		1	1	6
Thirst	1	1			1	1
Throat irritation	5	11	1	3	4	8

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Throat tightness	3	7			3	7
Thrombocytopenia	1	1			1	1
Thrombophlebitis superficial		1				1
Thrombosis		1				1
Tinnitus	4	8	2	5	2	3
Tongue discolouration		1				1
Tongue discomfort		2				2
Tongue disorder		1				1
Tongue erythema		1				1
Tongue oedema		2				2
Tongue pruritus	2	2			2	2
Transient aphasia		1				1
Transient ischaemic attack	1	1			1	1
Tremor	2	9	1	2	1	7
Trigeminal palsy		1				1
Tympanic membrane hyperaemia		1		1		
Type IV hypersensitivity reaction		1		1		
Urinary tract infection		2				2
Urticaria	10	27	5	9	5	18
Vaccination failure	1	2			1	2
Vaccination site bruising		1				1
Vaccination site erythema	1	20		13	1	7
Vaccination site haematoma		2		2		
Vaccination site hyperaesthesia	2	4			2	4
Vaccination site hypersensitivity	1	1			1	1
Vaccination site hypoaesthesia	1	1			1	1
Vaccination site induration		3		3		
Vaccination site joint movement impairment		1		1		
Vaccination site mass		3		1		2
Vaccination site movement impairment	2	8		1	2	7
Vaccination site oedema		12		11		1
Vaccination site pain	7	42	4	20	3	22

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site plaque	1	2	1	2		
Vaccination site pruritus		6		4		2
Vaccination site rash		1		1		
Vaccination site reaction		3		2		1
Vaccination site swelling		5		1		4
Vaccination site warmth	3	10	3	8		2
Vaginal infection		1				1
Venous thrombosis	1	1			1	1
Venous thrombosis limb	1	1			1	1
Vertigo	3	6		1	3	5
Vertigo positional	1	1			1	1
Viral infection		2				2
Vision blurred	2	4	2	3		1
Visual impairment	2	3			2	3
Vomiting	1	16		5	1	11
Vulvovaginal inflammation		1				1
Weber tuning fork test abnormal		1		1		
Weight increased	1	1			1	1
Wheezing	1	4			1	4
Wrong technique in product usage process		1		1		
	560	2,022	243	670	317	1352

* I=Interval, C=Cumulative
* AE=Adverse Event
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal distension		1		1		
Abdominal pain	2	3	1	2	1	1
Abdominal pain lower	1	4		2	1	2
Abdominal pain upper	1	3	1	1		2
Abdominal symptom		1		1		
Ageusia		1				1
Amnesia		1				1
Anaesthesia		1		1		
Anal incontinence	1	1			1	1
Anaphylactic reaction	3	8			3	8
Anaphylactic shock	1	2			1	2
Anosmia	1	1	1	1		
Aphasia	1	1			1	1
Appendicitis perforated	1	1			1	1
Arrhythmia	1	1			1	1
Arthralgia	6	19	3	11	3	8
Arthritis		1				1
Asthenia	7	15	3	7	4	8
Asthenopia		1				1
Asthma	1	1			1	1
Atrial fibrillation	2	3			2	3
Atrial flutter	1	1			1	1
Atypical pneumonia	1	1			1	1
Autoimmune arthritis		1				1
Axillary pain		2				2
Back pain	1	6	1	4		2
Balance disorder	1	1			1	1
Blepharitis		1				1
Blindness unilateral	1	1			1	1
Blood pressure decreased		1		1		
Blood pressure diastolic increased		1				1

* I=Interval, C=Cumulative

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure fluctuation	1	1			1	1
Blood pressure increased	2	4	1	1	1	3
Body temperature decreased	1	1	1	1		
Bone pain		1		1		
Burning sensation	2	5		2	2	3
Cardiovascular disorder	1	1			1	1
Carotid artery thrombosis	1	1			1	1
Cerebral infarction	3	4			3	4
Chest discomfort	1	2			1	2
Chest pain		1		1		
Chills	10	21	8	14	2	7
Cognitive disorder		2		1		1
Concussion	1	1			1	1
Condition aggravated		1				1
Contusion	1	1	1	1		
Cough	5	8			5	8
C-reactive protein increased	1	1	1	1		
Crohn's disease		1				1
Cyanosis	1	1			1	1
Decreased appetite		1				1
Deep vein thrombosis	2	3			2	3
Delusion		1		1		
Diarrhoea	4	7	1	4	3	3
Diplopia		1		1		
Disease recurrence	1	4			1	4
Disturbance in attention		1				1
Dizziness	9	18	3	5	6	13
Dysgeusia	1	1			1	1
Dysphagia		3		1		2
Dysphonia	3	3			3	3
Dyspnoea	5	16	1	3	4	13
Dyspnoea exertional		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear discomfort		1		1		
Ear pain		1				1
Epilepsy	1	1			1	1
Erysipelas	1	1			1	1
Erythema	1	8	1	4		4
Erythema multiforme		1				1
Eyelid oedema	2	3	1	2	1	1
Eye oedema	1	1			1	1
Eye pain	1	5	1	4		1
Eye swelling	1	1			1	1
Face oedema	1	3			1	3
Facial pain		1		1		
Facial paralysis		2				2
Facial paresis		1				1
Fall	2	3		1	2	2
Fatigue	16	39	7	18	9	21
Feeding disorder		1				1
Feeling abnormal	1	6			1	6
Feeling cold	5	7	3	4	2	3
Feeling hot	2	7	1	4	1	3
Fixed eruption		2		2		
Flushing		2				2
Foaming at mouth		1				1
Gait disturbance	1	4		1	1	3
General physical health deterioration	1	1	1	1		
Gingival swelling		1		1		
Grip strength decreased		1				1
Groin pain		1				1
Haematoma	1	2			1	2
Hallucination		1				1
Hallucination, auditory		1				1
Headache	24	54	14	28	10	26

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Head discomfort	1	4		2	1	2
Head injury	2	2			2	2
Heart rate increased	2	3			2	3
Heavy menstrual bleeding	1	1	1	1		
Hemianaesthesia		6				6
Hemiparaesthesia		2				2
Hemiparesis	2	3			2	3
Herpes zoster	2	5	1	4	1	1
Hot flush		1				1
Hyperhidrosis	2	3	2	2		1
Hypersensitivity	2	5		1	2	4
Hypertension	2	4			2	4
Hypoaesthesia		8		4		4
Hypoaesthesia oral		5		2		3
Hypogeusia	1	1	1	1		
Hypotension		1				1
Hypothermia		1				1
Immune thrombocytopenia		1				1
Impaired reasoning		1				1
Impaired work ability	1	3			1	3
Inappropriate affect	1	1			1	1
Inappropriate schedule of product administration	3	3	3	3		
Incorrect route of product administration		6		6		
Insomnia		2				2
Iritis		1				1
Irritability	1	1			1	1
Irritability postvaccinal		1		1		
Joint effusion		1				1
Joint range of motion decreased		1		1		
Joint swelling		1		1		
Limb injury		1				1
Lip oedema	1	2		1	1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lip pain		1
Lip swelling		2
Loss of consciousness	2	3
Loss of personal independence in daily activities		1
Lymphadenopathy	4	12
Lymph node pain		1
Malaise	9	16
Memory impairment		1
Mental impairment		1
Mesenteric vein thrombosis	1	1
Migraine		1
Migraine with aura		1
Mouth swelling		1
Multiple sclerosis relapse	1	1
Muscle twitching		1
Muscular weakness	1	2
Musculoskeletal disorder		2
Musculoskeletal pain		1
Musculoskeletal stiffness	1	4
Myalgia	16	44
Nausea	12	23
Neck pain	2	6
Neuralgia		2
Noninfective sialoadenitis		1
Nuchal rigidity	1	2
Obstruction		1
Ocular discomfort		1
Off label use	2	3
Ophthalmic artery thrombosis	1	1
Oral discomfort		2
Oral mucosal blistering		1
Oropharyngeal discomfort		3

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	1		1
		2	3
			1
2	5	2	7
			1
6	8	3	8
	1		
			1
		1	1
			1
			1
		1	1
			1
1	1		1
	1		1
			1
	3	1	1
9	22	7	22
9	12	3	11
2	5		1
	1		1
			1
	1	1	1
			1
2	3		
		1	1
	2		
	1		
	1		2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oropharyngeal pain	5	9	2	5	3	4
Pain	1	5			1	5
Pain in extremity	4	19	1	9	3	10
Pain of skin	2	2	2	2		
Pallor		1				1
Palpitations	3	3	1	1	2	2
Paraesthesia	1	8		3	1	5
Paraesthesia oral	2	9		4	2	5
Paronychia	1	1	1	1		
Peak expiratory flow rate decreased		1				1
Peripheral coldness	1	1			1	1
Peritonitis	1	1			1	1
Pharyngeal oedema	1	1			1	1
Pharyngeal paraesthesia		1				1
Pharyngeal swelling		1				1
Photophobia		1		1		
Photopsia		2				2
Photosensitivity reaction		1				1
Polyarthrits		1				1
Polymyalgia rheumatica		1				1
Presyncope		2				2
Product use issue		1		1		
Pruritus	3	7	2	6	1	1
Pyelonephritis	1	1			1	1
Pyrexia	21	48	14	26	7	22
Rash	3	3	1	1	2	2
Rash erythematous		3		1		2
Rash macular		2		1		1
Rash pruritic		2		1		1
Respiratory rate decreased		1				1
Respiratory tract infection		1				1
Retinal artery occlusion	1	1			1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Retinal haemorrhage		1				1
Retinal tear		1				1
Retinal vein thrombosis		1				1
Rhinorrhoea	3	4	2	3	1	1
Salivary gland enlargement		1				1
SARS-CoV-2 test negative	1	1	1	1		
Seizure		1				1
Self-injurious ideation		1				1
Sensation of foreign body		2				2
Sepsis	1	1			1	1
Sialoadenitis		1				1
Skin burning sensation	1	1			1	1
Skin warm		1		1		
Sluggishness	1	1			1	1
Sneezing	1	1	1	1		
Snoring		1				1
Somnolence	3	4	1	2	2	2
Speech disorder	1	2			1	2
Sudden hearing loss		1				1
Swelling		3		1		2
Swelling face	1	3			1	3
Synovial fluid white blood cells positive		1				1
Tachycardia	1	3			1	3
Taste disorder	1	1			1	1
Tendon pain		1				1
Tension headache	1	1			1	1
Thirst	3	3	2	2	1	1
Throat irritation		2				2
Tinnitus	1	2		1	1	1
Tongue discomfort		1		1		
Toothache		1		1		
Transient aphasia		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Transient ischaemic attack	1	1			1	1
Tremor	1	2			1	2
Trismus		1		1		
Ulcerative keratitis		1				1
Urticaria		5		2		3
Vaccination site erythema	5	9	4	7	1	2
Vaccination site haematoma		2		2		
Vaccination site hyperaesthesia		1				1
Vaccination site induration	1	1			1	1
Vaccination site macule		1		1		
Vaccination site mass	2	3	2	2		1
Vaccination site movement impairment	1	2	1	1		1
Vaccination site oedema	2	3	2	3		
Vaccination site pain	7	20	6	15	1	5
Vaccination site swelling		1		1		
Vaccination site warmth	3	5	3	4		1
Vision blurred		1				1
Visual impairment		4		1		3
Vomiting	5	8	5	6		2
	329	855	150	366	179	489

* I=Interval, C=Cumulative
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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1			1	1
Abdominal pain	3	4			3	4
Abdominal pain lower	1	1			1	1
Abdominal pain upper	2	2			2	2
Acute myocardial infarction		1				1
Acute respiratory failure		1				1
Ageusia	1	1			1	1
Alanine aminotransferase increased		1				1
Amaurosis fugax	1	1			1	1
Amputation stump pain	1	1	1	1		
Anaphylactic reaction		1				1
Anosmia	1	1			1	1
Anuria		2				2
Aortitis		1				1
Apathy	1	1			1	1
Aphasia	1	1			1	1
Aphonia	1	1			1	1
Apnoea		1				1
Arrhythmia	3	5			3	5
Arthralgia	3	6			3	6
Aspiration		1				1
Asthenia	5	8		1	5	7
Atrial fibrillation	1	2			1	2
Back pain	1	1			1	1
Bacterial infection	1	1			1	1
Balance disorder	1	1			1	1
Bell's palsy	2	2			2	2
Blindness transient	1	1			1	1
Blindness unilateral	1	1			1	1
Blister	1	1			1	1
Blood alkaline phosphatase increased		1				1
Blood bilirubin increased		1				1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased	1	3			1	3
Blood pressure increased	6	12	1	1	5	11
Blood pressure systolic increased	1	1			1	1
Bronchiolitis		1				1
Burning sensation	1	1			1	1
Cardiac arrest		1				1
Cardiac failure		2				2
Cardiac flutter		1				1
Cerebral infarction	6	8			6	8
Cerebrovascular accident		1				1
Cerebrovascular disorder	1	2			1	2
Chest discomfort	1	3			1	3
Chest pain	1	2			1	2
Chest X-ray abnormal		1				1
Chills	4	6			4	6
Cholelithiasis		1				1
Chronic obstructive pulmonary disease		1				1
Circulatory collapse		1				1
Clumsiness	1	1			1	1
Cold sweat		1				1
Coma scale abnormal		1				1
Condition aggravated	2	2			2	2
Confusional state	1	1			1	1
Contusion		1				1
Coordination abnormal	1	1			1	1
Coronary artery thrombosis		1				1
Cough	2	3			2	3
C-reactive protein	1	1			1	1
C-reactive protein increased	2	5	1	2	1	3
Cyanosis		1				1
Decreased appetite		2				2
Deep vein thrombosis	4	5			4	5

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dehydration		1				1
Depressed level of consciousness		1				1
Depressed mood	1	1			1	1
Diarrhoea	4	6			4	6
Diplopia	1	1			1	1
Disease recurrence	3	4	1	1	2	3
Disseminated varicella zoster virus infection	2	2			2	2
Disturbance in attention	1	1			1	1
Dizziness	5	10			5	10
Dizziness postural	1	1			1	1
Dysarthria		4				4
Dysmetria		1				1
Dysphonia	2	2	1	1	1	1
Dyspnoea	3	9			3	9
Ear discomfort		1				1
Emphysema	1	1			1	1
Epilepsy		1				1
Erysipelas	2	2			2	2
Erythema	1	3			1	3
Extrasystoles	1	2			1	2
Face oedema	1	2			1	2
Facial paralysis	2	3			2	3
Facial paresis	1	1	1	1		
Fall	2	4			2	4
Fatigue	8	13			8	13
Feeling abnormal	3	3			3	3
Feeling cold	2	3			2	3
Fine motor skill dysfunction	1	1			1	1
Fluid retention	1	1			1	1
Gait deviation	1	1			1	1
Gait disturbance	1	1			1	1
Gastrointestinal necrosis		1				1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal viral infection		1				1
Gaze palsy		1				1
General physical health deterioration	3	6			3	6
Giant cell arteritis		1				1
Glossodynia	1	1			1	1
Gout	2	2			2	2
Haematoma		1		1		
Haemodynamic instability		1				1
Headache	10	13	1	1	9	12
Heart rate increased	2	5			2	5
Hemiparesis	1	2			1	2
Hemiplegia		1				1
Herpes zoster		1				1
Herpes zoster cutaneous disseminated	1	1			1	1
Hyperhidrosis	2	2			2	2
Hyperlactacidaemia		1				1
Hypersensitivity	1	2	1	1		1
Hyperventilation		1				1
Hypoaesthesia	5	8	1	1	4	7
Hypoaesthesia oral	2	2	1	1	1	1
Hypokalaemia	1	1			1	1
Hyposmia		1		1		
Hypotonia	1	3			1	3
Illusion	1	1			1	1
Immune-mediated adverse reaction	1	1			1	1
Inflammatory marker increased	1	2			1	2
Insomnia	2	3			2	3
Intestinal ischaemia	2	3			2	3
IVth nerve paralysis	1	1			1	1
Jaundice		1				1
Joint range of motion decreased	1	1			1	1
Lacunar infarction	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lethargy	1	3			1	3
Lip oedema		1				1
Loss of consciousness	3	3			3	3
Lung disorder		1				1
Lymphadenopathy	1	1			1	1
Malaise	9	12			9	12
Mechanical ventilation		1				1
Memory impairment	1	1			1	1
Meniere's disease	1	1			1	1
Mesenteric artery stenosis	1	1			1	1
Mesenteric artery stent insertion	1	1			1	1
Mesenteric artery thrombosis		1				1
Mesenteric vein thrombosis	1	1			1	1
Middle insomnia		1				1
Mobility decreased	1	1			1	1
Monoparesis	1	2			1	2
Mouth swelling	1	1			1	1
Movement disorder	1	2			1	2
Muscle rigidity	1	1			1	1
Muscle spasms	2	3			2	3
Muscle twitching	1	1			1	1
Muscular weakness	1	4			1	4
Musculoskeletal stiffness	2	2			2	2
Myalgia	2	3	2	2		1
Myelitis transverse	1	1			1	1
Myocardial infarction		1				1
Nausea	5	10		2	5	8
Neck pain	3	5			3	5
Nephrolithiasis	1	1			1	1
Neuritis		1				1
Neurological symptom		1				1
Oedema		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oedema peripheral	1	3		1	1	2
Oropharyngeal pain	1	1			1	1
Oxygen saturation decreased		1				1
Pain	2	3			2	3
Pain in extremity	8	15	1	2	7	13
Pain of skin	1	2			1	2
Palatal swelling	1	1			1	1
Pallor		1				1
Palpitations	2	2			2	2
Paraesthesia	1	4			1	4
Paraesthesia oral	1	1			1	1
Paresis		1				1
Pelvic venous thrombosis		1				1
Peripheral swelling	3	3	1	1	2	2
Petit mal epilepsy	1	1			1	1
Pharyngeal oedema	1	2			1	2
Pharyngeal paraesthesia	1	1			1	1
Pharyngeal swelling	2	2	1	1	1	1
Platelet disorder		1				1
Pneumonia	2	5			2	5
Polymyalgia rheumatica	2	2			2	2
Porphyria		1				1
Portal vein thrombosis	1	1			1	1
Productive cough		1				1
Pruritus	3	3			3	3
Pulmonary embolism	2	7			2	7
Pulmonary haemorrhage		1				1
Pyelonephritis	1	1			1	1
Pyrexia	10	19			10	19
Radiculopathy	1	1			1	1
Rales		1				1
Rash		1				1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash macular	1	1			1	1
Rash vesicular	1	1			1	1
Renal failure		1				1
Respiratory arrest		1				1
Resuscitation		1				1
Retinal ischaemia	1	1			1	1
Retinal vascular occlusion	1	1			1	1
Retinal vascular thrombosis		1				1
Right ventricular failure		2				2
SARS-CoV-2 test negative	1	1			1	1
Seizure		1				1
Sensory loss		1				1
Sinusitis	1	1			1	1
Skull fractured base		1				1
Sleep disorder	1	1	1	1		
Slow speech		1				1
Small intestinal resection	1	1			1	1
Somnolence	2	3			2	3
Speech disorder	2	2			2	2
Spinal disorder	1	1			1	1
Spinal pain		1				1
Splenic infarction	1	1			1	1
Stiff tongue	1	1			1	1
Stomatitis	1	1			1	1
Sudden death		2				2
Swollen tongue	2	3			2	3
Syncope	1	2			1	2
Tachycardia	1	1			1	1
Throat tightness		1				1
Thrombolysis	1	1			1	1
Thrombophlebitis superficial	3	3	1	1	2	2
Thrombosis		2				2

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thrombotic cerebral infarction		1				1
Tinnitus	1	1			1	1
Tongue oedema		1				1
Transient ischaemic attack	1	3			1	3
Tremor	1	1			1	1
Tubulointerstitial nephritis	1	1			1	1
Urinary incontinence	1	1			1	1
Urinary tract infection	1	2			1	2
Urine porphobilinogen increased		1				1
Vaccination site hypoaesthesia		1				1
Vaccination site movement impairment	1	2			1	2
Vaccination site pain	2	4			2	4
Venous thrombosis		1				1
Venous thrombosis limb	2	2			2	2
Ventricular f brillation		1				1
Vertigo		1				1
Vertigo positional		1				1
Visual acuity reduced	1	1			1	1
Vitreous detachment	1	1			1	1
Vomiting	2	8		2	2	6
White blood cell count increased		1				1
	292	528	17	28	275	500

* I=Interval, C=Cumulative
* AE=Adverse Event
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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		4				4
Acne	1	1			1	1
Acquired haemophilia		2				2
Acute myocardial infarction		1				1
Amaurosis fugax		1				1
Anti factor VIII ant body positive		2				2
Aphasia		2				2
Apnoea	1	2			1	2
Areflexia		1				1
Arrhythmia		2				2
Arteriosclerosis	1	1			1	1
Arthralgia		4				4
Arthritis reactive		1				1
Asthenia	2	7			2	7
Asthma		1				1
Atelectasis	1	1			1	1
Atrial f brillation	1	5			1	5
Bacterial test positive		3				3
Balance disorder		1				1
Bedridden		1				1
Biopsy muscle abnormal	1	1			1	1
Blindness unilateral	1	1			1	1
Blood cholesterol increased	1	1			1	1
Blood creatine increased		1				1
Blood creatinine increased		1				1
Blood glucose decreased		1				1
Blood glucose increased	1	2			1	2
Blood lactic acid decreased		1		1		
Blood pressure decreased		1				1
Blood pressure diastolic decreased		1				1
Blood pressure increased	2	3			2	3
Blood uric acid increased		1				1

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* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Body temperature decreased		1				1
Body temperature increased		1		1		
Breath sounds abnormal	2	3		1	2	2
Burning sensation		1				1
Cardiac death	1	1			1	1
Cardiac disorder	2	2			2	2
Cardiac failure	2	7			2	7
Cardiac hypertrophy		1				1
Cerebral artery thrombosis		1				1
Cerebral haematoma	1	1			1	1
Cerebral haemorrhage	1	2			1	2
Cerebral infarction	1	8			1	8
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident		1				1
Chest discomfort		2		1		1
Chest pain	1	3			1	3
Chills	1	4	1	1		3
Circulatory collapse		1				1
Coma scale abnormal		1				1
Condition aggravated	1	3			1	3
Confusional state	3	6		1	3	5
Congestive cardiomyopathy		1				1
Cough		2		1		1
C-reactive protein abnormal	1	1			1	1
C-reactive protein increased	3	11	1	2	2	9
CREST syndrome		1				1
CSF protein increased		1				1
Cystitis		1				1
Deafness unilateral		2				2
Death	4	16			4	16
Decreased appetite		2				2
Deep vein thrombosis	3	4			3	4

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* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dehydration	1	1	1	1		
Delirium		1				1
Dementia Alzheimer's type		4				4
Depressed level of consciousness		4				4
Diarrhoea	3	6	2	2	1	4
Diverticulitis		1				1
Dizziness	1	9			1	9
Dysarthria		4				4
Dysphagia		4		1		3
Dysphonia		1		1		
Dyspnoea	5	24		2	5	22
Eating disorder		1		1		
Eczema		1				1
Electrocardiogram ST segment depression		1				1
Electrocardiogram T wave inversion		1				1
Embolic cerebral infarction	1	1			1	1
Encephalitis		1				1
Epilepsy		2				2
Epistaxis		2				2
Erysipelas		2				2
Erythema		1				1
Escherichia infection	1	1			1	1
Eye disorder		1				1
Eyelid ptosis		1				1
Face oedema		1				1
Facial paralysis		6				6
Facial paresis	2	2			2	2
Fall	1	7			1	7
Fatigue	2	24	1	7	1	17
Feeling abnormal		2				2
Feeling cold		1				1
Feeling drunk		1				1

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling hot		1				1
Fibrin D dimer increased		2		2		
Flank pain		1				1
Fluid intake reduced		1				1
Gait disturbance		2				2
Gait inability	1	1			1	1
Gaze palsy		1				1
General physical health deterioration	6	24		1	6	23
Giant cell arteritis	1	1			1	1
Glomerular filtration rate decreased	1	1	1	1		
Haematoma		1				1
Haematuria		1				1
Haemoglobin decreased		2				2
Haemorrhage	1	1			1	1
Hallucination, visual	1	1			1	1
Headache	3	12			3	12
Head discomfort		1				1
Heart rate decreased		1		1		
Heart rate irregular		2				2
Hemiparesis		3				3
Hemiplegia		1				1
Herpes zoster	5	8	2	2	3	6
Hip fracture		1				1
Hyperhidrosis		1				1
Hypernatraemia		1				1
Hypersensitivity		1				1
Hypertension		4		1		3
Hypoacusis		2		2		
Hypoaesthesia	1	2	1	1		1
Hyponatraemia		1				1
Hypophagia		1				1
Hyporeflexia		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypotension		2				2
Hypotonia		1				1
Inappropriate schedule of product administration	1	1	1	1		
Incorrect route of product administration		1		1		
Increased tendency to bruise		1				1
Increased upper airway secretion	1	3			1	3
Infection		2				2
Inflammation	1	1	1	1		
Influenza		1		1		
Insomnia	1	3			1	3
International normalised ratio decreased		1				1
Intervertebral disc disorder		1		1		
Joint injury		1				1
Joint swelling	1	1			1	1
Klebsiella infection	1	1			1	1
Laboratory test abnormal	1	1			1	1
Limb injury		1				1
Lip oedema		1		1		
Lip swelling		1				1
Loss of consciousness		3				3
Loss of control of legs		2				2
Loss of personal independence in daily activities	2	2			2	2
Lymphadenopathy		1		1		
Lymph node pain		1				1
Macular oedema	1	2			1	2
Malaise	1	10		1	1	9
Memory impairment	1	2			1	2
Migraine		1				1
Mobility decreased		2				2
Mouth haemorrhage		1				1
Muscle twitching		1				1
Muscular weakness	1	7		1	1	6

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* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal stiffness		2		1		1
Myalgia	1	8			1	8
Myocardial infarction		1				1
Nasal pruritus		1		1		
Nasopharyngitis		2				2
Nausea	2	10		2	2	8
Neck pain	1	2		1	1	1
Neuralgia		1		1		
Nightmare	1	1			1	1
Nodule		1				1
Obstruction		1				1
Oedema peripheral		3		2		1
Off label use	1	1	1	1		
Ophthalmic vein thrombosis		1				1
Opisthotonus		1				1
Oral disorder		1				1
Oropharyngeal pain		2		2		
Osteoarthritis		1		1		
Oxygen saturation decreased		1				1
Pain		4				4
Painful respiration		1				1
Pain in extremity	2	6			2	6
Peak expiratory flow rate decreased		1				1
Peripheral embolism		1				1
Peripheral swelling	1	3		1	1	2
Petit mal epilepsy		1				1
Pharyngeal oedema		1				1
Pigmentary glaucoma		1				1
Platelet count decreased	1	1			1	1
Pleural effusion	1	1			1	1
Pneumonia	1	7			1	7
Pneumonia aspiration		1				1

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* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Polycythaemia	1	1	1	1		
Poor quality sleep		1				1
Post herpetic neuralgia	1	1	1	1		
Post procedural haemorrhage		1				1
Productive cough		1				1
Pruritus	1	1			1	1
Pseudomonal sepsis		1				1
Pulmonary embolism		5				5
Pulmonary infarction		1				1
Pulmonary oedema		1				1
Pyelonephritis	1	3			1	3
Pyrexia	7	26	2	4	5	22
Rash	1	2			1	2
Rash macular		1				1
Rash papular	1	1			1	1
Rash vesicular	1	1	1	1		
Rectal haemorrhage		1				1
Red blood cells urine		1				1
Red blood cells urine positive		1				1
Reduced facial expression		1		1		
Renal disorder		1		1		
Renal failure	1	1			1	1
Respiratory rate increased	1	1			1	1
Retinal vascular occlusion		1				1
Retinal vein occlusion	1	1			1	1
Retinal vein thrombosis		1				1
Rheumatoid arthritis		1				1
Rhonchi		1				1
SARS-CoV-2 test negative		1				1
Secretion discharge		1		1		
Skin ulcer	1	1			1	1
Somnolence		1				1

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* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stertor	1	1			1	1
Strabismus		1				1
Stress		1				1
Stupor		1				1
Subcutaneous abscess		1				1
Sudden death		1				1
Suffocation feeling		1				1
Swelling		2		1		1
Swelling face		1				1
Syncope		2				2
Tachycardia		1				1
Throat irritation		1		1		
Thrombocytopenia	1	1			1	1
Thrombophlebitis superficial	1	1			1	1
Thrombosis		1				1
Tinnitus		1				1
Transient ischaemic attack		1				1
Traumatic intracranial haemorrhage	1	1			1	1
Tremor		4				4
Troponin I increased		1				1
Unresponsive to stimuli	1	3			1	3
Urinary retention		1				1
Urinary tract infection	2	6		1	2	5
Urogenital haemorrhage		1				1
Urticaria	2	3	2	2		1
Vaccination site bruising	1	1	1	1		
Vaccination site erythema		1				1
Vaccination site pain		1				1
Vaccination site reaction		1				1
Venous thrombosis		1				1
Vertigo		1				1
Visual acuity reduced		1				1

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* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Visual impairment	2	3			2	3
Vomiting	3	11	1	3	2	8
Weight decreased		1		1		
Wheezing	1	3		1	1	2
White blood cell count decreased	1	1	1	1		
White blood cell count increased		2				2
White blood cells urine		1				1
White blood cells urine positive		1				1
	138	617	23	79	115	538

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Anaphylactic reaction		1				1
Arrhythmia		2				2
Arthralgia	1	5		4	1	1
Asthenia	1	3	1	1		2
Atrial f brillation		1				1
Axillary pain	1	1	1	1		
Back pain	1	1			1	1
Balance disorder		1				1
Blood pressure decreased		1				1
Blood pressure increased		1		1		
Cerebral infarction		2				2
Cheilitis		1		1		
Chest pain		1				1
Chills	1	4	1	3		1
COVID-19		1				1
Death		1				1
Diarrhoea	1	1	1	1		
Dizziness	1	4	1	1		3
Drug ineffective		1				1
Ear pain		1		1		
Epistaxis		1				1
Erythema		1				1
Eye irritation		1		1		
Facial pain		1		1		
Fatigue	2	9	2	7		2
Feeling cold		1				1
Feeling hot		2		1		1
Gait disturbance		1				1
Headache	4	10	3	8	1	2
Head discomfort		1		1		
Heart rate irregular		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hemianaesthesia		1				1
Hemihyperaesthesia		1				1
Hemiparesis		1				1
Hyperacusis	1	1			1	1
Hypoaesthesia		1				1
Hypopnoea		1				1
Increased upper airway secretion		1				1
Lymphadenopathy		2		2		
Malaise		3		2		1
Maternal exposure during pregnancy		1		1		
Mental impairment		1				1
Migraine	1	1			1	1
Mobility decreased	1	2		1	1	1
Muscle fatigue	1	1	1	1		
Muscle spasms	1	1			1	1
Muscular weakness	1	1			1	1
Musculoskeletal stiffness		1		1		
Myalgia	2	6	1	5	1	1
Nasal congestion	1	1	1	1		
Nausea	1	4		3	1	1
Off label use		2		2		
Oral mucosal blistering		1		1		
Oropharyngeal pain	1	2	1	2		
Pain in extremity	2	5	2	4		1
Photosensitivity reaction	1	1			1	1
Poor quality product administered	1	13	1	13		
Product preparation error		12		12		
Product quality issue		1		1		
Product temperature excursion issue	1	1	1	1		
Pruritus		1		1		
Pyrexia	2	5	1	4	1	1
SARS-CoV-2 test negative		1		1		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Spinal pain	1	1			1	1
Thrombophlebitis superficial	1	1	1	1		
Tremor		1				1
Vaccination site erythema		2		2		
Vaccination site hyperaesthesia		1		1		
Vaccination site oedema	1	2		1	1	1
Vaccination site pain	2	5	1	4	1	1
Vaccination site pruritus		1		1		
Vaccination site warmth		1		1		
	37	156	22	105	15	51

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* AE=Adverse Event
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Country Where Event Occurred

FRANCE

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphonia		1				1
Asthenia		1				1
COVID-19		1		1		
C-reactive protein increased		1				1
Dysphonia		1				1
Dyspnoea		1				1
Exposure via breast milk		4		3		1
Face oedema		1				1
Foetal growth restriction	1	1			1	1
Foetal heart rate disorder	1	1			1	1
Maternal exposure during pregnancy	2	2	1	1	1	1
Myalgia		1				1
Nasal congestion		1				1
Neonatal respiratory acidosis	1	1			1	1
Premature baby	2	2	1	1	1	1
Pyrexia		2				2
Respiratory disorder		1				1
Rhinorrhoea		1				1
Umbilical cord thrombosis	1	1			1	1
Vaccination site pain		1				1
	8	26	2	6	6	20

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	3	6	3	5		1
Abdominal pain upper	1	4	1	2		2
Abortion spontaneous	5	7			5	7
Ageusia	1	1	1	1		
Allergy to vaccine		1				1
Amenorrhoea	1	1	1	1		
Amnesia	1	1			1	1
Anal incontinence	1	1	1	1		
Anaphylactic reaction	2	8			2	8
Anaphylactic shock	2	2			2	2
Angina pectoris	1	1			1	1
Angioedema	1	3			1	3
Ankylosing spondylitis	1	1			1	1
Anosmia	1	1	1	1		
Anxiety		1				1
Arrested labour	1	1			1	1
Arrhythmia	1	1			1	1
Artery dissection	1	1			1	1
Arthralgia	4	8	3	5	1	3
Asthenia	9	37	5	17	4	20
Asthmatic crisis		1				1
Auditory disorder		1				1
Autoimmune haemolytic anaemia		1				1
Axillary pain	1	1	1	1		
Back pain	3	4	1	1	2	3
Balance disorder		1				1
Blister		1				1
Blood pressure decreased	1	4	1	1		3
Blood pressure fluctuation		1		1		
Body temperature increased		1				1
Bone pain	1	2	1	1		1
Bradycardia	2	2			2	2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac arrest	1	1			1	1
Cerebral thrombosis		1				1
Cerebral venous thrombosis	1	1			1	1
Chest discomfort	3	5	1	2	2	3
Chest pain	3	5			3	5
Chills	4	12	1	3	3	9
Choking	1	1			1	1
Cold sweat	1	1			1	1
Condition aggravated	3	3			3	3
Conjunctivitis	1	1	1	1		
Coordination abnormal		1		1		
Costovertebral angle tenderness		1				1
Cough	1	5	1	1		4
COVID-19	5	11	1	1	4	10
C-reactive protein increased	1	2	1	1		1
Cyanosis	1	1	1	1		
Deafness neurosensory		1				1
Death	1	1			1	1
Decreased appetite	2	4	2	3		1
Diabetes mellitus		1				1
Diabetic ketoacidosis		1				1
Diarrhoea	1	5		1	1	4
Discomfort	2	8	2	3		5
Disease recurrence	1	3		1	1	2
Disorientation		1		1		
Disturbance in attention		1		1		
Dizziness	5	18	1	4	4	14
Drooling		1		1		
Drug ineffective	1	4			1	4
Dysphagia	2	3		1	2	2
Dyspnoea	4	8	2	2	2	6
Dyspnoea exertional		1				1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysuria		1		1		
Ear pain	1	2			1	2
Ecchymosis	1	1			1	1
Epilepsy	2	3			2	3
Epistaxis	3	5	1	2	2	3
Epstein-Barr virus infection		1				1
Erythema	1	3	1	1		2
Exposure during pregnancy	2	2			2	2
Eyelid oedema		1				1
Face oedema		3				3
Facial asymmetry	1	1			1	1
Facial paralysis	2	4			2	4
Factor II mutation		1		1		
Faeces soft		1		1		
Familial mediterranean fever	1	1			1	1
Fatigue	5	10	3	4	2	6
Febrile convulsion	1	2			1	2
Feeling cold	1	3			1	3
Feeling drunk		1		1		
Fine motor skill dysfunction		1		1		
Food refusal	1	1	1	1		
Formication		1				1
Gait disturbance		1				1
Gait inability		1				1
Gastrointestinal disorder	1	3	1	1		2
Gastrointestinal pain		1		1		
Generalised tonic-clonic seizure		1				1
Gynaecomastia	1	1	1	1		
Haematemesis		1				1
Haematuria	1	1	1	1		
Haemoglobin decreased		1				1
Haemorrhagic diathesis		1				1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache	18	45	9	19	9	26
Head injury		1				1
Hemiparesis	1	1			1	1
Hepatic cytolysis		1				1
Herpes simplex	1	1	1	1		
Herpes virus infection	1	1	1	1		
Hot flush		2		1		1
Hyperaesthesia	2	2			2	2
Hyperhidrosis	2	7		1	2	6
Hyperleukocytosis	1	1			1	1
Hypersensitivity	1	6		2	1	4
Hypertension	3	8		1	3	7
Hyperthermia	2	7		2	2	5
Hyperventilation	1	1			1	1
Hypoaesthesia		3				3
Hypoaesthesia oral	1	1			1	1
Hypophosphataemia	1	1	1	1		
Hypotension	3	7	1	1	2	6
Hypothermia		1				1
Hypoxia	1	1			1	1
Immune thrombocytopenia		1				1
Impaired work ability	1	2	1	1		1
Incorrect route of product administration		1		1		
Infection		2				2
Inflammation	1	1	1	1		
Influenza	1	2		1	1	1
Influenza like illness	15	41	5	8	10	33
Injected limb mobility decreased		2				2
Injection site erythema		1		1		
Insomnia		5		1		4
Intercostal neuralgia		1				1
Intermenstrual bleeding	1	1			1	1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ischaemic stroke		1				1
Laryngeal oedema		1				1
Leukopenia	1	1			1	1
Limb discomfort		2				2
Lip oedema		1				1
Livedo reticularis	1	1	1	1		
Loss of consciousness	4	7			4	7
Lymphadenitis	1	2		1	1	1
Lymphadenopathy	3	9	1	5	2	4
Lymphangitis	1	1			1	1
Lymphopenia		1				1
Malaise	7	26	2	5	5	21
Maternal exposure during pregnancy	1	1			1	1
Maternal exposure timing unspecified	2	3	1	2	1	1
Menstruation delayed	1	2	1	1		1
Migraine	1	1	1	1		
Migraine with aura		1		1		
Moaning		1				1
Mobility decreased	2	2	1	1	1	1
Monoplegia	1	1	1	1		
Movement disorder		1		1		
Muscle spasms		1				1
Muscle tightness	1	1	1	1		
Muscular weakness		1		1		
Musculoskeletal chest pain	1	3	1	1		2
Musculoskeletal stiffness	2	8	1	1	1	7
Myalgia	8	26	5	16	3	10
Myocardial infarction		1				1
Myocarditis	2	5			2	5
Nausea	5	23	3	9	2	14
Neck pain	2	4			2	4
Nephrotic syndrome	1	1			1	1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nervous system disorder		1				1
Neuralgia	1	4		2	1	2
Neutropenia		1				1
Ocular discomfort		1				1
Odynophagia	1	1			1	1
Oedema peripheral	2	4	2	3		1
Off label use	1	2		1	1	1
Optic neuritis	1	1			1	1
Optic neuropathy	1	1			1	1
Oral blood blister		1				1
Oropharyngeal pain	1	2	1	2		
Overdose	1	1	1	1		
Oxygen saturation decreased	2	3	1	1	1	2
Pain		7		4		3
Pain in extremity	6	13	4	8	2	5
Pallor	1	1	1	1		
Palpitations	1	2			1	2
Pancreatitis acute	1	1			1	1
Pancytopenia		2				2
Paraesthesia	5	14	2	4	3	10
Paralysis	1	1			1	1
Parosmia		1		1		
Pelvic venous thrombosis	1	1			1	1
Pericardial effusion	1	1			1	1
Pericarditis	2	6			2	6
Peripheral coldness		1		1		
Peripheral swelling	1	1	1	1		
Petechiae		1				1
Petit mal epilepsy		1				1
Pharyngeal paraesthesia		1				1
Phonophobia		1		1		
Pneumonia mycoplasmal	1	1			1	1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumothorax	1	1			1	1
Poor quality product administered		1		1		
Posterior reversible encephalopathy syndrome		1				1
Presyncope	2	4	1	2	1	2
Product temperature excursion issue		1		1		
Product use issue	2	3	1	2	1	1
Protein C increased		1				1
Proteinuria	2	2	1	1	1	1
Pruritus	1	7	1	3		4
Pulmonary embolism	1	3			1	3
Pulmonary sepsis	1	1			1	1
Purpura	1	1			1	1
Pyrexia	9	28	5	12	4	16
Rash	1	3		1	1	2
Rash erythematous		1				1
Rash maculo-papular	1	1	1	1		
Rash papular		1				1
Rash pruritic		1				1
Renal colic		1				1
Renal infarct	1	1			1	1
Restlessness		1				1
Rhinalgia		1				1
Rhinorrhoea		1		1		
SARS-CoV-2 test positive		1		1		
Seizure	3	3			3	3
Shock		1				1
Sinus tachycardia		1				1
Skin plaque		1		1		
Skin reaction	1	2	1	1		1
Somnolence	1	3			1	3
Speech disorder		2				2
Status epilepticus	1	1			1	1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stress cardiomyopathy	1	1			1	1
Suffocation feeling		1				1
Supraventricular tachycardia		2				2
Swollen tongue	1	1			1	1
Syncope	1	1			1	1
Tachyarrhythmia		1				1
Tachycardia	2	13		2	2	11
Tachypnoea		1				1
Taste disorder		1		1		
Tension headache	1	1			1	1
Tetany	1	1			1	1
Thirst		1				1
Thrombocytopenia	1	2			1	2
Tinnitus	1	1	1	1		
Tonsillitis		1				1
Transient ischaemic attack		1				1
Tremor	1	4			1	4
Type 1 diabetes mellitus		1				1
Type II hypersensitivity		1				1
Urinary incontinence	1	2	1	1		1
Urticaria	4	7	3	3	1	4
Uterine contractions abnormal	1	1			1	1
Uterine spasm	1	1			1	1
Vaccination complication		2		2		
Vaccination failure	3	6			3	6
Vaccination site discolouration		1				1
Vaccination site erythema	1	1			1	1
Vaccination site haematoma		1		1		
Vaccination site haemorrhage		1		1		
Vaccination site hyperaesthesia	1	1			1	1
Vaccination site lymphadenopathy		1				1
Vaccination site oedema	1	1	1	1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	3	29	2	10	1	19
Vaccination site paraesthesia		1		1		
Vaccination site pruritus		1				1
Vaccination site reaction	1	1	1	1		
Vaccination site swelling		2		1		1
Vascular purpura	1	1			1	1
Venous thrombosis limb		1				1
Vertigo	2	9		4	2	5
Vision blurred	1	2			1	2
Visual field defect		1				1
Vomiting	7	20	5	8	2	12
Wheezing		2				2
White blood cell count decreased		1				1
	320	873	121	274	199	599

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		2		2		
Abdominal mass	1	1	1	1		
Abdominal pain	10	31	4	10	6	21
Abdominal pain lower		1				1
Abdominal pain upper	6	12	2	4	4	8
Abnormal loss of weight	2	2			2	2
Abnormal uterine bleeding	1	1	1	1		
Abortion spontaneous	1	8			1	8
Abscess of salivary gland	1	1			1	1
Acute coronary syndrome		3				3
Acute febrile neutrophilic dermatosis		1				1
Acute myocardial infarction		1				1
Acute polyneuropathy	1	1			1	1
Acute respiratory failure		1				1
Acute vestibular syndrome		2		1		1
Adrenal insufficiency		1				1
Ageusia		3		2		1
Aggression		1				1
Agitation	1	2			1	2
Alanine aminotransferase increased		1		1		
Allergy to vaccine		1				1
Amaurosis		1				1
Amaurosis fugax	1	1			1	1
Amenorrhoea		1				1
Amnesia	1	1	1	1		
Anaemia		1				1
Anaphylactic reaction	6	13			6	13
Anaphylactic shock	3	6			3	6
Anaphylactoid reaction		2				2
Angina pectoris	2	5			2	5
Angioedema	1	13			1	13
Ankylosing spondylitis	2	4			2	4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anosmia	1	3		1	1	2
Antinuclear ant body positive		1				1
Anxiety	4	9	2	4	2	5
Anxiety disorder		1		1		
Apathy	1	1	1	1		
Aphasia	1	3		1	1	2
Aphonia		1				1
Aphthous ulcer	1	3		1	1	2
Apnoea		1				1
Appendicitis	1	2			1	2
Arrhythmia	7	14			7	14
Arterial disorder		1				1
Arteriovenous fistula thrombosis	1	1			1	1
Arteritis	1	1			1	1
Arthralgia	16	66	9	29	7	37
Arthritis		3		1		2
Arthritis reactive		1				1
Aspartate aminotransferase increased		1		1		
Aspiration	1	1			1	1
Asthenia	48	207	25	76	23	131
Asthma	1	6			1	6
Asthmatic crisis	2	4			2	4
Ataxia		1				1
Atrial fibrillation	2	7			2	7
Aura		2				2
Autoimmune hepatitis		1				1
Autoimmune thyroiditis		1				1
Axillary pain	2	7	1	4	1	3
Back pain	4	11	1	3	3	8
Balance disorder	2	5	1	1	1	4
Behaviour disorder		1				1
Blepharitis	1	1			1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood alkaline phosphatase increased		1		1		
Blood glucose fluctuation		1		1		
Blood glucose increased		2		1		1
Blood pressure abnormal		1				1
Blood pressure decreased	2	8	1	2	1	6
Blood pressure fluctuation	1	1			1	1
Blood pressure increased	7	11	4	6	3	5
Blood pressure systolic decreased	1	1	1	1		
Blood pressure systolic increased		1				1
Blue toe syndrome		1		1		
Body temperature increased		4				4
Bone pain		1				1
Bone swelling		1		1		
Bradycardia	2	6			2	6
Breast haematoma	1	1			1	1
Breast induration		1				1
Breast mass		1				1
Breast pain		2				2
Breast swelling	1	1			1	1
Bruxism	1	1	1	1		
Burning sensation	4	8	1	3	3	5
Burn oesophageal	1	1	1	1		
Bursitis		1				1
Capillary fragility	1	1			1	1
Capillary leak syndrome	1	1			1	1
Cardiac discomfort		1				1
Cardiac failure		1				1
Cardio-respiratory arrest		2				2
Carotid artery stenosis	1	1			1	1
Cerebellar infarction	1	2			1	2
Cerebral haemorrhage		1				1
Cerebral ischaemia		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebrovascular accident	1	2			1	2
Cervical radiculopathy	1	1			1	1
Cervicobrachial syndrome		1		1		
Chest discomfort	5	20	1	6	4	14
Chest pain	7	34		1	7	33
Chest X-ray abnormal	1	2			1	2
Chillblains	2	3	2	2		1
Chills	23	105	16	42	7	63
Choking	1	2			1	2
Choking sensation	1	1			1	1
Chorioretinitis	1	1			1	1
Choroidal neovascularisation	1	1			1	1
Chromaturia		1				1
Clonic convulsion	1	1			1	1
Clonus	1	1			1	1
Cold sweat	2	5	2	3		2
Colitis ulcerative	1	2			1	2
Condition aggravated	5	15	2	3	3	12
Confusional state	1	5			1	5
Conjunctival haemorrhage		2				2
Conjunctivitis	1	4	1	3		1
Constipation	1	1	1	1		
Contraindicated product administered		1				1
Cough	2	18	1	5	1	13
COVID-19	17	60		14	17	46
COVID-19 pneumonia	1	2			1	2
C-reactive protein increased	1	6		3	1	3
Cutaneous vasculitis		1				1
Cyanosis	1	1			1	1
Cystitis	1	1			1	1
Cytomegalovirus infection		1				1
Cytomegalovirus test positive		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness unilateral		2				2
Death		2				2
Decreased appetite	2	14	1	7	1	7
Deep vein thrombosis	7	10			7	10
Dehydration	1	2			1	2
Delirium		1				1
Dermatitis allergic	1	1			1	1
Dermo-hypodermatitis		1				1
Diabetes insipidus	1	1			1	1
Diabetes mellitus inadequate control	1	4			1	4
Diabetic ketoacidosis		1				1
Diabetic ketosis	1	1			1	1
Diabetic metabolic decompensation	1	1			1	1
Diarrhoea	7	48	3	16	4	32
Diarrhoea haemorrhagic		1				1
Diplegia		1				1
Diplopia		2				2
Discomfort	5	15	2	7	3	8
Disease recurrence	3	14		1	3	13
Disorientation		1				1
Disseminated varicella zoster virus infection	1	1			1	1
Disturbance in attention	2	6	2	3		3
Dizziness	18	68	10	23	8	45
Drug eruption	1	1			1	1
Drug hypersensitivity		1				1
Drug ineffective	8	25			8	25
Dry mouth	1	3	1	1		2
Dysaesthesia	4	7	1	3	3	4
Dysarthria	1	3	1	2		1
Dysgeusia	7	16	5	6	2	10
Dyskinesia	2	3			2	3
Dyslipidaemia	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspepsia	1	4			1	4
Dysphagia	5	14	3	6	2	8
Dysphonia		1				1
Dyspnoea	13	45	3	8	10	37
Dyspnoea exertional		3		1		2
Dysstasia		2		1		1
Dysuria	1	1	1	1		
Ear infection		1				1
Ear pain	1	10		3	1	7
Ear swelling		2				2
Eating disorder		1		1		
Eczema		1		1		
Electric shock sensation	1	3		1	1	2
Electrocardiogram abnormal		1				1
Electrocardiogram repolarisation abnormality		1				1
Electrocardiogram ST segment elevation	1	2			1	2
Encephalitis viral		1				1
Enterocolitis haemorrhagic		1				1
Enthesopathy	1	1			1	1
Eosinophilic bronchitis		1				1
Epicondylitis	1	1	1	1		
Epilepsy	2	4			2	4
Epistaxis	3	7	1	2	2	5
Epstein-Barr virus test positive		1		1		
Eructation		2				2
Erythema	5	29	3	11	2	18
Erythema multiforme		2				2
Erythema nodosum		2		1		1
Euphoric mood		1		1		
Exposure during pregnancy	1	2	1	2		
Extensive swelling of vaccinated limb		7		6		1
Extrasystoles	1	2			1	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Extremity contracture	1	1			1	1
Eye haemorrhage		1				1
Eyelid oedema		4		3		1
Eye movement disorder	1	1			1	1
Eye oedema		1		1		
Eye pain	2	6	2	5		1
Eye swelling	1	1			1	1
Face injury	1	2			1	2
Face oedema	2	10		1	2	9
Facial neuralgia	1	1			1	1
Facial pain		1				1
Facial paralysis	10	32			10	32
Facial paresis		1		1		
Fall	4	12	1	1	3	11
Fatigue	30	123	18	50	12	73
Fat tissue increased		1		1		
Feeding disorder	2	2			2	2
Feeling abnormal	3	6	1	2	2	4
Feeling cold	3	6	2	3	1	3
Feeling drunk	1	2	1	1		1
Feeling hot	6	17	3	7	3	10
Feeling of body temperature change		1		1		
Fibrin D dimer increased		1				1
Fibroma		1		1		
Flank pain	1	1			1	1
Flushing	1	9		2	1	7
Focal dyscognitive seizures		1				1
Food craving		1				1
Formication		3		1		2
Frostbite		1		1		
Functional gastrointestinal disorder	1	1			1	1
Gait disturbance		2		1		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gait inability		2				2
Gastroenteritis	2	2	1	1	1	1
Gastrointestinal disorder	2	3	2	3		
Gastrointestinal motility disorder		1				1
Gastrointestinal pain		1				1
Gastrooesophageal reflux disease		2				2
Generalised anxiety disorder		1				1
Generalised tonic-clonic seizure	1	1			1	1
General physical health deterioration	2	3	1	1	1	2
Genital haemorrhage		1				1
Genital herpes		1				1
Gingival bleeding		1				1
Gingivitis		1				1
Glomerulonephritis		1				1
Glossitis		1		1		
Glossodynia	1	3		2	1	1
Goitre	1	1			1	1
Gout		1				1
Guillain-Barre syndrome		1				1
Haematemesis		1				1
Haematoma	2	4		1	2	3
Haematuria	1	1			1	1
Haemoglobinaemia	1	1			1	1
Haemophagocytic lymphohistiocytosis		1				1
Haemorrhagic stroke		1				1
Haemorrhoids thrombosed		1				1
Hair colour changes		1		1		
Hallucination		3				3
Hallucination, auditory		1				1
Hallucination, olfactory		1				1
Hallucination, visual		1				1
Headache	72	274	40	104	32	170

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Head injury	1	2			1	2
Heart rate decreased	1	2	1	2		
Heart rate increased	1	5	1	2		3
Heart rate irregular		1				1
Heavy menstrual bleeding	1	2	1	1		1
Hemiparaesthesia		2				2
Hemiparesis	1	5			1	5
Hepatic cytolysis	2	3			2	3
Hepatic enzyme increased	1	1	1	1		
Hepatic steatosis		1		1		
Hepatitis viral		1				1
Hepatocellular injury		1				1
Hepatomegaly	1	1			1	1
Herpes simplex		1		1		
Herpes zoster	11	25	8	11	3	14
Herpes zoster reactivation		1		1		
Hormone level abnormal		1				1
Hot flush	2	17	1	7	1	10
Hyperacusis		1		1		
Hyperaesthesia	2	7	2	3		4
Hyperbilirubinaemia		2				2
Hyperchlorhydria	1	1	1	1		
Hyperglycaemia	1	2			1	2
Hyperhidrosis	2	25	2	7		18
Hyperleukocytosis		1				1
Hypersensitivity	10	31		2	10	29
Hypersomnia		1				1
Hypertension	29	107	2	10	27	97
Hypertensive crisis	5	20			5	20
Hyperthermia	7	20	1	4	6	16
Hyperthyroidism		1				1
Hypertriglyceridaemia	1	1			1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperventilation		2		1		1
Hypoacusis		3				3
Hypoaesthesia	5	24	2	11	3	13
Hypoaesthesia oral		4				4
Hypoglycaemia	2	7		1	2	6
Hypokalaemia		1				1
Hypokinesia		2				2
Hypoperfusion		1				1
Hypotension	7	30	2	6	5	24
Hypothermia		4				4
Hypotonia		2				2
Hypoventilation		1				1
Hypoxia	1	1			1	1
Immune reconstitution inflammatory syndrome	1	1			1	1
Immune thrombocytopenia		2				2
Impaired work ability	1	13		3	1	10
Inappropriate schedule of product administration	2	4	2	3		1
Incorrect route of product administration	1	5	1	4		1
Induration		2		1		1
Infection		1				1
Inflammation		2		1		1
Influenza	5	22	1	4	4	18
Influenza like illness	54	222	21	44	33	178
Inhibitory drug interaction		1		1		
Injected limb mobility decreased	3	13	2	5	1	8
Injection site erythema		1		1		
Injection site pain		1		1		
Injection site paraesthesia		1		1		
Injection site pruritus		3		3		
Injection site reaction		1				1
Insomnia	3	13		3	3	10
Intermenstrual bleeding		2				2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
International normalised ratio increased	1	1			1	1
Intracardiac thrombus	1	1			1	1
Intracranial artery dissection	1	1			1	1
Intracranial pressure increased		1				1
Iridocyclitis		1				1
Irritability		1				1
Ischaemic stroke		3				3
Joint ankylosis	1	1	1	1		
Joint range of motion decreased	1	1			1	1
Joint swelling		2				2
Joint warmth		1				1
Ketoacidosis	1	1			1	1
Labile blood pressure	1	2			1	2
Labyrinthitis	1	1	1	1		
Lacrimation increased		2		1		1
Lactic acidosis		1				1
Language disorder	1	1			1	1
Laryngeal discomfort	1	2			1	2
Laryngeal oedema	2	7			2	7
Laryngeal stenosis	1	1			1	1
Laryngitis		1				1
Larynx irritation		1				1
Left ventricular hypertrophy		1				1
Lichen planus		1				1
Limb discomfort	2	6		3	2	3
Lip injury	1	1			1	1
Lip oedema	1	4		1	1	3
Lipoma		1				1
Lip pain	1	2			1	2
Lip pruritus		1				1
Lip swelling	2	5	2	2		3
Livedo reticularis	1	2			1	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Localised oedema	1	3
Local reaction		1
Logorrhoea		1
Loss of consciousness	10	24
Loss of personal independence in daily activities	2	4
Lung disorder		2
Lung opacity	1	1
Lymphadenitis	2	6
Lymphadenopathy	15	70
Lymphangitis		1
Lymph node pain	1	4
Lymphoedema	1	3
Macroglossia		2
Malaise	20	93
Maternal exposure during pregnancy	7	9
Memory impairment		3
Meningeal disorder	1	1
Meningitis		1
Meningitis aseptic	1	1
Menstruation delayed	2	2
Microembolism		1
Middle insomnia	2	4
Migraine	3	15
Migraine with aura		2
Mobility decreased		5
Mononeuropathy multiplex		1
Monoplegia	1	1
Morning sickness		1
Motor dysfunction	5	10
Movement disorder	1	2
Mucosal pain		1
Mucous stools		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	3
	1		
			1
		10	24
2	2		2
			2
		1	1
	2	2	4
10	35	5	35
			1
	1	1	3
	2	1	1
			2
7	28	13	65
4	5	3	4
			3
1	1		
			1
		1	1
2	2		
			1
		2	4
2	5	1	10
	2		
	1		4
			1
		1	1
	1		
2	3	3	7
1	1		1
	1		
	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Multiple sclerosis	2	2			2	2
Muscle contractions involuntary		1				1
Muscle contracture		4		1		3
Muscle discomfort	1	1			1	1
Muscle fatigue	1	2	1	1		1
Muscle spasms	4	7	2	4	2	3
Muscle spasticity	1	1			1	1
Muscle tightness		1		1		
Muscle twitching	1	1	1	1		
Muscular weakness	2	12		3	2	9
Musculoskeletal chest pain		2				2
Musculoskeletal pain		2		2		
Musculoskeletal stiffness	7	46	3	16	4	30
Myalgia	25	132	20	57	5	75
Myasthenia gravis	1	1			1	1
Myocardial infarction	2	4			2	4
Myocarditis	2	3			2	3
Myoclonus		1				1
Myositis		2				2
Nasal congestion	2	2	1	1	1	1
Nasal injury	1	1			1	1
Nasopharyngitis	1	3	1	3		
Nausea	34	144	19	57	15	87
Near death experience		1				1
Neck injury		1				1
Neck mass	1	1	1	1		
Neck pain	5	12	4	7	1	5
Nephropathy		1				1
Nephrotic syndrome	1	1			1	1
Nerve injury		1				1
Neuralgia	5	21	3	8	2	13
Neuralgic amyotrophy	2	2			2	2

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuritis		1				1
Neurological symptom	1	1			1	1
Neuromuscular pain		1				1
Neuromyopathy		2				2
Neuropathy peripheral	1	3			1	3
Neutropenia	1	2			1	2
Neutrophil count decreased		1		1		
Neutrophil count increased		1		1		
Nightmare	1	1	1	1		
Night sweats	1	4	1	3		1
Noninfective chorioretinitis		1				1
N-terminal prohormone brain natriuretic peptide increased		1		1		
Nystagmus		1				1
Ocular discomfort	1	2	1	2		
Ocular hyperaemia		1				1
Odynophagia		3		2		1
Oedema		3		1		2
Oedema peripheral		3				3
Off label use	1	5	1	5		
Ophthalmic herpes zoster	3	3			3	3
Ophthalmic migraine		2		1		1
Oral dysaesthesia		3		2		1
Oral herpes	1	2	1	2		
Oral pain	1	2	1	2		
Oral pruritus		2				2
Oropharyngeal discomfort	1	3		1	1	2
Oropharyngeal oedema		1				1
Oropharyngeal pain	2	8	2	7		1
Orthostatic hypotension	1	5		1	1	4
Otitis externa		1		1		
Overdose		1		1		

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oxygen saturation decreased	2	4	1	1	1	3
Pain	17	74	6	23	11	51
Pain in extremity	15	42	9	14	6	28
Pain in jaw	1	2			1	2
Pain of skin		1				1
Palatal disorder	1	1	1	1		
Palatal oedema		4				4
Pallor		4				4
Palpitations	4	25	1	12	3	13
Pancreatitis	2	2			2	2
Pancreatitis acute	1	4			1	4
Panic attack		1				1
Paraesthesia	28	89	10	32	18	57
Paraesthesia oral	4	15	3	6	1	9
Paralysis	1	2			1	2
Paresis		1				1
Pelvic pain		4				4
Periarthritis		1				1
Pericardial effusion		1				1
Pericarditis	8	15			8	15
Peripheral coldness	1	3	1	1		2
Peripheral ischaemia		1				1
Peripheral sensory neuropathy		1				1
Peripheral swelling	2	7	1	1	1	6
Pernio-like erythema		2		2		
Petechiae	1	2	1	1		1
Pharyngeal paraesthesia	1	4	1	3		1
Pharyngeal swelling	1	1	1	1		
Pharyngitis		1		1		
Phlebitis	2	3			2	3
Phlebitis superficial	1	1	1	1		
Phonophobia		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Photophobia		4				4
Photopsia	1	1			1	1
Photosensitivity reaction		1		1		
Piloerection		1				1
Pneumonia		1				1
Pneumonia respiratory syncytial viral	1	1			1	1
Pneumonia viral	1	1			1	1
Pneumonitis		1		1		
Pneumothorax		1				1
Polyarthrits	1	1			1	1
Polydipsia		2		1		1
Polymenorrhoea	2	2	2	2		
Polyneuropathy	2	4			2	4
Polyp		1		1		
Poor quality product administered		12		12		
Portal vein thrombosis	1	1			1	1
Post herpetic neuralgia	1	1	1	1		
Post lumbar puncture syndrome	1	1	1	1		
Post vaccination syndrome	1	1			1	1
Presyncope	7	19	2	4	5	15
Proctitis		1		1		
Product administered at inappropriate site	1	2	1	1		1
Productive cough	1	2			1	2
Product preparation issue	3	6	3	6		
Product temperature excursion issue		12		12		
Product use issue		3		3		
Pruritus	10	29	2	8	8	21
Psychomotor hyperactivity		1				1
Psychomotor skills impaired		2		1		1
Pulmonary embolism	7	12			7	12
Pulmonary pain		1				1
Punctate keratitis	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Purpura		2				2
Pyelonephritis	1	1			1	1
Pyelonephritis acute	1	1			1	1
Pyrexia	44	177	29	65	15	112
Radial nerve palsy		1				1
Radiculitis brachial	1	1			1	1
Rash	3	21		8	3	13
Rash erythematous	1	3			1	3
Rash macular		2				2
Rash maculo-papular	1	4		1	1	3
Rash papular		3		1		2
Rash pruritic	2	3	1	1	1	2
Raynaud's phenomenon		3		2		1
Rectal haemorrhage		1				1
Red blood cell sedimentation rate increased		2		2		
Renal pain		1				1
Respiratory depression		2				2
Respiratory disorder	1	3			1	3
Respiratory distress		1				1
Respiratory tract infection		1				1
Respiratory tract oedema		1				1
Restlessness	1	2	1	1		1
Retinal vein occlusion		2				2
Rhabdomyolysis		1				1
Rheumatic disorder		1				1
Rheumatoid arthritis	2	4			2	4
Rhinitis	1	5	1	4		1
Rhinorrhoea	1	3			1	3
Rotator cuff syndrome		1				1
Salivary hypersecretion	1	2	1	1		1
SARS-CoV-2 ant body test positive		3		3		
SARS-CoV-2 test positive		2		1		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sciatica	1	1	1	1		
Scleral disorder		1				1
Scleritis		1				1
Sedation		1		1		
Seizure	1	3			1	3
Sense of oppression	1	1			1	1
Sensorimotor disorder		1				1
Sensory disturbance	2	4	1	2	1	2
Sensory loss	1	4	1	3		1
Shoulder injury related to vaccine administration		1				1
Sickle cell anaemia with crisis	1	1			1	1
Sinus pain		1				1
Sinus tachycardia	2	8	2	3		5
Sjogren's syndrome		1				1
Skin discolouration		1				1
Skin induration		1				1
Skin lesion		1				1
Skin mass		1				1
Skin plaque	1	3	1	2		1
Skin reaction		3		3		
Skin tightness	1	1	1	1		
Skin warm	1	1			1	1
SLE arthritis		1				1
Sleep disorder	3	9	2	4	1	5
Sluggishness		1		1		
Somnolence	1	2			1	2
Speech disorder	2	5			2	5
Stress	1	4		2	1	2
Stupor	1	1	1	1		
Subclavian vein thrombosis	1	1			1	1
Subileus		1				1
Sudden hearing loss	1	4			1	4

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			Nonserious		Serious	
			I	C	I	C
Suffocation feeling	1	1			1	1
Supraventricular extrasystoles		1				1
Supraventricular tachycardia		1				1
Suspected COVID-19		2		1		1
Swelling	1	4	1	3		1
Swelling face	1	2			1	2
Swelling of eyelid	1	2	1	1		1
Swollen tongue	1	3	1	1		2
Syncope	2	14			2	14
Synovial cyst		1				1
Systemic lupus erythematosus		1				1
Tachyarrhythmia	1	2		1	1	1
Tachycardia	28	83	4	13	24	70
Tachypnoea		1				1
Tendon disorder		1				1
Tendonitis		3				3
Tension	1	1	1	1		
Tetany		1				1
Therapeutic response unexpected		1		1		
Thermohypoaesthesia		1		1		
Thirst		1				1
Throat irritation	1	3	1	2		1
Throat tightness	2	4	2	2		2
Thrombocytopenia	2	3			2	3
Thrombocytopenic purpura		1				1
Thrombophlebitis superficial	3	9		1	3	8
Thrombosis	2	4			2	4
Thymoma	1	1			1	1
Thyroiditis	1	1			1	1
Tinnitus	8	19	4	7	4	12
Tongue biting	1	1			1	1
Tongue discomfort		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue movement disturbance		1				1
Tongue oedema		4		2		2
Tongue paralysis		1				1
Tonic clonic movements		2				2
Tonsillitis	1	2			1	2
Tooth loss	1	1			1	1
Toxicity to various agents		1				1
Toxic skin eruption	1	2			1	2
Tracheal pain	1	1			1	1
Transaminases increased	1	2			1	2
Transient ischaemic attack	3	5			3	5
Tremor	4	16	3	6	1	10
Trigeminal neuralgia	1	2	1	1		1
Troponin increased	1	5		1	1	4
Type 1 diabetes mellitus		1				1
Type I hypersensitivity		2				2
Type III immune complex mediated reaction		1				1
Ulnar nerve palsy		1				1
Underdose	3	5	3	5		
Urinary incontinence		2				2
Urticaria	9	28	4	9	5	19
Uterine contractions during pregnancy	1	1			1	1
Vaccination complication		1				1
Vaccination failure	12	24			12	24
Vaccination site erythema	8	17	5	10	3	7
Vaccination site exfoliation		1				1
Vaccination site granuloma		1				1
Vaccination site haematoma	1	3			1	3
Vaccination site hyperaesthesia		1				1
Vaccination site hypersensitivity		3		3		
Vaccination site induration		5		5		
Vaccination site inflammation	4	8	1	2	3	6

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site joint pain		1				1
Vaccination site movement impairment	1	8	1	3		5
Vaccination site nodule		2				2
Vaccination site oedema	2	5	1	2	1	3
Vaccination site pain	33	150	24	80	9	70
Vaccination site paraesthesia	3	8	2	6	1	2
Vaccination site pruritus	2	7	2	4		3
Vaccination site rash		2		1		1
Vaccination site reaction	2	6	2	3		3
Vaccination site recall reaction		1		1		
Vaccination site swelling	4	10	2	5	2	5
Vaccination site warmth		4		1		3
Vaginal haemorrhage		1				1
Vascular pain		1		1		
Vascular purpura		1		1		
Vascular rupture	1	1			1	1
Vascular stenosis		1				1
Vasculitis		1				1
Vasoplegia syndrome	1	1			1	1
Venous thrombosis		1				1
Venous thrombosis limb		1				1
Ventricular arrhythmia		1				1
Ventricular extrasystoles		5		1		4
Ventricular tachycardia		1				1
Vertigo	15	40	4	11	11	29
Vertigo positional		1				1
Vestibular disorder		1				1
Vestibular neuritis	2	3			2	3
Viral infection	1	1			1	1
Vision blurred		7		1		6
Visual field defect		1				1
Visual impairment	1	5		1	1	4

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vocal cord paralysis	1	1			1	1
Vomiting	11	60	4	12	7	48
Weight decreased	2	4	1	2	1	2
Wheezing	1	1	1	1		
White blood cell count decreased		1		1		
Wrist fracture	1	1			1	1
Wrong product administered	1	1	1	1		
	1,303	4,803	516	1504	787	3299

* I=Interval, C=Cumulative
* AE=Adverse Event
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal distension	1	5	1	2		3
Abdominal pain	11	59	6	27	5	32
Abdominal pain upper	2	14	1	5	1	9
Abdominal rigidity		2				2
Abnormal sensation in eye		1		1		
Abscess		1		1		
Accommodation disorder		1				1
Acne		1		1		
Activated partial thromboplastin time prolonged		1				1
Activated partial thromboplastin time shortened		1				1
Acute coronary syndrome	2	6			2	6
Acute kidney injury	2	2			2	2
Acute myocardial infarction	1	3			1	3
Acute pulmonary oedema	1	2			1	2
Acute respiratory failure		4				4
Acute sinusitis		1		1		
Acute vestibular syndrome		2				2
Adrenal mass		1		1		
Ageusia	2	7	1	4	1	3
Aggression	1	1			1	1
Agitation		1				1
Air embolism		1				1
Alanine aminotransferase increased		3		3		
Alexia		1				1
Allergy to vaccine		1		1		
Altered state of consciousness		1				1
Amaurosis fugax		1				1
Amnesia	1	2			1	2
Anaemia	1	1			1	1
Anaemia macrocytic		1				1
Anaesthesia oral	2	4	2	2		2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	2	18			2	18
Anaphylactic shock		2				2
Aneurysm ruptured	1	1			1	1
Angina pectoris	1	5			1	5
Angioedema	4	19			4	19
Ankylosing spondylitis		3				3
Anosmia		4		2		2
Anterograde amnesia	1	1			1	1
Anxiety		1				1
Aortic arteriosclerosis		1				1
Aortic dissection		2				2
Apathy		2		1		1
Aphasia	2	5			2	5
Aphonia		1				1
Aphthous ulcer		2		1		1
Appendicitis	1	1			1	1
Areflexia	1	1			1	1
Arrhythmia	2	15			2	15
Arrhythmia supraventricular		1				1
Artery dissection	1	1			1	1
Arthralgia	27	136	18	60	9	76
Arthritis	1	2			1	2
Aspartate aminotransferase increased		2		2		
Asphyxia		1				1
Asthenia	62	303	51	135	11	168
Asthma	1	6			1	6
Asthmatic crisis	1	3			1	3
Asymptomatic COVID-19	3	6		1	3	5
Ataxia	1	3	1	2		1
Atrial fibrillation	6	23			6	23
Atrial flutter		2				2
Atrioventricular block first degree	1	1			1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Atypical pneumonia		1				1
Autoimmune thyroiditis	1	3			1	3
Axillary mass	1	1	1	1		
Axillary pain	2	9	1	5	1	4
Back pain	4	28	3	13	1	15
Balance disorder		14		3		11
Basedow's disease		1				1
Bed rest		1				1
Bedridden	1	1			1	1
Behaviour disorder	1	1			1	1
Bell's palsy	1	1			1	1
Bicytopenia	1	1			1	1
Blastocystis infection		1				1
Blindness unilateral		1				1
Blister		1		1		
Block vertebra	1	1			1	1
Blood alkaline phosphatase increased	1	2		1	1	1
Blood bilirubin increased	1	1			1	1
Blood creatinine abnormal		1				1
Blood culture positive		1				1
Blood folate decreased		1				1
Blood glucose increased		3		3		
Blood osmolarity increased	1	1	1	1		
Blood pressure abnormal	1	2	1	1		1
Blood pressure decreased	1	8	1	2		6
Blood pressure fluctuation	1	2			1	2
Blood pressure inadequately controlled	1	1			1	1
Blood pressure increased	5	18	4	7	1	11
Blood pressure systolic increased	1	1			1	1
Blood thyroid stimulating hormone increased		2		1		1
Blood urine present		1		1		
Body temperature decreased		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Body temperature increased	2	5	2	4		1
Bone pain		1		1		
Bone swelling	1	2	1	2		
Bradycardia		8				8
Bradyphrenia		1				1
Brain oedema	1	1			1	1
Breast pain		2		1		1
Bronchial secretion retention		1		1		
Bronchitis	2	5	1	3	1	2
Bronchopneumopathy		1		1		
Bronchospasm	1	4			1	4
Bundle branch block left		2				2
Burning sensation	3	13	2	5	1	8
Burn oesophageal	1	1			1	1
Burn oral cavity		1				1
Bursal fluid accumulation		1		1		
Bursal haematoma		1				1
Bursitis		3		1		2
Calculus bladder	1	1	1	1		
Camptocormia	1	1	1	1		
Cardiac arrest	2	5			2	5
Cardiac disorder		1				1
Cardiac failure		4				4
Cardiac fibrillation		1				1
Cardiogenic shock		1				1
Cardio-respiratory arrest	2	8			2	8
Cardiovascular disorder	2	3	1	1	1	2
Carotid artery occlusion		1				1
Cataract		1				1
Catatonia	1	1			1	1
Cell death		1				1
Cellulitis		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebellar syndrome	1	1			1	1
Cerebral artery stenosis		1				1
Cerebral haematoma		1				1
Cerebral haemorrhage		1				1
Cerebral hyperperfusion syndrome		1				1
Cerebral thrombosis		1				1
Cerebrovascular accident	5	10			5	10
Cervical radiculopathy	1	2		1	1	1
Cervicobrachial syndrome	1	1	1	1		
Chest discomfort	8	31	3	15	5	16
Chest pain	14	57	6	17	8	40
Chillblains	4	6	4	6		
Chills	23	155	19	69	4	86
Choking		1				1
Choking sensation		1		1		
Cholecystitis acute	1	1			1	1
Cholestasis	1	1			1	1
Cholestatic liver injury		1				1
Chondrocalcinosis		1				1
Chronic obstructive pulmonary disease		2				2
Circulatory collapse		1				1
Clumsiness	1	2	1	1		1
Cognitive disorder		1		1		
Cold sweat	1	4		1	1	3
Colitis		1		1		
Complex regional pain syndrome		1		1		
Condition aggravated	6	25	2	7	4	18
Conduction disorder		1				1
Conductive deafness	1	1			1	1
Confusional state		7		2		5
Conjunctival haemorrhage	1	7			1	7
Conjunctival irritation		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctivitis		2				2
Constipation		2		1		1
Contusion	3	3	3	3		
Coordination abnormal		1				1
Coronary artery disease		1				1
Coronary artery occlusion	1	1			1	1
Coronary artery stenosis		2				2
Cough	6	39	6	20		19
COVID-19	31	98	1	20	30	78
COVID-19 pneumonia	2	5			2	5
C-reactive protein increased	2	12		4	2	8
Cutaneous vasculitis		1				1
Cyanosis		1				1
Cystic lymphangioma		1				1
Cystitis		1				1
Cytomegalovirus infection		1				1
Daydreaming		2				2
Deafness	2	6			2	6
Deafness unilateral	2	5			2	5
Death	2	6			2	6
Decreased appetite	7	31	4	12	3	19
Deep vein thrombosis	14	20			14	20
Dehydration	2	3		1	2	2
Delirium		3				3
Delusion		1		1		
Demyelination		1				1
Depressed level of consciousness		3				3
Depression		2		1		1
Dermal cyst		2		1		1
Dermatitis bullous	2	2			2	2
Dermatitis exfoliative generalised		1				1
Detachment of retinal pigment epithelium	1	1			1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diabetes insipidus		1				1
Diabetes mellitus inadequate control	1	4			1	4
Diabetic ketoacidosis	1	2			1	2
Diarrhoea	18	73	12	29	6	44
Diarrhoea haemorrhagic	1	2			1	2
Diplopia	3	7		1	3	6
Discomfort	5	20	5	8		12
Disease recurrence	3	21		2	3	19
Disinhibition		1				1
Disorientation		6		2		4
Disturbance in attention		2				2
Diverticulum intestinal		1		1		
Dizziness	13	92	11	36	2	56
Dizziness postural		1				1
Drooling		1		1		
Drug hypersensitivity		1				1
Drug ineffective	17	49			17	49
Dry eye		4		3		1
Dry mouth		2		1		1
Dry throat		2		1		1
Dysaesthesia	1	10		4	1	6
Dysarthria	1	3			1	3
Dysgeusia	6	17	6	12		5
Dysgraphia		1				1
Dyshidrotic eczema		2		2		
Dyskinesia	1	1			1	1
Dyspepsia	1	3			1	3
Dysphagia	5	12	3	4	2	8
Dysphemia		3				3
Dysphonia	2	9	2	5		4
Dyspnoea	18	74	9	21	9	53
Dyspnoea at rest		2				2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea exertional	3	10		2	3	8
Dysstasia	2	4	1	2	1	2
Dysuria		3				3
Ear discomfort		1				1
Ear disorder		2		2		
Ear pain	1	7		3	1	4
Ear swelling		1		1		
Ecchymosis	1	1	1	1		
Eczema		2		1		1
Electric shock sensation	2	3	2	2		1
Electrocardiogram QRS complex prolonged	1	1			1	1
Electrocardiogram repolarisation abnormality		1				1
Electrocardiogram ST segment depression		1				1
Electrocardiogram ST-T segment abnormal		1				1
Electrocardiogram T wave abnormal		1		1		
Emphysema		1				1
Encephalitis	1	1			1	1
Encephalopathy	1	1			1	1
Enterocolitis haemorrhagic	1	1			1	1
Eosinophil count increased		1		1		
Epicondylitis	1	1			1	1
Epilepsy	4	8			4	8
Epistaxis	3	8	2	3	1	5
Epstein-Barr virus infection reactivation		1				1
Erectile dysfunction		2				2
Eructation	1	2	1	1		1
Erysipelas	1	4			1	4
Erythema	4	35	4	18		17
Erythema of eyelid		1		1		
Escherichia test positive		1		1		
Euphoric mood	1	1	1	1		
Extensive swelling of vaccinated limb		4		4		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Extrasystoles		10		2		8
Extremity necrosis		1				1
Eye contusion		1		1		
Eye haemorrhage		1				1
Eye injury		1				1
Eye irritation	2	3	1	2	1	1
Eyelid disorder	1	2	1	1		1
Eyelid function disorder		1				1
Eyelid injury	1	1			1	1
Eyelid myoclonus		1				1
Eyelid oedema		6		1		5
Eyelid ptosis		1				1
Eye movement disorder		1		1		
Eye oedema	1	1			1	1
Eye pain	1	6	1	3		3
Eye swelling		3		1		2
Face oedema		10		1		9
Facial pain		4		1		3
Facial paralysis	14	45			14	45
Facial paresis	1	4		2	1	2
Faeces discoloured	1	1	1	1		
Fall	4	17		4	4	13
Familial mediterranean fever		1				1
Fatigue	30	168	23	85	7	83
Fear		1		1		
Feeding disorder	1	1			1	1
Feeling abnormal	5	17	5	12		5
Feeling cold	1	13	1	6		7
Feeling drunk		4		2		2
Feeling hot	3	12	3	7		5
Feeling jittery	1	1	1	1		
Feeling of body temperature change		2				2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Flank pain		1				1
Flushing	3	6	3	4		2
Folate deficiency	1	1	1	1		
Foot deformity		1		1		
Formication	1	7		3	1	4
Functional gastrointestinal disorder		2				2
Gait disturbance	1	10	1	3		7
Gait inability		4				4
Gamma-glutamyltransferase increased	1	5		4	1	1
Gastric pH decreased		1		1		
Gastric ulcer	1	1			1	1
Gastric ulcer haemorrhage	1	1			1	1
Gastritis		1				1
Gastroenteritis	1	2		1	1	1
Gastrointestinal disorder	3	7	3	3		4
Gastrointestinal hypermotility		1		1		
Gastrointestinal inflammation		1				1
Gastrointestinal motility disorder		1		1		
Gastrointestinal pain		2		2		
Gastrooesophageal reflux disease		1		1		
Gaze palsy		1				1
Generalised onset non-motor seizure		1				1
Generalised tonic-clonic seizure	1	3			1	3
General physical health deterioration	1	6			1	6
Genital herpes		1				1
Gingival discomfort		1				1
Gingival pain	1	1	1	1		
Glomerular filtration rate decreased		1				1
Glossodynia	1	1	1	1		
Groin pain		1		1		
Gross motor delay		1				1
Guillain-Barre syndrome	1	2			1	2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemarthrosis		1				1
Haematochezia		2				2
Haematoma		4				4
Haematuria		2				2
Haemolysis	1	1			1	1
Haemolytic anaemia		1				1
Haemorrhagic transformation stroke	1	1			1	1
Haemorrhoids		1				1
Hallucination		2				2
Hallucination, visual		1				1
Headache	95	417	72	203	23	214
Head discomfort	1	5	1	4		1
Head injury		2				2
Heart rate increased	1	10		5	1	5
Heart rate irregular		1				1
Heart sounds abnormal		1				1
Hemianopia		2				2
Hemianopia homonymous		1				1
Hemiparaesthesia		1				1
Hemiparesis	2	3			2	3
Hemiplegia	1	1			1	1
Henoch-Schonlein purpura		1		1		
Hepatic cytolysis	1	5			1	5
Hepatic enzyme abnormal	1	1			1	1
Hepatic enzyme increased		2		1		1
Hepatic infarction		1				1
Hepatic steatosis	1	1	1	1		
Hepatitis cholestatic		2				2
Hepatitis infectious mononucleosis		1				1
Hepatocellular injury		1				1
Hepatomegaly	1	2	1	1		1
Herpangina		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes ophthalmic		2				2
Herpes pharyngitis		1				1
Herpes simplex	2	5	2	3		2
Herpes zoster	27	51	19	28	8	23
Herpes zoster meningoradiculitis	1	1			1	1
Herpes zoster reactivation	1	1	1	1		
Hoffmann's sign		1		1		
Horner's syndrome		1				1
Hot flush	7	23	4	12	3	11
Hyperaesthesia	1	3	1	2		1
Hyperaesthesia eye	1	1	1	1		
Hyperhidrosis	7	34	3	11	4	23
Hyperhomocysteinaemia	1	1	1	1		
Hyperkalaemia		1				1
Hyperleukocytosis		1				1
Hypermetabolism	1	1			1	1
Hypersensitivity	2	34	1	17	1	17
Hypersomnia		1		1		
Hypertension	43	187	11	37	32	150
Hypertensive crisis	8	39			8	39
Hypertensive encephalopathy		1				1
Hypertensive urgency		1				1
Hyperthermia	4	18	2	6	2	12
Hyperthyroidism		1				1
Hypertrophic cardiomyopathy		1				1
Hyperventilation		1		1		
Hypoaesthesia	11	26	5	11	6	15
Hypoaesthesia eye	1	1	1	1		
Hypoaesthesia oral		3		1		2
Hypocalcaemia	1	1			1	1
Hypokalaemia		4				4
Hypokinesia		3		1		2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypotension	7	34	1	7	6	27
Hypotensive crisis		1				1
Hypothermia	2	5			2	5
Hypothyroidism		1				1
Hypotonia		1		1		
Hypoventilation	1	1			1	1
Illness		3				3
Immune thrombocytopenia	1	3			1	3
Immunodeficiency		1				1
Immunoglobulin G4 related disease	1	1			1	1
Immunoglobulins increased		1		1		
Impaired work ability	4	12			4	12
Inappropriate schedule of product administration	2	5	2	5		
Incorrect dose administered		1		1		
Incorrect route of product administration	1	7	1	7		
Induration		1				1
Infection	1	3		2	1	1
Infectious mononucleosis		1				1
Inflammation	4	12	1	3	3	9
Inflammatory pain		2				2
Influenza	7	31	4	8	3	23
Influenza like illness	46	254	27	61	19	193
Initial insomnia		1				1
Injected limb mobility decreased	3	15	1	2	2	13
Injection site pain		1		1		
Injection site rash		1				1
Injection site reaction		1		1		
Injury	1	1	1	1		
Inner ear disorder		1				1
Insomnia	4	31	3	12	1	19
International normalised ratio abnormal		1				1
International normalised ratio increased	1	1	1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Intervertebral disc disorder		1		1		
Intervertebral disc protrusion		1		1		
Intestinal ischaemia		1				1
Intracranial aneurysm	1	1			1	1
Iridocyclitis	1	1			1	1
Irritability		1		1		
Ischaemia		1				1
Ischaemic stroke	12	18			12	18
Joint ankylosis		1				1
Joint effusion		2		1		1
Joint range of motion decreased	1	3			1	3
Joint stiffness		4		1		3
Joint swelling	2	8	1	4	1	4
Jugular vein thrombosis	1	2			1	2
Lacrimation increased		4		3		1
Lacunar infarction		1				1
Laryngeal discomfort	2	5	1	2	1	3
Laryngeal dyspnoea		1				1
Laryngeal oedema	2	6			2	6
Laryngitis allergic		1				1
Laryngospasm	1	1			1	1
Left atrial dilatation	1	1			1	1
Left ventricular dilatation		2		2		
Left ventricular hypertrophy		1				1
Leukoencephalopathy		1				1
Leukopenia		4				4
Ligament sprain		1				1
Limb discomfort		4		2		2
Lipase increased		2		2		
Lip erythema	1	1	1	1		
Lip haematoma		1				1
Lip haemorrhage		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lip oedema		5				5
Lipoma		1				1
Lip pruritus	1	1	1	1		
Lip swelling	1	2			1	2
Livedo reticularis	1	2	1	1		1
Liver disorder	1	1			1	1
Localised oedema		2		1		1
Local reaction		2		2		
Loss of consciousness	9	33			9	33
Loss of libido		1		1		
Loss of personal independence in daily activities	2	2			2	2
Lung cancer metastatic	1	1			1	1
Lung disorder	3	5	1	2	2	3
Lung opacity		1				1
Lyme disease		1				1
Lymphadenitis	1	6		4	1	2
Lymphadenopathy	14	59	11	29	3	30
Lymphangitis		1				1
Lymph node pain		3		1		2
Lymphocyte count decreased		1				1
Lymphopenia		5		2		3
Macroglossia		1				1
Macule		1		1		
Madarosis		1				1
Malaise	24	128	15	45	9	83
Malignant peritoneal neoplasm	1	1			1	1
Malnutrition	1	2		1	1	1
Mastitis	1	1			1	1
Mean cell volume decreased		1		1		
Medication error		1		1		
Melaena	2	2			2	2
Memory impairment		4				4

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Meniere's disease	1	1			1	1
Meningeal disorder		1				1
Meningitis aseptic		1				1
Meningoencephalitis herpetic	1	2			1	2
Mental disorder	1	1			1	1
Mental fatigue		1				1
Mental impairment		1				1
Mesenteric vein thrombosis		1				1
Metamorphopsia		1		1		
Middle insomnia		4		3		1
Migraine	3	17	3	10		7
Migraine with aura		1				1
Mitral valve incompetence		1				1
Mobility decreased		5		2		3
Monoclonal gammopathy		1				1
Monoclonal immunoglobulin increased		1				1
Mononucleosis syndrome		1				1
Monoparesis	2	4	2	2		2
Monoplegia	1	3			1	3
Motor dysfunction	2	9	1	1	1	8
Mouth haemorrhage	1	1	1	1		
Mouth ulceration		2		2		
Movement disorder	1	1	1	1		
Mucous stools	1	1			1	1
Muscle contractions involuntary		2		1		1
Muscle contracture		2		1		1
Muscle fatigue		2		1		1
Muscle hypertrophy	1	1			1	1
Muscle rigidity	1	1	1	1		
Muscle spasms	2	11	1	4	1	7
Muscle tightness	2	2	2	2		
Muscular weakness	3	14	2	5	1	9

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal chest pain		3		2		1
Musculoskeletal disorder	1	2	1	2		
Musculoskeletal pain	2	2			2	2
Musculoskeletal stiffness	8	44	5	10	3	34
Myalgia	48	203	42	102	6	101
Myalgia intercostal		1				1
Myasthenia gravis	1	2			1	2
Mydriasis		1				1
Myelitis		1				1
Myocardial infarction	2	6			2	6
Myocardial ischaemia	1	4			1	4
Myocardial necrosis marker increased		1				1
Myocarditis	1	4			1	4
Myoclonus		1				1
Myokymia		1		1		
Myositis		1		1		
Nasal congestion	1	3		2	1	1
Nasal herpes		1				1
Nasopharyngitis	3	8	2	5	1	3
Nausea	37	189	27	80	10	109
Neck pain	8	23	5	10	3	13
Neoplasm		1				1
Nephrotic syndrome	1	1			1	1
Nerve compression		1		1		
Nerve conduction studies abnormal		1		1		
Nerve injury	1	1			1	1
Nervousness		1				1
Nervous system disorder		1				1
Neuralgia	5	19	2	5	3	14
Neuritis		2		2		
Neuroleptic malignant syndrome	1	1			1	1
Neurological symptom	1	2	1	1		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuropathy peripheral	1	2			1	2
Neutropenia	1	3			1	3
Neutrophil count decreased		1				1
Neutrophil count increased		1		1		
Neutrophilia		2		2		
Neutrophilic dermatosis		1				1
Nightmare		1		1		
Night sweats	1	4			1	4
Nitrite urine present		1		1		
Nocturia		1		1		
Noninfective gingivitis		1				1
Normochromic anaemia		1				1
Normochromic normocytic anaemia		1		1		
Nystagmus	1	2	1	1		1
Obstructive airways disorder		1		1		
Occipital neuralgia	1	3			1	3
Ocular discomfort	1	4	1	4		
Ocular hyperaemia	1	4			1	4
Oedema	1	4		1	1	3
Oedema mouth		1				1
Oedema mucosal	1	1	1	1		
Oedema peripheral	4	10	2	3	2	7
Oesophageal pain		1				1
Oesophageal spasm		1				1
Off label use	2	9	2	9		
Oliguria		1		1		
Ophthalmic herpes zoster	5	9			5	9
Optic neuritis		1				1
Oral herpes	2	3	2	2		1
Oral pain	1	2	1	2		
Oral pruritus		1		1		
Orbital haematoma	1	1			1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oropharyngeal candidiasis		1				1
Oropharyngeal discomfort	1	3	1	3		
Oropharyngeal pain	4	9	4	9		
Oropharyngeal swelling		1				1
Orthopnoea		2				2
Osteoarthritis		3		2		1
Otolithiasis		1				1
Ovarian cancer	1	1			1	1
Overdose	1	5	1	5		
Oxygen saturation decreased	3	14		3	3	11
Oxygen saturation increased		1				1
Pain	17	93	10	46	7	47
Painful respiration		1				1
Pain in extremity	20	85	11	38	9	47
Pain in jaw	1	3	1	1		2
Pain of skin		4		2		2
Palatal oedema	1	2	1	1		1
Pallor	2	10	1	1	1	9
Palpitations	14	37	5	13	9	24
Pancreatic steatosis	1	1	1	1		
Pancreatitis	1	2			1	2
Pancreatitis acute	2	5			2	5
Pancytopenia	1	1			1	1
Papilloedema	1	1			1	1
Papule		2		1		1
Paraesthesia	17	73	11	24	6	49
Paraesthesia ear		1				1
Paraesthesia oral	2	7	2	4		3
Paralysis	2	2			2	2
Paresis		1				1
Parkinsonism		1				1
Parosmia	1	3		2	1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Parotitis	1	2			1	2
Partial seizures		1				1
Pelvic venous thrombosis	1	1			1	1
Peptic ulcer		1				1
Periarthritis	1	2			1	2
Pericardial effusion	3	4			3	4
Pericarditis	3	7			3	7
Periorbital haematoma		1				1
Peripheral artery thrombosis	1	3			1	3
Peripheral coldness	2	3	1	2	1	1
Peripheral ischaemia		1				1
Peripheral swelling	3	14	1	5	2	9
Peripheral venous disease		1				1
Persistent depressive disorder		1				1
Persistent postural-perceptual dizziness		1				1
Petechiae	1	3	1	2		1
Petit mal epilepsy		3				3
Phaeochromocytoma		1				1
Pharyngeal disorder		1				1
Pharyngeal oedema		1				1
Pharyngeal paraesthesia	2	4	2	2		2
Pharyngeal swelling		1		1		
Phlebitis	2	4			2	4
Phlebitis superficial		1		1		
Photophobia		7		2		5
Photopsia		2		1		1
Platelet count decreased		1				1
Platelet count increased	1	1			1	1
Pleural effusion	1	2		1	1	1
Pleurisy	1	1	1	1		
Pleuropericarditis	1	1			1	1
Pneumonia	1	5			1	5

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonia aspiration		5				5
Pollakiuria		1		1		
Polyarthrits	1	2			1	2
Polychondritis		1				1
Polyneuropathy		2				2
Poor quality product administered		23		23		
Portal vein thrombosis	1	2			1	2
Presyncope	8	23	5	12	3	11
Priapism		1				1
Procalcitonin increased	1	1			1	1
Proctitis haemorrhagic	1	1			1	1
Product administration error		1				1
Productive cough		1		1		
Product preparation error		2		2		
Product preparation issue	1	7	1	7		
Product temperature excursion issue		23		23		
Product use issue		6		6		
Proteinuria		1				1
Pruritus	8	32	7	18	1	14
Pseudodementia		1				1
Psoriasis		2		1		1
Psoriatic arthropathy		1				1
Psychomotor skills impaired		1		1		
Pulmonary alveolar haemorrhage		1				1
Pulmonary embolism	17	30			17	30
Pulmonary infarction		1				1
Pulmonary oedema		2				2
Pulpitis dental		1				1
Purpura	3	3	2	2	1	1
Pyrexia	54	278	38	123	16	155
Rales		2				2
Rash	8	30	4	15	4	15

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash erythematous	1	7		3	1	4
Rash macular		2				2
Rash maculo-papular	1	7	1	6		1
Rash papular		2		2		
Rash pruritic	1	4	1	3		1
Rash pustular		1				1
Rash vesicular		1		1		
Raynaud's phenomenon	1	1	1	1		
Rebound effect		1				1
Rectal haemorrhage	1	2			1	2
Red blood cells urine positive		1				1
Renal colic		1				1
Renal cyst haemorrhage		1				1
Renal disorder	1	1			1	1
Renal failure		1				1
Renal impairment		1				1
Renal infarct		1				1
Renal pain		1				1
Respiratory disorder	1	5			1	5
Respiratory distress	1	4			1	4
Respiratory failure		2				2
Respiratory rate increased		1		1		
Restlessness		3		2		1
Retinal artery occlusion		3				3
Retinal detachment	1	1			1	1
Rheumatic fever		1				1
Rheumatoid arthritis	1	6			1	6
Rhinitis	1	3	1	2		1
Rhinorrhoea		6		2		4
Rhonchi		1				1
Rib fracture	1	1			1	1
Road traffic accident		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rotator cuff syndrome	1	2
Salivary hypersecretion	1	3
SARS-CoV-2 ant body test negative		3
SARS-CoV-2 ant body test positive		1
SARS-CoV-2 test positive	1	6
Scan abdomen abnormal	1	1
Sciatica	1	4
Seizure	1	5
Sense of oppression		1
Sensorimotor disorder		1
Sensory disturbance	1	5
Sensory loss		1
Sepsis	1	2
Septic shock		1
Serum ferritin increased	1	1
Shoulder injury related to vaccine administration	1	1
Sinus arrest		1
Sinusitis	1	3
Sinus tachycardia		5
Sjogren's syndrome		2
Skin disorder		1
Skin lesion	1	1
Skin mass		1
Skin plaque		1
Skin reaction		1
Skin warm	1	3
Sleep apnoea syndrome		1
Sleep disorder	1	5
Sleep disorder due to general medical condition, insomnia type	1	3
Snoring		1
Somnolence		11

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	2		
1	2		1
	3		
	1		
	3	1	3
		1	1
1	2		2
		1	5
			1
			1
	1	1	4
	1		
		1	2
			1
		1	1
		1	1
			1
		1	3
	1		4
			2
	1		
1	1		
	1		
	1		
			1
1	3		
	1		
	1	1	4
1	2		1
	1		
	3		8

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Speech disorder	4	6	2	2	2	4
Spinal osteoarthritis		1		1		
Spinal pain		3				3
Splenic infarction		1				1
Spondylitis		1				1
Spondyloarthropathy		1		1		
Staphylococcal bacteraemia		1				1
Status epilepticus		1				1
Status migrainosus		1				1
Stomatitis		1				1
Stress cardiomyopathy		1				1
Subarachnoid haemorrhage		1				1
Subdural haematoma		1				1
Sudden death	1	3			1	3
Sudden hearing loss		1				1
Sudden onset of sleep		1				1
Suffocation feeling	1	5	1	2		3
Suicidal ideation		1				1
Sunburn		1				1
Supraventricular extrasystoles		2				2
Supraventricular tachycardia	1	4			1	4
Suspected COVID-19	1	2			1	2
Swelling	2	3	2	2		1
Swelling face	1	1	1	1		
Swollen tongue	1	4		2	1	2
Syncope	2	9			2	9
Synovial cyst	2	3	1	1	1	2
Synovitis	1	1			1	1
Tachyarrhythmia	1	2			1	2
Tachycardia	21	96	9	34	12	62
Tachypnoea		4				4
Target skin lesion		1				1

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Temporal lobe epilepsy		1				1
Temporomandibular joint syndrome		1		1		
Tendon disorder	1	2	1	1		1
Tendonitis	3	6	1	3	2	3
Tendon pain	1	3	1	3		
Tenosynovitis		1		1		
Tension		2				2
Tension headache		1				1
Thermal burns of eye		1				1
Thirst		3		2		1
Throat irritation	1	4	1	2		2
Throat tightness	2	4	2	2		2
Thrombocytopenia	5	12			5	12
Thrombocytosis		1		1		
Thrombophlebitis	2	6	1	2	1	4
Thrombophlebitis superficial	4	6		1	4	5
Thrombosed varicose vein		1				1
Thrombosis	4	7			4	7
Thrombosis mesenteric vessel		1				1
Thyroiditis subacute	1	1			1	1
Thyroid mass		1		1		
Tinnitus	5	30	4	9	1	21
Tongue biting		1		1		
Tongue coated		1				1
Tongue injury		1		1		
Tongue oedema		2		1		1
Tongue spasm	1	1	1	1		
Tonsillar hypertrophy		1		1		
Tonsillitis	2	2			2	2
Toothache	1	2	1	1		1
Torticollis	1	2	1	1		1
Toxicity to various agents		1				1

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Transient global amnesia		1				1
Transient ischaemic attack	3	8			3	8
Transplant rejection	1	1			1	1
Tremor	6	24	4	9	2	15
Trigeminal neuralgia	1	1			1	1
Trismus		1		1		
Troponin increased	1	1			1	1
Type I hypersensitivity	1	1			1	1
Type III immune complex mediated reaction	1	1			1	1
Underdose	1	6	1	6		
Upper respiratory tract congestion	1	1	1	1		
Urinary retention		1				1
Urinary tract discomfort		1		1		
Urine odour abnormal		1		1		
Urticaria	13	37	5	16	8	21
Urticaria chronic		1				1
Uveitis		1				1
Vaccination complication	1	3		1	1	2
Vaccination failure	24	32			24	32
Vaccination site abscess		1		1		
Vaccination site bruising		1		1		
Vaccination site cellulitis		1				1
Vaccination site coldness		1		1		
Vaccination site discharge		1				1
Vaccination site discomfort		1				1
Vaccination site erythema	4	27	3	16	1	11
Vaccination site haematoma	1	6	1	5		1
Vaccination site haemorrhage		1				1
Vaccination site hypersensitivity	1	12	1	12		
Vaccination site induration	2	8	2	6		2
Vaccination site infection		1				1
Vaccination site inflammation	6	18	6	11		7

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site joint movement impairment		1				1
Vaccination site joint pain	1	2	1	1		1
Vaccination site mass		1		1		
Vaccination site movement impairment	2	11		5	2	6
Vaccination site nodule		1		1		
Vaccination site oedema		10		3		7
Vaccination site pain	39	207	35	121	4	86
Vaccination site papule		1		1		
Vaccination site paraesthesia	1	4	1	1		3
Vaccination site pruritus	2	14	2	8		6
Vaccination site rash		1				1
Vaccination site reaction	2	11		6	2	5
Vaccination site swelling	2	11	2	8		3
Vaccination site thrombosis		1				1
Vaccination site urticaria	1	1	1	1		
Vaccination site warmth		9		5		4
Vagus nerve disorder		1				1
Vascular purpura	1	4		1	1	3
Vasculitis	1	1	1	1		
Vasodilatation		1		1		
Vena cava thrombosis		1				1
Venous thrombosis	1	3			1	3
Venous thrombosis limb		1				1
Ventricular extrasystoles	1	5		2	1	3
Ventricular fibrillation		4				4
Ventricular tachycardia	1	2			1	2
Vertigo	19	72	11	28	8	44
Vertigo positional	1	7			1	7
Vestibular disorder	1	3	1	2		1
Vestibular neuronitis	1	7			1	7
Viral infection		2		1		1
Viral pharyngitis	1	1			1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vision blurred	3	9	2	5	1	4
Visual acuity reduced		3				3
Visual field defect	2	2			2	2
Visual impairment	3	8	1	1	2	7
Vitreous floaters	1	1			1	1
Vomiting	16	77	12	27	4	50
Vomiting projectile	1	1			1	1
Von Willebrand's factor activity decreased		1				1
Walking disability		2				2
Weight decreased		7		1		6
Weight increased	1	1			1	1
Wheezing		1				1
White blood cell count increased	1	2	1	1		1
Withdrawal hypertension	1	2		1	1	1
Wrist fracture	1	1			1	1
	1,613	6,972	816	2592	797	4380

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* AE=Adverse Event
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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2		2		
Abdominal distension	1	2		1	1	1
Abdominal pain	12	23	6	9	6	14
Abdominal pain lower		1		1		
Abdominal pain upper	5	13	2	5	3	8
Abdominal wall haematoma	1	1			1	1
Acne		1		1		
Acquired haemophilia		1				1
Activated partial thromboplastin time abnormal		1				1
Activated partial thromboplastin time prolonged	1	1			1	1
Acute abdomen		1				1
Acute coronary syndrome	7	11			7	11
Acute generalised exanthematous pustulosis	1	1			1	1
Acute kidney injury	5	12			5	12
Acute myeloid leukaemia		1				1
Acute myocardial infarction		1				1
Acute pulmonary oedema	4	8			4	8
Acute respiratory distress syndrome	5	11			5	11
Acute respiratory failure	1	3			1	3
Acute vestibular syndrome	1	2			1	2
Affective disorder	1	1			1	1
Ageusia	3	4	2	3	1	1
Aggression		1				1
Agitation	2	7		1	2	6
Alanine aminotransferase increased	2	3			2	3
Albuminuria		1				1
Allodynia	1	1	1	1		
Altered state of consciousness		2				2
Amaurosis	1	1			1	1
Amaurosis fugax		1				1
Amnesia	2	4			2	4
Amyotrophy		1				1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia	6	12	2	4	4	8
Anaphylactic reaction		2				2
Anaphylactic shock		2				2
Anaphylactoid reaction	1	1			1	1
Anaphylactoid shock	1	1			1	1
Aneurysm	1	1			1	1
Angina pectoris	1	5			1	5
Angina unstable		1				1
Angioedema	9	23	1	1	8	22
Anosmia	1	2		1	1	1
Anterograde amnesia		1				1
Anti-neutrophil cytoplasmic antibody positive vasculitis		1				1
Antinuclear ant body positive	1	1	1	1		
Antisynthetase syndrome		1				1
Anuria	1	1			1	1
Anxiety	5	12	3	5	2	7
Aortic arteriosclerosis	2	2	1	1	1	1
Aortic valve incompetence		1				1
Apathy	1	2		1	1	1
Aphasia	5	12		1	5	11
Aphthous ulcer	1	3	1	2		1
Apnoea	1	1			1	1
Appendicitis	1	2			1	2
Appendicitis perforated		1				1
Application site warmth		1		1		
Arrhythmia	17	39			17	39
Arrhythmia supraventricular		1				1
Arterial thrombosis	1	3			1	3
Arteriosclerosis	1	2	1	1		1
Arteriosclerosis coronary artery		1				1
Arteriovenous malformation	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	20	49	11	23	9	26
Arthritis	1	7		3	1	4
Arthritis reactive		3				3
Arthropathy		1		1		
Aspartate aminotransferase increased	1	2			1	2
Asphyxia	1	1			1	1
Asthenia	42	127	27	56	15	71
Asthma	2	4	1	1	1	3
Asthmatic crisis	3	6			3	6
Asymptomatic COVID-19		4		1		3
Ataxia	1	4	1	3		1
Atelectasis		1				1
Atrial f brillation	23	51			23	51
Atrial flutter	1	1			1	1
Atrial thrombosis	1	1			1	1
Atrioventricular block		4				4
Atrioventricular block complete	3	3			3	3
Atrioventricular block second degree	1	2			1	2
Autoimmune thyroiditis	1	2			1	2
Back pain	4	14	3	7	1	7
Bacteraemia	1	1			1	1
Bacterial infection		1				1
Bacterial pyelonephritis		1				1
Bacterial sepsis		1				1
Balance disorder	8	11	4	5	4	6
B-cell lymphoma		1				1
Behaviour disorder	1	3			1	3
Bell's palsy	2	3			2	3
Benign prostatic hyperplasia	2	3	2	3		
Biliary colic	1	1	1	1		
Bilirubin conjugated increased		1		1		
Bladder dysfunction	1	1	1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blindness	1	2			1	2
Blindness unilateral	1	1			1	1
Blister		2				2
Blood alkaline phosphatase increased		1		1		
Blood bilirubin abnormal		1		1		
Blood bilirubin increased	1	2	1	2		
Blood bilirubin unconjugated increased		1		1		
Blood blister	1	1			1	1
Blood creatinine increased	2	2	1	1	1	1
Blood glucose decreased	1	1			1	1
Blood glucose increased	1	4		2	1	2
Blood immunoglobulin G decreased	1	1	1	1		
Blood lactate dehydrogenase increased	3	4	2	3	1	1
Blood lactic acid increased	1	1			1	1
Blood loss anaemia		1				1
Blood parathyroid hormone increased		1		1		
Blood pressure decreased	3	6	3	5		1
Blood pressure fluctuation	1	2		1	1	1
Blood pressure inadequately controlled	1	2			1	2
Blood pressure increased	6	11	2	4	4	7
Blood pressure systolic decreased		2		1		1
Blood pressure systolic increased		2				2
Blood thyroid stimulating hormone increased		2		1		1
Blood uric acid increased		1		1		
Blood urine present	2	2	2	2		
Body temperature increased		2				2
Bone abscess		1				1
Bone pain		1				1
Bone swelling	1	1			1	1
Bradycardia	2	15			2	15
Bradyphrenia		1				1
Brain natriuretic peptide increased	1	2			1	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Brain oedema	2	2			2	2
Brain stem stroke	1	1			1	1
Bronchial obstruction		1				1
Bronchitis	2	3			2	3
Bronchospasm	2	3	1	1	1	2
Bundle branch block right		3		1		2
Burning sensation	2	6	1	4	1	2
Bursitis	1	1			1	1
Carcinoembryonic antigen increased		1				1
Cardiac arrest	3	12			3	12
Cardiac discomfort		1		1		
Cardiac disorder		2		1		1
Cardiac failure	5	17			5	17
Cardiac failure acute		1				1
Cardiogenic shock	3	3			3	3
Cardiomegaly	2	2			2	2
Cardiomyopathy		1				1
Cardiopulmonary failure	1	1			1	1
Cardio-respiratory arrest	8	21			8	21
Cardio-respiratory distress		1				1
Carotid artery occlusion	1	3			1	3
Carotid artery thrombosis		2				2
Cell death		1				1
Cerebellar stroke	1	1			1	1
Cerebellar syndrome	2	2			2	2
Cerebral amyloid angiopathy	2	2			2	2
Cerebral arteriosclerosis	1	2	1	1		1
Cerebral atrophy	1	2			1	2
Cerebral disorder	1	1	1	1		
Cerebral haematoma		2				2
Cerebral haemorrhage	1	3			1	3
Cerebral infarction	4	10			4	10

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral venous thrombosis	1	1			1	1
Cerebrovascular accident	18	33			18	33
Cervical cord compression		1				1
Cervical radiculopathy	1	2	1	1		1
Chest discomfort	8	21	2	8	6	13
Chest injury	1	1			1	1
Chest pain	27	53	9	13	18	40
Chillblains	4	4	4	4		
Chills	23	56	16	32	7	24
Choking sensation	1	1	1	1		
Cholelithiasis	2	2	1	1	1	1
Cholestasis	5	8			5	8
Cholestatic liver injury	1	1			1	1
Chromaturia		1		1		
Chronic kidney disease	1	1			1	1
Chronic obstructive pulmonary disease	1	6			1	6
Circulatory collapse	1	3			1	3
Citrobacter infection		1				1
Claudication of jaw muscles		1				1
Clumsiness	1	1	1	1		
Cluster headache		1				1
Cognitive disorder	1	1	1	1		
Cold sweat		3		3		
Coma	2	7			2	7
Condition aggravated	12	29	2	4	10	25
Confusional state	8	16		1	8	15
Congestive cardiomyopathy		1				1
Conjunctival haemorrhage	2	8			2	8
Conjunctival hyperaemia		1		1		
Conjunctivitis		1				1
Constipation	6	9	6	9		
Contusion	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronary artery disease		1				1
Coronary artery occlusion	2	3			2	3
Coronary artery stenosis	2	2			2	2
Coronavirus infection		1		1		
Cough	7	24	4	10	3	14
COVID-19	32	85	2	10	30	75
COVID-19 pneumonia	3	10			3	10
Cranial nerve paralysis	1	1			1	1
C-reactive protein increased	4	19	2	9	2	10
Crohn's disease		1				1
Crying	1	1	1	1		
Cryoglobulins present	1	1	1	1		
Cutaneous lupus erythematosus		1				1
Cutaneous vasculitis	1	1			1	1
Cyanosis		2				2
Deafness	1	4			1	4
Deafness neurosensory		1				1
Deafness unilateral		5				5
Death	3	25			3	25
Decreased appetite	8	21	4	8	4	13
Decreased interest		1				1
Decubitus ulcer		3		1		2
Deep vein thrombosis	55	69			55	69
Defect conduction intraventricular		1				1
Dehydration	1	6		1	1	5
Delirium	1	3			1	3
Depressed level of consciousness	2	5			2	5
Depressed mood	1	1	1	1		
Dermabrasion		1		1		
Dermatitis bullous		1				1
Dermatitis exfoliative generalised		1				1
Dermatomyositis		2				2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermo-hypodermatitis		3				3
Diabetes mellitus	4	7			4	7
Diabetes mellitus inadequate control	1	5			1	5
Diabetic hyperosmolar coma	1	1			1	1
Diabetic ketosis		1				1
Diabetic metabolic decompensation		1				1
Diarrhoea	24	60	9	25	15	35
Dilatation ventricular	1	1	1	1		
Diplopia	4	10			4	10
Discomfort	7	17	3	4	4	13
Disease progression	1	1			1	1
Disease recurrence	14	33			14	33
Disorientation		4		1		3
Disseminated intravascular coagulation		1				1
Disturbance in attention	4	4	2	2	2	2
Diverticulitis		2				2
Diverticulum intestinal	1	1			1	1
Dizziness	26	51	10	18	16	33
Dizziness postural		2				2
Drop attacks	1	2			1	2
Drug eruption		1		1		
Drug ineffective	12	33	1	1	11	32
Drug interaction	1	2	1	2		
Drug reaction with eosinophilia and systemic symptoms		1				1
Dry mouth	1	3		1	1	2
Dysaesthesia	1	3	1	2		1
Dysarthria	5	11	3	4	2	7
Dyschromatopsia	1	1			1	1
Dysgeusia	1	3	1	2		1
Dysgraphia	1	2	1	1		1
Dyskinesia	1	2			1	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyslipidaemia		1		1		
Dysmetria	1	2			1	2
Dyspepsia	2	3	1	1	1	2
Dysphagia	3	4	1	2	2	2
Dysphonia	1	1			1	1
Dyspnoea	39	68	12	18	27	50
Dyspnoea at rest		3				3
Dyspnoea exertional	3	11	1	1	2	10
Dysstasia	1	4			1	4
Ear haemorrhage		1		1		
Ear pain		3		1		2
Ecchymosis	3	3	2	2	1	1
Eczema		1				1
Electric shock sensation		1				1
Electrocardiogram QRS complex prolonged	1	2			1	2
Electrocardiogram ST segment elevation	1	1			1	1
Electrocardiogram T wave inversion		1				1
Electroencephalogram abnormal		1				1
Embolic stroke	1	2			1	2
Embolism	1	1			1	1
Encephalitis		1				1
Enlarged uvula		1				1
Enteritis	1	1			1	1
Enterococcal infection		1				1
Enthesopathy	1	1			1	1
Eosinophilia	1	5			1	5
Epilepsy	4	10			4	10
Epistaxis	11	17	1	5	10	12
Epstein-Barr virus infection reactivation	2	2			2	2
Epstein-Barr virus test positive	1	1			1	1
Erectile dysfunction		1				1
Eructation		1				1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erysipelas	1	4			1	4
Erythema	10	30	7	16	3	14
Erythema multiforme	1	1			1	1
Erythema nodosum		1				1
Erythema of eyelid		1				1
Escherichia urinary tract infection	1	3			1	3
Extrapyramidal disorder		1		1		
Extrasystoles	1	7		3	1	4
Eye haemorrhage	1	4			1	4
Eye irritation		2		1		1
Eyelid haematoma		1		1		
Eyelid oedema	1	3	1	1		2
Eyelid ptosis		1		1		
Eye movement disorder	2	2	1	1	1	1
Eye pain	3	3	2	2	1	1
Eye swelling	1	1			1	1
Face injury	2	3			2	3
Face oedema	1	7			1	7
Facial asymmetry		1				1
Facial bones fracture	1	1			1	1
Facial pain	2	3	2	2		1
Facial paralysis	26	53			26	53
Facial paresis		1				1
Faeces discoloured		1		1		
Faeces soft		1		1		
Fall	15	31	4	6	11	25
Fatigue	27	90	17	53	10	37
Fear of death		1				1
Febrile bone marrow aplasia	1	1			1	1
Feeding disorder	1	1			1	1
Feeling abnormal	1	4	1	2		2
Feeling cold	2	6		2	2	4

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling drunk	1	4			1	4
Feeling hot		5		1		4
Feeling of body temperature change		1		1		
Femur fracture		1				1
Fibrin D dimer increased	8	11	1	1	7	10
Flatulence	1	3	1	2		1
Fluid overload	1	1			1	1
Flushing	1	3		1	1	2
Focal dyscognitive seizures		1				1
Folate deficiency	1	1	1	1		
Food aversion		1				1
Formication	1	1	1	1		
Gait disturbance	9	14	5	9	4	5
Gait inability	2	3	1	2	1	1
Gamma-glutamyltransferase increased		4		3		1
Gastric ulcer	1	1			1	1
Gastritis erosive		1				1
Gastroenteritis	1	2			1	2
Gastrointestinal disorder	3	4	3	4		
Gastrointestinal haemorrhage		2				2
Gastrointestinal motility disorder		1		1		
Gastrointestinal pain		2		1		1
Gastrointestinal sounds abnormal		1		1		
Gastrointestinal wall thickening		1		1		
Gastrooesophageal reflux disease	1	2	1	2		
Gaze palsy		1				1
Generalised tonic-clonic seizure	2	6			2	6
General physical health deterioration	5	15	3	4	2	11
Giant cell arteritis	1	4			1	4
Gingival bleeding	1	1	1	1		
Glycosylated haemoglobin increased	1	2		1	1	1
Gout		1		1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Guillain-Barre syndrome	1	3			1	3
Haematemesis		1				1
Haematochezia		1				1
Haematoma	2	5		1	2	4
Haematoma muscle	1	2			1	2
Haematuria	1	2			1	2
Haemodynamic instability	1	2		1	1	1
Haemoglobin decreased		2		2		
Haemophagocytic lymphohistiocytosis		1				1
Haemoptysis		2				2
Haemorrhage		1				1
Haemorrhagic stroke	3	5			3	5
Haemorrhagic transformation stroke	2	2			2	2
Haemorrhoids thrombosed	1	1			1	1
Haemothorax		1				1
Hallucination		1				1
Hallucination, auditory		1				1
Hallucination, visual	2	2			2	2
Hand fracture	1	1			1	1
Headache	64	141	35	58	29	83
Head discomfort	2	3	1	2	1	1
Head injury	4	8			4	8
Heart rate decreased	2	3	1	2	1	1
Heart rate increased	4	6	2	2	2	4
Heart rate irregular		1				1
Heart sounds abnormal		1				1
Hemianaesthesia		1				1
Hemianopia homonymous		2				2
Hemiapraxia		1				1
Hemiataxia	1	1			1	1
Hemiparaesthesia	1	1			1	1
Hemiparesis	3	7			3	7

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hemiplegia	4	7			4	7
Hepatic cyst		1				1
Hepatic cyst infection		1				1
Hepatic cytolysis	4	8			4	8
Hepatic enzyme increased		1				1
Hepatic failure	1	1			1	1
Hepatic function abnormal	1	1			1	1
Hepatic haematoma		1				1
Hepatic infarction	1	1			1	1
Hepatic pain		1		1		
Hepatic steatosis	1	1	1	1		
Hepatitis	1	2			1	2
Hepatitis acute	1	2			1	2
Hepatitis B		1				1
Hepatitis E	2	2			2	2
Hepatocellular injury	1	2			1	2
Hepatojugular reflux		1		1		
Hepatomegaly	1	2			1	2
Herpes ophthalmic	1	1			1	1
Herpes simplex	1	1			1	1
Herpes simplex test positive	1	1			1	1
Herpes virus infection		1		1		
Herpes zoster	52	83	29	40	23	43
Herpes zoster cutaneous disseminated	1	1			1	1
Herpes zoster meningoencephalitis		2				2
Herpes zoster reactivation	1	1	1	1		
High density lipoprotein decreased	1	1	1	1		
Hippocampal atrophy		1		1		
Hot flush	1	8		4	1	4
Hyperaesthesia		2		2		
Hyperbilirubinaemia	1	3			1	3
Hypercalcaemia of malignancy		1		1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperchloraemia		1				1
Hypergammaglobulinaemia	1	1	1	1		
Hyperglycaemia	1	8		2	1	6
Hyperglycinaemia		1				1
Hyperhidrosis	4	17	1	7	3	10
Hyperkalaemia	1	3			1	3
Hyperleukocytosis		3				3
Hypermetropia	1	1			1	1
Hypernatraemia	2	4	1	2	1	2
Hyperpathia	1	1	1	1		
Hypersensitivity	4	14	1	4	3	10
Hypersensitivity pneumonitis	1	1			1	1
Hypersomnia		1		1		
Hypertension	92	204	6	18	86	186
Hypertensive crisis	12	60			12	60
Hypertensive encephalopathy	1	1			1	1
Hyperthermia	5	13	2	5	3	8
Hyperthyroidism		2				2
Hypertrophic cardiomyopathy		1				1
Hyperventilation	1	1			1	1
Hypervitaminosis B12		1				1
Hypoacusis	2	7		2	2	5
Hypoaesthesia	6	9	3	6	3	3
Hypoalbuminaemia	2	2	1	1	1	1
Hypocalcaemia	1	2			1	2
Hypogammaglobulinaemia	1	2			1	2
Hypoglycaemia	1	3	1	1		2
Hypokalaemia	2	3			2	3
Hyponatraemia	1	2	1	2		
Hypophagia		1		1		
Hypotension	7	32	1	5	6	27
Hypothermia	1	4			1	4

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypothyroidism	1	1			1	1
Hypotonia	1	3	1	1		2
Hypovitaminosis	1	1	1	1		
Hypovolaemic shock		1				1
Hypoxia	4	13			4	13
Hypoxic-ischaemic encephalopathy	1	1			1	1
Illrd nerve paralysis	2	3			2	3
Illness	2	2	2	2		
Illusion		1				1
Immune thrombocytopenia	6	8			6	8
Impaired driving ability	1	2			1	2
Inappropriate schedule of product administration	3	5	3	5		
Incoherent		1				1
Incorrect route of product administration	1	3	1	3		
Increased bronchial secretion		1				1
Infarction	1	2			1	2
Infection	2	2	1	1	1	1
Inflammation	9	17	4	8	5	9
Influenza	7	13	4	6	3	7
Influenza like illness	24	66	12	33	12	33
Injected limb mobility decreased	4	6	2	2	2	4
Injection site erythema		3		3		
Injection site haematoma	1	1	1	1		
Injection site haemorrhage	1	1	1	1		
Injection site oedema		1		1		
Injection site pain		2		2		
Injection site swelling		1		1		
Inner ear disorder		1		1		
Insomnia	6	21	4	14	2	7
International normalised ratio increased	1	4		1	1	3
Interstitial lung disease	4	5			4	5
Intestinal ischaemia	2	4			2	4

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Intestinal obstruction		1				1
Intracardiac thrombus		1				1
Ischaemic stroke	47	74			47	74
IVth nerve paralysis	1	1			1	1
Jaundice		1				1
Joint effusion	2	3	1	1	1	2
Joint stiffness	1	2			1	2
Joint swelling	1	1	1	1		
Jugular vein thrombosis	1	2			1	2
Ketonuria	1	1			1	1
Klebsiella infection		1				1
Laboratory test abnormal	1	1	1	1		
Lacrimation increased	1	1	1	1		
Lactic acidosis	1	1			1	1
Language disorder		2				2
Laryngeal discomfort	2	2			2	2
Laryngeal dyspnoea		1				1
Laryngeal oedema		1				1
Laryngeal stenosis	1	1			1	1
Laryngitis		1				1
Left ventricular failure	1	1			1	1
Lethargy	1	1	1	1		
Leukocyte alkaline phosphatase increased	1	1			1	1
Leukocytosis	1	3		1	1	2
Leukocyturia	1	2		1	1	1
Leukoencephalopathy		3				3
Leukopenia		1				1
Ligament sprain	1	1			1	1
Limb discomfort	6	7	4	5	2	2
Lip dry	1	1	1	1		
Lip erosion		1				1
Lip oedema		2				2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lip pain		1				1
Lip swelling	2	4	1	2	1	2
Lithiasis		1		1		
Livedo reticularis	2	5	2	3		2
Liver abscess	1	1			1	1
Liver function test abnormal	2	2	1	1	1	1
Liver function test increased		1				1
Liver injury	2	3			2	3
Loss of consciousness	21	46			21	46
Loss of personal independence in daily activities	3	3			3	3
Low density lipoprotein increased		1				1
Lower respiratory tract congestion	1	1			1	1
Lumbar puncture	1	1			1	1
Lung disorder	2	8		2	2	6
Lymphadenopathy	4	14	4	9		5
Lymphadenopathy mediastinal		1		1		
Lymphoedema	1	3	1	2		1
Lymphopenia	2	7	1	2	1	5
Major depression	1	1			1	1
Malaise	27	89	7	29	20	60
Malignant hypertension		1				1
Malignant peritoneal neoplasm	1	1			1	1
Malnutrition		1				1
Mediastinitis	1	1			1	1
Melaena	1	1			1	1
Memory impairment		1		1		
Meningioma	1	1			1	1
Meningitis aseptic	1	1			1	1
Meningorrhagia		1				1
Mental impairment	1	1			1	1
Mesenteric artery thrombosis	1	1			1	1
Mesenteric vein thrombosis	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Metabolic acidosis	2	2			2	2
Metamorphopsia	1	2	1	1		1
Microangiopathy	1	1			1	1
Microcytic anaemia	1	1			1	1
Middle insomnia		2				2
Migraine	1	3	1	1		2
Mixed liver injury	1	1			1	1
Mobility decreased	1	3			1	3
Monoclonal gammopathy		1				1
Mononeuropathy multiplex	1	1			1	1
Monoparesis		3		1		2
Monoplegia		1				1
Moraxella infection		1				1
Motor dysfunction	4	7	2	2	2	5
Mouth haemorrhage	1	2	1	2		
Mouth ulceration		1		1		
Movement disorder	1	1	1	1		
Multiple organ dysfunction syndrome	1	4			1	4
Multiple sclerosis relapse	1	1			1	1
Muscle fatigue		1		1		
Muscle rigidity		1		1		
Muscle spasms	4	7	3	4	1	3
Muscle twitching	1	1			1	1
Muscular weakness	3	10	1	5	2	5
Musculoskeletal chest pain	2	2	2	2		
Musculoskeletal disorder		1				1
Musculoskeletal pain	1	2		1	1	1
Musculoskeletal stiffness	6	12	5	8	1	4
Mutism		1				1
Myalgia	23	60	15	31	8	29
Myasthenia gravis	1	1			1	1
Myasthenia gravis crisis		1				1

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myelitis	1	1			1	1
Myelodysplastic syndrome		1				1
Myocardial infarction	9	15			9	15
Myocardial necrosis marker increased		1				1
Myocarditis	2	2			2	2
Myoclonus	2	4			2	4
Nasal congestion	2	2	1	1	1	1
Nasal discomfort	1	1			1	1
Nasopharyngitis		2		2		
Nausea	28	75	15	37	13	38
Near death experience		1				1
Neck pain	4	7	2	4	2	3
Needle issue		1		1		
Nephrotic syndrome		1				1
Nervous system disorder	2	5			2	5
Neuralgia	3	9	2	4	1	5
Neuralgic amyotrophy	1	2			1	2
Neurological decompensation	1	2			1	2
Neuromuscular pain		1		1		
Neuromyelitis optica spectrum disorder	1	1			1	1
Neuropathy peripheral	2	3			2	3
Neutropenia	2	6			2	6
Neutrophil count decreased	1	1	1	1		
Nightmare		1				1
Night sweats		1		1		
Nocturnal dyspnoea	1	1	1	1		
Normal pressure hydrocephalus		1				1
N-terminal prohormone brain natriuretic peptide increased	1	2	1	1		1
Nystagmus	1	2		1	1	1
Obstruction gastric		1				1
Occipital neuralgia	2	2	1	1	1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular myasthenia		1				1
Odynophagia		1		1		
Oedema	3	4	1	1	2	3
Oedema genital		1				1
Oedema mouth	1	1			1	1
Oedema peripheral	6	19	2	6	4	13
Oedematous pancreatitis	1	1			1	1
Oesophageal discomfort	1	1			1	1
Off label use	4	7	4	7		
Oliguria	1	1			1	1
Ophthalmic herpes zoster	9	15			9	15
Ophthalmic migraine		1				1
Optic ischaemic neuropathy		2				2
Oral discomfort	1	1	1	1		
Oropharyngeal discomfort	1	1	1	1		
Oropharyngeal pain	2	5	2	4		1
Orthopnoea		1				1
Orthostatic hypertension	1	1			1	1
Osteoarthritis	2	4		1	2	3
Otitis externa	1	1	1	1		
Overdose	3	5	3	5		
Oxygen saturation decreased	10	28	2	4	8	24
Pain	10	35	3	15	7	20
Painful respiration	2	2			2	2
Pain in extremity	23	42	11	23	12	19
Pain in jaw	1	4			1	4
Pallor	2	7	1	2	1	5
Palpitations	7	20	3	6	4	14
Pancreatic cyst	1	1			1	1
Pancreatitis	1	1			1	1
Pancreatitis acute	3	4			3	4
Pancytopenia	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Papule		1		1		
Paraesthesia	9	22	7	11	2	11
Paraesthesia oral	2	4	1	2	1	2
Paralysis	1	3			1	3
Paraplegia	1	1			1	1
Paresis		1				1
Parkinsonism		1				1
Parkinson's disease	1	1			1	1
Partial seizures		2				2
Parvovirus B19 test positive	1	1			1	1
PCO2 increased	1	1			1	1
Pemphigoid		3				3
Pericardial effusion	2	7			2	7
Pericarditis	5	12			5	12
Periorbital oedema		1				1
Periorbital pain		1				1
Peripheral artery thrombosis	1	1			1	1
Peripheral coldness	1	3	1	3		
Peripheral embolism		1				1
Peripheral ischaemia	3	7	1	1	2	6
Peripheral sensorimotor neuropathy	1	1			1	1
Peripheral swelling	3	7	1	3	2	4
Peripheral venous disease	1	2	1	2		
Peritonitis	3	3			3	3
Persecutory delusion		1				1
Petechiae	4	5	2	3	2	2
Pharyngeal oedema	1	1			1	1
Pharyngitis	2	2	1	1	1	1
Phlebitis	8	11	2	4	6	7
Phlebitis superficial		1		1		
Photophobia	1	2	1	1		1
Photopsia	1	3			1	3

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Physical examination abnormal	1	1	1	1		
Platelet count increased		1				1
Pleural effusion	6	8		1	6	7
Pleurisy		1				1
Pleuropericarditis	1	1			1	1
Pneumonia	1	7			1	7
Pneumonia aspiration	2	9			2	9
Pneumonia bacterial		3				3
Pneumonia moraxella		1				1
Pneumonia pneumococcal		1				1
Pneumonitis	1	1			1	1
Pneumothorax		1				1
Pollakiuria		1		1		
Polyarthrits	1	2			1	2
Polymyalgia rheumatica	3	4			3	4
Poor quality product administered		30		30		
Portal hypertension	1	1			1	1
Portal vein phlebitis	1	1			1	1
Portal vein thrombosis	3	3			3	3
Pre-existing condition improved	1	1	1	1		
Prerenal failure		1				1
Presbycusis		1		1		
Presyncope	4	8	1	2	3	6
Procalcitonin increased	1	2		1	1	1
Product administered at inappropriate site	1	1	1	1		
Productive cough		2		1		1
Product preparation error		1		1		
Product preparation issue	1	4	1	4		
Product temperature excursion issue		28		28		
Product use issue		2		2		
Prohormone brain natriuretic peptide increased	1	1			1	1
Prostatitis		3		1		2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Proteinuria		1				1
Prothrombin level abnormal		1				1
Pruritus	5	23	4	8	1	15
Pseudomonal bacteraemia	1	1			1	1
Pseudomonal sepsis	1	1			1	1
Psychomotor retardation		1				1
Pulmonary arterial hypertension	2	2			2	2
Pulmonary arterial pressure increased	1	1	1	1		
Pulmonary congestion		1				1
Pulmonary embolism	72	116			72	116
Pulmonary hypertension		1				1
Pulmonary infarction	3	3			3	3
Pulmonary oedema	1	4			1	4
Purpura	4	7		1	4	6
Pyelonephritis		1				1
Pyelonephritis acute	1	1			1	1
Pyrexia	51	149	32	70	19	79
Quadrantanopia	1	1			1	1
Quadriparesis	1	2			1	2
Rales	1	3	1	1		2
Rash	7	19	4	7	3	12
Rash erythematous	3	7	2	3	1	4
Rash macular		1				1
Rash maculo-papular	1	5		1	1	4
Rash papular		1				1
Rash pruritic		4		1		3
Raynaud's phenomenon	1	1	1	1		
Rectal haemorrhage	1	3			1	3
Red blood cell count decreased	1	1	1	1		
Renal artery thrombosis	1	1			1	1
Renal colic	2	2	1	1	1	1
Renal failure	5	8			5	8

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal impairment	1	1			1	1
Renal tubular necrosis	1	1			1	1
Respiratory alkalosis	1	3			1	3
Respiratory arrest		1				1
Respiratory disorder	2	3	1	1	1	2
Respiratory distress	3	11			3	11
Respiratory failure	2	6			2	6
Respiratory rate decreased	1	1			1	1
Respiratory tract infection	1	2			1	2
Restlessness		1				1
Retinal artery occlusion	3	3			3	3
Retinal detachment	2	2			2	2
Retinal fovea disorder		1				1
Retinal haemorrhage	2	2			2	2
Retinal vein occlusion	1	2			1	2
Retinal vein thrombosis	2	2	1	1	1	1
Retrograde amnesia		1				1
Rhabdomyolysis	1	4			1	4
Rheumatoid arthritis	2	6			2	6
Rheumatoid factor increased		1				1
Rheumatoid factor positive	1	1	1	1		
Rhinitis	2	2	2	2		
Rhinorrhoea	2	4	1	2	1	2
Rhonchi		1				1
Rib fracture		2				2
Right ventricular dilatation	1	1	1	1		
Right ventricular failure	1	1			1	1
Road traffic accident		4		1		3
Romberg test positive		1		1		
Salivary hypersecretion	1	1	1	1		
SARS-CoV-2 ant body test negative		4		4		
SARS-CoV-2 test false positive		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
SARS-CoV-2 test positive	1	4			1	4
Sciatica	1	1	1	1		
Scleritis	2	2			2	2
Seizure	2	15			2	15
Sense of oppression		1				1
Sensorimotor disorder		1				1
Sensory loss		4		1		3
Sepsis	3	8			3	8
Septic shock	2	5			2	5
Serum ferritin increased	1	2		1	1	1
Serum sickness		1				1
Shock	3	3			3	3
Shock haemorrhagic	1	3			1	3
Sinus bradycardia	1	1			1	1
Sinus disorder		1				1
Sinusitis		1				1
Sinus tachycardia		5		2		3
Skin discolouration		1		1		
Skin exfoliation		1				1
Skin fissures		1				1
Skin hyperpigmentation		1				1
Skin lesion	1	5		1	1	4
Skin reaction	1	1	1	1		
Sleep disorder	1	3	1	2		1
Sleep disorder due to general medical condition, insomnia type		1		1		
Snoring	1	1	1	1		
Somnolence	7	14	4	9	3	5
Speech disorder	2	5	1	2	1	3
Spinal cord infarction		1				1
Spinal cord ischaemia		1				1
Spinal osteoarthritis	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Spinal pain		1		1		
Splenic vein thrombosis	1	1			1	1
Sputum abnormal		1				1
Staphylococcal bacteraemia		2				2
Staphylococcal sepsis		1				1
Staring		1				1
Status epilepticus		4				4
Stereotypy		1				1
Sternal fracture		1				1
Stertor		1				1
Strabismus	1	1			1	1
Stress		2		2		
Stress cardiomyopathy		2				2
Subarachnoid haemorrhage		2				2
Subcutaneous haematoma	1	1	1	1		
Subdural haematoma	2	2			2	2
Subileus	1	1			1	1
Subretinal haematoma	1	1			1	1
Sudden death	7	24			7	24
Sudden hearing loss		3				3
Sudden onset of sleep		1				1
Suffocation feeling	1	1	1	1		
Suicidal ideation	1	1			1	1
Superinfection	1	1			1	1
Superinfection viral		1				1
Supraventricular extrasystoles	2	4	1	1	1	3
Supraventricular tachycardia	2	5			2	5
Suspected COVID-19		1				1
Swelling face	4	7	2	3	2	4
Symmetrical drug-related intertriginous and flexural exanthema	1	1			1	1
Syncope	8	17			8	17

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Synovial cyst	1	1	1	1		
Tachyarrhythmia		1				1
Tachycardia	20	63	3	15	17	48
Tachycardia paroxysmal		1				1
Tachypnoea		4				4
Tenderness		1		1		
Tendonitis	2	4	1	1	1	3
Tenosynovitis	1	1			1	1
Tension	3	3	2	2	1	1
Tension headache	1	1	1	1		
Terminal state		1				1
Testicular pain		1		1		
Therapeutic response unexpected	1	1	1	1		
Thirst		2		1		1
Throat irritation		3		2		1
Thrombocytopenia	11	20			11	20
Thrombocytosis	1	1			1	1
Thrombophlebitis	7	12	1	1	6	11
Thrombophlebitis superficial	12	14	1	2	11	12
Thrombosis	10	12			10	12
Thyroid mass	1	1	1	1		
Tinnitus	12	20	5	7	7	13
Tongue biting		1				1
Tongue discolouration	1	1			1	1
Tongue haematoma		2		2		
Tongue oedema	2	2			2	2
Tongue pruritus	1	1			1	1
Tonic clonic movements		4				4
Tonic convulsion		2				2
Torticollis		1		1		
Toxic skin eruption		1				1
Toxocariasis		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Toxoplasmosis		1		1		
Transient global amnesia	2	2			2	2
Transient ischaemic attack	15	23			15	23
Tremor	9	25	6	10	3	15
Tricuspid valve incompetence	1	2			1	2
Troponin abnormal	1	1			1	1
Troponin increased	1	7	1	3		4
Type 2 diabetes mellitus		1				1
Type I hypersensitivity		1				1
Ulcer	1	1			1	1
Ultrasound scan abnormal	1	1			1	1
Underdose	3	8	3	8		
Upper-airway cough syndrome		1				1
Urinary incontinence		2				2
Urinary tract infection	2	3	1	1	1	2
Urinary tract infection bacterial		1				1
Urticaria	5	17	5	8		9
Urticarial vasculitis	1	1			1	1
Uveitis	1	1			1	1
Uvulitis		1				1
Vaccination complication	1	1			1	1
Vaccination failure	20	39			20	39
Vaccination site abscess		1				1
Vaccination site dermatitis		1		1		
Vaccination site discomfort	1	1	1	1		
Vaccination site dysaesthesia		1				1
Vaccination site erythema	3	13	3	11		2
Vaccination site haematoma		2		1		1
Vaccination site hypersensitivity		2		2		
Vaccination site hypoaesthesia		1				1
Vaccination site induration	1	6	1	4		2
Vaccination site inflammation	1	5			1	5

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site joint inflammation		1				1
Vaccination site mass		2		1		1
Vaccination site movement impairment	2	3	1	1	1	2
Vaccination site oedema		4		3		1
Vaccination site pain	20	59	15	40	5	19
Vaccination site plaque		1				1
Vaccination site pruritus	2	7	2	4		3
Vaccination site reaction	1	5		3	1	2
Vaccination site swelling	3	6	3	4		2
Vaccination site urticaria	1	2	1	1		1
Vaccination site warmth		5		3		2
Varicella virus test positive	1	2			1	2
Varicella zoster virus infection	1	1			1	1
Varicose vein		1		1		
Vascular encephalopathy		1				1
Vascular graft thrombosis	2	2			2	2
Vascular occlusion	1	1			1	1
Vascular pain	1	1	1	1		
Vascular purpura	4	5	2	2	2	3
Vascular stent stenosis	1	1			1	1
Vasculitis	3	4	2	3	1	1
Vein rupture		1				1
Venous thrombosis	1	1			1	1
Venous thrombosis limb	4	6	1	1	3	5
Ventricular arrhythmia	1	1			1	1
Ventricular extrasystoles	2	4			2	4
Ventricular fibrillation	3	4			3	4
Ventricular hypokinesia		1				1
Ventricular tachycardia	3	7			3	7
Vertigo	18	44	7	14	11	30
Vertigo positional	2	5	1	1	1	4
Vestibular disorder		1				1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vestibular neuritis	2	2			2	2
Viral infection	1	2		1	1	1
Visceral venous thrombosis	1	1			1	1
Vision blurred	9	11	4	4	5	7
Visual acuity reduced	1	2			1	2
Visual field defect		1				1
Visual impairment	8	12	7	7	1	5
Vitamin D deficiency		1				1
Vlth nerve paralysis	2	2			2	2
Vitreous detachment	1	1			1	1
Vomiting	29	57	17	26	12	31
Vulval haemorrhage	1	1			1	1
Weight decreased	1	1	1	1		
Weight increased	3	5	2	3	1	2
Wheezing		1				1
White blood cell count decreased	1	2	1	1		1
White blood cell count increased		2		1		1
Withdrawal hypertension		1				1
Wrong technique in product usage process		1		1		
Yellow skin		1		1		
	2,326	5,479	695	1545	1631	3934

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1		1		
Abdominal mass		1		1		
Abdominal pain	1	12	1	5		7
Abdominal pain lower		1		1		
Abdominal pain upper	5	12	2	4	3	8
Abnormal behaviour		3		2		1
Abnormal faeces		1		1		
Accelerated hypertension		1		1		
Accidental overdose		1		1		
Acidosis hyperchloraemic		1				1
Acquired haemophilia		1				1
Activated partial thromboplastin time prolonged	1	1			1	1
Acute coronary syndrome		9				9
Acute kidney injury	6	22			6	22
Acute myeloid leukaemia		1				1
Acute myocardial infarction		1				1
Acute pulmonary oedema	2	20			2	20
Acute respiratory distress syndrome	4	15			4	15
Acute respiratory failure	1	10			1	10
Acute vestibular syndrome		1				1
Adrenocortical insufficiency acute	1	2			1	2
Adult failure to thrive	1	2			1	2
Aerococcus urinae infection		1				1
Aerophagia		1				1
Affective disorder		1		1		
Age-related macular degeneration		1				1
Ageusia		2		2		
Aggression		4		1		3
Agitation	2	14		5	2	9
Agnosia		1				1
Agranulocytosis		2				2
Allergy to vaccine		2		1		1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Altered state of consciousness	2	13			2	13
Amaurosis		1				1
Amnesia	1	5		1	1	4
Amnesic disorder	1	3			1	3
Anaemia	3	8			3	8
Anaesthesia		1				1
Anaphylactic reaction	1	9			1	9
Anaphylactic shock		6				6
Aneurysm ruptured		1				1
Angina pectoris		2				2
Angina unstable		1				1
Angioedema	3	18			3	18
Anticoagulation drug level below therapeutic		2		1		1
Anuria		2				2
Anxiety	1	9	1	5		4
Aortic aneurysm	1	1	1	1		
Aortic bruit		1		1		
Aortic dilatation	1	1			1	1
Aortic dissection	1	1			1	1
Aortic stenosis	1	2			1	2
Aortic valve calcification		1				1
Aortic valve incompetence		3				3
Apathy		4		2		2
Aphasia	6	19	2	6	4	13
Aplasia		1				1
Aplastic anaemia		1				1
Apnoea		1				1
Appendicitis	1	1			1	1
Arrhythmia	4	30			4	30
Arrhythmia supraventricular		3				3
Arterial disorder	1	1			1	1
Arterial occlusive disease	1	1			1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arterial thrombosis	1	1			1	1
Arteriosclerosis	1	2			1	2
Arteriosclerosis coronary artery	1	1	1	1		
Arteriovenous fistula thrombosis		1				1
Arthralgia	4	16	2	6	2	10
Arthritis	1	2			1	2
Aspartate aminotransferase increased		1		1		
Aspiration		4				4
Asthenia	43	185	26	67	17	118
Asthma		1				1
Asthmatic crisis	2	2			2	2
Asymptomatic COVID-19		15		1		14
Ataxia	1	5		2	1	3
Atrial f brillation	24	80			24	80
Atrial flutter	1	5		1	1	4
Atrial thrombosis		1				1
Atrioventricular block	2	5		1	2	4
Atrioventricular block complete	1	4			1	4
Axillary pain	1	2	1	2		
Axillary vein thrombosis		1		1		
Back pain	2	9	1	4	1	5
Bacterial sepsis		1				1
Bacterial test positive		2		1		1
Bacteriuria	1	1			1	1
Balance disorder	3	8	2	4	1	4
Bedridden	1	2		1	1	1
Behaviour disorder		7		1		6
Benign breast neoplasm		1		1		
Benign prostatic hyperplasia		1				1
Beta 2 microglobulin increased		1		1		
Bicytopenia	1	1			1	1
Bipolar disorder		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder dilatation	1	2	1	1		1
Blindness	1	2			1	2
Blindness cortical	1	1			1	1
Blindness transient		1				1
Blindness unilateral		3				3
Blister	1	1			1	1
Blood albumin decreased		1		1		
Blood alkaline phosphatase increased		1		1		
Blood bicarbonate decreased		1				1
Blood calcium decreased		1		1		
Blood chloride increased	1	1			1	1
Blood cholesterol increased	1	1			1	1
Blood creatine phosphokinase increased		1				1
Blood creatinine decreased		1				1
Blood creatinine increased	2	4	1	3	1	1
Blood fibrinogen increased	2	2	2	2		
Blood glucose increased	1	1			1	1
Blood immunoglobulin G increased	1	1	1	1		
Blood lactate dehydrogenase increased		1		1		
Blood potassium increased		1		1		
Blood pressure abnormal		1		1		
Blood pressure decreased	1	4			1	4
Blood pressure diastolic decreased	1	4		2	1	2
Blood pressure fluctuation		3		1		2
Blood pressure increased	8	15	1	1	7	14
Blood pressure systolic decreased		1		1		
Blood pressure systolic increased		4		1		3
Blood sodium decreased		1		1		
Blood sodium increased		3		1		2
Blood thyroid stimulating hormone decreased		1		1		
Blood thyroid stimulating hormone increased		1		1		
Blood urea increased	2	2	1	1	1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Body temperature decreased		2		1		1
Body temperature increased	2	3	2	2		1
Bone pain		1				1
Bradyarrhythmia	1	1	1	1		
Bradycardia	4	27			4	27
Bradykinesia	1	1	1	1		
Brain contusion		1				1
Brain hypoxia		1				1
Brain natriuretic peptide increased		3		2		1
Brain scan abnormal		1				1
Brain stem haemorrhage		1				1
Breast swelling		1		1		
Breath sounds abnormal	2	3	2	2		1
Bronchiectasis	1	1			1	1
Bronchiolitis		2				2
Bronchitis	5	12	2	3	3	9
Bronchopneumopathy		3				3
Bronchospasm	1	5			1	5
Bundle branch block		1				1
Bundle branch block left	1	4		1	1	3
Bundle branch block right	1	5		2	1	3
Burning sensation	1	3	1	2		1
Burn oral cavity		1				1
Bursal haematoma	1	1			1	1
Cachexia	1	1			1	1
Cardiac arrest	3	14			3	14
Cardiac discomfort		1				1
Cardiac failure	17	87			17	87
Cardiac failure acute	1	5			1	5
Cardiac failure congestive		3				3
Cardiac fibrillation		1				1
Cardiac flutter	1	3			1	3

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac tamponade		1				1
Cardiogenic shock	1	5			1	5
Cardiomegaly		1				1
Cardiopulmonary failure	2	5			2	5
Cardio-respiratory arrest	4	21			4	21
Cardio-respiratory distress		1				1
Cardiovascular disorder		3				3
Carotid arteriosclerosis	1	1			1	1
Carotid artery stenosis		1				1
Carotid artery thrombosis		1				1
Cell death		2				2
Central nervous system lesion		1				1
Cerebellar ataxia		1		1		
Cerebellar haematoma		1				1
Cerebellar infarction		1				1
Cerebellar stroke	1	2			1	2
Cerebellar syndrome		3				3
Cerebral amyloid angiopathy		1				1
Cerebral atrophy		1				1
Cerebral disorder		1				1
Cerebral haematoma	2	7			2	7
Cerebral haemorrhage	1	7			1	7
Cerebral infarction	2	6			2	6
Cerebral ischaemia	1	1			1	1
Cerebral venous thrombosis		2				2
Cerebrovascular accident	10	36			10	36
Cervicobrachial syndrome	1	3			1	3
Chest discomfort	2	8	1	2	1	6
Chest injury	1	2			1	2
Chest pain	7	32	2	9	5	23
Chest X-ray abnormal		1				1
Chills	4	17	3	7	1	10

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Choking		3				3
Cholecystitis		3				3
Cholestasis	1	3			1	3
Cholestatic liver injury	1	1			1	1
Chondrocalcinosis	1	1			1	1
Chronic kidney disease	3	4			3	4
Chronic obstructive pulmonary disease		8		2		6
Circadian rhythm sleep disorder		1		1		
Circulatory collapse		3				3
Clinomania		1		1		
Clonus		2		1		1
Cognitive disorder	4	7	1	2	3	5
Colitis		2				2
Coma	2	12			2	12
Coma scale abnormal		1				1
Communication disorder	2	2			2	2
Condition aggravated	7	25	1	6	6	19
Confusional state	10	39	1	6	9	33
Conjunctival haemorrhage	1	2			1	2
Conjunctival oedema		1		1		
Conjunctivitis		1		1		
Conjunctivitis bacterial		1				1
Constipation	4	8	3	7	1	1
Contusion	1	3		2	1	1
Coordination abnormal	1	1	1	1		
Coronary artery disease	1	1	1	1		
Coronary artery insufficiency		1				1
Coronary artery stenosis		2				2
Coronavirus infection		2		1		1
Cough	7	26	5	12	2	14
COVID-19	107	276		19	107	257
COVID-19 pneumonia	12	23			12	23

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
C-reactive protein increased	8	26	3	12	5	14
Creatinine renal clearance decreased	1	2	1	1		1
Crepitations		3		2		1
Culture urine positive		1		1		
Cutaneous vasculitis	1	1			1	1
Cyanosis	2	9	1	3	1	6
Cystitis klebsiella		1				1
Dacryocystitis	1	1			1	1
Deafness	1	2			1	2
Deafness unilateral	1	1			1	1
Death	8	87			8	87
Decreased appetite	14	31	7	17	7	14
Deep vein thrombosis	31	53			31	53
Deformity		1		1		
Degenerative mitral valve disease	1	1			1	1
Dehydration	6	26		6	6	20
Delirium		2				2
Delusion		3		1		2
Dementia	1	4			1	4
Dependent rubor		1				1
Depressed level of consciousness	2	13			2	13
Dermatitis bullous	1	3			1	3
Dermatosis	1	1	1	1		
Dermo-hypodermatitis		2				2
Diabetes mellitus	1	6			1	6
Diabetes mellitus inadequate control		2				2
Diabetic coma		1				1
Diabetic hyperosmolar coma		1				1
Diabetic ketoacidosis		1				1
Diabetic metabolic decompensation		1				1
Diarrhoea	9	65	5	23	4	42
Diarrhoea haemorrhagic		3				3

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea infectious		2				2
Diplopia	1	3			1	3
Discomfort	4	20	2	8	2	12
Disease progression		1				1
Disease recurrence	12	33	1	1	11	32
Disorientation	6	18	1	4	5	14
Disturbance in attention	1	5	1	2		3
Diverticulum intestinal		1				1
Dizziness	17	40	10	21	7	19
Dizziness postural	1	1	1	1		
Dropped head syndrome		1				1
Drug eruption	1	1			1	1
Drug ineffective	45	96		1	45	95
Drug interaction		1				1
Dry mouth	2	3	2	3		
Dry skin	1	2		1	1	1
Dysarthria	4	14	2	3	2	11
Dysgeusia	2	4	1	2	1	2
Dyskinesia	1	3	1	3		
Dyslipidaemia		1		1		
Dyspepsia		1		1		
Dysphagia	1	7		1	1	6
Dysphonia		3		2		1
Dyspnoea	27	100	8	18	19	82
Dyspnoea at rest	1	3			1	3
Dyspnoea exertional	4	9	2	5	2	4
Dysstasia		2				2
Dysuria		2		1		1
Ear discomfort		1		1		
Ear haemorrhage	1	1			1	1
Ear infection		1				1
Ear pain	1	3	1	2		1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eating disorder		1				1
Ecchymosis	1	1			1	1
Eczema	1	2			1	2
Eczema nummular		1				1
Ejection fraction abnormal	1	1			1	1
Ejection fraction decreased	2	3	1	1	1	2
Electrocardiogram abnormal	1	1			1	1
Electrocardiogram PR prolongation		1				1
Electrocardiogram QRS complex shortened		1				1
Electrocardiogram QT interval abnormal		1				1
Electrocardiogram repolarisation abnormality	1	1			1	1
Electrocardiogram T wave inversion		1				1
Embolic stroke		3				3
Embolism		1				1
Embolism venous		1				1
Emotional distress		1		1		
Encephalitis	3	4			3	4
Endocrine ophthalmopathy		1				1
Enuresis		1				1
Eosinophilia		1				1
Epilepsy	3	18			3	18
Epistaxis	2	11		2	2	9
Erysipelas	3	7			3	7
Erythema	11	23	6	10	5	13
Erythema multiforme	1	2			1	2
Erythrosis	1	1	1	1		
Escherichia bacteraemia		1				1
Escherichia infection		1				1
Escherichia pyelonephritis	1	1			1	1
Escherichia test positive		1		1		
Escherichia urinary tract infection	2	3			2	3
Exophthalmos		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposure to SARS-CoV-2		1				1
Extensive swelling of vaccinated limb		1				1
Extensor plantar response		1				1
Extradural haematoma		1				1
Extrapyramidal disorder		2				2
Extrasystoles	2	5	1	1	1	4
Extremity necrosis	1	2		1	1	1
Eye discharge		1				1
Eye disorder		1				1
Eye haemorrhage		1				1
Eye inflammation	1	1			1	1
Eye injury		1				1
Eye irritation	1	1			1	1
Eyelid oedema	1	4	1	1		3
Eyelid ptosis		1				1
Eye oedema		1				1
Eye pain		2		1		1
Eye swelling		1				1
Face oedema	3	14	2	3	1	11
Facial asymmetry		1				1
Facial bones fracture		2				2
Facial paralysis	5	34			5	34
Facial paresis		1				1
Faecaloma	1	3			1	3
Faecal vomiting		2				2
Failure to thrive		1				1
Fall	20	72	7	18	13	54
Fatigue	9	59	6	32	3	27
Fear		1				1
Febrile convulsion	1	1			1	1
Feeding disorder	1	1			1	1
Feeling abnormal		3		1		2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling cold		3		2		1
Feeling hot	2	4	1	2	1	2
Feeling of body temperature change	1	1	1	1		
Femoral neck fracture		1				1
Femur fracture		3				3
Fibrin D dimer increased	3	5			3	5
Flank pain		1		1		
Flatulence	1	1	1	1		
Fluid overload	1	1	1	1		
Fluid retention		1				1
Flushing		3		1		2
Foaming at mouth		1				1
Folate deficiency	1	1			1	1
Food aversion		1		1		
Foot fracture	1	1			1	1
Fracture		1				1
Functional gastrointestinal disorder		1				1
Gait disturbance	3	12	3	7		5
Gait inability	3	4	2	2	1	2
Gamma-glutamyltransferase increased	1	3		1	1	2
Gangrene		1				1
Gastric volvulus		1				1
Gastritis	1	1			1	1
Gastroenteritis		1				1
Gastrointestinal disorder	2	6	2	4		2
Gastrointestinal haemorrhage	1	2			1	2
Gastrointestinal pain	1	1			1	1
Generalised oedema		1				1
Generalised tonic-clonic seizure	1	5			1	5
General physical health deterioration	15	52	3	12	12	40
Genital herpes zoster		1				1
Giant cell arteritis	2	7			2	7

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gingival bleeding	1	1	1	1		
Gingival discomfort		1		1		
Glaucoma		1				1
Glomerular filtration rate decreased	3	7	1	2	2	5
Glossitis		1				1
Glycosylated haemoglobin increased	1	1	1	1		
Goitre		1		1		
Gout	2	4	1	2	1	2
Guillain-Barre syndrome	2	3			2	3
Guttate psoriasis		1		1		
Haemarthrosis	1	2			1	2
Haematemesis		4				4
Haematochezia	1	3			1	3
Haematoma	4	12	1	2	3	10
Haematoma muscle		1				1
Haematuria	1	4			1	4
Haemodynamic instability		1		1		
Haemoglobin decreased		5		2		3
Haemoglobinuria		1				1
Haemolytic anaemia		1				1
Haemophagocytic lymphohistiocytosis		2				2
Haemoptysis		3				3
Haemorrhagic disorder		1				1
Haemorrhagic stroke	1	16			1	16
Haemorrhagic transformation stroke		1				1
Hallucination	2	9			2	9
Hallucination, auditory		3				3
Hallucinations, mixed	1	3			1	3
Hallucination, visual		9				9
Headache	34	83	23	42	11	41
Head discomfort		1				1
Head injury	1	12		1	1	11

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate decreased	2	8		3	2	5
Heart rate increased	1	3	1	3		
Heart rate irregular		2				2
Heart sounds abnormal	2	4	2	3		1
Heart valve incompetence	1	1	1	1		
Hemianopia		1				1
Hemiparesis	2	9			2	9
Hemiplegia	2	18			2	18
Hepatic cytolysis	1	5			1	5
Hepatic function abnormal		2		2		
Hepatic lesion		1		1		
Hepatic pain	1	1			1	1
Hepatic steatosis		1				1
Hepatitis acute		1				1
Hepatocellular injury	1	1			1	1
Herpes ophthalmic		1				1
Herpes simplex test positive		1		1		
Herpes zoster	44	80	29	41	15	39
Herpes zoster cutaneous disseminated		1				1
High-pitched crying		1		1		
Hippocampal atrophy		1				1
Hostility		1				1
Hot flush		8		3		5
Humerus fracture		1				1
Hyperaesthesia	1	1			1	1
Hypercalcaemia		1		1		
Hypercapnia		2				2
Hypercholesterolaemia		1		1		
Hyperferritinaemia	2	3	1	1	1	2
Hyperglycaemia	2	6	2	5		1
Hyperhidrosis	4	7	2	2	2	5
Hyperkalaemia	2	6			2	6

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperlactacidaemia	2	3			2	3
Hyperleukocytosis	3	16			3	16
Hypernatraemia	1	6		2	1	4
Hypersensitivity	2	8	1	4	1	4
Hypersensitivity vasculitis		1				1
Hypersomnia	1	4	1	2		2
Hypertension	38	176	6	22	32	154
Hypertensive crisis	10	65			10	65
Hypertensive encephalopathy	1	1			1	1
Hyperthermia	8	31	2	9	6	22
Hyperthyroidism		1				1
Hypertonia		2				2
Hypertriglyceridaemia	1	1	1	1		
Hyperuricaemia	1	2		1	1	1
Hypoacusis		1				1
Hypoesthesia	3	6		1	3	5
Hypoalbuminaemia	1	2			1	2
Hypocapnia	1	1	1	1		
Hypogammaglobulinaemia	1	1			1	1
Hypoglycaemia	1	6		1	1	5
Hypokalaemia	1	2			1	2
Hyponatraemia	4	4	1	1	3	3
Hypoperfusion		1		1		
Hypotension	9	69	1	16	8	53
Hypothermia	1	6			1	6
Hypothyroidism	1	1			1	1
Hypotonia	1	4		1	1	3
Hypovolaemic shock		1				1
Hypoxia	2	15			2	15
Idiopathic pulmonary fibrosis	1	1			1	1
IIIrd nerve paralysis		1				1
III-defined disorder		1				1

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Illness		1		1		
Immune thrombocytopenia	5	7			5	7
Impetigo	1	1			1	1
Inappropriate schedule of product administration	3	11	3	10		1
Incoherent	2	7	1	4	1	3
Incontinence	1	2			1	2
Incorrect dose administered	2	6	1	5	1	1
Incorrect route of product administration	2	3	2	3		
Increased bronchial secretion		2				2
Induration	1	1	1	1		
Infarction		3				3
Infection		3		1		2
Inflammation	4	19	2	9	2	10
Inflammatory marker increased	1	1			1	1
Influenza	1	6	1	3		3
Influenza like illness	7	37	3	9	4	28
Injected limb mobility decreased		1				1
Injection site hyperaesthesia		1		1		
Insomnia	3	6	1	4	2	2
Insulin-requiring type 2 diabetes mellitus		1				1
Intermittent claudication	1	1			1	1
International normalised ratio abnormal		2		1		1
International normalised ratio increased	2	6	1	1	1	5
Interstitial lung disease	2	6			2	6
Intervertebral disc compression		1				1
Intestinal ischaemia		2				2
Intestinal obstruction	1	2			1	2
Intracardiac thrombus		1				1
Intracranial haematoma		1				1
Iron binding capacity total abnormal	1	1			1	1
Iron deficiency anaemia		1				1
Ischaemic cardiomyopathy		1				1

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ischaemic limb pain		1				1
Ischaemic stroke	22	66			22	66
Jaundice		3				3
Jaundice cholestatic		1				1
Jaw fracture	1	1			1	1
Joint dislocation		1				1
Joint effusion		1				1
Joint injury		1				1
Joint swelling		1		1		
Jugular vein distension		1				1
Klebsiella infection		1				1
Laboratory test abnormal		1				1
Lacrimation increased		1				1
Lactic acidosis		1				1
Lactobacillus infection		1				1
Lacunar stroke		2				2
Language disorder	1	2	1	1		1
Large intestine infection		2				2
Laryngeal discomfort		1				1
Laryngeal oedema		1				1
Left atrial dilatation	2	3	1	1	1	2
Left ventricular dysfunction	1	2	1	1		1
Left ventricular end-diastolic pressure increased		1				1
Left ventricular failure	1	4			1	4
Left ventricular hypertrophy	1	1	1	1		
Leukocytosis		1		1		
Leukocyturia	3	6	1	3	2	3
Leukoencephalopathy		1				1
Lichenoid keratosis	1	1			1	1
Limb discomfort	3	4	2	3	1	1
Lip blister	1	1	1	1		
Lip dry	1	1	1	1		

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lip oedema	2	8	1	3	1	5
Lip swelling	1	2	1	1		1
Listless		1				1
Livedo reticularis		5		2		3
Liver function test increased	1	1			1	1
Lividity		1				1
Localised oedema		4		2		2
Loss of consciousness	8	43			8	43
Loss of personal independence in daily activities	1	8		2	1	6
Low density lipoprotein increased	1	1			1	1
Lower respiratory tract congestion	1	6			1	6
Lower respiratory tract infection		1				1
Lung abscess	1	2			1	2
Lung disorder	4	29		3	4	26
Lung opacity		1				1
Lyme disease		1				1
Lymphadenitis		2		1		1
Lymphadenopathy	2	4	2	3		1
Lymphocyte count decreased		1		1		
Lymphopenia	5	11	1	4	4	7
Macular oedema		1				1
Major depression	1	2			1	2
Malaise	18	107	4	30	14	77
Malnutrition	3	5	1	2	2	3
Mass		1				1
Mean cell volume decreased		1				1
Melaena		1				1
Memory impairment		1		1		
Meniere's disease		1				1
Meningitis		1				1
Meningitis aseptic	1	2			1	2
Meningoencephalitis herpetic		1				1

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Meningoradiculitis		1				1
Mental impairment	1	3			1	3
Mesenteric vein thrombosis	1	1			1	1
Metabolic acidosis	2	2			2	2
Metastases to peritoneum		1				1
Microcytic anaemia	1	1	1	1		
Migraine		1		1		
Miosis		1				1
Mitral valve calcification		2				2
Mitral valve disease		1				1
Mitral valve incompetence	1	4			1	4
Mitral valve stenosis		1				1
Mobility decreased	1	4		3	1	1
Monocytosis	2	4	1	2	1	2
Monoparesis	1	1	1	1		
Monoplegia	1	1			1	1
Mood altered	1	1			1	1
Motor dysfunction	4	8	3	4	1	4
Mouth haemorrhage		1				1
Movement disorder		4		1		3
Mucosal discolouration		1				1
Multiple organ dysfunction syndrome	2	5			2	5
Muscle contracture		1		1		
Muscle disorder		1		1		
Muscle spasms	4	6	2	3	2	3
Muscle strength abnormal		1				1
Muscle tightness		1		1		
Muscle twitching	2	2			2	2
Muscular weakness	3	9	1	1	2	8
Musculoskeletal discomfort		1		1		
Musculoskeletal stiffness		8		1		7
Mutism		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	9	25	4	8	5	17
Myasthenia gravis		1				1
Myasthenia gravis crisis		1				1
Mydriasis		4		2		2
Myelocytosis		1				1
Myelofibrosis		1				1
Myocardial infarction	4	27			4	27
Myocardial ischaemia		2				2
Myocardial necrosis		1				1
Myocarditis		1				1
Myoclonus		1				1
Nasal congestion		1		1		
Nasopharyngitis	1	1	1	1		
Nausea	16	53	11	21	5	32
Near death experience		1				1
Neck pain		1		1		
Necrosis	1	2			1	2
Necrotising colitis		1				1
Nervous system disorder	2	3	1	2	1	1
Neuralgia		2		1		1
Neurological decompensation		1		1		
Neurological examination abnormal		1				1
Neuropathy peripheral	1	1			1	1
Neutropenia		1				1
Neutrophil count abnormal		1				1
Neutrophil count decreased		1				1
Neutrophil count increased	1	4		2	1	2
Neutrophilia	1	1	1	1		
Nocturnal dyspnoea		1				1
Noninfective gingivitis		1		1		
Normocytic anaemia		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
N-terminal prohormone brain natriuretic peptide increased	3	6	2	2	1	4
Nystagmus		1		1		
Occipital neuralgia	1	1			1	1
Ocular discomfort	1	1			1	1
Ocular hyperaemia	1	3	1	1		2
Ocular vascular disorder		1				1
Odynophagia	1	1			1	1
Oedema	1	5	1	3		2
Oedema peripheral	12	31	6	8	6	23
Off label use	1	7	1	6		1
Oligoarthritis	1	1			1	1
Ophthalmic herpes zoster	7	19	1	1	6	18
Oppositional defiant disorder	1	1			1	1
Oral discomfort		1		1		
Oral disorder		1		1		
Oral fungal infection		1		1		
Orbital haematoma		1				1
Organising pneumonia	1	1			1	1
Oropharyngeal pain	1	4	1	3		1
Orthopnoea	1	1	1	1		
Otitis externa		2		1		1
Ovarian neoplasm	1	1			1	1
Overdose	1	3	1	3		
Oxygen saturation abnormal		1				1
Oxygen saturation decreased	22	103	7	14	15	89
Pain	5	23	4	11	1	12
Pain in extremity	8	25	4	10	4	15
Pain in jaw	1	6	1	3		3
Pain of skin		1				1
Pallor	2	10		1	2	9
Palpitations	2	10	1	5	1	5

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pancreatitis	1	1			1	1
Pancreatitis acute	1	2			1	2
Pancytopenia		2				2
Panic attack		1		1		
Paraesthesia	3	6	1	1	2	5
Paraesthesia oral	1	1			1	1
Paralysis		3				3
Parkinson's disease		1				1
Parophthalmia		1				1
Parotitis	1	1			1	1
Partial seizures		3				3
Peau d'orange		1		1		
Pelvic fracture	2	3			2	3
Pelvic haematoma	1	1	1	1		
Pemphigoid	1	2			1	2
Periarthritis		1				1
Pericardial effusion	2	3			2	3
Pericardial haemorrhage		1				1
Pericarditis		3				3
Periorbital haematoma	2	2	2	2		
Periorbital oedema	1	1			1	1
Periorbital pain		1		1		
Periorbital swelling		1				1
Peripheral arterial occlusive disease	1	1			1	1
Peripheral artery occlusion	1	1			1	1
Peripheral artery thrombosis	3	4			3	4
Peripheral coldness	2	6	1	4	1	2
Peripheral ischaemia	3	6	2	2	1	4
Peripheral swelling	4	6	3	4	1	2
Persecutory delusion		1		1		
Petechiae	1	4		3	1	1
Petit mal epilepsy		4				4

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			Nonserious		Serious	
			I	C	I	C
Pharyngitis	1	2	1	2		
Phlebitis	1	10		4	1	6
Phlebitis superficial	1	1			1	1
Pituitary tumour benign	1	1	1	1		
Platelet count decreased	1	4	1	3		1
Platelet count increased	1	1	1	1		
Pleural effusion	2	6	1	1	1	5
Pleuropericarditis	1	1			1	1
Pneumocephalus	1	1			1	1
Pneumococcal sepsis		1				1
Pneumonia	4	27			4	27
Pneumonia aspiration	2	18			2	18
Pneumonia bacterial	1	2			1	2
Pneumonitis		3				3
Pneumoperitoneum		1				1
Pneumothorax		1				1
Pollakiuria	1	1	1	1		
Polyarthrits	1	2			1	2
Polymyalgia rheumatica	3	4			3	4
Polyneuropathy		1				1
Polyserositis		1				1
Poor quality product administered		55		55		
Prerenal failure		2				2
Presyncope		7		4		3
Proctitis	1	1	1	1		
Product administered at inappropriate site	1	1	1	1		
Productive cough	2	6	2	3		3
Product preparation error		2		2		
Product temperature excursion issue		54		54		
Product use issue		2		2		
Progressive supranuclear palsy		1				1
Prostatic specific antigen increased	1	1			1	1

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			Nonserious		Serious	
			I	C	I	C
Prostatitis		1		1		
Proteinuria		1		1		
Prothrombin time prolonged	1	1			1	1
Prothrombin time shortened		2		1		1
Pruritus	9	20	4	11	5	9
Psoriasis		1				1
Psychomotor skills impaired	3	4	2	2	1	2
Pulmonary arterial hypertension	1	3			1	3
Pulmonary arterial pressure increased		2				2
Pulmonary artery dilatation		1				1
Pulmonary congestion	1	2			1	2
Pulmonary embolism	39	85			39	85
Pulmonary infarction		3				3
Pulmonary oedema	1	9			1	9
Pulmonary sepsis		1				1
Pulse abnormal		1		1		
Pulse absent	2	5		2	2	3
Pupils unequal		1		1		
Purpura	3	7		1	3	6
Pyelonephritis	4	8			4	8
Pyrexia	46	162	22	52	24	110
Quadriplegia		2				2
Radius fracture	1	1			1	1
Rales	3	12	3	4		8
Rash	3	9	2	5	1	4
Rash erythematous	1	7		2	1	5
Rash macular		2		1		1
Rash maculo-papular	5	8			5	8
Rash pruritic	2	5		2	2	3
Rash vesicular		2				2
Recalled product administered		1		1		
Rectal haemorrhage	2	6			2	6

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			Nonserious		Serious	
			I	C	I	C
Renal colic	1	1			1	1
Renal cyst		1				1
Renal failure	2	17			2	17
Renal impairment		2				2
Respiration abnormal		2				2
Respiratory acidosis		1				1
Respiratory alkalosis	1	2	1	1		1
Respiratory arrest	1	2			1	2
Respiratory depression		2				2
Respiratory disorder	2	8		1	2	7
Respiratory distress	4	31			4	31
Respiratory failure	1	8			1	8
Respiratory fatigue		1				1
Respiratory rate decreased		1				1
Respiratory rate increased		2		1		1
Respiratory tract congestion		1				1
Respiratory tract infection	1	2			1	2
Respiratory tract infection bacterial		1				1
Restlessness	1	6		3	1	3
Retinal artery occlusion		2				2
Retinal artery thrombosis	1	1			1	1
Retinal haemorrhage	1	1			1	1
Retinal infarction	1	1			1	1
Retinal vein occlusion		3				3
Rhabdomyolysis		1				1
Rheumatoid arthritis	2	3			2	3
Rhinitis		2		1		1
Rhinorrhoea	1	4	1	2		2
Rhonchi		1		1		
Rib fracture	1	2			1	2
Right ventricular dilatation		1				1
Road traffic accident		1				1

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			Nonserious		Serious	
			I	C	I	C
Salivary gland disorder		1		1		
Salivary hypersecretion	1	1			1	1
SARS-CoV-2 ant body test negative		1		1		
SARS-CoV-2 ant body test positive	1	1	1	1		
SARS-CoV-2 test positive	2	19		3	2	16
Scan abnormal	1	1			1	1
Secretion discharge	1	1	1	1		
Seizure	2	8			2	8
Seizure anoxic		1				1
Sensorimotor disorder		1		1		
Sensory disturbance		1				1
Sensory loss	1	4			1	4
Sepsis		4				4
Septic shock	1	3			1	3
Shock	1	5			1	5
Sialoadenitis		1				1
Sinus arrhythmia	1	1	1	1		
Sinus bradycardia	1	3			1	3
Sinusitis	1	1	1	1		
Sinus tachycardia		2				2
Skin abrasion	1	1	1	1		
Skin discolouration	1	2		1	1	1
Skin exfoliation	1	1	1	1		
Skin lesion	1	3		2	1	1
Skin necrosis	1	2			1	2
Skin ulcer		2		1		1
Skin warm		1		1		
Sleep apnoea syndrome	1	2			1	2
Sleep disorder	1	1	1	1		
Sleep talking		1		1		
Somnolence	4	25	2	12	2	13
Speech disorder	2	12	1	2	1	10

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Spinal compression fracture		2				2
Spinal cord infarction		1				1
Splenic artery aneurysm	1	1			1	1
Status epilepticus		3				3
Stereotypy		1				1
Stomatitis		1		1		
Stress		1		1		
Stridor	1	1			1	1
Subarachnoid haemorrhage	1	1			1	1
Subclavian vein thrombosis		1				1
Subdural haematoma	1	3			1	3
Subileus		1				1
Sudden death	6	43			6	43
Sudden hearing loss	1	1			1	1
Suffocation feeling		1				1
Superinfection	2	3	1	1	1	2
Superinfection bacterial		1				1
Superior vena cava syndrome		1				1
Supraventricular extrasystoles	1	1	1	1		
Supraventricular tachyarrhythmia		1				1
Supraventricular tachycardia	1	2			1	2
Suspected COVID-19	5	7			5	7
Swelling		3		2		1
Swelling face	1	3			1	3
Swollen tongue		1				1
Syncope	3	14			3	14
Systemic inflammatory response syndrome	1	3	1	1		2
Systolic hypertension	2	3			2	3
Tachyarrhythmia	4	7	1	3	3	4
Tachycardia	9	63	3	14	6	49
Tachypnoea	2	8	2	4		4
Tendon disorder	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tendon rupture		1				1
Tension		3		3		
Therapeutic response unexpected		1		1		
Thirst		1		1		
Throat irritation		1		1		
Throat tightness		1				1
Thrombocytopenia	5	16			5	16
Thrombocytopenic purpura	1	1			1	1
Thrombolysis		1				1
Thrombophlebitis	2	2			2	2
Thrombophlebitis superficial	5	9		2	5	7
Thrombosis		5				5
Thrombotic stroke	1	1			1	1
Thyroid disorder		1		1		
Thyroxine free decreased		1		1		
Tinnitus		3		3		
Tongue biting	1	2			1	2
Tongue coated		1				1
Tongue discolouration		1				1
Tongue disorder		1				1
Tongue dry		1				1
Tongue oedema	1	3			1	3
Tonic clonic movements		1				1
Tooth abscess		2		1		1
Toothache		1		1		
Tooth infection		1		1		
Torticollis		1				1
Toxic skin eruption	1	1			1	1
Transcription medication error		1		1		
Transient aphasia	1	1			1	1
Transient global amnesia	1	2	1	1		1
Transient ischaemic attack	14	34			14	34

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tremor	5	15	2	6	3	9
Trigeminal neuralgia		1				1
Tri-iodothyronine free decreased		1		1		
Trismus		1		1		
Troponin increased	3	7	1	2	2	5
Tumour perforation		1				1
Type I hypersensitivity	1	1			1	1
Underdose		1		1		
Unresponsive to stimuli		2				2
Urinary incontinence	3	5	1	2	2	3
Urinary retention	1	4			1	4
Urinary tract candidiasis		1				1
Urinary tract infection	3	10	1	2	2	8
Urinary tract infection bacterial		2				2
Urine odour abnormal		1		1		
Urosepsis		1				1
Urticaria	3	11	2	5	1	6
Vaccination complication		1				1
Vaccination failure	80	169			80	169
Vaccination site bruising	1	1	1	1		
Vaccination site eczema		1				1
Vaccination site erythema	2	12	2	10		2
Vaccination site haematoma	1	4			1	4
Vaccination site induration		3		2		1
Vaccination site inflammation		6		3		3
Vaccination site joint pain		1		1		
Vaccination site macule	1	1	1	1		
Vaccination site oedema		2				2
Vaccination site pain	8	28	8	18		10
Vaccination site paraesthesia		1				1
Vaccination site pruritus	1	1	1	1		
Vaccination site rash		2		1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site reaction	4	7	3	5	1	2
Vaccination site swelling	1	3	1	3		
Vaccination site urticaria		1		1		
Vascular graft thrombosis	1	1			1	1
Vascular purpura	4	7			4	7
Vascular stent thrombosis		1				1
Vasculitis	1	1			1	1
Vasoplegia syndrome		1				1
Vein rupture		1				1
Vena cava thrombosis		1				1
Venous oxygen saturation decreased		2				2
Venous thrombosis	2	2			2	2
Venous thrombosis limb	1	3		1	1	2
Ventricular extrasystoles		4		1		3
Ventricular failure		1				1
Ventricular hypokinesia	2	3			2	3
Ventricular tachycardia		1				1
Vertigo	6	17	3	6	3	11
Vertigo positional		1				1
Vestibular disorder	1	2			1	2
Vestibular neuritis		1				1
Vestibulitis		1				1
Viral infection		1		1		
Viral pharyngitis	1	1			1	1
Vision blurred	1	7		2	1	5
Visual acuity reduced	1	2			1	2
Visual acuity reduced transiently		1				1
Visual brightness		1				1
Visual field defect	1	1			1	1
Visual impairment	1	7		2	1	5
Vitamin D deficiency		1		1		
Vlth nerve paralysis		2				2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vitreous floaters		1				1
Vomiting	17	86	11	32	6	54
Vomiting projectile	1	1			1	1
Weight decreased	2	7	1	1	1	6
Weight increased	1	3	1	1		2
Wheezing		3		1		2
White blood cell count decreased	1	3	1	2		1
White blood cell count increased	1	2		1	1	1
White matter lesion		1				1
Wound	1	2	1	1		1
Wrong patient received product		1		1		
	1,718	6,275	456	1433	1262	4842

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Accidental exposure to product	1	1	1	1		
Accidental overdose		1		1		
Ageusia	1	2	1	1		1
Allergy to vaccine		1		1		
Anosmia	1	2	1	1		1
Arrhythmia		1				1
Arthralgia	1	4	1	3		1
Asthenia	4	13	4	11		2
Asthma		1		1		
Asymptomatic COVID-19		9				9
Bladder disorder	1	1	1	1		
Blindness	1	1			1	1
Blood pressure decreased		1		1		
Bone pain		1				1
Bradycardia		1				1
Breast abscess		1				1
Chest pain		2		1		1
Chills	3	7	3	6		1
Circumstance or information capable of leading to medication error		1		1		
Condition aggravated		1		1		
Cough		2		1		1
COVID-19	13	94	3	9	10	85
C-reactive protein increased		1		1		
Deafness	1	1			1	1
Death	1	1			1	1
Diarrhoea		1		1		
Diplopia		1		1		
Disease recurrence	1	2			1	2
Dizziness	3	3	3	3		
Drug ineffective	8	91			8	91

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysgeusia		1		1		
Epistaxis	1	1	1	1		
Erysipelas	1	1			1	1
Erythema		1		1		
Exposure during pregnancy	1	2			1	2
Exposure via skin contact		1		1		
Extrasystoles		1		1		
Eyelid irritation		1		1		
Eyelid oedema		2		2		
Face oedema		2		2		
Facial paralysis		1				1
Fall		3				3
Fatigue	6	16	6	16		
Feeling abnormal		1		1		
Functional gastrointestinal disorder		1				1
Gait inability		1		1		
General physical health deterioration		2				2
Glaucoma	1	1			1	1
Haemorrhagic stroke		1				1
Headache	2	13	2	9		4
Hepatitis acute	1	1			1	1
Herpes zoster	2	6	2	5		1
Hot flush	1	3	1	3		
Hyperaesthesia	1	1	1	1		
Hypertension	3	9	1	5	2	4
Hypertensive crisis		1				1
Hypoaesthesia	1	1	1	1		
Hypotension		1				1
Hypoxia		1				1
Illness	1	1	1	1		
Immune thrombocytopenia		1				1
Immunoglobulins increased	2	2	2	2		

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Inappropriate schedule of product administration	1	5
Incorrect dose administered	2	2
Incorrect route of product administration		2
Influenza	2	3
Influenza like illness	1	6
Injection site pain	1	3
Intercepted product preparation error		1
Lethargy	1	1
Limb discomfort		1
Lip oedema		2
Liquid product physical issue	4	4
Lymphadenitis	1	2
Lymphadenopathy		2
Lymphopenia	1	1
Maternal exposure during pregnancy	3	4
Migraine		1
Monoplegia		1
Musculoskeletal stiffness	1	2
Myalgia	1	6
Nausea		4
Needle issue		2
No adverse event		2
Occipital neuralgia		1
Occupational exposure to product		2
Oedema	1	1
Oedema peripheral		1
Off label use	1	7
Ophthalmic herpes zoster		1
Oral pruritus	1	1
Overdose	6	7
Oxygen saturation decreased	1	1
Pain	3	6

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	5		
2	2		
	2		
2	3		
1	2		4
1	3		
	1		
1	1		
	1		
	2		
4	4		
1	2		
	1		1
1	1		
2	3	1	1
	1		
			1
1	2		
1	3		3
	2		2
	2		
	2		
			1
	2		
1	1		
	1		
1	7		
			1
1	1		
6	7		
		1	1
3	6		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in extremity	3	7	3	7		
Pancreatitis		1				1
Paraesthesia		2		1		1
Paraesthesia oral		1		1		
Pathological fracture	1	1			1	1
Periarthritis		1				1
Pharyngeal paraesthesia	1	1	1	1		
Pollakiuria	1	1	1	1		
Poor quality product administered	190	253	190	253		
Product administered at inappropriate site		1		1		
Product complaint		15		15		
Product contamination physical	2	3	2	3		
Product label confusion		1		1		
Product physical issue	6	7	6	7		
Product preparation error	34	34	34	34		
Product preparation issue		7		7		
Product quality issue	1	2	1	2		
Product storage error	6	7	6	7		
Product temperature excursion issue	143	187	143	187		
Product use issue		2		2		
Pruritus	1	1	1	1		
Pulmonary embolism	1	3			1	3
Pulmonary pain		1		1		
Pyrexia	11	26	10	22	1	4
Rash	1	2	1	2		
Renal artery stenosis		1				1
Retinal vein occlusion		1				1
Rheumatic disorder		1		1		
Rheumatoid arthritis	2	2			2	2
SARS-CoV-2 ant body test negative		6		6		
SARS-CoV-2 test positive		3		1		2
Serology negative		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sluggishness		1		1		
Small for dates baby		1				1
Spine malformation	1	1			1	1
Suspected COVID-19		2		1		1
Swelling face		2		2		
Synovial cyst	1	1	1	1		
Syringe issue	1	1	1	1		
Tachycardia	1	4		1	1	3
Tinnitus	1	2		1	1	1
Trisomy 21	1	1			1	1
Underdose	1	9	1	9		
Vaccination failure	2	3			2	3
Vaccination site dysaesthesia		1		1		
Vaccination site erythema		1		1		
Vaccination site haemorrhage		1		1		
Vaccination site hypersensitivity		2		2		
Vaccination site lymphadenopathy		1		1		
Vaccination site movement impairment		1				1
Vaccination site pain	4	13	4	13		
Vaccination site pruritus		1		1		
Vaccination site swelling		1		1		
Vasoconstriction		1		1		
Ventricular tachycardia	1	1			1	1
Volvulus of small bowel	1	1			1	1
Vomiting	2	2	2	2		
Wrong technique in product usage process	1	4	1	4		
	518	1,057	475	783	43	274

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Country Where Event Occurred

FRENCH GUIANA

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cerebral venous sinus thrombosis	1	1	1	1
Ischaemic stroke	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

FRENCH POLYNESIA

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Apraxia	1	1	1	1
Asthenia	1	1	1	1
Dyspnoea	1	1	1	1
Dysstasia	1	1	1	1
Facial paralysis	1	1	1	1
	5	5	5	5

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute respiratory distress syndrome		1		1
Arthralgia		1		1
Asthenia		2		2
Cardiopulmonary failure		1		1
Confusional state		1		1
Dermatitis bullous		1		1
Dermatosis		1		1
Dyspnoea		1		1
Dysstasia		1		1
Haemoptysis		1		1
Hyperaesthesia		1		1
Hyperthermia		1		1
Memory impairment		1		1
Movement disorder		1		1
Oxygen saturation decreased		1		1
Pulmonary embolism		1		1
Staphylococcal sepsis		1		1
Toxic epidermal necrolysis		1		1
		19		19

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Country Where Event Occurred
FRENCH SOUTHERN TERRITORIES

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Death		1		1
		1		1

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Country Where Event Occurred

GAMBIA

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Blood creatinine increased		1		1
Hypertension		1		1
Oedema peripheral		1		1
		3		3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

GEORGIA

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Liquid product physical issue	1	1	1	1		
Pneumonia		1				1
Poor quality product administered	1	1	1	1		
Sepsis		1				1
	2	4	2	2		2

* I=Interval, C=Cumulative
* AE=Adverse Event

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Country Where Event Occurred

GERMANY

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic shock		2				2
Blood pressure decreased	1	1			1	1
Bloody discharge		1		1		
Chills		1		1		
Condition aggravated		1		1		
Diarrhoea		1		1		
Dizziness		1				1
Dyspnoea		3		1		2
Erythema		1				1
Exposure via breast milk	2	8	2	8		
Flushing		1				1
Haemorrhage		1				1
Headache		3		3		
Hypersensitivity		2		1		1
Hypoaesthesia		1		1		
Hypotension		1				1
Hypotonia		1		1		
Incorrect route of product administration		1		1		
Lymphopenia		1		1		
Malaise		1				1
Multiple sclerosis		1				1
Muscle spasms		1		1		
Myalgia		1		1		
Myocarditis	1	1			1	1
Off label use		2		2		
Pain in extremity		2		2		
Palpitations		1		1		
Paraesthesia		1		1		
Product administered to patient of inappropriate age		1		1		
Product use issue		1		1		
Pustule		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia		3		2		1
SARS-CoV-2 ant body test		1		1		
Seizure		1				1
Sensory loss		1		1		
Somnolence	1	1			1	1
Stridor	1	1			1	1
Thrombocytopenia		1				1
Vaccination site erythema		1		1		
Vaccination site pain	1	3	1	3		
Vaccination site swelling		1		1		
Vomiting		1		1		
	7	61	3	42	4	19

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal pain	2	7			2	5		2
Abdominal pain lower	2	4			2	4		
Abdominal pain upper		3				2		1
Abnormal faeces	4	8			4	8		
Abortion spontaneous		2						2
Abscess		1						1
Acne		1				1		
Acute myocardial infarction		1						1
Ageusia		1						1
Agranulocytosis		1						1
Alopecia		1						1
Altered state of consciousness				1				
Amenorrhoea	1	1					1	1
Anaphylactic reaction	1	17					1	17
Anaphylactic shock	1	2		1			1	2
Anaphylactoid reaction		1						1
Angina pectoris	1	2					1	2
Angioedema		1						1
Anorectal disorder		1						1
Anosmia		2				1		1
Apathy		1				1		
Appendicitis				1				
Arrhythmia	1	4					1	4
Arthralgia	9	27		9	9	25		2
Arthritis reactive		1						1
Aspartate aminotransferase increased	1	1					1	1
Asthenia	18	47			17	43	1	4
Asthma	1	6			1	4		2
Autonomic nervous system imbalance		1						1
Axillary pain	1	3			1	3		
Back pain	4	11			4	10		1
Bladder dysfunction		1						1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blister		1
Blood lactate dehydrogenase increased	1	1
Blood potassium decreased		1
Blood potassium increased	1	1
Blood pressure decreased		2
Blood pressure increased		3
Blood uric acid increased	1	1
Body temperature decreased	1	1
Body temperature increased	9	13
Breast cancer	1	1
Breast pain		
Bronchial obstruction		1
Bronchitis bacterial		1
Bronchospasm		1
Burning sensation		5
Capillary nail refill test abnormal		1
Cardiac disorder	1	1
Cardiovascular disorder	2	6
Cardiovascular insufficiency		2
Cerebral venous sinus thrombosis	2	2
Cerebrovascular accident		1
Chest discomfort	4	6
Chest pain	2	5
Chills	44	90
Circulatory collapse	5	16
Cold sweat	2	2
Colitis ulcerative	1	1
Condition aggravated		1
Confusional state	1	2
Conjunctival haemorrhage		2
Conjunctivitis	1	2
Contusion	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
					1
				1	1
			1		1
			3		
		1	1		
		1	1		
		9	13		
				1	1
	1				
					1
					1
			1		4
			1		
				1	1
		2	3		3
					2
				2	2
					1
		4	5		1
		2	5		
	13	43	81	1	9
				5	16
		2	2		
				1	1
			1		
		1	1		1
					2
		1	1		1
				1	1

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* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cough		7
COVID-19	2	12
COVID-19 pneumonia		1
Craniocerebral injury		1
Cyanosis	1	3
Deafness	1	2
Death	1	1
Decreased appetite	1	1
Deep vein thrombosis	2	3
Depressed level of consciousness		1
Depression		2
Diarrhoea	6	25
Discomfort	2	2
Disease recurrence	1	3
Disturbance in attention	5	10
Dizziness	29	74
Drug eruption		1
Drug ineffective	2	8
Dry mouth	1	4
Dry skin	1	1
Dysaesthesia		1
Dysgeusia		1
Dysmenorrhoea	1	1
Dysphagia		1
Dysphonia		1
Dyspnoea	6	30
Dyspnoea at rest	1	1
Dyspnoea exertional	1	3
Dysuria		2
Ear discomfort	3	3
Ear pain		2
Eating disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1		5		2
		1	3	1	9
					1
					1
		1	2		1
				1	2
				1	1
		1	1		
				2	3
					1
			2		
	5	6	22		3
	2	2	2		
			1	1	2
		5	10		
	18	27	56	2	18
					1
				2	8
		1	4		
		1	1		
					1
			1		
		1	1		
			1		
					1
	2	4	15	2	15
				1	1
		1	1		2
					2
		3	3		
			2		
			1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Emotional disorder		1
Enanthema		1
Enteritis		1
Epilepsy	1	2
Epistaxis		1
Epstein-Barr virus infection reactivation		3
Erysipelas		1
Erythema	5	17
Erythema migrans	1	1
Extrapyramidal disorder		2
Eye haemorrhage	1	1
Eye infarction	1	1
Eyelid oedema		1
Eye pain	1	2
Eye swelling	2	2
Facial paralysis		3
Facial paresis	2	7
Fall	1	2
Fatigue	43	108
Feeling cold	3	10
Feeling hot	4	10
Feeling of body temperature change	2	3
Flank pain	1	2
Flatulence		2
Flushing	3	11
Frequent bowel movements	1	1
Gastrointestinal disorder		1
Gastrointestinal pain	1	1
General physical health deterioration	1	3
Genital herpes		1
Gingival swelling	1	1
Groin pain		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
				1	2
			1		
					3
					1
	2	5	13		4
		1	1		
			1		1
				1	1
				1	1
					1
		1	2		
		2	2		
					3
			5	2	2
				1	2
	20	43	102		6
		3	8		2
		4	8		2
		2	3		
		1	2		
			2		
		3	8		3
		1	1		
					1
	1	1	1		
			1	1	2
			1		
		1	1		
			1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haematochezia	1	1
Haematocrit increased	1	1
Haematology test abnormal	1	1
Haematoma	2	3
Haemoglobin increased	1	1
Haemoptysis		2
Haemorrhage	1	1
Headache	78	174
Head discomfort	1	2
Head injury		2
Heart rate increased		4
Heavy menstrual bleeding	2	2
Hemiparaesthesia		1
Hemiparesis		1
Herpes zoster	9	14
Hot flush	1	5
Hyperhidrosis	2	10
Hypersensitivity	3	17
Hypertension		7
Hyperthermia		1
Hyperventilation		3
Hypoacusis	1	3
Hypoaesthesia	6	15
Hypoaesthesia oral		2
Hypogeusia	1	1
Hypoglycaemia		1
Hypokalaemia	1	1
Hypokinesia		1
Hyposmia	1	1
Hypotension		11
Hypothyroidism		1
Hypotonia	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
				1	1
		2	3		
				1	1
			2		
				1	1
	23	75	157	3	17
		1	2		
					2
			3		1
		2	2		
					1
					1
		8	11	1	3
		1	5		
		2	9		1
	1	3	6		11
			2		5
					1
			1		2
			1	1	2
	1	5	12	1	3
					2
				1	1
			1		
				1	1
			5		6
					1
		1	3		1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Illness		1
Immune thrombocytopenia		2
Inappropriate schedule of product administration	1	3
Incorrect route of product administration	4	12
Inflammation	1	1
Influenza	2	4
Influenza like illness	15	30
Insomnia	3	4
Intestinal obstruction		1
Irregular breathing		1
Jaundice		1
Joint range of motion decreased	1	1
Joint swelling		1
Lacrimation increased		1
Language disorder	1	1
Leukopenia	1	1
Limb discomfort	7	16
Lipase increased	1	1
Lip swelling		1
Listless	1	1
Local reaction		5
Loss of consciousness	1	3
Lymphadenitis	1	5
Lymphadenopathy	10	21
Lymph node pain	3	9
Lymphocyte count decreased		1
Lymphopenia		1
Malaise	10	27
Maternal exposure during pregnancy	1	4
Mean cell volume decreased	1	1
Menstrual cycle management	1	1
Mental impairment		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					2
		1	3		
		4	12		
		1	1		
		2	4		
		15	30		
		3	4		
					1
					1
			1		
		1	1		
					1
			1		
				1	1
				1	1
		7	14		2
		1	1		
					1
		1	1		
			4		1
				1	3
			2	1	3
		10	21		
		3	9		
			1		
					1
	21	10	23		4
		1	4		
		1	1		
		1	1		
					1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Middle insomnia		1
Migraine	3	6
Mobility decreased	1	4
Monocyte count increased	1	1
Monocytosis		1
Monoparesis	1	1
Monoplegia		1
Mouth swelling		1
Movement disorder	1	2
Multiple sclerosis relapse		1
Muscle mass		1
Muscle spasms	2	4
Muscle strain		
Muscle tightness	1	1
Muscle twitching		2
Muscular weakness	4	9
Musculoskeletal pain	1	1
Musculoskeletal stiffness		1
Myalgia	10	42
Myocarditis	5	13
Nasal congestion		2
Nasopharyngitis	2	6
Nausea	21	53
Neck pain	4	7
Neuralgic amyotrophy		1
Neurodermatitis		1
Neutropenia		1
Obesity	1	1
Obstructive airways disorder		1
Ocular discomfort	1	1
Ocular hyperaemia	1	1
Oedema		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		3	6		
		1	3		1
		1	1		
					1
		1	1		
					1
					1
			1	1	1
					1
			1		
		2	3		1
	1				
	1	1	1		
			2		
		3	6	1	3
		1	1		
			1		
	11	10	39		3
				5	13
			2		
	1	2	5		1
	16	20	45	1	8
		4	7		
					1
			1		
					1
		1	1		
		1	1		
			1		1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oedema peripheral		1
Oesophageal irritation		1
Off label use	1	8
Oligoarthritis		1
Optic neuritis	1	1
Oral candidiasis		1
Oral pain		1
Oropharyngeal blistering		1
Oropharyngeal pain	4	9
Otitis media		1
Overdose	1	1
Oxygen saturation decreased		1
Pain	1	12
Painful respiration	1	1
Pain in extremity	47	95
Pain of skin	1	1
Palatal swelling		1
Palpitations	2	16
Panic attack		1
Panic disorder		1
Paraesthesia	6	21
Paraesthesia oral	1	3
Paralysis		2
Pelvic pain		1
Pericarditis	1	2
Peripheral circulatory failure		1
Peripheral swelling	3	7
Peripheral vascular disorder	4	11
Petechiae	2	4
Pharyngeal erythema	1	1
Pharyngeal swelling		1
Phobia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
		1	8		
					1
				1	1
					1
					1
					1
		4	9		
			1		
		1	1		
			1		
		1	11		1
		1	1		
		47	91		4
		1	1		
					1
	1	2	9		7
					1
			1		
	1	5	13	1	8
		1	2		1
					2
			1		
				1	2
					1
		3	6		1
		4	7		4
		1	2	1	2
		1	1		
	1				1
		1	1		

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* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Platelet count increased	1	1
Pneumonia		1
Polyarthrits		1
Polydipsia		1
Polymenorrhoea	1	1
Polyneuropathy		1
Polyuria		1
Poor quality product administered	3	8
Poor quality sleep		1
Presyncope	1	9
Product storage error	2	2
Product temperature excursion issue	2	7
Product use issue		5
Pruritus	8	22
Psychogenic seizure	1	1
Pulmonary embolism		3
Pulmonary pain	1	1
Pulse waveform abnormal		1
Pustule	1	2
Pyrexia	50	98
Rash	12	30
Rash erythematous	1	3
Rash macular		1
Rash maculo-papular		1
Rash papular		1
Rash pruritic	1	6
Rash vesicular	2	3
Red blood cell count increased	1	1
Red cell distribution width decreased	2	2
Respiration abnormal	1	2
Respiratory distress	2	17
Respiratory tract oedema		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
					1
					1
		1	1		
					1
					1
		3	7		1
					1
		1	5		4
		2	2		
		2	6		1
			5		
	1	7	14	1	8
				1	1
					3
				1	1
			1		
	1	1	2		
	13	50	91		7
	2	12	19		11
		1	2		1
			1		
					1
			1		
		1	4		2
		2	3		
				1	1
		1	1	1	1
		1	2		
				2	17
					1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Restlessness	2	4
Retching		1
Rhinorrhoea		1
SARS-CoV-2 ant body test positive	1	6
SARS-CoV-2 test positive		2
Seizure	1	8
Sensation of foreign body		6
Sensory disturbance	2	8
Sensory loss		1
Shock		1
Sinusitis		1
Sinus tachycardia		3
Skin burning sensation		1
Skin discolouration	1	1
Skin disorder		1
Skin haemorrhage	1	1
Skin irritation		1
Skin laceration		1
Skin reaction	1	2
Sleep disorder	2	2
Somatic symptom disorder		1
Somnolence	4	8
Spinal cord ischaemia		1
Spinal pain	1	2
Status epilepticus		1
Stress	2	2
Stridor		2
Sudden hearing loss		1
Supraventricular tachycardia		1
Suspected COVID-19	1	1
Swelling	1	7
Swelling face	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	4		
			1		
			1		
		1	6		
			1		1
				1	8
			1		5
		2	7		1
					1
					1
			1		
			1		2
			1		
		1	1		
					1
				1	1
			1		
					1
		1	2		
		2	2		
					1
		3	5	1	3
					1
		1	1		1
					1
		2	2		
					2
					1
			1		
				1	1
		1	5		2
		1	2		3

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Swollen tongue	1	2
Syncope	2	17
Tachycardia	2	23
Tachypnoea		1
Tension headache		1
Therapeutic response unexpected		1
Thermal burn	1	1
Thirst	1	2
Throat irritation		3
Throat tightness	1	6
Thrombocytopenia	1	2
Thrombophlebitis superficial	1	1
Tinnitus	2	3
Tongue coated	1	2
Tongue pruritus		1
Tonsillitis	1	1
Tremor		9
Type 1 diabetes mellitus		2
Type 2 diabetes mellitus	1	1
Urticaria	3	13
Vaccination failure		1
Vaccination site bruising		1
Vaccination site discomfort		1
Vaccination site dysaesthesia	1	1
Vaccination site erythema	4	9
Vaccination site granuloma		1
Vaccination site haematoma		2
Vaccination site hypersensitivity		1
Vaccination site induration	1	1
Vaccination site inflammation		
Vaccination site lymphadenopathy	1	1
Vaccination site movement impairment	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		1
				2	17
	1	2	14		9
					1
			1		
			1		
		1	1		
	1	1	2		
	1		3		
		1	2		4
				1	2
		1	1		
		2	2		1
		1	2		
					1
		1	1		
			1		8
					2
				1	1
	1	2	8	1	5
					1
			1		
			1		
		1	1		
	1				
		1	1		
		1	2		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site pain	52	135		21	52	133		2
Vaccination site paraesthesia		2				2		
Vaccination site pruritus	4	7			4	7		
Vaccination site rash		2				2		
Vaccination site reaction	2	5			2	5		
Vaccination site swelling	9	25		6	9	24		1
Vaccination site urticaria		1				1		
Vaccination site warmth	1	4			1	4		
Vasculitis	1	1					1	1
Vertebral wedging		1						1
Vertigo		5				5		
Viral rash		1				1		
Visual field defect		1						1
Visual impairment	2	6			1	1	1	5
Vomiting	6	16		5	5	10	1	6
Vulvitis		1						1
Vulvovaginal discomfort		1						1
Vulvovaginal mycotic infection	1	2			1	1		1
Vulvovaginal pain		1						1
Weight decreased		1						1
Wheezing		2						2
White blood cell count decreased		1				1		
	805	2,237		210	714	1659	91	578

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort		2				2		
Abdominal pain	11	18		1	10	16	1	2
Abdominal pain lower	1	1			1	1		
Abdominal pain upper	3	10			3	7		3
Abnormal behaviour	1	1			1	1		
Abnormal faeces	4	11			4	11		
Abortion missed		1						1
Abortion spontaneous		2						2
Accidental overdose		9				7		2
Acute myeloid leukaemia		1						1
Acute myocardial infarction		2						2
Ageusia	1	4			1	4		
Agitation		1				1		
Allergy to vaccine	2	3			1	1	1	2
Allodynia		1				1		
Alopecia areata		1				1		
Amnesia		5				1		4
Anaemia	2	2			2	2		
Anaesthesia oral	1	1			1	1		
Anaphylactic reaction	2	48					2	48
Anaphylactic shock	1	6					1	6
Anaphylactoid reaction		1						1
Anger	1	1			1	1		
Angina pectoris	4	11					4	11
Angioedema	1	15					1	15
Anosmia	1	3			1	3		
Antibody test negative	1	1					1	1
Anxiety	2	6			2	4		2
Aphasia		3				1		2
Aphthous ulcer	1	1			1	1		
Application site vesicles		1						1
Arrhythmia	7	25					7	25

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arteriosclerosis		1
Arthralgia	25	59
Ascites		1
Aspiration		2
Asthenia	32	74
Asthma	3	12
Ataxia		1
Atrial fibrillation		2
Atypical pneumonia		1
Autoimmune disorder	3	3
Autoimmune thyroiditis		1
Axillary pain	2	6
Back pain	8	13
Balance disorder	2	2
Basedow's disease	1	2
Bell's palsy	1	3
Bladder discomfort		2
Bladder pain		1
Blepharitis		1
Blister		3
Blood blister	1	1
Blood count abnormal		1
Blood creatine phosphokinase increased	2	2
Blood glucose decreased		1
Blood glucose increased		2
Blood methaemoglobin present		1
Blood potassium decreased		1
Blood pressure abnormal		1
Blood pressure decreased	1	5
Blood pressure fluctuation		2
Blood pressure increased	6	18
Blood sodium decreased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
	8	23	51	2	8
					1
					2
		30	66	2	8
		2	8	1	4
					1
					2
					1
				3	3
					1
		2	6		
		8	13		
		2	2		
				1	2
				1	3
			2		
			1		
			1		
			3		
		1	1		
					1
		2	2		
			1		
			2		
			1		
					1
			1		
	1		1	1	4
			2		
	2	4	9	2	9
			1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood thyroid stimulating hormone increased		1
Body temperature decreased		1
Body temperature increased	13	27
Bone pain	5	14
Bowel movement irregularity		1
Bradycardia		1
Bradyphrenia	1	1
Brain death		1
Brain stem infarction	1	1
Breast abscess	1	1
Breast cancer recurrent	1	1
Bronchial irritation	1	1
Bronchial obstruction		1
Bundle branch block right		1
Burning sensation	1	5
Burning sensation mucosal	1	1
Bursitis		1
Cardiac arrest		1
Cardiac discomfort		1
Cardiac failure		2
Cardiac hypertrophy	1	1
Cardiac valve disease	1	1
Cardiogenic shock	1	1
Cardiomyopathy	1	2
Cardiovascular disorder	2	15
Cardiovascular insufficiency		4
Cerebellar ataxia		1
Cerebellar syndrome		2
Cerebral infarction		3
Cerebral thrombosis	1	1
Cerebral venous sinus thrombosis	2	6
Cerebral venous thrombosis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
1	1	13	26		1
		5	14		
			1		
					1
		1	1		
					1
				1	1
				1	1
		1	1		
					1
					1
		1	4		1
		1	1		
	1		1		
					1
					1
					2
				1	1
				1	1
				1	1
				1	2
		1	10	1	5
					4
					1
					2
					3
				1	1
				2	6
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebrovascular accident		2
Cervical radiculopathy	1	1
Cervical vertebral fracture	1	1
Cervix haematoma uterine		1
Chest discomfort	4	12
Chest pain	5	17
Chest X-ray abnormal		1
Chills	90	170
Chronic idiopathic pain syndrome	1	1
Chronic obstructive pulmonary disease	1	1
Circulatory collapse	2	8
Coagulopathy	1	1
Cold sweat		5
Colitis ulcerative	1	2
Condition aggravated	2	5
Conjunctivitis		2
Constipation	2	2
Coronary artery thrombosis		1
Coronavirus infection		1
Cough	7	27
COVID-19	7	32
C-reactive protein increased		1
Crying	1	1
Cutaneous vasculitis		1
Cyanosis	1	4
Deafness		3
Deafness bilateral		1
Deafness transitory		1
Deafness unilateral		1
Death	2	5
Decreased appetite	2	8
Deep vein thrombosis	4	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		1	1		
				1	1
					1
		2	7	2	5
		5	11		6
					1
1	9	85	155	5	15
		1	1		
		1	1		
	1			2	8
		1	1		
					5
				1	2
		1	2	1	3
			2		
		2	2		
					1
			1		
		7	21		6
		1	9	6	23
			1		
		1	1		
					1
		1	3		1
					3
					1
					1
				2	5
		2	8		
				4	8

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dehydration	1	1
Depressed level of consciousness		3
Depressed mood	1	1
Depression	2	3
Depressive symptom	1	1
Dermatitis allergic		6
Dermatitis atopic		1
Dermatitis contact	1	1
Diabetes mellitus		1
Diaphragmalgia		1
Diarrhoea	21	59
Digestive enzyme abnormal		1
Diplopia		4
Discomfort		
Disease recurrence		1
Disorientation		2
Disturbance in attention	4	10
Dizziness	44	122
Dizziness postural		1
Drug eruption	2	2
Drug ineffective	6	18
Dry eye		1
Dry mouth	1	6
Dysaesthesia	1	5
Dysarthria		2
Dysgeusia	4	9
Dysmenorrhoea	2	2
Dyspepsia		2
Dysphagia	1	7
Dysphonia		8
Dyspnoea	11	62
Dyspnoea at rest		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					3
		1	1		
		2	3		
		1	1		
			3		3
			1		
		1	1		
					1
			1		
	5	18	51	3	8
			1		
			2		2
	1				
			1		
			1		1
		4	9		1
	17	39	96	5	26
					1
		2	2		
				6	18
			1		
		1	2		4
		1	4		1
			1		1
		4	8		1
		2	2		
			2		
			1	1	6
			7		1
		8	32	3	30
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dyspnoea exertional	2	7
Ear discomfort		3
Ear pain	4	5
Eczema	2	6
Eczema asteatotic	1	1
Electrocardiogram ST segment depression	1	2
Embedded device		1
Endometriosis	1	1
Eosinophil count decreased		1
Epilepsy		6
Episcleritis		1
Epistaxis		2
Erythema	7	33
Evans syndrome		1
Exercise tolerance decreased		
Exposure during pregnancy	1	1
Extrasystoles		1
Eye irritation	4	8
Eyelid function disorder	1	1
Eyelid haematoma	1	1
Eyelid oedema		1
Eyelid ptosis	1	1
Eye pain		3
Eye pruritus		4
Eye swelling	2	3
Face oedema	1	2
Facial nerve disorder		2
Facial pain		2
Facial paralysis	4	16
Facial paresis	5	11
Fall	2	2
Fatigue	105	237

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	6		1
			1		2
		3	4	1	1
		2	6		
		1	1		
				1	2
					1
		1	1		
			1		
			1		6
	1		2		
		7	24		9
					1
	1				
		1	1		
					1
		4	7		1
				1	1
		1	1		
					1
		1	1		
			3		
			2		2
		2	3		
		1	1		1
			1		1
			2		
				4	16
		3	6	2	5
				2	2
1	24	103	227	2	10

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Fear		1
Feeling abnormal	2	10
Feeling cold	10	18
Feeling hot	3	18
Feeling jittery		
Feeling of body temperature change	1	6
Fibrin D dimer increased		1
Fibromyalgia	1	1
Flatulence		1
Flushing	11	33
Formication	1	1
Gait disturbance	4	8
Gastrointestinal pain	1	2
Generalised tonic-clonic seizure		2
General physical health deterioration	1	2
Genital herpes	2	2
Gingivitis		2
Guillain-Barre syndrome		1
Haematemesis		1
Haematochezia	1	3
Haematocrit decreased		1
Haematoma	2	4
Haematuria		1
Haemoglobin decreased		1
Haemorrhage		3
Hallucination	2	4
Hallucination, visual	1	1
Headache	151	335
Head discomfort	4	8
Heart rate decreased	1	1
Heart rate increased	5	10
Heavy menstrual bleeding	3	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		2	9		1
		10	16		2
		3	13		5
	1				
		1	6		
					1
		1	1		
	1		1		
		11	20		13
		1	1		
		3	5	1	3
		1	1		1
					2
			1	1	1
		2	2		
					2
					1
					1
				1	3
			1		
		2	4		
			1		
			1		
					3
				2	4
				1	1
1	22	143	300	8	35
		1	4	3	4
				1	1
		4	6	1	4
		2	2	1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hemiparaesthesia		2
Hemiparesis	1	2
Hepatic enzyme increased		2
Hepatic pain		1
Herpes dermatitis		1
Herpes simplex		1
Herpes simplex reactivation		1
Herpes zoster	17	23
Herpes zoster meningitis	1	2
Herpes zoster oticus		1
HIV test positive		1
Hordeolum		1
Hot flush	1	8
Hunger		1
Hyperacusis		1
Hyperaesthesia	1	3
Hyperhidrosis	10	16
Hyperpyrexia	1	1
Hypersensitivity	6	39
Hypersomnia		1
Hypertension	4	29
Hypertensive crisis	1	8
Hyperthyroidism		1
Hypertonia		1
Hyperventilation		7
Hypoaesthesia	8	24
Hypoaesthesia eye	1	1
Hypoaesthesia oral	2	8
Hypotension	1	15
Hypothermia		2
Hypotonia	5	9
Hypoxia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
				1	2
					2
			1		
			1		
			1		
					1
		16	20	1	3
				1	2
					1
					1
			1		
		1	6		2
			1		
			1		
		1	3		
	1	9	15	1	1
				1	1
	3	5	16	1	23
					1
	3	3	14	1	15
				1	8
					1
			1		
			3		4
	1	6	20	2	4
		1	1		
		1	7	1	1
			6	1	9
					2
		5	8		1
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Idiopathic intracranial hypertension		1
Illness	1	1
Immune thrombocytopenia		1
Immunisation reaction		
Impaired work ability	1	2
Inappropriate schedule of product administration	1	7
Incorrect dose administered	2	2
Incorrect route of product administration	13	35
Infection		2
Influenza	6	8
Influenza like illness	33	67
Injected limb mobility decreased		1
Injection site pain	1	3
Insomnia	1	4
Joint range of motion decreased	1	3
Joint stiffness	1	1
Jugular vein thrombosis	2	2
Keratoconus		1
Lacrimation increased	1	6
Laryngeal oedema	1	4
Laryngospasm		1
Leukopenia	1	1
Limb discomfort	14	23
Lipid metabolism disorder		1
Lip swelling	1	4
Livedo reticularis		1
Local reaction	3	8
Loss of consciousness	1	4
Lower respiratory tract congestion		1
Lung disorder		2
Lymphadenitis	3	5
Lymphadenopathy	25	56

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1		
					1
1	1				
		1	2		
		1	7		
		2	2		
		12	34	1	1
			1		1
		6	8		
		33	66		1
			1		
		1	3		
		1	3		1
			2	1	1
		1	1		
				2	2
					1
		1	4		2
				1	4
					1
				1	1
		14	21		2
			1		
		1	1		3
			1		
		3	6		2
				1	4
			1		
			2		
		3	5		
		24	52	1	4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lymphangitis		1
Lymphatic disorder	2	2
Lymph node pain	7	13
Lymphocyte count decreased		1
Lymphoedema	1	2
Macular degeneration		
Macular hole		
Malaise	16	43
Mastitis	1	1
Maternal exposure during pregnancy	3	8
Memory impairment		1
Meningitis aseptic		1
Meningitis viral		1
Menstrual cycle management	1	1
Menstrual disorder	2	2
Menstruation irregular	3	4
Mental disorder	1	2
Mental impairment	1	1
Mesenteric vein thrombosis	1	1
Microembolism		1
Migraine	5	10
Migraine without aura	1	1
Misleading laboratory test result	1	1
Mobility decreased	2	5
Monocyte count decreased		1
Monoplegia	1	2
Mouth swelling		1
Movement disorder	2	4
Multiple sclerosis		1
Multiple sclerosis relapse		1
Muscle spasms	1	4
Muscle spasticity		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		2	2		
		7	13		
			1		
		1	2		
1	1				
1	1				
	25	15	35	1	8
				1	1
		2	6	1	2
			1		
					1
					1
		1	1		
		2	2		
		2	3	1	1
		1	2		
				1	1
				1	1
					1
		5	9		1
		1	1		
		1	1		
		2	5		
			1		
				1	2
					1
		1	3	1	1
1	1				1
1	1				1
		1	4		
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle tightness	1	2
Muscle twitching	2	6
Muscular weakness	6	12
Musculoskeletal chest pain		3
Musculoskeletal discomfort	1	1
Musculoskeletal disorder		1
Musculoskeletal pain	1	2
Musculoskeletal stiffness	1	2
Myalgia	47	115
Myasthenia gravis		1
Myelitis	1	1
Myocardial infarction		1
Myocarditis	5	8
Myoglobin blood increased		1
Myosclerosis		2
Myositis	1	1
Nasal congestion		2
Nasal discomfort	1	1
Nasopharyngitis	7	15
Nausea	36	94
Neck pain	9	24
Nervous system disorder		1
Neuralgia	7	10
Neurodermatitis		1
Neuropathy peripheral		2
Neutropenia		1
Neutrophil count increased		1
Night sweats	3	4
Nodule		1
Nuchal rigidity	1	1
Nystagmus		1
Obstructive airways disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	1
		2	5		1
		5	10	1	2
			1		2
		1	1		
			1		
		1	1		1
			1	1	1
	15	47	107		8
					1
				1	1
					1
				5	8
					1
					2
		1	1		
			1		1
		1	1		
		7	14		1
	18	32	78	4	16
		8	22	1	2
					1
		7	10		
			1		
					2
					1
			1		
		3	4		
			1		
		1	1		
					1
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ocular discomfort	2	5
Ocular hyperaemia	2	6
Ocular icterus		1
Odynophagia	1	1
Oedema peripheral	1	2
Off label use	3	9
Ophthalmic herpes simplex	1	1
Optic nerve disorder		
Optic neuritis		2
Optic neuropathy		1
Oral herpes	3	6
Oral mucosa erosion		1
Oral mucosal eruption		1
Oral mucosal erythema	1	1
Oropharyngeal blistering	1	1
Oropharyngeal pain	4	11
Oropharyngeal swelling		1
Orthopnoea		1
Orthostatic hypotension		1
Orthostatic intolerance		2
Overdose		1
Oxygen saturation decreased		2
Pain	15	31
Painful respiration	1	1
Pain in extremity	81	173
Pain of skin	2	3
Palpitations	6	32
Panic attack	1	1
Panic reaction	1	1
Paraesthesia	15	57
Paraesthesia oral	3	11
Paralysis	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	4		1
		2	5		1
			1		
	1	1	1		
		1	1		1
		3	9		
				1	1
1	1				
					2
					1
		3	5		1
			1		
			1		
		1	1		
				1	1
	1	4	9		2
					1
					1
			1		
			1		1
					1
					2
		15	28		3
		1	1		
		78	160	3	13
		2	3		
	2	5	26	1	6
				1	1
		1	1		
	2	11	30	4	27
		2	8	1	3
				1	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Paresis		1
Paresis cranial nerve	1	1
Parosmia	1	3
Pemphigus		1
Performance status decreased	1	2
Pericardial effusion		1
Perioral dermatitis		1
Peripheral circulatory failure	2	5
Peripheral coldness	2	4
Peripheral swelling	3	6
Peripheral vascular disorder	7	18
Personality change		2
Petechiae	1	4
Pharyngeal hypoaesthesia		2
Pharyngeal oedema		1
Pharyngeal swelling		6
Pharyngitis bacterial	1	1
Photopsia		1
Photosensitivity reaction	1	2
Physical deconditioning	1	1
Platelet count decreased	2	2
Pleocytosis		1
Pleural effusion		1
Pneumonia		1
Poisoning		1
Pollakiuria		2
Polyneuropathy		1
Poor quality product administered	5	24
Poor quality sleep		1
Pregnancy with contraceptive device		1
Presyncope		5
Product administered at inappropriate site	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
		1	2		1
					1
		1	2		
					1
			1		
		2	4		1
		2	4		
		3	5		1
	1	7	13		5
			1		1
		1	3		1
			2		
					1
			1		5
				1	1
			1		
		1	2		
		1	1		
		1	1	1	1
			1		
					1
					1
			2		
1	1				1
		5	23		1
			1		
					1
			5		
		1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Product complaint		1
Product storage error	5	7
Product supply issue		1
Product temperature excursion issue	3	21
Product use issue	2	4
Protein urine present		1
Prurigo		1
Pruritus	12	41
Pruritus allergic		2
Psychological factor affecting medical condition		1
Psychomotor retardation	1	1
Psychomotor skills impaired	1	1
Pulmonary embolism	6	11
Pulmonary pain	1	3
Pulmonary sarcoidosis		1
Pupils unequal		1
Pustule	1	1
Pyelonephritis acute	1	1
Pyrexia	97	195
Quality of life decreased	1	1
Rash	12	35
Rash erythematous		2
Rash macular	3	4
Rash maculo-papular		2
Rash papular	1	1
Rash pruritic	3	8
Rash pustular		1
Rash vesicular	2	4
Raynaud's phenomenon		1
Red blood cell count decreased		1
Red blood cell sedimentation rate increased		1
Renal failure	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		5	7		
			1		
		3	20		1
		2	4		
			1		
			1		
		12	30		11
			1		1
					1
		1	1		
		1	1		
				6	11
		1	2		1
					1
					1
		1	1		
				1	1
	8	94	176	3	19
		1	1		
	1	12	23		12
			2		
		2	3	1	1
			2		
		1	1		
		2	7	1	1
			1		
		2	4		
			1		
			1		
			1		
				1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Renal pain		2
Respiration abnormal		1
Respiratory distress	5	40
Respiratory failure		1
Respiratory rate increased		2
Respiratory symptom		1
Resting tremor		1
Restlessness	3	6
Retching		2
Retinal disorder		1
Retinopathy		1
Retrograde amnesia		1
Revers ble cerebral vasoconstriction syndrome		1
Rhabdomyolysis	1	1
Rheumatic disorder		1
Rheumatoid arthritis		2
Rhinalgia		1
Rhinitis	2	2
Rhinorrhoea	2	9
SARS-CoV-2 ant body test negative		2
SARS-CoV-2 ant body test positive	3	15
SARS-CoV-2 test positive	1	3
Scratch		1
Seasonal allergy	1	2
Seizure	1	5
Sensation of foreign body	1	8
Sensitive skin	1	1
Sensory disturbance	10	25
Sensory level abnormal		2
Sinusitis	1	2
Sinus tachycardia	1	3
Skin burning sensation	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
			1		
				5	40
					1
			2		
			1		
					1
		2	5	1	1
			2		
					1
					1
					1
					1
					1
				1	1
					1
					2
			1		
		2	2		
		2	8		1
			2		
		2	14	1	1
			2	1	1
			1		
		1	2		
				1	5
		1	4		4
		1	1		
		8	20	2	5
			2		
		1	2		
		1	1		2
		1	2		

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin discolouration	1	4
Skin lesion		1
Skin swelling		1
Sleep disorder		2
Sneezing		3
Somnolence	17	24
Speech disorder		3
Spinal pain	1	2
Splenomegaly	1	1
Stomatitis		2
Stress		2
Stridor	1	4
Subarachnoid haemorrhage		1
Sudden death	2	3
Sudden hearing loss		3
Sudden visual loss		1
Suicidal ideation	1	1
Superinfection bacterial		2
Supraventricular extrasystoles		2
Swelling	1	10
Swelling face	2	5
Swelling of eyelid	2	2
Swollen tongue		6
Syncope	5	19
Tachyarrhythmia		2
Tachycardia	13	61
Tachycardia induced cardiomyopathy		1
Tachypnoea		2
Taste disorder	2	6
Tenderness	2	3
Tension	1	1
Tension headache		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		1
					1
			1		
			2		
			3		
		13	18	4	6
			1		2
		1	2		
				1	1
					2
			2		
				1	4
					1
				2	3
					3
					1
				1	1
					2
			1		1
		1	9		1
	1	2	3		2
		2	2		
			3		3
	1			5	19
			1		1
	5	11	34	2	27
					1
			1		1
		2	4		2
		2	3		
		1	1		
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tetany		1
Thirst	1	3
Throat irritation	2	11
Throat tightness	2	13
Thrombocytopenia	1	2
Thrombophlebitis		1
Thrombophlebitis superficial	1	2
Thrombosis		3
Thyroiditis acute		1
Tinnitus	2	6
Tongue discomfort	1	1
Tongue disorder		1
Tonic convulsion		1
Tonsillar disorder	1	1
Tonsillitis bacterial		2
Transaminases increased	1	1
Transient ischaemic attack	1	2
Tremor	6	19
Trichoglossia	1	2
Trigeminal neuralgia		1
Ulnar nerve injury	1	1
Underdose		1
Urticaria	6	18
Urticaria physical	1	1
Vaccination complication	2	2
Vaccination failure	1	4
Vaccination site dermatitis		1
Vaccination site discomfort	3	5
Vaccination site dysaesthesia		1
Vaccination site erythema	12	30
Vaccination site haematoma	1	4
Vaccination site hyperaesthesia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	3		
		2	10		1
		2	8		5
				1	2
			1		
			1	1	1
					3
					1
		2	4		2
		1	1		
			1		
					1
		1	1		
					2
		1	1		
				1	2
		2	9	4	10
			1	1	1
			1		
		1	1		
			1		
		6	13		5
		1	1		
		1	1	1	1
				1	4
			1		
		3	5		
			1		
		12	30		
		1	4		
			1		

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site hypoaesthesia		1						1
Vaccination site induration		7				7		
Vaccination site joint movement impairment		2				2		
Vaccination site joint pain		2				2		
Vaccination site lymphadenopathy		1				1		
Vaccination site movement impairment	1	7			1	7		
Vaccination site oedema		1				1		
Vaccination site pain	79	228		24	79	225		3
Vaccination site papule		1				1		
Vaccination site paraesthesia		3				3		
Vaccination site pruritus	3	11			3	11		
Vaccination site reaction	3	7			3	7		
Vaccination site swelling	12	32		4	12	31		1
Vaccination site urticaria		1				1		
Vaccination site warmth	7	17		1	7	17		
Vasculitis		1						1
Venous thrombosis in pregnancy		1						1
Venous thrombosis limb	2	3					2	3
Ventricular extrasystoles	1	1					1	1
Vertigo	1	4			1	3		1
Vision blurred		4				2		2
Visual field defect		1						1
Visual impairment	2	17			2	8		9
Vomiting	10	30		3	8	23	2	7
Weight bearing difficulty		1						1
Weight decreased	1	1					1	1
Wheezing		3				1		2
White blood cell count increased		1						1
	1,695	4,647	11	225	1463	3460	232	1187

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort		2				2		
Abdominal pain	4	12			3	7	1	5
Abdominal pain lower	3	5			3	4		1
Abdominal pain upper	3	7			3	6		1
Abnormal faeces	1	4			1	3		1
Accidental overdose		5				4		1
Acute abdomen		2						2
Acute febrile neutrophilic dermatosis		1						1
Acute kidney injury	1	2					1	2
Acute myeloid leukaemia		1				1		
Acute myocardial infarction	1	6					1	6
Acute phase reaction		1				1		
Acute respiratory distress syndrome		3						3
Acute respiratory failure		1						1
Acute stress disorder		2						2
Adverse event	1	1			1	1		
Ageusia	3	4			3	4		
Agitation		1						1
Allergic oedema		1						1
Allergy to vaccine		2				1		1
Altered state of consciousness		1						1
Amnesia	1	1					1	1
Amnestic disorder		1						1
Anaesthesia		1						1
Anaphylactic reaction	5	18					5	18
Anaphylactic shock	2	6					2	6
Angina pectoris	2	5					2	5
Angioedema	3	7					3	7
Anosmia		1				1		
Anxiety		3				2		1
Aortic arteriosclerosis	1	1			1	1		
Apathy	1	3			1	3		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Aphasia	2	2
Arrhythmia	8	16
Arterial disorder	1	1
Arterial thrombosis		2
Arthralgia	15	44
Arthritis		1
Arthropathy		1
Asthenia	21	52
Asthma	1	3
Asymptomatic COVID-19		2
Ataxia		1
Atrial f brillation	1	1
Atrial tachycardia		1
Autonomic nervous system imbalance		1
Axillary pain		2
Axillary vein thrombosis	1	1
Back pain	5	12
Bladder discomfort	1	1
Blindness transient	1	1
Blood calcium increased		1
Blood cholesterol increased		1
Blood glucose abnormal		1
Blood glucose decreased		1
Blood glucose fluctuation		1
Blood glucose increased		1
Blood immunoglobulin M increased		1
Blood pressure fluctuation	1	1
Blood pressure increased	3	11
Blood test abnormal	1	1
Body temperature decreased		1
Body temperature fluctuation	1	1
Body temperature increased	5	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2		
	1			8	16
		1	1		
					2
	5	15	41		3
					1
					1
		21	50		2
		1	2		1
			1		1
					1
				1	1
					1
			1		
			1		1
				1	1
		5	11		1
		1	1		
				1	1
			1		
			1		
					1
					1
			1		
			1		
				1	1
		2	7	1	4
		1	1		
			1		
		1	1		
		5	10		2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bone pain	4	13
Booster dose missed	1	1
Bradycardia		2
Brain death		1
Brain oedema	1	2
Brain stem infarction		1
Breast pain	1	2
Bronchial disorder		1
Bronchitis		1
Bronchospasm	1	2
Burning sensation	1	4
Cardiac arrest	3	5
Cardiac discomfort		1
Cardiac failure		3
Cardiac fibrillation		1
Cardiac hypertrophy	1	1
Cardiac procedure complication	1	1
Cardiomyopathy	1	1
Cardiovascular disorder		6
Cardiovascular insufficiency	3	3
Cerebral haemorrhage	1	3
Cerebral infarction	1	2
Cerebral venous sinus thrombosis	3	3
Cerebral ventricle collapse		1
Cerebrovascular accident		2
Chest discomfort	4	6
Chest pain	1	6
Chills	42	86
Chronic lymphocytic leukaemia	1	1
Chronic obstructive pulmonary disease		1
Circulatory collapse	2	8
Cold sweat		6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	11		2
		1	1		
					2
					1
				1	2
					1
		1	2		
			1		
			1		
				1	2
		1	2		2
				3	5
			1		
					3
					1
		1	1		
				1	1
				1	1
			2		4
				3	3
				1	3
				1	2
				3	3
					1
					2
		3	5	1	1
			4	1	2
	4	42	80		6
				1	1
					1
				2	8
			5		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Colitis ulcerative		3
Communication disorder		1
Complement factor C3 increased		1
Condition aggravated		1
Confusional state	1	1
Conjunctival haemorrhage	1	1
Conjunctivitis	1	2
Constipation	1	2
Coronary artery disease		1
Coronary artery dissection		1
Coronary artery stenosis		1
Coronavirus infection	1	1
Coronavirus test positive		1
Cough	5	19
COVID-19	7	45
COVID-19 pneumonia		2
Cranial nerve disorder		1
C-reactive protein increased	1	2
Creutzfeldt-Jakob disease		2
Cutaneous vasculitis		1
Cyanosis	1	2
Cystitis	1	1
Deafness	1	2
Deafness unilateral	1	2
Death	5	11
Decreased appetite	4	12
Deep vein thrombosis	5	7
Defaecation urgency		1
Depressed level of consciousness		2
Depressed mood	1	1
Depression		2
Dermatitis allergic	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
			1		
			1		
					1
		1	1		
				1	1
		1	1		1
		1	2		
					1
					1
					1
				1	1
			1		
		5	15		4
	1	1	10	6	35
					2
			1		
		1	2		
					2
					1
		1	1		1
		1	1		
				1	2
				1	2
				5	11
		4	9		3
				5	7
			1		
			1		1
		1	1		
			1		1
		1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dermatitis bullous	1	1
Diabetes mellitus inadequate control		1
Diarrhoea	8	36
Diarrhoea haemorrhagic	1	1
Diet refusal		1
Diplopia		1
Disease recurrence	2	6
Disseminated intravascular coagulation		1
Disturbance in attention	4	10
Diverticulitis	1	3
Dizziness	16	67
Drug ineffective	4	22
Drug interaction		1
Dry age-related macular degeneration		1
Dry eye	1	2
Dry mouth		4
Dysaesthesia	2	6
Dysarthria	1	1
Dysgeusia		4
Dysgraphia	1	1
Dyskinesia	1	1
Dysphagia		8
Dysphemia	1	1
Dyspnoea	7	27
Dyspnoea at rest		1
Dyspnoea exertional	1	4
Dysstasia		1
Dysuria	1	1
Ear discomfort	1	2
Ear pain	1	1
Eczema	1	2
Embolic stroke		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
		7	29	1	7
				1	1
					1
			1		
		1	1	1	5
					1
		4	9		1
				1	3
	6	16	53		14
				4	22
			1		
					1
		1	2		
			3		1
		2	3		3
		1	1		
			3		1
		1	1		
		1	1		
			5		3
		1	1		
		5	14	2	13
					1
		1	1		3
			1		
		1	1		
			1	1	1
		1	1		
		1	1		1
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Enanthema	1	1
Encephalitis		1
Enteritis		1
Epicondylitis	1	1
Epilepsy	1	9
Epistaxis	1	2
Eructation	1	1
Erysipelas	1	1
Erythema	6	19
Euphoric mood	1	1
Extrasystoles		1
Eye discharge	1	1
Eye haemorrhage		2
Eye infection	1	1
Eye irritation	1	3
Eyelid irritation	1	1
Eye pain	1	2
Eye pruritus	1	2
Eye swelling		1
Face oedema	1	2
Facial discomfort	2	2
Facial paralysis	5	9
Facial paresis	2	8
Faecaloma	1	1
Fall		2
Fatigue	49	119
Fear	1	1
Feeling abnormal	2	4
Feeling cold	8	13
Feeling hot	3	9
Fibrin D dimer increased		1
Fibromyalgia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
					1
		1	1		
				1	9
		1	1		1
		1	1		
				1	1
		5	14	1	5
		1	1		
			1		
		1	1		
					2
		1	1		
		1	3		
		1	1		
		1	2		
		1	1		1
			1		
		1	2		
		2	2		
				5	9
			2	2	6
				1	1
					2
	10	48	111	1	8
		1	1		
		2	4		
		8	13		
		2	4	1	5
			1		
		1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Flatulence	1	3
Flushing	3	7
Functional gastrointestinal disorder		1
Gait disturbance	2	4
Gastric disorder	1	1
Gastrointestinal haemorrhage	1	1
Gastrointestinal inflammation	1	1
Gastrointestinal motility disorder		1
Gastrointestinal necrosis		2
Gastrointestinal pain	1	1
General physical health deterioration	3	10
Giant cell arteritis		1
Gingival swelling		1
Glomerular filtration rate decreased		1
Glossitis	1	1
Guillain-Barre syndrome		1
Haematochezia		1
Haematoma	2	5
Haemolytic uraemic syndrome	1	1
Haemoptysis	1	1
Haemorrhage	1	1
Hallucination	1	1
Hallucination, auditory		1
Hand dermatitis	1	1
Headache	63	167
Head discomfort	2	3
Heart rate increased	4	4
Heavy menstrual bleeding	1	1
Hemiparesis		3
Hepatic enzyme increased		1
Hepatic failure		3
Hepatitis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		1
		2	4	1	3
			1		
		2	4		
		1	1		
				1	1
		1	1		
			1		
					2
		1	1		
		3	6		4
					1
			1		
			1		
		1	1		
					1
					1
		1	1	1	4
				1	1
		1	1		
				1	1
				1	1
					1
		1	1		
	12	59	146	4	21
		2	3		
		3	3	1	1
		1	1		
					3
			1		
					3
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Herpes virus infection	1	2
Herpes zoster	17	27
Herpes zoster infection neurological		1
Herpes zoster oticus		1
Huntington's disease		3
Hyperaesthesia	1	2
Hyperglycaemia		1
Hyperhidrosis	2	14
Hypersensitivity	2	17
Hypersomnia		1
Hypertension	5	19
Hypertensive crisis		5
Hypertensive emergency		1
Hyperthyroidism		1
Hypertonia		1
Hyperventilation		1
Hypoaesthesia	2	10
Hypoaesthesia oral	1	2
Hypoglycaemia		1
Hypophagia		1
Hypotension	6	15
Hypothyroidism	1	1
Hypotonia	1	4
Ileectomy		1
Illness		1
Immune thrombocytopenia	1	3
Impaired driving ability	1	1
Impaired work ability		1
Inappropriate schedule of product administration	1	6
Incomplete course of vaccination		1
Incorrect dose administered		1
Incorrect route of product administration	8	23

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
		16	23	1	4
					1
					1
					3
		1	2		
					1
		2	13		1
		2	9		8
					1
		3	8	2	11
					5
					1
					1
					1
					1
		2	7		3
		1	2		
			1		
					1
		6	12		3
				1	1
		1	4		
					1
			1		
				1	3
		1	1		
					1
		1	6		
			1		
			1		
		8	22		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Induration	1	2
Infection		3
Infection susceptibility increased	1	1
Infective exacerbation of chronic obstructive airways disease		2
Inflammatory marker increased	1	1
Influenza	8	8
Influenza like illness	18	35
Injection site pain		1
Insomnia	2	3
Intestinal gangrene		1
Intestinal haemorrhage	1	1
Intestinal obstruction		1
Intracardiac thrombus	1	1
Ischaemic cerebral infarction		1
Ischaemic stroke		1
IVth nerve disorder		1
IVth nerve paresis		1
Jaundice		1
Joint range of motion decreased		1
Joint swelling	1	2
Lacrimation increased	2	3
Language disorder		1
Laryngeal oedema		2
Left ventricular failure		1
Leukocytosis		1
Leukopenia		1
Lhermitte's sign		1
Limb discomfort	10	17
Lipids increased		1
Lip oedema		1
Lip swelling	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
	1		2		1
				1	1
					2
		1	1		
		8	8		
		18	35		
			1		
		1	2	1	1
					1
				1	1
					1
				1	1
					1
					1
			1		
			1		
		1	1		1
		2	3		
					1
					2
					1
					1
			1		
		10	15		2
			1		
			1		
		1	1		3

* I=Interval, C=Cumulative
* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Local reaction	3	6
Loss of consciousness	1	10
Loss of personal independence in daily activities	1	2
Low density lipoprotein increased		1
Lung disorder	1	1
Lung infiltration		1
Lymphadenopathy	12	22
Lymphangitis	1	1
Lymph node pain	3	5
Lymphopenia		1
Malaise	19	36
Medical induction of coma	1	1
Memory impairment		2
Meningism		2
Mental disorder		1
Mesenteric vein thrombosis		3
Microscopic polyangiitis		1
Micturition disorder		1
Middle insomnia		1
Migraine	2	4
Mobility decreased		2
Monoparesis		1
Monoplegia		1
Motion sickness	1	1
Mouth swelling		1
Movement disorder	3	6
Multiple sclerosis	1	1
Multiple sclerosis relapse		2
Muscle discomfort	1	2
Muscle spasms	5	9
Muscle tightness		2
Muscle twitching		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	6		
				1	10
		1	2		
			1		
		1	1		
					1
	1	12	21		1
				1	1
		3	5		
					1
	4	19	30		6
				1	1
			1		1
			1		1
			1		
					3
					1
			1		
			1		
		1	2	1	2
			2		
					1
					1
		1	1		
					1
		3	5		1
				1	1
					2
		1	2		
		4	6	1	3
			2		
			1		

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscular weakness	1	2
Musculoskeletal chest pain		3
Musculoskeletal pain		2
Musculoskeletal stiffness	1	1
Myalgia	15	46
Myelitis		2
Myocardial infarction	5	6
Myocardial ischaemia		1
Myocarditis	6	7
Myositis		1
Nasal congestion		1
Nasopharyngitis	4	12
Nausea	22	62
Neck pain	3	9
Neoplasm malignant	1	1
Nervousness		1
Nervous system disorder	1	1
Neuralgia	9	11
Neuralgic amyotrophy		3
Neuritis		2
Night sweats	2	2
Nuchal rigidity		1
Obstructive airways disorder		1
Occipital neuralgia		1
Ocular discomfort		1
Ocular hyperaemia	1	1
Oculogyric crisis		1
Odynophagia		1
Off label use	1	6
Ophthalmic herpes zoster	1	1
Ophthalmic vein thrombosis	2	4
Oral discomfort	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		1
			1		2
			2		
		1	1		
	8	14	42	1	4
					2
				5	6
					1
				6	7
			1		
			1		
		4	11		1
	1	22	54		8
		3	8		1
				1	1
			1		
				1	1
		9	11		
			1		2
			2		
		2	2		
			1		
					1
			1		
		1	1		
					1
			1		
		1	6		
				1	1
				2	4
		1	1		

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral herpes	1	2
Oral mucosal blistering		1
Oral mucosal erythema	1	1
Oropharyngeal blistering		1
Oropharyngeal discomfort		1
Oropharyngeal pain	4	9
Orthopnoea		1
Orthostatic hypotension		1
Overdose	2	2
Overweight	1	1
Oxygen saturation decreased	2	5
Pain	5	20
Painful respiration	2	4
Pain in extremity	50	96
Pallor		3
Palpitations	7	19
Panic attack		1
Paraesthesia	5	20
Paraesthesia oral	3	8
Paralysis	1	1
Paresis		5
Parosmia		1
Partial seizures		1
Pelvic pain		1
Pelvic venous thrombosis		1
Performance status decreased	1	3
Pericardial effusion		1
Peripheral circulatory failure		2
Peripheral coldness	2	2
Peripheral swelling	2	6
Peripheral vascular disorder	1	5
Personality change		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
			1		
		1	1		
					1
			1		
		4	8		1
					1
			1		
		2	2		
		1	1		
		2	3		2
		5	17		3
		1	3	1	1
		49	89	1	7
			1		2
	1	6	11	1	8
					1
		5	15		5
		3	7		1
				1	1
			1		4
			1		
					1
			1		
		1	1		2
					1
			2		
		2	2		
		1	3	1	3
		1	2		3
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Petechiae	1	3
Pharyngeal swelling	1	4
Pharyngitis		2
Phlebitis		1
Photophobia	1	1
Photopsia		1
Pituitary tumour benign	1	1
Platelet function test abnormal	1	1
Pneumonia		4
Pneumonia aspiration		2
Pneumonitis	1	1
Pollakiuria	1	1
Polyarthrits	1	1
Polyneuropathy		2
Poor quality product administered	5	14
Postoperative wound infection	1	1
Presyncope	2	3
Product administration error	1	1
Productive cough	1	1
Product preparation issue		1
Product storage error	2	2
Product supply issue		1
Product temperature excursion issue	4	13
Product use issue		2
Prostatitis	1	1
Pruritus	4	19
Psoriasis		1
Psychomotor retardation		1
Pulmonary embolism	7	13
Pulmonary infarction	1	1
Pulmonary oedema	1	1
Pulmonary pain	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	2
			2	1	2
			2		
			1		
		1	1		
			1		
				1	1
		1	1		
					4
					2
				1	1
		1	1		
				1	1
					2
		5	14		
				1	1
		2	2		1
		1	1		
		1	1		
			1		
		2	2		
		4	13		
			2		
		1	1		
	1	4	17		2
			1		
					1
				7	13
				1	1
				1	1
		1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pupillary disorder		1
Pyrexia	48	107
Quadripareisis		1
Radiculopathy		2
Rash	7	20
Rash erythematous	3	3
Rash macular	1	2
Rash maculo-papular	1	2
Rash pruritic	2	2
Rash pustular	2	2
Rash vesicular	1	2
Rectal polyp		1
Reduced facial expression	1	1
Renal disorder		1
Renal failure		3
Renal impairment		1
Renal pain		1
Respiration abnormal		1
Respiratory distress	3	13
Respiratory failure		7
Respiratory rate decreased		1
Respiratory rate increased		1
Respiratory tract infection		1
Restlessness	1	7
Retching		3
Retinal artery occlusion		1
Retinal tear		2
Retinal vein thrombosis	1	1
Rhabdomyolysis		1
Rheumatic disorder	1	1
Rhinitis	1	3
Rhinorrhoea	3	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
	4	48	93		14
					1
			1		1
	1	7	15		5
		3	3		
		1	2		
		1	2		
		2	2		
		2	2		
		1	2		
			1		
		1	1		
					1
					3
					1
					1
			1		
				3	13
					7
			1		
			1		
					1
		1	6		1
			2		1
					1
					2
				1	1
					1
		1	1		
		1	3		
		3	10		

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Salivary hypersecretion	1	1
SARS-CoV-2 ant body test negative		2
SARS-CoV-2 ant body test positive	1	9
SARS-CoV-2 test positive		2
Scratch		1
Secondary hypertension		1
Seizure	1	7
Sensation of blood flow		1
Sensation of foreign body		2
Sense of oppression		1
Sensory disturbance	4	9
Sensory level abnormal		2
Sepsis	1	1
Sialoadenitis		1
Sinus tachycardia		1
Skin abrasion		1
Skin burning sensation	3	4
Skin discolouration	1	2
Skin haemorrhage	1	1
Skin swelling		1
Sleep apnoea syndrome	1	1
Sleep disorder	3	7
Snoring		2
Somnolence	2	12
Speech disorder		1
Spinal disorder		1
Spinal pain		1
Status epilepticus		3
Stomatitis		1
Stress	1	1
Subclavian artery thrombosis		1
Subclavian vein thrombosis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
			2		
		1	9		
			2		
			1		
			1		
				1	7
			1		
					2
			1		
		4	9		
			1		1
				1	1
					1
					1
		3	3		1
		1	2		
		1	1		
			1		
		1	1		
		3	7		
			2		
		2	10		2
					1
					1
					1
					3
					1
		1	1		
					1
				1	1

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sudden cardiac death	1	1
Sudden death	1	2
Sudden hearing loss	2	4
Superior sagittal sinus thrombosis		1
Supraventricular extrasystoles		1
Supraventricular tachycardia	1	2
Suspected COVID-19	1	2
Swelling	1	4
Swelling face	3	12
Swollen tongue	2	6
Syncope	1	17
Tachycardia	6	20
Tachypnoea		1
Taste disorder		2
Tenderness	1	1
Tenosynovitis	1	1
Tension		1
Therapeutic response unexpected	1	2
Thinking abnormal	1	1
Throat irritation		2
Throat tightness		4
Thrombectomy		1
Thrombocytopenia		1
Thrombophlebitis superficial		1
Thrombosis	6	8
Thrombotic microangiopathy	1	1
Tinnitus	4	6
Tongue disorder		1
Tonsillar hypertrophy		1
Transaminases increased	1	2
Transient aphasia		1
Transient ischaemic attack		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	2
				2	4
					1
			1		
		1	1		1
		1	1		1
		1	4		
	2	3	7		5
		1	4	1	2
				1	17
		5	12	1	8
					1
			2		
		1	1		
		1	1		
			1		
		1	2		
		1	1		
			2		
			3		1
					1
					1
				6	8
				1	1
		3	4	1	2
			1		
			1		
		1	2		
					1
					2

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tremor	1	7
Trichoglossia	1	1
Trigeminal neuralgia		1
Trismus	1	1
Type IV hypersensitivity reaction	1	1
Unresponsive to stimuli		2
Urine odour abnormal		1
Urosepsis		1
Urticaria	3	11
Vaccination complication		1
Vaccination failure	3	9
Vaccination site discomfort	2	2
Vaccination site erythema	4	10
Vaccination site hyperaesthesia		1
Vaccination site induration	2	2
Vaccination site joint movement impairment		1
Vaccination site lymphadenopathy		1
Vaccination site movement impairment	1	1
Vaccination site pain	31	83
Vaccination site pruritus	1	2
Vaccination site reaction	5	8
Vaccination site swelling	9	20
Vaccination site warmth	3	7
Vaginal haemorrhage	1	1
Varicella zoster virus infection		1
Vasculitis		2
Venous thrombosis	3	3
Venous thrombosis limb	2	2
Ventricular extrasystoles		1
Ventricular tachycardia	1	1
Vertigo		1
Vestibular neuronitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	6		1
		1	1		
			1		
		1	1		
				1	1
					2
			1		
					1
		3	10		1
					1
				3	9
		2	2		
	1	4	8		2
			1		
		2	2		
					1
			1		
		1	1		
	7	31	78		5
		1	2		
		5	7		1
	2	9	19		1
		3	6		1
		1	1		
			1		
			1		1
				3	3
				2	2
			1		
				1	1
			1		
			1		

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Visceral venous thrombosis		1						1
Vision blurred		3				2		1
Visual field defect	1	1					1	1
Visual impairment	2	4			2	3		1
Vitreous disorder		1						1
Vomiting	6	18			5	15	1	3
Weight bearing difficulty	1	1			1	1		
Weight decreased	1	1					1	1
Wheezing		1				1		
White blood cell count increased		1				1		
	1,028	2,817		73	835	1940	193	877

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort		1				1		
Abdominal pain	1	1			1	1		
Abdominal pain lower	1	1			1	1		
Abdominal pain upper	2	3					2	3
Abnormal faeces	1	1			1	1		
Acidosis		1						1
Acute febrile neutrophilic dermatosis		1						1
Acute myocardial infarction	1	2					1	2
Acute respiratory distress syndrome	1	2					1	2
Acute respiratory failure		1						1
Adverse event	1	1			1	1		
Age-related macular degeneration	1	1					1	1
Ageusia		1				1		
Aggression		1						1
Allergy to vaccine		1						1
Alopecia		2				1		1
Amino acid level decreased		1				1		
Anaphylactic reaction	3	5					3	5
Angioedema		4						4
Antibody test abnormal		1				1		
Anxiety	1	1			1	1		
Aortic aneurysm		1						1
Aortic dissection		1						1
Apathy	1	1			1	1		
Aphasia	1	2					1	2
Application site erythema	1	1			1	1		
Application site pain	1	1			1	1		
Application site warmth	1	1			1	1		
Arrhythmia	3	6					3	6
Arterial occlusive disease	3	3					3	3
Arthralgia	4	8			4	8		
Arthropathy	1	1			1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Aspiration		1
Asthenia	6	20
Asthma		2
Asymptomatic COVID-19		2
Atrial fibrillation	1	2
Back pain	1	3
Balance disorder	1	3
Basal ganglia haemorrhage		1
Basilar artery thrombosis		2
Bedridden		1
Blindness unilateral		1
Blister		1
Blood creatine phosphokinase increased	1	2
Blood lactate dehydrogenase increased	1	1
Blood pressure abnormal		1
Blood pressure decreased		1
Blood pressure increased	1	3
Blood pressure systolic increased	1	1
Blood test abnormal		1
Blood uric acid increased	1	1
Body temperature increased	3	5
Bone pain		2
Brain injury		1
Brain oedema		1
Brain stem ischaemia	1	1
Breast pain		1
Bronchitis		2
Burning sensation	1	2
Cardiac arrest	2	6
Cardiac disorder	1	1
Cardiac failure	2	4
Cardiac failure acute	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		4	15	2	5
					2
					2
				1	2
		1	3		
		1	2		1
					1
					2
					1
					1
			1		
				1	2
		1	1		
			1		
			1		
		1	2		1
				1	1
			1		
		1	1		
		3	5		
			2		
					1
					1
				1	1
			1		
			1		1
		1	2		
				2	6
		1	1		
				2	4
				1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiac ventricular thrombosis	1	1
Cardiogenic shock	2	2
Cardiovascular disorder		1
Cerebral artery embolism	1	1
Cerebral haemorrhage	3	6
Cerebral infarction	6	9
Cerebral ischaemia	1	4
Cerebral venous sinus thrombosis	3	3
Cerebrovascular accident	11	17
Cerebrovascular disorder	1	1
Chest discomfort	2	2
Chest pain	2	4
Chills	3	12
Chronic inflammatory demyelinating polyradiculoneuropathy		1
Chronic obstructive pulmonary disease		1
Circulatory collapse	2	6
Condition aggravated	1	2
Contusion	1	1
Coordination abnormal	1	1
Coronary artery disease	1	1
Coronavirus test positive	1	1
Cor pulmonale		1
Cough	2	2
COVID-19	7	43
COVID-19 pneumonia		4
C-reactive protein increased	2	3
CSF cell count increased	1	1
CSF protein increased	1	1
Cystitis haemorrhagic		1
Dark circles under eyes		1
Death	13	52

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				2	2
			1		
				1	1
				3	6
				6	9
				1	4
				3	3
				11	17
				1	1
		2	2		
		2	4		
		3	10		2
					1
					1
				2	6
				1	2
				1	1
		1	1		
				1	1
				1	1
					1
		2	2		
		1	6	6	37
					4
		2	3		
				1	1
				1	1
					1
			1		
				13	52

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* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Decreased appetite		2
Deep vein thrombosis	13	19
Dehydration		1
Delusion		1
Dementia		1
Diarrhoea	6	12
Diarrhoea haemorrhagic	1	1
Diet refusal		1
Disease recurrence		2
Disturbance in attention	1	3
Dizziness	5	14
Drug ineffective	7	29
Drug interaction		2
Dysarthria	1	3
Dysgeusia		1
Dysphagia	2	2
Dysphonia	1	2
Dyspnoea	4	14
Dyspnoea exertional	1	1
Eczema	1	6
Embolus cerebral infarction	1	1
Encephalitis		1
Epilepsy	1	2
Epistaxis		2
Erysipelas	1	2
Erythema	2	2
Erythema multiforme		1
Eye pain	1	1
Eye pruritus		2
Eye swelling		1
Facial paralysis	1	3
Facial paresis	4	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
				13	19
					1
					1
					1
	1	4	6	2	6
				1	1
					1
			1		1
		1	2		1
		5	13		1
				7	29
			1		1
				1	3
			1		
				2	2
		1	1		1
		3	8	1	6
		1	1		
			5	1	1
				1	1
					1
				1	2
			2		
				1	2
		1	1	1	1
					1
		1	1		
			1		1
					1
				1	3
		1	1	3	3

* I=Interval, C=Cumulative
* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Fall		4
Fatigue	10	25
Feeling abnormal	1	2
Feeling cold		1
Feeling hot		1
Femur fracture		1
Fibrin D dimer increased	1	2
Fibromyalgia	1	1
Flushing		1
Freezing phenomenon	1	1
Gait disturbance	2	3
Gastrointestinal necrosis		1
Gastrointestinal pain		1
General physical health deterioration	1	8
Genital haemorrhage		1
Giant cell arteritis	1	1
Gingival bleeding		2
Groin pain	1	1
Guillain-Barre syndrome	1	1
Haematemesis		1
Haematochezia	1	1
Haemolytic uraemic syndrome		1
Haemorrhagic diathesis	1	1
Hallucination	1	1
Headache	14	23
Head discomfort		1
Heart rate decreased	1	2
Heart rate increased		1
Hemiataxia	1	1
Hemiparesis	3	3
Hemiplegia		2
Heparin-induced thrombocytopenia test positive		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					4
		9	21	1	4
		1	2		
					1
			1		
					1
		1	2		
		1	1		
					1
				1	1
		1	2	1	1
					1
					1
			3	1	5
					1
				1	1
			1		1
		1	1		
				1	1
					1
				1	1
				1	1
		14	21		2
					1
		1	1		1
					1
				1	1
				3	3
					2
			1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hepatitis	1	1
Herpes zoster	9	14
Huntington's disease	1	1
Hyperhidrosis	2	3
Hyperkalaemia		1
Hypersensitivity	3	8
Hypersomnia		1
Hypertension	1	8
Hypertensive crisis		1
Hypoaesthesia	1	2
Hypoaesthesia oral		2
Hypotension	2	4
Hypotonia		3
Hypoventilation		1
Hypoxia		1
Immune thrombocytopenia	2	2
Inappropriate schedule of product administration	1	3
Incomplete course of vaccination		1
Incontinence	1	1
Incorrect route of product administration		5
Infarction		1
Influenza		1
Influenza like illness	4	5
Injected limb mobility decreased	1	1
Injection site discomfort		1
Insomnia	1	1
Intentional product misuse		1
Internal haemorrhage		1
Intestinal infarction	1	1
Intestinal ischaemia	1	1
Irregular breathing		1
Ischaemia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		8	12	1	2
		1	1		
		2	3		
					1
		3	4		4
			1		
		1	3		5
					1
			1	1	1
			1		1
		1	2	1	2
			1		2
					1
					1
				2	2
		1	3		
			1		
				1	1
			5		
					1
					1
		4	4		1
		1	1		
			1		
		1	1		
			1		
					1
				1	1
				1	1
					1
				1	1

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* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ischaemic cerebral infarction		1
Joint stiffness	1	1
Jugular vein thrombosis	2	2
Lacrimation increased		1
Limb discomfort	2	3
Lipids increased	1	1
Lip swelling	1	1
Listless		1
Liver disorder		1
Local reaction	1	1
Loss of consciousness	1	5
Loss of personal independence in daily activities	1	1
Lymphocytic infiltration		1
Malaise	5	13
Malignant melanoma		1
Meningoencephalitis herpetic	1	1
Mental disorder		2
Mesenteric vascular occlusion	1	1
Mesenteric vein thrombosis	1	2
Microscopic polyangiitis		1
Migraine	1	1
Mobility decreased		1
Monoparesis	1	2
Monoplegia		1
Mood altered	1	1
Mouth haemorrhage		1
Multiple organ dysfunction syndrome		2
Muscular weakness		1
Musculoskeletal stiffness	1	1
Myalgia	4	8
Myocardial infarction	3	5
Myocarditis	5	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1		
				2	2
			1		
		1	2	1	1
		1	1		
		1	1		
			1		
					1
				1	1
				1	5
		1	1		
					1
		4	8	1	5
					1
				1	1
					2
				1	1
				1	2
					1
		1	1		
			1		
			1	1	1
					1
		1	1		
			1		
					2
					1
		1	1		
	1	4	7		1
				3	5
				5	5

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nasopharyngitis	1	4
Nausea	6	9
Neck pain	2	2
Neuralgia		1
Neuralgic amyotrophy		1
Neurological symptom	1	1
Night sweats		1
Ocular hyperaemia		1
Off label use		4
Oliguria		1
Onychoclasia		1
Open angle glaucoma	1	1
Ophthalmic herpes zoster	1	1
Ophthalmic vein thrombosis	1	1
Optic atrophy	1	1
Optic ischaemic neuropathy		1
Oral fungal infection		1
Organising pneumonia	1	1
Overdose	1	1
Oxygen saturation decreased	1	2
Pain	3	4
Pain in extremity	3	9
Pallor		1
Palpitations	2	2
Pancytopenia	1	1
Panic reaction		1
Paraesthesia	3	6
Paraesthesia oral	1	3
Paresis		1
Parkinson's disease		1
Pelvic venous thrombosis		1
Pericardial effusion	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4		
		5	6	1	3
		2	2		
			1		
					1
		1	1		
			1		
			1		
			4		
					1
			1		
				1	1
				1	1
				1	1
					1
					1
				1	1
		1	1		
				1	2
		2	2	1	2
		2	7	1	2
			1		
		2	2		
				1	1
			1		
		3	5		1
			2	1	1
			1		
					1
					1
				1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Peripheral circulatory failure		1
Peripheral coldness		1
Peripheral swelling	3	3
Peripheral vascular disorder		2
Personality change		1
Platelet count decreased	1	1
Platelet count increased	1	1
Pleural effusion	1	1
Pleuritic pain		1
Pneumonia	4	5
Pneumonitis	1	1
Polycythaemia	1	1
Polyneuropathy	1	1
Poor quality product administered	1	2
Post herpetic neuralgia	1	1
Presyncope	1	1
Product storage error	1	1
Product temperature excursion issue		1
Pruritus	2	3
Pulmonary artery thrombosis		1
Pulmonary embolism	18	24
Pulmonary haemorrhage	1	2
Pulmonary oedema		1
Pulmonary sepsis		1
Pulmonary thrombosis	2	2
Pulmonary vasculitis		1
Pyrexia	3	19
Rash	3	7
Rash macular	1	2
Rash maculo-papular	1	1
Rash pruritic	1	1
Red blood cell sedimentation rate increased	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
		2	2	1	1
					2
					1
				1	1
				1	1
				1	1
			1		
				4	5
				1	1
				1	1
				1	1
		1	2		
		1	1		
		1	1		
		1	1		
			1		
		1	2	1	1
					1
				18	24
				1	2
					1
					1
				2	2
					1
		3	7		12
		2	4	1	3
		1	2		
		1	1		
		1	1		
		1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Renal disorder	1	1
Renal failure		1
Respiration abnormal	1	1
Respiratory distress		7
Respiratory failure	1	4
Respiratory rate increased	1	1
Respiratory tract infection viral		1
Retrograde amnesia		1
Rhabdomyolysis	1	3
Rheumatoid arthritis	1	1
Rhinalgia	1	1
Rhinorrhoea		2
Rhonchi		1
Right ventricular failure	1	1
Rosacea		1
SARS-CoV-2 ant body test positive		1
SARS-CoV-2 sepsis		1
SARS-CoV-2 test positive	1	1
Seizure	1	5
Sepsis	1	1
Shock		1
Shock haemorrhagic		1
Skin exfoliation		2
Skin warm		1
Sleep disorder	1	2
Sneezing		1
Somnolence	2	3
Spontaneous haematoma	1	1
Status epilepticus		1
Subarachnoid haemorrhage		1
Subclavian vein thrombosis	1	2
Sudden cardiac death		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
		1	1		
					7
				1	4
		1	1		
			1		
			1		
				1	3
				1	1
		1	1		
			1		1
				1	1
					1
			1		
				1	5
				1	1
					1
					1
			2		
			1		
		1	2		
			1		
		2	3		
				1	1
					1
					1
				1	2
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sudden death	2	6
Superinfection bacterial		1
Supraventricular extrasystoles		1
Suspected counterfeit product		1
Swelling		1
Swelling face	1	3
Swollen tongue	1	2
Syncope	2	5
Systemic lupus erythematosus		1
Tachyarrhythmia	1	1
Tachycardia	1	3
Taste disorder		1
Therapeutic response unexpected	1	1
Throat clearing	1	1
Thrombocytopenia	1	1
Thrombophlebitis superficial	2	3
Thrombosis	2	2
Tinnitus	1	1
Tongue discomfort	1	1
Tongue oedema		2
Transient global amnesia	1	2
Transient ischaemic attack	1	1
Tremor		2
Type IV hypersensitivity reaction		4
Unresponsive to stimuli		2
Urticaria		2
Vaccination failure		5
Vaccination site abscess	1	1
Vaccination site discomfort	1	1
Vaccination site erythema	2	3
Vaccination site haematoma		1
Vaccination site irritation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	6
					1
					1
			1		
			1		
		1	2		1
		1	2		
				2	5
					1
				1	1
		1	2		1
			1		
		1	1		
		1	1		
				1	1
		1	2	1	1
				2	2
				1	1
				1	1
					2
			1	1	1
				1	1
			2		
			4		
					2
			1		1
					5
				1	1
		1	1		
		2	3		
			1		
			1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site pain	5	16		1	5	16		
Vaccination site rash	1	1			1	1		
Vaccination site swelling	3	4			3	4		
Venous thrombosis	1	2					1	2
Venous thrombosis limb	3	3					3	3
Ventricular f brillation	1	1					1	1
Ventricular tachycardia		1						1
Vertigo	1	1					1	1
Visual acuity reduced	2	2			1	1	1	1
Visual field defect	1	1			1	1		
Visual impairment	2	5			2	2		3
Vomiting	3	8				4	3	4
Weight decreased		1						1
Wrong product administered		2				2		
	429	1,030		3	192	418	237	612

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	1	1					1	1
Abdominal pain	1	6			1	2		4
Abdominal pain lower	1	2			1	2		
Abscess limb		1						1
Abscess neck		1						1
Acute abdomen		1						1
Acute coronary syndrome		5						5
Acute generalised exanthematous pustulosis		1						1
Acute kidney injury	5	18					5	18
Acute myocardial infarction	3	15					3	15
Acute respiratory distress syndrome		1						1
Acute respiratory failure	1	3					1	3
Acute right ventricular failure		1						1
Ageusia		3				3		
Aggression		2						2
Agitation		2						2
Alanine aminotransferase increased		1						1
Allergic oedema		1				1		
Allergy to vaccine	2	2			1	1	1	1
Altered state of consciousness		5						5
Amaurosis fugax		1						1
Amnesia		1						1
Anaemia	1	4				1	1	3
Anaphylactic reaction		11						11
Anaphylactic shock		2						2
Angina pectoris	1	5					1	5
Angioedema	2	10					2	10
Anosmia		1				1		
Anxiety	1	1			1	1		
Aortic aneurysm		2						2
Aortic dissection		1						1
Aortic valve stenosis		1						1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Apathy		6
Aphasia		11
Aphthous ulcer		1
Arrhythmia		9
Arterial disorder	1	1
Arterial occlusive disease		1
Arteriosclerosis		1
Arthralgia	6	16
Ascites	1	1
Aspartate aminotransferase increased	1	2
Aspiration		1
Asthenia	10	39
Asthma		1
Asymptomatic COVID-19	2	4
Ataxia		5
Atrial f brillation	2	20
Atrial flutter		1
Atrioventricular block complete		5
Atrioventricular block first degree		1
Autoimmune disorder		1
Automatism		1
Back pain	2	3
Balance disorder	4	4
Basal ganglia infarction		1
Basilar artery occlusion		1
Bedridden		1
Bell's palsy	1	1
Beta haemolytic streptococcal infection	1	1
Blindness	1	1
Blister		1
Blood blister	1	1
Blood calcium decreased		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		5
			2		9
					1
					9
				1	1
					1
					1
		6	15		1
				1	1
		1	1		1
					1
		8	21	2	18
					1
				2	4
					5
				2	20
			1		
					5
			1		
					1
					1
		2	3		
		4	4		
					1
					1
			1		
				1	1
				1	1
				1	1
					1
		1	1		
			2		1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood count abnormal	1	1
Blood creatine phosphokinase increased	1	2
Blood creatine phosphokinase MB increased		1
Blood creatinine increased		1
Blood disorder		1
Blood glucose decreased	1	2
Blood glucose fluctuation		1
Blood lactate dehydrogenase increased		2
Blood potassium decreased		2
Blood pressure decreased	1	9
Blood pressure fluctuation		1
Blood pressure immeasurable	1	3
Blood pressure increased	1	7
Blood pressure systolic increased		1
Blood sodium decreased		1
Blood urine present		1
Body temperature increased		9
Bone pain		1
Bradyarrhythmia		1
Bradycardia	1	4
Brain stem infarction	1	1
Brain stem ischaemia	1	1
Breast pain	1	1
Bronchitis		1
Bronchitis bacterial		1
Bronchitis chronic		1
Bronchospasm		4
Bundle branch block right		1
Burning sensation	1	2
Bursitis		1
Capillary nail refill test abnormal		1
Carbon dioxide decreased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
			1	1	1
			1		
					1
					1
				1	2
			1		
					2
			1		1
			3	1	6
			1		
				1	3
		1	2		5
					1
					1
			2		7
			1		
					1
				1	4
				1	1
				1	1
				1	1
					1
					1
			1		
			2		2
					1
		1	2		
					1
					1
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiac aneurysm		1
Cardiac arrest	2	15
Cardiac death		1
Cardiac discomfort	1	1
Cardiac failure	2	35
Cardiac failure acute	1	2
Cardiac failure congestive	1	5
Cardiac fibrillation		1
Cardiogenic shock	1	8
Cardiopulmonary failure		1
Cardio-respiratory arrest		2
Cardiovascular disorder	2	6
Cardiovascular insufficiency		2
Carotid artery occlusion		1
Cerebral artery occlusion	1	1
Cerebral atrophy		1
Cerebral haemorrhage	7	16
Cerebral infarction	2	8
Cerebral ischaemia		3
Cerebral thrombosis		2
Cerebral venous sinus thrombosis	4	7
Cerebral venous thrombosis		1
Cerebrovascular accident	8	41
Cerebrovascular disorder	1	2
Chest discomfort	1	4
Chest pain	5	10
Chills	7	21
Cholelithiasis		1
Chronic kidney disease		2
Chronic obstructive pulmonary disease		5
Circulatory collapse	2	21
Clonus		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				2	15
					1
		1	1		
				2	35
				1	2
				1	5
					1
				1	8
					1
					2
		1	2	1	4
					2
					1
				1	1
					1
				7	16
				2	8
					3
					2
				4	7
					1
				8	41
				1	2
		1	2		2
		3	5	2	5
		6	17	1	4
			1		
					2
					5
				2	21
					1

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* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Coagulopathy	1	3
Cognitive disorder		2
Cold sweat		1
Coma		2
Condition aggravated	4	7
Confusional state	1	16
Conjunctival hyperaemia		1
Conjunctivitis		1
Constipation		1
Contusion	1	3
Coordination abnormal		1
Coronary artery disease	1	1
Coronary artery thrombosis	1	1
Coronavirus infection		10
Coronavirus test positive		1
Cor pulmonale	1	1
Cough	4	16
COVID-19	11	126
COVID-19 pneumonia	1	14
Cranial nerve decompression		1
C-reactive protein increased	2	10
Crepitations		1
Cutaneous vasculitis		1
Cyanosis	2	5
Death	34	175
Decreased appetite	4	11
Deep vein thrombosis	6	24
Dehydration	1	5
Delirium	1	7
Delusion		1
Dementia	1	7
Dementia of the Alzheimer's type, with delirium		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
					2
					1
					2
		2	2	2	5
		1	5		11
					1
					1
			1		
				1	3
					1
				1	1
				1	1
			7		3
					1
				1	1
		2	9	2	7
		2	43	9	83
				1	14
					1
		1	5	1	5
					1
					1
				2	5
				34	175
		3	8	1	3
				6	24
		1	1		4
				1	7
					1
				1	7
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Demyelinating polyneuropathy	1	1
Depressed level of consciousness	1	4
Depressed mood		1
Depression		1
Dermatitis allergic	1	5
Dermatitis bullous		1
Diabetes mellitus	1	2
Diabetic nephropathy	1	1
Diarrhoea	10	28
Diet refusal		4
Diplopia	1	2
Disease progression		1
Disease recurrence		1
Disorientation		5
Disturbance in attention	2	14
Diverticulitis	2	2
Dizziness	12	40
Dizziness postural		1
Drug ineffective	10	60
Drug interaction	1	2
Dry skin		1
Dry throat		1
Dysarthria		2
Dyskinesia		1
Dyslalia		1
Dysphagia	1	7
Dysphonia	1	3
Dyspnoea	18	60
Dyspnoea exertional	3	7
Dysstasia	1	2
Eastern Cooperative Oncology Group performance status worsened		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	4
					1
			1		
		1	4		1
					1
				1	2
		1	1		
		9	21	1	7
					4
				1	2
					1
					1
			3		2
		2	4		10
				2	2
		10	20	2	20
			1		
				10	60
			1	1	1
			1		
			1		
					2
					1
					1
			5	1	2
		1	2		1
		7	16	11	44
		2	3	1	4
			1	1	1
			1		

* I=Interval, C=Cumulative
* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eating disorder		1
Eczema	1	1
Effusion		1
Electrocardiogram QT prolonged		1
Electrocardiogram T wave inversion		1
Electrolyte depletion		1
Electrolyte imbalance		1
Embolic cerebral infarction		1
Embolism	1	2
Embolism arterial		1
Emphysema		1
Encephalitis		1
Encephalitis autoimmune	1	2
Enuresis	1	1
Epilepsy	1	16
Epistaxis	2	3
Erysipelas	3	5
Erythema	3	14
Essential tremor		1
Eye haemorrhage	1	2
Eyelid exfoliation	1	1
Eyelid oedema		2
Eye pruritus	1	2
Eye swelling		1
Face oedema		1
Facial paralysis	2	11
Facial paresis	1	9
Factor VIII inhibition		1
Faeces discoloured		1
Fall	4	16
Fatigue	22	44
Febrile infection		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	1		
					1
					1
					1
			1		
					1
					1
				1	2
					1
					1
					1
				1	2
				1	1
				1	16
		1	1	1	2
				3	5
		3	12		2
					1
				1	2
		1	1		
			1		1
		1	1		1
			1		
			1		
				2	11
			1	1	8
					1
			1		
		1	3	3	13
	2	21	36	1	8
					3

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Feeling abnormal		1
Feeling cold	3	6
Feeling drunk		1
Feeling hot		2
Femoral neck fracture		1
Femur fracture		1
Fibrin D dimer increased	3	4
Flatulence		1
Fluid retention		1
Flushing		2
Food refusal		3
Fracture		1
Gait disturbance	2	7
Gait inability		1
Gamma-glutamyltransferase increased	1	1
Gastritis	1	1
Gastrointestinal disorder		1
Gastrointestinal haemorrhage	1	1
Gastrointestinal pain		1
Generalised tonic-clonic seizure		1
General physical condition abnormal		9
General physical health deterioration	1	45
Gingival bleeding		1
Gingival swelling		1
Glomerular filtration rate decreased		1
Glomerulonephritis minimal lesion		1
Glycosylated haemoglobin increased	1	1
Gout		1
Granulocyte count increased		1
Guillain-Barre syndrome	1	1
Guttate psoriasis	1	1
Haematemesis		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		3	5		1
			1		
			1		1
					1
					1
		2	3	1	1
			1		
			1		
					2
			1		2
					1
				2	7
			1		
		1	1		
		1	1		
			1		
				1	1
					1
					1
		1	10		35
					1
					1
			1		
			1		
			1		
				1	1
		1	1		
					2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haematochezia	1	2
Haematocrit decreased		1
Haematoma		3
Haematuria	1	1
Haemoglobin decreased		4
Haemoptysis		2
Haemorrhage	2	4
Haemorrhagic diathesis	1	1
Haemothorax		1
Hallucination		2
Hallucinations, mixed		1
Hallucination, visual	1	1
Headache	12	31
Head injury		1
Heart rate decreased		1
Heart rate increased		4
Hemiparesis	3	17
Hemiplegia		2
Hepatic cirrhosis		1
Hepatic enzyme increased		1
Hepatic failure		1
Hepatitis cholestatic		2
Herpes simplex		1
Herpes simplex encephalitis		1
Herpes zoster	22	34
Herpes zoster infection neurological		1
Herpes zoster meningitis	1	2
Herpes zoster meningoencephalitis	1	1
Hot flush	1	1
Hyperaesthesia		1
Hypercalcaemia		2
Hyperglycaemia	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
			1		
			1		2
		1	1		
			1		3
			1		1
				2	4
				1	1
					1
					2
					1
				1	1
		10	16	2	15
					1
					1
			3		1
				3	17
					2
					1
			1		
					1
					2
					1
					1
		20	29	2	5
					1
				1	2
				1	1
		1	1		
					1
					2
		1	1		1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyperhidrosis	2	5
Hypernatraemia	1	1
Hyperpyrexia		1
Hypersensitivity	3	17
Hypersensitivity vasculitis		2
Hypersomnia		1
Hypertension	5	21
Hypertensive crisis	1	6
Hypertensive heart disease	1	1
Hypoaesthesia	2	3
Hyponatraemia	1	7
Hypophagia		1
Hyporesponsive to stimuli		1
Hypotension	1	7
Hypothermia		1
Hypotonia	2	4
Hypoxia		1
Idiopathic intracranial hypertension		1
IIIrd nerve paresis		1
Ileus		1
Ileus paralytic	1	3
Illness	1	2
Immature granulocyte count increased		1
Immune thrombocytopenia	1	5
Impaired healing		1
Inadequate aseptic technique in use of product		1
Inappropriate schedule of product administration	4	10
Incomplete course of vaccination	1	2
Incontinence	1	2
Incorrect route of product administration	4	26
Infarction		1
Inflammation	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	5
				1	1
					1
		2	6	1	11
					2
			1		
		2	5	3	16
				1	6
				1	1
		1	1	1	2
			3	1	4
					1
					1
			1	1	6
					1
				2	4
					1
					1
					1
					1
				1	3
		1	1		1
			1		
				1	5
					1
			1		
		4	10		
		1	2		
		1	1		1
		4	26		
					1
		2	2		2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Inflammatory marker increased		1
Influenza		1
Influenza like illness	2	6
Insomnia		1
Intentional product misuse		1
International normalised ratio decreased		1
International normalised ratio increased		1
Intestinal infarction		1
Intestinal ischaemia		2
Intracardiac thrombus	1	1
Intracranial aneurysm		1
Ischaemia		3
Ischaemic cardiomyopathy		1
Ischaemic cerebral infarction		2
Ischaemic stroke	1	5
Jaundice		1
Jaw clicking		1
Joint range of motion decreased		1
Joint swelling		1
Klippel-Trenaunay syndrome	1	1
Koebner phenomenon	1	1
Lacrimation increased		1
Language disorder		1
Large intestine perforation	1	1
Laryngeal obstruction		1
Laryngeal oedema		1
Leukaemia		1
Leukopenia	2	2
Limb discomfort	2	3
Limb injury	1	1
Lipase increased		1
Lip oedema		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
		1	2	1	4
			1		
			1		
			1		
					1
					2
				1	1
					1
					3
					1
					2
				1	5
					1
					1
			1		
		1	1		
					1
					1
				1	1
					1
					1
				2	2
		1	2	1	1
		1	1		
					1
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lip swelling		2
Listless		2
Liver function test increased		1
Local reaction	1	4
Loss of consciousness	3	9
Loss of control of legs	1	1
Lymphadenopathy		1
Lymphoedema	1	2
Lymphopenia	1	2
Malaise	5	16
Malignant pleural effusion		1
Marasmus		1
Memory impairment		2
Meningism		1
Meningitis	1	2
Metabolic acidosis		1
Metabolic disorder		1
Microcytic anaemia		2
Micturition urgency		1
Miller Fisher syndrome	1	1
Mobility decreased	1	7
Monocyte count increased		1
Monoparesis		1
Monoplegia	1	1
Motor dysfunction		1
Movement disorder		3
Multimorbidity		1
Multi-organ disorder		1
Multiple organ dysfunction syndrome		7
Muscle spasms		1
Muscle strength abnormal		1
Muscle swelling		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
			1		1
					1
		1	3		1
				3	9
				1	1
			1		
			1	1	1
				1	2
		4	11	1	5
					1
					1
					2
					1
					1
					2
			1		
				1	1
		1	4		3
			1		
					1
				1	1
					1
			1		2
					1
					1
					7
					1
			1		
			1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle tightness	1	1
Muscle twitching		2
Muscular weakness	3	5
Musculoskeletal discomfort		1
Musculoskeletal pain		1
Myalgia	3	10
Myocardial infarction	11	17
Myocarditis	4	5
Myocarditis infectious		1
Myocarditis septic		1
Myoclonus		1
Myositis		1
Nasal congestion	1	1
Nasopharyngitis	1	5
Nausea	11	40
Neck pain	1	1
Necrosis		1
Nephrotic syndrome		1
Nervous system disorder		3
Neuralgia	2	3
Neuritis		1
Neuropathy peripheral	1	1
Normocytic anaemia	1	1
Nuchal rigidity		1
Obesity	1	1
Obstructive pancreatitis		1
Ocular hyperaemia		1
Ocular myasthenia	1	1
Oedema		1
Oedema peripheral	1	3
Off label use	2	4
Ophthalmic herpes zoster	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
			1		1
		3	3		2
			1		
					1
		3	9		1
				11	17
				4	5
					1
					1
					1
					1
		1	1		
		1	3		2
		9	25	2	15
		1	1		
					1
					1
					3
		2	3		
					1
				1	1
				1	1
					1
		1	1		
					1
					1
				1	1
					1
		1	3		
		2	4		
				1	3

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ophthalmic vein thrombosis	2	4
Oral discomfort		1
Organ failure		1
Organising pneumonia	1	1
Oropharyngeal pain	1	2
Osteoporosis		1
Overdose		1
Oxygen saturation decreased		8
Pain	3	11
Pain in extremity	7	21
Pallor		4
Palpitations		2
Pancreatitis acute	1	2
Pancreatitis necrotising	1	1
Pancytopenia		2
Papilloedema		1
Paraesthesia		3
Paraesthesia oral		1
Paranoia		1
Parkinsonism		1
Parkinson's disease	1	1
Parosmia	1	1
Partial seizures		1
Pathogen resistance		1
Pelvic venous thrombosis	2	2
Pemphigus		1
Performance status decreased	2	2
Pericardial effusion	1	1
Peripheral circulatory failure		2
Peripheral embolism		1
Peripheral swelling	2	7
Peripheral vascular disorder		8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	4
			1		
					1
				1	1
		1	2		
			1		
					1
					8
		3	5		6
		5	14	2	7
					4
					2
				1	2
				1	1
					2
					1
			1		2
			1		
					1
					1
				1	1
				1	1
					1
					1
				2	2
					1
		1	1	1	1
				1	1
					2
					1
		2	5		2
			1		7

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Peritonitis		1
Peroneal nerve injury		1
Personality change		4
Petechiae	1	5
Pharyngeal inflammation		1
Pharyngeal swelling		2
Platelet count decreased		3
Pleocytosis		2
Pleural effusion		1
Pleurisy		1
Pneumonia	8	37
Pneumonia aspiration		1
Pneumonia bacterial		2
Pneumonia streptococcal	1	1
Pneumonia viral		1
Polymyalgia rheumatica		2
Polymyositis	1	1
Polyneuropathy		1
Poor quality sleep		1
Postictal state		1
Presbycusis		1
Presyncope		1
Product administered at inappropriate site		1
Product dose omission issue		1
Productive cough	1	1
Product preparation issue		1
Proteinuria		1
Pruritus	7	14
Psoriasis		1
Psychomotor hyperactivity		2
Pulmonary artery thrombosis	1	1
Pulmonary embolism	17	57

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					4
			1	1	4
			1		
					2
			1		2
					2
					1
					1
				8	37
					1
					2
				1	1
					1
				1	1
					1
					1
					1
			1		
			1		
		1	1		
			1		
					1
		7	10		4
					1
					2
				1	1
				17	57

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pulmonary fibrosis		1
Pulmonary hypertension		1
Pulmonary infarction	1	3
Pulmonary oedema		3
Pulmonary pain	1	1
Pulmonary sepsis		1
Pulse absent		1
Purpura		1
Pustule	1	2
Pyramidal tract syndrome		1
Pyrexia	14	65
Quadripareisis		1
Rales		1
Rash	2	13
Rash erythematous		1
Rash macular	1	2
Rash maculo-papular	1	3
Rash pruritic	2	4
Rash vesicular	1	1
Reaction to excipient		1
Red blood cell count decreased		1
Red blood cell sedimentation rate increased		1
Renal failure	2	11
Renal pain	1	1
Respiratory arrest		1
Respiratory disorder	1	1
Respiratory distress	1	24
Respiratory failure	2	11
Respiratory fume inhalation disorder		1
Respiratory tract infection		5
Respiratory tract inflammation		1
Restlessness	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				1	3
					3
		1	1		
					1
					1
					1
		1	1		1
					1
	1	8	22	6	43
					1
					1
		2	5		8
			1		
		1	2		
		1	3		
		1	2	1	2
		1	1		
			1		
			1		
				2	11
		1	1		
					1
		1	1		
				1	24
				2	11
					1
					5
					1
		1	1	1	3

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* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Resuscitation		1
Retinal vein thrombosis		1
Rheumatoid arthritis	2	2
Rhinalgia		1
Rhinitis allergic		1
Rhinorrhoea	1	4
Rhonchi		1
Rib fracture	1	1
Right ventricular failure		1
SARS-CoV-2 ant body test positive		1
SARS-CoV-2 test positive		9
Seizure	2	14
Sensory disturbance	1	1
Sepsis		3
Septic arthritis staphylococcal		1
Septic shock	1	4
Shock		1
Skin cancer	1	1
Skin discolouration	3	3
Skin haemorrhage		1
Skin necrosis		1
Skin ulcer		1
Sleep disorder	1	2
Slow speech	1	1
Sneezing		4
Soft tissue infection		1
Somnolence	4	15
Sopor		1
Speech disorder	1	3
Spinal pain	1	1
Staphylococcal sepsis		2
Status epilepticus		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				2	2
			1		
					1
		1	3		1
					1
				1	1
					1
			8		1
				2	14
		1	1		
					3
					1
				1	4
					1
				1	1
		3	3		
					1
					1
			1		
		1	2		
		1	1		
			3		1
					1
		2	5	2	10
					1
		1	2		1
		1	1		
					2
					2

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* AE=Adverse Event
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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Stress		1
Stress cardiomyopathy	1	1
Stridor		1
Stupor		1
Subarachnoid haemorrhage		1
Subclavian vein thrombosis		1
Subcutaneous abscess		1
Subdural haematoma		1
Subileus		2
Sudden cardiac death	1	3
Sudden death	7	28
Sudden onset of sleep		1
Superior sagittal sinus thrombosis	1	1
Swelling	1	2
Swelling face	1	4
Swelling of eyelid	1	3
Swollen tongue		5
Syncope	7	24
Systemic inflammatory response syndrome		1
Tachyarrhythmia		2
Tachycardia		7
Tachypnoea	1	1
Tendonitis	1	2
Tendon pain	1	1
Tendon rupture		1
Thalamic infarction		1
Therapeutic response unexpected		2
Throat irritation		1
Throat tightness		6
Thrombocytopenia	8	11
Thrombophlebitis	1	3
Thrombosis	7	14

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
					1
					1
					1
					1
			1		1
				1	3
				7	28
					1
				1	1
		1	2		
		1	4		
		1	2		1
			1		4
				7	24
					1
					2
			1		6
				1	1
		1	1		1
		1	1		
					1
					1
			2		
			1		
			3		3
				8	11
		1	2		1
				7	14

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Toxicity to various agents		1
Transaminases increased	1	2
Transient global amnesia		1
Transient ischaemic attack		2
Tremor	1	5
Tryptase increased		1
Unresponsive to stimuli	1	7
Upper gastrointestinal haemorrhage		2
Upper respiratory tract infection		5
Urea urine	1	1
Urinary incontinence	1	1
Urinary tract infection		3
Urinary tract inflammation		1
Urticaria	3	8
Vaccination complication	1	4
Vaccination failure	2	12
Vaccination site discomfort	1	1
Vaccination site erythema	2	5
Vaccination site haematoma		2
Vaccination site haemorrhage		1
Vaccination site hypersensitivity		1
Vaccination site pain	12	22
Vaccination site pruritus		1
Vaccination site rash		2
Vaccination site reaction	1	3
Vaccination site swelling	1	6
Vaccination site urticaria		1
Vaccination site warmth	1	3
Varicella zoster virus infection	1	1
Varicose vein		1
Vascular dementia		1
Vascular encephalopathy		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	2
					1
					2
			1	1	4
					1
				1	7
					2
			1		4
		1	1		
				1	1
			1		2
					1
		3	6		2
				1	4
				2	12
		1	1		
		2	3		2
			2		
			1		
			1		
		11	18	1	4
					1
			1		1
		1	2		1
		1	4		2
					1
		1	2		1
		1	1		
			1		
					1
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Venous occlusion		1						1
Venous thrombosis	1	3					1	3
Venous thrombosis limb	5	6			1	1	4	5
Ventricle rupture	1	1					1	1
Ventricular extrasystoles		1						1
Ventricular f brillation		4						4
Ventricular tachycardia		1						1
Vision blurred		1						1
Visual acuity reduced		1						1
Visual field defect		1				1		
Visual impairment	1	5			1	1		4
Vlth nerve paralysis		1						1
Vomiting	8	49			5	23	3	26
Weight increased		1				1		
White blood cell count decreased		1				1		
White blood cell count increased	1	2			1	1		1
Wound		1				1		
	671	2,867		3	297	805	374	2062

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* AE=Adverse Event
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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal distension	1	2	1	2		
Abdominal pain	2	7	2	6		1
Abdominal pain lower		2		1		1
Abdominal pain upper	1	4	1	4		
Abscess rupture	1	1			1	1
Accidental exposure to product	1	2	1	2		
Acne	2	2	2	2		
Acute kidney injury		1				1
Acute myocardial infarction	1	1			1	1
Ageusia	1	4	1	4		
Agitation		1				1
Alanine aminotransferase increased	1	2	1	1		1
Allergic oedema		1				1
Allergy to vaccine		1		1		
Alopecia	1	1	1	1		
Amnesia	2	3	1	1	1	2
Anaphylactic reaction	7	10			7	10
Anaphylactic shock	6	8			6	8
Angina pectoris	3	4			3	4
Angioedema		3				3
Anosmia	1	2	1	2		
Antibody test abnormal		2		2		
Aphasia		3		2		1
Arrhythmia	2	2			2	2
Arthralgia	18	39	18	37		2
Aspartate aminotransferase increased	1	2	1	2		
Aspermia	1	1	1	1		
Asthenia	23	44	21	41	2	3
Asthenopia		1		1		
Asthma	2	4	2	4		
Asymptomatic COVID-19	3	4	1	1	2	3

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Atrial f brillation	1	2			1	2
Autoimmune pancreatitis	1	1			1	1
Autoimmune thyroiditis		1				1
Axillary pain	3	5	3	5		
Back pain	5	9	5	8		1
Bladder irritation	1	1	1	1		
Bladder pain	1	1	1	1		
Blister		1		1		
Blister infected		1		1		
Blood glucose decreased		1		1		
Blood glucose fluctuation		1		1		
Blood glucose increased	1	1			1	1
Blood pressure abnormal	1	1	1	1		
Blood pressure decreased	1	2			1	2
Blood pressure fluctuation		2		2		
Blood pressure increased	1	4		3	1	1
Blood urine present		1				1
Body temperature increased	22	45	22	45		
Bone pain	2	4	2	4		
Borrelia infection	2	2			2	2
Brain oedema		1				1
Breast cancer	1	1			1	1
Breast inflammation	1	1			1	1
Breast swelling	1	1			1	1
Bronchitis	1	1	1	1		
Burning sensation	1	6		3	1	3
Cardiovascular disorder	13	25	11	23	2	2
Cellulitis		1				1
Cerebral haemorrhage		1				1
Cerebral infarction		1				1
Cerebral venous sinus thrombosis	1	1			1	1
Cerebrovascular accident	2	6			2	6

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chest discomfort	2	3
Chest pain	3	4
Chills	77	156
Chronic obstructive pulmonary disease		1
Circulatory collapse	4	8
Circumoral oedema		1
Circumstance or information capable of leading to medication error	1	3
Cluster headache		1
Coagulation time prolonged		1
Cognitive disorder	1	2
Cold sweat	1	1
Coma	1	1
Condition aggravated	2	6
Confusional state	2	2
Contusion		2
Coronary artery disease	1	1
Cough	7	11
COVID-19	90	317
COVID-19 pneumonia		1
Cranial nerve disorder		1
C-reactive protein increased	2	3
Cystitis	1	2
Deafness		2
Death	5	22
Decreased appetite	3	4
Deep vein thrombosis	1	3
Dehydration	1	2
Dermatitis	1	1
Dermatitis allergic	2	2
Diarrhoea	12	28
Diarrhoea haemorrhagic	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	2	1	1
3	4		
75	154	2	2
	1		
		4	8
	1		
1	3		
	1		
	1		
1	2		
1	1		
		1	1
	3	2	3
		2	2
	1		1
		1	1
7	11		
36	95	54	222
			1
	1		
1	2	1	1
1	2		
			2
		5	22
3	4		
		1	3
1	2		
		1	1
2	2		
12	28		
		1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diplopia	1	1	1	1		
Discomfort	3	4	3	3		1
Disease recurrence	1	4		2	1	2
Disorientation	2	3			2	3
Disturbance in attention		9		9		
Dizziness	35	77	33	72	2	5
Drug eruption		1		1		
Drug hypersensitivity	1	1			1	1
Drug ineffective	52	217		1	52	216
Drug interaction	2	3	2	2		1
Dry mouth	2	2	2	2		
Dry throat	1	1	1	1		
Dysgeusia	3	6	2	4	1	2
Dysgraphia		1		1		
Dysmenorrhoea	1	1	1	1		
Dyspepsia		2		2		
Dysphagia		1				1
Dyspnoea	13	30	10	20	3	10
Ear congestion	1	1	1	1		
Ear discomfort	1	1	1	1		
Ear pain	1	5	1	5		
Ear swelling	1	1	1	1		
Eczema		1		1		
Electric shock sensation		1		1		
Electroencephalogram abnormal	1	1	1	1		
Endocrine ophthalmopathy	1	1			1	1
Enteritis	1	1	1	1		
Eosinophilia		1				1
Epilepsy	1	1			1	1
Epistaxis	1	1	1	1		
Erectile dysfunction	3	3			3	3
Erythema	7	15	7	14		1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Escherichia infection		1				1
Exercise tolerance decreased	1	1			1	1
Expired product administered	1	1	1	1		
Exposure during pregnancy	7	9	7	9		
Exposure via breast milk	4	6	4	6		
Exposure via skin contact	1	1	1	1		
Eye disorder	1	1			1	1
Eye haemorrhage		1				1
Eye inflammation	1	1	1	1		
Eye oedema	1	1	1	1		
Eye pain	3	4	3	4		
Eye pruritus	1	2	1	1		1
Eye swelling	1	2	1	2		
Facial discomfort	1	1	1	1		
Facial pain	1	2	1	2		
Facial paralysis	3	10			3	10
Facial paresis	4	12	2	8	2	4
Fall	3	5	1	1	2	4
Fatigue	127	285	125	280	2	5
Feeling abnormal	3	7	2	6	1	1
Feeling cold	13	27	12	26	1	1
Feeling hot	6	13	6	11		2
Feeling of body temperature change	2	7	2	7		
Feeling of despair		1		1		
Femoral artery embolism		1				1
Fine motor skill dysfunction	1	1	1	1		
Fistula		1				1
Flushing	2	5	2	5		
Formication	1	2	1	2		
Gait disturbance	6	7	3	4	3	3
Gait inability	1	2	1	1		1
Gamma-glutamyltransferase increased	1	2	1	1		1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastric dilatation	1	1	1	1		
Gastritis		1		1		
Gastrointestinal disorder	1	1	1	1		
Gingival pain	1	1	1	1		
Gingivitis	1	1	1	1		
Guillain-Barre syndrome	3	3			3	3
Haematoma	1	3	1	2		1
Haematoma infection		1				1
Haemoglobin decreased	1	1	1	1		
Haemoptysis	1	1	1	1		
Haemorrhage	1	2			1	2
Hair disorder	1	1	1	1		
Headache	140	335	139	330	1	5
Head discomfort		4		4		
Heart rate increased	1	1			1	1
Heavy menstrual bleeding	1	2	1	2		
Hemiparesis		1				1
Hepatic enzyme increased	1	1			1	1
Herpes ophthalmic	1	1			1	1
Herpes simplex		1		1		
Herpes zoster	29	40	26	36	3	4
Herpes zoster oticus		1				1
Herpes zoster reactivation		1		1		
Histiocytosis	1	1			1	1
Hot flush	4	7	3	6	1	1
Hunger	1	1	1	1		
Hyperaesthesia	1	3	1	3		
Hyperhidrosis	9	14	7	12	2	2
Hypersensitivity	13	22	8	15	5	7
Hypersensitivity vasculitis		1				1
Hypersomnia	3	4	3	4		
Hypertension	5	9	3	6	2	3

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertensive crisis		1				1
Hyperventilation	1	1	1	1		
Hypoacusis	4	4	4	4		
Hypoaesthesia	9	20	9	18		2
Hypoaesthesia oral	2	4	2	4		
Hypokinesia	1	1	1	1		
Hypotension	3	4	2	3	1	1
Hypothermia		1				1
Hypotonia	1	1	1	1		
IIIrd nerve paresis	1	1			1	1
Illness	2	5	2	5		
Inappropriate schedule of product administration	8	16	8	16		
Incomplete course of vaccination	1	2	1	2		
Incorrect dose administered	2	4	2	4		
Incorrect route of product administration	5	8	5	8		
Increased appetite	1	1	1	1		
Increased upper airway secretion		1		1		
Infection	2	5	1	1	1	4
Inflammation	2	3	1	1	1	2
Inflammatory marker increased	1	1	1	1		
Influenza		2		2		
Influenza like illness	17	27	17	27		
Initial insomnia	1	3	1	3		
Injected limb mobility decreased		1		1		
Injection site hypoaesthesia	1	1	1	1		
Injection site pain	3	3	3	3		
Injection site swelling	2	2	2	2		
Insomnia	8	13	8	13		
International normalised ratio increased	1	1	1	1		
Intestinal haemorrhage		1				1
Intraocular pressure increased	1	2		1	1	1
Iridocyclitis		2				2

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Iron deficiency	1	1	1	1		
Joint effusion	1	1	1	1		
Joint range of motion decreased	1	1	1	1		
Joint swelling	1	1	1	1		
Lack of spontaneous speech	1	1	1	1		
Limb deformity	1	1	1	1		
Limb discomfort	9	19	9	18		1
Lip pain	1	1	1	1		
Lip swelling	2	3	2	3		
Liquid product physical issue	3	3	3	3		
Listless	1	1	1	1		
Liver function test abnormal	1	1	1	1		
Liver function test increased		1				1
Localised infection		1		1		
Local reaction		2		2		
Loss of consciousness	2	3			2	3
Loss of personal independence in daily activities		1		1		
Lyme disease	1	1			1	1
Lymphadenitis	1	1	1	1		
Lymphadenopathy	28	50	28	50		
Lymph node pain	10	17	10	17		
Lymphocyte count increased	1	1			1	1
Lymphoedema	2	2	2	2		
Malaise	19	53	18	50	1	3
Maternal exposure before pregnancy	1	2	1	2		
Maternal exposure during pregnancy	28	57	27	56	1	1
Maternal exposure timing unspecified		1		1		
Medication error		1		1		
Meningoencephalitis herpetic	1	1			1	1
Menstrual disorder	1	7	1	7		
Middle insomnia		1		1		
Migraine	4	4	4	4		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Migraine with aura	1	1	1	1		
Mobility decreased	1	4		2	1	2
Monoplegia	1	1			1	1
Mouth swelling	1	1	1	1		
Movement disorder	4	7	3	3	1	4
Multiple sclerosis	1	1			1	1
Multiple sclerosis relapse	1	1			1	1
Muscle contractions involuntary		1				1
Muscle spasms	2	3	1	1	1	2
Muscle spasticity	1	1	1	1		
Muscle swelling	1	1	1	1		
Muscle twitching		3		2		1
Muscular weakness	3	6	3	6		
Musculoskeletal chest pain	1	1	1	1		
Musculoskeletal discomfort		1		1		
Musculoskeletal disorder	1	1	1	1		
Musculoskeletal stiffness	2	3	2	3		
Myalgia	52	127	50	125	2	2
Mycoplasma infection		1		1		
Myoclonus		1		1		
Myofascial spasm	1	1	1	1		
Nasal congestion	2	3	2	3		
Nasopharyngitis	8	14	8	13		1
Natural killer T cell count decreased		1		1		
Nausea	41	81	41	81		
Neck pain	6	10	6	10		
Neoplasm		1				1
Nephrolithiasis		1				1
Nerve injury	1	1			1	1
Nervous system disorder	2	3	1	2	1	1
Neuralgia	2	5	2	5		
Neuritis		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neurodermatitis	2	4	2	4		
Night sweats	1	5	1	5		
No adverse event	1	3	1	3		
Occupational exposure to product		1		1		
Ocular discomfort	1	2	1	2		
Oedema		1				1
Oedema peripheral		1				1
Off label use	9	20	9	20		
Oral discomfort	3	3	3	3		
Oral herpes	1	1	1	1		
Oropharyngeal pain	9	17	9	17		
Oxygen saturation decreased	1	1	1	1		
Pain	14	30	13	25	1	5
Pain in extremity	107	229	105	226	2	3
Pain in jaw	1	3	1	3		
Pain of skin		2		2		
Pallor	1	1	1	1		
Palpitations	6	12	6	11		1
Panic attack		2		1		1
Paraesthesia	13	25	12	24	1	1
Paraesthesia oral	2	6	2	6		
Paralysis	1	2			1	2
Parkinsonian rest tremor		1		1		
Parkinson's disease		1				1
Parosmia	3	3	3	3		
Pelvic fracture		1				1
Performance status decreased	1	2	1	2		
Peripheral coldness	2	2	2	2		
Peripheral embolism		2		1		1
Peripheral ischaemia		1				1
Peripheral swelling	4	11	3	9	1	2
Peripheral vascular disorder		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Petechiae	1	2	1	1		1
Petit mal epilepsy		1				1
Pharyngeal inflammation	1	1	1	1		
Pharyngeal paraesthesia		1		1		
Photophobia	2	2	2	2		
Platelet count decreased	2	2			2	2
Pleural effusion	1	1			1	1
Pneumonia	2	4			2	4
PO2 decreased		1				1
Pollakiuria	1	1	1	1		
Polyneuropathy		1				1
Poor peripheral circulation	1	1	1	1		
Poor quality product administered	7	14	7	14		
Poor quality sleep	2	6	2	6		
Premature separation of placenta	1	1			1	1
Presyncope	1	2	1	2		
Product administered at inappropriate site	1	1	1	1		
Product administration error	1	1	1	1		
Product dose omission issue		2		1		1
Product leakage		1		1		
Product preparation error	1	4	1	4		
Product preparation issue	2	8	2	8		
Product prescribing error	1	1	1	1		
Product quality issue	1	3	1	3		
Product temperature excursion issue		3		3		
Product use issue	5	15	4	14	1	1
Prostatic specific antigen increased	1	1	1	1		
Proteinuria	1	1	1	1		
Pruritus	7	14	7	11		3
Pseudoallergic reaction		2		1		1
Psoriasis	1	1	1	1		
Pulmonary embolism	4	8			4	8

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pustule	2	5	2	4		1
Pyrexia	80	186	78	181	2	5
Rash	8	23	5	17	3	6
Rash erythematous	1	2	1	2		
Rash macular		1		1		
Rash papular		1		1		
Rash pruritic	3	5	3	5		
Raynaud's phenomenon		1		1		
Renal disorder		1				1
Renal function test abnormal	1	1	1	1		
Renal pain	1	2	1	2		
Respiratory arrest	1	1			1	1
Respiratory disorder	2	2	2	2		
Respiratory distress		4				4
Respiratory failure		1				1
Restlessness	1	1	1	1		
Retching	1	1			1	1
Retinal artery occlusion	1	1			1	1
Retinal detachment	1	1			1	1
Retinal vein thrombosis	1	1			1	1
Rheumatic disorder		1		1		
Rheumatoid arthritis	3	3			3	3
Rhinitis	1	2	1	2		
Rhinorrhoea	2	7	2	7		
Salivary gland enlargement		2		2		
Salivary hypersecretion	1	1	1	1		
SARS-CoV-2 ant body test negative	2	18	2	17		1
SARS-CoV-2 ant body test positive		5		5		
SARS-CoV-2 test false positive		4		4		
SARS-CoV-2 test positive	3	33	2	19	1	14
Seasonal allergy	1	1	1	1		
Seizure	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensation of foreign body		4		1		3
Sensitive skin	1	2	1	2		
Sensorimotor disorder	1	1	1	1		
Sensory disturbance	3	3	3	3		
Sinus congestion	1	3	1	3		
Sinusitis	1	1	1	1		
Skin burning sensation	2	4	2	3		1
Skin disorder	1	1	1	1		
Skin exfoliation		1		1		
Skin necrosis	1	1			1	1
Skin reaction	2	2	2	2		
Skin sensitisation	1	1	1	1		
Sleep apnoea syndrome	1	1			1	1
Sleep disorder	2	5	2	5		
Somnolence	2	3	2	3		
Speech disorder	1	2		1	1	1
Spinal disorder	1	1	1	1		
Spinal pain	2	2	2	2		
Sudden hearing loss		3				3
Suffocation feeling	1	1	1	1		
Suspected COVID-19	2	5	1	1	1	4
Swelling	4	7	3	5	1	2
Swelling face	5	9	5	7		2
Swelling of eyelid	1	2	1	2		
Swollen tongue	1	3	1	2		1
Syncope	1	2			1	2
Tachycardia	5	12	3	7	2	5
Temporomand bular joint syndrome		1		1		
Tenderness	1	1	1	1		
Tendon pain	1	2	1	1		1
Tenosynovitis		1		1		
Therapeutic response unexpected	5	10	5	10		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thirst	1	1	1	1		
Throat irritation	2	4	2	4		
Throat tightness		1				1
Thrombocytopenia		1				1
Thrombophlebitis superficial	1	1			1	1
Thrombosis	3	7			3	7
Tinnitus	4	7	4	7		
Tongue discomfort	1	3	1	3		
Tongue disorder	2	2	1	1	1	1
Toothache		1		1		
Transaminases increased		1		1		
Tremor	1	2		1	1	1
Trigeminal nerve paresis	1	1			1	1
Trigeminal neuralgia	1	1	1	1		
Trigeminal neuritis	1	1	1	1		
Trismus	1	1			1	1
Tumour marker increased	1	1			1	1
Underdose	3	23	3	23		
Urinary incontinence	1	1	1	1		
Urinary retention		1				1
Urticaria	8	14	8	12		2
Vaccination complication	3	3	3	3		
Vaccination failure	3	15			3	15
Vaccination site abscess	1	1			1	1
Vaccination site bruising		3		3		
Vaccination site discolouration		1		1		
Vaccination site discomfort	1	6	1	6		
Vaccination site erythema	8	15	7	14	1	1
Vaccination site haematoma		1		1		
Vaccination site haemorrhage		2		2		
Vaccination site hyperaesthesia		2		2		
Vaccination site induration		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site inflammation	1	1	1	1		
Vaccination site joint pain	1	1	1	1		
Vaccination site lymphadenopathy	3	5	3	5		
Vaccination site movement impairment	2	6	2	6		
Vaccination site pain	92	305	91	303	1	2
Vaccination site paraesthesia	1	2	1	2		
Vaccination site pruritus	6	7	6	7		
Vaccination site pustule		1		1		
Vaccination site rash	3	3	3	3		
Vaccination site reaction	2	3	2	3		
Vaccination site swelling	9	21	9	21		
Vaccination site urticaria	1	1	1	1		
Vaccination site warmth	7	12	7	12		
Varicella		1		1		
Varicophlebitis	1	1			1	1
Vascular occlusion		1				1
Vasculitis		1				1
Venous thrombosis	1	2			1	2
Venous thrombosis limb	2	3	1	1	1	2
Ventricular f brillation	1	1			1	1
Vertigo	1	3	1	3		
Vestibular neuronitis	1	1			1	1
Viral rash		1		1		
Vision blurred		3		2		1
Visual impairment	4	6	3	5	1	1
Vomiting	11	22	11	20		2
Vulvovaginal swelling		1		1		
Weight decreased	2	2	2	2		
Weight increased	1	1	1	1		
White blood cell count decreased	2	3	1	2	1	1
White blood cell count increased		1		1		
Wound	1	1	1	1		

* I=Interval, C=Cumulative

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Wrong product administered	2	2	2	2		
Wrong technique in product usage process	2	5	2	5		
	1,866	4,322	1560	3434	306	888

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

GREECE

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Crying		1		1		
Exposure via breast milk		1		1		
Fall		1				1
Restlessness		1		1		
Skin lesion		1				1
Syncope		1				1
		6		3		3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	2			2	2
Allergy to vaccine		1				1
Anaphylactic reaction		1				1
Arthralgia	1	7	1	3		4
Back pain	1	1			1	1
Blood pressure abnormal		1				1
Blood pressure increased		2		1		1
Bronchospasm		2				2
Burning sensation		2		1		1
Cachexia		1				1
Catarrh	1	1	1	1		
Cerebrovascular accident	1	1			1	1
Chest pain	2	3			2	3
Chills	3	5	1	2	2	3
Cough		2		1		1
COVID-19		5		1		4
C-reactive protein increased		2		2		
CSF polymorphonuclear cell count increased		1				1
Diabetes mellitus inadequate control		2				2
Diarrhoea		1		1		
Discomfort		1				1
Dizziness	1	5	1	5		
Drug ineffective		2				2
Dry throat		1				1
Dyskinesia		1		1		
Dyspnoea	1	3			1	3
Electromyogram abnormal		1		1		
Erythema		3		2		1
Eyelids pruritus		1		1		
Fatigue	5	13	4	9	1	4
Fibrin D dimer increased		1		1		
Fibrosis	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematocrit decreased		1		1		
Haematuria		1				1
Haemodynamic instability	1	1			1	1
Headache	7	14	5	11	2	3
Head discomfort		1		1		
Heart rate abnormal		1				1
Heart rate increased		1		1		
Hordeolum		1		1		
Hyperhidrosis	1	1	1	1		
Hypersensitivity		3				3
Hypertension		3		1		2
Hypoaesthesia	3	6	2	5	1	1
Hypotension		1		1		
Infection	1	1	1	1		
Inner ear disorder	1	1	1	1		
Insulin resistance		1				1
Intercostal neuralgia		1		1		
Intervertebral disc degeneration		1		1		
Intervertebral disc protrusion		1		1		
Laryngospasm		1				1
Left ventricular hypertrophy		1				1
Leukocytosis		1		1		
Livedo reticularis		1		1		
Lymphadenitis		7		4		3
Lymphadenopathy	1	7		5	1	2
Lymph node pain		1				1
Lymphopenia		1		1		
Malaise		3		2		1
Migraine		1		1		
Muscle fatigue		1		1		
Muscle tightness		1				1
Musculoskeletal stiffness		1		1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	4	13	4	8		5
Myocarditis	2	2			2	2
Nausea		1		1		
Neck pain		1				1
Oedema	1	1			1	1
Oedema peripheral		1		1		
Oral herpes		2		2		
Oropharyngeal pain		3		2		1
Pain in extremity		5		5		
Palpitations		3		1		2
Pruritus	1	5		1	1	4
Pyrexia	8	19	6	13	2	6
Rash		8		4		4
Rash erythematous	1	1	1	1		
Somnolence		1		1		
Syncope	1	1			1	1
Tachycardia		6		2		4
Tachypnoea		1		1		
Throat irritation		1		1		
Tremor		1		1		
Urticaria	1	1	1	1		
Vaccination failure		2				2
Vaccination site erythema		1		1		
Vaccination site oedema		1		1		
Vaccination site pain	9	13	9	12		1
Vaccination site rash		1		1		
Vertigo	1	1	1	1		
Vomiting		2		1		1
	63	242	40	141	23	101

* I=Interval, C=Cumulative

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1		1		
Abdominal pain	1	5	1	3		2
Abdominal pain upper		5		4		1
Abortion spontaneous		1				1
Ageusia	2	3	1	1	1	2
Alanine aminotransferase increased		2		2		
Allergy to vaccine		2		1		1
Anaphylactic reaction	1	10			1	10
Anaphylactic shock		1				1
Angioedema		5				5
Ankylosing spondylitis		1				1
Anosmia		2		1		1
Anxiety		1		1		
Aphonia	1	1			1	1
Arrhythmia	1	7			1	7
Arthralgia	14	49	13	29	1	20
Aspartate aminotransferase increased		1		1		
Asthenia	5	23	5	15		8
Asthma	1	1			1	1
Asthmatic crisis		1				1
Asymptomatic COVID-19		2				2
Ataxia	1	1			1	1
Atrial fibrillation	1	4			1	4
Axillary pain	1	2	1	1		1
Back pain	2	3	2	2		1
Balance disorder		1		1		
Bell's palsy	1	1			1	1
Blepharitis		1		1		
Blepharospasm		1		1		
Blister		2		2		
Blood creatine phosphokinase increased		1		1		
Blood glucose abnormal		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood glucose decreased	1	1	1	1		
Blood pressure decreased		4		2		2
Blood pressure diastolic increased		1		1		
Blood pressure increased	3	26	1	12	2	14
Blood pressure systolic		1				1
Blood pressure systolic abnormal		1				1
Blood pressure systolic increased		1				1
Body dysmorphic disorder		1				1
Bone pain	2	3	2	2		1
Breast swelling	1	1	1	1		
Bronchial hyperreactivity		1				1
Bronchospasm	1	6	1	1		5
Burning sensation	1	13	1	8		5
Bursitis		1		1		
Cachexia		3				3
Capillary disorder		1		1		
Carpal tunnel syndrome	1	1	1	1		
Cerebral haemorrhage	1	1			1	1
Cervical radiculopathy		1				1
Cervix erythema		1				1
Chest discomfort		5		1		4
Chest pain	2	9		3	2	6
Chills	10	60	10	36		24
Choking sensation		1				1
Cholinergic syndrome		4				4
Clonus		1				1
Complex regional pain syndrome		2				2
Condition aggravated	1	3	1	1		2
Confusional state		3		1		2
Cough	1	15	1	5		10
COVID-19	1	10	1	4		6
Cranial nerve palsies multiple	1	1			1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
C-reactive protein increased	2	2	2	2		
Cyanosis		2		1		1
Deafness	1	1			1	1
Decreased appetite		2		2		
Deep vein thrombosis	1	1			1	1
Defaecation urgency		1				1
Dermatitis allergic		1				1
Dermatomyositis		1				1
Diabetes mellitus inadequate control		1				1
Diarrhoea	2	13	2	10		3
Diastolic hypertension		1				1
Diplopia	1	3			1	3
Discomfort		4		2		2
Disease recurrence		1				1
Disorientation	1	1	1	1		
Disturbance in attention		1				1
Dizziness	9	50	9	32		18
Drowning		1				1
Drug ineffective		7				7
Drug interaction		1				1
Dry mouth		4		3		1
Dry throat		8		2		6
Dysarthria		1				1
Dysgeusia	6	15	6	10		5
Dyskinesia		1				1
Dysmenorrhoea	1	1	1	1		
Dyspepsia		1				1
Dysphagia	2	16		2	2	14
Dysphonia	1	9	1	3		6
Dysphoria		1				1
Dyspnoea	2	15	2	8		7
Ear pain		3		2		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eating disorder		1				1
Enlarged uvula	1	1			1	1
Epigastric discomfort		1				1
Eructation		4		3		1
Erythema	5	37	4	24	1	13
Extrasystoles		3		2		1
Eyelid irritation		1				1
Eyelid oedema		2		2		
Eyelid ptosis		1				1
Eye oedema		1				1
Eye pain		1				1
Eye pruritus		1		1		
Face oedema		2		1		1
Facial paresis	1	5			1	5
Fatigue	16	61	15	36	1	25
Feeling abnormal		1				1
Feeling hot		4		2		2
Flatulence		2				2
Flushing		26		11		15
Formication	1	1			1	1
Gait disturbance	1	6		1	1	5
Gait inability		1				1
Gamma-glutamyltransferase increased		1				1
Gastroenteritis		1				1
Gastrointestinal disorder		5		5		
Gastrointestinal hypermotility		1				1
Gastrointestinal pain	1	1	1	1		
Glossodynia		2				2
Granuloma annulare		1		1		
Guillain-Barre syndrome		3				3
Haematoma	1	1	1	1		
Haemoptysis		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache	23	99	21	68	2	31
Head discomfort	1	2	1	2		
Heart rate decreased		1				1
Heart rate increased		13		9		4
Heart rate irregular		1				1
Heavy menstrual bleeding	1	2			1	2
Hepatic pain	1	1	1	1		
Herpes zoster	1	6	1	2		4
Hot flush	1	2	1	1		1
Hyperhidrosis		13		11		2
Hyperpyrexia	1	1			1	1
Hypersensitivity	2	18		4	2	14
Hypersensitivity vasculitis		1				1
Hypertension	2	15	2	7		8
Hypertensive crisis		6				6
Hypertensive emergency		1				1
Hypoaesthesia	14	56	9	29	5	27
Hypoaesthesia oral	4	15	3	6	1	9
Hypokalaemia		1				1
Hyponatraemia		1				1
Hypotension		10		3		7
Hypotonia	1	4	1	2		2
Illness		2		1		1
Impaired gastric emptying		1				1
Impaired work ability		1				1
Incorrect route of product administration	1	2	1	2		
Inflammation		3		1		2
Influenza like illness		1		1		
Injection site pain	2	2	2	2		
Insomnia		2		1		1
Iridocyclitis		1				1
Jaw disorder	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint effusion		1				1
Joint range of motion decreased		1		1		
Joint swelling	1	1	1	1		
Lacrimation increased	1	1	1	1		
Laryngeal oedema		1				1
Laryngeal pain		1				1
Laryngospasm		2				2
Lethargy	1	2	1	2		
Lichenoid keratosis		1		1		
Limb discomfort	1	3	1	1		2
Lip oedema		3		2		1
Lip pain		2				2
Lip swelling	1	2	1	1		1
Localised oedema		3		1		2
Local reaction		1		1		
Loss of consciousness		2				2
Lymphadenitis	3	13	3	4		9
Lymphadenopathy	4	25	3	10	1	15
Lymph node pain	2	3	2	3		
Malaise	5	22	4	12	1	10
Maternal exposure during pregnancy		2		2		
Mechanical urticaria		1		1		
Meningism		1		1		
Menstruation delayed	1	1	1	1		
Menstruation irregular	1	3	1	2		1
Middle insomnia		1		1		
Migraine	1	5	1	3		2
Miller Fisher syndrome	1	1			1	1
Mucosal dryness		1				1
Muscle discomfort		1				1
Muscle injury		1		1		
Muscle spasms	2	5	1	1	1	4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle tightness		1		1		
Muscular weakness		6		2		4
Musculoskeletal discomfort	2	3	2	3		
Musculoskeletal stiffness		1				1
Myalgia	24	85	23	59	1	26
Myelitis		2				2
Myocardial infarction		1				1
Myocarditis		1				1
Nasal pruritus		1		1		
Nausea	3	32	2	22	1	10
Neck pain		3		3		
Nervous system disorder	1	1			1	1
Neuritis		1				1
Neuritis cranial		1				1
Ocular hyperaemia		1				1
Oedema		1				1
Off label use		1		1		
Ophthalmoplegia	1	1			1	1
Oral herpes		1				1
Oropharyngeal pain	1	7	1	4		3
Oxygen saturation abnormal		1				1
Oxygen saturation decreased		2				2
Pain	3	13	3	5		8
Pain in extremity	11	26	11	23		3
Pain in jaw		1				1
Pallor		3		2		1
Palpitations	1	17	1	10		7
Pancreatitis		1				1
Panic attack	1	1	1	1		
Panic reaction		1				1
Paraesthesia		1				1
Paralysis		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paratracheal lymphadenopathy		1				1
Parosmia	1	2	1	1		1
Peripheral coldness		6				6
Peripheral swelling	1	1	1	1		
Petechiae		2		1		1
Pharyngeal oedema		1		1		
Pharyngeal swelling	1	1			1	1
Pharyngitis		1		1		
Platelet count increased		1		1		
Polyarthrits		1				1
Polymenorrhoea	2	2	2	2		
Polyneuropathy		2				2
Poor quality sleep		1		1		
Post herpetic neuralgia		1				1
Presyncope		12		5		7
Priapism	1	1			1	1
Product use issue		1		1		
Pruritus	5	41	3	25	2	16
Pruritus allergic		1				1
Psoriasis		1		1		
Psoriatic arthropathy		1				1
Pulse abnormal		1				1
Purpura		1				1
Pyrexia	32	112	30	74	2	38
Rash	3	35	2	14	1	21
Rash erythematous		2		2		
Rash macular		1		1		
Rash morbilliform	1	1	1	1		
Rash papular		1				1
Rash pruritic	1	8	1	5		3
Rhinitis		1		1		
Rhinorrhoea	1	2	1	1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Salivary gland pain		1		1		
Sciatica		1				1
Seizure		1				1
Sensation of foreign body		1				1
Sensory loss		1				1
Shock		1				1
Skin burning sensation		2		1		1
Skin lesion	1	1	1	1		
Skin reaction		1				1
Soft tissue swelling		1		1		
Somnolence		7		5		2
Spinal pain		2				2
Suffocation feeling	1	1	1	1		
Swelling		4		1		3
Swelling face		1				1
Syncope		4				4
Tachycardia	3	37	3	17		20
Taste disorder		1				1
Temporomand bular joint syndrome		1		1		
Tension headache	1	1	1	1		
Terminal state		1				1
Thirst		1		1		
Throat irritation		7		3		4
Throat tightness		1				1
Thrombosis	3	3			3	3
Thyroiditis		1				1
Thyroiditis acute		1				1
Tinnitus	1	6		3	1	3
Tongue discomfort		1				1
Tongue oedema		1				1
Tonsillitis		1		1		
Tremor		9		5		4

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Trigeminal neuralgia	1	2	1	1		1
Trigeminal neuritis	1	1			1	1
Urticaria	3	6	3	4		2
Uveitis		2				2
Vaccination failure		1				1
Vaccination site bruising	1	1	1	1		
Vaccination site discomfort		1		1		
Vaccination site erythema		3		2		1
Vaccination site hyperaesthesia		1		1		
Vaccination site hypoaesthesia		3		2		1
Vaccination site lymphadenopathy		1				1
Vaccination site movement impairment		1		1		
Vaccination site oedema	1	5	1	4		1
Vaccination site pain	35	79	35	72		7
Vaccination site rash	1	1	1	1		
Vaccination site reaction		1		1		
Vaccination site swelling		1		1		
Vaccination site warmth		2		1		1
Venous thrombosis	1	1			1	1
Vertigo	2	8	1	5	1	3
Viral infection		1		1		
Vision blurred		1		1		
Vomiting	2	11		5	2	6
Water pollution		1				1
White blood cell count decreased		1		1		
	351	1,777	289	957	62	820

* I=Interval, C=Cumulative

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1			1	1
Abdominal pain	3	7	3	5		2
Abdominal pain upper	4	5	2	3	2	2
Acne	1	1	1	1		
Activated partial thromboplastin time prolonged	1	1	1	1		
Acute myocardial infarction		2				2
Acute respiratory distress syndrome		1				1
Allergy to vaccine		1				1
Alopecia		1		1		
Amylase decreased	1	1	1	1		
Anaemia		1				1
Anaphylactic reaction	3	4			3	4
Anaphylactic shock		5				5
Anaphylactoid reaction		1				1
Angioedema		5				5
Anxiety		1		1		
Arrhythmia	1	2			1	2
Arthralgia	5	20	4	10	1	10
Arthritis		1		1		
Arthritis enteropathic		1				1
Asthenia	8	21	5	12	3	9
Asymptomatic COVID-19		1				1
Atrial fibrillation	2	5			2	5
Autonomic nervous system imbalance		1				1
Axillary pain		1		1		
Back pain		1		1		
Balance disorder	1	2			1	2
Bell's palsy		1				1
Blister		1		1		
Blood creatine phosphokinase increased	1	1	1	1		
Blood creatine phosphokinase MB increased	1	1	1	1		
Blood creatinine decreased	1	1	1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood fibrinogen increased	1	1	1	1		
Blood glucose increased	1	1	1	1		
Blood lactate dehydrogenase increased	1	1	1	1		
Blood magnesium increased	1	1	1	1		
Blood phosphorus decreased	1	1	1	1		
Blood potassium decreased	1	1	1	1		
Blood pressure abnormal		1				1
Blood pressure diastolic increased		1		1		
Blood pressure increased	10	21	10	15		6
Blood pressure systolic decreased	1	1	1	1		
Blood pressure systolic increased		3		1		2
Blood sodium increased	1	1	1	1		
Blood triglycerides increased		1				1
Body temperature increased	1	1	1	1		
Bone pain	1	4	1	3		1
Bradycardia		1				1
Brain death		1				1
Breast pain		1		1		
Bronchospasm		1				1
Burning sensation	1	10	1	8		2
Carbohydrate antigen 125 increased		1		1		
Carcinoembryonic antigen increased		1				1
Cardiac arrest	2	5			2	5
Cardiac discomfort		1				1
Cardiac failure		1				1
Cardiac valve disease		1				1
Cerebral haemorrhage	1	1			1	1
Cerebrovascular accident	1	1			1	1
Chest discomfort	1	1			1	1
Chest pain	4	10	3	5	1	5
Chills	6	27	6	12		15
Coma	1	1			1	1

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Complex regional pain syndrome		1		1		
Condition aggravated		2				2
Confusional state	1	3			1	3
Conjunctival hyperaemia		1		1		
Contusion	1	2	1	2		
Coronary artery stenosis	1	1			1	1
Cough	1	7		1	1	6
COVID-19	2	4	1	1	1	3
C-reactive protein increased	1	1	1	1		
Deafness		1				1
Death	1	1			1	1
Deep vein thrombosis		1				1
Dehydration		1				1
Dermatitis allergic	1	2			1	2
Diarrhoea	3	11	3	7		4
Diplegia		1				1
Diplopia		1				1
Discomfort		1		1		
Disease recurrence	2	3			2	3
Disorientation		1		1		
Diverticulitis		1				1
Dizziness	2	20	1	13	1	7
Drug ineffective	1	3			1	3
Dry eye		2		2		
Dry mouth		4		3		1
Dry throat	1	4		1	1	3
Dysarthria		1				1
Dysgeusia		2		2		
Dyspepsia		2		1		1
Dysphagia		5		2		3
Dysphonia		6		2		4
Dysphoria		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea	2	12	1	3	1	9
Dysstasia		1				1
Ear pain		1				1
Eating disorder symptom		1		1		
Eczema	1	1	1	1		
Enlarged uvula		1				1
Eosinophil count decreased	1	1	1	1		
Eructation		1				1
Erythema	1	18		10	1	8
Extrasystoles		2		1		1
Eyelid oedema		1				1
Eyelids pruritus		1				1
Eye pruritus		1				1
Face oedema		2				2
Facial paralysis	1	1			1	1
Facial paresis		1				1
Fall		1				1
Fatigue	13	38	10	22	3	16
Feeling cold		3		3		
Feeling drunk		1				1
Feeling hot	1	2		1	1	1
Fibrin D dimer increased	1	1	1	1		
Flushing	1	2			1	2
Gait disturbance		2		2		
Gastric pH decreased	1	1			1	1
Gastrointestinal disorder		2		1		1
Goitre		1				1
Guillain-Barre syndrome		1				1
Haematocrit decreased	1	1	1	1		
Haemoglobin decreased	1	1	1	1		
Haemoptysis		1				1
Headache	18	47	14	29	4	18

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Head discomfort	1	3	1	3		
Heart rate increased	1	7		3	1	4
Hepatic function abnormal	1	1	1	1		
Herpes ophthalmic		1				1
Herpes zoster		4		2		2
Hiccups	1	1	1	1		
Hot flush		1				1
Hyperhidrosis	1	10			1	10
Hypersensitivity		5		3		2
Hypertension	4	13	2	7	2	6
Hypertensive crisis		7				7
Hypoacusis		1				1
Hypoaesthesia	5	20	2	11	3	9
Hypoaesthesia oral	2	8	2	6		2
Hyporeflexia		1				1
Hypotension	1	4			1	4
Hypothermia		1				1
Hypotonia	1	2		1	1	1
Immunoglobulins increased		1				1
Incorrect route of product administration		1		1		
Inflammation		1				1
Influenza	1	1	1	1		
Injection site hypoaesthesia		1		1		
Injection site pain	2	3	2	3		
Insomnia		3		2		1
International normalised ratio decreased	1	1	1	1		
Irritability		1		1		
Joint stiffness		1				1
Joint swelling		1		1		
Laryngeal oedema		4				4
Laryngospasm		2				2
Leukocytosis		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Limb discomfort		1		1		
Limb mass	1	1	1	1		
Lip oedema		4		1		3
Lip swelling	1	3		2	1	1
Loss of consciousness		1				1
Lymphadenitis	2	7	2	3		4
Lymphadenopathy	4	11	4	10		1
Lymph node pain		1		1		
Lymphocyte count decreased	1	1	1	1		
Lymphoedema		1				1
Malaise	2	6	2	4		2
Meningomyelitis herpes		1				1
Mental impairment	1	1			1	1
Mobility decreased	1	1			1	1
Monoparesis		1				1
Mouth swelling	1	1	1	1		
Mouth ulceration		2		2		
Muscle spasms	1	1			1	1
Muscle strain		1		1		
Muscular weakness		3		1		2
Myalgia	15	48	13	33	2	15
Myocardial infarction	2	3			2	3
Nasal congestion		1		1		
Nausea	1	13	1	8		5
Neck mass	1	1	1	1		
Neck pain		2		1		1
Neoplasm progression	1	1	1	1		
Nervousness		1				1
Neuralgia		1				1
Neuropathy peripheral		2				2
Nystagmus		1		1		
Ocular hyperaemia		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oedema		2		1		1
Oedema peripheral	1	1	1	1		
Off label use		1		1		
Oral herpes		1		1		
Oral mucosal erythema		1		1		
Oropharyngeal pain		2				2
Orthostatic hypotension		1		1		
Pain	3	9		2	3	7
Pain in extremity	2	8	2	6		2
Pain in jaw		1		1		
Palpitations	1	10	1	4		6
Paraesthesia		1				1
Paralysis	1	1			1	1
Paresis		1				1
Parotid gland enlargement		1				1
Pericarditis	1	1			1	1
Peripheral coldness		3		2		1
Peripheral swelling		1		1		
Peripheral venous disease		1		1		
Pharyngeal abscess	1	1			1	1
Pharyngeal oedema	1	1			1	1
Photophobia		1				1
Platelet count decreased	1	1	1	1		
Pleural effusion	1	1			1	1
Pneumonia		1				1
Portal vein thrombosis	1	1			1	1
Presyncope		1				1
Product use issue		1		1		
Protein total decreased	1	1	1	1		
Prothrombin time prolonged	1	1	1	1		
Pruritus	4	17	2	9	2	8
Pulmonary embolism		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary fibrosis		1				1
Pulmonary mass		1				1
Pulse abnormal		1		1		
Pupillary reflex impaired	1	1			1	1
Pupils unequal	1	1			1	1
Pyrexia	22	59	18	38	4	21
Rash	3	21	2	12	1	9
Rash maculo-papular	3	6	2	3	1	3
Rash pruritic		2		1		1
Raynaud's phenomenon		1				1
Red blood cell count decreased	1	1	1	1		
Reflexes abnormal		1				1
Respiratory tract infection		1				1
Rheumatoid arthritis		2				2
Rhinitis allergic		1		1		
Rhinorrhoea		1		1		
Salivary gland enlargement		1				1
Sarcoidosis		1				1
SARS-CoV-2 test positive		1		1		
Sjogren's syndrome		1				1
Somnolence	2	8	2	5		3
Spinal pain		1				1
Stress		1		1		
Swelling	1	2		1	1	1
Swelling face		1				1
Swollen tongue	1	1			1	1
Syncope		1				1
Tachyarrhythmia	1	1			1	1
Tachycardia	5	14	2	7	3	7
Taste disorder		2				2
Teething		1				1
Temporomandibular joint syndrome		1		1		

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tension		1		1		
Throat irritation		4		4		
Thrombosis	1	3			1	3
Thyroid cyst		1				1
Thyroiditis		1		1		
Tinnitus		1				1
Tongue oedema		1				1
Tongue ulceration		1		1		
Tonsillar hypertrophy		1				1
Tremor		3		1		2
Trismus		1		1		
Troponin increased	1	1	1	1		
Underdose	1	1	1	1		
Urticaria	2	3	1	2	1	1
Uveitis		1				1
Vaccination site discomfort		1		1		
Vaccination site erythema	1	2	1	1		1
Vaccination site irritation	1	2	1	1		1
Vaccination site oedema	1	2	1	2		
Vaccination site pain	20	48	19	43	1	5
Vaccination site pruritus	1	3	1	2		1
Vaccination site rash	1	2		1	1	1
Vasculitis		1				1
Ventricular arrhythmia		1				1
Ventricular f brillation	1	1			1	1
Vertigo	1	4	1	3		1
Vision blurred	1	2		1	1	1
Vomiting	3	6	3	3		3
Wa king disability		1				1
White blood cell count increased	1	1	1	1		
Wrong technique in product usage process	1	1	1	1		
	288	1,005	195	525	93	480

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	2			1	2
Abdominal pain upper		2		2		
Accident	1	1			1	1
Acne	1	2	1	2		
Acute coronary syndrome	1	1			1	1
Acute kidney injury	1	1			1	1
Acute myocardial infarction	3	3			3	3
Acute respiratory failure	1	1			1	1
Anaphylactic reaction		1				1
Anaphylactic shock		1				1
Angina pectoris	1	1			1	1
Angioedema		2				2
Aphasia		1				1
Arrhythmia		2				2
Arteriovenous graft thrombosis		1				1
Arthralgia	3	5	2	4	1	1
Aspiration		1				1
Asthenia	2	2	2	2		
Atrial f brillation	1	1			1	1
Atypical pneumonia	1	1			1	1
Audiogram abnormal		1		1		
Back pain	1	3	1	2		1
Bell's palsy	1	2			1	2
Blood parathyroid hormone increased	1	1	1	1		
Blood pressure decreased		1				1
Blood pressure increased	2	5			2	5
Body temperature decreased	1	1	1	1		
Bone pain		1		1		
Bradycardia	2	2			2	2
Brain death		1				1
Burning sensation	2	5	1	4	1	1
Cardiac arrest	1	2			1	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Catarrh		1		1		
Cerebral haemorrhage		1				1
Cerebrovascular accident	2	2			2	2
Chest discomfort		1				1
Chest pain		1		1		
Chills	3	6	3	4		2
Cold sweat	1	1			1	1
Coma		1				1
Confusional state		1				1
Conjunctival hyperaemia		1		1		
Coronary artery thrombosis		1				1
Cough	1	1			1	1
COVID-19	2	7		2	2	5
Death	3	3			3	3
Decreased appetite	1	1			1	1
Deep vein thrombosis	2	4			2	4
Depression	1	1			1	1
Dermatitis allergic	1	1			1	1
Diarrhoea	3	4	2	2	1	2
Diplegia	1	2			1	2
Dizziness	4	6	2	2	2	4
Dizziness postural	1	1			1	1
Drug ineffective	2	4			2	4
Dysarthria	1	1	1	1		
Dysphagia	1	2		1	1	1
Dysphoria		1				1
Dyspnoea	1	6		2	1	4
Ear, nose and throat examination abnormal		1		1		
Ear pain	1	1			1	1
Electric shock sensation	1	1	1	1		
Electrocardiogram repolarisation abnormality		1				1
Embolic stroke	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Enlarged uvula		1				1
Epilepsy		1				1
Episcleritis		1				1
Epistaxis	2	3	2	3		
Erythema	2	4	1	3	1	1
Eye irritation	1	1	1	1		
Eyelid oedema		1		1		
Eyelid ptosis	1	1			1	1
Eye pruritus	1	1			1	1
Facial paralysis		1				1
Facial paresis	1	4	1	2		2
Fall	1	2			1	2
Fatigue	9	11	7	9	2	2
Feeling hot	1	1	1	1		
Femur fracture	1	1			1	1
Foot deformity		1				1
Gait disturbance	1	1			1	1
Gastrointestinal haemorrhage		1				1
Glycosylated haemoglobin decreased		1		1		
Granulocytopenia	1	1			1	1
Guillain-Barre syndrome		2				2
Haematocrit decreased		1				1
Haematoma		1				1
Haematuria	1	1			1	1
Headache	9	14	6	10	3	4
Heart rate decreased		3				3
Heart rate increased		1				1
Hemianaesthesia	1	1			1	1
Hemiparesis	1	2			1	2
Herpes simplex reactivation		1		1		
Herpes zoster	4	5	2	2	2	3
Hyperhidrosis	2	4		1	2	3

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypersensitivity	2	4		1	2	3
Hypertension	1	4		2	1	2
Hypertensive crisis		1				1
Hypoaesthesia	1	4	1	2		2
Hypoaesthesia oral	2	2	1	1	1	1
Hypoglycaemia		2		2		
Hypotension	1	2		1	1	1
Hypothermia	2	2			2	2
Incorrect route of product administration	2	2	2	2		
Intervertebral disc protrusion	1	1			1	1
Ischaemic cerebral infarction	1	2			1	2
Leukaemia		1				1
Limb discomfort	1	1			1	1
Limb mass	1	1	1	1		
Lip oedema	2	2			2	2
Lip swelling	2	3	2	3		
Localised oedema	1	1			1	1
Loss of consciousness	1	4			1	4
Lymphadenitis		1				1
Lymphadenopathy	2	3	2	3		
Lymph node pain		1		1		
Malaise	2	3	2	3		
Mastication disorder	1	1	1	1		
Memory impairment		1				1
Migraine	1	1			1	1
Monoplegia	1	1			1	1
Muscle spasms	1	1			1	1
Muscular weakness	2	3	1	2	1	1
Musculoskeletal chest pain		1		1		
Musculoskeletal stiffness		1		1		
Myalgia	6	10	5	8	1	2
Myocardial infarction	2	3			2	3

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myocarditis	1	1			1	1
Nail discolouration		2		2		
Nausea	2	2			2	2
Neutrophil count decreased	1	1			1	1
Onycholysis		1		1		
Ophthalmic artery thrombosis	1	1			1	1
Oropharyngeal pain	1	1			1	1
Osteoarthritis	1	1	1	1		
Oxygen saturation decreased		1				1
Pain	5	8	1	2	4	6
Pain in extremity	6	10	3	6	3	4
Paraparesis		1				1
Parotid gland enlargement		1		1		
Periorbital swelling		1		1		
Peripheral swelling	3	3	2	2	1	1
Presyncope	1	1			1	1
Productive cough	1	1			1	1
Pruritus	1	2	1	2		
Pulmonary embolism	1	1			1	1
Pulmonary oedema	1	2			1	2
Pulmonary pain	1	1			1	1
Pulse absent		1				1
Purpura	1	1			1	1
Pyrexia	14	22	9	14	5	8
Rash	2	3	2	2		1
Rash macular	1	1	1	1		
Rash maculo-papular		1				1
Rash pruritic	1	1	1	1		
Salivary gland pain		1		1		
Skin burning sensation	1	1	1	1		
Skin papilloma	1	1			1	1
Somnolence	1	1	1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Speech disorder		1				1
Supraventricular tachycardia	1	1			1	1
Suspected COVID-19	3	3	2	2	1	1
Swelling	2	2	1	1	1	1
Swelling face		1		1		
Swollen tongue	1	2	1	2		
Syncope	1	4			1	4
Systolic dysfunction	1	1			1	1
Tachycardia	2	3	1	1	1	2
Tendon pain	1	1			1	1
Therapeutic response unexpected		2		2		
Thrombocytopenia	1	1			1	1
Thrombosis	3	3			3	3
Thrombotic stroke	1	1			1	1
Tinnitus		1		1		
Tongue oedema	1	3			1	3
Tooth fracture	1	1	1	1		
Transient ischaemic attack	2	2			2	2
Urticaria	1	1			1	1
Uveitis		2				2
Vaccination site discomfort		1		1		
Vaccination site erythema	1	1	1	1		
Vaccination site pain	5	6	4	5	1	1
Vaccination site pruritus	1	1	1	1		
Venous thrombosis	1	1			1	1
Vision blurred	2	2	1	1	1	1
Visual impairment	1	2		1	1	1
Vitiligo	1	1	1	1		
Vomiting	2	2	1	1	1	1
White blood cell count decreased	1	1			1	1
	227	400	95	171	132	229

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- * AE=Adverse Event
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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		2		1		1
Acute myocardial infarction		1				1
Acute respiratory failure		1				1
Aggression		1				1
Agitation		1				1
Anaphylactic reaction		2				2
Angina pectoris		1				1
Angioedema		3				3
Arrhythmia		1				1
Arteriosclerosis		1				1
Arthralgia	1	7	1	4		3
Asthenia		5		3		2
Atrial f brillation	3	4			3	4
Auscultation		1		1		
Back pain		3		3		
Blindness	1	1			1	1
Blood calcium decreased		1		1		
Blood gases abnormal		1				1
Blood glucose abnormal		2		2		
Blood glucose increased		1		1		
Blood iron decreased		1		1		
Blood potassium decreased		1		1		
Blood pressure decreased		1		1		
Blood pressure fluctuation		1		1		
Blood pressure inadequately controlled		1		1		
Blood pressure increased		10		4		6
Blood pressure systolic increased		1				1
Blood urea increased		1		1		
Bone pain	1	1	1	1		
Bronchospasm		1				1
Burning sensation		2		1		1
Burning sensation mucosal		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bursitis		1				1
Cardiac arrest	1	5			1	5
Carotid artery occlusion		1				1
Central nervous system stimulation		1				1
Cerebral haemorrhage	1	1			1	1
Cerebral ischaemia	1	2			1	2
Cerebral venous thrombosis		1				1
Cerebrovascular accident		4				4
Chest discomfort		1				1
Chest pain		1				1
Chills		5		3		2
Cholecystitis	1	1			1	1
Cholelithiasis		1				1
Cholestasis	1	1			1	1
Circumoral oedema		1				1
Communication disorder		1		1		
Complex regional pain syndrome		2				2
Confusional state	1	5	1	2		3
Constipation		1		1		
Coronary artery stenosis		1				1
Cough	1	4	1	3		1
COVID-19	1	5			1	5
Deafness unilateral		1				1
Death	1	6			1	6
Decreased appetite	1	3	1	2		1
Deep vein thrombosis		1				1
Dermatitis allergic		1				1
Diabetes mellitus inadequate control		1				1
Diarrhoea	2	5	1	3	1	2
Diplegia		1				1
Disease recurrence		2				2
Disorientation		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	2	9	2	5		4
Drug ineffective	1	3			1	3
Dysarthria		1				1
Dysphagia		3		1		2
Dysphoria		1				1
Dyspnoea	2	14	1	3	1	11
Dysstasia		2		1		1
Encephalitis	1	1			1	1
Enlarged uvula		1				1
Epistaxis		1		1		
Erythema		5		3		2
Eye haemorrhage		1				1
Eyelid oedema		1		1		
Eye swelling		1				1
Facial paralysis		3				3
Facial paresis	1	4			1	4
Fall	1	4	1	3		1
Fatigue	2	14	2	8		6
Feeding disorder		1		1		
Femur fracture		1				1
Fine motor skill dysfunction		1				1
Flushing		1				1
Gait disturbance		2		1		1
Gait inability	1	2	1	1		1
Gastrointestinal disorder		1		1		
Genital herpes zoster		1				1
Guillain-Barre syndrome		1				1
Haematochezia		1				1
Haemoglobin decreased		1		1		
Haemolysis	1	1			1	1
Headache	1	8	1	6		2
Head discomfort	1	1	1	1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate decreased		1				1
Hemiparesis		1				1
Hepatitis		1				1
Hepatorenal syndrome	1	1			1	1
Herpes dermatitis		1				1
Herpes ophthalmic		1				1
Herpes zoster	1	3	1	2		1
Hydrocephalus	1	1			1	1
Hyperbilirubinaemia	1	1			1	1
Hyperhidrosis	1	2	1	1		1
Hypersensitivity		1				1
Hypertension		6		1		5
Hypertensive crisis		1				1
Hypertrophic cardiomyopathy		1				1
Hypoaesthesia		8		2		6
Hypoaesthesia oral		2				2
Hypoalbuminaemia		1		1		
Hypoglycaemia	1	3		1	1	2
Hypokalaemia		1				1
Hyponatraemia		2		1		1
Hypotension		1				1
Hypothermia		1				1
Hypotonia		2		1		1
Impaired self-care		1				1
Incorrect route of product administration		1		1		
Infection		1		1		
Injection site erythema	1	1	1	1		
Injection site mass	1	1	1	1		
Insomnia		1		1		
Ischaemic stroke	1	2			1	2
Jaundice	2	2			2	2
Lacrimation increased	1	1	1	1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lethargy	1	4	1	3		1
Lip oedema		2				2
Listeriosis	1	1			1	1
Loss of consciousness		3				3
Loss of personal independence in daily activities		1		1		
Lower limb fracture	1	1			1	1
Lower respiratory tract infection		1				1
Lymphadenopathy		1				1
Malaise	1	5	1	4		1
Memory impairment		1				1
Migraine		2		2		
Mobility decreased	2	2	1	1	1	1
Movement disorder		1		1		
Muscle spasms		1				1
Muscular weakness		2				2
Myalgia	1	3	1	3		
Myocardial infarction		1				1
Nasopharyngitis		1		1		
Nausea		2		2		
Ocular hyperaemia		1				1
Oedema peripheral		3		1		2
Off label use		1		1		
Ophthalmic artery thrombosis		1				1
Oral disorder	1	1			1	1
Oropharyngeal pain		1		1		
Orthostatic hypotension		1				1
Overdose		1		1		
Oxygen saturation decreased		4				4
Pain in extremity	2	6	2	6		
Palpitations	2	2	2	2		
Pancreatic carcinoma	1	1			1	1
Paralysis		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paresis		1				1
Parotitis		1		1		
Peripheral swelling		1		1		
Petit mal epilepsy		1				1
Pneumonia	1	1			1	1
Polydipsia		1		1		
Polyneuropathy		1				1
Polyuria		1		1		
Product preparation error		1		1		
Product use issue		1		1		
Protein total decreased		1		1		
Prothrombin time prolonged		1		1		
Pruritus	1	6	1	1		5
Pulmonary embolism	2	3			2	3
Pyrexia	5	22	4	14	1	8
Rash		6		3		3
Rash papular	1	1			1	1
Rash pruritic		1		1		
Renal failure		1				1
Renal impairment		1				1
Respiratory failure		1				1
Respiratory tract infection		1				1
Retinal artery thrombosis	1	1			1	1
Retinal vein thrombosis	1	1			1	1
Scleritis		1				1
Skin burning sensation		1		1		
Somnolence	2	5	2	4		1
Speech disorder		3		2		1
Sputum increased		1				1
Sputum purulent		1				1
Stomatitis	1	1			1	1
Sudden death		3				3

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Suspected COVID-19		2		1		1
Swelling face		1				1
Syncope	1	5			1	5
Tachycardia	2	5	2	3		2
Tachypnoea		1		1		
Tension		1		1		
Thrombosis		1				1
Thrombosis in device	1	1			1	1
Tongue oedema		1				1
Transaminases increased	1	1	1	1		
Transient ischaemic attack		1				1
Tremor		2		2		
Urinary incontinence		2		1		1
Urinary tract infection		2				2
Urine analysis abnormal	1	1	1	1		
Urticaria	1	2	1	2		
Vaccination failure		1				1
Vaccination site haemorrhage		1		1		
Vaccination site pain	10	12	10	11		1
Venous thrombosis limb		1				1
Vertigo		2		1		1
Viral infection		1		1		
Vomiting	1	8		3	1	5
Wheezing		1		1		
	90	464	50	192	40	272

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain	1	2	1	2		
Abscess	1	1	1	1		
Anaphylactic reaction		1				1
Anaphylactoid reaction		1				1
Arthralgia	1	7	1	6		1
Asthenia		4		4		
Asymptomatic COVID-19		2				2
Back pain		3		3		
Blister	1	2	1	2		
Blood pressure decreased		1				1
Blood pressure increased		6		5		1
Bone pain	1	1	1	1		
Bradycardia		1				1
Bronchospasm		1				1
Bruxism	1	1			1	1
Burning sensation	2	6	2	6		
Catarrh		1		1		
Chest discomfort		1		1		
Chest pain	1	3	1	2		1
Chills	3	11	2	8	1	3
Circumstance or information capable of leading to medication error		2		2		
Cold sweat		1				1
Conjunctivitis		1		1		
Contusion	1	1	1	1		
Cough		5		5		
COVID-19	6	16		4	6	12
Cyanosis		1		1		
Deafness unilateral		1				1
Depression		1		1		
Diarrhoea		3		2		1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Discomfort		1		1		
Dizziness	2	15	2	12		3
Drug ineffective	7	14			7	14
Dry mouth		1		1		
Dysgeusia	3	7	3	5		2
Dyskinesia	2	5	2	5		
Dyspepsia		2		2		
Dysphagia	1	3	1	2		1
Dysphonia		2				2
Dyspnoea	2	7	2	5		2
Dysstasia		1				1
Eczema		1		1		
Electric shock sensation		1		1		
Erythema	3	9	3	9		
Expired product administered		1		1		
Eye irritation		2		2		
Eyelid ptosis		1				1
Face oedema		1		1		
Facial paresis	1	2	1	2		
Fatigue	4	17	3	16	1	1
Fibrin D dimer increased		1				1
Fibromyalgia		1		1		
Flushing	1	4	1	3		1
Gait disturbance		1		1		
Gastrointestinal disorder	1	3	1	3		
Headache	4	15	4	13		2
Heart rate increased		3		3		
Hemiparesis		1				1
Herpes zoster		5		5		
Hyperhidrosis		1		1		
Hypersensitivity	1	10	1	8		2
Hypertension	1	4	1	4		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia	1	14	1	10		4
Hypoaesthesia oral	1	10	1	6		4
Hypotension		4		1		3
Incomplete course of vaccination		1		1		
Incorrect route of product administration		1		1		
Influenza like illness		1		1		
Injury		1		1		
Intermenstrual bleeding	1	2	1	2		
Lacrimation increased		1		1		
Laryngeal oedema		1				1
Lethargy	1	2	1	1		1
Limb discomfort		1		1		
Limb injury		1		1		
Lip oedema	1	1	1	1		
Liquid product physical issue		4		4		
Local reaction		1		1		
Loss of consciousness	1	1			1	1
Lymphadenopathy	1	4	1	3		1
Lymph node pain	1	2	1	2		
Lymph node palpable	1	1	1	1		
Malaise	1	5	1	5		
Maternal exposure during pregnancy	1	3	1	3		
Menstruation delayed		1		1		
Migraine		1		1		
Monoparesis		1				1
Muscle spasms		1		1		
Muscle tightness	1	1	1	1		
Myalgia	2	9	2	8		1
Myoclonus	1	1			1	1
Nasal congestion		1		1		
Nausea		2		1		1
Neck pain	1	1	1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
No adverse event	1	4	1	4		
Occupational exposure to product		1		1		
Ocular hyperaemia		1		1		
Oedema		1		1		
Oedema peripheral	1	1	1	1		
Off label use		1		1		
Ophthalmic herpes zoster	1	1			1	1
Oral discomfort		1		1		
Oropharyngeal discomfort		2		2		
Oropharyngeal pain	2	3	2	3		
Oxygen saturation decreased		1		1		
Pain	2	13	2	13		
Pain in extremity	3	9	3	9		
Palpitations		1		1		
Pancreatitis		1				1
Papilloedema		1				1
Paraesthesia		1		1		
Periorbital oedema		2		2		
Peripheral coldness	1	1	1	1		
Peripheral swelling	1	1	1	1		
Pollakiuria		1		1		
Poor quality product administered		4		4		
Product quality issue		1		1		
Pruritus	4	9	4	8		1
Pulmonary thrombosis		2				2
Pyrexia	7	29	6	26	1	3
Rash		8		2		6
Rash macular		1		1		
Rash papular	1	1	1	1		
Rash pruritic		2		2		
Reaction to excipient		1				1
Respiratory tract infection		1				1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
SARS-CoV-2 ant body test positive		2		2		
SARS-CoV-2 test positive	1	1			1	1
Skin burning sensation	1	1	1	1		
Skin irritation		1		1		
Soft tissue swelling		1				1
Somnolence		3		3		
Speech disorder		1				1
Swelling	1	1	1	1		
Syncope	1	1			1	1
Tachycardia		10		7		3
Therapeutic response unexpected	1	3	1	3		
Tinnitus		2		2		
Toothache	1	1	1	1		
Tremor		3		3		
Urinary tract infection		1		1		
Urticaria	1	2	1	2		
Vaccination site bruising	1	2	1	2		
Vaccination site discomfort		2		2		
Vaccination site hypoaesthesia		1		1		
Vaccination site induration		1		1		
Vaccination site inflammation	1	2	1	2		
Vaccination site oedema	1	2	1	2		
Vaccination site pain	5	24	5	24		
Vaccination site warmth		1		1		
Vasoconstriction		1				1
Vertigo		1		1		
Visual impairment		1				1
Vomiting		4		3		1
Wrong technique in product usage process		2		2		
	107	497	85	388	22	109

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

GUINEA

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Headache		1		1
Hypertension		1		1
		2		2

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Country Where Event Occurred

HAITI

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia		1		1
Dizziness		1		1
Dyskinesia		1		1
Vertigo		1		1
		4		4

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred
HOLY SEE (VATICAN CITY STATE)

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia		1		1
Extensive swelling of vaccinated limb		1		1
Injected limb mobility decreased		1		1
Oedema peripheral		2		2
Pain in extremity		1		1
Periorbital oedema		1		1
Vaccination site pain		1		1
		8		8

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Country Where Event Occurred

HONDURAS

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19	2	2	2	2
Illness	2	2	2	2
	4	4	4	4

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

HONG KONG

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abdominal pain		1		1
Loss of consciousness		1		1
Syncope		1		1
		3		3

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Allergy to vaccine		1		1		
Anaphylactoid reaction	1	1			1	1
Bell's palsy	1	1			1	1
Chest discomfort	1	1	1	1		
Chest pain	2	2			2	2
Contusion		1				1
Dizziness	3	7			3	7
Fall		1				1
Hypersensitivity	1	1			1	1
Hyperventilation	1	1			1	1
Hypoaesthesia	1	3			1	3
Injury		1				1
Loss of consciousness	4	7			4	7
Nausea	1	2	1	1		1
Presyncope	2	2			2	2
Pruritus	1	1			1	1
Pyrexia	2	2	1	1	1	1
Rash	6	8	1	2	5	6
Seizure	5	6			5	6
Syncope	6	8			6	8
Vaccination site hypoaesthesia	1	1			1	1
Vomiting		1				1
	39	60	4	6	35	54

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion spontaneous		1				1
Allergy to vaccine		1				1
Anaphylactic reaction		1				1
Anaphylactoid reaction		1				1
Arthralgia	1	1			1	1
Back pain		1				1
Bell's palsy	7	8			7	8
Blood pressure increased		4		3		1
Burning sensation		1		1		
Cardiac arrest	1	1			1	1
Cerebrovascular accident	1	1			1	1
Chest discomfort	3	6	1	3	2	3
Chest pain	3	7	1	3	2	4
Coma	2	2			2	2
Coronary artery disease	2	2			2	2
Death	1	1			1	1
Dizziness	10	17	4	8	6	9
Dysphagia	1	1	1	1		
Dyspnoea	3	5	2	2	1	3
Epilepsy	1	1			1	1
Erythema	1	1			1	1
Essential hypertension		1				1
Fall		1				1
Headache	3	5	1	2	2	3
Hyperhidrosis		2		2		
Hypersensitivity		2		1		1
Hypertension	5	6	2	2	3	4
Hyperventilation		2				2
Hypoaesthesia	5	9		3	5	6
Lip injury		1				1
Lip swelling	1	1	1	1		
Loss of consciousness	4	9			4	9

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise	1	1			1	1
Musculoskeletal stiffness	1	1	1	1		
Myalgia		1		1		
Nausea	1	2	1	1		1
Neck pain	1	1			1	1
Pain	1	1	1	1		
Palpitations	5	17	1	6	4	11
Pharyngeal swelling		1		1		
Presyncope	2	4		1	2	3
Pruritus	1	1			1	1
Rash	5	14	2	7	3	7
Seizure	6	10			6	10
Swelling	1	1	1	1		
Swelling face	1	1			1	1
Swelling of eyelid	2	2	2	2		
Syncope	7	9			7	9
Tenderness	1	1	1	1		
Transient ischaemic attack	1	1			1	1
Urticaria	1	2	1	1		1
Vaccination site erythema	1	2	1	2		
Vaccination site pain		2		1		1
Vaccination site pruritus		1		1		
Vaccination site swelling		1		1		
Vomiting		1		1		
	94	181	25	62	69	119

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	1	1	1	1		
Aortic dissection	1	1			1	1
Asthenia		1		1		
Bell's palsy	2	3			2	3
Blood pressure increased	3	6	2	4	1	2
Cardiac arrest	1	1			1	1
Cerebrovascular accident		1				1
Chest discomfort	2	5	1	2	1	3
Chest pain	3	6	1	1	2	5
Coronary artery disease		1				1
Dermatitis allergic	1	1	1	1		
Dizziness	7	16	3	7	4	9
Dyspnoea	2	5		2	2	3
Fatigue		1		1		
Headache		1				1
Hypersensitivity		2		1		1
Hypertension	4	14	2	4	2	10
Hypertensive crisis	1	1			1	1
Hypoaesthesia	1	5		1	1	4
Loss of consciousness		1				1
Lower respiratory tract infection	1	1			1	1
Lung opacity	1	1			1	1
Malaise		1		1		
Muscle twitching		1		1		
Muscular weakness		1				1
Musculoskeletal chest pain	1	1	1	1		
Nausea		1		1		
Neuralgia		1		1		
Palpitations	11	13	4	4	7	9
Paresis		1				1
Pruritus		1		1		
Pyrexia		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash	1	6		4	1	2
Syncope		1				1
Tachycardia	1	1			1	1
	45	105	16	41	29	64

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		1				1
Bell's palsy	2	2			2	2
Blood pressure increased	1	1			1	1
Chest discomfort		2		1		1
Chest pain		2				2
Coronary artery disease		1				1
Dizziness	1	6	1	3		3
Headache	1	2		1	1	1
Hypertension	1	4		1	1	3
Hypoaesthesia		2				2
Ischaemic stroke		1				1
Loss of consciousness	1	1			1	1
Myocardial infarction	1	1			1	1
Myocardial ischaemia		1				1
Palpitations	1	3			1	3
Pneumonia	1	1			1	1
Pyrexia		1				1
Rash		1		1		
Syncope		1				1
Tachycardia	1	1			1	1
	11	35	1	7	10	28

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bell's palsy	1	1	1	1
Drug hypersensitivity		1		1
Essential hypertension	1	1	1	1
	2	3	2	3

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute haemorrhagic conjunctivitis	1	1	1	1		
Aphasia		1		1		
Arthralgia		2		2		
Asthenia		1		1		
Axillary pain	1	1	1	1		
Chills	1	1	1	1		
Conjunctival haemorrhage	1	1			1	1
Decreased appetite		1		1		
Dizziness		2		2		
Facial paralysis		1				1
Fatigue		2		2		
Headache		1		1		
Hypoaesthesia		1		1		
Injection site pain		1		1		
Loss of consciousness		1				1
Lymphadenopathy		2		2		
Migraine		1		1		
Movement disorder		1		1		
Musculoskeletal stiffness		1		1		
Myalgia	1	1	1	1		
Paraesthesia		1		1		
Paralysis		1				1
Pyrexia	1	1	1	1		
Rash pruritic	1	1	1	1		
Seizure		1				1
Syncope		1				1
Tremor		1		1		
Vaccination site pain		1		1		
	7	32	6	26	1	6

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

HUNGARY

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour		1		1		
Akinesia	1	1			1	1
Ataxia	1	1			1	1
Cerebrovascular accident	1	1			1	1
Drug interaction	1	1	1	1		
Eczema infantile	1	1	1	1		
Exposure during pregnancy		1		1		
Exposure via breast milk	43	80	42	79	1	1
Haematochezia	1	1			1	1
Immune-mediated adverse reaction	1	1	1	1		
Irritability		1		1		
Lip disorder	1	1			1	1
Malaise	1	1	1	1		
Maternal exposure during breast feeding		1		1		
Movement disorder	1	1			1	1
Nasal congestion		1		1		
Nasopharyngitis		1		1		
Overfeeding of infant		1		1		
Petechiae	1	1			1	1
Poor quality sleep	2	2	1	1	1	1
Pyrexia		3		3		
Restlessness	1	2		1	1	1
Rhinorrhoea		2		2		
Sleep disorder		2		2		
Thrombocytopenia	1	1			1	1
Transient ischaemic attack	1	1			1	1
Upper respiratory tract infection		1		1		
	59	112	47	100	12	12

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abortion missed		1				1
Aphthous ulcer		1		1		
Arrhythmia		1				1
Arthralgia	1	4	1	3		1
Asthenia	1	7	1	6		1
Axillary pain	1	1	1	1		
Back pain	1	2	1	2		
Blood pressure ambulatory increased		1		1		
Bone pain	1	1	1	1		
Bruxism	1	1	1	1		
Cardiomegaly		1				1
Chest discomfort		3		3		
Chest pain	1	6		4	1	2
Chills	3	7	3	7		
Confusional state		1		1		
COVID-19	1	1			1	1
Decreased appetite		1		1		
Diarrhoea		3		3		
Disturbance in attention		1				1
Dizziness	3	11	3	10		1
Drug hypersensitivity		1		1		
Dry mouth	2	3	2	3		
Dry throat	1	1	1	1		
Dysgeusia	1	1	1	1		
Dysphemia		1				1
Dyspnoea		1				1
Dyspnoea exertional		1				1
Ear discomfort		1		1		
Ear pain		1		1		
Ear pruritus		1		1		
Erythema		1		1		

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* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema multiforme		1				1
Exposure during pregnancy	1	1	1	1		
Facial pain	1	2	1	2		
Facial paresis	1	3	1	2		1
Fatigue	3	6	3	6		
Feeling abnormal	1	1	1	1		
Feeling hot		1		1		
Feeling of body temperature change	1	1	1	1		
Headache	6	15	6	13		2
Heart rate increased	1	2	1	2		
Hyperhidrosis	1	1	1	1		
Hyperthyroidism	1	1			1	1
Hypoaesthesia		3		2		1
Hypoaesthesia oral		2		1		1
Hypoglycaemia		1		1		
Influenza like illness		1		1		
Initial insomnia	1	1	1	1		
Injected limb mobility decreased	1	1	1	1		
Insomnia		1		1		
Joint range of motion decreased	1	1	1	1		
Lethargy		2		2		
Lymphadenopathy	2	7	2	6		1
Lymph node pain	1	2	1	2		
Malaise	2	6	2	5		1
Maternal exposure during pregnancy		1				1
Memory impairment		1				1
Menstruation irregular	1	1	1	1		
Migraine		2		2		
Muscular weakness	2	2	2	2		
Musculoskeletal stiffness		1		1		
Myalgia	3	12	3	12		
Nasal congestion	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	2	10	2	10		
Neck pain	1	1	1	1		
Off label use	2	4	2	4		
Oropharyngeal pain	1	4	1	4		
Painful respiration	1	1			1	1
Pain in extremity	5	11	5	11		
Palpitations		1		1		
Panic attack		1		1		
Peripheral coldness		1		1		
Peripheral nerve paresis		1				1
Peripheral swelling		1				1
Petechiae		1		1		
Polyarthrititis		1				1
Productive cough		1		1		
Product use issue	2	4	2	4		
Pulmonary arterial pressure increased		1				1
Pulpitis dental		1		1		
Pyrexia	6	19	6	17		2
Rash	1	3	1	3		
Rash erythematous		1		1		
Respiratory symptom	1	1	1	1		
Retching		1		1		
Rhinorrhoea	1	1	1	1		
SARS-CoV-2 test positive		1				1
Sensitive skin		1		1		
Skin burning sensation		1		1		
Somnolence	1	2	1	2		
Speech disorder	1	1			1	1
Swelling	1	1	1	1		
Tremor	2	4	2	4		
Tricuspid valve incompetence		1				1
Urticaria		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination failure	1	1			1	1
Vaccination site discomfort		1		1		
Vaccination site erythema	1	5	1	5		
Vaccination site hypoaesthesia		1		1		
Vaccination site mass	1	1	1	1		
Vaccination site movement impairment		1		1		
Vaccination site pain	2	9	2	9		
Vaccination site pruritus	1	2	1	2		
Vaccination site swelling		2		2		
Vaginal discharge		1		1		
Vision blurred	1	2	1	2		
Vomiting		1		1		
	86	264	80	229	6	35

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1		1		
Abdominal pain	1	5	1	5		
Abdominal pain upper		2		2		
Abortion		1				1
Abortion missed		1				1
Adnexa uteri pain		1		1		
Ageusia		2		2		
Allergy to vaccine		1				1
Anaphylactic reaction		1				1
Anaphylactic shock		1				1
Angina pectoris	2	3			2	3
Angioedema		1				1
Anosmia		4		4		
Arrhythmia	1	1			1	1
Arthralgia	9	17	9	16		1
Arthritis reactive		1				1
Arthropathy		1		1		
Asphyxia	1	1			1	1
Asthenia	10	40	10	37		3
Ataxia		1		1		
Atrial f brillation	1	2			1	2
Axillary pain	1	3	1	3		
Back pain	4	7	4	7		
Balance disorder	1	1	1	1		
Bell's palsy		1				1
Bezold-Jarisch reflex		1		1		
Blepharospasm		1		1		
Blindness		1				1
Blister		1		1		
Blood glucose increased		1		1		
Blood pressure decreased	1	2	1	2		
Blood pressure fluctuation	2	5	2	3		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased	2	8	2	5		3
Blood test abnormal	1	1	1	1		
Blood thyroid stimulating hormone decreased		1		1		
Body temperature increased		1		1		
Bone pain	1	2	1	2		
Bradyphrenia		1		1		
Breast discomfort		2		2		
Burning sensation	2	6	2	6		
Cardiovascular disorder		1				1
Cerebral ischaemia		1				1
Cerebrovascular accident	1	1			1	1
Chest discomfort	3	4	3	3		1
Chest pain	3	6	2	5	1	1
Chills	7	32	7	32		
Chromaturia		1		1		
Cold sweat		2		2		
Condition aggravated		1		1		
Cough	1	5	1	4		1
COVID-19		5		1		4
Cyanosis		1				1
Cystitis	1	1	1	1		
Dark circles under eyes		1		1		
Decreased appetite	2	3	2	3		
Deep vein thrombosis		1				1
Defaecation urgency		1		1		
Depression		1		1		
Dermal cyst	1	1	1	1		
Diarrhoea	2	9	2	9		
Disease recurrence	3	3	2	2	1	1
Dizziness	4	25	3	21	1	4
Drug hypersensitivity		1		1		
Drug ineffective		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry eye		1		1		
Dry mouth		1				1
Dysgeusia	1	5	1	4		1
Dyspepsia		2		2		
Dysphagia		5		1		4
Dysphonia		2		1		1
Dyspnoea	5	8	4	5	1	3
Dyspnoea exertional	1	2	1	2		
Ear discomfort		1		1		
Ear pain		1		1		
Ear pruritus		1		1		
Epistaxis		1		1		
Erythema	1	4	1	4		
Extrasystoles	1	1	1	1		
Eye disorder	1	1	1	1		
Eye irritation		1		1		
Eye oedema		1				1
Eye pain		1		1		
Eye pruritus		1		1		
Facial neuralgia	1	1	1	1		
Facial paresis	1	2	1	2		
Fatigue	8	30	8	30		
Fear of death	2	3	2	3		
Feeling abnormal		4		3		1
Feeling hot	1	4	1	3		1
Feeling of despair	1	1	1	1		
Fibrin D dimer increased	1	1			1	1
Flushing		1				1
Foetal death	1	1			1	1
Gait disturbance		2		2		
Gastrointestinal disorder	1	1	1	1		
Gastrooesophageal reflux disease		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
General symptom	1	1	1	1		
Glossitis	1	2	1	2		
Guillain-Barre syndrome		1				1
Haematoma		1				1
Haemorrhage		1				1
Headache	13	51	13	48		3
Head discomfort	1	1	1	1		
Heart rate decreased		1		1		
Heart rate increased	2	8	2	7		1
Heart rate irregular		1		1		
Heat stroke	1	1	1	1		
Hemiparesis		1				1
Herpes virus infection		1		1		
Herpes zoster		3		3		
Hot flush	1	4	1	3		1
Hyperaesthesia		3		3		
Hyperhidrosis		4		4		
Hypersensitivity		2		2		
Hypertension	1	4		2	1	2
Hypoaesthesia	7	16	6	14	1	2
Hypoaesthesia oral	1	2	1	2		
Hypotension		2				2
Incontinence	1	1	1	1		
Incorrect route of product administration		1		1		
Inflammation	1	2	1	2		
Influenza		1		1		
Injection site pain	1	1	1	1		
Injection site warmth	1	1	1	1		
Insomnia		3		3		
Intervertebral disc protrusion		1		1		
Iodine uptake decreased		1		1		
Joint swelling	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lacrimation increased		2		2		
Lactation disorder		1		1		
Lethargy		1				1
Lhermitte's sign		1		1		
Lip swelling		1		1		
Liver function test increased	1	1	1	1		
Loss of consciousness	1	1			1	1
Lung disorder	1	1	1	1		
Lymphadenitis		2		2		
Lymphadenopathy	8	29	8	24		5
Lymph node pain	3	8	3	7		1
Lymphocyte count decreased		1		1		
Macular oedema		1				1
Malaise	6	20	6	19		1
Maternal exposure during pregnancy		1		1		
Meibomian gland dysfunction		1		1		
Menstruation irregular	1	2	1	2		
Micturition urgency		1		1		
Migraine	1	4	1	3		1
Mobility decreased		1		1		
Monocyte count increased		1		1		
Mouth swelling		1		1		
Movement disorder	1	1	1	1		
Muscle spasms	1	1	1	1		
Muscle twitching		1		1		
Muscular weakness		3		3		
Musculoskeletal chest pain		1		1		
Musculoskeletal stiffness	2	2	2	2		
Myalgia	10	28	10	28		
Myelopathy		1				1
Nasopharyngitis	2	2	2	2		
Nausea	11	29	10	26	1	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neck pain	1	2	1	2		
Nervous system disorder	1	1	1	1		
Nipple pain		1		1		
Oedema peripheral		1				1
Off label use	18	32	18	32		
Oral herpes		1		1		
Oropharyngeal pain	1	7	1	6		1
Overdose		1		1		
Oxygen saturation decreased		1		1		
Pain	3	5	3	5		
Painful respiration		1		1		
Pain in extremity	9	36	8	34	1	2
Pain of skin	1	3	1	3		
Pallor		2		2		
Palpitations	5	9	5	8		1
Paraesthesia	1	4	1	2		2
Paranasal sinus discomfort		1		1		
Performance status decreased	1	1	1	1		
Pericarditis		1				1
Peripheral swelling	2	4	2	4		
Pharyngeal swelling		2		1		1
Pityriasis rosea		1		1		
Polyarthrits		1				1
Post-acute COVID-19 syndrome	1	2		1	1	1
Productive cough	1	1	1	1		
Product use issue	18	34	18	34		
Pruritus	3	7	3	7		
Psychiatric symptom		1				1
Pulmonary embolism	1	1			1	1
Pyrexia	19	56	18	55	1	1
Rash	1	3	1	2		1
Rash erythematous		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash maculo-papular		1		1		
Red blood cell sedimentation rate increased		1		1		
Renal cyst		1		1		
Renal pain		2		2		
Retching		1		1		
Retinal vascular thrombosis	1	1			1	1
Rhinorrhoea	2	5	2	5		
Salivary gland enlargement		1		1		
Sarcoidosis	1	1			1	1
SARS-CoV-2 test positive		3		3		
Sensation of foreign body		3		2		1
Serum ferritin increased		1		1		
Sinus tachycardia	1	1			1	1
Sjogren's syndrome		1				1
Skin burning sensation	1	1	1	1		
Skin disorder	1	1	1	1		
Skin lesion		1		1		
Skin sensitisation		1		1		
Skin swelling	1	1	1	1		
Sleep deficit	1	1	1	1		
Sleep disorder		2		2		
Sleep disorder due to general medical condition, insomnia type	1	1	1	1		
Somnolence		3		3		
Speech disorder	1	1	1	1		
Stress		1		1		
Stridor		1				1
Swelling		1		1		
Swelling of eyelid		1		1		
Syncope	1	3			1	3
Tachycardia	2	8	1	4	1	4
Tachypnoea		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thirst	1	2	1	1		1
Throat irritation	2	2	2	2		
Throat tightness	2	4	1	2	1	2
Thrombophlebitis		1		1		
Thyroiditis subacute		1		1		
Thyroxine free increased		1		1		
Tinnitus		4		4		
Tonsillar hypertrophy		1		1		
Total lung capacity decreased	1	1	1	1		
Tremor	2	7	2	5		2
Tri-iodothyronine free increased		1		1		
Upper respiratory tract infection		1		1		
Urinary tract inflammation	1	1	1	1		
Urinary tract pain		1		1		
Urine output increased	1	1	1	1		
Urticaria	6	8	6	8		
Vaccination complication	1	2	1	2		
Vaccination failure		3				3
Vaccination site coldness		1		1		
Vaccination site discolouration	1	1	1	1		
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	2	9	2	9		
Vaccination site hypoaesthesia	1	1	1	1		
Vaccination site induration		1		1		
Vaccination site lymphadenopathy	1	1	1	1		
Vaccination site movement impairment	1	2	1	2		
Vaccination site nodule		1		1		
Vaccination site oedema	1	1	1	1		
Vaccination site pain	10	36	10	36		
Vaccination site pruritus		1		1		
Vaccination site swelling	4	9	4	9		
Vaccination site warmth		3		3		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular pain	1	1	1	1		
Visual impairment		1				1
Vomiting	4	11	4	10		1
White blood cell count decreased	1	1	1	1		
White matter lesion		1		1		
Wound		1		1		
	324	1,011	298	883	26	128

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		2		2		
Abdominal pain upper		2		2		
Acute myocardial infarction	1	2			1	2
Allergic oedema	1	1			1	1
Anaphylactic reaction		2				2
Angioedema		1				1
Anxiety		1		1		
Arthralgia	4	10	4	9		1
Asphyxia		1				1
Asthenia	5	17	4	15	1	2
Atrial fibrillation		1				1
Axillary pain		2		2		
Back pain	2	2	1	1	1	1
Bell's palsy	1	1			1	1
Blister		1		1		
Blood glucose increased		2		2		
Blood pressure decreased		2		2		
Blood pressure increased	3	10	2	7	1	3
Blood pressure systolic increased		1				1
Body temperature increased		1		1		
Bradycardia	1	2			1	2
Bronchial neoplasm	1	1			1	1
Burning sensation		1		1		
Bursitis		1		1		
Cardiac arrest	2	2			2	2
Cardiopulmonary failure	1	1			1	1
Cardiovascular disorder	1	1			1	1
Cartilage injury		1				1
Chest discomfort		3		3		
Chest pain		1		1		
Chills	4	21	4	20		1
Circulatory collapse		2				2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat		1		1		
Condition aggravated	1	2	1	1		1
Constipation		1		1		
Cough		3		3		
COVID-19	1	3		2	1	1
COVID-19 pneumonia	2	2			2	2
Craniofacial fracture		1				1
Death		1				1
Decreased appetite		1		1		
Deep vein thrombosis		1				1
Depressed mood		1		1		
Dermatitis herpetiformis		1		1		
Diarrhoea	1	3	1	3		
Disease recurrence	1	1			1	1
Dizziness	3	10	3	8		2
Drug ineffective	2	3			2	3
Dry eye		2		2		
Dysgeusia		3		3		
Dysphagia	1	5		1	1	4
Dysphonia		1		1		
Dyspnoea	1	7		3	1	4
Ear pain	1	2	1	2		
Ear pruritus		1		1		
Eosinophilia	1	1	1	1		
Erythema	2	6	2	6		
Extrasystoles		1				1
Eye inflammation		1		1		
Eye irritation		1		1		
Eye oedema		1				1
Face oedema		1				1
Facial paralysis		1				1
Facial paresis	1	1	1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fall		2		1		1
Fatigue	5	17	5	17		
Fear of death		1		1		
Feeling abnormal		1		1		
Feeling cold		2		2		
Feeling hot	1	2	1	2		
Feeling of body temperature change		1		1		
Feeling of despair		1		1		
Flushing		3		3		
Gait disturbance	1	2		1	1	1
Glossodynia	1	2		1	1	1
Haematemesis	1	1			1	1
Headache	5	27	5	25		2
Heart rate increased	2	4	1	3	1	1
Herpes zoster	1	2	1	2		
Hot flush		1		1		
Hyperaemia		1		1		
Hyperhidrosis	1	3	1	3		
Hypersensitivity		2		2		
Hypoaesthesia		3		2		1
Hypoaesthesia oral	1	3		1	1	2
Hypokinesia		1				1
Hyporeflexia		2		2		
Hypotension		1		1		
Hypovolaemic shock	1	1			1	1
Illness		1		1		
Incorrect route of product administration	1	1	1	1		
Increased appetite	1	1	1	1		
Influenza like illness		1		1		
Injection site urticaria		1		1		
Insomnia	1	5	1	5		
Irritability	1	1	1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint range of motion decreased		1		1		
Lacrimation increased		2		2		
Laryngeal oedema		1				1
Lethargy	1	2	1	2		
Limb discomfort		1		1		
Lip swelling		1				1
Localised oedema		1		1		
Local reaction		2		2		
Loss of consciousness	1	1			1	1
Lung neoplasm	1	1			1	1
Lymphadenitis		1		1		
Lymphadenopathy	1	9	1	9		
Lymph node pain		4		4		
Malaise	2	14	2	13		1
Mastication disorder		1		1		
Metabolic acidosis		1				1
Mobility decreased	1	1	1	1		
Monoplegia		1				1
Mood altered		2		2		
Muscle spasms	1	1			1	1
Muscle strain		2		2		
Muscular weakness	2	4	2	4		
Musculoskeletal chest pain		1		1		
Musculoskeletal stiffness		1				1
Myalgia	3	13	3	12		1
Nasal congestion		1		1		
Nasopharyngitis	1	1	1	1		
Nausea	6	16	6	15		1
Neck pain	1	1	1	1		
Neoplasm progression	1	2			1	2
Neuralgia		1		1		
Odynophagia		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oedema peripheral		2		1		1
Oesophageal haemorrhage	1	1			1	1
Oesophageal varices haemorrhage	1	1			1	1
Oral herpes	1	1	1	1		
Oropharyngeal pain	1	5		4	1	1
Oxygen consumption increased		1		1		
Pain	1	2	1	2		
Pain in extremity	4	15	3	14	1	1
Pain of skin	1	1	1	1		
Pallor		2		2		
Palpitations		2		1		1
Peripheral coldness		1		1		
Peripheral swelling	1	2	1	2		
Pharyngeal oedema	2	2	1	1	1	1
Photopsia		1		1		
Pneumonia		1				1
Poor quality sleep		1		1		
Presyncope	1	1	1	1		
Progressive multifocal leukoencephalopathy	1	1			1	1
Prostatomegaly	1	1	1	1		
Pruritus	1	5	1	4		1
Pulmonary embolism	1	1			1	1
Pulmonary oedema	1	1			1	1
Pulseless electrical activity		1				1
Pyrexia	8	31	7	29	1	2
Rash	1	4	1	3		1
Rash erythematous		3		3		
Rash maculo-papular		2		1		1
Rash pruritic		3		3		
Rash vesicular		1		1		
Respiratory distress		2				2
Restlessness		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rheumatoid arthritis	1	1			1	1
Rhinorrhoea	1	3	1	3		
SARS-CoV-2 ant body test negative		1		1		
SARS-CoV-2 ant body test positive		1		1		
SARS-CoV-2 test positive		1				1
Sensation of foreign body		3				3
Sensitive skin		1		1		
Sensory loss		1		1		
Sinusitis		1		1		
Skin burning sensation		4		3		1
Skin ulcer	1	1	1	1		
Skin warm		1		1		
Sleep disorder	1	1	1	1		
Somnolence	2	4	2	4		
Stress	1	2	1	2		
Sudden death	1	1			1	1
Swelling		1		1		
Swelling face		1		1		
Swelling of eyelid		1		1		
Syncope	1	2			1	2
Tachycardia		3		2		1
Taste disorder		1		1		
Tenosynovitis	1	1	1	1		
Tension		1		1		
Therapeutic response unexpected		1		1		
Thirst		1		1		
Throat irritation		1		1		
Thrombosis	1	1			1	1
Thrombotic stroke		1				1
Tinnitus	1	2	1	2		
Tongue oedema	1	1			1	1
Tremor		2		2		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria	1	4	1	3		1
Vaccination site coldness	1	1	1	1		
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	2	8	2	8		
Vaccination site haematoma		1		1		
Vaccination site haemorrhage		1		1		
Vaccination site joint movement impairment	1	1			1	1
Vaccination site movement impairment	1	1	1	1		
Vaccination site nodule		2		2		
Vaccination site oedema		1		1		
Vaccination site pain	4	14	4	13		1
Vaccination site paraesthesia		1		1		
Vaccination site pruritus	2	4	2	4		
Vaccination site rash	1	2	1	2		
Vaccination site swelling	3	8	3	8		
Vaccination site vesicles	1	2	1	2		
Vaccination site warmth	2	4	2	4		
Varicose vein		2		2		
Vision blurred		1		1		
Visual impairment		1		1		
Vomiting		2		2		
White coat hypertension		1		1		
Wound		2		1		1
Wound complication		1		1		
	152	571	107	457	45	114

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain	2	4	2	4		
Acute kidney injury	1	1			1	1
Acute respiratory distress syndrome	2	2			2	2
Acute respiratory failure		1				1
Anaphylactic reaction	1	1			1	1
Anuria	1	1			1	1
Arteriosclerosis	1	1			1	1
Arthralgia	3	3	3	3		
Asphyxia		1				1
Asthenia	4	11	4	9		2
Asthenopia	1	1	1	1		
Atrial f brillation		2				2
Axillary mass		1		1		
B-cell type acute leukaemia		1				1
Blood pressure fluctuation	1	2		1	1	1
Blood pressure increased	1	4		2	1	2
Bone pain		1		1		
Bradycardia	2	2			2	2
Brain injury	1	1			1	1
Burning sensation		2		2		
Cachexia	1	1			1	1
Cardiac arrest	1	1			1	1
Cardiac disorder	1	2			1	2
Cardiac failure	3	4			3	4
Cardiopulmonary failure	2	2			2	2
Cellulitis		1				1
Cervical neuritis		1		1		
Chills	5	7	4	6	1	1
Choking		1				1
Cholinergic syndrome	1	1			1	1
Circulatory collapse	2	3			2	3

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* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Condition aggravated	1	3			1	3
Congestive hepatopathy	1	1			1	1
Cough	4	8	1	4	3	4
COVID-19	10	23			10	23
COVID-19 pneumonia	5	6			5	6
Cutaneous symptom		1				1
Death	4	4			4	4
Decreased appetite	1	3	1	3		
Deep vein thrombosis	1	2			1	2
Dehydration	1	1			1	1
Dementia	1	1			1	1
Depression		1		1		
Diarrhoea	2	6	2	6		
Discomfort		1		1		
Dizziness	3	7	2	6	1	1
Drug ineffective	7	16			7	16
Dysphagia		3		1		2
Dysphonia		1				1
Dyspnoea	7	11	1	4	6	7
Eczema		1		1		
Erysipelas		1				1
Erythema		2		1		1
Exposure to SARS-CoV-2	1	1	1	1		
Eye haemorrhage	1	2			1	2
Eye inflammation		1				1
Eye pain	1	3	1	3		
Facial paralysis		1				1
Fall		1				1
Fatigue	3	5	3	5		
Feeling abnormal		1		1		
Flushing	1	1	1	1		
Full blood count abnormal		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gait disturbance		1		1		
General physical health deterioration	1	1			1	1
Gingival pain		1		1		
Haemoptysis		1				1
Headache	4	11	4	11		
Head discomfort		1		1		
Heart rate increased	1	2			1	2
Herpes zoster	1	4	1	4		
Hyperhidrosis	3	4	2	3	1	1
Hypersensitivity		1				1
Hypertensive crisis		1				1
Hypoaesthesia	1	4		3	1	1
Hypoaesthesia oral		1		1		
Hypotension	1	3		1	1	2
Illness		1		1		
Inflammation		1		1		
Ischaemic stroke	1	1			1	1
Lethargy		1		1		
Lip oedema		1				1
Lip swelling		1				1
Loss of consciousness	1	3			1	3
Lower limb fracture		1				1
Lymphadenitis	1	1	1	1		
Lymphadenopathy	1	2			1	2
Malaise	2	5	2	5		
Megacolon		1				1
Migraine	1	1	1	1		
Monocytosis		1				1
Mouth swelling		1				1
Mucosal inflammation		1				1
Multiple organ dysfunction syndrome	1	1			1	1
Muscle spasms	1	2	1	2		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal stiffness	1	2		1	1	1
Myalgia	3	5	3	5		
Nasal congestion	1	1	1	1		
Nasopharyngitis	2	2	2	2		
Nausea	2	6	2	5		1
Neoplasm	1	1			1	1
Neuralgia		2		1		1
Night sweats		1		1		
Ophthalmic herpes zoster		1				1
Oropharyngeal pain		3		1		2
Pain		1		1		
Pain in extremity	1	5	1	5		
Pain of skin		2		2		
Paraesthesia		1		1		
Paraplegia	1	1			1	1
Peripheral swelling	1	1	1	1		
Pneumonia	2	2			2	2
Pneumonitis	1	1			1	1
Poor quality product administered		1		1		
Product complaint		1		1		
Pruritus		1		1		
Pulmonary embolism	1	1			1	1
Pyrexia	7	15	4	9	3	6
Radiculopathy		1		1		
Rash	1	2	1	1		1
Rash macular	1	2		1	1	1
Rash pruritic		2		2		
Respiratory failure	3	4			3	4
Retinal artery thrombosis	1	1			1	1
Retinal vein thrombosis	1	1			1	1
Rhinorrhoea	1	1	1	1		
SARS-CoV-2 test positive		1		1		

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* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sciatica		1				1
Sensation of foreign body		1				1
Sepsis	1	1			1	1
Shock	1	1			1	1
Skin burning sensation		1		1		
Skin discolouration		1		1		
Skin hypertrophy		1		1		
Skin ulcer		1				1
Somnolence		1				1
Spinal osteoarthritis		1		1		
Status epilepticus	1	1			1	1
Sudden death	2	2			2	2
Suspected COVID-19	1	2			1	2
Swelling face	1	1			1	1
Syncope		2				2
Tachycardia	1	1			1	1
Thirst		1		1		
Throat tightness		1				1
Thrombophlebitis	1	2			1	2
Toothache		1		1		
Type IV hypersensitivity reaction		1				1
Urosepsis	1	1			1	1
Urticaria	1	1			1	1
Vaccination failure		1				1
Vaccination site erythema	1	5	1	5		
Vaccination site inflammation		1		1		
Vaccination site mass		1		1		
Vaccination site pain	1	4	1	4		
Vaginal infection	1	1	1	1		
Vasoconstriction		1				1
Vasodilatation	1	1			1	1
Vomiting		1		1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Weight decreased		1				1
	160	366	58	174	102	192

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* AE=Adverse Event
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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	2			2	2
Acute respiratory failure		1				1
Aggression		1				1
Anaemia	1	2			1	2
Anal incontinence		1				1
Anaphylactic reaction	1	1			1	1
Anaphylactic shock	1	1			1	1
Angina pectoris		1				1
Angioedema	1	1			1	1
Anuria		1				1
Arteriosclerosis		1				1
Arthralgia		1				1
Asphyxia	1	1			1	1
Asthenia	3	14	2	4	1	10
Atrial fibrillation	1	1			1	1
Atrioventricular block complete	1	1			1	1
Biliary tract disorder		1				1
Blood pressure decreased		1				1
Blood pressure increased		1		1		
Bradycardia	1	1			1	1
Bronchitis		2		1		1
Bronchospasm	1	1			1	1
Burning sensation		1		1		
Cachexia	1	1			1	1
Capillaritis		1		1		
Cardiac arrest	1	1			1	1
Cardiac disorder		1				1
Cardiac failure	3	9			3	9
Cardiac failure congestive	1	1			1	1
Cardiogenic shock	1	1			1	1
Cardiomegaly		1		1		
Cardiopulmonary failure	2	3			2	3

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiovascular insufficiency	1	1			1	1
Cerebrovascular accident		2				2
Chest discomfort		1		1		
Chest pain		1				1
Chills		3		3		
Circulatory collapse	2	2			2	2
Clostridium difficile infection	1	1			1	1
Condition aggravated		3		1		2
Confusional state	1	4		1	1	3
Cough	2	3		1	2	2
COVID-19	17	21	1	1	16	20
COVID-19 pneumonia	5	5			5	5
Cyanosis	1	1			1	1
Death	8	13			8	13
Decreased appetite	2	3	2	2		1
Decubitus ulcer		1				1
Deep vein thrombosis	2	2			2	2
Dementia		1				1
Diarrhoea	2	4	1	2	1	2
Dizziness	3	3	2	2	1	1
Drug ineffective	13	18			13	18
Dysphonia	1	2			1	2
Dyspnoea	5	9		1	5	8
Dysstasia	1	1			1	1
Dysuria	1	1	1	1		
Emphysema		1				1
Erythema	1	2		1	1	1
Eye pruritus	1	1			1	1
Face oedema		1				1
Fall		2				2
Fatigue	1	5	1	4		1
Feeding disorder		2				2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling abnormal		1				1
Femoral neck fracture		1				1
Fibrin D dimer increased		1				1
Foaming at mouth		1				1
Gait inability	1	1			1	1
Gastritis erosive		1				1
Gastrointestinal haemorrhage		1				1
General physical health deterioration		1		1		
Glomerular filtration rate decreased		1		1		
Haematoma		2				2
Headache	2	4	1	3	1	1
Head injury	1	1			1	1
Heart rate increased	1	1	1	1		
Hyperhidrosis		1				1
Hypersensitivity	1	2		1	1	1
Hypertensive encephalopathy	1	1			1	1
Hypokinesia	1	1			1	1
Hypotension		2				2
Hypotonia		1				1
Ileus paralytic	1	1			1	1
Inappropriate schedule of product administration		1		1		
Ischaemic cardiomyopathy	1	1			1	1
Ischaemic stroke	1	2			1	2
Lack of spontaneous speech	1	1	1	1		
Left ventricular failure	1	2			1	2
Listless		1				1
Loss of consciousness	1	4			1	4
Lymphadenitis	1	1			1	1
Lymphadenopathy	2	2	1	1	1	1
Malaise	3	6	3	6		
Melaena		1				1
Micturition urgency	1	1	1	1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Multiple organ dysfunction syndrome	1	1			1	1
Musculoskeletal stiffness		1		1		
Myocardial infarction	2	2			2	2
Nausea	2	5	2	5		
Neoplasm malignant	1	1			1	1
Noninfective gingivitis		1		1		
Ocular hyperaemia	1	1			1	1
Oedema blister		1				1
Off label use		1		1		
Oxygen saturation decreased	1	2	1	1		1
Pain		1		1		
Pain in extremity	2	5	1	3	1	2
Pallor		1				1
Pancreatitis acute	1	1			1	1
Paralysis		1				1
Peripheral coldness		1		1		
Peripheral swelling		2		1		1
Peripheral venous disease		1				1
Pharyngitis		1		1		
Pneumonia	2	4			2	4
Polyneuropathy		1				1
Poor peripheral circulation		1		1		
Potentiating drug interaction		1		1		
Product administered at inappropriate site		1		1		
Pruritus	2	2	1	1	1	1
Psychiatric symptom		1				1
Pulmonary embolism	3	3			3	3
Pulmonary oedema	1	1			1	1
Pyrexia	6	12	3	6	3	6
Rash pruritic	1	1			1	1
Renal impairment	1	2			1	2
Respiratory arrest	1	1			1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory disorder		1		1		
Respiratory distress	1	1			1	1
Respiratory failure	1	1			1	1
Respiratory muscle weakness	1	1			1	1
SARS-CoV-2 test positive	3	4			3	4
Somnolence		3		1		2
Sudden death	2	2			2	2
Suspected COVID-19	2	2			2	2
Swelling face	1	2		1	1	1
Syncope	4	6			4	6
Tachycardia	1	1			1	1
Tachypnoea	1	1			1	1
Tension		1		1		
Throat tightness	1	1			1	1
Thrombophlebitis superficial	1	2			1	2
Tooth disorder		1				1
Transient ischaemic attack		1				1
Type 1 diabetes mellitus	1	1			1	1
Urinary incontinence		1		1		
Urticaria	1	1			1	1
Vaccination failure	3	3			3	3
Vaccination site erythema		6		6		
Vaccination site pain		7		7		
Vaccination site swelling		4		4		
Vascular dementia	1	1			1	1
Vein disorder		1		1		
Vomiting	1	3	1	1		2
	169	347	27	97	142	250

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Alanine aminotransferase increased		1		1		
Alopecia		1		1		
Angina pectoris		3				3
Antibody test negative		1		1		
Antibody test normal		1		1		
Arthralgia	4	6	4	6		
Aspartate aminotransferase increased		1		1		
Asphyxia		2				2
Asthenia	7	12	6	11	1	1
Asthenopia		1		1		
Autoimmune thyroiditis		1				1
Back pain	1	5	1	5		
Balance disorder	1	1	1	1		
Bilirubin conjugated increased	1	1			1	1
Blood bilirubin increased	1	1			1	1
Blood glucose decreased		1		1		
Blood glucose increased		1				1
Blood pressure decreased	1	2		1	1	1
Blood pressure fluctuation	2	2	2	2		
Blood pressure increased	4	10	2	4	2	6
Breast mass		1				1
Burning sensation		2		1		1
Catarrh	1	1	1	1		
Cerebral infarction		1				1
Chest discomfort	1	1	1	1		
Chest pain	1	3	1	3		
Chills	3	14	3	14		
Cholecystitis		1				1
Chromaturia		1		1		
Chronic obstructive pulmonary disease		1		1		
Condition aggravated	1	2	1	2		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coordination abnormal		1		1		
Cough		1		1		
COVID-19	5	20	2	4	3	16
COVID-19 pneumonia	2	2			2	2
Decreased appetite	2	5	2	5		
Dehydration		1				1
Dermatitis allergic		1		1		
Diarrhoea	3	9	1	6	2	3
Diarrhoea haemorrhagic		1				1
Disease recurrence		1				1
Disturbance in attention		1		1		
Dizziness	7	11	6	10	1	1
Drug ineffective	3	16			3	16
Drug interaction		1		1		
Dysarthria	1	1			1	1
Dysgeusia		1		1		
Dyspnoea	1	2	1	2		
Ear discomfort		1				1
Ear swelling		1				1
Enteritis		1				1
Erythema		6		6		
Exposure during pregnancy		2		2		
Exposure via breast milk	4	5	4	5		
Eye haemorrhage	1	2			1	2
Eyelid oedema		1		1		
Eye movement disorder	1	1	1	1		
Face oedema		1		1		
Fatigue	2	8	2	8		
Feeling abnormal	1	6	1	6		
Feeling hot	1	5	1	4		1
Food aversion	1	1	1	1		
Frequent bowel movements	1	1	1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Functional gastrointestinal disorder		1		1		
Gamma-glutamyltransferase increased		1		1		
Gastric disorder	1	1	1	1		
Haematochezia		1				1
Haematoma		1		1		
Haematuria		1				1
Haemorrhage	1	2			1	2
Headache	12	26	12	26		
Heart rate increased	3	4	1	2	2	2
Heavy menstrual bleeding	1	1	1	1		
Hepatic enzyme abnormal	1	1			1	1
Hepatic enzyme increased		1		1		
Hepatic function abnormal	1	1	1	1		
Herpes zoster	3	6	3	6		
Hot flush		1		1		
Hypersensitivity		5		3		2
Hypertension	1	1	1	1		
Hypertensive crisis	1	1			1	1
Hyperthyroidism	1	1			1	1
Hypoaesthesia	5	9	3	7	2	2
Hypoaesthesia oral		2		2		
Ileus	1	1			1	1
Illness		1		1		
Incorrect product formulation administered		1		1		
Incorrect route of product administration	1	2		1	1	1
Induration		1		1		
Inflammation	1	2	1	2		
Influenza like illness		2		2		
Insomnia	1	2	1	2		
Joint swelling	1	1	1	1		
Limb discomfort	1	1	1	1		
Liquid product physical issue		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy		3		3		
Lymph node pain		1		1		
Lymphoedema		1		1		
Malaise	1	12	1	12		
Memory impairment		1		1		
Menstruation delayed	1	2	1	2		
Migraine		1		1		
Monoplegia		1				1
Muscle fatigue		1		1		
Muscle tightness		1		1		
Muscle twitching		1				1
Muscular weakness	1	4	1	4		
Myalgia	4	13	4	13		
Nasopharyngitis		1		1		
Nausea	5	9	4	8	1	1
Neck pain		1		1		
Nervous system disorder	1	1			1	1
Neuralgia	1	1	1	1		
Off label use	29	55	29	55		
Oropharyngeal pain		1		1		
Pain		3		3		
Pain in extremity	6	18	6	18		
Pain of skin		1		1		
Palpitations	1	2	1	2		
Pelvic inflammatory disease	1	1			1	1
Periarthritis		1		1		
Peripheral swelling	2	4	2	4		
Pharyngeal oedema		1		1		
Pharyngeal swelling		1		1		
Pneumonia		1				1
Pollakiuria		1				1
Polymenorrhoea	1	1	1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Presyncope	2	2	2	2		
Productive cough		1		1		
Product use in unapproved indication		1		1		
Product use issue	29	53	29	53		
Pruritus		3		3		
Pulmonary embolism		1				1
Pyrexia	7	26	7	26		
Rash		3		3		
Rash erythematous		3		2		1
Rash macular		1		1		
Rash pruritic		2		1		1
Rhinorrhoea		2		2		
SARS-CoV-2 ant body test positive		1		1		
SARS-CoV-2 test positive	1	3		1	1	2
Sensitive skin	1	2	1	2		
Skin burning sensation		1		1		
Skin discolouration	2	2	1	1	1	1
Skin disorder		1		1		
Skin haemorrhage	1	1	1	1		
Somnolence		3		3		
Speech disorder		1		1		
Suspected counterfeit product		1		1		
Suspected COVID-19	1	1	1	1		
Swelling face		1		1		
Swollen tongue		1		1		
Tension headache		1		1		
Therapeutic response unexpected		1		1		
Tremor	2	4	1	2	1	2
Urinary tract infection	1	1	1	1		
Urticaria		3		2		1
Uveitis		1				1
Vaccination site discolouration		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site erythema	1	3	1	3		
Vaccination site induration		1		1		
Vaccination site macule		1		1		
Vaccination site movement impairment		3		3		
Vaccination site nodule		1		1		
Vaccination site pain	8	18	8	18		
Vaccination site pruritus		1		1		
Vaccination site swelling		4		4		
Vasculitis		1		1		
Vomiting		1		1		
Weight decreased	3	3	1	1	2	2
Wheezing		1				1
	216	596	179	492	37	104

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Country Where Event Occurred

ICELAND

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysphoria	1	1			1	1
Exposure via breast milk	1	1			1	1
Off label use		4		4		
Product use in unapproved indication		2		2		
Product use issue		3		3		
Pyrexia	1	2		1	1	1
	3	13		10	3	3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		1		1		
Axillary pain		1		1		
Back pain		1		1		
Bone pain	1	2	1	2		
Chills		3		3		
Cold sweat	1	1	1	1		
Cough		1		1		
Decreased appetite		1		1		
Discomfort	1	2	1	2		
Disease recurrence		1		1		
Dizziness		1		1		
Dry mouth		1		1		
Dry throat		1		1		
Dysgeusia	1	1	1	1		
Erythema		1		1		
Fatigue	1	5	1	5		
Feeling cold		1		1		
Feeling hot		1		1		
Headache	3	12	3	12		
Head discomfort	1	1	1	1		
Hyperhidrosis		1		1		
Hypoaesthesia		3		3		
Influenza like illness	1	1	1	1		
Lymphadenopathy		3		3		
Malaise	1	6	1	5		1
Muscular weakness		1		1		
Myalgia	3	11	3	11		
Nasopharyngitis		1		1		
Nausea		3		3		
Neck pain	1	1	1	1		
Off label use	1	1	1	1		
Oropharyngeal pain		2		2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in extremity	1	1	1	1		
Pallor		1		1		
Product use issue	1	1	1	1		
Pruritus	1	3	1	3		
Pyrexia	4	16	4	16		
Rash	1	2	1	2		
Rhinorrhoea		1		1		
Sensory loss		1		1		
Skin burning sensation		1		1		
Sleep disorder	1	1	1	1		
Thirst		1		1		
Vaccination site erythema		1		1		
Vaccination site pain	3	10	3	10		
Vaccination site swelling		1		1		
Vaccination site warmth		1		1		
Vomiting	1	1	1	1		
	29	116	29	115		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	1			1	1
Arrhythmia	1	1			1	1
Arthralgia	2	5	2	5		
Arthritis	1	2	1	2		
Asthenia		2		2		
Axillary pain		2		2		
Blood pressure increased		1		1		
Bone pain		1		1		
Bradycardia		1				1
Breast inflammation		1		1		
Chest discomfort	1	3	1	3		
Chest pain		2		2		
Chills	5	12	5	12		
Cold sweat		1		1		
Decreased appetite		1		1		
Delirium		2				2
Discomfort		1		1		
Dizziness	4	11	4	11		
Dyspnoea	1	2	1	2		
Erythema		2		2		
Fall		1		1		
Fatigue	1	9	1	9		
Feeling abnormal	1	3	1	3		
Feeling cold		1		1		
Fibrin D dimer increased		1				1
Headache	9	29	9	29		
Head discomfort		1		1		
Heart rate increased	2	3	2	3		
Hepatic enzyme increased		1		1		
Hot flush		1		1		
Hyperhidrosis		1		1		
Hypoaesthesia	2	4	2	4		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypotension	1	1	1	1		
Influenza like illness		1		1		
Injection site pain		2		2		
Injection site swelling	1	1	1	1		
Insomnia		2		2		
Joint stiffness		1		1		
Joint swelling		1		1		
Limb discomfort		1		1		
Loss of consciousness		1				1
Lymphadenopathy	1	3	1	3		
Malaise	5	15	5	15		
Maternal exposure during pregnancy		1		1		
Memory impairment		1		1		
Migraine		1		1		
Muscle twitching		2		2		
Muscular weakness	1	1	1	1		
Myalgia	8	18	8	18		
Nausea	5	13	5	13		
Ocular discomfort		1		1		
Oedema peripheral		1		1		
Oropharyngeal pain		2		2		
Pain		2		2		
Pain in extremity	3	9	3	8		1
Pallor		1		1		
Palpitations	1	1	1	1		
Periorbital swelling		1		1		
Peripheral embolism		1				1
Pharyngeal swelling		1		1		
Poor quality sleep		1		1		
Presyncope	1	1	1	1		
Pruritus		2		2		
Pulmonary pain	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia	8	18	8	18		
Rash		2		2		
Sensitive skin		1		1		
Skin discolouration		1		1		
Sleep disorder		1				1
Sluggishness		1		1		
Swelling		1		1		
Syncope		1				1
Tachycardia	1	2	1	2		
Throat tightness	1	1	1	1		
Tremor		1		1		
Urticaria	1	1	1	1		
Vaccination site erythema		2		2		
Vaccination site inflammation		2		2		
Vaccination site irritation	1	1	1	1		
Vaccination site pain	6	15	6	15		
Vaccination site reaction		1		1		
Vaccination site swelling		1		1		
Vaccination site warmth	1	2	1	2		
Visual impairment		1		1		
Vomiting	1	2	1	2		
	79	258	77	247	2	11

* I=Interval, C=Cumulative
* AE=Adverse Event
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arrhythmia	1	1			1	1
Arthralgia		1		1		
Back pain		1		1		
Blood pressure increased	1	1	1	1		
Chest pain	1	1			1	1
Chills		2		2		
Cough		1		1		
Decreased appetite		1		1		
Dizziness	1	2	1	2		
Dysgeusia		1		1		
Dyspnoea		2		2		
Electrocardiogram QT prolonged	1	1			1	1
Fatigue		2		2		
Feeling abnormal		1		1		
Gastrointestinal pain		1		1		
Headache		5		5		
Heart rate increased	1	2	1	2		
Hypersomnia		1		1		
Hypoaesthesia	1	1			1	1
Malaise		2		2		
Myalgia		5		5		
Nasopharyngitis		1		1		
Pruritus		1		1		
Pulmonary embolism	1	1			1	1
Pyrexia		6		6		
Sensitive skin		1		1		
Speech disorder	1	1			1	1
Syncope	1	1			1	1
Tremor	1	1	1	1		
Vaccination site pain		4		4		
	11	52	4	45	7	7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anal incontinence		1		1		
Aphasia	1	1			1	1
Asthenia		2		2		
Atrial fibrillation		1				1
Back pain	1	1			1	1
Bell's palsy	1	1			1	1
Breath sounds abnormal		1				1
Chills	1	1	1	1		
Cough		2		2		
Death		2				2
Decreased appetite		1		1		
Disorientation	1	1			1	1
Dyspnoea		1		1		
Dyspraxia	1	1			1	1
Fluid overload		1				1
Headache	1	2	1	2		
Hepatic enzyme increased		1				1
Hypertension		1		1		
Hypoperfusion		1				1
Malaise		1		1		
Myalgia	1	1	1	1		
Nasopharyngitis	1	2	1	2		
Nausea		1		1		
Oxygen saturation decreased		1				1
Pain	1	1			1	1
Pneumonia		1				1
Productive cough		1		1		
Pulmonary oedema		1				1
Pyrexia	1	4	1	3		1
Respiratory arrest		1				1
Tachycardia		1				1
Urinary incontinence		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urine flow decreased		1				1
Vaccination site pain		1		1		
Vaccination site swelling		1		1		
	11	43	5	23	6	20

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction		2				2
Aortic aneurysm		1				1
Aphasia		2		1		1
Arthralgia		1		1		
Asthenia		2		2		
Asthma		1				1
Back pain		1		1		
Balance disorder		1				1
Blood pressure decreased		1				1
Cardiac failure		2				2
Cerebrovascular accident		1				1
Chest pain		1				1
Chills		1		1		
Chronic obstructive pulmonary disease		1				1
Confusional state		1				1
Contusion		1				1
Cough		1				1
Death		4				4
Deep vein thrombosis		1				1
Delirium		1				1
Depressed level of consciousness		1				1
Disease progression		1				1
Dizziness		1		1		
Dyspnoea		2				2
Erythema		2		2		
Fatigue		2		1		1
Headache	1	2	1	2		
Hypercapnia		1				1
Hyperhidrosis		1				1
Hypoxia		2				2
Joint swelling		1		1		
Loss of consciousness		2				2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lung infiltration		1				1
Malaise	1	8	1	4		4
Motor dysfunction		1				1
Myocardial infarction		1				1
Nasopharyngitis		2		2		
Nausea	1	1	1	1		
Noninfective sialoadenitis		1		1		
Oxygen saturation decreased		1				1
Pain in extremity		1				1
Peripheral artery thrombosis		1				1
Peripheral swelling		1				1
Personality change		1				1
Pneumonia		3				3
Pneumonia aspiration		1				1
Pyrexia		8		5		3
Respiration abnormal		1				1
Respiratory failure		1				1
Rhinorrhoea		2		2		
Salivary gland enlargement		1		1		
Sepsis		1				1
Sudden death	1	3			1	3
Syncope		1				1
Transient ischaemic attack		2				2
Vaccination site erythema		3		3		
Vaccination site inflammation		1		1		
Ventricular tachycardia		1				1
	4	94	3	33	1	61

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anencephaly		1				1
Ear pain		1		1		
Fatigue		1		1		
Headache	1	2	1	2		
Maternal exposure during pregnancy		1		1		
Myalgia	1	3	1	3		
Oropharyngeal pain		2		2		
Painful respiration		1		1		
Pain in extremity		1		1		
Pulmonary pain		1		1		
Pyrexia	1	3	1	3		
	3	17	3	16		1

* I=Interval, C=Cumulative
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Country Where Event Occurred

INDIA

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19		1				1
Drug ineffective		1				1
Inappropriate schedule of product administration		1		1		
Off label use		1		1		
		4		2		2

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Asthenia		1		1
COVID-19	1	1	1	1
Dizziness		1		1
Drug ineffective	1	1	1	1
Fatigue		1		1
Headache		1		1
Loss of consciousness		1		1
Oxygen saturation decreased		1		1
Pain		1		1
Vaccination site pain		1		1
Vomiting		1		1
	2	11	2	11

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19	1	1	1	1
COVID-19 pneumonia	1	1	1	1
Drug ineffective	1	1	1	1
Myocardial infarction	1	1	1	1
	4	4	4	4

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	1			1	1
Drug ineffective	1	1			1	1
Suspected counterfeit product		1		1		
	2	3		1	2	2

* I=Interval, C=Cumulative
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Country Where Event Occurred

IRAQ

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19	1	1	1	1
Pyrexia	1	1	1	1
	2	2	2	2

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cerebrovascular accident	1	1	1	1
Chest pain	1	1	1	1
Hyperhidrosis	1	1	1	1
Myocardial infarction	1	1	1	1
	4	4	4	4

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cough		1		1
COVID-19	1	1	1	1
Headache		1		1
Myalgia		1		1
Nausea		1		1
Pyrexia		1		1
Vaccination site pain		1		1
	1	7	1	7

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Cerebrovascular accident	1	1			1	1
COVID-19	1	1	1	1		
Gait disturbance	1	1	1	1		
Lacunar infarction	1	1			1	1
Vaccination site pain	1	1	1	1		
	6	6	4	4	2	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Mastitis	1	1			1	1
Oxygen saturation decreased	1	1	1	1		
Pyrexia	1	1	1	1		
	5	5	4	4	1	1

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	1			1	1
Decreased appetite		1		1		
Deep vein thrombosis	1	1			1	1
Drug ineffective	1	1			1	1
Fatigue		1		1		
Insomnia		1		1		
Limb discomfort	1	1	1	1		
Pain in extremity	1	1	1	1		
Paraesthesia	1	1	1	1		
Pyrexia		1		1		
Tremor	1	1	1	1		
Vaccination site pain		1		1		
	7	12	4	9	3	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

IRELAND

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Exposure via breast milk		1		1
Rash		1		1
Urticaria		1		1
		3		3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		2				2
Abdominal pain upper	1	2	1	1		1
Abortion spontaneous		1				1
Abortion threatened	1	1			1	1
Accidental overdose		1		1		
Ageusia	1	2			1	2
Agitation	2	2	1	1	1	1
Allergy to vaccine		1				1
Anaphylactic reaction		1				1
Angiotensin converting enzyme increased		1				1
Anosmia		1				1
Anxiety		2				2
Arthralgia	6	16	2	7	4	9
Asthenia	4	14	2	4	2	10
Axillary mass		2		1		1
Axillary pain	2	3	1	2	1	1
Back pain	4	5	2	2	2	3
Bell's palsy	1	3			1	3
Blepharospasm		1				1
Blindness		1				1
Blister		1				1
Blood pressure increased		2				2
Blood pressure systolic increased	1	1			1	1
Body temperature increased		1				1
Bone pain		1		1		
Breath odour		1				1
Burning sensation	1	3			1	3
Cellulitis		1				1
Chest discomfort		1				1
Chest pain	3	6			3	6
Chillblains	1	1			1	1
Chills	4	13	3	5	1	8

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat	1	2	1	1		1
Condition aggravated	1	1	1	1		
Confusional state		2				2
Contusion		1		1		
Cough	1	1	1	1		
COVID-19	1	1			1	1
C-reactive protein increased		1				1
Deafness		1				1
Decreased appetite	3	6	2	2	1	4
Depressed level of consciousness	1	1			1	1
Depression	2	2	1	1	1	1
Diarrhoea	2	8	1	2	1	6
Diplopia		1				1
Discomfort	2	2			2	2
Disease recurrence	1	1			1	1
Disturbance in attention		1				1
Dizziness	8	17	4	7	4	10
Drug ineffective	1	1			1	1
Dysarthria		1				1
Dyskinesia		1		1		
Dysphagia		1				1
Dyspnoea	3	7			3	7
Dyspnoea exertional	1	1			1	1
Dysstasia		1				1
Ear discomfort		1				1
Ear infection		1				1
Ear pain		2		1		1
Erythema	1	3		1	1	2
Exposure during pregnancy	1	2		1	1	1
Extra dose administered	1	1	1	1		
Eye irritation	1	1			1	1
Eyelid rash	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye movement disorder		1				1
Eye pruritus	1	1			1	1
Facial pain	1	1			1	1
Fatigue	10	31	8	18	2	13
Feeding disorder	1	1			1	1
Feeling abnormal	2	2	1	1	1	1
Feeling hot	2	3	1	1	1	2
Feeling of body temperature change	2	3	1	1	1	2
Flatulence		1				1
Flushing		1				1
Gait inability		2				2
Gastroesophageal reflux disease		1				1
Hallucination		1				1
Headache	13	33	7	14	6	19
Head injury	1	1			1	1
Heart rate increased	1	3			1	3
Heavy menstrual bleeding		1		1		
Herpes zoster		1				1
Hyperhidrosis	1	6			1	6
Hypersensitivity		1				1
Hypoaesthesia	4	6	2	2	2	4
Hypopnoea	1	1			1	1
Hypotension		1				1
Impaired driving ability		1				1
Impaired work ability	4	6	2	2	2	4
Inflammation		1				1
Influenza like illness		1		1		
Injected limb mobility decreased	1	1			1	1
Injection site pain	1	1			1	1
Insomnia	3	7	1	1	2	6
Intermenstrual bleeding		1				1
Limb discomfort	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Loss of personal independence in daily activities		1				1
Lymphadenopathy		4				4
Lymph node pain		2				2
Malaise	5	8	4	4	1	4
Mastitis		1				1
Maternal exposure during pregnancy	2	4	2	4		
Menstrual disorder		1		1		
Migraine	4	5	2	3	2	2
Mobility decreased		1				1
Muscle fatigue		1		1		
Muscle twitching	1	2		1	1	1
Musculoskeletal chest pain	1	1			1	1
Musculoskeletal stiffness		3		1		2
Myalgia	10	22	7	12	3	10
Myokymia		1				1
Nausea	6	26	3	12	3	14
Neck mass		1				1
Neck pain	2	4	1	2	1	2
Neuritis cranial		1				1
Neutropenia		1				1
Night sweats	1	2	1	2		
Oligomenorrhoea		1		1		
Oral herpes		1				1
Oral pain	1	1			1	1
Oropharyngeal pain		1				1
Pain	5	16	4	7	1	9
Pain in extremity	4	16	2	8	2	8
Pain in jaw		1		1		
Pallor		1				1
Palpitations	1	6			1	6
Paraesthesia	2	5	1	2	1	3
Peripheral coldness	1	1	1	1		

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* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Photophobia		1				1
Photosensitivity reaction	1	1			1	1
Presyncope		2		1		1
Pruritus	2	5			2	5
Purpura	1	1			1	1
Pyrexia	12	28	8	14	4	14
Rash	3	8	2	4	1	4
Rash erythematous	2	4			2	4
Rash pruritic	1	2			1	2
Respiratory rate increased		1				1
Retching		2				2
Retroplacental haematoma	1	1			1	1
Sciatica	2	2	1	1	1	1
Sinusitis		1				1
Skin burning sensation		1				1
Sleep disorder		1				1
Somnolence	1	1			1	1
Stridor		1				1
Swelling	1	1	1	1		
Swelling of eyelid	1	1			1	1
Syncope	5	10			5	10
Syringe issue	1	1	1	1		
Tachycardia		5				5
Tenderness		1				1
Thinking abnormal	1	1	1	1		
Tinnitus		1				1
Toothache	1	1	1	1		
Tremor	2	3			2	3
Urinary incontinence	1	1			1	1
Urticaria	2	6	1	2	1	4
Urticarial vasculitis		1				1
Urticaria papular		1		1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination error		1		1		
Vaccination site erythema		1				1
Vaccination site mass	1	1	1	1		
Vaccination site pain	4	15	1	7	3	8
Vaccination site pruritus		2				2
Vaccination site swelling		2				2
Vaccination site warmth		1				1
Vision blurred		1				1
Vitreous floaters	1	1	1	1		
Vomiting	7	22	3	6	4	16
Wheezing		2				2
	215	579	98	195	117	384

* I=Interval, C=Cumulative
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		4		2		2
Abdominal distension		3		1		2
Abdominal infection		1				1
Abdominal pain	1	3			1	3
Abdominal pain lower	1	1	1	1		
Abdominal pain upper	2	3	1	1	1	2
Abortion spontaneous	1	3			1	3
Ageusia	2	5	1	2	1	3
Allergy to vaccine		1				1
Amenorrhoea		1				1
Anaemia		1				1
Anaphylactic reaction	2	8			2	8
Anaphylactic shock		1				1
Aneurysm	1	1	1	1		
Angioedema	1	4			1	4
Ankylosing spondylitis	1	1			1	1
Anosmia	1	2		1	1	1
Anxiety	2	3	2	2		1
Aphasia		1				1
Arthralgia	22	46	9	15	13	31
Asthenia	5	31	1	7	4	24
Asthma		1				1
Axillary pain	2	9	1	2	1	7
Back pain	4	18	1	3	3	15
Bedridden	3	4			3	4
Bell's palsy	2	4			2	4
Blood glucose fluctuation		1				1
Blood pH decreased		1				1
Blood pressure decreased	1	1			1	1
Blood pressure increased		4				4
Blood pressure systolic increased		1		1		
Blood urine present		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bloody discharge		1				1
Body temperature decreased		1				1
Body temperature increased		1		1		
Bone pain	2	6			2	6
Bradycardia		1				1
Breast mass		1				1
Breast pain		4				4
Breast swelling		3				3
Breast tenderness		1		1		
Burning sensation	2	3			2	3
Carbon dioxide increased		1				1
Cardiac arrest		1				1
Cardiac flutter	1	1			1	1
Cerebrovascular accident		1				1
Cheilitis		1				1
Chest discomfort	3	17	1	2	2	15
Chest pain	6	18	1	2	5	16
Chills	19	51	9	13	10	38
Chromaturia		2		1		1
Cluster headache		1		1		
Cold sweat	1	4	1	2		2
Colitis ulcerative	1	1			1	1
Complicated appendicitis		1				1
Condition aggravated	2	3	1	1	1	2
Confusional state		1				1
Conjunctivitis		1		1		
Constipation		1				1
Corneal reflex decreased		1				1
Coronary artery occlusion		1				1
Coronary artery thrombosis		1				1
Cough	2	10	2	3		7
COVID-19		3				3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
C-reactive protein increased	1	1	1	1		
Cyst		1				1
Decreased activity		1				1
Decreased appetite	2	10		2	2	8
Deep vein thrombosis		1				1
Dehydration		2		1		1
Delirium	1	1			1	1
Dental paraesthesia	1	1	1	1		
Depressed mood		1				1
Dermatitis allergic	1	2			1	2
Diarrhoea	9	18	4	5	5	13
Discomfort	1	9			1	9
Disease recurrence		3				3
Disorientation		3				3
Disturbance in attention		3		2		1
Dizziness	22	57	5	10	17	47
Dizziness postural	1	1			1	1
Drug ineffective		2				2
Dry eye		1				1
Dry mouth		1				1
Dry throat		2				2
Dysarthria		2				2
Dysgeusia	3	7	2	3	1	4
Dyskinesia	1	1			1	1
Dysphagia		1				1
Dysphonia		1				1
Dyspnoea	3	12			3	12
Dyspnoea at rest		1				1
Dyspnoea exertional		2				2
Dysstasia		1				1
Ear pain	1	2			1	2
Eating disorder	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Emotional distress		1				1
Encephalitis		1				1
Epicondylitis	1	1			1	1
Epistaxis		1				1
Eructation	1	1	1	1		
Erythema	2	5	1	3	1	2
Erythema of eyelid		1				1
Excessive eye blinking		1				1
Exposure during pregnancy		1		1		
Extensive swelling of vaccinated limb		1		1		
Eye infection	1	1			1	1
Eye irritation		2		1		1
Eyelids pruritus		1				1
Eye movement disorder		1				1
Eye pain	2	6			2	6
Eye pruritus	1	1			1	1
Eye swelling		1		1		
Facial nerve disorder		1		1		
Facial neuralgia	1	1			1	1
Facial pain	2	3	1	2	1	1
Facial paralysis	1	4			1	4
Facial paresis		1				1
Fall	1	1			1	1
Fatigue	26	87	14	31	12	56
Feeding disorder		1				1
Feeling abnormal	2	9	1	2	1	7
Feeling cold		6		1		5
Feeling drunk		2				2
Feeling hot	6	14	3	4	3	10
Feeling jittery	1	1			1	1
Feeling of body temperature change	2	3	1	1	1	2
Flank pain		3				3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Flushing	1	4			1	4
Frequent bowel movements	1	1	1	1		
Furuncle		1				1
Gait disturbance		3				3
Headache	39	136	16	30	23	106
Heart rate decreased		1				1
Heart rate increased	5	12	2	3	3	9
Heart rate irregular		2				2
Heavy menstrual bleeding	2	2	2	2		
Hemiparaesthesia	1	1			1	1
Hemiparesis		1				1
Hepatic pain	1	1			1	1
Herpes zoster	1	2	1	1		1
Hordeolum	1	2			1	2
Hyperaesthesia		1				1
Hyperaesthesia teeth	1	1	1	1		
Hyperhidrosis	3	13		1	3	12
Hyperpyrexia		1				1
Hypersensitivity		3				3
Hypersomnia	1	1	1	1		
Hypertension	5	18	1	1	4	17
Hyperventilation		1				1
Hypoaesthesia	8	28	5	12	3	16
Hypoaesthesia oral		7		1		6
Hypoglycaemia		1				1
Hypopnoea		1				1
Hypotension	1	7		2	1	5
Hypotonia		1				1
Illness		2		1		1
Impaired driving ability		2				2
Impaired work ability	8	20	2	4	6	16
Inappropriate schedule of product administration	2	5	2	5		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Incorrect dose administered	1	1			1	1
Inflammation	1	2			1	2
Influenza		1				1
Influenza like illness	4	15	2	6	2	9
Injected limb mobility decreased	1	1	1	1		
Injection site pain		2		1		1
Insomnia	8	18	2	3	6	15
Intermenstrual bleeding		1				1
Irritability		1				1
Irritable bowel syndrome		1				1
Joint range of motion decreased		1				1
Joint stiffness	1	5	1	2		3
Joint swelling		1				1
Kidney infection	1	1			1	1
Lacrimation decreased		1				1
Lacrimation increased		1				1
Lethargy	5	13	2	3	3	10
Limb discomfort	3	7	2	4	1	3
Lip dry		1				1
Lip swelling	2	7	1	1	1	6
Localised infection	1	1	1	1		
Loss of consciousness	2	5			2	5
Loss of personal independence in daily activities	4	6		1	4	5
Lymphadenopathy	10	26	1	4	9	22
Lymph node pain	3	5	2	2	1	3
Malaise	13	41	6	13	7	28
Mass		1				1
Mastitis		1				1
Maternal exposure during breast feeding		2		2		
Maternal exposure during pregnancy	1	4		2	1	2
Memory impairment		1				1
Menstrual disorder	1	2			1	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Menstruation irregular	1	1			1	1
Micturition urgency		1		1		
Migraine	2	6	1	2	1	4
Mobility decreased	1	3			1	3
Mood swings		1				1
Muscle spasms	2	4	1	1	1	3
Muscle tightness	1	2	1	1		1
Muscle twitching		6				6
Muscular weakness	2	8			2	8
Musculoskeletal chest pain		1				1
Musculoskeletal discomfort	1	2	1	1		1
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	2	6	1	3	1	3
Myalgia	19	49	10	13	9	36
Myelitis transverse		1				1
Myocarditis	1	2			1	2
Nasal congestion	1	4	1	2		2
Nausea	20	79	8	18	12	61
Neck pain	1	8	1	2		6
Negative thoughts		1				1
Nerve compression		1				1
Nerve injury	1	2			1	2
Nervousness		2		1		1
Nervous system disorder		1				1
Neuralgia	1	4			1	4
Nystagmus		1				1
Off label use	3	11	3	11		
Oral hyperaesthesia	1	1			1	1
Oropharyngeal discomfort	1	2	1	1		1
Oropharyngeal pain	2	8	1	3	1	5
Orthostatic hypotension		1				1
Otitis media	1	1			1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oxygen saturation decreased		2				2
Pain	12	49	5	11	7	38
Pain in extremity	11	43	7	16	4	27
Pallor	1	7	1	2		5
Palpitations	3	14	1	3	2	11
Panic attack		1				1
Paraesthesia	12	40	5	10	7	30
Paraesthesia ear	1	1			1	1
Paraesthesia oral	3	10	2	4	1	6
Paranasal sinus discomfort		1				1
Pericardial effusion	1	1			1	1
Pericarditis	1	1			1	1
Periorbital oedema		1		1		
Periorbital swelling		1				1
Peripheral coldness	1	1			1	1
Peripheral swelling	2	4			2	4
Pharyngeal hypoaesthesia		1		1		
Pharyngeal paraesthesia		5		3		2
Pharyngeal swelling	2	4	1	1	1	3
Photophobia		1				1
Pollakiuria		1				1
Polymenorrhoea	1	1	1	1		
Poor quality product administered		1		1		
Poor quality sleep		1		1		
Presyncope	1	2	1	2		
Productive cough	1	1			1	1
Product leakage	1	1	1	1		
Product preparation error	1	2		1	1	1
Product use issue	1	6	1	6		
Pruritus	6	18	3	8	3	10
Psoriasis	2	2	2	2		
Pulmonary embolism		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia	30	85	12	24	18	61
Quality of life decreased		1				1
Rash	10	25	3	8	7	17
Rash erythematous	2	7		1	2	6
Rash macular	2	3	1	1	1	2
Rash pruritic	2	5	1	3	1	2
Rash vesicular	1	1	1	1		
Rectal haemorrhage	1	1			1	1
Red blood cell sedimentation rate increased	1	1	1	1		
Respiration abnormal		1				1
Respiratory failure		1				1
Retching		1				1
Road traffic accident		1				1
Salivary hypersecretion		1		1		
Seizure	1	1			1	1
Sensation of foreign body		1				1
Sensitive skin		1				1
Sensory disturbance	2	2	1	1	1	1
Sensory loss		1				1
Sinus congestion		1				1
Sinus pain		1				1
Skin burning sensation	1	2	1	1		1
Skin laceration		1		1		
Skin papilloma		1				1
Skin warm		1				1
Skin wrinkling		1				1
Sleep disorder	1	1			1	1
Somnolence	2	5	1	1	1	4
Speech disorder		1				1
Stress		1		1		
Stridor		2				2
Sudden onset of sleep		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Suspected COVID-19	1	2	1	2		
Swelling		5		1		4
Swelling face		6		1		5
Swelling of eyelid	1	3		1	1	2
Swollen tongue	1	5			1	5
Syncope	4	13			4	13
Syringe issue	1	1	1	1		
Tachycardia	3	14		1	3	13
Taste disorder		2				2
Tenderness		1				1
Tension headache		1				1
Thirst	1	1	1	1		
Throat irritation		3		2		1
Throat tightness		3				3
Thrombosis		1				1
Thyroiditis acute	1	1			1	1
Tidal volume decreased		1				1
Tinnitus	2	4		1	2	3
Tongue disorder		1				1
Transient ischaemic attack		1				1
Tremor	1	6	1	1		5
Trigeminal nerve disorder		2				2
Trigeminal neuralgia	1	2			1	2
Tympanic membrane perforation	1	1			1	1
Type IV hypersensitivity reaction		1				1
Underdose	1	1	1	1		
Unresponsive to stimuli		2				2
Upper-airway cough syndrome	1	1	1	1		
Upper respiratory tract infection		1		1		
Urinary incontinence		1				1
Urinary retention		1				1
Urinary tract infection		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urine odour abnormal		1		1		
Urticaria	3	9	2	4	1	5
Urticaria chronic	1	1			1	1
Uveitis	1	1			1	1
Vaccination failure		1				1
Vaccination site bruising		1				1
Vaccination site discomfort		2		1		1
Vaccination site erythema	5	9	1	2	4	7
Vaccination site induration	1	1			1	1
Vaccination site inflammation	1	2		1	1	1
Vaccination site irritation		1				1
Vaccination site joint movement impairment		1				1
Vaccination site mass	2	2	1	1	1	1
Vaccination site movement impairment	1	1			1	1
Vaccination site pain	8	29	2	13	6	16
Vaccination site paraesthesia		2		1		1
Vaccination site pruritus	5	7	1	2	4	5
Vaccination site rash	1	1			1	1
Vaccination site swelling	4	7		1	4	6
Vaccination site urticaria		1		1		
Vaccination site warmth	1	2	1	1		1
Vaginal haemorrhage		1				1
Vertigo	3	5	1	2	2	3
Viral labyrinthitis	1	1	1	1		
Vision blurred	2	3			2	3
Visual impairment		2				2
Vitreous floaters		3				3
Vomiting	4	21	1	1	3	20
Vomiting projectile	1	1	1	1		
Weight bearing difficulty		1				1
Weight decreased		1				1
Wheezing		2				2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
White blood cell count decreased	1	1			1	1
	585	1,905	226	486	359	1419

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	2		1	1	1
Abdominal pain	2	2			2	2
Abdominal pain upper	1	4		2	1	2
Ageusia		1		1		
Alanine aminotransferase increased		1				1
Amnesia	1	1			1	1
Anaphylactic reaction		1				1
Angioedema		1				1
Anxiety		2				2
Arrhythmia	2	2			2	2
Arthralgia	9	16	2	4	7	12
Arthritis	2	2			2	2
Aspiration		1				1
Aspiration joint	1	1	1	1		
Asthenia	7	15		1	7	14
Asthenopia	1	1			1	1
Atrial tachycardia	1	1			1	1
Back pain	2	5		1	2	4
Balance disorder	1	2	1	2		
Bedridden	1	1			1	1
Bell's palsy	2	4			2	4
Blindness transient		1				1
Blood bilirubin increased		1				1
Blood lactic acid increased		1				1
Blood pressure diastolic increased		1				1
Blood pressure increased		2				2
Bone pain	1	1	1	1		
Breast swelling		1				1
Burning sensation		2		1		1
Cellulitis	1	3			1	3
Chest discomfort	1	2		1	1	1
Chest pain	1	3			1	3

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills	9	16	2	3	7	13
Chromaturia		1				1
Condition aggravated	3	3	2	2	1	1
Confusional state	2	3			2	3
Contusion	1	1	1	1		
Cough	1	3	1	1		2
COVID-19	1	3	1	1		2
C-reactive protein increased		1				1
Cyanosis	1	2			1	2
Dark circles under eyes		1				1
Deafness		1				1
Decreased appetite	4	5			4	5
Dermatitis	1	3	1	2		1
Diarrhoea	3	5	2	2	1	3
Diplopia		2		1		1
Discomfort		2				2
Disorientation	1	1			1	1
Disturbance in attention	1	1			1	1
Dizziness	7	22	3	4	4	18
Dry eye	1	2			1	2
Dry skin	1	1	1	1		
Dysarthria	1	1	1	1		
Dysgeusia	1	3	1	2		1
Dyspnoea	2	6			2	6
Ear pain	1	1			1	1
Emotional distress	1	1			1	1
Eosinophil count increased		1				1
Epistaxis		1		1		
Eye discharge		1				1
Eye pruritus		2		1		1
Eye swelling		1				1
Facial pain	1	1	1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial paralysis	1	1			1	1
Facial paresis	1	1			1	1
Faeces pale		1				1
Fall	2	2			2	2
Fatigue	15	32	5	11	10	21
Feeding disorder	1	1			1	1
Feeling abnormal	4	7	1	3	3	4
Feeling cold		1				1
Feeling hot	1	6			1	6
Flank pain		1				1
Flushing	1	3	1	1		2
Formication		1				1
Gait disturbance	1	1			1	1
Gait inability		1		1		
Gastric disorder		1				1
Gastrointestinal sounds abnormal	1	1	1	1		
Generalised tonic-clonic seizure	1	1			1	1
Glossodynia		1		1		
Headache	24	42	9	13	15	29
Head injury	1	1			1	1
Heart rate increased		1				1
Herpes zoster reactivation		1				1
Hot flush	2	2	1	1	1	1
Hyperhidrosis	2	4			2	4
Hypersensitivity	1	3	1	2		1
Hypersomnia	3	3			3	3
Hypertension	2	5		1	2	4
Hypoaesthesia	2	7		1	2	6
Hypoaesthesia oral	1	2			1	2
Impaired work ability	7	10	2	2	5	8
Infection		1		1		
Influenza		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Influenza like illness	1	3	1	1		2
Injected limb mobility decreased		1				1
Injection site movement impairment		1				1
Injection site pain		1				1
Injury	1	2			1	2
Insomnia	4	6	2	2	2	4
Intervertebral disc disorder	1	1	1	1		
Jaundice		1				1
Jaw disorder	1	1	1	1		
Joint stiffness		1				1
Joint swelling	1	2			1	2
Joint warmth	1	1			1	1
Lethargy	4	6			4	6
Limb discomfort		3				3
Lip discolouration		1				1
Lip swelling		4				4
Liver function test increased		1				1
Loss of consciousness	2	3			2	3
Loss of control of legs		1				1
Loss of personal independence in daily activities	2	2			2	2
Lower respiratory tract infection		1				1
Lymphadenopathy	1	4			1	4
Lymph node pain		2				2
Malaise	5	12	2	3	3	9
Memory impairment	1	1			1	1
Metabolic acidosis		1				1
Migraine	1	2	1	1		1
Muscle spasms		3		1		2
Musculoskeletal chest pain		1				1
Musculoskeletal stiffness	2	2			2	2
Myalgia	8	18	2	5	6	13
Mydriasis		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myocardial infarction		1				1
Myocarditis	1	1			1	1
Nasal discomfort		1		1		
Nasopharyngitis	2	2	2	2		
Nausea	13	22	4	5	9	17
Neck pain	4	4	2	2	2	2
Neuralgia	1	1			1	1
Night sweats	1	2	1	1		1
Oral herpes		1				1
Oral pruritus		1		1		
Oropharyngeal pain	1	1			1	1
Oxygen saturation decreased		1				1
Pain	7	18	2	4	5	14
Pain in extremity	5	13	4	7	1	6
Pain in jaw	3	3	2	2	1	1
Palpitations	1	2			1	2
Paraesthesia	1	8		1	1	7
Paraesthesia oral	1	4		1	1	3
Periarthritis		1				1
Periorbital discomfort		1		1		
Peripheral swelling	1	6			1	6
Pneumonia		2				2
Presyncope	1	2	1	1		1
Product preparation issue		1		1		
Pruritus	2	4			2	4
Psychomotor hyperactivity		1				1
Pulmonary embolism		1				1
Pulmonary pain	1	1			1	1
Pulmonary sepsis		1				1
Pulse abnormal		1				1
Pupils unequal		1		1		
Pyrexia	14	29	5	8	9	21

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash	5	7			5	7
Rash papular	1	1			1	1
Rheumatoid arthritis	1	1			1	1
Rhinitis		1				1
Salivary hypersecretion		1		1		
SARS-CoV-2 test positive		1				1
Seizure		1				1
Sensation of foreign body		1				1
Sensory disturbance	1	1			1	1
Sensory loss		1				1
Sinus headache	1	1			1	1
Sinusitis	1	1			1	1
Sinus pain	1	1	1	1		
Skin exfoliation		1				1
Sleep disorder	1	1			1	1
Sneezing		1		1		
Somnolence	1	3			1	3
Speech disorder		1		1		
Spinal pain	1	1			1	1
Supraventricular extrasystoles	1	1			1	1
Supraventricular tachycardia		1				1
Suspected product quality issue		1		1		
Swelling	1	4		1	1	3
Swelling face	2	3	1	1	1	2
Swollen tongue		2				2
Syncope	3	7			3	7
Tachycardia		3				3
Tenderness	1	1			1	1
Tetany	1	1	1	1		
Thirst	1	1			1	1
Throat irritation		1				1
Tinnitus		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue biting		1				1
Tongue rough	1	1			1	1
Toothache	1	1			1	1
Tremor		2				2
Troponin increased		1				1
Underdose		1		1		
Urticaria	2	4	1	1	1	3
Vaccination site cellulitis	1	1			1	1
Vaccination site erythema		3		1		2
Vaccination site induration	1	1	1	1		
Vaccination site mass		1				1
Vaccination site pain	4	4	3	3	1	1
Vaccination site swelling	1	1	1	1		
Vaccination site warmth		2				2
Ventricular extrasystoles	1	1			1	1
Vertigo		1				1
Vision blurred	1	2	1	2		
Visual field defect	1	1	1	1		
Visual impairment		1		1		
Vomiting	5	9	1	1	4	8
Wheezing		1				1
	295	650	88	157	207	493

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1			1	1
Abdominal pain	1	1			1	1
Acute cardiac event		1				1
Acute respiratory distress syndrome	1	1			1	1
Agitation		1				1
Angiopathy	1	1			1	1
Aphasia	1	1			1	1
Arthralgia	1	3	1	2		1
Asthenia	3	4	1	1	2	3
Back pain		1		1		
Bedridden	1	1			1	1
Bell's palsy		1				1
Cardiac arrest	1	1			1	1
Cardiac failure		1				1
Cerebral infarction	1	1			1	1
Chest pain		1		1		
Chills	2	4	2	2		2
Cold sweat		1				1
Confusional state		2				2
Death	1	2			1	2
Diarrhoea		1				1
Disseminated varicella zoster virus infection	1	1			1	1
Dizziness	1	3	1	2		1
Dyspnoea exertional	1	1			1	1
Emotional distress	1	1			1	1
Erythema		1				1
Exfoliative rash	1	1			1	1
Eye movement disorder		1				1
Facial paralysis		2				2
Fall	1	1			1	1
Fatigue	1	2	1	2		
Feeling abnormal	1	2			1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gait disturbance		1				1
Groin pain	1	1			1	1
Headache	1	3	1	1		2
Hyperhidrosis	1	2			1	2
Hypertension		1				1
Hypoaesthesia	1	1	1	1		
Hypoglycaemia		1				1
Hypotonia		1				1
Impaired work ability		2				2
Influenza like illness	1	2	1	2		
Injected limb mobility decreased		1		1		
Limb discomfort	1	1	1	1		
Loss of consciousness		1				1
Malaise	3	5	1	1	2	4
Migraine		1				1
Migraine with aura		1				1
Mobility decreased	1	1	1	1		
Musculoskeletal stiffness	1	2	1	2		
Myalgia	1	2	1	1		1
Nausea	1	3	1	1		2
Neutropenia	1	1			1	1
Oral herpes		1		1		
Pain		2		1		1
Pain in extremity	1	1	1	1		
Pericarditis	1	1			1	1
Photopsia		1				1
Pneumonia	1	1			1	1
Presyncope		1				1
Pyrexia	2	4	1	1	1	3
Respiratory arrest	2	2			2	2
Respiratory rate increased		1				1
Retching		1				1

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* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Seizure like phenomena	1	1			1	1
Sudden death		1				1
Supraventricular tachycardia		1				1
Syncope	1	1			1	1
Tachycardia	1	1			1	1
Tardive dyskinesia		1				1
Tongue movement disturbance		1				1
Transient ischaemic attack	2	2			2	2
Unresponsive to stimuli		1				1
Vaccination site bruising	1	1	1	1		
Vaccination site pain	2	3	2	3		
Vaccination site reaction	1	1	1	1		
Varicella zoster virus infection	1	1			1	1
Vertigo	1	2	1	2		
Vomiting	1	1			1	1
	56	116	22	34	34	82

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	2	2	2		
Abdominal pain		2		1		1
Abnormal loss of weight	1	1			1	1
Acute myocardial infarction	2	2			2	2
Anal incontinence	1	1			1	1
Anaphylactic reaction		1				1
Anaphylactoid reaction	1	1			1	1
Angina pectoris	1	1			1	1
Aortic aneurysm		1				1
Aphasia	1	2			1	2
Arthralgia	1	1	1	1		
Asthenia	1	4			1	4
Atrial f brillation		1				1
Back pain		1				1
Balance disorder	1	1	1	1		
Bell's palsy	1	3			1	3
Blood sodium decreased		1				1
Brain injury	1	1			1	1
Cardiac arrest		2				2
Cardiac failure congestive		1				1
Cardio-respiratory arrest	1	1			1	1
Cerebral disorder		1				1
Cerebral infarction		1				1
Cerebrovascular accident	5	6			5	6
Cerebrovascular insufficiency		1				1
Chest pain	1	2	1	1		1
Chills	1	3			1	3
Coma		1				1
Condition aggravated	1	1	1	1		
Confusional state	2	3	1	1	1	2
Constipation	1	1	1	1		
Cough	1	1			1	1

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* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19		4				4
Cyanosis	1	3		1	1	2
Deafness unilateral	1	1			1	1
Death	1	9			1	9
Decreased appetite	3	3	1	1	2	2
Decubitus ulcer	1	1			1	1
Deep vein thrombosis	1	6			1	6
Depressed level of consciousness		2				2
Diabetes mellitus inadequate control	1	1			1	1
Disease recurrence		1				1
Disorientation		1				1
Drug ineffective	1	1			1	1
Dysarthria	1	2			1	2
Dyspepsia	1	1	1	1		
Dysphagia	1	1			1	1
Dysphonia	1	1			1	1
Dyspnoea	1	4			1	4
Dyspnoea at rest		1				1
Ear pain	1	1	1	1		
Electrocardiogram change	1	1			1	1
Encephalopathy		1				1
Epilepsy		1				1
Epistaxis		1				1
Eyelid ptosis		1				1
Face injury		1				1
Facial paralysis	3	3			3	3
Faeces discoloured		1				1
Fall	2	3			2	3
Fatigue	5	6	1	1	4	5
Feeling abnormal		2				2
Feeling hot	1	1	1	1		
Fluid intake reduced	1	1			1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gait disturbance		1				1
General physical health deterioration	1	5			1	5
Haematemesis		1				1
Haemoglobin decreased		1				1
Headache	1	2			1	2
Heart rate irregular		1				1
Hemiparesis	1	2			1	2
Herpes zoster	1	1			1	1
Herpes zoster oticus	1	1			1	1
Hyperhidrosis	1	3	1	1		2
Hypersomnia		1				1
Hypopnoea		1				1
Hypotension		2				2
Hypoxia		1				1
Inappropriate schedule of product administration		1		1		
Lethargy	1	1			1	1
Loss of consciousness		4				4
Loss of control of legs	1	1			1	1
Loss of personal independence in daily activities	1	1			1	1
Lower respiratory tract infection	1	1			1	1
Malaise	3	6			3	6
Melaena		1				1
Memory impairment		1				1
Mobility decreased	1	2			1	2
Muscular weakness	1	1			1	1
Myocardial infarction		1				1
Myocardial ischaemia		1				1
Nausea	2	2			2	2
Neck pain	1	1	1	1		
Normal pressure hydrocephalus		1				1
Off label use		1		1		
Oxygen saturation decreased	2	8			2	8

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain	1	2			1	2
Pain in extremity	1	1			1	1
Pallor		3		1		2
Pancreatitis relapsing		1				1
Peripheral swelling	1	1			1	1
Platelet count decreased		1				1
Pneumonia	2	2			2	2
Pneumonitis		1				1
Presyncope		1				1
Pruritus		1				1
Pulmonary embolism	1	1			1	1
Pulse abnormal		1				1
Pulseless electrical activity	1	1			1	1
Pyrexia	2	10	1	1	1	9
Rales		1				1
Rash		1				1
Rash erythematous		1				1
Rash macular		1				1
Respiratory arrest	1	1			1	1
Respiratory distress		1				1
Respiratory rate decreased		3				3
Respiratory rate increased	1	1			1	1
Respiratory tract infection		3				3
Restlessness	1	1			1	1
Seizure		2				2
Skin discolouration		1		1		
Skin disorder	1	1			1	1
Sudden death		2				2
Suspected COVID-19	1	1			1	1
Syncope	2	4			2	4
Tachycardia		1				1
Tenderness		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thrombosis		1				1
Thrombotic stroke	1	1			1	1
Tonic clonic movements		1				1
Transient ischaemic attack		2				2
Tremor		1				1
Troponin increased	1	1			1	1
Unresponsive to stimuli	2	3			2	3
Upper gastrointestinal haemorrhage		1				1
Urinary incontinence		1				1
Urinary tract infection	1	1			1	1
Urine output decreased	1	1			1	1
Urticaria		2				2
Vomiting	2	3			2	3
Weight bearing difficulty	1	1			1	1
Weight increased	1	1			1	1
Wheezing		1				1
	102	253	16	22	86	231

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1			1	1
Abdominal pain upper		1				1
Accidental exposure to product		3		3		
Anxiety	2	2	1	1	1	1
Arthralgia	2	6	2	4		2
Asthenia	1	6		3	1	3
Asthma		1				1
Back pain	1	1			1	1
Bell's palsy		2				2
Blood pressure increased		2				2
Bone pain		1				1
Burning sensation		1				1
Cellulitis		1				1
Cerebrovascular accident		1				1
Chest discomfort		3		1		2
Chillblains		1				1
Chills	8	11	5	7	3	4
Choking sensation		1		1		
Circumstance or information capable of leading to medication error		1		1		
Cough	1	2			1	2
COVID-19	5	7			5	7
Cyanosis	1	1	1	1		
Diarrhoea		2		1		1
Discomfort		1		1		
Disease recurrence		1				1
Dizziness	3	8		4	3	4
Drug ineffective	5	8			5	8
Dysgeusia	2	2	2	2		
Dyspnoea	2	5		1	2	4
Eczema		1				1
Emotional distress		1				1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema		1				1
Erythema nodosum	1	1			1	1
Expired product administered		1		1		
Exposure during pregnancy	1	1	1	1		
Exposure via breast milk		5		5		
Exposure via skin contact		2		2		
Eye swelling		1				1
Facial pain		1				1
Facial paralysis		1				1
Fatigue	9	16	8	12	1	4
Feeling abnormal	1	1	1	1		
Feeling cold	1	4	1	2		2
Feeling hot	2	6	1	2	1	4
Feeling of body temperature change		1				1
Flatulence		1		1		
Haematochezia		1				1
Hangover		1		1		
Headache	14	25	11	16	3	9
Heart rate increased		1				1
Hemiparesis		1				1
Hyperhidrosis		2		1		1
Hypersensitivity		1				1
Hypertension	1	1	1	1		
Hypoaesthesia		2		1		1
Hypoaesthesia oral	2	4	2	2		2
Hypotension		1		1		
Illness		1		1		
Impaired work ability	1	2			1	2
Inappropriate schedule of product administration	1	2	1	2		
Incorrect dose administered	5	8	5	8		
Influenza	1	1	1	1		
Influenza like illness	2	2	2	2		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injury associated with device		2		2		
Insomnia	1	1	1	1		
Intermenstrual bleeding		1				1
IVth nerve paralysis		1				1
Lethargy	1	2	1	1		1
Limb discomfort	1	1	1	1		
Lip swelling		2				2
Loss of consciousness		1				1
Loss of personal independence in daily activities	1	3		1	1	2
Lymphadenopathy		2		1		1
Lymph node pain		1				1
Malaise	2	4	2	3		1
Maternal exposure during pregnancy		3		3		
Migraine	1	1	1	1		
Mobility decreased	1	1			1	1
Muscle spasms		1		1		
Musculoskeletal stiffness		2		2		
Myalgia	4	8	4	5		3
Nausea	5	14	5	10		4
Neck pain		1				1
Neuralgia		1				1
Neuropathy peripheral		1				1
Night sweats		1		1		
No adverse event		1		1		
Off label use		1		1		
Oral herpes		1		1		
Oropharyngeal pain		3				3
Overdose	1	1	1	1		
Pain	6	10	4	7	2	3
Pain in extremity	4	7	4	6		1
Pallor		1		1		
Palpitations	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Panic attack		2				2
Paraesthesia	5	8	4	7	1	1
Paraesthesia oral	1	2		1	1	1
Peripheral coldness	1	1	1	1		
Peripheral swelling	1	1	1	1		
Pharyngeal swelling		1				1
Platelet count decreased		1				1
Poor quality product administered	1	12	1	12		
Presyncope	1	3		2	1	1
Product packaging quantity issue		1		1		
Product preparation error	1	1	1	1		
Product preparation issue	4	10	4	10		
Product temperature excursion issue	1	2	1	2		
Pruritus	4	6	4	5		1
Pyrexia	5	11	2	5	3	6
Rash	5	8	3	3	2	5
Rhinitis		1				1
Seizure	1	1			1	1
Sensory disturbance		1		1		
Skin discolouration		1				1
Skin tightness		1				1
Sneezing	1	1	1	1		
Somnolence		1		1		
Speech disorder	1	1	1	1		
Supraventricular tachycardia		1				1
Suspected COVID-19		1				1
Suspected product quality issue		4		4		
Swelling face		1				1
Syncope	1	2			1	2
Tachycardia	1	2			1	2
Thirst		1				1
Throat tightness		1		1		

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tremor		1		1		
Type III immune complex mediated reaction		1				1
Underdose		9		9		
Urticaria		2		1		1
Vaccination site discharge		1		1		
Vaccination site discolouration		1				1
Vaccination site erythema	2	3	2	2		1
Vaccination site inflammation	1	1	1	1		
Vaccination site mass		2				2
Vaccination site pain		3		2		1
Vaccination site pruritus		1				1
Vaccination site warmth	2	3	2	3		
Vaginal haemorrhage		2				2
Visual impairment		1				1
Vomiting	2	7	1	5	1	2
Wheezing		1				1
White blood cell count increased		1		1		
Wound		1		1		
Wrong technique in product usage process		11		11		
	147	408	100	244	47	164

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Country Where Event Occurred

ISRAEL

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arterial thrombosis		1				1
Arthralgia		1		1		
Asthenia	1	3	1	3		
Blood creatine phosphokinase increased	1	1			1	1
Bradycardia	1	1			1	1
Chest discomfort		1		1		
Chest pain	1	6		3	1	3
Chills		1		1		
Cough		1				1
C-reactive protein increased	1	1	1	1		
Decreased appetite		1		1		
Diarrhoea		1		1		
Dyspnoea	1	2			1	2
Electrocardiogram abnormal		1				1
Exposure via breast milk		3		3		
Fatigue	1	2	1	2		
Feeling hot	1	1	1	1		
Headache		2		2		
Hyperventilation		1		1		
Musculoskeletal disorder	1	1	1	1		
Myalgia		2		2		
Myocarditis	2	15			2	15
Myositis	1	1			1	1
Nausea	1	1	1	1		
Neck pain		1		1		
Off label use	2	4	2	4		
Pain		1		1		
Pain in extremity	3	3	3	3		
Pericarditis		5				5
Product administered to patient of inappropriate age		2		2		
Productive cough		1		1		

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product use issue	2	2	2	2		
Pyrexia	1	3	1	3		
Vomiting		2		2		
	21	75	14	44	7	31

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain upper		1		1		
Abortion missed	1	1			1	1
Acute kidney injury		1				1
Adverse event		1		1		
Anal haemorrhage		1		1		
Anaphylactic reaction	1	1			1	1
Anaphylactic shock		1				1
Angioedema		1				1
Antinuclear ant body positive		1		1		
Antiphospholipid antibodies positive		1				1
Anxiety		1		1		
Arthralgia	1	2	1	2		
Asthenia	12	29	12	27		2
Asthma		1				1
Asymptomatic COVID-19		1				1
Axillary pain		1		1		
Back pain	1	8	1	7		1
Bell's palsy		1				1
Blood creatine phosphokinase increased	1	1			1	1
Blood iron decreased		1				1
Blood pressure abnormal	1	1	1	1		
Blood pressure increased	1	2			1	2
Bone pain		1		1		
Breast tenderness		1		1		
Cardiogenic shock		1				1
Cerebrovascular accident		1				1
Chest discomfort		2		1		1
Chest pain	5	14	5	10		4
Chills	8	18	8	17		1
Conjunctival disorder		1				1
Coronavirus infection	1	1			1	1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	2	4	2	4		
COVID-19		2		2		
C-reactive protein increased		1				1
Crying	1	1	1	1		
Deafness unilateral		2				2
Decreased appetite	1	1	1	1		
Deep vein thrombosis		1				1
Diarrhoea	1	5	1	5		
Discomfort		1		1		
Disturbance in attention	1	1	1	1		
Dizziness	6	9	6	8		1
Drug ineffective	1	2			1	2
Dry throat	1	1	1	1		
Dysgeusia	1	1	1	1		
Dysmenorrhoea	1	1	1	1		
Dysphonia	1	1	1	1		
Dyspnoea	1	4	1	4		
Electrocardiogram abnormal		1		1		
Electrocardiogram T wave inversion		1				1
Emotional disorder	1	1	1	1		
Erythema		3		3		
Exposure during pregnancy		1				1
Exposure to contaminated water		1		1		
Eye pain	1	1	1	1		
Eye swelling	1	1	1	1		
Facial pain		1		1		
Facial paralysis		1				1
Fatigue	5	14	5	13		1
Feeling abnormal	1	3	1	2		1
Feeling cold		1		1		
Feeling hot	1	1	1	1		
Foetal death		1				1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gait disturbance		1		1		
Gingival pain		1		1		
Haemorrhage		1				1
Headache	9	21	9	20		1
Heart rate increased	2	4	2	4		
Herpes zoster	1	1	1	1		
Hormone level abnormal	1	1	1	1		
Hyperhidrosis	1	3	1	3		
Hypersensitivity		1				1
Hypoaesthesia	4	8	4	8		
Hypotension	1	1	1	1		
Incorrect dose administered		1		1		
Infection		1		1		
Inflammation		1				1
Insomnia		1		1		
Intermenstrual bleeding	1	1	1	1		
Joint noise		1		1		
Joint range of motion decreased	1	1	1	1		
Leukocytosis		1				1
Lip swelling	1	1	1	1		
Liver injury		1				1
Loss of consciousness		1				1
Loss of personal independence in daily activities		1		1		
Lung disorder		1		1		
Lymphadenopathy		2		2		
Malaise	1	3	1	3		
Maternal exposure during pregnancy	1	2		1	1	1
Menstrual disorder	1	1	1	1		
Menstruation irregular	2	2	2	2		
Movement disorder		1		1		
Multiple organ dysfunction syndrome		1				1
Muscle contractions involuntary		1		1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscular weakness	1	3		1	1	2
Musculoskeletal stiffness		1		1		
Myalgia	11	14	11	14		
Myocarditis	6	42			6	42
Nasal congestion	1	1	1	1		
Nasopharyngitis		1		1		
Nausea	3	7	3	7		
Neck pain		2		2		
Neuritis		1		1		
Nightmare	1	1	1	1		
Non-Hodgkin's lymphoma		1				1
Oedema peripheral		1		1		
Off label use		1		1		
Oropharyngeal pain	1	4	1	4		
Overdose		2		2		
Pain	1	8	1	6		2
Pain in extremity	4	13	4	13		
Pain in jaw		1		1		
Pallor		1		1		
Palpitations		2		1		1
Paraesthesia	2	5	2	5		
Paralysis		1				1
Pericarditis		10				10
Peripheral coldness		1		1		
Peripheral swelling		1		1		
Pleuritic pain		1		1		
Polymenorrhoea	1	1	1	1		
Premature labour		1				1
Presyncope		1				1
Product administered at inappropriate site		1		1		
Product preparation error		1		1		
Product use issue		2		2		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pruritus	1	3	1	2		1
Pulmonary embolism		1				1
Purpura		1		1		
Pyrexia	13	32	13	28		4
Rash	2	3	2	2		1
Rash pruritic	1	1	1	1		
Seizure		1				1
Sensory loss	1	1	1	1		
Shock		1				1
Sinus tachycardia		1				1
Skin discolouration		2		2		
Skin disorder		1		1		
Suffocation feeling		1				1
Superior sagittal sinus thrombosis		1				1
Swelling face	1	1	1	1		
Systemic inflammatory response syndrome		7				7
Tachycardia		1				1
Taste disorder	1	1	1	1		
Tenderness		1		1		
Testicular pain		1		1		
Throat tightness	1	1			1	1
Tic	1	1	1	1		
Tinnitus		3		1		2
Toothache		1		1		
Transient ischaemic attack	1	1			1	1
Tremor	1	2	1	2		
Troponin increased		2				2
Urticaria	1	1	1	1		
Uterine pain	1	1	1	1		
Vaccination site bruising		1		1		
Vaccination site discomfort		1		1		
Vaccination site erythema		2		1		1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site joint movement impairment		1		1		
Vaccination site pain	8	21	8	21		
Vaccination site pruritus		1		1		
Vaccination site reaction		1		1		
Vaccination site swelling	1	3	1	2		1
Vaginal haemorrhage	1	4	1	2		2
Vitamin B12 decreased		1				1
Vomiting	2	3	2	3		
Wheezing	1	1	1	1		
	159	487	143	347	16	140

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal pain	2	6			2	5		1
Abdominal pain upper		1				1		
Abortion spontaneous		2						2
Acute kidney injury	2	3					2	3
Acute respiratory distress syndrome		1						1
Adnexa uteri pain		1				1		
Ageusia		1				1		
Allergy to vaccine		1						1
Alopecia	1	1			1	1		
Amenorrhoea	2	2			2	2		
Amylase increased	1	1					1	1
Anaemia		1				1		
Anaesthesia	1	1			1	1		
Anaesthesia oral		1				1		
Anal haemorrhage		1				1		
Anaphylactic reaction		3						3
Aneurysm ruptured	1	1					1	1
Angina pectoris		1						1
Angioedema		1						1
Anorectal discomfort		1				1		
Anxiety	1	4			1	4		
Aphasia		1						1
Arrhythmia	1	1					1	1
Arthralgia	5	16			5	14		2
Arthritis reactive		1						1
Asthenia	26	53			25	47	1	6
Atrial fibrillation		3						3
Atrioventricular block	1	1					1	1
Axillary pain	1	1			1	1		
Back pain	4	8			3	7	1	1
Bell's palsy		3						3
Blister	1	2			1	1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood chloride increased		1
Blood creatine phosphokinase increased		1
Blood creatinine abnormal		1
Blood glucose increased		1
Blood iron decreased	1	1
Blood lactate dehydrogenase increased		1
Blood phosphorus decreased	1	1
Blood pressure abnormal		1
Blood pressure fluctuation		1
Blood pressure increased		2
Blood pressure systolic increased		1
Blood triglycerides increased	1	1
Body temperature decreased		1
Bone pain	4	4
Breast inflammation		1
Bruxism	1	1
Cardiac arrest		2
Cardiac failure	1	1
Cerebrovascular accident		2
Chest discomfort	2	3
Chest pain	4	8
Chills	14	40
Choking		3
Cold sweat	1	1
Confusional state	3	3
Contusion	1	2
Cough	2	6
COVID-19	2	11
C-reactive protein increased	1	1
Deafness		3
Deafness neurosensory		2
Death	1	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
			1		
					1
				1	1
					1
				1	1
					1
					1
					2
			1		
				1	1
			1		
		4	4		
			1		
				1	1
					2
				1	1
					2
		1	1	1	2
		4	6		2
		13	36	1	4
					3
		1	1		
		3	3		
		1	2		
		1	4	1	2
	1			2	11
				1	1
					3
					2
				1	7

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Decreased activity	1	1
Decreased appetite	1	5
Deep vein thrombosis		1
Depressed mood		3
Depression		1
Diarrhoea	2	10
Discomfort	4	4
Disease recurrence		3
Disturbance in attention	1	1
Dizziness	9	24
Drug hypersensitivity		1
Drug-induced liver injury		1
Drug ineffective	1	8
Dysgeusia	1	7
Dyskinesia		3
Dysmenorrhoea	1	1
Dyspepsia	1	3
Dysphagia		4
Dysphemia		1
Dyspnoea	2	17
Dyspnoea exertional	1	1
Dysstasia	1	2
Ear discomfort	1	5
Ear pain	1	3
Eosinophilic oesophagitis		1
Eosinophilic pneumonia acute		1
Epilepsy	1	1
Epistaxis	1	2
Erythema	1	7
Erythema nodosum	1	1
Exposure during pregnancy	1	4
Exposure to SARS-CoV-2		

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	4		1
					1
			2		1
					1
		2	8		2
		4	4		
			2		1
		1	1		
		9	20		4
					1
					1
	1			1	8
		1	7		
			2		1
		1	1		
		1	3		
			3		1
					1
		2	7		10
		1	1		
		1	1		1
		1	3		2
		1	3		
			1		
					1
				1	1
				1	2
		1	5		2
				1	1
		1	3		1
	1				

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Extensive swelling of vaccinated limb		1
Eye infection		1
Eye pain		1
Eye swelling		1
Facial pain		1
Facial paralysis	2	10
Faeces soft	1	1
Fall		1
Fatigue	10	37
Feeling abnormal	2	7
Feeling cold	2	4
Feeling hot		2
Feeling of body temperature change		1
Food craving		1
Formication	1	1
Gait disturbance		2
Generalised oedema	1	1
Generalised tonic-clonic seizure	1	1
Gingival bleeding		1
Glomerular filtration rate decreased		1
Glomerulonephritis minimal lesion	2	2
Haematochezia		1
Hangover		1
Headache	19	59
Heart rate increased	2	6
Heart rate irregular	1	1
Heavy menstrual bleeding	6	8
Hemiparaesthesia		1
Hemiparesis	1	1
Hepatitis		1
Herpes virus infection		1
Herpes zoster	1	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
					1
					1
					1
				2	10
		1	1		
			1		
		10	36		1
		1	5	1	2
		2	4		
			2		
			1		
			1		
		1	1		
					2
				1	1
				1	1
					1
					1
				2	2
					1
			1		
		19	52		7
		2	6		
		1	1		
		6	8		
					1
				1	1
					1
			1		
		1	8		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hot flush	2	2
Hyperacusis	1	1
Hyperbilirubinaemia		1
Hyperhidrosis		4
Hypersensitivity	1	8
Hypersomnia		1
Hypertension		1
Hypoacusis	1	3
Hypoaesthesia	4	18
Hypoaesthesia oral		6
Illness		1
Impaired quality of life		1
Inappropriate schedule of product administration		4
Inflammation of wound		1
Inflammatory marker increased		1
Influenza like illness	2	5
Insomnia	1	3
Intermenstrual bleeding	3	4
International normalised ratio increased		1
Joint range of motion decreased	1	1
Joint swelling		2
Laryngeal inflammation		1
Laryngitis bacterial		1
Leukocytosis		1
Leukopenia		1
Ligament sprain	1	1
Limb discomfort	1	2
Loss of consciousness		2
Loss of libido		1
Loss of personal independence in daily activities		1
Lymphadenopathy	1	12
Lymphocyte count decreased	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2		
		1	1		
					1
			4		
		1	3		5
			1		
			1		
		1	2		1
		4	14		4
			5		1
			1		
			1		
			4		
			1		
					1
		2	5		
		1	3		
		3	4		
					1
				1	1
			1		1
			1		
					1
					1
					1
		1	1		
		1	2		
					2
			1		
			1		
		1	8		4
				1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lymphopenia		1
Malaise	1	9
Maternal exposure during pregnancy	4	7
Maternal exposure timing unspecified		1
Mean cell haemoglobin decreased		1
Menstrual disorder	4	5
Menstruation delayed	4	4
Menstruation irregular	8	10
Mental disorder	1	1
Migraine	1	2
Migraine with aura	1	1
Miliaria		1
Mobility decreased		2
Mood swings	1	1
Multiple sclerosis		3
Multiple sclerosis relapse		1
Muscle contractions involuntary		1
Muscle rigidity		1
Muscle spasms	1	2
Muscular weakness	2	3
Musculoskeletal chest pain	1	1
Musculoskeletal stiffness	1	1
Myalgia	14	38
Myocarditis	4	18
Nasopharyngitis	1	2
Nausea	9	20
Neck pain	1	1
Nephrotic syndrome	2	2
Nervousness		1
Neuralgia		2
Neutrophil count decreased		1
Neutrophil count increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			6	1	3
		4	7		
			1		
					1
		3	4	1	1
		4	4		
		8	10		
		1	1		
		1	2		
		1	1		
			1		
			1		1
		1	1		
					3
					1
			1		
			1		
		1	2		
		2	3		
		1	1		
				1	1
		12	34	2	4
				4	18
		1	2		
		8	18	1	2
				1	1
				2	2
			1		
			1		1
			1		
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Night sweats	1	1
Ocular discomfort	2	2
Odynophagia		3
Off label use		3
Oral herpes		1
Oropharyngeal pain	3	8
Osteomyelitis		1
Otitis media		1
Ovulation delayed	1	1
Oxygen saturation decreased		1
Pain	9	20
Pain in extremity	8	19
Pain in jaw	2	2
Pallor		1
Palpitations		3
Paraesthesia	3	24
Paraesthesia oral	1	6
Paralysis		2
Parosmia	1	3
Pelvic pain		1
Pericardial effusion	1	1
Pericarditis	1	7
Peripheral coldness		1
Peripheral swelling		1
Pharyngeal swelling		3
Pleural effusion	1	1
Pleuritic pain		1
Pneumonia	1	1
Polymenorrhoea	1	1
Poor quality product administered		1
Poor quality sleep		1
Premenstrual syndrome	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1	1	1
			2		1
			3		
					1
		2	6	1	2
					1
			1		
		1	1		
					1
		8	17	1	3
		7	16	1	3
		2	2		
			1		
			3		
		3	18		6
		1	5		1
					2
		1	3		
			1		
				1	1
				1	7
			1		
					1
			1		2
		1	1		
					1
				1	1
		1	1		
			1		
			1		
		2	2		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Presyncope	2	4
Product administered at inappropriate site		1
Product use issue	1	3
Pruritus	1	8
Pulmonary congestion	1	1
Pulmonary embolism		3
Pulseless electrical activity		1
Pupil fixed		1
Pyrexia	19	46
Rash	2	7
Rash maculo-papular		1
Rash pruritic	1	2
Reduced facial expression		1
Respiratory arrest		1
Right ventricular enlargement		1
Ruptured cerebral aneurysm		1
Sensory disturbance		2
Sensory loss		1
Sinus tachycardia	1	2
Skin tightness	1	1
Sleep attacks	1	1
Sleep disorder due to general medical condition, insomnia type		1
Sneezing		2
Somnolence	1	2
Speech disorder		4
Still birth		1
Streptococcal infection		1
Stress		1
Subarachnoid haemorrhage	1	1
Suffocation feeling		1
Suicidal ideation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3	1	1
			1		
		1	3		
		1	6		2
				1	1
					3
					1
					1
		19	40		6
		2	5		2
			1		
		1	2		
			1		
					1
			1		
			2		
					1
		1	2		
		1	1		
		1	1		
			1		
			1		1
		1	2		
			2		2
					1
					1
			1		
				1	1
					1
					1

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Swelling		2
Swollen tongue		2
Syncope		1
Systemic inflammatory response syndrome		1
Tachycardia	1	2
Taste disorder		1
Therapeutic response unexpected	1	1
Thirst		1
Throat irritation		1
Throat tightness		1
Thrombosis	1	1
Tinnitus	1	7
Tongue discomfort		1
Tonsillitis		1
Toothache	1	1
Tremor		2
Trigeminal neuralgia	1	1
Twin pregnancy		1
Urine sodium increased	1	1
Urticaria		3
Uterine contractions abnormal		1
Uterine haemorrhage		1
Uterine pain		1
Uveitis		1
Vaccination failure	1	3
Vaccination site cellulitis		1
Vaccination site discomfort	1	1
Vaccination site erythema	3	6
Vaccination site haematoma	1	1
Vaccination site haemorrhage	1	1
Vaccination site inflammation		1
Vaccination site movement impairment	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
					2
					1
					1
				1	2
			1		
		1	1		
			1		
					1
					1
				1	1
		1	4		3
			1		
					1
		1	1		
		1	1		
			1		
				1	1
			1		2
			1		
			1		
					1
				1	3
			1		
		1	1		
		2	5	1	1
		1	1		
		1	1		
			1		
		1	1		

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site oedema	1	1					1	1
Vaccination site pain	17	47			17	47		
Vaccination site reaction	1	1			1	1		
Vaccination site swelling	2	4			1	3	1	1
Vaginal haemorrhage	7	12			7	9		3
Vaginal ulceration	1	1			1	1		
Vein discolouration		1				1		
Vertigo	1	2			1	1		1
Vision blurred	1	3			1	3		
Vomiting	2	7			1	5	1	2
Vulval ulceration	1	1			1	1		
Walking disability	1	1			1	1		
Weight decreased	1	3			1	2		1
Wrong technique in product usage process		1				1		
Yawning		2				1		1
Yellow skin	1	1			1	1		
	378	1,139		3	313	805	65	334

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Activated partial thromboplastin time shortened		1				1
Acute myocardial infarction		3				3
Allergy to vaccine		2		1		1
Anaphylactic reaction		2				2
Anaphylactic shock		1				1
Anger		1		1		
Angina pectoris		2				2
Anosmia		1		1		
Anxiety		2				2
Aphonia		1				1
Aphthous ulcer		1		1		
Arrhythmia		3				3
Arthralgia	2	8	2	7		1
Arthritis	1	1	1	1		
Arthritis infective	1	1			1	1
Asthenia	4	29	3	24	1	5
Asymptomatic COVID-19		1				1
Atelectasis		1				1
Atrial fibrillation		2				2
Autoimmune haemolytic anaemia		1				1
Back pain		4		3		1
Bell's palsy	1	5			1	5
Blood chloride increased		1		1		
Blood glucose increased		2		1		1
Blood pressure increased	2	5	1	3	1	2
Bone pain	1	3	1	3		
Burning sensation		1				1
Cardiac arrest		4				4
Cardiac failure		1				1
Cardiac flutter		1				1
Cardiac tamponade		1				1
Cerebellar haemorrhage		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral ischaemia		1				1
Cerebrovascular accident		1				1
Chest discomfort		1		1		
Chest pain		4		3		1
Chills	3	12	3	11		1
Chronic obstructive pulmonary disease		1				1
Cold sweat		1		1		
Confusional state		1				1
Constipation	1	1	1	1		
Cough		2		1		1
COVID-19		8		1		7
C-reactive protein increased		1		1		
Crying		1				1
Death		6				6
Decreased appetite		1		1		
Depressed level of consciousness		1				1
Diabetic ketoacidosis		1				1
Diarrhoea		1		1		
Diverticulitis		1				1
Dizziness		7		5		2
Drug hypersensitivity		1		1		
Drug ineffective		6				6
Dysarthria		1				1
Dysgeusia	1	2	1	2		
Dysmenorrhoea		1		1		
Dysphagia		1				1
Dyspnoea	1	12	1	5		7
Dyspnoea exertional		1		1		
Dysstasia		1		1		
Ear discomfort		1		1		
Ear pain		1		1		
Encephalitis		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Epilepsy		1				1
Erythema		3		3		
Eyelid oedema		1		1		
Eye pain	1	1	1	1		
Facial asymmetry		1		1		
Facial nerve disorder		1		1		
Facial paralysis		6				6
Facial paresis		1				1
Fall		1		1		
Fatigue	1	12	1	11		1
Feeling abnormal	1	3	1	3		
Feeling cold	1	3	1	3		
Feeling hot		2		2		
Formication		2		2		
General physical health deterioration		1				1
Guillain-Barre syndrome	1	2			1	2
Haematemesis	1	1			1	1
Headache	3	19	3	18		1
Head discomfort		1		1		
Heart rate increased	1	1			1	1
Heavy menstrual bleeding		1		1		
Hepatic function abnormal		1				1
Herpes zoster	1	8		5	1	3
Hyperhidrosis		1		1		
Hypersensitivity	1	5		1	1	4
Hypertension		2		1		1
Hypoaesthesia		6		6		
Hypoaesthesia oral		2		1		1
Hyponatraemia		1				1
Hypotension		3		1		2
Immune thrombocytopenia		2				2
Impaired gastric emptying	1	1			1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inappropriate schedule of product administration	1	2	1	2		
Infective tenosynovitis	1	1			1	1
Influenza		2		2		
Influenza like illness		4		4		
Insomnia	1	1	1	1		
International normalised ratio decreased		1				1
Limb injury		1		1		
Lip pruritus		1		1		
Lip swelling		2		1		1
Liver function test abnormal	1	1	1	1		
Loss of consciousness		3				3
Loss of personal independence in daily activities	1	1	1	1		
Lung disorder		1				1
Lymphadenopathy		1		1		
Lymphocyte count increased		1		1		
Malaise	1	10	1	8		2
Mean cell haemoglobin concentration decreased		1		1		
Mean cell haemoglobin decreased		2		2		
Mean cell volume decreased		1		1		
Mean platelet volume increased		1		1		
Mobility decreased		1		1		
Muscle twitching		1		1		
Muscular weakness		3		2		1
Musculoskeletal stiffness		1		1		
Myalgia	5	16	4	14	1	2
Myocardial infarction		3				3
Myocarditis		3				3
Nasopharyngitis		2		2		
Nausea	3	13	1	8	2	5
Neck pain		4		4		
Oedema mouth		1				1
Ophthalmic herpes zoster		2				2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral discomfort		2		2		
Oral herpes		1		1		
Oral pain		1		1		
Oropharyngeal discomfort		1		1		
Oropharyngeal pain		2		2		
Pain		9		6		3
Pain in extremity	1	13	1	13		
Palmar erythema		1		1		
Palpitations		4		3		1
Pancreatitis acute	1	1			1	1
Pancreatitis chronic	1	1			1	1
Paraesthesia	1	10	1	9		1
Paraesthesia oral		3		3		
Parosmia		1		1		
Pericardial effusion	1	1			1	1
Pericarditis	1	1			1	1
Peripheral swelling		1				1
Pharyngeal paraesthesia		1		1		
Pharyngeal swelling		1		1		
Pleurisy	1	1			1	1
Poor quality product administered		2		2		
Product deposit		1		1		
Product packaging quantity issue		1		1		
Pruritus	1	3	1	2		1
Pulse abnormal		1				1
Purpura		1				1
Pyrexia	4	17	4	13		4
Rash	3	8	2	5	1	3
Rash macular		1		1		
Recall phenomenon		1		1		
Red blood cell count increased		1		1		
Respiratory arrest		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory disorder		1				1
Rhinorrhoea		1		1		
SARS-CoV-2 ant body test negative		2		1		1
SARS-CoV-2 test positive		1				1
Seizure		1				1
Sensory disturbance	1	2	1	2		
Sensory loss		1		1		
Skin burning sensation		1		1		
Speech disorder		2		1		1
Sudden death		1				1
Sudden hearing loss		2				2
Swelling face		1		1		
Swollen tongue		1				1
Syncope		1				1
Systemic inflammatory response syndrome		1				1
Tachycardia		4		4		
Taste disorder		1		1		
Therapeutic response unexpected	1	2	1	2		
Thirst		1				1
Thrombocytopenia		1				1
Thrombosis		1				1
Tinnitus	1	2	1	1		1
Tongue oedema		1				1
Transient ischaemic attack		1				1
Tremor		2		2		
Urticaria		2		1		1
Vaccination failure		2				2
Vaccination site cellulitis		1				1
Vaccination site erythema		1		1		
Vaccination site lymphadenopathy		1		1		
Vaccination site movement impairment		1		1		
Vaccination site pain	2	21	2	21		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site paraesthesia		1		1		
Vaccination site swelling		1		1		
Ventricular fibrillation		2				2
Vertigo		1				1
Vestibular neuronitis		1				1
Vlith nerve paralysis		1				1
Vomiting	1	3			1	3
Wheezing		2				2
	66	529	45	331	21	198

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		2		2		
Abdominal pain upper		1		1		
Acute myocardial infarction		1				1
Alcohol intolerance		1		1		
Anaemia		1				1
Anaphylactic reaction		1				1
Arthralgia	2	7	2	6		1
Arthritis		1		1		
Arthropathy		1		1		
Asthenia		11		11		
Asthma		1		1		
Atrial f brillation		2				2
Back pain		2		2		
Bell's palsy		5				5
Blindness transient		1				1
Blood pressure decreased		1		1		
Blood pressure increased	2	7	2	6		1
Bone pain		1		1		
Cardiac arrest		2				2
Cardiac death		1				1
Cardiac disorder		1				1
Cardiac dysfunction	1	1			1	1
Cardiac failure		2				2
Cardiomegaly	1	1			1	1
Cerebral haemorrhage		1				1
Cerebrovascular accident		5				5
Cheilitis		1		1		
Chest pain		6		3		3
Chills		8		8		
Cholelithiasis		1		1		
Chronic lymphocytic leukaemia		1				1
Cold sweat		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Confusional state		1				1
COVID-19	4	13		2	4	11
Deafness neurosensory		2				2
Deafness unilateral		1				1
Death	1	13			1	13
Decreased appetite		2		2		
Deep vein thrombosis	1	2			1	2
Depression		1		1		
Diarrhoea		2		2		
Disseminated intravascular coagulation		1				1
Dizziness		9		8		1
Drug ineffective	4	11			4	11
Dysgeusia		2		2		
Dyspepsia		3		3		
Dyspnoea		8		2		6
Dyspnoea exertional		1		1		
Dysstasia		1				1
Ear discomfort		1		1		
Ear infection		1		1		
Ear pain		1		1		
Erythema		3		3		
Erythromelalgia	1	1			1	1
Eye haemorrhage		1				1
Eye pain	1	2	1	1		1
Eye swelling		1				1
Facial paralysis		6				6
Facial paresis		1				1
Fall		2				2
Fatigue	1	9	1	9		
Feeling abnormal		5		2		3
Feeling cold		4		4		
Feeling hot		2		2		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Food refusal		1				1
Formication		1		1		
Gait disturbance		3				3
General physical health deterioration		1				1
Guillain-Barre syndrome		2				2
Haemolytic anaemia		1				1
Headache	3	13	3	13		
Heart rate increased		1		1		
Hepatitis acute		1				1
Herpes zoster		2		1		1
Hip fracture		1				1
Hot flush	1	1	1	1		
Hyperhidrosis		2		2		
Hypertension	1	3			1	3
Hypoaesthesia		5		5		
Hypoaesthesia oral		2		2		
Hypoaesthesia teeth		1		1		
Hypotension		1		1		
Hypoventilation		1				1
Illrd nerve paralysis		1				1
Illness		1		1		
Incomplete course of vaccination	1	1	1	1		
Influenza		1		1		
Influenza like illness		1		1		
Insomnia		2		2		
Jaundice		1		1		
Leukocytosis		2				2
Lip disorder		1		1		
Lip swelling		1		1		
Localised infection		1				1
Loss of consciousness		2				2
Lymphocytosis		1		1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise	1	2	1	2		
Mobility decreased	1	1	1	1		
Movement disorder		2		1		1
Multiple sclerosis relapse		2				2
Muscle spasms	1	1	1	1		
Muscular weakness		1				1
Musculoskeletal chest pain		1		1		
Myalgia	4	12	4	10		2
Myasthenia gravis		1				1
Myocardial infarction		2				2
Myocarditis	2	2			2	2
Nausea		7		5		2
Nephrolithiasis		1				1
Nervous system disorder		1		1		
Neuralgic amyotrophy		1				1
Neutropenia		1				1
Oral herpes		1		1		
Oropharyngeal pain		2		2		
Overdose		1		1		
Oxygen saturation decreased		1		1		
Pain	1	2	1	2		
Pain in extremity	2	9	2	9		
Pain in jaw		1		1		
Palpitations		2		2		
Pancreatitis		1				1
Pancytopenia		1				1
Paraesthesia		6		5		1
Paraesthesia oral		2		2		
Pelvic fracture		1				1
Pericardial effusion	1	2			1	2
Pericarditis	1	5			1	5
Peripheral coldness		1		1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pleural effusion		1				1
Pneumonia		2				2
Pneumonia aspiration		1				1
Product preparation error		1		1		
Pseudomonas infection		1				1
Psoriatic arthropathy		1				1
Pulmonary embolism	1	2			1	2
Pulpitis dental		1		1		
Pyrexia	2	12	2	9		3
Rash	2	4	2	4		
Rash vesicular		1				1
Recall phenomenon		1		1		
Respiratory disorder		1		1		
Respiratory rate increased		1				1
Rhinorrhoea		1		1		
Rib fracture		1				1
Seizure		3				3
Sensory loss		1				1
Sinus bradycardia	1	1			1	1
Skin burning sensation		2		2		
Skin exfoliation		1		1		
Skin reaction		1		1		
Speech disorder		1		1		
Sudden hearing loss		1				1
Swelling face		1		1		
Syncope	1	5			1	5
Tachycardia		1				1
Thrombosis		2				2
Tic	1	1	1	1		
Tonic convulsion		1				1
Toothache		1		1		
Tooth injury		1		1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Transient ischaemic attack		1				1
Tremor		4		4		
Underdose		1		1		
Urosepsis		1				1
Urticaria		2		1		1
Vaccination site erythema	1	1	1	1		
Vaccination site induration	1	1	1	1		
Vaccination site pain	2	4	2	4		
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	1	2	1	2		
Vertigo		4		2		2
Vomiting		4		4		
Wheezing		1		1		
	53	410	32	231	21	179

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory failure		1				1
Agitation		1		1		
Angioedema		1				1
Aphasia		1		1		
Aspiration		1				1
Asthenia		7		4		3
Atrial f brillation	1	1			1	1
Back pain		1				1
Blood pressure decreased		1				1
Bone pain		1		1		
Brain death		1				1
Brain injury		1				1
Brain oedema		1				1
Cardiac arrest		4				4
Cardiac disorder		1				1
Cardiac failure		4				4
Cardiac failure chronic		1				1
Cerebrovascular accident		2				2
Chills	1	1	1	1		
Chronic obstructive pulmonary disease		1				1
Circulatory collapse		1				1
Contusion		1				1
Cough		1		1		
COVID-19		3		1		2
C-reactive protein increased		1				1
Crying		1		1		
Death		6				6
Diarrhoea		1		1		
Dizziness		3		1		2
Drug hypersensitivity		1				1
Drug ineffective		2				2
Dyskinesia		3		2		1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspepsia		1		1		
Dyspnoea	1	7		1	1	6
Endocarditis		1				1
Erythema	1	1	1	1		
Eye irritation		2		1		1
Face injury		1				1
Facial paralysis		2				2
Faeces soft	1	1	1	1		
Fall		2				2
Fatigue		2		1		1
Feeling cold		1		1		
Gait disturbance		1		1		
Gastric haemorrhage		1				1
Gastrointestinal necrosis		1				1
General physical health deterioration		2				2
Haematemesis		1				1
Haemorrhage		1				1
Headache		2		2		
Herpes virus infection	1	1	1	1		
Herpes zoster		1		1		
Hypertension		1				1
Hypotension		1				1
Hypothermia		1				1
Inflammation	1	2			1	2
Ischaemic stroke		1				1
Lacrimation increased		2		1		1
Leukocytosis		2				2
Loss of consciousness		2				2
Lung infiltration		1				1
Malaise		1		1		
Movement disorder		1		1		
Myalgia	1	3	1	3		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myocardial infarction		2				2
Oedema		1				1
Pain		3		3		
Pain in extremity		1				1
Pericardial effusion	1	1			1	1
Peripheral artery occlusion		1				1
Peripheral ischaemia		1				1
Personality change		1		1		
Pleural effusion	1	2			1	2
Pneumonia aspiration		1				1
Productive cough	1	1			1	1
Psychomotor hyperactivity		1		1		
Pulmonary embolism		1				1
Pulmonary oedema		2				2
Pyrexia	1	3			1	3
Respiratory disorder		1				1
Respiratory distress		1				1
Restlessness		1				1
Seizure		3				3
Sepsis		1				1
Septic shock		1				1
Slow speech		1				1
Speech disorder		1				1
Sudden hearing loss		1				1
Suffocation feeling		1				1
Syncope		2				2
Systemic inflammatory response syndrome		1				1
Therapeutic response unexpected	1	2	1	2		
Tinnitus		1				1
Transient ischaemic attack		4				4
Unresponsive to stimuli		1				1
Vomiting	1	2			1	2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	14	154	6	40	8	114

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		2		2		
Abdominal pain upper		1		1		
Abnormal faeces	1	1	1	1		
Ageusia		1		1		
Alanine aminotransferase increased	1	1	1	1		
Allergy to vaccine		1		1		
Alopecia		1		1		
Anaemia	1	1			1	1
Angina pectoris		1				1
Angioedema		1				1
Anosmia		2		2		
Anxiety		1		1		
Arrhythmia		1				1
Arthralgia	7	21	4	15	3	6
Aspartate aminotransferase increased	1	1	1	1		
Asthenia	13	56	11	53	2	3
Asthenopia		1		1		
Asymptomatic COVID-19		3				3
Atrial f brillation		1				1
Back pain	1	4	1	4		
Balance disorder		1		1		
Basedow's disease		1				1
Bell's palsy		4				4
Blood creatine phosphokinase increased	1	1			1	1
Blood fibrinogen increased	1	1			1	1
Blood immunoglobulin M increased		1		1		
Blood iron decreased	1	1			1	1
Blood pressure fluctuation	1	1			1	1
Blood pressure increased	2	4	2	3		1
Body temperature decreased	1	3	1	3		
Body temperature increased	1	1	1	1		
Bone pain	1	1	1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast engorgement		1		1		
Breast pain		1		1		
Burning sensation	2	2	2	2		
Cartilage injury		1				1
Cerebrovascular accident		1				1
Chest discomfort	2	4	1	3	1	1
Chest pain	2	6	1	4	1	2
Chills	17	41	17	41		
Choking		1				1
Chronic inflammatory demyelinating polyradiculoneuropathy		1				1
Cold sweat		1		1		
Condition aggravated	1	4	1	3		1
Conduction disorder	1	1	1	1		
Confusional state		2		2		
Conjunctivitis	1	1	1	1		
Coronavirus infection	2	5			2	5
Cough	2	5	2	5		
COVID-19	3	35		4	3	31
C-reactive protein increased	1	2		1	1	1
Cyanosis	1	1	1	1		
Death		1				1
Decreased appetite	1	4	1	4		
Depressed mood		2		2		
Diarrhoea	1	6	1	6		
Discomfort		3		3		
Disease recurrence		2		1		1
Dizziness	8	18	8	18		
Drug ineffective	4	32			4	32
Dry mouth		1		1		
Dysaesthesia		1		1		
Dyschromatopsia		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysgeusia		2		2		
Dysphagia		1		1		
Dyspnoea	3	10	2	5	1	5
Dyspnoea exertional		1		1		
Dysstasia		1		1		
Ear pain	2	3	2	3		
Eczema	1	1	1	1		
Electric shock sensation		1		1		
Epistaxis		1				1
Erythema	2	3	2	2		1
Expired product administered	2	2	2	2		
Exposure during pregnancy	2	3	2	3		
Exposure via breast milk	4	6	4	6		
Extensive swelling of vaccinated limb		1		1		
Eye infection		2		2		
Eye irritation	1	1	1	1		
Eyelid function disorder		1		1		
Eye pain	1	6	1	5		1
Eye swelling		2		1		1
Facial pain	1	1	1	1		
Facial paralysis		1				1
Fall		1		1		
Fatigue	10	33	9	32	1	1
Fear of injection	1	1	1	1		
Feeling abnormal	4	8	4	6		2
Feeling cold	2	8	2	8		
Feeling hot	1	1	1	1		
Finger deformity	1	1			1	1
Flushing	1	1	1	1		
Foetal death		2				2
Foetal exposure during pregnancy		1				1
Foetal heart rate abnormal		1				1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Foetal movement disorder		1				1
Frustration tolerance decreased	1	1	1	1		
Gastroenteritis viral		1		1		
Gingivitis		1		1		
Guillain-Barre syndrome		1				1
Hallucination		1				1
Hallucination, auditory		1				1
Headache	24	64	24	63		1
Head discomfort		2		2		
Head injury		1				1
Heart rate increased	1	3	1	2		1
Heavy menstrual bleeding	8	8	8	8		
Hemiplegia		1				1
Hepatic enzyme increased		1				1
Hepatic failure		1				1
Hepatic function abnormal		1				1
Hepatomegaly	1	1			1	1
Herpes simplex		1		1		
Herpes zoster	1	7	1	7		
High risk pregnancy	1	1	1	1		
Hormone level abnormal		1		1		
Hot flush	1	1	1	1		
Hyperhidrosis		2		2		
Hypersensitivity	1	4	1	3		1
Hypertension		1		1		
Hypoaesthesia	2	14	2	14		
Hypoaesthesia oral		3		3		
Hypomenorrhoea	1	3	1	3		
Inappropriate schedule of product administration		2		2		
Incomplete course of vaccination		1		1		
Incorrect dose administered		1		1		
Incorrect route of product administration	1	1	1	1		

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inflammation		2		2		
Influenza	1	1	1	1		
Influenza like illness	2	7	2	7		
Initial insomnia		1		1		
Injection site erythema	1	1	1	1		
Insomnia	3	5	2	4	1	1
Intentional dose omission		1		1		
Intermenstrual bleeding	3	3	3	3		
International normalised ratio increased		1		1		
Joint range of motion decreased	1	2			1	2
Joint swelling	1	2	1	2		
Leukocytosis		1				1
Limb discomfort		1		1		
Lip pruritus		1		1		
Liquid product physical issue	3	18	3	18		
Liver function test increased		1		1		
Loss of consciousness		2				2
Lymphadenopathy	2	8	2	8		
Malaise	2	11	2	9		2
Maternal exposure during pregnancy	2	3	2	3		
Mechanical urticaria		1		1		
Menstrual disorder	4	5	4	5		
Menstruation irregular	4	4	4	4		
Mental disorder		1		1		
Migraine	1	2	1	2		
Mobility decreased		2		1		1
Monoplegia		1				1
Mood altered		1		1		
Motor dysfunction		1				1
Movement disorder	1	2	1	2		
Multiple sclerosis relapse		1				1
Muscle contractions involuntary		2		2		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle disorder		1		1		
Muscle spasms	1	3	1	3		
Muscular weakness	1	2	1	1		1
Musculoskeletal chest pain		1		1		
Musculoskeletal discomfort		1		1		
Musculoskeletal disorder	1	1			1	1
Myalgia	15	39	14	37	1	2
Myasthenia gravis		1				1
Myocarditis		4				4
Nasopharyngitis		1		1		
Nausea	3	22	3	22		
Neck pain	5	8	2	4	3	4
Nervous system disorder	1	1	1	1		
Neuralgia		1				1
Neuralgic amyotrophy		2		2		
Night sweats	1	1	1	1		
Noninfective encephalitis	1	1			1	1
Ocular discomfort		1		1		
Ocular hyperaemia		1		1		
Odynophagia	1	1	1	1		
Oedema peripheral		1				1
Off label use		1		1		
Oral herpes	1	5	1	4		1
Oropharyngeal pain	3	5	3	5		
Overdose		2		2		
Pain	11	21	10	19	1	2
Pain in extremity	9	26	8	24	1	2
Pain in jaw		1		1		
Palpitations	2	3	2	3		
Paraesthesia	9	18	8	16	1	2
Paraesthesia oral		6		5		1
Paralysis		1				1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraplegia		1				1
Pericardial effusion	1	2			1	2
Pericarditis		18				18
Peripheral coldness	1	3	1	3		
Peripheral swelling	1	4	1	4		
Photopsia		1		1		
Pneumonia		3				3
Pneumonia pseudomonal	1	1			1	1
Polymenorrhoea	1	1	1	1		
Polyneuropathy		1				1
Poor quality product administered	7	36	7	36		
Poor quality sleep	1	2	1	2		
Premenstrual syndrome		1		1		
Presyncope	1	2	1	2		
Product administered at inappropriate site	1	2	1	2		
Product colour issue	1	1	1	1		
Product complaint		1		1		
Product packaging quantity issue		11		11		
Product preparation error		2		2		
Product preparation issue		2		2		
Product quality issue	2	2	2	2		
Product temperature excursion issue	1	1	1	1		
Product use issue		1		1		
Pruritus	1	4	1	4		
Pyrexia	19	60	17	56	2	4
Rash	2	8	2	7		1
Rash macular		1		1		
Respiratory disorder		1				1
Restlessness		1		1		
Rhabdomyolysis		1				1
Rhinalgia		1		1		
Rhinorrhoea		2		2		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
SARS-CoV-2 ant body test negative		1		1		
SARS-CoV-2 test positive		1				1
Schizophrenia		1				1
Seizure		9				9
Sensory disturbance		1				1
Skin discolouration		1		1		
Sleep disorder		2		1		1
Sneezing		1		1		
Somnolence		2		2		
Stress		1		1		
Sudden cardiac death		1				1
Suspected COVID-19		1				1
Swelling		1		1		
Swelling face	1	2	1	1		1
Swollen tongue		1				1
Syncope		3				3
Syndactyly		1				1
Tachycardia		1		1		
Therapeutic response unexpected	6	10	6	10		
Thinking abnormal		1		1		
Throat irritation	1	1	1	1		
Tooth loss	1	1	1	1		
Tracheal oedema		1				1
Transaminases increased	1	1			1	1
Tremor	1	2	1	2		
Ultrasound breast abnormal	1	1			1	1
Underdose		2		2		
Urinary tract infection	1	2		1	1	1
Urticaria		1		1		
Uveitis		1				1
Vaccination failure	1	6			1	6
Vaccination site erythema	2	8	2	8		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site hypersensitivity		2		2		
Vaccination site lymphadenopathy		1		1		
Vaccination site movement impairment	1	2	1	2		
Vaccination site pain	9	52	9	51		1
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling		8		8		
Vaccination site vesicles		1		1		
Vaccination site warmth	1	1	1	1		
Vaginal haemorrhage		2		2		
Vertigo		2		2		
Vision blurred		4		4		
Vomiting	5	10	5	10		
Walking disability	1	1	1	1		
Weight decreased	1	2	1	1		1
Wrong technique in product usage process		2		2		
	337	1,166	292	925	45	241

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ITALY

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1			1	1
Crying		1				1
Decreased appetite		1		1		
Ecchymosis	1	1			1	1
Epistaxis	1	1			1	1
Exposure via breast milk	2	8	2	5		3
Fatigue		1		1		
Febrile convulsion		1				1
Haemorrhage	1	1			1	1
Headache	1	1			1	1
Infantile vomiting		1		1		
Insomnia		1				1
Nervousness		1				1
Off label use	1	1	1	1		
Platelet count decreased	1	1			1	1
Product administered to patient of inappropriate age	1	2	1	2		
Pyrexia	1	2		1	1	1
Vomiting		1		1		
	11	27	4	13	7	14

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal distension	1	2				1	1	1
Abdominal pain	9	52			7	48	2	4
Abdominal pain lower		1				1		
Abdominal pain upper	2	15			2	14		1
Abnormal dreams	1	1			1	1		
Abscess		1						1
Accidental overdose	1	1					1	1
Acute polyneuropathy	1	1					1	1
Acute respiratory distress syndrome		1						1
Administration site erythema		2				2		
Administration site oedema		1				1		
Administration site pain		18				18		
Administration site reaction		1				1		
Administration site swelling		1				1		
Adrenomegaly	1	2			1	2		
Ageusia	3	5			3	5		
Agitation		1				1		
Amenorrhoea	1	2				1	1	1
Amnesia		1				1		
Anaesthesia	1	2			1	2		
Anaesthesia oral		1				1		
Anal incontinence		1				1		
Anaphylactic reaction		10						10
Anaphylactic shock	1	1					1	1
Angioedema	2	5					2	5
Anosmia	2	5			2	4		1
Antinuclear ant body positive		1						1
Anuria		1						1
Anxiety	2	9			1	5	1	4
Aphasia	1	2					1	2
Aphonia		2				1		1
Aphthous ulcer		3				3		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Appendicitis	1	1
Application site oedema		2
Arrhythmia		3
Arthralgia	67	541
Arthritis	1	2
Arthritis reactive		
Asthenia	61	393
Asthenopia		3
Asthma	1	4
Asthmatic crisis	1	2
Asymptomatic COVID-19	4	9
Atrial fibrillation		1
Axillary pain	2	19
Back pain	4	37
Balance disorder	2	3
Bell's palsy	1	4
Binocular eye movement disorder		1
Blindness	1	1
Blister	1	2
Blood pressure decreased	1	5
Blood pressure increased	1	4
Blood pressure systolic increased		3
Blood thyroid stimulating hormone increased		1
Body temperature abnormal	1	1
Body temperature increased		1
Bone pain	3	26
Bradycardia		4
Breakthrough pain		1
Bronchospasm	1	5
Burning sensation		3
Catheter site pain		1
Central nervous system lesion	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			2		
					3
		58	499	9	42
		1	2		
	1				
		61	369		24
			3		
		1	1		3
				1	2
			1	4	8
					1
	1	2	19		
		4	29		8
		1	2	1	1
				1	4
					1
				1	1
		1	2		
		1	4		1
		1	4		
			3		
			1		
		1	1		
			1		
		3	23		3
1	1				4
					1
		1	1		4
			3		
			1		
				1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chest discomfort	1	8
Chest pain	6	22
Chillblains		1
Chills	59	460
Choking		1
Choking sensation		3
Chromaturia		1
Circulatory collapse	1	1
Clonus		1
Cluster headache		1
Cognitive disorder		1
Cold burn		2
Cold sweat	2	11
Colitis	2	2
Condition aggravated		2
Confusional state	2	15
Conjunctivitis		2
Contusion		2
Convulsions local		1
Coordination abnormal		1
Cough	6	27
COVID-19	14	44
C-reactive protein abnormal		1
Cyanosis		2
Cystitis haemorrhagic	1	1
Deafness		1
Deafness neurosensory	1	1
Decreased appetite	2	8
Deep vein thrombosis	1	1
Depressed level of consciousness		6
Dermal cyst		1
Dermatitis		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			5	1	3
		3	12	3	10
			1		
		51	422	8	38
					1
			2		1
					1
				1	1
					1
			1		
					1
			2		
		1	9	1	2
		1	1	1	1
			1		1
		1	9	1	6
			1		1
			1		1
					1
		2	14	4	13
		1	14	13	30
					1
			1		1
				1	1
					1
		2	6		2
				1	1
					6
			1		
			4		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dermatitis bullous		1
Dermatitis herpetiformis		1
Diaphragmatic spasm		1
Diarrhoea	19	98
Diarrhoea haemorrhagic	1	1
Diplegia		1
Diplopia		2
Discomfort	4	9
Disease recurrence		
Disorientation		1
Dissociation		1
Disturbance in attention		2
Dizziness	27	114
Drug ineffective	5	12
Dry eye		1
Dry mouth	3	13
Dry skin		1
Dysaesthesia	1	2
Dysentery	2	20
Dysgeusia	1	13
Dyskinesia	1	1
Dyslalia		1
Dysmetria		1
Dyspepsia		8
Dysphagia	1	14
Dysphonia		5
Dyspnoea	10	50
Dyspnoea at rest	1	1
Dyspnoea exertional		1
Dysuria		1
Ear discomfort		1
Ear infection		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
			1		
		14	83	5	15
				1	1
					1
			2		
		2	5	2	4
	1				
					1
			1		
			2		
		19	81	8	33
				5	12
			1		
		3	12		1
			1		
		1	2		
	1			2	20
			11	1	2
				1	1
					1
			6		2
		1	6		8
			2		3
		2	27	8	23
				1	1
			1		
			1		1
			1		

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* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ear pain		4
Ectopic pregnancy		1
Electrocardiogram abnormal		1
Electrocardiogram change	1	1
Encephalopathy		1
Epididymitis	1	1
Epistaxis		2
Erectile dysfunction	1	1
Eructation		1
Erythema	5	50
Erythema nodosum		1
Euphoric mood		2
Extra dose administered	1	1
Eye haemorrhage	1	1
Eye irritation	1	7
Eyelid oedema		2
Eye oedema		2
Eye pain		2
Eye pruritus		2
Eye swelling		1
Face injury		1
Face oedema		1
Facial nerve disorder		1
Facial paralysis	3	10
Facial paresis	2	4
Faeces soft		1
Fall	1	4
Fatigue	52	406
Febrile convulsion		4
Feeling abnormal	1	4
Feeling cold	3	34
Feeling hot	5	21

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		2
					1
					1
				1	1
					1
				1	1
			2		
				1	1
			1		
1	1	5	37		13
					1
			2		
				1	1
				1	1
		1	7		
			2		
			2		
			2		
			1		1
			1		
					1
					1
					1
				3	10
		1	1	1	3
			1		
1	1			1	4
		45	381	7	25
			3		1
		1	3		1
		2	31	1	3
		3	15	2	6

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* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Feeling jittery		1
Feeling of body temperature change	1	4
Fibrin D dimer increased		1
Flank pain	1	2
Flatulence		1
Flushing	2	25
Foaming at mouth	1	1
Frequent bowel movements		1
Furuncle		1
Gait disturbance		1
Gastritis		1
Gastroenteritis		3
Gastrointestinal disorder	3	12
Gastrointestinal pain		3
Gastrooesophageal reflux disease		1
General physical health deterioration		1
Gingival oedema		1
Gingival swelling		1
Glossitis		1
Goitre		1
Guillain-Barre syndrome	1	1
Haematoma	1	3
Haematuria		1
Headache	167	1,020
Head discomfort		5
Head injury		1
Heart rate decreased		2
Heart rate increased		1
Heat stroke		1
Heavy menstrual bleeding	1	1
Hemianaesthesia		2
Hemiparaesthesia	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	3		1
					1
		1	2		
			1		
		2	23		2
				1	1
			1		
			1		
1	1		1		
			1		
			3		
		3	12		
			3		
			1		
					1
			1		
					1
					1
					1
				1	1
			2	1	1
					1
	3	154	953	13	67
			5		
					1
			1		1
					1
			1		
		1	1		
					2
				2	3

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hemiparesis		1
Herpes ophthalmic		1
Herpes simplex		2
Herpes virus infection		1
Herpes zoster	1	5
Hidradenitis		1
Hot flush	5	17
Hyperaemia	1	3
Hyperaesthesia		3
Hyperglycaemia		1
Hyperhidrosis	8	55
Hyperpyrexia	2	30
Hypersensitivity		8
Hypertension		2
Hypertensive crisis		3
Hyperthermia	1	5
Hypertonia		
Hypoacusis	1	2
Hypoaesthesia	2	27
Hypoaesthesia oral	1	7
Hyposmia	1	1
Hypotension	4	37
Hypotensive crisis		1
Hypotonia		3
Illrd nerve paralysis		1
Illness	1	3
Immune system disorder		1
Impaired quality of life	3	3
Incorrect dose administered		1
Incorrect route of product administration	1	4
Induration	1	3
Inflammation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
			2		
			1		
	1	1	3		2
					1
		4	15	1	2
			1	1	2
			3		
					1
		6	43	2	12
	1			2	30
			5		3
			2		
					3
		1	4		1
1	1				
			1	1	1
	1	2	25		2
		1	6		1
				1	1
1	1	2	18	2	19
					1
			1		2
			1	1	2
			1		
		1	1	2	2
			1		
		1	4		
		1	3		
			1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Influenza	1	6
Influenza like illness	1	19
Initial insomnia		6
Injected limb mobility decreased		7
Injection		1
Injection site erythema	1	32
Injection site haematoma		1
Injection site haemorrhage		1
Injection site induration		4
Injection site infection	1	2
Injection site lymphadenopathy		1
Injection site muscle weakness		1
Injection site oedema		44
Injection site pain	15	400
Injection site pruritus		6
Injection site rash		1
Injection site reaction		10
Injection site swelling		5
Injection site urticaria		9
Injection site warmth		1
Injury		1
Insomnia	11	55
Instillation site bruise		1
Intermittent claudication	1	1
Irritability		1
Jaw fracture		1
Joint range of motion decreased		1
Joint swelling		2
Laryngeal oedema		6
Laryngeal pain	1	2
Laryngospasm	1	2
Lethargy		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	5		1
	1	1	17		2
			5		1
			7		
			1		
		1	32		
			1		
			1		
			4		
		1	2		
			1		
			1		
			44		
		14	399	1	1
			6		
			1		
			10		
			5		
			9		
			1		
			1		
		7	48	4	7
			1		
				1	1
			1		
			1		1
					6
		1	2		
		1	1		1
			1		

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* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Limb discomfort	3	10
Lip erythema		1
Lip oedema		11
Lipoma	1	1
Lip pain		1
Lip pruritus		2
Lip swelling		8
Localised oedema		3
Local reaction		1
Loss of consciousness	4	29
Loss of personal independence in daily activities		2
Lymphadenitis	2	9
Lymphadenopathy	27	306
Lymph node pain	2	23
Lymphocytosis	1	1
Lymphoedema		1
Macroglossia		1
Malaise	32	228
Maternal exposure during pregnancy	1	3
Maternal exposure timing unspecified		1
Mechanical urticaria	1	3
Menstrual disorder	2	3
Menstruation delayed	1	1
Menstruation irregular	2	2
Middle insomnia	1	4
Migraine	5	38
Migraine with aura	1	1
Mobility decreased	1	3
Motion sickness		1
Motor dysfunction		4
Mouth swelling		1
Mouth ulceration		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	8	1	2
			1		
			7		4
		1	1		
			1		
					2
			6		2
			2		1
			1		
				4	29
			2		
		2	7		2
	4	25	279	2	27
	2	2	20		3
		1	1		
			1		
					1
		27	210	5	18
		1	3		
					1
			1	1	2
		2	3		
		1	1		
		2	2		
			3	1	1
		2	33	3	5
		1	1		
		1	3		
			1		
			3		1
			1		
			1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Movement disorder		1
Muscle contractions involuntary	1	1
Muscle fatigue		3
Muscle oedema		1
Muscle rigidity	1	3
Muscle spasms	1	7
Muscle swelling		1
Muscle twitching		2
Muscular weakness	4	15
Musculoskeletal chest pain	1	4
Musculoskeletal disorder		1
Musculoskeletal pain	10	67
Musculoskeletal stiffness		7
Myalgia	92	766
Myasthenia gravis		1
Mydriasis		1
Myocarditis	1	6
Myoclonus		1
Nasal congestion	3	7
Nasal obstruction		1
Nasopharyngitis	3	14
Nausea	49	323
Neck pain	3	20
Nerve injury		1
Neuralgia	2	4
Neuritis		1
Neuropathy peripheral		2
Neutropenia	1	1
Night sweats	1	4
Nuchal rigidity		2
Nystagmus	1	2
Obstructive airways disorder		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	1		
			3		
			1		
			1	1	2
			6	1	1
			1		
			2		
		2	11	2	4
		1	4		
			1		
	1	9	62	1	5
			5		2
	1	84	729	8	37
					1
					1
				1	6
			1		
			2	3	5
			1		
		2	12	1	2
	1	42	288	7	35
		3	19		1
			1		
		1	2	1	2
					1
					2
				1	1
		1	4		
			2		
				1	2
			1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ocular discomfort	1	1
Ocular hyperaemia	1	5
Oculogyric crisis	1	1
Oedema		3
Oedema peripheral		3
Oesophageal pain		1
Off label use	2	2
Ophthalmic herpes zoster		1
Optic neuritis	1	1
Oral discomfort		2
Oral dysaesthesia		2
Oral herpes		2
Oral pruritus		3
Oropharyngeal discomfort		4
Oropharyngeal oedema		1
Oropharyngeal pain	2	17
Oropharyngeal plaque		1
Oropharyngeal swelling		1
Orthostatic hypotension		2
Otolithiasis	1	1
Overdose	2	8
Oxygen saturation decreased	1	3
Pain	18	92
Painful respiration		1
Pain in extremity	24	195
Pain of skin		1
Palatal swelling		2
Pallor	2	6
Palpable purpura		1
Palpitations		4
Paraesthesia	17	111
Paraesthesia oral	3	30

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	4		1
				1	1
			2		1
			3		
			1		
		1	1	1	1
					1
				1	1
			2		
			2		
			2		
					3
			4		
					1
		2	16		1
					1
			1		
			1		1
				1	1
		2	8		
				1	3
		18	82		10
			1		
	1	22	178	2	17
			1		
					2
1	1	2	5		1
			1		
			2		2
		12	88	5	23
		3	21		9

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Paralysis		1
Pelvic pain	1	1
Pericardial effusion	1	2
Pericarditis	1	2
Perineal pain		1
Periorbital swelling		1
Peripheral coldness	1	3
Peripheral swelling	5	15
Petechiae	2	2
Pharyngeal erythema	1	2
Pharyngeal mass		1
Pharyngeal paraesthesia		2
Pharyngeal swelling		4
Pharyngitis		1
Photophobia	1	7
Photosensitivity reaction	1	1
Pneumothorax		1
Polydipsia		1
Polymenorrhoea	2	2
Presyncope	5	41
Product administered at inappropriate site		2
Product preparation issue		1
Product use issue	1	1
Pruritus	4	62
Pruritus allergic		1
Psoriasis		1
Psoriatic arthropathy		1
Psychogenic pseudosyncope	1	1
Pulmonary embolism	1	1
Puncture site induration		2
Pupils unequal	1	1
Pyrexia	164	1,027

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1		
				1	2
				1	2
			1		
			1		
1	1			1	3
		4	11	1	4
		1	1	1	1
		1	2		
					1
					2
			1		3
			1		
		1	7		
		1	1		
					1
			1		
		2	2		
1	1	3	23	2	18
			2		
			1		
		1	1		
1	1	4	51		11
			1		
			1		
					1
		1	1		
				1	1
			2		
		1	1		
	4	145	911	19	116

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Quality of life decreased	1	3
Rash	6	59
Rash erythematous		3
Rash macular	1	1
Rash maculo-papular		2
Rash pruritic	1	5
Rash scarlatiniform		1
Rash vesicular		2
Renal pain	1	2
Respiratory arrest		1
Respiratory disorder		1
Respiratory distress	1	2
Respiratory fatigue	2	4
Restlessness		1
Retching		3
Rhinitis		2
Rhinitis allergic		1
Rhinorrhoea	3	5
Salivary gland pain		1
SARS-CoV-2 ant body test		1
SARS-CoV-2 ant body test positive		1
SARS-CoV-2 test negative		1
SARS-CoV-2 test positive	2	5
Scintillating scotoma		1
Seizure	2	2
Sensation of foreign body	1	6
Sensitive skin		2
Sensory loss		3
Shock		1
Sinus tachycardia		3
Skin burning sensation		2
Skin discolouration		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	1	1
		6	43		16
	1		1		2
		1	1		
			2		
		1	2		3
			1		
					2
			1	1	1
					1
			1		
				1	2
		1	1	1	3
			1		
			3		
			2		
			1		
		1	3	2	2
			1		
					1
			1		
			1		
		1	3	1	2
			1		
				2	2
			3	1	3
			2		
			1		2
1	1				1
			2		1
			1		1
			1		

* I=Interval, C=Cumulative
* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin discomfort	1	2
Skin exfoliation		1
Skin irritation	1	1
Skin laceration		1
Skin reaction		6
Sleep disorder		2
Sneezing	1	1
Soft tissue infection		1
Somnolence	8	54
Sopor		1
Speech disorder		1
Spinal pain	1	2
Stomatitis	1	1
Stridor		1
Stupor		1
Sudden hearing loss	1	2
Suffocation feeling		2
Swelling	1	8
Swelling face		8
Swollen tongue	1	6
Syncope	9	42
Tachycardia	11	65
Tachycardia paroxysmal		1
Tachypnoea	2	3
Takayasu's arteritis	1	1
Taste disorder		2
Tendonitis		1
Tension headache		2
Terminal insomnia		1
Testicular pain	1	1
Tetany		2
Thermal burns of eye		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
			1		
		1	1		
					1
			5		1
			2		
		1	1		
					1
		5	46	3	8
			1		
			1		
		1	2		
				1	1
					1
			1		
				1	2
			1		1
		1	8		
			6		2
		1	2		4
				9	42
		5	43	6	22
	1				1
		1	2	1	1
				1	1
			2		
			1		
			2		
			1		
				1	1
			1		1
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Thought blocking		1
Throat irritation		7
Throat tightness	2	14
Thrombocytopenia	1	2
Thrombophlebitis		1
Thyroid pain		1
Tinnitus		3
Tongue biting	1	1
Tongue discomfort		1
Tongue erythema		1
Tongue oedema	2	5
Tongue pruritus		2
Tonic clonic movements		1
Tonsillar hypertrophy	1	2
Tonsillitis		3
Toothache		1
Torticollis		1
Tracheal pain		1
Tremor	3	27
Trigeminal nerve disorder		1
Trigeminal palsy	1	1
Troponin T increased		2
Type 1 diabetes mellitus		1
Type I hypersensitivity		1
Umbilical haematoma		1
Underdose		2
Urinary incontinence		1
Urinary tract infection		1
Urticaria	8	59
Urticaria thermal		1
Uveitis		1
Vaccination complication	2	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					7
		2	10		4
				1	2
					1
					1
			2		1
				1	1
					1
			1		
		1	1	1	4
			1		1
					1
		1	2		
			2		1
			1		
			1		
					1
		1	17	2	10
			1		
				1	1
					2
					1
					1
					1
			2		
					1
			1		
		7	48	1	11
			1		
					1
		2	13		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination failure	11	24
Vaccination site dermatitis		1
Vaccination site discomfort	1	3
Vaccination site erythema	4	25
Vaccination site haematoma		2
Vaccination site hypoaesthesia		6
Vaccination site induration	1	5
Vaccination site joint erythema		1
Vaccination site joint movement impairment		1
Vaccination site joint pain		4
Vaccination site joint swelling		5
Vaccination site joint warmth		1
Vaccination site lymphadenopathy	1	6
Vaccination site mass		2
Vaccination site movement impairment		6
Vaccination site oedema	6	75
Vaccination site pain	131	652
Vaccination site paraesthesia	1	11
Vaccination site pruritus	2	13
Vaccination site rash		1
Vaccination site reaction	2	21
Vaccination site swelling	12	47
Vaccination site urticaria	2	6
Vaccination site vesicles		1
Vaccination site warmth	1	6
Vascular purpura		1
Vasodilatation		1
Vertigo	9	60
Vertigo positional		1
Vestibular neuronitis	1	3
Viral corneal ulcer		1
Vision blurred	2	18

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				11	24
					1
		1	3		
		4	18		7
			2		
			5		1
		1	4		1
			1		
			1		
			4		
			5		
			1		
		1	5		1
			2		
			6		
		6	73		2
		123	621	8	31
		1	9		2
		1	10	1	3
					1
		2	21		
		12	42		5
		2	5		1
			1		
		1	4		2
			1		
					1
		5	48	4	12
			1		
			1	1	2
					1
		1	13	1	5

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Visual impairment	1	4			1	3		1
Vitritis		1						1
Vomiting	11	77			7	63	4	14
Weight decreased		2						2
Wheezing	2	2					2	2
Wound			1	1				
	1,495	10,077	12	39	1182	8607	313	1470

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* AE=Adverse Event
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	4	12			3	10	1	2
Abdominal distension		12				8		4
Abdominal migraine		1				1		
Abdominal pain	19	174			18	149	1	25
Abdominal pain lower		1						1
Abdominal pain upper	12	80		1	10	64	2	16
Abdominal rigidity		3				3		
Abortion		2						2
Abortion missed	1	1					1	1
Abortion spontaneous	2	6					2	6
Acarodermatitis	1	1					1	1
Accommodation disorder	1	2				1	1	1
Acne	1	1			1	1		
Acquired macroglossia		1						1
Acute abdomen		1						1
Acute myocardial infarction	2	2					2	2
Acute respiratory failure		1						1
Administration site joint pain	1	1			1	1		
Administration site movement impairment		1				1		
Administration site oedema		8				8		
Administration site pain	1	39			1	39		
Administration site paraesthesia		1				1		
Administration site pruritus		1				1		
Administration site rash		1				1		
Administration site reaction		4				4		
Administration site swelling		1				1		
Adnexa uteri pain	1	1			1	1		
Adrenomegaly		1				1		
Ageusia	6	25	1	1	3	14	3	11
Agitation	3	19		1	3	15		4
Alanine aminotransferase increased	1	2			1	2		
Allergic cough		1						1

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Allergy to vaccine	1	5
Allodynia		2
Alopecia		2
Amenorrhoea	4	5
Amnesia	1	4
Amylase increased		3
Anaemia	1	2
Anaesthesia	3	22
Anaesthesia oral		5
Anal sphincter atony		1
Anamnestic reaction	1	1
Anaphylactic reaction	5	41
Anaphylactic shock	1	8
Anaphylactoid reaction		2
Angina pectoris		3
Angioedema	5	35
Angiomyolipoma		1
Angular cheilitis		1
Anosmia	7	21
Anterograde amnesia		1
Anti-thyroid antibody positive		2
Anuria		2
Anxiety	3	15
Anxiety disorder due to a general medical condition		1
Apathy	1	3
Aphasia	1	5
Aphonia	2	3
Aphthous ulcer	1	7
Appetite disorder	1	1
Aptyalism	1	2
Arrhythmia	3	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		3
			1		1
					2
		3	4	1	1
			1	1	3
			1		2
			1	1	1
		3	19		3
			3		2
					1
		1	1		
				5	41
				1	8
					2
					3
				5	35
					1
			1		
1	2	5	15	2	6
					1
			2		
					2
		2	9	1	6
			1		
		1	1		2
			1	1	4
		2	2		1
	1	1	5		2
		1	1		
			1	1	1
				3	11

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arterial occlusive disease	1	1
Arterial thrombosis		
Arteriovenous fistula		1
Arthralgia	216	1,603
Arthritis	2	6
Arthropathy	1	1
Arthropod sting		2
Aspartate aminotransferase increased	1	1
Asphyxia		1
Asthenia	174	1,113
Asthenopia		6
Asthma	2	15
Asthma exercise induced		1
Asthmatic crisis	2	9
Asymptomatic COVID-19	9	14
Ataxia		1
Atrial fibrillation		2
Atrial flutter		1
Auditory disorder	1	2
Aura	1	3
Autoimmune arthritis	1	1
Autoimmune disorder	1	1
Autoimmune thyroiditis		3
Axillary pain	18	100
Azotaemia		1
Back pain	20	98
Balance disorder	2	16
Band sensation		6
Barotrauma		1
Basedow's disease	1	2
Bell's palsy	5	14
Benign hydatidiform mole	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
1	1				
					1
	7	188	1447	28	156
		1	4	1	2
				1	1
			2		
		1	1		
					1
1	6	161	973	13	140
			5		1
		1	8	1	7
					1
1	2			2	9
		3	3	6	11
					1
					2
			1		
				1	2
		1	3		
				1	1
				1	1
					3
	2	17	91	1	9
					1
	1	18	84	2	14
		1	10	1	6
			4		2
			1		
				1	2
1	1			5	14
				1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Biliary colic		1
Blepharitis	1	1
Blepharospasm		3
Blindness		2
Blister	1	5
Blister infected		1
Blood calcium decreased		1
Blood disorder	1	1
Blood glucose decreased		1
Blood glucose increased		2
Blood potassium decreased		1
Blood pressure decreased	2	13
Blood pressure diastolic increased	1	2
Blood pressure fluctuation		3
Blood pressure increased	11	67
Blood pressure systolic decreased		1
Blood pressure systolic increased		2
Body temperature decreased		2
Body temperature fluctuation	1	1
Body temperature increased	4	30
Bone marrow oedema		1
Bone pain	20	109
Bradycardia	1	6
Bradykinesia	2	4
Bradyphrenia		1
Brain neoplasm		1
Brain oedema		1
Breast cyst		1
Breast enlargement		1
Breast inflammation	1	1
Breast oedema		3
Breast pain	3	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1		
			3		
					2
		1	4		1
			1		
			1		
				1	1
			1		
			1		
			6	2	7
			1	1	1
			2		1
2	2	6	37	5	30
			1		
					2
			2		
		1	1		
	1	4	29		1
					1
		17	91	3	18
1	1			1	6
		2	3		1
			1		
					1
					1
			1		
		1	1		
			2		1
		3	9		4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Breast swelling		1
Breath odour		1
Breath sounds		1
Breath sounds abnormal		2
Bronchitis	1	2
Bronchitis chronic	1	1
Bronchospasm	3	20
Bronchostenosis	1	2
Brow ptosis		1
Burning mouth syndrome		2
Burning sensation	6	22
Burn oral cavity		1
Butterfly rash		1
Capillary fragility		2
Cardiac arrest	1	1
Cardiac disorder		1
Cardiomyopathy	1	1
Cardiovascular disorder		1
Carotid artery dissection		2
Catarrh	1	3
Catheter site pain		1
Cauda equina syndrome	1	1
Central cord syndrome		1
Cerebral haemorrhage		3
Cerebral thrombosis	1	1
Cerebral venous sinus thrombosis	1	1
Cerebrovascular insufficiency	1	1
Cervical radiculopathy		1
Cervicobrachial syndrome	3	8
Chest discomfort	12	60
Chest expansion decreased		1
Chest pain	12	80

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
					1
					2
		1	1		1
		1	1		
		1	8	2	12
				1	2
			1		
			1		1
		5	17	1	5
					1
			1		
			1		1
				1	1
					1
			1		1
					2
		1	3		
			1		
				1	1
					1
					3
				1	1
				1	1
				1	1
			1		
		1	5	2	3
	2	10	36	2	24
			1		
1	2	7	49	5	31

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chillblains	1	6
Chills	186	1,164
Choking		1
Choking sensation		1
Cholelithiasis		1
Chronic fatigue syndrome	2	2
Circadian rhythm sleep disorder		1
Circulatory collapse		1
Circumoral oedema		4
Circumoral swelling		1
Clonus		2
Cluster headache		1
Cold sweat	1	13
Compulsions		1
Condition aggravated	3	9
Confusional state	11	66
Conjunctival haemorrhage	1	3
Conjunctival hyperaemia	2	3
Conjunctival irritation		1
Conjunctivitis	5	14
Connective tissue disorder		1
Connective tissue inflammation		1
Constipation	1	5
Contusion	1	5
Corneal dystrophy		1
Corneal opacity	1	2
Cough	23	119
COVID-19	55	109
Cramp-fasciculation syndrome		1
Cranial nerve disorder	1	4
Cranial nerve paralysis		1
C-reactive protein increased	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			4	1	2
	4	166	1012	20	152
					1
					1
			1		
		2	2		
			1		
					1
			4		
					1
			1		1
			1		
		1	8		5
					1
		1	4	2	5
	1	7	43	4	23
				1	3
		1	1	1	2
			1		
		2	7	3	7
					1
			1		
		1	5		
			4	1	1
					1
				1	2
		15	63	8	56
3	3	8	17	47	92
			1		
			2	1	2
					1
		1	3		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Crying		1
Cyanosis	3	9
Cystitis	1	2
Cystitis haemorrhagic		3
Dactylitis		1
Deafness neurosensory		2
Deafness unilateral	1	1
Death		1
Decreased appetite	11	59
Deep vein thrombosis	1	4
Dehydration		1
Delirium		1
Dementia Alzheimer's type		1
Demyelinating polyneuropathy		2
Demyelination		1
Depressed level of consciousness	6	27
Depressed mood	1	2
Depression	1	2
Dermatitis	2	5
Dermatitis acneiform	1	1
Dermatitis allergic		5
Dermatitis atopic		2
Dermatitis bullous	3	5
Dermatitis exfoliative generalised		1
Dermatitis psoriasiform		1
Device issue		1
Diaphragmatic spasm		1
Diarrhoea	70	380
Diarrhoea haemorrhagic		1
Diastolic hypertension		1
Diastolic hypotension		1
Diplegia		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	2	2	7
		1	2		
					3
					1
					2
				1	1
					1
		11	53		6
				1	4
					1
					1
					1
				6	27
		1	2		
			1	1	1
		1	3	1	2
		1	1		
			4		1
			2		
	1			3	5
					1
			1		
			1		
					1
	2	63	321	7	59
					1
			1		
					1
					2

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Diplopia	4	14
Discomfort	1	11
Disease recurrence	2	9
Disorientation		13
Dissociation		1
Disturbance in attention	2	21
Dizziness	35	223
Drug abuse		1
Drug hypersensitivity		4
Drug ineffective	25	43
Dry eye	1	4
Dry mouth	4	47
Dry skin		3
Dry throat	1	7
Dysaesthesia	5	23
Dysaesthesia pharynx		2
Dysarthria		2
Dysentery	6	92
Dysgeusia	11	85
Dysgraphia	2	2
Dyskinesia		2
Dyspepsia	1	12
Dysphagia	7	51
Dysphemia		1
Dysphonia	3	28
Dyspnoea	31	217
Dyspnoea at rest		3
Dyspnoea exertional	2	10
Dysstasia		2
Dystonia		1
Dysuria		1
Ear discomfort	1	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	8	3	6
		1	9		2
			3	2	6
1	1		8		5
			1		
		1	12	1	9
	1	23	155	12	68
					1
					4
		1	1	24	42
		1	3		1
	1	4	29		18
					3
		1	5		2
		3	17	2	6
			2		
			1		1
2	4			6	92
	1	11	74		11
		1	1	1	1
			1		1
		1	11		1
	2	4	32	3	19
					1
	1		10	3	18
	1	22	104	9	113
					3
		1	6	1	4
			1		1
					1
			1		
		1	8		3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ear disorder		2
Ear infection		6
Ear pain	5	29
Ear pruritus		3
Ear swelling	1	3
Ecchymosis		2
Eczema	1	1
Eczema eyelids	1	1
Eczema nummular		1
Electric shock		1
Electric shock sensation	1	1
Electrocardiogram abnormal		2
Embolism	1	1
Emotional disorder	1	2
Emotional distress	1	1
Enanthema		1
Encephalopathy		1
Endometriosis		1
Endothelial dysfunction	1	1
Enteritis	1	1
Enthesopathy		2
Eosinophil count decreased		1
Epilepsy	1	4
Epistaxis	2	8
Erectile dysfunction	3	3
Eructation		2
Erysipelas	1	1
Erythema	28	219
Erythema multiforme		1
Erythema nodosum		3
Exophthalmos	1	1
Exposure during pregnancy	3	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
			5		1
		4	21	1	8
			3		
			1	1	2
			1		1
		1	1		
		1	1		
			1		
					1
		1	1		
			1		
					1
		1	1		
			1		1
				1	1
		1	2		
		1	1		
					1
					1
					1
		1	1		
		1	1		
			1		1
					1
				1	4
			3	2	5
				3	3
			2		
				1	1
1	1	21	161	7	58
					1
			2		1
				1	1
		3	4		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Exposure to SARS-CoV-2		1
Extensive swelling of vaccinated limb		2
Extraocular muscle paresis		1
Extrasystoles		11
Extremity contracture		1
Eye allergy		1
Eye colour change		1
Eye disorder		1
Eye haematoma	1	1
Eye irritation	2	38
Eyelid myoclonus		2
Eyelid oedema		12
Eyelid pain		1
Eyelid ptosis		5
Eyelids pruritus		1
Eye movement disorder		1
Eye oedema	2	6
Eye pain	3	26
Eye paraesthesia	1	4
Eye pruritus	2	13
Eye swelling	2	7
Face injury	1	1
Face oedema	4	21
Facial asymmetry	1	1
Facial bones fracture	1	1
Facial discomfort		1
Facial nerve disorder		2
Facial neuralgia		1
Facial pain	1	9
Facial paralysis	4	20
Facial paresis	4	23
Facial spasm	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2		
					1
			6		5
			1		
			1		
					1
					1
				1	1
		2	35		3
					2
			4		8
					1
			3		2
			1		
					1
		1	3	1	3
		2	17	1	9
		1	4		
		1	5	1	8
		2	4		3
				1	1
1	1	3	10	1	11
				1	1
				1	1
			1		
			1		1
					1
			3	1	6
				4	20
1	1	3	13	1	10
			1	1	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Faeces soft		1
Fall	1	2
Fatigue	173	1,307
Fear-related avoidance of activities	1	1
Febrile convulsion		7
Feeling abnormal	3	19
Feeling cold	14	110
Feeling hot	17	112
Feeling jittery		3
Feeling of body temperature change		5
Female sexual dysfunction		1
Fibrin D dimer increased	1	1
Fibromuscular dysplasia		1
Fibromyalgia		2
Flank pain	1	4
Flat affect		3
Flatulence		1
Fluid retention		2
Flushing	4	74
Foetal death	1	1
Folliculitis		1
Food aversion		1
Foreign body in throat		1
Foreign body sensation in eyes		1
Frequent bowel movements		2
Gait disturbance	2	21
Gait inability	1	1
Gastritis	3	3
Gastroenteritis	1	4
Gastrointestinal disorder	5	21
Gastrointestinal hypermotility		1
Gastrointestinal motility disorder	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	2
1	3	152	1179	21	128
		1	1		
			4		3
		3	15		4
		11	97	3	13
		11	78	6	34
			2		1
			4		1
			1		
		1	1		
					1
			1		1
		1	4		
			2		1
			1		
			1		1
		4	60		14
				1	1
			1		
			1		
					1
			1		
			2		
		1	15	1	6
				1	1
		2	2	1	1
		1	4		
		5	19		2
					1
		1	1		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastrointestinal pain	2	6
Gastrointestinal sounds abnormal	1	1
Gastroesophageal reflux disease	1	4
Generalised tonic-clonic seizure	1	2
Genital discomfort		1
Genital rash	1	1
Gingival bleeding	2	2
Gingival discolouration		1
Gingival discomfort		
Gingival pain		1
Gingivitis		1
Glare		1
Gliositis		1
Glomerulonephritis		1
Glossitis		2
Glossodynia		3
Glottal incompetence		1
Goitre	1	2
Gravitational oedema	1	1
Grip strength decreased		1
Groin pain	2	6
Guillain-Barre syndrome		1
Haematochezia		1
Haematocrit decreased		1
Haematoma		4
Haematospermia	1	1
Haematuria		2
Haemodynamic instability	1	1
Haemoglobin decreased		3
Haemorrhage		1
Hallucination		4
Hallucination, auditory		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	5		1
		1	1		
		1	4		
				1	2
					1
		1	1		
				2	2
					1
	1				
			1		
			1		
			1		
			1		
					1
			2		
					3
					1
		1	2		
		1	1		
			1		
	1	1	5	1	1
					1
					1
			1		
			3		1
				1	1
			1		1
				1	1
			2		1
					1
					4
					2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hallucination, olfactory		2
Hallucination, visual		5
Hand deformity		1
Hand dermatitis	1	3
Haptoglobin increased		1
Headache	538	2,712
Head discomfort	4	7
Head injury		1
Heart rate abnormal		1
Heart rate decreased	2	3
Heart rate increased	2	10
Heart rate irregular		1
Heavy menstrual bleeding	7	12
Hemianaesthesia	1	5
Hemianopia heteronymous		1
Hemianopia homonymous	1	1
Hemidysaesthesia		3
Hemihyperaesthesia	1	2
Hemiparaesthesia	3	20
Hemiparesis	1	10
Hemiplegia		2
Hepatic enzyme increased	1	1
Hepatic pain		3
Hepatitis A antibody positive		1
Hepatitis acute		1
Hepatitis B antibody positive		1
Hepatitis cholestatic	1	1
Herpes ophthalmic	1	3
Herpes simplex	1	4
Herpes virus infection	3	7
Herpes zoster	7	22
Herpes zoster infection neurological		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					5
			1		
		1	3		
					1
	10	489	2406	49	306
		4	7		
					1
					1
				2	3
		2	6		4
					1
		6	7	1	5
				1	5
					1
				1	1
					3
				1	2
				3	20
				1	10
					2
				1	1
			3		
			1		
					1
			1		
				1	1
				1	3
		1	3		1
		2	4	1	3
		6	17	1	5
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Herpes zoster oticus		1
Herpes zoster reactivation	2	2
Histamine intolerance		1
Hot flush	8	63
Hyperacusis		2
Hyperaemia	1	5
Hyperaesthesia	2	7
Hyperglycaemia	2	4
Hyperhidrosis	15	117
Hyperpyrexia	6	102
Hyperreflexia		1
Hypersensitivity	5	41
Hypersomnia		4
Hypertension	11	73
Hypertensive crisis	3	35
Hyperthermia	4	21
Hyperthyroidism	1	2
Hypertonia		2
Hypertrophy of tongue papillae	1	1
Hyperventilation		5
Hypoacusis	1	7
Hypoaesthesia	11	103
Hypoaesthesia oral	2	33
Hypogeusia	1	2
Hypoglycaemia	1	3
Hypokinesia		1
Hyponatraemia	1	1
Hypoperfusion	1	1
Hyporeflexia	1	2
Hyporesponsive to stimuli		2
Hyposmia		2
Hypotension	9	70

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		2	2		
			1		
		7	53	1	10
			2		
		1	4		1
		2	5		2
				2	4
	1	12	91	3	26
	2			6	102
					1
	2	2	14	3	27
			4		
	1	7	34	4	39
				3	35
		4	18		3
				1	2
			2		
		1	1		
	1		2		3
			1	1	6
	1	9	79	2	24
		1	25	1	8
		1	2		
			1	1	2
			1		
				1	1
		1	1		
		1	1		1
			2		
			1		1
1	1	4	42	5	28

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypotensive crisis		3
Hypothermia	3	13
Hypotonia		4
Hypotonic-hyporesponsive episode		1
Hypoxia		1
Idiopathic urticaria		1
Idiosyncratic drug reaction	1	1
Illness	4	9
Immobile		1
Immune thrombocytopenia	1	1
Immunodeficiency common variable	1	1
Impaired quality of life	1	2
Impaired work ability		1
Inappropriate schedule of product administration	1	5
Incontinence		1
Incorrect dosage administered		1
Incorrect dose administered		3
Incorrect route of product administration	2	15
Increased upper airway secretion		2
Increased viscosity of bronchial secretion		1
Induration		6
Infection	1	1
Inflammation	1	4
Inflammatory pain		2
Influenza	4	18
Influenza like illness	21	96
Infusion site joint swelling		1
Infusion site lymphadenopathy		1
Infusion site pain		3
Initial insomnia	1	11
Injected limb mobility decreased	2	16
Injection site discomfort		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
				3	13
			3		1
			1		
					1
			1		
		1	1		
		4	7		2
					1
				1	1
				1	1
		1	2		
					1
		1	5		
					1
			1		
			3		
		2	15		
			1		1
					1
			6		
		1	1		
		1	4		
			1		1
		4	16		2
		21	89		7
			1		
			1		
			3		
			9	1	2
		1	15	1	1
			1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site erythema		80
Injection site haematoma		4
Injection site haemorrhage		1
Injection site hypoaesthesia		1
Injection site induration		6
Injection site infection		5
Injection site joint erythema		1
Injection site joint pain		1
Injection site lymphadenopathy		1
Injection site oedema	1	145
Injection site pain	29	942
Injection site paraesthesia		9
Injection site pruritus		23
Injection site rash		1
Injection site reaction		11
Injection site swelling	1	29
Injection site urticaria		15
Injection site warmth		5
Injury		1
Insomnia	17	142
Intentional product misuse		1
Intermenstrual bleeding		5
Interstitial lung disease		3
Intestinal pseudo-obstruction		1
Intranasal hypoaesthesia		1
Intranasal paraesthesia		1
Intraocular pressure increased	1	1
Iridocyclitis		1
Irritability	1	5
IVth nerve paralysis	1	1
Jaundice	1	1
Joint ankylosis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			80		
			4		
			1		
			1		
			6		
			5		
			1		
			1		
			1		
		1	145		
		29	941		1
			9		
			23		
			1		
			11		
		1	29		
			15		
			5		
			1		
		14	125	3	17
			1		
			3		2
					3
					1
			1		
			1		
		1	1		
					1
		1	4		1
				1	1
				1	1
			1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Joint contracture		1
Joint effusion		1
Joint hyperextension		1
Joint lock	1	3
Joint range of motion decreased	1	4
Joint stabilisation	1	1
Joint stiffness		1
Joint warmth		1
Labyrinthitis	1	6
Lacrimation disorder		1
Lacrimation increased	2	13
Lactose intolerance	1	1
Lagophthalmos		1
Laryngeal discomfort		1
Laryngeal dyspnoea		2
Laryngeal obstruction		2
Laryngeal oedema	5	43
Laryngeal stenosis		1
Laryngospasm	1	7
Lethargy		2
Leukocytosis		1
Leukopenia		3
Limb discomfort	7	47
Limb immobilisation		1
Lipase increased		2
Lip erythema		3
Lip oedema	5	42
Lip pain		1
Lip pruritus	2	10
Lip swelling	3	19
Localised infection	1	1
Localised oedema	3	16

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
			1		
		1	3		
		1	3		1
		1	1		
			1		
					1
			4	1	2
					1
		1	11	1	2
		1	1		
			1		
			1		
					2
					2
				5	43
					1
				1	7
			2		
			1		
					3
		6	41	1	6
			1		
			1		1
			2		1
	1	4	23	1	19
			1		
			6	2	4
		1	10	2	9
				1	1
		3	14		2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Local reaction	1	8
Logorrhoea	1	1
Loss of consciousness	9	46
Loss of control of legs		1
Loss of personal independence in daily activities		1
Lymphadenitis	5	29
Lymphadenopathy	124	892
Lymphangitis		6
Lymphatic obstruction		1
Lymph node abscess		1
Lymph node pain	8	70
Lymphocyte count increased		1
Lymphocytosis		1
Lymphoedema		2
Lymphopenia		3
Macroglossia	1	1
Madarosis		1
Malaise	91	757
Mastication disorder		1
Mastitis		3
Maternal exposure during pregnancy	5	14
Mean cell haemoglobin concentration decreased		1
Mean cell haemoglobin decreased		1
Mechanical urticaria		2
Memory impairment		5
Menstrual cycle management		1
Menstrual disorder	7	7
Menstruation delayed	2	2
Menstruation irregular	12	13
Mental disorder		2
Mental impairment	1	3
Micturition urgency	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	8		
				1	1
				9	46
					1
			1		
		5	19		10
1	9	110	785	14	107
					6
					1
					1
1	2	8	60		10
					1
			1		
			2		
					3
				1	1
					1
2	3	85	700	6	57
					1
					3
		5	14		
			1		
			1		
	1		2		
			2		3
			1		
		7	7		
		2	2		
		12	13		
			1		1
				1	3
		1	1		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Middle insomnia		1
Migraine	15	120
Migraine with aura	2	3
Mobility decreased	1	7
Monocyte count decreased		1
Mononeuritis	2	2
Monoparesis	6	9
Monoplegia	1	3
Mood altered	1	3
Mood swings	1	2
Motion sickness		1
Motor dysfunction		8
Mouth haemorrhage		1
Mouth swelling	1	3
Mouth ulceration		1
Movement disorder		11
Mucosal dryness		1
Mucosal hyperaemia		1
Mucosal inflammation		1
Multi-organ disorder	1	1
Multiple sclerosis	1	3
Multiple sclerosis relapse	2	2
Muscle contractions involuntary	1	8
Muscle contracture		7
Muscle discomfort	1	2
Muscle fatigue		3
Muscle oedema		4
Muscle rigidity	3	12
Muscle spasms	3	31
Muscle strain		1
Muscle strength abnormal	1	1
Muscle swelling		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
1	1	15	97		23
		2	3		
		1	6		1
					1
		1	1	1	1
		6	8		1
				1	3
		1	2		1
			1	1	1
			1		
			5		3
			1		
		1	2		1
					1
			4		7
			1		
					1
			1		
				1	1
				1	3
				2	2
			6	1	2
			6		1
		1	2		
			2		1
			2		2
		2	8	1	4
	1	2	25	1	6
			1		
		1	1		
					1

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle tightness	1	3
Muscle twitching	1	5
Muscular weakness	10	58
Musculoskeletal chest pain		13
Musculoskeletal discomfort		2
Musculoskeletal disorder	1	2
Musculoskeletal pain	26	248
Musculoskeletal stiffness	3	18
Myalgia	262	1,873
Myalgia intercostal		2
Myasthenia gravis		2
Myasthenia gravis crisis		1
Mydriasis	1	1
Myelitis	1	1
Myocarditis	1	1
Myoclonus		3
Myositis	1	2
Narcolepsy		2
Nasal congestion	5	14
Nasal discomfort	1	2
Nasal herpes	1	1
Nasal obstruction	3	5
Nasal oedema		2
Nasopharyngitis	17	45
Nausea	145	1,021
Neck pain	20	89
Nerve compression	1	3
Nervousness		2
Nervous system disorder		1
Neuralgia	4	16
Neuralgic amyotrophy		1
Neuritis	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		1
		1	4		1
		8	43	2	15
			10		3
			1		1
		1	2		
		25	216	1	32
		2	9	1	9
	5	241	1710	21	163
			1		1
					2
					1
		1	1		
				1	1
				1	1
					3
		1	1		1
					2
		3	10	2	4
			1	1	1
		1	1		
		3	4		1
					2
		13	32	4	13
	5	129	874	16	147
	1	17	72	3	17
		1	2		1
			2		
					1
	1	3	10	1	6
			1		
		1	3		2

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neurodermatitis		1
Neurological symptom		2
Neuropathy peripheral		7
Neurosensory hypoacusis		
Neurotoxicity		1
Neutrophil count increased		1
Neutrophil percentage increased		1
Nightmare	2	3
Night sweats	2	14
Nipple disorder	1	1
Nipple pain		1
No adverse event		1
Noninfective gingivitis		2
Non-pitting oedema		2
Nuchal rigidity		12
Obstruction		1
Obstructive airways disorder		2
Occupational exposure to product		1
Ocular discomfort	1	6
Ocular hyperaemia		19
Odynophagia		3
Oedema	3	19
Oedema mouth		3
Oedema mucosal		1
Oedema peripheral	3	19
Oesophageal pain		1
Oesophageal spasm		1
Off label use	6	18
Oligomenorrhoea	1	1
Ophthalmic herpes simplex		2
Ophthalmic migraine		1
Optic neuritis		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		1
					7
1	1				
					1
					1
					1
		1	2	1	1
		2	13		1
		1	1		
			1		
			1		
			1		1
			1		1
			5		7
			1		
					2
			1		
		1	6		
			12		7
			2		1
		3	18		1
	1		2		1
					1
		2	13	1	6
					1
					1
		6	17		1
				1	1
					2
					1
					4

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Optic neuropathy		1
Oral discomfort	1	10
Oral dysaesthesia	2	4
Oral herpes	5	32
Oral pain	1	3
Oral pruritus	1	8
Orbital haematoma		1
Oropharyngeal discomfort	1	18
Oropharyngeal pain	18	85
Oropharyngeal swelling	1	1
Orthostatic hypotension		3
Osteitis	1	1
Osteoarthropathy		1
Otitis media acute	1	1
Ovarian cyst	1	1
Overdose	5	15
Oxygen saturation decreased	1	17
Pain	46	339
Pain in extremity	109	694
Pain in jaw	1	11
Pain of skin	1	3
Palatal disorder		1
Palatal oedema	1	10
Palatal swelling		1
Palatal ulcer	1	1
Pallor	2	9
Palpitations	4	29
Pancreatitis		1
Panic attack	2	8
Panic reaction		2
Papule	1	3
Paraesthesia	68	470

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
	1		7	1	3
		1	3	1	1
		5	26		6
		1	3		
		1	5		3
					1
		1	10		8
		17	65	1	20
		1	1		
			3		
		1	1		
			1		
		1	1		
		5	15		
			1	1	16
1	2	41	289	5	50
2	2	99	629	10	65
		1	6		5
		1	2		1
			1		
		1	5		5
			1		
		1	1		
	1	2	5		4
		3	19	1	10
					1
		1	4	1	4
			2		
		1	2		1
3	5	52	343	16	127

* I=Interval, C=Cumulative
* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Paraesthesia ear		1
Paraesthesia oral	20	155
Paralysis		2
Paraparesis		3
Paratracheal lymphadenopathy		1
Paresis	1	6
Paresis cranial nerve		1
Parosmia	1	6
Parvovirus B19 test positive		1
Pelvic pain		2
Pericardial effusion	1	4
Pericarditis	2	7
Periorbital discomfort		1
Periorbital oedema	1	6
Periorbital swelling	1	6
Peripheral coldness		7
Peripheral swelling	9	52
Peristalsis vis ble		1
Petechiae	2	6
Petit mal epilepsy	1	2
Pharyngeal disorder		2
Pharyngeal erythema		5
Pharyngeal hypoaesthesia		2
Pharyngeal oedema		5
Pharyngeal paraesthesia	1	14
Pharyngeal swelling	1	9
Pharyngitis	1	7
Pharyngitis streptococcal	1	1
Pharyngotonsillitis	1	1
Phlebitis		3
Phlebitis superficial		1
Photophobia	4	24

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
	1	14	101	6	54
					2
					3
			1		
		1	3		3
					1
			4	1	2
			1		
			2		
				1	4
				2	7
					1
		1	4		2
		1	5		1
	1		6		1
1	1	8	45	1	7
			1		
			3	2	3
				1	2
			1		1
			2		3
			1		1
					5
		1	7		7
		1	3		6
	1	1	6		1
		1	1		
				1	1
			2		1
			1		
		3	18	1	6

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Photopsia	1	5
Photosensitivity reaction	1	4
Piloerection		1
Pityriasis rosea		2
Plantar fasciitis		1
Platelet count increased	1	1
Platelet disorder	1	1
Pleural effusion		1
Pneumonia bacterial	1	1
PO2 decreased		1
Pollakiuria		2
Polyarthrits		2
Polydipsia		1
Polymenorrhoea	4	4
Polyneuropathy		1
Polyneuropathy in malignant disease	1	1
Polyuria		3
Poor quality sleep		1
Portal hypertension	1	1
Post-traumatic neck syndrome	1	1
Premenstrual pain		2
Presyncope	8	91
Procalcitonin increased	1	1
Product administered at inappropriate site		1
Productive cough		1
Product preparation issue		1
Product use issue	3	11
Proteinuria	1	3
Pruritus	29	243
Pruritus genital		1
Psoriasis		1
Psoriatic arthropathy		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4		1
		1	2		2
					1
			1		1
			1		
		1	1		
				1	1
					1
				1	1
					1
			1		1
					2
			1		
		4	4		
					1
				1	1
			2		1
			1		
				1	1
		1	1		
			2		
	1	5	57	3	34
		1	1		
			1		
					1
			1		
		3	9		2
		1	3		
	1	24	194	5	49
			1		
					1
					2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Psychomotor hyperactivity	1	1
Psychotic disorder		1
Pulmonary embolism	1	4
Pulmonary oedema		1
Puncture site induration		1
Puncture site pain		1
Pustule		4
Pyrexia	425	2,646
Q fever		5
Quality of life decreased	1	3
Radiculitis brachial		3
Radiculopathy		3
Rales		1
Rash	23	176
Rash erythematous	2	15
Rash macular	4	10
Rash maculo-papular		2
Rash maculovesicular		1
Rash morbilliform		2
Rash papular		5
Rash pruritic	2	31
Rash pustular	1	1
Rash vesicular	1	4
Raynaud's phenomenon		1
Red blood cell count increased		1
Reduced facial expression		1
Renal colic	1	1
Renal impairment	1	1
Renal infarct	1	1
Renal pain	3	6
Respiration abnormal	1	1
Respiratory depression	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
				1	4
					1
			1		
			1		
			2		2
2	24	381	2257	44	389
					5
			1	1	2
			3		
			2		1
					1
	2	21	122	2	54
		2	11		4
		4	9		1
			2		
			1		
			2		
			4		1
		2	21		10
		1	1		
		1	4		
			1		
			1		
					1
				1	1
				1	1
				1	1
		2	5	1	1
		1	1		
				1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory disorder	1	9
Respiratory distress	1	13
Respiratory failure		1
Respiratory fatigue		5
Respiratory rate increased		1
Respiratory tract oedema		1
Restless legs syndrome		2
Restlessness	2	6
Retching	3	24
Retrograde amnesia		1
Reynold's syndrome	1	1
Rheumatic disorder		1
Rheumatoid arthritis		1
Rhinitis	3	8
Rhinitis allergic	1	2
Rhinorrhoea	3	13
Rosacea		1
Sacroiliitis		1
Salivary hypersecretion	1	9
Sarcoidosis	1	1
SARS-CoV-2 ant body test positive		1
SARS-CoV-2 test positive	6	12
Scarlet fever		
Sciatica	4	5
Sciatic nerve neuropathy	1	1
Scintillating scotoma	1	3
Scleral hyperaemia		1
Seasonal allergy		1
Seborrhoeic dermatitis		1
Sedation		3
Seizure	1	7
Sensation of foreign body		10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4		5
				1	13
					1
			1		4
					1
					1
					2
		2	6		
		3	16		8
					1
				1	1
			1		
					1
		3	6		2
		1	2		
		2	10	1	3
					1
			1		
			6	1	3
				1	1
			1		
1	1	2	3	4	9
	1				
		3	4	1	1
		1	1		
		1	3		
			1		
					1
			1		
			2		1
				1	7
			6		4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sense of oppression		6
Sensory disturbance	1	5
Sensory loss	1	5
Severe acute respiratory syndrome		1
Shock		2
Sinus bradycardia		1
Sinus headache		1
Sinusitis		1
Sinus pain		2
Sinus tachycardia		7
Sjogren's syndrome		1
Skin burning sensation		8
Skin discolouration	1	2
Skin hypertrophy	1	1
Skin induration		1
Skin irritation	2	3
Skin laceration	1	2
Skin lesion	1	5
Skin mass	1	1
Skin oedema		1
Skin reaction	5	19
Skin swelling	1	1
Skin tightness		3
Skin warm		4
Sleep disorder	1	7
Sneezing	1	1
Somnolence	23	131
Sopor		2
Speech disorder		9
Spider vein		1
Spinal epidural haematoma	1	1
Spinal pain	3	19

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		3
		1	2		3
			2	1	3
					1
					2
			1		
			1		
			1		
			2		
	1		2		5
					1
			8		
		1	1		1
		1	1		
					1
		2	2		1
			1	1	1
		1	5		
		1	1		
			1		
		5	14		5
		1	1		
			1		2
			2		2
		1	7		
		1	1		
		19	110	4	21
			2		
			5		4
			1		
				1	1
		3	18		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Splenomegaly		1
Stomatitis		2
Strabismus	1	1
Stress		1
Stridor		2
Stupor		7
Subarachnoid haemorrhage		1
Subclavian vein thrombosis	1	1
Submaxillary gland enlargement		1
Sudden death		1
Sudden hearing loss	1	1
Sudden onset of sleep		1
Suffocation feeling		5
Superinfection bacterial		1
Suspected COVID-19	4	5
Swelling	8	49
Swelling face	6	25
Swelling of eyelid		5
Swollen tongue	2	20
Syncope	9	54
Systemic lupus erythematosus		1
Tachyarrhythmia		2
Tachycardia	48	272
Tachycardia paroxysmal	1	3
Tachypnoea	1	12
Taste disorder	3	14
Temperature intolerance		2
Temporomandibular joint syndrome	1	2
Tenderness		6
Tendon disorder	1	1
Tendonitis		1
Tenosynovitis		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			2		
				1	1
			1		
					2
			3		4
					1
				1	1
			1		
					1
				1	1
					1
			3		2
					1
				4	5
		6	39	2	10
		3	12	3	13
			5		
		1	10	1	10
	2			9	54
					1
			2		
	3	31	165	17	107
			2	1	1
		1	6		6
		1	7	2	7
			2		
		1	2		
			5		1
		1	1		
			1		
			1		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tension headache	1	6
Terminal insomnia		2
Therapeutic response unexpected	1	1
Thirst	2	7
Thirst decreased	1	1
Throat irritation	5	38
Throat tightness	7	54
Thrombocytopenia	1	6
Thrombophlebitis	1	1
Thrombophlebitis superficial	3	4
Thrombosis	2	4
Thyroglobulin increased		1
Thyroglossal cyst		1
Thyroid disorder	1	2
Thyroid hormones increased		1
Thyroiditis subacute		3
Thyroid mass		1
Thyroid pain		1
Tinnitus	6	21
Tongue biting	1	1
Tongue blistering	1	1
Tongue discolouration	1	2
Tongue discomfort		6
Tongue disorder		1
Tongue dry	1	5
Tongue eruption		1
Tongue erythema		1
Tongue geographic	1	1
Tongue movement disturbance		1
Tongue oedema		17
Tongue pruritus	2	5
Tongue ulceration		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4		2
			2		
		1	1		
		2	7		
		1	1		
		4	24	1	14
		4	20	3	34
				1	6
		1	1		
		1	1	2	3
1	1			2	4
					1
					1
		1	2		
			3		1
					1
			1		
		4	11	2	10
				1	1
		1	1		
		1	1		1
			5		1
			1		
		1	3		2
			1		
					1
		1	1		
					1
	1		8		9
		2	4		1
			2		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tonic clonic movements		1
Tonic convulsion		1
Tonsillar erythema		1
Tonsillar hypertrophy	1	3
Tonsillitis		1
Toothache		1
Torticollis	2	5
Toxic skin eruption		2
Tracheitis	1	2
Tremor	15	86
Trigeminal nerve disorder		6
Trigeminal neuralgia		4
Trismus	1	1
Type I hypersensitivity	1	6
Type IV hypersensitivity reaction		1
Underdose		6
Upper airway obstruction	1	2
Upper respiratory tract inflammation		1
Urinary incontinence	1	2
Urinary retention	1	2
Urinary tract infection	1	1
Urine flow decreased		1
Urine output decreased		1
Urticaria	26	193
Urticaria papular		1
Use of accessory respiratory muscles		3
Uveitis		2
Vaccination complication	15	83
Vaccination error		1
Vaccination failure	32	60
Vaccination site anaesthesia		1
Vaccination site bruising		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
			1		
		1	3		
			1		
			1		
		2	5		
					2
		1	1		1
2	4	11	50	4	36
			3		3
			4		
		1	1		
				1	6
					1
			6		
				1	2
					1
			1	1	1
				1	2
				1	1
			1		
					1
1	1	20	131	6	62
			1		
					3
					2
	1	15	77		6
			1		
3	4			32	60
					1
			1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site discomfort	1	2
Vaccination site erythema	20	77
Vaccination site haematoma	2	9
Vaccination site hyperaesthesia		1
Vaccination site hypersensitivity	1	1
Vaccination site hypoaesthesia		6
Vaccination site induration	5	13
Vaccination site infection	1	1
Vaccination site inflammation	4	7
Vaccination site ischaemia		1
Vaccination site joint erythema		1
Vaccination site joint inflammation		1
Vaccination site joint movement impairment		5
Vaccination site joint pain	3	8
Vaccination site joint swelling		5
Vaccination site lymphadenopathy		13
Vaccination site mass	1	2
Vaccination site movement impairment		13
Vaccination site nerve damage	1	1
Vaccination site nodule		1
Vaccination site oedema	24	212
Vaccination site pain	345	1,741
Vaccination site paraesthesia	7	18
Vaccination site pruritus	6	35
Vaccination site rash	1	5
Vaccination site reaction	8	47
Vaccination site swelling	29	112
Vaccination site urticaria	3	19
Vaccination site vesicles		2
Vaccination site warmth	3	17
Vaginal haemorrhage	1	2
Vaginal infection		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
		19	59	1	18
		2	9		
					1
		1	1		
			5		1
		4	11	1	2
		1	1		
		4	6		1
					1
			1		
			1		
			4		1
		3	8		
			5		
			11		2
		1	2		
			13		
		1	1		
			1		
		24	203		9
	4	330	1601	15	140
		4	12	3	6
		6	31		4
		1	5		
		8	45		2
	1	27	89	2	23
		3	14		5
			2		
		3	13		4
			1	1	1
			2		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vascular rupture		1
Vasculitic rash		2
Vasculitis	1	6
Vasoconstriction		8
Vasodilatation		1
Vasomotor rhinitis		1
Venous occlusion	1	1
Venous thrombosis		1
Ventricular arrhythmia	1	2
Ventricular extrasystoles	1	5
Ventricular f brillation	1	1
Vertigo	27	227
Vertigo CNS origin	1	1
Vertigo positional		2
Vessel puncture site swelling		1
Vestibular neuronitis	1	1
Virologic failure	1	1
Vision blurred	9	28
Visual acuity reduced		1
Visual field defect	1	3
Visual impairment	7	17
Vitamin D deficiency		1
Vocal cord dysfunction		1
Vocal cord paralysis		2
Volvulus		1
Vomiting	42	255
Vomiting projectile		2
Vulvovaginal candidiasis	1	2
Vulvovaginal pain		1
Weight decreased	1	2
Wheezing	4	13
White blood cell count decreased	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		1
			4	1	2
			3		5
					1
			1		
				1	1
					1
				1	2
			2	1	3
				1	1
1	1	21	182	6	45
				1	1
			1		1
			1		
				1	1
		1	1		
		8	21	1	7
			1		
			1	1	2
	1	6	11	1	6
			1		
					1
					2
					1
	4	33	191	9	64
					2
		1	2		
			1		
			1	1	1
		2	6	2	7
		1	2		

* I=Interval, C=Cumulative
* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
White blood cell count increased		2						2
Withdrawal hypertension	1	1			1	1		
Wound		1						1
Wrong technique in product usage process		1				1		
Xerosis		1						1
Yellow skin		1				1		
Yolk sac tumour site unspecified	1	1					1	1
	4,860	30,712	45	190	3959	24754	901	5958

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	6	9			4	7	2	2
Abdominal distension	5	12			4	10	1	2
Abdominal pain	25	160			21	135	4	25
Abdominal pain lower	1	2			1	2		
Abdominal pain upper	18	76		1	14	61	4	15
Abdominal rigidity		1				1		
Accommodation disorder		1						1
Acute coronary syndrome		2						2
Acute kidney injury	1	2					1	2
Acute motor axonal neuropathy		1						1
Acute myocardial infarction	1	3					1	3
Acute polyneuropathy		1						1
Acute respiratory failure	1	3					1	3
Adenoviral conjunctivitis		1				1		
Administration site erythema		1				1		
Administration site induration	1	1			1	1		
Administration site oedema		7				7		
Administration site pain	2	31			2	31		
Administration site paraesthesia		1				1		
Administration site pruritus		2				2		
Administration site reaction		2				1		1
Administration site swelling		2				2		
Administration site warmth		1				1		
Adnexa uteri pain		1				1		
Ageusia	8	24	1	3	4	17	4	7
Agitation		8				5		3
Akathisia		1				1		
Akinesia		1						1
Alanine aminotransferase increased		2				1		1
Allergy to vaccine	2	6	1	1		1	2	5
Alopecia	1	3				1	1	2
Alpha globulin increased		1				1		

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Altered pitch perception		1
Altered state of consciousness		1
Amnesia	3	7
Amylase increased		1
Anaemia	1	1
Anaesthesia		18
Anaesthesia oral		1
Anal haemorrhage	1	1
Anaphylactic reaction	3	24
Anaphylactic shock		6
Anaphylactoid reaction	1	3
Angina pectoris	1	3
Angioedema	3	21
Ankylosing spondylitis	1	1
Anosmia	8	18
Anterograde amnesia		1
Anuria		1
Anxiety	3	19
Apathy		1
Aphasia	3	6
Aphonia		5
Aphthous ulcer	2	9
Apnoea		1
Application site paraesthesia		1
Aptyalism		1
Areflexia	1	1
Arrhythmia	1	12
Arterial occlusive disease	1	1
Arthralgia	137	1,116
Asthenia	125	765
Asthenopia		3
Asthma	1	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
		1	4	2	3
			1		
				1	1
			17		1
			1		
				1	1
1	2			3	24
	1				6
				1	3
				1	3
				3	21
				1	1
1	2	6	12	2	6
					1
					1
		1	15	2	4
			1		
1	1		1	3	5
			3		2
		2	9		
					1
			1		
			1		
				1	1
				1	12
				1	1
	2	119	973	18	143
	2	117	659	8	106
			3		
			4	1	6

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Asthmatic crisis		4
Asymptomatic COVID-19	8	16
Ataxia	1	2
Atrial fibrillation	3	7
Atrial flutter		1
Atrial tachycardia	1	3
Auditory disorder		2
Aura	1	2
Autoimmune hepatitis	1	1
Autoimmune thyroiditis		2
Axillary mass		1
Axillary pain	7	59
Back disorder		1
Back injury	1	1
Back pain	19	86
Balance disorder	3	10
Band sensation		
Basophil percentage increased		1
Bedridden		1
Bell's palsy	2	7
Bladder dysfunction		1
Blepharospasm		1
Blindness	1	3
Blindness unilateral	1	2
Blister	2	4
Blood alcohol increased	1	1
Blood alkaline phosphatase increased		1
Blood fibrinogen increased		1
Blood glucose increased		1
Blood lactate dehydrogenase increased		1
Blood pressure abnormal	2	4
Blood pressure decreased	3	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1				4
		1	1	7	15
				1	2
				3	7
					1
			2	1	1
			2		
		1	2		
				1	1
					2
			1		
	3	6	53	1	6
					1
				1	1
	2	14	67	5	19
		1	8	2	2
1	1				
			1		
			1		
				2	7
					1
					1
				1	3
				1	2
		1	2	1	2
				1	1
					1
			1		
			1		
					1
		2	4		
	1	3	3		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood pressure fluctuation	1	4
Blood pressure increased	11	52
Blood pressure systolic increased		2
Blood thyroid stimulating hormone increased	1	2
Bloody discharge		1
Body temperature increased	2	15
Bone pain	11	77
Bowel movement irregularity	1	1
Bradycardia		9
Bradykinesia		1
Breakthrough pain		1
Breast abscess		1
Breast discomfort		3
Breast enlargement		1
Breast oedema		2
Breast pain	2	8
Breast swelling		2
Breath sounds		1
Bronchial disorder	1	1
Bronchial wall thickening		1
Bronchiectasis		1
Bronchitis		1
Bronchospasm	3	17
Bullous haemorrhagic dermatosis	1	1
Bundle branch block right		1
Burning sensation	2	8
Bursitis	1	1
Bursitis infective		1
Butterfly rash		1
Capillary fragility	1	1
Cardiac arrest	1	3
Cardiac dysfunction	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	3
		7	32	4	20
					2
			1	1	1
					1
		2	12		3
		11	62		15
		1	1		
					9
			1		
			1		
					1
			2		1
			1		
			2		
		1	5	1	3
			1		1
			1		
		1	1		
					1
					1
			1		
	1		5	3	12
				1	1
					1
		2	5		3
				1	1
					1
					1
				1	1
				1	3
				1	1

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardio-ankle vascular index		1
Cardio-respiratory arrest		1
Cardioversion	1	1
Catarrh	1	6
Central nervous system vasculitis	2	2
Central pain syndrome		1
Cerebral disorder		1
Cerebral haemorrhage	1	1
Cerebral ischaemia	1	1
Cerebral venous sinus thrombosis	1	2
Cerebrovascular accident	1	2
Cervicobrachial syndrome		4
Change of bowel habit	1	1
Chest discomfort	7	29
Chest pain	15	56
Chills	138	847
Choking sensation	1	1
Chorioretinopathy	1	1
Chromaturia	1	2
Chronic respiratory failure		1
Circulatory collapse	1	2
Circumoral oedema	1	2
Circumoral swelling		1
Clonus		1
Clostridial infection	1	1
Cluster headache		1
Coagulation factor increased		1
Coagulopathy		1
Cold sweat	1	9
Colitis	1	2
Condition aggravated		6
Confusional state	6	49

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
		1	1		
			3	1	3
				2	2
			1		
					1
				1	1
				1	1
				1	2
				1	2
			3		1
				1	1
1	1	5	17	2	12
3	3	8	37	7	19
	3	124	715	14	132
				1	1
				1	1
			1	1	1
					1
				1	2
		1	2		
					1
					1
				1	1
			1		
					1
					1
		1	4		5
		1	2		
			2		4
		4	38	2	11

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Conjunctival haemorrhage		5
Conjunctival hyperaemia		3
Conjunctival irritation		2
Conjunctivitis	3	19
Conjunctivitis allergic	1	2
Constipation	1	2
Contusion		1
Corneal bleeding		1
Coronary artery dissection		1
Cough	29	118
COVID-19	51	91
COVID-19 pneumonia	1	5
Cramp-fasciculation syndrome		1
Cranial nerve paralysis	3	3
Craniocerebral injury	1	1
C-reactive protein abnormal		1
C-reactive protein increased		4
Crying		1
Cyanosis	1	3
Cyst		1
Cystitis	1	5
Cystitis haemorrhagic		1
Deafness	1	3
Deafness neurosensory	2	2
Death	1	3
Decreased appetite	5	40
Deep vein thrombosis	8	11
Defaecation urgency		1
Delusion		1
Dental discomfort	1	1
Depersonalisation/derealisation disorder		1
Depressed level of consciousness	3	17

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					5
			1		2
			1		1
		2	15	1	4
			1	1	1
		1	2		
			1		
					1
					1
2	3	18	74	11	44
2	3	14	24	37	67
	1			1	5
					1
				3	3
				1	1
			1		
			1		3
			1		
				1	3
			1		
		1	4		1
					1
				1	3
		1	1	1	1
				1	3
	1	4	34	1	6
				8	11
			1		
			1		
		1	1		
			1		
				3	17

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Depression	1	2
Dermal cyst	1	1
Dermatitis	2	3
Dermatitis acneiform	1	1
Dermatitis allergic		3
Dermatitis bullous		6
Dermatitis exfoliative		1
Dermatitis herpetiformis		2
Diabetes mellitus	1	1
Diaphragmalgia		1
Diarrhoea	44	251
Diplopia	7	12
Discomfort	6	10
Discouragement	1	1
Disease progression	1	1
Disease recurrence	1	8
Disorientation		7
Disturbance in attention	2	12
Dizziness	32	150
Drooling		1
Drug eruption		1
Drug hypersensitivity		2
Drug ineffective	18	36
Drug interaction		1
Dry eye		3
Dry mouth	8	39
Dry skin		2
Dry throat		2
Duodenal ulcer haemorrhage	1	1
Dysaesthesia	3	11
Dysarthria		2
Dysentery	4	68

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
		1	1		
		1	2	1	1
		1	1		
			1		2
					6
					1
			1		1
				1	1
			1		
		38	208	6	43
		2	5	5	7
		6	10		
		1	1		
				1	1
			1	1	7
	1		6		1
	1	1	9	1	3
	2	24	114	8	36
			1		
			1		
			1		1
				18	36
1	1				1
			2		1
		7	32	1	7
					2
			2		
				1	1
		1	7	2	4
1	1		1		1
	3			4	68

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysgeusia	11	62
Dysgraphia		2
Dyskinesia		1
Dysmetria		1
Dyspepsia	3	13
Dysphagia	2	40
Dysphonia	4	21
Dyspnoea	25	120
Dyspnoea exertional	1	6
Dysstasia	4	5
Dysuria		2
Ear discomfort		6
Ear disorder		1
Ear infection		3
Ear pain	6	20
Ear pruritus		2
Ear swelling		1
Ecchymosis	1	2
Eczema	2	3
Eczema asteatotic	1	1
Effusion		1
Electric shock sensation		1
Electrocardiogram abnormal		1
Embolism		2
Emphysema		1
Encephalitis	1	1
Enteritis		1
Enthesopathy	1	1
Eosinophil count increased		1
Epicondylitis		2
Epiglottic oedema		1
Epilepsy	3	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	2	9	54	2	8
			1		1
			1		
					1
		3	12		1
	1	2	24		16
		3	11	1	10
2	5	8	41	17	79
			3	1	3
		3	3	1	2
			1		1
			5		1
					1
			2		1
			11	6	9
			2		
			1		
			1	1	1
		1	2	1	1
		1	1		
					1
			1		
					1
					2
					1
				1	1
1	1		1		
				1	1
					1
			2		
					1
1	1			3	7

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Episcleritis		1
Epistaxis	3	14
Erectile dysfunction		2
Erythema	26	162
Erythema multiforme		4
Erythema nodosum	1	3
Erythema of eyelid		3
Erythematotelangiectatic rosacea		1
Euphoric mood		1
Exophthalmos	2	2
Extensive swelling of vaccinated limb		4
Extrasystoles	2	12
Extravasation		1
Eye discharge	1	1
Eye disorder		2
Eye haematoma		1
Eye haemorrhage		2
Eye irritation	8	34
Eyelid function disorder		1
Eyelid oedema	2	14
Eyelid pain		1
Eyelid ptosis	4	8
Eyelids pruritus	1	2
Eye movement disorder		1
Eye oedema	1	3
Eye pain	7	33
Eye paraesthesia	1	4
Eye pruritus	2	10
Eye swelling		2
Face oedema	4	22
Facial asymmetry		1
Facial bones fracture		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		3	13		1
					2
1	2	20	113	6	49
					4
			2	1	1
			2		1
			1		
			1		
				2	2
			2		2
1	1	1	8	1	4
			1		
		1	1		
			2		
					1
					2
	1	8	29		5
					1
	1	2	10		4
			1		
		1	2	3	6
		1	2		
			1		
		1	2		1
	1	5	29	2	4
		1	2		2
			5	2	5
			2		
		3	12	1	10
					1
					1

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Facial discomfort		3
Facial nerve disorder		2
Facial neuralgia		3
Facial pain		4
Facial paralysis	3	16
Facial paresis	1	10
Facial spasm		1
Faeces hard		1
Faeces pale	1	1
Fall	3	6
Fasciitis		1
Fatigue	119	866
Febrile convulsion		1
Feeling abnormal	3	13
Feeling cold	13	85
Feeling drunk		1
Feeling hot	12	80
Feeling jittery		2
Feeling of body temperature change	1	6
Feeling of despair	1	1
Fibrin D dimer increased	1	2
Fibromyalgia	1	1
Flank pain		2
Flatulence		4
Fluid retention		1
Flushing	9	48
Food allergy		1
Frequent bowel movements		1
Fungal infection		1
Gait disturbance	4	14
Gait inability		3
Gamma-glutamyltransferase increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		
			1		1
			2		1
			4		
				3	16
			5	1	5
			1		
			1		
				1	1
		1	1	2	5
			1		
	3	100	754	19	112
					1
		3	12		1
	1	13	74		11
			1		
		9	59	3	21
			1		1
			3	1	3
		1	1		
				1	2
		1	1		
			2		
			4		
			1		
1	1	8	42	1	6
					1
			1		
			1		
		4	7		7
					3
					1

* I=Interval, C=Cumulative
* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastric dilatation		1
Gastritis	2	2
Gastroenteritis		2
Gastrointestinal disorder	2	17
Gastrointestinal pain	7	8
Gastrointestinal sounds abnormal		1
Generalised oedema		1
Generalised tonic-clonic seizure		2
Genital pain	1	1
Gingival bleeding		1
Gingival discomfort	1	1
Gingival pain		1
Gingival swelling		1
Gingivitis		3
Glossitis		4
Glossodynia	2	3
Grip strength decreased		1
Groin pain	1	2
Grunting		1
Guillain-Barre syndrome		2
Guttate psoriasis		1
Haematochezia		1
Haematoma	1	6
Haematuria		3
Haemochromatosis		1
Haemolysis	1	1
Haemorrhagic diathesis	1	1
Haemorrhoids	1	1
Haemorrhoids thrombosed	2	2
Hallucination		1
Hallucinations, mixed		1
Headache	373	1,862

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		2	2		
			1		1
	1	2	14		3
		6	7	1	1
			1		
			1		
					2
		1	1		
			1		
		1	1		
			1		
			1		
			3		
			4		
		2	3		
					1
	1		1	1	1
					1
					2
					1
					1
			4	1	2
			3		
			1		
				1	1
				1	1
		1	1		
				2	2
					1
					1
2	8	340	1616	33	246

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Head discomfort	2	14
Heart rate decreased		2
Heart rate increased	2	15
Heat stroke		3
Heavy menstrual bleeding	5	5
Hemianaesthesia	1	4
Hemiparaesthesia	1	6
Hemiparesis		4
Hemiplegia		1
Hepatic encephalopathy		
Herpes ophthalmic		3
Herpes simplex	2	3
Herpes simplex encephalitis		1
Herpes virus infection	2	5
Herpes zoster	14	27
Herpes zoster oticus	1	1
Herpes zoster reactivation	1	1
HIV infection		1
Hormone level abnormal	1	1
Hot flush	12	36
Hydrocephalus		1
Hyperacusis		2
Hyperaemia		1
Hyperaesthesia	1	7
Hypercapnia	1	1
Hypercholesterolaemia		1
Hypercreatininaemia		1
Hyperglycaemia		4
Hyperhidrosis	9	75
Hyperkinesia		1
Hyperpyrexia	5	94
Hyperreflexia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	12		2
			2		
		2	9		6
			2		1
		3	3	2	2
				1	4
				1	6
					4
					1
1	1				
					3
		2	3		
					1
		1	3	1	2
		13	20	1	7
				1	1
		1	1		
					1
				1	1
		8	25	4	11
					1
			1		1
			1		
		1	7		
				1	1
					1
					1
			3		1
		6	56	3	19
			1		
	1			5	94
				1	1

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypersensitivity	10	30
Hypersensitivity vasculitis		1
Hypersomnia	1	2
Hypertension	17	78
Hypertensive crisis	8	43
Hyperthermia	1	12
Hyperthyroidism		1
Hypertonia		1
Hypertransaminasaemia		2
Hypertrophy of tongue papillae	1	2
Hyperventilation		3
Hypoacusis	1	6
Hypoaesthesia	7	35
Hypoaesthesia oral	1	10
Hypoglycaemia		2
Hypokinesia		2
Hyporeflexia		1
Hyporesponsive to stimuli		1
Hypotension	8	41
Hypotensive crisis		1
Hypothermia	1	9
Hypothyroidism	1	1
Hypotonia		3
Hypoxia	1	3
Illrd nerve disorder		1
Illness	3	4
Immunisation	1	2
Immunisation anxiety related reaction		1
Impaired gastric emptying		1
Inappropriate affect		1
Inappropriate schedule of product administration	1	3
Incomplete course of vaccination	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	2	5	14	5	16
					1
		1	2		
1	1	7	41	10	37
	2			8	43
		1	9		3
					1
			1		
1	1				2
		1	1		1
			1		2
1	1		2	1	4
		6	29	1	6
		1	8		2
			2		
			1		1
					1
			1		
	1	5	26	3	15
					1
		1	1		8
				1	1
			3		
				1	3
					1
		3	4		
		1	2		
			1		
					1
			1		
		1	3		
		1	1		

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Incontinence	1	1
Incorrect route of product administration	3	11
Induration		2
Infected cyst		1
Infection		2
Inflammation		7
Influenza	5	17
Influenza like illness	8	54
Infusion site pain		1
Infusion site paraesthesia		1
Initial insomnia	1	8
Injected limb mobility decreased		9
Injection related reaction		1
Injection site discharge		1
Injection site discomfort	1	2
Injection site erythema	2	52
Injection site haematoma	1	5
Injection site hypersensitivity		2
Injection site hypoaesthesia		2
Injection site induration		3
Injection site infection		5
Injection site inflammation		2
Injection site joint erythema		1
Injection site joint pain	1	3
Injection site joint swelling		1
Injection site muscle weakness		1
Injection site oedema	1	111
Injection site pain	16	670
Injection site paraesthesia		3
Injection site pruritus		17
Injection site rash	1	3
Injection site reaction		5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		3	11		
			2		
					1
			1		1
			4		3
		5	17		
		7	46	1	8
			1		
			1		
		1	7		1
	1		8		1
			1		
			1		
		1	2		
		2	52		
		1	5		
			2		
			2		
			3		
			5		
			2		
			1		
		1	3		
			1		
			1		
		1	111		
		16	669		1
			3		
			17		
		1	3		
			5		

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site swelling		24
Injection site urticaria		8
Injection site warmth	1	4
Injury	1	2
Insomnia	18	108
Intermenstrual bleeding	1	3
Intermittent claudication		1
International normalised ratio increased	1	1
Intestinal ischaemia	2	2
Intracranial pressure increased	1	1
Intranasal paraesthesia		1
Irritability	3	8
Irritable bowel syndrome	1	1
Ischaemic stroke	1	2
IVth nerve disorder		1
Jaundice		1
Joint dislocation		1
Joint effusion		1
Joint instability		1
Joint lock		1
Joint range of motion decreased	2	9
Joint stiffness		1
Joint swelling	2	5
Joint warmth		1
Labyrinthitis		4
Lacrimation increased	3	16
Laryngeal discomfort		1
Laryngeal dyspnoea		1
Laryngeal oedema	3	27
Laryngospasm	1	9
Larynx irritation		1
Lateropulsion		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			24		
			7		1
		1	4		
				1	2
		17	101	1	7
		1	2		1
			1		
				1	1
				2	2
				1	1
			1		
		1	4	2	4
		1	1		
				1	2
					1
			1		
					1
			1		
					1
			2	2	7
			1		
		2	4		1
					1
			1		3
		2	11	1	5
					1
					1
				3	27
			5	1	4
			1		
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lethargy	2	3
Leukocytosis		1
Leukopenia		1
Ligament sprain	1	1
Limb discomfort	5	21
Lipase increased		3
Lip disorder		1
Lip dry		2
Lip erythema	1	1
Lipodystrophy acquired		1
Lip oedema	3	22
Lip pain		1
Lip pruritus		7
Lip swelling	5	17
Localised oedema	2	15
Local reaction	2	3
Loss of consciousness	10	23
Loss of libido		1
Loss of personal independence in daily activities	1	2
Lung neoplasm malignant		1
Lung opacity	1	1
Lymphadenitis	3	13
Lymphadenopathy	57	457
Lymphangitis		2
Lymph node pain	5	35
Lymph node palpable		2
Lymphocytosis		1
Lymphoedema		6
Macroglossia	1	1
Macular rupture		1
Magnetic resonance imaging head abnormal	1	1
Malaise	71	585

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3		
			1		
					1
				1	1
		4	19	1	2
			2		1
					1
			2		
		1	1		
					1
		2	13	1	9
			1		
			3		4
	1	4	14	1	3
		1	12	1	3
		2	3		
				10	23
			1		
			1	1	1
					1
		1	1		
		3	13		
	2	52	393	5	64
					2
	2	4	31	1	4
			2		
			1		
			4		2
				1	1
					1
				1	1
1	2	63	542	8	43

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mastication disorder		1
Mastitis	1	4
Maternal exposure during pregnancy		2
Mechanical urticaria		4
Mechanical ventilation	1	1
Mediastinal disorder	1	1
Medication error		1
Memory impairment	1	2
Menstrual disorder	1	1
Menstruation irregular	1	1
Mental impairment		1
Micturition disorder		1
Micturition urgency	1	2
Middle insomnia		5
Migraine	8	71
Migraine with aura		3
Miosis		1
Mitral valve incompetence		1
Mobility decreased	1	2
Monoparesis	4	4
Monoplegia		5
Morning sickness		1
Motor dysfunction	1	15
Mouth swelling		2
Movement disorder	1	7
Mucosal dryness		2
Mucosal ulceration		1
Mucous stools		1
Multiple organ dysfunction syndrome		1
Multiple sclerosis	1	1
Muscle contractions involuntary	1	3
Muscle contracture		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	4
			1		1
	1		2		2
				1	1
		1	1		
			1		
				1	2
				1	1
		1	1		
					1
			1		
		1	1		1
			5		
	2	8	60		11
			3		
			1		
					1
		1	1		1
		3	3	1	1
					5
			1		
			11	1	4
			1		1
			2	1	5
			2		
					1
			1		
					1
				1	1
			2	1	1
	1		2		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle rigidity	3	9
Muscle spasms	3	22
Muscle swelling		1
Muscle tightness		3
Muscle twitching	2	5
Muscular weakness	2	28
Musculoskeletal chest pain	2	14
Musculoskeletal disorder		1
Musculoskeletal pain	18	167
Musculoskeletal stiffness	6	19
Myalgia	188	1,285
Myasthenia gravis crisis	1	1
Myeloid leukaemia	1	1
Myocardial infarction		2
Myocardial necrosis marker increased		1
Myocarditis	1	2
Myoclonus		1
Myokymia		1
Myositis	2	5
Narcolepsy		1
Nasal congestion	8	12
Nasal discomfort	2	5
Nasal herpes		2
Nasal oedema	1	1
Nasal pruritus		1
Nasopharyngitis	10	25
Nausea	101	696
Neck pain	10	64
Neoplasm	1	1
Nervousness	2	3
Nervous system disorder		1
Neuralgia	1	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	9		
		2	15	1	7
					1
			2		1
		1	3	1	2
			22	2	6
		1	9	1	5
			1		
		17	140	1	27
		5	14	1	5
	5	174	1146	14	139
				1	1
				1	1
					2
					1
				1	2
					1
			1		
	1	1	2	1	3
					1
		6	10	2	2
		2	5		
			2		
		1	1		
			1		
		8	21	2	4
1	6	87	577	14	119
	1	5	47	5	17
		1	1		
		2	3		
					1
		1	10		3

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neuralgic amyotrophy		
Neuritis		5
Neurological symptom	1	1
Neuromuscular pain	1	1
Neuropathy peripheral	3	8
Neurosensory hypoacusis		1
Neutropenia		1
Nightmare	1	1
Night sweats	1	6
Nocturia		1
Nocturnal dyspnoea	1	1
Nodule		1
Non-cardiac chest pain		1
Noninfective gingivitis	1	1
Nuchal rigidity		8
Nystagmus		2
Obstructive airways disorder	1	1
Occipital neuralgia		1
Ocular discomfort	3	5
Ocular hyperaemia	3	16
Oculogyric crisis		1
Odynophagia		5
Oedema	4	15
Oedema mouth	1	4
Oedema mucosal		1
Oedema peripheral	4	21
Oedematous pancreatitis		1
Oesophageal spasm		1
Off label use	2	7
Oncologic complication	1	1
Ophthalmic herpes zoster		2
Optic ischaemic neuropathy		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1				
			5		
				1	1
		1	1		
				3	8
					1
					1
		1	1		
		1	6		
			1		
		1	1		
			1		
					1
		1	1		
			7		1
					2
				1	1
		2	4	1	1
		3	13		3
					1
	1		3		2
		4	13		2
		1	2		2
					1
		2	16	2	5
					1
					1
		2	7		
		1	1		
					2
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral candidiasis		1
Oral discomfort	6	17
Oral disorder	1	2
Oral dysaesthesia		2
Oral herpes	4	26
Oral mucosal erythema		2
Oral pain	1	3
Oral pruritus		4
Orbital oedema		1
Oropharyngeal discomfort		4
Oropharyngeal oedema		1
Oropharyngeal pain	13	52
Oropharyngeal spasm		1
Oropharyngeal swelling		2
Orthopnoea		1
Otitis externa		1
Overdose	10	31
Ovulation pain	1	1
Oxygen saturation decreased	3	25
Pain	52	293
Pain in extremity	91	490
Pain in jaw	1	3
Pain of skin		2
Palatal oedema		10
Palatal swelling		2
Pallor	1	8
Palpitations	5	20
Pancreatitis		1
Panic attack	1	1
Panniculitis		1
Papilloedema	1	1
Papule		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		5	13	1	4
		1	2		
			2		
		4	19		7
			1		1
		1	2		1
			2		2
					1
			4		
					1
	1	9	43	4	9
					1
			1		1
					1
			1		
		8	27	2	4
				1	1
1	1	1	8	2	17
		46	250	6	43
	1	77	425	14	65
		1	3		
			2		
			8		2
			2		
		1	6		2
		3	11	2	9
					1
		1	1		
					1
				1	1
			3		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Paraesthesia	50	285
Paraesthesia ear		1
Paraesthesia mucosal	1	2
Paraesthesia oral	18	105
Parainfluenzae virus infection	1	1
Paralysis		2
Paraparesis		1
Paresis		1
Parosmia	1	8
Partial seizures	1	3
Penile erythema		1
Penile ulceration		1
Pericardial effusion		1
Pericarditis	1	4
Perioral dermatitis		1
Periorbital oedema		7
Periorbital pain		2
Periorbital swelling	3	9
Peripheral artery thrombosis		1
Peripheral coldness	2	12
Peripheral embolism		1
Peripheral ischaemia		1
Peripheral paralysis	1	1
Peripheral sensorimotor neuropathy		1
Peripheral swelling	8	52
Peripheral venous disease	1	2
Petechiae	4	6
Pharyngeal erythema	1	2
Pharyngeal mass	2	2
Pharyngeal oedema		5
Pharyngeal paraesthesia	4	11
Pharyngeal swelling		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	2	36	209	14	76
			1		
		1	1		1
1	3	11	72	7	33
				1	1
					2
					1
					1
		1	6		2
				1	3
			1		
			1		
					1
				1	4
			1		
			5		2
			2		
		2	7	1	2
					1
		2	10		2
					1
					1
				1	1
					1
		6	41	2	11
		1	2		
		1	3	3	3
		1	1		1
				2	2
	1		2		3
		3	5	1	6
			2		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pharyngitis	1	4
Phlebitis		3
Phlebitis superficial		1
Photophobia		14
Photopsia		4
Pityriasis rosea		2
Pleurisy		1
Pleuropericarditis		1
Plicated tongue	1	2
Pneumonia		5
Pneumonia bacterial		1
Pneumonitis		3
Pollakiuria		2
Polyarthrits		1
Polydipsia	1	2
Polyuria	1	2
Presyncope	7	40
Product administered at inappropriate site		5
Productive cough	1	3
Product preparation issue	1	2
Product use issue	1	4
Pruritus	29	188
Pruritus genital		1
Pseudomembranous colitis	1	1
Psoriasis	1	1
Psychiatric decompensation	1	1
Psychomotor hyperactivity	1	3
Pulmonary embolism	4	6
Pulmonary hypoperfusion		1
Pulmonary microemboli		1
Pulmonary oedema		1
Pulmonary pain		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	3
			2		1
					1
			12		2
			1		3
			2		
					1
					1
		1	1		1
					5
					1
					3
			1		1
					1
		1	2		
		1	2		
		2	20	5	20
			5		
				1	3
		1	2		
		1	4		
1	2	20	144	9	44
			1		
				1	1
				1	1
		1	1		
			2	1	1
			1	4	5
					1
					1
					1
			2		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pulse abnormal		1
Pulse volume decreased		1
Puncture site induration		1
Puncture site pain		1
Pyrexia	321	1,920
Q fever		3
Quality of life decreased	1	3
Radiculopathy		1
Rales		1
Rash	24	121
Rash erythematous	4	12
Rash macular	2	7
Rash maculo-papular	1	4
Rash papular	2	3
Rash papulosquamous		1
Rash pruritic	6	16
Rash vesicular	1	4
Raynaud's phenomenon	1	2
Reaction to excipient		1
Rectal haemorrhage	1	2
Red blood cell sedimentation rate increased		3
Renal colic	2	2
Renal pain		7
Respiratory depression		1
Respiratory disorder	1	5
Respiratory distress		8
Respiratory failure	1	4
Respiratory fatigue		2
Respiratory rate increased		1
Respiratory tract infection	1	2
Respiratory tract oedema	2	5
Restless legs syndrome		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
			1		
			1		
	8	284	1595	37	325
					3
		1	1		2
			1		
			1		
	1	16	84	8	37
		3	10	1	2
		1	5	1	2
		1	3		1
		2	2		1
			1		
		5	12	1	4
		1	4		
			1	1	1
					1
				1	2
			1		2
			7		
					1
		1	2		3
	1				8
				1	4
			1		1
			1		
				1	2
				2	5
					1

* I=Interval, C=Cumulative

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Restlessness	3	8
Retching	1	7
Retinal degeneration		1
Retinal detachment		2
Retinal disorder		1
Retinal vascular thrombosis		
Retinal vein thrombosis	1	2
Retrograde amnesia		1
Rhabdomyolysis		1
Rheumatic disorder		1
Rheumatoid arthritis		3
Rhinalgia	1	3
Rhinitis	5	21
Rhinorrhoea	5	19
Rhonchi		1
Rib fracture	1	1
Salivary hypersecretion		1
Sarcoidosis		1
SARS-CoV-2 ant body test		1
SARS-CoV-2 ant body test negative		1
SARS-CoV-2 ant body test positive		1
SARS-CoV-2 test positive	3	7
Scab		1
Sciatica	1	6
Scratch	1	1
Secretion discharge	1	2
Sedation		4
Seizure	1	4
Seizure like phenomena		1
Sensation of foreign body		8
Sense of oppression		1
Sensitive skin	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	5		3
1	1	1	6		1
					1
					2
					1
	1				
				1	2
			1		
					1
					1
					3
		1	2		1
1	1	3	15	2	6
		4	13	1	6
			1		
				1	1
			1		
					1
					1
			1		
					1
1	1	3	3		4
					1
			4	1	2
		1	1		
		1	1		1
			3		1
				1	4
					1
			4		4
			1		
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sensorimotor disorder		1
Sensory disturbance	3	3
Sensory loss		1
Septic shock		1
Severe acute respiratory syndrome		2
Shock		1
Sinusitis	1	1
Sinus pain	1	2
Sinus rhythm		1
Sinus tachycardia		5
Skin burning sensation	2	9
Skin discolouration	2	6
Skin exfoliation		1
Skin hypertrophy		1
Skin irritation		2
Skin laceration		2
Skin lesion		4
Skin mass		2
Skin oedema		1
Skin reaction	2	11
Skin striae		1
Skin swelling		1
Skin tightness		1
Skin warm		1
Skull fractured base	1	1
Sleep disorder		7
Sluggishness		1
Sneezing	1	6
Somnolence	16	100
Speech disorder	1	3
Spinal pain	1	8
Status epilepticus		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		2	2	1	1
			1		
					1
					2
					1
		1	1		
				1	2
			1		
			4		1
			6	2	3
		1	3	1	3
			1		
			1		
			2		
			1		1
			2		2
			2		
			1		
		1	7	1	4
			1		
					1
			1		
					1
				1	1
			6		1
					1
			4	1	2
		13	86	3	14
		1	1		2
		1	8		
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Stoma site pain		1
Stomatitis	1	3
Stridor		1
Stupor		6
Subarachnoid haemorrhage	1	3
Subcutaneous haematoma		1
Sudden death	1	2
Sudden onset of sleep		1
Suffocation feeling	3	4
Superinfection bacterial		1
Supraventricular extrasystoles		1
Supraventricular tachycardia	1	2
Suspected COVID-19	1	2
Swelling	13	42
Swelling face	4	21
Swelling of eyelid		3
Swollen tongue	3	19
Syncope	9	38
Systemic lupus erythematosus		1
Tachyarrhythmia	1	3
Tachycardia	26	145
Tachycardia paroxysmal	1	4
Tachypnoea	1	13
Taste disorder	3	11
Temporomand bular joint syndrome		2
Tenderness		3
Tendonitis	1	1
Tendon pain	1	3
Tension	1	4
Tension headache	1	5
Testicular pain	1	1
Thirst		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1	1	2
			1		
			4		2
				1	3
					1
				1	2
					1
		1	1	2	3
					1
					1
		1	2		
				1	2
		9	33	4	9
	1	2	14	2	7
			2		1
		2	11	1	8
				9	38
					1
			2	1	1
1	2	14	95	12	50
			2	1	2
			7	1	6
		2	9	1	2
			1		1
			3		
				1	1
			1	1	2
		1	3		1
		1	5		
				1	1
			2		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Throat irritation	4	22
Throat tightness	4	45
Thrombocytopenia	4	7
Thrombophlebitis	3	5
Thrombophlebitis superficial	2	5
Thrombosis	5	6
Thrombotic thrombocytopenic purpura	1	1
Thyroiditis acute	2	2
Tinnitus	6	23
Tongue coated		2
Tongue discolouration		1
Tongue discomfort		6
Tongue disorder		2
Tongue dry		2
Tongue erythema		1
Tongue oedema	4	17
Tongue pruritus	1	8
Tonsillar hypertrophy		3
Tonsillar inflammation	1	1
Toothache	1	3
Torticollis		3
Tracheitis		2
Transaminases increased		2
Transient ischaemic attack	2	2
Traumatic fracture		1
Tremor	16	64
Trigeminal nerve disorder		1
Trigeminal neuralgia	1	4
Trigger finger		1
Type I hypersensitivity	4	6
Underdose	1	3
Upper airway obstruction		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	14		8
1	3	1	21	3	24
1	1			4	7
		1	3	2	2
			1	2	4
				5	6
				1	1
				2	2
		4	18	2	5
			2		
			1		
			6		
			1		1
			2		
			1		
		3	9	1	8
			5	1	3
			3		
		1	1		
			2	1	1
			3		
			2		
			1		1
				2	2
					1
		11	40	5	24
					1
			2	1	2
			1		
				4	6
		1	3		
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Urinary retention		1
Urinary tract infection		1
Urine odour abnormal		1
Urticaria	20	123
Urticaria chronic		1
Urticaria physical		1
Urticaria vesiculosa		1
Use of accessory respiratory muscles		3
Uveitis		3
Vaccination complication	22	62
Vaccination failure	22	39
Vaccination site bruising		2
Vaccination site cellulitis		1
Vaccination site discharge		1
Vaccination site discolouration		1
Vaccination site discomfort		1
Vaccination site eczema		1
Vaccination site erythema	22	75
Vaccination site extravasation		2
Vaccination site haematoma	2	4
Vaccination site hypersensitivity		1
Vaccination site hypoaesthesia		2
Vaccination site induration	9	14
Vaccination site inflammation		3
Vaccination site irritation		1
Vaccination site joint erythema		1
Vaccination site joint movement impairment	1	3
Vaccination site joint pain		3
Vaccination site joint swelling	3	14
Vaccination site lymphadenopathy	1	7
Vaccination site mass	1	1
Vaccination site movement impairment	1	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
			1		
		17	93	3	30
			1		
			1		
					1
			2		1
					3
	1	22	53		9
2	3			22	39
			2		
					1
			1		
			1		
			1		
		17	56	5	19
			1		1
		2	4		
					1
			2		
		9	13		1
			2		1
			1		
			1		
		1	3		
			3		
		3	14		
		1	5		2
		1	1		
		1	9		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site nodule		1
Vaccination site oedema	13	138
Vaccination site pain	257	1,164
Vaccination site paraesthesia	2	12
Vaccination site phlebitis		1
Vaccination site pruritus	11	27
Vaccination site rash	2	8
Vaccination site reaction	9	32
Vaccination site swelling	29	90
Vaccination site ulcer	1	1
Vaccination site urticaria	1	8
Vaccination site vesicles		2
Vaccination site warmth		11
Vaginal haemorrhage	1	3
Vascular purpura		1
Vascular skin disorder	1	1
Vasculitis		2
Vasculitis necrotising	1	2
Vasodilatation		1
Venous thrombosis	2	3
Venous thrombosis limb	2	2
Ventricular extrasystoles		5
Ventricular fibrillation		1
Ventricular tachycardia		1
Vertigo	22	172
Vertigo positional		
Vestibular neuritis		1
Viral infection	1	1
Vision blurred	6	29
Visual acuity reduced		1
Visual field defect		3
Visual impairment	2	15

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		12	130	1	8
	1	245	1085	12	79
		2	10		2
			1		
		6	17	5	10
		2	7		1
		9	27		5
		26	66	3	24
				1	1
		1	5		3
			1		1
			8		3
			1	1	2
					1
				1	1
			2		
		1	1		1
			1		
				2	3
	1			2	2
			5		
					1
					1
		20	142	2	30
	1				
					1
				1	1
1	1	2	20	4	9
					1
			3		
	1		9	2	6

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vitreoretinal traction syndrome	1	2					1	2
Vitreous detachment		2		1				2
Vitreous disorder		3				1		2
Vitreous floaters		3						3
Vomiting	38	205		2	29	142	9	63
Vomiting projectile		1				1		
Vulvovaginal burning sensation		1				1		
Wandering pacemaker		1						1
Weight decreased		1				1		
Wheezing		6				5		1
Xanthopsia		1						1
Xerophthalmia		1						1
Yellow skin		1				1		
	3,797	21,746	45	160	2914	17177	883	4569

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort		1						1
Abdominal distension		2						2
Abdominal pain	5	14			2	9	3	5
Abdominal pain lower	1	1					1	1
Abdominal pain upper	4	8	1	1	2	5	2	3
Abscess limb		1				1		
Accidental overdose	1	1			1	1		
Activated partial thromboplastin time shortened	1	1			1	1		
Acute abdomen		1						1
Acute coronary syndrome	2	2					2	2
Acute myocardial infarction	4	5					4	5
Acute respiratory failure	1	3					1	3
Administration site oedema		3				3		
Administration site pain		1				1		
Ageusia	1	1					1	1
Agitation	1	1					1	1
A bumin CSF increased	1	1					1	1
Allergy to vaccine	1	2				1	1	1
Altered state of consciousness		1						1
Amaurosis fugax	1	2					1	2
Amnesia	3	3			1	1	2	2
Amylase increased	1	1					1	1
Anaemia	3	3					3	3
Anal incontinence		1						1
Anaphylactic reaction	2	2					2	2
Anaphylactic shock	1	1					1	1
Angina unstable	1	1					1	1
Angioedema	3	8					3	8
Anosmia	1	1					1	1
Anxiety	1	1					1	1
Aortic arteriosclerosis	1	1					1	1
Aortic dissection		1						1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Aortic valve calcification	1	1
Aphasia	5	9
Aphonia		2
Apical granuloma	1	1
Application site coldness		1
Arrhythmia	1	4
Arterial thrombosis	1	1
Arteriosclerosis	2	2
Arthralgia	13	75
Asphyxia	1	1
Aspiration	1	1
Asthenia	28	102
Asthenopia		1
Asymptomatic COVID-19	4	6
Ataxia	1	1
Atelectasis	1	2
Atrial fibrillation	5	10
Atrial flutter		1
Axillary pain		1
Azotaemia	1	1
Back pain	2	5
Balance disorder	2	4
Basilar artery occlusion	1	1
Bell's palsy	5	10
Bladder obstruction		1
Bladder spasm	1	1
Blindness unilateral	1	1
Blood creatinine increased	2	2
Blood fibrinogen increased	1	2
Blood glucose abnormal	1	1
Blood glucose increased	1	1
Blood pressure abnormal	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				5	9
			1		1
		1	1		
			1		
				1	4
				1	1
				2	2
	1	11	62	2	13
				1	1
				1	1
	1	5	67	23	35
			1		
		1	1	3	5
				1	1
				1	2
				5	10
					1
			1		
				1	1
		1	2	1	3
		1	2	1	2
				1	1
				5	10
					1
				1	1
				1	1
		1	1	1	1
		1	2		
				1	1
		1	1		
				1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood pressure decreased		2
Blood pressure increased	5	11
Blood pressure systolic increased		1
Blood urea increased	1	1
Body temperature decreased		1
Body temperature increased		1
Bone pain	3	9
Bradycardia		2
Breast pain		1
Breath sounds abnormal	1	1
Bronchitis	1	1
Burning sensation	1	3
Capillary fragility	1	1
Cardiac arrest	7	8
Cardiac disorder	1	1
Cardiac failure	1	2
Cardiac murmur	1	1
Cardiopulmonary failure	1	1
Cardio-respiratory arrest	3	5
Carotid artery occlusion	1	1
Catarrh		1
Central nervous system lesion	1	2
Cerebellar ataxia		1
Cerebral artery embolism	1	1
Cerebral haematoma		1
Cerebral haemorrhage	4	4
Cerebral infarction	1	1
Cerebral ischaemia	6	8
Cerebral venous thrombosis	1	2
Cerebrovascular accident	5	8
Cervical radiculopathy		1
Chest discomfort	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
1	1	1	6	4	5
					1
		1	1		
			1		1
		2	6	1	3
	1				2
			1		
				1	1
		1	1		
		1	3		
		1	1		
				7	8
				1	1
				1	2
				1	1
				1	1
				3	5
				1	1
					1
		1	1		1
					1
				1	1
					1
				4	4
				1	1
				6	8
				1	2
				5	8
					1
			1	1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chest injury		
Chest pain	16	18
Chills	7	57
Choking sensation		1
Chromaturia	1	1
Chronic kidney disease	1	1
Clonic convulsion	3	3
Clonus		2
Cold sweat	2	3
Colitis ischaemic		1
Coma	1	1
Condition aggravated		3
Confusional state	7	12
Conjunctival haemorrhage	1	1
Conjunctival irritation		1
Constipation	4	5
Coronary artery disease	1	2
Cough	3	8
COVID-19	4	14
COVID-19 pneumonia	4	5
Cranial nerve paralysis	2	2
Craniocerebral injury	1	1
Cyanosis	1	2
Cystitis haemorrhagic		1
Deafness	1	1
Death	3	5
Decreased appetite	4	8
Deep vein thrombosis	9	12
Defect conduction intraventricular		1
Dehydration	1	2
Dental dysaesthesia	1	1
Depressed level of consciousness	3	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1				
		4	6	12	12
		3	47	4	10
					1
		1	1		
				1	1
				3	3
			1		1
				2	3
					1
				1	1
					3
		3	4	4	8
				1	1
					1
		2	2	2	3
				1	2
		2	6	1	2
		1	3	3	11
				4	5
				2	2
				1	1
				1	2
					1
				1	1
				3	5
		1	3	3	5
				9	12
					1
				1	2
				1	1
	1			3	5

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Diarrhoea	7	30
Diplegia		1
Diplopia	2	5
Discomfort	1	2
Disease progression	1	1
Disease recurrence	3	4
Disorientation	1	4
Disturbance in attention	1	1
Diverticulitis		1
Dizziness	9	17
Drug hypersensitivity		1
Drug ineffective	2	8
Dry mouth	3	4
Dysaesthesia		2
Dysarthria	8	9
Dysbiosis		1
Dyschezia		1
Dysentery	1	4
Dysgeusia	1	3
Dyskinesia	1	1
Dysphagia	4	9
Dysphonia	3	6
Dyspnoea	23	37
Dyspnoea exertional	1	1
Dyspraxia	1	1
Dysuria		2
Ear haemorrhage	1	1
Ear infection		1
Ear pain		3
Ear pruritus		1
Ecchymosis	3	3
Eczema	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	25	3	5
					1
		1	3	1	2
		1	2		
				1	1
		1	1	2	3
				1	4
				1	1
					1
		6	14	3	3
					1
				2	8
		1	2	2	2
			2		
		1	1	7	8
					1
					1
				1	4
		1	3		
		1	1		
			2	4	7
		1	3	2	3
		6	11	17	26
				1	1
				1	1
					2
				1	1
			1		
			3		
			1		
		2	2	1	1
		1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Electrocardiogram repolarisation abnormality		1
Electrolyte imbalance		1
Embolism		1
Emphysema		1
Encephalitis	1	2
Enthesopathy		1
Epilepsy	3	6
Epistaxis	1	1
Erectile dysfunction		1
Erysipelas	1	1
Erythema	4	21
Erythema multiforme	1	1
Extrasystoles		3
Eye disorder		1
Eye irritation		2
Eyelid function disorder	1	1
Eyelid oedema	1	2
Eyelid retraction		1
Eye pain		2
Eye pruritus		2
Eye swelling		1
Face oedema	1	1
Facial asymmetry	1	1
Facial paralysis	5	8
Facial paresis	3	7
Fall	6	7
Fatigue	11	60
Feeling cold		9
Feeling hot		1
Feeling of body temperature change		1
Fibrin D dimer increased	1	4
Flatulence	3	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
					1
				1	2
					1
				3	6
				1	1
					1
				1	1
		2	15	2	6
				1	1
			2		1
					1
			2		
		1	1		
			1	1	1
					1
			1		1
			2		
			1		
				1	1
				1	1
				5	8
			2	3	5
1	1	2	2	4	5
		4	50	7	10
			9		
			1		
					1
		1	3		1
		2	3	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Flushing	3	5
Focal dyscognitive seizures		1
Functional gastrointestinal disorder		1
Gait disturbance	3	7
Gait inability		1
Gallbladder disorder	1	1
Gastrointestinal disorder		2
Gastrointestinal pain		1
Gastrointestinal sounds abnormal	1	2
Gastroesophageal reflux disease		1
Gaze palsy		1
Generalised tonic-clonic seizure	1	1
General physical health deterioration	1	1
Genital herpes zoster		1
Gingival bleeding	2	3
Gingival oedema		1
Guillain-Barre syndrome	1	1
Haematemesis	1	1
Haematochezia	2	2
Haematoma	2	3
Haematuria		1
Haemorrhagic infarction		1
Haemorrhagic stroke	1	1
Hallucination		2
Headache	32	124
Head discomfort	1	2
Heart rate increased	1	1
Hemianopia		1
Hemiparaesthesia		1
Hemiparesis	4	5
Hemiplegia	3	6
Hepatic steatosis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3	2	2
					1
			1		
		2	3	1	4
					1
				1	1
			2		
			1		
		1	2		
			1		
					1
				1	1
				1	1
					1
				2	3
					1
				1	1
				1	1
				2	2
				2	3
					1
					1
				1	1
					2
2	2	22	101	10	23
		1	1		1
				1	1
					1
					1
				4	5
				3	6
				1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hepatitis acute	1	1
Herpes virus infection		2
Herpes zoster	7	15
Herpes zoster oticus		1
Hot flush	1	3
Hyperaemia	1	2
Hyperaesthesia		1
Hypercapnia		1
Hypergammaglobulinaemia benign monoclonal	1	1
Hyperglycaemia	1	1
Hyperhidrosis	1	10
Hyperpyrexia	6	11
Hypersensitivity	1	5
Hypertension	7	15
Hypertensive crisis	11	15
Hypoacusis	1	2
Hypoaesthesia	1	5
Hypoaesthesia oral	3	3
Hypoglossal nerve disorder		1
Hypokinesia	1	1
Hyponatraemia		1
Hypopituitarism	1	1
Hyposmia		1
Hypotension	5	12
Hypotensive crisis	1	2
Hypothermia	1	2
Hypovolaemia		1
Hypoxia	2	4
Illness	1	1
Immobilisation prolonged	1	1
Impaired fasting glucose	1	1
Impaired quality of life		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			2		
		5	8	2	7
					1
			2	1	1
				1	2
			1		
					1
				1	1
				1	1
		1	7		3
				6	11
1	1		2	1	3
			3	7	12
				11	15
				1	2
			2	1	3
		1	1	2	2
					1
				1	1
					1
		1	1		
			1		
		1	3	4	9
				1	2
				1	2
					1
				2	4
		1	1		
				1	1
				1	1
			1		1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Inappropriate schedule of product administration		1
Incontinence		1
Incorrect route of product administration	1	3
Inflammation		1
Influenza		1
Influenza like illness		4
Injection site erythema		7
Injection site hyperaesthesia		1
Injection site infection		1
Injection site oedema		9
Injection site pain		45
Injection site paraesthesia		1
Injection site pruritus		3
Injection site reaction		2
Injection site swelling		4
Injection site urticaria		1
Injury		1
Insomnia	2	7
Inspiratory capacity abnormal		1
Intentional product use issue	1	1
Intermittent claudication	1	1
Internal haemorrhage	1	1
International normalised ratio increased	1	1
Interstitial lung disease	2	3
Intervertebral disc degeneration	1	1
Intervertebral discitis		1
Intestinal congestion		1
Intestinal infarction	1	1
Intestinal ischaemia		4
Ischaemia	4	4
Ischaemic stroke	4	5
Jaundice	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
		1	3		
			1		
			1		
			4		
			7		
			1		
			1		
			9		
			45		
			1		
			3		
			2		
			4		
			1		
			1		
			5	2	2
			1		
		1	1		
				1	1
				1	1
				2	3
				1	1
					1
			1		
				1	1
					4
				4	4
				4	5
				2	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Joint range of motion decreased		1
Lacrimation increased	2	4
Lagophthalmos		1
Laryngeal oedema	5	10
Laryngospasm		2
Leukocytosis	1	1
Leukopenia		1
Limb discomfort	1	2
Limb injury	1	1
Lipase increased	1	1
Lip oedema	3	5
Lip swelling	1	1
Listeriosis		1
Livedo reticularis	1	1
Liver disorder	1	1
Localised oedema	1	1
Loss of consciousness	6	9
Loss of personal independence in daily activities		1
Lung cancer metastatic	1	1
Lymphadenitis		1
Lymphadenopathy	1	15
Lymphadenopathy mediastinal	1	1
Lymphangitis		1
Lymph node palpable		1
Lymphocyte count increased	1	1
Macroglossia		1
Macule	1	1
Malaise	7	48
Maternal exposure during pregnancy	2	2
Melaena	1	2
Metabolic acidosis	1	1
Metamorphopsia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	3	1	1
					1
				5	10
					2
				1	1
					1
		1	1		1
				1	1
				1	1
		1	2	2	3
				1	1
					1
				1	1
		1	1	1	1
				6	9
					1
				1	1
					1
		1	13		2
				1	1
					1
			1		
		1	1		
					1
				1	1
	1	3	39	4	9
		2	2		
				1	2
				1	1
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Middle insomnia		2
Migraine	2	7
Monoclonal gammopathy	1	1
Motion sickness		1
Motor dysfunction	2	6
Mouth swelling		1
Movement disorder		2
Muscle contracture		1
Muscle fatigue		1
Muscle rigidity		1
Muscle spasms	1	6
Muscular weakness	1	2
Musculoskeletal chest pain		2
Musculoskeletal pain	2	16
Musculoskeletal stiffness		2
Myalgia	15	89
Myocardial infarction	3	3
Myocardial ischaemia	2	2
Nasal congestion	1	2
Nasopharyngitis		5
Nausea	11	48
Neck pain	1	5
Necrotising fasciitis	1	1
Nervous system disorder	2	2
Neuralgia	1	1
Neurogenic bladder		1
Night sweats		1
Nocturnal dyspnoea	1	1
Non-Hodgkin's lymphoma	1	1
Normal pressure hydrocephalus	1	1
Obstructive airways disorder	1	1
Ocular hyperaemia		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
1	1	1	6	1	1
				1	1
			1		
			3	2	3
					1
			2		
					1
					1
			1		
		1	6		
				1	2
			1		1
		1	14	1	2
			2		
	1	9	72	6	17
				3	3
				2	2
		1	2		
			3		2
1	1	6	35	5	13
			4	1	1
				1	1
				2	2
				1	1
					1
			1		
		1	1		
				1	1
				1	1
				1	1
			2		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Odynophagia	1	1
Oedema	1	3
Oedema mouth		3
Oedema mucosal	1	2
Oedema peripheral	5	8
Oesophageal oedema		1
Off label use	1	1
Oliguria		2
Optic neuritis		2
Oral discomfort		2
Oral herpes	1	4
Oral pain		1
Oral pruritus		1
Oropharyngeal discomfort	1	1
Oropharyngeal pain	1	4
Osteoarthritis	1	1
Otitis media		1
Overdose	3	9
Oxygen saturation decreased	6	10
Pain	3	23
Pain in extremity	15	45
Pain of skin		1
Palatal oedema	1	5
Pallor	1	4
Palpitations	2	2
Panic attack		1
Papilloedema		2
Paraesthesia	5	19
Paraesthesia oral	2	8
Paraparesis	1	1
Parosmia		1
Parotid gland enlargement		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
			1	1	2
			3		
				1	2
			2	5	6
					1
		1	1		
					2
					2
			2		
			2	1	2
					1
			1		
				1	1
		1	3		1
		1	1		
					1
		3	8		1
		1	2	5	8
		3	21		2
		9	32	6	13
			1		
			2	1	3
			2	1	2
		1	1	1	1
			1		
					2
	1	2	9	3	10
			5	2	3
				1	1
					1
			1		1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Paroxysmal arrhythmia		1
Performance status decreased	1	1
Pericardial effusion	3	6
Pericarditis	1	1
Periorbital oedema		1
Periorbital swelling		1
Peripheral coldness	1	2
Peripheral ischaemia	1	1
Peripheral nerve palsy	1	1
Peripheral paralysis	1	1
Peripheral swelling	3	4
Peritonsillar abscess		1
Petechiae	2	2
Pharyngeal oedema	1	2
Pharyngeal paraesthesia		1
Pharyngitis	1	4
Phlebitis	1	1
Phlebitis superficial	1	1
Photopsia	1	1
Pityriasis rosea		1
Platelet count decreased		1
Platelet count increased		1
Pleural effusion	1	4
Pleuropericarditis	1	1
Pneumatoxis		1
Pneumonia	1	5
Pneumonia legionella		1
Pneumonitis	1	1
Polyarthrits		1
Polyneuropathy	1	1
Polyuria	2	2
Poor quality sleep	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1		
				3	6
				1	1
					1
			1		
			1	1	1
				1	1
		1	1		
				1	1
		3	3		1
					1
				2	2
				1	2
					1
		1	3		1
		1	1		
				1	1
				1	1
			1		
			1		
					1
				1	4
				1	1
					1
				1	5
					1
				1	1
					1
				1	1
		2	2		
				1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Portal vein thrombosis	2	2
Post herpetic neuralgia		1
Post thrombotic syndrome	1	1
Presyncope	7	15
Product dose omission issue		1
Product preparation issue	1	1
Product use in unapproved indication	1	1
Product use issue	1	1
Prurigo		1
Pruritus	4	17
Pulmonary artery thrombosis	2	2
Pulmonary embolism	11	14
Pulmonary mass		1
Pulmonary oedema	1	1
Pulmonary thrombosis	1	1
Pupils unequal	1	1
Purpura	2	2
Pustular psoriasis		1
Pyrexia	51	209
Q fever		1
Quadripareisis	1	2
Quality of life decreased	3	3
Radial nerve palsy	1	1
Rales	1	2
Rash	2	8
Rash erythematous	1	4
Rash papular		1
Rash pruritic		1
Rectal haemorrhage	2	2
Renal failure	1	1
Renal impairment	1	1
Respiratory acidosis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
					1
				1	1
		2	6	5	9
			1		
		1	1		
		1	1		
		1	1		
			1		
		1	11	3	6
				2	2
1	1			11	14
					1
				1	1
				1	1
				2	2
					1
2	2	33	158	18	51
					1
				1	2
		1	1	2	2
				1	1
				1	2
		2	6		2
		1	1		3
			1		
					1
				2	2
				1	1
				1	1
				1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory disorder		1
Respiratory distress		1
Respiratory failure	4	8
Respiratory fatigue	1	1
Respiratory tract haemorrhage		1
Retching	2	5
Retinal artery embolism	1	1
Retinal artery occlusion	2	2
Retinal ischaemia	1	1
Retinal vein occlusion	1	2
Retinal vein thrombosis	1	1
Rhabdomyolysis	1	1
Rhinalgia		1
Rhinorrhoea	1	2
SARS-CoV-2 test negative	1	1
SARS-CoV-2 test positive	1	3
Scab		1
Sciatica		1
Seizure	1	4
Sensation of foreign body	2	2
Sensitisation		1
Sensory loss	1	2
Sepsis	1	2
Septic shock	2	3
Shift to the left	1	1
Shock	1	1
Sinusitis		1
Sinus tachycardia		1
Sitting disability		1
Skin exfoliation		1
Skin induration	1	1
Sleep disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				4	8
				1	1
					1
		1	4	1	1
				1	1
				2	2
				1	1
				1	2
				1	1
				1	1
			1		
		1	2		
				1	1
			1	1	2
			1		
			1		
				1	4
		1	1	1	1
			1		
				1	2
				1	2
				2	3
		1	1		
				1	1
					1
					1
			1		
			1		
		1	1		
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Somnolence	3	11
Sopor		1
Speech disorder	2	4
Spinal pain		1
Spontaneous haematoma	1	1
Squamous cell carcinoma	1	1
Stenosis	2	2
Stertor		1
Strabismus	1	1
Strangury		
Stress	1	1
Sudden death	3	7
Supraventricular extrasystoles		1
Suspected COVID-19	1	1
Swelling		4
Swelling face	1	3
Swelling of eyelid		1
Swollen tongue	1	3
Syncope	11	17
Tachyarrhythmia	1	1
Tachycardia	5	15
Tachypnoea		2
Taste disorder	1	3
Telangiectasia	1	1
Temperature regulation disorder	1	1
Tenderness	1	1
Therapeutic response unexpected	1	1
Throat irritation	2	4
Throat tightness	3	8
Thrombocytopenia	5	8
Thrombophlebitis	4	4
Thrombophlebitis superficial	3	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	10		1
					1
				2	4
			1		
		1	1		
				1	1
				2	2
					1
				1	1
1	1				
				1	1
				3	7
			1		
			2		2
			1	1	2
					1
			1	1	2
2	3			11	17
		1	1		
		2	6	3	9
			1		1
		1	1		2
		1	1		
		1	1		
		1	1		
		1	3	1	1
			4	3	4
				5	8
		4	4		
		1	1	2	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Thrombosis	3	6
Tinnitus		1
Tongue oedema	2	5
Torticollis		1
Tracheal pain		1
Transaminases increased	1	1
Transient ischaemic attack	1	2
Tremor	2	8
Trigeminal neuritis		1
Trismus	1	1
Troponin increased	1	1
Unresponsive to stimuli		1
Upper respiratory tract inflammation		1
Urinary incontinence		2
Urinary retention	1	1
Urine output decreased	1	1
Urticaria	1	9
Urticaria papular	1	1
Use of accessory respiratory muscles		1
Uterine leiomyoma	1	1
Uveitis		1
Vaccination complication		1
Vaccination failure	8	13
Vaccination site discomfort	1	1
Vaccination site erythema	4	8
Vaccination site haematoma		1
Vaccination site induration		1
Vaccination site inflammation	1	3
Vaccination site joint swelling		1
Vaccination site lymphadenopathy		1
Vaccination site oedema	2	15
Vaccination site pain	16	96

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	6
					1
		1	2	1	3
			1		
			1		
				1	1
				1	2
			4	2	4
					1
		1	1		
				1	1
					1
			1		
			1		1
				1	1
				1	1
			5	1	4
				1	1
					1
				1	1
					1
			1		
			1	8	12
		1	1		
		4	7		1
			1		
					1
		1	2		1
			1		
			1		
		2	14		1
	1	15	91	1	5

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site pallor		1				1		
Vaccination site paraesthesia		1				1		
Vaccination site pruritus	1	3			1	3		
Vaccination site reaction	1	3			1	2		1
Vaccination site swelling	5	7			4	6	1	1
Vaccination site warmth		1						1
Vasculitis	2	4			1	1	1	3
Vena cava thrombosis	1	1					1	1
Venous arterialisation	1	1					1	1
Venous thrombosis	3	3			2	2	1	1
Venous thrombosis limb	4	4		1	1	1	3	3
Ventricular extrasystoles	1	2					1	2
Vertebral artery occlusion	1	1					1	1
Vertigo	2	14		1	2	11		3
Vestibular neuronitis		2				1		1
Vision blurred	3	4			1	1	2	3
Visual impairment	1	1					1	1
Vitamin B12 deficiency	1	1			1	1		
Vlth nerve paralysis		2						2
Vlth nerve paresis		1				1		
Vitreous detachment	1	3					1	3
Vomiting	15	30	1	1	4	14	11	16
Wheezing	1	1					1	1
Wound	1	1					1	1
Wrong product administered	1	1			1	1		
			16	27	306	1446	655	1213

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal pain	3	10	3	3	2	4	1	6
Abdominal pain lower	1	1			1	1		
Abdominal pain upper	3	5	1	1			3	5
Abdominal tenderness	1	1			1	1		
Abnormal behaviour		1				1		
Acidosis	1	1					1	1
Acquired haemophilia			1	1				
Acute coronary syndrome	1	6					1	6
Acute kidney injury	2	5		1			2	5
Acute myocardial infarction	3	9					3	9
Acute pulmonary oedema	1	3					1	3
Acute respiratory distress syndrome		1						1
Acute respiratory failure	2	7					2	7
Administration site movement impairment		1						1
Age-related macular degeneration		1						1
Ageusia		1				1		
Aggression			1	1				
Agitation	3	7				2	3	5
Allergic reaction to excipient		1						1
Allergic respiratory symptom		1						1
Allergy to vaccine		1						1
Alopecia	1	1			1	1		
Alpha tumour necrosis factor increased		1						1
Altered state of consciousness	1	2					1	2
Amnesia	4	5				1	4	4
Anaemia	3	6	1	1	1	2	2	4
Anaemia macrocytic		1						1
Anaesthesia		1						1
Anal erythema		1						1
Anal incontinence		1						1
Anaphylactic reaction		4		2				4
Anaphylactoid reaction	1	1					1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Aneurysm ruptured		1
Angina pectoris	2	2
Angioedema	2	3
Angiopathy		1
Anosmia		1
Anuria	1	2
Anxiety		2
Aortic dilatation		1
Aortic valve stenosis		1
Apallic syndrome	1	1
Aphasia	8	18
Aphonia	1	1
Areflexia	1	1
Arrhythmia	1	5
Arteriosclerosis	1	2
Arteriosclerotic retinopathy		1
Arteriospasm coronary		1
Arthralgia	12	30
Arthritis	2	2
Asthenia	23	61
Asthenopia		1
Asthma		1
Asthmatic crisis		
Asymptomatic COVID-19	8	14
Ataxia		1
Atrial f brillation	6	18
Atrial flutter	1	3
Atrioventricular block	1	1
Atrioventricular block complete		1
Atrioventricular block first degree		1
Atrioventricular block second degree	1	1
Autoimmune disorder	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				2	2
				2	3
					1
			1		
1	1			1	2
			1		1
			1		
					1
				1	1
1	2			8	18
				1	1
				1	1
				1	5
		1	1		1
					1
					1
1	1	7	17	5	13
				2	2
4	7	4	23	19	38
					1
					1
	1				
				8	14
					1
1	1			6	18
				1	3
1	1			1	1
					1
			1		
		1	1		
				1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Azotaemia		1
Back pain	3	4
Balance disorder	1	6
Behaviour disorder	1	1
Bell's palsy	2	4
Blindness	1	2
Blister	1	3
Blood bilirubin increased		1
Blood creatinine increased		1
Blood glucose abnormal		1
Blood glucose increased	1	1
Blood pressure decreased	1	1
Blood pressure increased	10	15
Blood pressure systolic increased		1
Body temperature abnormal		1
Body temperature decreased	1	1
Body temperature increased		3
Bone marrow disorder	1	1
Bone pain	1	3
Bradycardia		1
Bradykinesia		2
Bradyphrenia		2
Brain compression		1
Brain stem haemorrhage		1
Brain stem stroke		1
Breast swelling	1	1
Breath sounds abnormal	1	1
Bronchitis		1
Bronchospasm		1
Burning sensation	1	1
Cardiac arrest	5	21
Cardiac disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1	2	3
1	3		1	1	5
				1	1
	1			2	4
				1	2
			1	1	2
					1
			1		
					1
				1	1
		1	1		
1	1	2	3	8	12
			1		
			1		
				1	1
1	1		2		1
				1	1
			1	1	2
1	1				1
1	1				2
1	1		1		1
					1
					1
					1
		1	1		
				1	1
					1
					1
				1	1
				5	21
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiac failure	6	17
Cardiac failure congestive	1	4
Cardiac fibrillation		1
Cardiac valve disease	1	1
Cardiogenic shock		1
Cardiomegaly	1	1
Cardiopulmonary failure	1	2
Cardio-respiratory arrest	2	7
Carotid arteriosclerosis	1	1
Carotid artery stenosis	1	1
Carotid artery thrombosis	2	2
Cerebellar haemorrhage	1	2
Cerebellar stroke	1	1
Cerebral artery occlusion	1	3
Cerebral artery thrombosis		1
Cerebral haematoma	1	1
Cerebral haemorrhage	9	17
Cerebral infarction		2
Cerebral ischaemia	3	13
Cerebral thrombosis		1
Cerebral venous sinus thrombosis		1
Cerebral ventricle collapse		1
Cerebrovascular accident	7	20
Cerebrovascular disorder		
Chest discomfort		2
Chest pain	8	18
Chills	5	16
Cholangitis		1
Cholecystitis acute		1
Cholelithiasis		1
Chronic obstructive pulmonary disease		1
Circulatory collapse		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1			6	17
				1	4
					1
				1	1
					1
		1	1		
				1	2
				2	7
				1	1
				1	1
				2	2
				1	2
				1	1
				1	3
					1
				1	1
				9	17
					2
				3	13
2	2				1
1	1				
					1
1	2			7	20
1	1				
1	1		2		
1	1	1	3	7	15
			7	5	9
					1
					1
					1
					1
					2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Coagulation test abnormal	1	1
Cognitive disorder	1	2
Cold sweat		1
Coma	3	7
Coma scale abnormal		1
Complicated appendicitis	1	1
Condition aggravated	3	9
Confusional state	7	25
Conjunctival haemorrhage	3	5
Conjunctival hyperaemia		1
Conjunctivitis	1	1
Constipation		1
Contraindicated product administered		1
Contusion	2	2
Coordination abnormal	1	1
Coronary artery disease		1
Coronary artery stenosis		2
Cough	7	11
COVID-19	22	44
COVID-19 pneumonia	6	11
Cranial nerve disorder	1	1
C-reactive protein abnormal	1	1
C-reactive protein increased	1	2
Crying		
Cyanosis		1
Cystitis	1	1
Deafness		1
Deafness unilateral		1
Death	3	8
Decreased appetite	9	18
Deep vein thrombosis	17	25
Dehydration	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
	1	1	2		
					1
				3	7
					1
				1	1
1	1			3	9
4	9		6	7	19
	2			3	5
			1		
				1	1
			1		
					1
		1	1	1	1
	1			1	1
					1
					2
1	1	1	2	6	9
2	3	2	2	20	42
	1			6	11
				1	1
		1	1		
			1	1	1
1	1				
					1
		1	1		
					1
					1
				3	8
1	1	2	4	7	14
	1			17	25
				1	4

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Delirium	2	2
Delirium febrile	1	1
Delusion	2	3
Depressed level of consciousness	1	4
Depression	1	1
Dermatitis allergic		1
Dermatitis bullous	1	4
Dermatitis exfoliative generalised		1
Diaphragmatic disorder	1	1
Diarrhoea	4	19
Dilatation atrial		1
Diplopia	2	3
Discomfort	1	2
Disease recurrence	2	11
Disorientation	4	8
Disseminated varicella zoster virus infection		1
Disturbance in attention		1
Diverticulum	1	1
Dizziness	1	12
Drooling		1
Drug ineffective	3	14
Dry mouth		2
Dry skin	1	1
Dysarthria	8	14
Dysentery	1	6
Dyskinesia		1
Dyslalia	1	1
Dyslexia		1
Dysphagia	5	10
Dysphonia	1	1
Dyspnoea	27	66
Dyspnoea exertional	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
				1	1
				2	3
				1	4
				1	1
					1
				1	4
					1
				1	1
3	4	1	8	3	11
					1
			1	2	2
				1	2
		1	1	1	10
1	2	1	1	3	7
					1
					1
				1	1
			1	1	11
					1
2	3			3	14
			1		1
				1	1
4	5			8	14
				1	6
					1
				1	1
					1
2	2	1	1	4	9
				1	1
7	10	6	10	21	56
1	1	1	1		1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysstasia	3	4
Dysuria	1	4
Ear haemorrhage		1
Ear pain	1	2
Ear swelling	1	1
Eating disorder	1	1
Ecchymosis	2	5
Electrocardiogram T wave inversion		
Embolic stroke	1	2
Embolism	2	2
Embolism venous		1
Encephalitis		1
Enteritis		1
Enterococcal infection		1
Enuresis	1	1
Epilepsy	1	4
Epistaxis	6	8
Erectile dysfunction	1	2
Eructation	1	1
Erysipelas		2
Erythema	10	25
Erythema multiforme	1	1
Escherichia sepsis	1	1
Essential hypertension		
Exposure during pregnancy	1	1
Exposure to SARS-CoV-2		1
Eye haemorrhage	2	2
Eye infection		1
Eye irritation		1
Eyelid bleeding	1	1
Eyelid oedema		1
Eyelid ptosis	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1			3	4
			1	1	3
			1		
		1	1		1
		1	1		
				1	1
				2	5
	1				
				1	2
1	1			2	2
					1
					1
			1		
					1
				1	1
				1	4
		3	5	3	3
				1	2
				1	1
1	1				2
2	3	5	14	5	11
				1	1
				1	1
1	1				
		1	1		
			1		
				2	2
					1
			1		
				1	1
					1
			1	2	2

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye movement disorder	1	1
Eye pain		3
Face injury		1
Face oedema	2	9
Facial asymmetry		1
Facial pain		1
Facial paralysis	5	11
Facial paresis	3	3
Fall	3	9
Fatigue	11	32
Feeding disorder		1
Feeling abnormal		2
Feeling cold	1	3
Feeling hot		4
Femur fracture	1	1
Fibrin D dimer increased	3	6
Flatulence	1	1
Fluid retention		1
Flushing		6
Foaming at mouth		2
Full blood count abnormal	1	1
Full blood count increased		1
Gait disturbance	5	9
Gait inability	2	3
Gastrointestinal disorder		1
Gastrointestinal haemorrhage		1
Gastrointestinal pain		1
Gaze palsy	2	2
Generalised tonic-clonic seizure		1
General physical health deterioration	1	5
General symptom	1	1
Gingival bleeding		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			3		
					1
1	1		1	2	8
					1
					1
	1			5	11
				3	3
				3	9
1	1	4	22	7	10
					1
					2
			2	1	1
			3		1
				1	1
1	1	1	3	2	3
		1	1		
					1
1	1		4		2
					2
		1	1		
			1		
		1	1	4	8
				2	3
			1		
					1
			1		
				2	2
					1
			1	1	4
		1	1		
					1

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Glaucoma	1	1
Glossitis		1
Goitre	1	1
Guillain-Barre syndrome	2	3
Haematemesis		2
Haematochezia	1	1
Haematocrit decreased	1	1
Haematoma	3	6
Haematoma muscle	1	1
Haematuria	1	2
Haemoglobin decreased	3	4
Haemoperitoneum		1
Haemorrhage	1	2
Haemorrhage subcutaneous		1
Haemorrhagic cerebral infarction		1
Haemorrhagic diathesis	1	1
Haemorrhagic infarction	1	1
Haemorrhagic stroke	3	4
Hallucination	6	8
Hallucination, auditory		1
Hallucination, visual		1
Headache	5	30
Head discomfort		1
Head injury		
Heart rate decreased		1
Heart rate increased		2
Heart rate irregular		1
Hemianopia	1	1
Hemianopia homonymous		1
Hemidysaesthesia	1	1
Hemiparesis	6	17
Hemiplegia	2	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
		1	1		
				2	3
1	1				2
				1	1
		1	1		
			1	3	5
		1	1		
				1	2
		1	1	2	3
					1
				1	2
					1
					1
				1	1
				1	1
				3	4
2	2			6	8
1	1				1
					1
6	8	2	15	3	15
					1
1	1				
					1
					2
					1
				1	1
					1
				1	1
				6	17
				2	6

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hepatic enzyme increased		
Hepatitis acute		1
Herpes ophthalmic	1	2
Herpes virus infection		1
Herpes zoster	22	26
Herpes zoster cutaneous disseminated	1	1
Herpes zoster infection neurological	2	2
Herpes zoster reactivation		1
Hiatus hernia	1	1
Hiccups		1
Hyperbilirubinaemia		1
Hypercapnia	1	1
Hyperglycaemia	1	2
Hyperhidrosis	2	7
Hyperpyrexia	3	12
Hypersensitivity	1	2
Hypertension	4	11
Hypertensive crisis	7	18
Hypertensive heart disease		3
Hyperthermia		3
Hypertonia	1	1
Hypertrophic cardiomyopathy		1
Hyperventilation		1
Hypoaesthesia	2	3
Hypoglycaemic unconsciousness	1	1
Hypokalaemia		2
Hypokinesia		1
Hyponatraemia		
Hyporesponsive to stimuli	1	2
Hypotension	4	21
Hypotensive crisis		1
Hypothermia	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1				1
				1	2
			1		
		18	19	4	7
				1	1
				2	2
					1
				1	1
			1		
					1
				1	1
				1	2
		1	3	1	4
1	1			3	12
1	1			1	2
		2	5	2	6
				7	18
					3
			1		2
				1	1
					1
				2	3
				1	1
					2
					1
1	1				
				1	2
	2		5	4	16
					1
				1	2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypotonia		1
Hypoxia	3	6
Illrd nerve paralysis	1	2
Immune-mediated adverse reaction	1	1
Immune thrombocytopenia	1	2
Impaired quality of life	3	4
Inappropriate schedule of product administration	2	5
Incontinence		1
Incorrect dose administered	1	1
Incorrect route of product administration		3
Infarction		1
Inflammation		1
Influenza like illness		1
Injection site erythema	1	1
Injection site pain		4
Insomnia	2	6
International normalised ratio increased	1	4
Interstitial lung disease	3	5
Intestinal obstruction	1	2
Intra-abdominal haemorrhage	1	1
Intracardiac thrombus	1	1
Intraventricular haemorrhage		2
Ischaemia	3	7
Ischaemic stroke	8	18
Jaundice		2
Jaundice cholestatic		1
Joint lock	1	1
Joint swelling		1
Klebsiella infection	1	1
Laboratory test abnormal		1
Lacrimation increased		1
Lactic acidosis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				3	6
				1	2
				1	1
	1			1	2
			1	3	3
		2	4		1
			1		
		1	1		
			3		
					1
					1
			1		
		1	1		
			4		
			1	2	5
			1	1	3
				3	5
				1	2
				1	1
				1	1
					2
				3	7
1	1			8	18
					2
					1
				1	1
					1
				1	1
					1
					1
				1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lacunar stroke		1
Lagophthalmos		1
Language disorder		1
Laryngeal dyspnoea		1
Laryngeal oedema		3
Left ventricular dysfunction		1
Left ventricular failure		1
Left ventricular hypertrophy		1
Lens disorder	1	1
Lethargy	1	1
Leukaemia		1
Leukocytosis	1	1
Leukopenia		
Lichen sclerosus	1	1
Limb immobilisation	1	1
Lip disorder		1
Lip oedema	1	2
Lip pruritus		1
Lip swelling		1
Livedo reticularis		1
Liver abscess	1	1
Localised oedema		1
Logorrhoea		1
Loss of consciousness	6	24
Loss of personal independence in daily activities	1	1
Lung disorder		1
Lung opacity	1	1
Lymphadenopathy	2	5
Lymphangitis		1
Lymphocyte count decreased		1
Macroglossia		
Maculopathy		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
			1		
					1
					3
			1		
					1
					1
		1	1		
				1	1
					1
	1			1	1
	1				
				1	1
				1	1
					1
			1	1	1
					1
	1		1		
				1	1
			1		1
					1
				6	24
				1	1
					1
				1	1
		1	3	1	2
					1
			1		
1	1				
					2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Malaise	8	39
Mean cell volume increased		1
Mesenteric vein thrombosis	1	1
Metabolic acidosis		1
Metamorphopsia	1	1
Migraine		1
Miller Fisher syndrome	1	1
Mitral valve incompetence		3
Mitral valve stenosis		1
Mobility decreased	1	2
Monocyte count increased		1
Monoplegia	1	1
Mood altered	1	1
Motor dysfunction	1	3
Mouth haemorrhage		1
Movement disorder	2	3
Multiple organ dysfunction syndrome		2
Muscle contractions involuntary		1
Muscle rigidity	1	2
Muscle spasms	1	2
Muscular weakness	8	11
Musculoskeletal pain	1	5
Musculoskeletal stiffness	2	3
Myalgia	6	20
Myasthenia gravis crisis		1
Myocardial infarction	2	5
Myocardial ischaemia	2	4
Myringitis		1
Nasal congestion	1	1
Nausea	7	22
Neck pain	1	1
Necrotising fasciitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
4	4		15	8	24
			1		
				1	1
					1
		1	1		
					1
				1	1
					3
					1
				1	2
			1		
				1	1
		1	1		
1	1			1	3
					1
1	1		1	2	2
	1				2
					1
				1	2
		1	1		1
		1	1	7	10
			3	1	2
		1	1	1	2
	1	2	7	4	13
					1
				2	5
				2	4
					1
				1	1
3	3	2	12	5	10
				1	1
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nephropathy	1	1
Nervous system disorder	2	3
Neuralgia	2	2
Neurological symptom	1	1
Neurologic neglect syndrome		1
Neuromuscular pain	1	1
Neutropenia		
Neutrophil count increased		1
Neutrophilia		2
Occult blood positive	2	2
Ocular discomfort		1
Ocular hyperaemia	1	1
Oedema peripheral	3	8
Off label use	5	10
Oliguria		1
Ophthalmic herpes zoster	2	2
Optic disc haemorrhage	1	1
Oral candidiasis	1	1
Oral herpes		2
Orchitis		1
Organic brain syndrome		1
Oropharyngeal pain		1
Overdose	4	9
Oxygen saturation abnormal		
Oxygen saturation decreased	9	25
Pain	5	8
Pain in extremity	13	23
Pallor		3
Palpable purpura		1
Palpitations	1	1
Pancreatitis		1
Pancreatitis acute		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				2	3
		2	2		
1	2			1	1
					1
				1	1
	1				
			1		
					2
		1	1	1	1
			1		
				1	1
4	6	1	3	2	5
		5	9		1
					1
				2	2
				1	1
				1	1
			1		1
					1
					1
		4	9		
	1				
1	2		2	9	23
		1	3	4	5
2	2	4	8	9	15
1	1		2		1
					1
		1	1		
					1
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Paraesthesia	5	13
Paraesthesia oral	1	3
Paraparesis		1
Partner stress		1
Pelvic fracture	1	1
Pemphigoid	1	2
Pericardial effusion		3
Pericarditis	2	3
Periorbital oedema	1	2
Peripheral coldness	2	2
Peripheral ischaemia	1	2
Peripheral swelling	5	9
Persecutory delusion	1	1
Petechiae		1
Petit mal epilepsy		1
Pharyngeal mass		1
Pharyngeal oedema	1	1
Pharyngeal paraesthesia		1
Phlebitis		1
Platelet count decreased	1	1
Pleural effusion	1	5
Pleurisy	1	1
Pneumonia	6	13
Pneumonia aspiration	1	1
Pneumonia bacterial		1
Pneumonitis	2	3
Pollakiuria		1
Polymyalgia rheumatica	1	2
Polyuria	1	2
Poor quality product administered	1	1
Posture abnormal	1	1
Presyncope	4	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
2	2	1	4	4	9
			1	1	2
					1
			1		
				1	1
				1	2
					3
				2	3
		1	1		1
				2	2
				1	2
		2	3	3	6
				1	1
	1				1
					1
			1		
				1	1
			1		
			1		
				1	1
		1	2		3
		1	1		
				6	13
				1	1
					1
				2	3
			1		
				1	2
				1	2
		1	1		
				1	1
1	1		1	4	7

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Procalcitonin increased		1
Productive cough		1
Product preparation error	4	4
Product preparation issue	1	2
Product use issue	2	5
Protein C increased	1	1
Pruritus	6	11
Psychomotor hyperactivity	2	4
Psychomotor skills impaired		1
Pulmonary air leakage	1	1
Pulmonary congestion	1	2
Pulmonary embolism	28	43
Pulmonary hypertension	1	2
Pulmonary infarction		1
Pulmonary oedema		1
Pulmonary thrombosis	1	1
Pulse volume decreased		1
Purpura		1
Pyrexia	44	175
Quadripareisis	1	1
Quality of life decreased		1
Rales		1
Rash		7
Rash macular		1
Rash maculo-papular		1
Rash morbilliform	1	1
Rash pruritic	1	3
Raynaud's phenomenon	1	1
Rectal haemorrhage	2	3
Red blood cell count decreased		1
Red blood cell sedimentation rate increased		1
Red cell distribution width increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
		4	4		
		1	2		
		2	5		
				1	1
		4	7	2	4
		1	2	1	2
					1
		1	1		
				1	2
3	5			28	43
				1	2
					1
					1
				1	1
			1		
1	2				1
7	12	20	88	24	87
				1	1
					1
					1
			6		1
					1
			1		
				1	1
		1	2		1
				1	1
				2	3
					1
					1
			1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Regurgitation		1
Renal failure	5	8
Renal impairment		1
Renal pain		1
Respiratory alkalosis	1	1
Respiratory arrest		2
Respiratory disorder		3
Respiratory distress	1	3
Respiratory failure	12	23
Restlessness		1
Retching		4
Retinal artery occlusion		2
Retinal drusen		1
Retinal oedema		1
Retinal vein thrombosis		2
Rheumatoid arthritis		1
Rhinitis	1	1
Right ventricular dilatation		1
Right ventricular dysfunction	1	1
Rosai-Dorfman syndrome	1	1
Salivary hypersecretion		1
SARS-CoV-2 ant body test negative		1
SARS-CoV-2 ant body test positive	1	1
SARS-CoV-2 test		2
SARS-CoV-2 test positive	1	9
Scleral discolouration	2	3
Scrotal erythema		1
Seizure	2	2
Senile dementia	1	1
Sensation of foreign body	1	1
Sense of oppression		
Sensory loss	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				5	8
					1
					1
				1	1
					2
					3
				1	3
1	1			12	23
					1
			2		2
					2
					1
					1
					2
					1
		1	1		
			1		
				1	1
				1	1
			1		
					1
				1	1
					2
2	2			1	9
		2	2		1
					1
				2	2
				1	1
		1	1		
1	1				
				1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sepsis	2	4
Septic shock		2
Seroconversion test negative	1	5
Serratia test positive		1
Shock	1	1
Skin discolouration		1
Skin exfoliation	1	2
Skin hypertrophy	1	1
Skin lesion	1	2
Sleep disorder		2
Slow speech		1
Sluggishness	1	1
Soliloquy		1
Somnolence	1	12
Sopor	2	9
Speech disorder	6	12
Spinal compression fracture	1	1
Spinal pain	1	2
Spontaneous haematoma		
Status epilepticus	1	1
Stenotrophomonas test positive		1
Stridor	1	1
Stupor		1
Subarachnoid haemorrhage	1	1
Subdural haematoma	1	2
Sudden death	2	13
Suicidal ideation	1	1
Supraventricular tachycardia		1
Suspected COVID-19		1
Swelling	1	1
Swelling face		7
Syncope	9	25

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	4
					2
			3	1	2
					1
				1	1
					1
				1	2
				1	1
				1	2
			2		
					1
		1	1		
			1		
	2	1	5		7
1	3		1	2	8
	1			6	12
				1	1
			1	1	1
1	1				
				1	1
					1
				1	1
				1	2
	1			2	13
				1	1
					1
					1
				1	1
			5		2
4	5			9	25

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Systolic hypertension		1
Tachyarrhythmia		
Tachycardia	2	6
Tachycardia paroxysmal		1
Tachypnoea	2	3
Testicular neoplasm		1
Thalamus haemorrhage	1	1
Throat tightness		2
Thromboangiitis obliterans		1
Thrombocytopenia	8	17
Thrombocytosis	1	1
Thrombophlebitis	2	4
Thrombophlebitis superficial		5
Thrombosis	4	7
Thrombotic stroke	1	1
Thyroid mass	1	1
Tinnitus		1
Tongue biting	1	1
Tongue oedema	1	3
Tongue pruritus		1
Torticollis	1	1
Transient ischaemic attack	4	8
Tremor	1	5
Tricuspid valve incompetence		2
Trigeminal neuralgia		1
Troponin		1
Troponin I increased		1
Troponin increased	1	2
Troponin T increased		1
Underdose	1	1
Undersensing		1
Unresponsive to stimuli		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
1	1				
2	3	1	3	1	3
			1	2	2
					1
				1	1
					2
					1
	1			8	17
				1	1
		2	3		1
	1				5
				4	7
				1	1
		1	1		
1	1				1
				1	1
				1	3
					1
		1	1		
				4	8
				1	5
					2
					1
					1
				1	2
					1
		1	1		
					1
					2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Upper limb fracture		1
Upper respiratory tract infection		1
Urinary incontinence		2
Urinary retention		2
Urinary tract infection	2	2
Urinary tract infection bacterial		1
Urine output decreased		1
Urosepsis		1
Urticaria	1	12
Vaccination failure	23	47
Vaccination site bruising	1	1
Vaccination site discomfort	1	1
Vaccination site erythema	1	4
Vaccination site haematoma	1	1
Vaccination site inflammation		4
Vaccination site oedema		
Vaccination site pain	7	16
Vaccination site reaction		2
Vaccination site swelling		3
Vaccination site warmth	1	1
Vascular calcification	1	1
Vascular device infection	1	1
Vasculitis	2	3
Vasculitis necrotising		1
Venous thrombosis	3	5
Venous thrombosis limb		2
Ventricular arrhythmia		1
Ventricular dysfunction	1	1
Ventricular fibrillation		1
Ventricular tachycardia		1
Vertebrobasilar insufficiency	1	1
Vertigo	3	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					2
					2
				2	2
					1
					1
					1
		1	6		6
			5	23	42
				1	1
		1	1		
			3	1	1
		1	1		
			4		
	1				
	1	6	13	1	3
			2		
	1		2		1
	1	1	1		
		1	1		
				1	1
		1	2	1	1
					1
				3	5
			1		1
					1
				1	1
					1
					1
				1	1
3	5	1	5	2	5

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vision blurred		3						3
Visual acuity reduced	2	2		1	1	1	1	1
Visual impairment	2	8			1	2	1	6
Vitamin D decreased	1	1			1	1		
Vitreous floaters	1	1					1	1
Vitreous haemorrhage		1						1
Vomiting	15	47	2	3	3	20	12	27
Weight decreased		1						1
White blood cell count increased	1	2				1	1	1
Wrong product administered	1	1			1	1		
Wrong technique in product usage process	1	1			1	1		
Xerophthalmia		1						1
	1,000	2,588	137	216	202	631	798	1957

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1		1		
Abdominal pain	2	4	2	3		1
Abdominal pain upper		1		1		
Abortion spontaneous		1				1
Abscess	1	1	1	1		
Acute coronary syndrome		1				1
Agitation		1				1
Amenorrhoea	1	1	1	1		
Amnesia	2	2	2	2		
Anaphylactic reaction		4				4
Anaphylactic shock		2				2
Antibody test abnormal		2		2		
Arthralgia	13	33	13	31		2
Asthenia	10	23	10	23		
Asthenopia		1		1		
Asthma		1				1
Asymptomatic COVID-19		1				1
Autoimmune disorder	1	1			1	1
Axillary pain	3	4	3	4		
Back pain	1	3	1	2		1
Bell's palsy		2				2
Blister		2		2		
Blood pressure fluctuation		1		1		
Blood pressure increased	2	3	1	2	1	1
Body temperature decreased	1	1	1	1		
Bone pain	1	5	1	5		
Breast disorder	1	1			1	1
Breast pain		1		1		
Breath odour	1	1	1	1		
Breath sounds abnormal		1		1		
Burning sensation		1				1
Chest discomfort		3		3		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chest pain	1	3
Chills	6	17
Circumstance or information capable of leading to medication error		1
Cold urticaria		1
Confusional state	1	2
Conjunctivitis	1	1
Contusion	1	1
Cough		2
COVID-19	29	88
C-reactive protein increased	1	1
Crying	1	1
Dark circles under eyes	1	1
Deafness bilateral		1
Decreased appetite		1
Deep vein thrombosis	1	1
Dehydration	1	1
Dermal cyst		1
Dermatitis allergic	1	1
Diarrhoea	7	14
Diplopia		1
Discomfort	1	2
Distract bility	1	1
Dizziness	5	11
Dizziness postural	1	1
Drug ineffective	26	78
Dry mouth		4
Dysaesthesia		1
Dysentery	1	2
Dysgeusia		4
Dyspnoea	1	4
Dysuria		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	3		
5	16	1	1
	1		
	1		
1	2		
1	1		
1	1		
	2		
	6	29	82
1	1		
1	1		
1	1		
			1
	1		
		1	1
		1	1
	1		
1	1		
6	13	1	1
	1		
1	2		
1	1		
5	10		1
		1	1
		26	78
	4		
	1		
		1	2
	4		
	2	1	2
			1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Enterocolitis		1				1
Epistaxis	1	1	1	1		
Erythema	2	9	2	8		1
Euphoric mood	1	1	1	1		
Exposure during pregnancy	4	5	4	5		
Exposure via breast milk	2	2	2	2		
Eye irritation	2	2	2	2		
Eye pain	1	2	1	2		
Eye pruritus	1	1	1	1		
Eye swelling	1	1	1	1		
Facial nerve disorder		1		1		
Facial pain		1		1		
Facial paralysis	1	2			1	2
Fall		1		1		
Fatigue	15	27	15	24		3
Feeling abnormal	1	1	1	1		
Feeling cold	2	2	2	2		
Feeling hot	2	5	2	5		
Fibrin D dimer increased	1	1	1	1		
Flushing		1		1		
Foetal growth restriction		1				1
Gait inability		2		2		
Gastrointestinal disorder	2	2	2	2		
Gilbert's syndrome	1	1	1	1		
Glossodynia		1		1		
Haematoma	1	1	1	1		
Headache	20	51	20	47		4
Head discomfort		1		1		
Heart rate increased		1		1		
Hemidysaesthesia		1				1
Hemiparaesthesia		2				2
Herpes zoster		1				1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hot flush	1	1	1	1		
Hyperacusis	1	1	1	1		
Hyperhidrosis	2	4	1	3	1	1
Hyperpyrexia		3				3
Hypersensitivity		1				1
Hypertension		1				1
Hypertensive crisis		2				2
Hyperthermia		1		1		
Hyperventilation		1		1		
Hypoaesthesia		2		1		1
Hypoaesthesia oral	1	3	1	3		
Hypoglycaemia		1		1		
Hypokalaemia		1				1
Hypotension	2	2	2	2		
Hypothermia		1				1
Illness	1	1	1	1		
Inappropriate schedule of product administration	4	8	4	8		
Incorrect dose administered	1	2	1	2		
Inflammatory bowel disease	1	1			1	1
Influenza	3	4	3	4		
Influenza like illness		3		3		
Injection site erythema	1	2	1	2		
Injection site hypersensitivity		1		1		
Injection site pain		3		3		
Injection site swelling		1		1		
Injection site urticaria		1		1		
Injection site warmth		1		1		
Insomnia	1	3	1	3		
Joint swelling	2	2	2	2		
Lacrimation increased	1	1	1	1		
Laryngeal oedema	1	2			1	2
Limb discomfort	1	4	1	3		1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lip oedema	1	5	1	5		
Lip pain		1		1		
Loss of consciousness	1	1			1	1
Lymphadenopathy	7	24	7	24		
Lymph node pain	2	3	2	3		
Malaise	1	8	1	8		
Maternal exposure before pregnancy		1		1		
Maternal exposure during pregnancy	2	6	2	6		
Meningeal disorder		1		1		
Menstruation delayed	2	2	2	2		
Migraine		5		5		
Muscle disorder		1		1		
Muscle spasms	1	2	1	1		1
Muscle tightness		1		1		
Muscular weakness		2		1		1
Musculoskeletal disorder		1				1
Musculoskeletal pain		4		4		
Myalgia	10	25	10	25		
Nasopharyngitis	1	1	1	1		
Nausea	7	17	7	14		3
Neuralgia	1	3	1	2		1
Neuropathy peripheral		1				1
Night sweats		2		2		
No adverse event	1	2	1	2		
Occupational exposure to product	1	1	1	1		
Oedema	1	1	1	1		
Oedema peripheral	1	1	1	1		
Off label use	7	14	7	14		
Oral discomfort	1	1	1	1		
Oropharyngeal discomfort	1	1	1	1		
Overdose	1	1	1	1		
Oxygen saturation decreased		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain	1	6	1	6		
Pain in extremity	17	30	16	28	1	2
Pallor		1		1		
Palpitations		2		2		
Pancreatitis		1				1
Paraesthesia	7	15	7	15		
Paraesthesia oral		3		2		1
Paresis cranial nerve		1		1		
Pericardial effusion		1				1
Pericarditis		1				1
Peripheral coldness		1		1		
Peripheral sensory neuropathy		1		1		
Peripheral swelling	3	4	3	4		
Petechiae		1		1		
Pharyngeal paraesthesia		1				1
Pharyngeal swelling		1		1		
Phlebitis	1	1	1	1		
Photophobia	1	1	1	1		
Photopsia	1	1	1	1		
Photosensitivity reaction	1	1	1	1		
Pityriasis rosea		1		1		
Pleural effusion		1				1
Pneumonia		1				1
Poor quality product administered	6	8	6	8		
Presyncope		1		1		
Product administration error	5	7	5	7		
Product label confusion		1		1		
Product leakage	1	1	1	1		
Product preparation error	1	1	1	1		
Product preparation issue	1	2	1	2		
Product use issue	3	6	3	6		
Pruritus	3	8	3	5		3

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Psoriasis		1		1		
Pulmonary embolism	1	1			1	1
Pyrexia	21	58	21	58		
Rash	4	7	4	6		1
Rash macular	1	2	1	2		
Red blood cell sedimentation rate increased	1	1	1	1		
Rhinitis	1	1	1	1		
Root canal infection		1		1		
SARS-CoV-2 ant body test negative		4		4		
SARS-CoV-2 ant body test positive		4		4		
SARS-CoV-2 test false positive		1		1		
SARS-CoV-2 test positive		1				1
Scalloped tongue	1	1	1	1		
Sensory disturbance	1	1	1	1		
Sinus tachycardia		1		1		
Skin reaction		1		1		
Sneezing	1	1	1	1		
Somnolence	4	7	4	7		
Stomatitis		1		1		
Subcutaneous abscess		1				1
Sudden death		1				1
Swelling	2	2	2	2		
Swelling face	1	3	1	3		
Syncope		5				5
Tachycardia	4	8	3	6	1	2
Therapeutic response unexpected		1		1		
Throat tightness		1		1		
Thrombocytopenia	1	1			1	1
Thrombophlebitis	1	1	1	1		
Thrombosis	1	1			1	1
Tinnitus		1				1
Tongue discolouration		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue dry		1		1		
Tongue oedema		1		1		
Tongue paralysis		1				1
Tooth infection		1		1		
Tremor		2		2		
Underdose	1	3	1	3		
Urinary incontinence	1	1	1	1		
Urticaria	1	10	1	10		
Vaccination failure	3	5			3	5
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	1	2	1	2		
Vaccination site haematoma		1		1		
Vaccination site joint pain	1	1	1	1		
Vaccination site joint swelling	1	1	1	1		
Vaccination site movement impairment	1	2	1	2		
Vaccination site oedema		2		2		
Vaccination site pain	16	61	16	60		1
Vaccination site paraesthesia	1	2	1	2		
Vaccination site pruritus	1	1	1	1		
Vaccination site rash	1	3	1	2		1
Vaccination site swelling	1	5	1	5		
Vaccination site urticaria		2		2		
Vaccination site warmth		2		2		
Varicella	1	1	1	1		
Vertigo	1	6	1	4		2
Vestibular disorder		1				1
Vision blurred	1	1	1	1		
Visual field defect	1	1	1	1		
Visual impairment		1		1		
Vomiting	4	6	3	4	1	2
Wrong product administered	3	3	3	3		
Wrong technique in product usage process	1	2	1	2		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	404	1,063	325	789	79	274

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

JAPAN

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	1	1			1	1
Exposure via breast milk	1	1	1	1		
Headache	1	1	1	1		
Nausea	1	1	1	1		
Rash	1	1			1	1
	5	5	3	3	2	2

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	3	14		5	3	9
Abdominal pain	16	33	11	20	5	13
Abdominal pain lower	1	1			1	1
Abdominal pain upper	4	5	2	3	2	2
Abdominal tenderness	1	1	1	1		
Abnormal sensation in eye	2	2			2	2
Accident		1				1
Acute coronary syndrome		2				2
Acute disseminated encephalomyelitis	2	2			2	2
Acute endocarditis		1				1
Allergy to vaccine	4	5	3	4	1	1
Altered state of consciousness	4	8			4	8
Amnesia		1				1
Anaemia	1	3		1	1	2
Anaphylactic reaction	102	247	1	1	101	246
Anaphylactic shock	2	10			2	10
Anaphylactoid reaction		2				2
Angioedema	1	3			1	3
Antiphospholipid antibodies positive		1				1
Anxiety	4	6	2	3	2	3
Apnoea		2				2
Apnoeic attack		1				1
Areflexia	1	1			1	1
Arrhythmia	1	1			1	1
Arthralgia	42	61	27	39	15	22
Asthenia	18	27	9	11	9	16
Asthma	10	14	3	4	7	10
Autonomic nervous system imbalance		1				1
Autophony		1		1		
Axillary pain	2	2	2	2		
Back pain	7	9	4	6	3	3
Blepharospasm	1	1	1	1		

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* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood glucose decreased		1				1
Blood pressure abnormal	1	3		1	1	2
Blood pressure decreased	19	37	4	13	15	24
Blood pressure diastolic decreased	1	1	1	1		
Blood pressure diastolic increased		2		1		1
Blood pressure fluctuation		1		1		
Blood pressure increased	32	48	14	22	18	26
Blood pressure systolic		1		1		
Blood pressure systolic increased	4	7	3	4	1	3
Body temperature increased	3	6	2	5	1	1
Bradycardia	4	7			4	7
Bradykinesia	1	1			1	1
Bradyphrenia		1				1
Brain compression		1				1
Brain neoplasm		1				1
Brain oedema		1		1		
Breast cancer		1				1
Breath sounds abnormal		1				1
Bronchitis	1	1	1	1		
Bronchospasm	1	2			1	2
Burning sensation	2	3		1	2	2
Burnout syndrome	1	1	1	1		
Calculus urinary		1		1		
Cardio-respiratory arrest	1	2			1	2
Cardiovascular disorder	1	1			1	1
Cerebral haemorrhage	1	2			1	2
Chest discomfort	9	16	6	10	3	6
Chest pain	3	6	2	2	1	4
Chills	41	64	25	37	16	27
Choking sensation	2	2	2	2		
Chromaturia	1	1			1	1
Circulatory collapse		2				2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat	8	24	2	11	6	13
Coma scale abnormal		1				1
Completed suicide	1	1			1	1
Complex regional pain syndrome	1	2			1	2
Condition aggravated		3		1		2
Conjunctival hyperaemia	5	9	3	4	2	5
Conjunctival oedema	1	1	1	1		
Contusion	1	1	1	1		
Cough	29	58	4	8	25	50
COVID-19	4	4	2	2	2	2
CSF protein increased		1				1
Cutaneous symptom		2		1		1
Cyanosis	1	2			1	2
Decreased appetite	8	12	4	7	4	5
Dehydration	2	3			2	3
Depressed level of consciousness	6	14			6	14
Derealisation	1	1	1	1		
Dermatitis		1		1		
Dermatitis allergic	2	2	1	1	1	1
Diarrhoea	25	42	14	28	11	14
Diastolic hypotension		1				1
Discomfort	4	9	3	5	1	4
Disease recurrence	1	1			1	1
Disseminated intravascular coagulation	1	1			1	1
Dissociative disorder	1	2	1	2		
Dizziness	43	82	15	35	28	47
Dizziness postural	2	4	2	4		
Drug eruption	2	2	2	2		
Drug hypersensitivity	1	3			1	3
Drug ineffective	2	2			2	2
Dry skin	1	1			1	1
Dysaesthesia		1		1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyskinesia	3	3	2	2	1	1
Dysmenorrhoea	1	1	1	1		
Dysphagia		2				2
Dysphonia	4	5	4	5		
Dysphoria	8	10	3	5	5	5
Dyspnoea	60	109	19	41	41	68
Dysstasia	4	4	1	1	3	3
Dysuria		1				1
Ear discomfort	1	2	1	2		
Eczema		1				1
Electrocardiogram ST segment elevation	1	1			1	1
Emotional distress	1	1	1	1		
Encephalitis	1	1			1	1
Enteritis infectious		1				1
Enterocolitis	1	4			1	4
Enzyme level increased	1	1			1	1
Epigastric discomfort		2		1		1
Epistaxis	1	1	1	1		
Erythema	57	117	23	55	34	62
Erythema multiforme		1				1
Erythema of eyelid	1	2	1	1		1
Excessive eye blinking	1	2	1	1		1
Exposure during pregnancy		1		1		
Eye disorder		2		1		1
Eyelid oedema	2	4	2	3		1
Eyelid rash	1	1			1	1
Eyelids pruritus	1	1	1	1		
Eye movement disorder		1				1
Eye pain	1	1	1	1		
Eye pruritus	1	3	1	2		1
Eye swelling	1	2		1	1	1
Face oedema		3		2		1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial pain		2		1		1
Facial paralysis	1	4			1	4
Faeces discoloured	1	1			1	1
Faeces soft	1	5	1	4		1
Fall	6	11	2	7	4	4
Fatigue	22	24	18	18	4	6
Fear	1	1			1	1
Febrile convulsion	1	1			1	1
Feeding disorder	3	4	1	2	2	2
Feeling abnormal	50	90	22	41	28	49
Feeling cold	11	18	5	9	6	9
Feeling hot	13	25	8	16	5	9
Fibrin D dimer increased	1	1	1	1		
Flushing	9	17	3	7	6	10
Foreign body in respiratory tract	1	1			1	1
Foreign body sensation in eyes	1	1	1	1		
Fracture		1		1		
Frequent bowel movements		1		1		
Gait disturbance	4	6	1	1	3	5
Gait inability		1				1
Gamma-glutamyltransferase increased	1	1	1	1		
Gastric ulcer	2	2			2	2
Gastric ulcer haemorrhage	2	2			2	2
Gastroenteritis		1		1		
Gastrointestinal disorder	1	1			1	1
Gastrointestinal mucosal disorder		1				1
Gaze palsy		1				1
Glossodynia		1		1		
Grip strength decreased	1	4		2	1	2
Guillain-Barre syndrome	1	3			1	3
Haematochezia		1				1
Haematuria	2	2			2	2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemorrhage subcutaneous	3	3			3	3
Headache	119	184	70	108	49	76
Head discomfort	12	14	5	6	7	8
Heart rate decreased	1	3		1	1	2
Heart rate increased	12	20	5	8	7	12
Hemiparesis	1	1			1	1
Henoch-Schonlein purpura	1	2		1	1	1
Hepatic function abnormal	1	2			1	2
Herpes simplex	1	1	1	1		
Herpes virus infection		1				1
Herpes zoster	1	2	1	1		1
Hiccups	1	1			1	1
Hot flush	6	13	2	6	4	7
Hyperaesthesia		1				1
Hyperglycaemia		1		1		
Hyperhidrosis	11	17	4	8	7	9
Hypersensitivity	18	32	5	13	13	19
Hypertension	1	2		1	1	1
Hyperthermia	1	3		2	1	1
Hypertonia	1	1			1	1
Hyperventilation	17	25	5	7	12	18
Hypoacusis	2	3	1	2	1	1
Hypoaesthesia	45	65	28	41	17	24
Hypoaesthesia oral	3	6	1	1	2	5
Hypokalaemia	1	1			1	1
Hypophagia		2		1		1
Hypopnoea		1				1
Hyporeflexia	1	1			1	1
Hypotension	2	2	1	1	1	1
Hypothermia	1	1			1	1
Hypoxia	1	2			1	2
Illusion	3	4	3	3		1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Immobile	1	1			1	1
Immunisation reaction	1	1	1	1		
Impaired driving ability	1	1			1	1
Impaired work ability	1	1	1	1		
Incoherent	1	1	1	1		
Incorrect route of product administration		2		2		
Injection site hypoaesthesia		1		1		
Injection site pain		1		1		
Injection site pruritus	1	2		1	1	1
Injection site vesicles		1				1
Injection site warmth		1		1		
Internal haemorrhage	2	4			2	4
Lacrimation increased	1	1	1	1		
Laryngeal discomfort	4	6	1	1	3	5
Laryngeal oedema	1	1			1	1
Laryngeal pain		1		1		
Laryngospasm		1				1
Larynx irritation	1	1	1	1		
Limb discomfort	3	7	1	2	2	5
Lip discolouration	1	1			1	1
Lip haemorrhage	1	1	1	1		
Lip pruritus	1	2	1	1		1
Lip swelling	1	2			1	2
Loss of consciousness	11	24			11	24
Lymphadenopathy	9	13	8	12	1	1
Lymph node pain	1	1	1	1		
Malaise	88	146	58	94	30	52
Melaena	1	2			1	2
Meningitis		1				1
Meningitis aseptic	1	3			1	3
Menstrual disorder	1	1	1	1		
Mental disorder	2	2	1	1	1	1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mobility decreased	4	4	3	3	1	1
Monoplegia	3	3			3	3
Mouth swelling		1		1		
Movement disorder	1	4	1	1		3
Mucosal haemorrhage		1		1		
Multiple sclerosis		1				1
Muscle spasms	4	8		1	4	7
Muscle tightness		1		1		
Muscle twitching	1	2	1	1		1
Muscular weakness	12	21	6	9	6	12
Musculoskeletal stiffness	3	3	1	1	2	2
Myalgia	30	44	25	32	5	12
Myelitis		1				1
Myocardial infarction	1	1			1	1
Myocarditis	1	5			1	5
Myositis	1	1	1	1		
Nail discolouration	1	1			1	1
Nasal congestion	1	1	1	1		
Nasal obstruction	2	3			2	3
Nasopharyngitis	3	3	1	1	2	2
Nausea	118	190	51	85	67	105
Neck pain	4	6	2	3	2	3
Nephropathy	1	1	1	1		
Neuralgia	1	1			1	1
Neurological symptom		1				1
Neuropathy peripheral	10	19			10	19
Norovirus infection	1	1	1	1		
Nystagmus	2	2	1	1	1	1
Obstructive airways disorder	2	3			2	3
Ocular hyperaemia	3	3	1	1	2	2
Oculomucocutaneous syndrome	3	3			3	3
Odynophagia	1	1	1	1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oedema		1				1
Oedema mucosal	1	1			1	1
Oedema peripheral	3	3	3	3		
Opisthotonus		1				1
Oral discomfort	2	3	1	2	1	1
Oral pruritus	1	1	1	1		
Oropharyngeal discomfort	26	60	11	21	15	39
Oropharyngeal pain	2	5	2	3		2
Orthostatic intolerance		1				1
Ovarian haemorrhage	1	1			1	1
Oxygen saturation decreased	6	9	3	3	3	6
Pain	16	22	8	14	8	8
Pain in extremity	16	29	10	16	6	13
Pallor	14	24	5	11	9	13
Palpitations	22	50	10	28	12	22
Panic attack	2	2			2	2
Panic disorder	1	1			1	1
Paraesthesia	6	11	4	6	2	5
Paraesthesia oral	1	2		1	1	1
Paralysis	3	4			3	4
Parotid gland enlargement	1	1	1	1		
Paroxysmal sympathetic hyperactivity	1	1			1	1
Pericarditis		1				1
Peripheral circulatory failure	1	1			1	1
Peripheral coldness	6	13	2	9	4	4
Peripheral nerve palsy	1	1	1	1		
Peripheral nerve paresis		1				1
Peripheral swelling	4	4	2	2	2	2
Pharyngeal oedema	1	1	1	1		
Pharyngeal paraesthesia	2	2	1	1	1	1
Pharyngeal swelling	2	3	1	2	1	1
Pharyngitis	1	1	1	1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngitis bacterial	1	2			1	2
Photopsia		2		1		1
Physical deconditioning	1	4		1	1	3
Pneumothorax		2				2
Poor quality sleep		1		1		
Presyncope	21	47	9	33	12	14
Product administered at inappropriate site	1	2	1	2		
Productive cough		2		1		1
Protein urine present	1	1			1	1
Prurigo	1	1			1	1
Pruritus	63	130	18	57	45	73
Pulse abnormal		1				1
Purpura	1	2	1	2		
Pyrexia	126	220	88	154	38	66
Radial pulse abnormal		2		1		1
Radial pulse increased		1				1
Rash	45	80	19	40	26	40
Rash erythematous	3	5	1	2	2	3
Rash papular	1	1			1	1
Rash pruritic		1		1		
Rectal tenesmus		1				1
Red blood cells urine positive	1	1			1	1
Respiratory alkalosis		1		1		
Respiratory disorder	4	8	2	3	2	5
Respiratory distress	1	5			1	5
Respiratory failure	1	1			1	1
Respiratory rate decreased		2		1		1
Respiratory rate increased	1	2			1	2
Respiratory symptom		1				1
Restlessness	1	1			1	1
Rhinorrhoea	4	7	1	3	3	4
Road traffic accident		1		1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Salivary hypersecretion	1	1			1	1
Scratch	1	1	1	1		
Seizure	5	6			5	6
Sensation of foreign body	5	6	1	2	4	4
Sensory disturbance	8	10	6	8	2	2
Sensory loss	1	1	1	1		
Shock		3				3
Shock symptom		1				1
Sinus bradycardia		1		1		
Sinus tachycardia	3	4	1	2	2	2
Skin abrasion		1				1
Skin fissures		1		1		
Sleep disorder		1				1
Sleep disorder due to general medical condition, insomnia type		1				1
Slow response to stimuli		1				1
Sneezing	1	2			1	2
Somatic symptom disorder	1	2		1	1	1
Somnolence	5	7	3	5	2	2
Speech disorder		1				1
Stenosis		1				1
Stomatitis		1		1		
Streptococcal infection		1				1
Stridor		1				1
Subarachnoid haemorrhage		1				1
Sudden death	1	1			1	1
Sudden hearing loss		1				1
Supraventricular tachyarrhythmia	1	1			1	1
Supraventricular tachycardia	1	1	1	1		
Swelling	2	6	1	3	1	3
Swelling face	3	6	1	2	2	4
Swelling of eyelid	2	7	1	3	1	4

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Syncope	2	12			2	12
Tachyarrhythmia	1	1	1	1		
Tachycardia	10	23	3	6	7	17
Tachypnoea	5	8	2	3	3	5
Temperature intolerance		1				1
Tension	2	2	2	2		
Tension headache		1				1
Tetany	2	2	1	1	1	1
Thirst		1		1		
Throat clearing	1	1	1	1		
Throat irritation	11	19	7	10	4	9
Throat tightness	13	15	3	4	10	11
Tinnitus	2	4		2	2	2
Tongue disorder		1				1
Tongue oedema		1		1		
Tongue pruritus	1	1	1	1		
Tonsillar disorder		1		1		
Toxic skin eruption	1	2			1	2
Tracheal obstruction		2				2
Tracheal stenosis		2				2
Trance		1		1		
Tremor	14	23	5	8	9	15
Type I hypersensitivity		3				3
Type IV hypersensitivity reaction		1		1		
Unresponsive to stimuli		2				2
Urinary incontinence	1	1			1	1
Urinary occult blood positive	1	1			1	1
Urinary retention		1				1
Urticaria	45	83	14	38	31	45
Vaccination complication		1				1
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	13	17	10	12	3	5

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site haemorrhage	1	2	1	2		
Vaccination site hypoaesthesia	3	3	2	2	1	1
Vaccination site induration	1	1	1	1		
Vaccination site joint discomfort		1		1		
Vaccination site mass	2	2	1	1	1	1
Vaccination site movement impairment	1	1			1	1
Vaccination site pain	58	80	36	50	22	30
Vaccination site pruritus	6	12	4	8	2	4
Vaccination site rash	2	2	2	2		
Vaccination site swelling	20	24	16	18	4	6
Vaccination site urticaria	1	2		1	1	1
Vaccination site vesicles		1				1
Vaccination site warmth	2	2	1	1	1	1
Vaginal discharge	1	1	1	1		
Vaginal haemorrhage	1	1			1	1
Vasculitis	1	1	1	1		
Vertigo	4	7	1	2	3	5
Vision blurred		2		1		1
Visual impairment	3	4	2	3	1	1
Vomiting	39	64	17	31	22	33
Wheezing	5	12		1	5	11
White blood cell count decreased	1	1			1	1
White blood cells urine positive	1	1			1	1
White matter lesion	1	1			1	1
Yawning		1		1		
	2,159	3,846	980	1740	1179	2106

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	12	22	4	10	8	12
Abdominal distension		1		1		
Abdominal pain	28	49	13	22	15	27
Abdominal pain lower	3	4	2	2	1	2
Abdominal pain upper	8	16	5	8	3	8
Abdominal tenderness	1	1	1	1		
Abnormal sensation in eye		4		3		1
Accidental overdose	1	1	1	1		
Acidosis		1				1
Acoustic neuroma		1				1
Acute abdomen	1	1			1	1
Acute disseminated encephalomyelitis	2	2			2	2
Acute febrile neutrophilic dermatosis		1				1
Affective disorder		1		1		
Agitation	1	2		1	1	1
Allergic pharyngitis	1	1			1	1
Allergic reaction to excipient		1				1
Allergy to vaccine	2	8		3	2	5
Alopecia	1	1	1	1		
Altered state of consciousness	11	16			11	16
Amnesia	2	3	1	1	1	2
Anaemia	1	4		2	1	2
Anaesthesia dolorosa		1				1
Anaphylactic reaction	224	604		2	224	602
Anaphylactic shock	6	16			6	16
Anaphylactoid reaction	3	7			3	7
Aneurysm	1	1			1	1
Aneurysm ruptured	2	2			2	2
Angina pectoris	2	3			2	3
Angioedema	1	7		1	1	6
Anxiety	3	8	1	3	2	5
Anxiety disorder	1	1			1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic dissection		1				1
Aphasia	2	2			2	2
Aphonia	1	2		1	1	1
Apnoea	2	2			2	2
Arrhythmia	3	8			3	8
Arrhythmia supraventricular	1	1			1	1
Arterial occlusive disease	1	1	1	1		
Arthralgia	68	106	49	78	19	28
Arthritis	3	6		1	3	5
Arthritis reactive	1	1			1	1
Asphyxia	1	1			1	1
Asthenia	20	38	7	15	13	23
Asthenopia		1				1
Asthma	36	67	9	21	27	46
Atrial fibrillation	1	2			1	2
Atrial septal defect	1	1			1	1
Atrial tachycardia	1	2			1	2
Autonomic dysreflexia	2	2			2	2
Axillary pain	3	5	3	4		1
Back pain	12	22	8	14	4	8
Balance disorder	1	1			1	1
Blepharospasm	4	7	2	2	2	5
Blood alkaline phosphatase decreased		1		1		
Blood creatine phosphokinase increased	1	2		1	1	1
Blood creatinine decreased		1		1		
Blood pressure abnormal	3	3			3	3
Blood pressure ambulatory abnormal	1	1			1	1
Blood pressure decreased	28	42	5	13	23	29
Blood pressure diastolic decreased	3	4		1	3	3
Blood pressure diastolic increased	2	2	1	1	1	1
Blood pressure fluctuation		1				1
Blood pressure immeasurable	1	2		1	1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased	142	222	31	65	111	157
Blood pressure measurement		1		1		
Blood pressure systolic decreased	2	2			2	2
Blood pressure systolic increased	7	13	3	6	4	7
Body temperature decreased	1	1	1	1		
Body temperature increased	7	13	4	10	3	3
Bradycardia	3	7		1	3	6
Brain herniation	1	1			1	1
Brain stem infarction	1	1			1	1
Breath sounds abnormal	1	1			1	1
Bronchial obstruction		1				1
Bronchitis	1	1	1	1		
Bronchitis bacterial	1	1			1	1
Bronchospasm	3	4			3	4
Bronchostenosis		1				1
Bundle branch block right	1	2	1	2		
Burning sensation	4	5	2	2	2	3
Cardiac tamponade		1				1
Cardio-respiratory arrest	2	5			2	5
Cardiovascular disorder	1	4	1	4		
Carotid artery dissection	1	1			1	1
Cellulitis	3	4			3	4
Cerebral artery stenosis	1	1			1	1
Cerebral congestion		1				1
Cerebral haemorrhage	4	4			4	4
Cerebral infarction	2	3			2	3
Cerebral palsy	1	1			1	1
Cerebral venous sinus thrombosis		1				1
Cerebrovascular accident	1	1			1	1
Chest discomfort	31	49	13	23	18	26
Chest pain	3	5	1	2	2	3
Chills	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills	77	137	54	89	23	48
Choking	1	2			1	2
Choking sensation	2	3			2	3
Chromatopsia		1				1
Chromaturia	2	2	2	2		
Chronic obstructive pulmonary disease	1	1	1	1		
Chronic respiratory disease	1	1	1	1		
Circulatory collapse		2				2
Circumoral oedema	1	1			1	1
Circumoral swelling	2	2			2	2
Coccydynia	1	1	1	1		
Cold sweat	15	29	6	12	9	17
Colitis ischaemic		1				1
Colitis ulcerative	2	3			2	3
Colour blindness		1		1		
Coma	2	2			2	2
Communication disorder	1	1			1	1
Complex regional pain syndrome		2				2
Condition aggravated	4	6	1	1	3	5
Confusional state	1	1	1	1		
Conjunctival haemorrhage		1				1
Conjunctival hyperaemia	6	17	1	7	5	10
Conjunctival oedema	1	1	1	1		
Convulsions local		1				1
Cough	116	252	47	100	69	152
Cough variant asthma	1	1	1	1		
COVID-19	3	4	2	3	1	1
COVID-19 pneumonia	1	1			1	1
C-reactive protein increased		1				1
CSF cell count increased	1	1			1	1
Cubital tunnel syndrome	1	1			1	1
Cutaneous symptom	1	3		1	1	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cyanosis	2	5		2	2	3
Cystitis	2	2	1	1	1	1
Daydreaming		1				1
Deafness	6	7			6	7
Deafness neurosensory	3	4			3	4
Death	1	2			1	2
Decreased appetite	17	25	7	9	10	16
Deep vein thrombosis	2	3			2	3
Dehydration	2	3			2	3
Delirium		1				1
Depressed level of consciousness	16	30			16	30
Depressed mood	2	2			2	2
Dermatitis	2	2	1	1	1	1
Dermatitis allergic	2	5	2	4		1
Dermatitis atopic		2		1		1
Dermatitis bullous	1	1			1	1
Dermatitis contact		1		1		
Diabetes insipidus	1	1			1	1
Diabetes mellitus	1	1			1	1
Diarrhoea	51	83	30	44	21	39
Diplopia		1				1
Discomfort	7	18	5	12	2	6
Disease recurrence	3	5		1	3	4
Disorientation	1	1			1	1
Dissociative disorder	1	1	1	1		
Disturbance in attention	1	1	1	1		
Dizziness	83	149	40	79	43	70
Dizziness postural	6	9	5	7	1	2
Drug eruption	4	8	1	4	3	4
Drug hypersensitivity	4	7	2	3	2	4
Drug-induced liver injury	1	1			1	1
Drug ineffective	1	1			1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry mouth		3		1		2
Dry skin		1		1		
Dry throat	1	2		1	1	1
Duodenal ulcer	1	1			1	1
Dysaesthesia	2	2	1	1	1	1
Dysarthria	1	1			1	1
Dysgeusia	4	5	3	4	1	1
Dyskinesia	1	2			1	2
Dyspepsia		1		1		
Dysphagia	4	6	1	2	3	4
Dysphonia	13	30	5	15	8	15
Dysphoria	25	30	12	13	13	17
Dyspnoea	111	208	33	63	78	145
Dysstasia	11	12	3	3	8	9
Ear discomfort	8	13	5	7	3	6
Ear pain	1	1	1	1		
Ear pruritus	1	2			1	2
Eating disorder		2				2
Eczema	7	8	2	3	5	5
Eczema herpeticum		1				1
Electrocardiogram P wave abnormal	1	1	1	1		
Electrocardiogram QRS complex shortened	1	1			1	1
Electrocardiogram ST segment elevation	1	1			1	1
Embolic stroke	1	1			1	1
Enanthema	1	1			1	1
Encephalitis	1	1			1	1
Enteritis		1				1
Enterocolitis	2	3			2	3
Epigastric discomfort	1	1			1	1
Epilepsy	2	3			2	3
Epistaxis	1	3	1	1		2
Eructation		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	159	285	51	124	108	161
Erythema multiforme	1	1			1	1
Erythema of eyelid	2	2	2	2		
Eustachian tube dysfunction	1	1	1	1		
Exposure during pregnancy	2	2			2	2
Extrasystoles	1	2		1	1	1
Eye disorder		2				2
Eye haemorrhage		1				1
Eyelid function disorder		1				1
Eyelid irritation		1				1
Eyelid oedema	5	20	2	10	3	10
Eyelid pain	1	1			1	1
Eyelid ptosis		2				2
Eyelid rash	1	1			1	1
Eyelids pruritus	1	1			1	1
Eye movement disorder	2	3	1	1	1	2
Eye pain	2	5	1	2	1	3
Eye pruritus	7	15	1	5	6	10
Eye swelling		2				2
Face oedema	9	13	2	3	7	10
Facial paralysis	6	15			6	15
Fall	7	9	1	1	6	8
Fatigue	24	34	20	29	4	5
Feeding disorder	4	7	2	2	2	5
Feeling abnormal	126	211	54	93	72	118
Feeling cold	24	33	9	13	15	20
Feeling hot	45	74	21	37	24	37
Feeling jittery		1				1
Female reproductive tract disorder	1	1	1	1		
Fibrin degradation products increased		1				1
Fluid intake reduced	1	1			1	1
Flushing	25	40	8	12	17	28

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Foaming at mouth	1	1	1	1		
Foreign body in throat		2				2
Gait disturbance	5	10	1	2	4	8
Gastrointestinal disorder	3	5	2	2	1	3
Gastrointestinal hypermotility		1				1
Gastrointestinal hypomotility	1	1			1	1
Gastrointestinal oedema	2	2			2	2
Gaze palsy	1	4			1	4
Generalised oedema		1				1
General physical condition abnormal	1	1			1	1
General symptom	1	1	1	1		
Genital haemorrhage	3	3			3	3
Gingivitis	1	1	1	1		
Glomerulonephritis	1	1			1	1
Glossodynia	2	2	2	2		
Grip strength decreased	1	4	1	3		1
Groin pain	1	2			1	2
Grunting		1		1		
Guillain-Barre syndrome	2	6	1	1	1	5
Haemarthrosis		1				1
Haematochezia	3	5			3	5
Haematoma	1	1			1	1
Haematuria	1	1			1	1
Haemoptysis		1				1
Haemorrhage	2	2			2	2
Haemorrhage subcutaneous	4	11			4	11
Haemorrhagic disorder	1	1			1	1
Hallucination	1	1			1	1
Hallucination, visual		1				1
Headache	216	363	137	235	79	128
Head discomfort	16	33	10	20	6	13
Heart rate decreased	8	10	2	3	6	7

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate increased	32	53	7	19	25	34
Heavy menstrual bleeding	2	2	1	1	1	1
Hemiparesis		1				1
Hemiplegia	1	1			1	1
Henoch-Schonlein purpura	2	2	2	2		
Hepatic function abnormal	3	6		1	3	5
Hepatitis	1	1			1	1
Herpes simplex	1	1	1	1		
Herpes zoster	1	2	1	2		
Herpes zoster oticus		1				1
Hordeolum	1	1			1	1
Hot flush	27	55	16	32	11	23
Hyperaemia	2	3	1	1	1	2
Hyperaesthesia	1	1	1	1		
Hyperhidrosis	28	53	16	26	12	27
Hyperpyrexia		2				2
Hyperreflexia	1	1			1	1
Hypersensitivity	42	66	9	22	33	44
Hypertension	15	27	3	6	12	21
Hypertensive emergency	2	3			2	3
Hyperthermia	2	2			2	2
Hyperventilation	20	32	2	7	18	25
Hypoacusis	1	2			1	2
Hypoaesthesia	86	149	47	81	39	68
Hypoaesthesia oral	16	27	8	18	8	9
Hypochromic anaemia	1	1			1	1
Hypoglycaemia	2	2			2	2
Hypokalaemia		3				3
Hypokinesia		1		1		
Hypophagia	1	1			1	1
Hypopnoea	1	1	1	1		
Hypotension	1	1			1	1

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypothermia		1				1
Hypotonia		1				1
Hypoxia	1	2			1	2
IIIrd nerve paralysis		1				1
Ileus paralytic		1				1
Imaging procedure abnormal	1	1			1	1
Immunisation reaction	1	1			1	1
Impaired work ability	1	1	1	1		
Inappropriate schedule of product administration	2	2	2	2		
Incorrect dose administered	1	1	1	1		
Incorrect route of product administration		2		2		
Induration	1	2	1	2		
Infarction	1	1			1	1
Infection		1		1		
Inflammation	1	1			1	1
Injected limb mobility decreased		1		1		
Injection site erythema	1	2	1	1		1
Injection site hypoaesthesia	1	1	1	1		
Injection site muscle weakness		1		1		
Injection site pain		2		2		
Injection site pruritus		1		1		
Injection site rash		1		1		
Insomnia	4	6	1	3	3	3
Intention tremor	1	1			1	1
Intermenstrual bleeding	2	2	1	1	1	1
Internal haemorrhage	8	18	1	1	7	17
Interstitial lung disease	1	1			1	1
Intestinal ischaemia	1	1			1	1
Intestinal ulcer	1	1			1	1
Intracranial aneurysm	2	2			2	2
Intraventricular haemorrhage	2	2			2	2
Irregular breathing		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Irritability	1	1			1	1
Joint range of motion decreased	3	7	2	3	1	4
Joint swelling		2		2		
Lacrimation increased	3	5	1	3	2	2
Laryngeal discomfort	7	10	3	6	4	4
Laryngeal obstruction	1	2			1	2
Laryngeal oedema	6	9	1	2	5	7
Larynx irritation		2		1		1
Lethargy		1				1
Leukopenia		1				1
Limb discomfort	9	18	5	13	4	5
Lip oedema	2	4	1	2	1	2
Lip pruritus	1	3		1	1	2
Lip swelling	5	15	1	7	4	8
Listless		3		3		
Livedo reticularis		1		1		
Liver disorder		1				1
Liver function test abnormal	1	1			1	1
Local reaction		1		1		
Loss of consciousness	16	26			16	26
Lung infiltration		1				1
Lymphadenitis		1		1		
Lymphadenopathy	7	14	4	9	3	5
Lymph node pain	1	3		1	1	2
Lymphocyte percentage decreased		1		1		
Lymphoedema		1				1
Lymphoma	1	1			1	1
Malaise	161	290	110	198	51	92
Mass	1	1	1	1		
Maternal exposure during pregnancy		1		1		
Memory impairment	1	3		1	1	2
Meniere's disease	2	2			2	2

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Meningitis	1	1			1	1
Meningitis aseptic	1	5			1	5
Menstrual disorder	1	1	1	1		
Middle insomnia		1				1
Migraine	2	4			2	4
Mobility decreased	1	5	1	4		1
Monocyte percentage increased		1		1		
Monoparesis	1	1			1	1
Monoplegia	1	1			1	1
Mood altered	1	1			1	1
Motion sickness		1				1
Mouth swelling	1	3	1	3		
Movement disorder	7	10	5	7	2	3
Mucocutaneous disorder		1		1		
Mucocutaneous rash	1	1			1	1
Mucosal disorder		1		1		
Mucosal inflammation	1	1			1	1
Mucous stools	1	1	1	1		
Multi-organ disorder		1				1
Muscle atrophy		1		1		
Muscle fatigue	2	2	1	1	1	1
Muscle spasms	7	12	6	7	1	5
Muscle strain		1		1		
Muscle swelling	1	1	1	1		
Muscle tightness	4	6	1	2	3	4
Muscle twitching	2	3		1	2	2
Muscular weakness	21	41	7	12	14	29
Musculoskeletal chest pain		1		1		
Musculoskeletal discomfort	1	3	1	2		1
Musculoskeletal disorder	1	1			1	1
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	7	11	4	6	3	5

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mutism		1				1
Myalgia	65	114	55	97	10	17
Mydriasis		1		1		
Myocardial infarction	1	1			1	1
Myocarditis	1	1			1	1
Myopathy	1	1	1	1		
Myositis		2		1		1
Nasal congestion	10	13	7	7	3	6
Nasal mucosal disorder		1				1
Nasal obstruction	1	1			1	1
Nasal oedema	1	1	1	1		
Nasal pruritus	1	1	1	1		
Nasopharyngitis	1	3	1	3		
Nausea	206	335	91	151	115	184
Neck pain	6	10	4	6	2	4
Needle issue		1		1		
Neoplasm	1	1			1	1
Nervous system disorder	1	1	1	1		
Neuralgia	2	2			2	2
Neurological symptom	2	2			2	2
Neuropathy peripheral	21	36			21	36
Neutrophilic dermatosis		1		1		
Nightmare	1	1	1	1		
Night sweats		1		1		
Nystagmus	2	3	1	1	1	2
Ocular hyperaemia	4	18	2	11	2	7
Oculomucocutaneous syndrome	2	7			2	7
Odynophagia		1				1
Oedema	4	5	2	2	2	3
Oedema mouth	1	2			1	2
Oedema mucosal	1	1			1	1
Oedema peripheral	3	4	3	3		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Off label use	2	2	2	2		
Optic neuritis	1	1			1	1
Oral allergy syndrome	1	1	1	1		
Oral discomfort	5	13	3	8	2	5
Oral herpes	1	1	1	1		
Oral mucosa erosion		1		1		
Oral mucosal blistering		1		1		
Oral mucosal roughening	1	1	1	1		
Oral pain		1		1		
Oral pruritus	6	8	1	2	5	6
Orbital oedema	1	1			1	1
Oropharyngeal discomfort	101	207	38	81	63	126
Oropharyngeal pain	16	32	7	19	9	13
Orthostatic hypotension		1				1
Oxygen saturation decreased	12	21		2	12	19
Oxygen saturation increased	1	2			1	2
Pain	39	57	26	39	13	18
Pain in extremity	31	58	24	48	7	10
Palatal oedema	1	1			1	1
Pallor	32	42	10	12	22	30
Palmar erythema		1		1		
Palpitations	106	184	45	83	61	101
Panic attack	2	3	1	1	1	2
Panic disorder	1	1			1	1
Papule	1	2		1	1	1
Paraesthesia	9	18	5	14	4	4
Paraesthesia oral	6	10	2	5	4	5
Paralysis	1	2			1	2
Parosmia	4	5	1	2	3	3
Parotitis	1	2	1	2		
Periorbital oedema		1				1
Periorbital swelling	2	3	1	1	1	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral circulatory failure		1				1
Peripheral coldness	17	36	7	17	10	19
Peripheral swelling	5	9	3	7	2	2
Peritonitis		1				1
Petechiae	1	1	1	1		
Petit mal epilepsy		2				2
Pharyngeal erythema	1	1			1	1
Pharyngeal hypoaesthesia	1	1	1	1		
Pharyngeal inflammation	1	1	1	1		
Pharyngeal oedema	5	5	2	2	3	3
Pharyngeal paraesthesia	2	3		1	2	2
Pharyngeal stenosis	2	3			2	3
Pharyngeal swelling	4	10	1	4	3	6
Pharyngitis	2	2	2	2		
Phlebitis		1		1		
Photophobia	1	1			1	1
Photopsia	7	9	4	6	3	3
Physical deconditioning	2	8	1	6	1	2
Pigmentation disorder		1		1		
Piloerection		2				2
Platelet count decreased		2				2
Pneumonia		3				3
Pneumonia viral		1				1
Pollakiuria	1	2			1	2
Polydipsia	1	1	1	1		
Polyuria	2	2	1	1	1	1
Poor quality sleep	2	2	2	2		
Presyncope	47	74	20	35	27	39
Primary hyperaldosteronism	1	2		1	1	1
Product administered at inappropriate site	1	1	1	1		
Product container issue	1	1	1	1		
Productive cough	5	9	3	5	2	4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product preparation error	1	1	1	1		
Prolonged expiration	1	1			1	1
Protein total decreased		1		1		
Proteinuria	1	1			1	1
Prurigo	1	1	1	1		
Pruritus	198	363	77	178	121	185
Pulmonary artery thrombosis	1	2			1	2
Pulmonary embolism	2	3			2	3
Pulse abnormal	4	4			4	4
Puncture site pain	1	1			1	1
Purpura	2	2	2	2		
Pyrexia	186	339	125	239	61	100
Radial pulse abnormal	1	3			1	3
Rash	112	212	46	101	66	111
Rash erythematous	16	23	8	13	8	10
Rash macular	2	2	1	1	1	1
Rash papular		1		1		
Rash pruritic	4	4	3	3	1	1
Raynaud's phenomenon		1		1		
Reaction to excipient		1				1
Reduced facial expression		1				1
Respiratory disorder	2	6		1	2	5
Respiratory distress	1	5		1	1	4
Respiratory rate increased	3	7	2	3	1	4
Respiratory symptom	1	5		1	1	4
Restless legs syndrome	1	1	1	1		
Restlessness	2	2			2	2
Retching	1	1			1	1
Retinal haemorrhage	2	3			2	3
Retinal vein occlusion	2	2			2	2
Rheumatoid arthritis	2	2			2	2
Rhinalgia	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rhinorrhoea	16	29	9	17	7	12
Rotator cuff syndrome	1	1			1	1
Ruptured cerebral aneurysm	1	1			1	1
Salivary gland calculus	1	1	1	1		
Salivary hypersecretion	2	3	1	1	1	2
Sciatica	1	1	1	1		
Scleritis		1				1
Seizure	7	20		1	7	19
Sensation of foreign body	10	13	4	7	6	6
Sensitisation	1	1			1	1
Sensory disturbance	9	12	4	7	5	5
Serum sickness		1				1
Shock	3	3			3	3
Shoulder injury related to vaccine administration		1				1
Sialoadenitis		1				1
Sinus rhythm	1	2			1	2
Sinus tachycardia	7	9	1	1	6	8
Sjogren's syndrome	1	1			1	1
Skin discomfort	1	1			1	1
Skin exfoliation	1	1			1	1
Skin haemorrhage	1	1			1	1
Skin laceration	1	1			1	1
Skin plaque		1				1
Sleep disorder	1	1			1	1
Sneezing	2	6	1	4	1	2
Somatic symptom disorder	1	1	1	1		
Somnolence	15	25	9	15	6	10
Spinal column injury		1		1		
Sputum discoloured		1		1		
Sputum purulent		2				2
Sputum retention	2	3	1	2	1	1
Status asthmaticus	1	1			1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stenosis		1				1
Stomatitis	2	2	2	2		
Stress		2		2		
Stridor		6		3		3
Subarachnoid haemorrhage	7	10			7	10
Submaxillary gland enlargement		1		1		
Sudden death	1	1			1	1
Sudden hearing loss	1	5			1	5
Suffocation feeling		2		1		1
Sunburn		1		1		
Supraventricular extrasystoles	1	1			1	1
Supraventricular tachycardia	1	1			1	1
Swelling	12	17	10	14	2	3
Swelling face	9	15	5	6	4	9
Swelling of eyelid	4	8	4	6		2
Sympathicotonia		1				1
Syncope	4	8			4	8
Systemic lupus erythematosus	1	1			1	1
Tachycardia	55	80	21	30	34	50
Tachypnoea	3	10		5	3	5
Taste disorder	5	6	3	4	2	2
Tearfulness	1	1	1	1		
Tension	2	4	1	2	1	2
Tetany		1				1
Thirst	5	10	2	5	3	5
Throat irritation	33	53	15	30	18	23
Throat tightness	20	41	5	14	15	27
Thrombocytopenia	1	1			1	1
Thrombocytopenic purpura		1				1
Thrombophlebitis superficial		1		1		
Thrombosis		1				1
Thrombosis mesenteric vessel	1	1			1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tinnitus	4	6	2	2	2	4
Tongue discomfort	1	1			1	1
Tongue erythema	1	1			1	1
Tonic convulsion	1	1			1	1
Tonsillar hypertrophy	1	1	1	1		
Toothache	1	1	1	1		
Toxic skin eruption	1	4			1	4
Tracheal stenosis	1	1			1	1
Transient ischaemic attack	2	2			2	2
Tremor	25	41	10	14	15	27
Trigeminal nerve disorder		3				3
Trigeminal neuralgia	1	2		1	1	1
Troponin increased	1	1			1	1
Type I hypersensitivity	1	4			1	4
Type IV hypersensitivity reaction	2	2	1	1	1	1
Ulnar nerve palsy	1	1			1	1
Underdose		1		1		
Upper airway obstruction		1				1
Upper respiratory tract inflammation	1	1	1	1		
Urinary occult blood positive	1	1			1	1
Urinary retention	2	2			2	2
Urticaria	117	226	44	113	73	113
Uterine haemorrhage	1	1			1	1
Vaccination complication		1		1		
Vaccination site bruising	3	4	3	3		1
Vaccination site coldness	2	3	1	2	1	1
Vaccination site discomfort	2	2	2	2		
Vaccination site erythema	16	34	12	26	4	8
Vaccination site haematoma	1	1	1	1		
Vaccination site haemorrhage	2	4	2	3		1
Vaccination site hypoaesthesia	2	6	2	5		1
Vaccination site induration	5	7	4	6	1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site joint pain	1	1	1	1		
Vaccination site mass	1	2	1	2		
Vaccination site movement impairment	3	7	2	4	1	3
Vaccination site pain	126	216	98	175	28	41
Vaccination site papule		1		1		
Vaccination site paraesthesia	1	3		2	1	1
Vaccination site pruritus	16	29	11	22	5	7
Vaccination site rash	2	5	2	5		
Vaccination site reaction	1	3		2	1	1
Vaccination site swelling	32	43	28	36	4	7
Vaccination site urticaria	3	7	2	5	1	2
Vaccination site warmth	8	12	7	8	1	4
Vaginal haemorrhage	1	1			1	1
Vascular injury		1		1		
Vasculitis	2	3	2	3		
Vasodilatation		1		1		
Vasospasm		1				1
Ventricular extrasystoles		3		2		1
Vertebral artery dissection		1				1
Vertigo	8	12	3	3	5	9
Vestibular neuritis		1				1
Viral infection		1				1
Vision blurred	5	7	2	4	3	3
Visual acuity reduced	1	1			1	1
Visual brightness	1	1			1	1
Visual impairment	10	16	6	9	4	7
Vlth nerve disorder		1				1
Vitreous floaters		1		1		
Vomiting	69	125	25	47	44	78
Wheezing	16	34	5	7	11	27
White blood cell count decreased	1	2	1	1		1
White blood cell count increased		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Wrong technique in product usage process		1				1
Yawning	1	4	1	2		2
	4,926	8,908	2125	3999	2801	4909

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* AE=Adverse Event
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	4	9	2	4	2	5
Abdominal distension	2	2	1	1	1	1
Abdominal pain	10	17	4	7	6	10
Abdominal pain lower	1	3	1	2		1
Abdominal pain upper	2	4	1	2	1	2
Abdominal symptom	1	2			1	2
Abnormal behaviour	1	1	1	1		
Abnormal sensation in eye	1	2	1	1		1
Acute lymphocytic leukaemia		1				1
Acute myocardial infarction	1	1			1	1
Acute respiratory distress syndrome		2				2
Administration site movement impairment		1		1		
Allergy to vaccine	2	6		4	2	2
Altered state of consciousness	5	7			5	7
Amnesia	2	2			2	2
Anaemia	1	1			1	1
Anaphylactic reaction	80	221		1	80	220
Anaphylactic shock	5	8			5	8
Anaphylactoid reaction		3				3
Aneurysm		1				1
Angina unstable		1				1
Angioedema	2	3		1	2	2
Angiopathy	1	1			1	1
Anxiety	2	3	1	2	1	1
Anxiety disorder	1	1			1	1
Aphasia	1	2	1	1		1
Apnoea		1				1
Apraxia		1				1
Arrhythmia	3	5			3	5
Arthralgia	23	33	18	23	5	10
Arthritis	2	2	2	2		
Arthropathy	1	1			1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ascites		1				1
Asphyxia	1	1			1	1
Asthenia	8	12	4	7	4	5
Asthenopia	2	2	2	2		
Asthma	24	37	8	12	16	25
Asthmatic crisis	1	1			1	1
Atrioventricular block complete	1	1			1	1
Autonomic neuropathy		1				1
Back pain	6	8	4	6	2	2
Basilar artery occlusion	1	1			1	1
Blepharospasm	1	1	1	1		
Blister		1				1
Blood disorder	1	1	1	1		
Blood pressure abnormal	1	2			1	2
Blood pressure decreased	13	17	1	4	12	13
Blood pressure fluctuation	1	1	1	1		
Blood pressure increased	90	126	23	38	67	88
Blood pressure systolic decreased	3	3	3	3		
Blood pressure systolic increased	3	4	1	2	2	2
Body temperature abnormal		1		1		
Body temperature decreased	1	1	1	1		
Body temperature increased	4	4	2	2	2	2
Bowel movement irregularity	1	1	1	1		
Bradycardia	2	3			2	3
Breath sounds abnormal	2	3	1	1	1	2
Bronchial disorder	1	1			1	1
Bronchostenosis	1	2			1	2
Burning sensation	2	3	2	2		1
Calculus urinary	1	1	1	1		
Cardiac discomfort		1		1		
Cardiac failure	1	2			1	2
Cardiomyopathy	1	1			1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardio-respiratory arrest	1	2			1	2
Cellulitis		3				3
Cerebellar ataxia	1	1			1	1
Cerebral haemorrhage	5	7			5	7
Cerebral infarction	3	6			3	6
Cerebral venous sinus thrombosis	1	1			1	1
Cerebral venous thrombosis	1	1			1	1
Cerebral ventricular rupture	1	1			1	1
Cheilitis		1		1		
Chest discomfort	4	9		1	4	8
Chest pain	2	4		1	2	3
Chillblains	1	1			1	1
Chills	25	42	16	27	9	15
Cholinergic syndrome		1				1
Chromaturia	1	1			1	1
Clonus	1	1	1	1		
Cold sweat	9	16	2	5	7	11
Colitis		1				1
Colitis ischaemic	1	1			1	1
Completed suicide	1	1			1	1
Condition aggravated	1	1			1	1
Confusional state	1	2	1	2		
Conjunctival haemorrhage	1	2			1	2
Conjunctival hyperaemia	2	5	1	3	1	2
Contusion	1	1	1	1		
Coronary artery occlusion	1	1			1	1
Coronavirus infection	1	1			1	1
Cough	42	78	15	20	27	58
Cough variant asthma		1				1
COVID-19	5	5	3	3	2	2
Cutaneous symptom	1	1			1	1
Cyanosis	1	1	1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cystitis	1	1			1	1
Decreased appetite	5	9	4	6	1	3
Decreased vibratory sense		2				2
Deep vein thrombosis		1				1
Dehydration	2	4	1	2	1	2
Depressed level of consciousness	7	11	1	1	6	10
Dermatitis		1		1		
Dermatitis allergic	3	4	2	3	1	1
Dermatitis atopic	1	2	1	2		
Diarrhoea	20	31	12	17	8	14
Diplopia		1		1		
Discomfort	3	6	2	4	1	2
Disease recurrence	1	1			1	1
Disseminated intravascular coagulation		1				1
Diverticulitis		2				2
Diverticulum		1				1
Diverticulum intestinal haemorrhagic	1	1			1	1
Dizziness	35	52	14	27	21	25
Dizziness postural	1	4		1	1	3
Drowning		1				1
Drug eruption	1	4		2	1	2
Drug hypersensitivity	2	3			2	3
Dry skin	1	2		1	1	1
Dry throat		1		1		
Dysaesthesia		2				2
Dysarthria	2	2			2	2
Dyschezia	1	1			1	1
Dysgeusia	3	3	2	2	1	1
Dyskinesia	1	1			1	1
Dyslalia		1		1		
Dyspepsia		1				1
Dysphagia	3	3	1	1	2	2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysphonia	8	18	3	6	5	12
Dysphoria	7	8	2	2	5	6
Dyspnoea	35	70	8	21	27	49
Dysstasia	2	2	1	1	1	1
Dysuria	1	1			1	1
Ear discomfort	1	2	1	2		
Ear swelling	1	2	1	1		1
Eczema	2	4		1	2	3
Electrocardiogram T wave inversion	1	1			1	1
Electrolyte imbalance	1	1	1	1		
Embolism venous	1	2			1	2
Epigastric discomfort		1		1		
Epilepsy	1	1			1	1
Erythema	72	124	37	68	35	56
Erythema multiforme	2	2			2	2
Erythema of eyelid	2	2	1	1	1	1
Extrasystoles	1	1	1	1		
Eye disorder	1	2	1	1		1
Eyelid irritation	1	1	1	1		
Eyelid oedema	2	5	1	2	1	3
Eye oedema	1	2	1	1		1
Eye pain	1	1	1	1		
Eye pruritus	3	5	3	5		
Face oedema	3	6		1	3	5
Facial pain		2		1		1
Facial paralysis	3	6			3	6
Faeces soft	1	2		1	1	1
Fall	3	5	2	2	1	3
Fatigue	8	10	7	8	1	2
Feeling abnormal	53	83	30	47	23	36
Feeling cold	3	8	2	2	1	6
Feeling drunk	2	2	2	2		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling hot	14	25	5	14	9	11
Flatulence	1	1			1	1
Flushing	8	16	4	11	4	5
Gait disturbance	2	5	2	3		2
Gastroenteritis bacterial		1				1
Gastrointestinal disorder	1	1			1	1
Gastrointestinal haemorrhage		1				1
Gastrointestinal hypermotility		1				1
Gastrointestinal motility disorder	1	2		1	1	1
Gastrointestinal oedema	1	2			1	2
Gastrooesophageal reflux disease	1	1			1	1
Gingival bleeding	1	1			1	1
Glare	1	1	1	1		
Glassy eyes	1	1			1	1
Grunting		1				1
Guillain-Barre syndrome	2	2			2	2
Haematochezia	1	3			1	3
Haemorrhage	1	3			1	3
Haemorrhage subcutaneous	1	1			1	1
Hallucination, visual	2	2			2	2
Hand dermatitis	1	1			1	1
Headache	62	108	37	65	25	43
Head discomfort	4	12	3	8	1	4
Head injury	1	1			1	1
Heart rate decreased	1	2		1	1	1
Heart rate increased	14	22	10	17	4	5
Hemiplegia	2	3			2	3
Henoch-Schonlein purpura	2	2	1	1	1	1
Hepatic function abnormal	1	3			1	3
Hepatitis acute	2	2			2	2
Herpes simplex	1	1	1	1		
Herpes zoster	3	4	2	2	1	2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes zoster oticus		1				1
Hot flush	15	23	7	13	8	10
Hyperaemia		1				1
Hyperaesthesia		1				1
Hyperhidrosis	11	21	6	11	5	10
Hyperpyrexia	1	1			1	1
Hyperreflexia	1	2	1	1		1
Hypersensitivity	16	26	7	10	9	16
Hypertension	14	24	2	3	12	21
Hypertensive emergency		1				1
Hypertensive urgency		1				1
Hyperthermia		1				1
Hyperthyroidism	1	1			1	1
Hypertonia		1		1		
Hyperventilation	2	3	1	2	1	1
Hypoaesthesia	24	46	15	30	9	16
Hypoaesthesia oral	9	16	7	11	2	5
Hypokalaemia	1	1			1	1
Hyponatraemia	1	1	1	1		
Hypothermia	1	2			1	2
Hypoventilation		1				1
Hypoxia	1	2			1	2
Illusion	2	2	1	1	1	1
Immune system disorder	1	1			1	1
Incorrect route of product administration	1	1	1	1		
Induration	1	2	1	2		
Inflammation		1		1		
Injected limb mobility decreased	1	3	1	3		
Injection site swelling		1		1		
Insomnia	3	3	3	3		
Internal haemorrhage	2	2			2	2
Intracranial aneurysm	1	2			1	2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint range of motion decreased	1	2	1	1		1
Joint swelling	2	2	2	2		
Lacrimation increased	2	5		1	2	4
Lacunar infarction		1				1
Laryngeal discomfort		1				1
Laryngeal oedema	1	4	1	1		3
Larynx irritation	2	3			2	3
Lid margin discharge		1		1		
Limb discomfort	2	2	2	2		
Lip erythema		1				1
Lip oedema	1	1			1	1
Lip swelling	2	5		2	2	3
Loss of consciousness	6	10			6	10
Lymphadenitis	2	2	2	2		
Lymphadenopathy	2	2	2	2		
Lymph node pain	1	1	1	1		
Lymphocyte count increased	1	1	1	1		
Malaise	59	97	39	66	20	31
Melaena	1	2			1	2
Memory impairment	1	1	1	1		
Middle insomnia	1	1	1	1		
Mobility decreased	1	2			1	2
Monoparesis	1	1			1	1
Mouth swelling		2		1		1
Movement disorder	3	3	2	2	1	1
Multi-organ disorder		1		1		
Muscle spasms	1	4		3	1	1
Muscle tightness	3	3	3	3		
Muscle twitching	1	1	1	1		
Muscular weakness	5	9	3	5	2	4
Musculoskeletal discomfort	3	4	2	3	1	1
Musculoskeletal stiffness	1	3	1	3		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	18	29	15	25	3	4
Myocardial infarction	1	2			1	2
Nasal congestion	1	2	1	1		1
Nasal obstruction	2	5	1	2	1	3
Nasal oedema	1	1			1	1
Nasal pruritus		1				1
Nausea	56	89	22	40	34	49
Neck pain	1	3			1	3
Nephrotic syndrome	1	1			1	1
Neuralgia	1	1	1	1		
Neuritis		1		1		
Neurological symptom	2	2	1	1	1	1
Neuropathy peripheral	6	9			6	9
Obstructive airways disorder	1	2			1	2
Ocular hyperaemia	4	10	4	9		1
Oculomucocutaneous syndrome	2	5			2	5
Oedema	1	3			1	3
Oedema mucosal	1	1	1	1		
Oedema peripheral	3	5		1	3	4
Oliguria	1	1			1	1
Oral discomfort	3	4	2	3	1	1
Oral herpes	1	1			1	1
Oral mucosa haematoma		1		1		
Oral pruritus	1	4	1	2		2
Oropharyngeal discomfort	51	78	21	32	30	46
Oropharyngeal pain	4	14	4	12		2
Orthopnoea	1	1			1	1
Orthostatic hypotension	1	1			1	1
Otorrhoea		1				1
Oxygen saturation decreased	9	15	1	4	8	11
Pain	12	22	7	14	5	8
Pain in extremity	9	14	6	11	3	3

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain of skin	1	1	1	1		
Pallor	6	7	2	2	4	5
Palmar erythema	3	3			3	3
Palpitations	41	74	27	45	14	29
Paraesthesia	7	11	4	6	3	5
Paraesthesia oral	6	9	3	5	3	4
Parasympathetic nerve injury	1	1			1	1
Paresis	1	1			1	1
Periorbital swelling		1				1
Peripheral circulatory failure		1				1
Peripheral coldness	7	10	6	8	1	2
Peripheral swelling	6	9	4	7	2	2
Petechiae	1	1	1	1		
Pharyngeal disorder		1				1
Pharyngeal erythema		1		1		
Pharyngeal oedema	2	2	1	1	1	1
Pharyngeal paraesthesia		1		1		
Pharyngeal swelling	2	4		1	2	3
Pharyngitis	1	1	1	1		
Photopsia	1	1			1	1
Physical deconditioning	3	3			3	3
Platelet aggregation abnormal	1	1	1	1		
Platelet count decreased	1	1	1	1		
Pneumonia	1	1			1	1
Pollakiuria	1	2			1	2
Portal vein embolism	1	1			1	1
Portal vein thrombosis	1	1			1	1
Postmenopausal haemorrhage	1	1			1	1
Post thrombotic syndrome		1				1
Postural tremor		1				1
Posture abnormal	1	1			1	1
Posturing	1	1	1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Presyncope	20	24	8	11	12	13
Product administered at inappropriate site	2	2	2	2		
Productive cough	1	1	1	1		
Prostatitis		1				1
Prostatomegaly		1				1
Pruritus	86	141	36	65	50	76
Pulmonary embolism	1	1			1	1
Pulse abnormal	1	2	1	1		1
Puncture site pain		1		1		
Purpura	2	2	2	2		
Putamen haemorrhage	2	2			2	2
Pyelonephritis	2	2			2	2
Pyrexia	71	116	50	81	21	35
Quadripareisis	1	1			1	1
Radiation pneumonitis	1	1	1	1		
Rash	58	96	22	44	36	52
Rash erythematous	4	6	3	4	1	2
Rash papular	1	1			1	1
Reaction to excipient		1				1
Respiration abnormal	1	1			1	1
Respiratory alkalosis	1	1			1	1
Respiratory disorder	2	2	1	1	1	1
Respiratory distress		2				2
Respiratory rate increased	2	2			2	2
Respiratory symptom		1				1
Retinal haemorrhage	1	1			1	1
Rhinorrhoea	5	13	3	7	2	6
Ruptured cerebral aneurysm	1	1			1	1
Scar pain	1	1	1	1		
Scleral haemorrhage	1	1			1	1
Sedation	1	1	1	1		
Seizure	1	3			1	3

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensation of foreign body	4	8	1	4	3	4
Sensory disturbance	4	5	1	1	3	4
Shock	1	1			1	1
Shock haemorrhagic	1	1			1	1
Shock symptom	1	1			1	1
Sinus rhythm		1				1
Sinus tachycardia	2	3		1	2	2
Sitting disability		1		1		
Skin discolouration	1	1	1	1		
Skin exfoliation	1	1	1	1		
Slow speech	1	1	1	1		
Sneezing	3	5	3	4		1
Soft tissue atrophy		1				1
Somatic symptom disorder		1		1		
Somnolence	3	5	1	2	2	3
Speech disorder	2	3	1	2	1	1
Speech sound disorder		1		1		
Stenosis	1	1			1	1
Stomatitis	1	1			1	1
Stress		1				1
Stridor	1	1	1	1		
Subarachnoid haemorrhage	6	9			6	9
Sudden hearing loss		3				3
Supraventricular extrasystoles	1	1	1	1		
Swelling	5	9	3	5	2	4
Swelling face	3	9	3	8		1
Swelling of eyelid	4	8	1	4	3	4
Sympathicotonia	1	2	1	2		
Syncope	4	4			4	4
Tachycardia	8	13	5	8	3	5
Tachypnoea	3	5	1	2	2	3
Taste disorder	1	1			1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tenderness		1				1
Tension	2	2			2	2
Thalamic infarction	1	1			1	1
Thalamus haemorrhage	1	1			1	1
Thirst	3	4	1	1	2	3
Throat irritation	6	13	3	4	3	9
Throat tightness	9	15	3	7	6	8
Thyroid function test abnormal	1	1	1	1		
Thyroiditis acute	1	1			1	1
Thyroiditis subacute	1	1	1	1		
Tinnitus		1		1		
Tongue erythema	1	1	1	1		
Tongue oedema	1	1	1	1		
Tongue paralysis	1	1			1	1
Toothache		1		1		
Transient global amnesia	1	1			1	1
Tremor	7	7	6	6	1	1
Type I hypersensitivity	1	2			1	2
Underdose		1		1		
Upper respiratory tract inflammation	1	1	1	1		
Urinary occult blood	1	1			1	1
Urinary occult blood positive	1	1			1	1
Urinary retention	1	2			1	2
Urinary tract infection	2	2			2	2
Urine abnormality	1	1			1	1
Urine analysis abnormal	1	1			1	1
Urine output decreased	1	1			1	1
Urticaria	43	100	17	52	26	48
Vaccination site discolouration		1		1		
Vaccination site erythema	4	5	4	4		1
Vaccination site hypoaesthesia	1	1			1	1
Vaccination site induration	1	1			1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site movement impairment		3		2		1
Vaccination site necrosis		2				2
Vaccination site pain	35	70	29	61	6	9
Vaccination site papule	1	1	1	1		
Vaccination site paraesthesia	1	1	1	1		
Vaccination site pruritus	2	5	2	5		
Vaccination site rash		2		2		
Vaccination site swelling	13	18	11	14	2	4
Vaccination site warmth	1	2		1	1	1
Vaginal haemorrhage	1	1			1	1
Vagus nerve disorder		1				1
Ventricular extrasystoles	1	1	1	1		
Ventricular fibrillation		1				1
Ventricular hypokinesia		1				1
Ventricular tachycardia	1	1			1	1
Vertebral artery dissection		1				1
Vertigo	3	4	1	1	2	3
Vertigo positional	1	1	1	1		
Visual impairment	4	4	2	2	2	2
Vocal cord disorder		1				1
Vomiting	23	43	6	16	17	27
Wheezing	9	16	3	4	6	12
White blood cell count decreased	1	1	1	1		
White blood cell count increased	1	2		1	1	1
Yawning		1		1		
	1,928	3,322	860	1502	1068	1820

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1			1	1
Abdominal pain	2	3	2	3		
Abnormal sensation in eye	1	1			1	1
Acute myocardial infarction	4	4			4	4
Alanine aminotransferase increased		1				1
Allergic reaction to excipient		1				1
Altered state of consciousness	3	3			3	3
Anaphylactic reaction	11	27			11	27
Anaphylactic shock	2	2			2	2
Anxiety	3	4	2	2	1	2
Anxiety disorder	1	1			1	1
Aortic dissection	1	1			1	1
Aphasia	2	2			2	2
Arthralgia	2	2	2	2		
Arthritis	1	1	1	1		
Asthenia	1	1			1	1
Asthenopia	1	1	1	1		
Asthma	3	4			3	4
Back pain		1		1		
Bilirubinuria		1				1
Blindness unilateral	1	1			1	1
Blood creatine phosphokinase increased	2	2			2	2
Blood creatinine increased	1	1			1	1
Blood pressure decreased	3	5		1	3	4
Blood pressure diastolic decreased	1	1	1	1		
Blood pressure immeasurable	2	2	1	1	1	1
Blood pressure increased	14	17		2	14	15
Blood pressure systolic increased	1	1			1	1
Blood urea increased	1	1			1	1
Body temperature increased	1	1	1	1		
Bone pain	1	1			1	1
Bradycardia	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Brain herniation	1	1			1	1
Brain stem haemorrhage	1	2			1	2
Breath sounds abnormal	1	1			1	1
Bronchospasm	2	2	1	1	1	1
Cardiac arrest	1	1			1	1
Cardiac failure	2	2			2	2
Cardiac tamponade	1	1			1	1
Cardio-respiratory arrest	8	8			8	8
Cerebral haemorrhage		2				2
Cerebral infarction	2	2			2	2
Cerebral mass effect	1	1			1	1
Cerebrovascular disorder	1	1			1	1
Chest discomfort	1	2			1	2
Chest pain		2		1		1
Chills	6	7	5	6	1	1
Chronic obstructive pulmonary disease	1	1			1	1
Clonic convulsion	1	1			1	1
Cold sweat	2	3	1	2	1	1
Condition aggravated	1	1			1	1
Coronary artery stenosis	1	1			1	1
Coronavirus infection	1	1			1	1
Cough	3	8	1	1	2	7
COVID-19	1	1	1	1		
C-reactive protein increased	3	3	1	1	2	2
Cystitis	1	1			1	1
Decreased appetite	3	3	2	2	1	1
Depressed level of consciousness	4	4			4	4
Dermatitis allergic	1	2	1	2		
Diabetes mellitus	1	1			1	1
Diarrhoea	3	3	3	3		
Disturbance in attention		1				1
Dizziness	10	12	5	6	5	6

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyskinesia	1	1	1	1		
Dysphonia	2	3	1	1	1	2
Dyspnoea	14	17	4	4	10	13
Dysuria	1	1			1	1
Eating disorder	1	1	1	1		
Embolic cerebral infarction	1	1			1	1
Epilepsy	1	1			1	1
Erythema	7	13	1	4	6	9
Erythema of eyelid	1	1			1	1
Erythrospia	1	1	1	1		
Eye discharge	1	1	1	1		
Eye disorder	2	2	1	1	1	1
Eye haemorrhage	1	1			1	1
Eyelid ptosis	1	1			1	1
Eye movement disorder	1	1	1	1		
Eye pruritus	1	1			1	1
Facial paralysis	2	2			2	2
Fall	4	4			4	4
Fatigue	1	1			1	1
Feeding disorder	1	2	1	1		1
Feeling abnormal	9	13	5	8	4	5
Feeling hot	4	4	2	2	2	2
Flatulence	1	1			1	1
Flushing	2	3	1	2	1	1
Foreign body sensation in eyes	1	1	1	1		
Gait disturbance	1	2			1	2
General physical health deterioration	1	1			1	1
Haematoma	1	1			1	1
Headache	9	10	6	6	3	4
Head discomfort	1	2	1	2		
Heart rate decreased	1	1			1	1
Heart rate increased	3	4	2	2	1	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hemiplegia	1	1			1	1
Hot flush	4	6	2	4	2	2
Hyperhidrosis	4	4	1	1	3	3
Hypersensitivity	2	2			2	2
Hypertension	2	2			2	2
Hyperventilation	1	1			1	1
Hypoaesthesia	1	2			1	2
Hypoaesthesia oral	2	2	1	1	1	1
Inappropriate schedule of product administration		1		1		
Incorrect dose administered		1		1		
Inflammation	1	1	1	1		
Interstitial lung disease		1				1
Joint swelling	2	2	2	2		
Joint warmth	1	1	1	1		
Lacrimation increased	2	2			2	2
Limb discomfort	1	1			1	1
Lip swelling	1	1	1	1		
Loss of consciousness	3	3			3	3
Lymphadenopathy	1	1			1	1
Malaise	9	10	5	5	4	5
Multiple organ dysfunction syndrome	1	1			1	1
Muscle spasms	1	1			1	1
Muscle swelling	1	1			1	1
Muscular weakness	2	2	1	1	1	1
Musculoskeletal discomfort		1		1		
Myalgia	4	8	2	5	2	3
Myocardial infarction		1				1
Myocardial rupture	1	1			1	1
Myositis	1	1			1	1
Nasal congestion	1	1			1	1
Nasal obstruction	1	2			1	2
Nausea	8	12	5	6	3	6

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nephrotic syndrome		1				1
Neurological symptom	1	1			1	1
Obstructive airways disorder		1				1
Off label use		1		1		
Oropharyngeal discomfort	3	7	1	4	2	3
Oropharyngeal pain	1	2	1	1		1
Oxygen saturation decreased	5	6	2	2	3	4
Oxygen saturation immeasurable	1	1			1	1
Pain	4	4	3	3	1	1
Pain in extremity	1	1			1	1
Pallor	2	2			2	2
Palpitations	4	5	3	4	1	1
Pancreatitis acute	1	1			1	1
Paraesthesia	2	2			2	2
Pericardial effusion	2	2			2	2
Pericarditis	1	2			1	2
Periorbital swelling		1		1		
Peripheral coldness	1	1			1	1
Pharyngeal stenosis		1				1
Physical deconditioning	1	1	1	1		
Pneumonia aspiration	2	2			2	2
Presyncope	1	1			1	1
Productive cough		1		1		
Product leakage		1		1		
Protein urine present		1		1		
Pruritus	11	16	4	7	7	9
Pulmonary oedema	1	1			1	1
Pulse abnormal	1	1	1	1		
Pulseless electrical activity	1	1			1	1
Putamen haemorrhage	1	1			1	1
Pyrexia	14	18	7	8	7	10
Radial pulse abnormal	1	1	1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash	9	9	4	4	5	5
Rash erythematous	1	1			1	1
Rash pruritic	1	1	1	1		
Respiratory disorder	1	1			1	1
Respiratory failure	2	2			2	2
Rhinorrhoea	2	2	1	1	1	1
Salivary gland pain	1	1	1	1		
Seizure	3	3			3	3
Sensation of blood flow		1		1		
Sensory disturbance	1	1			1	1
Sepsis	1	1			1	1
Serum ferritin increased	1	1	1	1		
Shock	2	3			2	3
Skin reaction	1	1	1	1		
Somnolence	4	5	2	2	2	3
Speech disorder	1	1			1	1
Sputum increased	2	2			2	2
Sudden cardiac death	1	1			1	1
Suffocation feeling	1	1			1	1
Swelling	2	2	2	2		
Swelling face	1	2	1	2		
Swollen tongue	1	1	1	1		
Syncope	1	2			1	2
Tachycardia	4	6	3	4	1	2
Tachypnoea		1		1		
Tension	1	1	1	1		
Throat irritation	1	1	1	1		
Throat tightness	1	3	1	1		2
Thrombocytopenic purpura	1	1			1	1
Thrombotic cerebral infarction	1	1			1	1
Tic	1	1			1	1
Tremor	2	2	1	1	1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Upper gastrointestinal haemorrhage		1				1
Urinary tract infection	1	1			1	1
Urine abnormality		1				1
Urticaria	5	8	1	2	4	6
Vaccination site erythema	1	1	1	1		
Vaccination site induration		1		1		
Vaccination site pain	5	11	3	9	2	2
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	2	2	1	1	1	1
Ventricular fibrillation	1	1			1	1
Vertigo		4		1		3
Viral pericarditis		1				1
Vision blurred		1		1		
Visual field defect	1	1	1	1		
Vomiting	5	6	2	2	3	4
Wheezing	1	2			1	2
White blood cell count increased	2	2	1	1	1	1
Yawning		1		1		
	411	550	142	197	269	353

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1			1	1
Abdominal pain	1	1	1	1		
Acidosis	1	1			1	1
Acute kidney injury	1	1			1	1
Acute myocardial infarction	3	4			3	4
Altered state of consciousness	3	3			3	3
Amnesia	2	2	2	2		
Anal incontinence		1		1		
Anaphylactic reaction	10	17			10	17
Anaphylactic shock	1	1			1	1
Angina pectoris	1	1			1	1
Aortic dissection	2	2			2	2
Apnoea	3	3			3	3
Arrhythmia	3	4			3	4
Asphyxia	1	1			1	1
Aspiration	1	1			1	1
Asthma	3	4	2	2	1	2
Atrial fibrillation	1	1			1	1
Axillary pain	1	2	1	2		
Balance disorder		1				1
Bile duct cancer	1	1			1	1
Bile duct stone	1	1			1	1
Biliary dilatation	1	1			1	1
Blister	1	1	1	1		
Blood pressure decreased	5	6	2	2	3	4
Blood pressure immeasurable	1	1			1	1
Blood pressure increased	10	11	3	3	7	8
Brain herniation	1	1			1	1
Brain stem infarction	1	1			1	1
Bronchospasm	2	2			2	2
Cardiac arrest	7	7			7	7
Cardiac death		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac failure	4	7			4	7
Cardiac failure acute	4	5			4	5
Cardiac failure chronic		1				1
Cardiac failure congestive	1	1			1	1
Cardiac hypertrophy	1	1	1	1		
Cardiac tamponade	1	1			1	1
Cardiomyopathy	1	1			1	1
Cardio-respiratory arrest	11	13			11	13
Carotid artery stenosis	1	1			1	1
Cerebral artery embolism	1	1			1	1
Cerebral haemorrhage	2	3			2	3
Cerebral infarction	10	10			10	10
Cerebrovascular disorder	1	1			1	1
Chest discomfort	3	3			3	3
Chest pain	1	1			1	1
Chills	1	1	1	1		
Choking	1	1			1	1
Cholecystitis	1	1			1	1
Cold sweat		1				1
Condition aggravated	2	2			2	2
Coronary artery stenosis	1	1			1	1
Cough	3	3	2	2	1	1
Cyanosis	3	3			3	3
Death	4	4			4	4
Decreased appetite	3	3			3	3
Dehydration	3	3			3	3
Delirium	1	1			1	1
Dementia	1	1			1	1
Depressed level of consciousness	4	5			4	5
Diarrhoea	3	3			3	3
Disease recurrence	2	2	1	1	1	1
Dizziness	1	1	1	1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug eruption		1				1
Dysgeusia	1	1	1	1		
Dysphagia	1	1			1	1
Dyspnoea	6	7			6	7
Eczema	1	2	1	2		
Electrocardiogram change	1	1			1	1
Epilepsy	2	2			2	2
Erythema	3	4	1	1	2	3
Face oedema	1	1			1	1
Fall	3	3	2	2	1	1
Feeling abnormal	3	3	2	2	1	1
Feeling cold	1	1			1	1
Feeling hot	2	2	1	1	1	1
Flushing	1	2			1	2
Gait disturbance	1	1	1	1		
Gallbladder enlargement	1	1			1	1
Gastrointestinal haemorrhage	1	1			1	1
Gastrointestinal necrosis	1	1			1	1
Haematemesis	1	1			1	1
Haematochezia	2	2			2	2
Haemolytic anaemia	1	1			1	1
Haemorrhage	1	1			1	1
Heart rate increased	2	2			2	2
Hemiplegia	2	3			2	3
Hepatic enzyme increased	1	1			1	1
Hepatic function abnormal	1	1	1	1		
Hypoaesthesia	1	1			1	1
Hypophagia	2	2	1	1	1	1
Ileus paralytic	1	1			1	1
Inflammatory marker increased	1	1	1	1		
Insomnia	1	1	1	1		
Interstitial lung disease	1	1			1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Irregular breathing	1	1			1	1
Listless	1	1			1	1
Loss of consciousness	5	6			5	6
Malaise	8	9	4	5	4	4
Marasmus	2	2			2	2
Memory impairment	1	1	1	1		
Mesenteric arterial occlusion	1	1			1	1
Mesenteric artery thrombosis	1	1			1	1
Muscle tightness	1	1			1	1
Muscular weakness	1	1			1	1
Myocardial infarction	3	3			3	3
Myocardial ischaemia	3	3			3	3
Nausea	4	4			4	4
Nystagmus	1	1			1	1
Obstructive airways disorder	1	1			1	1
Oedema	1	1			1	1
Oral disorder	1	1	1	1		
Oral pruritus	1	1			1	1
Oropharyngeal discomfort	1	1	1	1		
Oxygen saturation decreased	9	10	1	1	8	9
Pain	3	3	2	2	1	1
Pallor	4	4	1	1	3	3
Palpitations	1	1			1	1
Pemphigoid	1	1			1	1
Peripheral vascular disorder	1	1			1	1
Physical deconditioning	1	1			1	1
Pleural effusion		1				1
Pneumonia	4	4			4	4
Pneumonia aspiration	2	2			2	2
Presyncope	1	1			1	1
Pruritus	2	4	2	3		1
Pulmonary artery thrombosis	1	1			1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary embolism	1	2			1	2
Pulmonary thrombosis	1	1			1	1
Pupils unequal		1		1		
Purpura	1	1	1	1		
Pyrexia	22	23	10	11	12	12
Rash		1		1		
Renal disorder	1	1			1	1
Renal impairment	1	1			1	1
Respiration abnormal	2	2			2	2
Respiratory acidosis	1	1	1	1		
Respiratory arrest	4	4			4	4
Respiratory distress	1	1			1	1
Respiratory failure	2	2			2	2
Seizure	3	3			3	3
Septic shock	2	2			2	2
Shock	1	1			1	1
Skin erosion	1	1	1	1		
Somnolence	1	1			1	1
Speech sound disorder	1	1			1	1
Strabismus	1	1			1	1
Stress cardiomyopathy	1	1			1	1
Subarachnoid haemorrhage	2	2			2	2
Subdural haematoma	1	1			1	1
Sudden cardiac death	1	1			1	1
Swelling	2	2	2	2		
Syncope	1	1			1	1
Tachycardia	1	1			1	1
Tachypnoea	2	2	1	1	1	1
Thrombotic thrombocytopenic purpura	1	1			1	1
Tremor	2	2			2	2
Urinary tract infection	1	1			1	1
Urinary tract infection bacterial	1	1	1	1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria	1	2	1	1		1
Use of accessory respiratory muscles	1	1			1	1
Vaccination site erythema		1		1		
Vaccination site pain	1	2	1	2		
Vaccination site rash		1		1		
Vaccination site swelling		1		1		
Vascular occlusion	1	1			1	1
Ventricular f brillation	1	1			1	1
Ventricular tachycardia	1	1			1	1
Visual impairment	1	1			1	1
Vomiting	8	9	1	2	7	7
Wheezing	7	8	2	2	5	6
	347	396	66	79	281	317

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal pain	2	5	2	4		1
Abdominal pain upper	2	2	1	1	1	1
Acute respiratory distress syndrome		1				1
Allergic gastroenteritis	1	1			1	1
Anaemia		1		1		
Anaphylactic reaction	15	44			15	44
Anaphylactic shock	5	8			5	8
Anaphylactoid reaction		1				1
Anxiety		2				2
Aortic dissection		1				1
Appendicitis	1	1			1	1
Arrhythmia	1	3			1	3
Arthralgia	23	25	23	25		
Arthritis	1	1	1	1		
Arthritis reactive		1				1
Asthenia	4	5	1	1	3	4
Asthma	1	6		2	1	4
Asymptomatic COVID-19		2				2
Atrioventricular block complete	1	1			1	1
Back pain	1	2	1	2		
Blister	1	1	1	1		
Blood glucose increased	1	1	1	1		
Blood pressure decreased		1		1		
Blood pressure increased	10	17	3	7	7	10
Blood pressure systolic increased	2	2			2	2
Bradycardia	1	1			1	1
Bronchostenosis		1				1
Capillaritis		1		1		
Cardiac failure		1				1
Cerebral haemorrhage	8	8			8	8
Cerebral infarction	3	4			3	4

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest discomfort	1	2	1	2		
Chillblains	1	1	1	1		
Chills	16	23	14	20	2	3
Choking sensation	1	1			1	1
Cold sweat		1				1
Condition aggravated		1				1
Convulsions local	1	1			1	1
Cough	3	12		4	3	8
COVID-19	19	26	4	5	15	21
C-reactive protein increased	1	1	1	1		
Deafness		1				1
Decreased appetite	2	3	2	2		1
Dementia Alzheimer's type	1	1			1	1
Dermatitis allergic		1				1
Diarrhoea	6	11	5	8	1	3
Discomfort	1	1	1	1		
Disease recurrence	1	1			1	1
Dizziness	9	13	8	10	1	3
Dizziness postural	1	1	1	1		
Drug eruption	1	2		1	1	1
Drug hypersensitivity		1		1		
Drug ineffective	14	21			14	21
Dysgeusia	1	2	1	1		1
Dyspepsia		1				1
Dysphagia		1				1
Dyspnoea	7	13	5	7	2	6
Ear discomfort	1	1	1	1		
Eczema	1	5		4	1	1
Erythema	7	21	5	15	2	6
Erythema ab igne		1		1		
Erythema multiforme		1				1
Eye haemorrhage	1	1			1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid oedema		1				1
Eye movement disorder	1	1	1	1		
Eye oedema	1	1	1	1		
Face oedema		1		1		
Facial paralysis	4	4			4	4
Faeces soft	1	1	1	1		
Fatigue	8	9	8	8		1
Feeding disorder	1	1	1	1		
Feeling abnormal	7	18	6	17	1	1
Feeling cold	1	2	1	1		1
Feeling hot	5	12	5	6		6
Fibromyalgia	1	1	1	1		
Flushing	1	5	1	3		2
Gait disturbance	1	1	1	1		
Gastroenteritis viral	1	1	1	1		
Gastrointestinal disorder	1	2	1	1		1
Gastrointestinal hypermotility		1				1
General physical health deterioration	3	4	1	1	2	3
Glare	1	1	1	1		
Glucose urine present	1	1	1	1		
Guillain-Barre syndrome	1	1			1	1
Haematuria	1	1			1	1
Haemorrhage subcutaneous	1	2			1	2
Haemorrhagic cerebral infarction	1	1			1	1
Headache	35	57	32	49	3	8
Head discomfort	2	2	2	2		
Heart rate increased	4	4	3	3	1	1
Heavy menstrual bleeding	1	1	1	1		
Hepatic function abnormal	1	2	1	2		
Hepatitis acute	1	1			1	1
Herpes virus infection	1	1			1	1
Herpes zoster	6	6	5	5	1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
HIV antibody positive		2		2		
Hot flush	3	5	2	3	1	2
Hyperhidrosis	5	10	4	7	1	3
Hyperpyrexia		2				2
Hypersensitivity	6	11	3	6	3	5
Hypertension	2	2	2	2		
Hyperthermia	3	4	3	3		1
Hyperventilation		1				1
Hypoaesthesia	12	15	9	11	3	4
Hypoaesthesia oral		1				1
Hypothyroidism		1				1
Inappropriate schedule of product administration	2	2	2	2		
Incorrect dose administered	1	3	1	3		
Incorrect route of product administration	2	3	2	3		
Injected limb mobility decreased	1	3	1	3		
Injury associated with device	1	1			1	1
Insomnia	1	1	1	1		
Internal haemorrhage	3	4			3	4
Interstitial lung disease	1	1			1	1
Joint range of motion decreased		2		2		
Laryngeal discomfort		1		1		
Limb discomfort	3	5	3	5		
Loss of consciousness	3	3			3	3
Lymphadenitis bacterial		1				1
Lymphadenopathy	6	7	6	7		
Lymph node pain	1	1	1	1		
Lymphoma		1				1
Malaise	32	59	26	52	6	7
Meningitis		2				2
Meningitis aseptic		1				1
Menstruation irregular	1	1	1	1		
Migraine	1	1			1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mobility decreased	1	2	1	2		
Motion sickness		1		1		
Movement disorder	1	1	1	1		
Muscle abscess	1	1			1	1
Muscle spasms	1	1	1	1		
Muscle tightness		1		1		
Muscular weakness		1		1		
Musculoskeletal stiffness	1	1	1	1		
Myalgia	35	58	35	58		
Nasal congestion	1	1	1	1		
Nasal mucosal disorder	1	1	1	1		
Nasal obstruction	1	1	1	1		
Nasopharyngitis	2	2	2	2		
Nausea	18	31	15	22	3	9
Needle issue	1	2	1	2		
Neuropathy peripheral	1	1			1	1
No adverse event	1	1	1	1		
Occupational exposure to product	1	1	1	1		
Ocular hyperaemia	2	3	1	2	1	1
Oedema mouth	1	1			1	1
Oedema mucosal		1				1
Off label use	2	2	2	2		
Optic atrophy		1				1
Oral discomfort	2	3	1	1	1	2
Oropharyngeal discomfort	3	10	1	5	2	5
Oropharyngeal pain	2	6	2	6		
Overdose		1		1		
Oxygen saturation decreased	1	1	1	1		
Pain	10	17	7	13	3	4
Pain in extremity	11	13	11	13		
Pallor	1	2	1	1		1
Palpitations	4	8	3	5	1	3

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia	1	1	1	1		
Paraesthesia oral		1		1		
Paralysis	1	1			1	1
Paresis	1	1			1	1
Parotitis		1		1		
Periorbital swelling		3		2		1
Peripheral nerve palsy	1	1	1	1		
Peripheral swelling	1	1	1	1		
Pharyngeal paraesthesia		1				1
Pharyngeal stenosis	1	1			1	1
Pharyngeal swelling	1	2			1	2
Physical deconditioning	2	4	1	2	1	2
Physical disability	1	1	1	1		
Piloerection	1	1	1	1		
Platelet count decreased	1	2			1	2
Pneumonia	2	2			2	2
Poor peripheral circulation	1	1	1	1		
Presyncope	1	3	1	3		
Product leakage		1		1		
Product preparation issue		2		2		
Pruritus	12	26	7	14	5	12
Purpura		1		1		
Pyrexia	56	103	43	86	13	17
Rash	16	32	12	24	4	8
Rash erythematous	1	1	1	1		
Rash papular	1	1	1	1		
Respiratory distress		1				1
Retinal haemorrhage		1				1
Rhinorrhoea	3	4	2	3	1	1
Salivary gland pain	1	1	1	1		
Seizure	1	4			1	4
Shock		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin disorder		1		1		
Sneezing	1	1			1	1
Somnolence	3	5	3	4		1
Stomatitis		1		1		
Sudden hearing loss	1	2			1	2
Suspected COVID-19	2	3	1	1	1	2
Swelling	3	6	3	6		
Swelling face	1	5	1	1		4
Syncope	1	1			1	1
Tachycardia	5	8	3	6	2	2
Tachypnoea	1	1	1	1		
Taste disorder	1	1	1	1		
Thirst		1		1		
Throat irritation	1	4		1	1	3
Throat tightness	1	1	1	1		
Thrombosis	1	2			1	2
Tinnitus	1	1	1	1		
Tremor	1	3	1	1		2
Trigeminal nerve disorder	1	1	1	1		
Type I hypersensitivity		1				1
Underdose	1	4	1	4		
Urticaria	13	31	9	24	4	7
Uveitis	1	1			1	1
Vaccination failure		1				1
Vaccination site bruising	1	1	1	1		
Vaccination site erythema	2	5	2	3		2
Vaccination site haemorrhage	1	1			1	1
Vaccination site lymphadenopathy	1	1	1	1		
Vaccination site movement impairment		2		2		
Vaccination site pain	43	72	42	70	1	2
Vaccination site paraesthesia		1		1		
Vaccination site pruritus	2	2	1	1	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site rash	1	1	1	1		
Vaccination site reaction		1		1		
Vaccination site swelling	10	15	10	15		
Vaccination site urticaria		1		1		
Vaccination site warmth	1	1	1	1		
Vasculitis	1	1	1	1		
Vasodilatation		1		1		
Vertigo	2	3	2	3		
Visual field defect		1		1		
Visual impairment	1	1	1	1		
Vomiting	5	11	5	8		3
Wheezing	2	2	1	1	1	1
White blood cell count increased	1	1			1	1
	692	1,224	490	824	202	400

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

JORDAN

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burning sensation	1	1	1	1		
COVID-19	1	1			1	1
Fatigue	1	1	1	1		
Pruritus	1	1	1	1		
Scratch	1	1	1	1		
Vaccination site pain	1	1	1	1		
	6	6	5	5	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia	1	1	1	1
Cough		1		1
Dysgeusia		1		1
Fatigue		2		2
Feeling cold	1	1	1	1
Headache		1		1
Influenza like illness		1		1
Injection site pain		1		1
Muscle spasms		1		1
Myalgia		1		1
Pain in extremity		1		1
Swelling		1		1
Swelling face		1		1
Testicular swelling		1		1
Vaccination site pain		1		1
	2	16	2	16

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne	1	1	1	1		
Anosmia		1		1		
Asthenia		1				1
Blood pressure increased		1				1
Cerebral thrombosis		1				1
Cerebrovascular accident		1				1
Confusional state		1				1
Erythema		1				1
Influenza		1		1		
Myalgia		1		1		
Obstructive airways disorder		1				1
Pruritus	1	1	1	1		
Swelling		1				1
Syncope		1				1
	2	14	2	5		9

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gangrene		1				1
Haematemesis		1				1
Mesenteric vein thrombosis		1				1
Pain		2		2		
Pain in extremity		2		2		
Weight decreased		1		1		
		8		5		3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abdominal pain		1		1
Condition aggravated		1		1
COVID-19		1		1
COVID-19 pneumonia		1		1
Hypoxia		1		1
Increased bronchial secretion		1		1
Increased viscosity of upper respiratory secretion		1		1
Lung disorder		1		1
Respiratory failure		1		1
Sputum retention		1		1
Tachypnoea		1		1
Vaccination failure		1		1
		12		12

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose	1	1	1	1		
Animal attack		1		1		
Arthralgia		1		1		
Asthma		1		1		
Chills		1		1		
COVID-19	1	3		1	1	2
Dizziness		1		1		
Drug ineffective	1	1			1	1
Dyspnoea		1				1
Fatigue		2		2		
Headache	1	2	1	2		
Inflammatory marker increased	1	1	1	1		
Loss of consciousness		1				1
Myalgia	1	2	1	2		
Pneumonia		1				1
Pyrexia	1	2	1	2		
Syncope		1				1
Tongue disorder		1		1		
Vaccination site pain		1		1		
	7	25	5	18	2	7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred
KOREA, REPUBLIC OF (SOUTH KOREA)

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Brain oedema	1	1	1	1
Cerebral infarction	1	1	1	1
	2	2	2	2

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint swelling		1		1
Lymphadenopathy	1	1	1	1
Swelling	1	1	1	1
	2	3	2	3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

KUWAIT

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headache		1		1
Lymphocyte percentage increased		1		1
Mean cell haemoglobin concentration increased		1		1
Polyp		1		1
Pyrexia		1		1
Splenomegaly		1		1
		6		6

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1			1	1
Axillary pain	1	1			1	1
Back pain	1	1			1	1
Breast pain	1	1			1	1
Ear pain	1	1			1	1
Headache		1		1		
Hyperhidrosis	1	1			1	1
Hypoaesthesia	1	1			1	1
Lymphadenopathy	1	1			1	1
Muscle tightness	1	1			1	1
Musculoskeletal chest pain	1	1			1	1
Musculoskeletal stiffness		1		1		
Pain		1		1		
Pain in extremity		1		1		
Paraesthesia	1	1			1	1
Peripheral swelling		1		1		
Tenderness		1		1		
	11	17		6	11	11

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fatigue		1		1
Lymphadenopathy		1		1
Myalgia		1		1
Neck pain		1		1
Pyrexia		1		1
Swelling		1		1
Tenderness		1		1
Vaccination site pain		1		1
Vaccination site swelling		1		1
		9		9

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthma		1		1
COVID-19		2		2
Fatigue		1		1
Maternal exposure during pregnancy	1	1	1	1
	1	5	1	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

LATVIA

090177e19749cf15\Approved\Approved On: 14-Jun-2021 14:01 (GMT)

- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		2		2		
Abdominal pain lower	1	1	1	1		
Abortion missed		1				1
Anosmia		1				1
Arrhythmia		1				1
Arthralgia	2	20	2	17		3
Asthenia	1	11	1	10		1
Asthma		1		1		
Bacille Calmette-Guerin scar reactivation		1		1		
Back pain		2		2		
Blood pressure increased		1				1
Body temperature increased	3	15	3	15		
Bone pain		1		1		
Burning sensation		2				2
Chest pain		1		1		
Chills	2	24	2	24		
Condition aggravated		1		1		
Confusional state		1		1		
Conjunctival haemorrhage		1				1
Cough		2		2		
COVID-19	1	4			1	4
C-reactive protein increased		2		2		
Deafness		1				1
Decreased appetite		1		1		
Depressed mood		1		1		
Disturbance in attention		3		1		2
Dizziness	1	8		5	1	3
Drug ineffective	1	3			1	3
Dyspnoea	1	4	1	2		2
Dyspnoea exertional		1		1		
Erythema		2		1		1
Exposure during pregnancy		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye pain	1	3	1	3		
Fatigue	4	29	3	23	1	6
Headache	5	37	4	33	1	4
Head injury	1	1			1	1
Hot flush		1		1		
Hyperacusis	1	1	1	1		
Hyperaesthesia		2		1		1
Hyperhidrosis	2	4	2	4		
Hypertension		1		1		
Hypoaesthesia		1				1
Inappropriate schedule of product administration	1	1	1	1		
Increased appetite		1		1		
Influenza like illness		1		1		
Lymphadenitis		1				1
Lymphadenopathy		10		8		2
Lymph node pain		1				1
Menstrual disorder	1	1	1	1		
Mental impairment		1				1
Muscle spasms		1		1		
Muscular weakness		3		1		2
Musculoskeletal stiffness		1		1		
Myalgia	4	24	4	22		2
Nasal congestion		1		1		
Nausea	2	10	2	10		
Neck pain		3		2		1
Neuralgia		1				1
Pain		2		1		1
Pain in extremity		2		1		1
Palpitations		1				1
Paraesthesia		2		1		1
Peripheral sensory neuropathy		1				1
Photophobia	2	3	2	2		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pruritus		1				1
Pyrexia	4	33	4	29		4
Rash		1		1		
Rash pruritic		2		2		
Rhinorrhoea		2		1		1
Sleep disorder		1		1		
Somnolence		2		2		
Syncope	1	1			1	1
Tachycardia		4				4
Throat irritation		2		2		
Urticaria	1	1			1	1
Urticaria papular	1	1			1	1
Vaccination failure		1				1
Vaccination site erythema		3		2		1
Vaccination site haematoma		1				1
Vaccination site hypoaesthesia		1				1
Vaccination site inflammation		1		1		
Vaccination site mass		1				1
Vaccination site oedema		3		2		1
Vaccination site pain	3	37	3	35		2
Vaccination site pruritus		1				1
Vaccination site rash		1				1
Vaccination site warmth		1				1
Vomiting		2		2		
	47	377	38	296	9	81

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		3		3		
Abdominal pain lower		1		1		
Abdominal pain upper		1				1
Abnormal sensation in eye		1		1		
Anaphylactic reaction		1				1
Angina pectoris		1				1
Anxiety		1				1
Arthralgia	4	27	3	26	1	1
Asthenia	1	12	1	10		2
Asthma		1				1
Axillary pain	1	1	1	1		
Blepharitis		1		1		
Blood pressure increased		1				1
Body temperature increased	4	28	4	27		1
Bone pain		1		1		
Bradycardia		1				1
Bundle branch block left		1				1
Chest pain		1		1		
Chills	4	30	4	30		
Cold sweat		2		1		1
Cough	1	5	1	5		
COVID-19		3				3
C-reactive protein increased		1		1		
Decreased appetite		4		4		
Dermatitis allergic	1	1	1	1		
Diarrhoea		5		5		
Disease recurrence		1				1
Disturbance in attention		3		2		1
Dizziness		8		6		2
Drug ineffective		1				1
Dry mouth		2		1		1
Dry skin		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysgeusia		4		2		2
Dysphonia		2		2		
Dyspnoea		3		2		1
Ear pain		2		1		1
Erythema	1	1	1	1		
Exposure during pregnancy		1				1
Eye pain	1	8		7	1	1
Fatigue	5	38	5	36		2
Feeling hot		2		2		
Flushing	1	1	1	1		
Generalised tonic-clonic seizure		1				1
Glossodynia	1	1	1	1		
Headache	7	43	6	38	1	5
Head discomfort		1		1		
Heart rate increased		1		1		
Hot flush	1	3	1	2		1
Hyperaesthesia		5		3		2
Hyperhidrosis	2	4	2	4		
Hypersensitivity	1	1	1	1		
Inappropriate schedule of product administration		1		1		
Initial insomnia		2		2		
Joint stiffness		1				1
Lacrimation increased		1		1		
Loss of proprioception		1				1
Lymphadenopathy	3	11	3	10		1
Lymph node pain		3		1		2
Malaise	1	1	1	1		
Migraine	1	2			1	2
Muscle spasms	1	2	1	1		1
Muscular weakness		1				1
Musculoskeletal discomfort	1	3	1	3		
Musculoskeletal stiffness	2	3	2	2		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	7	33	6	30	1	3
Nasal congestion	1	2	1	2		
Nasal oedema		1		1		
Nausea	3	13	3	12		1
Neuralgia		2				2
Neutrophil count increased		1		1		
Off label use		2		2		
Oropharyngeal pain		3		2		1
Pain	1	2	1	2		
Pain in extremity	2	5	2	4		1
Palatal swelling		1		1		
Palpitations		2				2
Paraesthesia	1	4			1	4
Paraesthesia oral	1	3	1	1		2
Peripheral coldness	1	3	1	2		1
Pharyngeal oedema		1		1		
Photophobia		2		2		
Polymenorrhoea	1	2	1	2		
Presyncope		1				1
Product use issue		1		1		
Pruritus		1		1		
Pulse volume decreased		1		1		
Purpura		2				2
Pyrexia	8	45	8	37		8
Rash		1		1		
Rash macular		1		1		
Rash pruritic		1		1		
Respiratory distress		1				1
Restless legs syndrome		1		1		
Sleep disorder		1		1		
Somnolence		5		3		2
Swelling face	2	2	1	1	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Syncope		1				1
Tachycardia		3		1		2
Thirst		1				1
Throat irritation		2		2		
Throat tightness	1	1	1	1		
Tongue spasm		1				1
Toothache		1		1		
Tunnel vision		1				1
Vaccination failure		2				2
Vaccination site erythema		7		6		1
Vaccination site hyperaesthesia	1	1	1	1		
Vaccination site lymphadenopathy		1		1		
Vaccination site mass		1				1
Vaccination site oedema	1	5	1	4		1
Vaccination site pain	5	35	5	33		2
Vaccination site pruritus		2		2		
Vaccination site rash		1				1
Vaccination site reaction		2		2		
Vaccination site swelling	1	2	1	2		
Vaccination site warmth	1	4	1	4		
Vertigo		2		2		
Vision blurred		1				1
Vomiting		5		4		1
	83	533	76	436	7	97

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety		1				1
Arthralgia	2	9	2	8		1
Asthenia	1	4	1	4		
Asymptomatic COVID-19	1	1			1	1
Atrial fibrillation		1				1
Bell's palsy		1				1
Blood pressure increased		1		1		
Body temperature decreased		1		1		
Body temperature increased	3	15	3	15		
Burning sensation		1				1
Chest discomfort		1				1
Chills	1	7	1	7		
Coordination abnormal		1		1		
Costovertebral angle tenderness		1		1		
Cough		2		2		
COVID-19		3		3		
Death	1	1			1	1
Decreased appetite	1	3	1	3		
Diarrhoea	1	1	1	1		
Diplopia		1				1
Disease recurrence		1				1
Disturbance in attention		2		2		
Dizziness		3		3		
Dyspnoea exertional		1		1		
Epistaxis		1				1
Extrasystoles		1				1
Eye pain		2		2		
Face oedema		1				1
Facial paresis		2				2
Fatigue	2	10	1	9	1	1
Gait disturbance		1		1		
Generalised oedema		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache	2	9	2	8		1
Heart rate increased		1				1
Herpes zoster		1				1
Hyperhidrosis		2		2		
Hypertension		1				1
Hypertensive crisis		2				2
Hypoacusis		1		1		
Illness		2		2		
Initial insomnia		1		1		
Insomnia	1	2		1	1	1
Joint range of motion decreased		1		1		
Joint stiffness		1		1		
Lacrimation increased		1				1
Lymphadenitis		1		1		
Lymphadenopathy		3		2		1
Lymph node pain		1		1		
Malaise		2		2		
Muscular weakness	1	2	1	2		
Myalgia	1	9	1	9		
Nasal congestion	1	1	1	1		
Nausea		5		5		
Night sweats		1		1		
Oedema mucosal		1				1
Oedema peripheral		1				1
Oral herpes	1	1	1	1		
Oropharyngeal pain		1		1		
Pain	1	2	1	2		
Pain in extremity	1	1	1	1		
Paraesthesia	1	3	1	1		2
Paraesthesia oral	1	1	1	1		
Peripheral swelling		1		1		
Pharyngeal paraesthesia	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pruritus	1	2	1	1		1
Pyrexia	4	14	4	13		1
Rash		2		1		1
Rash maculo-papular	1	1	1	1		
Sensitive skin	1	1	1	1		
Skin tightness		1				1
Sleep disorder due to general medical condition, insomnia type		1		1		
Somatic dysfunction		1				1
Somnolence	1	3	1	3		
Stomatitis		1				1
Syncope		1				1
Thirst		1		1		
Thrombosis	1	1			1	1
Transient ischaemic attack		1				1
Urticaria		1		1		
Vaccination failure	1	1			1	1
Vaccination site discolouration		1		1		
Vaccination site erythema		1		1		
Vaccination site oedema		1		1		
Vaccination site pain	4	11	4	11		
Vaccination site pruritus		1		1		
Vaccination site warmth		1		1		
Vasculitic rash		1		1		
Vertebrobasilar stroke		1				1
Vertigo		2		2		
	39	198	33	157	6	41

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1				1
Arrhythmia		1				1
Arthralgia		2		2		
Asthenia		1				1
Blood creatine phosphokinase increased		1		1		
Blood pressure decreased		1		1		
Condition aggravated		1				1
Diarrhoea		1		1		
Dizziness		2		2		
Ear discomfort		1				1
Fatigue		3		2		1
Gait disturbance		1		1		
Glomerular filtration rate decreased		1		1		
Headache		1		1		
Hyperhidrosis		1		1		
Hypertension		1		1		
Hypotension		1		1		
Hypothyroidism		1				1
Insomnia		1				1
Myalgia		3		3		
Nausea		1		1		
Oropharyngeal pain		1		1		
Pain in extremity		1		1		
Pyrexia		3		2		1
Rhabdomyolysis		1				1
Skin burning sensation		1				1
Vaccination site erythema		1		1		
Vaccination site pain		2		2		
		37	26		11	

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19	1	1	1	1
Drug ineffective	1	1	1	1
	2	2	2	2

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		1		1		
Body temperature increased	1	2	1	2		
Bradyphrenia		1		1		
Burning sensation		1		1		
Depression		1		1		
Dizziness		1		1		
Eye pain		1		1		
Fatigue		1		1		
Headache		3		2		1
Lymphadenopathy		1		1		
Lymph node pain		1		1		
Malaise		1		1		
Migraine		1		1		
Myalgia		1		1		
Nasopharyngitis		1		1		
Nausea		1		1		
Oral discomfort		1		1		
Oropharyngeal pain		1		1		
Pain in extremity		2		2		
Pyrexia		2		1		1
SARS-CoV-2 test positive		1				1
Upper respiratory tract congestion		1		1		
	1	27	1	24		3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

LEBANON

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Erythema		1		1
Pruritus		1		1
Throat tightness		1		1
		3		3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		1		1		
Chills		1		1		
Dermatitis allergic		1		1		
Dyspnoea		1		1		
Flushing		1		1		
Headache		1		1		
Hypersensitivity		1				1
Hypertension		1				1
Hypoaesthesia		1		1		
Incorrect route of product administration		1		1		
Malaise		1		1		
Oropharyngeal pain		1		1		
Panic attack		1		1		
Paraesthesia		2		2		
Pyrexia		2		2		
Rash		1				1
Tachycardia		1		1		
Urticaria		1		1		
Vaccination site pain		1		1		
Vision blurred		1		1		
		22		19		3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Aphasia	1	1			1	1
Back pain		1		1		
Chills		1				1
COVID-19	1	1			1	1
Drug ineffective	1	1			1	1
Headache		1		1		
Hypertension		1				1
Influenza		1		1		
Limb discomfort		1		1		
Muscle twitching		1		1		
Myalgia		1		1		
Neurological symptom	1	1			1	1
Oropharyngeal pain		1		1		
Pain in extremity		1		1		
Paraesthesia		1		1		
Pyrexia		1				1
	4	17		9	4	8

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebrovascular accident		1				1
Chills		1		1		
Confusional state	1	1	1	1		
COVID-19	1	1			1	1
Decreased appetite		1		1		
Dizziness		1		1		
Dysarthria	1	1	1	1		
Eyelid ptosis	1	1			1	1
Fatigue	1	1			1	1
Headache	1	2		1	1	1
Hypertension		1		1		
Muscular weakness	1	1	1	1		
Pain		1		1		
Pain in extremity		1		1		
Paralysis	1	1			1	1
Thrombocytopenia	1	1			1	1
Vaccination failure	1	1			1	1
Vomiting	1	1			1	1
	11	19	3	10	8	9

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19		1				1
Death		1				1
Embolism venous	1	1			1	1
Facial paresis		1				1
Fatigue		1		1		
Pyrexia		1		1		
Speech disorder		1		1		
	1	7		3	1	4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Adverse event	1	1	1	1		
Allergic reaction to excipient		1		1		
Back pain		1		1		
Bell's palsy		1				1
Chest discomfort		1		1		
Chest pain	1	1	1	1		
Chills		3		3		
COVID-19	2	15		4	2	11
Death		10				10
Dehydration		1		1		
Diarrhoea		1		1		
Drug ineffective	2	6			2	6
Dysphonia		1				1
Dyspnoea		1		1		
Extrasystoles		1				1
Fatigue		1		1		
Feeling cold		1		1		
Headache		1		1		
Hyperhidrosis		1		1		
Hypertension	1	3	1	3		
Hypoaesthesia	1	1	1	1		
Hypotension		1		1		
Incorrect route of product administration		1		1		
Inflammation	1	1	1	1		
Insomnia		1		1		
Irritable bowel syndrome		1		1		
Lack of spontaneous speech	1	1			1	1
Loss of consciousness		1				1
Lung disorder		1				1
Menstruation delayed	4	4	4	4		
Mood altered		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	1	2	1	2		
Neurological symptom	1	1			1	1
Paraesthesia	1	2	1	2		
Product container issue	1	1	1	1		
Pyelonephritis		1				1
Pyrexia		2		2		
Rash		1				1
Respiratory tract oedema		1				1
Rhinorrhoea		2		2		
Sciatica		1		1		
Swelling face	1	1	1	1		
Tachycardia		1		1		
Throat irritation		2		2		
Vaccination failure		4				4
	19	89	13	48	6	41

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

LIECHTENSTEIN

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes zoster	1	1			1	1
Incorrect dose administered		1		1		
Neuralgia	1	1			1	1
Wrong product administered	1	1	1	1		
	3	4	1	2	2	2

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

LITHUANIA

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Abdominal pain upper		2		1		1
Anaphylactic reaction		1				1
Angina pectoris		1				1
Anxiety		1				1
Apathy		1		1		
Arrhythmia	1	1			1	1
Arthralgia		3		3		
Asthenia	1	11		8	1	3
Axillary pain		1		1		
Blood pressure decreased		1				1
Blood pressure increased		1				1
Body temperature increased		1				1
Bone pain		1		1		
Chills		6		6		
Cold sweat	1	2		1	1	1
Coordination abnormal		1				1
Cough	1	3	1	3		
Decreased appetite		1		1		
Depressed level of consciousness		1				1
Diarrhoea		1		1		
Disorientation		1				1
Dizziness		5		3		2
Dry eye		1		1		
Dyspepsia		1		1		
Dyspnoea		1		1		
Ear pain		1		1		
Exposure during pregnancy		1		1		
Eye irritation		1		1		
Eye pain		2		2		
Fatigue		1		1		
Feeling abnormal		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling of body temperature change		1		1		
Headache	1	8	1	6		2
Heart rate increased		3		2		1
Herpes simplex		1		1		
Hypoaesthesia		2		2		
Hypotension	1	1			1	1
Lacrimation increased		2		2		
Loss of consciousness		1				1
Lymphadenopathy		2		2		
Lymph node abscess	1	3			1	3
Lymph node pain		1				1
Lymph node palpable		1				1
Menstruation delayed	1	1	1	1		
Mucosal disorder		1		1		
Myalgia		8		7		1
Nasopharyngitis	1	3	1	3		
Nausea	1	5	1	4		1
Night sweats	1	1	1	1		
Pain in extremity		2		2		
Pallor		1				1
Palpitations	1	1			1	1
Peripheral swelling		1		1		
Peritonitis		1				1
Peritonsillar abscess		1				1
Pruritus	2	2	1	1	1	1
Pyrexia	1	9	1	9		
Respiratory rate increased	1	1			1	1
Seizure		4				4
Slow response to stimuli		1		1		
Sneezing		1		1		
Somnolence		4		4		
Syncope		2				2

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* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia	1	2		1	1	1
Tendon pain		1		1		
Tinnitus		1		1		
Tonsillar hypertrophy		1		1		
Tremor	1	1			1	1
Urticaria	1	1	1	1		
Vaccination site erythema		1		1		
Vaccination site pain	1	10	1	10		
Vaccination site swelling		1		1		
Vomiting		1				1
	20	154	10	110	10	44

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Angina pectoris	1	2			1	2
Anxiety	1	1	1	1		
Arrhythmia		1				1
Arthralgia	2	8	2	7		1
Asthenia	5	16	3	12	2	4
Axillary pain		2		1		1
Back pain		2		2		
Blood pressure decreased	1	2			1	2
Blood pressure fluctuation	1	2	1	1		1
Blood pressure increased		1		1		
Body temperature increased		3		3		
Bone pain	1	4	1	4		
Chest discomfort	1	1	1	1		
Chills	2	12	2	10		2
Cognitive disorder		1				1
Cold sweat	1	1			1	1
Condition aggravated		1				1
Confusional state		1		1		
Convulsions local		1				1
Cough		1		1		
COVID-19		1		1		
Diarrhoea	1	3	1	3		
Disorientation		1				1
Dizziness	4	11	3	8	1	3
Dry mouth	1	1	1	1		
Dyspnoea	2	2	1	1	1	1
Ear disorder	1	1			1	1
Ear pain	1	1	1	1		
Epistaxis	1	1	1	1		
Erythema		1		1		
Eye irritation	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye pain		1		1		
Facial nerve disorder		1		1		
Fatigue	1	4	1	3		1
Feeling drunk		1		1		
Feeling hot		1		1		
Headache	4	19	4	16		3
Heart rate increased		1		1		
Hot flush		1		1		
Hyperhidrosis		1		1		
Hypertension		1		1		
Hypoaesthesia	1	3		2	1	1
Injected limb mobility decreased		1		1		
Injection site pain		1		1		
Loss of consciousness		2				2
Lymphadenopathy	1	4	1	3		1
Lymph node abscess	4	8			4	8
Memory impairment		1		1		
Muscle spasms		1		1		
Muscular weakness	1	2	1	2		
Myalgia	1	9	1	8		1
Myositis		1		1		
Nasal congestion	1	2		1	1	1
Nasopharyngitis	2	3	2	3		
Nausea	2	9	2	7		2
Neck pain		1		1		
Neuralgia		1				1
Oropharyngeal pain	1	2	1	2		
Overdose		1		1		
Pain		1		1		
Pain in extremity	3	11	3	11		
Pallor	2	2			2	2
Palpitations	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia	2	4	1	2	1	2
Paresis		1				1
Peripheral coldness		1		1		
Peripheral swelling	1	4	1	3		1
Pharyngeal disorder	1	1			1	1
Pneumonia		1				1
Polymyositis		1				1
Pruritus		1		1		
Pyrexia	4	20	4	19		1
Rash	1	2	1	2		
Rash maculo-papular		1		1		
Seizure		1				1
Sensitive skin		1		1		
Skin mass		1				1
Somnolence	1	1	1	1		
Speech disorder	1	1			1	1
Swelling	2	2	1	1	1	1
Swelling face	1	1			1	1
Syncope	1	3			1	3
Tachycardia	1	2			1	2
Thermal burns of eye	1	1			1	1
Tinnitus		1				1
Tongue movement disturbance	1	1			1	1
Tremor	1	5		3	1	2
Underdose		1		1		
Urinary incontinence		1		1		
Vaccination complication		1		1		
Vaccination site erythema	2	7	2	7		
Vaccination site induration		1		1		
Vaccination site inflammation		1		1		
Vaccination site pain	3	8	3	8		
Vaccination site reaction		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site swelling		5		5		
Vaccination site warmth		2		2		
Vomiting	1	3	1	3		
	78	275	51	204	27	71

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose		1				1
Angina pectoris		2				2
Arrhythmia	1	1			1	1
Arthralgia	3	9	3	9		
Asthenia	2	9	1	6	1	3
Atrial fibrillation	1	1			1	1
Axillary pain		2		2		
Balance disorder		1		1		
Bell's palsy		1				1
Blister	1	1			1	1
Blood pressure abnormal		1		1		
Blood pressure ambulatory increased		1		1		
Blood pressure fluctuation		1		1		
Blood pressure increased	1	6		1	1	5
Bone pain	1	2	1	2		
Cardiac arrest	1	1			1	1
Chest discomfort		1				1
Chest pain		1		1		
Chills	1	4	1	4		
Chronic gastritis		1		1		
Chronic sinusitis		1		1		
Condition aggravated	1	1	1	1		
Cough		1		1		
Death	1	1			1	1
Depressed level of consciousness	1	1			1	1
Diarrhoea		1				1
Diverticulum		1		1		
Dizziness	2	3	2	3		
Dysgeusia		1		1		
Dysphagia		1				1
Dyspnoea	2	5	2	4		1
Ear pain		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Epilepsy		1				1
Erythema		2		1		1
Eyelid function disorder		1				1
Eye pain		2		2		
Eye swelling	1	1	1	1		
Facial asymmetry		1				1
Facial paralysis		4				4
Fatigue		2		2		
Feeling hot		1				1
Flatulence		1		1		
Groin pain	1	1	1	1		
Haemolytic anaemia		1				1
Headache	2	10	2	8		2
Head discomfort		1		1		
Heart rate increased		4		2		2
Heart rate irregular		1		1		
Heavy menstrual bleeding	1	1	1	1		
Hyperhidrosis	1	2	1	2		
Hypersensitivity	1	1			1	1
Hypertension		1				1
Hypertensive crisis		1				1
Hypoacusis		1		1		
Hypoaesthesia		5		4		1
Hypoaesthesia oral		1				1
Insomnia	2	4	2	4		
Lacrimation increased		1				1
Lip swelling		1		1		
Local reaction		1				1
Loss of consciousness	1	1			1	1
Lymphadenopathy		2		2		
Lymph node abscess	1	3			1	3
Malaise	1	2		1	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Menstrual disorder	1	1	1	1		
Mobility decreased		1		1		
Muscle twitching		1		1		
Muscular weakness		1		1		
Musculoskeletal stiffness		1		1		
Myalgia	1	4	1	4		
Nasal congestion		1		1		
Nausea	4	6	4	5		1
Neck pain		2		2		
Non-cardiac chest pain		1		1		
Pain	1	1	1	1		
Pain in extremity	1	7	1	7		
Panic attack	1	1			1	1
Paraesthesia		2		2		
Paraesthesia oral	1	1	1	1		
Peripheral swelling	1	1	1	1		
Phlebitis	1	1			1	1
Photophobia	1	1	1	1		
Product preparation issue		1				1
Pruritus	1	3	1	3		
Pyrexia	4	8	4	8		
Rash	1	1			1	1
Rhinorrhoea	1	2	1	2		
Sensation of foreign body		1				1
Somnolence		1		1		
Stress		1		1		
Swelling face		1		1		
Swollen tongue	1	1	1	1		
Syncope		2				2
Tachycardia	1	1	1	1		
Taste disorder		1				1
Thrombophlebitis	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thrombosis	1	1			1	1
Tremor		1		1		
Urticaria	1	1			1	1
Vaccination site erythema		6		5		1
Vaccination site pain	1	8	1	7		1
Vaccination site pruritus		1		1		
Vaccination site swelling		4		3		1
Vaccination site warmth		1				1
Vomiting	1	3	1	1		2
	58	212	40	146	18	66

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Anaphylactic shock		1				1
Arrhythmia	1	1			1	1
Asthenia	3	3	2	2	1	1
Blood pressure increased	1	1			1	1
Body temperature increased	2	2	1	1	1	1
Death		2				2
Decreased appetite	1	1	1	1		
Deep vein thrombosis		1				1
Diarrhoea		1				1
Discomfort	1	1	1	1		
Dry mouth	1	1			1	1
Dysphagia	1	1			1	1
Dyspnoea	2	2	1	1	1	1
Ear pain	1	1	1	1		
Extrasystoles	1	1	1	1		
Eye disorder	1	1	1	1		
Fatigue	1	1	1	1		
Feeling abnormal	1	1			1	1
Feeling hot	1	1			1	1
Gait disturbance	1	2			1	2
Haemorrhagic stroke	1	1			1	1
Headache	1	1	1	1		
Head discomfort	1	1	1	1		
Heart rate increased	1	1			1	1
Hyperhidrosis	1	1			1	1
Hypersensitivity		1				1
Hypertension	1	1			1	1
Hypotension		1				1
Induration	1	1			1	1
Joint swelling	1	1			1	1
Limb discomfort	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Loss of consciousness	1	1			1	1
Malaise	1	1	1	1		
Musculoskeletal chest pain	1	1	1	1		
Myalgia	1	1	1	1		
Off label use		1		1		
Pain in extremity	2	3	1	1	1	2
Paralysis	1	1			1	1
Peripheral coldness	1	1			1	1
Peripheral swelling	1	1			1	1
Pneumonia	1	1			1	1
Product use issue		1		1		
Pulmonary embolism	1	1			1	1
Pulmonary oedema		1				1
Pulse abnormal	1	1			1	1
Pyrexia	1	1	1	1		
Rash	1	1	1	1		
Rash papular		1				1
Skin discolouration	1	1			1	1
Syncope	1	1			1	1
Tachycardia	1	1	1	1		
Throat tightness	1	1			1	1
Tongue dry	1	1			1	1
Tremor	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site mass	1	1	1	1		
Vaccination site pain	3	3	2	2	1	1
Vomiting		1				1
	55	69	24	26	31	43

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Asthenia	1	1	1	1		
Cardiogenic shock		1				1
Condition aggravated		1				1
COVID-19 pneumonia		1				1
Death		1				1
Dyspnoea		1				1
Dyspraxia	1	1	1	1		
Feeling abnormal	1	1	1	1		
Irritability		1				1
Loss of consciousness	1	2			1	2
Lymphopenia	1	1	1	1		
Malaise		2				2
Memory impairment	1	1	1	1		
Mental impairment	1	1			1	1
Pain		1				1
Rash	1	1			1	1
Rash maculo-papular	1	1			1	1
Vaccination failure		1				1
	9	21	5	5	4	16

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		1		1		
Bone pain		1		1		
Decreased appetite		1		1		
Diarrhoea		1		1		
Eye disorder		1		1		
Headache	1	4	1	4		
Lymph node abscess		1				1
Myalgia		2		2		
Nausea		1		1		
Pain in extremity		1		1		
Pain of skin		1		1		
Pyrexia		3		3		
Thrombosis		1				1
Vaccination site pain		1		1		
Visual impairment		1		1		
	1	21	1	19		2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

LUXEMBOURG

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	3	1	2		1
Back pain	1	1	1	1		
Chills	2	4	2	3		1
Diarrhoea		2				2
Dizziness	1	2	1	1		1
Fatigue		2				2
Headache	1	5	1	2		3
Hypotension		1				1
Hypotonia	1	1	1	1		
Illness	1	1	1	1		
Lymphadenopathy		1		1		
Malaise		1		1		
Myalgia	4	8	4	7		1
Nausea	2	2	2	2		
Peripheral swelling	1	1	1	1		
Presyncope	1	1	1	1		
Pruritus	1	1	1	1		
Pyrexia	1	2	1	1		1
Skin plaque	1	1	1	1		
Tachycardia		1				1
Tetany		1		1		
Tinnitus		1				1
Tonsillitis bacterial	1	1			1	1
Vaccination site induration	1	1	1	1		
Vaccination site reaction	2	3	2	2		1
	23	48	22	31	1	17

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1				1
Abdominal pain upper		1				1
Anxiety		1		1		
Arrhythmia		1				1
Arthralgia	4	12	1	2	3	10
Asthenia	2	4			2	4
Blood pressure fluctuation	1	1	1	1		
Bone pain	1	1			1	1
Cervical radiculopathy	1	1			1	1
Chest discomfort	2	4			2	4
Chest pain	1	3		1	1	2
Chillblains		1		1		
Chills	2	14	1	3	1	11
Cough		1				1
COVID-19		1				1
C-reactive protein	1	1	1	1		
Decreased appetite		1				1
Dermatitis allergic		1				1
Dermatitis bullous		1				1
Diarrhoea		2				2
Dizziness		4				4
Drug ineffective		1				1
Dry mouth		2				2
Dry skin		1				1
Dysgeusia		1				1
Dysphonia		2				2
Dyspnoea	1	3			1	3
Dyspnoea exertional	2	2			2	2
Epistaxis	1	1	1	1		
Erythema	1	1			1	1
Erythema nodosum		1				1
Eyelid oedema		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye pain		1				1
Eye swelling	1	1			1	1
Face oedema		1				1
Facial pain	1	1	1	1		
Facial paralysis	1	1			1	1
Fall		1				1
Fatigue	7	26	4	4	3	22
Fear of injection		1		1		
General physical health deterioration		1				1
Headache	9	33	5	9	4	24
Hemiparesis	1	1			1	1
Herpes zoster		1		1		
Hot flush		1				1
Hypersensitivity		1				1
Hypertension		2				2
Hypotension	1	1	1	1		
Influenza		4		1		3
Injected limb mobility decreased		1				1
Injection site reaction		1		1		
Insomnia	2	3	1	1	1	2
Joint swelling	1	1			1	1
Laryngeal discomfort		1				1
Lip pain	1	1	1	1		
Lymphadenitis	1	1	1	1		
Lymphadenopathy	3	7		3	3	4
Lymph node pain	1	1			1	1
Lymphoedema	1	1			1	1
Malaise		6				6
Migraine		1				1
Muscular weakness	1	1			1	1
Musculoskeletal stiffness		2				2
Myalgia	4	21	1	3	3	18

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	1	6	1	2		4
Neck pain	3	5		1	3	4
Oral herpes		1		1		
Pain	1	2	1	1		1
Pain in extremity	3	8	3	4		4
Palpitations		2				2
Panic attack		1		1		
Paraesthesia		1				1
Peripheral coldness		1				1
Peripheral swelling		3		2		1
Pharyngeal paraesthesia	1	1			1	1
Presyncope	1	1	1	1		
Productive cough		1				1
Pruritus		5		1		4
Psoriasis	1	1	1	1		
Pulmonary pain		1				1
Pyrexia	9	21	6	8	3	13
Rash		3				3
SARS-CoV-2 ant body test negative		1				1
Skin haemorrhage		1				1
Somnolence		1				1
Swelling face		1		1		
Tachycardia	1	3			1	3
Therapeutic response unexpected		1		1		
Throat tightness		1				1
Tongue ulceration		1				1
Tremor		2				2
Urticaria	1	2	1	2		
Uveitis	1	1			1	1
Vaccination complication		3		1		2
Vaccination site pain	2	4	1	1	1	3
Vaccination site reaction	3	19	3	15		4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site swelling	1	1	1	1		
Vertigo		1		1		
Vomiting		1				1
	85	308	39	85	46	223

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic oedema		1		1		
Anaphylactic reaction	1	1			1	1
Anxiety		1		1		
Arthralgia	1	6	1	2		4
Asthenia		1		1		
Asthmatic crisis		1				1
Back pain		1		1		
Bradyphrenia		1				1
Chest discomfort	1	1			1	1
Chills	1	2			1	2
Confusional state	1	1			1	1
Deafness	1	1			1	1
Diarrhoea		3		1		2
Diplopia		1				1
Dizziness		1				1
Dysaesthesia		1				1
Dyspnoea		1				1
Dyspnoea exertional		1				1
Epilepsy		3				3
Epistaxis		1				1
Erythema	1	1			1	1
Eyelid oedema		1		1		
Eye movement disorder		1				1
Face oedema		1				1
Fatigue	5	9	4	6	1	3
Feeding disorder		1				1
Feeling abnormal		1				1
Feeling hot		1				1
Haematoma	1	1			1	1
Haemoglobin decreased		1				1
Headache	2	8	2	3		5
Heart rate increased		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hemiparaesthesia		1				1
Hyperhidrosis		2				2
Hypersensitivity		1				1
Hypersomnia		1		1		
Hypertension	1	5			1	5
Hypoaesthesia		1				1
Hypotension	1	4			1	4
Influenza		2		1		1
Loss of consciousness	1	3			1	3
Lymphadenopathy	1	1	1	1		
Malaise	1	4			1	4
Myalgia	1	6		1	1	5
Nasopharyngitis		1		1		
Nausea	1	6	1	1		5
Oropharyngeal discomfort	1	2			1	2
Pain	1	1			1	1
Pallor		1				1
Panic reaction	1	1	1	1		
Paraesthesia	1	2			1	2
Paraesthesia oral		1		1		
Paresis		1				1
Pneumonia		1				1
Presyncope		1				1
Pruritus	1	2			1	2
Pulmonary embolism		1				1
Pulse abnormal		1				1
Pyrexia	1	4			1	4
Rash	1	1			1	1
Rectal haemorrhage		1				1
Swelling		1				1
Swelling face	1	2			1	2
Tachycardia		1				1

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urinary incontinence		1				1
Vaccination complication		1				1
Vaccination site pain	2	3	1	1	1	2
Vaccination site reaction	3	9	3	7		2
Vertigo	1	1	1	1		
Vitamin B12 deficiency		1				1
Vomiting		2				2
Weight decreased	1	1			1	1
Wheezing		1				1
	37	140	15	34	22	106

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome		1				1
Acute kidney injury		1				1
Altered state of consciousness		1				1
Apathy	1	1			1	1
Arrhythmia		1				1
Arthralgia	1	2		1	1	1
Carotid arteriosclerosis	1	1	1	1		
Claudication of jaw muscles	1	1			1	1
Confusional state	1	1			1	1
Conjunctivitis		1				1
C-reactive protein increased	2	2	1	1	1	1
Decreased appetite	1	1			1	1
Deep vein thrombosis	1	2			1	2
Dyspnoea	2	2			2	2
Fatigue	2	2	1	1	1	1
Feeling cold	1	1			1	1
Formication		1				1
Gait disturbance	1	1			1	1
Generalised tonic-clonic seizure	1	1			1	1
Haematoma		1		1		
Headache	1	1	1	1		
Hypernatraemia		1				1
Hypertension	1	1			1	1
Hyperthermia		1				1
Inflammation	1	1			1	1
Limb discomfort	1	1			1	1
Lung disorder		1				1
Muscular weakness		1				1
Myalgia	1	1			1	1
Pain in extremity		1		1		
Palpitations		1				1
Paraesthesia		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Phlebitis	1	1			1	1
Pneumonia	1	1			1	1
Pulmonary embolism	1	2			1	2
Sepsis		1				1
Vaccination site pain	1	1	1	1		
	25	43	5	8	20	35

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1				1
Anxiety		1				1
Atrial fibrillation		1				1
Blood pressure increased		1				1
Cardiac arrest	1	1			1	1
Cerebral haemorrhage		1				1
Cerebrovascular accident	1	1			1	1
Chest discomfort		1				1
Chills		1				1
COVID-19 pneumonia		1				1
Deep vein thrombosis	1	1			1	1
Dyspnoea		2				2
Fall		1				1
Fatigue	2	4	2	2		2
Headache	3	5	1	1	2	4
Hypersensitivity		1				1
Hypertension		1		1		
Hypertensive crisis	1	1			1	1
Hyperthermia		1		1		
Hypotension	1	1	1	1		
Hypoxia		1				1
Malaise	2	2	2	2		
Nausea		1				1
Oxygen saturation decreased		1				1
Pneumonia aspiration	1	1			1	1
Pulmonary embolism		1				1
Pyrexia	2	4	1	1	1	3
Respiratory failure		1				1
Speech disorder	1	1			1	1
Subdural haematoma	1	1			1	1
Tremor		1		1		
Urinary tract infection		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination complication	1	2			1	2
Venous thrombosis limb	1	1			1	1
Vlth nerve paralysis		1				1
Vomiting		1				1
Wheezing		1				1
	19	50	7	11	12	39

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coma	1	1	1	1
Hypersomnia	1	1	1	1
	2	2	2	2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

MACAO

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bell's palsy	1	1	1	1
	1	1	1	1

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute coronary syndrome		1		1
		1		1

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Facial paralysis	3	3	3	3
	3	3	3	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

MACEDONIA, THE FORMER YUGOSLAV

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia		1		1
Body temperature increased		1		1
Headache	1	2	1	2
Incorrect route of product administration		1		1
Malaise		1		1
Nasopharyngitis		1		1
Pyrexia	1	1	1	1
Rash maculo-papular		1		1
Rhinorrhoea		1		1
Vaccination site pain	1	1	1	1
	3	11	3	11

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		1		1		
Body temperature increased	1	1	1	1		
Eye oedema	1	1	1	1		
Headache		2		2		
Hypersensitivity	1	1	1	1		
Lip oedema	1	1	1	1		
Loss of consciousness		1				1
Malaise	2	2	2	2		
Myalgia	2	3	2	3		
Pyrexia	2	2	2	2		
Vaccination site pain		1		1		
	10	16	10	15		1

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Body temperature increased		1		1
Malaise		1		1
Pyrexia		1		1
		3		3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19	1	1	1	1
Pneumonia	1	1	1	1
	2	2	2	2

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

MALAYSIA

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Amnesia	1	1	1	1
Maternal exposure during pregnancy		1		1
Memory impairment	1	1	1	1
Saliva altered	1	1	1	1
	3	4	3	4

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		1		1		
Dizziness		1		1		
Fatigue		1		1		
Headache		1		1		
Heavy menstrual bleeding	1	1	1	1		
Hypoaesthesia		1		1		
Pyrexia		1		1		
Seizure		1				1
Vaccination site pain		2		2		
	1	10	1	9		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cellulitis		1				1
Pityriasis rosea		1		1		
Rash erythematous		1		1		
Rash papular		1		1		
Skin discolouration	1	1	1	1		
Skin necrosis		1				1
Vaccination site erythema		1		1		
Vaccination site pain	1	1	1	1		
Vaccination site swelling	1	1	1	1		
Vaccination site warmth		1		1		
	3	10	3	8		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abdominal discomfort	1	1	1	1
Abdominal pain upper	1	1	1	1
Abdominal sepsis	1	1	1	1
Blood uric acid increased	1	1	1	1
Cardiac disorder	1	1	1	1
Cerebral infarction	1	1	1	1
Death	1	1	1	1
Gastrointestinal necrosis	1	1	1	1
Haemorrhagic stroke	1	1	1	1
Haemorrhagic transformation stroke	1	1	1	1
Hepatic function abnormal	1	1	1	1
Intestinal ischaemia	1	1	1	1
Labile blood pressure	1	1	1	1
Loss of consciousness	1	1	1	1
Malaise	1	1	1	1
Nausea	1	1	1	1
Perforation	1	1	1	1
Renal impairment	1	1	1	1
Septic shock	1	1	1	1
Speech disorder	1	1	1	1
Thrombosis	1	1	1	1
Vomiting	1	1	1	1
	22	22	22	22

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactoid reaction	1	1			1	1
Bronchospasm	1	1			1	1
Constipation		1		1		
Contusion	1	1	1	1		
COVID-19		1		1		
Death		1				1
Disseminated intravascular coagulation	1	1			1	1
Hair texture abnormal		1		1		
Headache		1		1		
Malaise		1		1		
Maternal exposure during pregnancy	2	2	2	2		
Musculoskeletal stiffness		1		1		
Neuropathy peripheral		2				2
No adverse event	4	5	4	5		
Platelet count decreased	1	1	1	1		
Product complaint	1	1	1	1		
Rash	1	1	1	1		
Urticaria	1	1	1	1		
	14	24	11	18	3	6

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

MALTA

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Anaphylactic reaction		1				1
Bell's palsy		1				1
Chills	1	3	1	3		
Cough		1		1		
Deafness	1	1			1	1
Deep vein thrombosis		1				1
Diarrhoea		1		1		
Erythema	1	1	1	1		
Fatigue	1	2	1	2		
Fear of injection		1		1		
Headache	2	3	2	3		
Hot flush		1		1		
Hyperhidrosis		1		1		
Hypersensitivity	1	2	1	2		
Hypoaesthesia		1				1
Inappropriate schedule of product administration	1	1	1	1		
Influenza like illness	1	2	1	2		
Injection		1		1		
Insomnia	1	1	1	1		
Lethargy		3		3		
Limb discomfort	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Malaise		2		2		
Mouth ulceration		1		1		
Myalgia		1		1		
Nausea	1	1	1	1		
Oral pain		1		1		
Oropharyngeal pain		1		1		
Pain		3		3		
Pain in extremity	2	5	2	4		1
Parosmia		1		1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pigmentation disorder	1	1	1	1		
Pyrexia	2	7	2	7		
Rash	1	1	1	1		
Somnolence		1		1		
Swelling		1				1
Syncope		1				1
Taste disorder		1		1		
Thrombosis		1				1
Tinnitus	2	2			2	2
Tongue ulceration		1		1		
Vaccination site discomfort		1		1		
Vaccination site pain		3		3		
Vomiting	1	1	1	1		
	22	70	19	59	3	11

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		1		1		
Anaphylactic reaction		7				7
Angioedema		2				2
Arthralgia	1	3	1	3		
Arthritis infective		1				1
Asthenia	1	2	1	2		
Asthma		2				2
Bell's palsy		1				1
Bone pain		2		2		
Bronchospasm		3				3
Burning sensation		1		1		
Chest discomfort		2				2
Chills	4	9	4	9		
Cough		1				1
COVID-19		1				1
Decreased appetite		1		1		
Defaecation urgency		1		1		
Diarrhoea		2		1		1
Discomfort	1	1	1	1		
Dizziness		4		4		
Dysgeusia		2		1		1
Dysphonia		3				3
Dyspnoea		4				4
Erythema		3		1		2
Eye swelling		1				1
Facial paralysis		2				2
Fatigue	1	9	1	9		
Feeling abnormal		1		1		
Flushing		2				2
Gait disturbance		1		1		
Gait inability		1		1		

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache	1	4	1	4		
Heart rate increased		1				1
Hot flush		2		2		
Hyperhidrosis	1	2	1	2		
Hypersensitivity	1	5	1	1		4
Hypertension		1				1
Hypoaesthesia		2		2		
Impaired healing	1	1			1	1
Insomnia		1		1		
Lethargy	1	7	1	7		
Limb discomfort	2	4	2	3		1
Lip swelling		1				1
Loss of consciousness		2				2
Lymphadenopathy	1	2	1	2		
Malaise		2		2		
Migraine		1		1		
Mobility decreased		1		1		
Muscle spasms		1		1		
Muscle twitching		1		1		
Musculoskeletal stiffness		2		2		
Myalgia	2	10	2	10		
Nausea		5		2		3
Neck pain		2		2		
Night sweats		1		1		
Off label use		2		2		
Overdose		1		1		
Pain	3	7	3	7		
Pain in extremity		5		4		1
Palpitations		4		1		3
Paraesthesia	2	5	2	5		
Periorbital swelling	1	1			1	1
Peripheral swelling		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product administered at inappropriate site		1		1		
Product use issue		1		1		
Pruritus		5		2		3
Pyrexia	4	13	4	13		
Rash		5		1		4
Rash erythematous		3		1		2
Rash pruritic		2				2
Respiratory depression		1				1
Respiratory distress		3				3
Restlessness	1	1	1	1		
Retinal vein occlusion		1				1
Sinus tachycardia		1				1
Somnolence		2		2		
Swelling		2				2
Swelling face		2				2
Swollen tongue		1				1
Syncope		3				3
Tachycardia		4				4
Tachypnoea		1				1
Throat tightness		1				1
Toothache		1		1		
Traumatic haemorrhage	1	1			1	1
Urticaria		1				1
Use of accessory respiratory muscles		2				2
Vaccination failure		1				1
Vaccination site pain	4	11	4	11		
Vaccination site pruritus		1		1		
Vaccination site urticaria		2		1		1
Vertigo	1	1	1	1		
Vision blurred		2				2
Vomiting		3		2		1
Wheezing		2				2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	35	245	32	148	3	97

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	2	1	2		
Cerebrovascular accident		1				1
Dehydration		1		1		
Dysphagia		1				1
Erythema		1		1		
Fatigue		3		1		2
Goitre		1		1		
Headache		1		1		
Insomnia	1	1	1	1		
Lethargy		1		1		
Malaise	1	1	1	1		
Musculoskeletal stiffness	1	1	1	1		
Nausea	1	1	1	1		
Pain in extremity	1	1	1	1		
Panic reaction		1		1		
Paraesthesia	1	3	1	3		
Paraesthesia oral		2		2		
Peripheral coldness	1	1	1	1		
Pyrexia		3		1		2
Swelling face		1		1		
Vaccination site pain		1		1		
	8	29	8	23		6

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* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Arthritis reactive	1	1			1	1
Bell's palsy		1				1
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident	1	1			1	1
Chills		1		1		
Cough		1		1		
COVID-19		1		1		
Deep vein thrombosis	2	2			2	2
Diarrhoea	1	1	1	1		
Ear swelling		2		2		
Erythema		3		3		
Fatigue		3		3		
Fine motor skill dysfunction	1	1	1	1		
Flushing		1		1		
Grip strength decreased	1	1	1	1		
Headache		1		1		
Hemiplegia	1	1			1	1
Hypersensitivity		2		2		
Hypoaesthesia	1	1	1	1		
Lethargy		1		1		
Lip swelling	1	1	1	1		
Lymphadenopathy	1	2	1	2		
Malaise		2		2		
Ocular hyperaemia		1		1		
Periorbital swelling		1		1		
Pruritus	1	3	1	3		
Pulmonary artery thrombosis	1	1			1	1
Pulmonary embolism	1	1			1	1
Pyrexia		4		4		
Rash	1	3	1	3		
Soft tissue swelling	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Speech disorder	1	1	1	1		
Swelling face		1		1		
Ulcer		1		1		
Urinary retention	1	1			1	1
Urticaria	1	2	1	2		
Vaccination site erythema		1		1		
Vaccination site movement impairment		1		1		
Vaccination site pain		1		1		
Vaccination site pruritus		1		1		
Vaccination site rash		1		1		
	21	59	12	49	9	10

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* AE=Adverse Event
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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Activated partial thromboplastin time prolonged		2		2		
Activated partial thromboplastin time ratio increased		1		1		
Acute kidney injury	2	4			2	4
Alanine aminotransferase increased		1		1		
Altered state of consciousness	2	3			2	3
Arrhythmia	1	1			1	1
Arthralgia		1		1		
Asthenia		2		1		1
Atrial fibrillation	1	2			1	2
Basophil count increased		1		1		
Blood alkaline phosphatase increased		2		2		
Blood calcium decreased		1		1		
Blood creatinine increased		1		1		
Blood glucose increased		1		1		
Blood magnesium decreased		1		1		
Blood osmolality increased		1		1		
Blood phosphorus decreased		1		1		
Blood urea increased		2		2		
Cardiac arrest		2				2
Cardiac failure	1	1			1	1
Cardiac failure congestive	2	2			2	2
Cerebellar atrophy		1				1
Cerebral atrophy		2				2
Chest pain		1		1		
COVID-19	2	8			2	8
COVID-19 pneumonia		2				2
C-reactive protein increased		3		3		
Drug ineffective	1	4			1	4
Dyspnoea	1	3			1	3
Eosinophil count decreased		1		1		
Erythema		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fungal skin infection		1		1		
Generalised tonic-clonic seizure		1				1
Haematemesis		1				1
Haematocrit decreased		3		3		
Haemoglobin decreased		3		3		
Hypertension		1				1
Hypoaesthesia		1		1		
Hypothermia		1				1
Hypoxia	1	4			1	4
Immature granulocyte count increased		1		1		
International normalised ratio increased		1		1		
Lethargy	2	2			2	2
Lymphocyte count decreased		3		3		
Mean cell haemoglobin concentration decreased		1		1		
Mean cell haemoglobin concentration increased		1		1		
Mean cell volume increased		1		1		
Mean platelet volume decreased		1		1		
Monocyte count decreased		1		1		
Monocyte count increased		1		1		
Nausea		1		1		
Neck pain		1		1		
Neoplasm progression		1				1
Neutrophil count increased		3		3		
Normochromic normocytic anaemia		1		1		
Nucleated red cells		1		1		
Oxygen saturation decreased		1		1		
Peripheral coldness		1		1		
Platelet count decreased		1		1		
Platelet count increased		2		2		
Poor peripheral circulation		1		1		
Prothrombin time prolonged		1		1		
Pruritus		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary embolism		1				1
Red blood cell count decreased		3		3		
Red cell distribution width increased		2		2		
Renal failure	1	1			1	1
Respiratory arrest		2				2
Respiratory failure	1	2			1	2
Reticulocyte count increased		1		1		
Sepsis	1	3			1	3
Septic shock		1				1
Swelling face		1				1
Tachypnoea	1	3			1	3
Thrombocytopenia	2	3			2	3
Urinary tract infection	1	2		1	1	1
Urosepsis		1				1
Vaccination failure	1	4			1	4
Vaccination site induration		1		1		
White blood cell count increased		1		1		
	24	136		64	24	72

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burning sensation		1				1
Chest pain		1				1
COVID-19		1				1
Deep vein thrombosis	1	1			1	1
Drug ineffective		1				1
Fatigue	1	2	1	2		
Feeling of body temperature change		1				1
Heart rate increased		1		1		
Hypersensitivity		1		1		
Hypertension		1		1		
Pain in extremity		1		1		
Palpitations		1				1
Pericardial effusion	1	1			1	1
Tremor		1				1
	3	15	1	6	2	9

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

MEXICO

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposure via breast milk		1		1
Lymphadenopathy		1		1
		2		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	97	140	85	121	12	19
Abdominal pain lower	1	1	1	1		
Abdominal pain upper	2	2	2	2		
Abnormal faeces	2	3	2	3		
Abscess		1		1		
Ageusia		1		1		
Agitation	3	3	3	3		
Allergy to vaccine		1		1		
Allodynia		1		1		
Altered state of consciousness	1	1			1	1
Anaphylactic reaction		9				9
Anaphylactic shock		11				11
Angioedema		1				1
Anosmia	7	15	7	15		
Anxiety	15	25	14	19	1	6
Aphonia	1	2	1	2		
Application site hypoaesthesia	1	1	1	1		
Application site induration	1	1	1	1		
Application site oedema	1	1	1	1		
Application site pain	2	2	2	2		
Arthralgia	296	466	272	425	24	41
Asthenia	434	656	396	590	38	66
Asthma	1	1	1	1		
Asthmatic crisis	1	2			1	2
Atrial f brillation		2				2
Axillary mass		1		1		
Axillary pain	3	4	2	3	1	1
Back pain	14	20	12	18	2	2
Balance disorder		2		1		1
Blepharospasm	1	1	1	1		
Blister	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood glucose increased	1	1			1	1
Blood pressure abnormal	5	5	3	3	2	2
Blood pressure fluctuation	2	2	2	2		
Blood pressure increased	21	25	14	18	7	7
Body temperature increased	89	144	81	126	8	18
Bone disorder	1	1	1	1		
Bone pain	2	3	1	1	1	2
Bowel movement irregularity	1	2	1	2		
Bradycardia		4				4
Breast pain	1	1	1	1		
Bronchospasm	4	20	4	12		8
Burning sensation	1	1	1	1		
Cellulitis	2	11			2	11
Cheilitis	1	1	1	1		
Chest discomfort	10	12	9	10	1	2
Chest pain	18	44	15	35	3	9
Chills	289	434	268	388	21	46
Circumoral oedema	1	1			1	1
Cogwheel rigidity	1	1	1	1		
Cold sweat	1	1	1	1		
Conjunctival haemorrhage		1				1
Conjunctival hyperaemia		1		1		
Conjunctival irritation	1	1	1	1		
Conjunctivitis	2	4	2	4		
Constipation	1	1	1	1		
Cough	122	205	112	179	10	26
COVID-19	4	15	4	11		4
C-reactive protein abnormal	1	1	1	1		
Crying	14	22	13	20	1	2
Cyanosis		1		1		
Deafness unilateral		1				1
Decreased appetite	21	42	20	39	1	3

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Delirium		1				1
Dermatosis		1		1		
Diarrhoea	110	176	94	148	16	28
Diffuse large B-cell lymphoma		1				1
Discomfort	35	44	32	41	3	3
Disorientation		1				1
Disseminated Bacillus Calmette-Guerin infection		3				3
Disturbance in attention		1		1		
Dizziness	341	526	304	446	37	80
Drug ineffective		4				4
Dry mouth	5	9	4	5	1	4
Dysaesthesia	2	2	2	2		
Dysarthria	2	3	2	3		
Dysgeusia	11	18	11	17		1
Dysmenorrhoea	1	1	1	1		
Dysphagia	4	7		2	4	5
Dysphonia		1		1		
Dyspnoea	19	174	16	125	3	49
Dyspnoea exertional		4		4		
Dysstasia	1	2	1	1		1
Dystonia		1				1
Ear discomfort		2		2		
Ear disorder	1	2	1	2		
Ear pain	1	4	1	4		
Ear pruritus	1	1	1	1		
Electric shock sensation		1				1
Encephalitis	1	1			1	1
Enterococcal infection	1	1			1	1
Epistaxis		2		2		
Erythema	92	142	89	131	3	11
Erythema multiforme		1				1
Eye disorder		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye injury	7	12	6	8	1	4
Eye irritation	6	11	6	11		
Eyelid irritation	1	1	1	1		
Eyelid oedema	8	11	5	7	3	4
Eyelid pain	1	1			1	1
Eyelid ptosis		1		1		
Eye pain	7	10	7	10		
Eye paraesthesia	1	1	1	1		
Eye pruritus	1	1	1	1		
Face oedema	3	4	2	3	1	1
Facial paralysis		4				4
Facial paresis		1		1		
Faeces discoloured	1	2	1	2		
Faeces soft	1	1	1	1		
Fall		1		1		
Fasting		1		1		
Fatigue	298	472	268	419	30	53
Febrile convulsion	4	17	3	14	1	3
Feeding intolerance	1	1	1	1		
Feeling abnormal	2	4	2	3		1
Feeling cold	3	3	3	3		
Feeling hot	3	8	3	5		3
Feeling of body temperature change		1		1		
Feeling of despair	1	1	1	1		
Flatulence	1	1	1	1		
Flushing	7	9	7	9		
Frequent bowel movements		1		1		
Furuncle	1	1	1	1		
Gait disturbance	2	2			2	2
Gastroenteritis		1				1
Gastrointestinal disorder	1	1	1	1		
Gastrointestinal hypermotility	1	1	1	1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal hypomotility		1		1		
Gastroesophageal reflux disease	1	1	1	1		
Generalised oedema	2	2	1	1	1	1
Generalised tonic-clonic seizure		1				1
General physical condition abnormal		1				1
General physical health deterioration	1	5	1	5		
Guillain-Barre syndrome	1	2			1	2
Haematochezia		5				5
Haemorrhage		1				1
Haemorrhagic disorder		2				2
Headache	802	1,123	749	1029	53	94
Head discomfort	1	3	1	3		
Heart rate abnormal	1	1	1	1		
Heart rate increased	1	5		4	1	1
Hemiparaesthesia		1				1
Hemiparesis		1				1
Hemiplegia		1				1
Hot flush	1	2	1	2		
Hyperaemia	2	3	2	2		1
Hyperaesthesia	1	2	1	2		
Hyperhidrosis	18	30	15	23	3	7
Hyperpyrexia		1				1
Hypersensitivity	2	12	2	9		3
Hypertension	41	59	30	41	11	18
Hypertensive crisis		6				6
Hypertensive emergency		1				1
Hyperthermia	11	13	10	12	1	1
Hypoaesthesia	20	36	16	25	4	11
Hypoaesthesia oral	3	7	3	7		
Hypokinesia	2	7	1	5	1	2
Hyposmia		2		2		
Hypotension	8	19	5	9	3	10

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypothermia		3				3
Hypotonia		1		1		
Hypoventilation		2				2
Hypovolaemic shock		3				3
Hypoxia	1	2			1	2
Impaired work ability	1	1	1	1		
Incorrect route of product administration	3	3	3	3		
Induration	84	127	80	119	4	8
Inflammation	77	129	71	114	6	15
Influenza	1	3	1	3		
Injection site haematoma	1	1	1	1		
Injection site haemorrhage		1		1		
Injection site hypoaesthesia	1	1	1	1		
Injection site inflammation	1	1	1	1		
Injection site pain	3	3	3	3		
Injection site reaction	1	1	1	1		
Inner ear inflammation	1	1	1	1		
Insomnia	1	2	1	2		
Intermenstrual bleeding		1		1		
Intussusception		2				2
Irritability	40	70	34	59	6	11
Irritability postvaccinal		1		1		
Joint injury		1		1		
Lacrimation increased	2	6	2	6		
Laryngospasm		1		1		
Lethargy		2		1		1
Leukopenia		1				1
Lip discolouration		1		1		
Lip oedema	2	2	2	2		
Local reaction	42	60	42	58		2
Loss of consciousness	1	8			1	8
Loss of personal independence in daily activities	1	1			1	1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenitis	1	1	1	1		
Lymphadenopathy	15	37	12	33	3	4
Lymphoedema	1	1	1	1		
Lymphopenia	1	1	1	1		
Malaise	50	81	46	73	4	8
Mass		1		1		
Maternal exposure during pregnancy		3		3		
Meningitis		1				1
Migraine	2	2	2	2		
Mobility decreased	6	11	6	11		
Monocytosis	1	1	1	1		
Monoparesis	2	2	2	2		
Motor dysfunction	1	1	1	1		
Movement disorder	1	1	1	1		
Muscle contractions involuntary	1	3	1	1		2
Muscle fatigue	1	1	1	1		
Muscle spasms	1	1	1	1		
Muscle strength abnormal	1	1	1	1		
Muscular weakness	5	12	3	6	2	6
Musculoskeletal chest pain	1	1	1	1		
Musculoskeletal stiffness	1	1			1	1
Myalgia	373	575	347	533	26	42
Myoclonus	1	1	1	1		
Nail discolouration		1		1		
Nasal congestion	6	11	6	11		
Nasal discomfort	1	1	1	1		
Nasal obstruction		1		1		
Nasal pruritus	1	1	1	1		
Nasopharyngitis		3		3		
Nausea	332	485	301	429	31	56
Neck pain	6	10	6	10		
Nervousness	1	1	1	1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuritis		2		1		1
Nodule	87	134	82	124	5	10
Ocular discomfort		1		1		
Ocular hyperaemia		1		1		
Odynophagia	31	55	30	46	1	9
Oedema	97	165	87	139	10	26
Oedema peripheral	2	8	2	7		1
Off label use	8	11	8	11		
Optic neuritis	1	1			1	1
Oral candidiasis	1	1			1	1
Oral discomfort	1	1			1	1
Oropharyngeal discomfort	3	6	3	3		3
Oropharyngeal pain	151	246	138	224	13	22
Osteoarthropathy	1	1	1	1		
Otitis media acute		1		1		
Oxygen saturation decreased	2	13	1	5	1	8
Pain	493	682	469	635	24	47
Painful respiration		1		1		
Pain in extremity	37	48	34	43	3	5
Pain of skin	1	2	1	2		
Pallor	1	4	1	4		
Palmar erythema	1	1	1	1		
Palpitations	5	6	5	5		1
Paraesthesia	47	76	39	57	8	19
Paraesthesia oral	7	13	4	7	3	6
Paralysis	2	13			2	13
Paresis	2	2	2	2		
Partial seizures	1	1			1	1
Pelvic discomfort		1				1
Pelvic pain		1		1		
Peripheral coldness		3		2		1
Peripheral swelling	1	1	1	1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Petechiae		1				1
Pharyngeal disorder		1		1		
Pharyngeal hypoaesthesia		1				1
Pharyngeal inflammation	1	1	1	1		
Pharyngeal oedema		1				1
Pharyngeal paraesthesia	1	4	1	2		2
Pharyngotonsillitis	1	1			1	1
Phonophobia	1	1	1	1		
Photophobia	7	8	6	7	1	1
Photopsia	3	8	3	7		1
Pneumonia		2				2
Pneumonitis		1		1		
Prehypertension	2	2	2	2		
Product administered at inappropriate site	1	1	1	1		
Product use issue	9	12	9	12		
Prurigo		2		2		
Pruritus	104	158	90	125	14	33
Purpura	3	3	3	3		
Pyrexia	263	418	236	376	27	42
Radiculitis brachial		1				1
Rash	78	119	61	87	17	32
Rash erythematous	1	1	1	1		
Rash macular		1				1
Rash maculo-papular	1	1	1	1		
Rash pruritic	1	1	1	1		
Reflux gastritis	2	2	2	2		
Respiratory distress	15	166			15	166
Rhinitis	2	3	2	3		
Rhinorrhoea	141	214	136	206	5	8
Salivary hypersecretion	1	1	1	1		
Seizure	2	20			2	20
Sensation of foreign body	3	6	2	2	1	4

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensitive skin	507	667	482	624	25	43
Sensory loss		1		1		
Sepsis		1				1
Shock	1	3			1	3
Sinus tachycardia		1		1		
Skin burning sensation		1		1		
Skin lesion		1		1		
Skin sensitisation	8	8	8	8		
Sleep deficit	1	1	1	1		
Sneezing	1	2	1	2		
Somnolence	8	11	7	10	1	1
Suffocation feeling		1		1		
Suspected COVID-19	4	6	4	5		1
Swelling		3		1		2
Syncope	1	21			1	21
Tachyarrhythmia		1		1		
Tachycardia	148	270	135	227	13	43
Tachypnoea	3	6	2	3	1	3
Temperature intolerance		1		1		
Tenderness		2		2		
Tension headache	2	2	1	1	1	1
Thermal burns of eye		1				1
Thirst	1	3	1	2		1
Throat irritation	6	9	6	9		
Tinnitus	2	7	2	6		1
Tongue pruritus	1	1	1	1		
Tonsillar hypertrophy	1	1			1	1
Tonsillitis bacterial	1	1			1	1
Tremor	6	14	6	12		2
Trismus	1	1	1	1		
Urticaria	6	9	4	6	2	3
Vaccination complication	1	1	1	1		

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* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site abscess		1		1		
Vaccination site cellulitis		6		4		2
Vaccination site discomfort	3	6	3	6		
Vaccination site erythema	12	16	11	15	1	1
Vaccination site haemorrhage	1	1	1	1		
Vaccination site hyperaesthesia		1		1		
Vaccination site hypersensitivity	2	11	2	11		
Vaccination site hypoaesthesia	1	2	1	2		
Vaccination site induration	10	18	9	17	1	1
Vaccination site inflammation	3	8	3	8		
Vaccination site movement impairment	1	3	1	3		
Vaccination site nodule	3	8	3	8		
Vaccination site oedema	9	10	8	9	1	1
Vaccination site pain	212	310	202	294	10	16
Vaccination site papule	2	2	1	1	1	1
Vaccination site paraesthesia	4	6	4	6		
Vaccination site pruritus	7	8	7	8		
Vaccination site rash	1	1	1	1		
Vaccination site reaction		6		6		
Vaccination site swelling	5	8	5	8		
Vaccination site warmth	10	12	10	12		
Vaginal haemorrhage	3	3			3	3
Vasospasm	1	1	1	1		
Vertigo	14	26	10	19	4	7
Vision blurred	13	16	10	12	3	4
Visual acuity reduced	2	2			2	2
Visual impairment	2	3		1	2	2
Vomiting	110	179	94	148	16	31
Wheezing	1	2	1	2		
White coat hypertension	1	1	1	1		
Wrong technique in product usage process	1	1	1	1		
	7,259	11,565	6599	9936	660	1629

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal distension	2	3	2	3		
Abdominal pain	144	248	135	228	9	20
Abdominal pain lower		1		1		
Abdominal pain upper	3	9	3	8		1
Abnormal faeces	1	4	1	3		1
Abnormal sensation in eye	1	1	1	1		
Abscess	5	8	5	8		
Advanced sleep phase	1	1	1	1		
Affect lability		1		1		
Ageusia	2	8	2	7		1
Agitation	4	5	2	3	2	2
Akathisia		1		1		
Alanine aminotransferase increased		1		1		
Allergy to vaccine		3		2		1
Allodynia	1	2	1	2		
Amnesia	1	1	1	1		
Anaesthesia oral	1	1	1	1		
Anaphylactic reaction		13				13
Anaphylactic shock	3	27			3	27
Angina pectoris		1				1
Angioedema	1	8			1	8
Anosmia	25	41	25	38		3
Anxiety	27	51	20	40	7	11
Aphasia		1		1		
Aphonia	3	4	3	4		
Aphthous ulcer		1		1		
Application site pain	6	6	6	6		
Areflexia	1	1			1	1
Arrhythmia		4				4
Arthralgia	713	1,078	681	1005	32	73
Arthritis	1	1	1	1		

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathy	1	1	1	1		
Aspartate aminotransferase increased		1				1
Asterixis		1				1
Asthenia	896	1,381	843	1272	53	109
Asthenopia	1	1	1	1		
Asthma	2	3	2	3		
Asthmatic crisis		1				1
Ataxia		1		1		
Atrophy		1		1		
Atypical pneumonia		1				1
Auricular swelling	1	2	1	2		
Axillary pain	6	9	6	9		
Axonal neuropathy		1				1
Back pain	33	56	30	50	3	6
Balance disorder	1	3	1	2		1
Bell's palsy		4				4
Blepharitis		1		1		
Blepharospasm		1		1		
Blindness		1				1
Blindness transient		1				1
Blister	1	3	1	2		1
Blood glucose abnormal	2	2	1	1	1	1
Blood glucose decreased		1				1
Blood glucose increased	1	4	1	4		
Blood pressure abnormal	14	17	11	14	3	3
Blood pressure ambulatory abnormal	1	1			1	1
Blood pressure decreased	3	3	3	3		
Blood pressure diastolic increased	1	2	1	2		
Blood pressure fluctuation	3	3	3	3		
Blood pressure increased	81	111	55	73	26	38
Blood pressure systolic increased	2	2	2	2		
Body temperature abnormal	1	1			1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Body temperature decreased		1		1		
Body temperature fluctuation		1				1
Body temperature increased	138	222	129	206	9	16
Bone pain	1	1	1	1		
Bradycardia		12				12
Brain stem ischaemia		2				2
Breast pain	1	1	1	1		
Bronchial disorder		2		2		
Bronchospasm	23	67	17	42	6	25
Bruxism	1	1			1	1
Burning sensation	4	9	4	5		4
Catarrh		1		1		
Cellulitis		20				20
Cheilitis	2	3	1	2	1	1
Chest discomfort	25	38	24	34	1	4
Chest pain	60	116	55	100	5	16
Chest X-ray abnormal	1	1	1	1		
Chills	642	981	611	911	31	70
Choluria	1	2	1	1		1
Clonic convulsion		1				1
Coagulation time prolonged		1				1
Cold sweat		1		1		
Colitis	1	2	1	2		
Condition aggravated		3		2		1
Confusional state		3		2		1
Conjunctival disorder	1	1			1	1
Conjunctival haemorrhage		4				4
Conjunctival hyperaemia	1	4	1	3		1
Conjunctivitis	7	16	7	16		
Contusion	1	2	1	2		
Conversion disorder		2		2		
Cough	274	463	256	421	18	42

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Counterfeit product administered		2		2		
COVID-19	16	44	15	34	1	10
COVID-19 pneumonia		2				2
C-reactive protein increased		1		1		
Crying	22	43	21	40	1	3
Cyanosis	2	5	2	4		1
Deafness		1				1
Deafness unilateral		1				1
Death		1				1
Decreased appetite	78	127	74	118	4	9
Deficiency of bile secretion		1				1
Dehydration	2	6	2	4		2
Demyelination		3				3
Depressed level of consciousness	2	8			2	8
Depression	1	1	1	1		
Dermatitis	1	1	1	1		
Diabetic ketoacidosis		1				1
Diarrhoea	189	316	179	289	10	27
Diarrhoea haemorrhagic		1				1
Diplopia		1		1		
Discharge		1		1		
Discomfort	61	86	59	83	2	3
Disease recurrence		4		3		1
Disorientation	2	8	2	7		1
Disseminated Bacillus Calmette-Guerin infection	1	6			1	6
Dizziness	707	1,114	652	993	55	121
Dizziness postural		1		1		
Drug hypersensitivity		2				2
Drug ineffective	1	12			1	12
Dry mouth	16	31	15	27	1	4
Dry throat	5	6	5	6		
Dysaesthesia	6	8	6	8		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysarthria	1	3		2	1	1
Dysgeusia	20	39	20	36		3
Dyskinesia	1	2	1	2		
Dyslalia	1	1			1	1
Dyslipidaemia		1		1		
Dysmenorrhoea		1		1		
Dysphagia	6	17	5	13	1	4
Dysphonia	8	11	5	8	3	3
Dyspnoea	53	406	43	319	10	87
Dyspnoea at rest		1				1
Dyspnoea exertional	1	3		2	1	1
Dysstasia	2	2	2	2		
Ear discomfort	1	3	1	3		
Ear infection		3		3		
Ear pain	13	17	10	14	3	3
Eating disorder symptom	2	2	2	2		
Ecchymosis		2		1		1
Electric shock sensation	1	1	1	1		
Electrolyte imbalance		1				1
Emotional disorder	1	1	1	1		
Encephalitis post immunisation		1				1
Epigastric discomfort		1		1		
Epiglottic oedema		2				2
Epilepsy		1				1
Epistaxis	2	6	2	5		1
Erythema	160	269	141	234	19	35
Expired product administered	1	3	1	3		
Exposure during pregnancy	1	3	1	3		
Exposure to SARS-CoV-2		1		1		
External ear inflammation		1		1		
Eye discharge	1	1	1	1		
Eye disorder	1	3	1	3		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye inflammation	1	2		1	1	1
Eye injury	11	24	9	21	2	3
Eye irritation	7	13	7	13		
Eyelid oedema	8	12	8	11		1
Eyelid pain		1		1		
Eyelid ptosis	1	2	1	2		
Eyelid rash		1		1		
Eyelid sensory disorder	1	2	1	2		
Eyelids pruritus		1		1		
Eye pain	34	51	30	46	4	5
Eye pruritus	1	4	1	4		
Eye swelling		2		1		1
Face oedema	3	8	3	8		
Facial nerve disorder		1		1		
Facial pain	1	1	1	1		
Facial paralysis	2	13			2	13
Facial paresis		1		1		
Fall		1		1		
Fatigue	603	968	563	889	40	79
Febrile convulsion	7	24	6	16	1	8
Feeling abnormal	1	3	1	3		
Feeling cold	5	9	4	8	1	1
Feeling drunk		1		1		
Feeling hot	21	30	20	27	1	3
Feeling of body temperature change	1	1	1	1		
Feeling of despair	1	3	1	3		
Fibrosis		1		1		
Flushing	9	17	9	15		2
Foreign body in throat		1				1
Foreign body sensation in eyes		1		1		
Frequent bowel movements	1	1	1	1		
Gait disturbance	6	9	3	6	3	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastritis		1		1		
Gastroenteritis		1		1		
Gastrointestinal disorder	1	2	1	1		1
Gastrointestinal hypermotility		1		1		
Gastrointestinal motility disorder		3		3		
Gastrointestinal pain	1	1	1	1		
Generalised oedema	1	2	1	2		
Generalised tonic-clonic seizure		4				4
General physical health deterioration	3	9	2	8	1	1
Genital paraesthesia		1		1		
Gingival hypertrophy	1	1	1	1		
Glabellar reflex abnormal		1		1		
Glossodynia	1	1	1	1		
Groin pain		1		1		
Guillain-Barre syndrome	3	4			3	4
Haematochezia	1	8			1	8
Haematoma		1		1		
Haemoptysis		1		1		
Haemorrhage	1	10			1	10
Haemorrhagic disorder		3				3
Hallucination, visual		2				2
Headache	1,623	2,317	1515	2119	108	198
Head discomfort	2	2	1	1	1	1
Heart rate abnormal	1	3	1	3		
Heart rate increased	9	15	4	9	5	6
Heart rate irregular		1				1
Hemiparaesthesia	2	7			2	7
Hemiparesis		7				7
Hemiplegia		1				1
Hepatic function abnormal		1		1		
Hepatic pain		1		1		
Herpes zoster	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hot flush	4	6	4	6		
Hunger		1		1		
Hyperaemia	7	10	7	10		
Hyperaesthesia	2	8	2	8		
Hyperbilirubinaemia		1				1
Hyperglycaemia	1	2	1	1		1
Hyperhidrosis	45	71	40	59	5	12
Hypernatraemia		1				1
Hyperoxia	1	1	1	1		
Hyperreflexia		1		1		
Hypersensitivity	9	30	5	22	4	8
Hypersomnia	1	2	1	2		
Hypertension	130	197	84	125	46	72
Hypertensive crisis	3	35			3	35
Hypertensive emergency		1				1
Hyperthermia	16	26	15	24	1	2
Hypoacusis		2		2		
Hypoaesthesia	39	56	34	48	5	8
Hypoaesthesia oral	19	26	18	24	1	2
Hypoglycaemia	3	3	1	1	2	2
Hypokinesia	9	12	8	11	1	1
Hypopnoea	1	1	1	1		
Hyposmia	1	1	1	1		
Hypotension	18	30	8	17	10	13
Hypothermia		11				11
Hypotonia	1	3	1	3		
Hypovolaemic shock		17				17
Hypoxia	2	2			2	2
Inappropriate schedule of product administration	1	5	1	5		
Incorrect route of product administration	5	6	5	6		
Increased appetite	1	1	1	1		
Induration	174	270	170	260	4	10

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Infection	1	1	1	1		
Inflammation	163	241	153	225	10	16
Influenza	2	5	1	4	1	1
Influenza like illness	1	3	1	3		
Injection site hypoaesthesia	1	1	1	1		
Injection site pain	7	8	7	8		
Injection site pruritus	1	1	1	1		
Injection site reaction	1	1	1	1		
Insomnia	7	8	7	8		
Inspiratory capacity abnormal	1	1	1	1		
Intracranial aneurysm		1				1
Intussusception		6				6
Irritability	63	132	60	117	3	15
Irritability postvaccinal	1	3	1	3		
Jaundice		1				1
Joint injury	1	1			1	1
Joint stiffness		1		1		
Lacrimation increased	2	10	2	10		
Laryngeal discomfort	1	1	1	1		
Laryngeal inflammation		1				1
Laryngeal obstruction		1				1
Laryngeal oedema		4				4
Laryngospasm	1	2	1	1		1
Lethargy	5	5	4	4	1	1
Leukopenia		1				1
Limb discomfort	7	9	7	8		1
Lip disorder		1		1		
Lip oedema	8	13	6	11	2	2
Lip pain	1	2	1	2		
Lip pruritus	1	1	1	1		
Livedo reticularis	1	4		3	1	1
Localised oedema	2	5	2	5		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Local reaction	102	132
Loss of consciousness		8
Loss of personal independence in daily activities	3	5
Lymphadenitis		1
Lymphadenopathy	67	115
Lymphangitis		1
Lymph node pain	2	2
Lymphopenia		2
Macule	1	1
Malaise	108	163
Mastication disorder	1	1
Maternal exposure during pregnancy	1	5
Mean cell haemoglobin concentration decreased		1
Mean cell haemoglobin decreased		1
Mean cell volume decreased		1
Mean platelet volume decreased		1
Mechanical urticaria	2	3
Memory impairment	1	1
Meningitis		1
Menstrual disorder		1
Menstruation irregular	1	1
Metamorphopsia	1	1
Migraine	3	3
Mobility decreased	14	21
Monocyte count increased		1
Mononeuropathy		2
Monoparesis	1	2
Motor dysfunction		1
Mouth haemorrhage		1
Movement disorder	5	10
Mucosal dryness		2
Mucous stools		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
99	128	3	4
			8
3	4		1
	1		
64	107	3	8
			1
2	2		
	1		1
1	1		
96	147	12	16
		1	1
1	5		
	1		
	1		
	1		
1	2	1	1
1	1		
			1
	1		
1	1		
1	1		
3	3		
14	21		
	1		
			2
1	2		
	1		
			1
4	7	1	3
	2		
	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle atrophy		1		1		
Muscle contractions involuntary	1	4	1	4		
Muscle contracture	1	3	1	3		
Muscle fatigue		3		3		
Muscle rigidity	1	2		1	1	1
Muscle spasms	6	14	6	13		1
Muscle spasticity	1	2			1	2
Muscle strength abnormal	1	2	1	2		
Muscle tightness	1	2	1	2		
Muscular weakness	13	24	10	18	3	6
Musculoskeletal chest pain	2	3	2	3		
Musculoskeletal discomfort	1	1	1	1		
Musculoskeletal stiffness	1	2	1	2		
Myalgia	834	1,261	793	1172	41	89
Myelitis		1				1
Myelitis transverse		1				1
Myoclonus	1	2	1	2		
Myopathy		1		1		
Narcolepsy		1				1
Nasal abscess		1				1
Nasal congestion	12	21	12	21		
Nasal dryness	1	1	1	1		
Nasal obstruction		1		1		
Nasal oedema	1	1	1	1		
Nasal turbinate hypertrophy	1	1	1	1		
Nasopharyngitis	2	5	1	2	1	3
Nausea	643	968	585	863	58	105
Near death experience		1				1
Neck pain	11	27	11	27		
Nerve degeneration		1				1
Nervousness	3	8	3	7		1
Nervous system disorder		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuritis		3		1		2
Neuropathy peripheral	1	2			1	2
Night sweats		1		1		
Nodule	174	282	169	269	5	13
Nystagmus	3	4	2	3	1	1
Obstruction	1	1	1	1		
Ocular discomfort	1	1	1	1		
Ocular hyperaemia		7		6		1
Ocular icterus	1	1	1	1		
Odynophagia	57	89	54	83	3	6
Oedema	220	344	202	307	18	37
Oedema mouth	1	1	1	1		
Oedema peripheral	7	14	7	14		
Off label use	5	8	5	8		
Oral candidiasis		1		1		
Oral discomfort	2	3	1	1	1	2
Oral disorder		2		1		1
Oral dysaesthesia		1		1		
Oral herpes		1		1		
Oral mucosal eruption	1	1	1	1		
Oral pruritus	3	3	3	3		
Oropharyngeal discomfort	4	10	4	8		2
Oropharyngeal pain	313	517	299	482	14	35
Osteoarthropathy	2	2	2	2		
Otitis externa		1		1		
Otitis media		1		1		
Oxygen saturation abnormal	1	8	1	5		3
Oxygen saturation decreased	16	37	7	22	9	15
Pain	982	1,396	938	1301	44	95
Painful respiration		1		1		
Pain in extremity	79	123	78	120	1	3
Pain in jaw		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain of skin	1	3	1	3		
Pallor	2	7	2	5		2
Palmar erythema		1		1		
Palpitations	11	30	9	25	2	5
Papule		2		2		
Paraesthesia	109	188	99	165	10	23
Paraesthesia oral	25	47	21	39	4	8
Paralysis	3	14			3	14
Paraparesis		1				1
Paresis	2	4	2	4		
Parosmia		1		1		
Patient elopement	2	3	2	3		
Pelvic pain	1	2	1	2		
Pericardial disease		1		1		
Periorbital oedema	1	2	1	2		
Peripheral coldness	2	7	2	7		
Peripheral motor neuropathy		1				1
Peripheral swelling		3		1		2
Peroneal nerve injury		1				1
Persistent depressive disorder		1		1		
Petechiae	2	6	2	4		2
Pharyngeal disorder	1	3	1	3		
Pharyngeal erythema	2	3	2	3		
Pharyngeal hypoaesthesia	1	1			1	1
Pharyngeal inflammation		2				2
Pharyngeal oedema		2				2
Pharyngeal paraesthesia	2	3	2	2		1
Pharyngeal swelling	2	2			2	2
Pharyngitis		1				1
Photophobia	11	14	10	13	1	1
Photopsia	7	8	5	5	2	3
Photosensitivity reaction	3	4	3	4		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pigmentation disorder		1		1		
Piloerection	1	1	1	1		
Platelet count increased		1		1		
Pleural effusion		1		1		
Pneumonia		11				11
Pollakiuria	1	1	1	1		
Polydipsia	1	1			1	1
Presyncope		3		1		2
Productive cough	7	9	6	7	1	2
Product supply issue		1		1		
Product use issue	3	4	3	4		
Prurigo	1	1	1	1		
Pruritus	214	310	184	268	30	42
Pulmonary oedema		1				1
Pulmonary pain	1	1	1	1		
Purpura	5	8	4	6	1	2
Pustule	1	1	1	1		
Pyrexia	510	814	486	756	24	58
Radiculopathy		2				2
Rales	1	2	1	2		
Rash	134	231	111	189	23	42
Rash erythematous	1	2	1	2		
Rash macular	1	1	1	1		
Rash maculo-papular		4		3		1
Rash papular	2	2	2	2		
Rash pruritic	2	2	2	2		
Raynaud's phenomenon		2		2		
Reflexes abnormal		1		1		
Respiration abnormal	1	1	1	1		
Respiratory disorder	1	2	1	2		
Respiratory distress	36	382			36	382
Respiratory rate increased	2	3	2	3		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory tract infection viral		1		1		
Restlessness		1		1		
Retching	1	1	1	1		
Rhinitis	3	4	3	4		
Rhinorrhoea	291	460	279	435	12	25
Ruptured cerebral aneurysm		1				1
Sacroiliitis		1				1
Salivary hypersecretion	8	9	8	9		
SARS-CoV-2 ant body test negative		2		2		
SARS-CoV-2 test positive	2	5	2	3		2
Scab		1				1
Sciatica		1				1
Sciatic nerve neuropathy		1				1
Secondary hypertension	2	2	2	2		
Secretion discharge		1		1		
Seizure	8	47			8	47
Sensation of foreign body	15	27	13	19	2	8
Sensitisation		1		1		
Sensitive skin	991	1,315	951	1234	40	81
Sensory disturbance	3	4	3	4		
Sensory loss	1	3		1	1	2
Shock		2				2
Sinusitis	1	1	1	1		
Sinus tachycardia		3		1		2
Skeletal injury		1		1		
Skin discolouration	1	2	1	2		
Skin exfoliation		1		1		
Skin haemorrhage		1		1		
Skin injury		1		1		
Skin lesion	1	2	1	2		
Skin plaque	1	1			1	1
Skin sensitisation	28	30	28	30		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin swelling		1		1		
Sleep disorder		1				1
Slow response to stimuli		2		2		
Slow speech	1	1			1	1
Sneezing	5	6	5	6		
Soft tissue swelling	1	1	1	1		
Somnolence	24	35	24	33		2
Speech disorder		2		2		
Spinal pain	2	2	2	2		
Sputum discoloured		1		1		
Sputum purulent		1				1
Stevens-Johnson syndrome		3				3
Stridor	1	3			1	3
Subarachnoid haemorrhage		2				2
Sudden infant death syndrome		1				1
Suffocation feeling	2	3	2	2		1
Suspected counterfeit product		2		2		
Suspected COVID-19	4	6	2	4	2	2
Sweating fever		1				1
Swelling	7	9	6	8	1	1
Swelling face	1	3	1	2		1
Swelling of eyelid	1	1	1	1		
Swollen tongue	1	2	1	2		
Syncope	2	50			2	50
Synovial cyst		1		1		
Systemic lupus erythematosus		1				1
Tachycardia	345	606	303	508	42	98
Tachycardia paroxysmal	1	1	1	1		
Tachypnoea	3	9	2	5	1	4
Taste disorder	1	1	1	1		
Temperature intolerance	1	2	1	2		
Temperature regulation disorder	2	3	2	3		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tenderness	1	3		2	1	1
Thirst	1	2	1	2		
Throat irritation	13	23	13	22		1
Throat tightness		2		2		
Thrombocytopenia		2				2
Thrombocytopenic purpura		3		2		1
Tic	1	1	1	1		
Tinnitus	6	12	6	11		1
Tongue oedema	1	3	1	2		1
Tongue paralysis	2	3			2	3
Tongue pruritus	1	1	1	1		
Toothache		1		1		
Transaminases increased		1				1
Traumatic lung injury		2		2		
Tremor	13	26	11	24	2	2
Tympanic membrane disorder		1		1		
Tympanic membrane perforation	1	1			1	1
Type I hypersensitivity		1				1
Upper-airway cough syndrome		1		1		
Urinary incontinence		2		2		
Urinary tract infection		1		1		
Urticaria	4	9	2	7	2	2
Vaccination complication	1	3	1	2		1
Vaccination failure	1	1			1	1
Vaccination site abscess		1		1		
Vaccination site cellulitis	1	14	1	7		7
Vaccination site discomfort		1		1		
Vaccination site erythema	15	27	13	24	2	3
Vaccination site haemorrhage		1				1
Vaccination site hyperaesthesia	3	5	3	5		
Vaccination site hypersensitivity	11	36	9	34	2	2
Vaccination site hypoaesthesia	6	8	6	8		

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site induration	15	35	14	30	1	5
Vaccination site inflammation	12	23	11	20	1	3
Vaccination site joint movement impairment	4	5	4	5		
Vaccination site joint pain		1		1		
Vaccination site movement impairment	10	14	10	14		
Vaccination site nodule	11	18	11	16		2
Vaccination site oedema	23	35	21	31	2	4
Vaccination site pain	424	605	407	578	17	27
Vaccination site paraesthesia	8	10	8	10		
Vaccination site pruritus	13	15	11	12	2	3
Vaccination site rash	2	4		1	2	3
Vaccination site reaction	11	20	10	19	1	1
Vaccination site swelling	7	8	7	8		
Vaccination site warmth	14	27	13	26	1	1
Vaginal haemorrhage		1		1		
Varicella	1	1	1	1		
Vascular headache	1	1	1	1		
Vasodilatation	1	2		1	1	1
Vertigo	22	39	19	34	3	5
Vestibular function test abnormal	1	1			1	1
Vestibular neuritis		1				1
Vision blurred	23	48	20	42	3	6
Visual field defect	1	1	1	1		
Visual impairment	1	1	1	1		
Vomiting	158	285	132	234	26	51
Wheezing	1	2	1	1		1
White blood cell count increased		1				1
Wrong technique in product usage process		1		1		
Xerophthalmia		1				1
	15,167	24,733	14002	21577	1165	3156

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	2	1	2		
Abdominal pain	21	39	20	36	1	3
Abdominal pain upper	1	3	1	3		
Abnormal faeces	1	1	1	1		
Abscess	1	3	1	2		1
Acne		1		1		
Acute myocardial infarction		1				1
Anaphylactic reaction		4				4
Anaphylactic shock		10				10
Angioedema		1				1
Anosmia	3	4	3	4		
Antibody test negative		1		1		
Anxiety	3	10	3	6		4
Aphonia	1	1	1	1		
Apnoeic attack	1	1			1	1
Application site pain	1	1	1	1		
Arrhythmia		2				2
Arthralgia	103	166	93	148	10	18
Asphyxia	1	1			1	1
Asthenia	152	237	135	211	17	26
Asthma		1		1		
Atrial fibrillation	1	1			1	1
Aura		1				1
Axillary pain	1	4	1	4		
Back pain	3	6	3	6		
Balance disorder	1	2	1	2		
Bell's palsy		3				3
Blister	1	2	1	2		
Blood glucose increased	1	1	1	1		
Blood pressure abnormal	4	4	1	1	3	3
Blood pressure ambulatory increased	1	1	1	1		
Blood pressure diastolic increased	1	1			1	1

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure fluctuation	1	1	1	1		
Blood pressure increased	23	32	13	19	10	13
Blood pressure systolic increased	2	2	1	1	1	1
Body temperature increased	23	39	21	36	2	3
Bradycardia	1	3			1	3
Brain oedema		1				1
Breast pain	1	2	1	2		
Bronchospasm	5	15	3	8	2	7
Burning sensation	2	3	2	3		
Cardiac failure	1	1			1	1
Cardio-respiratory arrest	1	1			1	1
Cellulitis	3	14			3	14
Cerebral small vessel ischaemic disease	1	1			1	1
Cerebrovascular accident		1				1
Cheilitis	1	1	1	1		
Chest discomfort	5	11	5	10		1
Chest pain	10	20	5	14	5	6
Chills	103	157	96	141	7	16
Chromaturia	1	1	1	1		
Circumoral oedema	1	1	1	1		
Circumstance or information capable of leading to medication error	1	1	1	1		
Colitis	1	1	1	1		
Condition aggravated		1				1
Confusional state	2	3	2	3		
Conjunctival haemorrhage	1	1			1	1
Conjunctival hyperaemia	3	3	3	3		
Conjunctivitis	2	3	2	3		
Contusion		1		1		
Coordination abnormal	1	1	1	1		
Cough	46	80	40	70	6	10
COVID-19	4	14	3	6	1	8

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19 pneumonia	1	3			1	3
Crying	3	4	3	4		
Cyanosis	1	1			1	1
Deafness bilateral	1	1			1	1
Death		1				1
Decreased activity	1	2	1	2		
Decreased appetite	15	33	15	30		3
Dehydration		1		1		
Demyelinating polyneuropathy		1				1
Dermatitis allergic		1		1		
Dermatosis		1		1		
Diarrhoea	37	58	30	45	7	13
Diplegia		1				1
Diplopia		1		1		
Discomfort	11	16	11	14		2
Disease recurrence		1				1
Disorientation		1		1		
Disturbance in attention		1		1		
Dizziness	144	240	122	200	22	40
Dizziness postural	1	1	1	1		
Drug ineffective	1	6			1	6
Dry mouth	7	9	7	8		1
Dry skin	1	1	1	1		
Dry throat		1				1
Dysaesthesia		3		2		1
Dysgeusia	3	5	3	5		
Dyskinesia	1	1	1	1		
Dyslalia		1				1
Dyspepsia		2		2		
Dysphagia	1	4		3	1	1
Dysphonia	2	5		2	2	3
Dyspnoea	17	105	10	77	7	28

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dystonia		1				1
Ear discomfort		1		1		
Ear disorder	1	1	1	1		
Ear pain		2		1		1
Ecchymosis	1	2	1	2		
Embolism		1				1
Epistaxis	3	4	3	4		
Eructation	1	1	1	1		
Erythema	33	53	30	50	3	3
Eye injury	3	4	3	3		1
Eyelid oedema	3	4	2	3	1	1
Eyelid ptosis		2		2		
Eye movement disorder		1				1
Eye oedema	1	1	1	1		
Eye pain	4	5	4	5		
Eye pruritus	1	2	1	2		
Face oedema		1		1		
Facial discomfort	1	1	1	1		
Facial nerve disorder		1		1		
Facial paralysis	1	5			1	5
Facial paresis		1		1		
Facial spasm		1		1		
Faecal volume decreased	1	1	1	1		
Fall	1	3	1	2		1
Fatigue	117	187	103	165	14	22
Fear	1	1	1	1		
Febrile convulsion	1	2		1	1	1
Feeling abnormal		2		1		1
Feeling cold	2	4	2	3		1
Feeling hot	4	7	3	6	1	1
Feeling of despair	1	1	1	1		
Flank pain		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Flatulence	1	1	1	1		
Flushing	1	1	1	1		
Gait disturbance	1	1	1	1		
Gastrointestinal disorder	1	1	1	1		
Gastrointestinal haemorrhage		1				1
Gastrooesophageal reflux disease		1		1		
Generalised tonic-clonic seizure		2				2
General physical condition abnormal	1	1	1	1		
General physical health deterioration		2		2		
General symptom		1				1
Glossitis	2	2			2	2
Guillain-Barre syndrome		3				3
Haematochezia		3				3
Haematoma		1		1		
Haemorrhage		8				8
Haemorrhagic disorder		3				3
Hallucination, visual		1				1
Headache	290	423	251	362	39	61
Heart rate increased		3		3		
Hemiparaesthesia		1				1
Hemiparesis	1	2			1	2
Herpes zoster	2	2	2	2		
Hot flush		1		1		
Hyperaemia		2		2		
Hyperglycaemia		1				1
Hyperhidrosis	6	12	5	8	1	4
Hypersensitivity	3	9	3	7		2
Hypertension	41	57	26	34	15	23
Hypertensive crisis	3	27			3	27
Hypertensive urgency	1	1			1	1
Hyperthermia	4	7	4	7		
Hypoacusis		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia	6	9	4	5	2	4
Hypoaesthesia oral	1	4		2	1	2
Hypoglycaemia		1				1
Hypokinesia	1	2	1	2		
Hypotension	5	7	3	3	2	4
Hypothermia	1	4			1	4
Hypovolaemic shock		5				5
Hypoxia	2	2			2	2
Impaired quality of life	1	1	1	1		
Incorrect dose administered	1	1	1	1		
Induration	34	53	32	49	2	4
Inflammation	30	45	26	41	4	4
Influenza like illness		1		1		
Injection site erythema	1	1	1	1		
Insomnia	1	3	1	3		
Intussusception		2				2
Irritability	12	21	12	18		3
Ischaemic stroke		1				1
Joint swelling		1		1		
Lacrimation increased	3	3	3	3		
Laryngeal oedema		3				3
Laryngospasm		1				1
Larynx irritation		1				1
Lateropulsion		1				1
Lethargy		1				1
Leukopenia		1				1
Limb discomfort	1	3	1	3		
Lip disorder		1		1		
Lip oedema	1	2		1	1	1
Listless	1	1	1	1		
Localised oedema	1	1	1	1		
Local reaction	21	26	21	26		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Loss of consciousness	3	5			3	5
Lymphadenopathy	3	9	2	6	1	3
Macule	1	1	1	1		
Malaise	18	28	13	19	5	9
Masticatory pain		1		1		
Metamorphopsia		1		1		
Mobility decreased	4	7	3	6	1	1
Monoparesis		1				1
Monoplegia		1				1
Movement disorder	2	3	1	2	1	1
Mumps	1	1	1	1		
Muscle spasms	3	5	3	5		
Muscle strength abnormal	1	1			1	1
Muscular weakness	6	10	3	5	3	5
Musculoskeletal discomfort	1	1	1	1		
Musculoskeletal pain	2	2	2	2		
Myalgia	120	190	110	170	10	20
Nasal congestion	3	5	3	5		
Nasal dryness	1	1	1	1		
Nasal pruritus		2		2		
Nausea	113	180	95	150	18	30
Neck pain	3	5	3	5		
Nervousness	1	1	1	1		
Nervous system disorder		1				1
Neuralgia		1		1		
Neuropathy peripheral	1	2			1	2
Nodule	33	54	31	49	2	5
Obstructive airways disorder	1	2			1	2
Ocular discomfort	1	1	1	1		
Ocular hyperaemia	2	3	2	3		
Odynophagia	7	12	7	12		
Oedema	41	67	34	58	7	9

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oedema peripheral		2		2		
Off label use	1	2	1	2		
Oral administration complication		1		1		
Oral pruritus	1	1			1	1
Oropharyngeal discomfort		1		1		
Oropharyngeal pain	40	76	38	70	2	6
Osteoarthritis	2	2	2	2		
Otitis media	1	1	1	1		
Overdose	1	1	1	1		
Oxygen saturation abnormal		2		1		1
Oxygen saturation decreased	9	16	3	9	6	7
Pain	176	275	165	251	11	24
Pain in extremity	11	25	10	24	1	1
Pain in jaw		1				1
Pain of skin		1		1		
Pallor	2	3		1	2	2
Palpitations	3	7	1	5	2	2
Paraesthesia	22	37	20	29	2	8
Paraesthesia mucosal		1				1
Paraesthesia oral	7	10	5	6	2	4
Paralysis	2	3			2	3
Parotid gland enlargement		1		1		
Parotitis	1	2	1	2		
Peripheral coldness	1	1	1	1		
Peripheral swelling	1	1	1	1		
Petechiae	1	1	1	1		
Petit mal epilepsy		1				1
Pharyngeal disorder	1	1	1	1		
Pharyngeal oedema		1				1
Pharyngeal paraesthesia	2	3	2	3		
Pharyngeal swelling	2	2			2	2
Pharyngitis	1	1	1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Photophobia		1		1		
Photopsia	1	1	1	1		
Pneumonia	1	5			1	5
Productive cough	1	2	1	2		
Product use issue	1	2	1	2		
Pruritus	36	61	29	50	7	11
Pulmonary pain		1		1		
Pulse absent	1	1			1	1
Purpura	1	1	1	1		
Pyrexia	69	123	63	111	6	12
Rash	22	42	15	30	7	12
Rash erythematous		1				1
Rash pruritic	2	2	2	2		
Respiratory disorder		2		1		1
Respiratory distress	14	98			14	98
Respiratory failure		3				3
Rhinalgia		1		1		
Rhinorrhoea	49	75	46	69	3	6
Salivary hypersecretion	2	3	2	2		1
Seizure	3	11			3	11
Sensation of foreign body	6	9	4	4	2	5
Sensitisation		1		1		
Sensitive skin	171	244	159	225	12	19
Skin burning sensation		1		1		
Skin discolouration	1	1	1	1		
Skin disorder		1		1		
Skin sensitisation	2	2	2	2		
Sleep inertia		1				1
Sneezing	3	3	1	1	2	2
Somnolence		4		4		
Stevens-Johnson syndrome		2				2
Suffocation feeling	1	1	1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Suspected COVID-19	1	1			1	1
Swelling		2		2		
Syncope	1	11			1	11
Synovial cyst	1	1	1	1		
Tachycardia	44	105	33	80	11	25
Tachypnoea		3		1		2
Taste disorder		1		1		
Tenderness	1	1	1	1		
Tension headache		1		1		
Therapeutic response unexpected	2	2	2	2		
Thirst		1		1		
Throat irritation	2	3	1	1	1	2
Throat tightness	2	2			2	2
Thrombosis	1	1			1	1
Tinnitus	10	12	10	12		
Tongue oedema		1		1		
Toothache		1		1		
Tremor	2	5	2	5		
Upper airway obstruction		1				1
Urinary retention	1	1			1	1
Urticaria	2	4	2	4		
Vaccination error	1	1	1	1		
Vaccination site abscess		1		1		
Vaccination site cellulitis		3		3		
Vaccination site discomfort	1	4	1	4		
Vaccination site erythema	3	9	3	8		1
Vaccination site haematoma	1	2	1	2		
Vaccination site haemorrhage	1	1	1	1		
Vaccination site hyperaesthesia		1		1		
Vaccination site hypersensitivity		2		2		
Vaccination site induration	4	9	4	8		1
Vaccination site inflammation	4	7	4	7		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site movement impairment		1		1		
Vaccination site nodule	2	5	2	5		
Vaccination site oedema	7	11	7	10		1
Vaccination site pain	67	106	60	99	7	7
Vaccination site paraesthesia	2	2	2	2		
Vaccination site pruritus	2	4	1	3	1	1
Vaccination site rash	1	1	1	1		
Vaccination site reaction	2	5	2	4		1
Vaccination site swelling	1	2	1	2		
Vaccination site warmth	2	2	2	2		
Vascular test abnormal		1		1		
Vertigo	5	8	3	5	2	3
Vision blurred	9	12	7	9	2	3
Vomiting	29	54	25	42	4	12
Wheezing		4		1		3
Wrong technique in device usage process	1	1	1	1		
Wrong technique in product usage process	1	3	1	3		
	2,724	4,754	2327	3812	397	942

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* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	3	1	2		1
Abdominal distension	1	1	1	1		
Abdominal pain	5	12	4	8	1	4
Abdominal pain upper		1		1		
Abdominal symptom		1		1		
Abnormal faeces		1				1
Abscess	1	3		2	1	1
Accidental overdose	1	1			1	1
Acne	1	1	1	1		
Ageusia	2	2			2	2
Aggression		2		2		
Amnesia		1				1
Analgesic therapy	1	1	1	1		
Angioedema		1				1
Anosmia		1		1		
Anxiety		1		1		
Aphasia		1		1		
Aphthous ulcer		1		1		
Arrhythmia		1				1
Arthralgia	18	27	8	14	10	13
Arthritis	1	2		1	1	1
Asthenia	41	72	19	45	22	27
Asymptomatic COVID-19		1				1
Back pain	3	4		1	3	3
Balance disorder	1	1			1	1
Bell's palsy	1	1			1	1
Blepharitis	1	1	1	1		
Blister	2	2	2	2		
Blood glucose increased	1	1			1	1
Blood pressure abnormal	2	2			2	2
Blood pressure decreased		1				1
Blood pressure increased	7	12	2	3	5	9

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure systolic increased	2	2			2	2
Body temperature increased	9	15	5	11	4	4
Bradycardia	1	1			1	1
Breast pain	1	1			1	1
Bronchospasm	4	6	2	2	2	4
Burning sensation	1	1	1	1		
Cardio-respiratory arrest		1				1
Cardiovascular disorder		1		1		
Cellulitis	5	9			5	9
Cerebral haematoma		1				1
Chest discomfort	1	1			1	1
Chest pain	4	4	2	2	2	2
Chills	19	31	13	23	6	8
Choluria		1				1
Chorea	1	1			1	1
Colitis		1		1		
Condition aggravated	1	2			1	2
Constipation	1	1			1	1
Cough	14	20	3	6	11	14
Counterfeit product administered	1	1	1	1		
COVID-19	6	6			6	6
Crying		1		1		
Cyanosis	2	2			2	2
Cystitis		1		1		
Death	1	2			1	2
Decreased appetite	1	5	1	5		
Deep vein thrombosis	1	1			1	1
Depressed level of consciousness	1	2			1	2
Dermatitis allergic	1	1	1	1		
Dermatitis exfoliative generalised	1	1			1	1
Dermatosis	2	2	1	1	1	1
Diabetes mellitus		1				1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea	13	22	7	14	6	8
Discomfort	4	8	3	6	1	2
Disorientation	1	1	1	1		
Disseminated Bacillus Calmette-Guerin infection		2				2
Diverticulum intestinal		1				1
Dizziness	34	52	23	39	11	13
Drug ineffective	1	2			1	2
Dry mouth	1	2	1	2		
Dysarthria	1	1			1	1
Dysgeusia		1		1		
Dyslalia	1	1	1	1		
Dysphagia	1	1	1	1		
Dysphonia	3	3	3	3		
Dyspnoea	19	36	7	18	12	18
Dyspnoea exertional	1	1			1	1
Dysstasia		1		1		
Eating disorder		1		1		
Embolism		1				1
End stage renal disease		1				1
Epistaxis	1	1	1	1		
Erythema	8	16	6	12	2	4
Expired product administered	1	1	1	1		
Extensor plantar response	1	1			1	1
Eye discharge		1		1		
Eye haemorrhage	1	1			1	1
Eye irritation		1		1		
Eyelid oedema	1	1	1	1		
Eyelid ptosis		1		1		
Eye pain	2	2	2	2		
Eye swelling	1	1	1	1		
Facial pain	1	1	1	1		
Facial paralysis	1	3			1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fall	1	2			1	2
Fatigue	42	68	25	48	17	20
Febrile convulsion	1	1			1	1
Feeling cold		1		1		
Feeling hot	4	4	4	4		
Flushing	1	1	1	1		
Gait disturbance	3	4	1	2	2	2
Gait inability	1	1	1	1		
Gastritis		1		1		
Generalised tonic-clonic seizure	1	2			1	2
General physical health deterioration	1	1			1	1
Gingival bleeding	1	1			1	1
Gingival pain		1		1		
Gingival swelling		1		1		
Glossodynia		1		1		
Granuloma	1	1	1	1		
Guillain-Barre syndrome	2	4			2	4
Haematochezia		3				3
Haemolytic anaemia		1				1
Haemorrhage		7				7
Haemorrhagic disorder	2	4			2	4
Hallucination	1	1			1	1
Headache	56	86	36	63	20	23
Head discomfort	1	1	1	1		
Heart rate increased		1		1		
Hemiparaesthesia	1	1			1	1
Hemiparesis	2	3			2	3
Herpes virus infection	1	1	1	1		
Herpes zoster	1	2	1	2		
Hip fracture		1				1
Hyperacusis	1	1	1	1		
Hyperhidrosis	5	7	4	6	1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypersensitivity		1		1		
Hypersomnia		1		1		
Hypertension	18	20	3	3	15	17
Hypertensive crisis	5	12			5	12
Hyperthermia	2	3	2	3		
Hypoaesthesia		1		1		
Hypoaesthesia oral	2	3	1	1	1	2
Hypoglycaemia	2	2			2	2
Hypokinesia	1	1	1	1		
Hypotension	4	5	2	3	2	2
Hypothermia	1	1			1	1
Hypotonia	1	1			1	1
Hypovolaemic shock		5				5
Hypoxia	3	3			3	3
Inappropriate schedule of product administration		1		1		
Induration		7		7		
Inflammation	10	15	8	13	2	2
Influenza	1	1	1	1		
Insomnia	1	1	1	1		
Intussusception		2				2
Irritability	2	5		3	2	2
Ischaemic stroke	1	1			1	1
Jaundice		1				1
Jaw disorder	1	1	1	1		
Joint range of motion decreased		1		1		
Lacrimation increased	1	1	1	1		
Lacunar stroke	1	1			1	1
Limb discomfort	1	1	1	1		
Lip oedema		1		1		
Livedo reticularis	1	1			1	1
Local reaction		2		2		
Loss of consciousness	1	3			1	3

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lung disorder		1		1		
Lymphadenopathy	3	10	3	10		
Macule	1	1	1	1		
Malaise	5	9	3	7	2	2
Mechanical urticaria	1	1			1	1
Migraine		1		1		
Mobility decreased		1		1		
Movement disorder		1				1
Muscle spasms	1	1	1	1		
Muscle tightness		1		1		
Muscular weakness	2	4	1	2	1	2
Myalgia	24	39	12	22	12	17
Myalgia intercostal		1		1		
Myocardial infarction		1				1
Myoclonic epilepsy		1				1
Nasal congestion	1	1	1	1		
Nasal obstruction	1	1			1	1
Nasopharyngitis	1	2		1	1	1
Nausea	18	32	10	21	8	11
Neck pain		1		1		
Neuralgia	1	1	1	1		
Nodule	1	8	1	8		
Ocular hyperaemia	1	2		1	1	1
Odynophagia	5	6	2	3	3	3
Oedema	10	14	6	10	4	4
Oedema peripheral	2	4		2	2	2
Off label use	1	2	1	2		
Oropharyngeal pain	12	15	4	6	8	9
Overdose	1	1	1	1		
Oxygen saturation decreased	3	4	1	1	2	3
Pain	28	50	18	38	10	12
Pain in extremity	8	16	7	15	1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain of skin	1	1	1	1		
Panic attack	1	2	1	2		
Paraesthesia	5	6	2	3	3	3
Paraesthesia oral	1	2			1	2
Paralysis		3				3
Peripheral swelling	1	2	1	2		
Peripheral vascular disorder		1				1
Petechiae	1	1	1	1		
Pharyngeal erythema	1	1	1	1		
Photopsia	1	1	1	1		
Platelet count decreased		1				1
Pneumonia	5	7			5	7
Pneumonia bacterial	1	1			1	1
Poor quality product administered	1	2	1	2		
Presyncope	1	2	1	2		
Productive cough	1	1			1	1
Product use issue	1	2	1	2		
Pruritus	14	22	6	12	8	10
Pulmonary embolism	1	1			1	1
Pupillary disorder	1	1	1	1		
Purpura	1	1			1	1
Pyrexia	25	39	13	25	12	14
Rales	1	1			1	1
Rash	12	20	6	13	6	7
Rash macular		1		1		
Rash maculo-papular	1	1			1	1
Respiratory acidosis	1	1			1	1
Respiratory arrest		2				2
Respiratory distress	18	38			18	38
Rhinorrhoea	12	18	2	7	10	11
Scab	1	1	1	1		
Scratch	1	1	1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Screaming		1		1		
Seizure	1	3			1	3
Sensation of foreign body	1	1			1	1
Sensitive skin	27	42	18	31	9	11
Septic shock		1				1
Skin lesion		1		1		
Skin plaque	1	1	1	1		
Slow speech		1		1		
Somnolence	1	3	1	3		
Spinal pain	1	1	1	1		
Splenomegaly		1		1		
Stomatitis		1		1		
Suspected counterfeit product	1	1	1	1		
Suspected COVID-19	1	1	1	1		
Swelling	1	1	1	1		
Swelling face		1		1		
Swollen tongue		1		1		
Syncope	5	7			5	7
Tachycardia	11	20	7	15	4	5
Tachypnoea		1				1
Thermal burns of eye		1				1
Thrombocytopenia	1	1			1	1
Thrombocytopenic purpura	1	1			1	1
Thrombophlebitis superficial	1	1			1	1
Thrombosis	2	3			2	3
Tinnitus	2	3	2	2		1
Tremor	1	1	1	1		
Urinary tract infection	1	2	1	2		
Urticaria		1		1		
Vaccination error	1	1			1	1
Vaccination site bruising	1	1	1	1		
Vaccination site cellulitis	1	3	1	2		1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site dermatitis	1	1			1	1
Vaccination site erythema	3	5	3	5		
Vaccination site haematoma		1		1		
Vaccination site haemorrhage	1	2		1	1	1
Vaccination site hyperaesthesia		1		1		
Vaccination site hypersensitivity		1		1		
Vaccination site induration	1	3	1	3		
Vaccination site inflammation	1	2	1	2		
Vaccination site nodule	1	3	1	3		
Vaccination site oedema	3	4	3	4		
Vaccination site pain	20	36	14	30	6	6
Vaccination site pruritus	2	4	1	3	1	1
Vaccination site rash	1	1	1	1		
Vaccination site reaction		3		3		
Vaccination site swelling	1	1	1	1		
Vaccination site warmth	1	1	1	1		
Varicophlebitis	1	1	1	1		
Vascular injury	1	1	1	1		
Vasculitis	1	1	1	1		
Vertigo	2	3	1	2	1	1
Vision blurred	2	2	2	2		
Vomiting	9	16	4	9	5	7
Wheezing	1	1			1	1
Wrong product administered		1		1		
Wrong technique in product usage process	1	4		3	1	1
	819	1,403	418	829	401	574

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	3		1	2	2
Acute myocardial infarction		1				1
Angina unstable	1	1			1	1
Anosmia	1	1	1	1		
Arthralgia	7	9	2	4	5	5
Asthenia	14	23	7	12	7	11
Bedridden	1	1			1	1
Blood pressure increased	2	2			2	2
Body temperature increased		1		1		
Bronchitis	1	1	1	1		
Bronchospasm	1	1			1	1
Cardio-respiratory arrest		1				1
Cerebrovascular accident		1				1
Chest pain	3	3	2	2	1	1
Chills	5	9	2	4	3	5
Contusion		1		1		
Cough	5	7	3	4	2	3
COVID-19	1	2		1	1	1
COVID-19 pneumonia		1				1
Decreased activity	1	1			1	1
Decreased appetite	3	3	2	2	1	1
Dehydration	1	1	1	1		
Diarrhoea	6	8	2	4	4	4
Disorientation	1	1	1	1		
Disseminated Bacillus Calmette-Guerin infection		2				2
Dizziness	4	6	2	3	2	3
Drug ineffective	1	1			1	1
Dysgeusia	1	1	1	1		
Dysphagia	1	1			1	1
Dyspnoea	8	10	4	6	4	4
Dyspnoea exertional	1	1	1	1		
Epistaxis		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	1	3	1	2		1
Eye irritation		1		1		
Eyelid oedema	1	1			1	1
Eye oedema	1	1			1	1
Fall		1				1
Fatigue	12	17	5	8	7	9
Febrile convulsion	1	1			1	1
Flushing	1	1	1	1		
Gait disturbance		1		1		
Guillain-Barre syndrome		2				2
Haematochezia		1				1
Haemorrhage		1				1
Headache	15	20	8	11	7	9
Hemiparaesthesia		1				1
Hyperhidrosis	1	1	1	1		
Hypertension	4	5	1	1	3	4
Hypertensive crisis	1	1			1	1
Hypertensive emergency	1	1			1	1
Hyperthermia	1	1	1	1		
Hypoglycaemia	1	1	1	1		
Hypotension	1	1			1	1
Hypovolaemic shock		1				1
Induration		1				1
Inflammation	4	4	1	1	3	3
Influenza	1	1	1	1		
Insomnia	1	2			1	2
Intussusception		1				1
Irritability	4	5	2	2	2	3
Lacrimation increased		1		1		
Lip oedema	1	1			1	1
Lymphadenopathy		1		1		
Malaise	1	1	1	1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mood altered	1	1			1	1
Muscular weakness		2		1		1
Myalgia	8	11	3	5	5	6
Myocardial infarction		1				1
Nausea	5	8	2	4	3	4
Nodule		1				1
Ocular hyperaemia		1		1		
Oedema	5	5	1	1	4	4
Oedema peripheral	1	1			1	1
Oropharyngeal pain	3	4	2	2	1	2
Oxygen saturation decreased	2	2			2	2
Pain	6	10	3	5	3	5
Pain in extremity	1	2	1	1		1
Palpitations		1		1		
Paraesthesia	1	3	1	2		1
Paraesthesia oral	1	1			1	1
Paralysis	2	2			2	2
Paraparesis		1				1
Pneumonia	2	3			2	3
Productive cough	1	1			1	1
Pruritus		2		2		
Pyrexia	9	13	4	6	5	7
Rash		3		3		
Rash macular		1		1		
Rash maculo-papular		1		1		
Respiratory distress	8	10			8	10
Rhinorrhoea	2	3	1	2	1	1
Sensitive skin	6	9	3	4	3	5
Skin mass		1		1		
Skin reaction		1				1
Sleep disorder	1	1			1	1
Somnolence		1		1		

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* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling		1		1		
Tachycardia	5	5	1	1	4	4
Tachypnoea	1	1			1	1
Urticaria		2		1		1
Vaccination site erythema	1	2	1	2		
Vaccination site oedema	1	1	1	1		
Vaccination site pain	2	5	2	4		1
Vaccination site warmth	1	1	1	1		
Varicose vein	1	1			1	1
Vertigo	1	1			1	1
Vision blurred	2	2	1	1	1	1
Vomiting	4	7	1	2	3	5
	210	324	85	144	125	180

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain	1	2	1	2		
Acne		1		1		
Allergy to vaccine		3		3		
Amnesia	1	1	1	1		
Anaesthesia	1	1			1	1
Anaphylactic reaction		1				1
Anaphylactoid reaction		1				1
Anosmia		1		1		
Antibody test abnormal		2		2		
Antibody test negative		2		2		
Anxiety		1		1		
Arrhythmia		1				1
Arthralgia	1	7	1	7		
Asthenia	2	7	2	6		1
Back pain	2	3	2	3		
Blister		1				1
Blood pressure decreased		1				1
Blood pressure increased		2		1		1
Body temperature increased		1		1		
Bone pain		1		1		
Bradycardia		1				1
Bradykinesia	1	1			1	1
Bronchospasm		1				1
Burning sensation	1	2	1	2		
Burn oral cavity		1				1
Cerebral infarction		1				1
Cerebral ischaemia		1				1
Cerebrovascular accident		1				1
Chest pain		2		1		1
Chills	3	4	3	4		
Choking		1				1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Choking sensation		1				1
Conjunctivitis	1	1	1	1		
Cough		2		1		1
Counterfeit product administered		2		2		
COVID-19	6	19	1	4	5	15
COVID-19 pneumonia		1				1
Crying		1		1		
Cyanosis		1		1		
Decreased appetite		1		1		
Dermatitis allergic		1		1		
Diarrhoea	1	6	1	5		1
Discomfort		4		3		1
Dizziness	3	7	2	6	1	1
Drug hypersensitivity		1				1
Drug ineffective	5	14			5	14
Dysarthria	1	1			1	1
Dysphagia	1	1			1	1
Dysphonia		1				1
Dyspnoea		2		1		1
Epilepsy		1				1
Epistaxis		2		1		1
Eructation	1	1	1	1		
Erythema		3		3		
Exposure during pregnancy	1	2	1	2		
Eye haemorrhage	1	1			1	1
Eye irritation		1		1		
Eye swelling		1		1		
Facial paralysis		1				1
Fatigue	4	9	4	9		
Feeling abnormal		1		1		
Feeling cold	1	1	1	1		
Feeling of despair		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gait disturbance	1	2	1	2		
Gastritis		2		2		
Generalised oedema	1	1	1	1		
General physical health deterioration	1	1	1	1		
Genital tract inflammation		1		1		
Gingival bleeding		1		1		
Granuloma	1	1	1	1		
Guillain-Barre syndrome	1	1			1	1
Headache	3	13	2	10	1	3
Heart rate decreased		1		1		
Hemiparesis		1				1
Herpes zoster		1		1		
Hunger		1		1		
Hyperglycaemia		2		2		
Hyperhidrosis	1	2	1	1		1
Hypersensitivity	1	4		3	1	1
Hypoacusis	1	1	1	1		
Hypoaesthesia	1	4	1	4		
Hypoaesthesia oral	1	1	1	1		
Hypokinesia	2	2	1	1	1	1
Hypotension	1	1	1	1		
Illness	1	1	1	1		
Immunology test abnormal		1		1		
Inappropriate schedule of product administration	1	7	1	7		
Infarction	1	1			1	1
Influenza like illness	1	1	1	1		
Initial insomnia	1	1	1	1		
Joint range of motion decreased	1	1	1	1		
Laryngospasm		1		1		
Laziness		1		1		
Limb discomfort	1	1	1	1		
Localised oedema	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenitis		1		1		
Lymphadenopathy		6		5		1
Lymph node pain		1		1		
Malaise	2	7	2	6		1
Maternal exposure during pregnancy		7		7		
Measles		1				1
Melaena		1				1
Monoparesis		1				1
Mouth swelling		1				1
Muscle rigidity	1	1	1	1		
Muscle spasms		1		1		
Muscular weakness	4	4	3	3	1	1
Musculoskeletal stiffness		1		1		
Mutism	1	1			1	1
Myalgia	3	5	3	5		
Nasal congestion		1		1		
Nasopharyngitis	1	1	1	1		
Nausea	1	5	1	5		
Neck pain	1	2	1	2		
Nervousness		1		1		
Neutrophil count increased		2		2		
Night sweats		1				1
Noninfective gingivitis		1		1		
Obstructive airways disorder	1	1			1	1
Ocular discomfort		1		1		
Off label use		4		4		
Oral candidiasis		1		1		
Oropharyngeal pain	1	2	1	2		
Overdose		1		1		
Oxygen saturation decreased		1				1
Pain	2	10	2	10		
Pain in extremity	6	11	6	11		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in jaw	1	1			1	1
Palate injury		1		1		
Paraesthesia	1	7		5	1	2
Parotitis		1		1		
Peripheral swelling	1	1	1	1		
Pharyngeal oedema	1	2	1	1		1
Pharyngeal ulceration		1		1		
Platelet count increased		2		2		
Pneumonia		3				3
Poor quality product administered	1	2	1	2		
Presyncope	1	1	1	1		
Product colour issue		1		1		
Product complaint		1		1		
Product use issue		2		2		
Pruritus	1	2	1	2		
Purpura	1	1	1	1		
Pyelonephritis		1				1
Pyrexia	3	13	3	12		1
Rash		4		2		2
Rash macular		1		1		
Respiratory distress	1	3			1	3
Rhinitis		1		1		
Rhinorrhoea	1	2	1	2		
SARS-CoV-2 ant body test negative	1	1	1	1		
SARS-CoV-2 test positive	1	2	1	2		
Seizure		2				2
Skin discolouration		1		1		
Skin mass	1	1	1	1		
Somnolence		2		2		
Speech disorder	2	2	1	1	1	1
Stasis dermatitis		1		1		
Stress		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stridor	1	1	1	1		
Suffocation feeling	1	2	1	2		
Suspected counterfeit product	1	3	1	3		
Suspected COVID-19		2				2
Swelling		2		2		
Swelling face	1	1	1	1		
Synovial cyst		1		1		
Tachycardia	1	4	1	3		1
Therapeutic response unexpected	2	2	2	2		
Thermal burn		1				1
Throat tightness		1				1
Thrombosis	1	3			1	3
Toxic epidermal necrolysis		1				1
Toxicity to various agents		1				1
Transaminases increased		1				1
Urinary incontinence	1	1	1	1		
Urticaria	1	2	1	2		
Vaccination site discolouration	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site pain	4	13	4	13		
Vaccination site rash		1		1		
Vaccination site swelling		1		1		
Vertigo		1		1		
Vomiting		2		2		
Wrong product administered	1	2	1	2		
	122	413	93	304	29	109

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

MONACO

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19		1		1
Drug ineffective		1		1
Speech disorder		1		1
		3		3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

NETHERLANDS

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposure via breast milk		1		1
Listless		1		1
Muscular weakness		1		1
Pyrexia		1		1
		4		4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		3		3		
Abdominal pain	4	7	4	7		
Abdominal pain upper	2	6	2	6		
Abnormal dreams		1		1		
Abnormal loss of weight		1		1		
Abortion missed		1				1
Abortion spontaneous	2	6			2	6
Affect lability	1	2	1	2		
Ageusia		1		1		
Agitation	1	1	1	1		
Allergy to vaccine		2		1		1
Anal sphincter hypertonia		1		1		
Anaphylactic reaction		3				3
Angioedema		1				1
Anosmia		1		1		
Anxiety		1		1		
Aphasia		1		1		
Arthralgia	37	185	37	185		
Asthenia	1	3	1	3		
Axillary pain	2	7	2	7		
Back pain		2		2		
Balance disorder		1		1		
Bell's palsy		1				1
Blindness		1				1
Blindness unilateral		1				1
Blister		2		2		
Blood pressure increased		2		2		
Blood pressure systolic increased		1		1		
Body temperature increased	6	42	6	42		
Burning sensation		1		1		
Cardiac discomfort		1		1		
Cerebral venous sinus thrombosis	1	2			1	2

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* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest discomfort	1	7	1	5		2
Chest pain	1	11	1	11		
Chillblains		1		1		
Chills	51	295	51	293		2
Cold sweat	1	1	1	1		
Constipation		1		1		
Contusion	1	2	1	2		
Cough	1	3	1	3		
COVID-19	2	6	2	2		4
Cyanosis		1				1
Dacryocystitis		1				1
Dark circles under eyes		1		1		
Decreased appetite	2	3	2	3		
Decreased interest	1	1	1	1		
Deep vein thrombosis	1	1			1	1
Delirium febrile		1				1
Depressed level of consciousness		1				1
Dermatitis bullous		1				1
Diarrhoea	3	13	3	13		
Diplopia		1		1		
Discomfort		1		1		
Disturbance in attention		1		1		
Dizziness	7	44	7	40		4
Drug ineffective		4				4
Dry eye		1		1		
Dry mouth		1		1		
Dysarthria		1		1		
Dysgeusia		2		2		
Dyspepsia	1	2	1	2		
Dysphagia		3		2		1
Dyspnoea	2	16	2	14		2
Dyspnoea at rest		2				2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea exertional		1		1		
Ear discomfort		1		1		
Ear pain		1		1		
Emotional distress		1		1		
Encephalitis autoimmune		1				1
Endocrine ophthalmopathy		1				1
Epilepsy	1	7			1	7
Epistaxis		1		1		
Erectile dysfunction	1	1			1	1
Erythema	2	7	2	7		
Exposure during pregnancy	1	2		1	1	1
Extensive swelling of vaccinated limb	1	67	1	67		
Extrasystoles	1	1	1	1		
Eye pruritus		1		1		
Eye swelling	1	2	1	2		
Eye symptom		1		1		
Facial paralysis		1				1
Facial paresis		1		1		
Faeces discoloured		2		2		
Fatigue	96	438	96	437		1
Feeling abnormal	4	6	4	6		
Feeling hot		4		4		
Feeling jittery		1		1		
Feeling of body temperature change		1		1		
Flushing	1	2	1	2		
Frequent bowel movements		1		1		
Gait disturbance		2		2		
Gastroenteritis viral		1		1		
Gastrointestinal pain	1	1	1	1		
Generalised tonic-clonic seizure		4				4
Genital paraesthesia		1		1		
Gingival bleeding	1	1	1	1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Glossitis	1	1	1	1		
Haematocrit decreased		1		1		
Haemoglobin decreased		1		1		
Haemorrhage		1				1
Hallucination	1	1			1	1
Halo vision		1		1		
Headache	101	477	101	474		3
Head discomfort		2		1		1
Heart rate increased	1	3	1	3		
Hemianaesthesia		1				1
Hepatic failure		1				1
Hepatitis acute		1				1
Herpes zoster	3	4	3	4		
Hidradenitis		1		1		
Hot flush		1		1		
Hyperaesthesia teeth		1		1		
Hyperchlorhydria		1		1		
Hyperhidrosis	3	13	3	12		1
Hyperpyrexia	3	21			3	21
Hypersensitivity	2	10	2	5		5
Hypertension		8		7		1
Hyperventilation		3		1		2
Hypoacusis		1		1		
Hypoaesthesia		2		2		
Hypoaesthesia oral		1				1
Hyponatraemia		1		1		
Hypotension	3	4	3	3		1
Hypoxia		1				1
Injected limb mobility decreased		1		1		
Injection site discomfort		1		1		
Injection site inflammation	1	1	1	1		
Injection site pain		1		1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site swelling		1		1		
Injection site warmth	1	1	1	1		
Insomnia	1	3	1	3		
Intermenstrual bleeding	1	1	1	1		
Intracranial pressure increased	1	1			1	1
Irritable bowel syndrome	1	1	1	1		
Laryngitis		1		1		
Limb discomfort		2		2		
Lip swelling		1		1		
Listless		1		1		
Loss of consciousness		6				6
Lung disorder		1		1		
Lymphadenitis		1		1		
Lymphadenopathy	9	39	9	39		
Malaise	82	434	82	429		5
Maternal exposure during pregnancy		1		1		
Menstruation irregular	1	1	1	1		
Migraine	1	3	1	2		1
Muscle spasms	1	3		2	1	1
Muscle strain		1		1		
Muscle twitching	1	2	1	2		
Muscular weakness		2		1		1
Musculoskeletal chest pain		1		1		
Musculoskeletal pain	2	11	2	11		
Musculoskeletal stiffness	1	2	1	2		
Myalgia	126	525	126	525		
Myoclonus		1		1		
Nasal congestion	1	1	1	1		
Nasopharyngitis	1	6	1	6		
Nausea	45	247	45	244		3
Nephrolithiasis		3				3
Nightmare		1		1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Night sweats	1	2	1	2		
Nystagmus		1		1		
Ocular discomfort		1		1		
Ocular hyperaemia	1	1	1	1		
Odynophagia		1		1		
Oedema peripheral	1	1	1	1		
Oral herpes	1	1	1	1		
Oropharyngeal pain	4	9	4	9		
Oxygen saturation abnormal		1		1		
Pain	3	10	3	10		
Painful respiration		1		1		
Pain in extremity	1	15	1	15		
Pain of skin		4		4		
Palatal disorder	1	1	1	1		
Pallor		2		1		1
Palpitations	4	13	4	10		3
Papilloedema	1	1			1	1
Paraesthesia	5	10	5	10		
Paraesthesia oral		1		1		
Pelvic pain		1		1		
Periorbital discomfort	1	1	1	1		
Peripheral coldness	1	1	1	1		
Peripheral swelling	2	2	2	2		
Petechiae		1		1		
Pharyngeal paraesthesia		1				1
Pharyngeal swelling		3		1		2
Pharyngitis	1	1	1	1		
Photophobia		2		2		
Pityriasis rosea		1		1		
Pneumonia		2				2
Pollakiuria		1		1		
Presyncope		5		4		1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pruritus	4	13	4	13		
Pupillary disorder		1		1		
Pyrexia	34	201	33	195	1	6
Rash	1	8	1	7		1
Rash erythematous	2	3	2	3		
Rash papular	1	1	1	1		
Rash pruritic	2	2	2	2		
Renal impairment		1				1
Respiratory tract irritation		1		1		
Restless legs syndrome	1	1	1	1		
Restlessness	1	2	1	2		
Rheumatic disorder		1		1		
Seizure		2				2
Sensation of blood flow	1	1	1	1		
Sensation of foreign body	1	2	1	2		
Sinus tachycardia		1		1		
Skin discolouration		1		1		
Skin discomfort		1		1		
Skin exfoliation	1	1	1	1		
Skin induration		1		1		
Speech disorder		1		1		
Status epilepticus		2				2
Stomatitis	1	1	1	1		
Swelling		4		4		
Swelling face		3		2		1
Swelling of eyelid		3		3		
Swollen tongue		1		1		
Syncope	4	23			4	23
Tachycardia		3		2		1
Tachypnoea		1		1		
Tendonitis	1	1	1	1		
Thirst		1		1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Throat tightness		1				1
Thrombocytopenia		1				1
Tinnitus		1		1		
Tonsillitis	1	1	1	1		
Torticollis		1		1		
Tremor		2		2		
Urinary retention		2				2
Urinary tract infection		1		1		
Urticaria	1	10	1	6		4
Uvulitis		1		1		
Vaccination site bruising	3	21	3	21		
Vaccination site coldness		1		1		
Vaccination site discomfort	1	3	1	3		
Vaccination site erythema	25	126	25	126		
Vaccination site haematoma	14	43	14	43		
Vaccination site induration	3	9	3	9		
Vaccination site inflammation	46	151	46	151		
Vaccination site pain	78	322	78	322		
Vaccination site pruritus	10	52	10	52		
Vaccination site rash		1		1		
Vaccination site reaction		1		1		
Vaccination site swelling	38	162	38	162		
Vaccination site warmth	29	162	29	162		
Vasculitis		1		1		
Vertigo	1	6	1	6		
Vision blurred	1	6	1	6		
Visual impairment		3		2		1
Vomiting	3	12	3	12		
Wound		1		1		
	975	4,648	956	4467	19	181

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	1	4			1	4		
Abdominal pain	3	8			3	8		
Abdominal pain upper		7				7		
Abnormal behaviour	1	1					1	1
Abnormal dreams		1				1		
Abortion missed		1						1
Abortion spontaneous		5						5
Accommodation disorder		2				2		
Acute myocardial infarction		1						1
Ageusia		4				4		
Allergy to vaccine				1				
Allodynia	1	1			1	1		
Anaphylactic reaction		7						7
Anaphylactic shock		2						2
Anembryonic gestation		1						1
Angina pectoris		1						1
Angina unstable		1						1
Angioedema		6						6
Anosmia		3				3		
Anxiety	3	5			3	5		
Aphonia		1						1
Appendicitis		1						1
Arrhythmia		7						7
Arthralgia	37	312			37	311		1
Asthenia		3				3		
Asthma		1						1
Ataxia		1						1
Atrial f brillation	1	1					1	1
Autonomic nervous system imbalance		1						1
Axillary pain	3	13			3	13		
Back pain	2	5			2	5		
Balance disorder	1	3			1	2		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bell's palsy	1	2
Blood glucose decreased		2
Blood pressure decreased		2
Blood pressure fluctuation	1	1
Blood pressure increased		1
Body temperature increased	4	57
Bradycardia		1
Bronchospasm		1
Bundle branch block right		1
Burning sensation	1	1
Catatonia		1
Cerebellar infarction		1
Cerebellar ischaemia		1
Chest discomfort	2	7
Chest pain	2	16
Chillblains		1
Chills	73	453
Choking sensation		1
Cholecystitis		1
Cold sweat		4
Condition aggravated		1
Confusional state		2
Conjunctival haemorrhage		1
Contusion	1	1
Conversion disorder		1
Coordination abnormal		1
Cough	2	11
COVID-19	7	7
Cyanosis		1
Cystitis		1
Deafness	1	1
Deafness neurosensory		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
			2		
			1		1
			1	1	1
			1		
		4	56		1
					1
					1
			1		
		1	1		
					1
					1
					1
		1	6	1	1
		2	14		2
			1		
		71	450	2	3
					1
					1
			4		
					1
			1		1
					1
				1	1
					1
			1		
		2	9		2
		2	2	5	5
			1		
			1		
				1	1
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Deafness unilateral	1	1
Death		1
Decreased appetite	1	1
Deep vein thrombosis	1	1
Defaecation urgency	1	1
Delirium		1
Depressed level of consciousness		1
Depressed mood		1
Depression		2
Derealisation		1
Dermatitis bullous		1
Diaphragmalgia		1
Diarrhoea	5	29
Diplopia		1
Discomfort		1
Disease recurrence		1
Disturbance in attention		3
Diverticulitis	1	1
Dizziness	14	68
Drug ineffective	2	2
Dry eye		2
Dysarthria		2
Dysgeusia	1	11
Dysmenorrhoea	1	2
Dyspepsia		1
Dysphagia	4	6
Dyspnoea	9	44
Dyspnoea exertional		4
Ear pain	1	2
Eczema		2
Electric shock sensation		1
Epilepsy		7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
		1	1		
				1	1
		1	1		
					1
					1
			1		
			2		
			1		
					1
			1		
		5	29		
			1		
					1
					1
			3		
				1	1
		13	67	1	1
				2	2
			2		
			1		1
		1	11		
		1	2		
			1		
		4	5		1
	1	7	36	2	8
			2		2
		1	2		
			2		
			1		
					7

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Epistaxis		2
Eructation	1	1
Erysipelas		2
Erythema	4	20
Exposure during pregnancy		1
Extensive swelling of vaccinated limb	1	119
Extrasystoles		1
Eye disorder		1
Eye irritation	1	1
Eyelid ptosis		1
Eye pain	1	3
Eye pruritus		2
Eye swelling	1	3
Facial neuralgia	1	2
Facial pain		1
Facial paralysis		1
Facial paresis		1
Fall		1
Fatigue	119	628
Feeling abnormal		4
Feeling cold		6
Feeling drunk		2
Feeling hot	4	12
Feeling jittery		1
Fluid retention		1
Flushing	1	1
Food allergy		1
Gait disturbance	2	5
Gait inability		1
Gastric pH decreased		1
Generalised tonic-clonic seizure		2
Glossodynia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		1	1		
					2
		4	19		1
			1		
		1	118		1
			1		
			1		
		1	1		
			1		
		1	3		
			2		
		1	3		
		1	2		
			1		
					1
			1		
		119	626		2
			3		1
			5		1
			2		
		4	12		
			1		
			1		
		1	1		
			1		
		1	3	1	2
			1		
			1		
					2
			1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haemoptysis		1
Hallucination		1
Hallucination, olfactory	2	2
Hangover		1
Headache	132	696
Head discomfort		2
Heart rate decreased	2	2
Heart rate increased	4	7
Heavy menstrual bleeding	1	1
Hemiplegia		1
Hepatic pain		1
Hepatitis		1
Hepatitis cholestatic		1
Herpes simplex		1
Herpes zoster	5	7
Herpes zoster reactivation	1	1
Hot flush		2
Hyperhidrosis	2	7
Hyperpyrexia	5	34
Hypersensitivity	4	9
Hypersomnia		1
Hypertension	3	9
Hyperventilation		2
Hypoaesthesia	3	6
Hypoaesthesia oral		2
Hypoglycaemia		1
Hypotension	1	5
Ill-defined disorder		1
Inappropriate schedule of product administration	1	4
Incorrect route of product administration		1
Increased tendency to bruise		1
Increased upper airway secretion		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
				2	2
			1		
		132	692		4
			2		
		2	2		
		3	5	1	2
		1	1		
					1
			1		
					1
					1
			1		
		5	7		
		1	1		
			2		
		2	7		
				5	34
		3	7	1	2
			1		
		2	7	1	2
			2		
		1	3	2	3
			2		
			1		
		1	4		1
					1
		1	4		
			1		
			1		
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Influenza like illness	1	1
Injected limb mobility decreased	1	7
Injection site erythema		3
Injection site induration		1
Injection site inflammation		5
Injection site pain		8
Injection site pruritus		2
Injection site swelling		4
Injection site warmth		5
Insomnia		3
Intermenstrual bleeding	1	1
Intracranial pressure increased		1
Jaundice		1
Lacrimation increased		1
Limb discomfort		4
Lip swelling	2	3
Loss of consciousness	1	7
Loss of control of legs		1
Loss of personal independence in daily activities		1
Lung disorder		1
Lymphadenitis	1	1
Lymphadenopathy	15	79
Lymphangitis		2
Lymph node pain	1	5
Malaise	112	629
Maternal exposure during pregnancy		3
Memory impairment		1
Meniere's disease		1
Menstrual disorder	4	4
Menstruation delayed	1	1
Menstruation irregular	2	2
Mental disorder	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	7		
			3		
			1		
			5		
			8		
			2		
			4		
			5		
			3		
		1	1		
					1
					1
			1		
			3		1
		1	2	1	1
				1	7
					1
			1		
			1		
		1	1		
		15	79		
					2
		1	5		
		111	621	1	8
			2		1
			1		
					1
		4	4		
		1	1		
		2	2		
		1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mental impairment		1
Migraine	2	4
Multiple sclerosis		2
Muscle contractions involuntary		1
Muscle disorder		1
Muscle rigidity		1
Muscle spasms		2
Muscle strain		2
Muscle tightness		1
Muscular weakness		1
Musculoskeletal discomfort		2
Musculoskeletal pain	2	9
Musculoskeletal stiffness	3	8
Myalgia	136	692
Myelitis transverse	1	1
Nasal congestion	1	2
Nasal discomfort		1
Nasal dryness		1
Nasal inflammation		1
Nasopharyngitis	1	8
Nausea	53	290
Neck pain	3	4
Neuralgia		2
Neuropathy peripheral	1	2
Night sweats	2	2
Nodule		1
Ocular discomfort	1	1
Ocular hyperaemia		1
Oedema		1
Oedema peripheral	1	2
Off label use	1	4
Optic neuritis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		2	4		
					2
			1		
			1		
			1		
			2		
			2		
			1		
			1		
			2		
		2	9		
		3	8		
		136	689		3
				1	1
		1	2		
			1		
			1		
		1	8		
		53	288		2
		3	4		
			2		
				1	2
		2	2		
			1		
		1	1		
			1		
			1		
			1	1	1
		1	4		
					1

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral mucosal blistering		2
Oral pruritus	1	1
Oropharyngeal discomfort	1	3
Oropharyngeal pain	4	19
Oxygen saturation decreased		1
Pain	2	17
Painful respiration		1
Pain in extremity	10	48
Pain in jaw	1	6
Pain of skin	1	2
Pallor	2	6
Palpitations	3	20
Paraesthesia	11	32
Paraesthesia oral	4	17
Parosmia		2
Pericarditis		1
Periorbital swelling		1
Peripheral coldness		1
Peripheral swelling		5
Petechiae		1
Pharyngeal oedema		1
Pharyngeal paraesthesia		1
Pharyngeal swelling	2	8
Pituitary apoplexy		1
Pneumonia	1	3
Pneumonia aspiration		1
Polyuria		1
Presyncope		7
Pruritus	4	15
Psoriasis	1	1
Psychotic symptom		2
Pulmonary embolism		5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		1	1		
			2	1	1
		4	19		
			1		
		2	17		
			1		
		10	47		1
		1	6		
		1	2		
		2	5		1
		1	16	2	4
		8	28	3	4
		4	16		1
			2		
					1
			1		
			1		
			5		
			1		
					1
					1
		1	5	1	3
					1
				1	3
					1
			1		
			6		1
	1	3	14	1	1
		1	1		
					2
					5

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pulmonary pain		1
Pyrexia	50	304
Rash	5	18
Rash erythematous	1	5
Rash macular	2	2
Rash papular		3
Rash pruritic	3	4
Raynaud's phenomenon		1
Renal disorder		1
Respiratory disorder		1
Respiratory rate increased		1
Respiratory tract oedema		1
Restlessness	1	2
Retching		1
Rheumatoid arthritis		1
Rhinorrhoea	1	5
Salivary gland pain		1
Salivary hypersecretion	1	1
SARS-CoV-2 test positive	1	1
Sciatica		1
Sensation of foreign body		3
Sensory disturbance	1	1
Sinus tachycardia		2
Skin burning sensation		1
Skin discolouration	1	2
Skin irritation	2	2
Sneezing		2
Somnolence	1	3
Speech disorder		1
Staphylococcal infection	1	1
Stridor		2
Sudden hearing loss	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		45	294	5	10
	1	5	16		2
		1	5		
		2	2		
			3		
		3	4		
			1		
			1		
			1		
					1
					1
		1	2		
			1		
					1
		1	5		
			1		
		1	1		
		1	1		
					1
			1		2
		1	1		
			1		1
			1		
		1	2		
		2	2		
			2		
		1	3		
					1
				1	1
			1		1
				1	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Swelling		6
Swelling face	1	5
Swelling of eyelid	1	2
Swollen tongue	1	8
Syncope	2	22
Tachycardia	3	7
Taste disorder	1	4
Tendonitis		1
Throat irritation	1	2
Throat tightness	2	4
Thrombophlebitis		1
Thrombosis	1	4
Tinnitus	1	5
Tongue discolouration		1
Tongue discomfort		1
Tongue disorder		3
Tongue oedema		1
Tonsillitis	1	1
Toothache	1	1
Transient ischaemic attack		4
Tremor	2	11
Trismus	1	1
Urticaria	6	10
Vaccination failure	3	3
Vaccination site bruising	1	14
Vaccination site discomfort	3	9
Vaccination site erythema	38	208
Vaccination site haematoma	9	39
Vaccination site haemorrhage		1
Vaccination site induration	5	19
Vaccination site inflammation	63	235
Vaccination site irritation	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			6		
			3	1	2
		1	2		
			4	1	4
				2	22
		3	6		1
		1	4		
			1		
		1	2		
		1	3	1	1
			1		
				1	4
1	2	1	4		1
			1		
			1		
			2		1
					1
		1	1		
		1	1		
					4
		2	11		
		1	1		
		5	9	1	1
				3	3
		1	14		
		3	9		
		38	207		1
		8	38	1	1
			1		
		5	19		
		63	235		
		1	1		

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site movement impairment		1				1		
Vaccination site pain	121	557			120	555	1	2
Vaccination site paraesthesia		2				2		
Vaccination site pruritus	19	79			19	79		
Vaccination site rash		1				1		
Vaccination site reaction		3				3		
Vaccination site swelling	43	267			43	266		1
Vaccination site urticaria		1				1		
Vaccination site warmth	47	240			47	240		
Vertigo	1	7			1	5		2
Vertigo positional		1				1		
Vestibular neuronitis		1						1
Vision blurred	1	9			1	9		
Visual acuity reduced		1				1		
Visual impairment		2				2		
Vomiting	1	16			1	14		2
Wound infection		1						1
		1				1		
	1,344	7,113	1	6	1275	6789	69	324

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	1	5			1	5		
Abdominal distension		1				1		
Abdominal pain	1	4			1	4		
Abdominal pain lower		1				1		
Affect lability		1				1		
Ageusia		2				2		
Agitation		1				1		
Alanine aminotransferase increased		1				1		
Allodynia		1				1		
Anaphylactic reaction	2	5					2	5
Anaphylactic shock	1	2					1	2
Angina pectoris		2						2
Angioedema	2	5					2	5
Ankylosing spondylitis	1	1					1	1
Anosmia	1	2			1	2		
Anxiety	1	5				3	1	2
Apathy		1				1		
Aphasia		2						2
Aphonia	1	1			1	1		
Aphthous ulcer		1				1		
Arrhythmia	2	3					2	3
Arthralgia	39	199			39	199		
Aspartate aminotransferase increased		1				1		
Asthenia	1	3			1	3		
Asthma		2				1		1
Ataxia		1						1
Atrial f brillation	1	5					1	5
Auricular swelling		1				1		
Autonomic nervous system imbalance		1						1
Axillary pain	2	7			2	7		
Back pain	2	3			2	3		
Balance disorder		2				2		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bell's palsy	1	1
Blindness		1
Blindness unilateral		1
Blood alkaline phosphatase increased		1
Blood bilirubin increased		1
Blood creatine phosphokinase increased		1
Blood glucose fluctuation		3
Blood glucose increased		3
Blood pressure decreased	1	1
Blood pressure increased		1
Body temperature decreased	1	1
Body temperature increased	7	27
Bradykinesia		1
Bradyphrenia		2
Breast disorder female		1
Bronchospasm	1	1
Burning sensation		3
Bursitis		1
Cardiac failure	1	1
Catatonia		1
Cerebral infarction	1	2
Cerebrovascular accident		2
Cervical radiculopathy		1
Chest discomfort	1	7
Chest pain	1	5
Chills	68	317
Choking sensation		1
Cognitive disorder		1
Cold sweat		1
Colitis ulcerative	1	1
Condition aggravated		1
Conjunctival haemorrhage		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
					1
			1		
			1		
			1		
			3		
			3		
		1	1		
					1
		1	1		
		7	27		
			1		
			1		1
			1		
				1	1
			3		
			1		
				1	1
			1		
				1	2
					2
			1		
		1	6		1
		1	5		
		68	316		1
					1
			1		
			1		
				1	1
			1		
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Contusion		1
Coordination abnormal		2
Cough	2	11
COVID-19	5	7
C-reactive protein increased		2
Crying	1	2
Cystitis		1
Dandruff		1
Deafness unilateral		1
Decreased appetite	2	7
Decreased immune responsiveness		1
Deep vein thrombosis		3
Defaecation urgency	1	1
Delirium		1
Depressed level of consciousness		2
Depressed mood		3
Derealisation		1
Dermatitis		1
Diabetes mellitus inadequate control		1
Diarrhoea	5	14
Diplopia		1
Discomfort		1
Disease recurrence	1	2
Disorganised speech		1
Disturbance in attention		1
Dizziness	11	42
Drug hypersensitivity	1	1
Drug ineffective	1	1
Drug interaction	1	1
Dry eye		1
Dry mouth		2
Dry skin	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		1
		2	11		
		3	5	2	2
			2		
		1	2		
			1		
			1		
					1
		2	7		
					1
					3
		1	1		
					1
1	1				2
			3		
			1		
			1		
					1
		5	14		
			1		
			1		
				1	2
			1		
			1		
		11	41		1
				1	1
				1	1
				1	1
			1		
			2		
		1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysgeusia	1	11
Dysphagia		2
Dysphonia	2	3
Dyspnoea	5	24
Dyspnoea at rest	1	1
Dyspnoea exertional	1	1
Ear discomfort		2
Ear pain	1	3
Ecchymosis		1
Eczema	1	2
Electrocardiogram ST segment abnormal		1
Epilepsy		7
Episcleritis		1
Erectile dysfunction		1
Erysipelas		1
Erythema	4	13
Extensive swelling of vaccinated limb		70
Eye inflammation	1	1
Eye irritation	2	3
Eye pain		2
Eye pruritus	1	2
Eye swelling		3
Facial pain		2
Facial paralysis		1
Fall	1	3
Fatigue	84	381
Fear		1
Febrile convulsion		1
Feeling abnormal	2	8
Feeling cold	2	2
Feeling hot		4
Feeling jittery		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	11		
					2
				2	3
		4	20	1	4
				1	1
		1	1		
			2		
		1	3		
			1		
		1	2		
					1
					7
			1		
					1
					1
		3	10	1	3
			70		
		1	1		
		2	3		
			1		1
		1	2		
			2		1
			2		
					1
		1	3		
		84	378		3
			1		
			1		
		2	8		
		2	2		
			4		
			2		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Flushing		2
Food allergy	1	1
Gait disturbance		1
Gamma-glutamyltransferase increased		1
General physical health deterioration		1
Genital discomfort	1	1
Gingival pain		1
Glomerulonephritis minimal lesion		1
Glossodynia	2	2
Guillain-Barre syndrome	1	1
Haematochezia		1
Haematoma		2
Headache	114	446
Head discomfort		1
Heart rate increased	2	4
Hepatitis	1	1
Herpes ophthalmic		2
Herpes zoster	20	23
Hot flush		1
Hunger		1
Hyperacusis		1
Hyperaesthesia		1
Hyperhidrosis	2	8
Hyperpyrexia	2	22
Hypersensitivity	2	9
Hypersomnia		1
Hypertension	3	6
Hyperthyroidism	2	2
Hypoaesthesia	1	7
Hypoaesthesia oral	1	2
Hypoaesthesia teeth	1	1
Hypoglycaemia	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
				1	1
			1		
			1		
					1
		1	1		
			1		
					1
		1	1	1	1
				1	1
					1
			2		
		114	443		3
			1		
		2	4		
				1	1
					2
		20	22		1
			1		
			1		
			1		
		2	8		
				2	22
		2	7		2
			1		
		1	3	2	3
				2	2
			6	1	1
		1	2		
				1	1
		1	2		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypotension	2	2
Hypothermia		3
Hypoxia		2
Immune system disorder		1
Inappropriate schedule of product administration	1	3
Incontinence	1	1
Inflammation		1
Influenza like illness		6
Ingrowing nail		1
Injected limb mobility decreased	1	2
Injection site erythema	1	1
Injection site haematoma	1	1
Injection site inflammation	1	1
Injection site pain	2	4
Injection site swelling		2
Injection site warmth		1
Insomnia	1	1
International normalised ratio increased	1	1
Ischaemic stroke		1
Jaundice		1
Joint stiffness		1
Joint swelling	1	1
Lacrimation increased		1
Left ventricular hypertrophy		1
Lethargy		1
Limb discomfort	2	6
Lip blister		1
Lip swelling		2
Listless	2	3
Loss of consciousness	1	8
Loss of personal independence in daily activities	1	1
Lymphadenopathy	6	31

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
					3
					2
					1
		1	3		
				1	1
			1		
			6		
			1		
		1	2		
		1	1		
		1	1		
		1	1		
		2	4		
			2		
			1		
		1	1		
		1	1		
					1
			1		
			1		
		1	1		
			1		
					1
			1		
		2	6		
			1		
			1		1
		2	3		
				1	8
		1	1		
		6	31		

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lymph node pain		2
Lymphoedema	1	1
Malaise	93	399
Memory impairment		1
Menstrual disorder	2	2
Menstruation delayed	1	1
Migraine	1	2
Mood altered		1
Mucosal dryness		1
Muscle contractions involuntary		1
Muscle discomfort	1	1
Muscle disorder	1	1
Muscle spasms	1	7
Muscle strain		3
Muscular weakness	5	8
Musculoskeletal chest pain	1	1
Musculoskeletal disorder		1
Musculoskeletal pain	2	3
Musculoskeletal stiffness		3
Myalgia	91	383
Nasal congestion	1	1
Nasopharyngitis	2	9
Nausea	47	210
Neck pain	1	5
Nephrotic syndrome		2
Neuralgia		2
Neuropathy peripheral	1	3
Neutrophil count increased		1
Night blindness		1
Ocular hyperaemia		1
Oedema		2
Off label use		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		1	1		
		92	395	1	4
			1		
		2	2		
		1	1		
		1	2		
			1		
			1		
			1		
		1	1		
		1	1		
		1	6		1
			3		
		5	7		1
		1	1		
			1		
		2	3		
			3		
		91	383		
		1	1		
		2	8		1
		47	210		
		1	5		
					2
			2		
				1	3
			1		
			1		
			2		
			2		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oliguria		1
Oophoritis		1
Ophthalmic herpes zoster		1
Oral herpes	1	3
Oral pain		1
Oral pruritus		1
Oropharyngeal pain	3	6
Oxygen saturation decreased	1	3
Pain	4	18
Pain in extremity	3	23
Pain of skin		1
Pallor	1	2
Palpitations	2	19
Paraesthesia	5	14
Paraesthesia ear		1
Paraesthesia oral	2	17
Parosmia	1	2
Pelvic pain		1
Pemphigoid		1
Periorbital oedema		1
Periorbital swelling		1
Peripheral coldness		3
Peripheral swelling		3
Peroneal nerve palsy		1
Pharyngeal swelling	1	4
Photophobia	1	1
Piloerection		1
Platelet count increased		1
Pneumonia	3	6
Pneumonia aspiration		1
Polymenorrhoea	1	1
Poor quality sleep	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
					1
		1	3		
			1		
					1
		3	6		
			1	1	2
		4	18		
		3	22		1
			1		
		1	2		
		1	17	1	2
		5	13		1
			1		
		1	15	1	2
		1	2		
			1		
					1
			1		
			3		
			3		
			1		
				1	4
		1	1		
			1		
			1		
				3	6
					1
		1	1		
		1	1		

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Postmenopausal haemorrhage		2
Presyncope	1	3
Productive cough	1	2
Pruritus	5	13
Psoriasis	1	1
Pulmonary embolism		3
Pulmonary infarction		1
Pulmonary pain		2
Puncture site pain		1
Pyrexia	65	265
Rash	3	8
Rash erythematous	1	4
Rash macular		1
Rash maculo-papular		1
Rash papular	1	1
Rash pruritic		2
Rash vesicular	1	1
Rectal haemorrhage		1
Renal failure		1
Renal neoplasm		1
Respiratory failure		1
Respiratory rate increased		1
Respiratory symptom	1	1
Respiratory tract infection viral		1
Respiratory tract irritation		1
Resting tremor		1
Restlessness		1
Retinal detachment		1
Rheumatoid arthritis	2	2
Rhinitis		2
Rhinorrhoea	1	3
Right ventricular failure		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		1	3		
		1	2		
		4	10	1	3
		1	1		
					3
					1
			2		
			1		
		63	257	2	8
		3	7		1
		1	4		
			1		
			1		
		1	1		
			2		
		1	1		
					1
					1
					1
					1
		1	1		
					1
			1		
			1		
					1
				2	2
			2		
		1	3		
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
SARS-CoV-2 ant body test positive		1
Seizure		2
Sensation of foreign body		1
Sensitive skin		3
Sialoadenitis		2
Sinus bradycardia		1
Skin burning sensation		2
Skin discolouration		2
Skin irritation	1	2
Sneezing	1	3
Somnolence		4
Sputum increased		1
Stomatitis		1
Stridor	2	3
Sudden hearing loss		2
Supraventricular tachycardia		1
Swelling	2	5
Swelling face	1	7
Swelling of eyelid		2
Swollen tongue	1	2
Syncope	3	21
Tachycardia	1	6
Taste disorder		2
Thirst		1
Throat tightness		3
Thrombosis		1
Thunderclap headache		1
Tinnitus		2
Tongue discomfort		1
Tongue disorder	1	1
Tongue erythema	1	1
Transient ischaemic attack		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					2
			1		
			3		
					2
					1
			2		
			2		
		1	2		
		1	3		
			4		
			1		
			1		
				2	3
					2
					1
		2	5		
		1	6		1
			2		
				1	2
				3	21
			4	1	2
			2		
			1		
			2		1
					1
			2		
			1		
				1	1
		1	1		
					3

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tremor		1
Trichodynia	1	1
Trigeminal nerve disorder		1
Type 1 diabetes mellitus		1
Underweight		1
Unresponsive to stimuli		2
Urinary incontinence	1	1
Urinary tract infection		1
Urine output decreased		1
Urticaria		2
Vaccination failure	1	1
Vaccination site bruising		3
Vaccination site discolouration		1
Vaccination site discomfort		2
Vaccination site erythema	17	120
Vaccination site haematoma	4	21
Vaccination site induration		8
Vaccination site inflammation	36	127
Vaccination site lymphadenopathy	1	1
Vaccination site pain	74	320
Vaccination site papule		1
Vaccination site pruritus	8	44
Vaccination site rash		1
Vaccination site reaction		2
Vaccination site swelling	24	140
Vaccination site warmth	26	137
Vertigo		5
Vision blurred		2
Visual impairment		2
Vomiting	4	19
Vulvovaginal pain		1
Weight decreased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	1		
			1		
			1		1
			1		
					2
		1	1		
					1
			1		
			2		
				1	1
			3		
			1		
			2		
		17	120		
		4	21		
			8		
		36	127		
		1	1		
		73	319	1	1
			1		
		8	44		
			1		
			2		
		24	139		1
		26	137		
			5		
			2		
					2
		4	19		
			1		
			1		

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Weight increased		1				1		
Wheezing		1				1		
White blood cell count increased		1				1		
Wound haemorrhage		1				1		
	1,041	4,590	1	1	975	4316	66	274

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	2	2			1	1	1	1
Abdominal pain upper	3	3			2	2	1	1
Abnormal behaviour		1						1
Activated partial thromboplastin time prolonged	1	1					1	1
Acute coronary syndrome	1	2					1	2
Acute myocardial infarction	4	6					4	6
Ageusia		1				1		
Alanine aminotransferase increased	2	2			1	1	1	1
Amnesia	2	3			2	2		1
Amylase increased		1				1		
Anaemia	1	1			1	1		
Anal haemorrhage	1	1					1	1
Anaphylactic reaction		1						1
Aneurysm		1						1
Angina pectoris	1	2					1	2
Angioedema	3	3					3	3
Anxiety	1	3			1	3		
Aortic aneurysm	1	1					1	1
Aortic arteriosclerosis	1	2			1	1		1
Aortic dissection		1						1
Aortic thrombosis	1	1					1	1
Apathy		1						1
Aphasia	4	5			2	2	2	3
Aphonia	1	1			1	1		
Apraxia	1	1					1	1
Arrhythmia	14	15					14	15
Arthralgia	9	15			8	14	1	1
Aspartate aminotransferase increased	2	2					2	2
Asthenia	1	3			1	1		2
Asthma	2	3			2	2		1
Atrial fibrillation	9	13		1			9	13
Axillary pain		1				1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Azotaemia		1
Back pain	2	2
Bacterial infection		1
Balance disorder		2
Basilar artery thrombosis	1	1
Bell's palsy	3	3
Bleeding varicose vein	1	1
Blepharospasm	1	1
Blindness	1	1
Blindness transient	1	1
Blindness unilateral	1	1
Blood alkaline phosphatase increased		1
Blood bilirubin increased		2
Blood cholesterol increased	1	1
Blood creatinine decreased	1	1
Blood creatinine increased	1	1
Blood fibrinogen decreased	1	1
Blood glucose increased	4	4
Blood lactate dehydrogenase increased	1	1
Blood lactic acid increased	1	1
Blood potassium decreased		1
Blood pressure decreased	1	3
Blood pressure fluctuation	2	2
Blood pressure increased	1	3
Blood pressure systolic increased	1	1
Blood sodium increased	1	1
Blood urea increased	1	1
Body temperature decreased	1	1
Body temperature increased	1	2
Bradykinesia		1
Bradyphrenia		1
Breath sounds abnormal	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1	1	1
					1
			1		1
				1	1
				3	3
				1	1
		1	1		
				1	1
				1	1
				1	1
			1		
			2		
		1	1		
		1	1		
				1	1
				1	1
		2	2	2	2
				1	1
				1	1
			1		
		1	2		1
		2	2		
			1	1	2
		1	1		
				1	1
				1	1
		1	1		
		1	2		
			1		
			1		
		1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bronchiectasis	1	1
Bundle branch block right	2	2
Burning sensation		1
Calcium ionised decreased	1	1
Cardiac arrest	4	8
Cardiac death	2	2
Cardiac disorder	1	2
Cardiac failure	5	8
Cardiac failure acute		1
Cardiac fibrillation	2	2
Cardiac flutter	1	1
Cardiopulmonary failure		1
Carotid artery dissection	1	1
Cerebral artery thrombosis	2	2
Cerebral atrophy	1	1
Cerebral haemorrhage	4	7
Cerebral infarction	22	25
Cerebral ischaemia	1	1
Cerebral thrombosis	1	2
Cerebrovascular accident	8	11
Chest discomfort	2	4
Chest pain	2	5
Chillblains		1
Chills	15	30
Chorea		1
Circulatory collapse	1	3
Coagulation factor VIII level increased	1	1
Coagulopathy	1	1
Cognitive disorder	1	1
Cold sweat	1	2
Coma	1	1
Concussion		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				2	2
			1		
		1	1		
				4	8
				2	2
				1	2
				5	8
					1
				2	2
				1	1
					1
				1	1
				2	2
				1	1
				4	7
1	1			22	25
				1	1
				1	2
				8	11
		1	2	1	2
		1	3	1	2
			1		
		13	23	2	7
					1
				1	3
		1	1		
				1	1
		1	1		
		1	1		1
				1	1
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Condition aggravated	6	8
Confusional state	3	6
Conjunctival haemorrhage	1	1
Conjunctival oedema		1
Constipation	1	1
Contusion	1	2
Coronary artery stenosis		1
Cough	4	4
COVID-19	4	7
C-reactive protein increased	1	4
Cutaneous vasculitis	1	1
Cystitis	1	1
Death	3	12
Decreased appetite	3	5
Deep vein thrombosis	10	14
Delirium	1	6
Depressed level of consciousness		4
Depression		3
Depression suicidal	1	1
Dermatitis allergic	1	1
Dermatitis bullous	1	1
Diarrhoea	6	7
Diarrhoea haemorrhagic	1	1
Diplegia	1	1
Diplopia	1	3
Discomfort	1	1
Disease recurrence	1	1
Disorientation		1
Disturbance in attention	2	2
Diverticulitis	1	1
Dizziness	8	10
Drug ineffective	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	4	3	4
		1	2	2	4
1	1			1	1
					1
		1	1		
		1	2		
					1
		3	3	1	1
			1	4	6
			2	1	2
				1	1
				1	1
				3	12
		2	2	1	3
				10	14
				1	6
					4
			2		1
				1	1
		1	1		
				1	1
		5	6	1	1
				1	1
				1	1
			2	1	1
				1	1
				1	1
					1
		2	2		
				1	1
		6	7	2	3
				2	3

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* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dry mouth	1	1
Dysphagia	1	3
Dyspnoea	19	30
Dyspnoea at rest	1	1
Dysstasia	1	1
Electrocardiogram QT prolonged	1	1
Embolism arterial	1	1
Emphysema	1	1
Epidural haemorrhage	1	1
Epilepsy	2	8
Epistaxis	2	3
Erythema	1	2
Exercise tolerance decreased	1	1
Exposure to SARS-CoV-2	1	1
Extensive swelling of vaccinated limb		5
Eye contusion		1
Eye disorder	1	1
Eye haematoma		1
Eye irritation	1	1
Face oedema	1	2
Facial pain	1	1
Facial paralysis	1	3
Faeces hard	1	1
Fall	2	5
Fatigue	33	54
Feeding disorder		1
Feeling hot	2	2
Fibrin D dimer increased	1	2
Flank pain	1	1
Fluid intake reduced		2
Fluid retention	2	3
Gait disturbance	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	3
1	1	11	12	8	18
				1	1
				1	1
				1	1
		1	1		
				1	1
				2	8
1	1	2	3		
		1	2		
		1	1		
		1	1		
			5		
			1		
				1	1
					1
		1	1		
				1	2
		1	1		
				1	3
		1	1		
		1	1	1	4
		29	46	4	8
					1
		1	1	1	1
				1	2
				1	1
			1		1
		2	2		1
				1	1

* I=Interval, C=Cumulative

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gait inability	1	1
Gamma-glutamyltransferase increased		1
Gastrointestinal disorder	2	2
Gastrointestinal haemorrhage	1	1
Gastrointestinal pain	1	1
General physical health deterioration		2
Glomerular filtration rate decreased		1
Glossodynia	1	1
Haemarthrosis		1
Haematochezia	1	1
Haematocrit decreased		2
Haematocrit increased	1	1
Haematoma		1
Haemodynamic instability	2	2
Haemoglobin decreased	2	4
Hallucination	2	2
Hallucination, visual	1	1
Headache	22	38
Head discomfort	1	1
Heart rate decreased		1
Heart rate increased	2	7
Heart rate irregular	1	1
Hemianopia	1	1
Hemiparaesthesia	1	1
Hemiparesis	1	5
Hemiplegia	1	1
Henoch-Schonlein purpura	1	1
Herpes zoster	9	9
Hiatus hernia	1	1
Horner's syndrome	1	1
Hydrocephalus		1
Hyperaesthesia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		
		1	1	1	1
				1	1
		1	1		
					2
			1		
		1	1		
					1
				1	1
			2		
				1	1
			1		
		1	1	1	1
		1	3	1	1
				2	2
				1	1
		21	36	1	2
		1	1		
			1		
		2	3		4
				1	1
				1	1
				1	1
				1	5
				1	1
				1	1
		9	9		
		1	1		
				1	1
					1
			1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyperglycaemia		1
Hypernatraemia		1
Hyperpyrexia		1
Hypersensitivity	5	5
Hypersomnia	1	1
Hypertension	5	10
Hypertensive urgency		1
Hypoaesthesia	3	3
Hypoaesthesia oral	1	1
Hypoglycaemia		1
Hypokinesia	1	2
Hypophagia		2
Hypotension	4	8
Hypoxia	2	3
Ileus	1	1
Inappropriate schedule of product administration	2	2
Infection		2
Inflammatory marker increased	1	1
Influenza	1	1
Influenza like illness	2	2
Injection site inflammation		1
Injection site pain		1
Injection site pruritus		1
Injection site warmth		1
International normalised ratio increased	1	1
Intestinal haemorrhage		1
Intestinal ischaemia	2	2
Iron deficiency	1	1
Ischaemic cerebral infarction	4	10
Joint abscess		1
Leukaemia	1	1
Leukocytosis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
				5	5
		1	1		
			1	5	9
					1
		3	3		
		1	1		
					1
		1	2		
					2
	1	2	3	2	5
				2	3
				1	1
		2	2		
					2
		1	1		
		1	1		
		1	1	1	1
			1		
			1		
			1		
				1	1
					1
				2	2
				1	1
				4	10
					1
				1	1
		1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ligament sprain	1	1
Limb discomfort	1	1
Lip swelling	3	4
Listless	1	1
Localised oedema	1	1
Loss of consciousness	3	4
Loss of control of legs	2	2
Low density lipoprotein increased	1	1
Lymphadenopathy		1
Lymphangitis	1	1
Lymph nodes scan abnormal		1
Macroglossia	1	1
Malaise	32	66
Mastitis	1	1
Memory impairment	1	2
Meniere's disease		2
Meningitis		1
Mesenteric vein thrombosis	1	1
Metastases to lung	1	1
Mobility decreased	1	2
Monoparesis	1	1
Mouth swelling		1
Movement disorder		2
Muscle spasms	2	2
Muscle strain	2	2
Muscular weakness	3	3
Myalgia	20	42
Myelodysplastic syndrome	1	1
Myocardial calcification	1	1
Myocardial infarction	12	17
Nasal congestion	2	2
Nasopharyngitis	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1		
				3	4
		1	1		
				1	1
1	1			3	4
				2	2
		1	1		
			1		
				1	1
			1		
				1	1
		27	45	5	21
				1	1
		1	2		
					2
					1
				1	1
				1	1
				1	2
				1	1
					1
			2		
				2	2
		2	2		
		1	1	2	2
		20	39		3
				1	1
		1	1		
				12	17
		2	2		
		2	2		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nausea	11	32
Neck pain		1
Neuralgia	2	2
Neuropathy peripheral	1	2
Neutrophil count increased	1	1
Nocturnal dyspnoea	1	1
Obstructive airways disorder	1	1
Ocular vascular disorder	1	1
Oedema		1
Oedema peripheral	1	1
Off label use	2	2
Oral discomfort	1	1
Oropharyngeal pain		2
Oscillopsia		1
Oxygen saturation decreased	1	8
Pain	2	4
Painful respiration	1	1
Pain in extremity	9	12
Pain in jaw	1	1
Pallor		2
Palpitations		1
Paraesthesia	2	3
Paraesthesia oral		1
Paralysis		2
Pemphigoid	1	1
Peripheral coldness		1
Peripheral swelling	1	2
Periventricular leukomalacia	1	1
Pharyngeal oedema	1	1
Pharyngeal swelling	2	3
Platelet count decreased	1	2
Pleural effusion	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		10	27	1	5
			1		
		2	2		
				1	2
		1	1		
		1	1		
				1	1
				1	1
					1
		1	1		
		2	2		
		1	1		
			2		
			1		
		1	1		7
		2	4		
		1	1		
		9	12		
				1	1
			1		1
					1
		2	3		
			1		
					2
				1	1
			1		
		1	1		1
				1	1
				1	1
				2	3
			1	1	1
		1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pneumonia	7	10
Pneumonia aspiration	1	1
PO2 increased	1	1
Polyneuropathy chronic	1	1
Poor quality sleep		1
Portal vein thrombosis	1	1
Post concussion syndrome		1
Postictal state		1
Presyncope		1
Prothrombin time prolonged	1	1
Pruritus	1	1
Pulmonary embolism	22	29
Pulmonary hypertension		
Pulmonary infarction	1	2
Pulmonary mass	1	1
Pulmonary pain	1	1
Pulmonary sepsis	1	1
Purpura		1
Pyrexia	17	42
Red blood cell count decreased		2
Renal artery thrombosis	1	1
Renal failure	2	2
Renal impairment	1	1
Renal ischaemia	1	1
Respiratory failure	2	4
Respiratory rate decreased		1
Restlessness	1	2
Retching		1
Retinal artery occlusion	2	3
Retinal vein occlusion	1	1
Seizure	1	1
Sensory disturbance		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1			7	10
				1	1
				1	1
		1	1		
			1		
				1	1
			1		
			1		
					1
				1	1
		1	1		
				22	29
1	1				
				1	2
				1	1
		1	1		
				1	1
			1		
		12	26	5	16
			2		
				1	1
				2	2
				1	1
				1	1
				2	4
			1		
		1	2		
					1
				2	3
				1	1
				1	1
			1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sepsis		1
Shock	1	2
Skin abrasion	1	1
Skin discolouration		1
Skull fracture	1	1
Slow speech		1
Snoring	1	1
Somnambulism		2
Speech disorder	2	4
Sputum discoloured	1	1
Stress cardiomyopathy	1	1
Stridor	1	2
Subarachnoid haemorrhage	2	2
Sudden cardiac death	1	1
Sudden death	4	7
Suicidal ideation		1
Supraventricular tachycardia	1	1
Swelling face		2
Swollen tongue	5	7
Syncope	12	20
Systemic lupus erythematosus	1	1
Throat irritation	1	1
Throat tightness	1	1
Thrombocytopenia	12	12
Thrombophlebitis	1	2
Thrombophlebitis superficial	1	1
Thrombosis	2	6
Tongue oedema	1	1
Toothache		1
Torsade de pointes	1	1
Transient global amnesia		1
Transient ischaemic attack	15	24

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	2
		1	1		
					1
				1	1
			1		
		1	1		
			2		
		1	1	1	3
		1	1		
				1	1
				1	2
				2	2
				1	1
				4	7
					1
		1	1		
			1		1
			1	5	6
1	2			12	20
				1	1
				1	1
				1	1
		2	2	10	10
			1	1	1
				1	1
				2	6
				1	1
			1		
				1	1
			1		
				15	24

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Troponin I increased	1	1
Unresponsive to stimuli	1	2
Urinary incontinence	1	1
Urinary tract infection		1
Urticaria		1
Vaccination failure	1	1
Vaccination site bruising	1	1
Vaccination site discolouration	1	1
Vaccination site discomfort	1	1
Vaccination site erythema	1	8
Vaccination site haematoma		1
Vaccination site inflammation	2	4
Vaccination site movement impairment		1
Vaccination site pain	9	17
Vaccination site pallor		1
Vaccination site pruritus		3
Vaccination site swelling		4
Vaccination site warmth	1	6
Varicose vein	1	1
Vascular stent thrombosis		1
Ventricular extrasystoles	1	1
Ventricular f brillation		2
Ventricular tachycardia	1	1
Vertebrobasilar stroke	1	1
Vertigo	1	1
Vision blurred		1
Visual field defect	1	1
Visual impairment	2	2
Vomiting	6	10
Weight decreased		1
White blood cell count increased	2	3
Wound	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	2
				1	1
			1		
			1		
				1	1
		1	1		
		1	1		
		1	8		
			1		
		2	4		
			1		
		9	17		
					1
			3		
			4		
		1	6		
		1	1		
					1
				1	1
					2
				1	1
				1	1
		1	1		
			1		
				1	1
		2	2		
		4	5	2	5
					1
		1	2	1	1
		1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
	747	1,277	8	12	330	577	417	700

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	1	5			1	3		2
Abdominal distension		1				1		
Abdominal pain		4				2		2
Abdominal pain upper	2	4			1	3	1	1
Abnormal dreams		1				1		
Abnormal faeces		1						1
Abscess		1						1
Acne		1				1		
Activated partial thromboplastin time shortened		1				1		
Acute abdomen		1						1
Acute cardiac event		1						1
Acute coronary syndrome	1	1					1	1
Acute kidney injury	2	3					2	3
Acute myocardial infarction		5						5
Acute respiratory failure		1						1
Adrenal disorder		1						1
Ageusia		2				2		
Alanine aminotransferase decreased		1				1		
Altered state of consciousness		1						1
Amaurosis fugax		1						1
Amnesia		1						1
Amyloidosis	1	1					1	1
Anaemia		1				1		
Anamnestic reaction		1						1
Anaphylactic reaction		1						1
Angina pectoris	1	5					1	5
Angioedema	1	5					1	5
Anosmia		1				1		
Anxiety		2				2		
Aortic valve stenosis		4						4
Apallic syndrome		2						2
Aphasia	1	11				2	1	9

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Aphonia		1
Aphthous ulcer		1
Apraxia		1
Arrhythmia	4	14
Arterial thrombosis		1
Arthralgia	10	41
Arthritis		3
Aspartate aminotransferase increased		1
Aspiration		1
Asthenia	3	12
Asymptomatic COVID-19	1	1
Atrial fibrillation	3	21
Atrial flutter		2
Atrioventricular block complete		1
Azotaemia		1
Back pain	1	6
Bacterial test positive		1
Balance disorder		2
Basilar artery thrombosis		1
Basophil count decreased		1
Bedridden		2
Bell's palsy		2
Beta haemolytic streptococcal infection	1	1
Blindness		5
Blindness unilateral		1
Blister	1	2
Blood alcohol decreased		1
Blood bicarbonate decreased		2
Blood bilirubin increased		1
Blood calcium decreased		1
Blood cholesterol abnormal		1
Blood cholesterol increased	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
					1
1	1			4	14
					1
		8	27	2	14
			1		2
			1		
					1
		3	9		3
				1	1
		1	1	2	20
			1		1
					1
					1
		1	5		1
					1
			1		1
			1		1
					2
				1	1
	1				5
					1
		1	1		1
			1		
			2		
			1		
			1		
			1		
		1	4		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood creatinine increased	2	7
Blood glucose decreased		1
Blood glucose fluctuation	1	1
Blood glucose increased	2	7
Blood lactate dehydrogenase increased		1
Blood lactic acid increased		1
Blood loss anaemia		1
Blood potassium decreased		1
Blood pressure abnormal		1
Blood pressure decreased		3
Blood pressure increased		4
Blood pressure systolic increased		2
Blood sodium decreased		2
Blood urea abnormal		1
Blood urea increased	2	7
Blood uric acid increased		1
Body temperature decreased		4
Body temperature increased		12
Bradycardia	1	2
Brain death		1
Brain natriuretic peptide increased	1	2
Bronchitis		1
Burning sensation		2
Cachexia		3
Candida infection		1
Cardiac arrest	1	15
Cardiac asthma		7
Cardiac death		4
Cardiac disorder		5
Cardiac failure	4	31
Cardiac failure acute	1	4
Cardiac failure congestive		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	7		
			1		
		1	1		
		2	6		1
			1		
			1		
					1
			1		
					3
			3		1
					2
			2		
			1		
		2	7		
			1		
			2		2
			8		4
				1	2
					1
		1	2		
					1
			2		
					3
					1
				1	15
					7
					4
			1		4
				4	31
				1	4
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiac tamponade	1	1
Cardiac ventricular thrombosis		1
Cardiogenic shock		3
Cardiovascular disorder		2
Carotid arteriosclerosis		1
Carotid artery thrombosis	1	2
Cerebellar haematoma		1
Cerebral amyloid angiopathy		1
Cerebral atrophy		1
Cerebral haemorrhage	5	13
Cerebral infarction	12	31
Cerebral ischaemia	1	3
Cerebral thrombosis		3
Cerebrovascular accident	6	31
Cerebrovascular disorder		2
Chest discomfort	2	6
Chest injury		2
Chest pain	4	16
Chills	12	58
Choking		1
Cholelithiasis	1	1
Chronic obstructive pulmonary disease	2	6
Circulatory collapse	2	5
Coagulopathy		1
Cognitive disorder	1	2
Cold sweat		2
Coma	1	1
Coma hepatic		1
Condition aggravated	1	12
Confusional state	6	25
Conjunctival haemorrhage	1	1
Consciousness fluctuating		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
					3
					2
					1
				1	2
					1
					1
					1
				5	13
				12	31
				1	3
					3
	1			6	31
			1		1
		1	3	1	3
					2
		2	5	2	11
		7	40	5	18
					1
				1	1
			1	2	5
				2	5
			1		
		1	1		1
					2
				1	1
					1
			3	1	9
		4	13	2	12
				1	1
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Constipation		2
Contusion	1	3
Coombs negative haemolytic anaemia		1
Coordination abnormal		2
Coronary artery disease	1	2
Cough	2	6
COVID-19	4	21
COVID-19 pneumonia		2
C-reactive protein increased	1	8
Cutaneous vasculitis	1	3
Cyanosis		1
Cystitis	3	11
Cystitis noninfective		1
Deafness	1	2
Deafness transitory		1
Deafness unilateral		2
Death	1	23
Decreased appetite		14
Deep vein thrombosis	8	27
Dehydration	2	8
Delirium	5	21
Delusion		1
Dementia		3
Dementia Alzheimer's type		1
Depressed level of consciousness	4	11
Depression		1
Dermatitis	1	1
Dermatitis allergic		1
Diabetes mellitus inadequate control		1
Diarrhoea	3	16
Dilatation atrial		1
Diplopia		6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
		1	1		2
					1
			1		1
				1	2
		1	4	1	2
			2	4	19
					2
		1	6		2
				1	3
					1
		3	7		4
					1
				1	2
					1
					2
				1	23
			9		5
				8	27
			2	2	6
				5	21
			1		
					3
					1
				4	11
					1
		1	1		
			1		
					1
		2	12	1	4
					1
			4		2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Discomfort		2
Disease recurrence	1	9
Disorientation		1
Dissociation		1
Disturbance in attention	1	1
Dizziness	4	32
Drug hypersensitivity		1
Drug ineffective	4	12
Dry mouth		2
Dysarthria		7
Dysgraphia		2
Dyskinesia	1	1
Dyspepsia		1
Dysphagia	5	18
Dysphonia		3
Dyspnoea	5	62
Dyspnoea at rest	1	1
Dyspnoea exertional		1
Dysstasia		2
Ear pain	2	2
Ecchymosis		2
Electrolyte imbalance		1
Embolism		1
Emotional disorder		1
Emotional poverty		1
Encephalitis enteroviral		1
Endocarditis		1
Enterocolitis		1
Eosinophil count decreased		2
Epilepsy	2	10
Epistaxis	1	13
Eructation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
			2	1	7
			1		
			1		
		1	1		
		4	24		8
					1
				4	12
			2		
			1		6
			1		1
		1	1		
			1		
		2	6	3	12
					3
		1	14	4	48
				1	1
					1
			1		1
		2	2		
					2
					1
					1
					1
					1
					1
			2		
				2	10
		1	6		7
			1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Erysipelas	5	6
Erythema	4	11
Erythema nodosum		1
Escherichia urinary tract infection		1
Exercise tolerance decreased	1	1
Extensive swelling of vaccinated limb	3	20
Extrasystoles	1	1
Eye disorder		1
Eye haemorrhage	1	3
Eye infection	1	1
Eye inflammation	1	1
Eyelid ptosis		1
Eye movement disorder		1
Facial bones fracture		1
Facial pain		1
Facial paralysis	2	8
Facial paresis		2
Fall	4	26
Fatigue	28	144
Fear		1
Febrile convulsion		1
Feeding disorder	1	3
Feeling abnormal	1	6
Feeling cold		2
Feeling hot		4
Fibrin D dimer increased		2
Fluid intake reduced		1
Fluid retention		1
Fracture		1
Gait disturbance		6
Gait inability	1	4
Gamma-glutamyltransferase increased	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				5	6
		4	7		4
					1
					1
		1	1		
		3	20		
		1	1		
			1		
				1	3
				1	1
				1	1
			1		
			1		
					1
					1
				2	8
					2
	1	1	10	3	16
		21	94	7	50
					1
			1		
			2	1	1
		1	5		1
			2		
			1		3
			2		
					1
					1
					1
			4		2
		1	2		2
		1	2		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastric haemorrhage		1
Gastroenteritis		1
Gastrointestinal disorder		1
Gastrointestinal haemorrhage	1	7
Gastrointestinal obstruction		1
Gastrooesophageal reflux disease		1
Gaze palsy		1
General physical health deterioration	1	13
Giant cell arteritis		2
Glomerular filtration rate decreased	1	4
Glomerulonephritis minimal lesion	1	1
Glossodynia		1
Glucose tolerance impaired		1
Guillain-Barre syndrome	1	2
Haematemesis		1
Haematocrit decreased	1	3
Haematocrit increased		1
Haematoma		1
Haemodynamic instability		1
Haemoglobin abnormal		1
Haemoglobin decreased	1	8
Haemophagocytic lymphohistiocytosis		1
Haemophilia		1
Haemoptysis		2
Haemorrhage	2	3
Haemorrhoids		1
Hallucination	1	4
Hallucination, visual		1
Hand deformity		1
Hand fracture		1
Headache	15	69
Head discomfort	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
			1		
				1	7
					1
			1		
					1
		1	5		8
					2
		1	4		
				1	1
			1		
			1		
				1	2
					1
		1	3		
			1		
					1
					1
			1		
		1	5		3
					1
					1
			1		1
				2	3
			1		
				1	4
					1
					1
					1
		11	51	4	18
				1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Head injury		2
Heart rate abnormal	1	1
Heart rate decreased		3
Heart rate increased		5
Heart rate irregular		2
Hemianopia	1	1
Hemiparesis	3	9
Hemiplegia	1	4
Hepatic failure		1
Hepatic steatosis	1	1
Hepatitis C		1
Hernia	1	1
Hernia pain		1
Herpes ophthalmic		1
Herpes virus infection		1
Herpes zoster	27	29
Herpes zoster reactivation	2	3
Hiatus hernia	1	2
High density lipoprotein increased	1	1
Hip fracture		2
Hot flush		1
Human epidermal growth factor receptor decreased		1
Hyperaesthesia		1
Hypercalcaemia	2	2
Hyperglycaemia	2	2
Hyperhidrosis		8
Hyperkalaemia	2	3
Hypernatraemia		1
Hyperpyrexia	1	4
Hypersensitivity	1	4
Hypersomnia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		1	1		
			2		1
			3		2
			2		
				1	1
				3	9
				1	4
					1
				1	1
					1
		1	1		
			1		
					1
			1		
		27	27		2
		1	1	1	2
				1	2
		1	1		
					2
					1
					1
				2	2
		2	2		
			5		3
				2	3
					1
				1	4
			1	1	3
			1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypertension	4	19
Hypertensive crisis		1
Hypertriglyceridaemia		1
Hyperventilation		1
Hypoglycaemia	1	1
Hypokalaemia		1
Hyponatraemia	1	1
Hypophagia	1	5
Hypopnoea		1
Hyporesponsive to stimuli		1
Hypotension	1	12
Hypothermia	2	3
Hypothyroidism	1	1
Hypovolaemic shock		1
Hypoxia		11
Illness		1
Immune thrombocytopenia		1
Imperception		1
Inappropriate schedule of product administration	3	6
Incontinence		4
Infarction		2
Infection	1	3
Infection susceptibility increased		1
Inflammation		4
Inflammatory marker increased		1
Influenza like illness		2
Injection site pain	1	1
Injection site pruritus		1
Insomnia		1
Intentional product use issue		1
Intention tremor		1
International normalised ratio fluctuation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	7	1	12
					1
					1
					1
				1	1
					1
		1	1		
			1	1	4
			1		
			1		
			4	1	8
				2	3
				1	1
					1
					11
					1
					1
					1
		3	6		
			1		3
					2
		1	1		2
					1
			2		2
					1
			1		1
		1	1		
			1		
			1		
			1		
					1
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
International normalised ratio increased		3
Interstitial lung disease		1
Intestinal haemorrhage		1
Intestinal ischaemia		2
Intestinal obstruction		1
Iridocyclitis	1	2
Ischaemic cerebral infarction	1	19
Ischaemic stroke	1	2
IVth nerve paralysis		1
Jaundice		2
Joint swelling	2	2
Kidney infection		1
Lacrimation increased		1
Lacunar infarction		1
Left ventricular dysfunction		1
Left ventricular failure		1
Left ventricular hypertrophy		1
Leukopenia	1	2
Limb discomfort	1	4
Limb injury		2
Lip oedema	1	1
Listless	1	3
Livedo reticularis		1
Localised infection		1
Loss of consciousness	5	17
Loss of personal independence in daily activities		2
Lung disorder		4
Lyme disease	1	1
Lymphadenopathy		1
Lymphocyte count decreased		2
Macular degeneration		1
Malaise	32	187

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		2
					1
					1
					2
					1
				1	2
				1	19
				1	2
			1		
					2
		2	2		
					1
			1		
					1
					1
			1		
				1	2
		1	3		1
			1		1
		1	1		
		1	3		
					1
					1
				5	17
			1		1
					4
				1	1
					1
			1		1
					1
		19	104	13	83

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mean cell haemoglobin concentration increased	1	1
Mean cell haemoglobin increased	1	1
Mean cell volume increased		1
Melaena		1
Meniere's disease		2
Mental disorder	1	1
Mental impairment		3
Mesenteric artery thrombosis		1
Metabolic acidosis		1
Mobility decreased		2
Monocyte count increased		1
Monoparesis	1	3
Monoplegia		1
Mood altered		1
Mouth swelling		1
Movement disorder		2
Multiple organ dysfunction syndrome		2
Muscle spasms	1	2
Muscle strain		1
Muscle twitching		1
Muscular weakness	3	10
Musculoskeletal chest pain		1
Musculoskeletal discomfort		1
Musculoskeletal disorder		1
Musculoskeletal stiffness		1
Mutism		2
Myalgia	10	68
Myelodysplastic syndrome		1
Myelopathy		1
Myocardial infarction	3	18
Nasal congestion		2
Nasopharyngitis	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1		
			1		
					1
					2
				1	1
					3
					1
			1		
			2		
			1		
				1	3
					1
			1		
					1
					2
					2
		1	2		
					1
					1
			4	3	6
					1
			1		
					1
			1		
					2
		9	51	1	17
					1
					1
				3	18
			1		1
		1	4		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nausea	13	83
Neck pain		2
Nephrotic syndrome	1	1
Neuritis		1
Neurologic neglect syndrome	2	3
Neuropathy peripheral	1	1
Neutrophil count decreased		1
Neutrophil count increased	1	3
Night sweats		2
Normocytic anaemia	1	1
Ocular hyperaemia		3
Ocular myasthenia		1
Oedema	1	2
Oedema peripheral	2	6
Off label use	2	5
Optic nerve infarction		1
Oral bacterial infection		1
Oral discomfort		1
Oral disorder		1
Oral mucosal blistering		1
Oral mucosal erythema		1
Organ failure	1	1
Oropharyngeal blistering		1
Oropharyngeal pain	1	6
Osteomyelitis	1	1
Oxygen saturation abnormal		2
Oxygen saturation decreased	2	14
Pain	1	9
Painful respiration	1	1
Pain in extremity	5	15
Pain in jaw		3
Pallor		6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		7	48	6	35
					2
				1	1
					1
				2	3
				1	1
					1
		1	3		
			2		
		1	1		
			1		2
					1
				1	2
		1	2	1	4
		2	5		
					1
					1
			1		
			1		
					1
					1
				1	1
					1
			4	1	2
				1	1
					2
			1	2	13
		1	4		5
				1	1
		3	10	2	5
			2		1
			2		4

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Palpitations	1	3
Pancytopenia		1
Panic attack		1
Panniculitis		1
Paraesthesia	3	4
Paralysis	2	5
Paresis		2
Parkinson's disease		2
Pelvic fracture		1
Pericarditis		2
Periorbital haematoma	1	1
Peripheral coldness		3
Peripheral swelling	2	6
Peroneal nerve palsy		1
Personality disorder		1
Petechiae		2
Pharyngeal erythema		1
Pharyngeal swelling		1
Plasma cell leukaemia	1	1
Platelet count decreased		4
Platelet count increased		1
Pleural effusion		3
Pneumonia	6	25
Pneumonia aspiration		9
Pneumonia bacterial		1
Polymyalgia rheumatica	1	1
Posterior revers ble encephalopathy syndrome		1
Presyncope		1
Product administered at inappropriate site	1	1
Productive cough		1
Prolapse		1
Prothrombin time prolonged		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	2
					1
			1		
					1
		1	2	2	2
				2	5
			1		1
					2
					1
					2
		1	1		
			1		2
		2	4		2
					1
			1		
			2		
					1
					1
				1	1
			3		1
			1		
					3
				6	25
					9
					1
				1	1
					1
			1		
		1	1		
					1
			1		
			1		

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Prothrombin time ratio increased		1
Pruritus	1	3
Pulmonary arterial pressure increased		1
Pulmonary embolism	12	31
Pulmonary haemorrhage		1
Pulmonary hypertension		1
Pulmonary infarction	1	2
Pulmonary mass		1
Pulmonary oedema	1	3
Pupillary reflex impaired	1	1
Pyelonephritis		1
Pyrexia	9	82
Quadriplegia		1
Rash	1	4
Rash erythematous		2
Rash papular	1	1
Rash pruritic		4
Rectal haemorrhage		2
Rectal prolapse		1
Red blood cell count decreased	1	2
Red blood cell sedimentation rate increased	1	1
Reduced facial expression		1
Regurgitation		1
Renal disorder		1
Renal failure	1	3
Renal impairment	2	4
Renal infarct		1
Respiration abnormal		1
Respiratory disorder		1
Respiratory failure	1	7
Respiratory rate decreased		1
Respiratory rate increased	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	2		1
					1
				12	31
					1
					1
				1	2
					1
				1	3
				1	1
					1
1	1	5	34	4	48
					1
		1	3		1
			2		
		1	1		
			3		1
					2
					1
		1	2		
		1	1		
					1
			1		
			1		
				1	3
				2	4
					1
					1
				1	7
			1		
			2	1	2

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory tract infection		2
Restlessness		2
Retching		1
Retinal artery embolism	1	1
Retinal artery occlusion		1
Retinal vein occlusion	1	2
Rheumatoid arthritis		1
Right ventricular failure		1
Salivary hypersecretion		1
SARS-CoV-2 test positive		3
Scrotal injury		1
Secondary adrenocortical insufficiency		1
Secondary hypertension		1
Seizure	1	7
Sepsis		1
Serum ferritin abnormal		1
Shock		1
Sinus tachycardia		1
Skin discolouration		1
Skin swelling		1
Sleep disorder		1
Small intestinal obstruction		1
Snoring		1
Soft tissue infection		1
Soft tissue swelling		1
Somnolence	4	16
Speech disorder	2	8
Spinal cord compression		1
Spinal cord injury	1	1
Spinal epidural haemorrhage		1
Spinal meningeal cyst		1
Spinal osteoarthritis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
			1		1
					1
				1	1
					1
				1	2
					1
					1
					1
					3
			1		
					1
					1
				1	7
					1
					1
					1
			1		
					1
			1		
			1		
					1
			1		
					1
					1
		2	5	2	11
		1	4	1	4
					1
				1	1
					1
			1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Splenic infarction		1
Starvation	1	1
Status epilepticus		1
Stiff tongue		1
Subdural haematoma		2
Sudden cardiac death	2	6
Sudden death	2	13
Sudden hearing loss		2
Supraventricular tachycardia		1
Suspected COVID-19		2
Suspiciousness		1
Swelling		1
Swelling face	1	4
Swelling of eyelid		1
Swollen tongue	1	2
Symptom recurrence		1
Syncope	3	24
Tachycardia		1
Tachypnoea		3
Thinking abnormal	1	2
Thirst decreased		1
Throat tightness		1
Thrombocytopenia	4	7
Thrombophlebitis	1	5
Thrombophlebitis superficial	2	4
Thrombosis		13
Thrombosis mesenteric vessel		1
Thyroid mass	1	1
Tinnitus	1	2
Tongue biting	1	1
Tongue disorder		1
Toothache	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
					1
			1		
					2
				2	6
				2	13
					2
			1		
			1		1
			1		
			1		
		1	2		2
					1
		1	1		1
					1
				3	24
					1
			2		1
		1	2		
					1
					1
				4	7
		1	3		2
		1	1	1	3
					13
					1
				1	1
			1	1	1
		1	1		
					1
		1	1		

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Torticollis	1	1
Total cholesterol/HDL ratio decreased	1	1
Toxic skin eruption	1	2
Transient aphasia		1
Transient ischaemic attack	16	49
Transverse sinus thrombosis	1	1
Traumatic haematoma		1
Tremor	1	5
Troponin increased		2
Unresponsive to stimuli		5
Upper limb fracture		1
Urinary incontinence		3
Urinary retention		3
Urinary tract infection	2	7
Urine output decreased		1
Urosepsis	1	5
Urticaria	1	4
Vaccination failure	1	2
Vaccination site bruising	1	4
Vaccination site discomfort		1
Vaccination site erythema	4	24
Vaccination site haematoma		6
Vaccination site induration	1	1
Vaccination site inflammation	1	9
Vaccination site pain	7	42
Vaccination site pruritus		9
Vaccination site reaction	1	1
Vaccination site swelling	1	18
Vaccination site warmth	2	19
Vascular calcification	1	1
Vascular parkinsonism	1	1
Vasculitis		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1		
				1	2
					1
				16	49
				1	1
					1
			2	1	3
			1		1
					5
					1
			2		1
					3
		2	3		4
			1		
				1	5
			2	1	2
				1	2
		1	4		
			1		
		4	24		
			6		
		1	1		
		1	9		
		7	40		2
			9		
		1	1		
		1	18		
		2	19		
				1	1
				1	1
			2		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ventricular f brillation	1	2					1	2
Ventricular tachycardia	2	2					2	2
Vertebrobasilar stroke	1	1					1	1
Vertigo	1	2				1	1	1
Viral infection		2						2
Visual field defect	1	1					1	1
Visual impairment	2	8				1	2	7
Vitamin B12 deficiency	1	1			1	1		
Vomiting	8	35			5	16	3	19
Weight decreased		4				3		1
White blood cell count decreased		1				1		
White blood cell count increased	1	1			1	1		
Wrist fracture		1						1
	571	2,891	2	5	258	1190	313	1701

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain upper		2		2		
Abortion spontaneous		2				2
Anaphylactic shock		1				1
Anembryonic gestation		1				1
Arthralgia	3	17	3	17		
Axillary pain	1	1	1	1		
Basilar artery thrombosis		1				1
Blister	1	1	1	1		
Blood pressure increased		1				1
Body temperature increased	2	4	2	4		
Bradycardia		2				2
Breast pain		1		1		
Chest pain	1	4	1	4		
Chills	5	26	5	26		
Circumstance or information capable of leading to medication error		1		1		
Complement factor C1 increased	1	1	1	1		
Complement factor C3 increased	1	1	1	1		
Complement factor increased	1	1	1	1		
COVID-19	7	10	3	4	4	6
Crohn's disease		1				1
Deafness	1	1			1	1
Diarrhoea		3		3		
Discomfort		1		1		
Dizziness	3	9	3	9		
Drug ineffective	3	4			3	4
Dry eye	1	1	1	1		
Dry throat		1		1		
Dyspepsia		1		1		
Dyspnoea	2	3	2	3		
Ear pain	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Electric shock sensation		1		1		
Epistaxis	1	1	1	1		
Erythema		3		3		
Exposure to SARS-CoV-2		1		1		
Exposure via breast milk		1		1		
Extensive swelling of vaccinated limb		10		10		
Eye irritation	1	1	1	1		
Eye pain		1		1		
Fatigue	11	44	11	44		
Feeling cold		1		1		
Feeling hot		1		1		
Flank pain		1		1		
Gait disturbance		1		1		
Headache	16	61	16	61		
Heart rate abnormal		1		1		
Herpes zoster	4	4	4	4		
Hot flush		1		1		
Hyperhidrosis		2		2		
Hypersensitivity		1		1		
Hypertension	1	1	1	1		
Hypoaesthesia		1		1		
Illness	1	1	1	1		
Immune system disorder	1	1	1	1		
Incorrect dose administered	1	1	1	1		
Limb discomfort	2	2	2	2		
Loss of personal independence in daily activities	1	1	1	1		
Lymphadenopathy	4	11	4	11		
Lymph node pain	1	1	1	1		
Malaise	8	38	8	38		
Maternal exposure during pregnancy		1				1
Mouth swelling		1		1		
Muscle spasms	1	1			1	1

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal discomfort	1	1	1	1		
Musculoskeletal pain		2		2		
Musculoskeletal stiffness		1		1		
Myalgia	15	58	15	58		
Nasopharyngitis		1		1		
Nausea	3	22	3	22		
Neuropathy peripheral		1				1
Occupational exposure to product		1		1		
Oral herpes	1	1	1	1		
Oropharyngeal pain		1		1		
Pain	1	3	1	3		
Pain in extremity	3	8	3	8		
Palpitations	2	5	2	5		
Paraesthesia	2	4	2	4		
Paraesthesia oral		1		1		
Peripheral swelling	1	1	1	1		
Pharyngeal swelling	1	2	1	2		
Pollakiuria		1		1		
Poor quality product administered		1		1		
Presyncope	1	5	1	5		
Product label confusion		1		1		
Product packaging quantity issue	1	1	1	1		
Product preparation error		2		2		
Product preparation issue	1	2	1	2		
Product storage error		1		1		
Pruritus	3	3	3	3		
Pyrexia	7	26	7	26		
Rash	1	1	1	1		
Rash erythematous		1		1		
Respiratory disorder		1		1		
Restlessness		1		1		
Rheumatoid arthritis	1	1			1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rhinitis allergic	1	1	1	1		
Skin warm		1		1		
Suspected COVID-19	1	1			1	1
Swelling	1	2	1	2		
Swelling of eyelid	1	1	1	1		
Syncope		1				1
Tachycardia		4		4		
Taste disorder		1		1		
Thrombosis	1	1			1	1
Tinea versicolour	1	1	1	1		
Tinnitus		2		2		
Trigeminal neuralgia	1	1	1	1		
Urticaria		1		1		
Vaccination failure	2	3			2	3
Vaccination site discomfort	1	2	1	2		
Vaccination site erythema	5	17	5	17		
Vaccination site haematoma		4		4		
Vaccination site induration		1		1		
Vaccination site inflammation	8	21	8	21		
Vaccination site pain	13	54	13	54		
Vaccination site pruritus		9		9		
Vaccination site reaction		1		1		
Vaccination site swelling	6	22	6	22		
Vaccination site warmth	2	19	2	19		
Vaginal haemorrhage	1	2	1	2		
Vertigo	2	2	2	2		
Visual impairment		1		1		
	181	640	167	610	14	30

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* AE=Adverse Event

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Country Where Event Occurred

NEW ZEALAND

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypoglycaemia		1		1
		1		1

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
Asthenia	1	1	1	1
Heart rate increased	1	1	1	1
Hypoglycaemia		1		1
Nausea	1	2	1	2
	4	6	4	6

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19		1				1
Cerebrovascular accident	1	1			1	1
Chest discomfort	1	1			1	1
Drug ineffective		1				1
Exposure to SARS-CoV-2		1				1
Headache	1	1			1	1
Heart rate increased	1	1			1	1
Hypersensitivity	20	25			20	25
Hypoglycaemia		1		1		
Influenza like illness	1	2			1	2
Musculoskeletal stiffness	1	1			1	1
Myalgia	1	1			1	1
Product administration error	1	1	1	1		
Reactogenicity event		1				1
Seizure	1	1			1	1
Thrombosis	1	1			1	1
	30	41	1	2	29	39

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred
NORTHERN MARIANA ISLANDS

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia		1		1
Chest discomfort		1		1
Chills		1		1
Disorientation		1		1
Dizziness		1		1
Fatigue		1		1
Headache		1		1
Pain in extremity		1		1
Poor quality sleep		1		1
		9		9

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration		1		1
		1		1

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration		1		1
		1		1

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* AE=Adverse Event
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Country Where Event Occurred

NORWAY

090177e19749cf15\Approved\Approved On: 14-Jun-2021 14:01 (GMT)

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	3	1	2	1	1
Abdominal pain upper	1	3	1	2		1
Abnormal dreams		1		1		
Allergy to vaccine		1				1
Anaphylactic reaction	1	2			1	2
Angioedema		1				1
Anxiety	1	1			1	1
Arrhythmia		1				1
Arthralgia	5	8	4	7	1	1
Asthenia		1				1
Asthma		1				1
Axillary mass		1				1
Axillary pain		1				1
Back pain	1	2	1	2		
Blood glucose fluctuation		2		2		
Blood pressure decreased		1				1
Blood pressure increased	1	1	1	1		
Blood pressure systolic decreased		1				1
Bradycardia		1				1
Breast tenderness	1	1	1	1		
Chest discomfort		2		2		
Chest pain	2	4		1	2	3
Chills	2	8	2	5		3
Cold sweat	1	1			1	1
Cough	1	6		4	1	2
COVID-19	1	1			1	1
Decreased appetite	1	1			1	1
Depressed level of consciousness		1				1
Diabetes mellitus inadequate control		1				1
Diarrhoea	2	4	1	3	1	1
Diplopia		1		1		
Discomfort		3		2		1

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* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbance in attention		2		2		
Dizziness	4	13	3	7	1	6
Dysgeusia	1	1	1	1		
Dysphonia	1	1			1	1
Dyspnoea	3	10	1	6	2	4
Ear discomfort		1		1		
Eczema		1				1
Erythema	1	2	1	1		1
Extrasystoles		1				1
Facial paralysis		1				1
Facial paresis		3		2		1
Fatigue	2	18	2	16		2
Feeling abnormal		2		2		
Feeling drunk		1		1		
Feeling hot		1		1		
Fibrin D dimer increased	1	1			1	1
Frostbite	1	1	1	1		
General physical health deterioration	1	4		2	1	2
Grip strength decreased		1				1
Haematoma		1				1
Hallucination	1	1			1	1
Hallucination, auditory		2				2
Hallucinations, mixed		1				1
Hallucination, visual		1				1
Headache	7	33	7	27		6
Heart rate increased	1	3		1	1	2
Heavy menstrual bleeding	1	1	1	1		
Hemiparesis		2				2
Hot flush		1		1		
Hunger	1	1	1	1		
Hyperaesthesia		1				1
Hyperglycaemia		1		1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperhidrosis	1	3		2	1	1
Hypersensitivity		1				1
Hypertension	1	1			1	1
Hyperventilation	1	1			1	1
Hypoaesthesia		3		2		1
Hypoaesthesia oral	1	4		2	1	2
Hypogeusia		1		1		
Hypothermia		1				1
Immune thrombocytopenia		1				1
Increased tendency to bruise		1				1
Infection	1	1			1	1
Influenza like illness		2		2		
Lethargy	1	1	1	1		
Limb discomfort		1				1
Lymphadenopathy		2		1		1
Malaise		9		8		1
Memory impairment		2		2		
Mouth swelling		1				1
Musculoskeletal stiffness		1				1
Myalgia	5	17	4	14	1	3
Myopia		1				1
Nasal congestion		1		1		
Nasopharyngitis		1		1		
Nausea	3	17	1	11	2	6
Neck pain		1		1		
Neuroborreliosis		1				1
Neuropathy peripheral		1				1
Obstructive airways disorder		1				1
Odynophagia	1	1			1	1
Oral pruritus		1				1
Oropharyngeal pain	1	5	1	4		1
Oxygen saturation decreased	2	2			2	2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain		2		2		
Painful respiration	1	1			1	1
Pain in extremity	1	2	1	1		1
Pain of skin	1	1	1	1		
Pallor	1	1	1	1		
Palpitations	1	2	1	2		
Paraesthesia		1				1
Parosmia		1		1		
Peripheral swelling		1				1
Petechiae		1				1
Pharyngeal swelling	1	2			1	2
Photophobia	1	3	1	3		
Pneumonia	1	1			1	1
Presyncope		1				1
Productive cough	1	1			1	1
Pruritus	3	8	2	3	1	5
Pyrexia	6	25	5	22	1	3
Rash	1	2			1	2
Rash erythematous	1	2		1	1	1
Rash pruritic		1				1
Respiratory rate increased		1				1
Restlessness	1	2			1	2
Retching		1		1		
Reversible cerebral vasoconstriction syndrome	1	1			1	1
Rhinorrhoea		2		2		
Seizure	1	1			1	1
Sneezing		1		1		
Somnolence	1	3	1	3		
Swelling face		1				1
Swollen tongue	1	1	1	1		
Syncope		1				1
Tachycardia	1	2		1	1	1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tenderness		2		2		
Thrombocytopenia		1				1
Time perception altered		1		1		
Tremor	2	2	1	1	1	1
Urticaria	1	5	1	2		3
Vaccination failure	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site movement impairment		1				1
Vaccination site pain	3	9	3	6		3
Vaccination site reaction		1		1		
Vaccination site swelling	2	3	2	2		1
Vaccination site warmth		1				1
Vision blurred		1				1
Visual impairment	1	2	1	2		
Vomiting	2	3	1	2	1	1
	106	378	61	230	45	148

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain	4	11	3	7	1	4
Abdominal pain upper		6		1		5
Abnormal weight gain	1	1	1	1		
Abortion spontaneous	1	2			1	2
Acute kidney injury		1				1
Alanine aminotransferase increased		1		1		
Allergy to vaccine		1				1
Amnesia		2				2
Anaphylactic reaction	9	14			9	14
Anaphylactic shock	1	1			1	1
Angioedema	2	3			2	3
Apallic syndrome		1				1
Apathy		1				1
Apnoea		1				1
Appendicitis		2				2
Arrhythmia	2	2			2	2
Arthralgia	5	24	5	21		3
Arthritis		1				1
Arthritis reactive		1				1
Asthenia		2				2
Asthma	1	2	1	2		
Atrial f brillation	1	1			1	1
Autonomic nervous system imbalance		1				1
Axillary pain		2		2		
Back pain	1	3	1	2		1
Balance disorder	1	3	1	1		2
Basedow's disease		1				1
Bedridden		3		2		1
Bell's palsy	1	1			1	1
Blepharospasm		1		1		
Blindness transient	1	1			1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blister	1	1			1	1
Blood 25-hydroxycholecalciferol decreased		1		1		
Blood bilirubin increased		1		1		
Blood creatinine increased	1	1			1	1
Blood glucose decreased		1		1		
Blood glucose fluctuation		1		1		
Blood magnesium increased		1		1		
Blood pressure decreased	1	4		2	1	2
Blood pressure diastolic increased	1	1			1	1
Blood pressure increased	3	4	1	1	2	3
Blood pressure systolic increased		1				1
Bone pain		2		1		1
Bradycardia	2	3			2	3
Breast enlargement		1		1		
Breast pain		1		1		
Bronchospasm	1	1			1	1
Burning sensation		3		2		1
Cardiac arrest	1	1			1	1
Cardiac disorder	1	1			1	1
Cerebral haemorrhage		1				1
Cerebral thrombosis		1				1
Chest discomfort	3	7	1	4	2	3
Chest pain	3	11		4	3	7
Chills	7	25	6	19	1	6
Cold sweat	1	7		4	1	3
Concussion		1				1
Confusional state		2		1		1
Constipation		1				1
Contusion		2		1		1
Cough	4	7	1	3	3	4
COVID-19	1	3		1	1	2
Cyanosis		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased activity		1		1		
Decreased appetite		2		2		
Deep vein thrombosis	2	2			2	2
Depressed level of consciousness	1	1			1	1
Diarrhoea		6		3		3
Discomfort		1		1		
Disease recurrence		2		1		1
Diverticulitis		1				1
Dizziness	8	33	5	19	3	14
Drug ineffective		1				1
Dry mouth		3		3		
Dysarthria		2		1		1
Dysgeusia	2	4	1	2	1	2
Dyskinesia		1				1
Dysphagia		2		1		1
Dysphonia	2	2	1	1	1	1
Dyspnoea	15	31	3	10	12	21
Dyspnoea at rest	1	1			1	1
Ear discomfort		1		1		
Ear pain		1		1		
Ear swelling		1		1		
Ecchymosis		1				1
Epilepsy		1				1
Epistaxis		2		1		1
Erysipelas	1	1			1	1
Erythema	5	13	2	7	3	6
Eye disorder	1	1	1	1		
Eye irritation	1	1	1	1		
Eye pain		2		2		
Eye swelling	1	1	1	1		
Facial paralysis	1	1			1	1
Facial paresis	1	3	1	1		2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Faeces discoloured		1		1		
Fall		2				2
Fatigue	15	52	13	43	2	9
Febrile neutropenia	1	1			1	1
Feeling cold	2	4	2	4		
Feeling hot	4	8	3	6	1	2
Feeling of body temperature change		1		1		
Flatulence		1		1		
Flushing	3	4	2	3	1	1
Forced expiratory flow	1	1			1	1
Frostbite		1				1
Gastric disorder		1				1
General physical health deterioration	1	4		1	1	3
Glomerulonephritis minimal lesion		1				1
Grip strength decreased		1				1
Grunting	1	1			1	1
Haematoma		1				1
Haemorrhage		1				1
Hallucination		2				2
Hallucination, visual	1	1			1	1
Headache	17	57	14	48	3	9
Heart rate increased	2	9	1	5	1	4
Heart rate irregular	1	2		1	1	1
Hemiplegia	1	1			1	1
Herpes simplex reactivation		1		1		
Herpes zoster	3	3	3	3		
Hyperhidrosis	1	4	1	4		
Hypersensitivity	5	11	1	2	4	9
Hypersensitivity vasculitis	1	1			1	1
Hypersomnia	1	2	1	2		
Hypertension		1				1
Hyperthyroidism		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperventilation	3	6		1	3	5
Hypoaesthesia	5	10	4	8	1	2
Hypoaesthesia oral	3	5	3	4		1
Hypogeusia	1	1	1	1		
Hypokinesia	1	2	1	2		
Hyposmia	1	1	1	1		
Hypotension		4				4
Hypothyroidism	1	1			1	1
Immune thrombocytopenia		1				1
Incorrect route of product administration		1		1		
Increased viscosity of upper respiratory secretion		1		1		
Influenza		1		1		
Influenza like illness	4	7	4	6		1
Injection site pain		1		1		
Intranasal hypoaesthesia		1		1		
Intranasal paraesthesia		1		1		
Iridocyclitis		1				1
Joint swelling		1		1		
Lacrimation increased	1	1	1	1		
Limb discomfort		3		3		
Lip pruritus	1	2			1	2
Lip swelling	2	2	1	1	1	1
Loss of consciousness	3	4			3	4
Low density lipoprotein increased		1		1		
Lymphadenitis		2		1		1
Lymphadenopathy		2		2		
Lymphangitis		1				1
Lymph node pain	1	1	1	1		
Lymphocyte count decreased	1	1			1	1
Malaise	5	16	2	11	3	5
Mechanical urticaria	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Memory impairment		2		2		
Menstrual discomfort	1	1			1	1
Menstrual disorder	1	1	1	1		
Middle insomnia		1		1		
Migraine		3		2		1
Migraine with aura		1				1
Mobility decreased		1		1		
Mouth haemorrhage		1				1
Mouth swelling	1	1			1	1
Mouth ulceration		1				1
Multiple sclerosis	1	1			1	1
Muscle contractions involuntary	1	2	1	2		
Muscle spasms	1	4	1	2		2
Muscular weakness		3		1		2
Musculoskeletal pain		2		2		
Musculoskeletal stiffness	2	7	2	5		2
Myalgia	7	23	7	20		3
Myocardial infarction	1	1			1	1
Nasal congestion	3	4	2	3	1	1
Nasal pruritus		1				1
Nausea	12	35	7	24	5	11
Neck pain	2	7	2	6		1
Neuropathy peripheral		1				1
Neutropenia	1	1			1	1
Night sweats		1		1		
Obstructive airways disorder	1	1	1	1		
Ocular hyperaemia	1	2	1	1		1
Oral mucosa haematoma		1				1
Oral pruritus	2	3			2	3
Oropharyngeal discomfort	1	1			1	1
Oropharyngeal pain	2	3	1	2	1	1
Oropharyngeal swelling		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Orthostatic hypotension	1	2		1	1	1
Oxygen saturation decreased		2				2
Pain	1	7		5	1	2
Pain in extremity	4	13	4	13		
Pain of skin		1				1
Pallor	1	6		3	1	3
Palpitations	5	7	1	2	4	5
Paraesthesia	5	10	5	8		2
Paraesthesia oral	3	5	2	3	1	2
Paralysis	1	1			1	1
Paranasal sinus discomfort		1		1		
Pericarditis		2				2
Peripheral coldness	1	2	1	2		
Peripheral swelling		5		4		1
Petechiae	1	2	1	1		1
Pharyngeal paraesthesia	2	2			2	2
Pharyngeal swelling	2	4		1	2	3
Photophobia		1				1
Postictal state		1		1		
Presyncope		2		1		1
Productive cough	1	1	1	1		
Pruritus	5	11	3	6	2	5
Psychological trauma	1	1			1	1
Pulmonary embolism	2	4			2	4
Pulmonary necrosis		1				1
Pulmonary pain	1	1			1	1
Pyrexia	16	42	15	37	1	5
Rash	2	8		4	2	4
Rash erythematous	3	4		1	3	3
Rash pruritic	2	4	2	3		1
Respiratory alkalosis		1				1
Respiratory arrest		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory distress	1	1			1	1
Respiratory rate decreased		1		1		
Respiratory symptom	1	1			1	1
Respiratory tract congestion		1				1
Restlessness	2	6		2	2	4
Retching	2	6		1	2	5
Road traffic accident	1	1			1	1
Secretion discharge		1				1
Seizure		1				1
Shock		1				1
Sinoatrial block	1	1			1	1
Skin haemorrhage		1		1		
Skin laceration		1				1
Sleep disorder		1		1		
Sleep paralysis	1	1	1	1		
Somnolence	1	2	1	1		1
Speech disorder	1	4			1	4
Stridor		1				1
Sudden hearing loss	1	1			1	1
Swelling	3	4	1	1	2	3
Swelling face	1	4	1	2		2
Swelling of eyelid		2		1		1
Swollen tongue	3	3	1	1	2	2
Syncope	4	16			4	16
Systemic inflammatory response syndrome	1	1			1	1
Tachycardia	4	5		1	4	4
Taste disorder	1	1	1	1		
Tendon pain		1		1		
Thirst		1		1		
Throat clearing		1		1		
Throat irritation	2	5		1	2	4
Throat tightness	5	7	1	1	4	6

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thrombocytopenia		1				1
Thrombophlebitis		1				1
Thrombophlebitis superficial		1		1		
Tongue disorder	1	1			1	1
Tongue pruritus	1	1			1	1
Tooth avulsion		1				1
Tremor	1	4	1	3		1
Troponin I increased		1		1		
Urinary incontinence	1	1			1	1
Urticaria	9	13	4	5	5	8
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema		4		4		
Vaccination site hypoaesthesia		1		1		
Vaccination site movement impairment	1	1	1	1		
Vaccination site oedema		1		1		
Vaccination site pain	6	24	6	22		2
Vaccination site paraesthesia		2		2		
Vaccination site pruritus	1	4	1	3		1
Vaccination site reaction		2		2		
Vaccination site swelling	1	2	1	2		
Vaccination site warmth		2		2		
Vaginal haemorrhage	1	1			1	1
Ventricular extrasystoles		1		1		
Ventricular tachycardia		1				1
Vertigo		1		1		
Vertigo positional		1				1
Vision blurred	1	1	1	1		
Visual field defect	1	1			1	1
Visual impairment	1	1			1	1
Vomiting	6	10	3	5	3	5
Wheezing	3	4	1	1	2	3
White blood cell count decreased	1	1			1	1

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	373	1,037	185	586	188	451

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* I=Interval, C=Cumulative
* AE=Adverse Event
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal infection		1				1
Abdominal pain		1		1		
Abdominal pain upper	1	3	1	2		1
Abdominal wall haemorrhage		1				1
Acute myocardial infarction	1	1			1	1
Anaphylactic reaction	4	6			4	6
Angioedema	2	3			2	3
Antinuclear ant body increased		1		1		
Anti-thyroid antibody		1		1		
Anxiety	2	2			2	2
Arthralgia	2	7	1	5	1	2
Arthritis		1		1		
Asthenia		2		2		
Asthma	1	1			1	1
Asymptomatic COVID-19	1	1			1	1
Atrial fibrillation		1				1
Back pain		3		2		1
Balance disorder	1	1			1	1
Blood calcium decreased		1		1		
Blood glucose increased		1		1		
Blood phosphorus decreased		1		1		
Blood potassium decreased		1		1		
Blood pressure decreased	1	2		1	1	1
Blood pressure increased	2	2	1	1	1	1
Bone pain	1	1			1	1
Brain herniation	1	1			1	1
Brain injury	1	1			1	1
Brain oedema	1	1			1	1
Burning sensation	1	1			1	1
Cardiac arrest	2	3			2	3
Cellulitis	1	1			1	1
Cerebellar haemorrhage	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral artery embolism	1	1			1	1
Cerebral haemorrhage	1	1			1	1
Cerebral infarction	1	2			1	2
Chest pain	2	5		1	2	4
Chills	3	9	2	7	1	2
Circulatory collapse	1	2			1	2
Cold sweat	1	1			1	1
Coma		1				1
Confusional state	1	1			1	1
Coordination abnormal		1		1		
Cor pulmonale acute	1	1			1	1
Cough	3	6		2	3	4
COVID-19	1	3			1	3
C-reactive protein increased	1	4		2	1	2
Deep vein thrombosis	3	4			3	4
Defaecation urgency	1	1	1	1		
Dehydration	1	1	1	1		
Delirium		1				1
Diarrhoea		2		2		
Disease recurrence	2	2	1	1	1	1
Disorientation	2	2			2	2
Dizziness	5	9	1	4	4	5
Drug ineffective		1				1
Drug reaction with eosinophilia and systemic symptoms		1				1
Dysgeusia		2		2		
Dyspnoea	7	15		4	7	11
Dyspnoea exertional	1	1	1	1		
Ear pain		1		1		
Eosinophilia		1				1
Epistaxis	1	1	1	1		
Erysipelas		2				2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	1	2		1	1	1
Facial paresis	1	2	1	1		1
Fatigue	6	21	4	17	2	4
Fear	1	1			1	1
Fear of death		1		1		
Feeling cold		1		1		
Feeling hot	1	1			1	1
Flushing		1		1		
Frostbite	1	1			1	1
Gastritis		1		1		
Generalised tonic-clonic seizure	1	1			1	1
General physical health deterioration		1				1
Headache	9	22	5	14	4	8
Heart rate increased		2				2
Hemiparesis	2	2			2	2
Herpes zoster	2	2	2	2		
Hyperaesthesia		1				1
Hyperhidrosis		1		1		
Hyperpyrexia		1				1
Hypersensitivity	2	3		1	2	2
Hypertension	2	3	1	1	1	2
Hypoaesthesia	1	1	1	1		
Hyposmia		1		1		
Hypotension	1	2			1	2
Immune thrombocytopenia	1	1			1	1
Incomplete course of vaccination	1	1			1	1
Incorrect route of product administration		1		1		
Infection	2	2			2	2
Influenza		1		1		
Influenza like illness	2	3	1	2	1	1
Injection site muscle weakness		1		1		
Injection site pain	1	1	1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Insomnia	1	2	1	2		
International normalised ratio increased		1				1
Lethargy		1		1		
Lip swelling	2	2	1	1	1	1
Listless		1		1		
Livedo reticularis		1		1		
Loss of consciousness		1				1
Lymphadenopathy	1	1	1	1		
Lymphocytosis		1		1		
Malaise	2	5		3	2	2
Migraine		1				1
Multiple sclerosis	1	1			1	1
Muscle spasms		1				1
Musculoskeletal stiffness		1		1		
Myalgia	5	15	2	10	3	5
Nausea	7	12	3	7	4	5
Neck pain		1		1		
Nephrolithiasis		1				1
Neurofibromatosis	1	1			1	1
Neutropenia		1				1
Nightmare		1		1		
Nocturia	1	1	1	1		
Oropharyngeal pain		2		1		1
Pain	1	2	1	2		
Painful respiration		1		1		
Pain in extremity	4	6	4	5		1
Pain of skin		1		1		
Palpitations		2		1		1
Panic attack		1		1		
Paraesthesia	1	2		1	1	1
Paraesthesia oral	1	1	1	1		
Pericarditis	2	3			2	3

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral coldness		1		1		
Peripheral swelling		1		1		
Pharyngeal paraesthesia		1				1
Platelet count increased	1	1			1	1
Pneumonia	1	2			1	2
Prerenal failure	1	1			1	1
Presyncope		1				1
Pruritus	3	5		2	3	3
Psoriasis		1		1		
Psychomotor hyperactivity		1		1		
Pulmonary embolism	7	7			7	7
Pulmonary infarction	1	1			1	1
Pyrexia	5	20	1	11	4	9
Rash	1	3		1	1	2
Rash erythematous	1	1			1	1
Rash macular	1	1			1	1
Renal failure		1				1
Respiratory failure	1	1			1	1
Rhinorrhoea	1	2	1	2		
Sensation of foreign body	1	1			1	1
Sleep disorder due to general medical condition, insomnia type	1	1	1	1		
Somnolence		2		1		1
Status migrainosus		1				1
Stridor	1	1			1	1
Sudden death	1	1			1	1
Swelling face		1		1		
Syncope	1	3			1	3
Tachycardia		1		1		
Tachypnoea		1				1
Thirst	1	1	1	1		
Throat irritation	1	1			1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Throat tightness	2	3			2	3
Thrombocytopenia		2				2
Thrombophlebitis		1		1		
Tremor	1	1			1	1
Upper respiratory tract congestion	1	1			1	1
Upper respiratory tract irritation	1	1			1	1
Urosepsis		1				1
Urticaria	2	3	1	2	1	1
Vaccination failure	1	2			1	2
Vaccination site erythema		2		2		
Vaccination site pain	4	8	4	8		
Vaccination site pruritus		1		1		
Vaccination site rash		1		1		
Vaccination site swelling	1	1	1	1		
Vaccination site warmth	1	1	1	1		
Vaccine breakthrough infection		1				1
Vertigo	1	1			1	1
Vestibular neuronitis	1	1			1	1
Vomiting	3	5	2	2	1	3
Wheezing	1	1			1	1
White blood cell count increased		2		1		1
	186	407	55	193	131	214

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1			1	1
Abdominal pain		2				2
Abdominal pain upper	3	3			3	3
Abnormal behaviour		1				1
Acute kidney injury	1	1			1	1
Acute myocardial infarction	5	5			5	5
Acute respiratory failure	1	1			1	1
Adenoma benign		1				1
Aggression		1				1
Altered state of consciousness	1	4			1	4
Amnesia		1		1		
Anaphylactic reaction	3	5			3	5
Angina pectoris		2				2
Aphasia		1				1
Apnoeic attack		1				1
Arrhythmia	2	2			2	2
Arteriovenous fistula thrombosis		1				1
Arthralgia	5	6	1	2	4	4
Arthritis	1	1			1	1
Aspiration		1				1
Asthenia	2	3	1	1	1	2
Atelectasis		1				1
Atrial fibrillation	2	3			2	3
Atrial flutter	1	1			1	1
Auditory disorder		1		1		
Autoimmune hepatitis	1	1			1	1
Back pain	1	1			1	1
Bacterial test positive		1		1		
Balance disorder		2		1		1
Blood glucose increased	2	3	1	2	1	1
Blood potassium decreased	1	1			1	1
Blood pressure decreased		4				4

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased	2	2			2	2
Blood pressure systolic increased	1	1			1	1
Body temperature increased		1		1		
Bone pain	1	1			1	1
Brachiocephalic vein thrombosis	1	1			1	1
Bradycardia		1				1
Brain stem infarction	1	1			1	1
Burning sensation	1	1	1	1		
Bursitis	1	1			1	1
Cardiac arrest	1	2			1	2
Cardiac failure	1	1			1	1
Cardiac murmur	1	1	1	1		
Cardiomegaly		1				1
Cardiovascular disorder		1				1
Carotid artery occlusion		1				1
CD4 lymphocytes decreased	1	1			1	1
Cerebellar infarction		1				1
Cerebral artery embolism		1				1
Cerebral artery thrombosis	1	2			1	2
Cerebral haemorrhage	1	3			1	3
Cerebral infarction	1	4			1	4
Cerebral thrombosis		1				1
Cerebral venous thrombosis	1	1			1	1
Cerebrovascular accident	5	8			5	8
Chest pain	6	8		1	6	7
Chills		1				1
Chronic obstructive pulmonary disease		2				2
Circulatory collapse		1				1
Coating in mouth	1	1			1	1
Cognitive disorder	1	1	1	1		
Cold sweat	2	4			2	4
Colitis	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Concomitant disease aggravated		1				1
Concussion		1				1
Condition aggravated	2	3		1	2	2
Confusional state	4	12	1	3	3	9
Contusion	1	2	1	1		1
Coronary artery thrombosis	1	1			1	1
Cough	2	5	2	2		3
COVID-19	2	3	1	1	1	2
COVID-19 pneumonia	1	1			1	1
C-reactive protein increased	5	11	2	4	3	7
Cutaneous vasculitis	1	1			1	1
Death	1	3			1	3
Decreased appetite	1	1			1	1
Deep vein thrombosis	5	9			5	9
Dehydration	1	2	1	1		1
Delirium		1				1
Delusion		1				1
Depressed level of consciousness	1	2			1	2
Dermatitis allergic		1				1
Diarrhoea	3	8	1	2	2	6
Diarrhoea haemorrhagic	1	1			1	1
Discomfort		1		1		
Disease recurrence		1				1
Disseminated varicella zoster virus infection	1	1			1	1
Disturbance in attention	1	1	1	1		
Dizziness	6	13		3	6	10
Drug ineffective	1	1			1	1
Drug interaction		1		1		
Dysphonia	1	2		1	1	1
Dyspnoea	12	22	3	5	9	17
Electrolyte imbalance		1				1
Enthesopathy	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Epilepsy		4				4
Erysipelas	1	2			1	2
Erythema	1	2		1	1	1
Erythema multiforme	1	1			1	1
Eye haemorrhage	1	1			1	1
Face oedema		1				1
Facial paralysis	1	1			1	1
Facial paresis	1	1			1	1
Faeces discoloured	1	1			1	1
Fall	2	7		1	2	6
Fatigue	14	21	8	13	6	8
Feeling abnormal		1		1		
Feeling cold	1	1	1	1		
Feeling hot	2	4		2	2	2
Fibrin D dimer increased	2	2			2	2
Flushing		2		1		1
Foaming at mouth		1		1		
Frostbite	1	1	1	1		
Fungal infection	1	1			1	1
Gait disturbance	1	1			1	1
Gastroenteritis		1				1
Gastrointestinal haemorrhage	1	1			1	1
Generalised tonic-clonic seizure		1				1
General physical health deterioration	4	12		1	4	11
General symptom		1				1
Haematochezia	1	1			1	1
Haemorrhage subcutaneous		1				1
Hallucination		1				1
Headache	10	15	5	8	5	7
Head injury		1				1
Heart rate decreased	1	1			1	1
Heart rate increased	1	1	1	1		

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate irregular		1		1		
Hemianopia		1				1
Hemiplegia	1	3			1	3
Hepatic cyst		1				1
Herpes zoster	3	3	2	2	1	1
Hypercapnia		1				1
Hyperhidrosis	2	2	1	1	1	1
Hypertension	2	2	1	1	1	1
Hyperventilation	1	1			1	1
Hypoaesthesia		1		1		
Hypotension	1	4	1	1		3
Hypothermia		1				1
Hypoxia	1	3			1	3
Illness	1	2	1	2		
Immune-mediated adverse reaction	1	1			1	1
Immune system disorder	1	1			1	1
Impaired driving ability	1	1			1	1
Inappropriate schedule of product administration		1		1		
Incomplete course of vaccination	1	1			1	1
Incorrect route of product administration	1	2	1	2		
Increased bronchial secretion		1				1
Infection	3	3	1	1	2	2
Infective exacerbation of chronic obstructive airways disease		1				1
Inferior vena caval occlusion		1				1
Inflammation	1	1	1	1		
Influenza like illness	1	3	1	2		1
Intracardiac thrombus		1				1
Irritability postvaccinal		1				1
Joint swelling	2	2	1	1	1	1
Jugular vein thrombosis	1	1			1	1
Lethargy	2	3	1	1	1	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Leukocytosis	1	1
Listless	1	1
Loss of consciousness	3	6
Loss of personal independence in daily activities		1
Malaise	9	15
Malignant hypertension		1
Mania		1
Mastitis	1	1
Moaning		1
Monocytosis	1	1
Muscle spasms	2	3
Muscular weakness	1	2
Myalgia	6	9
Myocardial infarction	2	3
Nasal congestion	1	1
Nausea	7	19
Neck pain		1
Neuralgia	1	1
Neutropenia	1	1
Neutrophilia	1	1
Night sweats	1	1
N-terminal prohormone brain natriuretic peptide increased		1
Nystagmus		1
Obstructive airways disorder	1	2
Oedema peripheral		1
Off label use		1
Ophthalmic herpes zoster		1
Orbital oedema		1
Oropharyngeal pain	1	1
Oxygen saturation decreased		6
Pain	6	8

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
1	1		
		3	6
			1
3	8	6	7
			1
			1
		1	1
			1
1	1		
		2	3
1	1		1
2	2	4	7
		2	3
		1	1
2	8	5	11
	1		
		1	1
		1	1
1	1		
1	1		
			1
			1
		1	2
			1
	1		
			1
			1
		1	1
	1		5
1	3	5	5

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Painful respiration	1	1			1	1
Pain in extremity	4	4	1	1	3	3
Pallor		2				2
Palpitations	3	4	1	2	2	2
Pancreatitis	1	1			1	1
Paraesthesia	1	1			1	1
Paranoia		1				1
Pelvic venous thrombosis	2	2			2	2
Pericardial effusion	1	1			1	1
Pericarditis	3	3			3	3
Peripheral coldness		1				1
Peripheral swelling	2	2	1	1	1	1
Personality change		1				1
Petechiae	1	1			1	1
Pleural effusion	1	1			1	1
Pneumonia	2	9			2	9
Pneumonia aspiration		1				1
Polymyalgia rheumatica	1	1			1	1
Presyncope	2	3	1	1	1	2
Pruritus		1				1
Psoriasis	1	1			1	1
Pulmonary congestion		1				1
Pulmonary embolism	16	21			16	21
Pulmonary thrombosis		1				1
Purpura	1	1			1	1
Pyrexia	11	24	7	12	4	12
Radiculopathy	1	1			1	1
Rales		1				1
Rash	6	7	2	3	4	4
Rash macular	1	1	1	1		
Rash maculo-papular	1	1			1	1
Red blood cell sedimentation rate increased		1				1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal cyst		1				1
Renal failure		1				1
Respiratory acidosis		1				1
Respiratory arrest	1	1			1	1
Respiratory failure	1	5			1	5
Respiratory rate increased		3		1		2
Restlessness	1	1			1	1
Retching		2		1		1
Retinal artery occlusion	1	1			1	1
Rhinorrhoea		1		1		
Right ventricular failure	1	1			1	1
Road traffic accident	1	1			1	1
Salmonella test positive		1				1
Sepsis		1				1
Serum sickness	1	1			1	1
Skin discolouration	1	1			1	1
Skin warm	1	1	1	1		
Sleep disorder		1				1
Soft tissue infection	1	1			1	1
Somnambulism	1	1	1	1		
Somnolence	1	5		1	1	4
Speech disorder		1				1
Splenic infarction	1	1			1	1
Sputum increased		1		1		
Status epilepticus		1				1
Stenosis		1				1
Sudden death	1	2			1	2
Swollen tongue	4	4			4	4
Syncope	3	9			3	9
Systemic inflammatory response syndrome	1	1			1	1
Tachycardia	2	4		1	2	3
Throat tightness	4	4			4	4

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thrombocytopenia	2	3			2	3
Thrombophlebitis	1	1	1	1		
Thrombotic stroke	1	1			1	1
Transient ischaemic attack		2				2
Ulcer	1	1	1	1		
Unresponsive to stimuli		1				1
Urinary incontinence		1		1		
Urinary tract infection		1		1		
Urticaria	1	2			1	2
Vaccination failure		1				1
Vaccination site pain	1	4	1	4		
Vaccination site pruritus	1	1	1	1		
Vaccination site reaction	1	1			1	1
Vaccination site swelling	2	2	1	1	1	1
Vena cava thrombosis	1	1			1	1
Ventricular extrasystoles		1				1
Vertigo		2				2
Vision blurred		1				1
Visual impairment	1	3			1	3
Vomiting	4	11	1	3	3	8
Waking aid user	1	1	1	1		
Weight decreased	1	1	1	1		
White blood cell count increased		1		1		
	353	681	84	165	269	516

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain	1	4		2	1	2
Abdominal pain upper		5		2		3
Acute coronary syndrome		1				1
Acute kidney injury	1	3			1	3
Acute myocardial infarction		5				5
Aggression		1		1		
Agitation		1				1
Altered state of consciousness		4				4
Anal incontinence		1				1
Anaphylactic reaction		2				2
Anxiety		3		1		2
Aortic aneurysm	1	1			1	1
Aortic arteriosclerosis		1		1		
Aortic stenosis		1				1
Apathy		1				1
Aphasia		4				4
Apnoea	1	3			1	3
Arrhythmia		1				1
Arterial haemorrhage		1				1
Arteriosclerosis coronary artery		1				1
Arteriovenous fistula thrombosis		1				1
Arthralgia	3	5	2	3	1	2
Arthritis bacterial		1				1
Asthenia		9		4		5
Asthma	1	1			1	1
Asymptomatic COVID-19	3	3			3	3
Atrial f brillation	1	2			1	2
Atrial flutter		1				1
Atrioventricular block	1	1			1	1
Atrioventricular block first degree		1				1
Back pain		8		4		4

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacterial sepsis		1				1
Balance disorder		3		1		2
Bedridden		4				4
Bell's palsy		1				1
Blindness	1	2			1	2
Blood pressure decreased	2	6	2	2		4
Blood pressure diastolic decreased		1		1		
Blood pressure increased		2		2		
Blood pressure systolic increased	1	2			1	2
Body temperature decreased		1		1		
Body temperature fluctuation		1				1
Body temperature increased		1				1
Bradycardia		2				2
Brain stem stroke		1				1
Breath sounds abnormal		1				1
Bronchitis		1		1		
Cardiac arrest		1				1
Cardiac failure		4				4
Cardiac fibrillation		1				1
Cardio-respiratory arrest		1				1
Carotid arteriosclerosis		1		1		
Cerebral haemorrhage	1	8			1	8
Cerebral infarction	1	6			1	6
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident	3	22			3	22
Cerebrovascular disorder		1				1
Chest pain		5				5
Chills	2	7	1	3	1	4
Cholecystitis		1				1
Chronic kidney disease		1				1
Chronic obstructive pulmonary disease		4				4
Circulatory collapse		2				2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cognitive disorder		3		1		2
Cold sweat		5				5
Communication disorder		1		1		
Concomitant disease aggravated		1				1
Condition aggravated		6		1		5
Confusional state	1	22	1	8		14
Conjunctivitis		1		1		
Constipation		1		1		
Coordination abnormal		2				2
Coronary artery occlusion		1				1
Cough	1	8	1	5		3
COVID-19	7	7			7	7
COVID-19 pneumonia	1	1			1	1
C-reactive protein abnormal	1	1			1	1
C-reactive protein increased	3	24	1	5	2	19
Crepitations	1	1	1	1		
Cyanosis		1				1
Cystic lung disease		1		1		
Death	2	27			2	27
Decreased appetite	1	14	1	6		8
Decubitus ulcer		1		1		
Deep vein thrombosis	2	3			2	3
Defaecation disorder		1				1
Dehydration		2		1		1
Delirium	1	5			1	5
Delusion	1	1			1	1
Dementia		2				2
Dementia Alzheimer's type		1				1
Demyelinating polyneuropathy		1				1
Depressed level of consciousness		5				5
Depressed mood		1		1		
Diarrhoea	2	17	1	10	1	7

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diplopia		2				2
Discomfort		2		1		1
Disease recurrence	1	4			1	4
Disorientation		1				1
Dizziness	2	15	1	7	1	8
Drooling		1		1		
Drug ineffective	2	2			2	2
Drug interaction	1	4		2	1	2
Dry mouth		1				1
Dry skin		1		1		
Duodenitis		1				1
Dysarthria		5		1		4
Dysphagia		5		1		4
Dysphonia		3		3		
Dyspnoea	4	37	1	8	3	29
Dyspnoea at rest		1				1
Ear discomfort		1		1		
Embolic cerebral infarction		1				1
Emphysema		1		1		
Encephalitis brain stem	1	1			1	1
Epistaxis	1	2	1	2		
Erythema		3		3		
Exfoliative rash		1				1
Exposure to SARS-CoV-2	1	1	1	1		
Eye haemorrhage		2				2
Eyelid oedema	1	1	1	1		
Face injury	1	1			1	1
Facial paralysis		2				2
Facial paresis		3		1		2
Faeces discoloured		1				1
Fall	2	18	1	5	1	13
Fatigue	8	54	8	36		18

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling abnormal		2		1		1
Feeling hot		2				2
Femoral neck fracture		2				2
Femur fracture		1				1
Food refusal		1				1
Fracture		1				1
Gait disturbance		2		1		1
Gastric haemorrhage		1				1
Gastrointestinal haemorrhage	1	3			1	3
Gastrointestinal necrosis		1				1
General physical health deterioration	1	54		13	1	41
Giant cell arteritis		1				1
Glomerulonephritis chronic		1				1
Guillain-Barre syndrome		1				1
Haematemesis		2				2
Haemoglobin decreased		3				3
Haemorrhage		2				2
Haemorrhage subcutaneous		1				1
Haemothorax		1				1
Hallucination	1	4			1	4
Hallucination, visual	5	5			5	5
Headache	8	23	5	14	3	9
Head injury		1				1
Heart rate decreased	2	3	2	2		1
Heart rate increased	2	8	1	3	1	5
Heart rate irregular		1				1
Hemiparesis	1	4			1	4
Hemiplegia		2				2
Herpes zoster	6	6	6	6		
Hyperglycaemia		1				1
Hyperhidrosis	1	1			1	1
Hyperkalaemia		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypernatraemia		1				1
Hypertension		4		4		
Hyperventilation		4		3		1
Hypogeusia	1	1	1	1		
Hypokinesia		1				1
Hyponatraemia		2				2
Hypophagia		4				4
Hypotension		9		1		8
Hypoxia		2				2
Immobile		1				1
Immune-mediated adverse reaction		1				1
Immune thrombocytopenia	1	1			1	1
Inappropriate schedule of product administration		3		3		
Incontinence		1				1
Incorrect route of product administration		1		1		
Increased bronchial secretion		2		1		1
Infection	4	12		1	4	11
Inflammation		1				1
Inflammatory marker increased		1				1
Influenza like illness		2				2
International normalised ratio increased		1				1
Interstitial lung disease		1				1
Intestinal ischaemia		1				1
Intra-abdominal haematoma	1	1			1	1
Intracardiac thrombus		1				1
Iridocyclitis		1				1
Iron deficiency anaemia	1	1			1	1
Ischaemic stroke		3				3
Kidney fibrosis		1				1
Left ventricular failure		1				1
Lethargy		5		2		3
Leukocytosis		2		1		1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Local reaction		1				1
Loss of consciousness	2	10			2	10
Loss of personal independence in daily activities		1				1
Lower respiratory tract infection		1				1
Lung consolidation		1				1
Lung infiltration	1	1	1	1		
Lung opacity		3				3
Malaise	4	16	4	9		7
Malignant hypertension		1				1
Marasmus		1				1
Mediastinal haemorrhage		1				1
Melaena		1				1
Memory impairment	1	1	1	1		
Mental impairment		1				1
Mesenteric artery embolism		1				1
Metastases to peritoneum		1				1
Monoparesis		1				1
Monoplegia		1				1
Motor dysfunction		1		1		
Multiple fractures		1				1
Muscle rigidity		1				1
Muscle spasms		1				1
Muscle spasticity		1				1
Muscle twitching		1		1		
Muscular weakness		3		1		2
Musculoskeletal stiffness		1		1		
Myalgia	3	5	3	4		1
Myocardial infarction		1				1
Nasal congestion		3		3		
Nasopharyngitis		1				1
Nausea	5	31	3	18	2	13
Neck pain		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nodal rhythm		1				1
N-terminal prohormone brain natriuretic peptide increased		1				1
Ocular hyperaemia		1		1		
Oedema peripheral		4		2		2
Off label use		2		2		
Ophthalmic herpes zoster	1	2			1	2
Oropharyngeal pain		5		3		2
Orthostatic hypotension		1				1
Oxygen saturation decreased	1	12		1	1	11
Pain		8		3		5
Painful respiration	1	1			1	1
Pain in extremity	1	4		2	1	2
Pallor		4				4
Palpitations		1				1
Pancytopenia		1				1
Paraesthesia		1				1
Paralysis		1				1
Paresis		1		1		
Pericardial effusion		2				2
Pericardial haemorrhage		1				1
Pericarditis		3				3
Peripheral swelling		1				1
Petechiae	1	4		1	1	3
Pleural effusion		2				2
Pleurisy		1				1
Pneumonia		17				17
Pneumonia aspiration		2				2
Pneumonia bacterial		1				1
Pneumonitis		2				2
Presyncope		3				3
Productive cough		5				5

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pruritus		3				3
Psychiatric symptom	1	1	1	1		
Psychomotor hyperactivity		1				1
Pulmonary embolism	6	12			6	12
Pulmonary infarction	1	1			1	1
Pulmonary oedema		1				1
Pupil fixed		2				2
Pyelonephritis		1				1
Pyrexia	4	43	3	15	1	28
Rales		3		2		1
Rash		3		3		
Rash erythematous		1				1
Rash papular	1	1	1	1		
Rash pruritic	2	4	2	3		1
Rectal haemorrhage		2				2
Red blood cell sedimentation rate increased		1		1		
Renal impairment		1				1
Respiration abnormal		1				1
Respiratory arrest		3				3
Respiratory disorder		1				1
Respiratory failure	2	8			2	8
Respiratory rate increased	1	8		4	1	4
Respiratory tract infection		1				1
Restlessness		8		3		5
Retinal vein occlusion	1	1			1	1
Rhinorrhoea	1	4	1	4		
Rib fracture	1	1			1	1
Secretion discharge		1				1
Seizure	1	1			1	1
Sepsis		3				3
Sinoatrial block		1				1
Skin haemorrhage		1		1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sleep disorder		1				1
Snoring		1				1
Somnolence	1	9	1	6		3
Speech disorder		3		2		1
Spinal vascular disorder	1	1			1	1
Staphylococcal sepsis		1				1
Stridor		1				1
Subdural haematoma		1				1
Subdural haemorrhage		1				1
Sudden cardiac death		1				1
Sudden death		7				7
Supraventricular extrasystoles		1				1
Syncope		12				12
Tachycardia	1	5	1	2		3
Tachypnoea		2		1		1
Terminal state		1				1
Therapeutic product effect decreased		1		1		
Thirst		1				1
Thrombophlebitis		1		1		
Thrombophlebitis superficial		2				2
Thrombosis	1	2			1	2
Thrombotic stroke		1				1
Transfusion reaction		1		1		
Transient ischaemic attack	2	5			2	5
Tremor		5		1		4
Troponin increased		1				1
Tubulointerstitial nephritis		1				1
Unresponsive to stimuli		3				3
Urinary incontinence		1				1
Urinary retention		2				2
Urinary tract infection		5		4		1
Urosepsis		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria	5	6	5	5		1
Vaccination failure	11	11			11	11
Vaccination site erythema	3	7	3	6		1
Vaccination site haemorrhage	1	1	1	1		
Vaccination site pain	1	7	1	5		2
Vaccination site reaction		1				1
Vaccination site swelling	2	6	2	4		2
Vision blurred		1				1
Visual impairment		1		1		
Vlth nerve paralysis		1				1
Vomiting	2	30		10	2	20
Weight decreased		1		1		
Wheezing		2				2
	184	1,206	74	355	110	851

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	2	2			2	2
Atrial fibrillation		1				1
Bell's palsy	1	1			1	1
Cognitive disorder	1	1			1	1
Cold sweat		1		1		
Dizziness	1	4		3	1	1
Dry mouth		2		2		
Dyspnoea		1		1		
Exposure during pregnancy	1	2	1	2		
Fatigue	2	5	1	4	1	1
General physical health deterioration		1		1		
Headache	1	2	1	2		
Heart rate increased		1		1		
Hyperhidrosis		1		1		
Incorrect dose administered		5		5		
Incorrect route of product administration	1	1	1	1		
Injection site pain		2		2		
Intercepted product preparation error		1		1		
Malaise		1		1		
Maternal exposure during pregnancy		1		1		
Muscular weakness	1	1			1	1
Myalgia		1		1		
Off label use	6	7	6	7		
Pain	1	1	1	1		
Pain in extremity		1		1		
Pallor		1		1		
Paraesthesia		1		1		
Poor quality product administered	5	12	5	12		
Presyncope		1		1		
Product administered at inappropriate site		1		1		
Product preparation error		2		2		
Product preparation issue		8		8		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product temperature excursion issue	5	12	5	12		
Pyrexia	1	1	1	1		
Rash		1		1		
Sleep disorder	1	1			1	1
Tachycardia		1		1		
Tremor	1	1			1	1
Underdose		1		1		
Vaccination error		1		1		
Vaccination site pain		1		1		
Wrong technique in product usage process		1		1		
	31	94	22	84	9	10

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

OMAN

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	1			1	1
Diarrhoea		1		1		
Drug ineffective	1	1			1	1
Fatigue		1		1		
Gastritis		1		1		
Headache		1		1		
Inappropriate schedule of product administration		1		1		
Pain		1		1		
Product supply issue		1		1		
Pyrexia		1		1		
Therapeutic response unexpected		1		1		
Thrombosis	1	1			1	1
	3	12		9	3	3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

PALESTINIAN TERRITORY, OCCUPIED

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dyspnoea	1	1	1	1
Thirst	1	1	1	1
	2	2	2	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

PANAMA

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Asthenia	3	3	3	3		
Bronchospasm	2	2			2	2
Chills	2	2	2	2		
Cough	1	1	1	1		
Diarrhoea	1	1	1	1		
Discomfort	1	1	1	1		
Dizziness	3	3	3	3		
Dysgeusia	1	1	1	1		
Dyspnoea	2	2	1	1	1	1
Erythema	1	2	1	2		
Feeling hot	2	2	1	1	1	1
Headache	5	5	5	5		
Herpes zoster	1	1	1	1		
Hyperhidrosis	1	1	1	1		
Hypersensitivity	3	3	3	3		
Hypertension	1	1			1	1
Hypoaesthesia	1	1	1	1		
Hypoaesthesia oral	1	1	1	1		
Local reaction	1	1	1	1		
Lymphadenitis	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Musculoskeletal stiffness	1	1	1	1		
Nausea	1	1	1	1		
Pain	1	1	1	1		
Paraesthesia	1	1			1	1
Presyncope	1	1	1	1		
Pruritus	2	2	2	2		
Pyrexia	2	2	2	2		
Rash	1	1	1	1		
Seizure	1	1			1	1
Vaccination site erythema	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	1	1	1	1		
Vaccination site pruritus	1	1	1	1		
Vaccination site reaction	1	1	1	1		
Vision blurred	1	1	1	1		
Vomiting	1	1	1	1		
	53	54	46	47	7	7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Ageusia	2	2	2	2		
Allergy to vaccine	3	3	2	2	1	1
Anaphylactic reaction	1	1			1	1
Angioedema	1	1			1	1
Anosmia	2	2	2	2		
Arthralgia	3	4	3	4		
Asthenia	7	9	6	8	1	1
Asthmatic crisis	1	1			1	1
Axillary pain	1	1	1	1		
Back pain	3	3	3	3		
Bone pain	1	1	1	1		
Burning sensation	1	1	1	1		
Chest discomfort	3	3	3	3		
Chest pain	3	3	2	2	1	1
Chills	9	10	9	10		
Cough	2	2	2	2		
COVID-19	2	2	1	1	1	1
Diarrhoea	3	3	3	3		
Disease recurrence	1	1			1	1
Dizziness	7	7	7	7		
Drug ineffective	1	1			1	1
Dysgeusia	1	1	1	1		
Dysphonia	1	1	1	1		
Dyspnoea	2	3	1	1	1	2
Ear pain	1	1	1	1		
Erythema	1	1	1	1		
Fatigue	4	4	4	4		
Feeling hot	6	6	6	6		
Flushing	1	1	1	1		
Gait disturbance		1				1
Guillain-Barre syndrome	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache	24	24	24	24		
Hemiparesis		1				1
Hyperglycaemia	2	2	1	1	1	1
Hyperhidrosis	2	2	2	2		
Hypersensitivity	3	4	2	3	1	1
Hypertension	3	4	2	3	1	1
Hypertensive crisis	3	3			3	3
Hypertensive emergency	1	1			1	1
Hypoaesthesia	2	2	2	2		
Hypoaesthesia oral	1	2	1	1		1
Hypotension	2	2	2	2		
Hypotonia		1		1		
Hypotonic-hyporesponsive episode	2	4	1	2	1	2
Incorrect route of product administration	7	8	7	8		
Influenza like illness		1		1		
Irritability	1	2		1	1	1
Irritability postvaccinal	2	2	2	2		
Local reaction	3	5	2	4	1	1
Malaise	3	4	3	4		
Muscular weakness	1	1			1	1
Myalgia	8	8	8	8		
Nasal congestion	2	2	2	2		
Nasal oedema	1	1	1	1		
Nausea	7	7	7	7		
Neck pain	2	2	2	2		
Odynophagia	1	1	1	1		
Oedema	3	3	3	3		
Off label use	1	1	1	1		
Oropharyngeal pain	2	2	2	2		
Overdose		1		1		
Pain	7	7	7	7		
Pain in extremity	2	2	2	2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pallor		1		1		
Palpitations		1		1		
Paraesthesia	5	6	5	5		1
Photopsia	1	1	1	1		
Pigmentation disorder	1	1	1	1		
Presyncope	2	2	1	1	1	1
Product use issue	1	1	1	1		
Pruritus	4	4	3	3	1	1
Pulmonary pain		1				1
Pyrexia	17	19	16	17	1	2
Rash	10	10	9	9	1	1
Rash erythematous		1				1
Rash pruritic		1				1
Rhinorrhoea	3	3	3	3		
Salivary hypersecretion	1	1	1	1		
Seizure	1	1			1	1
Somnolence	1	1	1	1		
Syncope		2				2
Tachycardia	4	4	4	4		
Tinnitus	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination site cellulitis	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site oedema	1	1	1	1		
Vaccination site pain	9	10	9	9		1
Vaccination site reaction	6	7	6	7		
Vertigo	2	2	2	2		
Vomiting	2	2	2	2		
	249	281	222	241	27	40

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation	1	1	1	1		
Allergy to vaccine	5	5	5	5		
Anaphylactic reaction		1				1
Arthralgia	3	3	3	3		
Asthenia	3	5	3	5		
Back pain	2	2	2	2		
Blood pressure increased	1	1	1	1		
Chest pain	1	1	1	1		
Chills	7	7	7	7		
Cold sweat	1	1	1	1		
Cough	3	3	2	2	1	1
COVID-19	1	1	1	1		
Diarrhoea	1	1	1	1		
Disease progression	1	1	1	1		
Dizziness	5	5	4	4	1	1
Dyskinesia		1		1		
Dyspnoea	1	1	1	1		
Erythema	1	1	1	1		
Eye pain	1	1	1	1		
Fatigue	1	1	1	1		
Feeling cold	1	1	1	1		
Feeling hot	1	1	1	1		
Headache	10	11	9	10	1	1
Hypersensitivity	1	1	1	1		
Hypertension	3	3	3	3		
Hypoaesthesia	1	1	1	1		
Hypotonic-hyporesponsive episode	1	1			1	1
Incorrect route of product administration	1	1	1	1		
Irritability postvaccinal	1	1			1	1
Lip dry		1		1		
Lip oedema	2	2	2	2		
Local reaction	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenitis	1	1	1	1		
Lymphadenopathy	1	2	1	2		
Malaise	4	4	3	3	1	1
Migraine		1		1		
Myalgia	1	1	1	1		
Nausea	2	2	1	1	1	1
Neck pain	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Osteitis	1	1	1	1		
Pain	2	2	2	2		
Pain in extremity	1	1	1	1		
Pallor	2	2	1	1	1	1
Palpitations	3	3	3	3		
Papule	2	2	2	2		
Periorbital oedema	1	1	1	1		
Photosensitivity reaction		1		1		
Presyncope	1	1	1	1		
Pruritus	3	3	2	2	1	1
Pyrexia	11	11	11	11		
Rash	1	1	1	1		
Rhinorrhoea	1	1	1	1		
Tachycardia	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site oedema	1	1	1	1		
Vaccination site pain	4	5	4	5		
Vaccination site papule	1	1	1	1		
Vaccination site pruritus	1	1	1	1		
Vaccination site reaction	1	1	1	1		
Vaccination site warmth	1	1	1	1		
Vomiting	2	2	1	1	1	1
	115	125	104	113	11	12

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	1	1	1	1		
Arthralgia	1	1	1	1		
Asthenia	1	1	1	1		
Back pain	1	1			1	1
Chest pain	1	1	1	1		
Cough	1	1	1	1		
COVID-19	1	1	1	1		
Diarrhoea	1	1			1	1
Dizziness	5	5	5	5		
Dyspnoea	1	1			1	1
Fatigue	1	1	1	1		
Haematochezia	1	1			1	1
Haematoma	1	1	1	1		
Headache	7	7	6	6	1	1
Hot flush	1	1	1	1		
Hypertension	1	1			1	1
Hypotonia	1	1			1	1
Local reaction	1	1	1	1		
Malaise	1	1	1	1		
Monoparesis	1	1	1	1		
Myalgia	2	2	1	1	1	1
Oropharyngeal pain	1	1	1	1		
Pain	3	3	3	3		
Palpitations	1	1	1	1		
Paraesthesia	2	2	2	2		
Pyrexia	1	1	1	1		
Sciatica	1	1	1	1		
Seizure	1	1			1	1
Urinary incontinence	1	1			1	1
Vaccination site pain		1		1		
	43	44	33	34	10	10

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation	2	2	2	2		
Allergy to vaccine	2	2	2	2		
Anaphylactic reaction	1	1			1	1
Asthenia	2	2			2	2
Balance disorder	1	1	1	1		
Confusional state		1		1		
Cough	2	2	1	1	1	1
COVID-19	2	2	1	1	1	1
Depressed mood	1	1			1	1
Diarrhoea	2	2	2	2		
Dizziness	1	1			1	1
Drug ineffective	1	1			1	1
Dyspnoea	1	1	1	1		
Fatigue	1	2	1	2		
Hyperhidrosis	1	1	1	1		
Hypotension	1	1	1	1		
Incorrect route of product administration	1	1	1	1		
Lip oedema	1	1	1	1		
Pulmonary thrombosis	1	1			1	1
Pyrexia	2	2	1	1	1	1
Seizure	1	1			1	1
Vaccination site pain		1		1		
	27	30	16	19	11	11

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		2		2		
Arrhythmia	1	1			1	1
Asthenia		1		1		
Bradycardia	1	1			1	1
Diarrhoea	1	1	1	1		
Dry throat		1		1		
Dysphagia		1		1		
Flatulence		1		1		
Headache	1	1	1	1		
Hyperhidrosis	1	1	1	1		
Hypersensitivity		1		1		
Presyncope	1	1	1	1		
Pruritus	6	6			6	6
Rash	6	6			6	6
Rash pruritic		6				6
Syncope		1				1
	18	32	4	11	14	21

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

PERU

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposure via breast milk		1		1
Pyrexia		1		1
		2		2

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal pain	1	1	1	1
Chills	1	1	1	1
Diarrhoea	1	1	1	1
Fatigue	2	3	2	3
Food intolerance	1	1	1	1
Headache	3	5	3	5
Heart rate increased	1	1	1	1
Hunger	1	1	1	1
Nausea	2	2	2	2
Pain in extremity		1		1
Pyrexia		1		1
Vaccination site pain	1	2	1	2
	14	20	14	20

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
COVID-19	1	1			1	1
Drug ineffective	1	1			1	1
Headache		1		1		
Heart rate increased		1		1		
Pyrexia		1		1		
	3	6	1	4	2	2

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Back pain		1		1
Chest pain		1		1
Discomfort		1		1
Headache	1	3	1	3
Hyperhidrosis		1		1
Nasal dryness		1		1
Oropharyngeal pain		1		1
Pyrexia	1	2	1	2
Vaccination site pain		1		1
	2	12	2	12

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Application site acne	1	1	1	1
Back pain	1	1	1	1
Chest discomfort	1	1	1	1
Chest pain	1	1	1	1
Headache	1	1	1	1
Hypertension	1	1	1	1
Hypotension	1	1	1	1
Oropharyngeal pain	1	1	1	1
Otitis media	1	1	1	1
Pain in extremity	2	2	2	2
Tongue discomfort	1	1	1	1
Vaccination site hypoaesthesia	1	1	1	1
Vaccination site pain	2	2	2	2
Vaccination site pruritus	1	1	1	1
	16	16	16	16

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory failure	1	1			1	1
Arthralgia		1		1		
Bronchial disorder	1	1			1	1
COVID-19		1				1
COVID-19 pneumonia	1	1			1	1
Drug ineffective	2	3			2	3
General physical health deterioration	1	1			1	1
Oxygen saturation decreased	1	1			1	1
Pain		1		1		
Pain in extremity		1		1		
Paraesthesia	1	1	1	1		
Pyrexia		1		1		
Suspected COVID-19	1	1			1	1
Tremor	1	1	1	1		
	10	16	2	6	8	10

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Back pain	1	1	1	1		
Chills	1	1	1	1		
COVID-19		1		1		
Discomfort		1		1		
Dysphonia	1	1	1	1		
Epistaxis		1				1
Exposure via breast milk		1		1		
Hypertension	1	1			1	1
Off label use		2		2		
Pharyngeal inflammation	1	1	1	1		
Pharyngitis streptococcal	1	1	1	1		
Product use issue		2		2		
Pyrexia		1		1		
	7	16	6	14	1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

PHILIPPINES

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Blood pressure increased	1	1	1	1
Body temperature increased	1	1	1	1
Fatigue	1	1	1	1
Pain	1	1	1	1
Pain in extremity	1	1	1	1
Pyrexia	1	1	1	1
Thirst	1	1	1	1
Vaccination site movement impairment	1	1	1	1
Vaccination site pain	3	3	3	3
	11	11	11	11

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	2	2	2	2		
Asymptomatic COVID-19	1	1			1	1
Blood pressure increased	3	3	3	3		
Chills	1	1	1	1		
Diarrhoea	1	1	1	1		
Drug ineffective	1	1			1	1
Feeling cold	1	1	1	1		
Pain	2	2	2	2		
Pyrexia	2	2	2	2		
Vaccination site movement impairment	2	2	2	2		
Vaccination site pain	3	3	3	3		
	19	19	17	17	2	2

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Blood pressure increased	3	3	3	3
Dizziness	1	1	1	1
Headache	2	2	2	2
Pyrexia	1	1	1	1
Sinusitis	1	1	1	1
Somnolence	1	1	1	1
Therapeutic response unexpected	1	1	1	1
Vaccination site discomfort	1	1	1	1
Vaccination site pain	1	1	1	1
Vaccination site swelling	1	1	1	1
	13	13	13	13

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	1	1	1	1		
Dyspnoea	2	2	1	1	1	1
Gait inability	1	1	1	1		
Pain	1	1	1	1		
Pyrexia	1	1	1	1		
Rhinorrhoea	1	1	1	1		
	7	7	6	6	1	1

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vaccination site pain	2	2	2	2
	2	2	2	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

POLAND

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anxiety		1		1
Diarrhoea		1		1
Exposure via breast milk		3		3
Pyrexia		1		1
		6		6

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Abdominal pain upper	1	2	1	1		1
Ageusia		1		1		
Agitation		1				1
Alanine aminotransferase increased		1				1
Altered state of consciousness	2	2	1	1	1	1
Anaphylactic reaction		2				2
Angioedema		1				1
Anosmia		1		1		
Anxiety		2		1		1
Apnoea		1				1
Arrhythmia		1				1
Arthralgia		8		2		6
Asthenia	6	21	4	12	2	9
Asthma		1				1
Asthmatic crisis		1				1
Axillary pain		2		2		
Back pain	1	1	1	1		
Balance disorder	1	2	1	2		
Blood pressure decreased		2		1		1
Blood pressure increased	1	3	1	1		2
Body temperature fluctuation		1		1		
Body temperature increased		1				1
Bone pain		3				3
Bradycardia		2				2
Chest discomfort	1	1	1	1		
Chest pain	1	3	1	1		2
Chills	2	11	1	5	1	6
Contusion		1				1
Cough		1				1
COVID-19	2	3			2	3
C-reactive protein increased		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	1	3	1	2		1
Delirium		1				1
Derealisation	1	1	1	1		
Diarrhoea		3		2		1
Disturbance in attention		1				1
Dizziness	2	10	2	5		5
Drug ineffective	2	3			2	3
Dysgeusia		1		1		
Dyspnoea	1	4	1	2		2
Dyspnoea exertional		1				1
Ear discomfort	1	1	1	1		
Episcleritis	1	1			1	1
Epistaxis		1		1		
Erythema		1				1
Exposure during pregnancy		1		1		
Eye pain		5				5
Fatigue		6		6		
Feeling abnormal	1	1			1	1
Feeling cold		3				3
Feeling hot		1				1
Formication		1				1
Headache	4	22	3	12	1	10
Head discomfort	1	2	1	2		
Heart rate increased	1	1	1	1		
Hyperaesthesia		1		1		
Hyperhidrosis		3		2		1
Hypersensitivity		1				1
Hypertension	1	1			1	1
Hypoaesthesia	2	5	1	1	1	4
Hypoaesthesia oral	1	2			1	2
Hypotension	1	2	1	2		
Hypotonic-hyporesponsive episode		2		2		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Infection		1				1
Injection site pain		1		1		
Irregular breathing		1				1
Lacrimation increased		1				1
Laryngospasm		1				1
Lymphadenopathy		10		3		7
Lymph node pain		8		1		7
Malaise	4	6	2	2	2	4
Maternal exposure during pregnancy	1	1	1	1		
Movement disorder		1		1		
Muscle spasms	1	2	1	2		
Muscular weakness	1	1			1	1
Musculoskeletal stiffness		1		1		
Myalgia	1	15		6	1	9
Myocarditis		1				1
Nausea	4	10	3	7	1	3
Neck pain		5		2		3
Ocular hyperaemia	1	1			1	1
Off label use	1	1	1	1		
Optic neuritis		1				1
Pain		2		2		
Pain in extremity	1	14		6	1	8
Pallor		1				1
Palpitations	1	3		1	1	2
Pancreatitis acute		1				1
Paraesthesia	1	2	1	1		1
Paraesthesia oral	1	1	1	1		
Peripheral coldness		1				1
Pharyngeal hypoaesthesia		1				1
Presyncope	2	3	2	2		1
Product use issue	1	1	1	1		
Pyrexia	5	34	3	14	2	20

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash		3				3
Rash morbilliform		1				1
Respiratory disorder		1				1
Restlessness		1				1
Rhinitis		1				1
Seizure		2				2
Sensory disturbance	1	2			1	2
Skin lesion		1				1
Somnolence	1	2	1	1		1
Speech disorder	1	1	1	1		
Spinal pain		1				1
Syncope	2	5			2	5
Tachycardia	2	6	1	2	1	4
Tachypnoea		1				1
Taste disorder		1		1		
Thrombosis		1				1
Tinnitus	2	3	2	3		
Tremor		1				1
Vaccination site erythema		3		2		1
Vaccination site hypoaesthesia	1	1			1	1
Vaccination site pain	3	17	2	14	1	3
Vaccination site pruritus		2		2		
Vaccination site reaction		5				5
Vaccination site swelling		2		2		
Vertigo		2				2
Visual field defect		1		1		
Visual impairment		1		1		
Vomiting	1	4	1	2		2
Walking disability		1		1		
	79	383	49	170	30	213

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		6		2		4
Abdominal pain upper		2		2		
Ageusia	1	4	1	4		
Allergic respiratory symptom		2				2
Allergy to vaccine		2				2
Amnesia	1	1	1	1		
Anaphylactic reaction		6				6
Anaphylactic shock	1	8			1	8
Angioedema		5				5
Anosmia		3		3		
Anuria		1				1
Anxiety		1				1
Aphasia		1				1
Arrhythmia		4				4
Arthralgia	4	34	4	19		15
Arthritis		1		1		
Arthropathy	2	2	2	2		
Aspartate aminotransferase increased		1				1
Asphyxia		1				1
Asthenia	5	51	3	23	2	28
Asthma		5				5
Asymptomatic COVID-19		1		1		
Axillary pain	1	1			1	1
Back pain		6		6		
Balance disorder		1				1
Basophil count decreased		1		1		
Bell's palsy	1	1			1	1
Blindness	1	1			1	1
Blister		1				1
Blood creatine phosphokinase increased		3		1		2
Blood glucose increased	1	1	1	1		
Blood pressure abnormal		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased	2	11		2	2	9
Blood pressure increased	4	13	1	1	3	12
Blood smear test abnormal		1		1		
Body temperature increased	3	6	2	3	1	3
Bone pain		2				2
Brachial plexus injury		1				1
Breath sounds abnormal		1				1
Bronchial oedema		1				1
Cardiac arrest		1				1
Cardiovascular disorder		1				1
Chest discomfort		1		1		
Chest pain	1	5			1	5
Chills	3	36	3	19		17
Choking		1				1
Chromaturia		1				1
Circulatory collapse	1	1			1	1
Coagulopathy		1				1
Cold sweat	1	2			1	2
Confusional state	1	3	1	1		2
Conjunctival hyperaemia		1				1
Conjunctival pallor		1				1
Contusion		2		1		1
Cough	2	6	2	4		2
COVID-19	2	18		2	2	16
Decreased appetite		2		1		1
Deep vein thrombosis	1	1			1	1
Dermatitis allergic	1	2			1	2
Diarrhoea	2	6	1	2	1	4
Disease recurrence		1				1
Disorientation		1				1
Disturbance in attention	1	4	1	3		1
Dizziness	6	23	6	11		12

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug hypersensitivity		1				1
Drug ineffective		7				7
Dry mouth		2		1		1
Dysarthria		1				1
Dysgeusia	1	3	1	1		2
Dysphagia		3				3
Dyspnoea	1	17	1	3		14
Dyspnoea at rest		1				1
Dyspnoea exertional		1		1		
Dysstasia		1		1		
Ear pain		1		1		
Ecchymosis		1				1
Encephalopathy		1				1
Eosinophil count decreased		1		1		
Erythema	2	6	1	3	1	3
Exercise tolerance decreased		1		1		
Extrasystoles		1				1
Eyelid oedema		1				1
Eye pain		3		1		2
Eye pruritus		1				1
Face oedema	1	2	1	1		1
Facial paralysis	1	6			1	6
Fatigue	7	12	7	10		2
Fear	1	1			1	1
Febrile convulsion		4				4
Feeling abnormal	3	5	3	5		
Feeling cold		3		1		2
Feeling hot	1	4	1	3		1
Feeling of relaxation		1				1
Flushing		1				1
Formication	1	1			1	1
Generalised tonic-clonic seizure		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Glomerulonephritis chronic	1	1			1	1
Guillain-Barre syndrome		1				1
Haematoma		1		1		
Haematuria		1		1		
Headache	10	54	8	32	2	22
Heart rate increased	3	8	2	4	1	4
Hemiparesis		1				1
Herpes zoster	1	1	1	1		
Hot flush		1				1
Hydronephrosis		1				1
Hyperhidrosis	1	8		2	1	6
Hypersensitivity	1	18		2	1	16
Hypertension		4		1		3
Hypoaesthesia	4	19	2	6	2	13
Hypoaesthesia oral	1	7	1	3		4
Hypopnoea		2				2
Hypotension		1				1
Hypothermia		1				1
Hypotonia		1				1
Hypotonic-hyporesponsive episode		16		2		14
Inappropriate schedule of product administration		2		2		
Incorrect route of product administration	1	2	1	2		
Infection	1	1	1	1		
Influenza	1	2	1	2		
Influenza like illness	2	2	2	2		
Initial insomnia		1		1		
Injection site pain		2		2		
Injection site swelling		1		1		
Insomnia	3	4	3	4		
Joint range of motion decreased		1		1		
Joint swelling		1				1
Labyrinthitis		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lacrimation increased		3				3
Laryngospasm		6				6
Lip blister		1				1
Lip swelling		2				2
Lividity		2				2
Localised oedema		1				1
Loss of consciousness	2	12			2	12
Loss of personal independence in daily activities	1	1	1	1		
Lymphadenopathy	1	28	1	10		18
Lymph node pain		19		4		15
Lymphocyte count decreased		1		1		
Lymphoedema	1	1	1	1		
Malaise	6	18	5	12	1	6
Maternal exposure during pregnancy		2		2		
Memory impairment		2		1		1
Menstrual disorder	1	1	1	1		
Menstruation irregular	1	1	1	1		
Middle insomnia		1		1		
Migraine	1	1	1	1		
Mobility decreased	1	1	1	1		
Monocyte count decreased		1		1		
Monoparesis		1				1
Mood altered	1	1	1	1		
Multiple sclerosis relapse		1				1
Muscle injury		1				1
Muscular weakness	1	3			1	3
Musculoskeletal stiffness		1		1		
Myalgia	10	52	10	27		25
Myocardial hypoxia		1				1
Myoglobinuria		1				1
Nasal congestion		2		1		1
Nasopharyngitis	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	6	29	6	19		10
Neck pain		1		1		
Nervousness		1		1		
Neuropathy peripheral		1				1
Neutrophil count increased		1		1		
Oedema		1				1
Oedema peripheral		2				2
Off label use		2		2		
Oliguria		1		1		
Oropharyngeal pain		4		3		1
Oxygen saturation decreased	1	7	1	3		4
Pain		3		2		1
Painful respiration		1		1		
Pain in extremity	4	24	3	19	1	5
Pain of skin		2		1		1
Pallor	1	8			1	8
Palpitations	2	7	1	1	1	6
Paraesthesia	3	9	2	5	1	4
Paraparesis		2				2
Parosmia		2				2
Peripheral swelling		3		2		1
Petechiae		3		1		2
Pharyngeal swelling		1				1
Phlebitis		1		1		
Photophobia	1	2			1	2
Pneumonia	2	2			2	2
Poor quality product administered		1		1		
Presyncope	2	7	1	2	1	5
Product administered at inappropriate site		1		1		
Product use issue		1		1		
Protein urine present		1		1		
Pruritus	1	6	1	2		4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulpitis dental		1		1		
Pulse abnormal	1	1			1	1
Pyrexia	12	78	10	36	2	42
Radicular pain		1		1		
Rash		9		1		8
Rash erythematous	1	2	1	1		1
Rash macular		1		1		
Rash papular	1	4	1	2		2
Rash pruritic	1	1	1	1		
Rash rubelliform		1				1
Rash vesicular		1				1
Renal pain		1		1		
Respiratory arrest		2				2
Respiratory failure	1	1			1	1
Respiratory tract oedema		1				1
Rhabdomyolysis		1				1
Rhinitis		1				1
Rhinorrhoea		3		2		1
Sciatica		2		1		1
Seizure	1	12			1	12
Sensory disturbance	1	1			1	1
Shock symptom		1				1
Sinus pain	1	1	1	1		
Skin exfoliation		1				1
Skin hypertrophy		1		1		
Skin mass		1		1		
Sluggishness		1				1
Somnolence	1	5	1	3		2
Speech disorder	1	5		1	1	4
Spinal pain	1	3	1	2		1
Stress		1				1
Subclavian vein thrombosis		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sudden cardiac death		1				1
Suspected COVID-19		1		1		
Swelling	2	3	1	2	1	1
Swelling face	1	2	1	1		1
Swollen tongue		2				2
Syncope	3	14			3	14
Systemic lupus erythematosus		1				1
Tachyarrhythmia		1				1
Tachycardia	1	16	1	2		14
Tachypnoea		1				1
Taste disorder	1	3	1	2		1
Tension headache	1	1	1	1		
Therapeutic response unexpected		1		1		
Thirst		1		1		
Throat irritation	1	2		1	1	1
Thrombophlebitis		1		1		
Tinnitus	2	2	1	1	1	1
Tongue oedema		1				1
Toothache		2		1		1
Tracheal oedema		1				1
Tremor	1	2			1	2
Trigeminal neuralgia	1	2			1	2
Trigeminal neuritis		1				1
Type 2 diabetes mellitus	1	1			1	1
Urticaria		7		2		5
Vaccination complication		1		1		
Vaccination failure		5				5
Vaccination site discomfort		1				1
Vaccination site erythema	2	10		6	2	4
Vaccination site extravasation		2		1		1
Vaccination site hypersensitivity	1	1			1	1
Vaccination site induration		2		2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site movement impairment		2		2		
Vaccination site oedema	1	3	1	2		1
Vaccination site pain	12	49	11	42	1	7
Vaccination site pruritus		5		5		
Vaccination site reaction	1	30	1	5		25
Vaccination site swelling	2	9		5	2	4
Vaccination site warmth		3		2		1
Venous thrombosis		1				1
Ventricular extrasystoles		1				1
Vertigo		2		1		1
Vestibular neuronitis		1		1		
Vision blurred	1	1			1	1
Visual field defect		1		1		
Visual impairment	4	6	2	3	2	3
Vomiting	1	7		3	1	4
White blood cell count increased	1	1	1	1		
Wrong product administered	1	1	1	1		
	214	1,246	144	525	70	721

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1				1
Abdominal pain		4		1		3
Abdominal pain upper		2		1		1
Acute respiratory distress syndrome	1	1			1	1
Acute respiratory failure	1	1			1	1
Ageusia		4		2		2
Allergic reaction to excipient		1		1		
Altered state of consciousness		1				1
Anaemia		1				1
Anal incontinence		2		1		1
Anaphylactic reaction		4				4
Anaphylactic shock		2				2
Angioedema		4				4
Anosmia		4		2		2
Anuria		1				1
Anxiety		1		1		
Arrhythmia	1	3			1	3
Arthralgia	2	14	1	4	1	10
Arthropathy	1	2	1	2		
Asthenia	2	37	2	20		17
Back pain	1	4	1	3		1
Balance disorder	1	1	1	1		
Blood pressure decreased		7		1		6
Blood pressure fluctuation		1				1
Blood pressure increased	1	10		2	1	8
Blood thyroid stimulating hormone decreased		1				1
Body temperature decreased	1	2		1	1	1
Body temperature increased	1	6	1	5		1
Bone pain	1	6	1	4		2
Brain stem syndrome		1				1
Breast pain		1				1
Burning sensation		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorder	1	1	1	1		
Cardiovascular disorder		2		1		1
Cataract	1	1			1	1
Cerebellar stroke	1	1			1	1
Cerebrovascular accident		1				1
Chest discomfort		4		3		1
Chest pain	1	2	1	1		1
Chills	4	21	4	13		8
Choking sensation	1	2	1	1		1
Confusional state	2	5	1	2	1	3
Conjunctival hyperaemia		2		1		1
Contusion		1				1
Cough	1	10	1	4		6
COVID-19	3	10	1	3	2	7
C-reactive protein increased		2				2
Death	1	2			1	2
Decreased activity		1		1		
Decreased appetite		3		1		2
Defaecation urgency	1	1	1	1		
Diarrhoea		5		2		3
Discomfort		1		1		
Disease progression		1				1
Disorientation		1				1
Disturbance in attention	1	1			1	1
Dizziness	3	13	3	8		5
Drug hypersensitivity		1				1
Drug ineffective	1	4			1	4
Dry mouth		1		1		
Dysgeusia		1				1
Dyspnoea	2	10		1	2	9
Encephalopathy		1				1
Epigastric discomfort		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	1	6	1	2		4
Erythema multiforme		2				2
Eye disorder	1	1	1	1		
Eye irritation	1	1	1	1		
Eyelids pruritus		1				1
Eye pain	2	3	1	1	1	2
Face oedema		1				1
Facial pain	1	1	1	1		
Facial paralysis		3				3
Faeces soft		1				1
Fatigue	4	12	3	10	1	2
Febrile convulsion		1				1
Feeling abnormal	2	4	2	4		
Feeling cold		2		1		1
Feeling hot		3		2		1
Fibrin D dimer increased		1				1
Flatulence		1				1
Gait disturbance		1		1		
Gastrointestinal disorder		1		1		
Goitre		1				1
Haemorrhagic diathesis		1				1
Hallucination, olfactory		1				1
Headache	11	47	10	28	1	19
Head discomfort		1		1		
Heart rate increased	1	5			1	5
Herpes virus infection		1		1		
Herpes zoster	1	1	1	1		
Hot flush		1		1		
Hyperaesthesia		4		1		3
Hyperhidrosis	1	4	1	3		1
Hyperpyrexia		1				1
Hypersensitivity		5		1		4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia	2	6	1	2	1	4
Hypoaesthesia eye		2				2
Hypoaesthesia oral	1	1	1	1		
Hypotension		2				2
Hypotonia		1				1
Hypotonic-hyporesponsive episode		3				3
Immune thrombocytopenia	1	1			1	1
Inappropriate schedule of product administration		2		2		
Incorrect route of product administration	1	2	1	2		
Influenza like illness		4		3		1
Insomnia	4	4	3	3	1	1
Iritis	1	1			1	1
Joint stiffness	1	1	1	1		
Joint swelling		2		1		1
Labyrinthitis		1				1
Lacrimation increased		2				2
Laryngospasm		1				1
Lethargy		1		1		
Limb discomfort	1	1			1	1
Lip pruritus		1				1
Lividity		1				1
Loss of consciousness		7				7
Lymphadenopathy	1	14	1	6		8
Lymph node pain		9		2		7
Malaise	2	10	1	6	1	4
Memory impairment		1		1		
Migraine		1		1		
Mobility decreased	1	1	1	1		
Mood altered		1		1		
Movement disorder		1		1		
Muscle disorder	1	1	1	1		
Muscle spasms		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle tightness		1		1		
Muscular weakness	1	3	1	1		2
Musculoskeletal pain		1				1
Musculoskeletal stiffness		2		2		
Myalgia	4	24	3	11	1	13
Nasopharyngitis		1		1		
Nausea	1	15	1	5		10
Neck pain		2		1		1
Nervousness		1				1
Neuritis cranial		1				1
Night sweats	1	1	1	1		
Oedema		1				1
Oedema peripheral		1				1
Off label use		2		2		
Oropharyngeal pain		2		1		1
Pain in extremity	5	18	5	13		5
Pain in jaw	1	1	1	1		
Pallor		1		1		
Paraesthesia		4		1		3
Paraesthesia oral		1				1
Paresis		1		1		
Parosmia		1		1		
Peripheral coldness	1	1	1	1		
Peripheral swelling	1	2	1	1		1
Petechiae		1				1
Photophobia	2	2	2	2		
Pneumonia	1	3			1	3
Product use issue		1		1		
Prostatitis		1				1
Pruritus		2		1		1
Pyrexia	8	55	7	24	1	31
Rash erythematous		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash papular		1		1		
Rash pruritic		1		1		
Rash rubelliform		1				1
Rhinitis		1				1
Rhinorrhoea		1		1		
Seizure	1	5			1	5
Sensation of foreign body		1				1
Sensory disturbance		1				1
Sensory loss	1	1	1	1		
Somnolence	3	4	1	2	2	2
Speech disorder		2				2
Spinal pain		1		1		
Sudden death		1				1
Supraventricular extrasystoles		1				1
Suspected COVID-19		1				1
Swelling		1		1		
Swelling face		1				1
Syncope		4				4
Tachycardia	1	6	1	1		5
Tachypnoea		1				1
Taste disorder		2		2		
Throat tightness		2		1		1
Thrombosis	1	1			1	1
Thyroiditis		1				1
Thyroid pain		1				1
Tinnitus		1				1
Transaminases increased		1				1
Tremor		3		3		
Trigeminal nerve disorder		1		1		
Trigeminal neuralgia		1		1		
Urinary incontinence		1				1
Urinary tract inflammation		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria		3		1		2
Vaccination complication		1		1		
Vaccination failure		1				1
Vaccination site abscess sterile		2				2
Vaccination site erythema	1	6	1	4		2
Vaccination site extravasation		1		1		
Vaccination site hypersensitivity		1				1
Vaccination site inflammation		1		1		
Vaccination site oedema		2		2		
Vaccination site pain	7	23	6	18	1	5
Vaccination site pruritus		2		2		
Vaccination site rash		1				1
Vaccination site reaction	1	19	1	4		15
Vaccination site swelling	1	4	1	3		1
Vaccination site warmth	1	2	1	2		
Ventricular tachycardia	1	1			1	1
Vertigo		2				2
Vision blurred		1		1		
Visual acuity reduced	1	2			1	2
Visual impairment	1	2	1	1		1
Vomiting		8		2		6
White blood cell count increased		1				1
	128	742	92	332	36	410

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		2		2		
Abdominal pain lower		1				1
Abdominal pain upper	1	1	1	1		
Acute kidney injury		1				1
Acute myocardial infarction		2				2
Alanine aminotransferase increased		1				1
Allergic reaction to excipient		1		1		
Allergy to vaccine	1	1	1	1		
Altered state of consciousness		1				1
Anal incontinence		1				1
Anaphylactic reaction	1	1			1	1
Angioedema		1				1
Angiopathy		1				1
Anuria		1				1
Apnoea		1				1
Arrhythmia	1	2			1	2
Arteriosclerosis		1				1
Arthralgia	6	10	5	8	1	2
Arthropathy	1	1	1	1		
Aspartate aminotransferase increased		1				1
Asthenia	7	17	6	11	1	6
Asthma		1				1
Asymptomatic COVID-19	1	2			1	2
Atrial fibrillation	2	4			2	4
Atrial flutter		1				1
Back pain	2	2	2	2		
Bladder disorder	1	1	1	1		
Bleeding varicose vein		1				1
Blood glucose increased		1				1
Blood pressure decreased		1				1
Blood pressure diastolic increased		1				1
Blood pressure fluctuation		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased	3	5	1	1	2	4
Body temperature increased	2	3	1	1	1	2
Bone pain	1	2		1	1	1
Brain oedema		1				1
Breath sounds abnormal	1	1			1	1
Bursitis		1		1		
Cardiac arrest		2				2
Cardiogenic shock		1				1
Cerebral disorder	1	1			1	1
Cerebral haemorrhage		1				1
Cerebrovascular accident		3				3
Cervical spinal stenosis		1				1
Chest pain	1	2	1	1		1
Chills	2	8	2	4		4
Chromaturia	1	1	1	1		
Circulatory collapse		1				1
Coma		1				1
Confusional state	1	1	1	1		
Contusion		1				1
Coronary artery thrombosis		1				1
Cough	2	4	1	2	1	2
COVID-19	11	25	2	3	9	22
COVID-19 pneumonia	1	1			1	1
Cyanosis		1				1
Deafness unilateral		1				1
Death	1	3			1	3
Decreased appetite	1	2	1	1		1
Decreased immune responsiveness	1	1	1	1		
Decreased nasolabial fold		1		1		
Delirium	1	2			1	2
Depressed level of consciousness	1	2			1	2
Depressed mood	1	1	1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea	1	3	1	2		1
Discomfort		1		1		
Dizziness	5	6	5	5		1
Drug ineffective	8	17			8	17
Dysgeusia	1	1	1	1		
Dysphonia	1	2		1	1	1
Dyspnoea	1	2			1	2
Ecchymosis	1	1			1	1
Epistaxis	1	1	1	1		
Erysipelas		1				1
Erythema	1	3	1	2		1
Erythema multiforme	1	2			1	2
Eye pain	1	1	1	1		
Fall	1	3	1	1		2
Fatigue	1	2	1	1		1
Febrile convulsion		1				1
Feeling abnormal	4	4	4	4		
Feeling cold	1	4	1	2		2
Gait disturbance	1	2			1	2
Gait inability	1	2			1	2
Gastrointestinal disorder	1	1			1	1
General physical health deterioration		2				2
Grip strength decreased		1		1		
Haemoptysis		1				1
Haemorrhage subcutaneous		1				1
Haemorrhagic stroke	1	1			1	1
Headache	5	9	5	8		1
Heart rate abnormal		1		1		
Heart rate increased	1	1			1	1
Helplessness		1				1
Herpes virus infection		1		1		
Herpes zoster	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperaesthesia		2		1		1
Hyperhidrosis	1	2	1	2		
Hypersensitivity	1	2			1	2
Hypertension	2	3			2	3
Hypoaesthesia	2	2	1	1	1	1
Hypoaesthesia oral	1	1	1	1		
Hypotonia		1				1
Hypotonic-hyporesponsive episode	1	2			1	2
Immune system disorder	1	1	1	1		
Inappropriate schedule of product administration	2	2	2	2		
Incorrect route of product administration		3		3		
Inflammation		1				1
Influenza like illness	3	3	3	3		
International normalised ratio increased		1		1		
Intervertebral disc protrusion		1				1
Ischaemic stroke		1				1
Joint effusion		1		1		
Joint injury		1				1
Joint range of motion decreased		1		1		
Joint stiffness		1		1		
Joint swelling	1	3		1	1	2
Laryngeal pain	1	1	1	1		
Lividity	1	1			1	1
Loss of consciousness	1	4			1	4
Malaise	9	15	7	10	2	5
Memory impairment	1	1	1	1		
Metabolic acidosis		1				1
Mobility decreased	1	1	1	1		
Monoparesis	1	1			1	1
Muscle tightness		1		1		
Myalgia	4	9	3	6	1	3
Myocardial infarction	2	2			2	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nasopharyngitis	2	2	2	2		
Nausea	5	7	5	6		1
Nervousness	1	1	1	1		
Neuralgia	1	1	1	1		
Night sweats	1	1	1	1		
Oedema		1				1
Oral herpes		1		1		
Oxygen saturation decreased		2				2
Pain	3	5	2	3	1	2
Pain in extremity	6	11	6	10		1
Pain in jaw		1		1		
Palpitations	1	1	1	1		
Pancreatitis acute		1				1
Paraesthesia	1	1	1	1		
Paraesthesia oral	1	1	1	1		
Paralysis		1				1
Paraparesis		1				1
PCO2 abnormal		1				1
Peripheral swelling	1	1	1	1		
Petechiae	2	2			2	2
Pharyngeal erythema	1	1	1	1		
Pleural effusion		1		1		
Pneumonia viral		1				1
Presyncope	1	2	1	1		1
Prostatic specific antigen increased		1				1
Protein urine present	1	1	1	1		
Psychological trauma		1		1		
Pulmonary pain		1				1
Pyrexia	14	33	10	19	4	14
Rash	1	1			1	1
Rash macular	1	1	1	1		
Rash morbilliform	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash papular	1	1			1	1
Rash pruritic	1	1	1	1		
Rash rubelliform	1	1			1	1
Reaction to excipient		1		1		
Renal disorder	1	1			1	1
Renal failure		1				1
Respiration abnormal		1		1		
Respiratory disorder		1				1
Respiratory failure		4				4
Rheumatic disorder	1	1			1	1
Rheumatoid arthritis	1	1			1	1
Rhinorrhoea	1	1	1	1		
Seizure	2	4			2	4
Shock		1				1
Skin disorder	1	1	1	1		
Somnolence	1	2	1	1		1
Speech disorder	1	2	1	2		
Spinal cord compression		1				1
Spinal pain	1	1	1	1		
Sudden hearing loss		1				1
Suspected COVID-19		1				1
Swelling		2				2
Syncope	1	2			1	2
Synovial disorder		1		1		
Tachycardia	2	2	1	1	1	1
Temperature intolerance		1		1		
Thrombocytopenia		1				1
Thrombosis		5				5
Tinnitus	1	2	1	2		
Urinary incontinence		1				1
Urticaria	1	2			1	2
Vaccination failure	1	3			1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site discolouration	1	1			1	1
Vaccination site erythema	1	2	1	2		
Vaccination site infection		1		1		
Vaccination site pain	3	7	3	7		
Vaccination site reaction	1	3		1	1	2
Vaccination site scab		1		1		
Vaccination site swelling	2	2	2	2		
Vaccination site vesicles		1		1		
Vision blurred	1	1	1	1		
Visual impairment	1	1	1	1		
Vomiting	1	3	1	1		2
	208	461	128	208	80	253

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		2				2
Abdominal pain upper	1	1			1	1
Abscess	1	1	1	1		
Acute kidney injury		1				1
Acute myocardial infarction	1	2			1	2
Altered state of consciousness		1				1
Anaemia	1	1			1	1
Anal incontinence		1				1
Anaphylactic reaction		1				1
Anaphylactic shock		1				1
Angioedema		1				1
Anuria		1				1
Aortic aneurysm rupture		1				1
Aphasia		2		1		1
Arrhythmia		1				1
Arterial thrombosis	1	1			1	1
Arteriosclerosis		1		1		
Arthralgia	2	3	2	3		
Asthenia	5	21	4	10	1	11
Atrial fibrillation		1				1
Atrial flutter		1				1
Back pain		1				1
Balance disorder	1	2	1	2		
Bladder cancer		1				1
Blood glucose increased		1				1
Blood pressure abnormal		2		1		1
Blood pressure decreased		1				1
Blood pressure fluctuation	1	1			1	1
Blood pressure increased		1				1
Body temperature increased		1		1		
Bone density decreased		1		1		
Bone pain	1	2	1	2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bradyarrhythmia		1				1
Brain stem stroke		1				1
Breast disorder	1	1	1	1		
Burning sensation		1		1		
Cardiac arrest	6	14			6	14
Cardiac death		1				1
Cardiac fibrillation	1	1			1	1
Cardiogenic shock		1				1
Cerebral haematoma		2				2
Cerebrovascular accident	1	1			1	1
Chest pain	2	2	2	2		
Chills	2	3	2	2		1
Cognitive disorder		1		1		
Condition aggravated		1				1
Constipation	1	1	1	1		
Contusion	1	3	1	1		2
Cough	1	3	1	2		1
COVID-19	3	8			3	8
COVID-19 pneumonia		1				1
C-reactive protein increased		1		1		
Cyanosis		2				2
Death	1	9			1	9
Decreased appetite	1	4	1	2		2
Depressed level of consciousness		1				1
Diarrhoea	1	11	1	4		7
Distract bility		1		1		
Dizziness	2	4	2	3		1
Drug ineffective	1	3			1	3
Dysarthria		1				1
Dysgeusia		1				1
Dyspnoea	4	11	1	3	3	8
Dyspnoea exertional	1	1			1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear swelling		1				1
Ecchymosis	1	1			1	1
Electrolyte imbalance		1		1		
Embolism arterial	1	1			1	1
Embolism venous	1	1			1	1
Emphysema		1		1		
Erythema	2	3	1	1	1	2
Essential hypertension		1				1
Eye disorder		1		1		
Eye pain		1				1
Facial paralysis		2				2
Fall		3				3
Fatigue	1	3	1	3		
Feeling abnormal	1	2	1	1		1
Feeling cold		1				1
Feeling hot		2		2		
Gait disturbance		2		2		
Gastritis	1	1			1	1
Gastrointestinal disorder		1				1
Gastrointestinal haemorrhage		1				1
General physical health deterioration	1	1			1	1
Haematemesis		2				2
Haematuria		1				1
Haemoptysis	1	2		1	1	1
Haemorrhagic stroke		1				1
Headache	4	5	4	4		1
Head injury		1				1
Heart rate increased	1	2		1	1	1
Herpes zoster	1	1	1	1		
Hot flush	1	2	1	2		
Hyperhidrosis	1	4	1	2		2
Hypersensitivity		1				1

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* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoacusis	1	1	1	1		
Hypoaesthesia		3		1		2
Hypotension		1				1
Hypotonic-hyporesponsive episode		3				3
Illiteracy		1				1
Incorrect route of product administration	2	2	2	2		
Inflammation		1		1		
Insomnia		2		2		
Lacrimation increased		1				1
Lethargy		1				1
Lividity	1	2			1	2
Loss of consciousness	2	7			2	7
Lung disorder		1		1		
Lung opacity		1		1		
Lymphadenopathy		1				1
Lymph node pain	1	2	1	1		1
Malaise	2	8		4	2	4
Melaena		1				1
Mobility decreased		1				1
Movement disorder		1				1
Muscular weakness		1		1		
Musculoskeletal pain		1				1
Mutism		1		1		
Myalgia	3	7	3	6		1
Myocardial infarction		1				1
Nasopharyngitis	1	2	1	2		
Nausea	3	6	2	4	1	2
Neuralgia	1	1	1	1		
Ocular hyperaemia		1				1
Oedema peripheral	2	3	1	2	1	1
Oxygen saturation decreased	1	4			1	4
Pain	2	4	2	3		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in extremity	7	9	7	9		
Pain of skin	1	1	1	1		
Pallor		1				1
Parkinsonism	1	1			1	1
Peripheral swelling	1	2			1	2
Petechiae	1	1	1	1		
Pneumonia	2	7			2	7
Pneumonia viral		1				1
Pruritus	2	2	2	2		
Psychomotor retardation	1	1			1	1
Pulmonary calcification		1		1		
Pulmonary congestion		1				1
Pulmonary embolism	1	1			1	1
Pulmonary mass		1		1		
Pulmonary oedema	1	3			1	3
Pyrexia	5	19	4	10	1	9
Rash erythematous		1		1		
Rash pruritic		1		1		
Renal failure	1	2			1	2
Respiratory failure	1	1			1	1
Rhinorrhoea		1				1
SARS-CoV-2 test positive	1	1			1	1
Seizure	1	5			1	5
Sensory disturbance		1				1
Skin lesion	1	1	1	1		
Skin warm	1	1			1	1
Sleep disorder		1				1
Somnolence	1	1	1	1		
Speech disorder		2		1		1
Stupor		1				1
Sudden death		1				1
Suspected COVID-19	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling face		1				1
Swollen tongue		1				1
Syncope		5				5
Tachycardia	1	1			1	1
Taste disorder	1	1	1	1		
Therapeutic response unexpected		1		1		
Thrombosis		1				1
Transient ischaemic attack		1				1
Tremor		2		1		1
Type 2 diabetes mellitus		1				1
Urinary incontinence		1				1
Urticaria		1				1
Vaccination failure	2	3			2	3
Vaccination site erythema	3	3	3	3		
Vaccination site haemorrhage	1	1	1	1		
Vaccination site hypertrophy	1	1	1	1		
Vaccination site pain	3	6	3	6		
Vaccination site warmth	1	1	1	1		
Ventricular tachycardia	1	1			1	1
Visual impairment	1	2	1	1		1
Vomiting	1	9		1	1	8
Walking disability		1				1
Yellow skin	1	2	1	1		1
	133	404	75	153	58	251

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal distension	1	1	1	1		
Abdominal pain	1	4	1	4		
Abdominal pain lower		1		1		
Accidental exposure to product	1	1	1	1		
Adnexa uteri pain		1		1		
Adverse reaction		1		1		
Ageusia	1	2	1	2		
Alopecia	1	1	1	1		
Altered state of consciousness	1	1			1	1
Anaphylactic shock		2				2
Angioedema	1	1			1	1
Anosmia		3		3		
Antibody test abnormal		10		10		
Anuria		1				1
Anxiety	1	2	1	2		
Aphthous ulcer		1		1		
Arrhythmia	1	1			1	1
Arthralgia	7	33	7	32		1
Arthropathy	1	2	1	2		
Asthenia	20	49	20	47		2
Asthma		1				1
Asymptomatic COVID-19		7				7
Atrial fibrillation	1	1			1	1
Axillary mass		1		1		
Axillary pain	2	6	2	6		
Back pain	3	8	3	8		
Balance disorder	1	1	1	1		
Blood pressure abnormal	1	1	1	1		
Blood pressure decreased		3		1		2
Blood pressure fluctuation	1	1	1	1		
Blood pressure increased	1	3	1	2		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood urine present		1		1		
Body temperature increased	5	5	5	5		
Bone pain	1	7	1	7		
Breast enlargement		1		1		
Breast pain		1		1		
Burning sensation		1		1		
Cardiac arrest	1	1			1	1
Chest discomfort	1	2	1	2		
Chest pain	1	2	1	2		
Chills	20	47	20	46		1
Chorea		1		1		
Circumstance or information capable of leading to medication error		1		1		
Coagulopathy		1		1		
Confusional state		1		1		
Contraindicated product administered	1	1	1	1		
Contusion	2	2	2	2		
Cough	2	2	2	2		
COVID-19	19	52	5	8	14	44
Crying		1		1		
Cyanosis		1				1
Cystitis		1		1		
Deafness	1	3			1	3
Death		6				6
Decreased appetite	4	6	4	6		
Diarrhoea	6	16	6	16		
Disease recurrence		1				1
Disorientation	1	1	1	1		
Disturbance in attention	2	4	2	4		
Dizziness	8	16	8	16		
Drug ineffective	12	43			12	43
Dysarthria	1	1	1	1		

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysgeusia	1	3	1	2		1
Dyskinesia	1	1	1	1		
Dysmenorrhoea	1	1	1	1		
Dysphonia		2		2		
Dyspnoea	6	13	3	7	3	6
Dysstasia	1	1	1	1		
Dysuria	1	1	1	1		
Eating disorder		1		1		
Epistaxis		1		1		
Eructation	1	1	1	1		
Erythema	1	1	1	1		
Exercise tolerance decreased		1		1		
Exposure during pregnancy		3		3		
Exposure via breast milk	1	6	1	6		
Exposure via skin contact	1	1	1	1		
Extensive swelling of vaccinated limb		1		1		
Extremity contracture	1	2	1	2		
Eye pain	1	2	1	2		
Facial paralysis	1	3			1	3
Fatigue	10	19	10	18		1
Febrile convulsion		2				2
Feeling abnormal	7	12	7	12		
Feeling cold	1	8	1	8		
Feeling hot		4		4		
Feeling of body temperature change	1	1	1	1		
Fine motor skill dysfunction	1	1	1	1		
Flatulence		1		1		
Flushing		2		2		
Gait disturbance	1	1	1	1		
Gait inability	1	1	1	1		
Gastric disorder	1	1	1	1		
General physical health deterioration	1	1			1	1

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gingival swelling		1		1		
Headache	18	51	18	51		
Heart rate abnormal	1	1	1	1		
Heart rate increased	2	4	2	4		
Heart rate irregular	1	1	1	1		
Herpes virus infection		1		1		
Herpes zoster		1		1		
Hiccups	1	1	1	1		
Hot flush		1		1		
Hyperacusis		1		1		
Hyperaesthesia teeth		1		1		
Hypercoagulation	1	1			1	1
Hyperhidrosis	3	8	3	8		
Hyperpyrexia		1				1
Hypersensitivity	1	1	1	1		
Hypertension		2				2
Hypoaesthesia	6	13	6	13		
Hypoaesthesia oral	2	4	2	3		1
Hypoxia		1				1
Illness	1	2	1	2		
Inappropriate schedule of product administration		1		1		
Incorrect dose administered	2	3	2	3		
Incorrect route of product administration		1		1		
Increased upper airway secretion		1		1		
Infection		2		2		
Inflammation		2		2		
Influenza like illness	2	8	2	8		
Inner ear disorder	1	1			1	1
Insomnia	2	8	2	8		
Iritis		1		1		
Joint swelling	1	1	1	1		
Lacrimation increased	1	1	1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lagophthalmos		1		1		
Laryngeal oedema		1				1
Limb discomfort		1		1		
Lip swelling	1	1	1	1		
Localised oedema	1	1	1	1		
Loss of consciousness		3				3
Lung disorder		1		1		
Lymphadenopathy	6	18	6	16		2
Lymph node pain		3		3		
Macule		1				1
Malaise	10	36	10	36		
Maternal exposure during breast feeding		1		1		
Memory impairment	2	2	2	2		
Menstrual disorder	2	2	2	2		
Mental disorder	1	2	1	2		
Migraine	1	2	1	2		
Monoplegia	1	1			1	1
Motor dysfunction	1	1	1	1		
Muscular weakness	2	3	2	3		
Musculoskeletal pain		1		1		
Myalgia	12	52	12	51		1
Myocardial hypoxia		1				1
Myocardial infarction		1				1
Nasopharyngitis		1		1		
Nausea	9	21	9	21		
Neck pain		2		2		
Needle issue		1		1		
Nerve injury	1	1	1	1		
Neuralgia	1	1	1	1		
Nightmare		1		1		
Night sweats		1		1		
Oedema		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oesophageal spasm	1	1	1	1		
Off label use	1	11	1	10		1
Olfactory nerve disorder	1	1	1	1		
Oral candidiasis		1		1		
Oral herpes	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Oxygen saturation decreased		3		1		2
Pain	3	7	3	7		
Pain in extremity	22	45	22	44		1
Pain of skin	1	1	1	1		
Pallor	1	1	1	1		
Palpitations	1	2	1	2		
Paraesthesia	2	6	2	6		
Paraesthesia oral	1	1	1	1		
Paralysis		1				1
Paresis		1				1
Parosmia	1	2	1	2		
Parotitis		1		1		
Peripheral coldness		1		1		
Peripheral swelling	5	5	4	4	1	1
Pharyngeal hypoaesthesia		1				1
Pharyngeal swelling		1		1		
Photophobia	3	4	3	4		
Pneumonia		1				1
Pollakiuria	2	2	2	2		
Poor quality product administered	1	4	1	4		
Poor quality sleep		1		1		
Presyncope		1		1		
Product contamination physical		1		1		
Product label confusion		2		2		
Product leakage	1	1	1	1		
Product preparation error		1		1		

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product supply issue	2	2	2	2		
Product temperature excursion issue		1		1		
Product use issue	1	9	1	8		1
Pruritus	2	3	2	3		
Psoriatic arthropathy		1				1
Pulmonary mass	1	1	1	1		
Pulmonary oedema		1				1
Pyrexia	28	78	27	72	1	6
Radiculitis brachial		1		1		
Rash	1	4		3	1	1
Rash macular	1	1			1	1
Rash vesicular		1				1
Reaction to excipient	1	1	1	1		
Respiratory failure		1				1
Respiratory tract infection		1				1
Retching		1		1		
Rhinorrhoea		5		5		
Rotavirus infection	1	1	1	1		
SARS-CoV-2 ant body test negative		1				1
SARS-CoV-2 ant body test positive		1		1		
SARS-CoV-2 test positive	1	2	1	2		
Seizure	1	2			1	2
Sepsis		1				1
Sinus headache		1				1
Sinusitis	1	2	1	2		
Sleep disorder	1	1	1	1		
Somnolence	2	7	2	7		
Speech disorder developmental	1	1	1	1		
Spinal pain		1		1		
Suffocation feeling	1	1	1	1		
Suppressed lactation		2		1		1
Suspected COVID-19		1				1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling	3	5	3	5		
Swelling face	1	1	1	1		
Swollen tongue	1	1	1	1		
Syncope	1	5			1	5
Syringe issue	1	1	1	1		
Tachycardia	1	6		2	1	4
Tension headache		1		1		
Therapeutic response unexpected		2		2		
Thirst		1		1		
Thrombophlebitis	1	1	1	1		
Thrombophlebitis superficial	2	2	1	1	1	1
Thrombosis	3	4			3	4
Tinnitus		3		3		
Tonsillar hypertrophy		1		1		
Tremor	2	2	2	2		
Trigeminal nerve paresis	1	1			1	1
Ulnar nerve palsy		1		1		
Underdose	2	2	2	2		
Urticaria	1	1	1	1		
Vaccination failure		5				5
Vaccination site erythema	5	8	5	7		1
Vaccination site extravasation	1	1	1	1		
Vaccination site hypersensitivity		1		1		
Vaccination site induration		1		1		
Vaccination site macule		1		1		
Vaccination site movement impairment	1	2	1	2		
Vaccination site oedema		2				2
Vaccination site pain	21	58	21	57		1
Vaccination site paraesthesia		1		1		
Vaccination site pruritus	1	3	1	3		
Vaccination site reaction		5		5		
Vaccination site swelling		6		6		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site warmth		2		2		
Vein discolouration	1	1	1	1		
Vein disorder		1		1		
Viral infection		1		1		
Visual impairment	1	1	1	1		
Vomiting	4	14	4	13		1
Wheezing	1	1	1	1		
Wrong product administered	2	2	2	2		
		1		1		
	428	1,182	376	974	52	208

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* AE=Adverse Event

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Country Where Event Occurred

PORTUGAL

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Eructation		1		1
Exposure via breast milk	2	9	2	9
Infant irritability		1		1
Suspected COVID-19	1	1	1	1
	3	12	3	12

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal pain	2	6	2	3		3
Abdominal pain upper		1				1
Aborted pregnancy		1				1
Adenopathy syphilitic		1				1
Ageusia	1	2	1	1		1
Anaphylactic reaction		2				2
Angioedema		1				1
Anosmia	2	3	2	2		1
Anxiety		2		2		
Aphthous ulcer		2		1		1
Arrhythmia		1				1
Arthralgia	3	31	2	2	1	29
Asthenia	4	13	4	6		7
Asymptomatic COVID-19		3				3
Axillary pain	1	7	1	1		6
Back pain	2	6			2	6
Balance disorder		1				1
Bell's palsy	1	1			1	1
Blood pressure increased	1	1	1	1		
Body temperature increased		1		1		
Bradycardia		1				1
Breast pain		1				1
Bronchospasm		3				3
Chest discomfort		2				2
Chest pain	2	6	1	2	1	4
Chills	8	57	6	13	2	44
Cold sweat		2				2
Condition aggravated	1	3	1	2		1
Constipation		1				1
Cough		2		1		1
COVID-19	8	29	8	15		14

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	1	5		1	1	4
Depressed mood		1				1
Dermatitis allergic	1	2			1	2
Diarrhoea	2	14	2	4		10
Diastolic hypertension		1				1
Discomfort	1	2	1	1		1
Dizziness	7	27	6	8	1	19
Dizziness postural		1				1
Drug ineffective		10				10
Dry mouth		2				2
Dysgeusia	1	1	1	1		
Dysphagia		1				1
Dysphonia		1				1
Dyspnoea	1	8	1	1		7
Ear pain		2				2
Eczema		1				1
Episcleritis		1				1
Erythema	3	8	2	4	1	4
Exposure during pregnancy		1		1		
Face oedema	1	4		1	1	3
Facial asymmetry		1				1
Facial spasm		1				1
Fatigue	6	37	5	7	1	30
Febrile convulsion		1				1
Feeling cold		1				1
Feeling hot	2	4	2	2		2
Flatulence		1		1		
Flushing		2		1		1
Generalised tonic-clonic seizure		1				1
Haematoma		2		1		1
Headache	19	128	17	37	2	91
Hemiparaesthesia		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hot flush		1				1
Hyperaesthesia		1				1
Hyperhidrosis	2	7	1	1	1	6
Hypersensitivity		3				3
Hypertension		3				3
Hyperthermia	1	2	1	1		1
Hypoaesthesia	1	5		2	1	3
Hypoaesthesia oral		1				1
Hypoglycaemia		1				1
Hyposmia		1				1
Hypotension	1	6			1	6
Hypothermia		1				1
Illness		1		1		
Inappropriate schedule of product administration		2		1		1
Incorrect route of product administration	1	4	1	4		
Influenza		1				1
Injected limb mobility decreased		2		1		1
Insomnia	1	3			1	3
Joint range of motion decreased		1				1
Laryngeal oedema	1	3			1	3
Limb discomfort	1	1			1	1
Lip oedema	1	2			1	2
Localised oedema		1				1
Loss of personal independence in daily activities		1				1
Lymphadenitis		3		1		2
Lymphadenopathy	8	60	5	13	3	47
Lymph node pain	1	1	1	1		
Lymph node palpable		1				1
Malaise	5	18	4	7	1	11
Mastitis	1	1			1	1
Mobility decreased		2				2
Mood altered		1				1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Motor dysfunction		2				2
Movement disorder	1	2	1	1		1
Muscle twitching		1				1
Muscular weakness	1	3	1	1		2
Myalgia	24	142	20	35	4	107
Myoclonus		1				1
Nasal congestion	1	5			1	5
Nausea	10	55	6	15	4	40
Neck pain		2				2
Necrotic lymphadenopathy		1				1
Night sweats		1				1
Odynophagia	1	5	1	2		3
Oedema		2				2
Oedema peripheral		2				2
Off label use		1		1		
Oral candidiasis		1				1
Oral herpes	1	1	1	1		
Oropharyngeal oedema	1	1			1	1
Oropharyngeal pain	3	4	3	3		1
Orthopnoea		1				1
Orthostatic intolerance	1	1			1	1
Overdose	3	5	3	5		
Pain	1	15	1	3		12
Painful respiration		1				1
Pain in extremity	2	17		5	2	12
Pallor	1	4			1	4
Palpitations		2				2
Paraesthesia	3	18	3	7		11
Paraesthesia oral		2				2
Peripheral swelling		1		1		
Petechiae	1	2	1	1		1
Pityriasis rosea		1				1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Polydipsia		1				1
Presyncope		4		1		3
Product use issue		1		1		
Pruritus	3	5	1	2	2	3
Purpura		1				1
Pyelonephritis		1				1
Pyrexia	16	113	12	24	4	89
Rash	1	8		2	1	6
Rash macular		2				2
Rash maculo-papular		1				1
Rash pruritic		1		1		
Rhinitis		1		1		
Rhinorrhoea	2	5	2	2		3
SARS-CoV-2 test positive		1				1
Seizure		1				1
Sensation of foreign body		1		1		
Sensitive skin		2		1		1
Sinusitis		1		1		
Skin burning sensation		1				1
Skin warm		4				4
Sneezing		1				1
Somnolence	2	7	1	4	1	3
Spinal pain		1				1
Swelling		3		1		2
Syncope		7				7
Synovial cyst		1				1
Tachycardia	3	8	3	4		4
Throat irritation	1	3	1	1		2
Throat tightness		3				3
Thrombocytopenia		1				1
Tinnitus		1				1
Tongue oedema		2				2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tonic clonic movements		1				1
Tremor	1	9		2	1	7
Underdose	1	1	1	1		
Urinary tract infection		3				3
Urticaria		3		1		2
Vaccination failure		4				4
Vaccination site abscess		1		1		
Vaccination site eczema		2		1		1
Vaccination site erythema		16		4		12
Vaccination site haematoma		1		1		
Vaccination site induration		2				2
Vaccination site inflammation		1		1		
Vaccination site joint movement impairment	1	1	1	1		
Vaccination site lymphadenopathy		1				1
Vaccination site movement impairment	1	2			1	2
Vaccination site oedema	3	22	3	8		14
Vaccination site pain	33	129	28	64	5	65
Vaccination site paraesthesia		1				1
Vaccination site rash	1	1	1	1		
Vaccination site reaction		1		1		
Vaccination site swelling	1	9	1	3		6
Vaccination site warmth	1	3	1	2		1
Vaginal haemorrhage		1				1
Vision blurred	2	3	2	2		1
Vomiting	4	23	1	2	3	21
Wheezing		1				1
	238	1,345	179	381	59	964

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	4	2	2		2
Abdominal distension		1				1
Abdominal pain	1	16		2	1	14
Abdominal pain lower		1				1
Abdominal pain upper	1	12	1	4		8
Abnormal faeces		1				1
Abortion	1	1			1	1
Abortion spontaneous	1	2			1	2
Acne		1				1
Adenopathy syphilitic		1				1
Administration site bruise		1		1		
Administration site swelling		1		1		
Ageusia	1	2	1	1		1
Agitation		1				1
Allergy to vaccine		3				3
Alopecia	1	1	1	1		
Anaphylactic reaction	2	13			2	13
Anaphylactic shock		2				2
Anaphylactoid reaction		1				1
Angioedema	1	8			1	8
Anosmia	1	1	1	1		
Anxiety	3	6	2	3	1	3
Aphonia		1				1
Aphthous ulcer		1				1
Apnoea		1				1
Application site hyperaesthesia	1	1	1	1		
Arrhythmia	3	6			3	6
Arthralgia	31	152	25	37	6	115
Arthritis		1				1
Arthritis reactive		1				1
Asthenia	10	88	7	19	3	69
Asthenopia		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19		4				4
Atelectasis		1		1		
Atrioventricular block second degree	1	1			1	1
Autonomic nervous system imbalance		1				1
Autophony		1				1
Axillary lymphadenectomy		1				1
Axillary mass	1	1			1	1
Axillary pain	6	26	5	11	1	15
Back pain	4	13	4	5		8
Balance disorder	1	2	1	1		1
Bedridden		1				1
Bladder disorder		1				1
Blepharospasm	1	1	1	1		
Blister	1	1	1	1		
Blood potassium decreased	1	1			1	1
Blood pressure decreased		1				1
Blood pressure fluctuation		1				1
Blood pressure increased	2	6			2	6
Blood thyroid stimulating hormone increased		1				1
Body temperature increased		5		1		4
Bradycardia	1	5			1	5
Bradyphrenia	1	3			1	3
Breast pain		2		1		1
Breast swelling		2		1		1
Bronchospasm		2				2
Burning sensation	1	3	1	1		2
Bursitis		1				1
Cerebral venous sinus thrombosis		1				1
Chest discomfort	2	9	1	4	1	5
Chest pain	2	19	2	3		16
Chillblains		1		1		
Chills	23	135	20	37	3	98

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholinergic syndrome		1				1
Cold sweat		2				2
Computerised tomogram thorax abnormal		1		1		
Condition aggravated	1	6	1	2		4
Confusional state	1	2	1	1		1
Conjunctival haemorrhage		1				1
Contraindicated product administered		1		1		
Conus medullaris syndrome		1				1
Coordination abnormal	1	1	1	1		
Corneal degeneration		1				1
Corneal opacity		1				1
Cough	9	35	6	12	3	23
COVID-19	20	51	17	24	3	27
Crying		1		1		
Cutaneous vasculitis		1				1
Cyanosis		1				1
Deafness		1				1
Deafness transitory		1				1
Deafness unilateral	1	2			1	2
Decreased appetite	2	6			2	6
Depressed level of consciousness		1				1
Dermatitis exfoliative	2	3			2	3
Diarrhoea	14	56	8	16	6	40
Discomfort	4	7	3	3	1	4
Disease recurrence		1				1
Disturbance in attention		1				1
Dizziness	12	94	9	28	3	66
Dizziness postural		1				1
Drooling		1		1		
Drug hypersensitivity		1				1
Drug ineffective	1	18			1	18
Drug interaction		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry eye		1		1		
Dry mouth	2	8	2	4		4
Dry throat		1		1		
Dysarthria		3				3
Dysgeusia	3	23	2	15	1	8
Dyskinesia		1				1
Dyspepsia		1		1		
Dysphagia		9		1		8
Dysphonia	1	8		1	1	7
Dyspnoea	2	25		5	2	20
Dyspnoea at rest		1				1
Dyspnoea exertional		1				1
Dysuria		1				1
Ear congestion	1	1			1	1
Ear pain		1		1		
Eczema		1				1
Electrocardiogram ST segment depression	1	1	1	1		
Epistaxis		3		2		1
Eructation		1		1		
Erythema	5	19	3	7	2	12
Erythema nodosum		1				1
Exophthalmos		1				1
Exposure during pregnancy	2	7	2	6		1
Extrasystoles	1	3		1	1	2
Eye disorder	1	3		1	1	2
Eye irritation		2		2		
Eyelid myokymia		1				1
Eyelid oedema		3				3
Eyelid sensory disorder		1		1		
Eye movement disorder		1				1
Eye pain	1	3		2	1	1
Eye paraesthesia		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye swelling		1				1
Face oedema	3	12	1	3	2	9
Facial nerve disorder		1				1
Facial pain	2	2	1	1	1	1
Facial paralysis		5				5
Facial paresis		2				2
Facial spasm		1		1		
Faeces soft		1				1
Fatigue	28	156	23	45	5	111
Fear of injection	1	1			1	1
Feeling abnormal		1		1		
Feeling cold	2	9	1	2	1	7
Feeling hot	2	22	2	6		16
Flatulence		1				1
Flushing	1	13	1	3		10
Foreign body reaction	1	1			1	1
Functional gastrointestinal disorder		3				3
Gait disturbance		1				1
Gait inability		1		1		
Gastrointestinal disorder	2	2	1	1	1	1
Gastrointestinal pain		1				1
Generalised tonic-clonic seizure		2				2
Glossodynia		2		2		
Gonorrhoea		1				1
Groin pain		1				1
Haematoma	1	2			1	2
Haemoglobin decreased	1	1	1	1		
Headache	93	435	80	142	13	293
Head discomfort	1	4	1	2		2
Heart rate increased	4	8	3	3	1	5
Hemianaesthesia		1				1
Hemidysaesthesia		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hemiparaesthesia		1				1
Hemiparesis		1				1
Hot flush		2				2
Hydrocephalus		1				1
Hyperaemia		1				1
Hyperaesthesia	1	2	1	1		1
Hyperglycaemia		3		1		2
Hyperhidrosis	2	12	2	4		8
Hypersensitivity	2	6			2	6
Hypertension	3	24	1	3	2	21
Hypertensive crisis	1	2			1	2
Hyperthermia	1	8			1	8
Hyperventilation		1				1
Hypoacusis		3				3
Hypoaesthesia	6	16	1	4	5	12
Hypoaesthesia oral	2	11	1	4	1	7
Hypoglycaemia		2				2
Hypokinesia	1	1	1	1		
Hypoperfusion		1				1
Hypotension	4	13	2	2	2	11
Hypothermia		2				2
Hypothyroidism		1				1
Hypotonic-hyporesponsive episode		1				1
Impaired work ability		2		1		1
Inappropriate schedule of product administration	1	3	1	3		
Incorrect dose administered		2		2		
Incorrect route of product administration	2	14	2	14		
Inflammation		3				3
Influenza		5				5
Influenza like illness	1	3	1	2		1
Injection site pain	1	4	1	4		
Injection site swelling	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Insomnia	4	17	4	8		9
Inspiratory capacity decreased		1				1
Intercostal neuralgia		1				1
Intermenstrual bleeding	1	2	1	1		1
Joint microhaemorrhage	1	1			1	1
Joint range of motion decreased		2				2
Joint swelling		1				1
Lacrimation increased		1				1
Lacunar stroke		1				1
Laryngeal oedema	1	7			1	7
L bido decreased		1		1		
Limb discomfort	1	5		2	1	3
Lip erythema	1	1			1	1
Lip oedema	1	9		1	1	8
Lip pruritus		1				1
Lip swelling		2				2
Localised oedema		4				4
Loss of consciousness		2				2
Loss of personal independence in daily activities		2				2
Lymphadenitis	2	6	1	1	1	5
Lymphadenopathy	27	170	21	46	6	124
Lymph node pain	2	5	2	2		3
Lymph node palpable		1		1		
Macule	1	2			1	2
Magnetic resonance imaging head abnormal		1		1		
Malaise	9	64	7	18	2	46
Mastitis		2				2
Maternal exposure during pregnancy	1	4	1	4		
Meningioma		1				1
Meningitis viral		1				1
Migraine		5		1		4
Miliaria	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mobility decreased	1	4		2	1	2
Monocyte count increased		1		1		
Motor dysfunction		1				1
Movement disorder		2		2		
Muscle contractions involuntary		2		1		1
Muscle fatigue		3		1		2
Muscle rigidity		1				1
Muscle spasms		3		1		2
Muscular weakness	3	10	2	2	1	8
Musculoskeletal discomfort		1				1
Musculoskeletal disorder		1				1
Musculoskeletal pain	2	2	2	2		
Musculoskeletal stiffness	1	4	1	1		3
Myalgia	109	502	94	154	15	348
Myelitis		1				1
Myelosuppression		1				1
Myocarditis		2				2
Myoclonus	1	1	1	1		
Nasal congestion	1	2			1	2
Nasal discomfort		1		1		
Nasal dryness		1		1		
Nasal obstruction	1	1	1	1		
Nausea	39	177	27	48	12	129
Neck pain	4	14	2	6	2	8
Nervousness		2				2
Neuralgia		1				1
Neuropathy peripheral		1				1
Night sweats		2				2
Nodule	1	1	1	1		
Non-cardiac chest pain		1		1		
Nystagmus		4				4
Occupational exposure to SARS-CoV-2		1		1		

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular discomfort		2		2		
Ocular hyperaemia	1	3	1	1		2
Odynophagia	3	15	1	3	2	12
Oedema		4		1		3
Oedema mouth		2				2
Oedema peripheral	4	14	1	4	3	10
Oesophageal disorder		1				1
Off label use	3	14	3	14		
Oliguria		1				1
Ophthalmic herpes simplex		1				1
Oral candidiasis		1				1
Oral discomfort	1	1	1	1		
Oral herpes	1	2	1	1		1
Oral pain		1				1
Oropharyngeal discomfort	1	8	1	4		4
Oropharyngeal oedema		1				1
Oropharyngeal pain	2	10	2	5		5
Orthopnoea		1				1
Overdose	10	24	9	22	1	2
Oxygen saturation decreased	1	4			1	4
Pain	14	55	10	18	4	37
Pain in extremity	7	40	7	15		25
Pain in jaw	1	2	1	1		1
Palatal disorder		1				1
Pallor		6		1		5
Palpitations	6	17	3	5	3	12
Pancytopenia		1				1
Papule	2	2	2	2		
Paraesthesia	14	62	10	27	4	35
Paraesthesia ear	1	1			1	1
Paraesthesia oral	5	16	4	7	1	9
Paralysis		2				2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Parosmia	1	1			1	1
Perineal pain		1				1
Perioral dermatitis	1	1			1	1
Peripheral swelling		3				3
Petechiae	1	2			1	2
Pharyngeal cyst		2				2
Pharyngeal erythema		1				1
Pharyngeal hypoaesthesia		2		1		1
Pharyngeal inflammation		1				1
Pharyngeal oedema		1				1
Pharyngeal paraesthesia		5				5
Pharyngeal swelling		1				1
Pharyngitis		1				1
Phlebitis		1				1
Phonophobia		1				1
Photophobia		5		2		3
Pigmentation disorder	1	1	1	1		
Piloerection		4				4
Pityriasis rosea		1				1
Pleuritic pain		2				2
Polydipsia		3				3
Poor quality sleep		2				2
Postural orthostatic tachycardia syndrome		1				1
Presyncope	8	35	6	12	2	23
Procedural haemorrhage		1				1
Procedural nausea		1				1
Productive cough	1	3	1	1		2
Product use issue	2	12	2	12		
Pruritus	7	29	6	10	1	19
Pulmonary embolism	1	1			1	1
Purpura		1				1
Pyrexia	62	322	55	97	7	225

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash	7	41	3	10	4	31
Rash erythematous	1	3	1	2		1
Rash macular	1	6	1	1		5
Rash maculo-papular		3		1		2
Rash papular		3		2		1
Rash pruritic	1	7	1	4		3
Renal tubular necrosis		1				1
Respiratory disorder		1				1
Respiratory distress		2				2
Restlessness		1		1		
Rhinorrhoea	8	20	7	11	1	9
Salivary hypersecretion		2		2		
SARS-CoV-2 test positive	2	4	2	2		2
Scar		1		1		
Seizure		4				4
Sensation of foreign body		1				1
Sensory disturbance		1				1
Sensory loss		6		2		4
Sinusitis		1		1		
Sinus tachycardia		1				1
Skin lesion		1				1
Skin warm	1	3	1	2		1
Sleep disorder	1	3	1	1		2
Sluggishness	1	1	1	1		
Sneezing	1	1	1	1		
Somnolence	11	54	8	27	3	27
Speech disorder		2				2
Status epilepticus		1				1
Stomatitis		2		1		1
Sudden hearing loss		2				2
Suffocation feeling	1	1			1	1
Suppressed lactation		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Supraventricular extrasystoles	1	1			1	1
Swelling	1	6		1	1	5
Swelling face	1	2			1	2
Swelling of eyelid	1	1			1	1
Syncope	2	13			2	13
Synovial cyst		4				4
Tachyarrhythmia		2				2
Tachycardia	6	47	5	14	1	33
Tachypnoea		2				2
Taste disorder	1	7	1	2		5
Tenderness	1	1	1	1		
Tenosynovitis		1		1		
Terminal ileitis		1				1
Throat irritation	2	10	1	4	1	6
Throat tightness	1	6		1	1	5
Thrombophlebitis	1	3			1	3
Thrombosis	1	1			1	1
Thrombotic microangiopathy		1				1
Thyroid function test abnormal		1		1		
Thyroiditis		1				1
Thyroid mass		1				1
Tinnitus	1	4			1	4
Tongue disorder		1				1
Tongue dry		1		1		
Tongue eruption		1				1
Tongue oedema		12		3		9
Tongue paralysis	1	1			1	1
Tongue pruritus		1				1
Tongue rough		1		1		
Tonsillar hypertrophy		1				1
Tonsillar inflammation		1		1		
Tonsillitis bacterial		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tooth abscess		1		1		
Tremor	5	31	4	6	1	25
Trichoglossia		1		1		
Trigeminal palsy		1				1
Trismus		1				1
Urinary tract infection		2				2
Urticaria	5	14	4	5	1	9
Urticaria papular		1				1
Vaccination complication		2				2
Vaccination failure	2	10			2	10
Vaccination site cellulitis	1	1	1	1		
Vaccination site discolouration		1				1
Vaccination site discomfort		2		1		1
Vaccination site erythema	10	49	10	21		28
Vaccination site haematoma		4		2		2
Vaccination site hypersensitivity	1	1	1	1		
Vaccination site induration	5	10	5	5		5
Vaccination site inflammation		10		2		8
Vaccination site injury		1				1
Vaccination site joint movement impairment		2				2
Vaccination site joint pain		1				1
Vaccination site lymphadenopathy	1	2	1	1		1
Vaccination site movement impairment	2	3	1	1	1	2
Vaccination site nodule	1	1	1	1		
Vaccination site oedema	14	54	14	23		31
Vaccination site pain	87	382	81	202	6	180
Vaccination site paraesthesia		2		2		
Vaccination site pruritus	3	23	3	8		15
Vaccination site rash	1	6	1	2		4
Vaccination site reaction		5		3		2
Vaccination site swelling	5	20	5	9		11
Vaccination site warmth	7	21	6	11	1	10

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaginal haemorrhage		1				1
Ventricular extrasystoles	1	2	1	1		1
Vertigo	4	16	1	4	3	12
Vertigo positional		1				1
Vestibular neuronitis	1	1	1	1		
Vision blurred	1	5		2	1	3
Visual acuity reduced		1		1		
Visual impairment	1	4	1	1		3
Vomiting	12	42	8	11	4	31
Vulvovaginal burning sensation		1				1
Vulvovaginal swelling		1				1
Weight decreased		1		1		
	972	4,769	745	1570	227	3199

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		4		2		2
Abdominal pain	4	8	1	2	3	6
Abdominal pain upper	2	3			2	3
Acidosis		1				1
Acute myocardial infarction		1				1
Administration site swelling		1		1		
Administration site warmth		1		1		
Allodynia		1				1
Amylase increased		1				1
Anaphylactic reaction	4	7			4	7
Angina pectoris		1				1
Angioedema		2				2
Anosmia		2				2
Anxiety		4		2		2
Aphthous ulcer		1				1
Arrhythmia		2				2
Arthralgia	17	49	13	14	4	35
Asthenia	5	35	5	9		26
Asymptomatic COVID-19		1		1		
Aura		1		1		
Axillary pain	2	6	2	3		3
Back pain	1	4			1	4
Balance disorder	1	4			1	4
Bell's palsy	1	2			1	2
Blood pressure decreased		1				1
Blood pressure diastolic increased		1				1
Blood pressure increased	2	5	1	1	1	4
Body temperature abnormal		1				1
Body temperature decreased		1				1
Body temperature increased		1				1
Bone pain		2		1		1
Bradycardia		2				2

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bradypnoea		1				1
Breast discomfort		1				1
Breast pain		2		1		1
Bronchospasm		1				1
Burning sensation		5		1		4
Cardio-respiratory arrest		1				1
Cerebrovascular accident		1				1
Chapped lips	1	1	1	1		
Cheilitis		1		1		
Chest discomfort		5		1		4
Chest pain	1	6			1	6
Chills	13	49	10	17	3	32
Choking sensation		1				1
Circumoral oedema		1				1
Cold sweat	1	1			1	1
Condition aggravated	1	1			1	1
Conjunctival irritation		1				1
Contusion	1	1			1	1
Cough	3	11	2	2	1	9
COVID-19	8	34	7	15	1	19
Crohn's disease		1				1
Crying		1				1
Death		1				1
Decreased appetite	3	6	2	2	1	4
Deep vein thrombosis	2	2			2	2
Dermatitis bullous	1	1			1	1
Diarrhoea	7	28	4	6	3	22
Discomfort	2	4	2	3		1
Dizziness	10	35	3	7	7	28
Drug ineffective	1	15			1	15
Dry skin		1				1
Dry throat		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysgeusia	1	4	1	1		3
Dyspepsia		3				3
Dysphagia		1				1
Dysphonia	1	1	1	1		
Dyspnoea	1	5			1	5
Dyspnoea at rest		1				1
Dysstasia		1				1
Dystonia	1	1			1	1
Ear pain	1	2			1	2
Ecchymosis	2	2	1	1	1	1
Electric shock sensation	1	1			1	1
Epistaxis		2		1		1
Erythema	3	11	1	1	2	10
Exposure to SARS-CoV-2		1				1
Extrapyramidal disorder		1				1
Eye haemorrhage	1	1			1	1
Eye irritation		3		2		1
Eyelid oedema	1	2			1	2
Eyelids pruritus	1	1			1	1
Eye pain		1		1		
Eye pruritus		1				1
Eye swelling	1	1			1	1
Face oedema	2	10	1	1	1	9
Facial paralysis		1				1
Facial paresis	1	1			1	1
Fall		1		1		
Fatigue	13	48	11	15	2	33
Feeling abnormal		1				1
Feeling cold		5		2		3
Feeling hot	6	11	3	6	3	5
Feeling of body temperature change		1				1
Flatulence		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Flushing	1	4		2	1	2
Gastrointestinal disorder	1	1			1	1
Generalised tonic-clonic seizure	1	1			1	1
General symptom		1				1
Gynaecomastia		1				1
Haematoma	3	3			3	3
Haemoptysis		1				1
Hallucination		1				1
Headache	35	129	27	45	8	84
Head discomfort	1	2			1	2
Heart rate decreased	1	1			1	1
Hemiparesis	1	1			1	1
Hepatic mass	1	1	1	1		
Herpes zoster	3	4	1	1	2	3
Hot flush	1	2	1	1		1
Hyperaesthesia	1	1			1	1
Hyperhidrosis	3	12	1	2	2	10
Hyperlactacidaemia		1				1
Hypersensitivity		1				1
Hypertension	3	15		2	3	13
Hypertensive crisis	2	5			2	5
Hyperthermia		3		1		2
Hypoacusis	1	1			1	1
Hypoaesthesia	1	3		1	1	2
Hypoaesthesia oral		3		1		2
Hypokalaemia		1				1
Hypokinesia	1	1	1	1		
Hypotension	1	4	1	2		2
Inappropriate schedule of product administration	1	2	1	2		
Incorrect route of product administration	2	6	2	6		
Injection site erythema		1		1		
Injection site pain		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Insomnia	2	9	2	3		6
Jaundice	1	1			1	1
Joint range of motion decreased		2		1		1
Lacunar stroke		1				1
Laryngeal oedema		3				3
Lethargy		2				2
Leukocyturia		1		1		
Lipase increased		1				1
Lip oedema		3				3
Lip swelling		1				1
Liver function test abnormal	1	1			1	1
Liver injury	1	1			1	1
Localised oedema	1	2	1	1		1
Loss of consciousness	1	1			1	1
Loss of personal independence in daily activities		1				1
Lymphadenitis		3		2		1
Lymphadenopathy	9	38	5	6	4	32
Malaise	5	35	5	10		25
Mental fatigue		1				1
Migraine		2		1		1
Mobility decreased		1				1
Motor dysfunction		1				1
Muscle fatigue		2		1		1
Muscle tightness		1				1
Muscular weakness		3		1		2
Musculoskeletal disorder		1				1
Musculoskeletal stiffness	1	2			1	2
Myalgia	39	151	36	56	3	95
Myalgia intercostal		1				1
Myoclonus		2				2
Nasal congestion		1		1		
Nasal obstruction		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nasal oedema		1		1		
Nasopharyngitis		1				1
Nausea	15	65	7	21	8	44
Neck mass		1		1		
Neck pain	3	3	2	2	1	1
Neuropathy peripheral		1				1
Nipple disorder		1		1		
Nodule		1		1		
Odynophagia		1		1		
Oedema		3		1		2
Oedema mouth		1				1
Oedema mucosal		1				1
Oedema peripheral	1	4		1	1	3
Oesophageal pain		1				1
Off label use	1	1	1	1		
Oral discomfort		1		1		
Oral herpes		1				1
Oropharyngeal discomfort		9		4		5
Oropharyngeal pain		3				3
Overdose	3	7	3	7		
Oxygen saturation decreased		1				1
Pain	4	8	3	3	1	5
Pain in extremity	3	20	3	9		11
Pallor	2	4			2	4
Palmar-plantar erythrodysesthesia syndrome		1				1
Palpitations	1	8		2	1	6
Paraesthesia	7	22	5	8	2	14
Paraesthesia oral		7		1		6
Pericarditis		1				1
Peripheral coldness	1	4			1	4
Peripheral swelling	1	2			1	2
Petechiae	1	1	1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal hypoaesthesia		1				1
Pharyngeal swelling	1	1			1	1
Phlebitis	1	1			1	1
Polydipsia		1				1
Posture abnormal	2	2			2	2
Presyncope	2	7	1	2	1	5
Product administered at inappropriate site	1	2	1	2		
Proteinuria		1		1		
Pruritus	2	16	1	2	1	14
Pulmonary embolism	1	1			1	1
Puncture site haematoma		1				1
Purpura		1				1
Pyrexia	28	117	21	33	7	84
Rash	1	17	1	2		15
Rash erythematous		2		2		
Rash macular		2				2
Rash maculo-papular		1				1
Rash maculovesicular	1	1			1	1
Rash papular		1				1
Rash pruritic		3		1		2
Respiratory distress		1				1
Respiratory tract congestion		1				1
Retinal haemorrhage		1				1
Rhinalgia		1		1		
Rhinitis		1				1
Rhinorrhoea		4		2		2
SARS-CoV-2 test positive	4	5	3	3	1	2
Seizure		1				1
Shock		1				1
Sinus tachycardia		1				1
Skin exfoliation		1				1
Skin lesion	1	1			1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin reaction		2				2
Skin warm		1				1
Sleep disorder		3				3
Sneezing		1		1		
Somnolence	1	15	1	9		6
Stiff tongue		1				1
Swelling	1	4	1	1		3
Swelling face	1	1			1	1
Syncope		3				3
Synovial cyst	2	6	2	2		4
Tachyarrhythmia		1				1
Tachycardia	6	15	2	2	4	13
Takayasu's arteritis		1				1
Taste disorder		2				2
Telangiectasia	1	1			1	1
Tension headache		1				1
Throat irritation	1	2	1	2		
Throat tightness	1	2	1	1		1
Thrombophlebitis		1				1
Tinnitus		1		1		
Tongue coated		1				1
Tongue discomfort		1				1
Tongue dry		2				2
Tongue eruption		1				1
Tongue oedema		2				2
Tremor		3				3
Upper-airway cough syndrome		1				1
Urinary tract infection	1	1	1	1		
Urticaria	3	6	2	2	1	4
Urticaria cholinergic		1		1		
Vaccination complication	1	3	1	2		1
Vaccination failure	1	5			1	5

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site discomfort		1		1		
Vaccination site erythema	6	16	5	9	1	7
Vaccination site haematoma		1				1
Vaccination site induration	4	9	4	7		2
Vaccination site inflammation		4				4
Vaccination site joint inflammation		1				1
Vaccination site joint movement impairment		1				1
Vaccination site movement impairment		2		1		1
Vaccination site nodule	1	2	1	2		
Vaccination site oedema	4	17	4	9		8
Vaccination site pain	28	100	22	50	6	50
Vaccination site paraesthesia	1	1	1	1		
Vaccination site pruritus	2	10	2	4		6
Vaccination site rash		1		1		
Vaccination site reaction		1				1
Vaccination site swelling	4	10	3	3	1	7
Vaccination site urticaria		1				1
Vaccination site warmth	3	7	3	4		3
Vasculitis		1				1
Venous occlusion	1	1			1	1
Vertigo	3	10	2	2	1	8
Vision blurred	2	4		2	2	2
Visual acuity reduced	1	1			1	1
Vomiting	6	16	4	5	2	11
White blood cell count increased	1	1	1	1		
Wound		1		1		
	432	1,689	274	528	158	1161

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Abdominal symptom	1	1	1	1		
Acute myocardial infarction		2				2
Anaphylactic reaction		1				1
Anti-neutrophil cytoplasmic antibody positive vasculitis	1	1			1	1
Anxiety	1	1	1	1		
Arrhythmia	2	2			2	2
Arteriosclerosis		1		1		
Arthralgia	1	4	1	2		2
Asthenia	2	4	1	1	1	3
Asymptomatic COVID-19		7				7
Atrial fibrillation		1				1
Axillary pain	1	1			1	1
Back pain		2				2
Bacterial infection		1				1
Balance disorder	1	1	1	1		
Bedridden		1				1
Blood creatinine increased	1	1	1	1		
Blood pressure increased	1	2			1	2
Body temperature increased	1	1	1	1		
Bradycardia	1	1			1	1
Bronchial hyperreactivity	1	1			1	1
Cardiac disorder		1				1
Cardio-respiratory arrest	1	2			1	2
Cerebral artery occlusion	1	1			1	1
Cerebral thrombosis	1	1			1	1
Cerebral venous sinus thrombosis		1				1
Cerebrovascular accident	1	1			1	1
Chest pain	2	2	1	1	1	1
Chills	1	3	1	2		1
Condition aggravated		1				1

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* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Confusional state	1	2	1	1		1
Coordination abnormal	1	1			1	1
Cough	1	3			1	3
COVID-19		2		1		1
COVID-19 pneumonia		2				2
Deafness neurosensory	1	2			1	2
Deafness unilateral		1				1
Death	1	2			1	2
Decreased appetite		2				2
Deep vein thrombosis	1	1			1	1
Dermatologic examination abnormal	1	1			1	1
Diarrhoea	2	4	2	3		1
Diplopia	2	2			2	2
Discomfort	1	1	1	1		
Disorientation	1	1			1	1
Disturbance in attention	1	1	1	1		
Dizziness	6	8	2	3	4	5
Drug ineffective		1				1
Drug reaction with eosinophilia and systemic symptoms	1	1			1	1
Dysarthria	1	1			1	1
Dyspnoea	5	7	4	4	1	3
Dyspnoea exertional	1	1			1	1
Ear pain	1	1	1	1		
Ecchymosis		1				1
Epistaxis	1	2			1	2
Eye pain	2	2	2	2		
Eye pruritus	1	1	1	1		
Facial paralysis	1	1			1	1
Fatigue	1	7	1	3		4
Feeling cold	1	2	1	1		1
Feeling hot	1	1	1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Flushing		1				1
Gait inability	1	2	1	2		
Haematoma	1	2			1	2
Haemorrhagic stroke	1	1			1	1
Headache	4	8	3	5	1	3
Heart rate increased	1	1	1	1		
Herpes zoster	2	2			2	2
Herpes zoster cutaneous disseminated	1	1			1	1
Hyperhidrosis	1	1			1	1
Hypersensitivity	1	1			1	1
Hypertensive crisis	1	1			1	1
Hypoaesthesia	2	2			2	2
Hypotension		1				1
Hypoxia	1	1			1	1
Incorrect dose administered	1	1	1	1		
Incorrect route of product administration	1	1	1	1		
Injection site erythema		1		1		
Insomnia	1	2	1	2		
International normalised ratio increased		1				1
Intestinal obstruction	1	1			1	1
Ischaemic stroke	3	3			3	3
Localised oedema	1	1			1	1
Lung infiltration		1				1
Lymphadenopathy	2	3	1	1	1	2
Lymphoedema		1				1
Malaise	1	2		1	1	1
Mobility decreased	1	1	1	1		
Muscular weakness	1	1			1	1
Myalgia	2	12	1	6	1	6
Myocardial infarction		1				1
Myoclonus	1	1	1	1		
Nail pigmentation	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nasal congestion	1	1	1	1		
Nasopharyngitis	1	1	1	1		
Nausea	6	9	2	3	4	6
Neck pain	1	1	1	1		
Neurological symptom	1	1	1	1		
Oropharyngeal discomfort		1				1
Oropharyngeal pain	2	2	1	1	1	1
Overdose	1	2	1	2		
Oxygen saturation decreased		1				1
Pain	1	2	1	1		1
Pain in extremity	4	6	3	3	1	3
Pallor	1	1	1	1		
Papule	1	1			1	1
Paraesthesia	1	2	1	1		1
Parkinson's disease	1	1			1	1
Pericarditis	1	1			1	1
Peripheral artery occlusion		1				1
Peripheral artery stenosis		1				1
Peripheral nerve lesion	1	1	1	1		
Pneumonia	1	1			1	1
PO2 decreased		1				1
Presyncope	1	1			1	1
Product administered at inappropriate site	1	1	1	1		
Pruritus	3	6	2	2	1	4
Pulmonary embolism	2	2			2	2
Purpura	2	2	1	1	1	1
Pyrexia	1	8	1	3		5
Rash		2				2
Rash erythematous		1				1
Rash macular		3		1		2
Rhabdomyolysis		1				1
SARS-CoV-2 test positive		1				1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sciatica		1				1
Seizure	1	1			1	1
Skin burning sensation		1				1
Somnolence	1	5	1	2		3
Sudden death	1	1			1	1
Swelling of eyelid	1	1	1	1		
Swollen tongue	1	1			1	1
Syncope	1	2			1	2
Synovial cyst	1	1	1	1		
Tachycardia		1				1
Tachypnoea	1	1	1	1		
Thrombophlebitis superficial	1	1			1	1
Tinnitus	2	3	1	1	1	2
Transient ischaemic attack	1	1			1	1
Urinary tract infection bacterial		1				1
Urticaria	1	3		1	1	2
Vaccination failure		7				7
Vaccination site erythema	2	2	1	1	1	1
Vaccination site inflammation		1				1
Vaccination site movement impairment		1				1
Vaccination site oedema	1	2		1	1	1
Vaccination site pain	1	7	1	3		4
Vaccination site swelling	1	2	1	1		1
Vaccination site warmth	1	1			1	1
Varicella		1				1
Vasculitis	1	1			1	1
Venous thrombosis	1	1			1	1
Vertebral artery occlusion	1	1			1	1
Vertigo	4	4	2	2	2	2
Vision blurred	1	2	1	1		1
Visual impairment	1	1			1	1
Vomiting	2	3	1	1	1	2

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Age Range

65 - 79 years

Preferred Term

Wheezing

Interval Total #
Spontaneous AE

159

Cumulative Total #
Spontaneous AE

1

305

Spontaneous			
Nonserious		Serious	
I	C	I	C
72	101	87	204

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	2	1	1		1
Acute kidney injury		2				2
Acute myocardial infarction		1				1
Acute pulmonary oedema		1				1
Agitation		1				1
Altered state of consciousness		2				2
Anaemia		1		1		
Anaphylactic reaction		4				4
Anaphylactoid reaction		1				1
Angioedema		1				1
Anxiety		1		1		
Apathy		1				1
Aphasia	1	2			1	2
Arthralgia	1	1			1	1
Asthenia	1	16		1	1	15
Asymptomatic COVID-19	1	15			1	15
Ataxia	1	1			1	1
Atrial fibrillation	1	2			1	2
Atrioventricular block complete		2				2
Back pain	1	1	1	1		
Balance disorder	1	1			1	1
Behaviour disorder	1	1			1	1
Bell's palsy		2				2
Blindness		2				2
Blindness unilateral	2	3			2	3
Blood glucose fluctuation		1		1		
Blood glucose increased		1				1
Blood pressure diastolic decreased		1		1		
Blood pressure increased		1		1		
Blood pressure systolic increased		1		1		
Bradycardia		2				2
Bronchospasm		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac failure		1				1
Cardio-respiratory arrest		3				3
Cerebral artery thrombosis	1	1			1	1
Cerebral infarction	2	2			2	2
Cerebrovascular accident	8	15			8	15
Chest pain	1	2			1	2
Chills	1	3	1	2		1
Cholangitis		1				1
Cholestasis		1				1
Chronic kidney disease		1				1
Condition aggravated		1		1		
Contusion	1	2			1	2
Cough		13		2		11
COVID-19	2	41		4	2	37
COVID-19 pneumonia	1	3			1	3
Cutaneous vasculitis	1	1			1	1
Cyanosis		1				1
Death		5				5
Decreased appetite		18		2		16
Deep vein thrombosis	3	4			3	4
Depressed level of consciousness	1	1			1	1
Dermatitis	1	1			1	1
Dermatitis exfoliative generalised		1				1
Diarrhoea		5		2		3
Diplopia		1		1		
Disease recurrence	1	1			1	1
Disorientation		3		1		2
Dizziness	2	5	1	1	1	4
Drug-induced liver injury		1				1
Drug ineffective	1	12			1	12
Drug interaction		1				1
Dysarthria		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyslexia		1				1
Dyspnoea	3	9	1	1	2	8
Dyspnoea at rest		1				1
Dyspnoea exertional		1				1
Ecchymosis	1	1			1	1
Embolic stroke	1	2			1	2
Embolism venous	1	3			1	3
Emotional distress	1	1			1	1
Epistaxis		2		1		1
Erythema		2		1		1
Escherichia bacteraemia		1				1
Fall	2	5	1	2	1	3
Fatigue	3	16		4	3	12
Feeling hot		1		1		
Fibrin D dimer increased		2		2		
Food refusal		1				1
Gait disturbance		1				1
Gait inability		2				2
Gastric disorder		1				1
Haemoglobinuria		1				1
Haemorrhagic stroke	2	2			2	2
Haemorrhagic transformation stroke		1				1
Headache	1	5		2	1	3
Head injury		1				1
Heart rate decreased		1				1
Heart rate increased		1		1		
Hemiplegia		1				1
Hepatitis		1				1
Herpes zoster	1	1	1	1		
Hyperglycaemia		1				1
Hyperhidrosis	2	4	1	2	1	2
Hypertension	1	4			1	4

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia	1	1			1	1
Hypoglycaemia	2	2			2	2
Hypopnoea		1				1
Hypotension	1	9			1	9
Impetigo		1				1
Inappropriate schedule of product administration	1	1	1	1		
Influenza		1		1		
International normalised ratio decreased		1		1		
Ischaemic stroke	4	8			4	8
Jaundice		1				1
Joint swelling		1				1
Leukaemoid reaction		1				1
Leukocytosis		1				1
Limb mass		1		1		
Loss of consciousness		1				1
Loss of personal independence in daily activities		1				1
Lymphadenopathy		2		1		1
Lymphoproliferative disorder		1				1
Malaise	1	3			1	3
Moaning	1	1			1	1
Mobility decreased		2		1		1
Movement disorder	1	2			1	2
Muscular weakness	1	3			1	3
Musculoskeletal disorder	1	1	1	1		
Myalgia	3	7	2	4	1	3
Nausea	1	6			1	6
Neck pain	1	1	1	1		
Neutrophilia		1				1
Oedema peripheral	2	3			2	3
Oliguria		1		1		
Ophthalmic artery thrombosis	1	1			1	1
Oropharyngeal discomfort		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oxygen saturation decreased	1	7			1	7
Pain	1	4		3	1	1
Pain in extremity	1	3		1	1	2
Pallor		1				1
Paraesthesia		3		1		2
Paralysis	1	1			1	1
Patella fracture		1				1
Pericardial effusion		1				1
Peripheral swelling		2		1		1
Phlebitis	1	1			1	1
Platelet count increased		1		1		
Pneumonia	1	2			1	2
Pneumonia aspiration		2				2
Presyncope		2		1		1
Product administered at inappropriate site		1		1		
Pruritus	1	3	1	3		
Pulmonary embolism	3	7			3	7
Purpura	1	3		1	1	2
Pyrexia	2	11	2	5		6
Rash	1	8		2	1	6
Rash erythematous	1	1			1	1
Rash macular		1				1
Rash maculo-papular		1				1
Renal pain	1	1			1	1
Respiratory failure		1				1
Respiratory tract infection		1				1
Retinal artery occlusion	1	1			1	1
Rhabdomyolysis	1	1			1	1
Rhinorrhoea		1		1		
SARS-CoV-2 test positive		1				1
Seizure		2				2
Sepsis		1				1

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin lesion		1				1
Sneezing		1				1
Soft tissue haemorrhage		1		1		
Somnolence		4		1		3
Speech disorder		2		1		1
Stroke in evolution		1				1
Sudden cardiac death		1				1
Syncope		4				4
Systemic inflammatory response syndrome		1				1
Tachycardia		1				1
Tachypnoea		1				1
Thrombocytopenic purpura	1	1			1	1
Thrombophlebitis	1	1	1	1		
Thrombosis		2				2
Transient ischaemic attack		1				1
Tremor	1	4		2	1	2
Trigeminal neuralgia		1		1		
Upper gastrointestinal haemorrhage		1				1
Urinary tract infection		1				1
Urticaria	2	2			2	2
Vaccination failure	4	31			4	31
Vaccination site erythema	1	1	1	1		
Vaccination site hypoaesthesia		1				1
Vaccination site mass	1	1	1	1		
Vaccination site pain	2	6	2	5		1
Vasculitis	1	2			1	2
Vertigo	1	1			1	1
Visual impairment		1				1
Vomiting		8		2		6
Vulvovaginal burning sensation		1		1		
Wheezing		3		1		2
	113	537	21	95	92	442

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2		1		1
Abdominal pain		6		2		4
Abdominal pain upper	1	2	1	2		
Abortion spontaneous		1				1
Amenorrhoea		1		1		
Amnesia		1		1		
Anaphylactic reaction		1				1
Anxiety		1				1
Arthralgia	3	13	3	7		6
Asthenia	1	17		3	1	14
Asymptomatic COVID-19		1		1		
Axillary mass		1				1
Axillary pain	1	5	1	3		2
Back pain		4		2		2
Breast swelling		1		1		
Chest discomfort	1	1	1	1		
Chest pain		4		1		3
Chills	2	18	1	4	1	14
Choroiditis		1				1
Condition aggravated		1				1
Cough		3		1		2
COVID-19	5	34	5	11		23
Death		1				1
Decreased appetite		4		2		2
Deep vein thrombosis		2				2
Diarrhoea		13		7		6
Discomfort		1		1		
Dizziness	1	8	1	5		3
Drug ineffective	1	17			1	17
Dysarthria		1		1		
Dysgeusia		1		1		
Dyspepsia		1				1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysphonia		1		1		
Dyspnoea		4		1		3
Ear pain		1				1
Embolism	1	2			1	2
Erythema	1	5	1	3		2
Exposure during pregnancy		3		3		
Exposure via breast milk	1	4	1	4		
Eye haemorrhage	1	1			1	1
Face oedema		4		1		3
Facial paralysis		1				1
Fatigue	2	18	2	7		11
Feeling cold	1	3			1	3
Feeling hot	3	4	2	2	1	2
Gastrointestinal disorder	1	1	1	1		
Haematoma	1	1	1	1		
Headache	16	64	12	31	4	33
Heart rate increased	1	1	1	1		
Herpes zoster		1		1		
Hyperglycaemia		1				1
Hyperhidrosis		4		2		2
Hypersensitivity		5		4		1
Hypertensive crisis		1				1
Hyperthermia		2		2		
Hypoaesthesia		3		2		1
Hypoaesthesia oral		2		1		1
Hypoglycaemia	1	1	1	1		
Hypokalaemia		2				2
Immune system disorder		1		1		
Inappropriate schedule of product administration		1		1		
Incomplete course of vaccination	1	1	1	1		
Inflammation		1				1
Insomnia	1	3		1	1	2

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inspiratory capacity decreased		1				1
Irritability		1		1		
Laryngeal oedema		2				2
Lethargy		2		1		1
Lip oedema		1				1
Localised oedema	1	2	1	2		
Lymphadenitis		2		2		
Lymphadenopathy	3	12	3	6		6
Malaise	2	13	2	10		3
Maternal exposure during pregnancy	1	3	1	3		
Menstrual disorder		1		1		
Migraine		2		1		1
Muscle contractions involuntary	1	2			1	2
Muscular weakness	1	2	1	1		1
Musculoskeletal stiffness		1				1
Myalgia	14	70	12	34	2	36
Nasopharyngitis	1	1	1	1		
Nausea	5	23	4	14	1	9
Odynophagia		1				1
Oedema	1	1	1	1		
Off label use	2	5	2	5		
Oral discomfort		1		1		
Oral disorder		1				1
Oropharyngeal oedema		1		1		
Oropharyngeal pain		3		1		2
Overdose	2	4	2	4		
Oxygen saturation decreased		1				1
Pain	4	10	3	7	1	3
Pain in extremity	1	4		2	1	2
Pallor		1		1		
Pancreatitis		1				1
Papule	1	1	1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia		7		2		5
Paraesthesia oral		2		1		1
Peripheral coldness		2				2
Pharyngeal inflammation		1		1		
Photophobia		1				1
Pneumonia		1				1
Presyncope		2		1		1
Productive cough		1				1
Product preparation issue	1	1	1	1		
Product use issue	2	4	2	4		
Pruritus	1	5	1	2		3
Pyrexia	12	48	11	23	1	25
Rash	2	10	1	7	1	3
Rash erythematous	1	1	1	1		
Rash maculo-papular		1		1		
Rash pruritic	1	2	1	2		
Rash vesicular		1				1
Renal colic		1				1
Rhinorrhoea		3		1		2
SARS-CoV-2 test positive	2	5	1	1	1	4
Sensory loss		1				1
Skin exfoliation		1				1
Somnolence		2		1		1
Stomatitis		1		1		
Swelling		2		1		1
Syncope		2				2
Tachycardia	1	8	1	4		4
Taste disorder		1		1		
Tension headache	1	2	1	2		
Throat irritation		2		1		1
Thrombosis	1	1			1	1
Tongue discomfort	1	2			1	2

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue disorder		1		1		
Tongue oedema		1				1
Tonsillitis		1				1
Transaminases increased		1				1
Tremor	1	5	1	2		3
Urticaria		1				1
Urticaria cholinergic		1		1		
Vaccination failure		7				7
Vaccination site erythema		4		2		2
Vaccination site haemorrhage		1		1		
Vaccination site inflammation	1	1	1	1		
Vaccination site movement impairment		1				1
Vaccination site oedema	2	7	1	3	1	4
Vaccination site pain	10	55	8	38	2	17
Vaccination site pruritus		1				1
Vaccination site reaction		1				1
Vaccination site swelling		2		1		1
Vaccination site warmth		1		1		
Vision blurred	1	1			1	1
Visual impairment	1	1			1	1
Vitreous floaters		1				1
Vomiting	3	11	2	4	1	7
	133	721	104	347	29	374

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

PUERTO RICO

090177e19749cf15\Approved\Approved On: 14-Jun-2021 14:01 (GMT)

- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Axillary pain		1		1		
Bone disorder		1		1		
Bone pain		1		1		
Chest discomfort	1	1			1	1
Chest pain	1	2		1	1	1
Chills		1		1		
Facial paralysis	1	1			1	1
Fatigue		2		2		
Headache		2		2		
Hot flush	1	1			1	1
Hypotension	1	1			1	1
Inflammation		1		1		
Muscle spasms	1	1			1	1
Muscular weakness	1	1			1	1
Myalgia		1		1		
Nodule		1		1		
Pain in extremity		1		1		
Palpitations		1		1		
Paraesthesia	1	1			1	1
Pharyngeal swelling	1	1			1	1
Pyrexia		1		1		
Syncope	1	1			1	1
Tachycardia		1		1		
Vaccination site erythema		1		1		
Vaccination site inflammation		1		1		
Vaccination site pain		3		3		
Vaccination site swelling		1		1		
	10	33		23	10	10

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2		2		
Abdominal pain	1	1	1	1		
Antibody test abnormal		1		1		
Antinuclear ant body positive		1		1		
Arthralgia	1	5	1	5		
Asthenia		1		1		
Back pain		1		1		
Blepharospasm		1		1		
Blood test abnormal		1		1		
Burning sensation		1		1		
Chills	1	3	1	3		
Contraindicated product administered	1	1	1	1		
Decreased appetite		1		1		
Diarrhoea	1	3	1	3		
Dizziness		2		1		1
Dizziness postural		1		1		
Dry mouth		1		1		
Dyskinesia		1				1
Dyspepsia		1		1		
Dysphonia		1		1		
Dyspnoea	1	1	1	1		
Erythema		1		1		
Eyelid oedema	1	1	1	1		
Face oedema	1	1	1	1		
Facial pain		1		1		
Facial paralysis		3				3
Fatigue	1	9	1	9		
Flatulence		1		1		
Gait disturbance		1		1		
Gingival bleeding		1		1		
Haematoma		1		1		
Headache	2	15	2	15		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate decreased		1				1
Herpes zoster		1		1		
Hypertension	1	2	1	2		
Hypoaesthesia	1	5		3	1	2
Inappropriate schedule of product administration		2		2		
Limb discomfort		1		1		
Loss of personal independence in daily activities		2		2		
Lymphadenopathy	1	6	1	6		
Malaise		1		1		
Migraine		1				1
Movement disorder		1		1		
Muscle spasms	1	1			1	1
Musculoskeletal discomfort		1		1		
Musculoskeletal stiffness		1		1		
Myalgia	1	7	1	7		
Nausea	1	6	1	6		
Neck pain	1	2	1	2		
Neuralgia		1		1		
Night sweats		1				1
Oedema	1	1	1	1		
Oral herpes		1		1		
Oropharyngeal pain	1	1	1	1		
Pain		5		5		
Pain in extremity	1	4	1	4		
Paraesthesia	2	4	1	3	1	1
Peripheral swelling		1		1		
Photophobia		1		1		
Product dose omission issue	1	1	1	1		
Pruritus		1		1		
Pyrexia	1	11	1	11		
Rash		1		1		
Red blood cell sedimentation rate increased		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rhinorrhoea		1		1		
Sensation of blood flow	1	1	1	1		
Sinus arrhythmia		1				1
Sleep disorder		1		1		
Somnolence		1		1		
Speech disorder		1		1		
Stress		1		1		
Swelling		1		1		
Swelling face		1		1		
Tachycardia		1		1		
Taste disorder		2		2		
Vaccination site discomfort		1		1		
Vaccination site induration		1		1		
Vaccination site pain		3		3		
Vaccination site swelling		2		2		
Vaginal haemorrhage	1	1	1	1		
	27	162	24	149	3	13

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		2		2		
Arthralgia		2		2		
Blood pressure increased		1		1		
Burning sensation		1		1		
Chest pain		1		1		
Chills		2		2		
Death		1				1
Deep vein thrombosis		1				1
Depression		1		1		
Diarrhoea		1		1		
Discomfort		1		1		
Dizziness		2		2		
Dysgeusia		1		1		
Dyspnoea		1		1		
Electric shock sensation		1		1		
Erythema		2		2		
Fatigue		4		4		
Feeling cold		1				1
Flushing		1		1		
Headache	1	5		4	1	1
Head discomfort		1		1		
Heart rate increased		1		1		
Hyperhidrosis		1				1
Hypertension		1				1
Hypoaesthesia		2		2		
Insomnia		1		1		
Joint range of motion decreased		1		1		
Joint swelling		2		2		
Limb discomfort		1		1		
Lymphadenopathy		2		2		
Muscle spasms		1		1		
Myalgia		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea		2		2		
Oral discomfort		1		1		
Pain in extremity		3		3		
Peripheral swelling		1		1		
Photophobia		1		1		
Product administered at inappropriate site		1		1		
Productive cough		1		1		
Pyrexia		5		5		
Rash		2		2		
Somnolence		1		1		
Swelling face		2		2		
Tachycardia		1		1		
Thrombosis		1				1
Vaccination site pain		1		1		
Vaccination site swelling		2		2		
	1	72		65	1	7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Arthralgia		1		1		
Asthenia		1		1		
Balance disorder		1		1		
Burning sensation		1		1		
Cerebrovascular accident		1				1
Dizziness		1		1		
Headache		2		2		
Hypertension		1		1		
Hypoaesthesia		1		1		
Pruritus		1		1		
Rash		2		2		
Somnolence		1		1		
Vaccination site induration	1	1	1	1		
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	1	1	1	1		
Vaccination site warmth	1	1	1	1		
	4	19	4	18		1

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Dyspnoea		1		1
Illness		1		1
Pneumonia		1		1
Urinary tract infection		1		1
		4		4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia		1		1
Asymptomatic COVID-19		1		1
Chest discomfort		1		1
Chills		2		2
Dehydration		1		1
Dermatitis		1		1
Fatigue		2		2
Flushing		1		1
Headache		1		1
Hypoaesthesia		1		1
Inappropriate schedule of product administration		1		1
Lymphadenitis		1		1
Maternal exposure during pregnancy		1		1
Muscle spasms		1		1
Myalgia		2		2
Off label use		1		1
Pain		1		1
Pain in extremity		2		2
Peripheral swelling		1		1
Poor quality product administered		10		10
Pyrexia		2		2
Swelling face		1		1
Thirst		1		1
Urticaria		1		1
		38		38

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

QATAR

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic shock		1		1
		1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Back pain		1				1
Confusional state		1		1		
Cough		1				1
COVID-19		1				1
C-reactive protein increased		1				1
Depressed mood		1		1		
Dizziness		1				1
Drug ineffective		1				1
Dysgeusia		1		1		
Dyspepsia		1		1		
Erythema		1				1
Exposure during pregnancy		1		1		
Facial paralysis		1				1
Headache		2		2		
Heart rate decreased		1		1		
Hypertension		1		1		
Hypotension		1		1		
Inflammatory marker increased		1				1
Middle insomnia		1		1		
Mood altered		1		1		
Myalgia		1		1		
Nausea		1				1
Neck pain		1				1
Neutrophil count increased		1				1
Ocular hyperaemia		1				1
Pain in extremity		1				1
Peripheral coldness		1		1		
Platelet count increased		1				1
Presyncope		1				1
Product use issue		1		1		
Pyrexia		1				1
Rash		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Red blood cell sedimentation rate increased		1				1
Rhinovirus infection		1				1
Sleep disorder		1		1		
Starvation		1				1
Syncope		1				1
Tachycardia		2		1		1
White blood cell count increased		1				1
		41		17		24

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea	1	1			1	1
Gait disturbance		1		1		
Herpes zoster		1		1		
Overdose		1		1		
Product preparation error		1		1		
Pulse abnormal	1	1			1	1
Pyrexia	1	1			1	1
Tachycardia	1	1			1	1
Vertigo		1				1
	4	9		4	4	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		2		1		1
Blood pressure decreased		1		1		
Disturbance in attention		1		1		
Dizziness		1				1
Dyspnoea		1				1
Erythema		1		1		
Feeling hot		1				1
Heart rate increased		1		1		
Herpes zoster		1		1		
Hyperhidrosis		1				1
Muscle spasticity		1				1
Neuralgia		1		1		
Pyrexia		1		1		
		14		8		6

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19		2		1		1
Dyspepsia		1		1		
Feeling cold		1		1		
Sexual dysfunction	1	1	1	1		
Vaccination failure		1				1
	1	6	1	4		2

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

ROMANIA

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	1			1	1
Anaphylactic shock	1	2			1	2
Arthralgia	1	1			1	1
Exposure via breast milk	3	3	3	3		
Loss of consciousness		1				1
Malaise	2	2	1	1	1	1
Myalgia	1	1			1	1
Pyrexia	1	1			1	1
Suffocation feeling		1		1		
Syncope	1	1			1	1
	11	14	4	5	7	9

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Abdominal pain upper		1		1		
Administration site pain		1		1		
Administration site swelling		1		1		
Adnexa uteri pain		1				1
Anaphylactic shock	1	1			1	1
Angina pectoris		1				1
Anxiety		1				1
Arthralgia	2	11	1	6	1	5
Asthenia	4	7	4	6		1
Back pain	1	2			1	2
Blepharitis		1				1
Blood pressure increased		1		1		
Bone pain	1	3		1	1	2
Breast pain		2		1		1
Burning sensation		1				1
Burn of internal organs		1				1
Catarrh	1	1	1	1		
Cerebrovascular accident		1				1
Chest discomfort	1	1			1	1
Chest pain	1	2			1	2
Chills	7	25	4	11	3	14
Cold sweat		1				1
Confusional state	1	1			1	1
Contusion	1	1			1	1
Cough		2				2
COVID-19		5		1		4
Craniocerebral injury	1	1			1	1
Cyanosis		1				1
Decreased appetite	2	3	2	2		1
Deep vein thrombosis		2				2
Dehydration		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Delirium	1	1			1	1
Diarrhoea		3				3
Diplopia		1				1
Dizziness	4	11	3	4	1	7
Drug ineffective		3				3
Dysphagia	1	2	1	1		1
Dyspnoea	1	4		1	1	3
Ear pain		1				1
Emotional disorder	1	1	1	1		
Erythema	1	3	1	1		2
Eye pain		1				1
Fall	1	1			1	1
Fatigue	6	20	4	15	2	5
Gastric pH decreased		1		1		
Headache	4	25	4	15		10
Head discomfort		1				1
Heart rate increased	1	4		1	1	3
Herpes zoster		1				1
Hyperaesthesia	1	1	1	1		
Hypercoagulation	1	1			1	1
Hyperhidrosis		2				2
Hypersensitivity		2		2		
Hypoacusis		1				1
Hypoaesthesia	1	4		1	1	3
Hypoglycaemia	2	2			2	2
Hypotension	1	1			1	1
Hypotonia		1				1
Incorrect route of product administration		2		2		
Inflammation		1		1		
Insomnia	1	1	1	1		
Jaw disorder		1				1
Joint dislocation	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint swelling	1	1			1	1
Lip oedema		1				1
Loss of consciousness	3	4			3	4
Loss of personal independence in daily activities		1		1		
Lymphadenitis		1		1		
Lymphadenopathy	2	9	2	5		4
Malaise	2	6	1	2	1	4
Menstrual disorder		1				1
Migraine		1		1		
Muscle tightness	1	1	1	1		
Muscular weakness		1		1		
Musculoskeletal chest pain		1				1
Musculoskeletal disorder	1	1	1	1		
Musculoskeletal pain	1	1	1	1		
Myalgia	6	29	4	12	2	17
Nasal discomfort		1		1		
Nasal vestibulitis		1				1
Nausea	4	18	2	9	2	9
Neurological symptom		1				1
Neuropathy peripheral	1	1			1	1
Oedema peripheral	1	1			1	1
Off label use		1		1		
Optic neuritis		1				1
Oral pigmentation		1		1		
Pain	3	4	3	3		1
Pain in extremity		5		4		1
Pain of skin	1	2	1	1		1
Pallor		1				1
Palpitations		1				1
Panic attack		1		1		
Panic reaction	1	1			1	1
Paraesthesia	2	5		1	2	4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraplegia		1				1
Paratracheal lymphadenopathy		1				1
Parosmia		2		1		1
Peripheral swelling	1	2	1	1		1
Peripheral venous disease	1	1			1	1
Pharyngitis		1		1		
Polyuria		1				1
Product use issue		1		1		
Pruritus		2				2
Pyrexia	10	31	6	14	4	17
Rash		2		2		
Rash vesicular		1				1
Renal pain		1				1
SARS-CoV-2 ant body test negative		1		1		
SARS-CoV-2 ant body test positive		1		1		
Scar pain		1		1		
Seizure	2	2			2	2
Somnolence	4	9	3	6	1	3
Suppressed lactation		1		1		
Syncope	4	5			4	5
Tachycardia		3		2		1
Taste disorder		1		1		
Tremor	1	2			1	2
Urticaria		2		1		1
Vaccination failure		1				1
Vaccination site erythema	1	2	1	2		
Vaccination site oedema		1		1		
Vaccination site pain	5	33	5	26		7
Vaccination site paraesthesia		1				1
Vaccination site reaction		5		5		
Vaccination site swelling	1	2	1	2		
Vertigo		7				7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vision blurred		1				1
Vomiting	1	4	1	1		3
White blood cell count decreased	1	1	1	1		
	116	428	63	201	53	227

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* I=Interval, C=Cumulative
 * AE=Adverse Event
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	8	1	3	1	5
Abdominal pain upper	2	3			2	3
Abortion spontaneous	1	1			1	1
Acoustic neuroma		1				1
Administration site pain		2		2		
Administration site reaction		2		2		
Ageusia		3		2		1
Aggression	1	1			1	1
Agitation		1				1
Allergy to vaccine		1		1		
Amenorrhoea		1		1		
Anaphylactic reaction	1	6			1	6
Anaphylactic shock	2	4			2	4
Anaphylactoid reaction		1				1
Angina pectoris	1	1			1	1
Angioedema		2				2
Anosmia	1	3		1	1	2
Anxiety		6		1		5
Aphasia	1	1			1	1
Arrhythmia		4				4
Arthralgia	7	34	2	16	5	18
Asphyxia	1	3			1	3
Asthenia	2	22	1	11	1	11
Axillary pain	2	5	2	3		2
Back pain	1	6		2	1	4
Balance disorder		2		1		1
Blindness unilateral	1	1			1	1
Blister		1				1
Blood pressure abnormal	1	1	1	1		
Blood pressure fluctuation	2	4			2	4
Blood pressure increased	3	7	1	2	2	5
Blood pressure systolic increased		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Body temperature increased		1				1
Bone pain	2	8	1	2	1	6
Breast pain	3	4	1	1	2	3
Bronchitis		1				1
Bronchospasm		2				2
Bruxism	1	1	1	1		
Burning sensation	1	3	1	2		1
Cardio-respiratory arrest		1				1
Cardiovascular disorder	2	2			2	2
Cataract		1				1
Chest discomfort	1	3		1	1	2
Chest pain	2	12	1	4	1	8
Chills	22	70	8	26	14	44
Circulatory collapse	1	1			1	1
Circumoral oedema		1				1
Coagulopathy	1	1			1	1
Cognitive disorder	1	1			1	1
Cold sweat		2		1		1
Condition aggravated		1				1
Confusional state	1	1			1	1
Contusion	1	2		1	1	1
Cough	3	6		1	3	5
COVID-19	1	11		3	1	8
Cyanosis		1				1
Deafness unilateral	1	1			1	1
Death		1				1
Decreased appetite		6		2		4
Deep vein thrombosis		1				1
Dehydration	1	1			1	1
Dermatitis allergic		3				3
Diarrhoea	3	12	2	7	1	5
Diplopia	1	2		1	1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Discomfort	1	2	1	2		
Disturbance in attention		3				3
Dizziness	12	36	6	11	6	25
Drug eruption		2				2
Drug ineffective		6				6
Dry skin	1	1			1	1
Dysgeusia		1				1
Dysmenorrhoea	1	1	1	1		
Dysphagia		2		1		1
Dysphonia	1	3		2	1	1
Dyspnoea	5	11			5	11
Dysstasia	1	2			1	2
Ear congestion	1	1			1	1
Ear discomfort	1	1	1	1		
Ear pain	1	2		1	1	1
Erythema	3	6	1	1	2	5
Erythema nodosum		1				1
Exposure to SARS-CoV-2		1		1		
Extensive swelling of vaccinated limb		1				1
Eye haemorrhage		1				1
Eyelid oedema		1				1
Eyelid ptosis		1				1
Eye pain		1				1
Face oedema		2				2
Facial nerve disorder	1	1			1	1
Facial pain		1		1		
Facial paralysis	2	8			2	8
Facial paresis	2	3	1	1	1	2
Faeces soft	1	2	1	1		1
Fall	1	1			1	1
Fatigue	13	47	8	28	5	19
Feeling abnormal	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling cold		2		1		1
Feeling hot		3		1		2
Flatulence		1				1
Foaming at mouth		1				1
Gait disturbance	1	1			1	1
General physical health deterioration	1	4		3	1	1
Goitre		1				1
Guillain-Barre syndrome		1				1
Haemorrhage	2	2			2	2
Headache	28	106	12	51	16	55
Head discomfort	1	2	1	1		1
Heart rate abnormal	1	2		1	1	1
Heart rate decreased		2				2
Heart rate increased	7	16	3	3	4	13
Heavy menstrual bleeding	1	1	1	1		
Hemianaesthesia		1				1
Hemiparesis	2	3			2	3
Hemiplegia		1				1
Hepatic cytolysis		1				1
Herpes zoster	1	2		1	1	1
Hyperaemia		1				1
Hyperglycaemia		2		1		1
Hyperhidrosis	3	10	2	5	1	5
Hyperkalaemia		1				1
Hyperpyrexia		1				1
Hypersensitivity	4	20		13	4	7
Hypertension	7	31		3	7	28
Hypertensive crisis		1				1
Hypoacusis		3				3
Hypoaesthesia	10	20	4	8	6	12
Hypoaesthesia oral	1	3			1	3
Hypotension	3	9	1	1	2	8

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypothyroidism		1				1
Immobile		1				1
Impaired work ability		1				1
Inappropriate schedule of product administration	1	1	1	1		
Incorrect route of product administration		4		1		3
Induration	1	1	1	1		
Inflammation	3	3	1	1	2	2
Influenza like illness		2		2		
Injected limb mobility decreased	1	3	1	3		
Insomnia		5		1		4
Intervertebral disc protrusion	1	1			1	1
Intracranial pressure increased	1	2			1	2
Irregular breathing	1	1			1	1
Irritable bowel syndrome	1	1			1	1
Jaundice	2	2	1	1	1	1
Laryngeal oedema		1				1
Laryngospasm		1				1
Lethargy		1		1		
Lid sulcus deepened	1	1			1	1
Lipase increased		1		1		
Lip dry		1				1
Lip oedema	1	4		1	1	3
Lividity		1				1
Localised oedema		1				1
Local reaction		1		1		
Loss of consciousness	4	7			4	7
Lymphadenitis	3	9	1	3	2	6
Lymphadenopathy	11	21	3	5	8	16
Lymph node pain	1	2		1	1	1
Lymph node palpable		1		1		
Lymphopenia		1				1
Malaise	8	21	2	8	6	13

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Maternal exposure during pregnancy		2		2		
Memory impairment		1				1
Menometrorrhagia	1	1			1	1
Menstruation irregular	1	2	1	1		1
Mental status changes		1				1
Metamorphopsia		1				1
Migraine	1	3			1	3
Mobility decreased	1	2		1	1	1
Mood altered	1	1			1	1
Movement disorder		1				1
Mucosal dryness		1				1
Muscle contractions involuntary	1	3	1	2		1
Muscle discomfort	1	1			1	1
Muscle twitching	1	1			1	1
Musculoskeletal stiffness		1				1
Myalgia	27	77	14	36	13	41
Myoclonus	1	3			1	3
Nasal congestion	1	2			1	2
Nasal dryness	1	3		1	1	2
Nausea	13	48	5	19	8	29
Neck pain		1		1		
Nephrogenic diabetes insipidus	1	1			1	1
Nephropathy		1				1
Nervous system disorder		3		3		
Neurological symptom		2				2
Neuropathy peripheral	1	2			1	2
Night sweats	1	2		1	1	1
Nodule	1	1			1	1
Nystagmus		1		1		
Ocular discomfort		2		1		1
Oedema		1		1		
Oedema peripheral	2	3	1	1	1	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oedematous pancreatitis		1				1
Oesophageal oedema	1	1			1	1
Off label use	1	1	1	1		
Optic neuritis	1	1			1	1
Oropharyngeal discomfort		1				1
Oropharyngeal pain	2	4			2	4
Orthostatic hypotension	1	1			1	1
Overdose		1		1		
Oxygen saturation decreased		2				2
Pain	2	8	1	6	1	2
Pain in extremity	10	24	6	18	4	6
Pain of skin	1	2			1	2
Pallor	1	2			1	2
Palpitations	1	6			1	6
Panic attack		1		1		
Paraesthesia	4	24	2	8	2	16
Paraesthesia ear		1		1		
Paraesthesia oral	1	1	1	1		
Paralysis		1				1
Parosmia		1				1
Pericarditis	1	2			1	2
Peripheral arterial occlusive disease		1				1
Peripheral coldness		1		1		
Photophobia	1	2	1	1		1
Photosensitivity reaction		1				1
Pleurisy		1				1
Pneumonia	1	2			1	2
Polyuria	1	3			1	3
Presyncope		3		2		1
Productive cough		1				1
Product use issue	1	1	1	1		
Pruritus	1	7		3	1	4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary embolism	1	1			1	1
Pulmonary infarction	1	1			1	1
Pulse abnormal		1				1
Pulse volume decreased		1		1		
Pyrexia	26	88	11	40	15	48
Rales		1				1
Rash	3	10	1	6	2	4
Rash erythematous		4				4
Rash pruritic	1	3			1	3
Raynaud's phenomenon		1				1
Rectal haemorrhage		1				1
Renal pain	2	4			2	4
Respiratory disorder		1				1
Respiratory distress		2				2
Rhinitis	2	2	1	1	1	1
Rhinorrhoea	1	4	1	3		1
SARS-CoV-2 ant body test negative		1		1		
SARS-CoV-2 ant body test positive		1		1		
Sciatica	1	1	1	1		
Seizure	1	1			1	1
Sensation of foreign body	3	3			3	3
Sialoadenitis		1				1
Sinus tachycardia		2				2
Sitting disability		1				1
Skin burning sensation		1				1
Skin hypertrophy		1				1
Skin irritation		2				2
Skin plaque		1				1
Sleep disorder		1				1
Somnolence	5	21	3	9	2	12
Speech disorder		1				1
Spinal pain		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stomatitis		1				1
Stress cardiomyopathy	1	1			1	1
Suffocation feeling	4	6			4	6
Supraventricular tachycardia		1				1
Suspected COVID-19		2				2
Sweating fever		1				1
Swelling face	1	1	1	1		
Swollen tongue	1	1			1	1
Syncope	6	22			6	22
Syringe issue		1		1		
Systemic inflammatory response syndrome		1				1
Tachyarrhythmia		1				1
Tachycardia	1	18		3	1	15
Tachypnoea		1				1
Taste disorder		1				1
Tendon pain		1				1
Tetany	1	1	1	1		
Thirst		2				2
Throat irritation	1	1			1	1
Thrombophlebitis	1	1			1	1
Thrombosis	1	1			1	1
Thyroiditis subacute		1		1		
Tinnitus	3	7		1	3	6
Tongue spasm		1				1
Tremor	2	5		1	2	4
Urinary incontinence	2	2	2	2		
Urticaria	4	9	2	2	2	7
Vaccination complication	1	1			1	1
Vaccination error	1	1			1	1
Vaccination failure	1	4			1	4
Vaccination site discolouration	1	1	1	1		
Vaccination site erythema	1	7	1	6		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site haemorrhage	1	1			1	1
Vaccination site induration	1	5		4	1	1
Vaccination site inflammation	1	2	1	1		1
Vaccination site joint movement impairment		2		1		1
Vaccination site movement impairment		5		2		3
Vaccination site oedema	2	2	1	1	1	1
Vaccination site pain	23	87	16	58	7	29
Vaccination site paraesthesia		1		1		
Vaccination site pruritus	1	3	1	3		
Vaccination site reaction	1	15	1	15		
Vaccination site swelling	3	5	2	4	1	1
Vaccination site warmth	1	1	1	1		
Ventricular extrasystoles		1		1		
Ventricular tachycardia	1	1			1	1
Vertigo	2	13	1	3	1	10
Vestibular disorder		1		1		
Viral infection		1				1
Vision blurred	2	3			2	3
Visual field defect	1	2	1	1		1
Visual impairment		3				3
Vomiting	3	14	2	5	1	9
Wheezing		1				1
Wrong technique in product usage process		2		2		
	457	1,540	167	587	290	953

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	4	1	2		2
Abdominal pain upper	2	2	1	1	1	1
Acute pulmonary oedema		2				2
Administration site pain		1				1
Administration site reaction		2		2		
Alanine aminotransferase increased	1	1			1	1
Anaphylactic reaction	3	7			3	7
Anaphylactic shock	1	2			1	2
Anaphylactoid reaction		1				1
Angina pectoris	1	2			1	2
Angioedema		1				1
Anxiety	1	4			1	4
Apnoea		1				1
Arrhythmia		1				1
Arthralgia	5	17	2	9	3	8
Aspartate aminotransferase increased	1	1			1	1
Asthenia	4	9	1	5	3	4
Asthmatic crisis		1				1
Autoimmune disorder		1				1
Axillary pain		1		1		
Back pain	2	4	2	2		2
Balance disorder		2				2
Blood glucose decreased		1				1
Blood pressure abnormal		1				1
Blood pressure fluctuation		1				1
Blood pressure systolic increased		1				1
Body temperature abnormal	1	2	1	2		
Bone pain	1	2			1	2
Breast inflammation		2				2
Breast pain		1				1
Bronchospasm		1		1		
Burning sensation	2	2			2	2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac arrest		1				1
Cardio-respiratory arrest		1				1
Cerebrovascular accident	1	3			1	3
Chest discomfort	2	2			2	2
Chest pain	3	5			3	5
Chills	8	31	3	13	5	18
Cold sweat		1		1		
Coma		1				1
Coma hepatic		1				1
Condition aggravated		1				1
Confusional state		1		1		
Contusion	2	2			2	2
Cough	2	5	1	3	1	2
COVID-19	3	5	3	3		2
C-reactive protein increased	1	1	1	1		
Cyanosis		1		1		
Death		1				1
Decreased appetite	1	3		1	1	2
Depressed level of consciousness		1				1
Dermatitis allergic	1	2			1	2
Diarrhoea		1				1
Discomfort		1		1		
Disorientation		1				1
Dizziness	11	21	5	9	6	12
Drug ineffective		2				2
Dry mouth	1	3			1	3
Dry throat	1	1			1	1
Dysgeusia		1				1
Dysphagia	1	1			1	1
Dyspnoea	2	10		1	2	9
Ear discomfort		1		1		
Eructation		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	2	8		3	2	5
Eye haemorrhage		1				1
Eyelid oedema	1	1			1	1
Eye pruritus	1	2		1	1	1
Facial neuralgia		1				1
Facial pain		1				1
Facial paralysis		1				1
Facial paresis		1				1
Fall	1	1	1	1		
Fatigue	7	15	4	8	3	7
Feeding disorder	1	1	1	1		
Feeling cold		2				2
Feeling hot		1				1
Guillain-Barre syndrome	1	1			1	1
Haematuria	1	1	1	1		
Hallucination	1	1			1	1
Headache	12	39	7	15	5	24
Hearing disability	1	1			1	1
Heart rate decreased	1	1			1	1
Heart rate increased	3	7	1	1	2	6
Herpes simplex	1	1	1	1		
Herpes zoster	4	4	2	2	2	2
Horner's syndrome		1				1
Hot flush		1		1		
Hyperaesthesia		1		1		
Hyperglycaemia	1	2			1	2
Hyperhidrosis		3				3
Hyperkalaemia		1				1
Hypersensitivity	1	7		5	1	2
Hypertension	11	24		1	11	23
Hypoaesthesia	2	7		1	2	6
Hypoaesthesia eye		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia oral	2	4			2	4
Hypocalcaemia		1				1
Hypokinesia		1		1		
Hypotension	2	3		1	2	2
Hypoxic-ischaemic encephalopathy		1				1
Incorrect route of product administration		1		1		
Insomnia	2	4	2	3		1
Ischaemic stroke	1	2			1	2
Joint ankylosis		1				1
Joint instability	1	1			1	1
Joint stiffness		1				1
Joint swelling	1	1			1	1
Laryngeal oedema		1				1
Lip oedema		1				1
Lip swelling	1	1			1	1
Loss of consciousness	2	2			2	2
Lung disorder		1		1		
Lymphadenitis		1		1		
Lymphadenopathy	2	8		2	2	6
Malaise	7	13	3	4	4	9
Mean cell haemoglobin increased		1		1		
Mental disorder	1	1			1	1
Metabolic acidosis		1				1
Migraine	2	2			2	2
Mobility decreased		1				1
Monoparesis	1	1			1	1
Monoplegia		1				1
Mouth swelling		1				1
Muscle spasms	1	1			1	1
Muscular weakness	1	1	1	1		
Musculoskeletal stiffness	1	1	1	1		
Myalgia	11	33	5	14	6	19

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myositis	1	1			1	1
Nasal dryness		1				1
Nausea	4	17	2	6	2	11
Night sweats		1				1
Nodule	1	1	1	1		
Obstructive airways disorder		1				1
Ocular hyperaemia		1		1		
Odynophagia	1	1	1	1		
Oedema peripheral	2	2			2	2
Organic brain syndrome		1				1
Oropharyngeal pain	2	2	1	1	1	1
Oxygen saturation decreased		1				1
Pain	3	4	1	1	2	3
Pain in extremity	9	14	2	2	7	12
Pallor		2		1		1
Palpitations	3	6	1	1	2	5
Panic attack	1	1			1	1
Paraesthesia	2	5	1	1	1	4
Paresis	1	1			1	1
Pelvic pain		1				1
Petechiae		1				1
Presyncope		1		1		
Pruritus		1				1
Pulse abnormal		1		1		
Pulse volume decreased		1		1		
Pyrexia	16	38	6	13	10	25
Rash	2	5	2	3		2
Rash pruritic		1		1		
Respiration abnormal		1				1
Respiratory disorder		1		1		
Respiratory distress		1				1
Respiratory failure		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rheumatoid factor increased	1	1	1	1		
Rhinalgia		1				1
Rhinorrhoea	1	1	1	1		
Seizure		2				2
Sensory disturbance	1	1			1	1
Sensory loss		1		1		
Shock		1				1
Somnolence	3	7	2	5	1	2
Stomatitis		1				1
Stridor		1		1		
Suffocation feeling	1	2			1	2
Supraventricular tachycardia		1				1
Swelling	1	2		1	1	1
Swelling face	1	2			1	2
Swollen tongue	1	2	1	1		1
Syncope	4	11			4	11
Synovial cyst	1	1			1	1
Tachycardia	3	5		1	3	4
Taste disorder		1		1		
Teething		1				1
Thirst		1				1
Throat tightness		1		1		
Thrombophlebitis superficial	1	1			1	1
Thrombosis	1	1			1	1
Tongue oedema		1				1
Tremor	1	2			1	2
Urinary incontinence		1				1
Urticaria	1	5	1	3		2
Use of accessory respiratory muscles		1		1		
Vaccination site erythema		5		4		1
Vaccination site induration		1				1
Vaccination site inflammation	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site nodule		1		1		
Vaccination site oedema		1		1		
Vaccination site pain	6	19	3	14	3	5
Vaccination site reaction		5		5		
Vaccination site swelling		3		3		
Vaccination site urticaria		1		1		
Vertigo		5		1		4
Visual impairment	1	2			1	2
Vomiting	2	9	1	3	1	6
Weight increased		1				1
Wheezing		1		1		
Wrong technique in product usage process		1		1		
	238	660	79	225	159	435

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Acute coronary syndrome		1				1
Anaphylactic reaction	1	1			1	1
Angina pectoris		1				1
Aphonia		1		1		
Arrhythmia	1	1			1	1
Arthralgia	5	7	4	5	1	2
Asthenia	1	2	1	2		
Atrial fibrillation		1				1
Atrioventricular block		1				1
Autoimmune thyroiditis	1	1			1	1
Back disorder		1		1		
Back pain		1				1
Balance disorder	2	2			2	2
Blood fibrinogen increased		1		1		
Blood glucose increased		1				1
Blood pressure abnormal		1		1		
Blood pressure diastolic increased		1				1
Blood pressure increased	1	4		1	1	3
Blood pressure systolic increased		1				1
Blood uric acid increased		1		1		
Bone pain		1		1		
Bradycardia	1	1			1	1
Bronchospasm		1				1
Cardiac fibrillation		1				1
Cerebral small vessel ischaemic disease		1				1
Cerebrovascular accident	1	2			1	2
Cervical radiculopathy	1	1	1	1		
Chest pain	3	3	2	2	1	1
Chills	4	9	2	5	2	4
Coma		1				1
Condition aggravated		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough		1		1		
COVID-19	2	10	1	1	1	9
Death		1				1
Dementia		1				1
Dermatitis allergic	1	1			1	1
Diabetes mellitus		1				1
Diarrhoea		2				2
Disease recurrence	1	2	1	1		1
Disorientation	1	1	1	1		
Dizziness	3	9	1	4	2	5
Drug ineffective	1	4			1	4
Dry mouth		1				1
Dysphagia	2	3	1	1	1	2
Dyspnoea	1	2			1	2
Encephalopathy	1	1			1	1
Epistaxis		1		1		
Erythema		1		1		
Eye pain	1	1			1	1
Facial paralysis		1				1
Facial paresis	2	3			2	3
Fatigue	6	8	3	5	3	3
Feeling abnormal		1				1
Gait disturbance		2				2
General physical condition abnormal		1		1		
Headache	5	12	4	7	1	5
Heart rate increased	1	2			1	2
Hemiparesis	1	1			1	1
Herpes zoster	1	1	1	1		
High density lipoprotein decreased		1		1		
Hyperglycaemia	1	1			1	1
Hyperhidrosis	1	4			1	4
Hypertension	3	8	2	4	1	4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertensive crisis		1				1
Hypoaesthesia	2	4	1	2	1	2
Hypotension	1	1			1	1
Inappropriate schedule of product administration		1		1		
Incomplete course of vaccination		1		1		
Influenza like illness		1		1		
Intertrigo	1	1	1	1		
Laboratory test abnormal		1		1		
Lethargy	1	1			1	1
Loss of consciousness		2				2
Malaise	3	4	2	2	1	2
Metabolic acidosis	1	1			1	1
Muscle contracture		1				1
Muscle rigidity		1				1
Muscular weakness	1	2			1	2
Myalgia	5	13	3	7	2	6
Mydriasis	1	1			1	1
Myocardial infarction	1	2			1	2
Myocardial ischaemia		1				1
Nausea	2	5		1	2	4
Neck pain	1	1			1	1
Neuritis	1	1			1	1
Nitrite urine present		1		1		
Oedema peripheral		1				1
Off label use		1		1		
Osteoarthritis	1	1	1	1		
Osteoporosis	1	1	1	1		
Oxygen saturation decreased		1				1
Pain in extremity	1	2	1	1		1
Palpitations		1		1		
Paraesthesia	3	3	2	2	1	1
Paraesthesia oral	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Parkinson's disease		1				1
Peripheral coldness		1				1
Pollakiuria		1				1
Presyncope		1				1
Protein urine present		1		1		
Pruritus		1		1		
Pulse abnormal		2		1		1
Pyrexia	7	10	5	6	2	4
Rash		1				1
Red blood cells urine positive		1		1		
Respiratory failure	1	1			1	1
Rheumatic disorder		1		1		
Skin exfoliation	1	1			1	1
Sluggishness	1	1			1	1
Somnolence	3	6	1	2	2	4
Speech disorder	1	1			1	1
Spinal pain		1				1
Stress	1	1	1	1		
Swelling		1		1		
Syncope	1	6			1	6
Tachycardia	2	2	1	1	1	1
Thirst	1	2			1	2
Thrombophlebitis superficial		1		1		
Thrombosis		1				1
Tremor	1	1			1	1
Type 2 diabetes mellitus		1				1
Urine ketone body present		1		1		
Urticaria	1	2	1	1		1
Vaccination failure		3				3
Vaccination site joint movement impairment		1				1
Vaccination site pain	2	4	2	2		2
Vertigo	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vestibular disorder	1	1			1	1
Vision blurred		1				1
Visual acuity reduced		1				1
Visual impairment	2	3		1	2	2
Vomiting	1	1			1	1
Walking disability	1	1	1	1		
White blood cells urine positive		1		1		
Wrong product administered		2		2		
	114	274	51	106	63	168

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	1			1	1
Angioedema		1				1
Arthralgia	1	1			1	1
Asthenia	1	1	1	1		
Blood pressure increased	1	1			1	1
Cardio-respiratory arrest	1	1			1	1
Cerebrovascular accident	1	2			1	2
Chills	1	2			1	2
Confusional state	1	1	1	1		
COVID-19		3				3
Death	1	1			1	1
Dehydration	1	1			1	1
Diarrhoea	1	1			1	1
Disease recurrence		1				1
Dizziness	2	2			2	2
Drug ineffective		1				1
Dyspnoea	1	1			1	1
Fatigue	1	3	1	1		2
Feeling abnormal	1	1			1	1
Hypersomnia	1	1	1	1		
Hypertension	2	4	1	1	1	3
Insomnia	2	2	1	1	1	1
Lymphadenopathy	1	1			1	1
Malaise	2	2			2	2
Myalgia	3	4	2	2	1	2
Nausea	1	1			1	1
Neuronal neuropathy		1				1
Ocular vascular disorder	1	1			1	1
Paraesthesia	1	1			1	1
Paraplegia	1	1			1	1
Pyrexia	1	2			1	2
Seizure		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Somnolence		1				1
Swelling	1	1			1	1
Swelling face	1	1			1	1
Syncope	1	2			1	2
Thirst	1	1			1	1
Thrombosis	1	1			1	1
Tremor	1	1			1	1
Vaccination site swelling	1	1	1	1		
Ventricular arrhythmia	1	1			1	1
Visual impairment	1	1			1	1
Vomiting	1	1			1	1
	42	60	9	9	33	51

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion spontaneous		1				1
Accidental exposure to product	1	1	1	1		
Ageusia		2		1		1
Agitation	1	1	1	1		
Anaphylactic shock		1				1
Angioedema		1				1
Angle closure glaucoma		1				1
Anosmia	1	3	1	2		1
Anxiety		3		3		
Arthralgia	1	7	1	7		
Asthenia	4	15	4	15		
Asthma		1				1
Asymptomatic COVID-19		2				2
Back pain	1	2	1	2		
Blood pressure abnormal		1		1		
Blood pressure decreased		1				1
Blood pressure increased	1	2			1	2
Body temperature abnormal		1		1		
Body temperature increased	1	2	1	2		
Bradycardia	15	15			15	15
Breast inflammation	1	1	1	1		
Breast pain	1	1	1	1		
Bronchospasm		2		1		1
Burning sensation	1	2	1	1		1
Chest discomfort		3		3		
Chest pain		1				1
Chills	18	37	16	34	2	3
Circumstance or information capable of leading to medication error		3		3		
Condition aggravated		1				1
Coronavirus infection		1				1
Cough		3		2		1

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	7	161	1	7	6	154
Crying		1		1		
Death	1	7			1	7
Decreased appetite	1	2	1	2		
Dermatitis allergic		1		1		
Diarrhoea	1	2	1	2		
Disorientation	1	1	1	1		
Disturbance in attention	1	2	1	2		
Dizziness	3	15	2	14	1	1
Drug ineffective	7	82			7	82
Dry mouth	1	1			1	1
Dry throat	1	1			1	1
Dyspnoea		2		1		1
Dyspnoea exertional		1				1
Dysstasia	1	1			1	1
Emotional disorder	1	1	1	1		
Emotional distress		1		1		
Epiglottic oedema		1				1
Erythema	1	10	1	9		1
Erythema nodosum		1		1		
Exposure during pregnancy	1	2	1	2		
Exposure via breast milk		1		1		
Eyelid oedema		1		1		
Eyelid ptosis		1		1		
Facial asymmetry	1	1	1	1		
Facial paralysis		2				2
Facial paresis	1	3	1	3		
Fatigue	8	27	8	27		
Fear		1		1		
Feeling abnormal		4		3		1
Feeling cold		1		1		
Feeling hot	1	2	1	2		

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Flushing		1		1		
General physical condition abnormal		1		1		
General physical health deterioration	1	1	1	1		
Headache	25	53	24	52	1	1
Heart rate increased		2		1		1
Hemiparaesthesia		1				1
Herpes virus test		1		1		
Hyperaesthesia	1	1	1	1		
Hyperhidrosis	16	20	16	19		1
Hyperpyrexia	5	5			5	5
Hypersensitivity		1		1		
Hypertension	1	5	1	3		2
Hypoacusis	1	1			1	1
Hypoaesthesia	1	2	1	2		
Hypotension	15	15	15	15		
Illness	1	2	1	1		1
Inappropriate schedule of product administration	3	4	3	4		
Incoherent	1	1	1	1		
Incorrect route of product administration	15	16		1	15	15
Infarction		1				1
Inflammation		1		1		
Influenza like illness		5		5		
Injected limb mobility decreased		2		2		
Insomnia	1	1	1	1		
Intercepted medication error		1		1		
Intermenstrual bleeding	1	1	1	1		
Laboratory test abnormal		1		1		
Lethargy	1	1	1	1		
Limb injury		1				1
Lip oedema		1		1		
Lip swelling		2		1		1
Liquid product physical issue	1	1	1	1		

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Listeria test positive		1		1		
Loss of consciousness		1				1
Loss of personal independence in daily activities		1		1		
Lymphadenopathy	10	21	10	21		
Malaise	2	6	2	6		
Maternal exposure during pregnancy		1		1		
Medication error		3		3		
Menstrual disorder		1		1		
Menstruation irregular	3	3	3	3		
Muscle contracture		1		1		
Muscle spasms		1				1
Muscle swelling		1		1		
Muscular weakness		4		4		
Myalgia	18	41	17	40	1	1
Mydriasis	15	15	10	10	5	5
Nasal congestion	1	1	1	1		
Nasal discomfort		1		1		
Nasal oedema		1				1
Nausea	2	7	2	7		
Neuralgia		1				1
Neuropathy peripheral		1				1
No adverse event		1		1		
Ocular discomfort		1		1		
Odynophagia		1		1		
Oedema		2		1		1
Oedema peripheral		1				1
Off label use	5	8	5	8		
Oropharyngeal discomfort		1				1
Oxygen saturation abnormal		1				1
Oxygen saturation decreased		1		1		
Pain	5	11	5	11		
Pain in extremity	3	26	3	26		

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pallor	15	15	15	15		
Panic attack		1		1		
Paraesthesia	1	9		5	1	4
Paraesthesia oral		2		2		
Poor quality product administered	1	1	1	1		
Presyncope		1		1		
Product preparation error	1	13	1	13		
Product preparation issue		9		9		
Product quality issue		1		1		
Product use issue	2	4	2	4		
Pruritus		2		2		
Pyrexia	24	56	23	55	1	1
Rash		2		2		
Rash pruritic		2		2		
Rhinorrhoea		2		2		
SARS-CoV-2 ant body test negative		5		5		
SARS-CoV-2 ant body test positive	1	6	1	6		
SARS-CoV-2 test positive		9		3		6
Skin discolouration		2		2		
Skin irritation	1	1	1	1		
Sleep talking	1	1	1	1		
Somnolence	4	8	4	8		
Suspected COVID-19	2	5	1	2	1	3
Syncope	16	20			16	20
Systolic hypertension		1				1
Tachycardia		4		3		1
Toxocariasis		1				1
Toxoplasma serology positive		1		1		
Transaminases increased		1		1		
Tremor		1		1		
Underdose		3		3		
Urticaria	1	5	1	4		1

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria papular		1		1		
Vaccination failure		8				8
Vaccination site discolouration		1		1		
Vaccination site discomfort	1	4	1	4		
Vaccination site erythema	2	17	2	16		1
Vaccination site granuloma		1		1		
Vaccination site induration	2	2	2	2		
Vaccination site inflammation		1		1		
Vaccination site lymphadenopathy	1	3	1	3		
Vaccination site macule		1		1		
Vaccination site movement impairment		2		2		
Vaccination site nodule		1		1		
Vaccination site oedema		1		1		
Vaccination site pain	24	62	24	61		1
Vaccination site papule		1		1		
Vaccination site pruritus		2		2		
Vaccination site reaction		1		1		
Vaccination site swelling	2	3	2	3		
Vaccination site warmth		1		1		
Vertigo		2		2		
Vomiting	1	1	1	1		
Weight decreased		1				1
Wrong technique in product usage process	3	17	3	17		
	346	1,105	263	720	83	385

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* AE=Adverse Event

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Country Where Event Occurred

SAUDI ARABIA

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Death	1	1			1	1
Exposure via breast milk	2	2	2	2		
Poor feeding infant	2	2	2	2		
Product administered to patient of inappropriate age	1	1	1	1		
Retching	1	1	1	1		
	7	7	6	6	1	1

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1				1
Epistaxis	1	1	1	1		
Fatigue		1				1
Menstruation irregular		1		1		
Seizure		1				1
Vomiting		1				1
	1	6	1	2		4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Anaphylactic shock		1				1
Arthralgia	1	3	1	3		
Blood pressure decreased	1	1	1	1		
Cerebrovascular accident	1	1			1	1
Chills		2		2		
COVID-19		2		2		
Decreased appetite	1	1	1	1		
Disturbance in attention	1	1	1	1		
Dizziness	2	4	2	3		1
Fatigue	1	4	1	4		
Headache	3	7	3	7		
Heavy menstrual bleeding	1	1	1	1		
Hyperhidrosis		3		3		
Hypertension	1	1	1	1		
Hypotension		1				1
Lymphadenopathy	1	2	1	2		
Lymphoma		1				1
Malaise		1		1		
Mastication disorder		1		1		
Menstruation irregular	1	1	1	1		
Mouth ulceration		1		1		
Myalgia		4		4		
Nausea		1		1		
Oropharyngeal pain		1		1		
Pain in extremity	1	1	1	1		
Pain in jaw		1		1		
Pain of skin		1		1		
Peripheral coldness		1		1		
Pollakiuria		1		1		
Pyrexia		5		5		
Respiration abnormal	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Seizure		1				1
Stomatitis	1	1			1	1
Syncope		2				2
Tremor		1		1		
Vaccination site erythema		1		1		
Vaccination site pain	1	4	1	4		
Vaccination site pruritus		1		1		
Vaccination site swelling		1		1		
Vaginal infection	1	2	1	2		
Vomiting		1				1
Weight decreased	1	1	1	1		
	21	74	19	64	2	10

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		1		1		
Asthenia		1		1		
Cerebral haemorrhage	1	1			1	1
COVID-19	1	2	1	2		
C-reactive protein increased		1		1		
Fatigue		1		1		
Headache		1		1		
Herpes zoster		1		1		
Infection		1		1		
Lymphadenopathy		1		1		
Myalgia		1		1		
Nasopharyngitis		1		1		
Pain		1		1		
Pain in extremity		1		1		
Peripheral coldness		1		1		
Red blood cell sedimentation rate increased		1		1		
Rhinorrhoea		1		1		
Sleep disorder		1		1		
Vaccination site pain		2		2		
	2	21	1	20	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acquired haemophilia		1				1
Cardiac arrest		1				1
Carotid artery stenosis		1				1
Gait inability		1				1
Heart rate decreased		1				1
Hyperhidrosis		1				1
Movement disorder		1		1		
Musculoskeletal stiffness		1		1		
Pyrexia		1				1
Sitting disability		1				1
Syncope		1				1
Vomiting		1				1
		12		2		10

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fatigue		1		1
Feeling hot		1		1
Gait disturbance		1		1
Hot flush		1		1
Night sweats		1		1
Somnolence		1		1
Temperature intolerance		1		1
		7		7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Abortion	1	1			1	1
Accidental overdose		1		1		
Asthenia		1		1		
Axillary pain		1		1		
COVID-19	2	2			2	2
Death	1	1			1	1
Drug ineffective	2	2			2	2
Dysstasia		1				1
Extra dose administered	1	1	1	1		
Fatigue		1		1		
Gait disturbance		1				1
Headache		1		1		
Hypoaesthesia	1	1	1	1		
Inappropriate schedule of product administration		1		1		
Lymphadenopathy		1		1		
Malaise		1		1		
Mobility decreased		4		3		1
Myalgia		2		1		1
Off label use	2	2	2	2		
Overdose	1	1	1	1		
Pain		5		4		1
Pain in extremity		3		1		2
Product preparation issue		1		1		
Product use issue	2	2	2	2		
Pulmonary embolism		1				1
Pyrexia		1		1		
Sciatica		2		2		
Vaccination site pain		1		1		
Vaginal haemorrhage	1	1			1	1
	15	45	7	29	8	16

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

SERBIA

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposure via breast milk		1		1
		1		1

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 * AE=Adverse Event
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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Anosmia	1	1	1	1		
Arthralgia	2	2	2	2		
Body temperature increased	1	1	1	1		
COVID-19	1	3		2	1	1
C-reactive protein increased	1	1	1	1		
Drug ineffective	1	1			1	1
Fatigue	1	1	1	1		
Guillain-Barre syndrome	1	1			1	1
Headache	2	2	2	2		
Herpes zoster	1	1	1	1		
Leukopenia	1	1			1	1
Loss of consciousness	1	1			1	1
Lymphadenopathy	1	1	1	1		
Myalgia	3	3	3	3		
Nasal congestion	1	1	1	1		
Pain in extremity	1	1	1	1		
Pyrexia	2	2	2	2		
Thirst	1	1	1	1		
Vaccination complication	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site pain	2	2	2	2		
	28	30	23	25	5	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		2		1		1
Anaphylactoid reaction		1				1
Anosmia		1		1		
Arthralgia	3	10	2	8	1	2
Asphyxia		2				2
Asthenia	1	4	1	4		
Axillary pain		1		1		
Back pain	1	2	1	1		1
Blepharospasm		1				1
Blood bilirubin increased	1	1	1	1		
Blood calcium decreased	1	1	1	1		
Blood creatinine increased	1	1	1	1		
Blood iron decreased	1	1	1	1		
Body temperature increased	3	11	2	9	1	2
Bone pain		1		1		
Bronchospasm		2		1		1
Chest pain		2				2
Chills	3	7	2	5	1	2
Circulatory collapse	2	2			2	2
Confusional state		1		1		
Conjunctivitis		1		1		
Cough	1	3			1	3
COVID-19		1		1		
COVID-19 pneumonia		1				1
Decreased appetite		1		1		
Diarrhoea	1	2	1	2		
Dizziness		2		2		
Dysgeusia		1				1
Dyspnoea		2				2
Erythema		5		4		1
Eyelid ptosis		1				1
Eye pain		1		1		

* I=Interval, C=Cumulative

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial paresis		1				1
Fatigue	4	9	4	9		
Fear		1				1
Feeling cold	1	1	1	1		
Feeling hot		1		1		
Gamma-glutamyltransferase increased	1	1	1	1		
Headache	8	20	7	17	1	3
Head discomfort	1	1	1	1		
Herpes zoster		1		1		
Hyperhidrosis		3		2		1
Hypertension		3				3
Hypoaesthesia		1		1		
Hypoaesthesia oral		2		1		1
Inappropriate schedule of product administration		1		1		
Inflammatory marker increased		1		1		
Influenza like illness		2		2		
Insomnia		2		1		1
Joint stiffness		1				1
Laryngeal discomfort	1	1			1	1
Localised oedema		1		1		
Loss of consciousness		1				1
Lung disorder	1	1	1	1		
Lymphadenitis	1	1	1	1		
Lymphadenopathy	2	3	2	3		
Lymphangitis	1	1			1	1
Malaise	2	12	2	11		1
Monocyte count increased		1		1		
Movement disorder		1		1		
Muscular weakness		2		2		
Myalgia	5	17	4	15	1	2
Myocardial infarction		1				1
Nasal congestion	1	3		1	1	2

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	4	13	3	11	1	2
Neck pain	1	2			1	2
Nervousness		1				1
Oedema mucosal		1				1
Oedema peripheral		1		1		
Off label use		1		1		
Overdose		1				1
Pain		1		1		
Pain in extremity	1	8	1	8		
Pallor	1	2		1	1	1
Paraesthesia	1	3		2	1	1
Paraesthesia mucosal	1	1			1	1
Paraesthesia oral	2	2			2	2
Peripheral swelling		1				1
Pruritus	1	1	1	1		
Pulmonary pain		2		1		1
Pyrexia	10	31	10	29		2
Rash	1	2	1	2		
Rash macular	1	2	1	1		1
Rash pruritic	1	1	1	1		
Rhinorrhoea		1				1
SARS-CoV-2 test positive		2		1		1
Seizure	1	1			1	1
Skin reaction		1				1
Sleep disorder	1	2	1	2		
Sneezing		1				1
Somnolence		2		1		1
Swollen tongue		1		1		
Syncope		2				2
Tachycardia	1	3			1	3
Thrombophlebitis		1				1
Thrombosis	1	2			1	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tinnitus		1		1		
Tremor		1		1		
Tumour pseudoprogression	1	1			1	1
Urticaria	2	2	1	1	1	1
Vaccination complication	1	5		4	1	1
Vaccination site erythema		1		1		
Vaccination site induration		1		1		
Vaccination site lymphadenopathy	1	1	1	1		
Vaccination site oedema		1		1		
Vaccination site pain	2	11	2	11		
Vaccination site swelling		1		1		
Vertigo		1		1		
Vomiting	1	3	1	3		
Wrong product administered		1		1		
	85	300	61	219	24	81

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abscess		1				1
Ageusia		1		1		
Anosmia		1		1		
Arthralgia	1	1	1	1		
Asthenia		4		3		1
Axillary pain		1				1
Blood pressure increased		1				1
Body temperature increased	2	3	2	3		
Bone pain		1		1		
Burning sensation		1		1		
Chest discomfort		1		1		
Chills	1	4	1	3		1
Cough	3	3	3	3		
COVID-19	1	4	1	2		2
Diarrhoea	1	1	1	1		
Disease recurrence		1		1		
Dizziness	1	3	1	3		
Drug ineffective		2				2
Dry mouth		1		1		
Erythema		2		2		
Eyelid oedema		1		1		
Fatigue	5	9	5	8		1
Feeling abnormal		1		1		
Feeling cold		1		1		
Feeling hot		1		1		
Guillain-Barre syndrome	1	1			1	1
Haematoma		1		1		
Headache	2	7	2	6		1
Heart rate increased		1		1		
Hyperhidrosis		1		1		
Hypertension		4		2		2
Lip disorder		1		1		

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenitis		1				1
Lymphadenopathy		2		1		1
Malaise		6		5		1
Muscular weakness	1	1			1	1
Myalgia	2	3	2	3		
Myocarditis		1				1
Myositis		1				1
Nasopharyngitis		1		1		
Nausea	2	6	2	5		1
Oedema peripheral		1		1		
Oropharyngeal pain		1		1		
Pain		1				1
Pain in extremity	3	6	3	6		
Pain in jaw		1		1		
Pallor		1		1		
Palpitations		1		1		
Phlebitis		1				1
Pruritus		1		1		
Pyrexia	5	10	5	9		1
Rash	1	2	1	2		
Somnolence	1	1	1	1		
Superficial vein prominence		1		1		
Swelling		2		1		1
Swelling of eyelid	1	1	1	1		
Syncope	1	3			1	3
Tremor		1		1		
Urticaria		1		1		
Vaccination complication		1		1		
Vaccination site pain	1	2	1	2		
Vision blurred		2		1		1
	36	129	33	100	3	29

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Anxiety		1		1		
Arthralgia	2	3	2	3		
Blood lactate dehydrogenase increased		1				1
Chest pain	1	1	1	1		
Chills		1				1
COVID-19		1				1
C-reactive protein increased		2		1		1
Death		1				1
Dizziness	1	1	1	1		
Dyspnoea		1				1
Fall		1		1		
Fatigue	2	3	2	3		
Fear of death		1		1		
Fibrin D dimer increased		1		1		
Headache	3	4	3	4		
Huntington's disease		1				1
Hypertension		1				1
Hypopnoea		1				1
Lacrimation increased		1		1		
Lip pruritus		1		1		
Lip swelling		1		1		
Lymphadenopathy	1	1	1	1		
Malaise	1	3	1	2		1
Oedema mouth		1		1		
Oropharyngeal pain	1	1	1	1		
Oxygen saturation decreased		1				1
Pneumonia		1				1
Pyrexia	3	7	3	5		2
Red blood cell count increased		1		1		
Red blood cell sedimentation rate increased		1				1
Urticaria	1	1	1	1		

* I=Interval, C=Cumulative

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* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site erythema	1	2	1	2		
Vaccination site pain	1	1	1	1		
Vaccination site pruritus		1		1		
Wheezing		1				1
	18	53	18	37		16

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Balance disorder		1				1
Deafness		1				1
Deafness unilateral		1				1
Face oedema		1				1
Facial paralysis		1				1
Fall		1				1
Fatigue	1	1	1	1		
Haematemesis		1				1
Headache		1		1		
Ischaemic stroke		1				1
Nausea		1				1
Pain		1		1		
Pain in extremity		1		1		
Pancreatitis acute		1				1
Pyrexia	1	3	1	2		1
Tongue oedema		1				1
Urticaria		1		1		
Vaccination site erythema		1		1		
Vaccination site haematoma		1				1
Vaccination site oedema		1		1		
Vaccination site reaction		1		1		
Vomiting		1				1
	2	24	2	10		14

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		1		1		
Anosmia		1		1		
Anxiety		1		1		
Arthralgia		2		2		
Asthenia		2		2		
Back pain	1	1	1	1		
Blood pressure increased		1		1		
Body temperature increased	3	8	3	8		
Chest discomfort		1		1		
Chest pain		1		1		
Chills		3		3		
Confusional state	1	1	1	1		
Cough		1		1		
COVID-19	4	8	3	6	1	2
Decreased appetite	1	1	1	1		
Diarrhoea		1		1		
Dizziness		2		1		1
Drug ineffective	1	2			1	2
Dyspnoea		1		1		
Erythema	1	2	1	2		
Exposure during pregnancy		1		1		
Fatigue	1	3	1	3		
Headache	2	6	2	6		
Heavy menstrual bleeding	2	2	2	2		
Hyperaesthesia		1		1		
Hypersensitivity	1	3	1	2		1
Hypoaesthesia		1		1		
Inappropriate schedule of product administration	1	1	1	1		
Infection	1	1	1	1		
Intraocular pressure increased		1				1
Irritability		1		1		
Joint stiffness		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise	1	4	1	4		
Maternal exposure during pregnancy		1		1		
Musculoskeletal stiffness		1		1		
Myalgia	2	4	2	4		
Nausea		4		4		
No adverse event		1		1		
Oedema peripheral	1	1	1	1		
Optic neuritis		1				1
Oropharyngeal pain		1		1		
Pain in extremity	1	4	1	4		
Palpitations		1		1		
Paraesthesia		1		1		
Paraesthesia oral		1		1		
Photophobia		1		1		
Product supply issue	1	1	1	1		
Pyrexia	2	7	2	7		
Rash		1				1
Rash macular		1				1
SARS-CoV-2 ant body test negative		1		1		
SARS-CoV-2 test positive		1				1
Skin burning sensation		2		1		1
Somnolence		1		1		
Swelling of eyelid		1		1		
Tachycardia		1		1		
Urticaria		1		1		
Vaccination failure		1				1
Vaccination site erythema		1		1		
Vaccination site pain	4	10	4	10		
Vomiting		1		1		
	32	120	30	107	2	13

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

SINGAPORE

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		2				2
Anaphylactic reaction		6				6
Anaphylactic shock		2				2
Angioedema		2				2
Arthralgia		1				1
Asthenia		1		1		
Blood pressure decreased		1				1
Blood pressure increased		3				3
Cellulitis		1				1
Chest discomfort		5				5
Chills		2				2
Complement factor C3 increased		1				1
Cough		1				1
Dermatitis bullous		1				1
Diarrhoea		1				1
Dizziness		6		1		5
Dry eye		1				1
Dyskinesia		1				1
Dysphonia		3				3
Dyspnoea		7				7
Dysstasia		1				1
Enlarged uvula		1				1
Erythema		1				1
Eye disorder		1				1
Eye movement disorder		1				1
Fall		1				1
Flushing		2				2
Gait disturbance		1				1
Headache		2		2		
Hepatitis		1				1
Hunger		1		1		
Hyperhidrosis		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypersensitivity		1				1
Hypertension		2				2
Hyperthyroidism		1				1
Hypoaesthesia		1				1
Hypotension		3				3
Lacrimation increased		1				1
Laryngeal oedema		1				1
Lip swelling		3				3
Muscular weakness		1				1
Musculoskeletal stiffness		1				1
Myalgia		2		2		
Nausea		4		2		2
Nerve injury		1				1
Odynophagia		1				1
Oxygen saturation decreased		1				1
Pain		1				1
Pain in extremity		2		1		1
Palatal oedema		1				1
Palpitations		3				3
Periorbital swelling		1				1
Peripheral coldness		1		1		
Pruritus		4				4
Pupillary light reflex tests abnormal		1				1
Pyrexia		5		2		3
Radiculopathy		1				1
Rash		6		3		3
Rash macular		2				2
Respiratory tract infection		1				1
Seizure		1				1
Sensation of foreign body		1				1
Somnolence		1				1
Syncope		3				3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia		1				1
Throat irritation		1				1
Throat tightness		3				3
Tic		1				1
Tonic clonic movements		1				1
Tonic convulsion		1				1
Transaminases increased		1				1
Troponin increased		1				1
Unresponsive to stimuli		1				1
Urticaria		4		1		3
Vaccination site erythema		1		1		
Vaccination site hypoaesthesia		1				1
Vaccination site pain		2				2
Vaccination site paraesthesia		1				1
Vaccination site pruritus		1		1		
Vaccination site urticaria		1				1
Vestibular neuronitis		1				1
Visual impairment		1				1
Vomiting		3		1		2
		148		21		127

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		2				2
Abdominal tenderness		1				1
Acute kidney injury		1				1
Alanine aminotransferase increased		1				1
Allergy to vaccine		1				1
Anaphylactic reaction		5				5
Anaphylactic shock		2				2
Angioedema		2				2
Arthralgia		1				1
Aspartate aminotransferase increased		1				1
Asthma		2				2
Bell's palsy		1				1
Bicytopenia		1				1
Blepharospasm		1		1		
Blood alkaline phosphatase increased		1				1
Blood bilirubin increased		1				1
Blood pressure increased		2		1		1
Blood pressure systolic increased		1				1
Body temperature increased		1				1
Chest discomfort		6		2		4
Chest pain		2				2
Chills		2		1		1
Cough		2				2
Diarrhoea		2		1		1
Disease progression		1		1		
Disease recurrence		1				1
Dizziness		6		3		3
Drug reaction with eosinophilia and systemic symptoms		1				1
Dysgeusia	1	1	1	1		
Dysphagia		1				1
Dysphonia		4		1		3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea		10		1		9
Dyspnoea exertional		1		1		
Ectopic pregnancy	1	1			1	1
Enlarged uvula		2				2
Eosinophilia		1				1
Erythema multiforme		1				1
Extrasystoles		1				1
Eye colour change		1		1		
Eye pruritus		2		1		1
Fatigue	1	4	1	3		1
Flushing		1				1
Gastrooesophageal reflux disease		1				1
Haematuria		1				1
Hand dermatitis		1		1		
Headache		2		2		
Head discomfort		1		1		
Heart rate increased		3				3
Hyperhidrosis		1				1
Hypertension		1				1
Hypoaesthesia		1				1
Hypotension		1				1
Insomnia	1	1	1	1		
Lethargy		1		1		
Limb discomfort	1	1	1	1		
Lymphadenopathy		1		1		
Malaise		2				2
Muscular weakness		1				1
Myalgia		1				1
Nausea		5		2		3
Oedema peripheral		1		1		
Oropharyngeal pain		1				1
Pain in extremity	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Palatal oedema		1				1
Palpitations		5				5
Parosmia		2		2		
Periorbital swelling		3		1		2
Peripheral swelling		1				1
Petit mal epilepsy		1				1
Pharyngeal mass		1		1		
Pharyngeal swelling		1				1
Postural orthostatic tachycardia syndrome		1				1
Proteinuria		1				1
Pruritus		1				1
Pyrexia	1	5	1	2		3
Rash		6		2		4
Rash erythematous		1		1		
Rash macular		1				1
Rash maculo-papular		2		1		1
Rash pruritic		1				1
Renal impairment		1				1
Secretion discharge		1		1		
Seizure		1				1
Sensation of foreign body		2				2
Sensory disturbance		1				1
Sinus tachycardia		1				1
Sleep disorder		1		1		
Somnolence		1		1		
Swelling face		1				1
Swelling of eyelid		1				1
Swollen tongue		1				1
Syncope		1				1
Tachycardia		2				2
Throat irritation		3		2		1
Throat tightness		5		1		4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Transaminases increased		1				1
Upper respiratory tract congestion		1		1		
Urticaria		8				8
Vaccination complication		1				1
Vaccination site erythema	1	2	1	2		
Vaccination site mass		1		1		
Vaccination site pain	1	1	1	1		
Vaccination site pruritus	1	1	1	1		
Vaccination site rash	1	1	1	1		
Vaccination site urticaria	1	1	1	1		
Vertigo		1		1		
Vision blurred		1		1		
Visual impairment		1		1		
Vomiting		3		1		2
Wheezing		2		1		1
	12	194	11	60	1	134

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Acute psychosis		1				1
Anaphylactic reaction		4				4
Angioedema		3				3
Arthritis		1				1
Asthenia		1				1
Bell's palsy		1				1
Blood pressure systolic increased		2				2
Chest discomfort		1				1
Chest pain		1				1
Chills		1				1
Confusional state		1				1
Deafness neurosensory		1				1
Decreased appetite		1				1
Dehydration		1				1
Diarrhoea		2				2
Diplopia	1	1			1	1
Dizziness		6				6
Drooling		1				1
Dyskinesia		2				2
Dysphagia		1				1
Dysphonia		2				2
Dyspnoea		2				2
Enlarged uvula		1				1
Erythema		1				1
Eye movement disorder		2				2
Eye swelling		1				1
Facial asymmetry		1				1
Feeding disorder		1				1
Generalised tonic-clonic seizure		1				1
Gianotti-Crosti syndrome		1		1		
Haematocrit increased		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemoglobin increased		1				1
Headache		2				2
Hypersensitivity		2		1		1
Hypoaesthesia		3				3
Hypotension		1				1
Influenza like illness		1		1		
IVth nerve paralysis	1	1			1	1
Mental status changes		1				1
Neck pain		1				1
Optic neuritis		1				1
Oropharyngeal pain		1				1
Palpitations		1				1
Periorbital swelling		2				2
Pharyngeal swelling		1				1
Pituitary tumour	1	1			1	1
Rash		2		1		1
Rash macular		1				1
Rash papular		1				1
Respiratory rate decreased		1				1
Respiratory rate increased		1				1
Rheumatoid arthritis		1				1
Rhinorrhoea		1				1
Seizure		2				2
Sensation of foreign body		2				2
Status epilepticus		1				1
Tachycardia		1				1
Tenosynovitis		1				1
Throat tightness		1				1
Tongue biting		1				1
Toxic neuropathy		1				1
Unresponsive to stimuli		1				1
Vision blurred		2				2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term

Vomiting

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			2
	4	3	87

3

91

4

3

87

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* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne		1		1		
Anaphylactic reaction		2				2
Antineutrophil cytoplasmic antibody positive	1	1	1	1		
Breath sounds abnormal		1				1
Chest discomfort		1		1		
Chills		1				1
Confusional state		1				1
Cough		1				1
Cranial nerve disorder	1	1			1	1
Diplopia		1				1
Dizziness		2		1		1
Dry mouth		1		1		
Dyskinesia		1				1
Dyspnoea		2				2
Eye movement disorder		1				1
Facial paralysis		1				1
Fall		1				1
Fatigue		2		2		
Femoral neck fracture		1				1
Fibroma		1		1		
Generalised tonic-clonic seizure		1				1
Headache		1		1		
Hypertension		2				2
IIIrd nerve paralysis	1	1			1	1
Injection site swelling		1		1		
Migraine		1				1
Nausea		2		1		1
Oxygen saturation decreased		2				2
Pain in extremity		2		2		
Palpitations		1		1		
Pneumonia aspiration		1				1
Poor quality product administered		2		2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash		2				2
Skin abrasion		1				1
Skin lesion		1		1		
Somnolence		1				1
Unresponsive to stimuli		1				1
Vaccination site rash		1				1
Vaccination site reaction		1		1		
Vlth nerve paralysis		1				1
Vomiting		1				1
Wheezing		2				2
	3	53	1	18	2	35

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat		1				1
Deep vein thrombosis		1				1
Dysacusis		1		1		
Dyspnoea		1				1
Dyspnoea exertional		1				1
Herpes zoster	1	1	1	1		
Myocardial infarction		1				1
Pallor		1				1
Pulmonary embolism		1				1
Vaccination site pain		1		1		
	1	10	1	3		7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute generalised exanthematous pustulosis		1				1
Anaphylactic shock		1				1
Blood pressure increased		1		1		
Chills		1		1		
COVID-19	1	1			1	1
Dizziness		2		2		
Drug ineffective	1	1			1	1
Dysgeusia		1		1		
Eye swelling		1		1		
Fatigue	4	4	4	4		
Feeling abnormal	1	1	1	1		
Headache		1		1		
Hypertension	1	1			1	1
Hypoaesthesia		1		1		
Lip swelling		1		1		
Maternal exposure during pregnancy		1		1		
Myalgia	1	2	1	2		
Oedema peripheral	1	1	1	1		
Pain	1	2	1	2		
Pain in extremity	1	1	1	1		
Peripheral swelling	1	1	1	1		
Poor quality product administered		1		1		
Product preparation issue	1	1	1	1		
Product quality issue	1	1	1	1		
Pyrexia	2	4	2	4		
Rash		1		1		
Rash macular	1	1	1	1		
Syncope		1				1
Tachycardia	1	1			1	1
Taste disorder		1		1		
Tremor		1		1		
Urticaria	1	2	1	2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site bruising	1	1	1	1		
Vaccination site pain	1	2	1	2		
Vaccination site pruritus		1		1		
Vaccination site rash		1		1		
Vaccination site swelling	1	1	1	1		
Vision blurred		1		1		
Wrong technique in product usage process	1	1	1	1		
	24	50	20	43	4	7

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

SLOVAKIA

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposure via breast milk		1		1
		1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal dreams		1		1		
Altered state of consciousness		1				1
Angular cheilitis	1	1	1	1		
Arthralgia	1	6	1	5		1
Asthenia	4	12	4	11		1
Asymptomatic COVID-19	1	1			1	1
Axillary pain		1		1		
Back pain		1		1		
Blood pressure decreased	1	3	1	1		2
Blood pressure increased		3		1		2
Body temperature fluctuation		1		1		
Body temperature increased	2	10	2	9		1
Bone pain		1		1		
Brain contusion		1				1
Chest discomfort		1		1		
Chest pain		1		1		
Chills	3	17	3	15		2
Cold sweat		1		1		
Cough		2		2		
COVID-19		1		1		
Decreased appetite	1	2	1	2		
Dehydration		1		1		
Diarrhoea	1	2	1	2		
Dizziness	1	8	1	8		
Dry throat		1		1		
Dyskinesia		1		1		
Erythema	1	2	1	1		1
Eye irritation		1		1		
Eyelid rash		1		1		
Eye pain		1		1		
Fall		2		1		1
Fatigue	6	18	6	18		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling hot	1	2	1	2		
Flushing		1		1		
Headache	2	11	2	10		1
Head discomfort		1		1		
Hot flush	1	2	1	2		
Hyperhidrosis	1	6	1	5		1
Hypersensitivity		1		1		
Inflammation		1		1		
Insomnia	1	2	1	2		
Loss of consciousness		2				2
Loss of libido	1	1	1	1		
Lymphadenopathy	1	3	1	3		
Malaise		5		5		
Maternal exposure during pregnancy		1		1		
Migraine	1	2	1	2		
Myalgia	1	7	1	7		
Mydriasis		1		1		
Nausea	2	8	2	8		
Neck pain		1		1		
Oropharyngeal pain		2		2		
Pain		2		2		
Pain in extremity	3	15	3	15		
Pallor		2		1		1
Palpitations		1		1		
Paraesthesia	1	4	1	3		1
Peripheral coldness		1		1		
Photophobia		1		1		
Presyncope		1				1
Pruritus		1				1
Pyrexia	3	13	3	12		1
Rash papular		1		1		
Rash pustular		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rhinalgia		1		1		
Rhinitis		1		1		
Sudden hearing loss		1				1
Syncope		4				4
Tachycardia		3		2		1
Tension headache		2		2		
Throat tightness		1		1		
Tinnitus		2		2		
Tongue discolouration		1		1		
Tonic convulsion		1				1
Urticaria	1	1	1	1		
Vaccination failure	1	1			1	1
Vaccination site erythema		3		3		
Vaccination site hypersensitivity		1		1		
Vaccination site induration		2		2		
Vaccination site inflammation		1		1		
Vaccination site oedema		5		5		
Vaccination site pain	5	28	5	27		1
Vaccination site pruritus		1		1		
Vaccination site swelling		2		1		1
Vaccination site warmth		1		1		
Vertigo	1	6	1	6		
Vision blurred		1		1		
	50	279	48	246	2	33

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		1		1		
Abdominal pain upper		2		2		
Angioedema		1				1
Aphasia		1		1		
Arthralgia	1	17	1	17		
Asthenia	2	21	2	20		1
Atrial f brillation		1				1
Axillary pain		1		1		
Back pain		3		3		
Blood glucose increased		1		1		
Blood pressure decreased		1				1
Blood pressure increased	1	8	1	4		4
Body temperature increased	1	15	1	14		1
Brachial plexus injury		1				1
Bradycardia		1				1
Burning sensation		2		2		
Cardiac discomfort		1		1		
Cervicobrachial syndrome		1				1
Chest discomfort	1	3	1	3		
Chills	6	47	6	45		2
Conjunctivitis		2		1		1
Cough		2		2		
COVID-19	1	6		1	1	5
Cutaneous vasculitis		1		1		
Deafness		1				1
Decreased appetite		2		2		
Diarrhoea	1	2	1	2		
Diplopia		1		1		
Disorientation		1		1		
Dizziness	1	9	1	9		
Drug ineffective		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		1
	1		
	1		
	5		2
	4		
	1		
	1		
	1		2
	1		
	1		
	2		1
1	1		
2	22		
	1		
	4		
	1		
	1		
4	39		
	2		
	4		1
	2		1
	1		1
	3		1
	1		
1	2		
	1		
	1		1
	1		
4	11		
	1		1
	1		
	3		

Dry mouth

2

Dysaesthesia

1

Dysarthria

1

Dyspnoea

7

Erythema

4

Eye allergy

1

Eye irritation

1

Eye oedema

3

Eye pain

1

Eye pruritus

1

Face oedema

3

Facial paresis

1

1

Fatigue

2

22

Feeling abnormal

1

Feeling hot

4

Feeling of body temperature change

1

Gait disturbance

1

Headache

4

39

Heart rate increased

2

Hot flush

4

Hyperhidrosis

2

Hypersensitivity

1

Hypertension

3

Hypoaesthesia

1

Influenza like illness

1

2

Insomnia

1

Insulin resistance

1

Lymphadenitis

1

Lymphadenopathy

4

11

Lymphangitis

1

Lymph node pain

1

Malaise

3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Migraine	1	1	1	1		
Movement disorder		2		2		
Muscular weakness		1		1		
Musculoskeletal stiffness		1		1		
Myalgia	6	32	6	32		
Nasopharyngitis	1	1	1	1		
Nausea	2	18	2	16		2
Ocular hyperaemia		1		1		
Oedema		1		1		
Oedema peripheral		1		1		
Oral discomfort		1		1		
Pain		4		4		
Painful respiration	1	1	1	1		
Pain in extremity	5	21	5	21		
Pallor		1		1		
Palpitations		5		5		
Pancreatitis acute		1				1
Paraesthesia	1	13	1	10		3
Paraesthesia oral		3		2		1
Peripheral coldness		2		2		
Peripheral swelling		2		2		
Petechiae		1		1		
Presyncope	1	6	1	4		2
Product administered at inappropriate site		2		2		
Product administration error		1				1
Pruritus		1		1		
Pyrexia	3	28	3	28		
Rash		2		2		
Rectal haemorrhage	1	1			1	1
Restlessness		1				1
Retching		2		2		
SARS-CoV-2 test positive		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sinus tachycardia		2				2
Somnolence		1		1		
Sudden hearing loss		1				1
Syncope		3				3
Synovitis		1		1		
Tachycardia		6		5		1
Tachypnoea		1				1
Tendonitis		1		1		
Thirst		1		1		
Throat irritation		2		2		
Tinnitus		2		2		
Tissue infiltration		1		1		
Tryptase decreased		1		1		
Urticaria	1	1	1	1		
Vaccination failure	1	2			1	2
Vaccination site bruising	1	2	1	2		
Vaccination site erythema	2	5	2	5		
Vaccination site joint movement impairment		1		1		
Vaccination site oedema	1	2	1	2		
Vaccination site pain	10	36	10	36		
Vaccination site pruritus	1	2	1	2		
Vaccination site warmth	1	1	1	1		
Vertigo		6		6		
Viral infection		1				1
Vision blurred		1		1		
Vomiting	1	5	1	4		1
	68	533	65	475	3	58

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal pain		1				1
Arthralgia	1	10	1	10		
Asthenia		8		7		1
Asymptomatic COVID-19		1				1
Axillary pain		1		1		
Axillary vein thrombosis		1				1
Blood glucose increased		1		1		
Blood pressure decreased		1				1
Blood pressure increased		5				5
Body temperature increased	1	7	1	6		1
Burning sensation	1	1	1	1		
Chills	2	21	2	19		2
Condition aggravated		1		1		
Cough	1	2	1	2		
COVID-19		1				1
Decreased appetite		2		2		
Diarrhoea		3		3		
Dizziness		1				1
Drug ineffective		1				1
Dysphagia	1	2	1	2		
Enlarged uvula		1		1		
Extra dose administered		1		1		
Eye irritation	1	1	1	1		
Eyelid oedema	1	1	1	1		
Face oedema	1	1	1	1		
Facial paresis		1				1
Fatigue		9		9		
Headache	3	21	3	21		
Head discomfort		1		1		
Heart rate increased		1		1		
Hot flush		2		1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperaemia	1	1	1	1		
Hyperhidrosis		1		1		
Hypertension		1		1		
Influenza like illness	1	2	1	2		
Insomnia		1		1		
Lymphadenopathy	1	2	1	2		
Malaise		5		5		
Micturition urgency		1				1
Muscular weakness	1	2	1	1		1
Musculoskeletal discomfort		1		1		
Myalgia	2	11	2	11		
Nausea		4		4		
Neck pain		1		1		
Pain		1		1		
Pain in extremity	2	12	2	12		
Palpitations		1		1		
Paraesthesia	1	3	1	2		1
Pruritus		1		1		
Pyrexia	1	20	1	19		1
Rash		2		2		
Rash vesicular		1		1		
Rhinitis		1		1		
Somnolence		2		2		
Subclavian vein thrombosis		1				1
Syncope		1				1
Tachycardia		1				1
Thrombosis		1				1
Vaccination failure		1				1
Vaccination site movement impairment		1		1		
Vaccination site oedema	1	4	1	4		
Vaccination site pain	4	14	4	14		
Venous thrombosis limb		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vertigo		2		2		
Vision blurred	1	1	1	1		
Visual impairment		1				1
Vomiting		1		1		
	29	219	29	189		30

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* I=Interval, C=Cumulative
 * AE=Adverse Event
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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Acute myocardial infarction		1				1
Altered state of consciousness		1				1
Amnesia		1				1
Anaphylactic reaction		1				1
Aphasia		1				1
Asthenia	1	4			1	4
Balance disorder		1		1		
Blood pressure decreased		2		1		1
Blood pressure increased	1	4		1	1	3
Body temperature increased	1	2	1	1		1
Cerebral ischaemia		1				1
Chills		2		2		
Confusional state	1	1			1	1
Cough	1	1	1	1		
COVID-19		2				2
COVID-19 pneumonia	1	1			1	1
Cyanosis		1				1
Dehydration		1				1
Diarrhoea		1				1
Dizziness		3		1		2
Drug ineffective	1	2			1	2
Dyspnoea	1	2	1	2		
Eye irritation		1		1		
Fatigue	2	2	1	1	1	1
Feeling hot		1		1		
Headache		1		1		
Heart rate decreased		1		1		
Herpes zoster	1	1			1	1
Hyperhidrosis		1				1
Lacrimation increased		1		1		
Loss of consciousness		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise		1				1
Meningeal disorder	1	1			1	1
Nausea		2		1		1
Oxygen saturation decreased	1	1			1	1
Pain in extremity	1	1	1	1		
Pyrexia		2		1		1
Renal colic	1	1			1	1
Restlessness		1				1
Somnolence		1				1
Speech disorder		1				1
Subclavian vein stenosis		1				1
Syncope		3				3
Thrombosis		1				1
Tinnitus		2		2		
Tongue dry		1				1
Tremor		1				1
Vaccination site erythema		1		1		
Vaccination site induration		1		1		
Vaccination site oedema		1		1		
Vaccination site pain		7		7		
Vaccination site pruritus		1		1		
Venous thrombosis limb		1				1
Vertigo		1				1
Vision blurred		1		1		
Vomiting		1				1
Wheezing		1				1
	15	84	5	34	10	50

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		3		3		
Asphyxia		1				1
Blood pressure decreased		1				1
Blood pressure increased		2		2		
Body temperature decreased	1	1			1	1
Bone pain		1		1		
Cardiac failure		1				1
Cardiac failure chronic	1	1			1	1
Cardiac fibrillation		1				1
Chest discomfort		1				1
Chest pain		1		1		
Chills	1	1			1	1
Coronary artery disease	1	1			1	1
Diarrhoea		1				1
Dizziness		1				1
Dyspnoea	1	2			1	2
Eye pruritus		1		1		
Headache		1		1		
Heart rate increased		1		1		
Left ventricular hypertrophy	1	1			1	1
Malaise		1		1		
Musculoskeletal chest pain		1		1		
Myalgia		1		1		
Myocardial ischaemia		1				1
Pain in extremity		2		2		
Pneumonia	1	1			1	1
Prostatitis	1	1			1	1
Pruritus		1		1		
Pyelonephritis	1	1			1	1
Thirst		1		1		
Urinary tract infection	1	1			1	1
Urosepsis	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain		1		1		
Vomiting		1				1
	11	39		18	11	21

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Angioedema		1				1
Anosmia	1	1	1	1		
Arrhythmia	1	2			1	2
Arthralgia	2	2	2	2		
Asthenia	1	2	1	2		
Axillary pain		1		1		
Blood glucose increased	1	1	1	1		
Blood pressure decreased		1		1		
Body temperature increased	1	4	1	4		
Burning sensation		1		1		
Chest discomfort	1	2	1	2		
Chest pain	1	2	1	2		
Chills	1	6	1	6		
Cough		3		3		
COVID-19	2	6		1	2	5
Dermatitis allergic		1		1		
Diarrhoea		1		1		
Drug ineffective	2	6			2	6
Dry mouth		1		1		
Dyspnoea	1	1	1	1		
Epilepsy		1				1
Erysipelas		1				1
Erythema		1		1		
Fatigue	2	6	2	6		
Feeling hot		2		2		
Flatulence		1		1		
Headache	3	7	3	7		
Head discomfort		1		1		
Hyperhidrosis	1	1	1	1		
Hypertensive crisis		1				1
Limb discomfort		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lip oedema		1		1		
Lymphadenopathy	1	3	1	3		
Malaise	3	4	3	4		
Maternal exposure during pregnancy		2		2		
Myalgia		3		3		
Nasopharyngitis	1	1	1	1		
Nausea	3	7	3	7		
Ocular discomfort		1		1		
Off label use		2		2		
Pain		1		1		
Pain in extremity	4	13	4	13		
Pain of skin		1		1		
Paraesthesia	1	3	1	3		
Photophobia		1		1		
Presyncope		1		1		
Product use issue		1		1		
Pruritus	1	1	1	1		
Pyrexia	2	9	2	9		
Rash		1		1		
Rash pruritic		2		2		
SARS-CoV-2 ant body test positive		1				1
SARS-CoV-2 test positive		1				1
Sneezing	1	1	1	1		
Somnolence		1		1		
Urticaria	1	2	1	1		1
Vaccination site dermatitis		1		1		
Vaccination site erythema		1		1		
Vaccination site oedema		2		2		
Vaccination site pain	4	10	4	10		
Vaccination site urticaria		1		1		
Vomiting		1		1		
	43	149	38	128	5	21

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

SLOVENIA

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* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Anaphylactic reaction		1				1
Angioedema		1				1
Arthralgia		2		2		
Back pain	1	1	1	1		
Blindness unilateral		1				1
Body temperature increased	1	3	1	3		
Chills		1		1		
Decreased appetite	1	1	1	1		
Dehydration	1	1	1	1		
Diarrhoea	1	2	1	2		
Dizziness		1		1		
Erythema		1				1
Eye pruritus		1		1		
Fatigue		5		5		
Headache		7		7		
Hypertension		1				1
Hyperventilation		1				1
Hypoaesthesia		2		1		1
Lip swelling		1		1		
Lymphadenopathy		1		1		
Malaise		1				1
Maternal exposure during pregnancy		1		1		
Migraine		1				1
Migraine with aura		1				1
Myalgia	1	5	1	5		
Nausea		2		1		1
Neurological symptom		1		1		
Pain in extremity	1	1	1	1		
Pain of skin	1	1	1	1		
Paraesthesia		3		3		
Paraesthesia oral		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia		2		2		
Rash		1		1		
Sensory disturbance		1		1		
Sinus tachycardia		1				1
Somnolence		3		3		
Speech disorder		1		1		
Swollen tongue		2		2		
Tachycardia		1		1		
Thinking abnormal		1		1		
Throat tightness		1		1		
Tongue pruritus		2		2		
Urticaria		1				1
Vaccination site erythema		2		2		
Vaccination site oedema		1		1		
Vaccination site pain		10		10		
Vaccination site pruritus		1		1		
Vaccination site rash	1	1	1	1		
Vaccination site swelling	1	2	1	2		
Vertigo		1		1		
	10	89	10	76		13

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Abdominal pain lower		1		1		
Angina pectoris		1				1
Asthenia		1		1		
Atrial fibrillation		1				1
Atrial tachycardia		1				1
Body temperature increased		2		1		1
Bronchial disorder		1				1
Cerebral ischaemia	1	1			1	1
Chest discomfort		2				2
Chest pain	1	2		1	1	1
Chills		1		1		
Circulatory collapse		1				1
Confusional state		1				1
COVID-19		1				1
Deep vein thrombosis		1				1
Diarrhoea		4		3		1
Dizziness		3				3
Dysgeusia		2		2		
Dyspnoea		2		1		1
Epilepsy		1				1
Fatigue	1	12	1	8		4
Feeling abnormal		1		1		
Feeling hot		1				1
Gait inability		1				1
Guillain-Barre syndrome		2				2
Headache	2	9	1	6	1	3
Hot flush		1				1
Hypoaesthesia	1	1			1	1
Hypokalaemia		1				1
Hyposmia		2		2		
Insomnia		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ischaemic stroke	1	1			1	1
Lip oedema		1				1
Loss of consciousness		8				8
Lymphadenitis		1		1		
Lymphadenopathy		3		3		
Malaise		2		1		1
Migraine		1		1		
Muscle strength abnormal	1	1			1	1
Myalgia		2		1		1
Nasopharyngitis		2		2		
Nausea		2		1		1
Oedema peripheral		1				1
Pain in extremity		1		1		
Paraesthesia		3				3
Paraesthesia oral		1				1
Pityriasis rosea		1		1		
Pneumothorax spontaneous		1				1
Pulmonary embolism		1				1
Pyrexia		1		1		
Rash pruritic		2		2		
Seizure		1				1
Sensation of foreign body		1				1
Somnolence	1	4	1	3		1
Speech disorder	1	1			1	1
Syncope		2				2
Tongue biting		1				1
Total lung capacity decreased		1				1
Uterine spasm		1				1
Vaccination failure		1				1
Vaccination site pain	1	12	1	9		3
Vaccination site pruritus		2		2		
Vaccination site warmth		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ventricular extrasystoles		1		1		
Vertigo		5		3		2
Walking disability		1				1
	11	134	4	63	7	71

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphasia		1				1
Arthralgia		1		1		
Asthenia		1				1
Aura		1		1		
Axillary pain		1				1
Basilar artery thrombosis		1				1
B-cell lymphoma		1				1
B-cell type acute leukaemia		1				1
Bell's palsy		1				1
Blood pressure increased		1		1		
Body temperature increased		2		2		
Bradycardia		1				1
Cardiac tamponade		1				1
Cerebral thrombosis		1				1
Chest discomfort		1		1		
Chest pain		1				1
Chills		2		2		
Diarrhoea		1		1		
Ear pain		1				1
Epistaxis	1	1			1	1
Erythema		1		1		
Eyelid oedema		1		1		
Fatigue	2	5	2	4		1
Feeling hot		1		1		
Headache	2	8	2	6		2
Hypertension		2				2
Inappropriate schedule of product administration		1		1		
Ischaemic cerebral infarction		1				1
Lymphadenitis	1	1	1	1		
Malaise		4		3		1
Muscular weakness		1		1		
Myalgia	1	2	1	2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myocardial infarction		1				1
Myocardial rupture		1				1
Nausea	1	2	1	2		
Neutropenia		1				1
Night sweats		1				1
Off label use		1		1		
Oral herpes		1				1
Pain		1		1		
Pain in extremity	1	1	1	1		
Paraesthesia oral		1				1
Presyncope		1		1		
Protein total increased		1		1		
Pyrexia	1	2	1	2		
Quadripareisis		1				1
Restlessness		1		1		
Sensory disturbance		1				1
Somnolence	1	1	1	1		
Speech disorder		1				1
Suffocation feeling		1				1
Tachycardia		1		1		
Thrombocytopenia		2				2
Transient ischaemic attack		1				1
Vaccination site pain	1	10	1	8		2
Vertebral artery thrombosis		1				1
Vomiting		1		1		
	12	87	11	51	1	36

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site pain	1	1	1	1		
Arrhythmia		1				1
Arthralgia	1	1			1	1
Body temperature increased	1	1			1	1
Bradycardia		1				1
Brain injury		1				1
Cardiac arrest	1	1			1	1
Cardiac failure congestive		1				1
Cardiopulmonary failure		1				1
Cerebral haemorrhage		1				1
Cerebrovascular accident	1	1			1	1
Chest discomfort		1				1
Chest pain		1				1
Contusion		1		1		
Deep vein thrombosis	2	2			2	2
Diarrhoea	1	1	1	1		
Dyspnoea		1				1
Erythema	1	1			1	1
Extrasystoles		1				1
Fall		1				1
Haemoptysis	1	1			1	1
Headache	1	1			1	1
Hemiparesis	1	1			1	1
Hypersensitivity	1	2		1	1	1
Hypochromasia		1		1		
Immobile		1				1
Inappropriate schedule of product administration		1		1		
Irritability		1				1
Loss of consciousness	2	3			2	3
Lower respiratory tract infection		1				1
Metabolic acidosis		1				1
Mood altered		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	1	1			1	1
Myocardial infarction	1	1			1	1
Nausea	2	2	1	1	1	1
Oedema peripheral	1	1			1	1
Off label use		1		1		
Osteopenia		1		1		
Pelvic venous thrombosis	1	1			1	1
Peripheral swelling	1	1			1	1
Pneumonia		1				1
Polymyalgia rheumatica	1	1			1	1
Pulmonary oedema		1				1
Respiratory acidosis		1				1
Seizure	1	1			1	1
Sensation of foreign body	1	1			1	1
Skin abrasion		1		1		
Speech disorder	1	1			1	1
Subarachnoid haemorrhage		1				1
Sudden cardiac death		2				2
Sudden death		1				1
Tachycardia		1		1		
Thrombophlebitis superficial		1				1
Transient ischaemic attack	1	1			1	1
Unresponsive to stimuli		1				1
Vaccination site erythema		1		1		
Vaccination site pain	3	10	3	10		
Ventricular extrasystoles		1				1
	30	73	6	22	24	51

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Acute myocardial infarction		2				2
Acute respiratory failure		1				1
Anaemia	1	2			1	2
Aphasia		1				1
Arthralgia	1	1			1	1
Asthenia	1	3		2	1	1
Asymptomatic bacteriuria		1				1
Atrial fibrillation		2				2
Back pain	1	1	1	1		
Bedridden		1				1
Blood creatine phosphokinase increased		1				1
Body temperature increased	1	4	1	3		1
Bradycardia		2				2
Cardiac arrest	1	2			1	2
Cardiac failure		2				2
Cardiomegaly		1				1
Cardiopulmonary failure		1				1
Cerebrovascular accident	1	2			1	2
Chest pain	1	4	1	2		2
Circulatory collapse		2				2
Confusional state	1	3		1	1	2
Coordination abnormal		1				1
Cough		1				1
COVID-19		3				3
COVID-19 pneumonia		1				1
Decreased insulin requirement	1	1	1	1		
Deep vein thrombosis		1				1
Dementia		1				1
Diabetes mellitus		1				1
Diarrhoea		1		1		
Disease recurrence		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diverticulum intestinal		1				1
Dry mouth		1		1		
Dysarthria		1				1
Dysphagia		1		1		
Dyspnoea		4				4
Epilepsy		2				2
Factor VIII deficiency	1	1			1	1
Fall		3		1		2
Fatigue		3		3		
Feeling cold		1		1		
Feeling hot		1				1
Gait disturbance		1				1
General physical health deterioration		1				1
Haematoma	1	1			1	1
Haemorrhage	1	1			1	1
Headache	1	1	1	1		
Head injury		1		1		
Herpes zoster	1	1			1	1
Hypertension		2				2
Hypoglycaemia	1	1			1	1
Hypokalaemia		1		1		
Hypotension		1				1
Immobile		1				1
Infection	1	2	1	1		1
Ischaemic stroke		1				1
Joint injury	1	1	1	1		
Joint swelling	1	1			1	1
Loss of consciousness		3				3
Malaise	2	9	2	5		4
Memory impairment	1	1			1	1
Miosis		1				1
Mitral valve incompetence	1	1			1	1

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* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Monoparesis		1				1
Myalgia		1				1
Myocardial fibrosis		1				1
Myocardial infarction	1	2			1	2
Myoglobin blood increased		1				1
Nausea		2		1		1
Oedema peripheral		1				1
Oropharyngeal pain		1		1		
Oxygen saturation decreased		3				3
Pain in extremity		1				1
Paraesthesia	1	1			1	1
Paresis		1				1
Peripheral coldness		1		1		
Pharyngeal erythema		1		1		
Pneumonia		1				1
Pneumonia bacterial		1				1
Pulmonary embolism		2				2
Pulmonary hypertension	1	1			1	1
Pyrexia		2				2
Rash		1				1
Renal failure		1				1
Rhabdomyolysis		1				1
Skin disorder		1				1
Soliloquy		1		1		
Somnolence		2				2
Sudden death		1				1
Superficial vein prominence		1				1
Syncope	1	4			1	4
Tachycardia		1				1
Tongue movement disturbance		1		1		
Transient ischaemic attack	1	1			1	1
Tricuspid valve incompetence	1	1			1	1

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* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Unresponsive to stimuli		2				2
Urinary incontinence		1				1
Vaccination failure		1				1
Vaccination site erythema		7		7		
Vaccination site oedema		3		3		
Vaccination site pain	2	15	2	15		
Vascular stent thrombosis		1				1
Vertigo		5		1		4
Vomiting		3		1		2
Wheezing		1				1
White blood cell count increased		1		1		
	31	186	11	63	20	123

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain upper		1		1		
Arthralgia		2		2		
Asthenia	1	1	1	1		
Autoimmune thyroiditis		1				1
Body temperature increased	1	3	1	3		
Chest pain		1		1		
Chills		3		3		
Diarrhoea	1	1	1	1		
Dizziness		2		2		
Drug ineffective		1				1
Dyspnoea	1	1	1	1		
Eyelid disorder		1		1		
Fatigue	1	4	1	4		
Feeling cold	1	1	1	1		
Headache	2	5	2	5		
Inappropriate schedule of product administration		1		1		
Insomnia		2		2		
Lymphadenopathy		1		1		
Malaise		6		6		
Myalgia	1	5	1	5		
Nausea		1		1		
Neck pain		1		1		
Nightmare		1		1		
Off label use		1		1		
Pain		1		1		
Pain in extremity	1	1	1	1		
Paraesthesia		1		1		
Pyrexia	1	6	1	6		
Sinusitis		1		1		
Skin burning sensation		1		1		
Suspected COVID-19		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tremor	1	1	1	1		
Vaccination site pain	1	2	1	2		
Vaccination site swelling		1		1		
	13	64	13	61		3

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* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

SOUTH AFRICA

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal pain	1	1	1	1
Arthralgia	1	1	1	1
Asthenia	2	2	2	2
Back pain	1	1	1	1
Chills	1	1	1	1
Decreased appetite	1	1	1	1
Dehydration	1	1	1	1
Erythema	1	1	1	1
Fatigue	1	1	1	1
Feeding disorder	1	1	1	1
Groin pain	1	1	1	1
Headache	3	3	3	3
Heart rate increased	1	1	1	1
Malaise	1	1	1	1
Pain	4	4	4	4
Palpitations	2	2	2	2
Pruritus	1	1	1	1
Pyrexia	1	1	1	1
Swelling	1	1	1	1
Tinnitus	1	1	1	1
Vaccination site lymphadenopathy	1	1	1	1
Vaccination site rash	1	1	1	1
Vision blurred	1	1	1	1
Vomiting	1	1	1	1
	31	31	31	31

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Aphasia	1	1	1	1
Cerebral venous thrombosis	1	1	1	1
Cerebrovascular accident	1	1	1	1
Death	2	2	2	2
Illness	1	1	1	1
	6	6	6	6

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Bone pain	1	1	1	1
Conjunctivitis allergic	1	1	1	1
Diarrhoea	1	1	1	1
Dizziness	1	1	1	1
Fatigue	1	1	1	1
Headache	3	3	3	3
Lip swelling	1	1	1	1
	9	9	9	9

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dizziness	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

SPAIN

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation		1		1		
Condition aggravated		1		1		
Exposure via breast milk	1	5	1	3		2
Faeces discoloured		1				1
Gait disturbance		1				1
Headache		1				1
Infant irritability		1				1
Insomnia		1		1		
Psychotic disorder		1		1		
Pyrexia	1	1	1	1		
Seizure		1				1
Vomiting	1	2	1	1		1
	3	17	3	9		8

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal distension		1		1		
Abdominal pain	2	7	2	5		2
Abdominal pain lower		1		1		
Abortion missed		1				1
Activated partial thromboplastin time shortened	1	1	1	1		
Ageusia		1				1
Allergic cough	1	2	1	2		
Allergy to vaccine	2	3			2	3
Amenorrhoea	1	1			1	1
Amnesia		2		1		1
Anaphylactic reaction	1	11			1	11
Anaphylactic shock		3				3
Angioedema		6				6
Anosmia		1				1
Anxiety		4		4		
Aphasia		3				3
Aphonia	1	2	1	1		1
Appendicitis		2				2
Arthralgia	7	23	7	16		7
Asthenia	6	19	6	12		7
Asthma		2				2
Asthmatic crisis		1				1
Asymptomatic COVID-19		1				1
Autoimmune demyelinating disease		1				1
Axillary pain		4		4		
Back pain	1	2		1	1	1
Balance disorder		1				1
Basedow's disease	1	1			1	1
Base excess decreased		1		1		
Bedridden		1				1
Bell's palsy	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood bicarbonate increased		1		1		
Blood calcium decreased		1		1		
Blood glucose increased		1				1
Blood lactate dehydrogenase increased		1		1		
Blood pressure decreased		1		1		
Blood pressure diastolic increased		1				1
Blood pressure increased		1		1		
Body temperature increased		1		1		
Bowel movement irregularity	1	1	1	1		
Bradykinesia		1		1		
Bradyphrenia		1		1		
Breast mass		1		1		
Bronchial hyperreactivity		1				1
Bronchospasm		3				3
Burning sensation		1				1
Butterfly rash		1		1		
Cellulitis		1				1
Chest discomfort		2		1		1
Chest pain		5		1		4
Chills	8	30	8	19		11
Choking		1				1
Choking sensation	1	3			1	3
Chromaturia		1		1		
Circumoral swelling		1		1		
Cold sweat		2		1		1
Colitis		1		1		
Condition aggravated	2	5		1	2	4
Confusional state		1		1		
Conjunctival hyperaemia		1				1
Conjunctival laceration		1		1		
Contusion		1				1
Cough	5	8	2	3	3	5

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	2	8			2	8
Craniocerebral injury		1				1
Decreased appetite		3		1		2
Deep vein thrombosis	1	1			1	1
Depressed level of consciousness		1				1
Diabetic metabolic decompensation		1				1
Diarrhoea	10	26	8	16	2	10
Discomfort		1		1		
Disturbance in attention		2		1		1
Dizziness	11	36	10	22	1	14
Dizziness postural	1	1	1	1		
Drug hypersensitivity	1	1	1	1		
Drug ineffective		3				3
Drug intolerance	1	1	1	1		
Dry eye		1		1		
Dry skin	1	1	1	1		
Dry throat		1		1		
Dysgeusia	2	3			2	3
Dyshidrotic eczema	1	1	1	1		
Dysmenorrhoea		1		1		
Dyspepsia	1	1	1	1		
Dysphagia	1	4	1	1		3
Dyspnoea	8	22	3	4	5	18
Dyspnoea exertional		2				2
Encephalitis		2				2
Epigastric discomfort		1				1
Epilepsy	1	2			1	2
Episcleritis		1				1
Epistaxis	2	2	1	1	1	1
Epstein-Barr virus infection reactivation		1				1
Erythema	3	17	3	11		6
Eye discharge		1				1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye inflammation	1	1	1	1		
Eye pain	1	4	1	2		2
Eye pruritus		2				2
Face oedema		3				3
Facial paralysis	1	8			1	8
Fatigue	12	36	10	22	2	14
Feeling cold		2				2
Feeling hot		2		1		1
Fibrin D dimer increased		1				1
Flatulence		1		1		
Flushing		1		1		
Gait disturbance		1				1
Gait inability		1				1
Galactorrhoea		1				1
Gastrointestinal pain	1	1	1	1		
Gastroesophageal reflux disease		1		1		
General physical health deterioration		2		1		1
Groin pain		1				1
Haemoglobin decreased		1		1		
Haemoglobin increased		1		1		
Haemophagocytic lymphohistiocytosis		1				1
Haemoptysis	1	1			1	1
Hallucination		1				1
Headache	33	95	29	64	4	31
Head injury		2				2
Heart rate increased		1				1
Heavy menstrual bleeding	2	2	2	2		
Hemiparaesthesia		1				1
Hemiplegia		2				2
Hepatic failure		1				1
Hepatitis acute		2				2
Hepatomegaly		1				1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes simplex		1				1
Herpes virus infection		1				1
Herpes zoster	1	3	1	1		2
Hyperglycaemia		1				1
Hyperhidrosis		1				1
Hypersensitivity	1	4	1	2		2
Hypertension	1	1	1	1		
Hyperthyroidism		1				1
Hyperventilation		1				1
Hypoaesthesia		5		1		4
Hypoaesthesia oral		1				1
Hypoglycaemia		2				2
Hypokalaemia	1	1			1	1
Hypokinesia		2		1		1
Hyposmia	2	2			2	2
Hypotension		7		1		6
Hypoxia		1				1
Inappropriate schedule of product administration		2		2		
Incorrect route of product administration	1	3	1	3		
Increased upper airway secretion	1	1	1	1		
Infectious mononucleosis		1				1
Influenza	1	2	1	2		
Injection site pain		1		1		
Injection site paraesthesia	1	1	1	1		
Intermenstrual bleeding		2				2
Iridocyclitis	1	1			1	1
Ischaemic stroke		1				1
Lacrimation increased		1				1
Laryngeal oedema		3				3
Leukocytosis		1				1
Limb discomfort		1		1		
Lipase decreased		1		1		

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* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lip blister		1		1		
Lip oedema	1	3	1	2		1
Lip pruritus		3		3		
Lip swelling		2				2
Loss of consciousness	1	5			1	5
Loss of personal independence in daily activities		1				1
Lymphadenitis	1	4	1	3		1
Lymphadenopathy	8	32	7	16	1	16
Lymph node pain		1				1
Lymphocyte count increased		1		1		
Macroglossia		1				1
Malaise	12	40	12	28		12
Meniere's disease		1				1
Meningism		1				1
Menstrual disorder	3	3	3	3		
Menstruation irregular	2	2	2	2		
Mental impairment		1				1
Middle insomnia	1	1	1	1		
Migraine		2		1		1
Migraine with aura		1		1		
Mobility decreased		3		1		2
Monoparesis		1				1
Monoplegia		1				1
Mouth haemorrhage	1	1			1	1
Movement disorder		1				1
Multiple organ dysfunction syndrome		1				1
Muscle contractions involuntary	1	1			1	1
Muscle rigidity	1	1	1	1		
Muscular weakness	2	3	2	3		
Musculoskeletal chest pain		1		1		
Musculoskeletal pain		7		3		4
Musculoskeletal stiffness		2				2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	20	56	16	32	4	24
Myocarditis		1				1
Nasal congestion	2	4	1	3	1	1
Nasal pruritus		1				1
Nasopharyngitis		1		1		
Nausea	13	48	11	31	2	17
Neck pain	1	1	1	1		
Neuropathy peripheral	1	2			1	2
Neutrophil count increased		1		1		
Night sweats		3		1		2
Noninfective conjunctivitis	1	1	1	1		
Nuchal rigidity		2				2
Oculofacial paralysis		1				1
Odynophagia	2	4	1	2	1	2
Off label use		2		2		
Oral herpes		1		1		
Oral pain		1		1		
Oropharyngeal discomfort		1				1
Oropharyngeal pain	1	2	1	2		
Orthopnoea	1	1	1	1		
Orthostatic hypotension	1	1	1	1		
Ovarian cyst		1				1
Overdose		1		1		
Oxygen saturation decreased		1		1		
Pain	3	8	3	4		4
Pain in extremity	5	17	4	12	1	5
Palatal oedema		4				4
Pallor		2		1		1
Palpitations		2		1		1
Pancytopenia		1				1
Papule		1		1		
Paraesthesia	2	11	1	2	1	9

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia mucosal		1				1
Paraesthesia oral		4				4
Parosmia		1				1
Periarthritis		1				1
Pericarditis		1				1
Periorbital swelling		1		1		
Peripheral swelling	1	2		1	1	1
Petit mal epilepsy		1				1
Pharyngeal hypoaesthesia		1				1
Pharyngeal inflammation		1				1
Pharyngeal swelling		1				1
Pharyngotonsillitis		1				1
Photophobia		1		1		
Pleural effusion		1		1		
PO2 decreased		1		1		
Polymenorrhoea		1		1		
Presyncope	2	4	2	4		
Primary hyperthyroidism	1	1			1	1
Proctitis		1				1
Productive cough		1		1		
Pruritus	4	16	3	8	1	8
Psychomotor hyperactivity		1				1
Pulmonary embolism		4				4
Pyelonephritis		1				1
Pyrexia	34	111	27	72	7	39
Rash	1	12		6	1	6
Rash erythematous		2				2
Rash papular		3				3
Rash pruritic		2				2
Raynaud's phenomenon		2				2
Rectal discharge		1				1
Rectal haemorrhage		1				1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory disorder		1				1
Respiratory distress	1	5			1	5
Respiratory failure		1				1
Restlessness	1	1	1	1		
Rhinorrhoea		1		1		
Scleritis		1				1
Seizure		1				1
Sensation of foreign body	1	2	1	1		1
Sensory loss		2		1		1
Shock		1				1
Sinus bradycardia		1		1		
Sinus tachycardia	1	2			1	2
Skin lesion		1				1
Somnolence	1	7	1	4		3
Speech disorder		1				1
Spinal cord injury		1				1
Stridor	1	1			1	1
Swelling	2	3	2	3		
Swelling face		1				1
Swollen tongue		1				1
Syncope	2	14			2	14
Tachycardia	2	12	2	2		10
Temperature regulation disorder	3	6	3	4		2
Throat irritation	1	5	1	3		2
Throat tightness		1				1
Thrombophlebitis superficial		1				1
Thyroiditis	1	1			1	1
Thyroid mass	1	1			1	1
Tinnitus	1	1			1	1
Tongue oedema		2				2
Tongue pruritus		1				1
Tonsillitis		2				2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Toxic skin eruption		1				1
Transaminases increased	1	2			1	2
Transient ischaemic attack		1				1
Tremor		2				2
Underdose	1	1	1	1		
Urinary sediment abnormal		1		1		
Urinary tract infection	1	3	1	2		1
Urticaria	2	10	1	3	1	7
Uterine haemorrhage		1				1
Uvulitis		1				1
Vaccination complication		1				1
Vaccination failure	2	4			2	4
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	2	9	2	5		4
Vaccination site haematoma	1	1	1	1		
Vaccination site haemorrhage		1		1		
Vaccination site induration		1		1		
Vaccination site inflammation	1	6	1	6		
Vaccination site joint erythema	1	1	1	1		
Vaccination site joint swelling	1	1	1	1		
Vaccination site lymphadenopathy	1	4	1	2		2
Vaccination site movement impairment		1		1		
Vaccination site oedema	1	3	1	2		1
Vaccination site pain	13	39	13	28		11
Vaccination site paraesthesia	1	2	1	1		1
Vaccination site pruritus		6		3		3
Vaccination site rash		1				1
Vaccination site reaction		1		1		
Vaccination site swelling		1		1		
Vaccination site warmth	2	5	2	3		2
Vaginal discharge		1		1		
Ventricular extrasystoles		1				1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vertigo	2	5	1	2	1	3
Vestibular neuronitis	1	2			1	2
Viral rash		1				1
Vision blurred	1	3	1	1		2
Visual impairment		1				1
Vomiting	14	34	11	18	3	16
Wheezing		2				2
White matter lesion		1		1		
	351	1,322	268	660	83	662

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	1	4			1	3		1
Abdominal mass		1				1		
Abdominal pain	6	21			5	14	1	7
Abdominal pain lower	1	2			1	1		1
Abdominal pain upper	2	9			2	6		3
Abnormal faeces		1				1		
Abortion induced		1						1
Abortion missed	1	2					1	2
Abortion spontaneous		3						3
Accommodation disorder	1	1			1	1		
Acne	2	2			2	2		
Acoustic neuritis		1						1
Acute myocardial infarction	1	2					1	2
Acute respiratory failure	1	1					1	1
Adnexa uteri pain		1				1		
Ageusia	1	9			1	4		5
Akathisia	1	1			1	1		
Allergic reaction to excipient		1						1
Allergy to vaccine		4				1		3
Allodynia		1				1		
Alopecia		1						1
Amaurosis fugax		1						1
Amenorrhoea	1	2					1	2
Amino acid level increased	1	1			1	1		
Amnesia		1						1
Anaesthesia oral	1	1			1	1		
Anaphylactic reaction	2	18					2	18
Androgenetic alopecia		1						1
Anembryonic gestation	1	1					1	1
Angina pectoris		1						1
Angioedema	2	14					2	14
Angiopathy	1	1			1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anosmia	1	8
Antipsychotic drug level increased		1
Anuria		1
Anxiety	2	5
Aphonia	2	4
Aphthous ulcer	1	4
Appendicitis		1
Arrhythmia	2	2
Arthralgia	33	88
Arthritis		1
Arthritis reactive		1
Asphyxia		2
Asthenia	32	87
Asthma		1
Asymptomatic COVID-19		5
Atelectasis		1
Atrial fibrillation		1
Atrophic glossitis		1
Atypical haemolytic uraemic syndrome		1
Autoimmune hepatitis		1
Autoimmune hypothyroidism		1
Axillary pain		9
Axonal neuropathy		1
Bacille Calmette-Guerin scar reactivation		1
Back pain	3	16
Balance disorder	1	8
Bell's palsy		7
Biliary colic		1
Bladder spasm		1
Blepharitis		1
Blepharospasm	2	3
Blindness transient		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4		4
					1
					1
			3	2	2
		1	1	1	3
		1	2		2
					1
				2	2
		32	62	1	26
					1
					1
					2
		26	49	6	38
					1
			1		4
			1		
					1
					1
					1
			3		6
			1		
			1		
		2	7	1	9
		1	2		6
					7
					1
					1
			1		
		2	3		
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blindness unilateral		1
Blister	1	2
Blood creatine phosphokinase increased	1	1
Blood fibrinogen decreased		1
Blood fibrinogen increased		1
Blood glucose decreased		1
Blood iron decreased	1	1
Blood pressure abnormal		2
Blood pressure increased	1	5
Blood pressure systolic increased		1
Body temperature increased		1
Brachial plexopathy	1	1
Brachial plexus injury		1
Bradycardia		3
Bradyphrenia		2
Brain oedema		1
Breast oedema		1
Breast pain	3	3
Bronchitis bacterial		1
Bronchospasm		5
Bundle branch block right		1
Burning sensation	1	2
Bursitis		1
Cardiac failure acute		1
Cardio-respiratory arrest		1
Cardiovascular disorder	1	1
Carpal tunnel syndrome	1	1
Castleman's disease	1	1
Catarrh		2
Cellulitis		3
Cerebral disorder		1
Cerebral haemorrhage		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1		1
				1	1
			1		
			1		
					1
				1	1
			1		1
		1	2		3
			1		
			1		
		1	1		
					1
					3
					2
					1
					1
				3	3
					1
					5
					1
		1	1		1
					1
					1
				1	1
				1	1
				1	1
			1		1
					3
					1
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebral ischaemia		1
Cerebral venous sinus thrombosis	1	1
Cerebral venous thrombosis		2
Cervicobrachial syndrome		1
Cheilitis		2
Chest discomfort	3	15
Chest pain	2	21
Chills	36	91
Choking sensation		3
Chronic lymphocytic leukaemia		1
Chronic sinusitis	1	1
Citrobacter infection		1
Cold sweat		2
Concomitant disease aggravated		3
Condition aggravated	3	11
Confusional state		1
Conjunctival haemorrhage		1
Constipation		1
Contraindication to vaccination	1	1
Contusion		3
Corneal reflex decreased		1
Costochondritis		1
Cough	5	30
COVID-19	10	36
COVID-19 pneumonia		1
Craniocerebral injury		1
C-reactive protein increased		1
Cytomegalovirus test positive		1
Deafness		1
Deafness unilateral		1
Death	1	2
Decreased appetite		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
					2
					1
					2
		3	4		11
		2	9		12
		34	62	2	29
					3
					1
		1	1		
					1
			1		1
					3
		2	3	1	8
					1
					1
			1		
		1	1		
			1		2
					1
					1
		3	15	2	15
		3	13	7	23
					1
					1
			1		
					1
					1
				1	2
					4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Decreased nasolabial fold		1
Deep vein thrombosis	2	4
Dehydration		1
Delirium febrile		1
Demyelination		1
Depressed level of consciousness		5
Depressed mood		1
Dermatitis allergic		3
Dermatitis atopic		1
Dermatitis bullous		1
Diabetes mellitus inadequate control		2
Diaphragmalgia		1
Diarrhoea	25	78
Diarrhoea haemorrhagic		1
Diplopia		3
Discomfort	2	12
Disease recurrence		3
Disorganised speech		1
Disturbance in attention	3	7
Dizziness	25	106
Dizziness postural	1	3
Drowning		2
Drug hypersensitivity		2
Drug ineffective		11
Dry eye		1
Dry mouth		5
Dry skin		1
Dry throat		1
Dysaesthesia	3	8
Dysarthria	1	2
Dysgeusia	4	11
Dyspepsia		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				2	4
					1
					1
					1
					5
			1		
					3
					1
					1
					2
					1
		22	52	3	26
					1
			1		2
		2	8		4
			1		2
					1
		3	3		4
		17	57	8	49
		1	2		1
					2
					2
					11
					1
			1		4
					1
					1
		1	1	2	7
				1	2
		3	7	1	4
			1		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysphagia	1	7
Dysphonia	1	7
Dyspnoea	6	48
Dyspnoea exertional	2	7
Dystonia		1
Dysuria		3
Ear infection		1
Ear pain	3	9
Ecchymosis		1
Eczema		1
Effusion	1	1
Electrocardiogram ST segment elevation		1
Encephalopathy		1
Epididymitis	1	1
Epilepsy		3
Epistaxis		1
Epstein-Barr virus antibody positive		1
Erythema	4	26
Erythema multiforme		1
Essential tremor		2
Euphoric mood		1
Exposure during pregnancy		4
Extrasystoles	1	1
Eye irritation	1	1
Eyelid oedema	2	3
Eye pain	2	4
Eye swelling		1
Face oedema	3	10
Facial neuralgia		1
Facial pain	1	2
Facial paralysis	1	17
Facial paresis		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	1	5
			2	1	5
		4	13	2	35
		1	1	1	6
					1
			2		1
					1
		3	4		5
					1
					1
				1	1
					1
					1
				1	1
					3
			1		
					1
		2	9	2	17
					1
			1		1
					1
			3		1
				1	1
		1	1		
		1	1	1	2
		2	2		2
					1
				3	10
			1		
		1	1		1
				1	17
			1		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Fall		3
Fatigue	22	86
Febrile convulsion		2
Feeling abnormal	3	7
Feeling cold	2	5
Feeling drunk		1
Feeling hot	3	10
Feeling of body temperature change	1	1
Fibromyalgia	1	1
Flatulence		1
Floppy eyelid syndrome		1
Flushing	1	3
Foreign body in throat		1
Foreign body sensation in eyes		1
Formication	1	6
Fracture		1
Fumbling		1
Fungal skin infection		1
Gait disturbance	2	5
Gait inability		2
Galactorrhoea	1	1
Gastroenteritis		3
Gastrointestinal disorder		1
Gastrointestinal somatic symptom disorder		1
Generalised oedema	1	3
Generalised tonic-clonic seizure		1
General physical health deterioration		2
Genital ulceration		1
Gingival bleeding		1
Gingival discolouration	1	1
Gingival swelling	1	1
Gingivitis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
		20	55	2	31
					2
		3	4		3
		1	1	1	4
			1		
		1	4	2	6
		1	1		
				1	1
					1
					1
		1	1		2
					1
			1		
		1	3		3
					1
					1
		1	2	1	3
					2
				1	1
			2		1
			1		
			1		
				1	3
					1
					2
					1
					1
		1	1		
		1	1		
		1	1		

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Glossitis		4
Glossodynia		1
Goitre		1
Guillain-Barre syndrome		1
Haematochezia		1
Haematoma	1	3
Haemoptysis		1
Haemorrhage		2
Haemorrhagic diathesis		1
Hallucination		1
Hallucination, visual		1
Headache	103	324
Heart rate increased		3
Heart rate irregular		1
Heavy menstrual bleeding	2	3
Hemianaesthesia		1
Hemiparaesthesia	1	2
Hemiparesis	1	1
Hepatic cytolysis		1
Hepatic enzyme abnormal		1
Hepatitis		1
Hepatitis acute		1
Hepatitis B virus test positive		1
Herpes ophthalmic		1
Herpes simplex		1
Herpes virus infection	1	2
Herpes zoster	3	25
Herpes zoster reactivation	1	3
Hormone level abnormal	1	1
Hot flush	1	3
Hyperaemia	1	1
Hyperaesthesia	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					4
					1
			1		
					1
					1
		1	2		1
					1
					2
					1
					1
					1
		94	210	9	114
			1		2
					1
		2	2		1
					1
				1	2
				1	1
					1
					1
					1
			1		
					1
			1		
		1	2		
	1	3	6		19
		1	1		2
		1	1		
		1	2		1
		1	1		
		1	2		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyperdynamic left ventricle		1
Hyperglycaemia	1	5
Hyperhidrosis	3	12
Hyperpyrexia		1
Hypersensitivity	4	15
Hypersomnia	1	2
Hypertension	6	25
Hypertensive crisis	2	12
Hypertensive urgency		1
Hyperthermia		1
Hypertonia	1	1
Hypertransaminasaemia		2
Hypoacusis		3
Hypoesthesia	5	23
Hypoesthesia eye	1	1
Hypoesthesia oral	1	6
Hypocalcaemia	1	3
Hypoglycaemia	4	7
Hypophosphataemia		1
Hyporeflexia	1	2
Hypotension	1	8
Hypothermia	2	3
Hypotonia		1
Idiopathic angioedema		1
Immune thrombocytopenia		4
Immunisation reaction		1
Immunodeficiency	1	1
Inappropriate schedule of product administration	2	4
Incorrect dose administered		1
Incorrect route of product administration	2	2
Induration		1
Inflammation	2	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	5
		3	5		7
					1
		2	3	2	12
		1	1		1
		3	9	3	16
				2	12
					1
					1
				1	1
					2
					3
		2	7	3	16
		1	1		
		1	3		3
		1	2		1
		3	3	1	4
			1		
		1	1		1
		1	3		5
				2	3
			1		
					1
					4
			1		
				1	1
		2	4		
			1		
		2	2		
					1
		2	5		2

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Influenza	3	7
Influenza like illness	2	4
Injection site erythema		1
Injection site inflammation		1
Insomnia	1	4
Insulin resistance		1
Intermenstrual bleeding	2	9
Interstitial lung disease		1
Intervertebral disc disorder	1	1
Intra-abdominal haematoma	1	1
Intraventricular haemorrhage		1
Iron deficiency		1
Joint contracture		2
Joint injury		1
Joint range of motion decreased		1
Joint swelling		1
Joint warmth		1
Jugular vein thrombosis	1	1
Keratitis		1
Lacrimation increased		1
Laryngeal discomfort	1	1
Laryngeal disorder		1
Laryngeal oedema	1	6
Laryngitis		1
Larynx irritation		1
Lateral medullary syndrome	1	1
Leukocytosis	1	2
Leukopenia		1
Lichen planus		1
Limb discomfort	1	3
Limb immobilisation		1
Lip erythema		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3	1	4
		2	3		1
			1		
			1		
		1	3		1
					1
		1	2	1	7
					1
		1	1		
				1	1
					1
			1		
			2		
					1
					1
					1
					1
				1	1
					1
					1
				1	1
					1
				1	6
					1
					1
					1
				1	1
			1	1	1
					1
					1
		1	1		2
					1
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lip oedema	3	7
Lipoma		1
Lip pruritus		1
Lip swelling	2	7
Lividity		1
Local reaction	2	5
Loss of consciousness		7
Loss of personal independence in daily activities		1
Lymphadenitis	2	9
Lymphadenopathy	39	113
Lymphocytosis		1
Lymphopenia	1	2
Macular oedema		1
Malaise	48	130
Mass		1
Mastitis	1	1
Maternal exposure during pregnancy		2
Memory impairment	1	2
Menometrorrhagia	1	2
Menstrual disorder	2	2
Menstruation delayed		2
Menstruation irregular	4	4
Mental impairment	1	3
Mesenteric vein thrombosis	1	1
Migraine	2	8
Migraine with aura		1
Migraine without aura		1
Misophonia		1
Mobility decreased	1	3
Mononeuropathy		1
Monoparesis	1	2
Monoplegia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	3	6
			1		
					1
			1	2	6
					1
		2	2		3
					7
			1		
		1	5	1	4
		30	54	9	59
			1		
		1	2		
					1
		45	93	3	37
					1
				1	1
			2		
		1	1		1
				1	2
		2	2		
					2
		4	4		
				1	3
				1	1
		1	2	1	6
					1
					1
					1
		1	1		2
					1
		1	1		1
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mouth injury	1	1
Mouth swelling		1
Movement disorder		1
Mucosal disorder	1	1
Mucosal dryness		1
Multiple sclerosis		1
Muscle contractions involuntary		3
Muscle contracture		3
Muscle fatigue		1
Muscle injury	1	1
Muscle rigidity	1	2
Muscle spasms	3	7
Muscle tightness	1	4
Muscular weakness	1	8
Musculoskeletal chest pain		1
Musculoskeletal discomfort	2	4
Musculoskeletal pain	2	21
Musculoskeletal stiffness	1	4
Myalgia	55	178
Myelitis	1	2
Myocardial ischaemia		1
Myocarditis		2
Myoclonic dystonia		2
Myositis		1
Nasal congestion	1	7
Nasal disorder		1
Nasal obstruction	2	2
Nasopharyngitis	1	2
Nausea	38	113
Neck mass		1
Neck pain	1	11
Nervousness		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
			1		
		1	1		
					1
					1
			1		2
			2		1
			1		
		1	1		
				1	2
		2	4	1	3
		1	1		3
			3	1	5
			1		
		2	2		2
		1	6	1	15
		1	2		2
		54	134	1	44
				1	2
					1
					2
					2
					1
		1	4		3
			1		
		1	1	1	1
		1	2		
		36	80	2	33
			1		
		1	6		5
			2		2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neuralgia	1	5
Neuropathy peripheral		4
Neurosensory hypoacusis		1
Neutrophilic dermatosis		1
Nodule		1
Nuchal rigidity		1
Ocular discomfort	1	1
Ocular hyperaemia		2
Odynophagia	6	18
Oedema	1	5
Oedema mouth		1
Oedema peripheral	2	7
Off label use	1	6
Oral candidiasis		3
Oral discomfort		1
Oral dysaesthesia	1	2
Oral herpes	1	8
Oral pruritus		3
Orchitis	1	1
Oropharyngeal discomfort	1	3
Oropharyngeal pain	6	14
Orthostatic hypotension		1
Osteoarthritis		1
Overdose	2	4
Oxygen saturation decreased		2
Pain	9	23
Pain in extremity	21	46
Palatal oedema		7
Palatal swelling		2
Pallor	2	3
Palpitations	4	15
Panic attack	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		3
					4
					1
					1
			1		
					1
		1	1		
					2
		4	6	2	12
		1	3		2
					1
		1	1	1	6
		1	6		
			2		1
			1		
		1	1		1
		1	2		6
			1		2
				1	1
		1	1		2
		6	8		6
					1
			1		
		2	4		
					2
		9	20		3
		19	32	2	14
					7
			1		1
		1	1	1	2
		3	4	1	11
		1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Papule		1
Paraesthesia	17	82
Paraesthesia oral	4	12
Paraparesis	1	1
Paresis		1
Parotid gland enlargement		2
Parotitis	1	4
Pelvic pain		1
Periarthritis	1	2
Pericarditis	2	7
Periorbital abscess		1
Periorbital oedema		1
Periorbital pain		1
Peripheral artery thrombosis		1
Peripheral coldness		1
Peripheral swelling	2	5
Peripheral venous disease		1
Pernio-like erythema		2
Persistent depressive disorder		1
Petechiae		2
Petit mal epilepsy		1
Pharyngeal inflammation		2
Pharyngeal lesion	1	1
Pharyngeal oedema		4
Pharyngeal swelling		3
Phlebitis		1
Phlebitis superficial	1	2
Phonophobia		1
Photophobia		3
Photopsia		1
Pityriasis rosea	1	4
Pleuritic pain		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		10	28	7	54
		4	4		8
		1	1		
			1		
			2		
			1	1	3
			1		
				1	2
				2	7
					1
			1		
					1
					1
		1	1	1	4
					1
			1		1
			1		1
			1		1
		1	1		
			1		3
					3
					1
				1	2
					1
			1		3
				1	4
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pneumonia	1	1
Poor peripheral circulation		1
Portal vein thrombosis	1	1
Post thrombotic syndrome		1
Presyncope	4	16
Proctalgia		1
Product dose omission issue	1	1
Productive cough		2
Product use issue		3
Pruritus	14	53
Pruritus allergic	1	1
Psoriatic arthropathy		1
Psychomotor hyperactivity		2
Pulmonary embolism	3	6
Pulmonary hypertension	1	1
Pulmonary infarction		1
Pulmonary thrombosis		1
Pulse abnormal		1
Puncture site pain	1	1
Purpura		1
Pustule		1
Pyrexia	117	325
Rash	10	39
Rash erythematous	1	5
Rash macular	5	5
Rash maculo-papular		2
Rash papular	1	3
Rash pruritic		4
Rash vesicular		1
Raynaud's phenomenon		2
Rectal haemorrhage		1
Red blood cell count abnormal	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		
				1	1
					1
		3	6	1	10
			1		
		1	1		
					2
			3		
		12	23	2	30
		1	1		
					1
			1		1
				3	6
				1	1
					1
					1
		1	1		
					1
					1
		114	220	3	105
		6	13	4	26
		1	1		4
		4	4	1	1
			1		1
		1	1		2
			1		3
			1		
					2
					1
				1	1

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Red blood cell sedimentation rate increased		1
Respiratory distress		8
Respiratory rate decreased		1
Resting tremor	1	1
Restless legs syndrome		1
Restlessness		1
Retinal vein occlusion		1
Rheumatoid arthritis	1	1
Rhinitis		2
Rhinorrhoea	5	12
Rotator cuff syndrome	2	4
SARS-CoV-2 ant body test positive	1	3
SARS-CoV-2 test positive		2
Seizure		2
Sensation of foreign body		2
Sense of oppression		1
Sensory disturbance		1
Sensory loss	2	9
Serum ferritin abnormal	1	1
Sialoadenitis		1
Sinusitis		1
Sinus tachycardia		4
Skeletal injury		1
Skin discomfort	1	1
Skin exfoliation		2
Skin lesion		2
Skin odour abnormal		1
Skin reaction	1	2
Slow speech		1
Sneezing		1
Somnolence	3	12
Speech disorder	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					8
					1
				1	1
					1
					1
					1
				1	1
			1		1
		3	7	2	5
		1	1	1	3
		1	2		1
			1		1
					2
					2
					1
					1
			3	2	6
				1	1
					1
			1		
					4
					1
		1	1		
					2
					2
					1
		1	2		
					1
			1		
		3	9		3
		1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Spinal pain		1
Splenic vein thrombosis	1	1
Spontaneous haematoma		1
Stomatitis	1	4
Stridor		1
Subarachnoid haemorrhage	1	1
Subclavian vein thrombosis	1	1
Subcutaneous abscess		1
Suffocation feeling		2
Supraventricular extrasystoles		1
Supraventricular tachycardia		1
Swelling	1	3
Swelling face		4
Swollen tongue	2	7
Syncope	3	28
Systemic lupus erythematosus		1
Systemic lupus erythematosus rash		1
Tachycardia	7	42
Tachycardia paroxysmal		1
Tachypnoea		2
Temperature regulation disorder	4	21
Tenderness	1	2
Tendon disorder		1
Tendonitis	1	1
Tension headache		2
Testicular pain		1
Thirst		1
Throat irritation	4	11
Throat tightness	1	4
Thrombocytopenia	2	4
Thrombophlebitis	1	2
Thrombophlebitis superficial	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
					1
		1	3		1
					1
				1	1
				1	1
					1
					2
					1
					1
		1	2		1
			2		2
				2	7
				3	28
					1
			1		
		2	12	5	30
					1
					2
		3	10	1	11
		1	1		1
					1
				1	1
			1		1
			1		
		4	6		5
		1	2		2
				2	4
				1	2
			1	2	4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Thrombosis	1	1
Thunderclap headache		1
Tic		2
Tinnitus		10
Tongue disorder	1	2
Tongue eruption	1	1
Tongue erythema		1
Tongue injury	1	1
Tongue oedema	2	7
Tongue pruritus	1	3
Tongue ulceration		2
Tonsillitis	1	1
Tooth avulsion		1
Toxicity to various agents		1
Transferrin abnormal	1	1
Transverse sinus thrombosis	1	1
Tremor	3	10
Trigeminal neuralgia		2
Trigeminal neuritis	1	1
Trismus	1	1
Tunnel vision		1
Underdose	1	2
Urinary tract infection		2
Urinary tract infection bacterial		1
Urticaria	12	42
Uterine haemorrhage		1
Uterine leiomyoma	1	1
Vaccination failure	6	11
Vaccination site abscess		1
Vaccination site discomfort	1	5
Vaccination site erythema	1	6
Vaccination site haematoma	1	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
					2
			3		7
			1	1	1
				1	1
					1
		1	1		
			1	2	6
		1	1		2
			2		
				1	1
					1
					1
				1	1
				1	1
		3	4		6
					2
		1	1		
		1	1		
					1
		1	2		
					2
					1
		6	19	6	23
					1
		1	1		
				6	11
					1
		1	3		2
		1	3		3
				1	6

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site hyperaesthesia		2
Vaccination site hypoaesthesia		3
Vaccination site induration		3
Vaccination site inflammation	6	16
Vaccination site joint discomfort		1
Vaccination site joint erythema	2	9
Vaccination site joint inflammation		2
Vaccination site joint movement impairment		1
Vaccination site joint pain	3	3
Vaccination site joint swelling		1
Vaccination site lymphadenopathy	8	25
Vaccination site macule	2	2
Vaccination site movement impairment		3
Vaccination site oedema	2	4
Vaccination site pain	45	136
Vaccination site paraesthesia		5
Vaccination site phlebitis	1	1
Vaccination site pruritus	1	8
Vaccination site rash		1
Vaccination site reaction	2	4
Vaccination site swelling	2	8
Vaccination site urticaria	1	1
Vaccination site warmth	2	6
Vaginal haemorrhage	1	5
Varicella zoster virus infection	2	2
Vasculitis		2
Vasodilatation	1	1
Venous thrombosis limb		1
Vertigo	4	16
Vertigo positional		1
Vestibular migraine		1
Vision blurred	2	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
			1		2
			2		1
		6	11		5
			1		
		2	5		4
					2
					1
		3	3		
			1		
		6	14	2	11
		2	2		
			3		
		2	3		1
		42	101	3	35
			1		4
				1	1
		1	5		3
			1		
		2	3		1
		2	4		4
		1	1		
		1	2	1	4
			2	1	3
		1	1	1	1
					2
				1	1
					1
		3	5	1	11
					1
					1
		1	4	1	7

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Visual field defect	1	1					1	1
Visual impairment	1	1					1	1
Vitamin B12 decreased	1	1			1	1		
Vitamin D decreased	1	1			1	1		
Vomiting	13	55			12	33	1	22
Vulval ulceration		1						1
Vulvovaginal candidiasis		1						1
Wheezing		3						3
White matter lesion		1						1
	1,165	4,164		1	908	2056	257	2108

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	4	4	3	3	1	1
Abdominal distension		2		2		
Abdominal pain	3	11	3	7		4
Abdominal pain lower		1		1		
Abdominal pain upper	1	5		4	1	1
Abdominal symptom		1		1		
Acute kidney injury		1				1
Acute myocardial infarction		2				2
Acute respiratory failure		1				1
Administration site erythema		1		1		
Administration site pruritus		1		1		
Adrenal mass		1		1		
Ageusia	1	2	1	1		1
Agitation		1				1
Allergic oedema		1				1
Allergy to vaccine	1	5			1	5
Amaurosis fugax		1				1
Amnesia		2				2
Anal sphincter atony		2				2
Anaphylactic reaction	1	18			1	18
Anaphylactic shock		3				3
Angina pectoris	2	3			2	3
Angioedema		11				11
Anisometropia		1		1		
Anosmia	1	3	1	2		1
Anxiety	3	4	2	3	1	1
Aortic dissection		1				1
Aphonia		3		2		1
Aphthous ulcer	3	6	2	4	1	2
Arrhythmia	1	2			1	2
Arthralgia	22	62	19	45	3	17
Arthritis	1	2			1	2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthritis allergic		1				1
Asphyxia		1				1
Asthenia	15	56	13	32	2	24
Asthenopia	1	3	1	1		2
Asthma		1		1		
Asthmatic crisis		1				1
Asymptomatic COVID-19		3				3
Ataxia		1				1
Atelectasis		1				1
Atrial fibrillation	1	3			1	3
Axillary pain	1	5	1	5		
Back pain	5	10	5	8		2
Bacteraemia	1	1			1	1
Balance disorder		4		3		1
Bell's palsy	1	4			1	4
Biliary colic		1				1
Bladder spasm		1				1
Bladder sphincter atony		2				2
Blepharospasm		1				1
Blister		1				1
Blood pressure increased	2	9	1	7	1	2
Blood pressure systolic increased		1		1		
Body temperature decreased		1		1		
Bradycardia		2				2
Bradyphrenia		1				1
Bronchiectasis		1				1
Bronchospasm		3				3
Burning sensation		1				1
Burning sensation mucosal		1		1		
Bursitis		1				1
Cardiac tamponade	1	2			1	2
Carotid bruit		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cellulitis		1				1
Cerebellar syndrome		1				1
Cerebral venous thrombosis		1				1
Cerebrovascular accident		2				2
Cervicobrachial syndrome		1		1		
Cheilitis		2				2
Chest discomfort	1	7		1	1	6
Chest pain	1	11	1	2		9
Chills	22	56	22	48		8
Choking sensation		2		1		1
Chorioretinopathy		1				1
Claustrophobia	1	1	1	1		
Colitis ulcerative		1				1
Concomitant disease aggravated		1				1
Condition aggravated	1	6			1	6
Conjunctival haemorrhage	2	6			2	6
Constipation		2		2		
Cough	4	11	4	5		6
COVID-19	5	21		2	5	19
Craniocerebral injury		2				2
Cyanosis		1		1		
Deafness	1	1			1	1
Deafness unilateral		1				1
Decreased appetite	1	4	1	2		2
Deep vein thrombosis		4				4
Demyelination		1				1
Dental caries		1		1		
Depressed level of consciousness	2	6			2	6
Depressed mood		2		2		
Dermatitis	1	1			1	1
Dermatitis allergic	2	6	2	3		3
Dermatitis bullous		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermatitis contact		1				1
Diabetic metabolic decompensation		1				1
Diarrhoea	11	35	10	21	1	14
Diarrhoea haemorrhagic		1				1
Diplopia		5		1		4
Discomfort	3	5	3	4		1
Disease recurrence		1				1
Disorientation	1	1			1	1
Disturbance in attention		1				1
Dizziness	22	68	19	38	3	30
Dizziness postural		1		1		
Drug eruption		1		1		
Drug hypersensitivity	1	1	1	1		
Drug ineffective	2	11			2	11
Drug interaction		1				1
Dry mouth		1				1
Dry throat	1	2		1	1	1
Dysaesthesia	1	4		1	1	3
Dysarthria		1		1		
Dyschromatopsia		1				1
Dysgeusia	2	5	2	3		2
Dysphagia	1	5		1	1	4
Dysphonia		2				2
Dyspnoea	7	30	4	5	3	25
Dyspnoea at rest		1				1
Dyspnoea exertional	1	3		1	1	2
Dyssomnia	1	1	1	1		
Dysuria		1				1
Ear discomfort		1				1
Ear pain	1	1	1	1		
Eczema herpeticum		1				1
Electrocardiogram QRS complex shortened		2				2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Electrocardiogram T wave inversion		1				1
Encephalitis		2				2
Epiglottitis		1				1
Epilepsy		2				2
Epistaxis	1	1			1	1
Erythema	4	18	3	6	1	12
Erythema nodosum		1				1
Essential hypertension		1				1
Exercise tolerance decreased	1	1	1	1		
Extensive swelling of vaccinated limb		1		1		
Extensor plantar response		1		1		
Extrapyramidal disorder		1				1
Extrasystoles	1	3			1	3
Eye allergy	1	1	1	1		
Eye haemorrhage		1				1
Eyelid oedema		2		1		1
Eye pain		3		1		2
Eye pruritus		3		2		1
Face injury		1				1
Face oedema	2	4	1	1	1	3
Facial bones fracture		2				2
Facial pain		1		1		
Facial paralysis	3	10			3	10
Facial paresis		2				2
Faeces soft		1		1		
Fall		1		1		
Fatigue	27	55	23	40	4	15
Febrile convulsion		1				1
Feeling abnormal		2		1		1
Feeling cold	2	4	2	4		
Feeling hot	2	8	1	3	1	5
Fibrin D dimer increased		2				2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fibromyalgia		1				1
Flatulence	1	3	1	3		
Flushing	1	2	1	2		
Folate deficiency		1		1		
Foreign body in throat	1	1			1	1
Foreign body sensation in eyes		2		2		
Gait disturbance		3				3
Gallbladder enlargement		1				1
Gastroenteritis	1	3	1	2		1
Gastrointestinal disorder	2	2	2	2		
Gastroesophageal reflux disease		1				1
Generalised tonic-clonic seizure		1				1
General physical health deterioration		2		1		1
Genital herpes		1		1		
Giant papillary conjunctivitis		1				1
Gingival bleeding	1	2		1	1	1
Granulomatous liver disease		1				1
Groin pain	1	1	1	1		
Guillain-Barre syndrome	1	2			1	2
Haemangioma of liver	1	1	1	1		
Haematemesis	1	1			1	1
Haematoma		3		2		1
Headache	72	182	62	120	10	62
Heart rate increased		1		1		
Hemidysaesthesia		1				1
Hemiparaesthesia		3				3
Hemiparesis		2				2
Hepatic cyst		1		1		
Herpes ophthalmic		1				1
Herpes simplex		1				1
Herpes zoster	7	26	2	7	5	19
Herpes zoster oticus		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes zoster reactivation	1	2	1	1		1
Hydrocephalus	1	1			1	1
Hyperaemia		1		1		
Hyperaesthesia		2		1		1
Hyperfibrinogenaemia		1				1
Hyperglycaemia		1				1
Hyperhidrosis		3		1		2
Hypersensitivity	1	10	1	1		9
Hypersomnia	1	1	1	1		
Hypertension	5	28	3	9	2	19
Hypertensive crisis	4	15			4	15
Hyperthermia	1	1	1	1		
Hypertransaminasaemia		1		1		
Hypoacusis		3				3
Hypoaesthesia	1	7	1	1		6
Hypoaesthesia oral	1	3	1	1		2
Hypotension	4	10	1	2	3	8
Hypothermia		7				7
Hypothyroidism	1	2			1	2
Hypoxia	1	2			1	2
Ileus paralytic		1				1
Inappropriate schedule of product administration	2	4	2	4		
Incorrect route of product administration	3	5	3	5		
Induration		1		1		
Inflammation	2	8	2	5		3
Influenza		1				1
Influenza like illness	1	1	1	1		
Injury		1				1
Insomnia	2	5	1	2	1	3
Intestinal ischaemia		1				1
Intestinal obstruction		1				1
Intracranial pressure increased	1	1	1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Intraventricular haemorrhage	1	1			1	1
Iridocyclitis		1				1
Ischaemic stroke		3				3
Jaw fracture		1				1
Joint range of motion decreased		1				1
Labyrinthitis		1				1
Lacrimation increased		3		1		2
Laryngeal erythema		1				1
Laryngeal oedema		5				5
Laryngeal pain		1				1
Laryngospasm		1				1
Lip oedema		4				4
Lip pruritus		1				1
Localised oedema		1				1
Local reaction	1	3	1	2		1
Loss of consciousness	1	7			1	7
Loss of personal independence in daily activities	1	1	1	1		
Lymphadenitis	2	6	2	2		4
Lymphadenopathy	19	56	13	26	6	30
Lymphangitis		2				2
Lymph node pain	1	1			1	1
Malaise	28	80	27	62	1	18
Malnutrition		1		1		
Mass		1				1
Maternal exposure timing unspecified		1		1		
Mechanical urticaria		1				1
Menstrual disorder	2	2	2	2		
Mental impairment		2				2
Metamorphopsia	1	1	1	1		
Micturition urgency		1				1
Migraine	1	2			1	2
Migraine with aura		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mobility decreased		3				3
Monoplegia		1				1
Mouth swelling		1				1
Mouth ulceration	1	2			1	2
Movement disorder	1	2	1	1		1
Muscle contractions involuntary		1		1		
Muscle contracture		1		1		
Muscle spasms		1		1		
Muscular weakness	2	6	2	4		2
Musculoskeletal discomfort		2				2
Musculoskeletal disorder		1				1
Musculoskeletal pain	3	11	2	5	1	6
Myalgia	43	127	42	95	1	32
Myocardial infarction		1				1
Myositis		2				2
Nasal congestion		4		2		2
Nasopharyngitis	1	1	1	1		
Nausea	30	80	29	59	1	21
Neck pain	2	7	2	3		4
Nervousness	3	6	3	4		2
Neuralgia	1	1	1	1		
Neuralgic amyotrophy		2				2
Neurogenic shock		1				1
Neuropathy peripheral	1	1			1	1
Neutropenia		1				1
Night sweats		2		1		1
Noninfective gingivitis		1				1
Normochromic normocytic anaemia		1		1		
Nuchal rigidity		1				1
Ocular dysmetria		1		1		
Ocular hyperaemia	1	1			1	1
Odynophagia	4	8	2	5	2	3

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oedema	1	1	1	1		
Oedema mouth		2		1		1
Oedema peripheral	1	5		1	1	4
Off label use	2	3	2	3		
Ophthalmic herpes zoster	1	2			1	2
Optic neuritis	2	3			2	3
Oral candidiasis		1		1		
Oral dysaesthesia	1	1			1	1
Oral herpes	2	5	1	4	1	1
Oral pruritus		1				1
Oropharyngeal discomfort	1	3			1	3
Oropharyngeal oedema		3				3
Oropharyngeal pain	1	3		2	1	1
Oxygen saturation decreased		3		1		2
Pain	9	19	8	15	1	4
Pain in extremity	9	28	9	19		9
Pain in jaw		1		1		
Pain of skin	1	1	1	1		
Palatal oedema	1	3			1	3
Palatal swelling		1				1
Pallor		2		1		1
Palpitations	4	10	2	4	2	6
Panniculitis		1				1
Papilloedema	1	1	1	1		
Paraesthesia	7	34	4	10	3	24
Paraesthesia oral	3	9	1	3	2	6
Paraparesis		2				2
Partial seizures		1				1
Pericardial effusion	1	1			1	1
Pericarditis	1	4			1	4
Periorbital haematoma		1				1
Periorbital inflammation	1	1			1	1

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral coldness		2		1		1
Peripheral paralysis		1				1
Peripheral swelling		1				1
Persistent generalised lymphadenopathy		1				1
Petechiae		3				3
Pharyngeal erythema		3				3
Pharyngitis		1				1
Pharyngotonsillitis		1				1
Phlebitis		1		1		
Phlebitis superficial		1		1		
Photophobia		3		1		2
Photopsia		1		1		
Pigmentation disorder		1		1		
Pityriasis rosea		1				1
Pleuropericarditis	1	2			1	2
Pneumonia		3				3
Pneumonia aspiration		2				2
Polyarthrits		1				1
Poor peripheral circulation		1		1		
Poor quality sleep		1				1
Post herpetic neuralgia	1	1			1	1
Postmenopausal haemorrhage	2	2			2	2
Post viral fatigue syndrome		1				1
Presyncope	2	10	2	2		8
Product administered at inappropriate site	1	1	1	1		
Pruritus	6	31	4	11	2	20
Psoriasis		1				1
Pulmonary embolism	1	6			1	6
Pyrexia	94	244	88	184	6	60
Rash	3	14	2	4	1	10
Rash erythematous	1	4	1	1		3
Rash maculo-papular		2		1		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash papular	1	1	1	1		
Rash pruritic		3		1		2
Rash vesicular	1	1	1	1		
Raynaud's phenomenon		1				1
Reaction to excipient		1				1
Reaction to preservatives	1	1	1	1		
Rectal haemorrhage		1				1
Rectal tenesmus		1				1
Renal cyst		1		1		
Renal impairment	1	2			1	2
Respiratory arrest		1				1
Respiratory disorder		2				2
Respiratory distress		3				3
Respiratory failure		3				3
Restless legs syndrome	1	1	1	1		
Restlessness	2	2	2	2		
Retinal artery occlusion		1				1
Retinal artery thrombosis	1	1	1	1		
Retinal detachment	1	1	1	1		
Retinal vein thrombosis	1	1			1	1
Rhinalgia		1		1		
Rhinitis		1		1		
Rhinitis allergic	1	1	1	1		
Rhinorrhoea	1	4	1	4		
Rotator cuff syndrome	1	1	1	1		
SARS-CoV-2 ant body test negative		1		1		
Seizure	2	2			2	2
Sensation of foreign body	1	2			1	2
Sensory disturbance		1				1
Septic arthritis staphylococcal		1				1
Shoulder injury related to vaccine administration		1		1		
Sinus tachycardia		3		1		2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin disorder	1	1	1	1		
Skin lesion		1				1
Skin reaction		1				1
Skin sensitisation	1	1	1	1		
Sneezing		1		1		
Somnolence	1	3	1	1		2
Spasmodic dysphonia		1		1		
Speech disorder		1		1		
Spinal pain		1				1
Subarachnoid haemorrhage		1				1
Sudden death	1	4			1	4
Sudden visual loss		1				1
Superinfection bacterial		1				1
Supraventricular tachycardia		1				1
Swelling face	1	2	1	1		1
Swollen tongue		1				1
Syncope	1	21			1	21
Systemic inflammatory response syndrome		1				1
Systemic lupus erythematosus	1	1			1	1
Tachycardia	9	26	6	8	3	18
Temperature regulation disorder	4	13	3	10	1	3
Tendonitis		2		1		1
Tenosynovitis	1	2	1	1		1
Tension headache		2		1		1
Thalamus haemorrhage	1	1			1	1
Thirst	1	1	1	1		
Throat irritation	1	9	1	3		6
Throat tightness		1				1
Thrombophlebitis	1	2		1	1	1
Thrombophlebitis superficial	1	3			1	3
Thrombosed varicose vein	1	1	1	1		
Thyroiditis acute	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tic	1	2	1	1		1
Tinnitus	1	6		2	1	4
Tongue discomfort		1		1		
Tongue eruption		1		1		
Tongue oedema		6		1		5
Tongue pruritus		2		1		1
Tonic clonic movements		1				1
Toxic skin eruption	1	1			1	1
Tracheitis	1	1			1	1
Tracheobronchitis bacterial	1	1			1	1
Transient global amnesia		1				1
Transient ischaemic attack		2				2
Tremor	4	6	4	4		2
Type IV hypersensitivity reaction		1				1
Underdose	2	2	2	2		
Upper respiratory tract infection		1				1
Urinary retention		1				1
Urticaria	4	20	1	6	3	14
Uvulitis		1				1
Vaccination complication		2		1		1
Vaccination failure	3	5			3	5
Vaccination site cellulitis		2				2
Vaccination site discomfort	1	1	1	1		
Vaccination site erosion		1		1		
Vaccination site erythema	1	2	1	2		
Vaccination site haematoma		1		1		
Vaccination site hypersensitivity		1		1		
Vaccination site hypoaesthesia		1		1		
Vaccination site induration	3	5	3	4		1
Vaccination site inflammation	2	15	2	10		5
Vaccination site joint erythema	1	5	1	4		1
Vaccination site joint inflammation		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site joint swelling		1		1		
Vaccination site lymphadenopathy		6		3		3
Vaccination site movement impairment		1				1
Vaccination site oedema	1	2	1	1		1
Vaccination site pain	27	83	27	69		14
Vaccination site paraesthesia	2	3	1	2	1	1
Vaccination site reaction	1	2	1	1		1
Vaccination site swelling		3		2		1
Vasculitis		1				1
Vertigo		3		1		2
Viral infection	1	1	1	1		
Vision blurred	4	8	3	4	1	4
Visual acuity reduced		1				1
Visual field defect	1	1	1	1		
Visual impairment		1				1
Vitamin D deficiency		1		1		
Vitreous detachment		2				2
Vitreous floaters		1				1
Vogt-Koyanagi-Harada disease	1	1			1	1
Volvulus		1				1
Vomiting	11	38	9	23	2	15
Wheezing		2				2
White blood cell count decreased		1				1
Wound		1				1
Wrong technique in product usage process		1		1		
Yawning		1		1		
	770	2,576	595	1325	175	1251

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal distension	1	1	1	1		
Abdominal pain	4	4	2	2	2	2
Abdominal pain lower		1		1		
Abdominal pain upper	1	1			1	1
Acute aortic syndrome	1	1			1	1
Acute generalised exanthematous pustulosis		1				1
Acute kidney injury	3	4			3	4
Acute myocardial infarction	5	6			5	6
Acute respiratory failure		1				1
Agitation	1	2	1	1		1
Agranulocytosis	1	1			1	1
Alcohol poisoning		1				1
Anaemia	1	1			1	1
Anal incontinence	1	1			1	1
Anal sphincter atony		1				1
Anamnestic reaction	1	1			1	1
Anaphylactic reaction	4	4			4	4
Angioedema	1	3			1	3
Anisocytosis	1	1	1	1		
Anterograde amnesia	1	1			1	1
Antibody test abnormal		1		1		
Anuria	1	1			1	1
Anxiety	1	1			1	1
Aphasia		1				1
Arterial thrombosis	1	1			1	1
Arteriosclerosis coronary artery	1	1			1	1
Arthralgia	3	5	1	2	2	3
Arthritis	2	2			2	2
Aspiration	2	2			2	2
Asthenia	4	8		3	4	5
Asymptomatic COVID-19		1		1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Atelectasis	1	1	1	1		
Atrial fibrillation	5	5			5	5
Autoimmune thyroiditis	1	1			1	1
Axillary mass	1	1	1	1		
Back pain	1	2	1	2		
Balance disorder	3	3			3	3
Basal ganglia haematoma	1	1			1	1
Bell's palsy	3	4			3	4
Biliary colic	1	1			1	1
Blepharitis		1		1		
Blindness	1	1			1	1
Blister	1	1	1	1		
Blood chloride decreased		1		1		
Blood fibrinogen increased	2	2	2	2		
Blood glucose decreased	1	1	1	1		
Blood glucose increased	3	3	3	3		
Blood pressure decreased	2	3	1	1	1	2
Blood pressure diastolic decreased	1	1	1	1		
Blood pressure fluctuation	1	1			1	1
Blood pressure increased	2	2	1	1	1	1
Blood pressure systolic increased	1	1	1	1		
Blood sodium decreased		1		1		
Blood urea increased	3	3	3	3		
Bradycardia		1				1
Bradykinesia		1				1
Breath sounds abnormal		1				1
Bronchospasm	1	2			1	2
Cardiac arrest	1	1			1	1
Cardiac death	1	1			1	1
Cardiac failure	3	3			3	3
Cardiac failure acute		1				1
Cardiac failure congestive	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac murmur	1	1	1	1		
Cardiogenic shock	1	1			1	1
Cardio-respiratory arrest	5	6			5	6
Carotid arteriosclerosis	1	1	1	1		
Cellulitis		1				1
Cerebral haematoma		1				1
Cerebral haemorrhage	1	2			1	2
Cerebral venous sinus thrombosis	1	1			1	1
Cerebrovascular accident		1				1
Chest discomfort	1	1	1	1		
Chest pain	7	7	2	2	5	5
Chills		1				1
Cholangitis	1	1			1	1
Cholelithiasis	1	1			1	1
Chronic respiratory failure		1				1
Circumoral oedema	1	1			1	1
Coagulopathy	2	2			2	2
Colitis	1	1	1	1		
Complications of transplanted kidney	1	1			1	1
Condition aggravated	2	3			2	3
Confusional state	2	5	1	2	1	3
Conjunctival haemorrhage	1	2			1	2
Contusion	1	2		1	1	1
Coordination abnormal		1		1		
Cough		2		1		1
COVID-19	2	11	1	3	1	8
COVID-19 pneumonia	3	4			3	4
Craniocerebral injury	1	1			1	1
C-reactive protein increased	3	4	1	2	2	2
Death	1	3			1	3
Decreased appetite		1		1		
Deep vein thrombosis	14	14			14	14

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dehydration		1		1		
Depressed level of consciousness	2	5			2	5
Dermatitis	1	1			1	1
Diabetes mellitus	1	2			1	2
Diarrhoea	5	16	2	8	3	8
Discomfort	1	1			1	1
Disease recurrence	3	3			3	3
Disorientation	1	2		1	1	1
Dizziness	6	11	3	4	3	7
Dizziness postural	1	1	1	1		
Drug ineffective		1				1
Drug interaction	1	1			1	1
Dry eye	1	1	1	1		
Dry mouth	2	2	2	2		
Dysgeusia	1	1	1	1		
Dyslexia		1				1
Dyspepsia	2	2	1	1	1	1
Dysphagia	1	1			1	1
Dyspnoea	15	21	4	4	11	17
Dyspnoea exertional	1	1			1	1
Dysstasia		1		1		
Ear pain	2	2	1	1	1	1
Eczema	1	2	1	2		
Electrocardiogram abnormal	1	1			1	1
Embolic stroke	1	1			1	1
Emotional disorder	1	1			1	1
Emphysema	1	1	1	1		
Encephalitis		1				1
Encephalopathy		1				1
Epigastric discomfort	1	1			1	1
Epilepsy	1	2			1	2
Erythema	8	9	2	3	6	6

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Extensive swelling of vaccinated limb		1		1		
Eye disorder	1	1	1	1		
Eyelid disorder	1	1	1	1		
Eyelid pain	1	1			1	1
Eyelids pruritus	1	1			1	1
Eye pain	1	1			1	1
Face oedema	4	5			4	5
Facial pain	1	1	1	1		
Facial paralysis	7	7			7	7
Fall	1	7		4	1	3
Fatigue	5	8	4	4	1	4
Febrile convulsion		1				1
Feeling abnormal	2	2	2	2		
Feeling cold	1	1	1	1		
Feeling hot	3	3	1	1	2	2
Fibrin D dimer increased	3	4	1	1	2	3
Fibrinolysis abnormal	1	1			1	1
Flushing	3	3	1	1	2	2
Gait disturbance	3	4	2	2	1	2
Gait inability		1				1
Gastroenteritis	1	1			1	1
Gastrointestinal disorder		1		1		
Generalised tonic-clonic seizure	1	2			1	2
General physical health deterioration	3	3	1	1	2	2
Gingival bleeding	1	1			1	1
Gingival erythema	1	1			1	1
Gingival swelling		1				1
Gingivitis	1	1			1	1
Glomerular filtration rate decreased	1	1	1	1		
Guillain-Barre syndrome	1	1			1	1
Haematemesis	1	1			1	1
Haematoma	2	2			2	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematuria		1		1		
Haemodynamic instability	2	2			2	2
Haemoglobin decreased		1		1		
Haemorrhage intracranial	2	2			2	2
Haemorrhagic stroke	1	1			1	1
Hallucination	1	1			1	1
Headache	14	21	9	13	5	8
Head injury		1		1		
Heart rate increased	2	2	2	2		
Hemiparaesthesia		1				1
Hepatic cytolysis	1	1			1	1
Hepatic function abnormal	1	1			1	1
Hepatic lesion	1	1			1	1
Herpes ophthalmic	1	2			1	2
Herpes simplex	1	1			1	1
Herpes zoster	19	22	7	8	12	14
Herpes zoster cutaneous disseminated	1	1			1	1
Herpes zoster oticus	2	2			2	2
Hot flush		1				1
Hyperglycaemia	3	3			3	3
Hyperhidrosis	1	2			1	2
Hyperkalaemia	1	1			1	1
Hyperlactacidaemia	1	1			1	1
Hypersensitivity	2	3	1	1	1	2
Hypersensitivity vasculitis	1	1			1	1
Hypertension	7	13		1	7	12
Hypertensive crisis	7	7			7	7
Hypertransaminasaemia		1				1
Hyperventilation	1	1			1	1
Hypoaesthesia	2	3	1	2	1	1
Hypochromasia	1	1	1	1		
Hypoglycaemia	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypotension	5	8	2	3	3	5
Hypoxia	1	4			1	4
Illness	1	1	1	1		
Inappropriate schedule of product administration	1	1	1	1		
Incoherent		1				1
Incorrect dose administered		1		1		
Incorrect route of product administration	1	2	1	2		
Increased bronchial secretion		1				1
Infection		1		1		
Inflammation	1	1			1	1
Inflammatory bowel disease		1				1
Influenza like illness		1		1		
Inguinal hernia	1	1			1	1
International normalised ratio increased	2	2			2	2
Iron deficiency anaemia	1	1	1	1		
Ischaemic stroke	3	5			3	5
Jaundice	1	1	1	1		
Joint range of motion decreased	1	1	1	1		
Laryngeal oedema	1	2			1	2
Leukocytosis	2	2			2	2
Leukoencephalopathy		1				1
Ligament sprain		1		1		
Limb discomfort	1	1	1	1		
Lip oedema	1	2			1	2
Lip swelling		1				1
Loss of consciousness	2	7			2	7
Lung consolidation	1	1			1	1
Lung disorder		1				1
Lung infiltration	1	2		1	1	1
Lymphadenopathy	4	4	3	3	1	1
Lymphangitis		1				1
Lymphocyte count decreased	2	2	2	2		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphocyte percentage decreased		1		1		
Lymphopenia		1		1		
Malaise	13	20	7	11	6	9
Mastication disorder	1	1	1	1		
May-Thurner syndrome	1	1			1	1
Mean cell haemoglobin concentration decreased	1	1	1	1		
Mean cell volume decreased	1	1	1	1		
Mesenteric panniculitis	1	1			1	1
Mesenteric vein thrombosis	1	1			1	1
Metabolic acidosis	1	1			1	1
Microcytosis	1	1	1	1		
Mobility decreased		1		1		
Mouth swelling	1	1			1	1
Multiple organ dysfunction syndrome	1	2			1	2
Muscular weakness	1	3	1	2		1
Musculoskeletal disorder	1	1			1	1
Musculoskeletal pain	1	1			1	1
Musculoskeletal stiffness	1	1	1	1		
Myalgia	7	11	3	6	4	5
Myocardial ischaemia	1	1			1	1
Myocardial rupture		1				1
Myocarditis		1				1
Nasal congestion	1	2		1	1	1
Nasopharyngitis	1	1	1	1		
Nausea	8	10	6	8	2	2
Neck pain	2	2	1	1	1	1
Necrosis	1	1			1	1
Neoplasm progression	1	1	1	1		
Nervousness	1	1	1	1		
Neutrophil count decreased	1	1	1	1		
Neutrophil count increased	2	3	2	3		
Neutrophilia	1	2		1	1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neutrophil percentage increased	1	2	1	2		
Obstructive shock	1	1			1	1
Ocular icterus	1	1	1	1		
Odynophagia	1	1			1	1
Oedema	1	2		1	1	1
Oedema peripheral	3	4	2	2	1	2
Off label use	1	2	1	2		
Ophthalmic herpes zoster	3	4			3	4
Ophthalmic vein thrombosis	1	1			1	1
Oral candidiasis	1	1	1	1		
Oral discomfort	1	1			1	1
Oropharyngeal pain	2	2			2	2
Overdose		4		4		
Oxygen saturation decreased	5	8			5	8
Pain	2	5	1	2	1	3
Pain in extremity	8	8	5	5	3	3
Pain of skin	1	1	1	1		
Palatal oedema	2	2			2	2
Pallor		1				1
Palpitations	1	2		1	1	1
Paraesthesia	6	6	2	2	4	4
Pelvic venous thrombosis	1	1			1	1
Pericardial haemorrhage		1				1
Periorbital oedema	1	1			1	1
Peripheral artery thrombosis	1	1			1	1
Peripheral coldness		1				1
Peripheral ischaemia	1	2			1	2
Peripheral swelling	3	3	2	2	1	1
Petechiae		2		2		
Petit mal epilepsy	1	2			1	2
Pharyngeal inflammation	1	1			1	1
Pharyngeal oedema	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Photophobia	1	1	1	1		
Platelet count increased	1	1	1	1		
Pleural effusion	1	1	1	1		
Pleuritic pain	1	1			1	1
Pneumonia	2	7			2	7
Polyarthrits	1	1			1	1
Polydipsia	1	1			1	1
Portal vein thrombosis		1				1
Post herpetic neuralgia	2	2			2	2
Presyncope	1	1			1	1
Product preparation issue		4		4		
Product use issue		1		1		
Pruritus	5	6	1	1	4	5
Pulmonary embolism	18	18			18	18
Pulmonary haemorrhage		1				1
Pulmonary infarction	1	1			1	1
Pulmonary oedema	1	1			1	1
Pulmonary thrombosis		1				1
Pulse abnormal		1				1
Pulseless electrical activity	1	1			1	1
Purpura	1	1			1	1
Pyrexia	29	67	21	44	8	23
Rash	5	8	1	1	4	7
Rash erythematous	1	1			1	1
Renal failure		2				2
Renal impairment	2	3			2	3
Renal pain	1	1	1	1		
Respiratory alkalosis	1	1			1	1
Respiratory distress	1	2			1	2
Respiratory failure	2	2			2	2
Retinal artery occlusion	1	1			1	1
Retinal vein thrombosis	1	2			1	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rhinorrhoea		1		1		
Right ventricular dilatation	1	1			1	1
Right ventricular dysfunction	1	1			1	1
Salivary hypersecretion		1				1
Seizure	1	5			1	5
Sensation of foreign body		1				1
Sensory disturbance	1	1	1	1		
Sepsis	1	1			1	1
Silent thyroiditis		1				1
Sinus bradycardia	2	2	1	1	1	1
Sinus tachycardia		1				1
Skin lesion	1	1	1	1		
Skin necrosis		1				1
Skin reaction	1	2	1	1		1
Skin swelling	1	1	1	1		
Slow speech		1				1
Somnolence		1		1		
Speech disorder	1	1			1	1
Status epilepticus	1	2			1	2
Subdural haematoma	1	1			1	1
Sudden cardiac death		1				1
Sudden death	5	7			5	7
Supraventricular tachycardia	1	1			1	1
Swelling	2	2	2	2		
Swelling face	1	1	1	1		
Syncope	6	15			6	15
Systemic inflammatory response syndrome	1	1			1	1
Systolic dysfunction	1	1			1	1
Tachycardia	1	1			1	1
Tachypnoea		1				1
Temperature regulation disorder	1	1	1	1		
Tension headache		1		1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Throat irritation	2	2			2	2
Thrombocytopenia	5	6			5	6
Thrombophlebitis	4	5			4	5
Thrombophlebitis superficial	3	3			3	3
Thrombosis	1	1			1	1
Tongue coated		1				1
Tongue disorder	1	1	1	1		
Tongue injury	1	1			1	1
Tongue oedema	2	2			2	2
Tongue ulceration	1	1	1	1		
Transient global amnesia	2	2			2	2
Tremor	1	2	1	1		1
Troponin I increased	1	1			1	1
Urinary sediment present		1		1		
Urinary tract infection		3				3
Urticaria	2	5		1	2	4
Uvulitis	1	1			1	1
Vaccination failure	1	2			1	2
Vaccination site erythema	1	1			1	1
Vaccination site inflammation	1	3		2	1	1
Vaccination site joint erythema		2		1		1
Vaccination site joint movement impairment	1	1	1	1		
Vaccination site lymphadenopathy		1		1		
Vaccination site pain	7	14	5	11	2	3
Vaccination site pruritus	1	1			1	1
Vaccination site rash		1		1		
Vaccination site reaction	1	1	1	1		
Vaccination site warmth	1	1	1	1		
Vasoplegia syndrome	1	1			1	1
Venous haemorrhage	1	1			1	1
Venous thrombosis limb	1	2			1	2
Ventricular f brillation	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ventricular tachycardia	1	1			1	1
Vertigo	3	3	1	1	2	2
Vision blurred	1	2			1	2
Visual field defect	1	1	1	1		
Visual impairment	1	1			1	1
Vitamin D deficiency	1	1	1	1		
Vomiting	10	18	5	9	5	9
Weight bearing difficulty	1	1			1	1
White blood cell count increased	3	4	3	4		
Yellow fever	1	1			1	1
	653	993	209	339	444	654

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	3		1	1	2
Abdominal distension	1	1			1	1
Abdominal pain	3	7	1	3	2	4
Abdominal pain lower	1	1	1	1		
Abdominal pain upper	1	2			1	2
Abdominal wall haematoma	1	1			1	1
Abnormal behaviour	1	1			1	1
Activated partial thromboplastin time prolonged		1				1
Activated partial thromboplastin time shortened		1		1		
Acute coronary syndrome	1	2			1	2
Acute hepatic failure		1				1
Acute kidney injury	1	5			1	5
Acute leukaemia		1				1
Acute myocardial infarction	6	9			6	9
Acute psychosis		1				1
Acute pulmonary oedema	1	2			1	2
Acute respiratory distress syndrome		1				1
Acute respiratory failure	4	15			4	15
Ageusia		1				1
Agitation	1	4			1	4
Alanine aminotransferase increased	1	1	1	1		
Altered state of consciousness	1	1			1	1
Amnesia		3		3		
Amyloidosis senile	1	1			1	1
Anaemia	4	6	3	3	1	3
Anal incontinence	1	3	1	2		1
Anaphylactic reaction		6				6
Angina pectoris	1	1			1	1
Angioedema		4				4
Angular cheilitis		1		1		
Anxiety		1				1
Aortic aneurysm	1	1			1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic arteriosclerosis	3	3	2	2	1	1
Aortic elongation	1	1	1	1		
Aortic stenosis	1	1			1	1
Aortic valve calcification		1				1
Aortic valve incompetence	1	1			1	1
Apallic syndrome	1	1			1	1
Apathy		1				1
Aphasia	4	8	1	2	3	6
Aphonia	1	1			1	1
Apnoea		1				1
Arrhythmia	1	3			1	3
Arteriosclerosis	3	3			3	3
Arthralgia	5	10	1	4	4	6
Aspiration	4	5			4	5
AST/ALT ratio abnormal	2	2	2	2		
Asthenia	8	23	6	13	2	10
Asthenopia		1				1
Asymptomatic bacteriuria	1	1			1	1
Asymptomatic COVID-19	6	17		3	6	14
Atelectasis		1				1
Atrial f brillation	10	20			10	20
Atrioventricular block first degree		1		1		
Autoantibody negative		1				1
Autoimmune haemolytic anaemia		1				1
Autoimmune hepatitis		1				1
Axillary vein thrombosis	1	1			1	1
Back pain	1	2	1	2		
Bacteraemia		1				1
Bacterial disease carrier		1				1
Bacterial test		1				1
Bacteriuria	2	2	2	2		
Balance disorder		4		2		2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Basal cell carcinoma	1	1			1	1
Basal ganglia stroke	1	2			1	2
Basilar artery thrombosis		1				1
Bedridden		1				1
Bell's palsy	4	4			4	4
Bile duct stone	1	1			1	1
Biliary cyst		1		1		
Biliary sepsis	1	1			1	1
Blister		1		1		
Blood bicarbonate decreased		1				1
Blood chloride increased	1	1	1	1		
Blood cholesterol decreased	1	1	1	1		
Blood creatine phosphokinase increased	1	1			1	1
Blood creatinine decreased	2	2	2	2		
Blood creatinine increased	1	2	1	2		
Blood fibrinogen increased	6	7	5	6	1	1
Blood gases abnormal		1				1
Blood glucose increased	5	6	3	4	2	2
Blood lactate dehydrogenase increased	1	2	1	1		1
Blood lactic acid increased	2	2	2	2		
Blood parathyroid hormone increased	1	1	1	1		
Blood phosphorus increased	1	1			1	1
Blood potassium decreased	1	1	1	1		
Blood pressure abnormal		1				1
Blood pressure decreased	1	1			1	1
Blood pressure diastolic decreased	1	2	1	1		1
Blood pressure increased	5	6	3	4	2	2
Blood pressure systolic increased	2	2	1	1	1	1
Blood sodium increased	1	1	1	1		
Blood thyroid stimulating hormone increased		1		1		
Blood urea increased	4	5	4	4		1
Body temperature decreased	3	4	3	3		1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Body temperature increased	1	1			1	1
Bone disorder	1	1	1	1		
Bradycardia	1	4			1	4
Bradyphrenia		3		2		1
Breast haematoma		1				1
Bronchial hyperreactivity		1				1
Bronchitis		1				1
Bronchitis chronic	1	1	1	1		
Bronchospasm		6				6
Bulbar palsy	1	1			1	1
Bundle branch block left	1	2	1	1		1
Bundle branch block right	1	1			1	1
Cachexia		1				1
Capillary fragility	1	1	1	1		
Cardiac amyloidosis	1	1			1	1
Cardiac arrest	2	6			2	6
Cardiac disorder		2		1		1
Cardiac failure	5	21			5	21
Cardiac failure acute	3	8			3	8
Cardiac failure congestive	2	5			2	5
Cardiac murmur	1	1	1	1		
Cardiomegaly	3	6	2	2	1	4
Cardio-respiratory arrest	6	17			6	17
Cardio-respiratory distress		1				1
Cardiothoracic ratio increased		1				1
Cardiovascular disorder	1	1	1	1		
Cell death		1				1
Cellulitis	3	5			3	5
Cellulitis staphylococcal		1				1
Cephalhaematoma		1				1
Cerebellar infarction		1				1
Cerebellar stroke	1	1			1	1

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral arteriosclerosis	1	1			1	1
Cerebral artery embolism	1	1			1	1
Cerebral haematoma	1	3			1	3
Cerebral haemorrhage	1	5			1	5
Cerebral infarction	1	3			1	3
Cerebral ischaemia	1	1			1	1
Cerebral small vessel ischaemic disease	1	1			1	1
Cerebral thrombosis	1	1			1	1
Cerebral venous sinus thrombosis		1				1
Cerebrovascular accident	6	11			6	11
Cerebrovascular disorder		1				1
Chest discomfort	1	2			1	2
Chest injury		1				1
Chest pain	5	8	3	3	2	5
Chest X-ray abnormal	1	1	1	1		
Chills	1	6		1	1	5
Choking		1				1
Choking sensation	1	1			1	1
Cholecystitis	1	1			1	1
Cholestasis		1				1
Chronic kidney disease	1	3			1	3
Chronic obstructive pulmonary disease	2	3	1	1	1	2
Chronic respiratory failure		1				1
Circadian rhythm sleep disorder		1				1
Circulatory collapse		1				1
Circumoral swelling	1	1			1	1
Clostridium difficile colitis		1				1
Clostridium test positive	1	1			1	1
Cognitive disorder	3	7	1	2	2	5
Cold sweat	1	1			1	1
Colitis ischaemic	2	2			2	2
Colon neoplasm		1				1

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coma	1	1			1	1
Coma scale abnormal	1	1			1	1
Condition aggravated	7	10			7	10
Confusional state	5	15	3	6	2	9
Conjunctival haemorrhage		1				1
Conjunctival hyperaemia		1				1
Constipation	1	6	1	3		3
Coombs positive haemolytic anaemia		1				1
Coordination abnormal	1	2			1	2
Coronary artery stenosis	1	1			1	1
Cough	4	11	2	5	2	6
COVID-19	6	29	1	9	5	20
COVID-19 pneumonia	2	13			2	13
Craniocerebral injury	2	4			2	4
C-reactive protein increased	3	5	2	4	1	1
Crying	1	1	1	1		
CSF protein increased	1	1			1	1
Cutaneous vasculitis		1				1
Cyanosis		4		1		3
Deafness	1	1			1	1
Death	2	6			2	6
Decreased appetite	4	8	2	4	2	4
Decubitus ulcer	1	1	1	1		
Deep vein thrombosis	16	26			16	26
Dehydration	2	3	1	2	1	1
Delayed ischaemic neurological deficit	1	1			1	1
Delirium		3				3
Delusion		1				1
Depressed level of consciousness		9				9
Depressed mood		2		2		
Dermatitis allergic	1	2			1	2
Dermatitis bullous		1				1

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diabetes mellitus	1	1			1	1
Diabetes mellitus inadequate control	1	1			1	1
Diarrhoea	10	37	8	25	2	12
Diarrhoea haemorrhagic	1	1			1	1
Dilatation atrial		1				1
Dilatation ventricular	1	2			1	2
Diplopia	2	2			2	2
Discomfort	1	5		1	1	4
Disease recurrence	4	7			4	7
Disorientation	5	17	3	7	2	10
Diverticulitis intestinal haemorrhagic	1	1			1	1
Dizziness	14	24	8	13	6	11
Drug ineffective	6	19			6	19
Drug interaction		1		1		
Dry mouth		1				1
Duodenal ulcer haemorrhage		1				1
Dysarthria	6	11	4	6	2	5
Dyskinesia		1				1
Dyspepsia		1				1
Dysphagia	3	7	2	3	1	4
Dyspnoea	17	44	4	7	13	37
Dyspnoea at rest	1	1			1	1
Dyspnoea exertional		2		2		
Dyspnoea paroxysmal nocturnal	1	1			1	1
Dysstasia	1	1	1	1		
Dysuria	1	3	1	2		1
Ear pain		1				1
Eating disorder		1		1		
Ecchymosis	1	1	1	1		
Echolalia	1	1	1	1		
Electrocardiogram normal		1				1
Electrocardiogram QRS complex prolonged		1				1

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Electrocardiogram repolarisation abnormality		1				1
Electrocardiogram ST-T change		1				1
Electrolyte imbalance		1				1
Embolic stroke	3	5			3	5
Embolism venous	1	1			1	1
Encephalitis	1	1			1	1
Endocarditis	1	1			1	1
Enterococcal infection	1	2			1	2
Eosinophil count increased	1	1	1	1		
Epidermal necrosis		1				1
Epilepsy	1	1			1	1
Epistaxis	2	4			2	4
Erythema	3	7	3	7		
Escherichia bacteraemia	1	1			1	1
Escherichia infection		2				2
Escherichia urinary tract infection	1	1			1	1
Euphoric mood		2		1		1
Eyelid oedema		2				2
Eyelid ptosis	1	1	1	1		
Face oedema		2				2
Facial paralysis	4	9			4	9
Facial paresis	1	1	1	1		
Faecal vomiting	1	1			1	1
Faeces soft		1		1		
Fall	7	15	2	4	5	11
Fatigue	13	18	8	11	5	7
Febrile convulsion		1				1
Feeling abnormal	1	2	1	2		
Feeling cold		1				1
Feeling hot		3		3		
Femur fracture		1				1
Fibrin D dimer increased	3	6	1	2	2	4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fibrinolysis		1				1
Fluid overload		1				1
Flushing	1	2	1	1		1
Focal dyscognitive seizures	1	1			1	1
Fumbling	1	1			1	1
Gait disturbance	6	9	5	5	1	4
Gait inability		4		2		2
Gamma-glutamyltransferase increased		1		1		
Gastric disorder		1				1
Gastritis		1				1
Gastrointestinal haemorrhage	1	4			1	4
Gaze palsy		1				1
Generalised oedema	1	1	1	1		
Generalised tonic-clonic seizure	4	8			4	8
General physical health deterioration	4	8	2	4	2	4
Genital blister		1		1		
Giant cell arteritis		1				1
Glomerular filtration rate decreased	2	3	1	2	1	1
Glycosylated haemoglobin increased	1	1	1	1		
Goitre	2	2	1	1	1	1
Granulomatous liver disease	1	1			1	1
Guillain-Barre syndrome	1	5			1	5
Haemangioma	1	1	1	1		
Haematocrit decreased	4	5	4	5		
Haematoma	3	7	2	4	1	3
Haematoma muscle	2	5			2	5
Haematuria	2	4	1	1	1	3
Haemoglobin decreased	2	4	1	2	1	2
Haemoptysis		1				1
Haemorrhage	1	2			1	2
Haemorrhage intracranial		1				1
Haemorrhagic stroke		2				2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemorrhagic transformation stroke	1	1			1	1
Hallucination	2	4			2	4
Hallucination, auditory		1				1
Hallucinations, mixed		1				1
Hallucination, visual	1	2			1	2
Headache	9	23	6	14	3	9
Head discomfort		1				1
Head injury		1				1
Heart rate abnormal	1	1			1	1
Heart rate decreased		1				1
Hemianaesthesia	1	1			1	1
Hemihyperaesthesia		1				1
Hemiparaesthesia	1	1			1	1
Hemiparesis	2	4			2	4
Hemiplegia	1	3			1	3
Hepatic cyst	1	2	1	2		
Hepatic steatosis		1				1
Hepatitis acute		2				2
Hepatitis cholestatic		1				1
Herpes zoster	9	20	1	2	8	18
Herpes zoster cutaneous disseminated	1	3			1	3
Hiatus hernia	1	4	1	2		2
Hilar lymphadenopathy	1	1	1	1		
Humerus fracture	1	1			1	1
Hypercapnic coma	1	1			1	1
Hypercholesterolaemia		1		1		
Hyperglycaemia	2	5	1	1	1	4
Hyperhidrosis	4	6	2	4	2	2
Hyperkalaemia		1				1
Hypernatraemia		3		1		2
Hypersensitivity		2		1		1
Hypersensitivity vasculitis		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypersexuality		1				1
Hypertension	6	9			6	9
Hypertensive crisis	2	7			2	7
Hypertensive emergency		1				1
Hypertensive encephalopathy		1				1
Hypertensive urgency		2				2
Hypertrophic cardiomyopathy	1	1			1	1
Hyperuricaemia	1	1	1	1		
Hypoacusis	1	2	1	1		1
Hypoaesthesia	1	2			1	2
Hypoaesthesia eye		1				1
Hypocalcaemia	1	1	1	1		
Hypochromic anaemia	1	1			1	1
Hypokalaemia	1	2			1	2
Hypomagnesaemia	1	1			1	1
Hyponatraemia	1	4			1	4
Hypophagia	1	1	1	1		
Hypoproteinaemia	1	1	1	1		
Hyporesponsive to stimuli		1				1
Hypotension	4	14	1	4	3	10
Hypoventilation	2	2			2	2
Hypovolaemic shock		1				1
Hypoxia	2	10			2	10
Ileus paralytic	1	2			1	2
III-defined disorder		1				1
Illness	1	1	1	1		
Immobilisation syndrome		1		1		
Immune system disorder		1				1
Immune thrombocytopenia	5	7			5	7
Inappropriate schedule of product administration		2		2		
Incoherent	1	2	1	1		1
Incorrect dose administered	1	3	1	3		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Incorrect route of product administration	1	3	1	3		
Induration	1	1	1	1		
Infection		1				1
Infective exacerbation of bronchiectasis		1				1
Inflammation	1	1			1	1
Inflammatory bowel disease		1				1
Injury	1	2		1	1	1
Insomnia		1				1
International normalised ratio increased	4	4	2	2	2	2
Interstitial lung disease	1	2			1	2
Intestinal angina	1	1			1	1
Intestinal ischaemia	1	2			1	2
Intestinal obstruction	1	3			1	3
Iron deficiency	1	1	1	1		
Iron deficiency anaemia	1	1			1	1
Ischaemia	2	3	1	1	1	2
Ischaemic cerebral infarction		1				1
Ischaemic stroke	8	21			8	21
Joint dislocation	1	1	1	1		
Joint injury	1	2			1	2
Jugular vein thrombosis	1	1			1	1
Kaposi's sarcoma AIDS related		1				1
Keratitis		1				1
Lacunar infarction	1	1			1	1
Lacunar stroke		1				1
Large intestine infection		1				1
Laryngospasm		1		1		
Left ventricular failure	1	1			1	1
Lethargy		1				1
Leukoencephalopathy	1	1			1	1
Limb discomfort		1		1		
Lip oedema		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Liver function test abnormal		1				1
Localised infection		1				1
Localised oedema		1				1
Loss of consciousness	4	7			4	7
Lower respiratory tract infection		1				1
Lung disorder		1				1
Lung infiltration	1	3	1	2		1
Lymphadenopathy mediastinal	2	2	1	1	1	1
Lymphocyte count decreased	3	4	3	4		
Lymphocyte count increased	1	1	1	1		
Lymphopenia	1	1	1	1		
Malaise	17	46	9	22	8	24
Malnutrition	1	1	1	1		
Mean cell haemoglobin concentration decreased	1	2	1	2		
Mean platelet volume increased	1	1	1	1		
Melaena	1	4			1	4
Memory impairment	1	1	1	1		
Meningitis aseptic	1	1			1	1
Meningitis herpes		1				1
Meningoencephalitis herpetic	1	1			1	1
Mental disorder		1				1
Mental impairment	1	2			1	2
Mesenteric artery thrombosis	1	1			1	1
Mesenteric vein thrombosis	1	1			1	1
Microangiopathy	1	1	1	1		
Micturition urgency		1				1
Miosis		1				1
Mitral valve calcification	1	1			1	1
Mitral valve incompetence	1	1			1	1
Mitral valve stenosis	1	1			1	1
Mobility decreased		3		1		2
Mononeuritis	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Monoparesis	1	1			1	1
Mood altered		1				1
Morganella infection		1				1
Motor dysfunction	1	1			1	1
Mouth haemorrhage	1	1			1	1
Movement disorder	1	1	1	1		
Multiple organ dysfunction syndrome	1	4			1	4
Muscle contractions involuntary		1		1		
Muscle rigidity		1				1
Muscle spasms		1				1
Muscle strain	1	1			1	1
Muscular weakness	3	3	3	3		
Musculoskeletal chest pain	1	1			1	1
Musculoskeletal pain	3	5	2	2	1	3
Musculoskeletal stiffness	1	1	1	1		
Mutism	1	1			1	1
Myalgia	5	11	3	5	2	6
Myocardial infarction		1				1
Myocardial ischaemia		1				1
Myositis		1				1
Nasal herpes		1				1
Nausea	6	12	5	8	1	4
Neck pain	2	3	1	1	1	2
Necrosis		1				1
Neoplasm		2		1		1
Nephrotic syndrome	1	1			1	1
Nervous system disorder	1	3	1	1		2
Neuralgia		1		1		
Neuralgic amyotrophy		1				1
Neutropenia	1	1			1	1
Neutrophil count decreased	1	1			1	1
Neutrophil count increased	4	6	4	6		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neutrophilia		1				1
Nocturia	1	1	1	1		
N-terminal prohormone brain natriuretic peptide increased	1	2	1	1		1
Odynophagia		2				2
Oedema	1	1	1	1		
Oedema peripheral	5	10	3	5	2	5
Off label use		3		3		
Ophthalmic herpes zoster	1	1			1	1
Oral disorder		1				1
Oral mucosal blistering	1	2		1	1	1
Oropharyngeal discomfort		1		1		
Oropharyngeal pain		1				1
Orthopnoea	2	3	1	1	1	2
Overdose		2		2		
Oxygen saturation decreased	4	12	2	2	2	10
Pain	4	7	2	2	2	5
Pain in extremity	6	9	4	6	2	3
Pallor	2	3	1	1	1	2
Palpitations	1	2			1	2
Pancreatitis chronic		1				1
Pancytopenia	2	3			2	3
Panniculitis	1	1			1	1
Paraesthesia	3	4	2	2	1	2
Paraesthesia oral		1				1
Paroxysmal atrioventricular block	1	1			1	1
Partial seizures		1				1
Partial seizures with secondary generalisation	1	1			1	1
Patella fracture		1				1
PCO2 decreased		1		1		
PCO2 increased	2	2	2	2		
Penile discomfort		1		1		

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			Nonserious		Serious	
			I	C	I	C
Pericarditis	1	1			1	1
Periorbital haematoma	1	1	1	1		
Peripheral coldness		2		2		
Peripheral embolism		1				1
Peripheral ischaemia	2	3	1	1	1	2
Peripheral swelling	2	4		2	2	2
Peripheral vascular disorder	1	1			1	1
Peripheral venous disease	2	2	1	1	1	1
Persistent depressive disorder	2	2	1	1	1	1
Petechiae	2	3			2	3
Petit mal epilepsy		3				3
Platelet count decreased	7	8	6	6	1	2
Platelet count increased		1		1		
Pleural effusion	3	7			3	7
Pleuritic pain		1		1		
Pleuropericarditis	1	1			1	1
Pneumonia	1	7			1	7
Pneumonia aspiration	2	4			2	4
Pneumonitis		1				1
Pneumothorax		1				1
PO2 decreased	1	3	1	3		
Pollakiuria		1				1
Polyuria	1	2			1	2
Poor quality product administered		5		5		
Portosplenomesenteric venous thrombosis	1	1			1	1
Positron emission tomogram		1				1
Postmenopausal haemorrhage	1	1			1	1
Post-traumatic stress disorder	1	1			1	1
Prerenal failure		1				1
Presyncope	1	3		1	1	2
Procalcitonin increased	1	1			1	1
Productive cough	1	2	1	2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product preparation error		5		5		
Product use issue		1		1		
Prothrombin level decreased		1				1
Prothrombin level increased	1	1			1	1
Prothrombin time prolonged		3		2		1
Prothrombin time shortened	3	3	3	3		
Pruritus	5	9	3	3	2	6
Pseudomonal bacteraemia	1	1			1	1
Psychomotor hyperactivity	1	3		1	1	2
Pulmonary embolism	25	52			25	52
Pulmonary hypertension	1	3			1	3
Pulmonary infarction	1	3			1	3
Pulmonary oedema	1	1			1	1
Pulmonary sepsis		1				1
Pulmonary thrombosis		2				2
Pupils unequal	1	1	1	1		
Purpura	1	1			1	1
Pyrexia	33	120	23	76	10	44
Rales		1				1
Rash	1	6		2	1	4
Rash maculo-papular	1	2			1	2
Rash pruritic	1	2			1	2
Rectal haemorrhage	2	5			2	5
Red blood cell sedimentation rate increased		1		1		
Red cell distribution width increased	1	1	1	1		
Renal cyst	1	2	1	2		
Renal failure	1	4			1	4
Renal impairment	1	2			1	2
Respiration abnormal		1				1
Respiratory acidosis	1	3			1	3
Respiratory alkalosis	1	1			1	1
Respiratory disorder		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory distress	3	9			3	9
Respiratory failure	4	11			4	11
Respiratory fatigue	1	1			1	1
Respiratory tract infection	2	8			2	8
Restlessness		4		2		2
Restrictive cardiomyopathy	1	1			1	1
Retinal artery occlusion		1				1
Rhinitis	1	5	1	5		
Rhonchi	3	3	2	2	1	1
Rib fracture	2	3			2	3
Right ventricular failure	1	1			1	1
Right ventricular hypertrophy	1	1			1	1
SARS-CoV-2 test positive	1	4		3	1	1
Scab		1		1		
Scoliosis		1				1
Seizure	2	6			2	6
Sensory loss	1	1			1	1
Sepsis	1	3			1	3
Septic shock		2				2
Serratia infection	1	1			1	1
Serum ferritin increased	1	1	1	1		
Severe acute respiratory syndrome		1				1
Shock	1	1			1	1
Sinus arrest		1				1
Skin lesion	2	2	2	2		
Skin necrosis		1				1
Skin ulcer	1	5		3	1	2
SLE arthritis		1				1
Slow response to stimuli	1	1	1	1		
Slow speech		1		1		
Sneezing	1	2		1	1	1
Somnolence	2	6	1	3	1	3

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* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Speech disorder	2	3	1	1	1	2
Spinal osteoarthritis		1				1
Staphylococcal infection		1				1
Status epilepticus	2	2			2	2
Stevens-Johnson syndrome	1	1			1	1
Stupor		1				1
Subarachnoid haemorrhage	3	3			3	3
Subclavian vein thrombosis	1	1			1	1
Subcutaneous haematoma		1				1
Sudden death	4	16			4	16
Suicide attempt		1				1
Superinfection	1	1	1	1		
Superior sagittal sinus thrombosis	1	1			1	1
Swelling face	2	2	1	1	1	1
Swollen tongue		1				1
Syncope	5	13			5	13
Systolic dysfunction	1	1			1	1
Tachyarrhythmia		1				1
Tachycardia		5		2		3
Tachypnoea	5	9	3	5	2	4
Thalamic infarction		1				1
Therapeutic response unexpected	1	1	1	1		
Thrombocytopenia	7	12			7	12
Thrombophlebitis	2	3			2	3
Thrombophlebitis septic	1	1			1	1
Thrombophlebitis superficial	1	2			1	2
Thrombosis	1	3			1	3
Thrombosis mesenteric vessel	1	1			1	1
Thrombotic microangiopathy		1				1
Thrombotic thrombocytopenic purpura		1				1
Thyroxine decreased		1		1		
Tongue oedema	1	1			1	1

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Toxic skin eruption	1	2			1	2
Transient global amnesia	1	1			1	1
Transient ischaemic attack	3	8			3	8
Tremor	1	2		1	1	1
Tricuspid valve incompetence		1				1
Troponin I increased		1				1
Troponin T increased	1	3	1	1		2
Ulcer	1	1	1	1		
Upper gastrointestinal haemorrhage		1				1
Upper limb fracture		2		1		1
Urinary incontinence	1	2	1	2		
Urinary retention		1				1
Urinary tract infection	4	10	1	2	3	8
Urinary tract infection pseudomonal		1				1
Urosepsis		1				1
Urticaria	1	7		4	1	3
Vaccination complication	1	2			1	2
Vaccination failure	5	18			5	18
Vaccination site cellulitis	1	1			1	1
Vaccination site erythema	2	6	1	5	1	1
Vaccination site haematoma	1	2	1	1		1
Vaccination site hypoaesthesia		1				1
Vaccination site induration	3	5	2	4	1	1
Vaccination site inflammation	1	6		5	1	1
Vaccination site joint erythema		2		2		
Vaccination site lymphadenopathy	1	1			1	1
Vaccination site oedema	1	1			1	1
Vaccination site pain	7	13	5	11	2	2
Vaccination site rash		1				1
Vaccination site swelling		1		1		
Vaccination site warmth	1	3	1	3		
Vascular graft thrombosis	1	1			1	1

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* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vasoplegia syndrome		1				1
Venous pressure	1	1	1	1		
Venous thrombosis limb	3	6			3	6
Ventricular dysfunction	1	2	1	1		1
Ventricular enlargement		1				1
Ventricular fibrillation		1				1
Ventricular hypokinesia	1	1			1	1
Vertigo		1				1
Viral keratouveitis		1				1
Vision blurred	1	2			1	2
Visual impairment		1				1
Vitamin D deficiency	1	1	1	1		
Vomiting	14	42	10	25	4	17
Vulvovaginal candidiasis	1	1	1	1		
Walking disability	1	1			1	1
Wheezing		3		3		
White blood cell count decreased	1	1			1	1
White blood cell count increased	6	7	6	7		
White matter lesion	1	1			1	1
Wound	2	2	1	1	1	1
X-ray abnormal		1				1
Yersinia bacteraemia	1	1			1	1
Yersinia infection	1	1			1	1
	936	2,205	339	689	597	1516

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain	2	2	2	2		
Abdominal pain upper		1				1
Accidental overdose	1	1	1	1		
Allergic oedema		1				1
Allergic reaction to excipient	1	1			1	1
Amenorrhoea	1	1	1	1		
Anxiety	2	2	2	2		
Aphonia		1				1
Arthralgia	4	17	4	15		2
Arthritis reactive		1				1
Asthenia	7	10	7	7		3
Asymptomatic COVID-19		2				2
Axillary pain	2	2	2	2		
Back pain	2	3	2	3		
Blood pressure abnormal		1		1		
Blood pressure decreased	1	1			1	1
Blood pressure increased	2	3	1	1	1	2
Bradyphrenia	1	1	1	1		
Bronchitis	1	1	1	1		
Bruxism		1		1		
Burning sensation	1	1			1	1
Cardio-respiratory arrest	1	1			1	1
Carotid bruit		1				1
Cellulitis		1				1
Central nervous system lesion	1	1			1	1
Cerebellar ataxia	1	1	1	1		
Cerebrovascular accident		1				1
Chest discomfort	1	3	1	3		
Chest pain		3				3
Chills	10	16	8	14	2	2
Condition aggravated	1	1	1	1		

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Confusional state		1				1
Conjunctival haemorrhage		1				1
Cough	2	4	2	2		2
COVID-19	3	22		5	3	17
Device related thrombosis	1	1			1	1
Diabetes mellitus		1				1
Diabetic ketoacidosis		1				1
Diarrhoea	4	11	3	8	1	3
Discomfort		2		2		
Disease recurrence		1				1
Dizziness	8	17	7	12	1	5
Dizziness postural	1	1	1	1		
Drowning	1	1			1	1
Drug effective for unapproved indication	1	1	1	1		
Drug ineffective	4	20			4	20
Dry mouth		1				1
Dysgeusia	2	3	2	3		
Dysphagia	1	1	1	1		
Dysphonia		1				1
Dyspnoea	1	7	1	2		5
Ear discomfort	1	1			1	1
Epistaxis		2		1		1
Erythema	1	2			1	2
Exposure during pregnancy	2	3	2	3		
Exposure via breast milk	3	6	3	6		
Extensive swelling of vaccinated limb		1		1		
Extrasystoles	1	1	1	1		
Eyelid oedema		1				1
Eye swelling	1	1			1	1
Face oedema	1	1			1	1
Facial paralysis	1	3			1	3
Fatigue	20	35	19	28	1	7

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fear	1	1	1	1		
Feeling abnormal		1		1		
Feeling cold	1	1	1	1		
Feeling hot	1	3	1	3		
Foetal heart rate abnormal		1				1
Food allergy		1				1
Gastric disorder		1		1		
Gastritis		1		1		
Gastroenteritis		1		1		
Gingival bleeding		1				1
Gingivitis		1		1		
Headache	31	56	29	50	2	6
Heart rate increased		1		1		
Hemiparaesthesia		1				1
Herpes zoster	1	1			1	1
Hyperhidrosis		1				1
Hypersensitivity	2	5		1	2	4
Hypertension		4		1		3
Hypertensive crisis		1				1
Hypoaesthesia	4	6	4	6		
Hypoaesthesia oral	2	3	2	3		
Hypotension	1	1			1	1
Hypothermia	1	1			1	1
Inappropriate schedule of product administration	3	6	3	6		
Incorrect dose administered	2	2	2	2		
Inflammation		1		1		
Influenza		1		1		
Influenza like illness	1	2	1	2		
Injection site joint erythema	1	1	1	1		
Injection site pain	1	1	1	1		
Insomnia	1	2	1	2		
Intermenstrual bleeding	1	1	1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Jaw disorder		1		1		
Limb immobilisation	3	3	3	3		
Loss of consciousness		1				1
Lymphadenitis	1	2	1	1		1
Lymphadenopathy	9	13	9	11		2
Malaise	16	28	15	25	1	3
Maternal exposure during pregnancy	4	7	4	6		1
Medication error		1		1		
Menstrual disorder	1	1	1	1		
Monoplegia	1	1			1	1
Muscle contracture		1		1		
Muscle spasms		1		1		
Muscle tightness		1		1		
Muscular weakness		1				1
Musculoskeletal pain	2	4	2	3		1
Myalgia	13	28	13	23		5
Myoclonus		1				1
Nasal congestion	1	3	1	3		
Nasopharyngitis	1	2	1	2		
Nausea	8	12	7	10	1	2
Nervousness	2	2	2	2		
No adverse event		1		1		
Oedema peripheral	1	2			1	2
Off label use	7	9	7	9		
Oral discomfort		1		1		
Oropharyngeal pain	1	1	1	1		
Pain	2	2	1	1	1	1
Pain in extremity	6	9	6	9		
Palpitations		3				3
Panic reaction		1				1
Paraesthesia	8	15	6	9	2	6
Paraesthesia oral	1	2	1	2		

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral coldness	1	1	1	1		
Peripheral sensory neuropathy		1				1
Peripheral swelling		1		1		
Pertussis		2				2
Petechiae	1	1	1	1		
Photophobia	1	1			1	1
Pleuritic pain		1				1
Pneumonia bacterial	1	1			1	1
Poor peripheral circulation	1	1	1	1		
Poor quality product administered	1	1	1	1		
Presyncope		1				1
Product administration interrupted	1	1	1	1		
Product preparation issue	1	1	1	1		
Product use issue	4	7	4	7		
Pruritus	2	5	1	2	1	3
Pulmonary embolism		1				1
Pulmonary thrombosis	1	1			1	1
Pyrexia	33	57	31	47	2	10
Rash	2	6	1	3	1	3
Rash macular		1				1
Rash pruritic		1				1
Respiratory arrest		1				1
Respiratory distress	1	2			1	2
Restless legs syndrome	1	1	1	1		
Rhinorrhoea	1	1	1	1		
SARS-CoV-2 ant body test negative		1		1		
SARS-CoV-2 ant body test positive		2		2		
SARS-CoV-2 test positive		2		2		
Sense of oppression		1				1
Serology negative		1		1		
Skin lesion		1		1		
Skin tightness	1	1	1	1		

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sleep attacks	1	1	1	1		
Somnolence	3	4	2	3	1	1
Speech disorder		1				1
Stomatitis		1		1		
Suspected COVID-19	1	2			1	2
Swelling	4	4	3	3	1	1
Swollen tongue	1	1			1	1
Syncope	1	2			1	2
Tachycardia		7		2		5
Temperature intolerance		1		1		
Tenderness	1	1	1	1		
Tension headache		2		1		1
Throat irritation	1	2	1	2		
Thrombocytopenia	1	1			1	1
Tinnitus	1	1	1	1		
Tongue eruption		1		1		
Tongue pruritus		1		1		
Tremor	2	2	1	1	1	1
Tuberculosis		1				1
Urinary tract infection		1		1		
Urine output decreased		1		1		
Urticaria	3	3	1	1	2	2
Vaccination failure		1				1
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	3	3	3	3		
Vaccination site induration	3	3	3	3		
Vaccination site inflammation		4		4		
Vaccination site lymphadenopathy	1	4	1	3		1
Vaccination site movement impairment	1	2	1	2		
Vaccination site pain	3	21	3	19		2
Vaccination site rash		1		1		
Vaccination site reaction		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site swelling	2	2	2	2		
Vomiting	2	7	1	6	1	1
Wrong technique in product usage process	1	2	1	2		
	337	710	280	497	57	213

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

SWEDEN

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposure via breast milk	1	1	1	1		
Feeling abnormal		1				1
Nausea		1				1
Peripheral swelling		1				1
Pharyngeal swelling		1				1
Rash		1				1
Vaccination site movement impairment		1				1
	1	7	1	1		6

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal pain	1	1	1	1		
Abdominal pain upper	2	4	2	2		2
Abnormal dreams		1		1		
Abortion spontaneous		1				1
Acne	1	2	1	2		
Agitation		1		1		
Allodynia		1		1		
Anaphylactic reaction		4				4
Anosmia	1	1			1	1
Anxiety	1	3	1	3		
Arrhythmia	1	2			1	2
Arthralgia	3	9	2	4	1	5
Asthenia	3	4	3	4		
Axillary pain		3		3		
Back pain		3		1		2
Balance disorder		1		1		
Bell's palsy		1				1
Blindness	1	2			1	2
Blood creatinine increased		1		1		
Blood glucose abnormal		1		1		
Blood glucose decreased		1		1		
Blood potassium increased		1		1		
Blood pressure decreased	1	2			1	2
Blood pressure increased		2				2
Body temperature increased		1		1		
Breast cyst	1	1			1	1
Burning sensation		1				1
Cardiac arrest		1				1
Cardiac failure	1	1			1	1
Chest discomfort	1	1			1	1
Chest pain	1	5		2	1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills	11	24	8	15	3	9
Concussion		1		1		
Condition aggravated	1	3			1	3
Confusional state		2		1		1
Cough	2	5	1	3	1	2
COVID-19		2		2		
C-reactive protein increased		1				1
Decreased appetite		1				1
Diarrhoea	1	6	1	4		2
Discomfort		1				1
Disease recurrence		2		1		1
Disorientation		1		1		
Disturbance in attention		1		1		
Dizziness	5	18	3	11	2	7
Dry mouth		1				1
Dysphagia		2				2
Dyspnoea	2	12		2	2	10
Dysstasia		1				1
Electrocardiogram abnormal	1	1			1	1
Electrolyte imbalance		1		1		
Epilepsy		1				1
Epistaxis	1	2		1	1	1
Erythema	1	1			1	1
Extrasystoles	1	1	1	1		
Eye inflammation		1				1
Facial paralysis	1	2			1	2
Facial paresis		2				2
Fatigue	8	33	7	24	1	9
Feeding disorder		1		1		
Feeling abnormal		2		1		1
Feeling cold	1	2	1	2		
Feeling hot		5		3		2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling of body temperature change		1				1
Fluid retention		1				1
Flushing		1				1
Formication	1	1	1	1		
Furuncle		1				1
Gastric disorder		1		1		
Gastroenteritis		1				1
Glossodynia		1		1		
Haematoma		1				1
Haemorrhage		1				1
Hallucination, auditory		1				1
Headache	21	60	17	45	4	15
Head discomfort	1	2			1	2
Heart rate increased	2	7	1	1	1	6
Heart rate irregular		1		1		
Hepatic enzyme increased	1	1			1	1
Hot flush	1	2	1	2		
Hyperhidrosis		4		2		2
Hypersensitivity		3		1		2
Hypersomnia-bulimia syndrome		1				1
Hypertension	1	1			1	1
Hyperventilation		1				1
Hypoacusis		1				1
Hypoaesthesia	1	10		2	1	8
Hypoaesthesia oral		1		1		
Hypoxia		1				1
Illness		1		1		
Immune thrombocytopenia		1				1
Inappropriate schedule of product administration	1	1	1	1		
Increased insulin requirement	1	1	1	1		
Infection		1		1		
Influenza like illness	1	1	1	1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Initial insomnia		1				1
Injected limb mobility decreased	1	1	1	1		
Insomnia		2		2		
Intermenstrual bleeding	1	2	1	1		1
Joint stiffness		1		1		
Lip swelling		1				1
Local reaction		1		1		
Lymphadenopathy	3	5	3	5		
Lymph node pain	2	3	2	3		
Malaise		7		3		4
Menstrual disorder	2	2	1	1	1	1
Menstruation irregular	1	1			1	1
Migraine	1	1			1	1
Miosis		1		1		
Movement disorder	1	1			1	1
Muscle contractions involuntary		1				1
Muscle spasms		3				3
Muscle twitching		3				3
Muscular weakness		5				5
Musculoskeletal chest pain		1				1
Musculoskeletal stiffness	1	2	1	2		
Myalgia	7	20	7	14		6
Nasal congestion		2		1		1
Nasal oedema		1		1		
Nasopharyngitis		1				1
Nausea	4	17	2	9	2	8
Neck pain	1	2	1	2		
Neuralgia		1		1		
Night sweats	1	2		1	1	1
Oral herpes		1		1		
Oral mucosal blistering	1	1	1	1		
Oral pain		1		1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oropharyngeal discomfort		1		1		
Oropharyngeal pain		8		5		3
Oxygen saturation decreased		1				1
Pain	8	20	6	15	2	5
Pain in extremity	6	33	5	22	1	11
Palpitations		6		2		4
Panic attack		1				1
Paraesthesia		1				1
Paraesthesia oral	1	1	1	1		
Paranasal sinus haemorrhage		1		1		
Parosmia	1	1			1	1
PCO2 increased		1		1		
Periorbital pain		1		1		
Pharyngeal disorder		1				1
Pharyngeal mass		1				1
Pharyngeal oedema		1				1
Pharyngeal swelling		7				7
Platelet count decreased	1	2		1	1	1
Poor quality sleep		2		1		1
Product preparation issue		1		1		
Pruritus		2				2
Pulmonary embolism	1	2			1	2
Pulmonary pain		2				2
Purpura		1				1
Pyrexia	20	51	16	36	4	15
Rash		2		1		1
Rash erythematous	1	2			1	2
Rash pruritic		1				1
Respiratory disorder		1		1		
Respiratory rate increased		1				1
Rhinitis		1		1		
Rhinorrhoea		3		3		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Seizure		3				3
Septic shock		1				1
Sinus tachycardia	1	1			1	1
Skin ulcer		1				1
Sleep disorder	1	1	1	1		
Swelling	1	2		1	1	1
Swollen tongue		2				2
Syncope		8				8
Tachycardia		1		1		
Taste disorder	1	3		1	1	2
Tenderness	1	1	1	1		
Throat irritation	2	4	2	2		2
Tongue erythema		1		1		
Tremor		4				4
Underdose		1		1		
Urticaria	2	6	1	2	1	4
Vaccination site erythema	3	4	1	2	2	2
Vaccination site haematoma		1				1
Vaccination site induration		1		1		
Vaccination site movement impairment	1	3	1	3		
Vaccination site pain	15	36	12	30	3	6
Vaccination site pruritus	2	4		2	2	2
Vaccination site reaction	1	1			1	1
Vaccination site swelling	4	6	2	4	2	2
Vaccination site urticaria		1		1		
Vaccination site warmth	1	2	1	2		
Vestibular disorder	1	1	1	1		
Viral infection		1		1		
Vision blurred		1				1
Visual impairment		2		1		1
Vomiting	3	9	1	2	2	7
White blood cell count decreased	1	2		1	1	1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	194	685	127	379	67	306

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* I=Interval, C=Cumulative
 * AE=Adverse Event
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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	3	2	2		1
Abdominal distension		1				1
Abdominal pain	3	6	3	5		1
Abdominal pain lower		1				1
Abdominal pain upper	3	5	3	4		1
Abdominal tenderness	1	1	1	1		
Abnormal dreams	1	1			1	1
Abortion spontaneous	1	1			1	1
Acute kidney injury		1				1
Acute myocardial infarction		1				1
Adnexa uteri pain	1	1	1	1		
Ageusia		3		2		1
Akathisia	1	1			1	1
Amenorrhoea		1		1		
Amnesia		2				2
Anaphylactic reaction	1	12			1	12
Anaphylactic shock		1				1
Angina pectoris	1	1			1	1
Angioedema		3				3
Angiopathy	1	1	1	1		
Anosmia	1	5		2	1	3
Anxiety	1	5	1	2		3
Apathy		1				1
Aphasia		1				1
Aphthous ulcer	1	1	1	1		
Areflexia		1				1
Arrhythmia		1				1
Arthralgia	18	35	17	26	1	9
Arthritis	1	3	1	1		2
Asthenia	4	17	4	6		11
Asthenopia		2				2
Asymptomatic COVID-19		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Atrial f brillation		1				1
Axillary pain	6	13	6	10		3
Back pain	7	17	6	12	1	5
Basedow's disease	1	1			1	1
Bedridden	1	1	1	1		
Bell's palsy		2				2
Blindness		2				2
Blister		1		1		
Blood creatinine increased		1				1
Blood glucose decreased		1				1
Blood glucose increased		1				1
Blood pressure decreased		4		1		3
Blood pressure fluctuation	1	1			1	1
Blood pressure increased		1		1		
Blood pressure systolic increased		1		1		
Body temperature increased	1	1	1	1		
Breast pain	1	1	1	1		
Cardiac arrest		1				1
Cardiac fibrillation	1	1			1	1
Cardiac flutter		1				1
Cardiac murmur		1				1
Central pain syndrome		1				1
Cerebral ischaemia	1	1			1	1
Cerebrovascular accident		1				1
Chest discomfort	2	14	2	7		7
Chest pain	2	14		4	2	10
Chills	24	64	22	39	2	25
Cholecystitis		1				1
Chronic fatigue syndrome		1				1
Cognitive disorder		1				1
Cold sweat	2	9		2	2	7
Condition aggravated	1	3		1	1	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Confusional state	2	2	1	1	1	1
Cough	4	12	2	5	2	7
COVID-19	3	7	1	1	2	6
Cranial nerve disorder		1				1
C-reactive protein abnormal		1		1		
C-reactive protein increased		4				4
Decreased appetite		1				1
Deep vein thrombosis	1	4			1	4
Depressed mood		4		1		3
Diarrhoea	2	7	2	6		1
Diplopia		1		1		
Discomfort	1	3	1	2		1
Disease recurrence	1	2			1	2
Disturbance in attention		3		1		2
Dizziness	16	61	11	25	5	36
Dizziness exertional		1				1
Drug ineffective	1	2			1	2
Dry mouth	1	1	1	1		
Dry skin		1		1		
Dysaesthesia		1		1		
Dysarthria		1				1
Dysgeusia		5		1		4
Dyskinesia	1	1			1	1
Dyspepsia		1		1		
Dysphagia		2				2
Dysphonia		3		1		2
Dyspnoea	10	31	6	11	4	20
Dyspnoea exertional		3				3
Dystonia		1				1
Ear discomfort	2	4	1	1	1	3
Ear pain	1	3	1	1		2
Eczema		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Electric shock sensation		1		1		
Electrocardiogram ST segment elevation		1				1
Electrocardiogram T wave inversion		1				1
Epilepsy	1	1			1	1
Erythema		11		5		6
Escherichia urinary tract infection		1				1
Extrasystoles		2				2
Eye disorder		1				1
Eye irritation	1	3	1	1		2
Eyelids pruritus	1	1	1	1		
Eye pain		3		1		2
Eye pruritus		2				2
Eye swelling		1				1
Face injury		1				1
Facial discomfort		1		1		
Facial neuralgia		1				1
Facial pain		1				1
Facial paralysis		4				4
Facial paresis		6				6
Fall		4				4
Fatigue	43	122	36	73	7	49
Fear of death		1				1
Feeling abnormal	1	7	1	3		4
Feeling cold	4	12	4	9		3
Feeling hot	1	13		6	1	7
Feeling of body temperature change		2				2
Feeling of despair		1				1
Flank pain		1		1		
Flushing	1	2			1	2
Formication	1	3			1	3
Gait disturbance		2		1		1
Gallbladder disorder		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gallbladder oedema		1				1
Gastroesophageal reflux disease	1	1	1	1		
Generalised oedema		1				1
General physical health deterioration		1				1
Guillain-Barre syndrome		1				1
Haematoma		1				1
Haemorrhagic diathesis		1				1
Hallucination	1	2			1	2
Headache	66	156	59	105	7	51
Head discomfort	3	8	2	4	1	4
Heart rate decreased	1	1	1	1		
Heart rate increased	2	7		1	2	6
Heart rate irregular		1				1
Hemiparesis	1	2			1	2
Hepatitis acute		1				1
Herpes simplex		1				1
Herpes zoster	2	2	1	1	1	1
Horner's syndrome		1				1
Hyperacusis		1				1
Hyperaesthesia		1		1		
Hyperhidrosis	1	6		1	1	5
Hypersensitivity	2	17			2	17
Hypersomnia		2		1		1
Hypertension		4		2		2
Hyperventilation		2				2
Hypoacusis		2				2
Hypoaesthesia	2	37	1	10	1	27
Hypoaesthesia oral		7		1		6
Hypoglycaemia		1				1
Hypokinesia		1				1
Hyposmia	1	1			1	1
Hypotension		4		1		3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Illness	1	1	1	1		
Immunisation reaction		1				1
Incorrect route of product administration		1		1		
Increased upper airway secretion		1		1		
Inflammation		2				2
Influenza like illness	3	9	3	7		2
Injected limb mobility decreased		1		1		
Injection site pain	1	1	1	1		
Insomnia		3		1		2
Intention tremor		1				1
Joint stiffness		3		1		2
Joint swelling		2		1		1
Lacrimation increased		1				1
Laziness	1	1	1	1		
Lethargy		1				1
Leukopenia		2				2
Limb discomfort	2	3	1	1	1	2
Lip pain	1	1			1	1
Lip pruritus		1				1
Lip swelling		2		1		1
Liver disorder		1				1
Loose tooth		1				1
Loss of personal independence in daily activities		1		1		
Lung disorder	1	1	1	1		
Lymphadenitis		1				1
Lymphadenopathy	6	20	6	13		7
Lymphadenopathy mediastinal		1		1		
Lymph node pain	8	13	8	11		2
Lymphoedema		1				1
Malaise	17	29	14	21	3	8
Maternal exposure during pregnancy	2	2	1	1	1	1
Memory impairment		3		2		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mental fatigue	1	5	1	2		3
Metabolic acidosis		1				1
Migraine	4	11	4	7		4
Multiple sclerosis		2				2
Muscle fatigue	1	1	1	1		
Muscle spasms	1	7		3	1	4
Muscle tightness		1				1
Muscle twitching	2	4	2	2		2
Muscular weakness		7		2		5
Musculoskeletal discomfort		1				1
Musculoskeletal stiffness	8	20	8	11		9
Myalgia	29	68	27	43	2	25
Myelitis		1				1
Myocarditis		2				2
Myopia		1				1
Nasal congestion	1	7		2	1	5
Nasopharyngitis	2	5	2	2		3
Nausea	21	54	16	33	5	21
Neck pain	6	14	4	7	2	7
Nervousness		1				1
Neuralgic amyotrophy		1				1
Neuritis		1				1
Neuropathy peripheral		1				1
Nightmare		3				3
Nodule	1	2	1	2		
Obstructive airways disorder	1	2	1	1		1
Ocular discomfort		2				2
Oedema peripheral		1				1
Off label use	1	2	1	2		
Oral mucosal blistering		1				1
Oral pruritus		2		1		1
Oropharyngeal pain	4	13	3	10	1	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oropharyngeal spasm		1				1
Overdose		1		1		
Oxygen saturation decreased	1	1			1	1
Pain	16	42	16	27		15
Painful respiration	1	2	1	2		
Pain in extremity	33	76	26	56	7	20
Pain in jaw	1	3	1	2		1
Pain of skin	2	3	2	2		1
Pallor		3		1		2
Palpitations	6	21	1	5	5	16
Panic attack		1				1
Panic reaction		1				1
Paraesthesia	2	27	1	8	1	19
Paraesthesia oral	1	9		3	1	6
Parosmia	2	4	1	1	1	3
Periarthritis		1				1
Pericardial effusion		2				2
Periorbital discomfort		1				1
Peripheral coldness	1	3		1	1	2
Peripheral motor neuropathy		1				1
Peripheral sensory neuropathy		1				1
Peripheral swelling		2		1		1
Pharyngeal erythema		1				1
Pharyngeal hypoaesthesia		1				1
Pharyngeal paraesthesia		2				2
Pharyngeal swelling	4	9	1	4	3	5
Photophobia		2				2
Photosensitivity reaction	1	1	1	1		
Physical deconditioning		2		1		1
Pleural effusion		3		1		2
Pleurisy		1				1
Pneumonia		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Polyarthrititis		1				1
Poor quality product administered	3	6	3	6		
Post-acute COVID-19 syndrome	1	1	1	1		
Post viral fatigue syndrome		1		1		
Presyncope		2				2
Procalcitonin increased		2				2
Product colour issue		2		2		
Productive cough	1	2			1	2
Product preparation issue		3		3		
Product temperature excursion issue	3	4	3	4		
Product use issue	1	2	1	2		
Pruritus	5	17	4	8	1	9
Psoriasis		1		1		
Pulmonary embolism		4				4
Pulmonary infarction		1				1
Pulmonary pain	2	2	2	2		
Pulmonary thrombosis	1	1			1	1
Pulse pressure decreased		1		1		
Pyrexia	64	143	60	94	4	49
Rash	1	10	1	5		5
Rash erythematous		4		1		3
Rash maculo-papular		1				1
Rash pruritic		1		1		
Renal pain	1	1	1	1		
Renal tubular necrosis		1				1
Respiratory arrest	1	1			1	1
Respiratory disorder	1	1			1	1
Respiratory distress		7				7
Restless legs syndrome		1				1
Rhinorrhoea	2	8	2	8		
Rib fracture	1	1			1	1
Sciatica		1				1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Seizure	2	3			2	3
Sensation of foreign body		1				1
Sensitivity to weather change	1	1			1	1
Sensory disturbance		1				1
Sinus disorder		1		1		
Sinus tachycardia		1				1
Skin burning sensation		1				1
Skin discolouration		1		1		
Skin warm		1		1		
Sleep disorder		2				2
Sleep paralysis		1				1
Somnolence	2	5	2	3		2
Spinal pain	1	2	1	2		
Subarachnoid haemorrhage		1				1
Sudden hearing loss		1				1
Supraventricular extrasystoles		1				1
Supraventricular tachycardia		1				1
Swelling	4	9	4	6		3
Swelling face		4		1		3
Swollen tongue	1	5			1	5
Syncope		10				10
Systemic lupus erythematosus		1				1
Tachycardia	2	11	1	3	1	8
Taste disorder	1	2	1	1		1
Throat irritation	1	5		1	1	4
Throat tightness		3		1		2
Thrombocytopenia		1				1
Thrombosis	1	4			1	4
Tinnitus	3	12	1	1	2	11
Tongue discomfort		1		1		
Tongue pruritus		1				1
Toothache	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Transient ischaemic attack		1				1
Tremor	1	6	1	2		4
Trigeminal nerve paresis		1				1
Underdose		2		2		
Upper respiratory tract congestion		1		1		
Upper respiratory tract infection		1				1
Urticaria	8	23	7	12	1	11
Uterine inflammation		1		1		
Vaccination failure	1	4			1	4
Vaccination site bruising	1	2	1	1		1
Vaccination site erythema	9	21	7	15	2	6
Vaccination site hypoaesthesia		1		1		
Vaccination site induration	1	2	1	1		1
Vaccination site movement impairment	1	3	1	3		
Vaccination site nodule		2		2		
Vaccination site pain	47	107	43	92	4	15
Vaccination site paraesthesia	2	3	2	3		
Vaccination site pruritus	5	11	2	6	3	5
Vaccination site rash	1	1	1	1		
Vaccination site reaction	3	4	2	3	1	1
Vaccination site swelling	10	27	7	17	3	10
Vaccination site warmth	3	7	3	7		
Vaginal haemorrhage		1				1
Venous thrombosis		1				1
Vertigo		2				2
Vertigo positional		1		1		
Vision blurred	2	4	2	2		2
Visual field defect		3				3
Visual impairment		3				3
Vomiting	4	13	4	6		7
	680	2,121	541	1095	139	1026

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	3	1	2		1
Abdominal distension	1	1			1	1
Abdominal infection		1				1
Abdominal pain	4	12	2	8	2	4
Abdominal pain lower		1				1
Abdominal pain upper	1	2	1	1		1
Acute myocardial infarction	1	3			1	3
Acute respiratory distress syndrome	1	1			1	1
Ageusia		1				1
Allergy to vaccine		2				2
Amnesia		1				1
Anaphylactic reaction	1	6			1	6
Anaphylactic shock	2	2			2	2
Anaphylactoid reaction		1				1
Angina pectoris	1	1			1	1
Angioedema		1				1
Anosmia		1				1
Anxiety		2		2		
Apathy		1				1
Aphasia	1	1			1	1
Arrhythmia	2	3	1	1	1	2
Arthralgia	14	32	9	18	5	14
Asthenia	5	14	3	7	2	7
Asthenopia		2				2
Asthma	1	1			1	1
Atrial f brillation	2	3			2	3
Atrial septal defect		1				1
Axillary pain	1	3	1	2		1
Back pain	2	3	2	3		
Balance disorder		3				3
Bell's palsy		2				2
Blepharospasm		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blindness transient		1				1
Blood creatinine increased		1		1		
Blood fibrinogen decreased		1				1
Blood glucose decreased	1	1	1	1		
Blood glucose increased	1	1			1	1
Blood lactate dehydrogenase increased		1				1
Blood pressure decreased	1	2			1	2
Blood pressure diastolic increased	1	1	1	1		
Blood pressure increased		3				3
Body temperature increased	1	2	1	2		
Brain injury	1	1			1	1
Brain stem syndrome		1				1
Breast pain		1				1
Bronchospasm		1				1
Burning sensation	4	4	3	3	1	1
Cardiac arrest		2				2
Cardiac discomfort		2				2
Cardiac disorder		1				1
Cardiogenic shock		1				1
Cardiovascular disorder		1				1
Cerebellar syndrome		1				1
Cerebral artery embolism	1	1			1	1
Cerebral disorder	1	1			1	1
Cerebral haemorrhage	2	2			2	2
Cerebral microangiopathy		1				1
Cerebrovascular accident	2	3			2	3
Chest discomfort	3	7	1	2	2	5
Chest pain	3	6	1	2	2	4
Chills	21	51	14	34	7	17
Circulatory collapse		1				1
Coagulopathy		1				1
Cognitive disorder	1	1			1	1

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat		3		1		2
Concomitant disease aggravated		1				1
Condition aggravated		2				2
Confusional state	1	3	1	1		2
Constipation	1	2	1	2		
Contusion	1	1			1	1
Coronary artery thrombosis	1	1			1	1
Cough	3	9	1	5	2	4
COVID-19	4	5	2	3	2	2
Daydreaming	1	1	1	1		
Deafness unilateral		2				2
Death		1				1
Decreased appetite	2	3	1	1	1	2
Deep vein thrombosis	2	6			2	6
Depressed level of consciousness		3				3
Depression		1		1		
Depressive symptom	1	1			1	1
Derealisation		1				1
Dermatitis		1				1
Dermatitis bullous	1	1			1	1
Diarrhoea	8	22	4	14	4	8
Discomfort	1	4		2	1	2
Disease recurrence		2		1		1
Disturbance in attention	2	4	1	1	1	3
Dizziness	15	37	9	13	6	24
Dry mouth	3	3	2	2	1	1
Dysarthria	1	1			1	1
Dysgeusia		3		1		2
Dyshidrotic eczema	1	1			1	1
Dysphagia	1	3			1	3
Dysphonia	1	5		2	1	3
Dyspnoea	4	20	1	4	3	16

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea exertional	1	1	1	1		
Ear pain		1				1
Embolism	2	2			2	2
Encephalitis		1				1
Encephalopathy		1				1
Epilepsy		2				2
Epistaxis	2	4	1	3	1	1
Erysipelas		1				1
Erythema	2	11	1	6	1	5
Exercise tolerance decreased	1	1			1	1
Extrasystoles		1				1
Eye inflammation	2	2	1	1	1	1
Eye irritation		1				1
Eye pain	2	6	2	2		4
Eye swelling		1				1
Facial pain		2				2
Facial paralysis	2	3			2	3
Facial paresis		4				4
Fall	2	2			2	2
Fatigue	32	76	20	47	12	29
Fear	1	1			1	1
Feeling abnormal	1	4		1	1	3
Feeling cold	2	7	1	4	1	3
Feeling drunk	1	1	1	1		
Feeling hot	1	8	1	2		6
Flatulence		1		1		
Flushing	1	2	1	1		1
Formication		2		1		1
Gait disturbance	2	3			2	3
Gait inability		1				1
Gastritis		1		1		
General physical health deterioration		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Genital pain	1	1			1	1
Goitre		1				1
Haematuria		1				1
Haemorrhage		2				2
Hallucination, visual		1				1
Headache	48	106	35	67	13	39
Head discomfort		2		1		1
Heart rate increased	3	10		3	3	7
Heat stroke		1				1
Hemiplegia		1				1
Herpes zoster	1	3		1	1	2
Hot flush		1				1
Hyperhidrosis		4		2		2
Hypersensitivity	3	14		4	3	10
Hypertension	1	6		1	1	5
Hypertonic bladder	1	1			1	1
Hypoacusis	1	5			1	5
Hypoaesthesia	7	27	2	8	5	19
Hypoaesthesia oral	4	6			4	6
Hypokinesia	1	1			1	1
Hypoxia		1				1
Illness		2				2
Immune thrombocytopenia	1	1			1	1
Incontinence	1	1			1	1
Increased tendency to bruise	1	1			1	1
Infection	1	1			1	1
Influenza like illness	3	5	3	4		1
Injected limb mobility decreased	1	1	1	1		
Insomnia	2	5	2	2		3
Intraventricular haemorrhage	1	1			1	1
Jaw disorder		1				1
Joint lock		1				1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint range of motion decreased		2		1		1
Leukopenia	1	1			1	1
Ligament sprain	1	1			1	1
Limb discomfort	2	2	1	1	1	1
Lip swelling		4		1		3
Lip ulceration		1		1		
Loss of consciousness		2				2
Loss of personal independence in daily activities	1	1			1	1
Lymphadenopathy	2	7	1	4	1	3
Lymph node pain		2		2		
Malaise	7	24	3	14	4	10
Mania	1	1	1	1		
Mass		1				1
Memory impairment	2	4	1	1	1	3
Meningitis herpes		1				1
Mental fatigue		4				4
Metabolic disorder		2		1		1
Metastasis		1				1
Migraine	1	5	1	2		3
Mobility decreased	1	3		1	1	2
Mononeuritis	1	1			1	1
Monoparesis		1				1
Mouth swelling	2	3			2	3
Mouth ulceration		1		1		
Muscle fatigue		1				1
Muscle spasms	1	5		1	1	4
Muscle twitching		1				1
Muscular weakness	3	6	2	3	1	3
Musculoskeletal chest pain		1				1
Musculoskeletal stiffness	2	9	1	3	1	6
Myalgia	17	44	9	24	8	20
Myocardial infarction	1	1			1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myocarditis		1				1
Nasal congestion		2		1		1
Nasal dryness	1	1	1	1		
Nasal oedema	1	1			1	1
Nasopharyngitis	2	2	2	2		
Nausea	20	44	17	28	3	16
Neck pain	2	5	2	4		1
Nervous system disorder	1	1	1	1		
Neuralgia		1				1
Neuropathy peripheral	1	2			1	2
Noninfective gingivitis	1	1	1	1		
Ocular discomfort	1	1	1	1		
Oral herpes		2		1		1
Oral mucosal blistering		1				1
Oral pruritus		5		3		2
Oral viral infection		1				1
Oropharyngeal pain	2	7	1	4	1	3
Overdose		1		1		
Pain	19	42	14	23	5	19
Pain in extremity	21	48	15	30	6	18
Pain in jaw		1				1
Pain of skin	2	3	1	2	1	1
Palatal swelling		1				1
Palpitations	2	8		1	2	7
Panic reaction		1				1
Paraesthesia	6	16	2	4	4	12
Paraesthesia ear		1				1
Paraesthesia oral	2	4		1	2	3
Parosmia	1	2	1	1		1
Periorbital oedema		1				1
Periorbital pain		1				1
Periorbital swelling		2		1		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral artery thrombosis	1	1			1	1
Peripheral coldness		1				1
Peripheral swelling	3	10		2	3	8
Pharyngeal erythema		1		1		
Pharyngeal hypoaesthesia	1	3			1	3
Pharyngeal swelling	5	6	2	2	3	4
Photophobia		2				2
Platelet count decreased		1				1
Pneumonia		2				2
Polymyalgia rheumatica		1				1
Polyneuropathy	1	1			1	1
Poor quality product administered	2	2	2	2		
Prerenal failure	1	1			1	1
Presyncope		1				1
Product administered at inappropriate site		1		1		
Product administration error	1	1	1	1		
Product temperature excursion issue	2	2	2	2		
Pruritus	4	9	1	4	3	5
Pulmonary embolism	3	6			3	6
Pulmonary hypertension		1				1
Pyrexia	39	94	34	67	5	27
Rash	2	4	2	2		2
Rash erythematous	1	2			1	2
Rash macular		1		1		
Rash pruritic		1		1		
Reading disorder		1				1
Reduced facial expression		1				1
Renal impairment		1				1
Renal pain	1	3	1	2		1
Respiration abnormal		1				1
Respiratory arrest		1				1
Respiratory disorder	1	2			1	2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory distress		2				2
Retinal haemorrhage		1				1
Retinal tear	1	1			1	1
Rhinalgia		2		1		1
Rhinorrhoea	4	10	2	7	2	3
Seizure	1	2			1	2
Seizure like phenomena		2				2
Sensory disturbance		1		1		
Sensory loss	2	2	1	1	1	1
Sinus congestion		1		1		
Skin discolouration		1		1		
Skin reaction		1		1		
Skin swelling	1	1			1	1
Skin tightness		1				1
Sleep disorder	1	3	1	1		2
Sleep talking		1				1
Sluggishness		1				1
Sneezing	4	5	3	4	1	1
Snoring	1	1			1	1
Somnolence	2	2	1	1	1	1
Stomatitis	1	2	1	1		1
Stress		2		2		
Subarachnoid haemorrhage		1				1
Subcutaneous haematoma	1	1			1	1
Sudden visual loss		1				1
Supraventricular tachycardia	1	1			1	1
Suspected COVID-19		1		1		
Swelling	1	2	1	1		1
Swelling face	2	6		2	2	4
Swollen tongue	1	4			1	4
Syncope		2				2
Tachycardia	1	6	1	2		4

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Taste disorder	1	2	1	1		1
Tenderness		1				1
Throat irritation	1	5	1	2		3
Throat tightness		1				1
Thrombocytopenia		3				3
Thrombophlebitis	1	3		1	1	2
Thrombosis	1	5			1	5
Tinnitus		7				7
Tongue movement disturbance		1				1
Tongue pruritus		2				2
Tonsillitis	1	1			1	1
Torticollis		1				1
Transient ischaemic attack	2	4			2	4
Underdose	1	1	1	1		
Unresponsive to stimuli		1				1
Upper respiratory tract infection		1				1
Urticaria	2	11	1	5	1	6
Vaccination failure	1	1			1	1
Vaccination site bruising		1		1		
Vaccination site discolouration		1				1
Vaccination site erythema	5	11	3	8	2	3
Vaccination site haemorrhage	1	1	1	1		
Vaccination site induration		2		2		
Vaccination site lymphadenopathy		1				1
Vaccination site mass		1		1		
Vaccination site movement impairment	1	3	1	3		
Vaccination site pain	31	63	24	46	7	17
Vaccination site pruritus	3	4	1	2	2	2
Vaccination site reaction	1	2		1	1	1
Vaccination site swelling	4	16	2	12	2	4
Vaccination site warmth	1	5	1	4		1
Vasodilatation		1		1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vertigo	1	2	1	1		1
Vertigo positional	1	1	1	1		
Vision blurred		4		1		3
Visual impairment	2	5			2	5
Vomiting	7	14	5	7	2	7
Weight decreased	1	2			1	2
Weight increased		1				1
White blood cell count decreased	1	1	1	1		
Wound		1				1
	574	1,522	319	703	255	819

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1			1	1
Abdominal distension	1	1			1	1
Abdominal pain	4	11	2	2	2	9
Abdominal pain upper	3	4		1	3	3
Abnormal behaviour		1		1		
Abnormal uterine bleeding	1	1	1	1		
Abscess limb	1	1			1	1
Acetonaemia	1	1			1	1
Acute coronary syndrome	1	1			1	1
Acute kidney injury		1				1
Acute left ventricular failure		1				1
Acute myocardial infarction		1				1
Adrenal haemorrhage	1	1			1	1
Adrenocortical insufficiency acute		1				1
Ageusia		1		1		
Altered state of consciousness	2	3			2	3
Anaemia		1				1
Anaphylactic reaction	2	6			2	6
Anaphylactic shock		2				2
Angina pectoris	1	3			1	3
Angioedema		1				1
Anosmia		1		1		
Anxiety	2	4	1	1	1	3
Aortic rupture	1	1			1	1
Appendicitis	1	1			1	1
Arrhythmia	1	2			1	2
Arteriosclerosis		1				1
Arteriosclerosis coronary artery		1				1
Arthralgia	16	18	5	5	11	13
Arthritis	2	2	2	2		
Ascites		1				1
Asthenia	4	8	1	1	3	7

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma		1				1
Atrial f brillation	2	3			2	3
Atrial flutter		1				1
Atrioventricular block complete		1				1
Autonomic nervous system imbalance		1				1
Back pain	1	4		1	1	3
Balance disorder	4	7	2	2	2	5
Ballismus	1	1			1	1
Basedow's disease		1				1
Basilar artery thrombosis		1				1
Bedridden		1				1
Bell's palsy	2	2			2	2
Biliary tract disorder		1				1
Blepharospasm	1	1			1	1
Blindness	1	1			1	1
Blister	1	2	1	1		1
Blood alkaline phosphatase increased		1				1
Blood bilirubin increased		1				1
Blood creatine increased	1	1	1	1		
Blood glucose increased	1	2	1	1		1
Blood pressure abnormal		1				1
Blood pressure decreased		1				1
Blood pressure fluctuation		1				1
Blood pressure increased	3	4	1	2	2	2
Blood pressure measurement	1	1			1	1
Body temperature increased		1				1
Breath sounds abnormal		1				1
Bundle branch block right		1				1
Cardiac arrest	1	5			1	5
Cardiac failure		2				2
Cardiac failure acute		2				2
Cardiac fibrillation		1				1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac flutter	1	1			1	1
Cardiogenic shock		1				1
Cerebellar infarction	1	1			1	1
Cerebral haemorrhage	4	8			4	8
Cerebral infarction	2	3			2	3
Cerebral thrombosis		1				1
Cerebrovascular accident	10	13			10	13
Chest discomfort	3	3	1	1	2	2
Chest pain	2	6			2	6
Chills	9	15	4	6	5	9
Chronic obstructive pulmonary disease	1	3			1	3
Circulatory collapse		1				1
Circumoral swelling	1	1			1	1
Cold sweat	1	2			1	2
Colitis	1	1			1	1
Condition aggravated	2	6		1	2	5
Confusional state	2	7	1	1	1	6
Contusion	3	3	1	1	2	2
Coronary artery stenosis		1				1
Cough	3	6		1	3	5
COVID-19	4	7	2	2	2	5
COVID-19 pneumonia		1				1
C-reactive protein decreased	1	1	1	1		
C-reactive protein increased	2	3	1	2	1	1
Crying		1		1		
Cutaneous vasculitis	1	1			1	1
Cyanosis		1				1
Deafness	2	2			2	2
Death	2	14			2	14
Decreased appetite	1	2		1	1	1
Deep vein thrombosis	6	11			6	11
Dehydration		4		1		3

* I=Interval, C=Cumulative

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Delirium		1				1
Depressed level of consciousness		4				4
Depression	1	1	1	1		
Dermatitis		1		1		
Dermatitis psoriasiform	1	1			1	1
Diarrhoea	6	13	2	6	4	7
Diplopia	1	1			1	1
Discomfort		2				2
Disease recurrence	1	3			1	3
Dizziness	18	30	2	4	16	26
Drug ineffective		1				1
Dry eye	1	1			1	1
Dysarthria	1	2			1	2
Dysphagia		6		4		2
Dysphonia		2		1		1
Dyspnoea	11	28	1	2	10	26
Dyspnoea exertional	1	1			1	1
Dysstasia	2	3	1	1	1	2
Ear pain	1	1			1	1
Eating disorder		1				1
Ecchymosis	1	1			1	1
Electrocardiogram abnormal	1	1	1	1		
Embolism		1				1
Epilepsy		1				1
Epistaxis	2	4			2	4
Erysipelas	1	1			1	1
Erythema	2	6		1	2	5
Eye haemorrhage		1				1
Eye irritation	1	1			1	1
Eye pain		2				2
Facial paralysis		1				1
Facial paresis	1	2			1	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fall	1	4	1	2		2
Fatigue	16	38	4	14	12	24
Feeding disorder		1				1
Feeling abnormal		2		1		1
Feeling cold		1		1		
Feeling hot	3	3			3	3
Fibromyalgia		1				1
Fluid intake reduced		1				1
Gait disturbance	3	3	1	1	2	2
Gamma-glutamyltransferase increased		1				1
Gastric disorder		1				1
General physical health deterioration	1	10		3	1	7
Gingival bleeding	1	1			1	1
Gingival erythema	1	1			1	1
Gingival swelling	1	1			1	1
Goitre		1				1
Gout	1	1			1	1
Graft versus host disease		1				1
Haematemesis		3				3
Haematoma		2				2
Haemoglobin decreased		1				1
Haemorrhage intracranial		1				1
Haemorrhage subcutaneous	2	2			2	2
Hallucination		1				1
Headache	22	31	7	8	15	23
Head discomfort	1	1			1	1
Head injury		2		1		1
Heart rate increased	7	10		1	7	9
Hemiparaesthesia		1				1
Hemiparesis		1				1
Hepatic enzyme increased	1	1			1	1
Herpes zoster	1	6	1	1		5

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hiccups		1				1
Hip fracture		1				1
Hot flush		1				1
Hydrocholecystis	1	1			1	1
Hydrothorax		1				1
Hyperglycaemia	1	1			1	1
Hyperhidrosis		3		3		
Hypersensitivity	2	6			2	6
Hypertension	2	6			2	6
Hyperventilation	1	1	1	1		
Hypoaesthesia	3	7			3	7
Hypoaesthesia oral		1		1		
Hypoglycaemia	1	3			1	3
Hypokinesia		1				1
Hypophagia		1				1
Hypotension	1	5	1	2		3
Hypothermia		1				1
Illness		1				1
Inappropriate schedule of product administration		3		3		
Incorrect route of product administration		2		2		
Infection		5				5
Inflammation	1	2			1	2
Inflammatory marker increased	2	2			2	2
Influenza like illness	1	3		1	1	2
Infrequent bowel movements		1		1		
Injury	1	1	1	1		
Insomnia		1		1		
Internal haemorrhage	1	1			1	1
Intestinal haemorrhage		2				2
Intestinal ischaemia		2				2
Ischaemic stroke	3	5			3	5
Jaundice		1				1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint instability	1	1			1	1
Joint stiffness	1	1			1	1
Joint swelling	1	1	1	1		
Lactic acidosis		1				1
Lethargy		2		1		1
Leukocytosis	1	1	1	1		
Lipids increased	1	1			1	1
Lip pruritus		1				1
Lip swelling		1				1
Liver disorder		1				1
Loss of consciousness		3				3
Loss of personal independence in daily activities		1				1
Low density lipoprotein increased	1	1			1	1
Lung disorder		1				1
Lung infiltration		1				1
Lung transplant rejection		1				1
Lymphadenopathy		1		1		
Malaise	5	12	1	3	4	9
Meningitis		1				1
Microscopic polyangiitis	1	1			1	1
Migraine	1	1			1	1
Motor dysfunction		1				1
Multiple sclerosis		1				1
Muscle tone disorder		1				1
Muscular weakness	3	6			3	6
Musculoskeletal stiffness	1	3		1	1	2
Myalgia	13	19	3	5	10	14
Myelitis		1				1
Myocardial fibrosis		1				1
Myocardial infarction	5	8			5	8
Myocardial ischaemia		2				2
Myocarditis	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nail discolouration		1				1
Nasopharyngitis	5	7	3	5	2	2
Nausea	15	32	3	9	12	23
Neck pain	2	4			2	4
Necrotising fasciitis	1	1			1	1
Neoplasm progression	1	1			1	1
Nephrolithiasis		1				1
Nervousness	1	2	1	2		
Neuralgia		1		1		
Neurological symptom	1	1			1	1
Neutropenia	1	1			1	1
Nightmare		1		1		
Ocular hyperaemia	2	2			2	2
Off label use		3		3		
Ophthalmic herpes zoster		1				1
Ophthalmic migraine	1	1			1	1
Optic ischaemic neuropathy	1	1			1	1
Oral discomfort		1				1
Oropharyngeal pain	2	3	1	1	1	2
Osteoarthritis	2	2	1	1	1	1
Oxygen saturation decreased	1	5		1	1	4
Pain	6	9	2	2	4	7
Pain in extremity	18	20	6	7	12	13
Pain of skin		1				1
Palpable purpura	1	1			1	1
Palpitations	3	9	1	1	2	8
Pancytopenia		1				1
Paraesthesia	2	5		2	2	3
Paraesthesia oral		2		1		1
Parkinson's disease		1				1
Periorbital oedema		1				1
Peripheral coldness	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral embolism	1	1			1	1
Peripheral swelling	9	12	2	3	7	9
Personality change	1	1			1	1
Petechiae	2	5		1	2	4
Pharyngitis		1		1		
Pneumonia		3				3
Pneumonia aspiration		2				2
Poor quality product administered		1		1		
Presyncope		2		1		1
Procalcitonin decreased	1	1	1	1		
Product administered at inappropriate site	1	1			1	1
Productive cough		1				1
Pruritus	3	8	2	2	1	6
Psychotic disorder		1				1
Pulmonary artery thrombosis		1				1
Pulmonary embolism	17	30			17	30
Pulmonary haemorrhage	1	1			1	1
Pulmonary oedema		3				3
Pulmonary pain	1	1			1	1
Pulse abnormal		1				1
Pyrexia	22	53	13	25	9	28
Rash	3	5		1	3	4
Rash macular	1	1			1	1
Renal failure		1				1
Renal haemorrhage		1				1
Respiratory arrest		2				2
Respiratory disorder	1	1			1	1
Respiratory distress	1	2			1	2
Respiratory failure		1				1
Respiratory rate increased		1				1
Restless legs syndrome		1				1
Retinal vascular thrombosis	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Retinal vein occlusion	1	1			1	1
Rheumatoid arthritis	1	1			1	1
Rhinorrhoea		2		1		1
Rotator cuff syndrome	1	1			1	1
Sciatica		1		1		
Screaming		1		1		
Seizure	1	5			1	5
Sense of oppression		1				1
Sensory disturbance	1	1			1	1
Sepsis	1	3			1	3
Septic shock		1				1
Skin discolouration	1	1			1	1
Skin exfoliation	1	1			1	1
Skin reaction	1	1			1	1
Skin ulcer		1				1
Sleep disorder		1				1
Sleep paralysis		1		1		
Solar dermatitis		1				1
Somnolence	1	3	1	2		1
Speech disorder		2		1		1
Spleen disorder		1				1
Splenic artery thrombosis	1	1			1	1
Spontaneous haematoma		1				1
Status epilepticus		1				1
Stress cardiomyopathy	1	1			1	1
Subarachnoid haemorrhage	1	2			1	2
Subdural haematoma	1	2			1	2
Sudden death		1				1
Swelling	3	3	1	1	2	2
Swelling face	2	5			2	5
Swollen tongue		1				1
Syncope	3	4			3	4

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachypnoea		3		1		2
Temperature regulation disorder		1		1		
Tenderness	2	2	1	1	1	1
Throat irritation	2	2	1	1	1	1
Throat tightness		1				1
Thrombocytopenia	3	9			3	9
Thrombocytopenic purpura		1				1
Thrombophlebitis	2	2			2	2
Thrombosis	5	8			5	8
Tinnitus	3	3			3	3
Tongue discomfort		1				1
Tongue pruritus		1				1
Transaminases increased		1				1
Transient global amnesia	1	1			1	1
Transient ischaemic attack	4	4			4	4
Tremor		3		1		2
Troponin abnormal	1	1			1	1
Troponin increased		1		1		
Underdose		1		1		
Urinary incontinence		1				1
Urinary tract infection	1	2			1	2
Urticaria		5		2		3
Vaccination complication	1	1			1	1
Vaccination failure	2	4			2	4
Vaccination site discomfort		1				1
Vaccination site erythema	2	6		1	2	5
Vaccination site haematoma	1	1			1	1
Vaccination site joint pain	2	2			2	2
Vaccination site lymphadenopathy	1	1	1	1		
Vaccination site movement impairment	1	1			1	1
Vaccination site pain	5	9	2	5	3	4
Vaccination site pruritus	1	1			1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site rash		1				1
Vaccination site reaction	1	1			1	1
Vaccination site swelling	1	1			1	1
Vertigo		1		1		
Vestibular neuronitis	2	2			2	2
Vision blurred	2	3			2	3
Visual field defect	2	2			2	2
Visual impairment	1	2			1	2
Vitreous detachment	1	1			1	1
Vomiting	8	19	1	6	7	13
Wa king aid user	1	1			1	1
Wheezing		3		1		2
	518	1,123	104	232	414	891

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	2			1	2
Abdominal pain	2	5	1	2	1	3
Abdominal pain upper		1				1
Abdominal symptom		1				1
Abdominal wall haemorrhage		1				1
Abnormal behaviour	1	3			1	3
Abnormal sensation in eye		1				1
Acute kidney injury	1	5			1	5
Acute myocardial infarction	2	6			2	6
Acute respiratory failure	1	1			1	1
Ageusia	1	2			1	2
Aggression	1	2			1	2
Agitation		2				2
Akinesia		1				1
Altered state of consciousness		1				1
Amnesia	1	3			1	3
Anaemia	2	2			2	2
Anaphylactic reaction		2				2
Angina pectoris		2				2
Angioedema		1				1
Anosmia		1				1
Anxiety		5		1		4
Aortic aneurysm	1	1			1	1
Aortic aneurysm rupture		1				1
Aortic arteriosclerosis		2		1		1
Apathy	1	1			1	1
Aphasia		2				2
Apnoea		2				2
Appendicitis	1	1			1	1
Arrhythmia	1	2			1	2
Arterial thrombosis		1				1
Arteriosclerosis	2	3			2	3

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	2	7	1	3	1	4
Arthritis		2				2
Aspiration		1				1
Asthenia	2	12	2	5		7
Atelectasis		1				1
Atrial fibrillation	2	9			2	9
Atrial flutter	1	2			1	2
Atrial thrombosis		1				1
Atrioventricular block complete		1				1
Atypical pneumonia	1	2			1	2
Back pain		4		1		3
Balance disorder	2	7			2	7
Biliary colic	1	2			1	2
Biliary dilatation		1				1
Bladder dysfunction	1	1			1	1
Blindness	2	2			2	2
Blindness unilateral	1	1			1	1
Blood albumin increased	1	1			1	1
Blood creatinine increased		2		1		1
Blood glucose increased		1		1		
Blood phosphorus decreased		1		1		
Blood potassium increased		1				1
Blood pressure decreased	3	10	1	3	2	7
Blood pressure diastolic decreased		1		1		
Blood pressure increased		2		1		1
Blood pressure systolic increased		1				1
Body temperature decreased		2				2
Body temperature increased		2		1		1
Bone disorder		1		1		
Bradycardia		1				1
Brain herniation		1				1
Brain injury		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Brain scan abnormal		1				1
Bronchial haemorrhage		1				1
Bronchitis		1				1
Bundle branch block left		2		1		1
Bursitis		1				1
Cachexia		1				1
Cardiac arrest	2	14			2	14
Cardiac death		1				1
Cardiac discomfort	1	1			1	1
Cardiac disorder	1	4			1	4
Cardiac failure	2	17			2	17
Cardiac failure acute	1	1			1	1
Cardiac failure chronic		1				1
Cardiopulmonary failure		1				1
Catheter site haemorrhage		1		1		
Cerebellar haemorrhage		1				1
Cerebral artery embolism	1	3			1	3
Cerebral atrophy		1				1
Cerebral haemorrhage	3	7			3	7
Cerebral infarction	4	9			4	9
Cerebral small vessel ischaemic disease	1	1			1	1
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident	6	22			6	22
Cerebrovascular disorder	2	3			2	3
Chest discomfort	1	4		2	1	2
Chest pain	3	13		3	3	10
Chills	3	14		2	3	12
Chronic gastritis		1				1
Chronic obstructive pulmonary disease	1	4			1	4
Chronic respiratory failure		1				1
Circulatory collapse	1	5			1	5
Clostridium difficile colitis		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coeliac artery stenosis		1				1
Cognitive disorder	2	3			2	3
Colitis ulcerative	1	1			1	1
Coma	1	1			1	1
Condition aggravated	2	13		2	2	11
Confusional state	2	12		1	2	11
Constipation		1		1		
Contusion		2				2
Coordination abnormal		3				3
Coronary artery disease	1	1			1	1
Coronary artery occlusion		1				1
Cor pulmonale acute		1				1
Cough		14		6		8
COVID-19	3	16			3	16
C-reactive protein increased	1	9		5	1	4
Crepitations		2		1		1
Cyanosis		3		2		1
Deafness	1	1			1	1
Death	2	29			2	29
Decreased appetite	1	15	1	8		7
Decubitus ulcer		1		1		
Deep vein thrombosis	4	15			4	15
Dehydration		4		1		3
Delusional disorder, unspecified type		1				1
Dementia		1				1
Dementia Alzheimer's type		1				1
Depressed level of consciousness	1	14			1	14
Depression		1				1
Device related infection		1				1
Diarrhoea	4	18	2	5	2	13
Dilatation ventricular		1		1		
Diplopia	1	1			1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Discomfort		1				1
Disease recurrence	1	8		1	1	7
Disorganised speech		1				1
Disorientation		1				1
Dissociation		1				1
Disturbance in attention	1	1			1	1
Diverticulitis		1				1
Diverticulum		1		1		
Dizziness	10	29	2	6	8	23
Drug eruption		3		2		1
Drug ineffective	1	9			1	9
Drug intolerance	1	1			1	1
Dry mouth		1				1
Dysarthria		5		1		4
Dysphagia		3				3
Dyspnoea	11	54		5	11	49
Dyspnoea exertional		1				1
Dysstasia	1	2	1	1		1
Ear swelling		1				1
Eczema		1				1
Electrocardiogram ST segment elevation	1	2			1	2
Electrocardiogram ST-T segment depression	1	1			1	1
Embolic cerebral infarction		1				1
Embolism		2				2
Embolism arterial		1				1
Encephalitis		1				1
Energy increased		1				1
Epilepsy		1				1
Epistaxis	1	3	1	1		2
Erysipelas		5				5
Erythema	3	12	1	6	2	6
Escherichia infection		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Escherichia sepsis		1				1
Eye disorder		2				2
Eye haemorrhage		1				1
Eye pain	1	1			1	1
Facial paralysis	1	5			1	5
Facial paresis	1	4			1	4
Fall	6	15	2	4	4	11
Fatigue	18	62	6	26	12	36
Feeling abnormal		1		1		
Feeling cold		3		2		1
Feeling hot		3		3		
Femoral neck fracture		1				1
Fibrin D dimer increased	1	1			1	1
Fluid retention		1				1
Food refusal		1				1
Gait disturbance	4	5			4	5
Gait inability		1		1		
Gastric haemorrhage		1				1
Gastrointestinal disorder	1	1			1	1
Gastrointestinal haemorrhage		1				1
Gaze palsy	1	1			1	1
Generalised oedema		1				1
Generalised tonic-clonic seizure		1				1
General physical health deterioration	5	40	1	7	4	33
Glomerular filtration rate decreased		2		1		1
Glucose tolerance impaired	1	1			1	1
Gout		1				1
Grip strength decreased	1	1			1	1
Haematemesia		1				1
Haematochezia		1				1
Haematoma		2				2
Haemoglobin decreased		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemolytic anaemia		2				2
Haemoptysis		2				2
Haemorrhage		2				2
Haemorrhage subcutaneous		1				1
Hallucination	1	3			1	3
Hallucination, visual		2				2
Headache	7	20	1	5	6	15
Head discomfort		1				1
Head injury	1	3		1	1	2
Heart rate decreased		3		2		1
Heart rate increased		3				3
Heart rate irregular		2		2		
Helplessness		1				1
Hemiparesis	1	7			1	7
Hemiplegia	1	1			1	1
Hepatic enzyme increased		1				1
Hepatic pain	1	1			1	1
Herpes ophthalmic		1				1
Herpes virus infection	1	1			1	1
Herpes zoster	2	8		1	2	7
Hypercalcaemia		1				1
Hyperglycaemia		1				1
Hyperhidrosis	1	2			1	2
Hypernatraemia		1				1
Hyperparathyroidism primary		1		1		
Hypersensitivity		6				6
Hypersomnia	1	2			1	2
Hypertension	2	6			2	6
Hyperventilation	1	1			1	1
Hypoacusis	1	1			1	1
Hypoaesthesia	1	7		4	1	3
Hypoaesthesia oral		3		2		1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoalbuminaemia		1		1		
Hypoglycaemia		1				1
Hypokalaemia		2				2
Hypokinesia	1	1			1	1
Hypoperfusion		1				1
Hypophagia		1				1
Hypopnoea		1				1
Hypotension		15		2		13
Hypothermia		2				2
Hypovolaemic shock	1	1			1	1
Idiopathic pulmonary fibrosis		1				1
Illness		1				1
Immune thrombocytopenia		1				1
Inappropriate schedule of product administration	2	2	2	2		
Incontinence		1		1		
Incorrect route of product administration		3		3		
Increased upper airway secretion		1		1		
Infection	1	8		1	1	7
Inflammation	1	1			1	1
Influenza like illness		1				1
International normalised ratio increased		1				1
Interstitial lung disease	1	1			1	1
Intestinal haemorrhage		2				2
Intestinal ischaemia		1				1
Intracardiac thrombus	1	1			1	1
Irregular breathing		1		1		
Ischaemic stroke	4	11			4	11
Joint stiffness		1		1		
Lacunar infarction	1	1			1	1
Laryngeal oedema		1				1
Left ventricular hypertrophy		1				1
Leukocytosis		1				1

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* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Limb injury	1	2			1	2
Livedo reticularis		1		1		
Loss of consciousness	2	13			2	13
Lower limb fracture	1	1			1	1
Lung disorder		1				1
Lung infiltration	2	2			2	2
Lung opacity	1	1			1	1
Lymphadenopathy		1				1
Malaise	5	15		5	5	10
Memory impairment	2	4			2	4
Meningism		1				1
Mesenteric artery embolism		1				1
Monoplegia		1				1
Muscle spasms	1	3		1	1	2
Muscular weakness	2	10			2	10
Musculoskeletal discomfort	1	1			1	1
Musculoskeletal stiffness		3		1		2
Myalgia	3	12	1	4	2	8
Myelosuppression		1				1
Myocardial infarction	7	18			7	18
Myocardial ischaemia		1				1
Myocardial rupture		1				1
Nasal congestion		2		1		1
Nasopharyngitis		5		1		4
Nausea	5	23	1	6	4	17
Neck pain		1				1
Neoplasm progression		1				1
Neuropathy peripheral		1				1
Neuropsychiatric symptoms	1	1			1	1
N-terminal prohormone brain natriuretic peptide increased		1		1		
Obstructive airways disorder		2				2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oedema peripheral	1	2		1	1	1
Oesophageal ulcer haemorrhage		1				1
Off label use	2	2	2	2		
Ophthalmic herpes zoster	1	1			1	1
Oral discomfort		2				2
Oral mucosal blistering	2	2	2	2		
Oropharyngeal pain		1		1		
Oropharyngeal swelling	1	1			1	1
Orthostatic hypotension	1	2			1	2
Osteoarthritis	1	1			1	1
Oxygen saturation abnormal		1		1		
Oxygen saturation decreased	1	21		3	1	18
Pain	6	22	2	6	4	16
Painful respiration	1	2		1	1	1
Pain in extremity	4	14		3	4	11
Pain in jaw	1	1			1	1
Pallor		5		3		2
Palpitations		1		1		
Pancytopenia		1				1
Paraesthesia	1	5			1	5
Paranoia	1	1			1	1
Paraparesis	1	1			1	1
Paresis		1				1
Pemphigoid		2				2
Penile haemorrhage		1				1
Pericardial effusion		1				1
Pericardial haemorrhage		1				1
Pericarditis		1				1
Periorbital oedema		1				1
Peripheral coldness		1				1
Peripheral embolism	2	3			2	3
Peripheral swelling	5	14	2	3	3	11

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Petechiae		2				2
Petit mal epilepsy		2				2
Pharyngeal swelling		1				1
Phlebitis		1				1
Physical disability	1	1			1	1
Pleural effusion		2				2
Pneumonia	3	11			3	11
Pneumonia aspiration		1				1
Pneumonia bacterial		1				1
Pneumonia pneumococcal		1				1
Pneumonia streptococcal		1				1
Pneumothorax	1	1			1	1
Polyneuropathy	1	2			1	2
Postoperative wound complication		1				1
Post stroke epilepsy		1				1
Product administered at inappropriate site		1		1		
Productive cough	1	4			1	4
Pruritus	4	10	2	3	2	7
Psychotic disorder		2				2
Pulmonary embolism	14	42			14	42
Pulmonary fibrosis	2	2			2	2
Pulmonary oedema	3	9			3	9
Pulmonary thrombosis		2				2
Pulse abnormal		2		2		
Pyrexia	13	76	5	25	8	51
Rash	2	5		1	2	4
Rash erythematous		1				1
Rash macular		1		1		
Rash pruritic		1				1
Red blood cell sedimentation rate increased		1				1
Renal failure	1	2			1	2
Renal impairment		1				1

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal infarct		1				1
Respiratory arrest		2				2
Respiratory distress		5				5
Respiratory failure	2	4			2	4
Respiratory rate increased		6		1		5
Respiratory symptom	1	1			1	1
Retinal artery occlusion		1				1
Retinal vein occlusion		1				1
Retroperitoneal haemorrhage		1				1
Rhinitis		1		1		
Rhinorrhoea		2		1		1
Rib fracture		1				1
Scapula fracture		1				1
Seizure		2				2
Sensory disturbance	1	1			1	1
Sepsis	2	7			2	7
Sinus tachycardia	1	1			1	1
Skin discolouration		3				3
Skin disorder		1				1
Skin turgor decreased		1				1
Skin ulcer		2				2
Skin wound		1				1
Skull fracture	1	1			1	1
Slow speech		1				1
Somnolence	1	6		2	1	4
Speech disorder	1	3		1	1	2
Spinal subdural haemorrhage	1	1			1	1
Stevens-Johnson syndrome		1				1
Streptococcal bacteraemia		1				1
Stroke in evolution	1	1			1	1
Subarachnoid haemorrhage	1	2			1	2
Subdural haematoma	1	2			1	2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sudden death		5				5
Suspected COVID-19		1				1
Swelling		2		1		1
Swelling face	1	4		1	1	3
Swollen tongue		2		1		1
Syncope	2	8			2	8
Systemic inflammatory response syndrome		1				1
Tachycardia	1	3		1	1	2
Tachypnoea		2		1		1
Tenderness		2		1		1
Tenosynovitis		1				1
Throat irritation		1				1
Throat tightness		1				1
Thrombocytopenia	6	10			6	10
Thrombophlebitis	2	5	1	1	1	4
Thrombophlebitis superficial		1				1
Thrombosis	2	4			2	4
Tinnitus	2	2			2	2
Toxic epidermal necrolysis		1				1
Tracheal haemorrhage		1				1
Transient ischaemic attack	2	8			2	8
Tremor	3	5			3	5
Troponin I increased	1	1			1	1
Troponin increased	1	1			1	1
Troponin T increased	1	1			1	1
Unresponsive to stimuli		2				2
Upper gastrointestinal haemorrhage		1				1
Upper respiratory tract infection		1				1
Urinary retention		1				1
Urinary tract infection	2	12		6	2	6
Urine output decreased		2				2
Urosepsis		3				3

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria	1	7	1	3		4
Vaccination failure	2	3			2	3
Vaccination site discolouration	1	1			1	1
Vaccination site erythema	1	10	1	5		5
Vaccination site haematoma	1	2			1	2
Vaccination site haemorrhage	2	2			2	2
Vaccination site infection		1				1
Vaccination site pain	1	5	1	3		2
Vaccination site phlebitis		1		1		
Vaccination site pruritus		1				1
Vaccination site reaction		2				2
Vaccination site swelling	1	6		2	1	4
Vaccination site thrombosis		1				1
Vaccination site warmth	2	3	1	2	1	1
Varicose vein	1	1	1	1		
Vascular dementia		1				1
Vasculitis		1				1
Ventricular f brillation		2				2
Ventricular hypokinesia		1				1
Ventricular tachycardia		1				1
Vision blurred	1	1			1	1
Visual field defect		1				1
Visual impairment	1	1			1	1
Vitreous detachment	1	1			1	1
Vomiting	5	36	2	6	3	30
Wheezing	1	8		2	1	6
White blood cell count increased		2		2		
White blood cells urine positive		1		1		
Wound		1		1		
Wound necrosis		1				1
	381	1,666	50	295	331	1371

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1		1		
Abdominal pain upper		1		1		
Allergy to vaccine		1		1		
Arthralgia	1	2	1	2		
Asthenia	1	2	1	2		
Chills	4	5	3	4	1	1
Circumstance or information capable of leading to medication error		29		29		
COVID-19	2	25	2	23		2
Death		2				2
Diarrhoea		1		1		
Dizziness		1		1		
Drug ineffective		1				1
Dysphonia		1		1		
Dyspnoea		1				1
Erythema		3		3		
Facial paresis		1				1
Fatigue	1	1	1	1		
Feeling abnormal	1	1	1	1		
Gastrointestinal pain		1		1		
Headache	4	7	4	7		
Herpes zoster		1		1		
Hypoaesthesia		1				1
Hypoaesthesia oral		1				1
Incorrect route of product administration		3		3		
Lymphadenopathy	1	1	1	1		
Lymph node pain	1	1	1	1		
Malaise	3	5	3	5		
Maternal exposure during pregnancy	1	1	1	1		
Muscular weakness		1		1		
Musculoskeletal stiffness	1	2	1	2		
Myalgia		3		3		

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea		1		1		
Neck pain		1		1		
Neurological symptom		1				1
Pain		1		1		
Pain in extremity	2	10	2	10		
Paraesthesia		1		1		
Paralysis		1				1
Poor quality product administered		33		33		
Product colour issue		34		34		
Product preparation issue	1	1	1	1		
Pruritus		2		2		
Pyrexia	2	6	2	6		
Renal pain	1	1	1	1		
Rhinorrhoea		1		1		
Throat irritation		1		1		
Underdose	1	2	1	2		
Vaccination site erythema		1		1		
Vaccination site haemorrhage		1		1		
Vaccination site hypoaesthesia		1		1		
Vaccination site joint movement impairment		3		3		
Vaccination site movement impairment	1	1	1	1		
Vaccination site pain	3	10	3	10		
Vaccination site swelling	1	3	1	2		1
Vaccination site warmth		1		1		
Weight decreased		1		1		
	33	226	32	213	1	13

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Country Where Event Occurred

SWITZERLAND

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Diarrhoea	1	1	1	1
Generalised tonic-clonic seizure	1	1	1	1
Hypokalaemia	1	1	1	1
Nausea	1	1	1	1
Oropharyngeal pain	1	1	1	1
Pyrexia	1	1	1	1
	6	6	6	6

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Acute stress disorder		1				1
Anaphylactic reaction	2	2			2	2
Angioedema	1	2			1	2
Arthralgia	1	2	1	2		
Asthenia		1				1
Cardiac murmur	1	1			1	1
Cardiovascular disorder		1				1
Carotid bruit	1	1			1	1
Chest discomfort		1				1
Chills	3	5	2	2	1	3
Circulatory collapse	1	1			1	1
Cough		1				1
COVID-19		1				1
C-reactive protein increased	1	1			1	1
Crohn's disease	1	1			1	1
Diarrhoea	2	3	2	2		1
Dissociative disorder		1				1
Disturbance in attention	1	1	1	1		
Dizziness	2	4	2	3		1
Dysphagia	2	2			2	2
Dyspnoea	1	3		1	1	2
Epilepsy	1	1			1	1
Erythema		1		1		
Eye pain		1		1		
Fatigue	3	8	2	5	1	3
Gait disturbance		1				1
Headache	4	7	4	5		2
Hemianaesthesia	1	1			1	1
Hemiparaesthesia	1	1			1	1
Herpes zoster		1				1
Hyperhidrosis		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypersensitivity	1	2			1	2
Hypertension		2				2
Hypoaesthesia oral		1		1		
Hypotension		1				1
Iliac bruit	1	1			1	1
Influenza	1	1	1	1		
Influenza like illness		1		1		
Lymphadenopathy	3	4	3	3		1
Malaise	4	4	1	1	3	3
Mouth swelling	1	1			1	1
Muscle spasms		1				1
Myalgia	4	5	4	4		1
Myocarditis	1	1			1	1
Nasopharyngitis		1				1
Nausea	2	5	1	2	1	3
Neck pain	1	1	1	1		
Oral herpes		1				1
Pain		1		1		
Pain in extremity	1	5	1	3		2
Pallor		1				1
Palpitations	1	1			1	1
Paraesthesia		2		1		1
Paraesthesia oral	1	2		1	1	1
Performance status decreased	1	1	1	1		
Peripheral coldness		1				1
Presyncope	1	3			1	3
Pruritus		1				1
Pyrexia	2	7	2	4		3
Rash	1	3		1	1	2
Rash pruritic	1	1	1	1		
Somnolence	1	1			1	1
Supraventricular tachycardia	1	1			1	1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling of eyelid		1				1
Syncope	2	5			2	5
Tachycardia	1	2		1	1	1
Urticaria		1				1
Vaccination site cellulitis	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site pain	3	4	3	4		
Vaccination site swelling	1	1	1	1		
Vertigo	1	1			1	1
Vomiting	1	3	1	1		2
	72	144	38	60	34	84

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Acute stress disorder		1				1
Amnesia	1	1			1	1
Anaphylactic reaction	1	4			1	4
Anaphylactic shock		1				1
Angina pectoris		1				1
Angioedema	3	7			3	7
Aphthous ulcer	1	1	1	1		
Arthralgia	6	10	6	8		2
Asthenia	2	7	2	2		5
Asthma		3				3
Asymptomatic COVID-19		1		1		
Axillary lymphadenectomy		1				1
Back pain		1		1		
Balance disorder	1	1	1	1		
Bell's palsy	1	1			1	1
Blood pressure decreased		1		1		
Blood pressure increased	1	3	1	1		2
Body temperature increased	1	1	1	1		
Bradycardia	1	1			1	1
Breast haematoma		1				1
Breast pain		1				1
Bronchial hyperreactivity	1	1			1	1
Chest discomfort		3				3
Chest pain	2	3	1	1	1	2
Chills	8	14	6	6	2	8
Circulatory collapse		1				1
Cold sweat	1	1	1	1		
Cough	1	3	1	3		
COVID-19		6				6
C-reactive protein increased	1	1			1	1
Deafness unilateral	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deep vein thrombosis		1				1
Diarrhoea		3		1		2
Diplopia		1				1
Discomfort	1	1			1	1
Disease recurrence		2				2
Disturbance in attention		1		1		
Dizziness	4	10	2	2	2	8
Drug eruption		1				1
Drug ineffective		3				3
Drug interaction		1		1		
Dysaesthesia	2	4	1	1	1	3
Dysphagia	1	1	1	1		
Dysphonia		1		1		
Dyspnoea	3	5			3	5
Ear discomfort	1	1	1	1		
Electrocardiogram abnormal	1	1			1	1
Erythema	1	3			1	3
Eye discharge	1	1			1	1
Eye disorder	1	1			1	1
Eye pain	1	1			1	1
Fatigue	9	17	5	9	4	8
Feeling cold		1		1		
Feeling hot		4		1		3
Flushing		2				2
Gastrointestinal disorder		1				1
Hair growth abnormal		1		1		
Headache	15	29	10	15	5	14
Heart rate increased		1				1
Heavy menstrual bleeding	1	1	1	1		
Herpes virus infection	1	1			1	1
Herpes zoster	1	4			1	4
Hot flush	3	3			3	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperhidrosis	1	3	1	1		2
Hypersensitivity	4	13	1	4	3	9
Hypertension	1	5	1	2		3
Hypertensive crisis	1	1			1	1
Hypertonia	1	1			1	1
Hyperventilation		4				4
Hypoaesthesia oral		1				1
Hypotension	1	2			1	2
Illusion		1		1		
Immunisation anxiety related reaction		2				2
Inappropriate schedule of product administration	1	1	1	1		
Incorrect route of product administration	1	3	1	2		1
Influenza	1	2	1	1		1
Influenza like illness	3	3	3	3		
Insomnia		1		1		
Joint range of motion decreased	1	2	1	1		1
Joint swelling	1	1			1	1
Language disorder	1	1			1	1
Lethargy		1		1		
Lip swelling	1	1	1	1		
Livedo reticularis	1	1	1	1		
Lymphadenopathy	4	4	3	3	1	1
Lymph node pain	2	3	2	2		1
Malaise	3	14		2	3	12
Migraine	1	1	1	1		
Monoplegia		1				1
Muscle spasms		2				2
Muscle tightness	1	1			1	1
Muscular weakness	1	2			1	2
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	1	1	1	1		
Myalgia	11	18	9	12	2	6

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myelitis		1				1
Nasal congestion	1	1	1	1		
Nausea	4	7	3	4	1	3
Neck pain	1	1	1	1		
Neuralgia	2	3	1	1	1	2
Neuralgic amyotrophy		2				2
Neuropathy peripheral	1	1			1	1
Obstructive airways disorder		1				1
Ocular hyperaemia	1	1			1	1
Odynophagia	1	1	1	1		
Off label use	2	2	2	2		
Oropharyngeal pain	1	2	1	2		
Pain	1	5	1	1		4
Pain in extremity	4	7	2	2	2	5
Palpitations		3				3
Paraesthesia	3	5			3	5
Paraesthesia ear	1	1	1	1		
Periorbital swelling	1	1	1	1		
Peripheral coldness		1				1
Peripheral swelling	1	1			1	1
Photophobia	1	2	1	1		1
Pneumonia		1				1
Presyncope		3				3
Pruritus	3	5	1	1	2	4
Pyrexia	10	23	8	11	2	12
Rash	3	8	3	7		1
Rash erythematous		1				1
Rash papular		1				1
Respiratory distress		1				1
Restless legs syndrome	2	2			2	2
Rhinitis		1		1		
Sense of oppression		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensory disturbance	2	3			2	3
Sickle cell anaemia with crisis		1				1
Sinus disorder	1	1	1	1		
Sinus tachycardia		1				1
Skin reaction	2	2	2	2		
Spinal pain	1	1			1	1
Subclavian vein thrombosis	1	1			1	1
Sudden death		1				1
Swelling face	1	1	1	1		
Swelling of eyelid	1	1	1	1		
Syncope	1	3			1	3
Tachycardia	2	12	1	2	1	10
Tachypnoea		1				1
Tension	1	1			1	1
Therapeutic response unexpected		1		1		
Throat irritation		1				1
Throat tightness	1	2			1	2
Tinnitus	1	1	1	1		
Tongue dry	1	1			1	1
Tooth infection	1	1			1	1
Tremor	1	3	1	1		2
Trigeminal neuralgia		1				1
Troponin increased	1	1			1	1
Type II hypersensitivity		1				1
Urticaria	2	3	1	1	1	2
Vaccination failure		2				2
Vaccination site erythema	2	4	2	3		1
Vaccination site induration	1	2	1	1		1
Vaccination site lymphadenopathy		1				1
Vaccination site oedema		1		1		
Vaccination site pain	1	7	1	4		3
Vaccination site pruritus	2	3	2	3		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site reaction	1	1	1	1		
Vaccination site swelling	1	1	1	1		
Vaccination site urticaria	1	1	1	1		
Vaccination site warmth		2		1		1
Vertigo	4	5	1	1	3	4
Visual field defect	1	1			1	1
Visual impairment		2				2
Vomiting	2	4	2	2		2
	207	469	120	175	87	294

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Acute kidney injury		1				1
Acute stress disorder	1	1			1	1
Allergy to vaccine	1	1			1	1
Anaphylactic reaction	1	8			1	8
Angioedema		3				3
Aphonia	1	1	1	1		
Arthralgia	5	5	4	4	1	1
Asthenia	3	7	2	5	1	2
Atrial fibrillation	1	1			1	1
Atrioventricular block first degree	1	1			1	1
Autonomic nervous system imbalance	1	1	1	1		
Bedridden	1	1	1	1		
Blindness transient		1				1
Blood glucose increased		1		1		
Blood pressure increased		1		1		
Bradycardia	2	2			2	2
Cerebrovascular accident		1				1
Chest discomfort		1				1
Chest pain	1	1			1	1
Chills	3	6	1	1	2	5
Cholecystitis acute		1				1
Circulatory collapse	1	1			1	1
Colitis ulcerative	1	1			1	1
Condition aggravated	2	2	1	1	1	1
Contusion		1		1		
Cough	2	3	2	2		1
COVID-19	2	3			2	3
Craniocerebral injury		1		1		
Deep vein thrombosis		1				1
Dermatitis allergic	1	1			1	1
Diarrhoea	2	4	2	2		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea haemorrhagic	1	1			1	1
Dizziness	2	7	2	3		4
Dysaesthesia	1	1			1	1
Dyspnoea		5		2		3
Dyspnoea at rest	1	1			1	1
Dyspnoea exertional	1	1			1	1
Encephalopathy	1	1			1	1
Enthesopathy	1	1	1	1		
Epilepsy		1				1
Erythema		2				2
Erythema annulare		1				1
Eye haemorrhage		1				1
Eyelid oedema		2				2
Facet joint syndrome	1	1	1	1		
Facial paralysis	1	3			1	3
Facial paresis		1				1
Fall	1	2		1	1	1
Fatigue	9	12	6	8	3	4
Feeling cold		2		2		
Gastritis		1				1
Gastroesophageal reflux disease		1				1
Generalised tonic-clonic seizure	1	1			1	1
General physical health deterioration	1	1	1	1		
Haemophagocytic lymphohistiocytosis		1				1
Headache	10	14	8	9	2	5
Head discomfort	1	1	1	1		
Head injury	1	1			1	1
Hemianaesthesia	1	1			1	1
Herpes zoster		2				2
Hypercholesterolaemia	1	1			1	1
Hyperhidrosis		1				1
Hypersensitivity	1	9		1	1	8

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertension	1	6	1	2		4
Hyperthermia	1	1			1	1
Hyperventilation	1	1			1	1
Hypotension	1	2	1	1		1
Impaired work ability	1	2	1	2		
Inappropriate schedule of product administration		1		1		
Incorrect route of product administration		2		2		
Influenza like illness	2	3	1	2	1	1
Injection site discomfort	1	1	1	1		
Lip oedema		1				1
Lip swelling		1				1
Lower respiratory tract infection	1	1			1	1
Lymphadenopathy		3		1		2
Malaise	3	5	2	3	1	2
Middle insomnia		1		1		
Mobility decreased		1		1		
Muscular weakness	1	1			1	1
Musculoskeletal pain		1		1		
Musculoskeletal stiffness	1	1	1	1		
Myalgia	5	10	2	2	3	8
Myoclonus	1	1			1	1
Nausea	3	7	2	2	1	5
Oedema peripheral		2		1		1
Oesophageal perforation		1				1
Off label use		1		1		
Oropharyngeal oedema		1				1
Oropharyngeal pain	2	2	2	2		
Pain	1	1	1	1		
Pain in extremity	2	2	1	1	1	1
Paraesthesia	1	3	1	2		1
Paraesthesia oral		1				1
Periarthritis	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral swelling		1				1
Pharyngeal paraesthesia		1				1
Platelet count increased		1		1		
Presyncope	1	2			1	2
Pruritus	1	3	1	2		1
Psychiatric decompensation	1	1			1	1
Pulmonary embolism		1				1
Pyrexia	7	10	6	6	1	4
Rash	1	3			1	3
Rib fracture		1		1		
SARS-CoV-2 ant body test negative		1		1		
Sedation		1				1
Sense of oppression		1				1
Sensory disturbance	1	1			1	1
Septic shock		1				1
Skin lesion		1				1
Sleep disorder		1		1		
Sudden hearing loss		1				1
Synovitis	1	1	1	1		
Tendon rupture	1	1	1	1		
Throat tightness		1				1
Thrombocytopenia		1				1
Tinnitus		1				1
Tongue oedema		1				1
Transient ischaemic attack	1	1			1	1
Traumatic haematoma	1	1			1	1
Tremor	1	1	1	1		
Underdose		1		1		
Urticaria		1				1
Vaccination failure	2	2			2	2
Vaccination site erythema	1	2	1	1		1
Vaccination site haematoma		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	2	4		1	2	3
Vaccination site reaction		1				1
Vaccination site swelling		1				1
Vaccination site urticaria		1				1
Vertigo		1		1		
Vomiting	3	8	1	1	2	7
Wrong technique in product usage process		1		1		
	126	279	65	105	61	174

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		2				2
Abdominal pain lower		1				1
Acute kidney injury	1	1			1	1
Agitation		1				1
Alanine aminotransferase increased		1		1		
Amnesia		1		1		
Anaemia		1				1
Anaphylactic reaction		3				3
Anti-myelin-associated glycoprotein antibodies positive		1				1
Aphasia		2				2
Arrhythmia		2				2
Arthralgia	3	8	2	2	1	6
Ascites		1				1
Asthenia	1	1	1	1		
Asthma	1	1			1	1
Atrial f brillation	1	3			1	3
Atypical pneumonia	1	1			1	1
Back pain	2	2	1	1	1	1
Balance disorder	2	2	1	1	1	1
Blood alkaline phosphatase increased		1		1		
Blood pressure increased	2	4			2	4
Bronchial wall thickening	1	1	1	1		
Burning sensation	1	1	1	1		
Cardiac disorder	1	1			1	1
Cardiac failure acute		1				1
Cardiovascular disorder		1				1
Central nervous system lesion		1				1
Cerebrovascular accident	1	2			1	2
Cheilitis	1	1	1	1		
Chest injury	1	1			1	1
Chest pain		2				2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills	1	4	1	1		3
Cholestasis		1				1
Chronic obstructive pulmonary disease		1				1
Circulatory collapse		1				1
Cold sweat		1				1
Colitis microscopic	1	1			1	1
Condition aggravated	1	2	1	1		1
Confusional state	1	2			1	2
Conjunctivitis bacterial		1				1
Cough	1	2	1	1		1
COVID-19		3				3
COVID-19 pneumonia	1	2			1	2
Cranio-cerebral injury	1	1			1	1
C-reactive protein increased		1				1
Cystitis		1				1
Deafness unilateral		1				1
Decreased appetite		1				1
Deep vein thrombosis	2	3			2	3
Delirium		2				2
Dermatitis allergic		1		1		
Diarrhoea		1				1
Discomfort		1		1		
Disease recurrence	1	2			1	2
Disturbance in attention		2				2
Dizziness	3	8	2	4	1	4
Drug ineffective	1	2			1	2
Drug interaction	1	1	1	1		
Dysarthria		1				1
Dysgeusia		2		2		
Dyskinesia	1	1	1	1		
Dyspnoea	3	7		1	3	6
Embolic stroke		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Encephalitis	2	3			2	3
Encephalopathy		1				1
Eosinophilia		1		1		
Epilepsy		3				3
Epistaxis		1		1		
Erysipeloid		1				1
Erythema	1	3		1	1	2
Extrasystoles	1	1			1	1
Eye haematoma	1	1			1	1
Eyelids pruritus	1	1	1	1		
Facial bones fracture	1	1			1	1
Facial paralysis	1	1			1	1
Facial paresis		1				1
Fall	2	5		1	2	4
Fatigue	4	5	2	2	2	3
Feeling hot	1	1			1	1
Gait disturbance	1	3	1	2		1
Generalised tonic-clonic seizure		1				1
General physical health deterioration		1		1		
Gout		1				1
Haematemesis		1				1
Haemoptysis	1	1			1	1
Hallucination, visual		1				1
Headache	5	13	3	4	2	9
Head injury	1	1			1	1
Heart rate increased	1	1	1	1		
Herpes zoster	6	13	2	2	4	11
Hypersensitivity		3				3
Hypertension	4	8	1	1	3	7
Hypertensive crisis	1	2			1	2
Hypertensive emergency		1				1
Hypotension		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Immune thrombocytopenia		1				1
Infection		1		1		
Inflammation		1				1
Influenza like illness		1				1
Insomnia	2	2	2	2		
Ischaemic cerebral infarction		1				1
Joint dislocation		1				1
Joint swelling	1	1	1	1		
Keratitis	1	1			1	1
Loss of consciousness		1				1
Loss of personal independence in daily activities	1	1	1	1		
Lung consolidation	1	1	1	1		
Lung disorder		1				1
Lung infiltration	1	1			1	1
Lymphadenopathy	1	1	1	1		
Malaise		4				4
Metabolic syndrome		1				1
Monocytosis	1	2		1	1	1
Multiple sclerosis relapse	1	1			1	1
Musculoskeletal stiffness		1				1
Myalgia	3	6	2	2	1	4
Myocardial infarction		1				1
Nausea	3	6	2	4	1	2
Neck pain	2	2	1	1	1	1
Neuralgia	1	2	1	1		1
NIH stroke scale score decreased		1				1
Ophthalmic herpes zoster	1	2			1	2
Oral herpes	1	1	1	1		
Pain	1	2		1	1	1
Pain in extremity	3	5	2	3	1	2
Pallor	1	2	1	1		1
Palpitations		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pancreatitis		1				1
Paraesthesia		1				1
Paraesthesia oral		1				1
Parotitis		1				1
Petechiae	1	1			1	1
Pleocytosis		1				1
Pleural effusion		1		1		
Pneumonia bacterial		1				1
Pneumonia pneumococcal		1				1
Polyneuropathy		1				1
Presyncope		1				1
Pruritus	1	7	1	3		4
Pulmonary congestion	1	1			1	1
Pulmonary embolism	4	5			4	5
Pulmonary fibrosis		1				1
Pulmonary infarction	1	1			1	1
Pyrexia	6	14	2	5	4	9
Rash	1	2	1	1		1
Rash erythematous		1				1
Rash maculo-papular	1	3		1	1	2
Rash pruritic	1	1	1	1		
Rash pustular		1				1
Respiratory distress	1	1			1	1
Respiratory failure		1				1
Rheumatoid arthritis		2				2
Road traffic accident		1				1
Salivary hypersecretion		1				1
Scratch		1		1		
Sensory disturbance		1				1
Sepsis		1				1
Skin disorder		1				1
Skin reaction		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Somnolence		2				2
Speech disorder		1				1
Stress cardiomyopathy		1				1
Sudden death		2				2
Swelling face	1	1			1	1
Syncope		3				3
Tachycardia		2				2
Tendon rupture		1				1
Thrombocytopenia		1				1
Thrombophlebitis superficial	1	1			1	1
Thrombosis	1	1			1	1
Transient ischaemic attack		2				2
Upper gastrointestinal haemorrhage	1	1			1	1
Urinary incontinence		1				1
Urticaria	2	3	1	2	1	1
Vaccination failure		1				1
Vaccination site erythema		1		1		
Vaccination site haematoma	1	1	1	1		
Vaccination site pain	1	3	1	2		1
Vaccination site pruritus	1	2	1	1		1
Vaccination site rash	1	1	1	1		
Varicella zoster virus infection		1				1
Vascular encephalopathy		1				1
Vertigo	1	2	1	1		1
Vertigo positional		1				1
Visual impairment		1				1
Vomiting		3		2		1
White matter lesion		1		1		
	129	352	53	91	76	261

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal infection		1				1
Abdominal pain	1	5		1	1	4
Acute kidney injury		2				2
Acute myocardial infarction		2				2
Acute pulmonary oedema		2				2
Alopecia		1				1
Altered state of consciousness		1				1
Anal haemorrhage		1		1		
Anaphylactic reaction		1				1
Angioedema		1				1
Aphasia		2				2
Aphthous ulcer		1				1
Apnoea		1				1
Appendicitis		1				1
Arrhythmia	1	1			1	1
Arteriosclerosis		1				1
Arteriosclerosis coronary artery		1				1
Arthralgia	1	2	1	1		1
Asthenia	3	8	2	2	1	6
Atrial f brillation	1	3			1	3
Atrioventricular block second degree	1	1			1	1
Atrophy		1				1
Back pain		2		1		1
Blister		1		1		
Blood pressure decreased		1				1
Bradycardia	1	1			1	1
Brain hypoxia		1				1
Cardiac arrest		2				2
Cardiac failure		5				5
Cardiac failure acute		1				1
Cardiac failure chronic		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac failure congestive		1				1
Cardiac fibrillation		1				1
Cardiac valve disease		1				1
Cardiogenic shock	1	1			1	1
Cardio-respiratory arrest		1				1
Cerebral infarction		1				1
Cerebrovascular accident	1	3			1	3
Chills	2	4	2	3		1
Cholestasis		1				1
Chronic obstructive pulmonary disease		1				1
Circulatory collapse		1				1
Coma		2				2
Condition aggravated	2	3	1	1	1	2
Confusional state	1	3	1	1		2
Contusion	1	1	1	1		
Cough	1	3	1	1		2
COVID-19	1	7		1	1	6
COVID-19 pneumonia	1	1			1	1
Craniocerebral injury		1				1
C-reactive protein increased	1	4	1	2		2
CSF test abnormal		1				1
Death	2	8			2	8
Decreased appetite		2		1		1
Deep vein thrombosis	1	1			1	1
Dehydration		2				2
Delirium		3				3
Dementia		1				1
Dermatitis bullous	1	1			1	1
Dermatitis psoriasiform	1	1	1	1		
Diabetic ketoacidosis		1				1
Diabetic metabolic decompensation		1				1
Diarrhoea	3	7	2	4	1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Discomfort		1				1
Disease recurrence	1	1			1	1
Disorientation		2				2
Disturbance in attention		1				1
Dizziness	1	5	1	2		3
Duodenal ulcer haemorrhage	1	1			1	1
Dysarthria		1				1
Dyspnoea	2	7	2	2		5
Ear pain		1				1
Eczema	1	1	1	1		
Embolism		1				1
Enuresis		1				1
Epigastric discomfort	1	1	1	1		
Epilepsy		2				2
Epistaxis	1	1	1	1		
Erysipelas		2				2
Erythema	1	2			1	2
Extremity necrosis	1	1			1	1
Facial paralysis		1				1
Facial paresis		1				1
Fall	2	5	1	1	1	4
Fatigue	2	8	2	3		5
Feeding disorder		2		1		1
Flatulence	1	1	1	1		
Fluid overload		1				1
Gait disturbance		1				1
Gastric disorder		1				1
Gaze palsy	1	1			1	1
Generalised tonic-clonic seizure		1				1
General physical health deterioration		7		2		5
Glomerulonephritis minimal lesion		1				1
Haemorrhagic stroke		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache	3	6	2	5	1	1
Heart rate decreased		1				1
Hemiparesis	1	1			1	1
Hemiplegia		1				1
Hepatic cirrhosis		1				1
Hepatocellular injury		1				1
Herpes zoster	2	7			2	7
Hyperglycaemia		1				1
Hypersensitivity		1				1
Hypertension	1	4			1	4
Hypertensive crisis	1	2			1	2
Hyperthermia		1		1		
Hypoglycaemic coma		1				1
Hypotension		3				3
Incorrect route of product administration	3	6	3	6		
Inflammation		2				2
Insomnia	1	2	1	2		
Ischaemic cerebral infarction		2				2
Joint swelling		1				1
Left ventricular failure		1				1
Leukopenia	1	1			1	1
Liver disorder		1				1
Liver injury		1				1
Loss of consciousness		2				2
Lymphangiectasia		1				1
Lymphopenia		1				1
Malaise	1	5		1	1	4
Meniere's disease		1				1
Meningioma		1				1
Muscle disorder		1				1
Muscular weakness		1				1
Myalgia	2	3	1	2	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	3	10	3	4		6
Neck pain	1	2	1	1		1
Nervous system disorder		1				1
Neuralgia		1				1
Neutrophilia		1				1
Odynophagia	1	1	1	1		
Oedema peripheral	1	2			1	2
Ophthalmic herpes zoster		1				1
Oropharyngeal pain	2	3	2	2		1
Otitis media	1	1			1	1
Overdose	1	1	1	1		
Oxygen saturation decreased		3				3
Pain	1	3	1	2		1
Pain in extremity	1	1	1	1		
Pallor	1	1	1	1		
Paraesthesia	1	1	1	1		
Paranoia		1				1
Paresis	1	1	1	1		
Pemphigoid	2	2			2	2
Performance status decreased		1				1
Pericardial effusion		1				1
Peripheral swelling	1	1			1	1
Peripheral vascular disorder		1				1
Peripheral venous disease	1	1	1	1		
Pleural effusion		1				1
Pneumonia		3				3
Pneumonia aspiration	1	2			1	2
Presyncope	2	2	1	1	1	1
Pruritus	4	7	2	2	2	5
Pulmonary embolism	1	4			1	4
Pulmonary oedema		1				1
Purpura		1				1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyelitis	1	1			1	1
Pyelonephritis	1	1			1	1
Pyrexia	3	18	2	3	1	15
Rash	3	4	2	2	1	2
Rash papulosquamous	1	1	1	1		
Rash pruritic		1				1
Renal failure		2				2
Renal impairment		1				1
Respiratory depression		1				1
Respiratory distress		1				1
Respiratory failure		2				2
Respiratory paralysis		1				1
Respiratory tract infection		1				1
Scratch		1		1		
Seizure		1				1
Sensory disturbance		1				1
Sepsis		1				1
Septic shock	1	1			1	1
Skin infection	1	1	1	1		
Skin lesion	1	1	1	1		
Skin reaction	1	1	1	1		
Skull fracture		1				1
Somnolence		2				2
Spinal cord ischaemia		1				1
Spinal disorder	1	1	1	1		
Subdural haematoma		1				1
Sudden death		1				1
Superinfection bacterial	1	1			1	1
Swelling face		1		1		
Swollen tongue		1				1
Syncope	2	2			2	2
Tachycardia	1	3			1	3

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachypnoea		1				1
Tremor		1				1
Type I hypersensitivity		1				1
Underdose	1	1	1	1		
Urinary retention	1	1			1	1
Urinary tract infection		2				2
Urinary tract infection bacterial		1				1
Urogenital haemorrhage		1				1
Urticaria		2				2
Vaccination failure	2	3			2	3
Vaccination site erythema	2	4	2	3		1
Vaccination site induration	1	1	1	1		
Vaccination site pain	1	5	1	3		2
Vaccination site pruritus	1	1	1	1		
Vaccination site rash	1	2	1	2		
Vaccination site reaction	1	1	1	1		
Vaccination site swelling	1	2	1	1		1
Vaccination site warmth	1	1	1	1		
Ventricular fibrillation		1				1
Vertigo		1				1
Vomiting		8		1		7
Weight decreased		1		1		
	119	417	66	103	53	314

* I=Interval, C=Cumulative

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Amnesia		1		1		
Arrhythmia		2				2
Arthralgia	1	1	1	1		
Asthenia	1	2	1	1		1
Body temperature increased		1		1		
Bone formation increased		1		1		
Bone pain		1		1		
Burning sensation	1	1	1	1		
Chest pain		1				1
Chills	2	7	2	6		1
COVID-19		3				3
Depressed mood		1		1		
Diarrhoea		1				1
Dizziness	2	3	2	2		1
Drug ineffective		3				3
Dyspnoea		1				1
Ear pruritus		1				1
Facial paralysis	4	4			4	4
Fatigue	1	2	1	2		
Gastrointestinal disorder		2		2		
Gastrooesophageal reflux disease		1				1
Genital herpes		1				1
Headache	4	6	4	6		
Immune-mediated adverse reaction		1		1		
Influenza like illness		1				1
Lymphadenopathy	1	1	1	1		
Malaise	2	3	2	3		
Migraine		1		1		
Myalgia	1	4	1	4		
Nausea		2		1		1
Odynophagia		1				1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in extremity	1	3	1	3		
Peak expiratory flow rate decreased		1				1
Product administration error		1		1		
Pyrexia	5	8	5	6		2
Swelling face		1		1		
Tendon pain		1		1		
Therapeutic response unexpected		1		1		
Tumour marker increased		2		2		
Underdose		1		1		
Vaccination site pain	4	4	4	4		
Vaccination site reaction	1	1	1	1		
Viral infection		1		1		
Vomiting		1				1
Wrong product administered		1		1		
	32	89	28	61	4	28

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Country Where Event Occurred

THAILAND

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breast haematoma	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

TUNISIA

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia		2		2
Chills		1		1
Cough		1		1
Dizziness		2		2
Dysgeusia		1		1
Fatigue		1		1
Headache		1		1
Hypertension		1		1
Influenza like illness		1		1
Injection site pain		1		1
Musculoskeletal stiffness		1		1
Myalgia		2		2
Pain in extremity	1	1	1	1
Paraesthesia		1		1
Pyrexia		1		1
Vaccination site pain	1	3	1	3
	2	21	2	21

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Face oedema	1	1	1	1
Headache	1	1	1	1
Hypertension	1	1	1	1
Skin swelling	1	1	1	1
Vasculitis	1	1	1	1
	5	5	5	5

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19		1		1
Diarrhoea	1	1	1	1
Fatigue		1		1
Herpes zoster	4	4	4	4
Influenza	1	1	1	1
Joint range of motion decreased		1		1
Vertigo		1		1
	6	10	6	10

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* AE=Adverse Event

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Country Where Event Occurred

TURKEY

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose		1		1		
COVID-19		1				1
Drug ineffective		1				1
Incorrect dose administered		1		1		
Product preparation error		1		1		
		5		3		2

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* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Aphasia	1	1			1	1
Arthralgia	2	2	1	1	1	1
Asthenia	3	4	3	4		
Axillary pain	1	1	1	1		
Back pain	5	6	4	5	1	1
Blister	2	2	2	2		
Blood pressure systolic increased	1	1			1	1
Burning sensation	1	1	1	1		
Chills	1	2		1	1	1
Contusion	1	1	1	1		
COVID-19		1		1		
Cytomegalovirus infection	1	1			1	1
Deafness	1	1			1	1
Depressed level of consciousness	1	1			1	1
Dizziness	2	4	2	4		
Dry skin		1		1		
Dysphagia	1	1	1	1		
Dyspnoea	1	2		1	1	1
Erythema	2	4	2	4		
Fatigue	1	2	1	2		
Feeling hot	1	1	1	1		
Headache	6	10	5	9	1	1
Heart rate increased	2	2	1	1	1	1
Hyperacusis	1	1	1	1		
Hypersensitivity	2	2	1	1	1	1
Hypertension	1	1			1	1
Hypoaesthesia	2	2	2	2		
Hypokinesia	2	2	1	1	1	1
Hypotension	1	1	1	1		
Joint range of motion decreased	1	1	1	1		
Limb deformity	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy	1	1	1	1		
Malaise	1	1	1	1		
Mastication disorder	1	1	1	1		
Meningitis		1				1
Myalgia	2	2	2	2		
Nausea	1	2	1	2		
Neck pain	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Pain	1	1	1	1		
Pain in extremity	7	7	6	6	1	1
Paternal exposure during pregnancy	1	1	1	1		
Pelvic pain	1	1			1	1
Peripheral swelling	2	2	2	2		
Presyncope	1	1	1	1		
Pruritus	3	4	3	4		
Pyrexia	5	6	4	5	1	1
Rash	1	1	1	1		
Rash erythematous	1	1	1	1		
Rash pruritic	1	1	1	1		
Renal pain	1	1	1	1		
Seizure	1	1			1	1
Sensitive skin	1	1	1	1		
Simple partial seizures	1	1			1	1
Skin texture abnormal	1	1	1	1		
Swelling	1	1	1	1		
Swelling face		1		1		
Syncope	1	1			1	1
Tinnitus	3	3	3	3		
Urine abnormality	1	1	1	1		
Urticaria		1		1		
Vaccination site cellulitis	1	1			1	1
Vaccination site hypoaesthesia	1	1	1	1		

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	3	4	3	4		
Vaccination site pruritus	1	1	1	1		
Vein disorder	1	1	1	1		
Vomiting		1		1		
	98	122	77	99	21	23

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	2	3	2	3		
Asthenia	5	7	5	7		
Back pain	4	4	3	3	1	1
Body temperature decreased	1	1	1	1		
Chest pain	2	2	1	1	1	1
Chills	2	2	2	2		
Concentric sclerosis	1	1			1	1
COVID-19		1		1		
Dizziness	3	3	3	3		
Dry mouth	1	1	1	1		
Electrocardiogram abnormal	1	1			1	1
Erythema	1	1	1	1		
Fatigue	1	2	1	2		
Feeling cold	1	1	1	1		
Feeling hot	1	1	1	1		
Guillain-Barre syndrome	1	1			1	1
Headache	6	7	6	7		
Herpes zoster	1	2	1	2		
Hyperhidrosis	1	1	1	1		
Hypersensitivity	1	1	1	1		
Hypoaesthesia	1	1	1	1		
Incorrect route of product administration	2	2	2	2		
Influenza	1	1	1	1		
Invasive ductal breast carcinoma		1				1
Lymphadenopathy		1		1		
Malaise	1	2	1	2		
Mouth ulceration	1	1	1	1		
Muscle contracture	1	1	1	1		
Myalgia	3	3	3	3		
Nasopharyngitis	1	1	1	1		
Nausea	1	1	1	1		
Oropharyngeal pain	1	2	1	2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain	1	1	1	1		
Pain in extremity	4	5	4	5		
Pruritus	2	2	1	1	1	1
Pyrexia	4	5	4	5		
Rash pruritic	1	1	1	1		
Rhinorrhoea	1	1	1	1		
Somnolence	2	2	2	2		
Suspected COVID-19		1		1		
Tonsillar hypertrophy		1		1		
Tremor	1	1	1	1		
Vaccination site bruising	1	1	1	1		
Vaccination site pain	4	6	4	6		
Vaccination site swelling	1	1	1	1		
	71	88	65	81	6	7

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse event	1	1	1	1		
Arthralgia	2	3	2	3		
Asthenia	1	1	1	1		
Blister	1	1	1	1		
Blood pressure increased	1	1	1	1		
Bone pain	1	1	1	1		
Burning sensation	1	1	1	1		
Chills	1	1	1	1		
Cough		1		1		
COVID-19	1	1			1	1
Dizziness	1	1	1	1		
Drug ineffective	1	1			1	1
Dyspnoea	2	2	1	1	1	1
Erythema	1	1	1	1		
Eye pain	1	1	1	1		
Fatigue	1	1	1	1		
Feeling abnormal	1	1			1	1
Feeling cold	1	1	1	1		
Headache	7	7	6	6	1	1
Head discomfort	1	1	1	1		
Hypertension	1	1	1	1		
Hypoaesthesia	3	3	3	3		
Malaise	1	1	1	1		
Maternal exposure during pregnancy	1	2	1	2		
Muscle spasms	1	1	1	1		
Myalgia	2	2	2	2		
Nausea	1	1	1	1		
Nightmare	1	1	1	1		
Off label use	1	1	1	1		
Otitis media	1	1	1	1		
Overdose		1		1		
Pain	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in extremity	1	1	1	1		
Paraesthesia	1	1	1	1		
Presyncope	1	1			1	1
Product preparation error		1		1		
Product use issue	2	2	2	2		
Pruritus	1	1	1	1		
Pyrexia	1	2	1	2		
Rash	2	2	2	2		
Restless legs syndrome	1	1	1	1		
Sleep disorder	1	1	1	1		
Thrombosis	1	1			1	1
Toothache		2		2		
Vaccination site pain	2	3	2	3		
Vaccination site swelling	1	1	1	1		
	56	65	49	58	7	7

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred
TURKS AND CAICOS ISLANDS

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fatigue		1		1		
Generalised tonic-clonic seizure		1				1
Myalgia		1		1		
Neck mass		1		1		
Seizure		1				1
		5		3		2

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Haemorrhagic stroke		1		1
		1		1

* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

UKRAINE

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypoaesthesia		1		1
		1		1

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* I=Interval, C=Cumulative
 * AE=Adverse Event
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Country Where Event Occurred

UNITED ARAB EMIRATES

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Pain		1		1		
Swelling		1				1
		3		2		1

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Back pain		1		1		
Chills		1		1		
COVID-19		1				1
Dizziness		1		1		
Drug ineffective		1				1
Headache		2		2		
Lymphadenopathy	1	1	1	1		
Myalgia		1		1		
Nausea		3		3		
Pyrexia		2		2		
Swelling	1	1	1	1		
Vomiting		2		2		
	2	18	2	16		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Arthralgia		1		1		
Axillary pain	1	1	1	1		
Back pain		1		1		
Bell's palsy		1				1
Chest pain		2				2
Chills		2		2		
Decreased appetite		1		1		
Depressed level of consciousness		1				1
Depressed mood		1				1
Dizziness	1	2	1	1		1
Dysgeusia		1		1		
Dyspnoea	1	2	1	2		
Erythropeia		1				1
Fatigue		4		4		
Feeling abnormal		1		1		
Fibromyalgia		1		1		
Headache	2	5	2	4		1
Head discomfort	1	1	1	1		
Head injury		1				1
Heart rate increased	1	1	1	1		
Hypertension		1				1
Injected limb mobility decreased		1		1		
Injection site pain		1		1		
Lethargy	1	1	1	1		
Loss of consciousness		1				1
Lymphadenopathy	1	2	1	2		
Nausea	1	4	1	3		1
Neurotoxicity		1				1
Pain	1	1	1	1		
Pain in extremity		1		1		
Pruritus		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia		4		4		
Rash		2		2		
Skin irritation		1		1		
Sleep deficit		1		1		
Somnolence		1		1		
Sudden death		1				1
Syncope	1	1			1	1
Thrombosis		1				1
Vaccination site pain	1	3	1	3		
	13	62	12	46	1	16

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic shock	1	1			1	1
Back pain		1		1		
Blindness unilateral		1				1
Cough		1		1		
COVID-19		2		1		1
Dyspnoea		1				1
Fatigue		2		2		
Hypoxia		1				1
Inappropriate schedule of product administration		1		1		
Ocular vascular disorder		1				1
Pyrexia		2		2		
Tachypnoea		1		1		
Thrombosis		1				1
Vaccination site pain		1		1		
	1	17		10	1	7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased		1				1
COVID-19		1				1
Dizziness		1		1		
Drug ineffective		1				1
Gait disturbance		1		1		
Inappropriate schedule of product administration	1	1	1	1		
Ophthalmic herpes zoster		1				1
Pyrexia		1		1		
Rectal haemorrhage		1				1
Vaccination site pain		2		2		
Vision blurred		1		1		
	1	12	1	7		5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Arthralgia		1		1		
Asthenia		1		1		
Babesiosis		1				1
Bone pain		1		1		
Chest discomfort		1		1		
Cough	1	1	1	1		
COVID-19	3	9	1	2	2	7
Death		1				1
Dizziness		1		1		
Drug ineffective	2	7			2	7
Dysgeusia		1		1		
Erectile dysfunction		1				1
Facial paralysis		1				1
Fatigue		1		1		
Feeling abnormal		1		1		
Headache	1	3	1	3		
Hyperhidrosis		1		1		
Hypertension		1		1		
Hypoacusis		1				1
Hypoaesthesia		1				1
Lyme disease		1				1
Lymphadenopathy		1		1		
Lymph node pain		1		1		
Maternal exposure timing unspecified		1		1		
Muscle fatigue		1		1		
Myalgia		1		1		
Nasopharyngitis		1		1		
Neuralgia		1		1		
Off label use		1		1		
Pain		2		2		
Paraesthesia		1		1		

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonia		1				1
Product use issue		1		1		
Pyrexia	1	3	1	3		
Rash		1				1
Respiratory tract irritation		1		1		
SARS-CoV-2 ant body test negative		3		3		
Sciatica		2		2		
Suspected COVID-19		1				1
Tremor		1		1		
Urticaria		1				1
Vaccination failure		1				1
Vaccination site pain		2		2		
Vision blurred		1		1		
	8	68	4	42	4	26

* I=Interval, C=Cumulative

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Country Where Event Occurred

UNITED KINGDOM

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* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	3	6		2	3	4
Abnormal faeces		1				1
Agitation		1				1
Anaphylactic reaction	2	3			2	3
Anaphylactoid reaction		1				1
Angina pectoris		1				1
Angioedema		3				3
Antiphospholipid syndrome	1	1			1	1
Arteriospasm coronary		1				1
Arthralgia	4	12	2	6	2	6
Asthenia	1	4		1	1	3
Asthma		1				1
Autoimmune haemolytic anaemia	1	1			1	1
Axillary pain		1				1
Balance disorder		1		1		
Blood ketone body	1	1			1	1
Blood urine present		1				1
Body temperature abnormal	1	1			1	1
Body temperature increased	1	4	1	3		1
Cardiac discomfort		1				1
Carotid artery occlusion	1	1			1	1
Cerebral infarction		1				1
Cerebral venous sinus thrombosis	1	1			1	1
Cerebrovascular accident		1				1
Chest discomfort		2		1		1
Chest pain	1	4		1	1	3
Chills	4	12	2	6	2	6
Colitis	1	1			1	1
Confusional state	1	1			1	1
Constipation		1				1
Contusion		1		1		
Cough		2		2		

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* AE=Adverse Event

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	2	1	1		1
Crying		1				1
Cyanosis	1	1			1	1
Decreased appetite	4	6	3	3	1	3
Dehydration		1				1
Diarrhoea	4	9	1	4	3	5
Diarrhoea haemorrhagic		1				1
Diplegia	1	1			1	1
Discomfort		2		1		1
Disease recurrence		2				2
Disturbance in attention	1	1	1	1		
Dizziness	3	11	1	3	2	8
Dizziness exertional		1		1		
Dizziness postural		1				1
Drug ineffective		1				1
Dry throat		2		1		1
Dysarthria	1	1			1	1
Dysgeusia	1	3	1	2		1
Dysphemia	1	1			1	1
Dyspnoea	1	5		1	1	4
Dysuria		1				1
Ear pain	2	3		1	2	2
Epilepsy		2				2
Epileptic encephalopathy		1				1
Epistaxis		1				1
Erythema		1				1
Exertional headache		1		1		
Exposure via breast milk	8	42	5	26	3	16
Eye infection	1	1	1	1		
Fall		1		1		
Fatigue	10	25	4	11	6	14
Feeling abnormal	3	5	2	4	1	1

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* AE=Adverse Event

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling cold	1	1	1	1		
Feeling drunk	1	1	1	1		
Feeling hot	1	3		1	1	2
Feeling of body temperature change		1		1		
Flushing		2				2
Gait disturbance		1		1		
Generalised tonic-clonic seizure		1				1
Haemolysis	1	1			1	1
Haemorrhage	1	1			1	1
Headache	11	35	5	15	6	20
Heart rate abnormal	1	1			1	1
Heart rate increased		1				1
Heavy menstrual bleeding	1	2	1	2		
Hot flush	1	2	1	1		1
Hunger	1	1			1	1
Hyperacusis		1				1
Hyperhidrosis	1	2			1	2
Hypersensitivity	1	2	1	1		1
Hypoaesthesia	1	3	1	1		2
Hypotension		1				1
Illness	3	7	2	2	1	5
Immune thrombocytopenia	1	1			1	1
Inappropriate schedule of product administration	1	2		1	1	1
Incorrect route of product administration	1	1			1	1
Increased appetite	1	2		1	1	1
Infant irritability		2		1		1
Infection	1	2	1	2		
Influenza		1				1
Influenza like illness	1	2	1	2		
Injection site bruising	1	1	1	1		
Insomnia		2		1		1
Irritability	1	1	1	1		

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Jaundice	1	1			1	1
Joint swelling		1		1		
Jugular vein thrombosis		1				1
Lacrimation increased		1				1
Learning disorder	1	1			1	1
Lennox-Gastaut syndrome		1				1
Lethargy	3	3	2	2	1	1
Lip swelling	1	2	1	1		1
Loss of consciousness		1				1
Loss of personal independence in daily activities		1		1		
Lymphadenitis		1		1		
Lymphadenopathy	3	9	1	2	2	7
Malabsorption	1	1			1	1
Malaise	4	10	3	7	1	3
Mastitis		1				1
Maternal exposure during breast feeding		1				1
Menstruation delayed	1	1			1	1
Migraine	1	4			1	4
Miliaria		1		1		
Mobility decreased	1	3		2	1	1
Muscular weakness	1	1			1	1
Musculoskeletal stiffness		2				2
Myalgia	2	10	1	6	1	4
Mydriasis	1	1			1	1
Nasopharyngitis	2	4	1	2	1	2
Nausea	14	30	7	11	7	19
Neck pain	1	1			1	1
Nervousness		1				1
Off label use	4	18	3	17	1	1
Oral pain	1	1			1	1
Oropharyngeal pain	2	3	2	3		
Pain	5	17	2	8	3	9

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Painful respiration	1	1			1	1
Pain in extremity	7	21	4	10	3	11
Palpitations	2	3	1	1	1	2
Paraesthesia		2				2
Paranoia	1	1			1	1
Parosmia		1				1
Penile oedema	1	1	1	1		
Penis disorder	1	1	1	1		
Peripheral circulatory failure	1	1			1	1
Peripheral swelling	1	4	1	3		1
Petechiae	1	1	1	1		
Pharyngeal leukoplakia		1		1		
Pharyngeal swelling	1	1			1	1
Photophobia		1				1
Pineal gland cyst		1				1
Platelet count decreased		1				1
Pollakiuria	1	1	1	1		
Poor feeding infant		1				1
Product administered to patient of inappropriate age	8	25	8	24		1
Product use issue	5	16	5	15		1
Pruritus	2	7	2	4		3
Psychogenic seizure		1				1
Pulmonary pain	1	1			1	1
Purpura non-thrombocytopenic	1	1			1	1
Pyrexia	5	26	1	11	4	15
Rash	4	11	3	6	1	5
Rash erythematous	1	1			1	1
Rash macular	1	1	1	1		
Rash neonatal	1	1	1	1		
Rash papular		1				1
Rash pruritic	2	3			2	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rectal haemorrhage	1	1			1	1
Respiratory rate decreased		1				1
Rhinorrhoea	1	1			1	1
Screaming		1		1		
Seasonal allergy		1				1
Seizure		5				5
Sinus disorder		1				1
Sinusitis		1		1		
Sinus pain	1	1			1	1
Sinus tachycardia		1		1		
Skin exfoliation		1				1
Sleep disorder		1		1		
Sleep disorder due to general medical condition, insomnia type		1				1
Sneezing		1		1		
Somnolence	1	3	1	1		2
Spinal cord infarction	1	1			1	1
Spinal pain		1		1		
Status epilepticus		1				1
Superior sagittal sinus thrombosis		1				1
Suspected COVID-19	1	3	1	2		1
Swelling	1	6		3	1	3
Swelling face	1	1	1	1		
Swollen tongue	1	1			1	1
Syncope	2	7			2	7
Tachycardia		1				1
Taste disorder	1	1			1	1
Tenderness	1	2	1	2		
Thermal burn		1		1		
Thirst		1		1		
Thrombocytopenia	3	3			3	3
Thrombosis	1	2			1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tinnitus	1	1	1	1		
Tongue ulceration		1				1
Tonsillar hypertrophy		1		1		
Tremor	1	3		1	1	2
Urine analysis abnormal		1				1
Urticaria	1	3		1	1	2
Vaccination site cellulitis	1	1	1	1		
Vaccination site erythema		1		1		
Vaccination site inflammation	1	1	1	1		
Vaccination site joint pain	1	1	1	1		
Vaccination site movement impairment		1		1		
Vaccination site pain		6		4		2
Vaccination site rash	1	2	1	1		1
Vaccination site reaction		1				1
Vaccination site swelling	1	2	1	2		
Vertigo	1	2	1	1		1
Viral infection		1				1
Vision blurred		1				1
Vomiting	7	18	1	1	6	17
Weight decreased		1				1
Wheezing		2				2
Yellow skin		1		1		
	1	4	1	4		
	234	681	109	310	125	371

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* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	7	25			4	10	3	15
Abdominal distension	7	20			6	11	1	9
Abdominal pain	19	82			5	21	14	61
Abdominal pain lower	6	9			1	3	5	6
Abdominal pain upper	30	125			10	46	20	79
Abdominal rigidity		1						1
Abdominal tenderness	1	2					1	2
Abnormal behaviour	1	2				1	1	1
Abnormal clotting factor	1	1			1	1		
Abnormal dreams		8				5		3
Abnormal faeces		1				1		
Abnormal loss of weight	1	1					1	1
Abnormal sensation in eye		2				1		1
Abortion missed	2	2					2	2
Abortion spontaneous	5	21					5	21
Abscess		1						1
Accident	1	1					1	1
Accidental exposure to product		3				2		1
Acne	3	6			2	4	1	2
Acute abdomen		1						1
Acute kidney injury		2						2
Acute myocardial infarction	1	3					1	3
Administration site bruise	1	1			1	1		
Administration site joint movement impairment		2						2
Adverse drug reaction		4				4		
Ageusia	7	31			5	16	2	15
Agitation	1	9				4	1	5
Akathisia		1						1
Alanine aminotransferase increased		2						2
Alcohol interaction	1	1					1	1
Alexithymia		1				1		
Allergic reaction to excipient		2						2

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* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Allergy to vaccine		3
Allodynia	2	4
Alopecia		1
Altered state of consciousness		2
Amenorrhoea	13	17
Ammonia abnormal		1
Amnesia	1	6
Anaemia		1
Anal haemorrhage		2
Anal incontinence	1	2
Anaphylactic reaction	3	33
Anaphylactic shock	2	2
Anaphylactoid reaction	1	4
Anger		2
Angina pectoris	1	3
Angioedema		13
Anisomastia		1
Ankylosing spondylitis		1
Anosmia	1	11
Anovulatory cycle	1	2
Anticholinergic syndrome		1
Anxiety	8	37
Aphasia	1	2
Aphonia	1	5
Aphthous ulcer	1	4
Appendicitis		1
Application site vesicles		1
Arthralgia	78	543
Arthritis		3
Aspartate aminotransferase increased		1
Asthenia	32	160
Asthenopia	3	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		2
		2	2		2
					1
					2
		9	10	4	7
			1		
				1	6
					1
					2
				1	2
				3	33
				2	2
				1	4
			1		1
				1	3
					13
			1		
					1
			5	1	6
				1	2
					1
		2	16	6	21
				1	2
		1	4		1
				1	4
					1
					1
		33	243	45	300
			1		2
					1
		16	67	16	93
		2	4	1	7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Asthma	4	22
Asymptomatic COVID-19	1	2
Atonic seizures		2
Atrial fibrillation	1	2
Atrial tachycardia		1
Auditory disorder		1
Aura		3
Autoimmune disorder		1
Autoimmune neutropenia		1
Autonomic nervous system imbalance	1	2
Axillary mass	2	19
Axillary pain	44	175
Bacille Calmette-Guerin scar reactivation		3
Back pain	41	172
Balance disorder	4	13
Basedow's disease		1
Bedridden	3	3
Behaviour disorder		2
Behcet's syndrome		4
Bell's palsy	1	18
Benign lymph node neoplasm	1	1
Biliary colic	1	1
Binocular eye movement disorder		1
Bipolar I disorder		1
Blepharospasm	3	5
Blindness		3
Blister	6	11
Blood bilirubin abnormal	1	1
Blood blister		1
Blood creatine phosphokinase increased		1
Blood disorder	1	1
Blood glucose abnormal	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3	4	19
			1	1	1
					2
				1	2
					1
			1		
			3		
					1
					1
				1	2
		1	9	1	10
		24	65	20	110
			2		1
		25	81	16	91
		2	6	2	7
					1
		2	2	1	1
					2
					4
				1	18
				1	1
				1	1
					1
					1
		2	2	1	3
					3
		3	5	3	6
				1	1
					1
					1
				1	1
				1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood glucose decreased	1	3
Blood glucose fluctuation		2
Blood glucose increased	1	9
Blood heavy metal increased		1
Blood immunoglobulin E increased		1
Blood ketone body increased		1
Blood ketone body present		1
Blood potassium decreased		1
Blood pressure decreased		9
Blood pressure increased	2	11
Blood pressure orthostatic decreased		1
Blood prolactin increased		1
Blood test abnormal		2
Blood testosterone increased		1
Blood thyroid stimulating hormone increased		1
Blood urine present	1	2
Blue toe syndrome		2
Body temperature		3
Body temperature abnormal	5	12
Body temperature decreased		4
Body temperature fluctuation	1	9
Body temperature increased	5	33
Bone disorder		1
Bone pain	2	28
Bradycardia	1	4
Bradykinesia		2
Bradyphrenia	1	3
Brain neoplasm		1
Brain oedema		1
Breast abscess	2	2
Breast cancer	1	2
Breast mass	3	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
					2
			2	1	7
			1		
					1
					1
					1
			4		5
		1	6	1	5
					1
			1		
					2
			1		
			1		
				1	2
					2
			3		
		3	7	2	5
			1		3
			3	1	6
		4	22	1	11
					1
			11	2	17
				1	4
					2
				1	3
					1
					1
				2	2
				1	2
				3	4

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Breast pain	12	25
Breast swelling	1	5
Breast tenderness	2	6
Breath odour		4
Bruxism	2	2
Burning sensation	6	27
Bursitis		1
Campylobacter gastroenteritis	1	1
Candida infection		1
Cardiac arrest	2	4
Cardiac disorder		2
Cardiac flutter	1	5
Cardiovascular disorder	1	2
Carpal tunnel syndrome		2
Cellulitis		9
Cerebellar haemorrhage		1
Cerebral venous sinus thrombosis		3
Cerebral venous thrombosis		1
Cerebrovascular accident	2	6
Chapped lips		2
Cheilitis		2
Chest crushing		1
Chest discomfort	15	92
Chest pain	23	139
Chillblains	1	3
Chills	135	875
Choking		1
Choking sensation		1
Chondritis		1
Chromaturia	1	7
Chronic fatigue syndrome		2
Chronic gastritis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	7	7	18
			1	1	4
		1	2	1	4
			1		3
				2	2
		3	10	3	17
					1
				1	1
					1
				2	4
			1		1
				1	5
				1	2
					2
					9
					1
					3
					1
				2	6
			1		1
			2		
					1
		10	35	5	57
		10	42	13	97
		1	3		
		81	468	54	407
					1
					1
					1
			4	1	3
					2
					1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Circulatory collapse		2
Clumsiness	1	1
Cluster headache	3	14
Coagulation time prolonged	1	1
Coagulopathy		1
Coating in mouth	1	1
Coeliac disease		2
Cold sweat	13	64
Cold urticaria		1
Colitis		1
Colitis ulcerative		1
Condition aggravated	10	35
Confusional state	8	34
Congenital cystic lung		1
Congestive hepatopathy		1
Conjunctival haemorrhage		2
Conjunctival hyperaemia		1
Constipation	2	16
Constricted affect		1
Contusion	8	39
Coordination abnormal		5
Coronavirus test positive		1
Cortisol decreased		1
Costochondritis	2	6
Cough	24	130
COVID-19	15	84
C-reactive protein increased		1
Crohn's disease		1
Crying	1	11
Cyanosis	1	6
Cyst		1
Cystitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
				1	1
		1	4	2	10
				1	1
					1
		1	1		
					2
		5	29	8	35
			1		
					1
					1
		2	9	8	26
		4	8	4	26
					1
					1
					2
					1
		1	5	1	11
					1
		2	20	6	19
			2		3
			1		
					1
			1	2	5
		9	53	15	77
		5	29	10	55
					1
					1
			5	1	6
		1	3		3
			1		
			1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dark circles under eyes	1	1
Deafness	2	7
Deafness bilateral	1	1
Deafness unilateral		1
Death		2
Decreased appetite	18	112
Decreased interest	1	1
Deep vein thrombosis	4	7
Defaecation urgency		1
Dehydration	5	11
Delirium	2	8
Delusion	1	2
Delusional perception	1	1
Depressed level of consciousness		1
Depressed mood	3	12
Depression	2	4
Depression suicidal		2
Derealisation		1
Dermatitis	1	12
Dermatitis allergic	2	10
Dermatitis exfoliative		1
Device infusion issue		1
Diabetes mellitus	1	2
Diabetes mellitus inadequate control		2
Diabetic complication		2
Diabetic ketoacidosis		3
Diaphragmalgia		2
Diarrhoea	63	258
Diarrhoea haemorrhagic		2
Diplegia		1
Diplopia	1	4
Discharge		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				2	7
				1	1
					1
					2
		10	54	8	58
		1	1		
				4	7
					1
		2	3	3	8
				2	8
		1	1		1
				1	1
					1
		1	5	2	7
		1	2	1	2
					2
			1		
			5	1	7
		2	3		7
					1
					1
				1	2
					2
					2
					3
			1		1
		31	103	32	155
					2
					1
			3	1	1
					1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Discoloured vomit		1
Discomfort	4	26
Disease progression	1	1
Disease recurrence	4	34
Disorientation	4	14
Dissociation		2
Dissociative disorder		1
Disturbance in attention	10	35
Dizziness	130	625
Dizziness exertional	1	1
Dizziness postural	5	46
Drooling	1	3
Drooping shoulder syndrome		1
Drug eruption	1	3
Drug hypersensitivity		3
Drug ineffective	13	85
Dry eye	1	5
Dry mouth	4	25
Dry skin	3	14
Dry throat		6
Dysarthria		3
Dysgeusia	14	45
Dyskinesia	3	9
Dysmenorrhoea	25	33
Dyspepsia	2	9
Dysphagia	8	26
Dysphemia		1
Dysphonia	3	13
Dyspnoea	37	194
Dyspnoea at rest		1
Dyspnoea exertional	1	7
Dysstasia	2	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	10	3	16
				1	1
		1	6	3	28
		1	3	3	11
			1		1
			1		
		7	15	3	20
	1	72	292	58	333
				1	1
		2	19	3	27
			1	1	2
			1		
		1	3		
			1		2
				13	85
			2	1	3
		1	14	3	11
		3	8		6
			5		1
					3
		10	26	4	19
			3	3	6
		11	15	14	18
			3	2	6
		4	11	4	15
					1
		2	6	1	7
		14	49	23	145
					1
			2	1	5
			2	2	7

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dystonia		3
Dysuria	3	4
Ear discomfort		5
Ear disorder		2
Ear infection	1	4
Ear pain	18	52
Ear pruritus	1	2
Ear swelling		1
Eating disorder symptom		1
Eczema		5
Embolism		2
Emotional disorder	2	5
Emotional distress	1	4
Encephalitis		3
Encephalopathy		1
Endometriosis	1	3
Endometritis	1	1
Energy increased		1
Enlarged uvula	1	2
Eosinophil count increased		1
Epilepsy	2	9
Epinephrine increased		1
Epistaxis	8	30
Erectile dysfunction		2
Eructation	1	3
Erythema	23	147
Erythema multiforme		5
Erythema nodosum		2
Erythema of eyelid		1
Euphoric mood	1	4
Eustachian tube dysfunction		1
Exercise tolerance decreased	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
		1	2	2	2
			2		3
			2		
			1	1	3
		6	13	12	39
		1	1		1
					1
					1
			1		4
					2
			2	2	3
			2	1	2
					3
					1
			1	1	2
				1	1
			1		
				1	2
			1		
				2	9
					1
		4	13	4	17
					2
		1	2		1
		16	85	7	62
					5
			1		1
			1		
				1	4
					1
		1	1		2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Exfoliative rash		4
Expired product administered		1
Exposure during pregnancy	3	6
Exposure to SARS-CoV-2		1
Exposure via breast milk		1
Extensive swelling of vaccinated limb		3
Extrasystoles		1
Eye contusion		1
Eye discharge		1
Eye disorder	1	3
Eye infection		1
Eye injury		1
Eye irritation	2	10
Eyelid disorder	1	1
Eyelid function disorder		1
Eyelid pain		1
Eyelid ptosis	1	1
Eyelid rash		2
Eye movement disorder	2	2
Eye oedema		1
Eye pain	16	76
Eye pruritus	1	18
Eye swelling	3	21
Face injury		1
Face oedema		1
Facial discomfort		1
Facial pain	1	11
Facial paralysis	4	12
Facial paresis		3
Facial spasm	2	5
Faecaloma		2
Faeces discoloured		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					4
			1		
		3	6		
					1
			1		
			2		1
					1
			1		
					1
				1	3
					1
					1
		1	3	1	7
		1	1		
					1
					1
		1	1		
			1		1
				2	2
			1		
		9	27	7	49
		1	12		6
		2	9	1	12
			1		
					1
			1		
			4	1	7
				4	12
			1		2
				2	5
					2
					2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Fall	2	6
Fatigue	285	1,510
Fear	1	2
Febrile convulsion		2
Feeding disorder	2	6
Feeling abnormal	27	89
Feeling cold	23	111
Feeling drunk	2	6
Feeling hot	27	121
Feeling jittery		2
Feeling of body temperature change	10	48
Feeling of despair		1
Fibrin D dimer increased	1	2
Fibromyalgia	4	6
Fine motor skill dysfunction		1
Flank pain	1	4
Flat affect		1
Flatulence	2	6
Fluid imbalance		1
Fluid intake reduced		1
Fluid retention	1	1
Flushing	7	29
Foetal death		1
Foetal heart rate abnormal	1	1
Foetal hypokinesia	1	1
Folliculitis		1
Food allergy		1
Food refusal		1
Foreign body sensation in eyes		1
Formication		1
Freezing phenomenon	1	1
Frequent bowel movements		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3	2	3
1	5	172	753	113	757
			1	1	1
			2		
		1	5	1	1
		14	34	13	55
		11	51	12	60
		1	2	1	4
		11	68	16	53
			1		1
		5	24	5	24
					1
				1	2
		1	2	3	4
					1
			2	1	2
			1		
		2	6		
					1
					1
				1	1
		4	14	3	15
					1
		1	1		
				1	1
			1		
					1
					1
			1		
					1
		1	1		
					4

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Frustration tolerance decreased		1
Gait disturbance	5	27
Gait inability		9
Galactorrhoea		1
Gastric disorder		1
Gastric ulcer		1
Gastritis	1	3
Gastroenteritis	1	2
Gastroenteritis norovirus		1
Gastroenteritis viral		2
Gastrointestinal disorder		3
Gastrointestinal haemorrhage	1	1
Gastrointestinal motility disorder		1
Gastrointestinal pain		3
Gastrointestinal wall thickening		1
Gastrooesophageal reflux disease	2	7
Generalised tonic-clonic seizure		4
General physical health deterioration	1	1
Genital herpes	2	5
Genital pain	1	3
Genital tract inflammation		1
Genital ulceration	1	1
Gestational diabetes	1	1
Gingival bleeding	2	3
Gingival blister	1	1
Gingival disorder	1	1
Gingival pain	1	6
Gingivitis		1
Glomerulonephritis		1
Glomerulonephritis rapidly progressive		1
Glossodynia	1	4
Glucose tolerance impaired		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			4	5	23
			2		7
			1		1
					1
		1	1		2
		1	1		1
					1
			2		
			2		1
				1	1
			1		
					3
			1		
		1	2	1	5
					4
		1	1		
			2	2	3
		1	1		2
			1		
		1	1		
				1	1
		1	1	1	2
		1	1		
				1	1
			2	1	4
			1		
					1
					1
		1	4		
			1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Grip strength decreased		2
Groin pain	5	11
Habit cough	1	1
Haematemesis		4
Haematochezia	1	3
Haematoma		1
Haematuria	1	6
Haemoglobin decreased		1
Haemolytic anaemia		1
Haemoptysis	1	5
Haemorrhage	7	20
Haemorrhage subcutaneous		1
Haemorrhage urinary tract		1
Haemorrhagic stroke		2
Haemorrhoids		1
Hair texture abnormal		1
Hallucination	3	18
Hallucination, auditory	1	3
Hallucination, olfactory		1
Hallucinations, mixed		1
Hallucination, tactile		1
Hallucination, visual	1	2
Hangover	2	4
Headache	355	1,931
Head discomfort	5	21
Head injury		6
Heart rate		1
Heart rate abnormal	2	8
Heart rate decreased	2	4
Heart rate increased	15	62
Heat oedema		1
Heat stroke		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
		1	4	4	7
				1	1
					4
				1	3
					1
		1	2		4
					1
					1
				1	5
				7	20
					1
					1
					2
					1
					1
				3	18
				1	3
					1
					1
				1	2
		1	1	1	3
	1	221	990	134	941
		2	9	3	12
			4		2
					1
		1	2	1	6
			2	2	2
		5	20	10	42
					1
			1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Heavy menstrual bleeding	36	44
Hemianopia homonymous		1
Hemiparesis		2
Hemiplegia	1	3
Hemiplegic migraine		1
Hepatitis		1
Hepatitis viral		1
Herpes zoster	19	35
Herpes zoster reactivation	1	1
Hiccups	1	2
Hidradenitis		1
Hormone level abnormal		1
Hot flush	17	94
Hunger	1	4
Hyperacusis	1	4
Hyperaesthesia	3	19
Hyperaesthesia teeth	1	2
Hyperchlorhydria	1	1
Hyperglycaemia	1	3
Hyperhidrosis	32	171
Hyperintensity in brain deep nuclei		1
Hyperpyrexia		1
Hypersensitivity	12	48
Hypersomnia	9	19
Hypertension	3	21
Hyperthyroidism		1
Hyperventilation	3	5
Hypervigilance	1	1
Hypoacusis	3	11
Hypoaesthesia	26	136
Hypoaesthesia oral	5	21
Hypogeusia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		18	20	18	24
					1
					2
				1	3
					1
					1
					1
		13	19	6	16
		1	1		
				1	2
					1
					1
		8	44	9	50
			1	1	3
				1	4
		2	9	1	10
				1	2
				1	1
			1	1	2
		16	74	16	97
					1
					1
		7	17	5	31
		2	5	7	14
		1	9	2	12
					1
		2	2	1	3
				1	1
		1	4	2	7
		14	54	12	82
		3	10	2	11
		1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypoglycaemia	2	11
Hypoglycaemic coma		1
Hypokinesia	2	14
Hypomenorrhoea	4	7
Hypophagia		1
Hypopnoea	1	5
Hyporeflexia		1
Hyposmia	1	1
Hyposomnia		1
Hypotension	8	29
Hypothermia		2
Hypotonia		1
Hypovitaminosis		1
Idiopathic intracranial hypertension	1	3
IgA nephropathy	1	1
Illness	30	143
Immobile	1	1
Immune-mediated adverse reaction		1
Immune system disorder	2	2
Immune thrombocytopenia	3	10
Immunodeficiency		1
Immunosuppression	1	1
Impaired driving ability		1
Impaired healing		1
Impaired self-care		1
Impaired work ability		6
Inappropriate schedule of product administration	62	146
Incontinence		1
Incorrect dose administered		3
Incorrect route of product administration	1	9
Induration		1
Infected skin ulcer		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	2	10
					1
		1	8	1	6
		3	5	1	2
					1
				1	5
					1
		1	1		
					1
		2	10	6	19
					2
			1		
					1
				1	3
				1	1
	1	20	63	10	80
				1	1
					1
		1	1	1	1
				3	10
					1
				1	1
			1		
					1
			1		
			2		4
		58	139	4	7
					1
			2		1
		1	9		
					1
					1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Infection	3	10
Infectious mononucleosis		2
Inflammation	1	11
Influenza	16	81
Influenza like illness	29	152
Infusion site infection		1
Ingrown hair	1	1
Initial insomnia	1	2
Injected limb mobility decreased	1	3
Injection related reaction		1
Injection site erythema	2	5
Injection site hypoaesthesia	1	1
Injection site mass	3	4
Injection site pain	13	30
Injection site pruritus	1	2
Injection site rash	1	1
Injection site scab	1	1
Injection site swelling	3	4
Injection site warmth	1	1
Insomnia	22	128
Insulin resistance	1	2
Intermenstrual bleeding	4	5
Internal haemorrhage	1	1
International normalised ratio fluctuation		1
Intestinal obstruction		2
Iridocyclitis	1	1
Irregular breathing		1
Irritability	3	13
Irritable bowel syndrome		5
Ischaemia		1
Itching scar		2
Jaundice	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3	2	7
					2
			4	1	7
	2	8	33	8	48
		11	69	18	83
					1
				1	1
			1	1	1
		1	2		1
					1
		2	5		
		1	1		
		2	2	1	2
		10	24	3	6
		1	1		1
				1	1
		1	1		
		3	4		
				1	1
		12	61	10	67
			1	1	1
		2	3	2	2
				1	1
					1
					2
				1	1
					1
		2	9	1	4
			2		3
					1
			1		1
				1	2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Jaw disorder		1
Joint dislocation		1
Joint noise	1	1
Joint range of motion decreased	4	17
Joint stiffness	5	14
Joint swelling	7	16
Ketoacidosis		1
Kidney infection		1
Klebsiella infection		1
Labyrinthitis		4
Lacrimation increased	2	8
Lacunar infarction		1
Laryngeal obstruction		1
Laryngospasm		1
Laziness		1
Learning disability		1
Lethargy	23	171
Limb discomfort	21	106
Limb injury		1
Limb mass	1	5
Lip blister		1
Lip dry		8
Lip erythema		2
Lip exfoliation		1
Lipoma		1
Lip pain		4
Lip pruritus		1
Lip swelling	4	35
Lip ulceration		2
Livedo reticularis	1	3
Liver function test abnormal	1	1
Liver function test increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				1	1
		1	5	3	12
		3	6	2	8
		3	6	4	10
					1
					1
					1
					4
		1	5	1	3
					1
					1
					1
1	3	16	85	7	86
		7	52	14	54
					1
			3	1	2
			1		
			5		3
			2		
					1
			1		
		3	12	1	23
					2
		1	2		1
				1	1
					1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Liver injury		1
Localised infection		3
Local reaction		5
Lordosis	1	1
Loss of consciousness	6	38
Loss of libido		1
Loss of personal independence in daily activities	7	22
Loss of proprioception		1
Lower respiratory tract infection	3	8
Lung disorder		1
Lymphadenitis	5	15
Lymphadenopathy	119	514
Lymphangitis		2
Lymph gland infection		3
Lymph node pain	29	109
Lymph node palpable	1	2
Lymphoedema	2	8
Lymphoma		2
Lymphopenia		1
Maculopathy		1
Magnetic resonance imaging abnormal		1
Malaise	77	400
Mandibular mass	1	2
Mania		1
Mass	3	5
Mastitis	2	4
Mastocytosis		1
Maternal exposure before pregnancy	1	1
Maternal exposure during breast feeding		4
Maternal exposure during pregnancy	7	27
Medication error		1
Melaena		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		2
			1		4
				1	1
				6	38
					1
		2	6	5	16
					1
				3	8
					1
		3	9	2	6
		57	223	62	291
					2
			1		2
		8	36	21	73
			1	1	1
			1	2	7
					2
					1
					1
					1
	1	46	190	31	210
		1	2		
					1
		2	4	1	1
				2	4
					1
		1	1		
			2		2
1	2	2	10	5	17
			1		
					1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Memory impairment		7
Meningitis viral	1	1
Menopausal symptoms		1
Menstrual cycle management	1	1
Menstrual discomfort	1	1
Menstrual disorder	23	27
Menstruation delayed	35	48
Menstruation irregular	25	33
Mental disorder	1	4
Mental fatigue	1	12
Mental impairment	1	4
Metastases to lymph nodes		1
Middle ear effusion		1
Middle insomnia		11
Migraine	52	244
Migraine with aura	3	14
Migraine without aura	1	2
Miliaria		8
Mobility decreased	7	29
Monoparesis	1	2
Monoplegia	1	4
Mood altered	1	4
Mood swings	4	5
Morose		2
Motion sickness		3
Motor dysfunction		1
Mouth swelling	3	6
Mouth ulceration	4	20
Movement disorder	4	14
Mucosal haemorrhage		1
Mumps		1
Muscle atrophy		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			4		3
				1	1
			1		
		1	1		
				1	1
		17	19	6	8
		27	31	8	17
		15	16	10	17
			2	1	2
			2	1	10
				1	4
					1
					1
			7		4
		22	73	30	171
		1	4	2	10
				1	2
			5		3
		1	9	6	20
		1	1		1
				1	4
			2	1	2
		1	1	3	4
			2		
			1		2
					1
		2	2	1	4
		2	5	2	15
		2	3	2	11
					1
					1
			1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle contractions involuntary		1
Muscle disorder	2	2
Muscle fatigue	3	27
Muscle haemorrhage	1	1
Muscle rigidity		1
Muscle rupture		1
Muscle spasms	15	50
Muscle strain	1	4
Muscle swelling	1	2
Muscle tightness	2	5
Muscle twitching	5	15
Muscular weakness	11	72
Musculoskeletal chest pain	3	13
Musculoskeletal discomfort		6
Musculoskeletal disorder	2	2
Musculoskeletal pain		3
Musculoskeletal stiffness	18	92
Myalgia	166	992
Mydriasis	1	3
Myelitis		1
Myocardial infarction	1	3
Myocarditis	1	3
Myoclonus		1
Myofascial pain syndrome		1
Myositis	1	2
Nail discolouration		1
Nasal congestion	7	17
Nasal discomfort	2	2
Nasal dryness		1
Nasal oedema	1	1
Nasopharyngitis	12	62
Nausea	207	1,114

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				2	2
		2	8	1	19
				1	1
	1				1
					1
		7	16	8	34
			1	1	3
				1	2
			1	2	4
		3	6	2	9
		3	25	8	47
		1	3	2	10
			2		4
		1	1	1	1
			2		1
		7	35	11	57
	3	117	526	49	466
		1	2		1
					1
				1	3
				1	3
			1		
					1
				1	2
			1		
		2	8	5	9
		1	1	1	1
			1		
				1	1
		6	33	6	29
	2	114	520	93	594

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neck mass		1
Neck pain	34	150
Neoplasm	1	2
Nephrotic syndrome		1
Nerve compression	1	3
Nerve injury		4
Nervousness	2	11
Neuralgia	5	15
Neuritis	1	1
Neurogenic shock		2
Neurological symptom	1	2
Neuropathy peripheral		2
Neutropenia		3
Neutrophil count decreased	1	2
Nightmare	3	14
Night sweats	12	55
Nipple pain		3
Nipple swelling		1
Nodule		3
Non-cardiac chest pain		1
Noninfective encephalitis		1
No reaction on previous exposure to drug		1
Nuchal rigidity	1	2
Numb chin syndrome		1
Obstructive airways disorder	1	1
Ocular discomfort	1	5
Ocular hyperaemia	1	8
Odynophagia	2	9
Oedema		2
Oedema peripheral		4
Oesophagitis		1
Off label use	59	193

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		14	62	20	88
		1	1		1
					1
				1	3
			2		2
			4	2	7
		3	7	2	8
				1	1
					2
			1	1	1
					2
					3
		1	2		
		2	9	1	5
		8	33	4	22
					3
					1
			2		1
					1
			1		
		1	1		1
					1
				1	1
		1	2		3
		1	3		5
			2	2	7
					2
					4
			1		
		55	182	4	11

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oligomenorrhea	1	2
Ophthalmic migraine		2
Optic neuritis		1
Oral blood blister		1
Oral candidiasis		4
Oral discomfort	2	3
Oral herpes	4	7
Oral mucosal eruption	1	2
Oral mucosal erythema		1
Oral mucosal exfoliation		1
Oral pain	3	8
Oral pruritus	1	1
Oropharyngeal blistering		2
Oropharyngeal discomfort	1	7
Oropharyngeal pain	39	187
Oropharyngeal spasm		1
Orthostatic hypertension	1	1
Orthostatic hypotension		1
Oversensing	1	3
Ovulation pain	1	2
Oxygen saturation decreased	2	4
Pain	134	674
Painful respiration		6
Pain in extremity	185	879
Pain in jaw	6	21
Pain of skin	6	28
Palatal swelling		1
Palatal ulcer		1
Pallor	5	24
Palpitations	28	109
Pancreatitis		2
Pancreatitis acute		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		1
					2
					1
			1		
			2		2
		1	1	1	2
		1	4	3	3
		1	2		
					1
			1		
		2	4	1	4
		1	1		
					2
			3	1	4
		19	88	20	99
					1
				1	1
					1
				1	3
		1	1		1
			2	2	2
		79	351	55	323
					6
1	3	100	448	85	431
		2	5	4	16
		4	11	2	17
					1
					1
		2	13	3	11
		14	39	14	70
					2
					1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Panic attack	2	8
Panic disorder		1
Papilloedema		1
Papule		2
Paraesthesia	38	173
Paraesthesia oral	8	52
Paralysis	1	5
Paranasal sinus discomfort		2
Paranasal sinus inflammation		1
Paranoia		1
Paresis		1
Parosmia	4	11
Partial seizures	1	3
Pelvic haemorrhage		2
Pelvic pain	3	6
Pemphigoid		1
Pericardial effusion		2
Pericarditis		2
Periorbital oedema		1
Periorbital swelling	1	4
Peripheral coldness	4	19
Peripheral swelling	36	171
Peripheral vascular disorder		1
Periportal oedema	1	1
Persistent postural-perceptual dizziness		1
Personality change		3
Petechiae		3
Petit mal epilepsy		2
Pharyngeal haemorrhage	2	2
Pharyngeal hypoaesthesia		2
Pharyngeal inflammation		1
Pharyngeal mass	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3	1	5
			1		
					1
					2
		25	93	13	80
		4	21	4	31
				1	5
			1		1
					1
					1
		4	7		4
				1	3
					2
			2	3	4
					1
					2
					2
					1
				1	4
			5	4	14
		19	75	17	96
			1		
				1	1
					1
			1		2
			1		2
					2
				2	2
					2
					1
				1	1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pharyngeal oedema	1	4
Pharyngeal paraesthesia		2
Pharyngeal swelling	4	17
Pharyngeal ulceration		1
Pharyngitis		2
Pharyngitis streptococcal		1
Phonophobia		1
Photophobia	10	48
Photopsia		4
Photosensitivity reaction		9
Piloerection		1
Pityriasis	2	3
Pityriasis rosea	2	4
Plantar fasciitis		2
Platelet count decreased		3
Pleural effusion		2
Pleurisy		3
Pleuritic pain		2
Pneumonia		1
Poisoning	1	1
Pollakiuria	1	4
Polycystic ovaries	1	1
Polydipsia	2	2
Polymenorrhoea	9	10
Polymerase chain reaction positive	1	2
Polyuria	1	1
Poor quality sleep	6	19
Postmenopausal haemorrhage	1	1
Postural orthostatic tachycardia syndrome	2	3
Post viral fatigue syndrome	1	3
Potentiating drug interaction		1
Pregnancy		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	4
			1		1
		1	2	3	15
					1
					2
					1
			1		
		4	13	6	35
			1		3
			1		8
					1
		1	2	1	1
		1	1	1	3
					2
			1		2
					2
					3
					2
					1
				1	1
		1	2		2
		1	1		
		1	1	1	1
		4	5	5	5
		1	1		1
				1	1
		4	10	2	9
				1	1
			1	2	2
				1	3
					1
			1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pregnancy with contraceptive device	1	2
Pregnancy with implant contraceptive	1	1
Premenstrual syndrome	1	2
Presyncope	7	49
Primary cough headache		1
Prion disease		1
Procedural dizziness		1
Procedural pain	1	1
Proctalgia		1
Product administered at inappropriate site		2
Product administration error		1
Productive cough	2	6
Product use issue	9	60
Proteinuria		1
Protein urine present	1	1
Pruritus	35	177
Pruritus genital		1
Psoriasis	2	4
Psychogenic seizure	1	3
Psychomotor hyperactivity	1	3
Psychotic disorder		1
Pulmonary artery dilatation		1
Pulmonary embolism	3	9
Pulmonary pain	1	8
Pulmonary thrombosis		2
Pulpitis dental		1
Pulse abnormal		3
Puncture site bruise		2
Pupillary reflex impaired		2
Pupils unequal		2
Purpura		2
Pustule		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
				1	1
		1	1		1
		3	23	4	26
			1		
					1
			1		
				1	1
			1		
			1		1
					1
		1	3	1	3
		8	55	1	5
			1		
				1	1
		20	93	15	84
			1		
		1	2	1	2
			1	1	2
			2	1	1
					1
					1
				3	9
			2	1	6
					2
					1
			2		1
					2
			1		1
					2
			1		1
			1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pyrexia	203	1,394
Rash	50	215
Rash erythematous	5	56
Rash macular	5	26
Rash maculo-papular		5
Rash papular	1	15
Rash pruritic	8	42
Rash vesicular	1	2
Raynaud's phenomenon		1
Reaction to excipient		1
Rectal discharge		1
Rectal haemorrhage		2
Reduced facial expression		3
Renal impairment	1	1
Renal pain	3	9
Respiration abnormal		1
Respiratory disorder		1
Respiratory rate increased	1	6
Respiratory symptom	1	1
Restless legs syndrome	1	4
Restlessness	5	13
Retching	1	8
Rhabdomyolysis		3
Rheumatoid arthritis		1
Rhinitis	1	5
Rhinorrhoea	5	31
Right ventricular failure		1
Rosacea		1
Rubber sensitivity		1
Sacroiliitis		1
Salivary hypersecretion	1	3
SARS-CoV-2 test positive	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	2	131	661	72	733
		36	117	14	98
		3	34	2	22
		4	16	1	10
			2		3
		1	11		4
		7	20	1	22
			1	1	1
					1
			1		1
					2
			3		
				1	1
		1	4	2	5
					1
			1		
		1	4		2
		1	1		
		1	2		2
		1	5	4	8
			4	1	4
					3
					1
			3	1	2
		4	15	1	16
					1
			1		
					1
			1		
		1	2		1
				2	2

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* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Scalloped tongue	1	1
Scar pain		1
Sciatica	1	3
Scleral discolouration		3
Scratch		1
Screaming	1	2
Scrotal pain	1	2
Seasonal allergy	1	4
Seizure	5	38
Self-injurious ideation		1
Sensation of foreign body	2	5
Sense of a foreshortened future		3
Sensitive skin	1	21
Sensory disturbance	1	5
Sensory loss		3
Sepsis	1	2
Serositis		1
Sinonasal obstruction	1	3
Sinus bradycardia		1
Sinus congestion		3
Sinus disorder	2	2
Sinus headache	7	23
Sinusitis		3
Sinus pain	2	13
Sinus tachycardia		7
Skin burning sensation	2	10
Skin discolouration	1	8
Skin disorder	1	2
Skin exfoliation		2
Skin fissures		1
Skin haemorrhage		1
Skin infection		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		
		1	2		1
			1		2
					1
		1	1		1
		1	2		
		1	3		1
				5	38
					1
		2	3		2
			2		1
		1	10		11
		1	4		1
			2		1
				1	2
					1
			1	1	2
					1
			2		1
		1	1	1	1
		2	11	5	12
					3
				2	13
			3		4
			1	2	9
		1	1		7
		1	2		
			1		1
			1		
			1		
			1		2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin irritation	1	2
Skin laceration		1
Skin lesion	2	4
Skin mass		1
Skin odour abnormal	1	1
Skin reaction	1	4
Skin sensitisation		1
Skin swelling		5
Skin tightness	1	3
Skin ulcer	1	2
Skin warm	2	22
Sleep disorder	7	34
Sleep disorder due to a general medical condition		6
Sleep disorder due to general medical condition, insomnia type	1	6
Sleep paralysis		1
Sleep talking		1
Sleep terror	1	1
Sluggishness		2
Small intestinal haemorrhage		1
Sneezing	4	11
Snoring	1	1
Soft tissue swelling		1
Somnolence	21	79
Speech disorder	3	8
Spinal fracture	1	1
Spinal pain	3	5
Splinter haemorrhages		1
Sputum discoloured	1	1
Sputum increased	1	1
Staring		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		1
			1		
		2	3		1
					1
				1	1
			2	1	2
					1
			4		1
		1	1		2
				1	2
			11	2	11
		6	23	1	11
			5		1
		1	6		
			1		
			1		
				1	1
			2		
					1
		3	6	1	5
				1	1
			1		
		10	36	11	43
			2	3	6
				1	1
		2	2	1	3
					1
		1	1		
				1	1
					1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Status epilepticus	2	4
Steatorrhoea		1
Stevens-Johnson syndrome	1	1
Still birth		1
Stomatitis		1
Stress		6
Stridor	1	6
Stupor	1	1
Sudden death	1	1
Sudden visual loss		1
Suicidal ideation		1
Suicide attempt		1
Sunburn	1	1
Supraventricular tachycardia		4
Suspected COVID-19	5	85
Sweating fever	1	16
Swelling	26	146
Swelling face	6	29
Swelling of eyelid	2	9
Swollen tongue	3	30
Symptom recurrence		1
Syncope	28	129
Synovial cyst		1
Systemic lupus erythematosus		1
Tachycardia	11	70
Tachyphrenia		1
Tachypnoea		4
Taste disorder	4	9
Tearfulness		4
Teething		1
Temperature difference of extremities		1
Temperature intolerance		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	4
					1
				1	1
					1
			1		
			2		4
				1	6
		1	1		
				1	1
					1
					1
		1	1		
			1		3
		2	35	3	50
				1	16
		19	75	7	71
		4	8	2	21
		1	3	1	6
		1	13	2	17
			1		
				28	129
			1		
					1
		4	23	7	47
					1
			1		3
		2	3	2	6
			1		3
			1		
					1
					2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Temperature regulation disorder		2
Temporomand bular joint syndrome		2
Tenderness	9	45
Tension		2
Tension headache	2	40
Testicular pain	2	4
Testis discomfort		1
Therapeutic product effect increased		1
Therapeutic response unexpected		1
Thermal burn		1
Thirst	6	15
Thoracic outlet syndrome	1	1
Throat irritation		14
Throat tightness	2	19
Thrombocytopenia	1	6
Thrombosis	1	9
Thunderclap headache	1	3
Thyroxine free increased		1
Tic		1
Tinnitus	7	36
Tongue blistering	1	1
Tongue discolouration		2
Tongue discomfort		2
Tongue disorder		2
Tongue dry	1	1
Tongue pruritus		1
Tongue spasm		1
Tongue ulceration		2
Tonic convulsion		1
Tonsillar erythema		1
Tonsillar hypertrophy	2	8
Tonsillar inflammation	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
			2		
		7	31	2	14
			2		
		2	20		20
		2	4		
			1		
					1
					1
			1		
		4	8	2	7
				1	1
			3		11
			3	2	16
				1	6
				1	9
				1	3
					1
					1
		2	14	5	22
		1	1		
			2		
			1		1
			1		1
				1	1
			1		
					1
			1		1
					1
			1		
		1	4	1	4
			1	1	2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tonsillitis	1	7
Toothache	1	7
Tracheitis		1
Transaminases increased		1
Transient ischaemic attack	1	2
Tremor	23	130
Trigeminal neuralgia	2	3
Trismus	1	2
Troponin increased		1
Tunnel vision	1	1
Type 1 diabetes mellitus	1	2
Type IV hypersensitivity reaction		1
Ulnar nerve injury		1
Unresponsive to stimuli	2	5
Upper-airway cough syndrome		1
Upper airway obstruction		1
Upper limb fracture		1
Urinary incontinence	3	4
Urinary retention		5
Urinary tract infection		3
Urine abnormality		1
Urine ketone body present	1	1
Urine odour abnormal		1
Urine output decreased		4
Urticaria	13	92
Urticaria chronic	1	1
Urticaria thermal		1
Uterine haemorrhage		1
Uterine pain		1
Uterine spasm		1
Uveitis		2
Vaccination complication		5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		6
			2	1	5
			1		
					1
				1	2
		12	57	11	73
		1	2	1	1
		1	1		1
					1
				1	1
				1	2
					1
					1
				2	5
			1		
					1
					1
		1	1	2	3
					5
					3
			1		
				1	1
			1		
			2		2
		10	43	3	49
				1	1
			1		
					1
					1
			1		
					2
			3		2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site abscess		1
Vaccination site bruising	5	30
Vaccination site discharge		1
Vaccination site discolouration		3
Vaccination site discomfort		10
Vaccination site erythema	28	148
Vaccination site haemorrhage		1
Vaccination site hypersensitivity		1
Vaccination site hypoaesthesia	2	7
Vaccination site induration	1	8
Vaccination site infection		5
Vaccination site inflammation	1	17
Vaccination site joint erythema		1
Vaccination site joint movement impairment		4
Vaccination site joint pain		4
Vaccination site lymphadenopathy	1	6
Vaccination site macule		1
Vaccination site mass	15	67
Vaccination site movement impairment	5	25
Vaccination site necrosis		1
Vaccination site oedema	2	4
Vaccination site pain	88	663
Vaccination site papule		1
Vaccination site paraesthesia		4
Vaccination site pruritus	13	55
Vaccination site rash	4	31
Vaccination site reaction	4	9
Vaccination site swelling	23	136
Vaccination site urticaria	1	8
Vaccination site warmth	14	76
Vaginal cyst		1
Vaginal haemorrhage	9	22

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		5	22		8
					1
			2		1
			6		4
		22	87	6	61
			1		
					1
			3	2	4
		1	6		2
			2		3
			10	1	7
			1		
			1		3
			2		2
		1	4		2
			1		
	1	10	39	5	28
			7	5	18
					1
		2	4		
	1	63	396	25	267
					1
			1		3
		9	31	4	24
		3	15	1	16
		4	6		3
		19	81	4	55
			4	1	4
		12	45	2	31
					1
		4	7	5	15

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Varicella		1
Vascular headache		1
Vasculitis		1
Vasodilatation		2
Vasospasm		1
Vein disorder		1
Vein rupture		1
Ventricular extrasystoles	1	1
Ventricular fibrillation		1
Ventricular hypertrophy		1
Vertigo	8	48
Vertigo positional		2
Vestibular migraine		1
Vestibular neuronitis		1
Viral infection		1
Viral labyrinthitis		1
Viral pharyngitis		1
Viral rash		1
Visceral pain		1
Vision blurred	14	50
Visual field defect	1	2
Visual impairment	4	22
Visual snow syndrome		1
Vitreous floaters		1
Vomiting	63	339
Vomiting projectile		5
Vulval ulceration	1	1
Vulvovaginal candidiasis	1	2
Vulvovaginal pain	2	2
Weight decreased	2	7
Weight increased		1
Wheezing	3	19

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
					1
			1		1
			1		
					1
					1
				1	1
					1
					1
		2	9	6	39
					2
					1
					1
					1
			1		
					1
					1
			1		
		4	13	10	37
				1	2
		2	13	2	9
					1
					1
	1	34	133	29	206
			2		3
		1	1		
		1	1		1
				2	2
		1	2	1	5
			1		
			3	3	16

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
White blood cell count increased	2	2					2	2
Withdrawal syndrome		1						1
Wound complication		2				1		1
Wrong product administered		1				1		
Yawning		2				1		1
Yellow skin		3				3		
		2				2		
	5,006	24,901	4	30	2682	11402	2324	13499

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	33	110	1	1	14	44	19	66
Abdominal distension	12	43			5	20	7	23
Abdominal mass		1						1
Abdominal pain	43	181			17	69	26	112
Abdominal pain lower	7	16			1	5	6	11
Abdominal pain upper	75	303		1	29	89	46	214
Abdominal rigidity		5				2		3
Abdominal tenderness		3						3
Abnormal behaviour	1	2			1	1		1
Abnormal clotting factor	1	1					1	1
Abnormal dreams	11	35			7	22	4	13
Abnormal faeces	1	4			1	2		2
Abnormal loss of weight	1	1					1	1
Abnormal sensation in eye		8				3		5
Abortion missed	1	2					1	2
Abortion spontaneous	6	35	2	2			6	35
Abscess	1	2					1	2
Abscess jaw		1						1
Abscess oral		1				1		
Accident		1				1		
Accidental exposure to product		3				3		
Accidental overdose		1				1		
Achenbach syndrome		1				1		
Acidosis		1						1
Acne	1	3					1	3
Acne pustular		1				1		
Activated partial thromboplastin time prolonged	2	2					2	2
Acute abdomen		1						1
Acute cardiac event	1	1					1	1
Acute disseminated encephalomyelitis		1						1
Acute kidney injury		3						3
Acute myocardial infarction		2						2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Adenomyosis	1	1
Adiposis dolorosa	1	1
Administration site discomfort		1
Adnexa uteri pain	1	4
Adrenocortical insufficiency acute		2
Adverse drug reaction	1	7
Aerophagia	1	2
Affective disorder		1
Affect lability	1	3
African trypanosomiasis		2
Ageusia	14	70
Aggression	1	6
Agitation	2	15
Airway secretion clearance therapy		1
Alanine aminotransferase increased		2
A buminuria		1
Alcohol interaction		2
Alcohol intolerance		2
Allergic cough		4
Allergic oedema	1	1
Allergy to arthropod bite		1
Allergy to vaccine	3	24
Allodynia	1	2
Alopecia	7	21
Alopecia areata	2	4
Altered state of consciousness		2
Amenorrhoea	8	14
Amnesia	3	13
Anaemia	9	11
Anaemia vitamin B12 deficiency		1
Anal haemorrhage		3
Anal incontinence	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
			1		
				1	4
					2
		1	5		2
		1	1		1
					1
			1	1	2
					2
		11	34	3	36
			1	1	5
		1	2	1	13
					1
			1		1
					1
					2
					2
					4
				1	1
					1
		1	8	2	16
				1	2
		2	5	5	16
				2	4
					2
		4	5	4	9
		1	2	2	11
		1	1	8	10
					1
					3
		1	2		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anal sphincter atony		1
Anaphylactic reaction	14	124
Anaphylactic shock	2	7
Anaphylactoid reaction	1	7
Anaphylactoid shock		2
Anger		2
Angina bullosa haemorrhagica		1
Angina pectoris	2	11
Angioedema	7	43
Angular cheilitis		1
Ankle fracture		1
Ankylosing spondylitis		1
Anorectal discomfort		1
Anorectal swelling		1
Anorgasmia		1
Anosmia	9	36
Anovulatory cycle	2	2
Antibody test positive		1
Antiphospholipid syndrome		1
Antisynthetase syndrome	1	1
Anti-thyroid antibody positive		1
Anxiety	13	115
Aortic aneurysm rupture	1	1
Apathy	1	5
Aphasia	2	13
Aphonia	3	12
Aphthous ulcer		3
Apnoea		1
Appendicitis	1	4
Appendicitis perforated		1
Appetite disorder		4
Application site pain	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				14	124
				2	7
				1	7
					2
			2		
					1
				2	11
				7	43
					1
					1
					1
			1		
					1
					1
		8	18	1	18
		2	2		
			1		
					1
		1	1		
					1
		7	39	6	76
				1	1
				1	5
		2	5		8
	1		3	3	9
			1		2
					1
				1	4
					1
					4
				1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Apraxia		1
Areflexia		1
Arrhythmia	1	11
Arrhythmia supraventricular		1
Arterial thrombosis		1
Arthralgia	264	1,544
Arthritis	6	30
Arthritis bacterial		1
Arthritis reactive	1	7
Arthropathy		7
Arthropod bite		1
Asphyxia	1	1
Asthenia	74	346
Asthenopia	4	33
Asthma	10	64
Asthma prophylaxis		1
Asymptomatic COVID-19		4
Atonic seizures		1
Atrial fibrillation	1	10
Atrial flutter	1	1
Atrial tachycardia		1
Atrioventricular block second degree	1	1
Attention deficit hyperactivity disorder		1
Auditory disorder		1
Aura	2	6
Auricular swelling		1
Autism spectrum disorder	1	1
Autoimmune disorder	2	6
Autonomic nervous system imbalance		1
Autoscopy		3
Axillary lymphadenectomy		1
Axillary mass	14	59

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
				1	11
					1
					1
4	14	98	526	166	1018
		2	4	4	26
					1
				1	7
			2		5
					1
				1	1
		28	115	46	231
		4	12		21
		2	10	8	54
					1
			1		3
					1
				1	10
				1	1
			1		
				1	1
					1
					1
		1	2	1	4
					1
				1	1
				2	6
					1
			1		2
					1
		4	18	10	41

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Axillary pain	121	448
Bacille Calmette-Guerin scar reactivation	2	6
Back pain	96	412
Balance disorder	22	57
Barotitis media	1	1
Bedridden		9
Behaviour disorder		1
Behcet's syndrome		1
Bell's palsy	13	80
Binge eating		1
Bipolar disorder	1	2
Bladder disorder	1	5
Bladder dysfunction	1	1
Bladder pain		2
Bleeding time abnormal		1
Blepharitis	1	3
Blepharospasm	5	13
Blindness	2	9
Blindness transient	2	5
Blindness unilateral		1
Blister	12	49
Blood blister	1	6
Blood cholesterol increased		1
Blood disorder	1	1
Blood folate decreased		1
Blood glucose abnormal		2
Blood glucose decreased	2	4
Blood glucose fluctuation		4
Blood glucose increased		16
Blood immunoglobulin M abnormal		1
Blood iron decreased	1	1
Blood lactic acid increased		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		33	133	88	315
			1	2	5
	1	33	154	63	258
		11	15	11	42
		1	1		
			2		7
					1
					1
				13	80
					1
				1	2
				1	5
				1	1
					2
					1
			1	1	2
		1	3	4	10
				2	9
				2	5
					1
		2	16	10	33
			1	1	5
					1
				1	1
			1		
			1		1
				2	4
			1		3
			8		8
					1
				1	1
					2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood oestrogen increased		1
Blood pH abnormal	1	1
Blood phosphorus decreased		2
Blood potassium abnormal		1
Blood potassium decreased		2
Blood potassium increased		1
Blood pressure abnormal	2	4
Blood pressure decreased	2	12
Blood pressure diastolic decreased	1	2
Blood pressure diastolic increased		1
Blood pressure fluctuation	2	5
Blood pressure increased	8	76
Blood pressure orthostatic decreased	1	1
Blood pressure systolic increased	1	3
Blood test abnormal		3
Blood urine	1	1
Blood urine present	4	12
Blue toe syndrome	2	4
Body fat disorder		1
Body temperature	3	12
Body temperature abnormal	3	31
Body temperature decreased	5	17
Body temperature fluctuation	1	8
Body temperature increased	19	119
Bone disorder	1	1
Bone neoplasm	1	1
Bone pain	16	107
Bone swelling	3	9
Bowel movement irregularity		1
Bradycardia	3	14
Bradykinesia	2	4
Bradyphrenia		5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
					2
					1
			1		1
					1
				2	4
		1	4	1	8
		1	2		
					1
		1	1	1	4
		2	40	6	36
				1	1
			1	1	2
					3
				1	1
		1	4	3	8
				2	4
			1		
		3	9		3
		1	10	2	21
		2	5	3	12
		1	5		3
		10	54	9	65
				1	1
				1	1
		2	33	14	74
		1	4	2	5
					1
				3	14
		1	1	1	3
			2		3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Brain injury	1	1
Breast abscess		1
Breast cancer	1	4
Breast cancer stage III		1
Breast cyst		1
Breast discomfort		4
Breast disorder		1
Breast engorgement		1
Breast enlargement		2
Breast haematoma	1	1
Breast mass		12
Breast milk discolouration		1
Breast pain	27	97
Breast prosthesis user		1
Breast swelling	8	32
Breast tenderness	7	14
Breath odour	1	4
Bronchiectasis		1
Bronchitis		1
Bronchospasm	3	10
Bruxism		3
Burning sensation	28	104
Burn oral cavity		1
Burns second degree	1	2
Bursitis	1	5
Butterfly rash		1
Candida infection		3
Cardiac amyloidosis	1	1
Cardiac arrest	2	14
Cardiac discomfort		1
Cardiac disorder	1	3
Cardiac failure		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
				1	4
					1
					1
			2		2
					1
					1
					2
		1	1		
			4		8
			1		
		9	28	18	69
			1		
		1	7	7	25
		5	6	2	8
		1	3		1
					1
					1
			1	3	9
					3
		9	30	19	74
					1
			1	1	1
				2	14
			1		
			1	1	2
					3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiac flutter	8	23
Cardiac murmur	1	4
Cardiomegaly	1	1
Cardiomyopathy		1
Cardiospasm	1	1
Cardiovascular disorder		2
Carpal tunnel syndrome		2
Cataplexy		1
Cataract	1	1
Catarrh		3
Catatonia		1
Cellulitis	5	38
Cerebral artery occlusion		1
Cerebral congestion	1	1
Cerebral disorder	1	2
Cerebral haemorrhage	3	7
Cerebral infarction	1	3
Cerebral palsy	1	1
Cerebral thrombosis		1
Cerebral venous sinus thrombosis	2	8
Cerebrovascular accident	7	32
Cervical dysplasia		1
Cervicogenic headache		2
Chalazion		2
Change of bowel habit		1
Chapped lips		1
Cheilitis	1	4
Chest discomfort	60	260
Chest injury		1
Chest pain	80	383
Chillblains	2	12
Chills	269	1,685

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				8	23
			1	1	3
				1	1
				1	1
					2
			2		
					1
				1	1
			2		1
					1
				5	38
					1
				1	1
		1	2		
				3	7
				1	3
				1	1
					1
				2	8
				7	32
					1
			1		1
			1		2
					1
					2
					1
		1	2		2
	1	25	82	35	178
					1
	2	20	91	60	292
		1	7	1	5
1	12	132	628	137	1057

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Choking		2
Choking sensation	1	3
Cholecystitis infective		1
Chromaturia	2	5
Chronic fatigue syndrome	5	16
Chronic kidney disease		2
Chronic obstructive pulmonary disease		1
Chronic spontaneous urticaria	1	2
Circulatory collapse	1	6
Clavicle fracture	1	2
Clonic convulsion		2
Clostridium test positive		1
Clumsiness		2
Cluster headache	7	39
Coagulation time prolonged		1
Coagulopathy		3
Coeliac disease		2
Cognitive disorder	7	18
Coital bleeding	1	1
Cold-stimulus headache	2	3
Cold sweat	11	120
Colitis	3	4
Colitis ulcerative	4	12
Coma scale abnormal		1
Complicated appendicitis	1	1
Concussion		1
Condition aggravated	27	128
Confusional state	32	136
Congestive cardiomyopathy		1
Conjunctival haemorrhage	3	6
Conjunctival oedema		1
Conjunctivitis	2	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
			1	1	2
					1
			1	2	4
		3	3	2	13
					2
					1
				1	2
				1	6
		1	1		1
					2
					1
					2
			7	7	32
					1
					3
					2
		2	2	5	16
				1	1
			1	2	2
		6	43	5	77
			1	3	3
				4	12
					1
				1	1
					1
	1	6	33	21	95
	1	2	24	30	112
					1
				3	6
					1
		1	3	1	6

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Consciousness fluctuating		3
Constipation	5	25
Contraindicated product administered		1
Contraindicated product prescribed	1	1
Contusion	35	112
Conversion disorder	1	2
Coordination abnormal	1	9
Corneal erosion		1
Corneal reflex decreased		1
Coronary artery occlusion	1	1
Coronavirus test positive	1	1
Costochondritis	2	8
Costovertebral angle tenderness		1
Cough	56	332
COVID-19	35	182
Cranial nerve neoplasm benign	1	1
C-reactive protein abnormal		1
C-reactive protein increased		3
Creutzfeldt-Jakob disease		1
Crohn's disease	3	9
Crying	6	18
Cutaneous sarcoidosis		1
Cutaneous symptom		1
Cyanosis	3	13
Cyclothymic disorder		1
Cyst	2	3
Cystitis	3	12
Cytomegalovirus infection reactivation		1
Dairy intolerance	1	2
Dark circles under eyes		1
Deafness	11	31
Deafness bilateral		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
		2	5	3	20
					1
				1	1
		15	41	20	71
				1	2
			2	1	7
					1
					1
				1	1
		1	1		
		1	1	1	7
			1		
1	2	28	113	28	219
1	2	8	46	27	136
				1	1
					1
					3
					1
				3	9
		5	7	1	11
					1
					1
		1	7	2	6
					1
		1	1	1	2
		1	4	2	8
					1
				1	2
					1
				11	31
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Deafness neurosensory	1	7
Deafness unilateral	2	9
Death	1	10
Decreased activity	1	2
Decreased appetite	47	235
Decreased insulin requirement		1
Decreased interest		1
Deep vein thrombosis	3	21
Defaecation urgency		2
Deficiency anaemia		1
Dehydration	6	31
Delayed recovery from anaesthesia		2
Delirium	1	17
Delusion		1
Delusional perception		1
Dementia with Lewy bodies		1
Demyelination		1
Dental caries		1
Dental paraesthesia	1	1
Depersonalisation/derealisation disorder		2
Depressed level of consciousness	1	8
Depressed mood	18	56
Depression	5	27
Derealisation		2
Dermal cyst	1	1
Dermal filler injection		1
Dermatitis	6	12
Dermatitis allergic	2	21
Dermatitis atopic	1	4
Dermatitis bullous	1	3
Dermatitis contact	1	1
Dermatitis diaper		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	7
				2	9
				1	10
				1	2
	1	20	79	27	156
					1
					1
				3	21
					2
			1		
		2	15	4	16
			1		1
				1	17
					1
					1
					1
					1
				1	1
			1		1
				1	8
		9	17	9	39
			1	5	26
					2
		1	1		
			1		
		4	6	2	6
			6	2	15
		1	2		2
				1	3
				1	1
			1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dermatomyositis	1	3
Dermatosis		1
Device connection issue	1	1
Diabetes mellitus	1	4
Diabetes mellitus inadequate control	1	4
Diabetic eye disease		1
Diabetic ketoacidosis		1
Diarrhoea	127	701
Diarrhoea haemorrhagic		1
Diplegia	1	2
Diplopia	3	17
Discharge		1
Discoloured vomit		1
Discomfort	29	86
Disease progression		1
Disease recurrence	15	70
Disorganised speech		2
Disorientation	12	50
Dissociation		9
Disturbance in attention	15	73
Dizziness	310	1,490
Dizziness exertional		10
Dizziness postural	26	108
Dose calculation error		1
Dreamy state		1
Droping		3
Drug eruption		1
Drug hypersensitivity	1	5
Drug ineffective	27	177
Drug interaction	1	6
Drug level decreased		1
Drug withdrawal syndrome		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
			1		
		1	1		
				1	4
				1	4
			1		
					1
	1	66	252	61	449
					1
				1	2
			4	3	13
					1
					1
	1	12	31	17	55
					1
		4	10	11	60
			1		1
		1	11	11	39
			6		3
	1	3	23	12	50
1	5	112	504	198	986
			1		9
	1	13	46	13	62
			1		
					1
					3
					1
				1	5
1	2			27	177
			1	1	5
					1
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dry eye	3	16
Dry mouth	18	93
Dry skin	11	31
Dry throat	7	37
Duodenogastric reflux		1
Dysaesthesia		2
Dysarthria	4	30
Dyschezia		1
Dyschromatopsia		1
Dysentery		1
Dysgeusia	49	221
Dyshidrotic eczema	1	3
Dyskinesia	1	10
Dysmenorrhoea	38	56
Dysmorphism		1
Dyspepsia	9	43
Dysphagia	13	61
Dysphemia		2
Dysphonia	6	29
Dysphoria		1
Dyspnoea	117	605
Dyspnoea at rest	1	4
Dyspnoea exertional	7	33
Dysstasia	3	19
Dystonia		3
Dysuria	4	11
Ear canal erythema		1
Ear congestion	2	5
Ear discomfort	5	25
Ear disorder	2	9
Ear infection	4	18
Ear infection bacterial		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	6	2	10
		7	36	11	57
		3	11	8	20
	1	5	19	2	18
			1		
			1		1
		1	7	3	23
					1
			1		
					1
	1	32	129	17	92
				1	3
			3	1	7
		15	21	23	35
					1
		6	18	3	25
		6	23	7	38
					2
1	1	4	13	2	16
					1
	1	38	159	79	446
				1	4
			7	7	26
			6	3	13
					3
		2	3	2	8
			1		
		1	2	1	3
		3	11	2	14
		1	3	1	6
		1	5	3	13
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ear pain	40	169
Ear pruritus		2
Ear swelling	4	10
Eating disorder		5
Eczema	6	25
Eczema asteatotic		1
Eczema eyelids		3
Eczema weeping		1
Ehlers-Danlos syndrome	1	1
Electric shock		1
Electric shock sensation		4
Electrocardiogram abnormal		2
Electrocardiogram ST segment elevation		1
Electrocardiogram T wave inversion	1	1
Embolism	3	7
Emotional disorder	5	16
Emotional distress	3	7
Encephalitis	1	3
Encephalitis viral		1
Endometriosis	4	6
Energy increased	1	3
Enlarged uvula	1	2
Enteritis	1	1
Enuresis	1	2
Eosinophilia	1	1
Ephelides		1
Epicondylitis	1	3
Epididymitis		1
Epigastric discomfort		4
Epilepsy	9	27
Epiploic appendagitis	1	1
Episcleritis		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		12	54	28	115
			2		
		3	4	1	6
					5
		1	5	5	20
					1
			3		
			1		
				1	1
			1		
			4		
					2
					1
				1	1
				3	7
		1	5	4	11
			1	3	6
				1	3
					1
		1	1	3	5
				1	3
		1	1		1
				1	1
				1	2
				1	1
			1		
			1	1	2
					1
			1		3
				9	27
				1	1
					3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Epistaxis	16	60
Epstein-Barr virus infection		2
Erectile dysfunction		6
Eructation	2	7
Erythema	85	374
Erythema annulare		1
Erythema multiforme		3
Erythema nodosum	1	3
Erythema of eyelid		2
Erythrospia		2
Essential tremor		1
Euphoric mood	1	7
Eustachian tube disorder		1
Excessive cerumen production		1
Exercise tolerance decreased	1	5
Exertional headache		1
Exfoliative rash	1	1
Expired product administered	1	3
Exposure during pregnancy	6	29
Exposure to SARS-CoV-2		1
Exposure via breast milk	1	3
Extensive swelling of vaccinated limb	1	6
Extensor plantar response		1
External ear cellulitis		1
External ear disorder	1	1
Extraocular muscle paresis	1	2
Extrasystoles	4	17
Eye contusion		4
Eye discharge	2	6
Eye disorder	2	14
Eye haematoma	1	1
Eye haemorrhage		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		8	24	8	36
					2
					6
		1	1	1	6
	1	49	195	36	179
					1
					3
				1	3
					2
			1		1
					1
		1	4		3
					1
					1
			2	1	3
			1		
				1	1
		1	1		2
	1	4	22	2	7
					1
			1	1	2
			3	1	3
					1
					1
				1	1
				1	2
		2	5	2	12
			1		3
				2	6
		1	4	1	10
				1	1
					2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye infection	2	4
Eye inflammation	1	4
Eye irritation	2	22
Eyelid disorder		1
Eyelid exfoliation		1
Eyelid function disorder	1	2
Eyelid irritation		1
Eyelid margin crusting		1
Eyelid oedema		2
Eyelid pain		4
Eyelid ptosis	1	4
Eyelid rash		2
Eyelids pruritus	1	4
Eye movement disorder		4
Eye oedema		3
Eye pain	50	198
Eye paraesthesia		1
Eye pruritus	14	52
Eye swelling	20	100
Eye ulcer	1	2
Face crushing		1
Face oedema		4
Facial discomfort	1	4
Facial neuralgia		2
Facial pain	8	55
Facial paralysis	8	60
Facial paresis	1	17
Facial spasm	2	8
Faecal calprotectin increased	2	2
Faeces discoloured		4
Faeces pale		1
Failed in vitro fertilisation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	3
				1	4
			4	2	18
					1
					1
		1	1		1
					1
			1		
			1		1
			2		2
			1	1	3
					2
		1	2		2
					4
			2		1
		19	60	31	138
			1		
		5	16	9	36
		3	20	17	80
			1	1	1
					1
			2		2
			1	1	3
			2		
		2	17	6	38
	1			8	60
			4	1	13
		2	6		2
		2	2		
			3		1
			1		
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Fall	8	25
False positive investigation result		1
Familial hemiplegic migraine		1
Familial periodic paralysis		1
Fatigue	686	3,633
Fear		4
Fear of injection		1
Febrile convulsion	2	7
Feeding disorder	1	11
Feeling abnormal	92	375
Feeling cold	49	252
Feeling drunk	3	24
Feeling hot	76	343
Feeling jittery		8
Feeling of body temperature change	29	101
Feeling of despair	1	1
Fibrin D dimer increased	2	4
Fibromyalgia	5	18
Fine motor skill dysfunction	1	2
Finger deformity		1
Flank pain		8
Flashback		1
Flatulence	9	32
Fluid imbalance		1
Fluid retention	2	5
Flushing	22	123
Focal dyscognitive seizures		1
Foetal death		1
Food allergy	2	5
Food aversion		1
Food craving		2
Food intolerance	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	9	6	16
					1
					1
					1
7	34	285	1268	401	2365
			2		2
			1		
		1	4	1	3
		1	7		4
1	1	35	138	57	237
	2	18	95	31	157
			7	3	17
1	1	37	167	39	176
			3		5
		11	40	18	61
				1	1
			1	2	3
	1	1	2	4	16
			1	1	1
			1		
			4		4
					1
		3	9	6	23
			1		
		1	3	1	2
	1	13	52	9	71
					1
					1
			1	2	4
					1
			1		1
				1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Food poisoning		1
Food refusal	1	1
Foreign body sensation in eyes		4
Formication	3	11
Foveal reflex abnormal		1
Fracture blisters		1
Frequent bowel movements	1	6
Frustration tolerance decreased	2	2
Functional gastrointestinal disorder	1	1
Furuncle	2	5
Gait disturbance	13	69
Gait inability	1	17
Gastric antral vascular ectasia	1	1
Gastric dilatation		1
Gastric disorder	1	7
Gastric ulcer		1
Gastritis	1	6
Gastroenteritis		3
Gastroenteritis viral	1	2
Gastrointestinal disorder	1	5
Gastrointestinal haemorrhage	3	4
Gastrointestinal pain	5	11
Gastrointestinal sounds abnormal	1	7
Gastrointestinal stoma complication		1
Gastrooesophageal reflux disease	3	20
Generalised oedema		1
Generalised tonic-clonic seizure	2	8
General physical health deterioration		2
Genital haemorrhage	1	1
Genital herpes	1	3
Genital ulceration		1
Genitourinary symptom		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
			1		3
		1	3	2	8
					1
			1		
		1	4		2
				2	2
				1	1
		1	2	1	3
		4	11	9	58
			4	1	13
				1	1
					1
		1	2		5
					1
				1	6
					3
		1	1		1
			1	1	4
				3	4
		1	2	4	9
			3	1	4
					1
		1	4	2	16
			1		
				2	8
			1		1
				1	1
				1	3
					1
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gestational diabetes	1	2
Gingival abscess		1
Gingival bleeding	1	7
Gingival blister		2
Gingival discomfort		1
Gingival disorder		2
Gingival erythema		2
Gingival pain	5	15
Gingival pruritus		1
Gingival swelling	2	6
Gingivitis		2
Gingivitis ulcerative		2
Glaucoma		1
Glomerulonephritis minimal lesion		3
Glossitis		2
Glossodynia	4	40
Goitre		3
Gout	2	8
Graft versus host disease		1
Granuloma skin		1
Grief reaction		1
Grip strength		1
Grip strength decreased	3	10
Groin pain	5	27
Guillain-Barre syndrome	2	4
Habit cough		2
Haemarthrosis	1	1
Haematemesis	1	3
Haematochezia	3	8
Haematocrit increased		1
Haematoma		3
Haematuria		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		1
					1
			3	1	4
			2		
			1		
			1		1
			1		1
		2	3	3	12
					1
			1	2	5
			1		1
					2
					1
					3
			2		
		2	20	2	20
			1		2
		2	2		6
					1
			1		
					1
					1
		1	6	2	4
		1	8	4	19
				2	4
			1		1
				1	1
				1	3
				3	8
					1
					3
			1		2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haemoglobin decreased		3
Haemoglobin increased		1
Haemoptysis		7
Haemorrhage	23	37
Haemorrhage urinary tract		1
Haemorrhagic diathesis		1
Haemorrhoids	2	6
Haemorrhoids thrombosed		1
Hair colour changes	1	1
Hair dye user	1	1
Hallucination	4	25
Hallucination, auditory	1	2
Hallucination, olfactory		2
Hallucination, visual	2	3
Halo vision	3	3
Hand-arm vibration syndrome		1
Hand deformity		2
Hangover	3	12
Headache	831	4,373
Head banging		2
Head discomfort	19	71
Head injury	5	12
Head titubation	2	3
Heart disease congenital		1
Heart injury		2
Heart rate	3	9
Heart rate abnormal	6	16
Heart rate decreased		16
Heart rate increased	35	173
Heart rate irregular	3	14
Heart sounds abnormal	1	1
Heat exhaustion	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		2
					1
			2		5
	1			23	37
					1
					1
		1	1	1	5
					1
				1	1
				1	1
				4	25
				1	2
					2
				2	3
		1	1	2	2
					1
					2
		3	6		6
2	20	396	1675	435	2698
			1		1
		6	23	13	48
		1	5	4	7
		1	1	1	2
					1
					2
		1	3	2	6
		3	8	3	8
			2		14
		8	62	27	111
				3	14
		1	1		
		1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Heat oedema	1	3
Heavy menstrual bleeding	117	167
Hemiparaesthesia		1
Hemiparesis	1	5
Hemiplegia	1	6
Hemiplegic migraine		3
Hepatic haemorrhage	1	1
Hepatic pain	2	7
Hepatitis		2
Hepatitis A		1
Hepatitis E	1	1
Hepatitis viral		1
Hepatomegaly		1
Hereditary neuropathy with liability to pressure palsies		1
Herpes simplex	1	6
Herpes simplex reactivation		1
Herpes virus infection	1	3
Herpes zoster	83	158
Herpes zoster oticus	1	1
Herpes zoster reactivation		1
Hirsutism	1	1
Histamine intolerance		1
Histamine level increased		1
HIV infection	1	1
Hodgkin's disease	1	1
Hordeolum	3	4
Hormone level abnormal	2	3
Hot flush	35	164
Humerus fracture		1
Hunger	1	4
Hydrocephalus	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	2
	1	52	66	65	101
					1
				1	5
				1	6
					3
				1	1
		1	1	1	6
					2
					1
				1	1
					1
					1
					1
			3	1	3
			1		
			1	1	2
		34	64	49	94
				1	1
					1
				1	1
					1
			1		
				1	1
				1	1
		1	1	2	3
		2	2		1
		12	63	23	101
					1
		1	4		
				1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyperactive pharyngeal reflex		1
Hyperacusis	2	14
Hyperaesthesia	3	23
Hyperaesthesia teeth	1	1
Hypercapnia		1
Hyperchlorhydria	1	5
Hypergeusia		1
Hyperglycaemia	1	19
Hyperhidrosis	67	366
Hyperintensity in brain deep nuclei	1	1
Hyperkalaemia		1
Hypermobility syndrome	1	1
Hyperphagia		1
Hyperreflexia		1
Hypersensitivity	35	137
Hypersomnia	13	59
Hypertension	17	106
Hypertensive crisis		3
Hypertensive heart disease		1
Hyperthermia	1	1
Hyperthyroidism		2
Hypertonic bladder		1
Hypertrophic cardiomyopathy		1
Hyperventilation	2	7
Hypervigilance		1
Hypnagogic hallucination		1
Hypoacusis	8	21
Hypoaesthesia	104	446
Hypoaesthesia eye	1	4
Hypoaesthesia oral	20	100
Hypoaesthesia teeth	1	2
Hypoglycaemia	2	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			6	2	8
		1	11	2	12
				1	1
					1
			1	1	4
					1
			3	1	16
		21	106	46	260
				1	1
					1
				1	1
					1
		9	33	26	104
		5	25	8	34
		4	33	13	73
					3
					1
				1	1
					2
			1		
					1
			4	2	3
					1
					1
		4	10	4	11
	3	39	169	65	277
				1	4
		7	44	13	56
			1	1	1
		1	4	1	9

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypokalaemia		1
Hypokinesia	8	28
Hypomania		1
Hypomenorrhoea	5	10
Hyponatraemia		1
Hyponatraemic syndrome		1
Hypoperfusion		1
Hypophagia	1	3
Hypopnoea	4	18
Hyporeflexia		1
Hyporesponsive to stimuli	1	1
Hyposmia		3
Hypotension	14	71
Hypothermia		6
Hypothyroidism		5
Hypotonia	1	1
Hypoventilation		2
Hypovitaminosis		1
Hypovolaemic shock		1
Hypoxia		3
Idiopathic intracranial hypertension	1	1
Ileal perforation	1	1
Illness	71	277
Immediate post-injection reaction		1
Immune system disorder	1	6
Immune thrombocytopenia	8	14
Immunisation anxiety related reaction		1
Immunodeficiency		1
Immunodeficiency common variable		1
Immunology test		1
Impaired driving ability		6
Impaired gastric emptying	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		3	9	5	19
					1
		4	7	1	3
					1
					1
				1	3
			1	4	17
			1		
				1	1
			2		1
		7	23	7	48
					6
					5
				1	1
					2
			1		
					1
					3
				1	1
				1	1
		33	99	38	178
			1		
				1	6
				8	14
					1
					1
					1
			1		
			2		4
				2	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Impaired quality of life		2
Impaired work ability	4	10
Impetigo	1	1
Implant site pain		1
Implant site swelling	1	1
Inappropriate affect		1
Inappropriate schedule of product administration	171	335
Incision site pain		2
Incoherent		2
Incontinence	1	6
Incorrect dose administered	1	3
Incorrect route of product administration	2	13
Increased appetite	1	2
Increased bronchial secretion		1
Increased tendency to bruise	1	6
Increased upper airway secretion		4
Increased viscosity of bronchial secretion		1
Increased viscosity of upper respiratory secretion		3
Indifference	1	4
Induration		1
Infected dermal cyst		1
Infection	9	34
Infectious mononucleosis	1	2
Infectious pleural effusion		1
Infertility		1
Inflammation	16	53
Inflammatory pain	2	4
Influenza	41	226
Influenza like illness	89	463
Infusion related reaction		1
Initial insomnia	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
		1	2	3	8
				1	1
					1
		1	1		
					1
1	1	168	326	3	9
					2
			1		1
			2	1	4
		1	3		
		2	13		
		1	1		1
					1
			2	1	4
			1		3
					1
			1		2
		1	1		3
					1
					1
		2	9	7	25
				1	2
					1
					1
		4	23	12	30
		1	2	1	2
1	1	15	73	26	153
	1	47	191	42	272
					1
		1	3		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injected limb mobility decreased		13
Injection related reaction		4
Injection site bruising	1	1
Injection site erythema	8	11
Injection site hypoaesthesia	1	1
Injection site inflammation	1	1
Injection site joint movement impairment		1
Injection site mass	2	2
Injection site oedema		1
Injection site pain	16	36
Injection site pruritus	1	3
Injection site reaction		1
Injection site swelling	3	6
Injection site urticaria		1
Injection site warmth	2	3
Injury	1	5
Inner ear disorder		4
Inner ear inflammation		1
Insomnia	54	273
Insulin resistance		1
Insulin resistant diabetes	1	1
Intentional self-injury		2
Intermenstrual bleeding	16	19
Intermittent claudication	1	1
Internal haemorrhage	1	2
International normalised ratio abnormal		1
International normalised ratio decreased	1	2
Interstitial lung disease	1	2
Intestinal perforation	1	1
Intestinal pseudo-obstruction		1
Intranasal hypoaesthesia		1
Intranasal paraesthesia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			5		8
			3		1
		1	1		
		7	10	1	1
		1	1		
		1	1		
					1
		1	1	1	1
			1		
		15	30	1	6
		1	3		
					1
		3	6		
					1
		1	2	1	1
				1	5
					4
					1
		22	95	32	178
					1
				1	1
					2
		8	10	8	9
				1	1
				1	2
			1		
				1	2
				1	2
				1	1
					1
			1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Intrusive thoughts		1
Iridocyclitis		2
Iron deficiency anaemia		1
Irregular breathing		5
Irritability	4	25
Irritable bowel syndrome	2	12
Ischaemia	1	1
Itching scar		3
Jaundice		2
Jaw clicking		1
Jaw disorder	1	1
Joint effusion		5
Joint injury		6
Joint laxity		2
Joint lock		1
Joint noise	1	5
Joint range of motion decreased	18	64
Joint stiffness	8	49
Joint swelling	12	65
Joint warmth		4
Keratitis		1
Ketoacidosis		1
Kidney infection		2
Kidney small		1
Labia enlarged	1	1
Labyrinthitis	4	14
Lack of spontaneous speech		4
Lacrimal disorder		1
Lacrimation increased	5	29
Lactation disorder	1	3
Lactose intolerance		1
Lagophthalmos		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					2
			1		
					5
		2	6	2	19
		1	3	1	9
				1	1
			2		1
					2
					1
				1	1
			1		4
			3		3
					2
					1
		1	2		3
		6	18	12	46
		1	11	7	38
		4	17	8	48
			3		1
					1
					1
					2
					1
				1	1
		1	3	3	11
			1		3
					1
		1	5	4	24
				1	3
			1		
			1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Language disorder	1	2
Laryngeal disorder		1
Laryngeal pain		1
Laryngitis		1
Left ventricular hypertrophy		1
Lethargy	73	432
Leukopenia		1
Lhermitte's sign		1
L bido increased	1	1
Ligament sprain	1	3
Limb discomfort	70	297
Limbic encephalitis	1	1
Limb immobilisation	1	3
Limb injury	1	11
Limb mass	3	10
Lip blister		5
Lip discolouration		1
Lip disorder		4
Lip dry	1	7
Lip erythema		1
Lip exfoliation	1	3
Lip haemorrhage		1
Lip injury	1	1
Lip oedema		3
Lip pain	2	10
Lip pruritus		1
Lip swelling	21	122
Lip ulceration		2
Listless		1
Livedo reticularis		6
Liver function test abnormal	3	4
Liver function test increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
					1
					1
					1
					1
1	2	31	161	42	271
					1
					1
		1	1		
				1	3
	2	35	130	35	167
				1	1
			2	1	1
			2	1	9
			3	3	7
			1		4
					1
			2		2
			3	1	4
					1
			1	1	2
					1
		1	1		
					3
		1	6	1	4
			1		
		11	42	10	80
			2		
					1
			1		5
				3	4
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Liver injury		1
Localised infection		7
Localised oedema	4	6
Local reaction	3	9
Locked-in syndrome		1
Logorrhoea	1	2
Long thoracic nerve palsy		1
Loss of consciousness	15	72
Loss of control of legs	1	3
Loss of personal independence in daily activities	11	67
Lower respiratory tract infection	5	31
Lung disorder	1	4
Lupus-like syndrome		1
Lymphadenitis	8	36
Lymphadenopathy	342	1,444
Lymphangiopathy		1
Lymphangitis	1	2
Lymphatic disorder		1
Lymph gland infection	2	3
Lymph node abscess		1
Lymph node pain	72	303
Lymph node palpable	2	5
Lymph nodes scan abnormal		1
Lymphocytosis		1
Lymphoedema	6	29
Lymphoma	1	4
Lymphopenia		1
Macular degeneration		1
Macule		2
Maculopathy		1
Malaise	200	1,127
Mallory-Weiss syndrome	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		6
		2	3	2	3
		2	5	1	4
					1
				1	2
			1		
				15	72
				1	3
		4	22	7	45
				5	31
			1	1	3
					1
		5	14	3	22
	3	131	514	211	930
					1
				1	2
			1		
		1	1	1	2
					1
		25	85	47	218
		2	4		1
					1
					1
	1	3	8	3	21
				1	4
			1		
					1
			1		1
					1
	4	81	420	119	707
				1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Malnutrition		1
Malocclusion	1	1
Mania		2
Mass	2	11
Mast cell activation syndrome		2
Mastication disorder	1	3
Mastitis	1	9
Maternal exposure before pregnancy		2
Maternal exposure during breast feeding	10	19
Maternal exposure during pregnancy	22	73
Maternal exposure timing unspecified	1	3
Measles		1
Mechanical urticaria	1	2
Medication overuse headache	1	1
Melaena		1
Melanocytic naevus		1
Memory impairment	7	23
Meniere's disease		1
Meningitis		2
Meningitis aseptic		1
Meningitis viral		2
Menopause	2	2
Menstrual discomfort		1
Menstrual disorder	48	60
Menstruation delayed	66	89
Menstruation irregular	64	80
Mental disorder		2
Mental fatigue	7	35
Mental impairment	2	7
Mesenteric vein thrombosis	1	2
Metabolic acidosis		2
Metamorphopsia		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
					2
		1	2	1	9
					2
				1	3
				1	9
					2
		5	9	5	10
4	7	10	52	12	21
		1	3		
					1
		1	2		
		1	1		
					1
					1
		1	4	6	19
					1
					2
					1
					2
				2	2
					1
	1	34	39	14	21
1	1	55	63	11	26
	1	43	49	21	31
			1		1
		2	7	5	28
				2	7
				1	2
					2
			1		2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Metastases to lymph nodes	1	4
Micturition urgency	1	4
Middle ear inflammation		1
Middle insomnia	2	13
Migraine	87	427
Migraine with aura	6	26
Migraine without aura		1
Miliaria	7	17
Miosis		1
Misophonia	1	2
Mitral valve prolapse		1
Moaning		1
Mobility decreased	8	55
Moebius II syndrome	1	1
Monocytosis		1
Mononeuropathy		1
Monoparesis	5	13
Monoplegia	1	14
Mood altered	1	7
Mood swings	2	7
Morning sickness	1	2
Motion sickness	3	14
Motor dysfunction		1
Mouth breathing		2
Mouth cyst		1
Mouth haemorrhage		1
Mouth swelling	2	20
Mouth ulceration	9	60
Movement disorder	9	38
Mucous stools	1	1
Multiple injuries		1
Multiple sclerosis	2	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	4
		1	1		3
					1
		2	5		8
	2	31	108	56	319
			5	6	21
					1
		3	7	4	10
					1
				1	2
					1
					1
		3	19	5	36
				1	1
			1		
					1
		4	5	1	8
				1	14
		1	2		5
		1	4	1	3
				1	2
		1	7	2	7
					1
					2
			1		
			1		
		1	6	1	14
1	1	8	32	1	28
		6	11	3	27
				1	1
					1
				2	12

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Multiple sclerosis relapse	1	10
Mumps		1
Muscle atrophy		2
Muscle contractions involuntary	2	8
Muscle discomfort		1
Muscle disorder		1
Muscle fatigue	9	58
Muscle injury		1
Muscle mass	1	1
Muscle rigidity		1
Muscle rupture		1
Muscle spasms	46	164
Muscle spasticity	1	3
Muscle strain		3
Muscle swelling		5
Muscle tightness	1	16
Muscle twitching	12	54
Muscular weakness	35	159
Musculoskeletal chest pain	13	38
Musculoskeletal discomfort	6	22
Musculoskeletal disorder	2	10
Musculoskeletal pain		12
Musculoskeletal stiffness	48	207
Mutism		3
Myalgia	301	1,904
Myalgia intercostal		1
Myasthenia gravis		2
Mydriasis		2
Myelitis transverse	2	11
Myocardial fibrosis		1
Myocardial infarction	4	12
Myocardial oedema		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	10
					1
			1		1
			2	2	6
			1		
			1		
		2	15	7	43
					1
				1	1
			1		
					1
1	2	17	53	29	111
				1	3
			1		2
			3		2
		1	8		8
		7	23	5	31
		11	51	24	108
		3	10	10	28
		4	14	2	8
		1	3	1	7
			3		9
		18	75	30	132
			2		1
1	11	157	744	144	1160
					1
					2
					2
				2	11
					1
				4	12
					2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myocarditis	2	11
Myoclonus		2
Myofascial pain syndrome		2
Myopathy	2	2
Myositis	1	3
Nail discolouration		2
Narcolepsy		1
Nasal congestion	7	47
Nasal discharge discolouration		1
Nasal discomfort	2	11
Nasal disorder		1
Nasal dryness	1	3
Nasal herpes		2
Nasal oedema		2
Nasal pruritus		3
Nasopharyngitis	42	152
Nausea	400	2,217
Near death experience		1
Neck mass	2	9
Neck pain	85	395
Necrotic lymphadenopathy		2
Necrotising fasciitis		1
Negative thoughts		1
Neoplasm		1
Neoplasm malignant		2
Neoplasm progression	1	1
Nephritis		1
Nephrolithiasis	1	1
Nephrotic syndrome	1	5
Nerve block	1	1
Nerve compression	3	7
Nerve injury		5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	11
			1		1
					2
				2	2
			2	1	1
					2
					1
		5	20	2	27
			1		
		1	6	1	5
			1		
			1	1	2
			2		
			1		1
					3
		16	53	26	99
	6	182	826	218	1391
					1
		1	3	1	6
	2	29	137	56	258
					2
					1
					1
					1
					2
		1	1		
					1
				1	1
				1	5
				1	1
			2	3	5
					5

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nervousness	9	40
Nervous system disorder	1	4
Neuralgia	30	81
Neuritis	2	3
Neurogenic shock	1	5
Neurological symptom		6
Neurologic neglect syndrome		1
Neuromyelitis optica spectrum disorder		1
Neuropathy peripheral	6	20
Neutropenia	2	9
Neutrophil count increased		1
New daily persistent headache		1
Nightmare	7	23
Night sweats	22	112
Nipple exudate bloody		1
Nipple pain	2	8
Nipple swelling		3
Nodule		2
Non-cardiac chest pain	1	3
Non-tobacco user		1
No reaction on previous exposure to drug		1
Nuchal rigidity		1
Nystagmus		3
Obstructive airways disorder	2	4
Occipital neuralgia		2
Occupational exposure to product	1	2
Ocular discomfort	1	10
Ocular hyperaemia	9	39
Ocular sarcoidosis		1
Ocular vascular disorder	2	2
Odynophagia	4	16
Oedema	3	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	14	4	26
			2	1	2
		11	22	19	59
			1	2	2
				1	5
					6
					1
					1
				6	20
				2	9
			1		
			1		
		2	9	5	14
	1	12	50	10	62
					1
		1	4	1	4
			2		1
					2
				1	3
			1		
			1		
					1
					3
				2	4
					2
		1	2		
		1	7		3
		4	16	5	23
					1
		1	1	1	1
		2	8	2	8
			2	3	8

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oedema mouth		2
Oedema mucosal	1	1
Oedema peripheral	2	10
Oesophageal pain		2
Oesophageal spasm		1
Oesophageal stenosis		1
Off label use	168	529
Oligodendroglioma		1
Oligohydramnios		1
Oligomenorrhoea		2
Onychalgia	1	1
Onychoclasia		1
Ophthalmic herpes zoster	1	2
Ophthalmic migraine	2	5
Ophthalmoplegia		1
Optic disc haemorrhage	1	1
Optic nerve disorder		1
Optic neuritis	3	9
Oral allergy syndrome	1	1
Oral blood blister	2	3
Oral candidiasis	1	2
Oral discomfort	2	18
Oral disorder	2	8
Oral herpes	6	32
Oral mucosa erosion		1
Oral mucosal blistering	1	10
Oral mucosal eruption		1
Oral mucosal erythema		2
Oral mucosal exfoliation		2
Oral pain	7	26
Oral pruritus	1	7
Orbital swelling	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
		1	1		
		1	3	1	7
			2		
			1		
					1
1	1	162	498	6	31
					1
					1
					2
				1	1
			1		
				1	2
			1	2	4
					1
				1	1
					1
				3	9
				1	1
		2	3		
				1	2
		1	9	1	9
		2	4		4
	1	4	19	2	13
			1		
			5	1	5
			1		
			1		1
			1		1
		3	13	4	13
			3	1	4
				1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Orchitis		1
Oropharyngeal blistering	2	7
Oropharyngeal discomfort	2	23
Oropharyngeal oedema		1
Oropharyngeal pain	96	443
Oropharyngeal plaque		1
Orthostatic hypertension		1
Orthostatic hypotension		2
Oscillopsia		1
Osteitis	1	1
Osteonecrosis of jaw		1
Osteopenia	1	1
Otitis externa		1
Overdose		6
Oversensing	1	2
Overweight		1
Ovulation disorder	1	1
Ovulation pain	1	1
Oxygen saturation decreased	5	21
Pain	325	1,497
Painful respiration	1	14
Pain in extremity	500	2,122
Pain in jaw	19	67
Pain of skin	12	52
Palatal oedema		1
Palatal swelling		2
Palate injury	1	1
Pallor	12	48
Palmar erythema		1
Palmoplantar pustulosis	1	1
Palpitations	61	368
Pancreatic disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				2	7
		1	6	1	17
					1
1	2	54	177	42	266
			1		
					1
			1		1
			1		
				1	1
					1
				1	1
					1
			6		
				1	2
					1
				1	1
				1	1
		1	2	4	19
	4	138	581	187	916
			2	1	12
2	18	246	891	254	1231
		9	24	10	43
1	1	6	19	6	33
					1
					2
				1	1
		4	16	8	32
			1		
				1	1
	1	25	109	36	259
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pancreatitis	1	1
Pancreatitis acute		1
Panic attack	1	14
Panic disorder		1
Panic reaction	2	8
Papilloedema	1	1
Papule	4	11
Paraesthesia	128	567
Paraesthesia oral	36	255
Parainfluenzae viral laryngotracheobronchitis		1
Paralysis	5	19
Paramnesia		1
Paranasal sinus discomfort		7
Paranoia		3
Paresis		1
Parkinsonian gait	1	1
Paronychia	1	1
Parosmia	8	29
Parotid gland enlargement	1	1
Partial seizures		5
Patient elopement		1
Peak expiratory flow rate		1
Peak expiratory flow rate abnormal		1
Peak expiratory flow rate decreased		3
Pelvic haemorrhage	1	2
Pelvic pain	6	13
Pelvic venous thrombosis		2
Pemphigus		1
Penile swelling		1
Peptic ulcer haemorrhage	1	2
Periarthritis	7	16
Pericarditis	3	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
			4	1	10
					1
		1	1	1	7
				1	1
		3	7	1	4
	2	62	233	66	334
		26	143	10	112
					1
	1			5	19
					1
			3		4
			1		2
					1
		1	1		
		1	1		
		8	18		11
				1	1
					5
					1
					1
					3
				1	2
				6	13
					2
					1
					1
				1	2
		1	4	6	12
				3	7

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Perioral dermatitis		1
Periorbital cellulitis		1
Periorbital oedema		2
Periorbital pain		2
Periorbital swelling	5	21
Peripheral arterial occlusive disease	1	1
Peripheral artery occlusion	1	1
Peripheral circulatory failure		2
Peripheral coldness	22	87
Peripheral ischaemia	1	3
Peripheral sensory neuropathy		3
Peripheral swelling	129	484
Peripheral vein stenosis		1
Peroneal nerve palsy		2
Persistent genital arousal disorder	1	1
Personality disorder	1	1
Petechiae	6	24
Petit mal epilepsy		5
Phantom limb syndrome		1
Pharyngeal disorder	1	1
Pharyngeal erythema		4
Pharyngeal haemorrhage		1
Pharyngeal hypoaesthesia	1	7
Pharyngeal inflammation		5
Pharyngeal oedema		2
Pharyngeal paraesthesia	1	13
Pharyngeal swelling	12	72
Pharyngeal ulceration		2
Pharyngitis		4
Phlebitis	1	2
Phlebitis superficial	1	1
Phobia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
					2
			1		1
		4	8	1	13
				1	1
				1	1
					2
		8	29	14	58
			2	1	1
					3
	2	51	168	78	316
					1
					2
		1	1		
				1	1
		3	9	3	15
					5
					1
		1	1		
			2		2
					1
		1	4		3
					5
					2
		1	6		7
		5	21	7	51
					2
			1		3
		1	2		
				1	1
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Photophobia	14	81
Photopsia	7	20
Photosensitivity reaction	4	17
Pigmentation disorder		2
Piloerection	3	7
Pituitary tumour benign	1	1
Pityriasis		3
Pityriasis lichenoides et varioliformis acuta	1	2
Pityriasis rosea	3	9
Plantar erythema		1
Plantar fasciitis		1
Platelet count decreased	4	13
Platelet count increased		1
Pleural effusion		1
Pleurisy		3
Pleuritic pain	1	3
Plicated tongue		2
Pneumonia		5
Pneumonitis	1	3
Pneumothorax	1	2
Poisoning		3
Pollakiuria	4	10
Polyarthrits	1	3
Polychondritis		2
Polycystic ovaries	4	4
Polydipsia		3
Polymenorrhoea	15	22
Polymerase chain reaction positive	4	6
Polymyositis	1	1
Polyuria	1	1
Poor peripheral circulation		1
Poor quality sleep	11	43

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	24	9	57
		1	5	6	15
		1	3	3	14
			1		1
		3	3		4
				1	1
			1		2
			1	1	1
		1	4	2	5
					1
			1		
		2	3	2	10
					1
					1
					3
			2	1	1
			1		1
					5
				1	3
				1	2
					3
		1	2	3	8
				1	3
					2
		2	2	2	2
			1		2
	1	9	11	6	11
		2	4	2	2
				1	1
		1	1		
			1		
	1	5	22	6	21

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Post herpetic neuralgia	2	2
Postictal paralysis		1
Postictal state		1
Postmenopausal haemorrhage	3	6
Post procedural complication		1
Post-traumatic stress disorder		2
Postural orthostatic tachycardia syndrome	1	4
Posture abnormal		1
Post viral fatigue syndrome	2	13
Pre-existing condition improved		1
Pregnancy		2
Prehypertension		1
Premature delivery		1
Premature menopause	1	2
Premature ovulation	1	1
Premenstrual dysphoric disorder	2	2
Premenstrual pain	2	2
Premenstrual syndrome	2	2
Pressure of speech		1
Presyncope	17	92
Preterm premature rupture of membranes		2
Primary cough headache		1
Procedural dizziness		2
Procedural nausea		1
Proctalgia		1
Product administered at inappropriate site	2	8
Product administration error	1	1
Productive cough	5	24
Product preparation error		2
Product residue present		1
Product taste abnormal		1
Product use issue	20	222

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
					1
					1
				3	6
					1
					2
		1	1		3
			1		
		1	2	1	11
			1		
			1		1
			1		
					1
		1	1		1
		1	1		
				2	2
		1	1	1	1
		2	2		
					1
	1	10	42	7	50
					2
					1
					2
					1
					1
		2	7		1
		1	1		
		2	6	3	18
			2		
					1
			1		
		17	201	3	21

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Prophylaxis of nausea and vomiting		1
Proteinuria		1
Pruritus	143	636
Psoriasis	2	13
Psoriatic arthropathy	2	5
Psychogenic seizure		1
Psychomotor hyperactivity	1	7
Psychotic disorder	1	4
Pulmonary embolism	9	25
Pulmonary infarction	1	1
Pulmonary oedema		1
Pulmonary pain	2	12
Pulmonary sarcoidosis		1
Pulmonary sepsis		1
Pulmonary thrombosis	1	2
Pulse abnormal		2
Puncture site swelling		1
Pupil fixed		1
Purple glove syndrome		1
Purpura	1	7
Pustule		2
Pyelonephritis		1
Pylorospasm		1
Pyrexia	394	2,566
Q fever	1	2
Quality of life decreased		1
Radial pulse abnormal		1
Radiculitis brachial	1	2
Radiculopathy		1
Rales		3
Rash	170	620
Rash erythematous	35	166

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
1	2	83	297	60	339
			3	2	10
				2	5
					1
		1	1		6
				1	4
				9	25
				1	1
					1
			2	2	10
					1
					1
				1	2
					2
			1		
					1
					1
			3	1	4
					2
					1
			1		
3	15	171	967	223	1599
				1	2
					1
					1
				1	2
					1
					3
	1	96	293	74	327
	1	17	75	18	91

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rash macular	22	88
Rash maculo-papular	2	12
Rash morbilliform	2	7
Rash papular	11	49
Rash pruritic	41	155
Rash pustular		2
Rash vesicular	3	15
Raynaud's phenomenon	3	12
Reaction to excipient	1	1
Reaction to preservatives		1
Reading disorder	1	1
Rectal haemorrhage	5	11
Rectal injury		1
Rectal spasm		1
Red blood cell sedimentation rate increased		2
Red ear syndrome	1	1
Reduced facial expression		1
Reflux gastritis	1	1
Relapsing fever		1
Renal colic		1
Renal function test abnormal	1	1
Renal impairment	3	8
Renal injury	1	1
Renal pain	10	44
Respiration abnormal	2	12
Respiratory arrest		5
Respiratory disorder		6
Respiratory distress		6
Respiratory rate	1	1
Respiratory rate decreased		1
Respiratory rate increased	6	17
Respiratory symptom	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		16	49	6	39
		1	3	1	9
		1	3	1	4
		7	22	4	27
		27	66	14	89
					2
		3	8		7
		2	5	1	7
				1	1
					1
				1	1
				5	11
					1
			1		
					2
		1	1		
					1
		1	1		
					1
			1		
				1	1
				3	8
				1	1
		4	13	6	31
		2	6		6
	1				5
			1		5
					6
		1	1		
					1
		1	4	5	13
				1	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory tract infection	1	2
Respiratory tract irritation	2	4
Respiratory tract oedema		1
Restless legs syndrome	1	18
Restlessness	5	44
Retching	2	13
Retinal aneurysm		1
Retinal detachment	1	1
Retinal fovea disorder		1
Retinal injury	1	1
Retinal migraine	1	6
Retinal vein occlusion	1	2
Retinitis pigmentosa		1
Rheumatoid arthritis	1	13
Rhinalgia		6
Rhinitis	2	9
Rhinitis allergic		1
Rhinorrhoea	26	101
Right ventricular dysfunction	1	1
Road traffic accident	1	1
Rosacea	1	2
Rotator cuff syndrome	1	3
Sacroiliitis		1
Salivary gland enlargement	1	2
Salivary gland pain	1	3
Salivary hypersecretion	2	9
Sarcoidosis	1	5
SARS-CoV-2 ant body test negative		3
SARS-CoV-2 ant body test positive		1
SARS-CoV-2 test false positive		1
SARS-CoV-2 test negative		2
SARS-CoV-2 test positive	4	20

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
		1	2	1	2
					1
		1	5		13
		2	11	3	33
			3	2	10
					1
				1	1
					1
				1	1
				1	6
				1	2
					1
	1			1	13
			3		3
		1	4	1	5
			1		
	2	10	38	16	63
				1	1
		1	1		
				1	2
				1	3
					1
				1	2
		1	2		1
		1	4	1	5
				1	5
			1		2
					1
			1		
			2		
			3	4	17

* I=Interval, C=Cumulative

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Scab	2	3
Scalloped tongue		1
Scar	2	6
Schizophrenia		1
Sciatica	3	9
Scintillating scotoma	1	2
Scleral discolouration		1
Scleritis		1
Scleroderma associated digital ulcer		1
Scratch		3
Screaming	1	1
Scrotal pain		1
Seasonal allergy	6	7
Seborrhoea	1	1
Secondary transmission		1
Secretion discharge		1
Sedation		4
Seizure	12	73
Seizure cluster		2
Seizure like phenomena		1
Self-injurious ideation		1
Sensation of foreign body	1	15
Sense of a foreshortened future		1
Sensitive skin	11	41
Sensory disturbance	6	17
Sensory loss	4	20
Sepsis	1	3
Septic shock		1
Serum ferritin decreased	1	1
Shock	1	3
Sinonasal obstruction		2
Sinus congestion	1	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2	1	1
					1
		1	1	1	5
					1
		1	3	2	6
				1	2
			1		
					1
					1
			2		1
				1	1
					1
		1	2	5	5
		1	1		
					1
					1
			1		3
				12	73
					2
					1
					1
		1	6		9
					1
		5	19	6	22
		2	8	4	9
			6	4	14
				1	3
					1
				1	1
				1	3
					2
		1	4		5

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sinus headache	7	51
Sinusitis	3	11
Sinus pain	2	24
Sinus tachycardia		11
Skin abrasion		3
Skin burning sensation	9	48
Skin depigmentation		1
Skin discharge		1
Skin discolouration	5	23
Skin disorder	1	7
Skin erosion	2	5
Skin exfoliation	3	18
Skin hyperpigmentation	1	1
Skin indentation	2	2
Skin induration		1
Skin infection	1	2
Skin irritation	1	11
Skin laceration		1
Skin laxity		1
Skin lesion	6	11
Skin mass	1	3
Skin odour abnormal	2	4
Skin reaction	5	16
Skin sensitisation		7
Skin swelling	2	12
Skin temperature	1	4
Skin tightness	2	15
Skin ulcer	1	2
Skin warm	7	45
Skin weeping		1
Sleep apnoea syndrome	1	2
Sleep deficit		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	24	2	27
		2	4	1	7
		1	9	1	15
			4		7
			1		2
		5	21	4	27
					1
					1
		2	9	3	14
			2	1	5
		2	3		2
		1	6	2	12
		1	1		
		2	2		
			1		
		1	2		
		1	5		6
					1
					1
		2	4	4	7
		1	2		1
			2	2	2
		3	8	2	8
			1		6
		1	9	1	3
		1	2		2
			8	2	7
				1	2
		4	18	3	27
					1
				1	2
			1		3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sleep disorder	14	82
Sleep disorder due to a general medical condition	1	5
Sleep disorder due to general medical condition, insomnia type		6
Sleep paralysis		2
Sleep terror	1	3
Slow response to stimuli		2
Slow speech		2
Sluggishness		4
Small intestinal haemorrhage	1	1
Sneezing	11	52
Snoring		1
Social avoidant behaviour	2	2
Soft tissue injury		1
Soft tissue swelling		1
Solar lentigo		1
Solid organ transplant rejection	1	1
Somatic symptom disorder		1
Somnolence	41	202
Speech disorder	7	10
Spina bifida	1	1
Spinal disorder		2
Spinal fracture	1	1
Spinal pain	2	15
Spleen atrophy		1
Splenomegaly		2
Spondylitis	1	1
Sputum abnormal		1
Sputum discoloured		2
Sputum purulent		1
Staphylococcal abscess		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	29	9	53
			3	1	2
			1		5
			1		1
			1	1	2
					2
					2
					4
				1	1
		4	19	7	33
					1
		1	1	1	1
					1
			1		
					1
				1	1
					1
		20	84	21	118
		4	5	3	5
				1	1
			1		1
				1	1
		1	6	1	9
					1
					2
				1	1
					1
			1		1
					1
			1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Staphylococcal infection		2
Staring		1
Status epilepticus	3	13
Steatorrhoea	1	2
Stiff leg syndrome		1
Stiff tongue	1	2
Stomatitis	2	10
Strabismus	1	2
Stress	4	12
Stridor		4
Subarachnoid haemorrhage		1
Subclavian vein thrombosis		2
Subcutaneous abscess		2
Subcutaneous haematoma		1
Subdural haematoma		1
Sudden death	1	1
Sudden hearing loss	2	4
Sudden visual loss		1
Suicidal ideation	3	13
Sunburn		1
Superficial injury of eye		1
Superficial vein prominence		1
Suppressed lactation		2
Supraventricular tachycardia	1	10
Suspected COVID-19	14	159
Sweating fever	1	19
Swelling	117	452
Swelling face	36	178
Swelling of eyelid	8	28
Swollen joint count increased		1
Swollen tongue	19	101
Symphysiolysis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
				3	13
			1	1	1
					1
		1	1		1
		1	7	1	3
		1	1		1
			1	4	11
			1		3
					1
					2
			1		1
			1		
					1
				1	1
				2	4
					1
				3	13
			1		
					1
			1		
					2
			3	1	7
		6	60	8	99
				1	19
		42	176	75	276
		15	53	21	125
		2	7	6	21
					1
		9	32	10	69
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Symptom recurrence	1	2
Syncope	45	213
Synovial cyst	1	3
Syphilis	1	1
Syringe issue	1	1
Systemic candida		1
Systemic immune activation		1
Systemic inflammatory response syndrome		1
Systemic lupus erythematosus	1	5
Systemic lupus erythematosus rash	1	3
Tachycardia	19	190
Tachyphrenia		1
Tachypnoea		7
Taste disorder	6	41
Tearfulness	1	11
Teething		1
Telangiectasia		1
Temperature difference of extremities		2
Temperature intolerance		4
Temperature regulation disorder	2	4
Temporomandibular joint syndrome	1	2
Tenderness	24	73
Tendon disorder	1	1
Tendon injury		1
Tendonitis	1	7
Tendon pain	1	2
Tension	1	3
Tension headache	18	68
Terminal insomnia	1	4
Testicular pain	3	4
Testicular swelling	1	1
Testicular torsion		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		1
		1	1	44	212
		1	1		2
				1	1
		1	1		
					1
					1
					1
				1	5
			1	1	2
		9	60	10	130
					1
			2		5
		3	27	3	14
		1	5		6
					1
					1
					2
			1		3
				2	4
			1	1	1
1	2	16	39	8	34
				1	1
					1
		1	2		5
		1	2		
			1	1	2
		6	22	12	46
			1	1	3
				3	4
				1	1
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Therapeutic product effect delayed		1
Therapeutic response unexpected		5
Thermal burn	2	2
Thermal burns of eye	1	4
Thinking abnormal	2	9
Thirst	12	66
Throat clearing		1
Throat irritation	11	61
Throat tightness	11	93
Thrombocytopenia	7	21
Thrombophlebitis	2	4
Thrombophlebitis superficial		2
Thrombosis	15	37
Thrombotic microangiopathy		1
Thrombotic thrombocytopenic purpura		3
Thunderclap headache	1	1
Thyroid disorder		1
Thyroid function test abnormal		1
Thyroiditis	2	2
Tic		1
Tinnitus	63	178
Tongue biting		1
Tongue blistering		1
Tongue coated		2
Tongue cyst		1
Tongue discolouration	1	6
Tongue discomfort	1	11
Tongue disorder	3	11
Tongue dry	1	3
Tongue eruption		3
Tongue erythema		1
Tongue exfoliation	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		4
		1	1	1	1
				1	4
			3	2	6
		4	21	8	45
					1
		3	23	8	38
		6	30	5	63
				7	21
			1	2	3
			1		1
	1			15	37
					1
					3
				1	1
					1
			1		
				2	2
					1
		16	45	47	133
					1
			1		
			2		
					1
			1	1	5
			4	1	7
		1	3	2	8
			2	1	1
			2		1
			1		
				1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tongue injury		1
Tongue movement disturbance		2
Tongue oedema		7
Tongue paralysis		1
Tongue pruritus	1	5
Tongue rough		1
Tongue spasm	1	2
Tongue ulceration	2	6
Tonic convulsion		5
Tonsillar disorder	1	1
Tonsillar erythema		1
Tonsillar haemorrhage		1
Tonsillar hypertrophy	1	8
Tonsillar inflammation		1
Tonsillar ulcer		1
Tonsillitis	2	11
Tonsillitis bacterial	1	4
Toothache	7	15
Torticollis		1
Toxicity to various agents		1
Trance	1	1
Transaminases increased	1	1
Transient ischaemic attack	3	9
Traumatic haematoma	1	1
Tremor	43	253
Trichodynia		1
Trichoglossia	1	1
Trigeminal neuralgia	2	10
Trigger finger		1
Triple negative breast cancer	1	1
Trismus		7
Troponin increased	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					2
			2		5
					1
			1	1	4
			1		
		1	1		1
		2	4		2
					5
		1	1		
					1
					1
		1	3		5
			1		
					1
	1		2	2	9
				1	4
			4	7	11
					1
					1
		1	1		
				1	1
				3	9
				1	1
		13	79	30	174
					1
				1	1
		1	1	1	9
					1
				1	1
			1		6
				1	4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tumefactive multiple sclerosis		1
Tunnel vision		2
Type 1 diabetes mellitus		3
Type 2 diabetes mellitus		1
Type III immune complex mediated reaction		1
Type IV hypersensitivity reaction		2
Typical aura without headache	1	2
Ulcer		1
Ulcerative keratitis		2
Ulnar nerve injury		1
Umbilical cord abnormality	1	1
Underdose	1	3
Undersensing	1	1
Unresponsive to stimuli		5
Upper respiratory tract congestion		1
Upper respiratory tract infection		2
Urinary incontinence	4	10
Urinary retention	2	8
Urinary tract disorder	1	1
Urinary tract infection	5	22
Urine abnormality	1	2
Urine analysis abnormal		1
Urine flow decreased		1
Urine ketone body present		1
Urine output		1
Urine output decreased	1	1
Urine output increased		1
Urticaria	45	245
Urticaria chronic		1
Urticaria thermal		1
Uterine haemorrhage	2	3
Uterine leiomyoma	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					2
					3
					1
					1
					2
		1	1		1
					1
					2
					1
				1	1
		1	3		
		1	1		
					5
					1
			1		1
		3	5	1	5
				2	8
		1	1		
		3	5	2	17
		1	1		1
					1
					1
					1
			1		
		1	1		
					1
		25	106	20	139
					1
			1		
				2	3
				2	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Uterine pain	1	1
Uterine prolapse	1	1
Uveitis	1	3
Uvulitis		1
Vaccination complication	4	15
Vaccination error	1	1
Vaccination failure		2
Vaccination site abscess		3
Vaccination site bruising	12	56
Vaccination site cellulitis	2	15
Vaccination site discolouration	4	9
Vaccination site discomfort	5	28
Vaccination site dryness		1
Vaccination site eczema		1
Vaccination site erythema	54	282
Vaccination site haemorrhage	2	11
Vaccination site hyperaesthesia		3
Vaccination site hypersensitivity		1
Vaccination site hypoaesthesia		13
Vaccination site induration	8	40
Vaccination site infection	1	10
Vaccination site inflammation	6	22
Vaccination site irritation	1	4
Vaccination site joint discomfort		1
Vaccination site joint erythema		1
Vaccination site joint movement impairment	1	7
Vaccination site joint pain	3	8
Vaccination site joint swelling		1
Vaccination site lymphadenopathy		14
Vaccination site macule		1
Vaccination site mass	37	131
Vaccination site movement impairment	11	45

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
				1	3
			1		
		1	4	3	11
		1	1		
					2
			1		2
		5	23	7	33
		2	4		11
		1	3	3	6
		2	12	3	16
					1
			1		
		33	162	21	120
		1	3	1	8
			1		2
			1		
			5		8
		4	22	4	18
		1	4		6
		4	13	2	9
		1	3		1
			1		
					1
			3	1	4
		3	5		3
			1		
			3		11
			1		
		15	61	22	70
		3	17	8	28

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site necrosis		1
Vaccination site oedema	2	4
Vaccination site pain	213	1,410
Vaccination site paraesthesia	1	13
Vaccination site pruritus	29	122
Vaccination site rash	11	59
Vaccination site reaction	6	31
Vaccination site scar		2
Vaccination site swelling	54	342
Vaccination site urticaria	2	6
Vaccination site vesicles		5
Vaccination site warmth	38	170
Vaginal discharge	2	4
Vaginal disorder		1
Vaginal haemorrhage	24	49
Vaginal ulceration		1
Varicella		2
Varicose vein		1
Vascular headache	2	3
Vascular pain	1	3
Vasculitic rash		1
Vasculitis	1	3
Vein discolouration		1
Vein disorder	1	3
Vein rupture		1
Venous injury		3
Venous thrombosis		1
Ventricular arrhythmia		2
Ventricular extrasystoles		9
Ventricular fibrillation		1
Ventricular tachycardia		1
Vertebral lesion		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	2	1	2
	2	125	689	88	721
			8	1	5
		19	77	10	45
		5	31	6	28
		2	15	4	16
			1		1
		27	157	27	185
		1	4	1	2
			1		4
		22	88	16	82
		1	2	1	2
			1		
		7	13	17	36
					1
					2
					1
				2	3
				1	3
					1
		1	2		1
			1		
				1	3
					1
					3
					1
					2
			1		8
					1
					1
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vertigo	38	148
Vertigo labyrinthine	1	1
Vertigo positional	3	10
Vestibular disorder		2
Vestibular migraine		2
Vestibulitis	1	1
Viral infection	6	11
Viral labyrinthitis		2
Viral pericarditis		1
Viral pharyngitis	1	3
Viral rash	4	11
Viral test		1
Vision blurred	40	165
Visual acuity reduced	1	3
Visual field defect	2	6
Visual impairment	13	55
Vital capacity		1
Vitamin B12 decreased		1
Vitamin D		1
Vitreous detachment	1	2
Vitreous floaters	4	8
Vocal cord disorder		1
Vomiting	89	541
Vomiting projectile	3	10
Vth nerve injury		1
Vulval haemorrhage		2
Vulval oedema		1
Vulval ulceration		1
Vulvovaginal burning sensation		1
Vulvovaginal candidiasis		4
Vulvovaginal pain		3
Vulvovaginal swelling		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		8	27	30	121
		1	1		
				3	10
			1		1
					2
				1	1
			2	6	9
			1		1
					1
				1	3
		1	5	3	6
					1
		10	49	30	116
				1	3
		1	3	1	3
		2	13	11	42
					1
					1
					1
				1	2
		1	4	3	4
					1
	1	37	170	52	371
			2	3	8
					1
					2
			1		
			1		
					1
			2		2
			1		2
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vulvovaginal ulceration		2						2
Weight bearing difficulty	2	4					2	4
Weight decreased	2	12				1	2	11
Weight increased		1						1
Wheat-free diet		1						1
Wheezing	16	94			5	28	11	66
White blood cell count decreased		1						1
White blood cell count increased	1	5				3	1	2
Withdrawal syndrome	2	3				1	2	2
Wound	1	2			1	2		
Wound complication	1	1			1	1		
Wrong product administered	3	5			3	5		
Wrong technique in product usage process	1	1			1	1		
Yawning	1	8			1	2		6
Yellow skin		1				1		
	8	11			8	11		
	13,061	61,883	45	241	5639	22789	7422	39094

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	14	75		2	6	19	8	56
Abdominal distension	8	36			2	9	6	27
Abdominal infection		1						1
Abdominal lymphadenopathy		1						1
Abdominal migraine		1						1
Abdominal pain	24	132		1	9	41	15	91
Abdominal pain lower		11				1		10
Abdominal pain upper	43	201		1	17	54	26	147
Abdominal rigidity	1	1			1	1		
Abdominal tenderness		2				2		
Abnormal behaviour		1						1
Abnormal dreams	5	18			3	8	2	10
Abnormal faeces		1						1
Abnormal loss of weight	1	2					1	2
Abnormal sensation in eye		1						1
Abscess		4				2		2
Abscess oral		1						1
Accidental exposure to product	1	1			1	1		
Acne	2	5			1	1	1	4
Acne pustular		1						1
Activated partial thromboplastin time prolonged		2						2
Activated partial thromboplastin time shortened		1						1
Acute abdomen		1						1
Acute cardiac event		1						1
Acute coronary syndrome	1	3					1	3
Acute kidney injury	1	7					1	7
Acute leukaemia		1						1
Acute motor axonal neuropathy		1						1
Acute myocardial infarction		2						2
Acute vestibular syndrome		1				1		
Addison's disease		1						1
Adrenocortical insufficiency acute		3						3

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Adverse drug reaction	1	7
Affect lability		1
Ageusia	8	45
Agitated depression		1
Agitation		5
Airway burns		1
Alanine aminotransferase increased	1	5
Alcohol poisoning		1
Allergic cough		1
Allergic oedema	1	6
Allergy to arthropod bite		1
Allergy to arthropod sting		1
Allergy to chemicals	1	1
Allergy to vaccine		13
Allodynia		2
Alopecia	4	12
Altered state of consciousness	2	5
Amblyopia		1
Amenorrhoea	1	2
Amnesia	4	9
Anaemia	2	7
Anaesthesia oral	1	1
Anal fissure		1
Analgesic drug level		1
Anal pruritus		2
Anaphylactic reaction	7	65
Anaphylactic shock	2	7
Anaphylactoid reaction		3
Anaphylactoid shock	1	1
Anaphylaxis prophylaxis		1
Androgenetic alopecia		1
Angina pectoris	1	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		4
					1
		2	16	6	29
					1
			1		4
					1
		1	2		3
					1
					1
			1	1	5
			1		
					1
				1	1
			8		5
					2
				4	12
				2	5
			1		
				1	2
			1	4	8
			1	2	6
		1	1		
					1
					1
			1		1
				7	65
				2	7
					3
				1	1
					1
					1
				1	7

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Angina unstable		1
Angioedema	2	30
Anisocytosis		1
Ankle fracture		1
Ankylosing spondylitis		1
Anorectal discomfort		1
Anorgasmia	1	1
Anosmia	1	23
Antinuclear ant body increased	1	1
Antiphospholipid syndrome		1
Anxiety	7	49
Aortic embolus		1
Aortic stenosis		1
Aortic thrombosis	1	1
Apathy	1	4
Aphasia	4	9
Aphonia	4	10
Aphthous ulcer	1	4
Aplasia pure red cell	1	1
Apnoea		1
Apnoeic attack	1	1
Apparent death		1
Appendicitis		2
Appendicitis perforated		1
Appetite disorder		2
Arrhythmia	2	6
Arrhythmia supraventricular	1	3
Arterial disorder		1
Arterial thrombosis	1	1
Arteritis	1	2
Arthralgia	237	1,128
Arthritis	7	23

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				2	30
					1
					1
					1
					1
		1	1		
			8	1	15
		1	1		
					1
		2	15	5	34
					1
					1
				1	1
			3	1	1
		1	2	3	7
		2	2	2	8
		1	2		2
				1	1
					1
				1	1
					1
					2
					1
					2
				2	6
			1	1	2
					1
		1	1		
				1	2
1	8	90	330	147	798
		1	5	6	18

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arthritis reactive	3	4
Arthropathy	6	9
Ascites		1
Aspiration		1
Asthenia	54	262
Asthenopia	9	22
Asthma	8	36
Asymptomatic COVID-19	1	1
Ataxia		1
Atonic seizures		1
Atopy		1
Atrial fibrillation	4	28
Atrial flutter	1	2
Atrioventricular block	1	1
Atypical femur fracture		1
Auditory disorder	1	2
Aura		2
Auricular swelling		1
Autoimmune disorder	1	6
Autoimmune haemolytic anaemia	1	2
Autoimmune hepatitis	1	1
Autonomic nervous system imbalance		1
Autoscopy		1
Axillary mass	12	30
Axillary pain	50	181
Back disorder	1	1
Back pain	51	265
Bacterial diarrhoea		1
Bacterial infection	2	2
Balance disorder	12	53
Basal cell carcinoma		2
Bedridden	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	4
		2	3	4	6
					1
					1
1	2	15	71	39	191
		4	9	5	13
		1	8	7	28
				1	1
					1
					1
					1
				4	28
				1	2
				1	1
					1
				1	2
					2
					1
				1	6
				1	2
				1	1
					1
					1
		6	10	6	20
		13	52	37	129
		1	1		
	1	22	74	29	191
					1
				2	2
		2	8	10	45
					2
		2	2		2

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bell's palsy	16	68
Bipolar disorder	1	1
Bladder discomfort		1
Bladder disorder	1	2
Bladder irritation		1
Bladder pain		1
Blepharitis		1
Blepharospasm	1	5
Blindness		5
Blindness transient		3
Blister	15	42
Blood albumin decreased		1
Blood alcohol decreased	1	1
Blood alkaline phosphatase increased		2
Blood blister	1	5
Blood calcium decreased	1	1
Blood count abnormal		2
Blood creatine phosphokinase increased		1
Blood creatinine increased		1
Blood folate decreased	1	1
Blood glucose abnormal		3
Blood glucose decreased		6
Blood glucose fluctuation		6
Blood glucose increased	3	22
Blood iron decreased		1
Blood pH		1
Blood pH increased	1	2
Blood potassium decreased		1
Blood potassium increased	1	1
Blood pressure abnormal	1	1
Blood pressure decreased	3	19
Blood pressure diastolic decreased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				16	68
				1	1
			1		
		1	1		1
					1
					1
			1	1	4
					5
					3
		7	15	8	27
					1
				1	1
			1		1
			1	1	4
				1	1
					2
					1
			1		
				1	1
			2		1
			2		4
			2		4
			4	3	18
			1		
					1
			1	1	1
			1		
				1	1
		1	1		
		2	6	1	13
			1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood pressure fluctuation	2	4
Blood pressure increased	10	57
Blood pressure normal	1	1
Blood pressure systolic decreased		2
Blood pressure systolic increased		2
Blood sodium decreased		1
Blood test abnormal		2
Blood urine present		2
Blue toe syndrome		2
Body temperature	5	10
Body temperature abnormal	5	23
Body temperature decreased	2	10
Body temperature fluctuation	3	14
Body temperature increased	12	94
Bone disorder	1	1
Bone neoplasm		1
Bone pain	18	58
Bone swelling		2
Bowel movement irregularity		2
Brachial plexus injury		1
Bradycardia	1	4
Bradykinesia		1
Bradyphrenia	2	7
Brain injury		1
Brain neoplasm		1
Brain stem syndrome		1
Breast cancer	1	2
Breast cyst		1
Breast discomfort	1	3
Breast inflammation	1	1
Breast mass	2	5
Breast pain	10	39

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	2	3
		1	15	9	42
				1	1
					2
			1		1
					1
					2
					2
			2		
		2	4	3	6
		2	7	3	16
		1	2	1	8
		1	3	2	11
	2	4	42	8	52
		1	1		
					1
		6	15	12	43
			1		1
			1		1
				1	4
			1		
		2	3		4
					1
					1
					1
				1	2
			1		
		1	2		1
		1	1		
		1	1	1	4
		3	8	7	31

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Breast swelling	4	12
Breast tenderness	2	6
Breath sounds abnormal		2
Bronchial disorder		1
Bronchial secretion retention		1
Bronchiectasis	3	5
Bronchitis		3
Bronchopulmonary aspergillosis		1
Bronchospasm	1	2
Bruxism		1
Bulbar palsy		1
Burning feet syndrome		1
Burning sensation	25	69
Burn oesophageal		1
Burns second degree		2
Bursitis	4	6
Candida infection		2
Capsular contracture associated with breast implant	1	1
Cardiac arrest		8
Cardiac discomfort		1
Cardiac disorder	5	6
Cardiac failure		2
Cardiac failure acute		1
Cardiac flutter	4	19
Carotid artery dissection		1
Carpal tunnel syndrome	1	1
Cartilage injury	1	1
Cataplexy		1
Cataract	2	3
Catarrh	1	2
Cellulitis		21

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			5	4	7
			1	2	5
			1		1
			1		
				3	5
					3
					1
		1	2		
					1
					1
					1
		12	25	13	44
					1
			1		1
		1	1	3	5
			1		1
				1	1
					8
					1
		2	2	3	4
					2
					1
				4	19
					1
				1	1
				1	1
					1
				2	3
		1	2		
					21

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Central nervous system lesion		1
Cerebellar haemorrhage	1	1
Cerebellar infarction		1
Cerebral artery thrombosis		1
Cerebral haemorrhage	1	6
Cerebral infarction	1	7
Cerebral thrombosis		2
Cerebral venous sinus thrombosis	1	3
Cerebrospinal fluid leakage		1
Cerebrovascular accident	16	39
Cervical radiculopathy		1
Change of bowel habit	1	2
Chapped lips		4
Cheilitis	1	2
Chest crushing	1	3
Chest discomfort	28	128
Chest injury		1
Chest pain	60	216
Chillblains		4
Chills	178	1,171
Choking	3	7
Cholestasis	1	1
Chorea		1
Choroidal neovascularisation		2
Chromaturia	2	8
Chronic fatigue syndrome	3	11
Chronic kidney disease		1
Chronic lymphocytic leukaemia	1	2
Chronic lymphocytic leukaemia recurrent	1	1
Chronic obstructive pulmonary disease		5
Circulatory collapse	1	12
Clostridium difficile colitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
					1
					1
				1	6
				1	7
					2
				1	3
					1
				16	39
					1
		1	1		1
			2		2
				1	2
				1	3
		9	35	19	93
					1
		16	45	44	171
			3		1
1	4	99	413	79	758
				3	7
				1	1
					1
					2
		1	5	1	3
		1	2	2	9
					1
				1	2
				1	1
					5
				1	12
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Clumsiness	1	2
Cluster headache	6	19
Coagulopathy		1
Coccydynia		2
Coeliac disease	1	2
Cognitive disorder		7
Cold-stimulus headache		3
Cold sweat	9	70
Colitis	1	7
Colitis ischaemic		1
Colitis microscopic		1
Colitis ulcerative	2	5
Colon cancer		1
Coma		1
Communication disorder		1
Condition aggravated	19	68
Confusional state	11	65
Conjunctival haemorrhage		6
Conjunctivitis		8
Conjunctivitis viral		1
Constipation	2	15
Contusion	22	70
Coordination abnormal		11
Corneal disorder		1
Corneal reflex decreased		1
Coronary artery disease		2
Coronary artery thrombosis		1
Coronavirus infection		2
Costochondritis		5
Cough	33	224
Cough variant asthma	1	1
COVID-19	17	94

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		1
		1	4	5	15
					1
			2		
				1	2
			1		6
					3
		1	14	8	56
		1	1		6
					1
					1
				2	5
					1
					1
					1
		3	11	16	57
		4	9	7	56
					6
			3		5
			1		
		1	2	1	13
		2	20	20	50
			1		10
			1		1
					2
					1
			1		1
					5
	2	13	74	20	150
				1	1
		3	25	14	69

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
COVID-19 immunisation		2
COVID-19 pneumonia		4
Cranial nerve disorder		1
C-reactive protein increased	1	9
Crohn's disease	1	7
Crying	1	5
Cutaneous sarcoidosis		1
Cutaneous vasculitis	2	2
Cyanopsia		1
Cyanosis	1	7
Cyanosis central		1
Cyclic vomiting syndrome		1
Cyst	1	1
Cystitis	2	6
Cystitis interstitial		1
Dark circles under eyes	1	1
Deafness	4	25
Deafness bilateral	1	1
Deafness neurosensory	1	5
Deafness transitory		1
Deafness unilateral	2	5
Death	2	6
Decreased activity		1
Decreased appetite	31	192
Decreased immune responsiveness		2
Decreased interest		3
Decubitus ulcer		1
Deep vein thrombosis	8	33
Defaecation urgency		3
Dehydration	1	13
Deja vu		1
Delirium		6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					4
					1
			1	1	8
				1	7
			1	1	4
					1
				2	2
					1
				1	7
					1
					1
				1	1
		1	1	1	5
					1
				1	1
				4	25
				1	1
				1	5
					1
				2	5
				2	6
			1		
		15	63	16	129
					2
			1		2
					1
	1			8	33
					3
			3	1	10
					1
					6

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dementia		1
Dental discomfort		1
Depersonalisation/derealisation disorder		1
Depressed level of consciousness	2	6
Depressed mood	14	39
Depression	7	24
Derealisation		1
Dermatitis	2	7
Dermatitis allergic	1	16
Dermatitis atopic		2
Dermatitis bullous		1
Dermatitis contact		1
Dermatitis infected		1
Dermatomyositis	1	2
Device pacing issue		1
Device stimulation issue		1
Diabetes mellitus	4	13
Diabetes mellitus inadequate control		1
Diabetic coma		1
Diabetic ketoacidosis		1
Diabetic ketosis	1	1
Diaphragmalgia	2	2
Diarrhoea	74	483
Diarrhoea haemorrhagic		4
Diplegia		1
Diplopia	7	23
Discoloured vomit		2
Discomfort	16	47
Disease progression		1
Disease recurrence	25	82
Disorientation	9	33
Dissociation		5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
				2	6
		4	6	10	33
		1	1	6	23
					1
		1	3	1	4
		1	6		10
					2
					1
					1
				1	2
					1
			1		
				4	13
					1
					1
					1
				1	1
		1	1	1	1
	2	36	140	38	343
					4
					1
			3	7	20
			1		1
		10	21	6	26
					1
	1	4	8	21	74
		2	4	7	29
			1		4

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dissociative amnesia		1
Disturbance in attention	19	71
Dizziness	163	784
Dizziness exertional		7
Dizziness postural	12	90
Dreamy state		1
Droling		3
Drug eruption		1
Drug hypersensitivity		5
Drug-induced liver injury		1
Drug ineffective	16	86
Drug interaction	2	3
Drug withdrawal syndrome	1	1
Dry eye	4	13
Dry lung syndrome	1	1
Dry mouth	12	50
Dry skin	5	14
Dry throat	6	22
Duodenal ulcer haemorrhage		1
Duodenal ulcer perforation		1
Dysarthria	3	12
Dyschezia		2
Dysgeusia	35	129
Dyshidrotic eczema		2
Dyskinesia	3	12
Dysmenorrhoea	1	1
Dyspepsia	5	26
Dysphagia	8	32
Dysphemia	2	3
Dysphonia	2	21
Dyspnoea	84	362
Dyspnoea at rest	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		3	12	16	59
	6	65	234	98	550
					7
		3	17	9	73
			1		
			1		2
					1
					5
					1
				16	86
				2	3
		1	1		
		2	4	2	9
				1	1
		6	16	6	34
		1	2	4	12
		2	8	4	14
					1
					1
			2	3	10
			2		
		26	78	9	51
					2
		1	2	2	10
		1	1		
		1	8	4	18
		3	9	5	23
		1	2	1	1
			5	2	16
		17	62	67	300
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dyspnoea exertional	4	12
Dysstasia		14
Dystonia		2
Dysuria		5
Ear congestion		1
Ear discomfort	4	10
Ear haemorrhage		1
Ear infection	1	8
Ear pain	21	87
Ear pruritus		2
Ear swelling	1	6
Eating disorder	1	6
Eating disorder symptom		1
Eczema	2	12
Eczema asteatotic	1	1
Eczema herpeticum		2
Ehlers-Danlos syndrome		1
Electric shock		2
Electrocardiogram abnormal		1
Electrocardiogram change		1
Embolism	8	21
Embolism venous	1	1
Emotional disorder		2
Emotional distress	1	6
Emphysema	1	1
Encephalitis		3
Encephalitis viral	1	1
Endocarditis	1	1
Endometriosis	1	1
Enlarged uvula	1	4
Enteritis		3
Enthesopathy		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	4	10
			5		9
					2
			1		4
					1
		3	5	1	5
					1
			1	1	7
		9	30	12	57
					2
		1	2		4
				1	6
					1
			3	2	9
				1	1
					2
					1
					2
			1		
			1		
				8	21
				1	1
			1		1
			1	1	5
		1	1		
					3
				1	1
				1	1
				1	1
		1	2		2
					3
					1

* I=Interval, C=Cumulative

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Enuresis		2
Eosinophil count increased		1
Eosinophilia	1	2
Epicondylitis	1	2
Epigastric discomfort		2
Epiglottitis		1
Epilepsy	7	24
Epileptic aura		1
Epiphyses premature fusion		1
Episcleritis		1
Epistaxis	16	62
Erectile dysfunction		3
Erection increased		1
Eruclation		8
Erythema	54	186
Erythema induratum	1	1
Erythema multiforme		4
Erythema nodosum	2	4
Essential hypertension		1
Essential thrombocythaemia		1
Euphoric mood	3	6
Eustachian tube dysfunction		1
Evans syndrome		1
Excessive cerumen production		1
Exercise tolerance decreased		2
Exophthalmos		1
Exploding head syndrome		1
Exposure during pregnancy	1	7
Exposure to SARS-CoV-2		1
Exposure via skin contact	1	1
Extensive swelling of vaccinated limb		1
External ear inflammation	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
			1	1	1
		1	1		1
					2
					1
				7	24
					1
			1		1
		8	27	8	35
					3
					1
			2		6
		27	78	27	108
				1	1
				2	4
					1
					1
		1	3	2	3
					1
					1
			1		1
		1	1		
			1		
		1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
External ear pain		1
Extraocular muscle disorder		1
Extrasystoles	9	11
Eye colour change		1
Eye contusion	1	1
Eye discharge	1	4
Eye disorder	3	8
Eye haematoma		1
Eye haemorrhage	3	9
Eye infection	1	2
Eye inflammation	2	7
Eye injury	3	4
Eye irritation	4	15
Eyelid bleeding		1
Eyelid cyst		1
Eyelid disorder		1
Eyelid function disorder		2
Eyelid pain		1
Eyelid ptosis	1	5
Eyelids pruritus		2
Eye movement disorder		5
Eye pain	37	123
Eye pruritus	8	24
Eye swelling	13	58
Eye symptom	1	1
Face injury		1
Face oedema		1
Facial asymmetry		1
Facial discomfort	1	3
Facial nerve disorder		1
Facial neuralgia	1	3
Facial pain	7	34

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
		1	1	8	10
					1
				1	1
		1	2		2
			2	3	6
					1
				3	9
		1	1		1
			2	2	5
				3	4
		1	3	3	12
					1
					1
			1		
			1		1
					1
			4	1	1
			1		1
					5
		10	29	27	94
		6	12	2	12
		3	20	10	38
		1	1		
					1
					1
			1		
			1	1	2
			1		
				1	3
		2	9	5	25

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Facial paralysis	7	46
Facial paresis	2	10
Facial spasm	1	3
Faecal calprotectin		1
Faecal calprotectin increased	1	2
Faeces discoloured		4
Faeces hard		1
Faeces pale	1	2
Faeces soft	2	3
Fall	5	23
Fatigue	457	2,317
Fear	2	5
Febrile convulsion	1	2
Febrile infection	1	1
Feeding disorder	5	23
Feeling abnormal	38	232
Feeling cold	33	219
Feeling drunk		9
Feeling hot	44	181
Feeling jittery		2
Feeling of body temperature change	11	66
Feeling of despair		2
Feeling of relaxation	1	1
Femoral neck fracture	1	1
Fibrin D dimer increased	2	4
Fibromyalgia	5	13
Fine motor skill dysfunction	1	4
Finger deformity	1	1
Fingerprint loss	1	1
Fixed eruption		1
Flank pain	2	4
Flat affect		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				7	46
		1	6	1	4
			2	1	1
					1
				1	2
			2		2
					1
		1	2		
				2	3
		2	4	3	19
3	20	180	709	277	1608
				2	5
			1	1	1
				1	1
		4	11	1	12
	1	13	71	25	161
	1	10	79	23	140
			1		8
		21	81	23	100
					2
		3	16	8	50
					2
				1	1
				1	1
			1	2	3
		2	3	3	10
		1	1		3
				1	1
		1	1		
			1		
			1	2	3
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Flatulence	3	20
Fluid retention		1
Flushing	11	56
Foaming at mouth		1
Follicular lymphoma	1	1
Folliculitis		1
Food allergy		1
Food aversion		1
Food craving	1	2
Food intolerance		1
Food refusal		1
Forced expiratory volume increased		2
Foreign body sensation in eyes		7
Formication	1	3
Freezing phenomenon		1
Frequent bowel movements	2	7
Full blood count abnormal		1
Fungal infection		1
Furuncle	1	5
Gait disturbance	16	63
Gait inability	3	21
Galactorrhoea		2
Gallbladder disorder		1
Gamma-glutamyltransferase increased		1
Gastric antral vascular ectasia		1
Gastric disorder		4
Gastric varices haemorrhage		1
Gastritis	3	7
Gastroenteritis	1	3
Gastroenteritis viral		1
Gastrointestinal disorder		2
Gastrointestinal haemorrhage		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	6	1	14
					1
		3	29	8	27
					1
				1	1
					1
					1
					1
				1	2
					1
					1
					2
			2		5
			1	1	2
					1
		1	1	1	6
					1
					1
		1	2		3
		6	20	10	43
			1	3	20
					2
					1
					1
					1
			2		2
					1
		1	3	2	4
				1	3
					1
					2
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastrointestinal pain	2	14
Gastrointestinal sounds abnormal	1	4
Gastroesophageal reflux disease	5	14
Gastroschisis		1
Generalised oedema		1
Generalised tonic-clonic seizure	1	10
General physical health deterioration		1
Genital herpes	2	3
Genital herpes simplex	1	1
Genital lesion	1	2
Giant cell arteritis		1
Gingival bleeding		3
Gingival discomfort		1
Gingival disorder		2
Gingival pain	1	13
Gingival swelling	1	5
Gingivitis	1	1
Glaucoma	1	3
Glomerular filtration rate decreased	1	1
Glossitis	1	3
Glossodynia	4	25
Goitre		1
Gout	4	9
Grip strength decreased	3	11
Groin pain	5	14
Guillain-Barre syndrome	1	11
Haemangioma		1
Haemarthrosis		2
Haematemesis		1
Haematochezia		8
Haematoma		2
Haematospermia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4	1	10
		1	1		3
				5	14
					1
					1
				1	10
					1
				2	3
		1	1		
		1	2		
					1
					3
					1
			1		1
			3	1	10
			1	1	4
		1	1		
				1	3
				1	1
			1	1	2
		1	6	3	19
					1
		1	1	3	8
		1	2	2	9
		4	9	1	5
				1	11
			1		
					2
					1
			1		7
			1		1
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haematuria	1	6
Haemodynamic instability		1
Haemoglobin decreased	1	2
Haemoglobin increased		1
Haemoperitoneum		1
Haemoptysis	1	5
Haemorrhage	11	27
Haemorrhage urinary tract		1
Haemorrhagic diathesis		1
Haemorrhagic stroke		1
Haemorrhoids		3
Hair texture abnormal	1	1
Hallucination	5	23
Hallucination, olfactory		1
Hallucinations, mixed		1
Hallucination, visual	2	4
Hangover	5	14
Headache	493	2,761
Head banging		1
Head discomfort	5	37
Head injury	1	7
Heart injury	1	2
Heart rate	1	2
Heart rate abnormal	1	6
Heart rate decreased	3	9
Heart rate increased	21	111
Heart rate irregular	4	10
Heart sounds abnormal		1
Heat illness	1	2
Heavy menstrual bleeding	16	20
Hemianopia		1
Hemiparesis	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	6
					1
			1	1	1
					1
			1	1	4
				11	27
					1
					1
					1
					3
				1	1
				5	23
					1
					1
				2	4
		3	6	2	8
2	12	247	935	246	1826
			1		
		2	9	3	28
		1	3		4
				1	2
		1	1		1
	1			1	6
		2	3	1	6
		6	33	15	78
		1	1	3	9
					1
				1	2
		9	10	7	10
					1
				1	2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hemiplegia		5
Hemiplegic migraine		1
Hepatic cirrhosis		1
Hepatic enzyme increased		3
Hepatic failure		1
Hepatic function abnormal		1
Hepatic lesion		1
Hepatic pain		2
Hepatitis		3
Hepatitis viral		1
Herpes simplex	1	4
Herpes virus infection	2	4
Herpes zoster	118	201
Herpes zoster oticus	2	4
Herpes zoster reactivation	2	3
Hiatus hernia	1	1
Hip fracture		1
Homicidal ideation	1	1
Hordeolum		3
Horner's syndrome		1
Hot flush	19	78
Hunger		1
Hyperacusis	2	5
Hyperaesthesia	1	11
Hyperaesthesia teeth	1	3
Hyperchlorhydria		1
Hyperglycaemia	1	7
Hyperhidrosis	41	238
Hyperoxia		1
Hyperpyrexia	1	3
Hypersensitivity	15	76
Hypersomnia	4	57

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					5
					1
					1
			2		1
					1
					1
					1
					2
					3
					1
				1	4
		1	1	1	3
		48	65	70	136
				2	4
		2	2		1
				1	1
					1
		1	1		
			1		2
					1
		10	33	9	45
			1		
			1	2	4
		1	5		6
		1	2		1
					1
				1	7
1	1	15	74	26	164
					1
				1	3
		5	23	10	53
		1	22	3	35

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypertension	19	100
Hypertensive crisis	1	2
Hyperthermia		2
Hyperthyroidism	1	2
Hypertonic bladder		1
Hyperventilation	3	4
Hyphaema		1
Hypnopompic hallucination	1	1
Hypoacusis	4	10
Hypoaesthesia	65	222
Hypoaesthesia eye	2	4
Hypoaesthesia oral	15	59
Hypocalcaemia		1
Hypoglycaemia	3	9
Hypokinesia	7	11
Hypomenorrhoea	2	3
Hypophagia		6
Hypopnoea	7	12
Hyposmia		2
Hypotension	7	45
Hypothermia		5
Hypothyroidism		2
Hypoxia		5
IIIrd nerve disorder		1
IIIrd nerve paralysis		2
Ileus paralytic		1
Illness	33	168
Immobile		3
Immune-mediated adverse reaction		1
Immune system disorder	4	8
Immune thrombocytopenia	2	9
Immunodeficiency		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	27	16	73
				1	2
					2
				1	2
			1		
		3	3		1
					1
				1	1
		2	5	2	5
	1	34	90	31	132
		2	3		1
		13	36	2	23
					1
				3	9
		1	2	6	9
		2	3		
					6
		2	2	5	10
					2
		2	10	5	35
					5
					2
					5
					1
					2
					1
		16	53	17	115
					3
			1		
			1	4	7
				2	9
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Impaired driving ability	1	7
Impaired quality of life	1	1
Impaired work ability	3	8
Impetigo		1
Inappropriate schedule of product administration	114	219
Incision site pain		1
Incoherent	1	2
Incontinence	1	3
Incorrect dose administered		1
Incorrect route of product administration		8
Increased upper airway secretion		1
Increased viscosity of upper respiratory secretion	1	2
Induration	1	1
Infected cyst	1	1
Infection	4	17
Infectious mononucleosis	1	1
Infective pericardial effusion	1	1
Infective tenosynovitis	1	1
Inflammation	8	34
Inflammatory bowel disease		1
Inflammatory marker increased		2
Inflammatory pain	1	1
Influenza	30	163
Influenza like illness	55	378
Inhibitory drug interaction	1	2
Initial insomnia		3
Injected limb mobility decreased	1	1
Injection related reaction	1	7
Injection site erythema	2	4
Injection site indentation	1	1
Injection site mass		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4		3
				1	1
		1	2	2	6
					1
1	1	112	214	2	5
					1
		1	1		1
				1	3
			1		
			7		1
					1
				1	2
				1	1
				1	1
		2	6	2	11
				1	1
				1	1
				1	1
		3	11	5	23
					1
			1		1
				1	1
	2	14	46	16	117
	2	25	130	30	248
		1	1		1
			1		2
		1	1		
			1	1	6
		1	3	1	1
				1	1
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site pain	7	17
Injection site pruritus	1	2
Injection site reaction		1
Injection site swelling	1	4
Injury		1
Injury corneal		1
Inner ear inflammation	1	1
Insomnia	51	190
Insulin resistance		1
Intentional self-injury		1
Intermenstrual bleeding	1	2
Internal haemorrhage	1	1
Internal hernia		1
International normalised ratio decreased		3
International normalised ratio increased		2
Intervertebral disc compression		1
Intervertebral disc protrusion		1
Intestinal ischaemia		1
Intestinal obstruction		1
Intracranial pressure increased		1
Intraocular pressure increased		1
Iodine uptake increased		1
Iridocyclitis		2
Iritis		1
Iron deficiency		1
Irregular breathing		2
Irritability	2	10
Irritable bowel syndrome	2	10
Ischaemia	1	1
Ischaemic stroke		5
Jaundice		2
Jaw disorder	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	11	2	6
		1	2		
			1		
			2	1	2
					1
					1
				1	1
	1	17	53	34	137
					1
					1
				1	2
				1	1
					1
					3
					2
					1
					1
					1
					1
					1
					2
			1		
					1
			2		
		1	2	1	8
		1	2	1	8
				1	1
					5
					2
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Joint destruction		1
Joint effusion	1	4
Joint instability	1	1
Joint lock		2
Joint noise		1
Joint range of motion decreased	12	44
Joint stiffness	6	35
Joint swelling	12	56
Joint warmth		1
Ketoacidosis		1
Kidney infection	1	4
Labile blood pressure		1
Labyrinthitis	5	15
Lacrimal structural disorder	1	1
Lacrimation increased	5	19
Lagophthalmos	1	2
Language disorder		1
Large intestine perforation	1	1
Laryngeal pain		1
Latent autoimmune diabetes in adults		1
Lateral medullary syndrome		1
Left ventricular failure		1
Lethargy	47	241
Leukopenia		1
Lichenoid keratosis		2
Lichen planus	1	1
Ligament sprain	2	5
Limbal swelling		1
Limb crushing injury	1	1
Limb deformity	1	1
Limb discomfort	46	185
Limb immobilisation	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1	1	3
				1	1
					2
					1
		4	11	8	33
		1	4	5	31
		4	20	8	36
					1
					1
				1	4
					1
		2	5	3	10
				1	1
		3	6	2	13
				1	2
					1
				1	1
					1
					1
		14	69	33	172
					1
					2
				1	1
				2	5
					1
				1	1
		1	1		
2	2	26	85	20	100
		1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Limb injury	2	6
Limb mass	1	5
Limb operation		1
Lip blister	2	6
Lip discolouration	1	1
Lip disorder		2
Lip dry	3	9
Lip neoplasm	1	1
Lip pain	2	7
Lip pruritus	1	4
Lip scab		1
Lip swelling	20	72
Listless	2	2
Livedo reticularis		5
Liver disorder	1	1
Liver function test abnormal	1	6
Liver function test increased		4
Liver injury		1
Liver tenderness		1
Localised infection		2
Localised oedema		3
Local reaction	2	10
Loss of bladder sensation		2
Loss of consciousness	10	57
Loss of control of legs		2
Loss of libido	1	1
Loss of personal independence in daily activities	4	32
Lower motor neurone lesion	1	1
Lower respiratory tract infection	4	24
Lung disorder		2
Lung opacity		1
Lymphadenitis	5	14

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3		3
				1	5
					1
				2	6
				1	1
			2		
			2	3	7
				1	1
			2	2	5
			2	1	2
					1
		12	26	8	46
				2	2
			2		3
				1	1
			2	1	4
			2		2
					1
					1
					2
			1		2
		1	5	1	5
					2
				10	57
					2
				1	1
		1	9	3	23
				1	1
				4	24
			1		1
					1
		5	7		7

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lymphadenopathy	166	635
Lymphangioma		1
Lymph gland infection		1
Lymph node pain	39	140
Lymphocytosis		1
Lymphoedema	5	16
Lymphoma		3
Macular oedema	1	1
Macular rupture		1
Macule		2
Madarosis	1	2
MAGIC syndrome		1
Magnetic resonance imaging head abnormal		1
Malaise	143	849
Malignant hypertension	1	2
Mania		1
Mass	3	7
Mast cell activation syndrome		1
Mastication disorder		1
Mastitis		5
Maternal exposure during pregnancy		5
Maternal exposure timing unspecified	1	1
Measles		1
Mechanic's hand	1	1
Medial tibial stress syndrome		1
Medication error	1	3
Medication overuse headache		1
Melaena		1
Memory impairment	3	9
Meniere's disease		1
Meningitis		2
Meningitis bacterial		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	58	203	108	432
					1
					1
	1	15	42	24	98
					1
		2	6	3	10
					3
				1	1
					1
			1		1
				1	2
					1
					1
3	4	58	255	85	594
				1	2
					1
		1	2	2	5
					1
					1
					5
			5		
		1	1		
					1
				1	1
					1
				1	3
					1
					1
		2	3	1	6
					1
					2
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Meningitis pneumococcal		1
Meniscus injury		1
Menopausal symptoms		2
Menopause	3	4
Menstrual disorder	6	8
Menstruation delayed	2	2
Menstruation irregular	3	4
Mental disorder		3
Mental fatigue	7	20
Mental impairment		4
Mesenteric vein thrombosis		2
Metamorphopsia	2	4
Metastasis		1
Micturition disorder		2
Micturition urgency	2	6
Middle ear disorder	1	1
Middle ear effusion	1	1
Middle insomnia	1	10
Migraine	52	225
Migraine prophylaxis		1
Migraine with aura	4	20
Migraine without aura	1	3
Miliaria	1	10
Miosis	1	2
Misophonia	1	1
Moaning		1
Mobility decreased	12	63
Monoparesis		7
Monoplegia		4
Mood altered		1
Mood disorder due to a general medical condition		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
			1		1
		2	2	1	2
		5	6	1	2
		2	2		
		2	2	1	2
			1		2
		2	6	5	14
					4
					2
				2	4
					1
			1		1
		1	2	1	4
				1	1
		1	1		
		1	3		7
	2	9	30	43	195
					1
	1	1	5	3	15
		1	1		2
			1	1	9
		1	1		1
		1	1		
					1
		3	12	9	51
			1		6
					4
					1
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mood swings	1	1
Morning sickness	1	4
Motion sickness		4
Motor dysfunction		3
Mouth haemorrhage	1	5
Mouth injury	1	1
Mouth swelling	2	13
Mouth ulceration	7	28
Movement disorder	3	16
Mucosal disorder	1	1
Mucosal dryness	1	1
Mucous stools		3
Multiple sclerosis		9
Multiple sclerosis relapse		4
Multiple sclerosis relapse prophylaxis		1
Mumps	1	2
Muscle atrophy	1	1
Muscle contractions involuntary	2	3
Muscle contracture	1	1
Muscle discomfort	1	2
Muscle disorder		2
Muscle fatigue	6	39
Muscle injury		1
Muscle rigidity		3
Muscle rupture	1	1
Muscle spasms	19	81
Muscle spasticity	1	1
Muscle strain	4	9
Muscle swelling		4
Muscle tightness	1	13
Muscle twitching	3	19
Muscular weakness	19	103

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1		3
			2		2
			1		2
			1	1	4
				1	1
			2	2	11
		2	5	5	23
		1	4	2	12
		1	1		
				1	1
					3
					9
					4
					1
				1	2
				1	1
				2	3
		1	1		
				1	2
			1		1
		3	11	3	28
					1
					3
				1	1
		5	20	14	61
				1	1
		3	3	1	6
			1		3
			3	1	10
		1	10	2	9
		1	26	18	77

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Musculoskeletal chest pain	4	23
Musculoskeletal discomfort	5	19
Musculoskeletal disorder	2	5
Musculoskeletal pain	1	11
Musculoskeletal stiffness	27	152
Mutism		2
Myalgia	173	1,165
Myelitis		1
Myelitis transverse		4
Myocardial infarction	5	19
Myocardial ischaemia		1
Myocarditis	2	5
Myoclonus		2
Myofascial pain syndrome		1
Myopathy	1	1
Myositis		1
Nail discolouration		1
Nasal congestion	6	24
Nasal crusting	1	1
Nasal discomfort	2	12
Nasal disorder		1
Nasal dryness	1	2
Nasal herpes	1	1
Nasal obstruction		2
Nasal odour		3
Nasal oedema	2	5
Nasal pruritus		1
Nasopharyngitis	16	77
Natural killer T cell count increased		1
Nausea	199	1,375
Neck mass		3
Neck pain	53	250

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3	3	20
		2	7	3	12
			1	2	4
			2	1	9
		13	53	14	99
			1		1
2	9	86	378	87	787
					1
					4
				5	19
					1
				2	5
					2
			1		
				1	1
					1
					1
	1	1	4	5	20
		1	1		
		1	4	1	8
			1		
			1	1	1
				1	1
			1		1
			1		2
			1	2	4
			1		
		7	27	9	50
			1		
1	8	88	424	111	951
			2		1
		17	78	36	172

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neoplasm	2	3
Neoplasm malignant		1
Neoplasm progression	1	1
Neoplasm skin		1
Nephritis	1	1
Nephrotic syndrome		3
Nerve compression		1
Nerve degeneration		1
Nerve injury		3
Nervousness	6	33
Nervous system disorder	1	2
Neuralgia	16	52
Neurogenic shock		4
Neurological symptom		3
Neuropathy peripheral	4	13
Neutropenia	2	8
Neutrophil count decreased	1	4
Neutrophilia		1
Nightmare	6	17
Night sweats	12	51
Nipple pain		1
Nocturnal dyspnoea	1	1
Nodule	1	1
Non-Hodgkin's lymphoma		1
Noninfective gingivitis	1	3
Noninfective sialoadenitis		1
Nonspecific reaction	1	1
Nystagmus	1	4
Obstruction	1	1
Occipital neuralgia	2	2
Occupational exposure to SARS-CoV-2		1
Ocular discomfort	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	2
					1
				1	1
				1	1
					3
			1		
					1
			1		2
		1	7	5	26
			1	1	1
			13	16	39
					4
					3
				4	13
				2	8
		1	2		2
					1
		1	3	5	14
		4	16	8	35
					1
		1	1		
		1	1		
					1
				1	3
					1
		1	1		
				1	4
				1	1
				2	2
			1		
			1	2	4

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ocular hyperaemia	6	29
Odynophagia	1	2
Oedema	4	5
Oedema mouth		2
Oedema peripheral	4	9
Off label use	98	279
Oliguria		1
Onychalgia	1	1
Ophthalmic herpes zoster	1	2
Ophthalmic migraine	1	1
Ophthalmological examination abnormal		1
Ophthalmoplegia		2
Optic nerve disorder	1	1
Optic neuritis	1	3
Oral allergy syndrome		1
Oral blood blister		1
Oral candidiasis		3
Oral discomfort		7
Oral disorder	1	4
Oral herpes	6	29
Oral infection	1	1
Oral lichen planus		2
Oral mucosal blistering		4
Oral mucosal discolouration		1
Oral mucosal eruption		1
Oral mucosal erythema		1
Oral mucosal exfoliation		1
Oral mucosal roughening		1
Oral pain	6	29
Oral pruritus		3
Oral purpura		1
Orbital oedema		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	10	4	19
		1	1		1
			1	4	4
					2
		2	4	2	5
1	1	96	268	2	11
					1
		1	1		
				1	2
				1	1
			1		
					2
				1	1
				1	3
					1
					1
			2		1
					7
			1	1	3
		3	7	3	22
				1	1
					2
			2		2
					1
					1
					1
					1
		2	6	4	23
					3
					1
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Orchitis		1
Oropharyngeal blistering	1	4
Oropharyngeal discomfort		7
Oropharyngeal pain	41	213
Orthostatic hypotension		3
Osmophobia		1
Osteoarthritis	4	8
Osteochondritis		1
Ovarian haemorrhage	1	1
Overdose	1	7
Oversensing		3
Oxygen saturation		1
Oxygen saturation decreased	4	22
Pain	185	882
Painful respiration	1	8
Pain in extremity	280	1,339
Pain in jaw	7	34
Pain of skin	9	44
Palatal oedema		1
Palindromic rheumatism		1
Pallor	8	37
Palpitations	36	186
Pancreatic carcinoma		1
Pancreatitis acute	1	1
Pancreatitis necrotising		1
Panic attack	3	7
Panic disorder		3
Panic reaction		4
Papilloedema	2	3
Papule		4
Paraesthesia	93	337
Paraesthesia oral	30	158

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	4
			5		2
	1	23	70	18	143
			1		2
					1
			3	4	5
			1		
				1	1
			5	1	2
			1		2
					1
			2	4	20
	2	66	321	119	561
		1	2		6
3	10	137	482	143	857
		1	11	6	23
		4	11	5	33
					1
					1
		6	14	2	23
		16	53	20	133
					1
				1	1
					1
		2	3	1	4
			1		2
			1		3
				2	3
					4
		46	134	47	203
		22	81	8	77

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Paralysis	2	10
Paranoia		1
Parkinsonism		1
Parkinson's disease		2
Parosmia	5	22
Parotid gland enlargement		2
Parotitis	2	4
Partial seizures	1	1
Patient-device incompatibility	1	1
Pelvic pain	1	9
Pemphigus	1	1
Penile swelling		2
Peptic ulcer haemorrhage	1	1
Perforation	1	1
Periarthritis	8	13
Pericardial effusion		2
Pericarditis	2	2
Perineal pain		1
Periorbital oedema		1
Periorbital swelling	9	23
Peripheral coldness	13	48
Peripheral sensory neuropathy		1
Peripheral swelling	76	290
Peritonitis		1
Peroneal nerve palsy		1
Persistent postural-perceptual dizziness		1
Petechiae	4	11
Petit mal epilepsy		1
Phantom limb syndrome		1
Pharyngeal erythema	1	1
Pharyngeal hypoaesthesia	1	2
Pharyngeal oedema		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	10
					1
					1
					2
		3	8	2	14
			1		1
		1	2	1	2
				1	1
		1	1		
			2	1	7
				1	1
			1		1
				1	1
				1	1
		2	2	6	11
					2
				2	2
			1		
					1
		5	9	4	14
	1	5	15	8	33
			1		
	1	29	81	47	209
					1
					1
			1		
			3	4	8
					1
					1
				1	1
			1	1	1
			1		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pharyngeal paraesthesia	2	11
Pharyngeal pustule		1
Pharyngeal swelling	4	18
Pharyngeal ulceration	1	3
Pharyngitis		1
Pharyngitis streptococcal	1	2
Phlebitis	1	6
Photophobia	8	35
Photopsia	2	9
Photosensitivity reaction	1	3
Physical deconditioning		1
Pigmentation disorder	2	2
Piloerection		3
Pityriasis rosea		1
Plantar fasciitis		1
Platelet anisocytosis		1
Platelet count decreased	6	16
Platelet count increased		1
Pleural effusion	1	2
Pleural rub	1	1
Pleurisy	1	5
Pleuritic pain	1	5
Pneumonia	4	14
Pneumonia bacterial		1
Pneumonitis		3
Pneumothorax spontaneous		1
Pollakiuria	4	10
Polyarthrits	1	4
Polymerase chain reaction positive	2	3
Polymyalgia rheumatica		3
Polymyositis		1
Polyuria	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4	1	7
			1		
			3	4	15
		1	2		1
			1		
		1	1		1
			3	1	3
		2	7	6	28
			3	2	6
			2	1	1
					1
		1	1	1	1
					3
			1		
					1
					1
		2	3	4	13
					1
				1	2
		1	1		
				1	5
				1	5
				4	14
					1
			1		2
					1
		1	3	3	7
				1	4
			1	2	2
					3
					1
		1	1	1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Poor peripheral circulation	1	1
Poor quality product administered		1
Poor quality sleep	4	28
Portal vein thrombosis		1
Post herpetic neuralgia	4	4
Post lumbar puncture syndrome		1
Postmenopausal haemorrhage	7	10
Postprandial hypoglycaemia		1
Post procedural complication		1
Post stroke seizure		1
Postural orthostatic tachycardia syndrome		2
Post viral fatigue syndrome	5	11
Pouchitis		1
Premature menarche		1
Presyncope	8	41
Primary biliary cholangitis		1
Proctalgia	1	4
Proctitis		1
Proctitis ulcerative		1
Product administered at inappropriate site		8
Product dose omission issue		1
Productive cough	5	26
Product preparation error		2
Product use issue	1	91
Progressive macular hypomelanosis	1	1
Prophylaxis of nausea and vomiting	1	1
Prostatic abscess		1
Prostatitis		1
Proteinuria		1
Prothrombin time prolonged		1
Pruritus	91	330
Pseudolymphoma		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		
		2	4	2	24
					1
		1	1	3	3
					1
				7	10
					1
					1
					1
					2
		2	2	3	9
					1
			1		
		4	15	4	26
					1
			2	1	2
			1		
					1
			7		1
					1
		3	10	2	16
			2		
		1	86		5
				1	1
		1	1		
					1
					1
					1
					1
		52	143	39	187
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Psoriasis	3	10
Psoriatic arthropathy		5
Psychiatric symptom		1
Psychotic disorder		1
Pulmonary cavitation	1	1
Pulmonary embolism	12	54
Pulmonary hypertension		2
Pulmonary infarction		4
Pulmonary pain	2	18
Pulmonary sarcoidosis		1
Pulmonary thrombosis	3	5
Pulse abnormal		1
Pulseless electrical activity		1
Pulse pressure increased	1	1
Pupillary disorder		1
Pupils unequal		1
Purging		1
Purpura	1	3
Pustular psoriasis		1
Pyrexia	207	1,350
Q fever		4
Quality of life decreased		1
Radiculitis brachial	1	3
Radiculopathy		1
Radioisotope uptake increased		1
Rash	99	326
Rash erythematous	23	100
Rash macular	9	43
Rash maculo-papular	1	3
Rash morbilliform	2	4
Rash papular	13	38
Rash pruritic	22	89

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4	2	6
					5
					1
					1
				1	1
				12	54
					2
					4
			4	2	14
			1		
				3	5
					1
					1
		1	1		
					1
					1
		1	2		1
					1
2	9	107	444	100	906
					4
					1
			1	1	2
					1
					1
		44	132	55	194
		12	38	11	62
		4	23	5	20
		1	3		
				2	4
		8	18	5	20
		12	39	10	50

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rash pustular	1	1
Rash vesicular	7	12
Raynaud's phenomenon	1	6
Reaction to colouring		1
Reaction to excipient	1	1
Rectal abscess		1
Rectal discharge	2	2
Rectal haemorrhage	1	7
Red blood cell sedimentation rate abnormal		1
Red blood cell sedimentation rate increased		2
Reflux gastritis		1
Renal disorder		1
Renal failure		1
Renal impairment	1	4
Renal infarct	1	1
Renal pain	9	31
Respiration abnormal		5
Respiratory arrest		1
Respiratory disorder	1	9
Respiratory distress		1
Respiratory failure		4
Respiratory rate decreased		1
Respiratory rate increased	2	10
Respiratory tract congestion	1	1
Respiratory tract irritation		1
Respiratory tract oedema		1
Resting tremor	1	1
Restless legs syndrome	1	6
Restlessness	5	20
Retching	1	16
Retinal artery occlusion	2	2
Retinal haemorrhage		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		3	5	4	7
				1	6
					1
				1	1
					1
				2	2
				1	7
					1
					2
			1		
					1
					1
				1	4
				1	1
		5	13	4	18
			2		3
					1
			1	1	8
					1
					4
					1
		2	2		8
				1	1
			1		
					1
		1	1		
		1	3		3
		3	6	2	14
			7	1	9
				2	2
					2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Retinal injury		1
Retinal migraine	2	4
Retinal tear	1	2
Retinal toxicity		1
Retinal vein occlusion	3	5
Retinal vein thrombosis	1	2
Retinopathy		1
Reversible airways obstruction		1
Rheumatoid arthritis	2	17
Rhinalgia	1	3
Rhinitis		6
Rhinitis allergic		2
Rhinorrhoea	12	60
Road traffic accident	2	4
Rosacea	2	2
Rotator cuff syndrome	2	4
Sacroiliitis		2
Salivary gland disorder	1	2
Salivary gland enlargement		2
Salivary gland pain		2
Salivary hypersecretion	2	8
Salt craving		1
Sarcoidosis		4
SARS-CoV-2 ant body test		1
SARS-CoV-2 ant body test negative		1
SARS-CoV-2 test negative		1
SARS-CoV-2 test positive	1	9
Scab	2	3
Scar	2	2
Scar pain	1	1
Sciatica		2
Scintillating scotoma	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1	1	3
				1	2
					1
				3	5
				1	2
					1
					1
				2	17
			1	1	2
			3		3
					2
	3	8	23	4	37
		1	1	1	3
				2	2
		1	1	1	3
					2
				1	2
					2
					2
		1	3	1	5
					1
					4
			1		
					1
					1
			3	1	6
		1	2	1	1
				2	2
		1	1		
					2
		1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Scleritis		1
Screaming		1
Scrotal erythema		1
Scrotal exfoliation		1
Scrotal pain		2
Scrotal swelling		3
Seasonal allergy	4	7
Seborrhoeic dermatitis	1	1
Secretion discharge		1
Seizure	7	30
Semen discolouration		1
Sensation of foreign body	2	8
Sensitisation		2
Sensitive skin	3	14
Sensitivity to weather change		2
Sensory disturbance	3	15
Sensory loss	1	6
Sensory overload	1	1
Sepsis	1	5
Septic pulmonary embolism		1
Septic shock	1	3
Serositis		1
Serum ferritin decreased		1
Serum ferritin increased		1
Shock	1	5
Shoulder injury related to vaccine administration	1	4
Sinus bradycardia	2	2
Sinus congestion	2	4
Sinus disorder		1
Sinus headache	7	31
Sinusitis	2	8
Sinus pain	4	21

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
					1
			1		1
					3
		1	1	3	6
				1	1
					1
				7	30
					1
		1	1	1	7
					2
		2	6	1	8
					2
		1	8	2	7
			3	1	3
				1	1
				1	5
					1
				1	3
					1
					1
				1	5
				1	4
		1	1	1	1
		1	1	1	3
					1
	1	1	10	6	21
		2	2		6
		3	9	1	12

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* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sinus tachycardia	1	5
Sitting disability		1
Sjogren's syndrome	1	5
Skin abrasion		1
Skin burning sensation	9	19
Skin depigmentation		1
Skin discolouration	2	13
Skin disorder	2	5
Skin erosion		2
Skin exfoliation	3	8
Skin haemorrhage	1	2
Skin induration		1
Skin infection	1	2
Skin irritation	3	13
Skin laceration		1
Skin lesion	3	9
Skin mass	1	2
Skin odour abnormal	1	1
Skin plaque		1
Skin reaction	1	4
Skin sensitisation	1	3
Skin swelling	3	13
Skin temperature		2
Skin tightness		5
Skin ulcer		1
Skin warm	2	17
Skin weeping		1
Sleep apnoea syndrome	1	2
Sleep attacks		1
Sleep deficit		1
Sleep disorder	16	57

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		2
			1		
				1	5
			1		
	2	7	7	2	12
					1
		1	6	1	7
				2	5
					2
		2	2	1	6
			1	1	1
			1		
				1	2
		2	6	1	7
					1
		1	4	2	5
		1	1		1
				1	1
					1
				1	4
		1	2		1
		2	5	1	8
			1		1
			1		4
					1
	1		5	2	12
					1
				1	2
					1
			1		
		7	30	9	27

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Sleep disorder due to a general medical condition	1	4				1	1	3
Sleep disorder due to general medical condition, insomnia type		12				3		9
Sleep paralysis	1	1			1	1		
Sleep terror	1	5			1	1		4
Sluggishness		2				1		1
Small intestinal haemorrhage		1						1
Small intestinal obstruction		1						1
Sneezing	5	27		1	3	16	2	11
Soft tissue swelling		1						1
Solar dermatitis	1	1					1	1
Solar urticaria	1	1					1	1
Somnolence	25	121		1	8	38	17	83
Speech disorder	2	18			1	4	1	14
Spinal column injury		1						1
Spinal fracture	1	2					1	2
Spinal pain	1	7				1	1	6
Spinal stenosis		1						1
Splenic infarction	1	1					1	1
Spondylitis	1	2					1	2
Status epilepticus	1	6					1	6
Stiff tongue		1				1		
Stoma site discharge		1						1
Stoma site haemorrhage	1	1					1	1
Stomatitis	2	7				1	2	6
Strabismus		1				1		
Streptococcal endocarditis	1	1					1	1
Streptococcal sepsis	1	1					1	1
Stress	1	9				3	1	6
Stress cardiomyopathy		1						1
Stupor		1						1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Subarachnoid haemorrhage		2
Submaxillary gland enlargement		2
Sudden death		3
Sudden hearing loss	2	5
Sudden onset of sleep	1	1
Sudden visual loss	1	1
Suffocation feeling		1
Suicidal ideation	1	4
Sunburn		1
Suprapubic pain		1
Supraventricular extrasystoles		1
Supraventricular tachycardia	1	4
Suspected COVID-19	9	73
Sweating fever	1	10
Swelling	65	227
Swelling face	26	105
Swelling of eyelid	4	19
Swollen tongue	16	72
Symptom recurrence	1	1
Syncope	16	105
Synovial cyst		1
Syringe issue	1	1
Systemic inflammatory response syndrome		1
Systemic lupus erythematosus	1	7
Systemic lupus erythematosus rash		2
Tachyarrhythmia	1	1
Tachycardia	10	74
Tachypnoea	1	5
Taste disorder	10	39
Tearfulness	1	8
Temperature intolerance	1	5
Temperature perception test increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
			2		
					3
				2	5
				1	1
				1	1
			1		
				1	4
					1
			1		
					1
		1	2		2
		7	34	2	39
				1	10
		20	80	45	147
		8	23	18	82
		1	8	3	11
		6	23	10	49
				1	1
				16	105
					1
		1	1		
					1
				1	7
					2
				1	1
		6	25	4	49
			2	1	3
		7	21	3	18
			1	1	7
				1	5
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Temperature regulation disorder		3
Temporal lobe epilepsy		1
Temporomandibular joint syndrome	1	2
Tenderness	17	56
Tendon injury		2
Tendonitis	1	8
Tendon pain		1
Tendon rupture	1	1
Tenosynovitis stenosis		2
Tension		1
Tension headache	7	38
Testicular pain		2
Testicular swelling		2
Therapeutic response unexpected	4	10
Thermal burn		4
Thermal burns of eye		2
Thinking abnormal	2	5
Thirst	14	44
Throat clearing		1
Throat irritation	6	28
Throat tightness	2	27
Thrombocytopenia	7	23
Thrombocytosis		1
Thrombophlebitis		2
Thrombophlebitis superficial	2	3
Thrombosis	15	42
Thrombosis in device		1
Thyroiditis subacute		1
Thyroid pain		1
Tinnitus	44	138
Tongue biting	1	1
Tongue blistering		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		2
					1
				1	2
	2	9	36	8	20
					2
			1	1	7
					1
				1	1
					2
					1
	2	2	7	5	31
					2
					2
		4	9		1
					4
					2
		2	2		3
		5	16	9	28
					1
		3	7	3	21
		1	10	1	17
				7	23
			1		
			1		1
				2	3
2	2			15	42
					1
			1		
					1
		12	29	32	109
				1	1
			1		2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tongue coated		1
Tongue discolouration	3	5
Tongue discomfort	1	5
Tongue disorder	1	8
Tongue dry		3
Tongue eruption		2
Tongue erythema		1
Tongue oedema		4
Tongue pruritus	1	3
Tongue ulceration		2
Tonic clonic movements		2
Tonsillar disorder		2
Tonsillar hypertrophy	1	5
Tonsillar inflammation		1
Tonsillitis	2	5
Tooth abscess	1	2
Toothache	2	15
Tooth discolouration	1	1
Tooth extraction		1
Toxic anterior segment syndrome	1	1
Toxic skin eruption		1
Tracheitis		1
Transferrin decreased		1
Transient ischaemic attack	6	19
Transposition of the great vessels	1	1
Treatment noncompliance		1
Tremor	32	174
Trigeminal neuralgia	4	10
Trigger finger		1
Tri-iodothyronine		1
Tri-iodothyronine decreased		1
Trismus	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1				1
		1	3	2	2
			2	1	3
				1	8
			1		2
					2
			1		
					4
		1	1		2
			1		1
					2
			1		1
			2	1	3
			1		
		2	4		1
				1	2
			2	2	13
				1	1
					1
				1	1
					1
			1		
				6	19
				1	1
					1
		13	41	19	133
			2	4	8
					1
			1		
					1
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Troponin	1	1
Troponin increased	1	2
Tunnel vision		2
Tympanic membrane hyperaemia		1
Type 1 diabetes mellitus		2
Type 2 diabetes mellitus		2
Type IV hypersensitivity reaction		1
Typical aura without headache	1	1
Ulnar neuritis		1
Underdose		2
Unresponsive to stimuli		3
Upper-airway cough syndrome		2
Upper airway obstruction		1
Upper respiratory tract congestion		2
Upper respiratory tract infection		3
Urge incontinence	1	1
Urinary incontinence		9
Urinary retention		2
Urinary tract infection	1	14
Urinary tract pain		1
Urine abnormality	2	3
Urine flow decreased		1
Urine odour abnormal		2
Urine output		1
Urine output decreased	1	2
Urosepsis		1
Urticaria	28	114
Urticaria contact	1	1
Urticarial vasculitis	1	1
Urticaria papular		1
Urticaria thermal	1	1
Uterine contractions abnormal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	2
					2
					1
					2
					2
			1		
				1	1
					1
			2		
					3
					2
					1
					2
			1		2
				1	1
			2		7
					2
			1	1	13
					1
		1	2	1	1
					1
			1		1
				1	2
					1
		15	42	13	72
				1	1
				1	1
			1		
		1	1		
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Uterine haemorrhage		1
Uterine leiomyoma	1	1
Uterine pain		1
Uterine polyp	1	1
Uveitis		2
Vaccination complication		6
Vaccination failure		1
Vaccination site abscess		1
Vaccination site bruising	2	20
Vaccination site cellulitis		7
Vaccination site discolouration		1
Vaccination site discomfort	6	32
Vaccination site erythema	31	195
Vaccination site haematoma		1
Vaccination site haemorrhage	1	7
Vaccination site hyperaesthesia		2
Vaccination site hypersensitivity		1
Vaccination site hypoaesthesia	1	4
Vaccination site induration	6	25
Vaccination site infection		4
Vaccination site inflammation	3	19
Vaccination site irritation	1	5
Vaccination site joint erythema	1	2
Vaccination site joint movement impairment	2	4
Vaccination site joint pain		1
Vaccination site joint warmth		1
Vaccination site lymphadenopathy		3
Vaccination site mass	8	58
Vaccination site movement impairment	5	28
Vaccination site oedema		4
Vaccination site pain	118	769
Vaccination site paraesthesia		8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
					1
				1	1
					2
			3		3
					1
			1		
		2	10		10
			2		5
			1		
		2	18	4	14
		18	108	13	87
					1
			2	1	5
			1		1
					1
		1	2		2
		2	14	4	11
					4
		2	12	1	7
			1	1	4
		1	2		
			1	2	3
					1
			1		
			3		
1	1	5	22	3	36
		2	11	3	17
			1		3
	6	70	349	48	420
			2		6

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site photosensitivity reaction	1	1
Vaccination site pruritus	13	71
Vaccination site rash	5	21
Vaccination site reaction	1	12
Vaccination site scab		1
Vaccination site swelling	36	203
Vaccination site urticaria	1	3
Vaccination site vesicles		2
Vaccination site warmth	12	84
Vaginal disorder		1
Vaginal haemorrhage	5	12
Varicella	1	2
Varicose vein		3
Vascular headache	1	5
Vascular injury	1	2
Vasculitic rash		1
Vasculitis	1	4
Vasoconstriction		2
Vasodilatation		4
Vein disorder	1	3
Vena cava embolism		1
Vena cava thrombosis		1
Venous thrombosis		2
Ventricular arrhythmia	2	2
Ventricular extrasystoles	2	3
Ventricular fibrillation		1
Ventricular flutter	1	1
Ventricular hypertrophy		1
Ventricular tachycardia	2	3
Vertebral lesion	1	1
Vertigo	26	109
Vertigo labyrinthine	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		10	42	3	29
		3	8	2	13
1	1	1	4		8
					1
		17	91	19	112
		1	1		2
			1		1
		8	42	4	42
					1
			1	5	11
				1	2
			2		1
			2	1	3
				1	2
					1
				1	4
					2
					4
			1	1	2
					1
					1
					2
				2	2
				2	3
					1
				1	1
					1
				2	3
				1	1
		8	20	18	89
				1	2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vertigo positional	5	14
Vestibular migraine		4
Vestibular neuronitis	1	3
Viral infection	2	6
Viral labyrinthitis		1
Viral pharyngitis		1
Viral rash		1
Viral upper respiratory tract infection		1
Visceral venous thrombosis		1
Vision blurred	23	90
Visual acuity reduced		1
Visual brightness		1
Visual field defect	1	4
Visual impairment	10	39
Visuospatial deficit	1	1
Vitamin D deficiency		2
Vlth nerve paralysis	1	5
Vitiligo		1
Vitreous detachment	2	7
Vitreous floaters	3	9
Vitreous haemorrhage	1	1
Vomiting	60	361
Vomiting projectile	1	10
Vulval abscess		1
Vulvovaginal candidiasis		3
Vulvovaginal dryness	1	1
Vulvovaginal pruritus		1
Weight bearing difficulty		3
Weight decreased	5	16
Weight increased		1
Wheezing	13	50
White blood cell count decreased	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	5	12
			1		3
				1	3
			1	2	5
					1
					1
					1
					1
		9	23	14	67
					1
			1		
				1	4
		1	7	9	32
				1	1
					2
				1	5
					1
				2	7
		1	3	2	6
				1	1
		20	94	40	267
			1	1	9
					1
					3
				1	1
			1		
			2		1
		2	7	3	9
					1
		1	7	12	43
		1	1	1	4

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
White blood cell count increased		7				1		6
Wound haemorrhage		1						1
Wound infection		1						1
Wrong product administered		1						1
Wrong technique in product usage process	1	2			1	2		
Xanthopsia	1	1					1	1
Yellow skin		2						2
	5	9			5	9		
	7,955	38,001	28	154	3246	12093	4709	25908

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	9	55		1	3	11	6	44
Abdominal distension	8	26			1	4	7	22
Abdominal migraine	1	1			1	1		
Abdominal pain	21	84		1	11	18	10	66
Abdominal pain lower	2	7					2	7
Abdominal pain upper	32	131			6	20	26	111
Abdominal symptom		1						1
Abdominal tenderness		1				1		
Abnormal dreams	2	8			2	5		3
Abnormal loss of weight		1						1
Abnormal sensation in eye		1				1		
Abnormal weight gain	2	4			1	1	1	3
Abscess oral		1						1
Acarodermatitis		1						1
Acne		3						3
Acoustic neuroma		1						1
Acquired haemophilia		1						1
Acrochordon		1						1
Activated partial thromboplastin time prolonged	2	4			1	1	1	3
Acute disseminated encephalomyelitis		1						1
Acute febrile neutrophilic dermatosis		1						1
Acute kidney injury	3	8					3	8
Acute myocardial infarction	1	6					1	6
Acute respiratory distress syndrome		1						1
Adrenal haemorrhage	1	1					1	1
Adrenocortical insufficiency acute	1	4					1	4
Adverse drug reaction	1	7			1	5		2
Adverse reaction				1				
Affect lability		1						1
Ageusia	5	23		1	2	5	3	18
Aggression		2				1		1
Agitation	4	7			2	2	2	5

* I=Interval, C=Cumulative

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Alanine aminotransferase increased		4
Alcoholic hangover		1
Allergic reaction to excipient	1	3
Allergic sinusitis		1
Allergy to chemicals	1	1
Allergy to metals	1	1
Allergy to vaccine		6
Alopecia	5	8
Alopecia areata	1	1
Alopecia totalis		1
Altered state of consciousness		1
Amaurosis fugax	1	1
Amblyopia		1
Amegakaryocytic thrombocytopenia		1
Amenorrhoea		1
Amnesia	4	14
Anaemia	1	8
Anaemia megaloblastic		1
Anaemia vitamin B12 deficiency		1
Anal haemorrhage		1
Anal incontinence	1	5
Anaphylactic reaction		21
Anaphylactic shock		5
Aneurysm		1
Angina pectoris	3	14
Angioedema	5	15
Angiopathy	1	1
Anisocytosis		1
Ankylosing spondylitis		1
Anosmia	2	10
Anuria	1	1
Anxiety	7	33

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					4
					1
		1	1		2
					1
				1	1
		1	1		
			2		4
			1	5	7
				1	1
					1
					1
				1	1
					1
					1
		2	4	2	10
				1	8
					1
			1		
					1
	1		1	1	4
					21
					5
					1
				3	14
				5	15
				1	1
					1
					1
		1	3	1	7
				1	1
		2	6	5	27

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Apathy	1	6
Aphasia	3	8
Aphonia	1	4
Aphthous ulcer		2
Appetite disorder		1
Arrhythmia	4	16
Arrhythmia supraventricular		2
Arterial occlusive disease		2
Arterial rupture		1
Arterial stenosis	2	3
Arthralgia	151	619
Arthritis	9	35
Arthritis reactive		2
Arthritis viral		1
Arthropathy	1	5
Ascites		1
Aspiration		1
Asthenia	47	222
Asthenopia	1	8
Asthma	3	22
Asthma late onset		1
Asymptomatic COVID-19		1
Ataxia	1	2
Atrial fibrillation	7	40
Atrial flutter	2	5
Atrial tachycardia		1
Atrioventricular block		1
Atrioventricular block complete		1
Attention deficit hyperactivity disorder		1
Auditory disorder		3
Aura		1
Auricular swelling		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	1	4
			1	3	7
				1	4
					2
					1
				4	16
					2
					2
					1
				2	3
2	8	47	110	104	509
		1	2	8	33
					2
					1
		1	2		3
					1
					1
2	2	13	49	34	173
		1	1		7
		2	3	1	19
					1
					1
		1	1		1
	1			7	40
				2	5
					1
					1
					1
					1
					3
					1
					2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Autoimmune anaemia	1	2
Autoimmune disorder	4	7
Autoimmune haemolytic anaemia	2	3
Autoimmune neutropenia		1
Axillary mass	6	8
Axillary pain	14	34
Axonal neuropathy		1
Back pain	46	174
Bacterial infection	1	2
Balance disorder	25	73
Bed rest		1
Bedridden	1	3
Bell's palsy	6	47
Biliary colic		1
Bladder disorder	1	2
Bladder dysfunction		1
Bladder pain	3	5
Blindness	4	15
Blindness transient	1	1
Blindness unilateral	1	5
Blister	12	33
Blister infected		1
Blood alkaline phosphatase increased		1
Blood blister		2
Blood cholesterol increased	1	4
Blood count	1	1
Blood count abnormal		1
Blood glucose		2
Blood glucose decreased	2	8
Blood glucose fluctuation		2
Blood glucose increased	3	12
Blood immunoglobulin G increased	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
				4	7
				2	3
					1
		3	4	3	4
		3	8	11	26
					1
	1	10	22	36	152
		1	1		1
		5	10	20	63
					1
				1	3
				6	47
					1
				1	2
					1
				3	5
				4	15
				1	1
				1	5
		5	7	7	26
			1		
					1
					2
				1	4
		1	1		
					1
					2
			2	2	6
			1		1
			3	3	9
				1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood immunoglobulin M decreased	1	1
Blood iron increased		2
Blood lactate dehydrogenase increased		1
Blood pH		1
Blood pH increased		3
Blood pressure abnormal	1	3
Blood pressure decreased	3	8
Blood pressure diastolic increased		1
Blood pressure fluctuation	3	6
Blood pressure increased	14	48
Blood pressure systolic decreased		1
Blood sodium decreased	1	1
Blood test	1	1
Blood test abnormal	1	1
Blood thyroid stimulating hormone increased		1
Blood uric acid increased	1	1
Blood urine	2	3
Blood urine present	1	3
Body temperature	1	2
Body temperature abnormal	1	8
Body temperature decreased	2	6
Body temperature fluctuation	3	5
Body temperature increased	4	28
Bone pain	4	19
Bone swelling		1
Bowel movement irregularity	2	2
Bradycardia		5
Bradyphrenia	1	1
Brain stem stroke		1
Breast cancer	2	4
Breast enlargement		1
Breast inflammation	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		1
					1
					1
			1		2
			1	1	2
		1	2	2	6
					1
		1	2	2	4
		4	9	10	39
					1
				1	1
				1	1
				1	1
					1
		1	1		
				2	3
				1	3
				1	2
			1	1	7
		2	4		2
		1	1	2	4
1	1	3	7	1	21
	3	2	2	2	17
			1		
		1	1	1	1
					5
		1	1		
					1
				2	4
					1
				1	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Breast mass	1	3
Breast oedema		1
Breast pain	8	14
Breast swelling	2	5
Breast tenderness	1	2
Breath odour	1	2
Bronchiectasis		2
Bronchitis	1	2
Bruxism	1	1
Bundle branch block		1
Bundle branch block right		2
Burning mouth syndrome	1	1
Burning sensation	10	31
Bursitis	1	4
Cardiac arrest	1	15
Cardiac disorder	2	3
Cardiac failure	2	11
Cardiac failure acute		1
Cardiac flutter	5	16
Cardiogenic shock		2
Cardiomegaly		1
Carotid artery occlusion		1
Carpal tunnel syndrome		2
Catarrh	1	2
Cavernous sinus thrombosis		1
Cells in urine		1
Cellulitis	3	15
Central nervous system vasculitis		1
Cerebellar stroke		1
Cerebral artery thrombosis		1
Cerebral disorder		1
Cerebral haemorrhage	2	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
					1
		4	5	4	9
			1	2	4
			1	1	1
		1	1		1
					2
			1	1	1
		1	1		
					1
			1		1
				1	1
		3	7	7	24
		1	1		3
				1	15
				2	3
				2	11
					1
				5	16
					2
			1		
					1
					2
				1	2
					1
					1
					1
			1		
				2	8

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebral infarction		5
Cerebral small vessel ischaemic disease	1	1
Cerebral thrombosis		5
Cerebral venous sinus thrombosis	1	3
Cerebrovascular accident	15	61
Cervicobrachial syndrome		2
Cervicogenic headache	1	1
Cheilitis		1
Chest discomfort	14	72
Chest pain	30	123
Chest X-ray abnormal		1
Chillblains	1	8
Chills	106	471
Choking		2
Cholangitis		1
Cholelithiasis		1
Chorea		1
Chromatopsia		1
Chromaturia	2	5
Chronic fatigue syndrome	2	11
Chronic kidney disease	1	2
Chronic lymphocytic leukaemia	1	1
Chronic obstructive pulmonary disease	1	6
Circulatory collapse		11
Clumsiness		2
Cluster headache	1	4
Coagulopathy	2	3
Cognitive disorder	1	6
Cold-stimulus headache	1	1
Cold sweat	6	32
Colitis		1
Colitis ulcerative	1	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					5
				1	1
					5
				1	3
				15	61
					2
				1	1
			1		
		4	14	10	58
1	2	9	16	21	107
			1		
		1	6		2
4	6	29	72	77	399
					2
					1
					1
					1
			1		
			1	2	4
	1	1	2	1	9
				1	2
				1	1
				1	6
					11
					2
1	1	1	1		3
		1	2	1	1
			1	1	5
		1	1		
		1	2	5	30
					1
	1			1	6

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Coma		2
Communication disorder		2
Concussion		1
Condition aggravated	14	73
Confusional arousal		1
Confusional state	15	66
Congestive hepatopathy	1	1
Conjunctival haemorrhage		2
Conjunctivitis	1	5
Conjunctivitis bacterial		1
Constipation	4	19
Contrast media reaction		1
Contusion	20	57
Coordination abnormal	2	6
Corneal abrasion		1
Corneal graft rejection	1	1
Costochondritis		1
Cough	26	125
COVID-19	12	72
COVID-19 pneumonia	1	7
Cranial nerve disorder		1
Cranial nerve palsies multiple		1
C-reactive protein increased	3	11
Crepitations	1	2
Creutzfeldt-Jakob disease		1
Crohn's disease		2
Crying		5
Cutaneous vasculitis		2
Cyanosis		2
Cystitis	5	9
Cystitis interstitial		1
Cystitis-like symptom		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					2
			1		
	1	2	15	12	58
					1
		3	15	12	51
				1	1
					2
				1	5
					1
			3	4	16
					1
	2	6	16	14	41
				2	6
					1
				1	1
					1
		10	29	16	96
	1	5	6	7	66
				1	7
					1
					1
		1	3	2	8
		1	2		
					1
					2
					5
					2
			1		1
			1	5	8
					1
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Deafness	5	20
Deafness bilateral		1
Deafness neurosensory	1	1
Deafness transitory	1	2
Deafness unilateral	1	2
Death	1	24
Decreased appetite	33	156
Decreased interest		1
Deep vein thrombosis	14	36
Defaecation urgency		2
Dehydration	6	16
Delayed recovery from anaesthesia	1	1
Delirium	5	14
Dementia		2
Demyelination		2
Depressed level of consciousness		4
Depressed mood	4	12
Depression	2	23
Derealisation		1
Dermal cyst		1
Dermatitis	1	6
Dermatitis acneiform		1
Dermatitis allergic	3	13
Dermatitis atopic	1	1
Dermatitis bullous		2
Dermatitis contact	1	3
Dermatitis infected		1
Diabetes mellitus	1	4
Diabetes mellitus inadequate control		1
Diabetic ketoacidosis		1
Diaphragmalgia		2
Diarrhoea	69	324

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				5	20
					1
				1	1
				1	2
				1	2
				1	24
1	2	7	31	26	125
			1		
				14	36
					2
		1	2	5	14
				1	1
				5	14
					2
					2
					4
		2	3	2	9
			1	2	22
					1
					1
			1	1	5
					1
		2	4	1	9
				1	1
					2
				1	3
			1		
				1	4
					1
					1
					2
1	1	32	66	37	258

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Diarrhoea haemorrhagic		3
Diplegia		1
Diplopia	3	18
Discoloured vomit		1
Discomfort	12	32
Disease progression		1
Disease recurrence	20	68
Disorientation	4	24
Dissociation	1	2
Disturbance in attention	8	35
Diverticulitis		2
Diverticulum	1	1
Diverticulum intestinal		1
Dizziness	111	485
Dizziness exertional		3
Dizziness postural	12	46
Drooling	1	2
Drug eruption		1
Drug hypersensitivity	1	3
Drug-induced liver injury		1
Drug ineffective	6	65
Drug interaction	1	1
Drug level fluctuating		1
Dry eye	4	10
Dry mouth	11	41
Dry skin	7	16
Dry throat	1	7
Duodenogastric reflux		1
Dysarthria	1	15
Dysgeusia	7	48
Dysgraphia		2
Dyshidrotic eczema	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
					1
		1	5	2	13
					1
		4	14	8	18
					1
1	1	5	10	15	58
		1	3	3	21
				1	2
			5	8	30
					2
				1	1
					1
1	4	37	95	74	390
					3
		3	8	9	38
		1	1		1
					1
				1	3
					1
				6	65
		1	1		
					1
		3	5	1	5
	1	6	11	5	30
		3	6	4	10
	1		2	1	5
					1
			1	1	14
		5	18	2	30
					2
				1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dyskinesia	2	8
Dysmenorrhoea		1
Dyspepsia	6	24
Dysphagia	7	23
Dysphonia	2	8
Dyspnoea	47	234
Dyspnoea exertional	6	15
Dysstasia	6	17
Dysuria	3	14
Ear congestion		1
Ear discomfort	3	9
Ear disorder	1	3
Ear haemorrhage	1	1
Ear infection		3
Ear pain	16	47
Ear pruritus	1	4
Ear swelling	1	4
Eating disorder	3	11
Eczema	3	11
Eczema nummular		1
Electric shock sensation		2
Electrocardiogram abnormal		2
Embolic stroke		2
Embolism	11	23
Emotional disorder	1	4
Emotional distress	1	3
Emphysema		1
Encephalitis	2	2
Energy increased		1
Enlarged uvula		1
Enuresis	2	2
Eosinophilia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2	1	6
			1		
		2	7	4	17
		3	6	4	17
				2	8
		10	32	37	202
		2	5	4	10
		1	3	5	14
			6	3	8
					1
		1	2	2	7
			1	1	2
				1	1
			1		2
		4	8	12	39
			1	1	3
				1	4
			2	3	9
	1	1	2	2	9
			1		
			1		1
					2
					2
				11	23
				1	4
		1	1		2
					1
				2	2
					1
			1		
				2	2
				1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Epigastric discomfort		1
Epiglottitis		1
Epilepsy	3	12
Epistaxis	14	52
Erectile dysfunction		2
Eructation	1	4
Erythema	33	114
Erythema annulare		1
Erythema multiforme	3	6
Erythema of eyelid		1
Essential hypertension		1
Euphoric mood	1	1
Eustachian tube disorder	1	1
Excessive cerumen production	1	1
Excessive exercise	1	1
Exertional headache		2
Exfoliative rash	1	2
Exposure to extreme temperature		1
External ear inflammation		1
External ear pain		1
Extrasystoles	5	8
Extremity necrosis		1
Eye allergy		1
Eye complication associated with device		1
Eye contusion	1	5
Eye discharge		1
Eye disorder	5	7
Eye haemorrhage	3	5
Eye infection		3
Eye inflammation		1
Eye injury	1	1
Eye irritation	5	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				3	12
		5	8	9	44
					2
				1	4
	1	20	50	13	64
					1
				3	6
					1
					1
				1	1
				1	1
				1	1
				1	1
				1	2
					1
					1
			1		
				5	8
					1
			1		
	1	1	3		2
					1
		2	3	3	4
				3	5
					3
			1		
				1	1
		3	4	2	4

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eyelid disorder		2
Eyelid infection	1	1
Eyelid oedema	1	2
Eyelid pain	1	2
Eyelid ptosis		4
Eyelid rash		1
Eyelids pruritus		2
Eye movement disorder		1
Eye oedema		1
Eye pain	12	55
Eye pruritus	1	12
Eye swelling	6	14
Eye symptom		1
Face injury	1	3
Face oedema	1	6
Facial discomfort		2
Facial neuralgia		3
Facial pain	5	24
Facial paralysis	2	35
Facial paresis	1	9
Factitious disorder		1
Faeces discoloured	1	5
Faeces pale		1
Fall	12	46
Fatigue	252	1,171
Fear	1	5
Fear of falling		2
Feeding disorder	3	10
Feeling abnormal	30	128
Feeling cold	31	122
Feeling drunk	1	3
Feeling hot	22	82

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
				1	1
			1	1	1
				1	2
			2		2
			1		
					2
			1		
					1
		7	12	5	43
	2		4	1	8
	2	4	4	2	10
					1
				1	3
		1	3		3
			1		1
					3
		3	9	2	15
	1			2	35
		1	3		6
					1
		1	2		3
					1
		1	7	11	39
11	36	89	237	163	934
			1	1	4
					2
		1	3	2	7
1	2	11	37	19	91
1	3	7	27	24	95
				1	3
		7	25	15	57

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Feeling jittery	1	4
Feeling of body temperature change	7	20
Feeling of despair		1
Femoral artery embolism	1	1
Femoral neck fracture		1
Fibrin D dimer increased	1	5
Fibromyalgia	1	6
Fine motor skill dysfunction	1	1
Flank pain	2	6
Flashback		1
Flat affect	1	2
Flatulence	2	17
Fluid retention	1	5
Flushing	6	25
Follicular lymphoma		1
Folliculitis		1
Food craving	1	1
Food intolerance	1	2
Food poisoning		1
Foreign body sensation in eyes		3
Formication	1	4
Fractured skull depressed		1
Fracture pain	1	1
Freezing phenomenon		2
Frequent bowel movements		2
Full blood count increased		1
Functional gastrointestinal disorder		2
Furuncle		4
Gait disturbance	19	83
Gait inability	3	22
Gamma-glutamyltransferase increased	1	2
Gastric antral vascular ectasia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	3
		5	6	2	14
					1
				1	1
					1
				1	5
		1	2		4
		1	1		
			1	2	5
					1
			1	1	1
		1	4	1	13
				1	5
		4	7	2	18
					1
			1		
				1	1
			1	1	1
					1
					3
				1	4
					1
				1	1
					2
					2
					1
					2
					4
	1	3	14	16	69
	1	1	2	2	20
				1	2
				1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastric cancer		1
Gastric dilatation		2
Gastric disorder		3
Gastric haemorrhage		1
Gastritis		1
Gastroenteritis		4
Gastrointestinal disorder	1	3
Gastrointestinal haemorrhage		2
Gastrointestinal pain	2	14
Gastrointestinal sounds abnormal		2
Gastrooesophageal reflux disease	3	8
Generalised tonic-clonic seizure		4
Giant cell arteritis		2
Gingival bleeding	1	2
Gingival discomfort		1
Gingival pain	1	5
Gingival swelling		1
Gingivitis	1	1
Glossodynia	2	15
Glucose tolerance impaired	1	1
Glucose urine present		1
Goitre	1	2
Gout	6	14
Granulomatosis with polyangiitis	1	1
Grip strength decreased	2	5
Groin pain	2	12
Guillain-Barre syndrome	3	10
Guttate psoriasis		2
Habit cough		1
Haemarthrosis	1	1
Haematemesis	1	2
Haematochezia	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					2
			1		2
					1
					1
			1		3
			1	1	2
					2
			1	2	13
					2
		2	2	1	6
					4
					2
			1	1	1
					1
				1	5
					1
				1	1
		2	6		9
				1	1
					1
			1	1	1
				6	14
				1	1
				2	5
			1	2	11
				3	10
					2
					1
				1	1
				1	2
				1	4

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haematoma	2	4
Haematuria	1	2
Haemoglobin decreased	2	4
Haemolysis	2	3
Haemolytic anaemia	2	2
Haemoptysis	5	6
Haemorrhage	4	14
Haemorrhage subcutaneous		1
Haemorrhage urinary tract		3
Haemorrhagic stroke	2	2
Haemorrhoids		2
Hair texture abnormal		1
Hallucination	1	6
Hallucination, auditory		1
Hallucination, visual	1	1
Halo vision		1
Hand-arm vibration syndrome		1
Hand fracture		1
Hangover		4
Haptoglobin decreased		1
Headache	292	1,234
Head discomfort	4	19
Head injury		8
Heart injury	1	3
Heart rate	1	5
Heart rate abnormal	4	9
Heart rate decreased		5
Heart rate increased	16	64
Heart rate irregular	9	20
Heat oedema		1
Heat stroke	1	2
Heavy menstrual bleeding	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3	1	1
				1	2
			1	2	3
				2	3
				2	2
		1	1	4	5
				4	14
					1
					3
				2	2
					2
			1		
				1	6
					1
				1	1
					1
					1
					4
					1
5	17	110	248	182	986
		3	6	1	13
					8
				1	3
		1	2		3
			1	4	8
					5
		5	12	11	52
1	1	4	6	5	14
					1
		1	1		1
		1	2		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hemiparesis	1	3
Hemiplegia	1	1
Henoch-Schonlein purpura	1	1
Hepatitis	1	1
Hernia	1	1
Herpes ophthalmic		2
Herpes simplex	2	2
Herpes virus infection		1
Herpes zoster	100	191
Herpes zoster oticus		1
Herpes zoster reactivation	3	6
Hiatus hernia	1	1
Hiccups	1	2
Hip fracture		1
Hordeolum		1
Hot flush	13	43
Hyperacusis	1	6
Hyperaesthesia		4
Hyperaesthesia teeth	2	3
Hyperchlorhydria		1
Hypercoagulation		1
Hypergeusia	1	1
Hyperglycaemia		3
Hyperhidrosis	24	114
Hyperkalaemia		1
Hypersensitivity	8	46
Hypersomnia	2	19
Hypertension	17	75
Hypertensive crisis	2	2
Hypertensive urgency		1
Hyperthermia		2
Hyperthyroidism		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
				1	1
				1	1
				1	1
				1	1
					2
		1	1	1	1
					1
		42	54	58	137
					1
		3	3		3
		1	1		
				1	2
					1
					1
		5	8	8	35
			1	1	5
			1		3
		1	1	1	2
					1
					1
		1	1		
					3
	1	7	25	17	89
					1
		3	7	5	39
			3	2	16
		5	12	12	63
				2	2
					1
					2
					2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypertonic bladder		1
Hyperventilation		1
Hypervolaemia		1
Hypoacusis	3	13
Hypoaesthesia	20	86
Hypoaesthesia oral	7	22
Hypocalcaemia		1
Hypoglycaemia		5
Hypokalaemic syndrome		1
Hypokinesia	3	9
Hyponatraemia		3
Hypophagia	3	5
Hypopnoea	2	7
Hyporeflexia		1
Hypotension	7	21
Hypothermia		2
Hypothyroidism		3
Hypotonia		2
Hypovitaminosis		1
Hypovolaemia		1
Hypoxia		3
Illrd nerve disorder		1
Illrd nerve paralysis		3
Illness	22	122
Immobile	1	2
Immune system disorder	1	7
Immune thrombocytopenia	4	13
Immunisation		1
Impaired driving ability		3
Impaired gastric emptying	1	1
Impaired work ability	2	2
Inability to crawl		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
					1
		1	3	2	10
	1	8	24	12	62
		4	8	3	14
					1
			1		4
					1
				3	9
					3
		1	1	2	4
			1	2	6
					1
		3	4	4	17
					2
					3
					2
					1
					1
					3
					1
					3
	1	4	17	18	105
				1	2
		1	1		6
				4	13
					1
					3
				1	1
				2	2
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Inadequate analgesia		1
Inappropriate schedule of product administration	116	166
Incoherent	1	5
Incontinence		2
Incorrect route of product administration	1	8
Increased tendency to bruise		1
Induration		1
Infarction		1
Infection	4	12
Infective exacerbation of chronic obstructive airways disease		1
Inflammation	4	19
Inflammatory marker increased		2
Influenza	16	93
Influenza like illness	38	182
Infusion related reaction	1	1
Initial insomnia	1	1
Injected limb mobility decreased	2	3
Injection related reaction	1	8
Injection site coldness		1
Injection site erythema	3	3
Injection site haemorrhage	1	1
Injection site induration	1	1
Injection site muscle weakness		1
Injection site pain	2	8
Injection site pruritus	2	2
Injection site pustule		1
Injection site rash	1	1
Injection site warmth	1	2
Injury	2	2
Inner ear inflammation	1	1
Insomnia	35	117

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		112	159	4	7
			2	1	3
					2
		1	8		
					1
			1		
					1
				4	12
					1
		1	2	3	17
					2
2	2	4	13	12	80
3	4	16	32	22	150
				1	1
		1	1		
		2	2		1
				1	8
			1		
		3	3		
		1	1		
		1	1		
					1
		2	5		3
		2	2		
					1
		1	1		
		1	1		1
				2	2
				1	1
		10	29	25	88

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Insulin resistance	1	1
Intentional product use issue	1	1
Intermenstrual bleeding	1	2
International normalised ratio abnormal		1
International normalised ratio decreased		3
International normalised ratio increased		10
Interstitial lung disease		1
Intestinal haemorrhage		1
Intestinal ischaemia		2
Intestinal mass		1
Intestinal obstruction		1
Intracranial aneurysm		1
Intranasal paraesthesia		2
Intraocular pressure increased	1	1
Intravascular haemolysis		1
Iridocyclitis		2
Iron deficiency		2
Irregular breathing	1	2
Irregular sleep wake rhythm disorder		1
Irritability	4	8
Irritability postvaccinal	1	1
Irritable bowel syndrome	1	8
Ischaemia		1
Ischaemic hepatitis	1	1
Ischaemic stroke	1	8
Jaundice	2	4
Jaw clicking	1	1
Joint effusion	2	5
Joint lock		1
Joint microhaemorrhage		1
Joint noise		1
Joint range of motion decreased	10	25

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1		
			1	1	1
					1
			1		2
			2		8
					1
					1
					2
					1
					1
					1
			2		
				1	1
					1
					2
					2
				1	2
			1		
		2	4	2	4
				1	1
		1	1		7
					1
				1	1
				1	8
			1	2	3
				1	1
		1	2	1	3
					1
					1
					1
	1	2	5	8	20

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Joint stiffness	5	29
Joint swelling	24	75
Joint vibration		1
Joint warmth		1
Kidney infection		2
Labile blood pressure		1
Laboratory test abnormal	1	1
Labyrinthitis	1	10
Lacrimation increased		14
Laryngitis		1
Left ventricular dysfunction	1	1
Lethargy	19	99
Lichen sclerosus	1	1
Ligament disorder	1	2
Ligamentitis		1
Ligament sprain	1	1
Limb crushing injury		1
Limb discomfort	22	73
Limb immobilisation		2
Limb injury	2	4
Limb mass	2	6
Lip blister		1
Lip dry		3
Lip pain	1	7
Lip swelling	11	45
Listless		4
Livedo reticularis		2
Liver function test abnormal	1	3
Liver function test increased		3
Liver injury		2
Localised infection	1	1
Localised oedema		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4	4	25
		3	9	21	66
					1
					1
					2
					1
				1	1
				1	10
			4		10
					1
				1	1
	2	6	18	13	81
				1	1
				1	2
					1
				1	1
					1
1	4	10	26	12	47
			1		1
			1	2	3
		1	1	1	5
					1
					3
			1	1	6
	1	6	16	5	29
					4
					2
				1	3
					3
					2
		1	1		
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Local reaction		3
Loss of consciousness	6	50
Loss of control of legs	1	2
Loss of personal independence in daily activities	11	28
Lower respiratory tract infection	1	19
Lower respiratory tract infection viral		1
Lung disorder	1	1
Lymphadenitis		2
Lymphadenopathy	63	197
Lymphatic disorder	1	1
Lymph node pain	10	29
Lymphocyte count decreased		1
Lymphocytosis		1
Lymphoedema	2	5
Lymphoma		1
Lymphopenia		1
Macular hole		1
Macular oedema		2
Malaise	99	480
Malignant hypertension		1
Mallory-Weiss syndrome		1
Mass	1	2
Mass excision		1
Mastitis		1
Maternal exposure during pregnancy	1	3
Medial tibial stress syndrome	1	1
Medication error		2
Memory impairment		8
Meniere's disease		5
Meningitis	1	1
Meningitis viral	1	1
Menopausal symptoms		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		1
				6	50
				1	2
		2	7	9	21
				1	19
					1
		1	1		
			1		1
3	3	20	49	43	148
		1	1		
2	2	2	6	8	23
					1
					1
1	1	1	1	1	4
					1
					1
					1
					2
2	6	37	109	62	371
					1
					1
			1	1	1
			1		
					1
			2	1	1
				1	1
			1		1
			1		7
					5
				1	1
				1	1
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Menstrual disorder	1	1
Mental fatigue	1	5
Mental impairment		3
Mesenteric vein thrombosis	1	1
Metamorphopsia		3
Metastatic neoplasm		1
Microembolism		1
Microvascular coronary artery disease		1
Micturition disorder		1
Micturition urgency	2	5
Middle insomnia		5
Migraine	19	75
Migraine with aura	3	12
Miliaria		1
Moaning		1
Mobility decreased	8	28
Monoparesis	2	3
Monoplegia		2
Mood altered		1
Morning sickness		3
Morose		1
Motion sickness	1	5
Motor dysfunction		1
Mouth breathing		1
Mouth cyst		2
Mouth haemorrhage		1
Mouth swelling	3	6
Mouth ulceration	3	18
Movement disorder	4	13
Mucosal haemorrhage	1	1
Multiple allergies	1	2
Multiple organ dysfunction syndrome	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				1	5
	1				3
				1	1
					3
					1
					1
			1		
				2	5
			2		3
		5	13	14	62
		2	5	1	7
			1		
					1
		3	5	5	23
1	1	1	1	1	2
					2
					1
					3
					1
				1	5
					1
					1
			1		1
		1	2	2	4
		1	2	2	16
		1	2	3	11
				1	1
				1	2
				1	3

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Multiple sclerosis		2
Multiple sclerosis relapse		3
Muscle atrophy		1
Muscle contractions involuntary		1
Muscle fatigue	4	18
Muscle rigidity		2
Muscle rupture		1
Muscle spasms	17	56
Muscle spasticity	1	1
Muscle strain		3
Muscle swelling		1
Muscle tightness	2	14
Muscle tone disorder		1
Muscle twitching	2	8
Muscular weakness	21	85
Musculoskeletal chest pain	6	20
Musculoskeletal discomfort	6	17
Musculoskeletal disorder	3	3
Musculoskeletal pain	2	5
Musculoskeletal stiffness	28	112
Mutism	1	1
Myalgia	133	549
Myasthenia gravis		1
Myasthenia gravis crisis		1
Mydriasis	2	2
Myelitis transverse		2
Myelodysplastic syndrome		1
Myocardial infarction	5	31
Myocardial ischaemia	1	5
Myocardial rupture		1
Myocarditis	1	1
Myoclonus	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					3
					1
					1
		1	2	3	16
					2
					1
		7	14	10	42
		1	1		
					3
					1
			3	2	11
					1
		2	3		5
2	2	5	13	16	72
		1	1	5	19
			1	6	16
		1	1	2	2
				2	5
1	2	12	26	16	86
				1	1
2	8	50	107	83	442
					1
					1
		1	1	1	1
					2
					1
				5	31
				1	5
					1
				1	1
				1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myofascial pain syndrome		1
Myositis		5
Nail avulsion		1
Nail discolouration		1
Nail pigmentation		1
Nasal congestion	3	18
Nasal discomfort		5
Nasal dryness	1	1
Nasal injury		1
Nasal obstruction		1
Nasal odour	1	1
Nasal pruritus		1
Nasopharyngitis	13	48
Nausea	147	661
Neck injury		1
Neck mass		2
Neck pain	33	114
Necrosis	1	1
Needle issue		1
Negative thoughts		1
Neoplasm		1
Neoplasm malignant	1	1
Neoplasm recurrence	1	1
Nephrotic syndrome	1	1
Nerve compression		1
Nerve injury		1
Nervousness	3	24
Nervous system disorder		3
Neuralgia	11	33
Neuritis		1
Neurological symptom	3	5
Neuromuscular pain		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					5
			1		
			1		
					1
		1	4	2	14
			1		4
		1	1		
					1
			1		
				1	1
					1
		4	13	9	35
2	5	54	130	93	531
					1
					2
		9	20	24	94
				1	1
					1
					1
			1		
				1	1
				1	1
				1	1
					1
					1
			5	3	19
					3
		3	5	8	28
					1
				3	5
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neuromyopathy		1
Neuropathy peripheral	2	12
Neutropenia	1	4
Neutropenic sepsis		2
Neutrophil count abnormal		1
Nightmare	4	17
Night sweats	7	30
Nocturnal dyspnoea		1
Nodule		2
Non-cardiac chest pain		1
Nuchal rigidity		1
Obstructive pancreatitis		2
Occipital neuralgia		1
Ocular discomfort	2	4
Ocular hyperaemia	2	15
Ocular hypertension		1
Ocular myasthenia		1
Ocular vascular disorder	1	2
Odynophagia		2
Oedema	3	6
Oedema mouth	1	1
Oedema peripheral	2	6
Oesophageal discomfort		1
Oesophageal pain		1
Oesophageal spasm		1
Oesophageal varices haemorrhage		1
Off label use	104	210
Oliguria		1
Ophthalmic herpes zoster	1	3
Ophthalmic migraine	1	3
Ophthalmic vein thrombosis	1	1
Ophthalmoplegic migraine		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				2	12
				1	4
					2
					1
			2	4	15
	1	4	7	3	23
					1
			1		1
			1		
					1
					2
					1
		1	1	1	3
		1	5	1	10
					1
					1
		1	1		1
			1		1
			1	3	5
				1	1
			2	2	4
			1		
					1
					1
					1
		102	203	2	7
					1
				1	3
				1	3
				1	1
			1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Optic ischaemic neuropathy		1
Oral blood blister		1
Oral candidiasis	1	4
Oral discharge		1
Oral discomfort	2	9
Oral disorder		1
Oral herpes	14	25
Oral mucosal blistering	1	2
Oral mucosal exfoliation		1
Oral mucosal roughening		1
Oral pain	1	8
Oral papule		1
Oropharyngeal discomfort	1	5
Oropharyngeal pain	28	106
Osteoarthritis	3	12
Osteoporosis	1	1
Overdose	2	8
Oxygen saturation decreased	3	11
Pain	115	413
Painful respiration	1	3
Pain in extremity	197	664
Pain in jaw	6	25
Pain of skin	6	23
Pallor	3	15
Palmar erythema	1	1
Palpitations	20	102
Pancreatic carcinoma		1
Pancreatitis		1
Pancreatitis acute		1
Pancytopenia		1
Panic attack		1
Panic reaction	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				1	4
			1		
		1	2	1	7
					1
		7	9	7	16
		1	2		
					1
					1
		1	2		6
					1
		1	2		3
1	2	12	25	16	81
		2	2	1	10
				1	1
		2	8		
				3	11
1	5	30	92	85	321
			1	1	2
4	21	71	173	126	491
		3	6	3	19
		2	7	4	16
		1	4	2	11
				1	1
		10	19	10	83
					1
					1
					1
					1
			1	1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Papule		1
Paraesthesia	31	137
Paraesthesia oral	8	40
Paralysis	2	11
Paramnesia		1
Paranasal sinus discomfort		2
Paranasal sinus hypersecretion		1
Paranoia		2
Paraparesis		1
Parapsoriasis	1	1
Parkinson's disease	1	2
Parosmia	2	13
Parotid gland enlargement	1	1
Paroxysmal arrhythmia		1
Partial seizures	1	3
Patellofemoral pain syndrome		1
Paternal exposure before pregnancy		1
Paternal exposure during pregnancy	1	1
Pelvic discomfort		1
Pelvic pain	1	5
Pelvic venous thrombosis	1	1
Pemphigoid	1	2
Pemphigus	1	1
Periarthritis	2	6
Pericardial effusion	1	2
Pericardial haemorrhage	1	2
Pericarditis	2	6
Perinatal depression	1	1
Periorbital cellulitis		1
Periorbital discomfort	1	1
Periorbital haematoma		1
Periorbital infection	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
	1	13	30	18	107
	1	7	15	1	25
				2	11
					1
			1		1
					1
					2
					1
		1	1		
				1	2
		2	4		9
		1	1		
					1
				1	3
					1
					1
		1	1		
					1
			1	1	4
				1	1
				1	2
				1	1
				2	6
				1	2
				1	2
				2	6
				1	1
					1
		1	1		
					1
				1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Periorbital oedema		4
Periorbital pain		1
Periorbital swelling	1	9
Peripheral coldness	11	33
Peripheral embolism		1
Peripheral ischaemia	2	4
Peripheral sensory neuropathy		1
Peripheral swelling	50	149
Peripheral vein thrombus extension		1
Peripheral venous disease	1	1
Peroneal nerve palsy		1
Petechiae	1	4
Petit mal epilepsy		3
Pharyngeal enanthema		1
Pharyngeal inflammation		1
Pharyngeal oedema		1
Pharyngeal paraesthesia		3
Pharyngeal swelling	2	17
Pharyngeal ulceration		1
Pharyngitis		1
Phlebitis	2	7
Phlebitis superficial	1	1
Photophobia	4	13
Photopsia	6	17
Photosensitivity reaction	3	6
pH urine		1
pH urine abnormal	1	1
Physical disability		1
Pigmentation disorder		1
Pityriasis rosea		1
Plantar fasciitis		2
Plasma viscosity abnormal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		3
					1
		1	2		7
		6	12	5	21
					1
				2	4
			1		
		11	27	39	122
					1
				1	1
			1		
			1	1	3
					3
					1
			1		1
					3
		1	2	1	15
					1
					1
			1	2	6
				1	1
				4	13
		3	5	3	12
		2	3	1	3
					1
				1	1
					1
					1
			1		
					2
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Platelet count decreased	6	13
Platelet count increased		1
Platelet disorder		1
Pleurisy		2
Pleuritic pain	1	3
Pneumonia	3	16
Pneumonia fungal		1
Pneumonitis	1	3
Pollakiuria	2	6
Polychromasia		2
Polymyalgia rheumatica	7	20
Polyuria		1
Poor peripheral circulation		1
Poor quality sleep	5	15
Portal vein thrombosis	1	1
Post herpetic neuralgia	2	5
Post laminectomy syndrome		1
Postmenopausal haemorrhage	2	2
Post procedural constipation		1
Post-traumatic stress disorder	1	1
Postural orthostatic tachycardia syndrome		1
Post viral fatigue syndrome	3	14
Pre-existing condition improved		3
Pregnancy		1
Presyncope	3	23
Primary cough headache	1	1
Primary gastrointestinal follicular lymphoma		1
Primary headache associated with sexual activity		1
Procedural dizziness		1
Procedural nausea		2
Proctalgia	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2	5	11
					1
					1
					2
		1	1		2
				3	16
					1
				1	3
			1	2	5
					2
				7	20
					1
			1		
		2	3	3	12
				1	1
		2	3		2
					1
				2	2
			1		
				1	1
					1
	1			3	14
			2		1
			1		
		2	5	1	18
		1	1		
					1
					1
					1
					2
				1	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Product administered at inappropriate site	2	4
Product administration error	1	1
Product complaint		2
Productive cough	1	11
Product preparation issue	1	3
Product use issue	1	61
Prolapse		1
Prostate cancer	1	1
Prostatic disorder		1
Prostatic specific antigen increased	1	1
Prostatomegaly		2
Pruritus	69	220
Psoriasis	3	8
Psoriatic arthropathy		3
Psychogenic seizure		1
Psychotic disorder		1
Pulmonary artery thrombosis		1
Pulmonary congestion		2
Pulmonary embolism	21	68
Pulmonary fibrosis		1
Pulmonary mass	1	1
Pulmonary oedema	1	6
Pulmonary pain	1	6
Pulmonary thrombosis		2
Pulseless electrical activity		1
Puncture site bruise	1	1
Purpura	1	3
Pustular psoriasis	1	1
Pyrexia	96	485
Q fever	1	2
Quadrantanopia		2
Rales	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	4		
				1	1
					2
1	1		3	1	8
		1	3		
		1	59		2
					1
				1	1
			1		
			1		1
1	1	43	86	26	134
				3	8
					3
					1
					1
					2
				21	68
					1
				1	1
				1	6
			1	1	5
	1				2
					1
		1	1		
				1	3
		1	1		
1	3	24	67	72	418
				1	2
					2
				1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rash	82	217
Rash erythematous	29	92
Rash macular	16	35
Rash maculo-papular		2
Rash morbilliform	1	1
Rash papular	9	19
Rash pruritic	22	78
Rash vesicular	2	8
Raynaud's phenomenon	1	4
Reaction to excipient		1
Reaction to preservatives		2
Reaction to previous exposure to any vaccine		1
Reading disorder		1
Rectal discharge	2	2
Rectal haemorrhage	3	6
Reflux gastritis		1
Renal cyst		2
Renal disorder	1	3
Renal failure	1	4
Renal pain	2	15
Respiration abnormal	1	7
Respiratory acidosis	1	2
Respiratory arrest		4
Respiratory depression		1
Respiratory disorder	1	5
Respiratory distress	1	2
Respiratory failure		2
Respiratory muscle weakness		1
Respiratory rate increased	2	5
Respiratory symptom	1	2
Respiratory tract congestion		1
Respiratory tract infection		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		49	86	33	131
	2	15	33	14	59
		9	16	7	19
			1		1
				1	1
		6	8	3	11
		14	25	8	53
		2	4		4
			2	1	2
			1		
					2
					1
					1
		1	1	1	1
				3	6
					1
					2
				1	3
				1	4
			2	2	13
		1	1		6
				1	2
					4
					1
			1	1	4
				1	2
					2
					1
				2	5
	1			1	2
					1
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory tract irritation		1
Restless legs syndrome		1
Restlessness	1	8
Retching	2	11
Retinal artery occlusion	1	2
Retinal detachment		1
Retinal disorder		1
Retinal exudates		1
Retinal migraine		2
Retinal vasculitis		1
Retinal vein occlusion	2	6
Retroperitoneal haemorrhage		1
Revers ble cerebral vasoconstriction syndrome		1
Rheumatoid arthritis	8	27
Rhinitis		1
Rhinorrhoea	11	48
Rib fracture	1	1
Road traffic accident	1	1
Rotator cuff syndrome		1
Salivary duct obstruction		1
Salivary gland enlargement		1
Salivary gland pain	1	2
Salivary hypersecretion	1	3
Sarcoidosis		1
SARS-CoV-2 ant body test negative		2
SARS-CoV-2 ant body test positive		1
SARS-CoV-2 test		1
SARS-CoV-2 test positive		3
Scab	1	3
Scar pain	1	3
Sciatica	1	6
Scleritis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
			2	1	6
			1	2	10
				1	2
					1
			1		
					1
			2		
					1
				2	6
					1
					1
				8	27
					1
		3	10	8	38
				1	1
				1	1
					1
					1
		1	1		1
			1	1	2
					1
			1		1
			1		2
		1	1		2
		1	2		1
			1	1	5
				1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Scratch	2	4
Seasonal allergy	3	4
Seborrhoea		1
Secretion discharge	1	2
Seizure	3	31
Seizure cluster		2
Sensation of blood flow		2
Sensation of foreign body		3
Sensitive skin	1	6
Sensory disturbance	5	13
Sensory loss	1	8
Sepsis		9
Sepsis syndrome		1
Serum sickness		1
Serum sickness-like reaction		2
Severe acute respiratory syndrome		1
Shock	1	6
Shock symptom		1
Sialoadenitis		1
Sight disability		1
Sinus congestion	3	7
Sinus disorder	1	4
Sinus headache	3	20
Sinusitis	3	10
Sinus node dysfunction		1
Sinus pain	1	3
Sitting disability	1	2
Skin burning sensation	2	8
Skin discharge		1
Skin discolouration	1	6
Skin discomfort	1	1
Skin disorder	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	3
			1	3	3
					1
				1	2
				3	31
					2
					2
					3
		1	2		4
		3	4	2	9
			1	1	7
					9
					1
					1
					2
					1
				1	6
					1
					1
					1
		2	2	1	5
				1	4
1	1	1	3	2	17
		1	1	2	9
					1
		1	1		2
				1	2
			2	2	6
					1
				1	6
				1	1
				1	3

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin erosion		1
Skin exfoliation	5	10
Skin fissures	2	4
Skin haemorrhage		3
Skin induration		1
Skin infection		3
Skin irritation	3	13
Skin laceration		1
Skin lesion	5	11
Skin lesion inflammation	1	1
Skin mass		2
Skin odour abnormal	1	1
Skin papilloma	1	1
Skin reaction	4	7
Skin sensitisation	1	1
Skin striae	1	1
Skin swelling	2	6
Skin temperature		1
Skin test positive	1	1
Skin tightness	2	4
Skin ulcer		1
Skin warm	1	11
Skin weeping	1	2
Skin wrinkling		2
Skull fracture		1
Sleep apnoea syndrome		1
Sleep deficit	1	2
Sleep disorder	11	40
Sleep disorder due to a general medical condition	1	3
Sleep disorder due to general medical condition, insomnia type		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	3	4	7
		1	1	1	3
					3
					1
			2		1
		3	5		8
			1		
1	1	2	3	3	8
				1	1
			2		
				1	1
		1	1		
		2	2	2	5
		1	1		
				1	1
			2	2	4
					1
		1	1		
		1	1	1	3
					1
			1	1	10
				1	2
			1		1
					1
					1
				1	2
		2	8	9	32
				1	3
					2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Slow speech		1
Sluggishness		1
Small intestinal haemorrhage	1	2
Sneezing	7	24
Soft tissue inflammation	1	1
Solar lentigo	1	1
Somatic symptom disorder		1
Somnolence	13	63
Speech disorder	4	19
Spinal disorder		1
Spinal osteoarthritis		1
Spinal pain	2	9
Splenic artery embolisation		1
Splenic rupture		2
Splenic vein thrombosis	1	1
Sputum abnormal		1
Sputum discoloured		1
Sputum increased	1	1
Staring		1
Status epilepticus	2	4
Stevens-Johnson syndrome	1	3
Stomach mass	1	1
Stomatitis		6
Stress	2	4
Stridor		1
Stroke volume decreased	1	1
Subarachnoid haemorrhage	1	3
Subdural haematoma	1	1
Subdural haemorrhage		1
Sudden death	1	4
Sudden hearing loss		6
Suicidal behaviour		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
				1	2
		1	3	6	21
		1	1		
				1	1
					1
		6	16	7	47
	1		3	4	16
					1
					1
			1	2	8
					1
					2
				1	1
					1
				1	1
					1
				2	4
				1	3
				1	1
	1		1		5
				2	4
					1
				1	1
				1	3
				1	1
					1
				1	4
					6
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Suicidal ideation	1	1
Suicide attempt		1
Sunburn	1	1
Supraventricular tachycardia	2	2
Suspected COVID-19	5	54
Suspiciousness	1	1
Sweating fever	2	5
Swelling	35	96
Swelling face	14	59
Swelling of eyelid	1	9
Swollen tongue	10	39
Syncope	26	89
Synovial cyst		2
Synovitis		1
Systemic immune activation		1
Systemic lupus erythematosus	1	1
Systolic hypertension		1
Tachyarrhythmia	1	1
Tachycardia	4	33
Tachypnoea		1
Tardive dyskinesia		1
Taste disorder	6	26
Tearfulness	1	2
Temperature intolerance		3
Temperature regulation disorder	2	2
Tenderness	5	20
Tendon disorder	1	1
Tendon injury	2	4
Tendonitis		2
Tendon pain	1	3
Tendon rupture	1	1
Tension		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
				1	1
				2	2
		2	12	3	42
				1	1
				2	5
1	1	9	23	26	73
	1	5	14	9	45
			2	1	7
		3	8	7	31
	1			26	89
					2
					1
					1
	1			1	1
					1
	1	1	3	3	30
					1
					1
		4	8	2	18
		1	1		1
					3
				2	2
		3	14	2	6
				1	1
		1	1	1	3
					2
			1	1	2
				1	1
					2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tension headache	2	20
Terminal insomnia	1	2
Testicular swelling		1
Testis discomfort		1
Tetany		1
Therapeutic response unexpected	4	10
Thermal burn	1	3
Thinking abnormal		5
Thirst	6	21
Throat clearing	1	2
Throat irritation	3	11
Throat tightness	1	13
Thrombocytopenia	15	28
Thrombophlebitis		3
Thrombophlebitis superficial		1
Thrombosis	18	45
Thrombosis in device		1
Thrombotic stroke	1	1
Thyroiditis	1	1
Thyroxine free increased		1
Tinnitus	41	113
Tongue blistering	1	4
Tongue coated	1	2
Tongue discomfort		3
Tongue disorder	2	10
Tongue dry	1	2
Tongue erythema		1
Tongue movement disturbance	1	2
Tongue oedema		2
Tongue ulceration	1	3
Tonic convulsion		3
Tonsillar cyst		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	2	18
				1	2
			1		
					1
					1
		4	7		3
				1	3
			1		4
		2	4	4	17
				1	2
		1	1	2	10
		1	3		10
				15	28
			1		2
			1		
				18	45
					1
				1	1
		1	1		
					1
		10	15	31	98
				1	4
		1	1		1
					3
		1	3	1	7
		1	1		1
					1
		1	2		
					2
				1	3
					3
			1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Toothache	1	12
Tooth fracture		2
Tooth infection		1
Toxic epidermal necrolysis		1
Toxicity to various agents		
Tracheal inflammation		1
Tracheal pain		1
Transient global amnesia	2	5
Transient ischaemic attack	8	34
Traumatic haemorrhage		1
Tremor	23	137
Trigger finger		2
Tri-iodothyronine decreased		1
Trismus	1	1
Type 1 diabetes mellitus		2
Type 2 diabetes mellitus		1
Type IV hypersensitivity reaction		1
Typical aura without headache		1
Ulcer		1
Ulcerative keratitis		1
Unresponsive to stimuli	1	11
Upper-airway cough syndrome	1	2
Upper respiratory tract congestion		2
Ureteric stenosis		1
Urethral stenosis		1
Urinary incontinence		5
Urinary retention	1	5
Urinary tract infection	4	17
Urine abnormality	1	2
Urine flow decreased	1	2
Urine odour abnormal		2
Urine output		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	1	10
					2
					1
					1
	1				
			1		
			1		
		1	1	1	4
				8	34
					1
	3	8	23	15	114
			1		1
					1
				1	1
					2
					1
					1
					1
					1
				1	11
				1	2
			1		1
					1
					5
				1	5
	1	1	5	3	12
			1	1	1
			1	1	1
					2
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Urine output decreased		1
Urine output increased	1	2
Urticaria	13	47
Urticaria chronic		1
Uveitis	1	3
Vaccination complication	1	3
Vaccination failure	1	1
Vaccination site bruising	5	16
Vaccination site calcification		1
Vaccination site cellulitis	1	1
Vaccination site coldness		1
Vaccination site discolouration		1
Vaccination site discomfort	5	13
Vaccination site erythema	22	72
Vaccination site haemorrhage	1	4
Vaccination site hyperaesthesia	1	1
Vaccination site hypoaesthesia	1	1
Vaccination site induration	3	10
Vaccination site infection		4
Vaccination site inflammation	1	7
Vaccination site irritation	2	3
Vaccination site joint erythema		1
Vaccination site joint movement impairment	1	1
Vaccination site joint pain		1
Vaccination site lymphadenopathy		1
Vaccination site mass	9	26
Vaccination site movement impairment	3	7
Vaccination site necrosis		1
Vaccination site oedema		2
Vaccination site pain	92	322
Vaccination site paraesthesia	1	4
Vaccination site pruritus	13	35

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1	1	1
		7	16	6	31
					1
				1	3
				1	3
				1	1
		3	8	2	8
					1
				1	1
					1
					1
		3	8	2	5
		17	32	5	40
				1	4
				1	1
				1	1
		3	7		3
			1		3
		1	3		4
		2	2		1
					1
				1	1
					1
					1
		5	11	4	15
		1	3	2	4
					1
					2
1	1	59	143	33	179
			1	1	3
		13	25		10

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site rash	3	14
Vaccination site reaction	2	11
Vaccination site swelling	28	84
Vaccination site urticaria	1	1
Vaccination site vesicles		1
Vaccination site warmth	10	29
Vaccine breakthrough infection		1
Vaginal cyst		1
Vaginal haemorrhage	4	4
Varicella	2	2
Varicella zoster virus infection		1
Varicose vein		2
Vascular headache		1
Vascular pain	1	3
Vascular stent thrombosis		1
Vasculitic rash	1	3
Vasculitis	3	11
Vasodilatation	1	3
Vein disorder		2
Venous haemorrhage		1
Venous thrombosis		1
Venous thrombosis limb		1
Ventricular extrasystoles	2	2
Ventricular fibrillation		1
Ventricular tachycardia	1	3
Vertigo	25	105
Vertigo labyrinthine	2	4
Vertigo positional	1	6
Vestibular migraine		1
Vestibular neuritis	1	4
Viral infection	2	4
Viral sepsis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	7	1	7
		1	4	1	7
		19	44	9	40
		1	1		
					1
		7	14	3	15
					1
					1
				4	4
		1	1	1	1
					1
					2
					1
			2	1	1
					1
			1	1	2
			1	3	10
				1	3
			1		1
					1
					1
				2	2
					1
				1	3
		4	14	21	91
		1	1	1	3
			1	1	5
					1
				1	4
				2	4
				1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Virologic failure		1
Vision blurred	11	47
Visual acuity reduced		2
Visual impairment	15	43
Vlth nerve paralysis	1	1
Vitreous detachment	5	7
Vitreous floaters	4	8
Vitreous haemorrhage		2
Vitreous haze	1	1
Vomiting	43	225
Vomiting projectile	1	6
Vomiting psychogenic		1
Vulvovaginal pain		1
Vulvovaginal rash		1
Wa king aid user	1	1
Water pollution		1
Weight bearing difficulty		3
Weight decreased	7	18
Weight increased		2
Wheezing	3	20
White blood cell count abnormal		1
White blood cell count decreased		3
White blood cell count increased		2
White blood cell disorder		1
Withdrawal syndrome	1	2
Wound		5
Wound complication	2	2
Wound drainage	1	1
Wound secretion		2
Wrist fracture	1	2
Writer's cramp		1
Wrong product administered	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		4	9	7	38
					2
		7	16	8	27
				1	1
				5	7
		3	4	1	4
					2
				1	1
		10	36	33	189
				1	6
					1
			1		
			1		
				1	1
					1
			1		2
			1	7	17
					2
		1	4	2	16
					1
			1		2
					2
					1
			1	1	1
			1		4
		1	1	1	1
				1	1
					2
				1	2
					1
		2	3		

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* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Wrong technique in product usage process		1						1
Yellow skin	1	1					1	1
	4	7			4	7		
	5,493	21,451	69	219	1967	4727	3526	16724

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* AE=Adverse Event
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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal adhesions		2						2
Abdominal discomfort	2	13			1	5	1	8
Abdominal distension	2	12				4	2	8
Abdominal lymphadenopathy		1						1
Abdominal pain	4	33			2	8	2	25
Abdominal pain lower		4						4
Abdominal pain upper	5	28			3	12	2	16
Abdominal tenderness		1						1
Abnormal behaviour	1	2			1	1		1
Abnormal dreams		4				3		1
Abnormal weight gain		1						1
Accidental overdose		1				1		
Acidosis		2				1		1
Activated partial thromboplastin time prolonged	2	3					2	3
Activated partial thromboplastin time shortened		1						1
Acute abdomen		1						1
Acute aortic syndrome	1	1					1	1
Acute cardiac event		2						2
Acute coronary syndrome		1						1
Acute disseminated encephalomyelitis	1	1					1	1
Acute kidney injury		14						14
Acute myocardial infarction		8						8
Acute pulmonary oedema		1						1
Acute respiratory failure		1						1
Adverse drug reaction		1				1		
Age-related macular degeneration		1						1
Ageusia	2	10				2	2	8
Aggression		2						2
Agitation		12				5		7
Alanine aminotransferase increased		1						1
Alexia		1				1		
Allergy to vaccine		5				4		1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Alopecia		1
Altered state of consciousness		1
Alveolitis		1
Amnesia		14
Amylase increased		1
Anaemia	1	6
Anal incontinence	1	4
Anaphylactic reaction	1	16
Anaphylactic shock	1	1
Angina pectoris	1	8
Angioedema		9
Angle closure glaucoma	1	1
Ankylosing spondylitis		1
Anosmia	1	6
Anticoagulation drug level below therapeutic		1
Anuria		3
Anxiety	1	11
Aortic aneurysm		1
Aortic aneurysm rupture		1
Aortic arteriosclerosis		1
Aortic dissection		1
Aortic embolus		1
Aortic stenosis		1
Apathy		3
Aphasia		9
Aphonia	1	4
Appendicitis	1	2
Aptyalism		1
Areflexia		1
Arrhythmia		3
Arterial thrombosis		1
Arteriosclerosis coronary artery		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
			3		11
			1		
			1	1	5
				1	4
				1	16
				1	1
				1	8
					9
				1	1
					1
			2	1	4
					1
					3
			1	1	10
					1
					1
					1
					1
					3
			1		8
		1	1		3
				1	2
			1		
					1
					3
					1
					2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arthralgia	20	173
Arthritis	3	16
Arthritis reactive		1
Arthropathy		2
Ascites		1
Aspiration		4
Asthenia	12	112
Asthenopia		3
Asthma		4
Asymptomatic COVID-19		6
Ataxia		3
Atelectasis		1
Atrial f brillation	4	34
Atrial flutter		1
Atrioventricular block		1
Atrioventricular block complete		1
Autoimmune disorder		1
Autoimmune haemolytic anaemia	1	1
Autoscopy		1
Axillary pain	2	2
Axonal neuropathy		1
Back pain	4	62
Bacterial infection		1
Balance disorder	8	51
Bedridden	1	8
Bell's palsy	3	16
Bile duct stone		1
Biliary sepsis		1
Bite		1
Bladder pain		1
Blepharitis		1
Blindness		8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		8	39	12	134
			2	3	14
					1
			1		1
					1
					4
1	1	3	29	9	83
			1		2
					4
					6
					3
					1
				4	34
					1
					1
					1
				1	1
					1
				2	2
					1
		3	14	1	48
					1
1	2	5	18	3	33
		1	2		6
				3	16
					1
					1
					1
					1
					1
					8

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blindness transient		1
Blindness unilateral		1
Blister	10	22
Blood alkaline phosphatase increased		1
Blood blister	3	5
Blood creatine phosphokinase increased		2
Blood creatinine increased		1
Blood electrolytes increased		1
Blood fibrinogen decreased		1
Blood glucose decreased		1
Blood glucose fluctuation		1
Blood glucose increased		8
Blood lactic acid increased		2
Blood magnesium decreased		1
Blood potassium increased		1
Blood pressure abnormal		1
Blood pressure decreased		4
Blood pressure diastolic increased		1
Blood pressure increased		18
Blood pressure orthostatic abnormal		1
Blood pressure systolic decreased		1
Blood pressure systolic increased		1
Blood sodium decreased	2	7
Blood thrombin		1
Blood urea increased		2
Blood urine present	2	3
Blood viscosity increased		1
Bloody discharge		1
Blue toe syndrome	1	1
Body temperature		3
Body temperature abnormal	2	6
Body temperature decreased	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
		7	11	3	11
					1
		1	1	2	4
			1		1
					1
			1		
					1
					1
			2		6
			1		1
			1		
			1		
			1		
					4
					1
			6		12
					1
					1
					1
		1	3	1	4
					1
			1		1
		1	1	1	2
			1		
					1
		1	1		
			2		1
		1	3	1	3
				1	4

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Body temperature fluctuation		1
Body temperature increased	1	8
Bone contusion		1
Bone pain		8
Bradycardia		3
Bradyphrenia		1
Brain hypoxia		1
Brain injury		1
Brain oedema		1
Brain stem stroke		1
Breast cancer		1
Breast cancer stage I	1	1
Breast pain		2
Breath odour		1
Burning sensation	4	12
Bursitis	1	3
Cachexia		1
Cardiac arrest	1	21
Cardiac disorder	1	3
Cardiac failure	1	6
Cardiac failure chronic		1
Cardiac failure congestive		4
Cardiac valve disease		1
Cardiopulmonary failure		1
Cardio-respiratory arrest		1
Carotid artery disease		1
Carotid artery thrombosis		1
Carpal tunnel syndrome		1
Cellulitis	2	17
Central venous pressure abnormal		1
Central vision loss		1
Cerebellar infarction		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			4	1	4
			1		
			2		6
					3
					1
					1
					1
					1
					1
					1
				1	1
					2
			1		
		3	6	1	6
			1	1	2
					1
				1	21
				1	3
				1	6
					1
					4
					1
					1
					1
					1
				2	17
			1		
					1
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebellar stroke		1
Cerebral artery embolism	1	1
Cerebral artery thrombosis	1	2
Cerebral disorder		1
Cerebral haemorrhage	1	10
Cerebral infarction	3	13
Cerebral thrombosis		6
Cerebral venous sinus thrombosis		3
Cerebral venous thrombosis		1
Cerebrovascular accident	9	90
Cerebrovascular disorder	1	1
Charles Bonnet syndrome		1
Chest discomfort	2	21
Chest injury		1
Chest pain	6	53
Chillblains	1	2
Chills	12	161
Choking	1	1
Choking sensation		1
Cholelithiasis		2
Chromaturia		4
Chronic kidney disease		3
Chronic obstructive pulmonary disease	2	4
Circulatory collapse		17
Circumoral swelling		1
Clostridium difficile infection		1
Clot retraction		1
Cluster headache		4
Coagulation time prolonged		1
Coagulopathy		2
Cognitive disorder	1	12
Cold sweat		8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
				1	2
					1
				1	10
				3	13
					6
					3
					1
				9	90
				1	1
					1
		1	7	1	14
					1
	1	1	10	5	43
		1	2		
1	3	8	44	4	117
				1	1
					1
					2
			1		3
					3
		1	1	1	3
					17
			1		
					1
					1
			3		1
					1
					2
				1	12
			2		6

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Colitis	1	3
Colitis microscopic		1
Colitis ulcerative		2
Coma		1
Coma scale abnormal		2
Communication disorder		2
Condition aggravated	2	23
Confusional state	6	102
Conjunctival haemorrhage		4
Conjunctivitis		1
Conjunctivitis bacterial		1
Constipation	3	14
Contusion	6	25
Coordination abnormal	1	7
Corneal graft rejection	1	1
Coronary artery disease		2
Coronary artery occlusion		1
Coronary artery stenosis		1
Cor pulmonale		1
Costochondritis		1
Cough	5	54
Cough decreased		1
COVID-19	4	99
COVID-19 immunisation		1
COVID-19 pneumonia		16
C-reactive protein increased	2	9
Creatinine renal clearance decreased		1
Crying		3
Crystal arthropathy		1
Culture negative		1
Cutaneous vasculitis	1	1
Cyanosis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
					1
					2
					1
					2
			1		1
			3	2	20
		2	19	4	83
					4
					1
					1
		1	4	2	10
		1	6	5	19
			1	1	6
				1	1
					2
					1
					1
					1
		3	21	2	33
			1		
		1	10	3	89
					1
					16
			3	2	6
					1
			1		2
					1
					1
				1	1
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cystitis		1
Deafness	1	5
Deafness bilateral	1	1
Deafness neurosensory	1	1
Deafness unilateral	1	4
Death	4	58
Decreased appetite	11	113
Decreased interest	1	3
Decubitus ulcer		1
Deep vein thrombosis	8	31
Dehydration	1	17
Delirium		22
Delusion		2
Dementia		7
Dementia Alzheimer's type		1
Demyelination		1
Dental discomfort	1	1
Depressed level of consciousness		4
Depressed mood	3	7
Depression	1	3
Derealisation	1	1
Dermatitis		4
Dermatitis allergic		5
Dermatitis bullous		2
Dermatitis exfoliative		1
Dermatitis exfoliative generalised	1	1
Device related infection		1
Diabetes mellitus		4
Diabetes mellitus inadequate control		1
Diabetic diet		1
Diabetic ketoacidosis		1
Diarrhoea	14	174

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	5
				1	1
				1	1
				1	4
				4	58
	2	3	24	8	89
				1	3
					1
				8	31
			4	1	13
					22
			1		1
					7
					1
					1
				1	1
					4
		1	2	2	5
				1	3
				1	1
			2		2
			3		2
					2
					1
				1	1
					1
					4
					1
					1
					1
	1	13	52	1	122

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Diplegia		2
Diplopia	1	8
Discomfort	2	11
Disease progression	1	1
Disease recurrence	8	30
Disorganised speech		2
Disorientation		12
Disseminated intravascular coagulation		1
Disseminated varicella zoster virus infection		1
Dissociation		1
Disturbance in attention		4
Dizziness	16	191
Dizziness exertional		1
Dizziness postural		16
Drug hypersensitivity		2
Drug ineffective	3	103
Drug interaction		1
Drug withdrawal syndrome	1	1
Dry eye	1	4
Dry mouth	1	10
Dry skin	2	8
Dry throat		3
Dysarthria		21
Dysgeusia	1	13
Dyskinesia		4
Dyspepsia		10
Dysphagia	2	14
Dysphonia	1	4
Dyspnoea	18	149
Dyspnoea exertional		3
Dyssomnia		1
Dysstasia	1	14

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
			3	1	5
		1	5	1	6
				1	1
		1	3	7	27
					2
			1		11
					1
					1
			1		
			2		2
2	2	4	56	12	135
					1
			2		14
			2		
				3	103
			1		
				1	1
		1	4		
		1	4		6
		1	6	1	2
					3
			1		20
		1	5		8
					4
			1		9
		1	2	1	12
		1	2		2
		6	32	12	117
			2		1
			1		
			3	1	11

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysuria	1	3
Ear congestion	1	1
Ear discomfort		2
Ear infection		1
Ear pain	1	6
Ear swelling	1	1
Eating disorder		4
Eczema	2	5
Effusion	1	1
Electric shock sensation	1	3
Electrocardiogram abnormal		1
Electrocardiogram ST segment abnormal		1
Electrocardiogram ST segment elevation		2
Embolic cerebral infarction		1
Embolic stroke		2
Embolism	3	9
Emotional disorder		2
Emotional distress		4
Emphysema		1
Encephalitis	1	2
Encephalitis viral		1
Encephalopathy		1
Enteritis		1
Enuresis	1	4
Eosinophilia	1	1
Epiglottic oedema		1
Epilepsy	1	6
Epistaxis	6	40
Eructation	1	3
Erythema	12	72
Erythema multiforme	1	1
Essential hypertension		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
				1	1
					2
			1		
			1	1	5
				1	1
			1		3
		1	2	1	3
				1	1
			1	1	2
					1
					1
					2
					1
					2
				3	9
					2
			1		3
					1
				1	2
					1
					1
			1		
			2	1	2
		1	1		
					1
				1	6
		3	12	3	28
		1	1		2
		6	42	6	30
				1	1
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Expired product administered		1
Exposure keratitis		1
Extrasystoles	1	2
Eye allergy		1
Eye contusion		1
Eye discharge	1	1
Eye disorder		2
Eye haemorrhage	1	2
Eye infection		1
Eyelid disorder	1	1
Eye movement disorder	1	1
Eye pain	5	15
Eye pruritus	2	6
Eye swelling	3	13
Face oedema		1
Face presentation		1
Facial discomfort		1
Facial nerve disorder		1
Facial neuralgia		1
Facial pain		6
Facial paralysis	1	17
Facial paresis		3
Faeces discoloured		4
Faeces hard		1
Faeces pale		1
Fall	5	72
Fatigue	30	414
Fear		3
Feeding disorder		10
Feeling abnormal	5	39
Feeling cold	5	54
Feeling drunk		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
				1	2
					1
			1		
		1	1		
					2
				1	2
					1
				1	1
		1	1		
		2	4	3	11
		2	4		2
			3	3	10
					1
			1		
			1		1
			1		
			1		5
				1	17
			2		1
			3		1
					1
					1
		3	19	2	53
1	13	15	120	15	294
					3
			4		6
	1	1	13	4	26
		5	22		32
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Feeling hot	3	34
Feeling jittery		1
Feeling of body temperature change	1	7
Femoral neck fracture		1
Femur fracture		1
Fibrin D dimer increased		3
Fibromyalgia		3
Flank pain		2
Flatulence		5
Fluid intake reduced		1
Fluid retention	1	2
Flushing	3	9
Folliculitis		1
Food allergy		1
Food aversion		1
Food refusal		2
Foreign body in urogenital tract	1	1
Foreign body sensation in eyes	1	2
Fracture		1
Frequent bowel movements		2
Functional gastrointestinal disorder		1
Fungal skin infection		1
Furuncle		1
Gait disturbance	8	41
Gait inability	4	20
Gastric haemorrhage		1
Gastritis		2
Gastroenteritis		3
Gastroenteritis rotavirus		1
Gastroenteritis viral		1
Gastrointestinal carcinoma		1
Gastrointestinal disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	17	1	17
			1		
		1	3		4
					1
					1
					3
					3
			1		1
			1		4
					1
				1	2
		3	5		4
					1
					1
					1
			1		1
				1	1
		1	2		
					1
					2
					1
					1
					1
		5	10	3	31
			4	4	16
					1
					2
			1		2
					1
					1
					1
			1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastrointestinal pain		6
Gastrointestinal surgery		1
Gastroesophageal reflux disease	1	2
Generalised tonic-clonic seizure	1	5
General physical health deterioration	2	10
Genital herpes	1	1
Genital herpes simplex	1	1
Giant cell arteritis		1
Gingival pain		2
Glassy eyes		1
Glaucoma		1
Gliososis		1
Glomerulonephritis minimal lesion		1
Glossodynia		4
Gout		7
Gouty tophus		1
Grip strength decreased	1	3
Groin pain	1	2
Guillain-Barre syndrome	1	5
Haemarthrosis		1
Haematemesis		7
Haematochezia		4
Haematoma	1	4
Haematuria	1	3
Haemoglobin decreased	1	4
Haemolysis	1	1
Haemoptysis		3
Haemorrhage	5	16
Haemorrhage intracranial		5
Haemorrhage subcutaneous		1
Haemorrhage urinary tract		1
Haemorrhagic infarction		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					6
					1
		1	1		1
				1	5
		1	3	1	7
				1	1
				1	1
					1
			1		1
					1
					1
					1
			1		3
					7
					1
				1	3
		1	2		
				1	5
					1
					7
					4
			1	1	3
			1	1	2
			1	1	3
				1	1
					3
	1			5	16
					5
					1
					1
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haemorrhagic stroke		3
Haemorrhoids	1	1
Hair texture abnormal		1
Hallucination	1	25
Hallucination, auditory		1
Hallucination, visual		5
Halo vision	1	1
Hand-eye coordination impaired		1
Headache	22	306
Head banging	1	1
Head discomfort		5
Head injury		7
Heart injury		2
Heart rate abnormal		1
Heart rate decreased		5
Heart rate increased		13
Heart rate irregular	2	5
Heavy menstrual bleeding		1
Hemianopia homonymous		1
Hemiparesis		13
Hemiplegia		1
Hepatic artery embolism		1
Hepatic cirrhosis	1	1
Hepatic enzyme increased		1
Hepatic vein thrombosis	1	1
Hepatocellular carcinoma	1	1
Herpes simplex encephalitis		1
Herpes virus infection		1
Herpes zoster	34	95
Herpes zoster meningoencephalitis		1
Herpes zoster oticus	2	2
Herpes zoster reactivation	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
		1	1		
					1
				1	25
					1
					5
		1	1		
					1
3	6	9	87	13	219
				1	1
			2		3
			1		6
					2
					1
					5
			2		11
				2	5
					1
					1
					1
				1	1
			1		
				1	1
					1
					1
		17	40	17	55
					1
				2	2
				1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hilar lymphadenopathy	1	1
Hot flush	2	10
Hyperacusis	1	4
Hyperglycaemia	1	5
Hyperhidrosis	3	36
Hyperparathyroidism	1	1
Hyperpyrexia		1
Hypersensitivity	2	22
Hypersensitivity pneumonitis		1
Hypersomnia	3	15
Hypertension	4	30
Hypertensive crisis		1
Hypertensive heart disease		4
Hypertonia		2
Hyperventilation		2
Hypnagogic hallucination		1
Hypoacusis	1	4
Hypoaesthesia	4	29
Hypoaesthesia oral		1
Hypoglycaemia	1	4
Hypokinesia	1	6
Hyponatraemia		2
Hypophagia	1	4
Hypopnoea		4
Hyporeflexia		2
Hypotension		33
Hypothermia		6
Hypotonia	1	2
Hypoxia		5
Illness	2	50
Illusion		1
Immobile	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		2	6		4
				1	4
				1	5
		1	10	2	26
				1	1
					1
		2	9		13
					1
		1	4	2	11
	1	1	4	3	26
					1
					4
					2
					2
					1
		1	3		1
		1	4	3	25
					1
		1	2		2
				1	6
					2
				1	4
					4
			1		1
			7		26
					6
				1	2
					5
			10	2	40
			1		
				2	4

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Immune-mediated hepatic disorder		1
Immune system disorder	1	1
Immune thrombocytopenia	4	11
Immunisation reaction		1
Immunodeficiency	1	1
Impaired driving ability		1
Impaired gastric emptying		1
Impaired quality of life		1
Impaired work ability	1	1
Inappropriate schedule of product administration	25	80
Incoherent		1
Incomplete course of vaccination		1
Incontinence		8
Incorrect route of product administration	1	7
Increased tendency to bruise		2
Infarction		3
Infection	2	16
Inflammation	1	9
Inflammatory marker increased		1
Influenza	4	26
Influenza like illness	2	75
Infusion related reaction		1
Inguinal mass		1
Initial insomnia		1
Injection related reaction	1	1
Injection site cellulitis		1
Injection site erythema		3
Injection site paraesthesia	1	2
Injection site rash		1
Injection site swelling		2
Injury	1	1
Insomnia	5	32

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
				4	11
					1
				1	1
			1		
					1
					1
		1	1		
		25	80		
					1
			1		
					8
		1	7		
			2		
					3
			3	2	13
		1	4		5
					1
		3	9	1	17
1	1		18	2	57
					1
					1
					1
				1	1
					1
			2		1
		1	2		
					1
			1		1
				1	1
		4	11	1	21

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Internal haemorrhage	1	1
International normalised ratio abnormal		1
International normalised ratio decreased		5
International normalised ratio increased	1	21
Intestinal infarction		1
Intestinal obstruction		2
Intestinal perforation		2
Intracardiac thrombus	1	1
Invasive ductal breast carcinoma	1	1
Iron deficiency anaemia	1	2
Irregular breathing		1
Irritability	2	2
Ischaemia	1	1
Ischaemic stroke	1	13
Jaundice		1
Jaw clicking	1	1
Joint effusion		3
Joint injury	1	1
Joint lock		1
Joint range of motion decreased		4
Joint stiffness		5
Joint swelling	4	27
Jugular vein thrombosis		1
Kidney infection	1	1
Labyrinthitis	1	3
Lacrimation increased	1	7
Lacunar infarction		1
Left ventricular dysfunction		3
Left ventricular failure		1
Lethargy	6	52
Leukaemia		1
Limb discomfort	4	30

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
			1		4
			5	1	16
					1
					2
					2
				1	1
				1	1
				1	2
					1
				2	2
				1	1
				1	13
					1
		1	1		
			1		2
		1	1		
					1
					4
			1		4
		1	5	3	22
					1
				1	1
		1	1		2
		1	3		4
					1
					3
					1
	2	2	15	4	37
					1
		4	17		13

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Limb immobilisation		1
Limb mass		1
Lip blister		1
Lip dry		1
Lip pain		3
Lip swelling	2	31
Listless		3
Livedo reticularis		1
Liver function test abnormal		2
Liver function test increased		1
Localised infection		2
Localised oedema		1
Local reaction		2
Logorrhoea		1
Loss of consciousness	4	43
Loss of control of legs		1
Loss of personal independence in daily activities	1	8
Lower limb fracture		2
Lower respiratory tract infection		19
Lung consolidation		1
Lung disorder		1
Lung neoplasm malignant		3
Lymphadenitis		1
Lymphadenopathy	3	23
Lymphatic disorder		1
Lymph node pain		4
Lymphocyte count increased		1
Lymphocytosis	1	1
Lymphoedema	1	4
Lymphoma		1
Lymphopenia		1
Macular degeneration		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
					1
			1		
			2		1
		2	14		17
					3
					1
			1		1
					1
					2
			1		
			1		1
					1
				4	43
					1
			3	1	5
					2
					19
					1
					1
					3
					1
		3	11		12
					1
			1		3
					1
		1	1		
			1	1	3
					1
			1		
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Malaise	18	242
Mallory-Weiss syndrome		1
Mastication disorder		1
Melaena	1	4
Memory impairment	1	16
Mental disorder		1
Mental fatigue		2
Mental impairment		5
Mental status changes		1
Metamorphopsia		1
Microvascular coronary artery disease		1
Micturition disorder		1
Middle insomnia		2
Migraine	3	12
Migraine with aura	1	3
Miliaria		1
Mini mental status examination abnormal		1
Mitral valve incompetence		1
Mobility decreased	2	35
Monoparesis		2
Monoplegia		1
Mood swings		2
Morton's neuralgia		1
Motion sickness		1
Mouth haemorrhage		1
Mouth injury		1
Mouth swelling		3
Mouth ulceration		3
Movement disorder		10
Mucosal haemorrhage		1
Mucous stools		1
Multiple organ dysfunction syndrome		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	9	65	9	177
					1
					1
				1	4
			3	1	13
					1
			1		1
					5
					1
					1
					1
					1
					2
		1	4	2	8
		1	1		2
			1		
					1
					1
			11	2	24
					2
					1
					2
					1
			1		
			1		
					1
			2		1
					3
			2		8
					1
					1
					2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle discomfort	1	1
Muscle disorder		1
Muscle fatigue		6
Muscle injury		1
Muscle mass		1
Muscle rigidity		2
Muscle spasms	3	10
Muscle strain		1
Muscle twitching		3
Muscular weakness	5	67
Musculoskeletal chest pain		13
Musculoskeletal deformity		1
Musculoskeletal discomfort	1	6
Musculoskeletal disorder		2
Musculoskeletal pain		2
Musculoskeletal stiffness	5	30
Myalgia	15	154
Myasthenia gravis crisis		1
Myelitis		1
Myelitis transverse		1
Myocardial haemorrhage		1
Myocardial infarction	6	35
Myocardial ischaemia	1	8
Myocardial necrosis marker increased		1
Myoclonus		2
Myopathy	1	1
Myositis	1	2
Nail ridging		1
Narcolepsy		1
Nasal congestion	2	4
Nasal discomfort	1	2
Nasopharyngitis	2	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
1	1				6
			1		
					1
					2
1	1	2	3	1	7
					1
			1		2
			15	5	52
			4		9
					1
		1	3		3
					2
					2
	1	2	11	3	19
	1	10	53	5	101
					1
					1
					1
					1
				6	35
				1	8
					1
					2
				1	1
			1	1	1
					1
					1
		1	1	1	3
		1	1		1
			3	2	10

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nausea	16	206
Neck pain	4	37
Necrotising fasciitis		1
Neoplasm malignant		1
Nephrolithiasis		1
Nephrotic syndrome		1
Nerve compression		2
Nerve injury		1
Nervousness		10
Nervous system disorder		1
Neuralgia	1	8
Neurogenic shock		1
Neurological symptom		1
Neurologic neglect syndrome		1
Neuropathy peripheral		1
Neuropsychiatric symptoms		1
Neutropenia		2
Nightmare		1
Night sweats		6
Nocturia		1
Nocturnal dyspnoea		1
Nodule		3
Noninfective gingivitis		1
Nystagmus		1
Obsessive-compulsive symptom		1
Ocular discomfort	1	2
Ocular hyperaemia	2	9
Odynophagia		1
Oedema	2	5
Oedema peripheral	1	9
Off label use	24	102
Onychoclasia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	3	8	63	8	143
		1	11	3	26
					1
					1
					1
					1
					2
					1
			5		5
					1
			1	1	7
					1
					1
					1
					1
			1		
					2
			1		
	1		3		3
			1		
					1
					3
					1
					1
					1
		1	2		
		1	3	1	6
					1
			1	2	4
			3	1	6
		24	102		
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ophthalmic herpes simplex	1	1
Ophthalmic herpes zoster	1	4
Ophthalmic migraine		1
Optic ischaemic neuropathy	1	1
Optic neuropathy		1
Oral candidiasis	1	3
Oral discomfort	1	1
Oral herpes		1
Oral mucosal blistering		1
Oral mucosal eruption		2
Oral mucosal exfoliation		1
Oral pain	1	5
Orchitis		1
Oropharyngeal pain	2	19
Orthopnoea		2
Orthostatic hypotension		4
Osteoarthritis	1	3
Osteoporosis		1
Otorrhoea		1
Ovarian cyst		1
Overdose		3
Overflow diarrhoea		1
Oversensing		1
Oxygen consumption decreased		1
Oxygen saturation decreased	1	13
Pain	14	139
Painful respiration		3
Pain in extremity	30	225
Pain in jaw	1	5
Pain of skin		2
Pallor		11
Palpitations	6	26

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	4
					1
				1	1
					1
		1	1		2
		1	1		
					1
			1		
			1		1
			1		
			2	1	3
					1
		2	7		12
			1		1
			1		3
				1	3
					1
			1		
			1		
			3		
			1		
					1
			1		
			2	1	11
		8	53	6	86
			1		2
	2	17	86	13	139
		1	2		3
			1		1
			3		8
		3	9	3	17

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pancreatitis acute		1
Pancytopenia		2
Panic attack		5
Panic reaction	1	2
Papule	3	4
Paraesthesia	5	36
Paraesthesia oral	1	8
Paralysis	1	5
Paranoia		1
Parkinsonism		2
Parkinson's disease		2
Parosmia		1
Parotid gland enlargement		1
Parotitis		2
Pemphigoid		5
Pemphigus		1
Periarthritis		3
Pericardial haemorrhage		1
Pericarditis	1	5
Perineal pain	1	1
Periorbital oedema	1	1
Periorbital swelling		1
Peripheral circulatory failure		1
Peripheral coldness	3	13
Peripheral ischaemia		1
Peripheral swelling	12	77
Personality change		1
Petechiae		2
Petit mal epilepsy		2
Pharyngeal disorder	1	1
Pharyngeal erythema		1
Pharyngeal inflammation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					2
			1		4
				1	2
		1	1	2	3
		3	18	2	18
			6	1	2
				1	5
					1
			1		1
					2
			1		
					1
					2
					5
					1
	1				3
					1
				1	5
				1	1
		1	1		
			1		
					1
		3	4		9
					1
		2	25	10	52
					1
			1		1
					2
				1	1
					1
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pharyngeal oedema		1
Pharyngeal paraesthesia		1
Pharyngeal swelling		5
Pharyngeal ulceration		1
Pharyngitis streptococcal		1
Phlebitis	2	3
Photophobia	2	4
Photopsia		2
pH urine increased		1
Pigmentation disorder	1	2
Pityriasis rosea		1
Platelet count decreased	3	13
Pleural effusion	1	4
Pleuritic pain		1
Pneumonia	5	28
Pneumonia aspiration		7
Pneumonia staphylococcal		1
Pneumonitis		6
Pollakiuria		5
Polyarthrits	2	3
Polymyalgia rheumatica		9
Polyp		1
Polyuria		1
Poor quality sleep		6
Posterior revers ble encephalopathy syndrome		1
Post herpetic neuralgia	1	3
Postoperative ileus		1
Post procedural complication		1
Post procedural infection	1	1
Posture abnormal		1
Post viral fatigue syndrome		2
Pregnancy after post coital contraception	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
			2		3
					1
					1
				2	3
		1	2	1	2
					2
					1
		1	2		
					1
		1	4	2	9
				1	4
					1
				5	28
					7
					1
					6
			1		4
				2	3
					9
					1
			1		
			1		5
					1
		1	2		1
					1
					1
		1	1		
					1
					2
				1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Presyncope		8
Primary cough headache		1
Product administration error		1
Productive cough	2	8
Product preparation error		1
Product use issue	1	31
Prostatic specific antigen increased		1
Prostatomegaly		1
Pruritus	29	115
Psoriasis	1	4
Psychiatric symptom		1
Psychomotor hyperactivity		1
Psychotic behaviour		1
Psychotic disorder		3
Psychotic symptom		2
Pudendal canal syndrome	1	1
Pulmonary congestion	1	3
Pulmonary embolism	8	33
Pulmonary function test		1
Pulmonary haemorrhage		1
Pulmonary oedema	2	12
Pulmonary thrombosis		4
Pulse abnormal		2
Pulseless electrical activity		1
Purpura		6
Pustule		1
Pyrexia	10	192
Q fever		1
Rash	29	132
Rash erythematous	9	39
Rash macular	3	29
Rash maculo-papular	1	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		5
					1
			1		
			1	2	7
			1		
		1	31		
			1		
			1		
		21	73	8	42
			2	1	2
					1
			1		
					1
			1		2
					2
				1	1
				1	3
				8	33
					1
					1
				2	12
					4
					2
					1
			3		3
					1
1	1	6	46	4	146
					1
		22	76	7	56
		8	25	1	14
		2	17	1	12
			2	1	4

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rash morbilliform	2	3
Rash papular	1	3
Rash pruritic	10	44
Rash pustular		1
Rash vesicular	3	7
Reaction to excipient		1
Rectal haemorrhage	1	11
Red blood cell sedimentation rate increased		2
Red man syndrome		1
Regurgitation		1
Renal cancer		2
Renal disorder		1
Renal failure		3
Renal haemorrhage		1
Renal impairment		3
Renal mass	1	1
Renal pain		3
Repetitive speech		1
Respiration abnormal		1
Respiratory arrest		2
Respiratory disorder	2	4
Respiratory distress	1	2
Respiratory failure	1	2
Respiratory rate increased		2
Respiratory tract oedema		1
Restless legs syndrome		1
Restlessness		3
Retching		10
Reticulocyte count decreased		1
Retinal artery occlusion		1
Retinal injury		1
Retinal vein occlusion		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2	1	1
			2	1	1
		8	25	2	19
					1
		2	2	1	5
					1
				1	11
					2
					1
					1
					2
					1
					3
					1
					3
				1	1
			1		2
					1
					1
					2
				2	4
				1	2
				1	2
					2
					1
					1
					3
			4		6
					1
					1
					1
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Retroperitoneal lymphadenopathy	1	1
Rhabdomyolysis		2
Rheumatoid arthritis	1	5
Rhinitis	1	4
Rhinorrhoea	1	13
Rib fracture		1
Right ventricular enlargement		1
Road traffic accident		2
Rosacea		1
Salivary hypersecretion	1	3
Sarcoma		1
SARS-CoV-2 test positive		8
Scab		2
Scar	1	1
Sciatica	2	6
Sciatic nerve neuropathy		1
Screaming		1
Seasonal allergy		1
Secretion discharge		2
Seizure	3	29
Seizure anoxic	1	1
Senile dementia		1
Sensitive skin		1
Sensory disturbance	1	3
Sensory loss	1	2
Sepsis	1	12
Seronegative arthritis	1	1
Shock		1
Sight disability	1	1
Sinonasal obstruction		1
Sinus arrest		2
Sinus congestion		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					2
				1	5
			1	1	3
			3	1	10
					1
			1		
			1		1
					1
				1	3
					1
					8
			2		
				1	1
				2	6
					1
			1		
					1
			1		1
				3	29
				1	1
					1
			1		
			1	1	2
				1	2
				1	12
				1	1
					1
		1	1		
			1		
					2
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sinus disorder	1	1
Sinus headache		3
Sinusitis	1	3
Sinus tachycardia		1
Skin abrasion		2
Skin burning sensation	1	5
Skin cancer		1
Skin discolouration		14
Skin disorder		1
Skin erosion	1	3
Skin exfoliation	1	6
Skin haemorrhage	1	1
Skin hypertrophy		1
Skin induration		1
Skin infection		1
Skin injury		1
Skin irritation		7
Skin laceration		1
Skin mass		2
Skin reaction	1	5
Skin swelling	1	1
Skin tightness		1
Skin ulcer	1	3
Skin warm		4
Skin weeping		2
Sleep apnoea syndrome		1
Sleep attacks		1
Sleep disorder	2	22
Small intestinal obstruction		1
Sneezing		10
Snoring		1
Social avoidant behaviour		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					3
				1	3
					1
					2
		1	1		4
					1
			5		9
					1
		1	2		1
			1	1	5
				1	1
			1		
			1		
			1		
			1		
			1		6
					1
					2
		1	5		
		1	1		
					1
				1	3
			4		
					2
					1
					1
			10	2	12
					1
			5		5
			1		
					1

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Greater than or equal to 80 years

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Swelling	7	28
Swelling face	4	31
Swelling of eyelid		2
Swollen tongue	1	18
Syncope	1	49
Synovitis		3
Systemic lupus erythematosus rash		1
Systolic hypertension		1
Tachycardia	1	6
Tachypnoea		2
Taste disorder	2	7
Temperature regulation disorder		1
Tenderness	1	7
Tendonitis		1
Tenosynovitis		1
Tension headache		4
Terminal insomnia	1	1
Testicular pain		1
Testicular swelling		2
Thalamic infarction		1
Therapeutic procedure		1
Therapeutic product ineffective		1
Therapeutic response unexpected	1	8
Thermal burn		1
Thirst		5
Throat irritation	1	3
Throat tightness		5
Thrombocytopenia	9	21
Thrombocytopenic purpura	1	1
Thrombocytosis		1
Thrombophlebitis		2
Thrombophlebitis superficial		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1	4	18	3	10
			7	4	24
					2
		1	6		12
				1	49
					3
					1
					1
			1	1	5
					2
		1	2	1	5
					1
			3	1	4
					1
					1
					4
		1	1		
			1		
			2		
					1
			1		
					1
		1	8		
			1		
			2		3
		1	2		1
					5
				9	21
				1	1
					1
					2
			1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Thrombosis	5	22
Thrombotic thrombocytopenic purpura	1	3
Tinnitus	3	15
Tongue coated		1
Tongue discomfort	1	1
Tongue disorder		1
Tooth abscess	1	1
Toothache		1
Toxic epidermal necrolysis		1
Tracheitis		1
Transient ischaemic attack	1	25
Traumatic intracranial haemorrhage		1
Tremor	6	78
Trigeminal nerve disorder		1
Troponin increased		3
Tubulointerstitial nephritis		1
Tunnel vision		2
Type IV hypersensitivity reaction		1
Ulcer	1	4
Underdose		2
Underweight		2
Unresponsive to stimuli	1	13
Upper gastrointestinal haemorrhage		3
Upper limb fracture		5
Upper respiratory tract congestion	1	1
Upper respiratory tract infection		1
Urinary incontinence	1	14
Urinary retention	1	8
Urinary tract disorder		1
Urinary tract infection	2	17
Urinary tract infection bacterial		1
Urine analysis abnormal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				5	22
				1	3
		1	3	2	12
			1		
		1	1		
					1
				1	1
			1		
	1				1
					1
				1	25
					1
		1	14	5	64
			1		
					3
					1
					2
					1
			1	1	3
			2		
					2
				1	13
					3
					5
		1	1		
			1		
			3	1	11
				1	8
					1
			3	2	14
					1
			1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Urosepsis		1
Urticaria	8	44
Urticaria chronic		1
Urticaria papular		1
Uveitis		1
Vaccination failure		4
Vaccination site bruising	2	7
Vaccination site cellulitis		3
Vaccination site discolouration		1
Vaccination site discomfort	2	8
Vaccination site erythema	3	48
Vaccination site haematoma		1
Vaccination site haemorrhage		2
Vaccination site hypersensitivity		1
Vaccination site induration		4
Vaccination site infection		2
Vaccination site inflammation		3
Vaccination site joint movement impairment		1
Vaccination site joint pain		2
Vaccination site joint swelling		1
Vaccination site mass		8
Vaccination site movement impairment	1	4
Vaccination site oedema		1
Vaccination site pain	3	121
Vaccination site pruritus	2	15
Vaccination site pustule		1
Vaccination site rash	1	13
Vaccination site swelling		35
Vaccination site ulcer		1
Vaccination site urticaria		1
Vaccination site vesicles		2
Vaccination site warmth	1	19

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		6	28	2	16
					1
					1
					1
					4
1	1			2	7
			2		1
					1
		2	5		3
1	1	3	33		15
					1
			1		1
			1		
			3		1
					2
			1		2
			1		
			2		
					1
			3		5
			1	1	3
					1
		3	56		65
1	1	2	13		2
					1
		1	9		4
			22		13
					1
			1		
					2
		1	9		10

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccine breakthrough infection		11
Vaginal haemorrhage	2	3
Varicella		2
Vascular dementia		4
Vascular injury		2
Vasculitic rash		3
Vasculitis	1	8
Vasodilatation		1
Vein disorder	2	2
Venous thrombosis		1
Ventricular extrasystoles	1	2
Ventricular fibrillation		2
Vertebral artery stenosis		1
Vertigo	5	38
Vertigo positional		2
Viral infection		2
Viral labyrinthitis		1
Vision blurred	3	29
Visual acuity reduced		1
Visual impairment	1	15
Visual perseveration		1
Vitreous floaters	1	2
Vomiting	6	131
Vomiting projectile	1	2
Vulval haemorrhage		1
Walking disability	1	1
Weight decreased		6
Weight loss diet		1
Wheezing	2	13
White blood cell count increased		2
White blood cell disorder		1
White blood cells urine positive	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					11
				2	3
			2		
					4
					2
			1		2
			1	1	7
			1		
				2	2
					1
		1	1		1
					2
					1
	1	4	12	1	26
					2
			1		1
			1		
		3	15		14
			1		
			3	1	12
					1
				1	2
1	3	2	35	4	96
		1	2		
					1
				1	1
			1		5
					1
		1	6	1	7
					2
					1
		1	1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Wound	1	1					1	1
Wrong product administered	3	3			3	3		
		1				1		
	1,129	9,701	18	59	487	2758	642	6943

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	9	26			7	13	2	13
Abdominal distension	6	15			1	5	5	10
Abdominal pain	10	41			4	18	6	23
Abdominal pain lower	2	3			1	2	1	1
Abdominal pain upper	24	75			6	22	18	53
Abdominal tenderness	1	1					1	1
Abnormal behaviour		3				1		2
Abnormal dreams	2	6			1	4	1	2
Abnormal faeces		4				4		
Abnormal sensation in eye		1				1		
Abnormal uterine bleeding		1						1
Abortion spontaneous	2	8					2	8
Abscess		2						2
Abscess drainage		1						1
Accidental exposure to product	2	2			2	2		
Accidental overdose		17				16		1
Acne	2	4			1	3	1	1
Acoustic neuroma		1						1
Acquired haemophilia	1	1					1	1
Acute coronary syndrome		1						1
Acute hepatic failure	1	1					1	1
Acute kidney injury	1	4					1	4
Acute respiratory failure		1						1
Adjustment disorder with depressed mood		1						1
Adnexa uteri pain		2						2
Adverse drug reaction		4				3		1
Adverse event	1	2			1	2		
Affective disorder	1	1					1	1
Ageusia	2	14			1	4	1	10
Agitation	2	6			2	3		3
Alanine aminotransferase increased	1	2					1	2
Allergic oedema		1						1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Allergy to vaccine	1	4
Alopecia	2	3
Amenorrhoea	4	6
Amnesia	2	7
Anaemia	2	4
Anal haemorrhage		1
Anal hypoaesthesia	1	1
Anaphylactic reaction	11	45
Anaphylactic shock		3
Anaphylactoid reaction	1	2
Anaphylactoid shock		1
Anger		1
Angina pectoris	1	5
Angioedema	2	10
Ankyloglossia congenital	1	1
Ankylosing spondylitis		1
Anosmia	1	8
Anticoagulation drug level increased		1
Antinuclear antibody	1	1
Anxiety	8	32
Apathy	2	3
Aphasia	1	2
Aphonia	1	2
Aphthous ulcer		2
Apnoeic attack	1	1
Appendicitis		1
Appetite disorder		1
Application site acne	1	1
Areflexia	1	1
Arrhythmia		1
Arrhythmia supraventricular		2
Arterial thrombosis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	1	2
				2	3
		2	2	2	4
		1	3	1	4
				2	4
					1
				1	1
				11	45
					3
				1	2
					1
					1
				1	5
				2	10
				1	1
					1
		1	2		6
					1
				1	1
		6	16	2	16
				2	3
			1	1	1
		1	1		1
			1		1
				1	1
					1
			1		
				1	1
				1	1
					1
					2
					1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arthralgia	95	362
Arthritis	4	11
Arthritis reactive		4
Arthritis viral		1
Arthropathy		1
Arthropod bite	1	2
Aspartate aminotransferase increased		1
Asthenia	44	117
Asthenopia	3	8
Asthma	6	18
Asymptomatic COVID-19		7
Ataxia	1	1
Atrial fibrillation	5	16
Atrioventricular block		1
Aura		1
Autism spectrum disorder	1	1
Autoimmune disorder		1
Autoimmune haemolytic anaemia		1
Autoimmune hepatitis	1	1
Autoimmune thyroid disorder	1	1
Autoimmune uveitis		1
Autonomic nervous system imbalance	1	1
Autoscopy		1
Axillary mass	2	6
Axillary pain	36	88
Bacille Calmette-Guerin scar reactivation	1	1
Back injury		1
Back pain	23	83
Balance disorder	5	26
Bedridden		1
Bell's palsy	8	34
Bipolar disorder	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		48	134	47	228
		1	2	3	9
					4
			1		
					1
			1	1	1
					1
		21	50	23	67
		2	3	1	5
		3	6	3	12
					7
				1	1
				5	16
					1
			1		
				1	1
					1
					1
				1	1
				1	1
					1
				1	1
					1
		1	3	1	3
		10	25	26	63
		1	1		
					1
		10	34	13	49
		2	5	3	21
					1
				8	34
				1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bladder neoplasm		1
Bladder pain	2	3
Bleeding time prolonged	1	1
Blepharitis	1	1
Blepharospasm	3	6
Blindness	2	7
Blindness transient		1
Blindness unilateral		1
Blister	4	10
Blister rupture		1
Blood creatine phosphokinase increased	1	1
Blood follicle stimulating hormone increased	1	1
Blood glucose abnormal		1
Blood glucose decreased	2	5
Blood glucose increased	2	7
Blood growth hormone abnormal		2
Blood immunoglobulin G increased		1
Blood immunoglobulin M increased		1
Blood lactic acid increased		1
Blood luteinising hormone abnormal		1
Blood potassium decreased		2
Blood pressure abnormal	1	3
Blood pressure decreased	2	5
Blood pressure fluctuation	1	3
Blood pressure increased	6	25
Blood pressure measurement	1	1
Blood pressure systolic increased	1	2
Blood test abnormal	1	2
Blood urine		1
Blood urine present		2
Body temperature	1	2
Body temperature abnormal	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				2	3
				1	1
				1	1
		1	1	2	5
				2	7
					1
					1
		2	5	2	5
			1		
				1	1
				1	1
					1
		1	2	1	3
				2	7
			2		
			1		
			1		
			1		
			1		
					2
			2	1	1
		2	3		2
		1	1		2
			8	6	17
				1	1
		1	2		
				1	2
					1
			2		
		1	2		
		1	4		1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Body temperature decreased	2	5
Body temperature fluctuation		3
Body temperature increased	6	23
Bone disorder	1	1
Bone neoplasm		1
Bone pain	1	15
Bradycardia		2
Bradykinesia	1	2
Bradyphrenia	2	2
Brain stem syndrome		1
Breast cancer		2
Breast cellulitis		1
Breast discomfort	2	2
Breast inflammation		1
Breast mass		2
Breast pain	4	12
Breast swelling	2	6
Breast tenderness		1
Breath odour		1
Bronchiectasis	1	1
Bulimia nervosa		1
Bundle branch block right		1
Burning mouth syndrome	1	1
Burning sensation	8	26
Burns second degree	1	1
Bursitis		3
Butterfly rash		2
Candida infection	1	2
Cardiac arrest		5
Cardiac disorder		2
Cardiac dysfunction	1	1
Cardiac failure	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	2	4
			1		2
		4	13	2	10
		1	1		
			1		
			6	1	9
					2
				1	2
				2	2
					1
					2
					1
				2	2
					1
					2
		1	1	3	11
		1	3	1	3
					1
			1		
				1	1
					1
					1
		4	11	4	15
				1	1
					3
					2
				1	2
					5
					2
				1	1
				1	2

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiac flutter	3	6
Cardiac murmur		3
Cardiomyopathy	1	1
Catarrh		1
Cellulitis	4	13
Central vision loss		1
Cerebellar stroke		1
Cerebral artery embolism		1
Cerebral cyst	1	1
Cerebral haemorrhage	1	1
Cerebral infarction		1
Cerebral thrombosis		1
Cerebral venous sinus thrombosis	2	2
Cerebral venous thrombosis	2	2
Cerebrovascular accident	2	19
Cheilitis	1	1
Chest discomfort	7	53
Chest injury	1	1
Chest pain	33	88
Chillblains	1	6
Chills	90	388
Chloropsia	1	1
Choking		1
Choking sensation		1
Chorioretinopathy		1
Choroidal neovascularisation		1
Chromaturia	1	2
Chronic fatigue syndrome		3
Circulatory collapse	1	6
Circumstance or information capable of leading to medication error		4
Clinically isolated syndrome	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	6
					3
				1	1
			1		
				4	13
					1
					1
					1
				1	1
				1	1
					1
					1
				2	2
				2	2
				2	19
				1	1
		5	20	2	33
				1	1
		10	27	23	61
			4	1	2
		50	163	40	225
				1	1
					1
					1
					1
			1	1	1
					3
				1	6
			4		
				1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Clonus	1	1
Cluster headache	4	9
Coagulation time shortened	1	1
Coagulopathy		1
Coating in mouth	1	1
Cognitive disorder	4	7
Cold-stimulus headache		1
Cold sweat	6	23
Colitis		1
Colitis ulcerative		1
Coma	1	1
Communication disorder		2
Condition aggravated	9	34
Confusional state	10	29
Conjunctival haemorrhage	1	2
Conjunctival hyperaemia		1
Conjunctival oedema		1
Conjunctivitis		3
Connective tissue disorder	1	1
Consciousness fluctuating		1
Constipation	2	8
Contraindicated product administered		1
Contraindicated product prescribed		1
Contusion	11	29
Conversion disorder	1	1
Coordination abnormal	1	3
Corneal graft rejection	1	1
Coronary artery disease		2
Coronary artery thrombosis	1	1
Coronavirus infection		1
Cortisol decreased		1
Costochondritis	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		2	3	2	6
				1	1
					1
				1	1
		1	1	3	6
					1
		1	9	5	14
					1
					1
				1	1
			1		1
		3	7	6	27
		3	6	7	23
				1	2
					1
			1		2
				1	1
					1
		1	2	1	6
			1		
			1		
		6	13	5	16
				1	1
				1	3
				1	1
					2
				1	1
					1
		1	1		1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cough	17	84
COVID-19	13	156
COVID-19 immunisation		1
COVID-19 pneumonia		2
C-reactive protein increased	1	2
Crohn's disease		1
Croup infectious	1	1
Crying	1	4
CT hypotension complex		2
Cyanosis		1
Cystitis		2
Deafness	3	6
Deafness neurosensory		1
Deafness unilateral	2	4
Death	4	17
Decreased appetite	15	49
Decreased embryo viability		1
Deep vein thrombosis	10	17
Dehydration	2	8
Delirium	1	3
Delusion		1
Dementia	1	1
Demyelination	2	2
Dental paraesthesia	1	1
Depressed level of consciousness	1	4
Depressed mood	5	13
Depression	5	14
Dermatitis	3	10
Dermatitis allergic	1	2
Dermatitis atopic		3
Dermatitis contact	1	1
Dermatitis exfoliative generalised		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		7	38	10	46
		4	28	9	128
			1		
					2
				1	2
					1
				1	1
			1	1	3
					2
					1
					2
				3	6
					1
				2	4
				4	17
		10	24	5	25
					1
				10	17
		1	2	1	6
				1	3
			1		
				1	1
				2	2
				1	1
				1	4
			1	5	12
		1	2	4	12
		2	4	1	6
			1	1	1
					3
				1	1
					1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dermatitis infected		1
Diabetes mellitus		1
Diabetic ketoacidosis		1
Diaphragmatic disorder		1
Diarrhoea	47	160
Diastolic hypertension		1
Diplopia	2	8
Discomfort	4	15
Disease recurrence	12	25
Disorientation	5	13
Dissociation	1	1
Disturbance in attention	10	26
Diverticulitis		2
Diverticulum		1
Dizziness	113	383
Dizziness exertional		1
Dizziness postural	9	27
Drooling	1	1
Drug eruption		2
Drug ineffective	10	140
Drug interaction	3	5
Dry eye	3	9
Dry mouth	4	15
Dry skin	2	5
Dry throat	3	5
Dupuytren's contracture		1
Dysarthria	3	7
Dyschromatopsia	1	1
Dysdiadochokinesis		1
Dysgeusia	15	43
Dysgraphia	1	1
Dyskinesia		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
					1
		22	62	25	98
					1
			1	2	7
		1	6	3	9
		4	5	8	20
		2	5	3	8
		1	1		
		3	8	7	18
					2
			1		
		60	166	53	217
					1
		3	8	6	19
				1	1
					2
				10	140
		2	3	1	2
		2	3	1	6
		3	8	1	7
			2	2	3
		2	2	1	3
					1
			2	3	5
				1	1
					1
		9	25	6	18
				1	1
			1		2

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysmenorrhoea	11	13
Dyspepsia	3	10
Dysphagia	4	14
Dysphonia	1	4
Dyspnoea	42	158
Dyspnoea at rest		1
Dyspnoea exertional	2	7
Dysstasia	1	7
Dysuria	1	6
Ear discomfort	2	7
Ear haemorrhage	1	3
Ear infection	1	2
Ear pain	12	35
Ear pruritus	1	1
Ear swelling	2	2
Eating disorder		1
Eczema	4	6
Electric shock		1
Electric shock sensation	1	5
Electrocardiogram abnormal	1	1
Embolism	1	6
Emotional disorder	1	1
Enlarged uvula	1	1
Eosinophil count increased		1
Epicondylitis		1
Epididymitis		1
Epigastric discomfort		1
Epilepsy	4	13
Epinephrine increased	1	2
Epistaxis	5	27
Erectile dysfunction		2
Erection increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	3	8	10
		3	4		6
		2	6	2	8
			1	1	3
		15	42	27	116
					1
			1	2	6
			3	1	4
		1	2		4
			3	2	4
		1	1		2
		1	1		1
		7	13	5	22
				1	1
		2	2		
			1		
		1	2	3	4
			1		
		1	3		2
		1	1		
				1	6
				1	1
		1	1		
					1
					1
					1
			1		
				4	13
		1	2		
		3	11	2	16
					2
					1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Erythema	21	82
Erythema multiforme		2
Erythema of eyelid	1	1
Escherichia bacteraemia	1	1
Euphoric mood	1	2
Excessive granulation tissue		1
Exercise tolerance decreased		2
Exfoliative rash	1	2
Expired product administered		3
Exploding head syndrome	1	1
Exposure during pregnancy	6	7
Exposure via breast milk	11	76
Exposure via skin contact	2	2
Extensive swelling of vaccinated limb	1	1
External ear pain		2
Extrasystoles		3
Eye abscess		1
Eye colour change	1	1
Eye disorder		1
Eye inflammation	1	2
Eye injury	1	1
Eye irritation	3	8
Eyelid exfoliation	1	1
Eyelid function disorder	1	1
Eyelid irritation	1	2
Eyelid oedema		1
Eyelid pain	1	1
Eyelid ptosis		4
Eyelid rash	1	1
Eyelid skin dryness	1	1
Eye movement disorder	1	1
Eye pain	14	33

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		13	49	8	33
					2
				1	1
				1	1
				1	2
					1
					2
				1	2
			3		
				1	1
		5	6	1	1
		8	60	3	16
		2	2		
				1	1
			1		1
					3
					1
		1	1		
			1		
				1	2
		1	1		
		2	3	1	5
				1	1
		1	1		
			1	1	1
					1
				1	1
			2		2
				1	1
				1	1
		1	1		
		8	14	6	19

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye pruritus	3	5
Eye swelling	6	15
Facial discomfort		2
Facial neuralgia	1	1
Facial pain	2	11
Facial paralysis	6	22
Facial paresis	1	2
Facial spasm		1
Faeces discoloured	1	1
Faeces soft	2	3
Fall	2	13
Fatigue	219	794
Fear	2	3
Fear of injection		1
Feeding disorder	3	7
Feeling abnormal	23	97
Feeling cold	16	67
Feeling drunk	2	6
Feeling hot	23	68
Feeling jittery	1	4
Feeling of body temperature change	4	15
Feeling of despair		1
Feeling of relaxation		1
Fever neonatal	1	1
Fibrin D dimer increased	2	3
Fibromyalgia	1	2
Fine motor skill dysfunction		1
Flank pain		2
Flatulence	2	7
Fluid retention	2	4
Flushing	5	24
Foetal death	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	4		1
		2	7	4	8
					2
		1	1		
		2	5		6
				6	22
			1	1	1
					1
		1	1		
		1	1	1	2
			6	2	7
		105	322	114	472
		2	3		
			1		
		2	4	1	3
		10	34	13	63
		9	25	7	42
		2	6		
		14	40	9	28
				1	4
		3	8	1	7
					1
					1
				1	1
				2	3
		1	1		1
					1
			1		1
		1	2	1	5
				2	4
		1	10	4	14
				1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Foetal exposure during pregnancy		2
Foetal growth restriction	1	1
Foetal heart rate abnormal	1	1
Foetal malformation		1
Food aversion		2
Food intolerance		1
Food poisoning		1
Foreign body in gastrointestinal tract		1
Foreign body in mouth		1
Formication		3
Fracture	1	1
Frequent bowel movements	1	2
Gait disturbance	7	25
Gait inability	5	12
Gastric antral vascular ectasia		1
Gastric disorder	1	2
Gastric haemorrhage	1	1
Gastric ulcer	1	1
Gastritis	1	3
Gastroenteritis		3
Gastroenteritis viral		1
Gastrointestinal disorder	1	1
Gastrointestinal haemorrhage		1
Gastrointestinal pain	2	9
Gastrointestinal sounds abnormal		2
Gastrooesophageal reflux disease	3	4
Generalised tonic-clonic seizure	1	6
General physical health deterioration	1	3
Genital haemorrhage	1	2
Genital herpes	1	1
Genital herpes simplex	1	1
Genital rash	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
				1	1
				1	1
					1
					2
					1
					1
					1
			1		2
				1	1
				1	2
		2	6	5	19
		2	4	3	8
					1
		1	2		
				1	1
				1	1
				1	3
					3
					1
				1	1
					1
			1	2	8
					2
		1	1	2	3
				1	6
		1	1		2
				1	2
				1	1
				1	1
				1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Giant cell arteritis		1
Gingival bleeding	1	2
Gingival pain		5
Gingival swelling	1	1
Glossitis	1	2
Glossodynia	3	10
Gluten sensitivity	1	1
Glycopenia		1
Gonorrhoea		1
Gout	2	4
Groin pain	1	4
Guillain-Barre syndrome	2	5
Guttate psoriasis	1	1
Haemarthrosis		1
Haematemesis		3
Haematochezia		1
Haematoma		2
Haematuria	2	4
Haemolysis		1
Haemophilia		1
Haemoptysis		2
Haemorrhage	7	14
Haemorrhage in pregnancy		1
Haemorrhage subcutaneous		2
Haemorrhage urinary tract		1
Hair colour changes		1
Hair disorder		1
Hallucination	3	7
Hallucination, auditory	1	1
Hallucination, visual		1
Hangover	1	3
Headache	255	995

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1	1	1
			1		4
				1	1
		1	1		1
			5	3	5
				1	1
			1		
					1
				2	4
		1	1		3
				2	5
				1	1
					1
					3
					1
					2
				2	4
					1
					1
					2
				7	14
					1
					2
					1
			1		
			1		
				3	7
				1	1
					1
				1	3
		144	465	111	530

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Head discomfort	4	13
Head injury	1	3
Heart disease congenital		1
Heart rate	1	1
Heart rate abnormal	2	5
Heart rate decreased	2	4
Heart rate increased	14	51
Heart rate irregular		8
Heavy menstrual bleeding	24	28
Hemiplegia		1
Hemiplegic migraine	1	1
Hepatic cancer	1	1
Hepatic pain		2
Hepatic vascular thrombosis	1	1
Herpes simplex	1	1
Herpes simplex reactivation		1
Herpes zoster	44	63
Herpes zoster oticus		1
Hiatus hernia	1	1
Hordeolum	1	1
Hormone level abnormal	2	2
Hot flush	6	31
Hunger		1
Hyperacusis		2
Hyperaesthesia	1	6
Hyperaesthesia teeth	1	2
Hyperchlorhydria	1	1
Hypercoagulation	1	1
Hyperglycaemia		8
Hyperhidrosis	14	80
Hyperpyrexia	1	1
Hypersensitivity	13	37

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	7	2	6
			1	1	2
					1
		1	1		
			1	2	4
		1	1	1	3
		4	17	10	34
			1		7
		17	19	7	9
					1
				1	1
				1	1
			1		1
				1	1
				1	1
		20	31	24	32
					1
				1	1
		1	1		
				2	2
		4	13	2	18
					1
			1		1
			2	1	4
		1	2		
		1	1		
				1	1
			1		7
		2	24	12	56
				1	1
		3	13	10	24

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypersomnia	3	8
Hypertension	8	42
Hyperthyroidism	1	3
Hyperventilation		2
Hypoacusis	2	5
Hypoaesthesia	37	98
Hypoaesthesia eye	1	1
Hypoaesthesia oral	8	24
Hypocalcaemia		1
Hypogeusia		1
Hypoglycaemia	2	5
Hypokalaemic syndrome		1
Hypokinesia	2	8
Hypomenorrhoea	3	3
Hypophagia		1
Hypopnoea		1
Hyporesponsive to stimuli		1
Hyposmia	1	1
Hypotension	1	11
Hypothermia		1
Hypothyroidism	1	1
Hypotonia		1
Hypoxia		3
Hysteroscopy	1	1
IgA nephropathy		1
Illness	29	81
Immobile		1
Immune system disorder	1	1
Immune thrombocytopenia	1	3
Immunisation		1
Immunisation reaction	1	1
Immunology test	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3	2	5
		3	13	5	29
				1	3
			1		1
			1	2	4
		20	41	17	57
		1	1		
		5	12	3	12
					1
					1
		1	1	1	4
					1
		1	2	1	6
		1	1	2	2
					1
					1
					1
		1	1		
		1	3		8
					1
				1	1
					1
					3
				1	1
					1
		15	28	14	53
					1
				1	1
				1	3
					1
				1	1
				1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Impaired driving ability	1	1
Impaired healing		1
Impaired work ability	1	1
Inappropriate affect		1
Inappropriate schedule of product administration	43	94
Incontinence		2
Incorrect dose administered	3	6
Incorrect route of product administration	2	6
Increased insulin requirement		1
Increased upper airway secretion		1
Increased viscosity of upper respiratory secretion		1
Indifference		1
Induration		2
Infection		7
Inflammation	4	16
Inflammatory marker increased		2
Inflammatory pain		1
Influenza	16	63
Influenza like illness	34	120
Infusion related reaction		1
Injected limb mobility decreased	2	2
Injection related reaction		2
Injection site erythema		2
Injection site pain	4	10
Injection site pruritus	1	1
Injection site rash	1	1
Injection site warmth		1
Injury associated with device		1
Insomnia	24	65
Intentional product misuse		1
Intentional product use issue		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
				1	1
					1
		41	91	2	3
			1		1
		3	6		
		2	6		
					1
			1		
					1
			1		
			1		1
			3		4
		3	5	1	11
					2
			1		
		6	19	10	44
		19	57	15	63
					1
		2	2		
			1		1
			1		1
		2	4	2	6
		1	1		
		1	1		
					1
			1		
		9	28	15	37
			1		
			1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Intermenstrual bleeding	7	12
International normalised ratio decreased		2
International normalised ratio increased		2
Intervertebral disc protrusion		1
Intestinal angioedema	1	1
Intranasal paraesthesia	1	1
Intrusive thoughts		1
Iridocyclitis	1	1
Iritis		2
Iron deficiency anaemia		1
Irritability	1	5
Irritable bowel syndrome	3	4
Ischaemic stroke		2
Itching scar		1
IVth nerve paralysis		1
Jaundice	1	1
Joint injury		1
Joint noise	1	2
Joint prosthesis user		1
Joint range of motion decreased	2	8
Joint stiffness	2	4
Joint swelling	5	20
Jugular vein thrombosis		1
Keratitis		2
Kidney infection	1	2
Kidney transplant rejection		1
Labile hypertension	1	1
Labyrinthitis	1	3
Lacrimation increased	1	6
Lacunar stroke		1
Laryngeal pain		1
Laryngitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	4	4	8
					2
			1		1
			1		
				1	1
		1	1		
			1		
				1	1
					2
					1
				1	5
		1	1	2	3
					2
			1		
					1
				1	1
					1
				1	2
					1
		1	4	1	4
		1	1	1	3
		2	6	3	14
			1		
			2		
				1	2
					1
				1	1
				1	3
		1	1		5
					1
			1		
					1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lethargy	28	97
L bido decreased		1
L bido increased		1
Lichen planus	1	1
Limb discomfort	17	59
Limb injury	3	5
Limb mass	1	4
Lip dry	1	2
Lip erythema		1
Lip exfoliation	1	1
Lip pain		2
Lip swelling	12	32
Liquid product physical issue		3
Liver function test abnormal	3	4
Liver tenderness	1	1
Localised infection		2
Localised oedema	1	4
Local reaction	2	2
Loss of consciousness	6	29
Loss of control of legs		1
Loss of libido		2
Loss of personal independence in daily activities	4	10
Lower respiratory tract infection	2	5
Lung consolidation		1
Lung disorder		2
Lung infiltration		2
Lupus nephritis	1	1
Lymphadenitis	1	5
Lymphadenopathy	78	283
Lymphangitis		1
Lymph gland infection		1
Lymph node pain	15	49

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		13	53	15	44
					1
			1		
				1	1
		11	29	6	30
				3	5
			2	1	2
				1	2
					1
		1	1		
					2
		3	13	9	19
			3		
				3	4
				1	1
			1		1
		1	2		2
		2	2		
				6	29
					1
					2
			2	4	8
				2	5
					1
					2
			1		1
				1	1
		1	2		3
		22	95	56	188
					1
			1		
		1	11	14	38

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lymph node palpable		1
Lymphocyte count decreased		1
Lymphoedema	1	3
Lymphoma	1	2
Magnetic resonance imaging head abnormal		1
Major depression		3
Malaise	97	312
Mass	2	6
Mast cell activation syndrome	1	2
Mastoiditis	1	1
Maternal exposure during breast feeding	2	2
Maternal exposure during pregnancy	6	13
Maternal exposure timing unspecified	1	2
Mean cell volume decreased		1
Medication error	2	2
Memory impairment	3	9
Meniere's disease		1
Menometrorrhagia	1	1
Menopause	1	1
Menstrual disorder	12	13
Menstruation delayed	20	26
Menstruation irregular	13	17
Mental disorder		1
Mental fatigue	1	6
Mental impairment		1
Metamorphopsia	1	1
Metastases to lymph nodes		3
Micturition urgency		1
Middle insomnia	2	7
Migraine	25	89
Migraine with aura	1	5
Migraine without aura	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
		1	2		1
				1	2
					1
					3
		57	149	40	163
				2	6
				1	2
				1	1
				2	2
		4	8	2	5
		1	2		
					1
		2	2		
		2	6	1	3
					1
		1	1		
		1	1		
		7	7	5	6
		16	17	4	9
		8	10	5	7
			1		
				1	6
					1
		1	1		
					3
					1
		1	4	1	3
	1	9	30	16	59
			1	1	4
				1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Miliaria		3
Mitral valve incompetence	1	1
Mobility decreased	2	13
Monoparesis	1	3
Monoplegia	1	7
Mood altered	1	1
Mood swings	2	4
Morning sickness		1
Motion sickness	1	4
Mouth swelling	4	7
Mouth ulceration	6	14
Movement disorder	3	7
Multiple organ dysfunction syndrome		1
Multiple sclerosis		1
Multiple sclerosis relapse	1	2
Muscle atrophy		3
Muscle fatigue	1	1
Muscle mass	1	1
Muscle spasms	10	38
Muscle spasticity		1
Muscle strain	2	2
Muscle swelling	1	1
Muscle tightness	2	2
Muscle twitching	2	9
Muscular weakness	7	40
Musculoskeletal chest pain	3	12
Musculoskeletal discomfort	1	6
Musculoskeletal disorder	1	7
Musculoskeletal pain	1	2
Musculoskeletal stiffness	24	55
Myalgia	106	420
Myasthenia gravis	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		2
				1	1
		1	5	1	8
				1	3
				1	7
				1	1
				2	4
					1
				1	4
			1	4	6
		4	9	2	5
		2	4	1	3
					1
					1
				1	2
					3
		1	1		
		1	1		
		4	12	6	26
					1
		1	1	1	1
				1	1
		1	1	1	1
		2	3		6
		4	8	3	32
		1	4	2	8
		1	3		3
				1	7
			1	1	1
		14	24	10	31
		60	204	46	216
				1	3

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myelitis transverse	1	3
Myelosuppression		1
Myocardial infarction	3	10
Myocardial oedema	1	1
Myocarditis	1	2
Myoclonus		1
Myosclerosis	1	1
Nasal congestion	2	12
Nasal discomfort	1	2
Nasal disorder		1
Nasal dryness		3
Nasal injury	1	1
Nasal oedema	1	1
Nasopharyngitis	7	25
Nausea	132	506
Neck mass		1
Neck pain	28	90
Needle issue		1
Neonatal pneumothorax		1
Neonatal respiratory distress		1
Nephrotic syndrome	1	1
Nerve compression		1
Nerve injury	1	6
Nervousness	1	12
Nervous system disorder		2
Neuralgia	2	16
Neurogenic bladder		1
Neurogenic shock		4
Neurological symptom	1	3
Neuropathy peripheral		7
Neutropenia		2
Neutrophil count abnormal	4	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
					1
				3	10
				1	1
				1	2
					1
				1	1
		1	6	1	6
		1	1		1
					1
					3
		1	1		
		1	1		
		2	11	5	14
		69	217	63	289
			1		
		14	35	14	55
			1		
					1
					1
				1	1
					1
			3	1	3
		1	4		8
			1		1
		1	5	1	11
					1
					4
				1	3
					7
					2
		4	4		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nightmare	2	5
Night sweats	5	21
No adverse event	3	8
Nocturia	1	1
Nodule		1
No reaction on previous exposure to drug	1	1
Obstructive airways disorder	1	1
Occipital neuralgia	1	2
Occupational exposure to product		1
Ocular discomfort		1
Ocular hyperaemia	6	11
Odynophagia	1	1
Oedema	1	1
Oedema peripheral	2	6
Oesophageal pain		1
Off label use	43	116
Oligomenorrhoea	2	2
Ophthalmic herpes zoster	1	1
Optic neuritis	1	2
Oral blood blister		1
Oral candidiasis		1
Oral discomfort	3	5
Oral disorder	1	1
Oral dysaesthesia		1
Oral herpes	7	12
Oral mucosal blistering		1
Oral pain	3	9
Oral pruritus		4
Oropharyngeal discomfort	2	4
Oropharyngeal pain	21	78
Orthopnoea	1	3
Osteoarthritis		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2	1	3
		3	9	2	12
		3	8		
		1	1		
			1		
		1	1		
				1	1
				1	2
			1		
			1		
		3	4	3	7
				1	1
				1	1
			1	2	5
					1
		41	114	2	2
		2	2		
				1	1
				1	2
			1		
					1
		1	2	2	3
		1	1		
					1
		4	7	3	5
			1		
		3	5		4
			2		2
			2	2	2
		11	34	10	44
				1	3
					2

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Osteonecrosis of jaw		1
Ovarian vein thrombosis	1	1
Overdose	2	4
Oxygen saturation	1	1
Oxygen saturation decreased		4
Pain	96	331
Painful respiration	1	2
Pain in extremity	171	517
Pain in jaw	4	20
Pain of skin	7	16
Pallor	6	19
Palmar erythema		3
Palpitations	25	83
Pancreatic carcinoma		1
Pancreatitis	1	1
Pancreatitis acute	1	1
Panic attack	2	5
Panic reaction		2
Papule		2
Paraesthesia	35	142
Paraesthesia oral	20	70
Paralysis	2	6
Paresis	1	1
Parkinsonism		1
Parkinson's disease		2
Parophthalmia		1
Parosmia	5	10
Parotitis		1
Partial seizures		1
Peau d'orange		1
Pelvic pain		1
Pemphigoid		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
		2	4		
				1	1
					4
		50	145	46	186
				1	2
		95	247	76	270
		3	5	1	15
		3	4	4	12
		6	14		5
			1		2
		9	31	16	52
					1
				1	1
				1	1
		1	1	1	4
			2		
			1		1
		19	65	16	77
		15	47	5	23
				2	6
				1	1
					1
					2
					1
		3	5	2	5
			1		
					1
			1		
			1		
					1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Peptic ulcer haemorrhage		1
Periarthritis	3	9
Pericardial effusion		1
Pericarditis	1	2
Periorbital swelling	2	8
Peripheral coldness	4	17
Peripheral ischaemia	1	1
Peripheral sensory neuropathy	1	1
Peripheral swelling	42	123
Peroneal nerve palsy		3
Persistent postural-perceptual dizziness		1
Petechiae		2
Petit mal epilepsy		2
Pharyngeal disorder		1
Pharyngeal hypoaesthesia		1
Pharyngeal paraesthesia	1	4
Pharyngeal swelling	9	21
Pharyngeal ulceration	1	1
Pharyngitis	1	2
Phlebitis		1
Photophobia	3	16
Photopsia	3	4
Photosensitivity reaction		1
Physical disability	1	1
Pityriasis		1
Pityriasis lichenoides et varioliformis acuta	1	1
Pityriasis rosea		1
Plasma cell myeloma		1
Platelet count abnormal		1
Platelet count decreased	2	2
Pleural effusion		3
Pleurisy	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	2	2	7
					1
				1	2
			2	2	6
		2	10	2	7
		1	1		
		1	1		
		22	52	20	71
			1		2
					1
			2		
					2
					1
			1		
		1	4		
		2	7	7	14
				1	1
		1	2		
					1
		3	9		7
		2	2	1	2
					1
				1	1
			1		
		1	1		
			1		
					1
			1		
		1	1	1	1
					3
		1	1		1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pleuritic pain	1	2
Pneumonia		2
Pneumonia aspiration	1	1
Pneumonitis	1	1
Pneumothorax	1	1
Pollakiuria	5	7
Polyarthrits		1
Polymenorrhoea	4	5
Polymyalgia rheumatica	1	3
Polymyositis	1	1
Poor peripheral circulation	1	1
Poor quality product administered	11	93
Poor quality sleep	4	15
Poor venous access	1	1
Post herpetic neuralgia	1	1
Postmenopausal haemorrhage	3	4
Postpartum haemorrhage	1	1
Post viral fatigue syndrome	1	5
Pregnancy test positive		1
Premature baby		2
Premature separation of placenta	1	1
Presyncope	6	30
Product administered at inappropriate site		7
Product administered to patient of inappropriate age	2	2
Product administration error	1	1
Product complaint		1
Product contamination	1	1
Product contamination physical		1
Productive cough	2	11
Product label confusion		1
Product leakage	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
					2
				1	1
				1	1
				1	1
		5	5		2
					1
		3	4	1	1
				1	3
				1	1
				1	1
		11	93		
			8	4	7
				1	1
				1	1
				3	4
				1	1
				1	5
			1		
					2
				1	1
		4	16	2	14
			6		1
		1	1	1	1
		1	1		
			1		
		1	1		
			1		
		1	3	1	8
			1		
		1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Product packaging quantity issue		4
Product preparation error	3	8
Product preparation issue		1
Product quality issue	1	1
Product residue present	1	1
Product storage error	7	9
Product supply issue		1
Product temperature excursion issue	1	72
Product use issue	5	33
Prostatic pain		1
Prostatitis		1
Pruritus	53	148
Pseudofolliculitis		1
Psoriasis		3
Psoriatic arthropathy		1
Psychiatric symptom		1
Psychomotor hyperactivity	1	1
Pulmonary embolism	10	25
Pulmonary fibrosis	1	2
Pulmonary pain		4
Pulmonary thrombosis	1	4
Pulmonary tuberculosis		1
Puncture site discharge		1
Purpura	1	2
Pyrexia	116	558
Rash	58	157
Rash erythematous	16	42
Rash macular	6	15
Rash maculo-papular	3	3
Rash morbilliform	1	1
Rash papular	5	10
Rash pruritic	13	39

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			4		
		3	7		1
			1		
		1	1		
		1	1		
		7	9		
			1		
		1	72		
		5	33		
					1
					1
		33	79	20	69
					1
					3
					1
			1		
				1	1
				10	25
				1	2
			1		3
				1	4
					1
					1
			1	1	1
		57	268	59	290
		36	91	22	66
		5	13	11	29
		4	9	2	6
		2	2	1	1
		1	1		
		3	4	2	6
		9	20	4	19

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rash pustular	1	1
Rash vesicular		1
Raynaud's phenomenon	3	7
Reaction to excipient		1
Rectal haemorrhage	3	5
Red blood cell abnormality	1	1
Reflux gastritis		1
Renal failure		3
Renal haemorrhage		1
Renal impairment		1
Renal pain	4	14
Renal vasculitis		1
Respiratory arrest		1
Respiratory disorder	2	5
Respiratory rate decreased		1
Respiratory rate increased		1
Respiratory tract infection		2
Respiratory tract oedema	1	1
Restless legs syndrome	1	3
Restlessness	3	5
Retching	1	3
Retinal artery occlusion	1	1
Retinal artery thrombosis		1
Retinal exudates		1
Retinal haemorrhage	1	1
Retinal vein occlusion	1	1
Reversed hot-cold sensation		1
Rheumatic disorder		1
Rheumatoid arthritis	1	11
Rheumatoid factor increased	1	2
Rhinalgia	1	1
Rhinitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
		1	3	2	4
					1
				3	5
		1	1		
			1		
					3
					1
					1
			2	4	12
					1
					1
		1	3	1	2
					1
					1
					2
				1	1
			1	1	2
		2	2	1	3
		1	2		1
				1	1
					1
					1
				1	1
				1	1
					1
					1
				1	11
				1	2
		1	1		
					1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rhinorrhoea	10	30
Rosacea	2	2
Rotator cuff syndrome	1	3
Salivary gland pain		1
Salivary hypersecretion	2	3
Sarcoidosis	1	1
SARS-CoV-2 ant body test negative		6
SARS-CoV-2 test positive	1	12
Scab	1	1
Scar	1	2
Scarlet fever		1
Sciatica	1	3
Sciatic nerve injury	1	1
Sciatic nerve neuropathy	1	1
Scratch		1
Seasonal allergy	1	3
Secondary hypertension	1	1
Second primary malignancy		1
Sedation	1	1
Sedation complication		1
Seizure	10	24
Sensation of foreign body	1	2
Sensitive skin		2
Sensory disturbance	3	6
Sensory loss		2
Sepsis		1
Serotonin syndrome		1
Shock	1	2
Sialoadenitis	1	2
Sigmoidoscopy abnormal		1
Sinus disorder		1
Sinus headache	3	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		7	14	3	16
				2	2
				1	3
					1
			1	2	2
				1	1
			6		
		1	4		8
				1	1
		1	2		
					1
		1	2		1
				1	1
		1	1		
					1
			1	1	2
				1	1
					1
				1	1
					1
				10	24
				1	2
					2
		1	2	2	4
			1		1
					1
					1
				1	2
				1	2
					1
					1
		2	5	1	8

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sinusitis	1	3
Sinus pain	2	5
Sinus tachycardia		1
Skin abrasion		2
Skin burning sensation	1	3
Skin discolouration	3	3
Skin disorder		2
Skin erosion	1	1
Skin exfoliation	1	4
Skin infection	1	1
Skin irritation		4
Skin lesion	1	4
Skin odour abnormal		1
Skin reaction		3
Skin sensitisation		1
Skin swelling	3	5
Skin temperature	1	2
Skin tightness	1	3
Skin warm	3	7
Sleep apnoea syndrome		1
Sleep disorder	4	20
Sleep talking	1	1
Sluggishness		3
Sneezing	4	11
Soft tissue swelling		1
Somnambulism	1	1
Somnolence	14	39
Speech disorder		4
Spinal fracture		1
Spinal pain		3
Spontaneous haematoma	1	1
Status epilepticus		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		2
			1	2	4
					1
			2		
		1	2		1
				3	3
					2
				1	1
		1	3		1
				1	1
			1		3
		1	4		
			1		
			3		
			1		
		2	2	1	3
		1	1		1
		1	3		
		2	2	1	5
					1
		1	9	3	11
		1	1		
					3
		2	6	2	5
					1
				1	1
		9	11	5	28
			1		3
					1
					3
				1	1
					2

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Still birth	1	1
Stomatitis	1	7
Stress		1
Stridor	1	2
Subdural haemorrhage	1	1
Sudden death	1	2
Suicide attempt	1	2
Sunburn		1
Supraventricular tachycardia		1
Suspected COVID-19	7	39
Sweating fever		5
Swelling	42	95
Swelling face	24	52
Swelling of eyelid	4	7
Swollen tongue	7	27
Syncope	11	81
Synovial cyst		1
Synovial rupture		1
Tachycardia	7	39
Tachypnoea	2	6
Taste disorder	3	12
Tearfulness	1	1
Teething	1	1
Temperature difference of extremities		1
Temperature regulation disorder		3
TEMPI syndrome		1
Tenderness	9	23
Tendon rupture	1	1
Tension		1
Tension headache	6	23
Testicular pain		2
Therapeutic response unexpected	3	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	3		4
			1		
				1	2
				1	1
				1	2
				1	2
					1
					1
		4	21	3	18
					5
		15	38	27	57
		11	25	13	27
		1	2	3	5
		1	7	6	20
				11	81
					1
			1		
		5	20	2	19
			1	2	5
		1	6	2	6
				1	1
		1	1		
					1
			2		1
					1
		5	15	4	8
				1	1
			1		
		3	11	3	12
					2
		3	4		

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Thinking abnormal	3	4
Thirst	5	12
Throat clearing		1
Throat irritation	5	12
Throat tightness	7	18
Thrombocytopenia	7	12
Thrombocytopenic purpura	1	1
Thrombophlebitis superficial		1
Thrombosis	7	16
Thrombotic stroke		1
Thyroid neoplasm	1	1
Tinnitus	16	44
Tongue biting	1	1
Tongue blistering	1	2
Tongue coated	2	2
Tongue discolouration	1	2
Tongue discomfort	2	3
Tongue disorder	1	3
Tongue eruption		1
Tongue erythema		1
Tongue haemorrhage		1
Tongue paralysis	1	1
Tongue pruritus		1
Tongue ulceration	2	5
Tonic clonic movements		1
Tonic convulsion	2	2
Tonsillar hypertrophy	1	5
Tonsillitis		2
Toothache	3	6
Tooth disorder		1
Tooth erosion		1
Toxicity to various agents		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2	1	2
		3	5	2	7
					1
		4	10	1	2
		1	4	6	14
				7	12
				1	1
					1
				7	16
					1
				1	1
		3	8	13	36
				1	1
		1	1		1
				2	2
				1	2
		1	1	1	2
			2	1	1
					1
					1
			1		
				1	1
					1
		2	4		1
					1
				2	2
		1	3		2
					2
		2	2	1	4
			1		
			1		
					1

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* AE=Adverse Event

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Transient global amnesia		1
Transient ischaemic attack		8
Traumatic haematoma	1	1
Tremor	25	85
Tricuspid valve incompetence	1	1
Triple negative breast cancer		1
Trismus		2
Type I hypersensitivity		1
Ulcerative keratitis		1
Ulnar nerve injury		2
Underdose	3	9
Unresponsive to stimuli	1	6
Upper-airway cough syndrome	2	3
Upper respiratory tract infection		1
Urge incontinence	1	1
Urinary bladder haemorrhage		1
Urinary incontinence	1	6
Urinary retention	1	5
Urinary tract infection	2	17
Urine flow decreased	1	1
Urine odour abnormal	1	2
Urticaria	15	41
Urticaria chronic		1
Urticaria papular	2	2
Uterine leiomyoma	1	1
Uveitis		1
Vaccination error	1	1
Vaccination failure		2
Vaccination site bruising		7
Vaccination site cellulitis		3
Vaccination site coldness	1	2
Vaccination site cyst		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					8
				1	1
		16	36	9	49
				1	1
					1
					2
					1
					1
					2
		2	8	1	1
				1	6
			1	2	2
					1
				1	1
			1		5
				1	5
		1	1	1	16
				1	1
			1	1	1
		10	26	5	15
					1
		1	1	1	1
				1	1
					1
		1	1		
					2
			5		2
			1		2
		1	1		1
					1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site discolouration	1	1
Vaccination site discomfort	2	6
Vaccination site dryness		1
Vaccination site erythema	17	61
Vaccination site haemorrhage		4
Vaccination site hypersensitivity	1	1
Vaccination site hypoaesthesia		2
Vaccination site induration	3	6
Vaccination site infection		1
Vaccination site inflammation	1	6
Vaccination site joint discomfort		1
Vaccination site joint movement impairment	1	4
Vaccination site joint pain	1	1
Vaccination site lymphadenopathy		1
Vaccination site mass	7	28
Vaccination site movement impairment	4	11
Vaccination site nodule	1	2
Vaccination site oedema		1
Vaccination site pain	68	280
Vaccination site paraesthesia		4
Vaccination site pruritus	11	30
Vaccination site rash	4	21
Vaccination site reaction	2	4
Vaccination site scab		2
Vaccination site swelling	20	74
Vaccination site urticaria		1
Vaccination site vesicles	1	2
Vaccination site warmth	8	32
Vaccine breakthrough infection		5
Vaginal discharge	1	1
Vaginal haemorrhage	11	15
Varicella	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	3	1	3
			1		
		11	40	6	21
			1		3
		1	1		
			1		1
		3	6		
			1		
		1	5		1
			1		
		1	2		2
				1	1
					1
		5	17	2	11
			4	4	7
		1	1		1
					1
		38	170	30	110
			3		1
		9	20	2	10
		3	12	1	9
		2	4		
					2
		13	46	7	28
			1		
		1	2		
		4	18	4	14
					5
				1	1
		4	5	7	10
				2	2

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vasculitis		5
Vasodilatation		1
Vein disorder	1	1
Vertigo	16	52
Vertigo positional	1	5
Vestibular disorder		1
Vestibular neuronitis		2
Viral infection	1	2
Viral rash	1	3
Viral tonsillitis		1
Vision blurred	17	51
Visual acuity reduced		3
Visual field defect		1
Visual impairment	5	16
Vitamin D decreased	1	1
Vitamin D deficiency		1
Vitreous detachment		2
Vitreous disorder	1	1
Vitreous floaters	1	1
Vitreous haemorrhage	1	1
Vomiting	46	133
Vomiting projectile	1	3
Vulval haemorrhage		1
Vulvovaginal candidiasis	1	2
Vulvovaginal injury	1	1
Vulvovaginal pain		1
Vulvovaginal ulceration		1
Weight decreased	3	4
Weight increased	1	1
Weight loss poor		1
Wheezing	9	21
White blood cell count decreased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		2
					1
		1	1		
		5	14	11	38
				1	5
					1
					2
			1	1	1
		1	1		2
					1
		8	19	9	32
			1		2
					1
		3	7	2	9
		1	1		
					1
					2
				1	1
				1	1
				1	1
		27	58	19	75
				1	3
					1
				1	2
				1	1
					1
					1
		1	1	2	3
		1	1		
					1
		5	8	4	13
					1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
White blood cell count increased	1	1			1	1		
Wound	1	1					1	1
Wrong product administered	7	8			7	8		
Wrong technique in product usage process	1	4			1	4		
Yawning	1	1					1	1
	2	8			2	8		
	4,535	15,512		1	2168	6462	2367	9050

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Country Where Event Occurred

UNITED STATES

090177e19749cf15\Approved\Approved On: 14-Jun-2021 14:01 (GMT)

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* AE=Adverse Event

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	1	1			1	1
Abdominal pain upper	1	1	1	1		
Accidental exposure to product	1	1	1	1		
Accidental exposure to product by child	1	1	1	1		
Accidental overdose	1	1	1	1		
Ageusia	1	1	1	1		
Aggression	1	1	1	1		
Alanine aminotransferase increased	1	1			1	1
Allergy to vaccine		1		1		
Anaphylactic reaction	2	4			2	4
Anaphylactic shock	1	2			1	2
Anosmia	1	1	1	1		
Anxiety	1	1	1	1		
Aphasia		2		1		1
Areflexia	1	1			1	1
Arthralgia	4	6	4	6		
Aspartate aminotransferase increased	1	1			1	1
Asthenia	3	4	2	2	1	2
Asthma	1	2	1	2		
Autism spectrum disorder		1				1
Axillary pain	2	2	1	1	1	1
Back pain	4	5	4	5		
Balance disorder		1		1		
Basal ganglia infarction		1				1
Bedridden	2	2	1	1	1	1
Blister	1	1	1	1		
Blood calcium decreased	1	1	1	1		
Blood glucose increased		1		1		
Blood lactic acid increased		1				1
Blood pressure decreased	2	2	1	1	1	1
Body temperature increased	1	3	1	3		

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burning sensation	1	3	1	3		
Campylobacter infection	1	1			1	1
Cellulitis	1	1			1	1
Cerebral palsy		1				1
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident		1				1
Chest discomfort		1		1		
Chest pain	9	9	5	5	4	4
Chills	12	23	10	21	2	2
Circumstance or information capable of leading to medication error	1	2	1	2		
Completed suicide	1	1			1	1
Condition aggravated	2	2	1	1	1	1
Confusional state	2	2	1	1	1	1
Contusion	2	2	2	2		
Coprolalia	1	1	1	1		
Cough	4	5	4	4		1
COVID-19	7	11	5	7	2	4
Deafness unilateral	1	1			1	1
Death	2	3			2	3
Death neonatal		1				1
Decreased appetite	2	2	2	2		
Delirium	1	1			1	1
Depression	1	1	1	1		
Diarrhoea	4	6	4	5		1
Diet refusal	1	1			1	1
Discomfort	1	1	1	1		
Disease recurrence	1	1			1	1
Disorientation	2	3	1	2	1	1
Dizziness	16	24	13	18	3	6
Drug ineffective	2	4			2	4
Dry mouth		1		1		

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry skin	1	1	1	1		
Ductus arteriosus premature closure		1				1
Dysarthria	2	2	1	1	1	1
Dysgeusia		1		1		
Dyskinesia	1	2	1	2		
Dyspepsia	1	1	1	1		
Dysphagia	1	2	1	2		
Dysphonia	1	1	1	1		
Dyspnoea	4	6	2	4	2	2
Dysstasia	1	2	1	1		1
Ear discomfort	1	1	1	1		
Ear pain	1	1	1	1		
Electrocardiogram abnormal	1	1			1	1
Electrocardiogram ST segment elevation	1	1			1	1
Emotional distress	2	2	1	1	1	1
Epistaxis	2	2	2	2		
Erythema	1	2	1	1		1
Exercise electrocardiogram abnormal	1	1	1	1		
Expired product administered	1	1	1	1		
Exposure during pregnancy		1		1		
Exposure to SARS-CoV-2	1	1	1	1		
Exposure via breast milk	6	53	4	48	2	5
Extremity contracture	1	1	1	1		
Eye haemorrhage	1	1			1	1
Eye irritation		1		1		
Eye pain		2		2		
Eye swelling	2	3	1	2	1	1
Facial paralysis	1	3			1	3
Facial spasm		1				1
Faecal calprotectin decreased	1	1	1	1		
Faecal calprotectin increased	1	1	1	1		
Failure to thrive	1	1			1	1

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fall	1	2	1	2		
Fatigue	15	27	15	27		
Feeling abnormal	6	9	6	9		
Feeling hot	1	2		1	1	1
Feeling of body temperature change	1	1			1	1
Fever neonatal		2				2
Fibroblast growth factor 23	1	1	1	1		
Flatulence	1	1	1	1		
Flushing	1	1			1	1
Gastrointestinal tract irritation		1		1		
Guillain-Barre syndrome	1	1			1	1
Haemorrhage	1	1			1	1
Headache	25	40	20	32	5	8
Head discomfort	1	1	1	1		
Head injury	2	2	2	2		
Heart rate decreased	1	1	1	1		
Heart rate increased	4	7	4	7		
Hepatic enzyme increased	1	1			1	1
Hyperglycaemia		1				1
Hyperhidrosis	7	11	6	9	1	2
Hypersensitivity	3	5	3	3		2
Hypersomnia	1	1	1	1		
Hyperthermia		1		1		
Hyperventilation		1		1		
Hypoacusis	1	1	1	1		
Hypoaesthesia	1	2	1	2		
Hypokinesia	1	1	1	1		
Hypotension	1	2			1	2
Hypotonia		1		1		
IgA nephropathy	1	1			1	1
Illness	2	4	2	3		1
Inappropriate schedule of product administration	7	7	6	6	1	1

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Incoherent		1				1
Increased appetite		1		1		
Infantile vomiting		2		2		
Infant irritability		4		3		1
Influenza like illness	1	2	1	2		
Injection site pain	1	2	1	2		
Injury		1		1		
Insomnia	1	5	1	5		
Irritability		1		1		
Ischaemic cerebral infarction		1				1
Joint range of motion decreased	1	1			1	1
Kidney infection		1				1
Left ventricular dysfunction	1	1			1	1
Lethargy	2	4	2	4		
Ligament rupture		1				1
Limb discomfort	2	3	2	3		
Lip discolouration	2	2	2	2		
Loss of consciousness	8	15			8	15
Loss of personal independence in daily activities	1	1	1	1		
Lymphadenitis	1	2	1	2		
Lymphadenopathy	4	4	3	3	1	1
Malaise	4	7	2	4	2	3
Mass	1	1	1	1		
Maternal exposure during pregnancy	1	3			1	3
Maternal exposure timing unspecified	1	1	1	1		
Meconium aspiration syndrome	1	1			1	1
Memory impairment	2	2	1	1	1	1
Migraine	1	2		1	1	1
Mobility decreased		1				1
Motor dysfunction		1				1
Mouth ulceration	1	1	1	1		
Multisystem inflammatory syndrome in children	1	1			1	1

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle contractions involuntary		1		1		
Muscle spasms		1		1		
Muscle strain	1	1			1	1
Muscle tightness	1	1	1	1		
Muscle twitching		3		3		
Musculoskeletal discomfort		1		1		
Musculoskeletal stiffness	1	1	1	1		
Myalgia	2	5	1	4	1	1
Myocardial infarction	1	1			1	1
Myocardial necrosis marker increased	1	1			1	1
Myocarditis	2	2			2	2
Nasal congestion	2	3	2	3		
Nasopharyngitis	1	2	1	2		
Nausea	16	22	14	18	2	4
Neck pain	3	3	2	2	1	1
Needle issue	1	1	1	1		
Neutropenia neonatal		1				1
Ocular hyperaemia		1		1		
Off label use	17	30	16	29	1	1
Oropharyngeal discomfort	1	1	1	1		
Oropharyngeal pain	1	5	1	5		
Overdose	7	7	5	5	2	2
Oxygen saturation abnormal		1		1		
Pain	9	16	9	15		1
Pain in extremity	12	18	11	17	1	1
Pallor	5	6	5	5		1
Papule	1	1			1	1
Paraesthesia	1	4	1	3		1
Paranasal sinus discomfort		1		1		
Parosmia		1		1		
Pemphigoid	1	1			1	1
Pericarditis	2	2			2	2

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Periorbital swelling		1		1		
Peripheral swelling	3	4	3	4		
Piloerection		1		1		
Pityriasis rosea	1	1	1	1		
Platelet count decreased	1	1	1	1		
Poor feeding infant		1		1		
Poor quality product administered	8	8	8	8		
Postural orthostatic tachycardia syndrome	1	1			1	1
Premature baby	1	2			1	2
Presyncope	3	4	2	3	1	1
Product administered to patient of inappropriate age	12	31	12	31		
Product administration error	1	1	1	1		
Productive cough		1		1		
Product preparation error	5	5	5	5		
Product preparation issue	2	2	2	2		
Product storage error	3	3	3	3		
Product temperature excursion issue	5	5	5	5		
Product use issue	12	17	12	17		
Pruritus	2	3	2	3		
Pulmonary arterial pressure abnormal		1				1
Pyrexia	25	46	20	39	5	7
Rash	6	11	4	9	2	2
Rash neonatal		1		1		
Respiratory distress	1	1			1	1
Rhinorrhoea	5	7	5	7		
SARS-CoV-2 test positive	1	1	1	1		
Scab	1	1			1	1
Seizure	13	18			13	18
Seizure like phenomena	1	1			1	1
Sensitive skin		1		1		
Sensory loss	1	1			1	1

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sinusitis	1	1	1	1		
Skin discolouration	1	1	1	1		
Skin disorder	1	1	1	1		
Sleep terror	1	1	1	1		
Sneezing		1		1		
Soliloquy	1	1	1	1		
Somnolence	3	6	2	4	1	2
Spinal pain	1	1	1	1		
Status migrainosus	1	1			1	1
Streptobacillus infection	1	1			1	1
Swelling	3	3	1	1	2	2
Swelling face	2	2	1	1	1	1
Swelling of eyelid	1	1	1	1		
Syncope	10	12			10	12
Syringe issue	1	1	1	1		
Tachycardia	2	2	1	1	1	1
Taste disorder	1	1	1	1		
Tension	1	1			1	1
Thinking abnormal	1	1	1	1		
Throat irritation	2	2	1	1	1	1
Throat tightness	3	3			3	3
Thrombocytopenia	1	1			1	1
Thrombosis	1	1			1	1
Thrombotic thrombocytopenic purpura	2	2			2	2
Tic	2	2	2	2		
Tinnitus	1	2	1	1		1
Tongue discomfort	1	1	1	1		
Tonsillar inflammation		1		1		
Transaminases increased	1	1			1	1
Tremor	7	11	5	9	2	2
Trismus		1				1
Troponin increased	3	3			3	3

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Underdose	2	2	2	2		
Urinary tract infection		1				1
Urticaria	2	6	1	3	1	3
Vaccination site discomfort	1	1	1	1		
Vaccination site pain	3	7	3	7		
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	1	1	1	1		
Ventricular hypertrophy		1				1
Vestibular disorder	1	1	1	1		
Viral infection	1	1	1	1		
Vision blurred	3	5	3	3		2
Vomiting	8	13	6	8	2	5
Wheezing		1				1
White blood cell count increased	1	2	1	1		1
Wrong product administered		1		1		
	564	930	403	680	161	250

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	5	24			4	23	1	1
Abdominal distension	3	7			2	5	1	2
Abdominal pain	9	42			7	35	2	7
Abdominal pain lower	3	4			3	4		
Abdominal pain upper	11	48			11	46		2
Abdominal rigidity		1				1		
Abnormal behaviour	1	2			1	1		1
Abnormal dreams	1	2			1	2		
Abortion missed		1						1
Abortion spontaneous	9	16					9	16
Accident	1	2			1	1		1
Accidental exposure to product	1	2			1	2		
Accidental overdose	2	4			2	3		1
Acne		1						1
Acoustic neuritis		1				1		
Acute kidney injury	1	1					1	1
Administration site reaction		1				1		
Ageusia	7	31			7	27		4
Agitation	1	2			1	2		
Alanine aminotransferase increased	1	3			1	3		
Abumin globulin ratio decreased		1				1		
Allergy to vaccine	4	12			4	11		1
Alopecia	2	5			2	5		
Alopecia areata	1	2			1	2		
Altered state of consciousness		1						1
Amnesia	4	5			3	3	1	2
Amphetamines positive	1	1			1	1		
Anaphylactic reaction	6	39					6	39
Anaphylactic shock	2	5					2	5
Anaphylactoid reaction		1						1
Aneurysm		1						1
Anger		1						1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Angina pectoris	2	3
Angioedema	2	9
Anosmia	7	31
Antibody test negative		1
Anti-thyroid antibody positive	1	1
Anxiety	14	34
Apathy		1
Aphasia	1	4
Aphonia		1
Aphthous ulcer		2
Appendicitis	5	10
Arrhythmia	5	12
Arthralgia	23	181
Arthritis		5
Arthropathy	1	1
Aspartate aminotransferase decreased		1
Aspartate aminotransferase increased	1	3
Asthenia	20	135
Asthenopia		2
Asthma	2	9
Asymptomatic COVID-19		2
Ataxia		1
Atelectasis		1
Atrial fibrillation		1
Autoimmune disorder		1
Autoscopy		1
Axillary mass	2	5
Axillary pain	3	25
Back pain	16	70
Balance disorder	2	7
Basedow's disease		1
Bedridden	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	3
				2	9
		6	28	1	3
			1		
		1	1		
		14	31		3
			1		
			1	1	3
			1		
			2		
				5	10
				5	12
	1	21	175	2	6
			5		
		1	1		
			1		
			2	1	1
		19	120	1	15
			2		
		2	6		3
					2
					1
					1
					1
			1		
		2	5		
		3	25		
		14	64	2	6
		2	6		1
					1
		2	2		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bell's palsy	7	24
Bladder pain		1
Blepharospasm	1	4
Blindness	6	10
Blindness transient	1	2
Blindness unilateral	1	1
Blister	1	8
Blood alkaline phosphatase increased	1	1
Blood bilirubin increased		1
Blood cholesterol increased		1
Blood count abnormal	1	1
Blood creatine increased		1
Blood creatine phosphokinase increased		1
Blood glucose decreased		1
Blood glucose increased	1	2
Blood lactate dehydrogenase increased	1	1
Blood lactic acid increased		1
Blood potassium decreased		1
Blood potassium increased		1
Blood pressure abnormal	2	4
Blood pressure decreased		6
Blood pressure fluctuation		1
Blood pressure increased	2	19
Blood pressure systolic increased		1
Blood sodium decreased		2
Blood thyroid stimulating hormone decreased	1	1
Blood urine		1
Blood urine present	1	2
Body temperature abnormal		2
Body temperature decreased		3
Body temperature fluctuation		2
Body temperature increased	2	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				7	24
			1		
		1	4		
				6	10
				1	2
				1	1
		1	5		3
		1	1		
			1		
			1		
		1	1		
			1		
					1
					1
		1	1		1
		1	1		
			1		
			1		
			1		
		2	4		
			5		1
					1
		1	11	1	8
					1
			1		1
		1	1		
			1		
		1	2		
			1		1
			3		
			2		
		2	10		1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bone pain	1	9
Bowel movement irregularity		1
Brain death		1
Brain injury	1	1
Breakthrough pain	1	1
Breast disorder	1	1
Breast mass		2
Breast pain		2
Breast swelling		2
Breast tenderness	1	1
Bronchitis		1
Bronchospasm		2
Burning sensation	10	20
Burn oral cavity	1	1
Burns third degree	1	1
Cardiac disorder	1	5
Cardiac failure	1	1
Cardiac flutter	1	4
Cardiac murmur		1
Cardiac tamponade	2	2
Cardiomegaly	2	2
Cardiomyopathy		1
Cardiovascular disorder		1
Carotid artery occlusion		1
CD4 lymphocytes decreased	1	1
Cellulitis	1	1
Central pain syndrome		1
Cerebral venous sinus thrombosis		1
Cerebrovascular accident	3	6
Cerebrovascular disorder		1
Cerumen impaction		1
Cheilitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	9		
			1		
					1
				1	1
		1	1		
				1	1
			1		1
			2		
			1		1
		1	1		
			1		
					2
		8	17	2	3
				1	1
				1	1
		1	3		2
				1	1
				1	4
					1
				2	2
		2	2		
					1
			1		
					1
				1	1
				1	1
			1		
					1
				3	6
					1
			1		
			1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chest discomfort	15	57
Chest pain	29	90
Chills	104	673
Choking sensation		1
Cholelithiasis		1
Chromaturia	3	6
Circulatory collapse	1	2
Circumstance or information capable of leading to medication error	1	8
Clonus	1	2
Coagulation time prolonged		1
Cognitive disorder	1	2
Cold sweat		18
Cold urticaria	1	1
Colitis		1
Colitis ulcerative	1	1
Communication disorder		1
Concussion	1	3
Condition aggravated	7	32
Confusional state	2	13
Conjunctivitis	1	2
Constipation	2	6
Contusion	6	13
Coombs negative haemolytic anaemia	1	2
Coordination abnormal	1	2
Costochondritis		1
Costovertebral angle tenderness		1
Cough	18	85
COVID-19	30	137
COVID-19 immunisation		1
COVID-19 pneumonia	1	2
C-reactive protein increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		13	34	2	23
		19	65	10	25
		99	651	5	22
					1
					1
		3	6		
				1	2
		1	8		
			1	1	1
			1		
		1	1		1
			15		3
		1	1		
			1		
				1	1
					1
				1	3
1	1	6	29	1	3
		1	8	1	5
			1	1	1
		2	5		1
		5	11	1	2
				1	2
		1	2		
			1		
			1		
		16	67	2	18
		11	56	19	81
			1		
				1	2
					1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Crepitations	1	1
Crying	1	5
Cyanosis	1	6
Deafness	8	11
Deafness bilateral	1	1
Deafness neurosensory	1	2
Deafness transitory		1
Deafness unilateral		1
Death	1	5
Decreased appetite	8	39
Deep vein thrombosis		6
Defaecation urgency		1
Dehydration	4	25
Delirium	2	5
Demyelinating polyneuropathy		1
Depersonalisation/derealisation disorder		1
Depressed level of consciousness		1
Depressed mood	2	5
Depression	3	5
Dermatitis allergic		1
Dermatitis atopic		1
Device breakage		1
Diabetes mellitus		1
Diaphragmalgia	1	1
Diaphragmatic paralysis		1
Diarrhoea	22	111
Diarrhoea haemorrhagic	2	2
Diplegia	2	3
Discomfort	3	26
Disease recurrence	2	7
Disorientation		8
Disturbance in attention	3	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	4		1
			3	1	3
				8	11
				1	1
				1	2
					1
					1
				1	5
		8	36		3
					6
			1		
		4	16		9
				2	5
					1
			1		
					1
		2	5		
		3	4		1
			1		
			1		
					1
					1
		1	1		
					1
		21	105	1	6
				2	2
				2	3
		3	22		4
			3	2	4
			7		1
		3	8		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Disturbance in social behaviour		1
Dizziness	64	339
Dizziness postural	1	7
Drainage	1	1
Drug hypersensitivity	1	4
Drug ineffective	15	90
Dry eye	1	2
Dry mouth	1	12
Dry skin		2
Dry throat	1	12
Dysacusis	1	1
Dysaesthesia		1
Dysarthria	4	6
Dysgeusia	2	17
Dyskinesia		1
Dysmenorrhoea	4	8
Dyspepsia	1	6
Dysphagia	4	28
Dysphemia		3
Dysphonia		11
Dyspnoea	39	174
Dysstasia	4	9
Dystonia		3
Dysuria		2
Ear congestion		1
Ear discomfort	3	13
Ear disorder	1	2
Ear infection		2
Ear pain	7	18
Ear pruritus	1	1
Ear swelling		4
Eating disorder	3	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		60	293	4	46
		1	5		2
		1	1		
		1	3		1
				15	90
		1	2		
			11	1	1
			2		
		1	10		2
				1	1
			1		
		4	5		1
		2	15		2
					1
		2	6	2	2
		1	6		
		2	15	2	13
			3		
			6		5
		27	111	12	63
		2	4	2	5
					3
			2		
			1		
		3	12		1
		1	2		
			1		1
		6	17	1	1
		1	1		
			3		1
		2	4	1	1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ectopic pregnancy	1	1
Eczema	2	2
Ejection fraction abnormal		1
Electric shock sensation	1	1
Electrocardiogram abnormal		1
Electrocardiogram QT prolonged		2
Electrocardiogram ST segment elevation	1	1
Electrocardiogram T wave peaked		1
Emotional disorder		1
Emotional distress	1	1
Energy increased		1
Enlarged uvula		2
Enuresis		1
Eosinophil count increased		1
Eosinophilic oesophagitis	1	1
Epididymitis	1	1
Epilepsy	1	1
Epistaxis	2	8
Eructation		1
Erythema	7	57
Euphoric mood		2
Exercise tolerance decreased		1
Expired product administered	2	4
Exposure during pregnancy	2	13
Exposure to SARS-CoV-2		8
Exposure via skin contact	1	1
External ear pain	1	1
Extraocular muscle paresis		1
Eye discharge		3
Eye disorder		4
Eye infection		1
Eye irritation	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		2	2		
			1		
		1	1		
					1
					2
				1	1
			1		
			1		
		1	1		
			1		
			1		1
					1
				1	1
				1	1
				1	1
		1	6	1	2
			1		
		6	48	1	9
			2		
			1		
		1	3	1	1
		2	12		1
			7		1
		1	1		
		1	1		
					1
			3		
			4		
			1		
			1	1	1

* I=Interval, C=Cumulative

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eyelid disorder		1
Eyelid ptosis		2
Eye movement disorder	1	2
Eye pain	2	13
Eye pruritus	3	8
Eye swelling	5	25
Face injury		3
Face oedema		1
Facial discomfort	1	1
Facial neuralgia		1
Facial pain		7
Facial paralysis	2	8
Facial paresis		3
Facial spasm	1	3
Factor V Leiden mutation		1
Faeces discoloured		1
Faeces soft		1
Fall	6	15
Fatigue	113	651
Fear	1	3
Fear of injection		1
Feeding disorder	1	4
Feeling abnormal	27	91
Feeling cold	3	24
Feeling drunk	1	3
Feeling hot	12	59
Feeling jittery		3
Feeling of body temperature change	4	11
Fibrin D dimer increased		1
Fibromyalgia	1	1
Finger deformity	1	1
Flank pain		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					2
		1	2		
		2	12		1
		3	7		1
		4	20	1	5
			1		2
					1
		1	1		
					1
			6		1
				2	8
			1		2
			1	1	2
					1
			1		
			1		
		4	9	2	6
		111	636	2	15
		1	2		1
			1		
		1	3		1
		27	79		12
		3	22		2
		1	3		
		10	48	2	11
			3		
		4	11		
			1		
		1	1		
		1	1		
			1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Flatulence	1	2
Fluid imbalance		1
Flushing	2	32
Foaming at mouth		1
Foetal death		1
Foetal hypokinesia		1
Food poisoning	1	1
Foreign body in throat		1
Foreign body sensation in eyes		1
Formication		1
Full blood count abnormal		2
Fungal infection	1	1
Gait disturbance	3	8
Gait inability	4	7
Galactostasis	1	1
Gastritis	1	2
Gastroenteritis viral		2
Gastrointestinal disorder	1	4
Gastrointestinal inflammation		1
Gastrointestinal injury		1
Gastrointestinal pain	1	1
Gastrooesophageal reflux disease	2	4
Generalised anxiety disorder		2
Generalised tonic-clonic seizure	2	5
Genital herpes		1
Genital rash		1
Gingival blister		1
Gingival discolouration		1
Gingival discomfort		1
Gingival pain		2
Gingival ulceration		1
Glassy eyes		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
					1
		1	22	1	10
			1		
					1
					1
		1	1		
					1
			1		
			1		
			2		
		1	1		
		2	6	1	2
		1	3	3	4
		1	1		
		1	2		
			2		
		1	4		
			1		
			1		
		1	1		
		1	3	1	1
			2		
				2	5
					1
			1		
			1		
					1
					1
					2
			1		
			1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Glaucoma	1	1
Glossodynia	2	2
Goitre	2	2
Granuloma		1
Grunting		1
Guillain-Barre syndrome	3	3
Haematemesis	1	4
Haematochezia	2	9
Haematuria	1	1
Haemoglobin decreased	1	2
Haemoglobin urine present	1	1
Haemoptysis	2	3
Haemorrhage	3	6
Haemorrhage subcutaneous	1	1
Haemorrhagic diathesis	1	1
Haemorrhagic stroke		1
Hallucination	2	5
Hallucination, auditory		1
Hallucination, visual	1	2
Hangover	1	3
Headache	143	813
Head discomfort	5	10
Head injury	2	9
Heart injury		1
Heart rate decreased	1	2
Heart rate increased	15	88
Heart rate irregular		4
Heavy menstrual bleeding	10	16
Hemiparesis		5
Hemiplegia	1	1
Henoch-Schonlein purpura	1	1
Hepatic enzyme increased	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1	1	1
		1	1	1	1
					1
			1		
				3	3
				1	4
				2	9
				1	1
		1	1		1
		1	1		
			1	2	2
			1	3	5
				1	1
				1	1
				2	5
					1
				1	2
		1	3		
		135	776	8	37
		5	10		
		2	3		6
					1
		1	2		
		12	67	3	21
			3		1
		6	12	4	4
					5
				1	1
				1	1
		1	3		2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hepatic pain	1	1
Hepatomegaly	1	1
Herpes dermatitis	1	1
Herpes simplex		2
Herpes virus infection	1	1
Herpes zoster	11	19
Herpes zoster infection neurological	1	1
Herpes zoster oticus	1	1
Hot flush	6	26
Human chorionic gonadotropin increased	1	1
Hunger	1	3
Hyperacusis		3
Hyperaemia		1
Hyperaesthesia		3
Hyperglycaemia		1
Hyperhidrosis	24	96
Hyperpyrexia		3
Hypersensitivity	18	53
Hypersexuality	1	1
Hypersomnia		8
Hypertension	5	19
Hyperthermia		1
Hyperthyroidism	1	2
Hyperventilation	3	9
Hypoacusis	5	7
Hypoesthesia	33	122
Hypoesthesia oral	6	19
Hypoglycaemia		4
Hypokalaemia		1
Hypomenorrhoea		1
Hypopnoea		2
Hyporesponsive to stimuli		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
		1	1		
			2		
		1	1		
		8	14	3	5
				1	1
				1	1
		6	24		2
				1	1
		1	3		
			3		
			1		
			3		
			1		
		21	86	3	10
					3
		15	37	3	16
		1	1		
			8		
		5	14		5
			1		
				1	2
		3	7		2
		2	4	3	3
		25	93	8	29
		6	15		4
			2		2
					1
			1		
			2		
			1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypotension	7	23
Hypothermia		1
Hypoxia		1
Idiopathic urticaria	1	1
Illness	10	37
Immune thrombocytopenia		3
Immunisation		1
Immunisation reaction		1
Impaired work ability	1	2
Implant site nodule		1
Inappropriate schedule of product administration	7	78
Incoherent	1	2
Incorrect dose administered		2
Incorrect route of product administration	1	6
Increased appetite	1	1
Increased tendency to bruise	1	1
Increased upper airway secretion	1	1
Induration		1
Infection		2
Infectious mononucleosis	2	4
Inflammation	4	14
Influenza	1	6
Influenza like illness	10	46
Initial insomnia	1	1
Injected limb mobility decreased		1
Injection site cellulitis	1	1
Injection site erythema	2	9
Injection site pain	4	32
Injection site pruritus		4
Injection site rash	1	5
Injection site reaction		2
Injection site swelling		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	12	2	11
					1
					1
				1	1
		9	29	1	8
					3
			1		
					1
		1	2		
			1		
		7	78		
			1	1	1
			2		
		1	5		1
		1	1		
				1	1
				1	1
			1		
			1		1
		1	2	1	2
		3	11	1	3
		1	5		1
		10	42		4
				1	1
			1		
		1	1		
		2	9		
		4	32		
			4		
		1	5		
			2		
			4		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site urticaria		1
Injury	1	2
Insomnia	14	45
Inspiratory capacity decreased		1
Intellectual disability	1	1
Intentional self-injury	1	1
Intermenstrual bleeding	2	5
Intracranial aneurysm		2
Intracranial pressure increased		1
Intranasal paraesthesia		1
Intraventricular haemorrhage		1
Investigation abnormal	1	1
Iron deficiency		1
Irritability	4	6
Irritable bowel syndrome		2
Jaundice		2
Jaw disorder		1
Joint dislocation		1
Joint injury	1	3
Joint instability		1
Joint range of motion decreased	2	13
Joint stiffness	2	6
Joint swelling		2
Keratitis		1
Keratosis pilaris		1
Kidney infection	1	3
Lack of spontaneous speech		1
Lacrimal disorder		1
Lacrimation decreased		1
Lacrimation increased	2	3
Lactic acidosis		1
Laryngeal oedema		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	2
		13	41	1	4
			1		
				1	1
				1	1
		2	4		1
					2
					1
			1		
					1
		1	1		
			1		
		4	6		
			2		
					2
			1		
					1
		1	2		1
					1
		2	10		3
		1	5	1	1
			1		1
			1		
			1		
				1	3
					1
			1		
					1
		2	3		
					1
					1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lethargy	6	31
Ligament injury		1
Limb discomfort	2	13
Limb injury		1
Limb mass		2
Lipase decreased		1
Lipase increased		1
Lip blister		2
Lip disorder		1
Lip dry		1
Lip erythema		1
Lipids abnormal		1
Lip oedema		2
Lip swelling	7	28
Lip ulceration		1
Livedo reticularis	1	1
Liver function test abnormal		1
Liver function test increased	1	1
Localised infection	1	2
Localised oedema		2
Loss of consciousness	29	76
Loss of personal independence in daily activities	1	11
Low density lipoprotein increased		1
Lower respiratory tract infection		1
Lung disorder	1	5
Lymphadenitis		1
Lymphadenopathy	37	197
Lymph gland infection		1
Lymph node pain	10	39
Lymph node palpable		2
Lymphocyte count decreased		1
Macule		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	26	1	5
			1		
		2	12		1
			1		
			2		
			1		
					1
			2		
			1		
			1		
			1		
			1		
			1		
			1		1
		5	20	2	8
			1		
				1	1
					1
				1	1
		1	2		
			2		
				29	76
		1	8		3
			1		
					1
			4	1	1
			1		
		33	182	4	15
					1
		10	37		2
			2		
			1		
			1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Malaise	35	149
Mass		4
Mastitis	2	2
Maternal exposure during pregnancy	2	24
Melaena		1
Memory impairment	4	4
Meniere's disease		1
Meningism		1
Meningitis	1	1
Meningitis noninfective		1
Menstrual disorder	6	10
Menstruation delayed	1	1
Menstruation irregular	16	17
Mental impairment		6
Metabolic encephalopathy		1
Metabolic function test abnormal		1
Metamorphopsia		1
Micturition disorder		1
Micturition urgency	1	2
Middle insomnia		3
Migraine	14	72
Migraine with aura	1	2
Mobility decreased	1	9
Monoplegia	1	3
Mood altered	2	2
Mood swings		2
Motion sickness		2
Motor dysfunction	1	2
Mouth haemorrhage	1	1
Mouth swelling	1	4
Mouth ulceration	1	4
Movement disorder	4	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		31	138	4	11
			4		
				2	2
		2	24		
					1
		3	3	1	1
					1
			1		
		1	1		
					1
		6	10		
		1	1		
		16	17		
					6
					1
			1		
					1
					1
			1	1	1
			3		
		12	65	2	7
		1	2		
		1	7		2
				1	3
		2	2		
			1		1
			2		
		1	2		
		1	1		
			3	1	1
		1	4		
		2	6	2	2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mucosal disorder		1
Multiple organ dysfunction syndrome	1	1
Multiple sclerosis	1	1
Muscle discomfort		1
Muscle disorder		2
Muscle fatigue	1	4
Muscle spasms	9	31
Muscle strain	1	1
Muscle swelling		1
Muscle tightness	4	13
Muscle twitching	2	10
Muscular weakness	10	36
Musculoskeletal chest pain	1	7
Musculoskeletal discomfort		5
Musculoskeletal disorder	1	3
Musculoskeletal pain	1	4
Musculoskeletal stiffness	7	28
Myalgia	40	289
Mydriasis	3	4
Myelitis	1	1
Myocardial infarction	4	6
Myocardial necrosis marker increased	2	4
Myocardial strain		1
Myocarditis	15	20
Myoclonus		1
Myopathy	1	1
Myositis	1	1
Nail discolouration	1	1
Narcolepsy		1
Nasal congestion	12	54
Nasal discomfort	1	3
Nasal dryness		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
				1	1
			1		
			2		
			3	1	1
		6	25	3	6
		1	1		
			1		
		2	10	2	3
		2	10		
		8	28	2	8
		1	6		1
			4		1
		1	3		
		1	4		
		7	27		1
		37	277	3	12
		3	4		
				1	1
				4	6
				2	4
					1
		1	1	14	19
					1
				1	1
		1	1		
		1	1		
					1
		12	49		5
		1	3		
			2		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nasal injury	1	3
Nasal oedema		3
Nasal pruritus		1
Nasopharyngitis	7	28
Nausea	79	479
Near death experience	2	3
Neck mass	1	2
Neck pain	14	48
Neoplasm		1
Nephrolithiasis	1	1
Nephropathy		1
Nerve injury	1	3
Nervousness	3	14
Nervous system disorder	1	1
Neuralgia	1	8
Neuralgic amyotrophy	2	3
Neuritis	1	1
Neurological infection	1	1
Neurological symptom		2
Neuropathy peripheral	3	4
Neutrophil count decreased		1
Neutrophil count increased		1
Nightmare	1	3
Night sweats	4	21
Nipple pain		1
Nodule		3
Noninfective encephalitis		1
Occipital neuralgia		1
Ocular discomfort	1	4
Ocular hyperaemia	2	10
Ocular vascular disorder	3	3
Odynophagia		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	1	1
			1		2
			1		
		7	28		
		69	445	10	34
				2	3
		1	2		
		13	40	1	8
			1		
				1	1
			1		
		1	1		2
		3	13		1
		1	1		
		1	7		1
		2	2		1
		1	1		
				1	1
					2
				3	4
			1		
					1
		1	3		
		4	20		1
			1		
			1		2
					1
			1		
		1	3		1
		2	8		2
				3	3
			1		1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oedema	1	1
Oedema mouth		1
Oedema peripheral		1
Oesophageal disorder	1	1
Oesophagitis		1
Off label use	10	57
Oligomenorrhoea	1	1
Ophthalmic migraine	1	1
Optic neuritis		1
Oral blood blister	1	1
Oral discomfort		3
Oral disorder		3
Oral herpes	1	4
Oral mucosal eruption		1
Oral pain	1	4
Oral pruritus	1	3
Orbital oedema		1
Oropharyngeal discomfort	5	11
Oropharyngeal pain	16	76
Orthostatic intolerance		1
Otitis media		1
Ovarian cyst ruptured	1	1
Overdose	8	22
Oxygen saturation decreased		1
Pain	96	571
Painful respiration		3
Pain in extremity	73	338
Pain in jaw		5
Pain of skin	2	4
Palatal swelling		1
Pallor	4	14
Palmar erythema		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
			1		
				1	1
			1		
		10	55		2
		1	1		
				1	1
					1
		1	1		
			3		
			3		
		1	4		
			1		
		1	3		1
			1	1	2
					1
		4	9	1	2
		15	69	1	7
			1		
			1		
				1	1
		8	22		
					1
		88	537	8	34
			3		
	1	70	329	3	9
			5		
		2	4		
			1		
		3	10	1	4
			1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Palpitations	9	56
Pancreatitis		1
Panic attack	5	8
Panic disorder		1
Panic reaction	1	2
Papule	1	1
Paraesthesia	18	103
Paraesthesia oral	3	17
Paralysis	1	3
Paranasal sinus discomfort	2	9
Paranoia		1
Parosmia	3	5
Periarthritis		1
Pericardial effusion	1	2
Pericarditis	9	12
Periorbital swelling	1	5
Peripheral coldness	1	6
Peripheral swelling	4	38
Peripheral venous disease		1
Petechiae		2
Pharyngeal abscess	2	2
Pharyngeal enanthema		1
Pharyngeal erythema		2
Pharyngeal hypoaesthesia		4
Pharyngeal inflammation	1	1
Pharyngeal oedema		3
Pharyngeal paraesthesia		4
Pharyngeal swelling	7	31
Pharyngeal ulceration		1
Pharyngitis	1	2
Pharyngitis streptococcal	2	3
Phlebitis superficial		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		8	43	1	13
					1
		5	8		
			1		
		1	2		
		1	1		
		16	82	2	21
		2	14	1	3
				1	3
		1	8	1	1
			1		
		3	5		
					1
				1	2
				9	12
		1	4		1
		1	5		1
		3	34	1	4
					1
			1		1
				2	2
			1		
			2		
			3		1
				1	1
			2		1
			4		
		4	18	3	13
			1		
			1	1	1
		1	2	1	1
			1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Photophobia	1	4
Photopsia		1
Photosensitivity reaction		4
Phrenic nerve injury		1
Piloerection		4
Pityriasis		1
Pityriasis rosea		1
Platelet count decreased	2	5
Platelet count increased		2
Platelet disorder		1
Pleural effusion	4	5
Pleurisy		1
Pleuritic pain		1
Pneumonia		4
Pneumonitis		1
Pneumothorax	1	1
Pollakiuria	1	4
Polymenorrhoea		1
Polyserositis		1
Polyuria		2
Poor quality product administered	11	22
Poor quality sleep	1	6
Postictal state		1
Postpartum disorder		1
Postural orthostatic tachycardia syndrome		
Premature delivery		1
Premature labour		1
Premature rupture of membranes		1
Premenstrual syndrome	1	1
Presyncope	3	25
Primary headache associated with sexual activity		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4		
			1		
			4		
					1
			4		
			1		
			1		
		1	2	1	3
					2
					1
		1	2	3	3
					1
			1		
					4
					1
				1	1
			3	1	1
			1		
					1
			2		
		11	22		
		1	6		
			1		
			1		
	1				
					1
					1
					1
		1	1		
		3	21		4
					1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Procedural pain		1
Proctalgia	1	1
Product administered at inappropriate site		10
Product administration error		2
Product dose omission issue	1	1
Product formulation issue		1
Productive cough		2
Product preparation error	5	11
Product preparation issue	4	6
Product prescribing error	1	2
Product storage error		4
Product temperature excursion issue	9	15
Product use issue	6	39
Protein urine present		1
Pruritus	17	108
Psychotic disorder		1
Pulmonary embolism	3	10
Pulmonary infarction	1	2
Pulmonary oedema	2	2
Pulmonary pain	1	6
Pulmonary thrombosis		2
Pulse abnormal	1	1
Pulse absent		1
Pupil fixed		1
Purpura		1
Pyrexia	125	729
Rash	34	152
Rash erythematous	5	18
Rash macular	4	13
Rash maculo-papular		2
Rash morbilliform		3
Rash papular	1	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1		
			9		1
			1		1
		1	1		
					1
			1		1
		5	11		
		4	5		1
		1	2		
			4		
		9	15		
		6	37		2
			1		
		13	87	4	21
					1
				3	10
				1	2
				2	2
		1	6		
					2
		1	1		
					1
					1
			1		
		111	682	14	47
		33	132	1	20
		5	15		3
		4	11		2
			2		
			1		2
		1	8		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rash pruritic	4	20
Rash pustular	1	1
Reaction to excipient		1
Renal failure	2	2
Renal pain	2	4
Respiration abnormal		2
Respiratory disorder		6
Respiratory distress		7
Respiratory failure		1
Respiratory rate increased	1	3
Respiratory symptom		1
Respiratory tract congestion		4
Respiratory tract irritation		1
Restless legs syndrome		1
Restlessness	1	9
Retching	2	7
Retinal vein occlusion	1	2
Rhabdomyolysis	2	3
Rheumatoid arthritis		1
Rhinalgia		1
Rhinitis allergic	1	2
Rhinorrhoea	3	30
Road traffic accident	2	4
Ruptured cerebral aneurysm		2
Salivary gland neoplasm	1	1
Salivary hypersecretion	1	2
SARS-CoV-2 ant body test negative		2
SARS-CoV-2 test false positive		1
SARS-CoV-2 test positive	3	29
Scab		1
Scar		1
Schizophrenia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	17	1	3
				1	1
			1		
				2	2
		2	4		
			2		
			1		5
					7
					1
		1	2		1
			1		
			3		1
			1		
			1		
		1	8		1
		2	7		
				1	2
				2	3
					1
			1		
		1	2		
		3	29		1
				2	4
					2
				1	1
		1	2		
			2		
			1		
		1	5	2	24
			1		
			1		
					1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sciatica		1
Seasonal allergy	1	3
Secretion discharge	1	2
Seizure	12	34
Seizure like phenomena	1	2
Sensation of blood flow		1
Sensation of foreign body	2	8
Sensitisation	1	1
Sensitive skin	1	5
Sensory disturbance		1
Sensory loss	2	2
Shock	2	4
Shock symptom	1	2
Shoulder injury related to vaccine administration		1
Sinus congestion		5
Sinus disorder	1	1
Sinus headache	1	3
Sinusitis		8
Sinus pain	2	2
Sinus rhythm		1
Sinus tachycardia		3
Sitting disability		1
Skin burning sensation	1	7
Skin discharge	1	1
Skin discolouration	5	8
Skin discomfort		1
Skin disorder		5
Skin exfoliation	1	3
Skin hyperpigmentation	1	1
Skin irritation	1	2
Skin laceration	1	1
Skin lesion		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	3		
		1	2		
				12	34
				1	2
					1
		2	5		3
		1	1		
		1	5		
			1		
		1	1	1	1
				2	4
				1	2
			1		
			5		
		1	1		
		1	3		
			7		1
		2	2		
			1		
			1		2
			6	1	1
		1	1		
		4	6	1	2
			1		
			5		
			2	1	1
		1	1		
		1	2		
				1	1
			2		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin reaction		1
Skin swelling		1
Skin texture abnormal		1
Skin tightness		3
Skin warm	1	1
Sleep disorder	4	11
Slow response to stimuli		1
Slow speech		1
Sluggishness		4
Sneezing		6
Snoring		1
Somnolence	3	19
Speech disorder	2	15
Spinal pain		4
Sputum increased		1
Status epilepticus	1	1
Still's disease		
Stomatitis		4
Strabismus		1
Streptococcus test positive	1	1
Stress		2
Subarachnoid haemorrhage		3
Subcutaneous abscess		1
Sudden visual loss		1
Suicidal ideation		1
Suicide attempt		1
Sunburn		1
Suprapubic pain	1	1
Supraventricular extrasystoles	1	1
Supraventricular tachycardia	2	2
Suspected COVID-19	4	6
Suture related complication		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
			1		
			2		1
		1	1		
		4	11		
			1		
			1		
			3		1
			6		
					1
		2	18	1	1
		1	10	1	5
			3		1
			1		
1	1			1	1
			4		
					1
				1	1
			1		1
					3
			1		
					1
					1
			1		
				1	1
				1	1
				2	2
		2	3	2	3
					1

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* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Swelling	7	40
Swelling face	8	37
Swelling of eyelid	1	6
Swollen tongue	3	15
Syncope	21	92
Systemic inflammatory response syndrome	1	1
Systemic lupus erythematosus		1
Tachycardia	2	54
Tachypnoea		6
Tardive dyskinesia	1	2
Taste disorder	2	6
Temperature intolerance		1
Temperature regulation disorder		2
Temporomand bular joint syndrome		1
Tenderness	2	9
Tendonitis	1	2
Tension	1	1
Tension headache		4
Testicular disorder	1	1
Testicular pain	1	1
Therapeutic product effect delayed		1
Therapeutic response unexpected	1	1
Thinking abnormal	1	1
Thirst	4	11
Throat irritation	7	29
Throat tightness	9	41
Thrombocytopenia		3
Thrombophlebitis superficial		1
Thrombosis	6	13
Thunderclap headache		1
Thyroiditis	1	1
Thyroid pain	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		7	37		3
		8	30		7
			3	1	3
		2	10	1	5
				21	92
				1	1
					1
		1	31	1	23
			3		3
				1	2
		2	6		
			1		
			2		
					1
		2	9		
			1	1	1
		1	1		
			4		
		1	1		
		1	1		
			1		
		1	1		
		1	1		
		3	10	1	1
		7	21		8
		5	12	4	29
					3
					1
				6	13
					1
		1	1		
		1	1		

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* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Thyrotoxic crisis		2
Thyroxine free increased	1	1
Tic	1	1
Tinea pedis		1
Tinnitus	13	29
T-lymphocyte count decreased	1	1
Tongue discomfort		3
Tongue disorder		1
Tongue pruritus	1	2
Tonsillar disorder		1
Tonsillar hypertrophy	3	5
Tonsillar ulcer		1
Tonsillitis		1
Tonsillitis streptococcal	1	1
Tonsillolith	1	2
Toothache		1
Tooth injury	1	1
Torsade de pointes		1
Transaminases increased		2
Transient ischaemic attack	2	2
Tremor	13	59
Trigeminal neuralgia		4
Trismus		1
Troponin increased	6	9
Tuberculin test positive		1
Tunnel vision		5
Ulcer	1	1
Underdose	4	12
Unresponsive to stimuli	1	2
Upper-airway cough syndrome		4
Upper respiratory tract congestion		3
Urethral disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		1	1		
				1	1
			1		
		10	22	3	7
				1	1
			3		
					1
		1	2		
			1		
		1	3	2	2
			1		
			1		
				1	1
		1	2		
			1		
				1	1
					2
				2	2
		11	51	2	8
			1		3
			1		
		1	1	5	8
			1		
					5
		1	1		
		4	12		
				1	2
			4		
			3		
			1		

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* AE=Adverse Event

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Urinary incontinence	1	1
Urinary tract infection	1	4
Urine abnormality		1
Urine analysis abnormal		1
Urine odour abnormal		1
Urticaria	37	120
Urticaria chronic	1	1
Use of accessory respiratory muscles		1
Uterine haemorrhage	1	2
Uterine pain		1
Vaccination failure	9	18
Vaccination site bruising	1	5
Vaccination site cellulitis		1
Vaccination site discolouration		2
Vaccination site discomfort		3
Vaccination site erythema	10	66
Vaccination site haemorrhage	3	8
Vaccination site hypersensitivity		1
Vaccination site hypoaesthesia		5
Vaccination site induration	1	11
Vaccination site infection		1
Vaccination site inflammation		4
Vaccination site injury		1
Vaccination site joint movement impairment		1
Vaccination site lymphadenopathy		5
Vaccination site macule		1
Vaccination site mass	5	14
Vaccination site movement impairment	1	5
Vaccination site nodule		1
Vaccination site oedema		1
Vaccination site pain	47	369
Vaccination site papule		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	3		1
			1		
			1		
			1		
		28	92	9	28
		1	1		
			1		
				1	2
					1
				9	18
		1	5		
					1
			2		
			3		
		10	65		1
		3	8		
			1		
			4		1
		1	11		
			1		
			3		1
			1		
					1
			5		
			1		
		4	13	1	1
		1	5		
			1		
			1		
		47	366		3
			2		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site paraesthesia		6
Vaccination site pruritus	8	28
Vaccination site pustule	1	1
Vaccination site rash	3	19
Vaccination site reaction		5
Vaccination site scab		1
Vaccination site swelling	8	68
Vaccination site urticaria	1	5
Vaccination site vesicles	1	3
Vaccination site warmth	4	22
Vaginal haemorrhage	4	8
Vaginal lesion		1
Vascular pain		1
Vascular test abnormal	1	1
Vasculitis	1	1
Ventricular extrasystoles	1	1
Ventricular tachycardia		1
Vertigo	6	21
Viral infection		1
Viral myocarditis	1	1
Viral rash		1
Vision blurred	11	25
Visual acuity reduced		1
Visual field defect		3
Visual impairment	4	8
Vital functions abnormal	1	1
Vomiting	44	186
Vulval disorder		1
Vulvovaginal pain		1
Weight decreased	3	5
Weight increased	1	2
Wheezing	3	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			6		
		8	27		1
		1	1		
		3	18		1
			4		1
			1		
		8	65		3
		1	5		
		1	3		
		4	22		
		4	6		2
			1		
					1
				1	1
				1	1
				1	1
					1
		5	17	1	4
			1		
				1	1
			1		
		10	19	1	6
			1		
			2		1
		2	5	2	3
		1	1		
		38	163	6	23
			1		
					1
		1	2	2	3
		1	2		
		2	5	1	7

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
White blood cell count decreased	1	2				1	1	1
White blood cell count increased	1	5			1	2		3
Williams syndrome	1	1					1	1
Wound		1				1		
Wound haemorrhage	1	1					1	1
Wrong product administered		2				2		
Wrong technique in product usage process	1	4			1	3		1
X-ray abnormal	1	1			1	1		
Yellow skin		1				1		
		1				1		
	2,771	12,998	2	5	2155	10678	616	2320

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	21	83			19	77	2	6
Abdominal distension	7	16			7	15		1
Abdominal infection		1						1
Abdominal mass	1	1					1	1
Abdominal pain	26	97			18	77	8	20
Abdominal pain lower	2	8			1	5	1	3
Abdominal pain upper	32	115			27	101	5	14
Abdominal rigidity		1				1		
Abnormal behaviour	2	5			2	2		3
Abnormal dreams	1	13			1	12		1
Abnormal faeces	1	3			1	1		2
Abnormal sensation in eye	2	5			2	5		
Abnormal sleep-related event	1	1			1	1		
Abnormal uterine bleeding	1	1					1	1
Abnormal withdrawal bleeding		1				1		
Abortion		1						1
Abortion spontaneous	8	29					8	29
Abortion threatened	1	1					1	1
Abulia	1	1			1	1		
Acarodermatitis	1	1					1	1
Accident		1				1		
Accidental exposure to product	1	4			1	4		
Accidental overdose	3	13			3	11		2
Accidental underdose		1				1		
Acetonaemia		1				1		
Acne	2	10			2	10		
Acute coronary syndrome		2						2
Acute disseminated encephalomyelitis		2						2
Acute febrile neutrophilic dermatosis		1						1
Acute kidney injury	1	1					1	1
Acute myocardial infarction	2	5					2	5
Adenoma benign		1				1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Administration site erythema		1
Administration site pain		1
Administration site pruritus		1
Adrenocortical insufficiency acute		1
Adverse drug reaction		1
Adverse event		4
Adverse reaction		1
Affect lability	1	2
Ageusia	11	67
Aggression		2
Agitation	1	8
Alanine aminotransferase decreased		2
Alanine aminotransferase increased	2	4
Alcohol interaction	1	1
Allergic respiratory disease		1
Allergic sinusitis		2
Allergy test positive		1
Allergy to animal	1	1
Allergy to vaccine	5	27
Alopecia	1	6
Alopecia areata		1
Altered state of consciousness		1
Amenorrhoea	4	4
Amnesia	6	18
Amniotic cavity infection		1
Anaemia	3	4
Anaesthesia		1
Anal abscess	2	2
Anal haemorrhage	1	1
Anal incontinence		2
Anal pruritus		2
Anaphylactic reaction	11	111

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
			1		
					1
			1		
			4		
			1		
		1	1		1
		10	62	1	5
			1		1
			7	1	1
			1		1
		1	1	1	3
				1	1
			1		
			2		
			1		
		1	1		
		2	13	3	14
		1	6		
			1		
					1
		4	4		
		3	11	3	7
					1
		3	4		
			1		
				2	2
		1	1		
			2		
			2		
				11	111

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anaphylactic shock	2	14
Anaphylactoid reaction		3
Aneurysmal bone cyst	1	1
Aneurysm ruptured		1
Anger	3	4
Angina pectoris	8	9
Angioedema	6	33
Angiopathy		3
Anion gap decreased		1
Anion gap increased		1
Anisomastia		1
Ankylosing spondylitis	1	1
Anomalous pulmonary venous connection		1
Anosmia	9	65
Antinuclear ant body positive	1	1
Antiphospholipid syndrome	1	1
Anxiety	20	112
Anxiety disorder		1
Aortic disorder		1
Aortitis		1
Apathy		1
Aphasia	3	11
Aphonia	3	9
Aphthous ulcer	4	5
Appendicitis	11	27
Appendicitis perforated	1	2
Appetite disorder		1
Application site haemorrhage		1
Areflexia		1
Arrhythmia	6	21
Arterial stenosis	1	1
Arteriosclerosis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	14
					3
		1	1		
					1
		3	4		
				8	9
		1	1	5	32
			2		1
			1		
					1
			1		
				1	1
					1
		8	58	1	7
				1	1
				1	1
		18	100	2	12
					1
					1
					1
			1		
		2	4	1	7
		2	4	1	5
		2	3	2	2
				11	27
				1	2
			1		
					1
			1		
				6	21
				1	1
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arteriospasm coronary		3
Artery dissection	1	1
Arthralgia	114	674
Arthritis	6	17
Arthritis reactive		1
Arthropathy		3
Arthropod bite		1
Aspartate aminotransferase increased	2	4
Aspiration	1	1
Asthenia	67	331
Asthenopia	4	14
Asthma	2	32
Asymptomatic COVID-19	1	13
Ataxia	1	2
Atelectasis		2
Atopy	1	1
Atrial fibrillation	3	13
Atrioventricular block		1
Aura		2
Autoimmune disorder	3	9
Autoimmune thyroiditis		1
Autonomic dysreflexia	1	1
Autonomic nervous system imbalance	2	5
Autonomic neuropathy	1	2
Autoscopy	1	1
Axillary mass	3	18
Axillary pain	12	88
Back disorder		2
Back injury		1
Back pain	60	225
Bacteraemia		1
Bacterial infection		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
				1	1
		98	622	16	52
		3	12	3	5
					1
			2		1
			1		
		1	2	1	2
				1	1
		54	276	13	55
		4	13		1
			23	2	9
			3	1	10
			1	1	1
			1		1
		1	1		
				3	13
					1
			1		1
				3	9
					1
				1	1
			1	2	4
				1	2
		1	1		
		3	15		3
		11	84	1	4
			2		
			1		
		47	183	13	42
					1
			1		2

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bacterial test positive	1	1
Bacterial vaginosis	1	2
Bacteriuria		1
Balance disorder	10	49
Basedow's disease	1	2
Bed rest	1	1
Bedridden	3	5
Behaviour disorder		1
Bell's palsy	28	115
Bile acid malabsorption		1
Biliary colic	2	2
Bilirubin urine present		1
Binocular eye movement disorder		1
Bite		1
Bladder disorder	1	1
Bladder hypertrophy	1	1
Blepharospasm		4
Blindness	3	9
Blindness transient	1	3
Blindness unilateral		1
Blister	6	25
Blister rupture	1	1
Blood albumin decreased		1
Blood bilirubin increased		1
Blood calcium decreased		1
Blood calcium increased		1
Blood chloride decreased		1
Blood chloride increased		1
Blood cholesterol		1
Blood cholesterol abnormal		2
Blood cholesterol increased	1	2
Blood chromium increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	2		
					1
		5	35	5	14
				1	2
		1	1		
		2	4	1	1
					1
			3	28	112
			1		
		2	2		
			1		
					1
			1		
				1	1
				1	1
			4		
				3	9
				1	3
					1
			17	6	8
		1	1		
			1		
			1		1
			1		
			1		
			2		
		1	2		
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood count abnormal		1
Blood creatine phosphokinase increased		1
Blood creatinine decreased		2
Blood creatinine increased		2
Blood electrolytes decreased		1
Blood follicle stimulating hormone increased		1
Blood glucose abnormal	1	2
Blood glucose decreased	3	11
Blood glucose increased	7	16
Blood iron decreased		2
Blood ketone body increased		1
Blood lactic acid decreased		1
Blood phosphorus decreased		1
Blood potassium decreased		5
Blood pressure abnormal	1	9
Blood pressure decreased	3	25
Blood pressure diastolic decreased		2
Blood pressure diastolic increased		2
Blood pressure fluctuation		2
Blood pressure increased	11	115
Blood pressure systolic increased	1	4
Blood sodium decreased		1
Blood test abnormal		1
Blood thyroid stimulating hormone decreased	1	1
Blood thyroid stimulating hormone increased		1
Blood urine		1
Blood urine present	4	8
Body height decreased	1	1
Body mass index increased	1	1
Body temperature abnormal	1	10
Body temperature decreased	1	8
Body temperature fluctuation	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
			1		1
			1		1
					1
					1
		1	2		
		2	8	1	3
		2	6	5	10
			2		
					1
			1		
					1
			1		4
			6	1	3
		1	18	2	7
			2		
			2		
			2		
		4	71	7	44
			1	1	3
					1
			1		
				1	1
			1		
		4	8		
		1	1		
		1	1		
		1	9		1
		1	7		1
		1	3		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Body temperature increased	7	41
Bone pain	16	54
Bone swelling		2
Booster dose missed		2
Bowel movement irregularity	1	2
Brachial plexopathy		2
Bradycardia		1
Bradykinesia	1	2
Bradyphrenia		2
Brain cancer metastatic		1
Brain injury		2
Brain oedema	1	1
Brain stem haemorrhage	1	1
Brain stem infarction	1	1
Brain stem syndrome		1
Breast cancer	1	1
Breast cyst		1
Breast discharge		1
Breast discomfort	1	2
Breast disorder		4
Breast enlargement	1	1
Breast mass	1	5
Breast pain	6	23
Breast swelling	3	7
Breast tenderness	2	7
Breath odour		2
Bronchial disorder		1
Bronchitis		4
Bronchospasm	1	16
Brown-Sequard syndrome	1	1
Bruxism		1
Burning sensation	42	142

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	38	1	3
		16	46		8
			1		1
			2		
		1	1		1
			1		1
					1
		1	2		
			2		
					1
					2
				1	1
				1	1
				1	1
				1	1
			1		
			1		
		1	2		
			4		
		1	1		
		1	5		
		4	21	2	2
		3	7		
		2	6		1
			2		
			1		
			4		
		1	10		6
				1	1
			1		
		27	107	15	35

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Burns third degree	1	1
Bursitis	3	7
Butterfly rash		1
Candida infection		1
Capillary nail refill test abnormal		1
Carbon dioxide increased		1
Cardiac arrest		8
Cardiac discomfort		1
Cardiac disorder	1	5
Cardiac dysfunction	1	1
Cardiac failure		1
Cardiac flutter	2	14
Cardiac neoplasm unspecified		1
Cardiac valve sclerosis		1
Cardiac valve vegetation		1
Cardiogenic shock		2
Cardiomyopathy		1
Cardio-respiratory arrest		2
Cardiovascular disorder	2	4
Carpal tunnel syndrome	2	4
Catatonia		1
Cellulitis	6	14
Cellulitis gangrenous		1
Central nervous system lesion	1	2
Cerebellar ataxia		1
Cerebellar stroke		1
Cerebral disorder	3	7
Cerebral haemorrhage	1	3
Cerebral thrombosis	1	2
Cerebral venous sinus thrombosis		1
Cerebrovascular accident	14	41
Cervical incompetence	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		3	5		2
			1		
			1		
			1		
			1		
					8
			1		
			2	1	3
				1	1
					1
				2	14
					1
					1
					1
					2
					1
					2
			1	2	3
		2	3		1
					1
				6	14
					1
			1	1	1
			1		
					1
		2	5	1	2
				1	3
				1	2
					1
				14	41
				1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cervical radiculopathy	1	2
Cheilitis	1	5
Chest discomfort	34	199
Chest injury	1	3
Chest pain	50	213
Chillblains		3
Chills	244	1,627
Choking	1	5
Choking sensation		2
Cholecystitis	1	2
Cholestasis		2
Chromaturia	1	5
Chronic fatigue syndrome		1
Chronic inflammatory demyelinating polyradiculoneuropathy		1
Ciliary muscle spasm		1
Circadian rhythm sleep disorder		1
Circulatory collapse		2
Circumstance or information capable of leading to medication error	7	42
Claustrophobia		1
Clumsiness	1	3
Cluster headache		1
Coagulopathy	1	4
Coccidioidomycosis	1	2
Coccydynia	1	2
Coeliac disease	2	2
Cognitive disorder	3	11
Cold burn	1	1
Cold sweat	8	51
Colitis microscopic	1	1
Colitis ulcerative	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		1
		1	4		1
		26	152	8	47
				1	3
		28	139	22	74
			2		1
		225	1542	19	85
				1	5
			1		1
				1	2
					2
		1	5		
			1		
					1
			1		
			1		
					2
		7	42		
			1		
		1	2		1
			1		
				1	4
				1	2
		1	2		
				2	2
		2	6	1	5
				1	1
		8	46		5
				1	1
1	1			1	4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Coma		1
Concussion	1	4
Condition aggravated	39	120
Conductive deafness		1
Confusional state	9	54
Congestive cardiomyopathy		1
Conjunctival haemorrhage		1
Conjunctival irritation		1
Conjunctival oedema		1
Conjunctivitis	2	7
Conjunctivitis viral	1	1
Constipation	1	13
Contusion	18	48
Coordination abnormal		1
Corneal oedema		1
Corneal reflex decreased		2
Coronary artery dissection	1	1
Coronary artery thrombosis	1	1
Cor pulmonale acute		1
Costochondritis	2	4
Cough	53	257
COVID-19	96	406
COVID-19 immunisation		1
COVID-19 pneumonia	2	7
Cranial nerve disorder		1
Cranial nerve paralysis		1
C-reactive protein increased	1	3
Crohn's disease	2	2
Crying	4	18
CSF glucose increased	1	1
CSF protein increased	1	1
Cutaneous lupus erythematosus		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			2	1	2
		23	76	16	44
					1
		6	40	3	14
					1
					1
			1		
			1		
		2	7		
		1	1		
		1	13		
		14	42	4	6
					1
			1		
			1		1
				1	1
				1	1
					1
		2	3		1
		44	209	9	48
1	1	37	117	59	289
			1		
				2	7
					1
					1
		1	3		
				2	2
		4	17		1
				1	1
				1	1
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cutaneous vasculitis	1	1
Cyanosis		5
Cyst		2
Cystitis		1
Cyst rupture		1
Cytomegalovirus infection reactivation	2	2
Deafness	11	32
Deafness bilateral	1	2
Deafness neurosensory	3	7
Deafness transitory		2
Deafness unilateral	1	8
Death	4	13
Decreased appetite	33	122
Decreased immune responsiveness	1	1
Decreased interest		1
Deep vein thrombosis	11	29
Defaecation urgency		1
Dehydration	9	34
Delirium		7
Delusional perception	1	1
Dementia Alzheimer's type		1
Demyelinating polyneuropathy		1
Demyelination	1	1
Dental paraesthesia		1
Depressed level of consciousness		7
Depressed mood	6	12
Depression	6	12
Dermatitis	3	8
Dermatitis acneiform		1
Dermatitis allergic		4
Dermatitis atopic		1
Dermatitis bullous	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			2		3
			1		1
			1		
			1		
				2	2
				11	32
				1	2
				3	7
					2
				1	8
				4	13
		30	116	3	6
				1	1
			1		
				11	29
			1		
		6	25	3	9
			1		6
		1	1		
					1
					1
				1	1
			1		
					7
		5	10	1	2
		5	9	1	3
		2	6	1	2
			1		
			3		1
			1		
				1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dermatitis contact		3
Dermatitis exfoliative		1
Diabetes mellitus		2
Diabetic ketoacidosis		1
Diaphragmatic disorder		1
Diarrhoea	68	380
Diarrhoea haemorrhagic	1	5
Diffuse alopecia		1
Dilatation ventricular		1
Diplegia	1	1
Diplopia	2	8
Disability		1
Discomfort	18	70
Disease recurrence	5	35
Disorganised speech		1
Disorientation	9	30
Disseminated intravascular coagulation	1	1
Disseminated varicella zoster vaccine virus infection	1	1
Dissociation		1
Distract bility	1	1
Disturbance in attention	8	33
Diverticulitis		1
Dizziness	196	945
Dizziness exertional		2
Dizziness postural	1	9
Double stranded DNA antibody positive	1	1
Drooling		3
Dropped head syndrome		1
Drug eruption		1
Drug hypersensitivity	3	10
Drug ineffective	30	254

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		
					1
					2
					1
			1		
		58	353	10	27
				1	5
					1
					1
				1	1
		2	7		1
					1
		16	66	2	4
		2	24	3	11
					1
		4	15	5	15
				1	1
				1	1
			1		
		1	1		
		7	27	1	6
					1
1	1	158	789	38	156
			2		
		1	9		
				1	1
			3		
					1
			1		
		2	9	1	1
1	1			30	254

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Drug interaction	3	9
Drug screen positive		1
Dry eye	6	13
Dry mouth	3	39
Dry skin	4	9
Dry throat	4	19
Duodenogastric reflux		2
Dysaesthesia		3
Dysarthria	6	19
Dyschromatopsia		1
Dysgeusia	20	121
Dyskinesia	3	11
Dysmenorrhoea	8	15
Dyspepsia	8	26
Dysphagia	19	77
Dysphemia		1
Dysphonia	6	42
Dyspnoea	107	475
Dyspnoea at rest		1
Dyspnoea exertional	4	17
Dysstasia	5	17
Dystonia		2
Dysuria	2	4
Ear congestion	2	4
Ear discomfort	16	49
Ear disorder	2	8
Ear haemorrhage	1	1
Ear infection	2	5
Ear pain	13	72
Ear pruritus	1	8
Ear swelling	2	7
Eating disorder	5	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	7	1	2
			1		
		6	12		1
		2	30	1	9
		3	8	1	1
		4	16		3
			2		
			2		1
		4	11	2	8
			1		
		17	114	3	7
		3	8		3
		7	14	1	1
		7	23	1	3
		9	43	10	34
					1
		6	27		15
		64	289	43	186
					1
		2	12	2	5
		4	12	1	5
					2
		1	3	1	1
		1	1	1	3
		11	42	5	7
		2	6		2
				1	1
		2	4		1
		10	62	3	10
		1	6		2
		2	5		2
		4	9	1	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eczema	4	8
Ejection fraction decreased		1
Electric shock sensation	3	8
Electrocardiogram abnormal	1	8
Electrocardiogram PR shortened		1
Electrocardiogram QT prolonged		1
Electrocardiogram ST segment depression		1
Electrocardiogram ST segment elevation		1
Embolism		1
Emotional disorder	1	5
Emotional distress		1
Enanthema		1
Encephalitis		2
Encephalopathy	1	2
Endocarditis		1
Endocrine ophthalmopathy		1
Endometriosis	1	1
Energy increased	1	1
Enlarged uvula		5
Enteritis	1	1
Eosinophil count increased		1
Epicondylitis		2
Epilepsy	1	1
Epinephrine increased		1
Epistaxis	12	36
Epstein-Barr virus antibody positive	1	1
Epstein-Barr virus infection	1	1
Epstein-Barr virus infection reactivation		1
Erectile dysfunction	1	6
Erection increased		1
Eructation	2	4
Erythema	44	183

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	6	2	2
					1
		2	7	1	1
		1	8		
					1
					1
					1
					1
		1	4		1
			1		
			1		
					2
				1	2
					1
					1
				1	1
		1	1		
			2		3
				1	1
					1
			2		
				1	1
			1		
		12	32		4
				1	1
				1	1
					1
				1	6
					1
		2	3		1
		34	139	10	44

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Erythema marginatum		1
Erythema multiforme		4
Erythema nodosum	2	2
Erythema of eyelid		5
Erythrodermic psoriasis	1	1
Escherichia bacteraemia		1
Euphoric mood	1	5
Eustachian tube dysfunction		2
Exaggerated startle response		1
Excessive ocular convergence		1
Exercise electrocardiogram abnormal		1
Exercise lack of		1
Exercise tolerance decreased	1	2
Expired product administered	5	9
Exposure during pregnancy	7	31
Exposure to SARS-CoV-2	1	15
Exposure via breast milk		1
Exposure via skin contact	1	3
Extensive swelling of vaccinated limb		1
Extraocular muscle paresis		1
Extrasystoles		4
Extremity contracture		1
Eye contusion		3
Eye discharge	2	4
Eye disorder	2	14
Eye haemorrhage	2	14
Eye infection		1
Eye inflammation	2	5
Eye injury	1	1
Eye irritation	7	23
Eyelid disorder	1	3
Eyelid irritation		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					4
		1	1	1	1
			4		1
		1	1		
					1
		1	4		1
			2		
			1		
					1
					1
			1		
			1	1	1
		5	9		
		6	26	1	5
		1	13		2
			1		
		1	3		
			1		
					1
			4		
			1		
			3		
		2	4		
		2	12		2
				2	14
			1		
		1	3	1	2
				1	1
		6	22	1	1
		1	3		
			1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eyelid oedema		1
Eyelid pain		4
Eyelid ptosis		4
Eyelid rash		1
Eyelid sensory disorder		1
Eyelids pruritus		4
Eye movement disorder	1	6
Eye oedema		4
Eye pain	11	59
Eye paraesthesia		1
Eye pruritus	4	30
Eye swelling	17	72
Face injury		2
Face oedema		2
Facet joint syndrome		1
Facial asymmetry	1	1
Facial bones fracture		1
Facial discomfort		3
Facial nerve disorder		3
Facial neuralgia	1	3
Facial pain	6	34
Facial paralysis	5	42
Facial paresis	1	10
Facial spasm	1	1
Faeces discoloured		1
Faeces soft	1	1
Fall	9	42
False negative investigation result		1
Fasciitis		1
Fatigue	300	1,836
Fear		5
Fear of death	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			3		1
			2		2
			1		
			1		
			4		
		1	5		1
			4		
		10	53	1	6
					1
		3	24	1	6
		13	57	4	15
					2
			1		1
			1		
		1	1		
					1
			3		
			1		2
		1	3		
		5	26	1	8
			2	5	40
			7	1	3
				1	1
			1		
		1	1		
		5	25	4	17
					1
					1
		273	1737	27	99
			4		1
		1	1		1

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Febrile convulsion		1
Feeding disorder	8	18
Feeling abnormal	76	348
Feeling cold	14	81
Feeling drunk	4	11
Feeling hot	38	221
Feeling jittery	1	13
Feeling of body temperature change	8	29
Feeling of relaxation	1	1
Female reproductive tract disorder	1	1
Fibrin D dimer increased	3	7
Fibromuscular dysplasia	1	1
Fibromyalgia	1	3
Fine motor skill dysfunction		4
Fistula		1
Flank pain	1	9
Flatulence	3	10
Fluid retention		1
Flushing	8	140
Foetal death	1	4
Foetal exposure during pregnancy		1
Folliculitis		3
Food allergy	1	1
Food craving	1	1
Food intolerance	1	2
Foot fracture	1	1
Foreign body sensation in eyes	1	1
Formication		5
Freezing phenomenon		1
Frequent bowel movements		1
Frustration tolerance decreased	1	2
Fungal infection	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		4	12	4	6
		68	314	8	34
		13	75	1	6
		4	9		2
		34	189	4	32
		1	11		2
		7	25	1	4
		1	1		
				1	1
		2	4	1	3
				1	1
		1	3		
			3		1
			1		
			7	1	2
		2	9	1	1
			1		
		6	110	2	30
				1	4
			1		
			3		
		1	1		
		1	1		
		1	2		
				1	1
		1	1		
			4		1
			1		
			1		
		1	2		
		1	3		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gait disturbance	28	86
Gait inability	6	21
Gallbladder disorder		1
Gallbladder oedema		1
Gallbladder polyp		1
Gastric dilatation		1
Gastric disorder	1	2
Gastric pH decreased		2
Gastritis	1	5
Gastroenteritis viral		1
Gastrointestinal disorder	7	22
Gastrointestinal infection		1
Gastrointestinal inflammation	1	1
Gastrointestinal pain	2	13
Gastrointestinal sounds abnormal		3
Gastrointestinal tract irritation		2
Gastrointestinal viral infection		1
Gastrooesophageal reflux disease		7
Generalised tonic-clonic seizure	1	3
Genital herpes	1	3
Genital herpes simplex		2
Genital lesion		1
Genital ulceration		1
Gingival bleeding		4
Gingival erythema		2
Gingival pain	1	4
Gingival swelling		5
Glassy eyes		1
Glomerular filtration rate decreased		1
Glossitis		2
Glossodynia	2	11
Glycosylated haemoglobin increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		15	57	13	29
		2	10	4	11
					1
					1
			1		
			1		
		1	2		
			2		
		1	4		1
			1		
		7	21		1
			1		
		1	1		
		2	10		3
			3		
			2		
			1		
			6		1
				1	3
			2	1	1
			2		
			1		
			1		
			3		1
			2		
		1	4		
			4		1
			1		
			1		
			2		
		2	10		1
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gout		6
Granulocytes abnormal		1
Granuloma skin		1
Grip strength decreased	1	5
Groin pain	2	5
Gross motor delay	1	1
Grunting		3
Guillain-Barre syndrome	4	14
Haematemesis	1	2
Haematochezia	5	17
Haematocrit decreased		1
Haematoma		3
Haematuria		1
Haemoglobin decreased		4
Haemoglobin increased		1
Haemolytic anaemia		4
Haemoptysis	1	6
Haemorrhage	12	27
Haemorrhage intracranial	1	1
Haemorrhage subcutaneous		1
Haemorrhage urinary tract	1	1
Haemorrhoids	2	2
Hallucination	8	16
Hallucination, auditory	1	3
Hallucination, visual	2	4
Hand-eye coordination impaired		1
Hangover	2	8
Headache	408	2,304
Head discomfort	20	73
Head injury	5	9
Head titubation	1	1
Heart rate abnormal	2	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			5		1
					1
					1
		1	5		
		2	5		
				1	1
			2		1
				4	14
				1	2
				5	17
			1		
			3		
			1		
			2		2
			1		
					4
			2	1	4
				12	27
				1	1
					1
				1	1
		2	2		
		1	1	7	15
				1	3
				2	4
					1
		2	8		
		375	2149	33	155
		17	64	3	9
		3	4	2	5
		1	1		
		2	10		2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Heart rate decreased	1	11
Heart rate increased	60	310
Heart rate irregular	7	24
Heat illness		1
Heavy menstrual bleeding	30	54
Hemiparesis	4	5
Hemiplegia		4
Henoch-Schonlein purpura	1	1
Hepatic enzyme abnormal		1
Hepatic enzyme increased		2
Hepatic mass		1
Hepatic pain		1
Hepatitis C	1	1
Hepatomegaly		2
Herpes ophthalmic	1	1
Herpes simplex		3
Herpes simplex gastritis	1	1
Herpes simplex reactivation		1
Herpes simplex test positive	1	1
Herpes virus infection		3
Herpes zoster	38	83
Herpes zoster oticus		2
Heterophoria		1
Hiccups		1
Hidradenitis		1
Histamine level increased		1
HIV test false positive		2
HIV test negative		1
Hordeolum		5
Hormone level abnormal		2
Hospitalisation		1
Hostility	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			5	1	6
		38	228	22	82
		5	18	2	6
			1		
		21	42	9	12
1	1			4	5
					4
				1	1
					1
			2		
			1		
			1		
				1	1
			1		1
				1	1
			3		
				1	1
			1		
		1	1		
			3		
		27	60	11	23
					2
					1
			1		
			1		
					1
			2		
					1
			5		
			1		1
					1
		1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hot flush	11	79
Humerus fracture	1	1
Hunger		3
Huntington's disease		1
Hydrophobia		1
Hyperacusis	2	13
Hyperaesthesia	2	16
Hyperaesthesia teeth		2
Hyperbilirubinaemia		1
Hyperglycaemia	1	1
Hyperhidrosis	43	270
Hyperparathyroidism		1
Hyperpyrexia		3
Hypersensitivity	30	128
Hypersomnia	6	26
Hypersomnia-bulimia syndrome	1	1
Hypertension	24	107
Hypertensive crisis		3
Hypertensive emergency		1
Hypertensive heart disease		1
Hyperthyroidism	1	1
Hypertrichosis		1
Hyperventilation	4	12
Hypervigilance		2
Hypoacusis	9	24
Hypoaesthesia	94	441
Hypoaesthesia eye	2	5
Hypoaesthesia oral	19	119
Hypocalcaemia		1
Hypogeusia	1	2
Hypoglycaemia		4
Hypokalaemia	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		10	68	1	11
				1	1
			3		
			1		
			1		
		2	11		2
		2	15		1
			2		
					1
				1	1
		38	238	5	32
			1		
					3
		11	67	19	61
		4	24	2	2
				1	1
		10	63	14	44
					3
					1
					1
			1		
		3	7	1	5
			2		
		5	19	4	5
		70	344	24	97
		1	3	1	2
		16	92	3	27
					1
		1	2		
			4		
				1	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypokinesia	1	8
Hypomagnesaemia		1
Hypopituitarism	1	1
Hypopnoea	1	2
Hyporeflexia		1
Hyposmia		2
Hypotension	9	30
Hypothermia	2	3
Hypothyroidism		1
Hypotonia		1
Hypoxia		2
Idiopathic intracranial hypertension	1	2
Ill-defined disorder		1
Illness	20	86
Immobile	2	2
Immune-mediated arthritis		1
Immune system disorder	2	12
Immune thrombocytopenia	2	8
Immunodeficiency		1
Impaired driving ability	2	9
Impaired gastric emptying	2	3
Impaired healing	1	4
Impaired work ability	4	7
Impetigo	1	1
Impulsive behaviour		1
Inappropriate schedule of product administration	28	209
Incoherent		1
Incomplete course of vaccination		3
Incorrect dose administered	2	7
Incorrect route of product administration	5	43
Increased appetite	1	2
Increased tendency to bruise		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			6	1	2
					1
		1	1		
		1	2		
					1
			2		
		3	16	6	14
				2	3
					1
			1		
					2
				1	2
			1		
		18	78	2	8
				2	2
					1
		1	6	1	6
				2	8
					1
		1	7	1	2
				2	3
		1	4		
		2	4	2	3
				1	1
			1		
		26	207	2	2
					1
			3		
		2	7		
		5	42		1
		1	2		
			1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Increased upper airway secretion		3
Increased viscosity of bronchial secretion		1
Increased viscosity of upper respiratory secretion		1
Induration	1	4
Infarction	1	1
Infection	2	7
Infectious mononucleosis		1
Infertility female		1
Inflammation	12	39
Inflammatory bowel disease		1
Inflammatory marker increased	2	2
Influenza	9	27
Influenza like illness	33	147
Inhibitory drug interaction		1
Initial insomnia		3
Injected limb mobility decreased		3
Injection site discomfort		1
Injection site erythema	1	21
Injection site extravasation		1
Injection site haemorrhage		1
Injection site indentation		1
Injection site joint pain		1
Injection site mass		3
Injection site pain	12	91
Injection site paraesthesia		2
Injection site pruritus	1	10
Injection site rash	1	8
Injection site reaction		1
Injection site swelling	2	18
Injection site urticaria		1
Injection site warmth	2	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		
					1
			1		
		1	4		
				1	1
		2	4		3
			1		
					1
		11	36	1	3
					1
				2	2
		7	24	2	3
		29	134	4	13
			1		
			3		
			3		
			1		
		1	21		
			1		
			1		
			1		
			3		
		12	91		
			2		
		1	10		
		1	8		
			1		
		2	18		
			1		
		2	8		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injury	1	4
Insomnia	35	154
Inspiratory capacity decreased	1	1
Instillation site warmth	1	1
Insulin resistance		1
Intentional dose omission		1
Intermenstrual bleeding	8	18
Intervertebral disc protrusion		1
Intestinal obstruction	1	1
Intracardiac thrombus		2
Intracranial aneurysm		1
Intracranial pressure increased	1	3
Intranasal hypoaesthesia		1
Intraocular pressure increased		1
Intraocular pressure test abnormal	1	1
Iridocyclitis		1
Iritis		1
Irregular breathing		1
Irritability	3	14
Ischaemia	1	1
Jaundice		3
Jaw clicking		1
Jaw disorder	1	2
Joint adhesion	1	1
Joint contracture	1	1
Joint dislocation		2
Joint effusion	1	2
Joint injury	2	3
Joint instability		1
Joint lock		2
Joint noise	2	3
Joint range of motion decreased	3	25

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		1
		27	134	8	20
		1	1		
		1	1		
					1
			1		
		7	16	1	2
					1
				1	1
					2
					1
				1	3
			1		
			1		
		1	1		
					1
			1		
			1		
		3	13		1
				1	1
			1		2
			1		
		1	2		
		1	1		
		1	1		
			1		1
			2		
		2	3		
					1
			2		
		1	2	1	1
		3	23		2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Joint stiffness	7	23
Joint swelling	14	39
Jugular vein thrombosis	1	1
Labile blood pressure	1	1
Laboratory test abnormal	1	1
Labyrinthitis		1
Lack of spontaneous speech	1	2
Lacrimation increased	6	20
Large intestinal obstruction		1
Large intestine perforation		1
Laryngeal discomfort		1
Laryngeal oedema		1
Laryngeal pain	1	1
Laryngitis	1	4
Laryngospasm		3
Laziness		1
Lethargy	22	99
Lichen sclerosus		1
Ligament disorder		1
Ligament injury		1
Ligament pain		1
Ligament sprain		3
Limb deformity		1
Limb discomfort	15	85
Limb immobilisation	1	1
Limb injury	1	7
Limb mass	2	6
Lip blister	1	3
Lip disorder	1	6
Lip dry	1	2
Lip erythema	1	2
Lip exfoliation	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	21	1	2
		12	34	2	5
				1	1
				1	1
		1	1		
					1
		1	1		1
		6	17		3
					1
					1
			1		
					1
		1	1		
		1	4		
					3
			1		
		21	93	1	6
			1		
					1
			1		
			1		
			3		
			1		
		15	72		13
		1	1		
		1	6		1
		2	5		1
			2	1	1
			5	1	1
		1	1		1
		1	2		
		1	2		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lip infection		1
Lip injury	1	3
Lip oedema		1
Lipoma		1
Lip pain	2	4
Lip pruritus	1	9
Lip swelling	20	77
Listless		1
Livedo reticularis		5
Liver disorder		2
Liver function test abnormal		1
Liver injury		1
Liver tenderness		1
Local anaesthesia		1
Localised infection	1	1
Localised oedema	1	1
Local reaction		1
Loose body in joint		1
Loss of consciousness	25	115
Loss of employment		1
Loss of personal independence in daily activities	21	61
Loss of proprioception		1
Low density lipoprotein increased	1	1
Lower respiratory tract congestion	1	1
Lower respiratory tract infection		3
Lower respiratory tract infection bacterial	1	1
Lung disorder	2	5
Lung hyperinflation		1
Lung infiltration		1
Lupus myositis		1
Lyme disease	1	1
Lymphadenitis	2	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	2		1
			1		
			1		
		1	3	1	1
		1	7		2
		10	47	10	30
			1		
			3		2
			1		1
			1		
					1
			1		
			1		
				1	1
		1	1		
			1		
					1
1	1	2	2	23	113
			1		
		12	46	9	15
					1
		1	1		
		1	1		
					3
				1	1
		1	3	1	2
			1		
					1
					1
				1	1
		1	12	1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lymphadenopathy	97	601
Lymphangitis		1
Lymph gland infection		2
Lymph node pain	17	116
Lymph node palpable		1
Lymphocyte count decreased	1	1
Lymphocyte count increased		1
Lymphoedema		5
Lymphoma		2
Macroglossia		1
Major depression		2
Malaise	80	429
Malignant hypertension		1
Malnutrition		1
Mania		3
Mass	5	12
Mast cell activation syndrome	1	1
Mast cell degranulation present		1
Mastication disorder		1
Mastitis		6
Mastoid disorder		1
Maternal exposure during pregnancy	16	67
Maternal exposure timing unspecified	1	4
Measles	1	2
Medication error	1	2
Melanoma recurrent		2
Memory impairment	4	23
Meningeal disorder		1
Meningitis		2
Menopausal symptoms		1
Menopause		1
Menstrual disorder	19	37

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		90	570	7	31
					1
			2		
		15	110	2	6
			1		
		1	1		
					1
			5		
					2
					1
					2
		69	402	11	27
					1
			1		
			2		1
		5	11		1
				1	1
			1		
			1		
					6
					1
		14	63	2	4
		1	4		
				1	2
		1	2		
					2
		3	18	1	5
					1
					2
			1		
			1		
		18	34	1	3

* I=Interval, C=Cumulative

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Menstruation delayed	11	15
Menstruation irregular	22	40
Mental disorder	2	8
Mental fatigue		1
Mental impairment	3	22
Mesenteric vein thrombosis		1
Metabolic function test abnormal		2
Microangiopathic haemolytic anaemia		1
Micturition disorder	1	1
Middle ear effusion		1
Middle insomnia	1	18
Migraine	40	187
Migraine with aura	1	4
Miliaria	1	5
Miosis	1	2
Mobility decreased	9	39
Monocyte count increased		1
Mononeuropathy		1
Monoplegia	3	5
Mood altered		2
Morphoea	1	1
Motion sickness		3
Motor dysfunction	3	7
Mouth haemorrhage	1	1
Mouth injury	1	1
Mouth swelling	3	13
Mouth ulceration		5
Movement disorder	16	43
Mucosal disorder		1
Mucous stools		2
Multiple sclerosis	6	10
Multiple sclerosis relapse	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		9	12	2	3
		19	37	3	3
		2	7		1
			1		
				3	22
					1
			1		1
					1
		1	1		
			1		
		1	17		1
		27	159	13	28
		1	3		1
		1	5		
		1	2		
		6	30	3	9
					1
					1
				3	5
			2		
				1	1
			2		1
		1	2	2	5
		1	1		
		1	1		
		1	6	2	7
			4		1
		12	35	4	8
			1		
			2		
				6	10
				1	2

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle atrophy	1	2
Muscle contractions involuntary	2	4
Muscle discomfort	1	5
Muscle disorder		3
Muscle fatigue	3	13
Muscle haemorrhage	1	1
Muscle injury	2	2
Muscle rigidity		1
Muscle rupture	1	1
Muscle spasms	20	104
Muscle strain	2	5
Muscle swelling	2	5
Muscle tightness	8	44
Muscle twitching	11	30
Muscular weakness	17	115
Musculoskeletal chest pain	5	18
Musculoskeletal discomfort	2	17
Musculoskeletal disorder	2	6
Musculoskeletal pain	4	11
Musculoskeletal stiffness	19	97
Mutism		2
Myalgia	110	797
Mydriasis	1	1
Myelitis transverse	5	11
Myocardial infarction	9	25
Myocardial necrosis marker increased		1
Myocarditis	7	18
Myoclonus		1
Myokymia		1
Myopia		1
Myositis	2	5
Nail discolouration		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	1
		1	2	1	2
		1	5		
			2		1
		2	12	1	1
				1	1
		1	1	1	1
					1
				1	1
		18	84	2	20
		2	5		
		2	5		
		7	38	1	6
		10	25	1	5
		8	78	9	37
		5	18		
		2	16		1
		2	4		2
		4	8		3
		16	87	3	10
			2		
		101	750	9	47
		1	1		
				5	11
				9	25
					1
			1	7	17
					1
			1		
			1		
		2	2		3
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nasal congestion	17	108
Nasal discharge discolouration		1
Nasal discomfort	2	5
Nasal disorder		3
Nasal dryness	3	4
Nasal oedema		6
Nasal pruritus		1
Nasopharyngitis	18	69
Nausea	199	1,130
Near death experience	4	9
Neck injury		1
Neck mass	3	5
Neck pain	34	212
Needle issue		3
Neoplasm		1
Neoplasm progression		1
Neoplasm skin		2
Nephritis	1	1
Nephrolithiasis	2	3
Nephropathy		1
Nerve compression		6
Nerve injury	1	6
Nervousness	9	40
Nervous system disorder	6	9
Neuralgia	16	51
Neuralgic amyotrophy	1	3
Neuritis	1	1
Neurological symptom		3
Neuropathy peripheral	8	37
Neutrophil count decreased	1	2
Neutrophil count increased		2
Nightmare	1	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		17	102		6
			1		
		2	4		1
			3		
		3	3		1
			5		1
					1
		17	65	1	4
1	1	182	1018	17	112
				4	9
			1		
		3	5		
		28	186	6	26
			3		
			1		
					1
			2		
				1	1
				2	3
					1
			4		2
		1	4		2
		8	37	1	3
		4	6	2	3
		13	39	3	12
			1	1	2
				1	1
			1		2
		1	1	7	36
		1	1		1
			1		1
		1	9		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Night sweats	4	55
Nipple exudate bloody		1
Nipple infection		1
Nipple pain		3
Nipple swelling		1
No adverse event		4
Nocturia		1
Nocturnal dyspnoea	1	1
Nodule	4	5
Noninfective encephalitis	2	5
Noninfective gingivitis	1	1
Nuchal rigidity		2
Nystagmus	2	4
Obstructive airways disorder	3	7
Occupational exposure to SARS-CoV-2		2
Ocular discomfort		15
Ocular hyperaemia	3	23
Ocular vascular disorder		1
Odynophagia	1	9
Oedema	1	8
Oedema peripheral	1	9
Oesophageal pain	2	2
Off label use	25	185
Oligomenorrhoea	2	2
Ophthalmic herpes simplex		1
Ophthalmic herpes zoster	1	1
Ophthalmic migraine	1	3
Optic neuritis	1	3
Oral blood blister		1
Oral candidiasis		2
Oral discomfort	2	16
Oral disorder	3	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	51		4
			1		
			1		
			3		
			1		
			4		
					1
		1	1		
		4	5		
				2	5
		1	1		
			1		1
		2	3		1
		1	2	2	5
			2		
			12		3
		3	20		3
			1		
		1	6		3
		1	7		1
		1	7		2
		1	1	1	1
		23	181	2	4
		1	1	1	1
					1
				1	1
		1	3		
				1	3
					1
			2		
		2	14		2
		2	6	1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral herpes	9	24
Oral mucosal blistering	2	5
Oral mucosal discolouration	1	1
Oral mucosal eruption	1	4
Oral pain	1	8
Oral pruritus	2	11
Orchitis		1
Oropharyngeal blistering		2
Oropharyngeal cobble stone mucosa		1
Oropharyngeal discomfort	6	25
Oropharyngeal pain	40	233
Oropharyngeal plaque	1	1
Oropharyngeal spasm		1
Oropharyngeal swelling		2
Orthopnoea		1
Orthostatic hypertension	1	1
Orthostatic hypotension	1	2
Osteochondritis		1
Osteomyelitis		1
Otorrhoea	1	2
Ovarian cyst	2	3
Ovarian disorder		1
Ovarian enlargement		1
Ovarian vein thrombosis	1	1
Overdose	10	26
Oversensing		1
Overweight		1
Oxygen saturation		1
Oxygen saturation abnormal		1
Oxygen saturation decreased	5	16
Pain	253	1,481
Painful respiration	2	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		7	21	2	3
		1	4	1	1
		1	1		
			2	1	2
		1	7		1
		1	7	1	4
					1
					2
			1		
		3	17	3	8
		37	216	3	17
		1	1		
					1
			1		1
					1
				1	1
			1	1	2
			1		
					1
		1	2		
		2	2		1
					1
			1		
				1	1
		10	25		1
			1		
			1		
			1		
			1		
		1	7	4	9
1	1	227	1395	26	86
			4	2	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pain in extremity	210	1,125
Pain in jaw	7	39
Pain of skin	9	25
Palatal swelling		3
Pallor	1	35
Palmar erythema		3
Palpitations	47	230
Pancreatitis	2	5
Pancreatitis acute		3
Pancreatitis haemorrhagic	1	1
Pancytopenia	1	2
Panic attack	8	23
Panic disorder	2	4
Panic reaction		7
Papule		1
Paraesthesia	87	482
Paraesthesia ear		1
Paraesthesia mucosal		1
Paraesthesia oral	14	134
Paralysis	8	22
Paranasal sinus discomfort	5	20
Paranasal sinus hypersecretion	1	1
Paranoia		3
Paraplegia		1
Parkinson's disease	1	1
Parosmia	5	24
Parotid duct obstruction		1
Parotid gland enlargement	1	1
PCO2 decreased		1
Peau d'orange	1	1
Pelvic mass		2
Pelvic pain	1	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	191	1068	19	57
		6	34	1	5
		9	25		
			3		
		1	28		7
			2		1
1	1	37	171	10	59
				2	5
					3
				1	1
				1	2
		6	16	2	7
		2	4		
			6		1
			1		
		66	394	21	88
			1		
			1		
		9	101	5	33
			1	8	21
		4	19	1	1
		1	1		
			2		1
					1
				1	1
		3	20	2	4
					1
		1	1		
					1
		1	1		
					2
		1	5		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pemphigoid	1	1
Pemphigus	1	1
Penile erythema	1	1
Penile haemorrhage	1	1
Penile swelling	1	1
Penis disorder	1	1
Periarthritis		2
Pericardial disease		1
Pericardial effusion	2	3
Pericarditis	4	10
Periorbital pain		1
Periorbital swelling	5	14
Peripheral arterial occlusive disease		1
Peripheral coldness	9	46
Peripheral nerve injury		2
Peripheral swelling	42	163
Peripheral vascular disorder		1
Peripheral venous disease		1
Peroneal nerve palsy		1
Personality change		2
Petechiae		14
Pharyngeal disorder		3
Pharyngeal erythema		5
Pharyngeal haemorrhage		1
Pharyngeal hypoaesthesia	1	9
Pharyngeal mass		3
Pharyngeal oedema	1	6
Pharyngeal paraesthesia		14
Pharyngeal swelling	15	83
Pharyngitis		4
Pharyngitis streptococcal	2	3
Phlebitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
		1	1		
				1	1
		1	1		
		1	1		
			2		
					1
				2	3
				4	10
			1		
		3	11	2	3
					1
		7	39	2	7
					2
		32	145	10	18
			1		
			1		
					1
			1		1
			11		3
			2		1
			4		1
					1
			5	1	4
			2		1
			3	1	3
			11		3
		8	40	7	43
			3		1
		1	2	1	1
			1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Photophobia	10	35
Photopsia	1	5
Photosensitivity reaction	4	12
Physical examination abnormal		1
Pigmentation disorder		1
Piloerection	1	3
Pityriasis rosea	1	3
Plantar fasciitis		1
Platelet count decreased	1	8
Platelet count increased		3
Platelet disorder		1
Pleural effusion		4
Pleurisy	1	1
Pleuritic pain	1	4
Pneumocystis jirovecii pneumonia		1
Pneumonia	4	14
Pneumonitis	2	2
Pneumothorax	1	1
PO2 decreased		1
POEMS syndrome	1	1
Poisoning		1
Pollakiuria	2	9
Polyarthrits		1
Polymenorrhoea	7	9
Polyneuropathy		1
Polyuria		2
Poor peripheral circulation	1	5
Poor quality product administered	14	24
Poor quality sleep	2	15
Poor venous access		1
Porphyria acute		1
Portal vein thrombosis	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		9	32	1	3
		1	5		
		3	9	1	3
					1
					1
		1	2		1
		1	3		
			1		
			1	1	7
			2		1
			1		
			1		3
		1	1		
			3	1	1
					1
				4	14
		2	2		
				1	1
			1		
				1	1
					1
		1	8	1	1
					1
		6	8	1	1
					1
			1		1
			3	1	2
		14	24		
		2	15		
			1		
					1
				1	5

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Post-acute COVID-19 syndrome	1	1
Post herpetic neuralgia	2	2
Postmenopausal haemorrhage	2	4
Postoperative wound infection		1
Post-traumatic neck syndrome	1	2
Post-traumatic stress disorder		1
Postural orthostatic tachycardia syndrome	4	11
Post viral fatigue syndrome		1
Potentiating drug interaction	1	1
Pre-eclampsia	1	1
Pre-existing condition improved		2
Premature labour		1
Premature rupture of membranes	1	1
Premenstrual syndrome	1	5
Pressure of speech		2
Presyncope	15	80
Procedural site reaction		1
Product administered at inappropriate site	4	23
Product administration error	4	7
Product complaint		1
Product confusion		1
Product dose omission issue	5	10
Productive cough	2	16
Product leakage		1
Product preparation error	10	19
Product preparation issue	5	13
Product storage error	2	5
Product supply issue	1	2
Product temperature excursion issue	7	11
Product use issue	10	137
Protein total decreased		1
Protein total increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1	1	1
				2	4
					1
		1	1		1
			1		
		1	3	3	8
			1		
		1	1		
				1	1
			2		
					1
				1	1
		1	5		
			1		1
		9	58	6	22
					1
		4	21		2
		4	7		
			1		
			1		
		5	10		
		1	14	1	2
			1		
		10	17		2
		5	13		
		2	5		
		1	2		
		7	11		
		9	134	1	3
			1		
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Prothrombin time prolonged		2
Pruritus	68	366
Psoriasis	3	7
Psoriatic arthropathy		1
Psychomotor hyperactivity	1	3
Pulmonary artery occlusion		1
Pulmonary congestion	1	5
Pulmonary embolism	17	35
Pulmonary infarction		1
Pulmonary mass		1
Pulmonary oedema	1	3
Pulmonary pain	4	11
Pulmonary thrombosis	4	9
Pulse abnormal	1	5
Pupils unequal		1
Purpura		2
Pustule	1	2
Pyrexia	268	1,647
Radial nerve injury	1	1
Radiculitis brachial	2	4
Rash	73	401
Rash erythematous	9	58
Rash macular	5	40
Rash maculo-papular	2	7
Rash morbilliform	2	2
Rash papular	6	18
Rash pruritic	15	59
Rash pustular		1
Rash vesicular	1	8
Raynaud's phenomenon	2	5
Reaction to excipient	1	2
Reading disorder	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
		49	309	19	57
		3	7		
					1
		1	2		1
					1
				1	5
				17	35
					1
					1
				1	3
		3	8	1	3
				4	9
			2	1	3
					1
			2		
				1	2
		247	1533	21	114
				1	1
				2	4
		60	323	13	78
		8	43	1	15
		5	31		9
		2	7		
		1	1	1	1
		6	18		
		9	46	6	13
			1		
		1	5		3
		1	3	1	2
		1	2		
		1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rectal haemorrhage	1	5
Red blood cell count decreased	1	3
Red blood cell sedimentation rate increased	4	4
Red blood cells urine positive		1
Red ear syndrome		1
Reduced facial expression		1
Renal cyst	1	1
Renal disorder	3	4
Renal failure	1	2
Renal pain	5	12
Respiration abnormal	1	1
Respiratory arrest		1
Respiratory disorder	2	9
Respiratory distress		15
Respiratory failure		4
Respiratory rate decreased		3
Respiratory rate increased	2	12
Respiratory symptom		1
Respiratory tract congestion	1	8
Respiratory tract oedema		3
Restless legs syndrome	1	4
Restlessness	3	21
Restrictive pulmonary disease		1
Retching		5
Retinal artery occlusion		1
Retinal vein occlusion	1	3
Rhabdomyolysis	1	2
Rheumatoid arthritis	3	11
Rhinalgia	3	7
Rhinitis		2
Rhinitis allergic		1
Rhinorrhoea	13	108

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	5
			1	1	2
		3	3	1	1
			1		
			1		
			1		
		1	1		
			1	3	3
				1	2
		3	9	2	3
		1	1		
					1
		1	5	1	4
					15
					4
			3		
		2	8		4
			1		
			7	1	1
					3
		1	3		1
		2	18	1	3
					1
			5		
					1
				1	3
				1	2
				3	11
		3	7		
			2		
					1
		13	99		9

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rhinovirus infection		1
Right ventricular dysfunction		1
Road traffic accident	3	5
Rosacea		2
Salivary gland enlargement	1	2
Salivary gland pain	1	1
Salivary hypersecretion	1	3
SARS-CoV-1 test positive		1
SARS-CoV-2 ant body test negative		6
SARS-CoV-2 ant body test positive		3
SARS-CoV-2 test positive	3	53
Scab	3	4
Scar	1	3
Sciatica	3	4
Scleritis	1	3
Scleroderma		1
Scoliosis	1	1
Scratch	4	7
Screaming		2
Seasonal allergy	1	2
Secretion discharge		4
Sedation		3
Seizure	16	49
Seizure like phenomena		1
Self-injurious ideation		1
Sensation of foreign body		18
Sensitisation		1
Sensitive skin	4	14
Sensitivity to weather change	1	3
Sensorimotor disorder		1
Sensory disturbance	2	8
Sensory loss	2	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
		2	3	1	2
			2		
		1	2		
		1	1		
		1	3		
			1		
			5		1
			3		
		2	12	1	41
		2	3	1	1
		1	2		1
		2	3	1	1
				1	3
					1
		1	1		
		4	7		
			1		1
		1	2		
			3		1
			3		
				16	49
					1
			1		
			11		7
			1		
		3	13	1	1
		1	3		
					1
		1	6	1	2
		2	4		4

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sepsis		4
Serum ferritin decreased		1
Serum sickness		1
Shock		3
Shock symptom		1
Sialoadenitis		1
Sinus arrhythmia	1	1
Sinus congestion		6
Sinus disorder	3	12
Sinus headache		5
Sinusitis	2	22
Sinus pain	1	7
Sinus tachycardia	2	7
Sitting disability	1	3
Sjogren's syndrome		3
Skin burning sensation	7	21
Skin depigmentation		1
Skin discolouration	6	26
Skin discomfort		2
Skin disorder	4	13
Skin exfoliation	2	12
Skin hyperpigmentation		2
Skin hypertrophy		1
Skin indentation		2
Skin injury	1	3
Skin irritation	2	7
Skin laceration		3
Skin lesion	4	10
Skin mass		2
Skin odour abnormal		1
Skin oedema		1
Skin reaction	3	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					4
					1
					1
					3
					1
					1
		1	1		
			6		
		3	12		
			5		
		2	21		1
		1	7		
		2	4		3
		1	3		
					3
		5	17	2	4
			1		
		5	20	1	6
			2		
		4	11		2
		2	11		1
			2		
			1		
			2		
		1	3		
		1	6	1	1
			3		
		3	9	1	1
			2		
			1		
			1		
		3	5		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin sensitisation	1	1
Skin swelling	1	6
Skin temperature		1
Skin tightness	1	4
Skin ulcer		3
Skin warm	1	5
Skin weeping	1	1
Skin wrinkling	1	1
Sleep apnoea syndrome		1
Sleep deficit		2
Sleep disorder	8	32
Sleep disorder due to a general medical condition		2
Sleep disorder due to general medical condition, insomnia type		2
Sleep paralysis		2
Sleep talking		1
Slow response to stimuli	1	1
Slow speech	1	1
Sluggishness	4	11
Small fibre neuropathy	1	2
Sneezing	6	27
Snoring		1
Soft tissue disorder		1
Soft tissue injury	1	1
Soft tissue swelling	1	1
Soliloquy	1	1
Somnambulism	1	1
Somnolence	16	90
Speech disorder	9	43
Speech sound disorder		1
Spinal cord disorder		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	5		1
			1		
		1	3		1
			3		
		1	5		
				1	1
		1	1		
					1
			2		
		7	29	1	3
			2		
			2		
			2		
			1		
		1	1		
		1	1		
		4	11		
				1	2
		5	25	1	2
			1		
			1		
				1	1
		1	1		
		1	1		
		15	82	1	8
		2	17	7	26
			1		
					2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Spinal disorder		3
Spinal pain	5	18
Splenic vein thrombosis	1	1
Splenomegaly		2
Spondylitis	1	2
Sputum discoloured		4
Staphylococcal infection	1	4
Staring		2
Starvation	1	1
Stevens-Johnson syndrome		2
Sticky skin		1
Still's disease		1
Stomatitis	5	13
Strabismus	1	3
Strawberry tongue		1
Streptococcal infection		2
Stress	2	11
Stress urinary incontinence		1
Stridor		2
Substance abuse		1
Sudden cardiac death		1
Sudden death		1
Sudden hearing loss	2	5
Suffocation feeling		1
Suicidal ideation	5	8
Sunburn		1
Superficial vein prominence		1
Supraventricular extrasystoles		2
Supraventricular tachycardia	2	4
Suspected COVID-19	5	22
Swelling	39	157
Swelling face	26	128

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		2
		4	16	1	2
				1	1
			1		1
		1	1		1
			2		2
				1	4
			1		1
				1	1
					2
			1		
					1
		5	12		1
		1	2		1
			1		
			1		1
		1	10	1	1
			1		
					2
					1
					1
				2	5
			1		
				5	8
					1
					1
			2		
		2	2		2
		3	8	2	14
		34	138	5	19
		15	87	11	41

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Swelling of eyelid	3	19
Swollen tongue	13	85
Syncope	33	134
Synovial cyst	1	2
Synovial fluid analysis abnormal	1	1
Syringe issue		2
Systemic immune activation		1
Systemic inflammatory response syndrome		1
Systemic lupus erythematosus		3
Systemic scleroderma		1
Tachycardia	8	161
Tachyphrenia		3
Tachypnoea		9
Taste disorder	5	34
Temperature intolerance	1	6
Temperature regulation disorder	1	2
Tenderness	3	31
Tendonitis	1	3
Tendon pain		1
Tendon rupture	1	1
Tension	1	6
Tension headache	1	8
Terminal insomnia		2
Testicular pain	2	2
Testicular swelling	1	3
Tetany		2
Therapeutic response decreased	1	1
Therapeutic response unexpected		6
Thermal burn		1
Thinking abnormal	2	9
Thirst	3	23
Throat clearing		8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	19		
		4	41	9	44
1	1	1	2	32	132
		1	2		
				1	1
			2		
					1
					1
					3
					1
		5	105	3	56
			3		
			5		4
		4	30	1	4
		1	4		2
		1	2		
		3	28		3
		1	3		
			1		
		1	1		
		1	6		
		1	8		
			2		
		2	2		
		1	2		1
					2
		1	1		
			6		
			1		
			6	2	3
		2	21	1	2
			4		4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Throat irritation	14	109
Throat lesion	1	1
Throat tightness	20	116
Thrombocytopenia	1	11
Thrombophlebitis		2
Thrombophlebitis superficial	2	6
Thrombosis	30	61
Thrombotic microangiopathy		1
Thrombotic stroke		1
Thyroid disorder		2
Thyroid function test abnormal		1
Thyroiditis	1	1
Thyroiditis subacute	1	3
Thyroid mass		2
Thyroid pain	1	2
Thyrotoxic crisis		1
Tic		2
Tinnitus	52	157
Tongue blistering	2	5
Tongue coated		1
Tongue discolouration	1	3
Tongue discomfort	2	12
Tongue disorder	1	12
Tongue dry		2
Tongue eruption		3
Tongue erythema		1
Tongue haemorrhage		1
Tongue movement disturbance		1
Tongue pruritus	2	9
Tongue rough	1	1
Tongue ulceration	1	3
Tonsillar disorder		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		11	82	3	27
		1	1		
		11	66	9	50
				1	11
			2		
		1	4	1	2
				30	61
					1
					1
			2		
			1		
		1	1		
		1	3		
					2
		1	2		
					1
			2		
		32	106	20	51
		2	5		
					1
		1	2		1
		1	8	1	4
		1	7		5
			2		
			1		2
			1		
			1		
					1
		1	6	1	3
		1	1		
			2	1	1
			1		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tonsillar hypertrophy		2
Tonsillar inflammation	1	1
Tonsillitis	2	3
Tooth abscess	1	1
Toothache	1	12
Tooth disorder		1
Tooth fracture		1
Tooth injury		1
Toxicity to various agents	1	1
Tracheal deviation		1
Tracheitis	1	1
Transient ischaemic attack	3	9
Transverse sinus stenosis		1
Tremor	38	162
Tricuspid valve incompetence		1
Trigeminal neuralgia	1	6
Trigeminal neuritis		1
Trigger finger		2
Tri-iodothyronine increased	1	1
Trismus		6
Troponin increased	2	11
Tryptase decreased		1
Tryptase increased		1
Tunnel vision	1	7
Type IV hypersensitivity reaction		2
Ulcer		2
Ulcerative keratitis	1	1
Underdose	8	28
Undifferentiated connective tissue disease		1
Unresponsive to stimuli		2
Upper-airway cough syndrome	1	9
Upper gastrointestinal haemorrhage		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		1	1		
		1	2	1	1
		1	1		
		1	12		
					1
					1
					1
				1	1
					1
		1	1		
				3	9
					1
		30	126	8	36
					1
		1	5		1
			1		
			2		
				1	1
			4		2
				2	11
			1		
			1		
				1	7
			2		
			1		1
				1	1
		8	28		
					1
					2
		1	8		1
					1

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* AE=Adverse Event

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Upper limb fracture	1	1
Upper respiratory tract congestion	1	8
Upper respiratory tract infection	1	3
Urinary incontinence	3	13
Urinary retention	1	1
Urinary tract disorder		1
Urinary tract infection	1	6
Urine output decreased		1
Urine output increased		1
Urticaria	74	294
Urticaria chronic	1	2
Use of accessory respiratory muscles		2
Uterine contractions during pregnancy		2
Uterine disorder	1	1
Uterine haemorrhage	4	5
Uterine leiomyoma	1	1
Uterine pain	1	1
Uterine spasm		1
Uveitis		2
Uvulitis		1
Vaccination failure	23	67
Vaccination site bruising	4	27
Vaccination site cellulitis	2	8
Vaccination site coldness		4
Vaccination site dermatitis		1
Vaccination site discharge	1	1
Vaccination site discolouration	1	8
Vaccination site discomfort	5	19
Vaccination site dryness	1	1
Vaccination site erythema	22	173
Vaccination site extravasation	1	2
Vaccination site haemorrhage	3	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	5		3
		1	3		
		1	7	2	6
				1	1
			1		
		1	4		2
			1		
			1		
		56	225	18	69
			1	1	1
			1		1
			1		1
		1	1		
				4	5
				1	1
		1	1		
			1		
1	1				2
			1		
				23	67
		4	27		
			1	2	7
			4		
					1
		1	1		
		1	8		
		5	17		2
		1	1		
		21	167	1	6
		1	2		
		2	8	1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site hyperaesthesia		1
Vaccination site hypersensitivity		2
Vaccination site hypoaesthesia	1	10
Vaccination site induration	3	20
Vaccination site infection		1
Vaccination site inflammation	1	8
Vaccination site irritation		2
Vaccination site joint erythema		2
Vaccination site joint movement impairment	1	7
Vaccination site joint pain	1	7
Vaccination site joint swelling		2
Vaccination site lymphadenopathy	1	10
Vaccination site mass	7	30
Vaccination site movement impairment	1	19
Vaccination site nodule		5
Vaccination site oedema		2
Vaccination site pain	130	952
Vaccination site paraesthesia	2	11
Vaccination site pruritus	13	87
Vaccination site pustule		1
Vaccination site rash	11	49
Vaccination site reaction	1	11
Vaccination site scab	1	2
Vaccination site scar	1	2
Vaccination site swelling	20	169
Vaccination site thrombosis		1
Vaccination site ulcer		1
Vaccination site urticaria	1	26
Vaccination site vesicles	1	7
Vaccination site warmth	8	83
Vaginal haemorrhage	8	22
Vaginal infection		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2		
		1	10		
		3	20		
			1		
		1	8		
			2		
			1		1
		1	6		1
		1	5		2
			1		1
		1	9		1
		7	30		
		1	19		
			5		
			2		
		126	925	4	27
		2	10		1
		13	85		2
			1		
		10	46	1	3
		1	11		
		1	2		
		1	2		
		19	162	1	7
					1
			1		
		1	23		3
		1	7		
		7	81	1	2
		4	14	4	8
			1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Varicocele		1
Varicose vein	1	1
Vascular injury	1	1
Vascular rupture	1	2
Vasculitic rash	1	1
Vein discolouration	1	3
Vein disorder	2	2
Ventricular arrhythmia	1	2
Ventricular extrasystoles	1	9
Ventricular fibrillation		2
Ventricular tachycardia		1
Vertebral artery dissection		1
Vertigo	26	110
Vertigo positional	1	5
Vestibular disorder	1	1
Vestibular neuritis	1	2
VIIIth nerve lesion		1
Viral infection	1	4
Viral myelitis	1	1
Viral sepsis	1	1
Viral upper respiratory tract infection		1
Vision blurred	15	75
Visual acuity reduced		1
Visual field defect		1
Visual impairment	7	39
Vital functions abnormal	1	1
Vitamin B12 decreased		1
Vitamin D decreased		1
Vitamin D deficiency		1
Vitreous detachment	2	3
Vitreous floaters		1
Vocal cord disorder	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	1		
				1	1
		1	2		
		1	1		
		1	3		
		2	2		
				1	2
		1	8		1
					2
					1
					1
		22	84	4	26
		1	4		1
				1	1
				1	2
					1
		1	4		
				1	1
				1	1
					1
		13	57	2	18
			1		
			1		
		6	30	1	9
				1	1
					1
			1		
					1
				2	3
					1
				1	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vocal cord dysfunction		1				1		
Vocal cord paralysis		1						1
Vomiting	66	350			52	293	14	57
Vomiting projectile		7				7		
Vulvovaginal discomfort	1	1					1	1
Vulvovaginal mycotic infection	1	3			1	3		
Vulvovaginal pain	1	1					1	1
Vulvovaginal swelling	1	2				1	1	1
Walking disability	1	2					1	2
Weight bearing difficulty	1	1			1	1		
Weight decreased	8	20			4	13	4	7
Weight fluctuation		1				1		
Weight increased		3				3		
Wheezing	5	37			3	28	2	9
White blood cell count abnormal		1				1		
White blood cell count decreased	2	4			2	3		1
White blood cell count increased	2	14			1	8	1	6
White blood cells urine	1	1			1	1		
Winged scapula		1				1		
Withdrawal bleed		1				1		
Wound	1	3				1	1	2
Wound closure		1				1		
Wound haemorrhage		1				1		
Wrong product administered	3	8			3	8		
Wrong technique in product usage process	3	12			2	10	1	2
Xanthopsia		1				1		
Yawning	1	1			1	1		
Yellow skin		2				1		1
	7,561	38,364	11	12	5687	30975	1874	7389

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	29	95			28	90	1	5
Abdominal distension	8	31			6	27	2	4
Abdominal operation		1				1		
Abdominal pain	19	93			14	75	5	18
Abdominal pain lower		11				9		2
Abdominal pain upper	32	118			28	104	4	14
Abdominal rigidity		2				1		1
Abnormal behaviour	1	3				2	1	1
Abnormal clotting factor		1						1
Abnormal dreams	1	8			1	8		
Abnormal faeces	3	5			3	5		
Abnormal sensation in eye	1	3			1	3		
Accident		1				1		
Accidental exposure to product	1	4			1	4		
Accidental overdose	2	6			2	6		
Accidental underdose		1				1		
Acne	3	9			2	8	1	1
Acute kidney injury		1						1
Acute myocardial infarction		1						1
Acute pulmonary oedema		1						1
Acute respiratory distress syndrome		1						1
Acute respiratory failure		1	1	1				1
Administration site bruise		2				2		
Adnexa uteri pain		1				1		
Adrenal disorder		2				1		1
Adrenergic syndrome		1				1		
Adverse drug reaction	1	1			1	1		
Adverse event	1	2			1	2		
Adverse reaction		1				1		
Affect liability		1						1
Ageusia	7	62			5	57	2	5
Aggression	1	3				2	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Agitation	2	10
Alanine aminotransferase		1
Alanine aminotransferase increased	1	4
A bumin globulin ratio decreased		1
Alcohol interaction	1	1
Allergic cough	1	1
Allergic reaction to excipient		1
Allergy to arthropod sting	1	1
Allergy to chemicals		1
Allergy to vaccine	7	25
Alopecia	1	10
Alopecia universalis		2
Altered state of consciousness		1
Amaurosis fugax		1
Amnesia	5	17
Amylase increased		1
Anaemia		1
Anal haemorrhage		1
Anal incontinence		4
Anal skin tags		1
Anaphylactic reaction	7	82
Anaphylactic shock	1	5
Aneurysm		1
Anger	1	5
Angina pectoris	5	13
Angioedema	1	17
Animal bite		1
Anion gap abnormal		1
Anion gap increased		1
Ankle fracture		2
Anosmia	4	49
Anterior chamber cell		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	10		
			1		
		1	3		1
			1		
		1	1		
		1	1		
					1
				1	1
			1		
		2	9	5	16
		1	6		4
			2		
					1
					1
		4	13	1	4
			1		
			1		
					1
			3		1
			1		
				7	82
				1	5
					1
		1	5		
				5	13
				1	17
			1		
			1		
			1		
					2
		3	43	1	6
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Antibody test abnormal		1
Antibody test positive	1	1
Anti Kell antibody test positive		1
Antinuclear ant body positive	1	1
Anxiety	22	85
Anxiety disorder		1
Apathy		2
Aphasia	6	12
Aphonia	4	12
Aphthous ulcer		4
Apnoea	1	1
Appendicectomy		1
Appendicitis	3	14
Appendicitis perforated		4
Appendix disorder		2
Aptyalism		1
Arrhythmia	2	8
Arthralgia	125	621
Arthritis	10	24
Arthritis reactive	1	1
Arthropathy	2	13
Arthropod sting		1
Aspartate aminotransferase		1
Aspartate aminotransferase increased		3
Asphyxia		1
Aspiration	1	1
Asthenia	68	336
Asthenopia	1	8
Asthma	8	24
Asthma exercise induced		1
Asthma prophylaxis		1
Asymptomatic COVID-19	3	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	1		
			1		
		1	1		
		19	75	3	10
			1		
			2		
		4	6	2	6
		3	8	1	4
			4		
				1	1
			1		
				3	14
					4
			1		1
			1		
				2	8
		117	579	8	42
		8	19	2	5
				1	1
		2	13		
			1		
			1		
			3		
					1
				1	1
		64	308	4	28
		1	7		1
		6	20	2	4
			1		
			1		
			5	3	7

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ataxia		2
Atelectasis	3	4
Atrial fibrillation	7	28
Atrial flutter		3
Atrioventricular block complete	1	2
Atrioventricular block second degree		1
Attention deficit hyperactivity disorder	1	1
Aura	1	1
Auricular swelling		2
Autoimmune disorder	1	6
Autoimmune thyroid disorder		1
Autoimmune thyroiditis	1	3
Autoscopy		1
Axillary mass		8
Axillary pain	12	56
Back disorder	5	5
Back injury	2	3
Back pain	49	209
Bacteraemia	1	2
Bacterial infection	2	2
Bacterial pyelonephritis		1
Bacterial test positive	1	1
Balance disorder	14	46
Basal ganglia haemorrhage		2
Basal ganglia stroke		1
Basilar artery thrombosis	1	1
Basophil count increased		1
Bed rest		3
Bedridden	2	12
Bell's palsy	32	93
Biliary tract disorder		1
Bipolar disorder	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
		1	1	2	3
1	1			7	28
			1		2
				1	2
					1
		1	1		
		1	1		
			1		1
				1	6
					1
				1	3
			1		
			8		
		12	54		2
		5	5		
		2	3		
		46	185	3	24
				1	2
		1	1	1	1
					1
		1	1		
		10	35	4	11
					2
					1
				1	1
			1		
			3		
		1	10	1	2
			1	32	92
					1
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bladder discomfort		2
Bladder disorder		1
Bladder spasm		1
Blepharitis		1
Blepharochalasis		1
Blepharospasm	2	5
Blindness	4	9
Blindness transient	1	4
Blindness unilateral		6
Blister	14	34
Blood albumin decreased		1
Blood alcohol increased	2	2
Blood alkaline phosphatase		1
Blood alkaline phosphatase increased		2
Blood bilirubin abnormal		1
Blood bilirubin increased		3
Blood blister		2
Blood calcium decreased		1
Blood chloride decreased		1
Blood cholesterol decreased		1
Blood cholesterol increased	3	3
Blood copper increased		1
Blood creatine increased		1
Blood creatine phosphokinase abnormal		1
Blood creatine phosphokinase increased		3
Blood creatinine abnormal		1
Blood creatinine increased		1
Blood disorder		1
Blood electrolytes decreased	1	1
Blood glucose abnormal	2	2
Blood glucose decreased	6	11
Blood glucose fluctuation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
			1		
			1		
			1		
			1		
		2	5		
				4	9
				1	4
					6
		12	28	2	6
			1		
		1	1	1	1
			1		
			2		
					1
			1		2
			1		1
			1		
			1		
		2	2	1	1
			1		
			1		
			1		
			1		2
					1
			1		
			1		
				1	1
		1	1	1	1
		5	7	1	4
			1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood glucose increased	5	28
Blood immunoglobulin G		1
Blood immunoglobulin G increased	1	1
Blood iron decreased		1
Blood lactic acid increased		1
Blood magnesium decreased	1	1
Blood osmolarity decreased		1
Blood potassium decreased	1	8
Blood pressure abnormal	3	7
Blood pressure decreased	4	17
Blood pressure diastolic decreased		2
Blood pressure diastolic increased		2
Blood pressure fluctuation	1	6
Blood pressure increased	15	95
Blood pressure systolic increased	1	5
Blood sodium decreased	1	3
Blood test abnormal		1
Blood thyroid stimulating hormone decreased		1
Blood thyroid stimulating hormone increased		4
Blood triglycerides abnormal		1
Blood triglycerides decreased		2
Blood triglycerides increased	1	3
Blood urea decreased		1
Blood urea increased		1
Blood urine present	6	14
Blood zinc decreased	1	1
Blue toe syndrome		2
Body temperature		1
Body temperature abnormal	5	11
Body temperature decreased		10
Body temperature fluctuation		1
Body temperature increased	9	41

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	24	1	4
			1		
				1	1
					1
					1
				1	1
			1		
			5	1	3
		3	6		1
		3	6	1	11
			1		1
			1		1
		1	5		1
		8	52	7	43
		1	2		3
		1	3		
					1
					1
			3		1
			1		
			2		
		1	2		1
			1		
					1
		4	9	2	5
		1	1		
					2
			1		
		4	9	1	2
			9		1
			1		
		9	41		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bone contusion	1	1
Bone disorder		2
Bone pain	6	31
Bone swelling		1
Bowel movement irregularity	2	2
Brachial plexopathy		1
Bradycardia		2
Bradykinesia		2
Bradyphrenia		4
Brain natriuretic peptide increased	1	1
Brain oedema	4	6
Brain stem haemorrhage		1
Brain stem infarction		1
Brain stem syndrome		1
Breast discharge		2
Breast discomfort		4
Breast haematoma		1
Breast induration	1	1
Breast mass		2
Breast pain	9	26
Breast swelling	1	4
Breast tenderness	2	6
Breath odour	1	1
Breath sounds abnormal		2
Bronchial oedema		1
Bronchitis	3	5
Bronchospasm		9
Burning sensation	31	103
Burning sensation mucosal	1	1
Burn oesophageal		1
Bursitis	1	2
Butterfly rash		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
			2		
		4	28	2	3
			1		
		2	2		
					1
					2
			2		
			1		3
				1	1
				4	6
					1
					1
					1
			2		
			3		1
			1		
		1	1		
			2		
		8	23	1	3
		1	4		
		2	6		
		1	1		
			2		
					1
		2	4	1	1
			5		4
		25	82	6	21
		1	1		
			1		
		1	2		
			1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Caffeine consumption		1
Calcinosis	1	1
Candida infection	1	3
Capillary fragility		1
Cardiac amyloidosis	1	1
Cardiac arrest	3	7
Cardiac discomfort	1	1
Cardiac disorder	2	14
Cardiac failure		1
Cardiac failure congestive	2	3
Cardiac fibrillation		1
Cardiac flutter	4	13
Cardiac tamponade	1	1
Cardiac ventricular thrombosis	1	2
Cardio-respiratory arrest		1
Cardiospasm		3
Cardiovascular disorder	1	4
Carpal tunnel syndrome		1
Cartilage injury		1
Cataract	2	2
Cell marker decreased		1
Cellulitis	6	11
Cerebellar stroke		1
Cerebral artery occlusion		1
Cerebral disorder	2	5
Cerebral haemorrhage	2	7
Cerebral palsy		1
Cerebral thrombosis	1	5
Cerebral venous sinus thrombosis		1
Cerebrovascular accident	18	52
Cervical radiculopathy		1
Cervicobrachial syndrome		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	1		
		1	3		
			1		
				1	1
				3	7
		1	1		
		1	10	1	4
					1
				2	3
					1
				4	13
				1	1
				1	2
					1
			2		1
		1	4		
			1		
			1		
				2	2
					1
				6	11
					1
					1
		2	5		
				2	7
					1
				1	5
					1
				18	52
			1		
			1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Change in sustained attention		1
Cheilitis	1	1
Chest discomfort	28	141
Chest pain	48	142
Chest X-ray abnormal		1
Chillblains		1
Chills	193	1,143
Chloropsia	1	1
Choking		7
Choking sensation	1	4
Cholecystitis infective		1
Cholelithiasis	1	2
Cholelithiasis obstructive		1
Cholestasis		1
Chromaturia	1	2
Chronic fatigue syndrome	1	1
Chronic inflammatory demyelinating polyradiculoneuropathy	1	2
Chronic kidney disease		3
Chronic obstructive pulmonary disease		2
Circadian rhythm sleep disorder		1
Circulatory collapse		1
Circumoral swelling	1	3
Circumstance or information capable of leading to medication error	3	60
Clostridium difficile colitis		1
Clostridium difficile infection		1
Clumsiness		1
Coagulopathy	1	3
Coccydynia	1	2
Cognitive disorder	7	16
Cold-stimulus headache		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	1		
		24	108	4	33
		32	104	16	38
					1
			1		
		182	1072	11	71
				1	1
					7
			2	1	2
					1
			1	1	1
					1
					1
			1	1	1
		1	1		
				1	2
					3
					2
			1		
					1
		1	3		
		3	60		
					1
					1
			1		
		1	2		1
		1	2		
		7	14		2
			1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cold sweat	12	37
Colitis	3	5
Colitis ischaemic	1	3
Colitis microscopic	1	1
Colitis ulcerative		1
Coma	1	2
Communication disorder		1
Complex regional pain syndrome		1
Complicated appendicitis		1
Complication associated with device		1
Concussion		5
Condition aggravated	33	113
Confusional state	4	34
Congestive cardiomyopathy	1	1
Conjunctival haemorrhage		3
Conjunctivitis	1	5
Conjunctivitis viral		1
Consciousness fluctuating		1
Constipation	3	17
Contraindicated product administered		1
Contusion	20	60
Cooling therapy		1
Coordination abnormal	2	5
Corneal disorder		1
Corneal graft rejection		1
Corneal infection		1
Corneal infiltrates		1
Costochondritis		2
Cough	47	234
COVID-19	104	410
COVID-19 immunisation		1
COVID-19 pneumonia	2	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		11	32	1	5
		1	2	2	3
				1	3
				1	1
1	1				1
				1	2
			1		
			1		
					1
					1
			1		4
		20	83	13	30
		3	26	1	8
				1	1
					3
		1	5		
			1		
					1
		2	12	1	5
			1		
		16	54	4	6
			1		
		1	2	1	3
					1
					1
					1
					1
			1		1
		43	206	4	28
4	6	48	150	56	260
			1		
2	2			2	9

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cranial nerve injury	1	1
C-reactive protein increased		5
Crohn's disease	1	2
Crying	2	9
Crystal urine		1
Cutaneous vasculitis		1
Cyanosis	1	9
Cyst		2
Cystitis	2	3
Cystitis bacterial		1
Cystitis escherichia		1
Daydreaming		1
Deafness	11	35
Deafness bilateral	1	1
Deafness neurosensory		4
Deafness unilateral	4	18
Death	1	8
Decreased appetite	26	132
Deep vein thrombosis	15	33
Defaecation urgency	1	2
Dehydration	11	38
Delirium	2	9
Delirium febrile		1
Dementia Alzheimer's type		1
Dental caries	1	1
Dental discomfort		1
Depersonalisation/derealisation disorder		2
Depressed level of consciousness		2
Depressed mood	4	9
Depression	3	15
Dermatitis	1	4
Dermatitis acneiform	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			5		
				1	2
		1	7	1	2
			1		
			1		
			7	1	2
			2		
		2	2		1
					1
					1
			1		
			1	11	34
				1	1
					4
				4	18
				1	8
		25	125	1	7
				15	33
		1	2		
		5	21	6	17
				2	9
					1
					1
		1	1		
			1		
			2		
					2
		4	9		
		1	11	2	4
		1	4		
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dermatitis allergic	1	3
Dermatitis atopic		1
Dermatitis contact	1	3
Dermatomyositis		1
Diabetes mellitus	1	4
Diabetes mellitus inadequate control	1	3
Diabetic coma		1
Diaphragmalgia	1	1
Diarrhoea	76	330
Diarrhoea haemorrhagic	1	5
Diplopia	4	19
Disability		1
Discharge		1
Discomfort	12	58
Discouragement		1
Disease progression	1	2
Disease recurrence	11	40
Disorientation	7	20
Disseminated intravascular coagulation		1
Disseminated varicella zoster virus infection		1
Dissociation		2
Disturbance in attention	8	34
Diverticulitis		4
Dizziness	149	684
Dizziness postural	3	11
Drainage	1	2
Drug effective for unapproved indication		2
Drug hypersensitivity	3	19
Drug ineffective	49	242
Drug interaction		6
Dry eye	4	17
Dry mouth	9	40

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		
			1		
		1	3		
					1
				1	4
				1	3
					1
		1	1		
		70	300	6	30
				1	5
		3	12	1	7
			1		
			1		
		9	51	3	7
			1		
			1	1	1
		7	28	4	12
		5	13	2	7
					1
					1
			1		1
		7	27	1	7
					4
	1	128	581	21	103
		3	11		
		1	2		
			2		
			15	3	4
5	7	1	1	48	241
			6		
		4	15		2
		9	35		5

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dry skin	5	14
Dry throat	2	7
Duodenogastric reflux	1	1
Dysaesthesia	2	4
Dysarthria	8	18
Dysentery		1
Dysgeusia	13	98
Dysgraphia		1
Dyskinesia	4	13
Dyslexia		1
Dysmenorrhoea	5	8
Dyspareunia		1
Dyspepsia	5	29
Dysphagia	14	62
Dysphemia	1	2
Dysphonia	4	41
Dyspnoea	89	365
Dyspnoea exertional		4
Dysstasia	4	21
Dystonia	1	3
Dysuria	3	8
Ear congestion	1	7
Ear discomfort	7	33
Ear disorder		5
Ear haemorrhage		1
Ear infection	4	8
Ear injury		1
Ear pain	16	62
Ear pruritus	3	8
Ear swelling	3	7
Eating disorder	9	24
Eating disorder symptom		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	13		1
		2	7		
		1	1		
		2	4		
		6	11	2	7
					1
		12	90	1	8
					1
		4	11		2
			1		
		5	7		1
			1		
		5	28		1
	1	6	43	8	19
		1	1		1
		2	30	2	11
	1	61	235	28	130
			2		2
		4	18		3
				1	3
		2	5	1	3
			4	1	3
		5	26	2	7
			4		1
					1
		4	7		1
			1		
		14	56	2	6
		1	6	2	2
		2	6	1	1
		8	20	1	4
			1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ecchymosis	1	1
Eczema	1	5
Ejection fraction decreased		1
Electric shock	1	1
Electric shock sensation	4	11
Electrocardiogram abnormal	1	4
Embolic stroke	1	1
Emergency care	1	1
Emotional disorder	3	8
Emotional distress		4
Encephalitis	1	1
Encephalopathy		1
Endocrine disorder	1	1
Endocrine ophthalmopathy	1	1
Endometrial thickening		1
Energy increased	1	9
Enlarged uvula	2	4
Enteritis		1
Enterocolitis haemorrhagic	1	1
Eosinophilia		1
Epigastric discomfort		1
Episcleritis		2
Epistaxis	11	35
Epstein-Barr virus antibody		1
Epstein-Barr virus antibody positive		2
Epstein-Barr virus antigen positive		1
Erectile dysfunction	1	3
Eructation	1	8
Erythema	47	208
Erythema multiforme		1
Erythema nodosum		1
Erythema of eyelid		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	5		
					1
		1	1		
		3	10	1	1
			2	1	2
				1	1
		1	1		
		3	8		
			2		2
				1	1
					1
		1	1		
				1	1
			1		
		1	9		
		1	2	1	2
					1
				1	1
			1		
			1		
			2		
		10	32	1	3
			1		
			2		
			1		
				1	3
		1	8		
		42	180	5	28
					1
			1		
			1		2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Escherichia urinary tract infection		1
Euphoric mood	1	7
Exercise tolerance decreased		1
Exophthalmos	1	3
Expired product administered	2	4
Exposure to SARS-CoV-2	4	16
Exposure via skin contact		2
External ear disorder		1
External ear pain		2
Extra dose administered		1
Extrasystoles		2
Extremity contracture		1
Eye allergy		1
Eye colour change	1	1
Eye contusion	1	4
Eye discharge	2	7
Eye disorder	3	21
Eye haematoma	1	1
Eye haemorrhage	4	18
Eye inflammation		4
Eye injury		3
Eye irritation	4	22
Eyelid disorder		4
Eyelid function disorder		1
Eyelid irritation		2
Eyelid margin crusting		1
Eyelid oedema	1	2
Eyelid pain		3
Eyelid ptosis	2	6
Eyelid sensory disorder		1
Eyelids pruritus	2	4
Eye movement disorder		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	7		
			1		
				1	3
		2	4		
		4	14		2
			2		
			1		
			2		
			1		
			2		
			1		
			1		
		1	1		
		1	4		
		2	7		
		2	18	1	3
				1	1
				4	18
			3		1
			3		
		4	18		4
			4		
			1		
			2		
			1		
		1	2		
			3		
		1	5	1	1
			1		
		2	2		2
			2		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye oedema	2	4
Eye pain	8	36
Eye paraesthesia		1
Eye pruritus	9	26
Eye swelling	10	52
Eye ulcer		1
Face injury		2
Face oedema	2	3
Facial bones fracture		1
Facial discomfort	1	7
Facial nerve disorder		3
Facial pain	2	18
Facial paralysis	5	21
Facial paresis	1	4
Faeces discoloured	2	8
Faeces soft		5
Fall	13	43
False positive investigation result		1
Fatigue	256	1,378
Fear		10
Fear of falling	1	1
Febrile convulsion		1
Febrile neutropenia	1	1
Feeding disorder	8	22
Feeling abnormal	95	393
Feeling cold	28	93
Feeling drunk		6
Feeling hot	30	138
Feeling jittery		6
Feeling of body temperature change	6	22
Feeling of relaxation		1
Fibrin D dimer increased	3	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	4		
		8	34		2
			1		
		7	20	2	6
		9	39	1	13
			1		
			2		
		1	2	1	1
					1
		1	7		
			1		2
		2	18		
				5	21
		1	4		
		1	6	1	2
			3		2
		9	27	4	16
			1		
	1	241	1306	15	72
			9		1
		1	1		
					1
				1	1
		7	19	1	3
		88	362	7	31
		26	84	2	9
			6		
		30	120		18
			4		2
		6	22		
			1		
		2	6	1	2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Fibromyalgia	2	6
Fine motor skill dysfunction		1
Finger deformity		1
Flank pain	1	6
Flatulence	2	14
Fluid intake reduced		1
Fluid retention	2	4
Flushing	12	89
Foaming at mouth	1	1
Folliculitis		1
Food aversion	1	2
Food poisoning		1
Foot deformity		1
Foot fracture	1	1
Foreign body aspiration		1
Foreign body in eye		1
Foreign body in throat		1
Foreign body sensation in eyes	2	3
Formication		4
Freezing phenomenon		2
Frequent bowel movements		2
Frostbite		1
Frustration tolerance decreased	3	9
Full blood count		1
Functional gastrointestinal disorder		2
Fungal infection	1	2
Fungal skin infection		1
Furuncle		1
Gait disturbance	30	110
Gait inability	8	28
Gallbladder disorder		3
Gastric disorder		7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	6		
			1		
			1		
			4	1	2
		2	14		
			1		
		1	3	1	1
		10	69	2	20
				1	1
			1		
		1	2		
			1		
			1		
				1	1
					1
			1		
					1
		2	3		
			4		
			2		
			2		
			1		
		3	9		
			1		
			2		
		1	2		
			1		
			1		
		23	89	7	21
		4	17	4	11
			2		1
			6		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastric infection		1
Gastritis	1	1
Gastroenteritis		2
Gastroenteritis viral		4
Gastrointestinal disorder	1	12
Gastrointestinal haemorrhage		2
Gastrointestinal hypomotility		1
Gastrointestinal motility disorder	1	1
Gastrointestinal oedema		1
Gastrointestinal pain	1	5
Gastrointestinal sounds abnormal	1	1
Gastrooesophageal reflux disease	2	10
Generalised tonic-clonic seizure	2	3
General physical health deterioration		1
Genital herpes	1	2
Genital swelling		1
Gingival abscess	1	1
Gingival bleeding		5
Gingival blister		1
Gingival discomfort	1	1
Gingival disorder		1
Gingival erythema		2
Gingival pain	3	9
Gingival recession		1
Gingival swelling		5
Glassy eyes		2
Glaucoma	1	1
Glomerular filtration rate abnormal		1
Glomerular filtration rate decreased	1	2
Glossitis		2
Glossodynia	2	12
Glycosylated haemoglobin increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
			1		1
			4		
		1	10		2
					2
			1		
		1	1		
					1
		1	5		
		1	1		
		2	10		
				2	3
					1
			1	1	1
			1		
		1	1		
			5		
					1
		1	1		
			1		
			2		
		3	9		
			1		
			4		1
			2		
		1	1		
			1		
			1	1	1
			2		
		2	12		
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Goitre	1	4
Good syndrome		1
Gout	5	9
Grip strength decreased	1	8
Groin pain	4	8
Grunting		4
Guillain-Barre syndrome	2	6
Haematemesis	1	1
Haematochezia	3	12
Haematocrit increased		1
Haematology test abnormal		1
Haematoma		2
Haematuria	2	3
Haemoglobin decreased	3	6
Haemolysis		1
Haemolytic anaemia		1
Haemophagocytic lymphohistiocytosis		1
Haemoptysis	2	5
Haemorrhage	11	23
Haemorrhage intracranial		1
Haemorrhage urinary tract	5	6
Haemorrhagic stroke	1	2
Haemorrhoids		4
Hair disorder		1
Hair injury	1	2
Hallucination	2	9
Hallucination, auditory		2
Hallucination, visual		2
Hand fracture		2
Hangover	1	6
Headache	357	1,690
Head discomfort	14	67

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		1
					1
		3	7	2	2
		1	7		1
		3	6	1	2
			3		1
				2	6
				1	1
1	1			3	12
			1		
			1		
			2		
				2	3
		1	2	2	4
					1
					1
					1
			3	2	2
			1	11	22
					1
				5	6
				1	2
			3		1
			1		
		1	2		
				2	9
					2
					2
					2
		1	5		1
		341	1580	16	110
		14	57		10

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Head injury	2	11
Head titubation		1
Hearing disability	1	2
Heart injury		1
Heart rate abnormal	1	8
Heart rate decreased	7	14
Heart rate increased	54	208
Heart rate irregular	4	16
Heart valve incompetence		1
Heat illness		1
Heavy menstrual bleeding	5	10
Helicobacter infection		1
Hemianaesthesia		
Hemiparesis	1	2
Hemiplegia	1	1
Hemiplegic migraine	1	1
Hepatic enzyme abnormal		1
Hepatic enzyme increased		3
Hepatic failure	1	2
Hepatic necrosis		1
Hepatic pain	2	2
Hepatic steatosis		2
Hepatitis		1
Hepatitis acute		2
Hepatitis C	1	1
Hepatitis cholestatic		1
Hernia	2	2
Herpes simplex	1	3
Herpes virus infection	1	3
Herpes zoster	51	98
Herpes zoster reactivation	1	1
Hiccups	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			6	2	5
			1		
			1	1	1
					1
		1	6		2
		4	9	3	5
		43	168	11	40
		3	13	1	3
			1		
			1		
		4	8	1	2
					1
1	1				
				1	2
				1	1
		1	1		
					1
			2		1
				1	2
					1
		2	2		
			2		
					1
					2
				1	1
					1
		1	1	1	1
		1	3		
		1	3		
		41	79	10	19
		1	1		
		1	2		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hidradenitis		1
Histamine level increased		2
HIV test positive	1	1
Hordeolum		3
Hot flush	18	54
Hunger	1	5
Hydronephrosis		1
Hyperacusis	3	8
Hyperaesthesia	3	8
Hyperaesthesia teeth	2	3
Hypercholesterolaemia	1	1
Hyperglycaemia		2
Hyperhidrosis	46	200
Hypermetropia		1
Hyperpyrexia	1	2
Hypersensitivity	37	118
Hypersomnia	8	37
Hypertension	27	93
Hypertensive emergency		2
Hyperthyroidism		1
Hypertonia		1
Hyperventilation	3	12
Hypoacusis	8	24
Hypoaesthesia	78	269
Hypoaesthesia eye		4
Hypoaesthesia oral	11	75
Hypoaesthesia teeth		1
Hypobarism		1
Hypogeusia		4
Hypoglycaemia	1	3
Hypokalaemic syndrome		1
Hypokinesia	2	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2		
		1	1		
			3		
		16	51	2	3
		1	5		
					1
		3	8		
		2	7	1	1
		2	3		
		1	1		
			1		1
		42	177	4	23
			1		
				1	2
		23	84	14	34
		7	32	1	5
		10	39	17	54
					2
					1
			1		
		3	12		
		6	19	2	5
		64	217	14	52
			4		
		7	55	4	20
			1		
					1
			4		
		1	1		2
			1		
		1	9	1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyponatraemic syndrome		1
Hypophagia	1	3
Hypopnoea	2	4
Hyposmia		2
Hypotension	8	22
Hypothermia		1
Hypothyroidism	1	4
Hypoxia	2	4
Hysterectomy		1
Idiosyncratic drug reaction		1
IIIrd nerve paralysis		1
Iliotibial band syndrome		1
III-defined disorder	1	1
Illness	53	167
Illness anxiety disorder		1
Immobile	1	3
Immune system disorder	4	14
Immune thrombocytopenia		3
Immunisation		1
Immunodeficiency	3	6
Immunoglobulins abnormal		1
Immunosuppression		1
Impaired driving ability	1	6
Impaired gastric emptying	1	1
Impaired healing		1
Impaired quality of life		1
Impaired work ability	1	10
Impatience	1	1
Inappropriate schedule of product administration	29	149
Incoherent		1
Incorrect dosage administered		1
Incorrect dose administered	2	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	3		
		2	4		
			2		
		5	13	3	9
					1
				1	4
				2	4
					1
			1		
					1
			1		
		1	1		
		48	154	5	13
			1		
				1	3
		3	12	1	2
					3
			1		
				3	6
			1		
					1
		1	4		2
				1	1
					1
					1
		1	10		
		1	1		
		28	148	1	1
					1
			1		
		2	7		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Incorrect product administration duration		1
Incorrect route of product administration	3	21
Increased appetite	1	1
Increased tendency to bruise		1
Increased upper airway secretion		3
Infection	4	10
Infectious mononucleosis	1	1
Inflammation	13	35
Inflammatory marker increased	1	1
Inflammatory pain		1
Influenza	14	34
Influenza A virus test positive		1
Influenza B virus test positive		1
Influenza like illness	26	136
Infusion site mobility decreased		1
Initial insomnia		1
Injected limb mobility decreased		1
Injection site bruising		3
Injection site discomfort		2
Injection site erythema	1	11
Injection site hypoaesthesia		1
Injection site inflammation		1
Injection site mass	1	5
Injection site nodule		1
Injection site pain	3	64
Injection site pruritus		2
Injection site rash		1
Injection site swelling		8
Injection site urticaria		1
Injection site warmth		3
Injury	1	3
Inner ear disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		3	20		1
		1	1		
			1		
			1		2
		2	8	2	2
		1	1		
		12	31	1	4
		1	1		
			1		
		14	33		1
			1		
			1		
		24	127	2	9
			1		
			1		
			1		
			2		
		1	11		
			1		
			1		
		1	5		
			1		
		3	63		1
			2		
			1		
			8		
					1
			3		
		1	2		1
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Inner ear inflammation		2
Insomnia	42	152
Inspiratory capacity decreased	1	1
Insulin resistant diabetes		1
Intentional product misuse		1
Intermenstrual bleeding	1	1
Internal haemorrhage	1	2
International normalised ratio decreased		2
International normalised ratio increased		1
Intervertebral disc degeneration		1
Intervertebral disc protrusion		3
Intestinal haemorrhage		1
Intestinal obstruction		1
Intracranial pressure increased		1
Intraocular pressure increased		1
Intrusive thoughts		1
Iritis	1	2
Irregular sleep wake rhythm disorder		2
Irritability	3	10
Irritable bowel syndrome	1	3
Ischaemic stroke	2	4
Jaundice	1	3
Jaw clicking		1
Jaw cyst		1
Jaw disorder	1	4
Job dissatisfaction		1
Joint dislocation	1	5
Joint effusion		1
Joint injury	1	5
Joint instability		1
Joint lock		1
Joint noise	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		39	138	3	14
		1	1		
			1		1
		1	1		
				1	2
			1		1
					1
			1		
			2		1
1	1				1
					1
					1
			1		
			1		
		1	2		
			2		
		3	10		
		1	3		
				2	4
			1	1	2
			1		
			1		
	1	1	3		1
			1		
		1	1		4
			1		
		1	5		
					1
			1		
		1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Joint range of motion decreased	6	20
Joint stiffness	3	17
Joint swelling	12	52
Joint warmth		1
Keratic precipitates		2
Keratitis		2
Keratosis pilaris		1
Kidney infection	3	4
Knee operation		1
Labile hypertension		1
Laboratory test abnormal		1
Labyrinthitis	1	2
Lack of spontaneous speech		1
Lacrimation increased	6	25
Lacunar stroke		1
Large intestine infection		1
Laryngeal oedema		1
Laryngeal pain		1
Laryngitis	1	3
Latent autoimmune diabetes in adults		1
Laziness		1
Left ventricular hypertrophy	1	1
Lethargy	18	76
Leukocytosis		1
Ligament injury	1	1
Ligament rupture	1	1
Ligament sprain		1
Limb discomfort	24	84
Limb injury	1	7
Limb mass	1	4
Lipase increased		1
Lip blister	1	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	15	1	5
		3	15		2
		9	42	3	10
			1		
					2
					2
			1		
				3	4
					1
			1		
			1		
				1	2
					1
		6	23		2
					1
					1
					1
			1		
			2	1	1
					1
			1		
		1	1		
		18	73		3
					1
		1	1		
		1	1		
			1		
		23	79	1	5
		1	7		
		1	4		
			1		
			3	1	5

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lip disorder	3	3
Lip dry	1	2
Lip erythema		2
Lipids increased		1
Lip injury	1	3
Lip oedema		1
Lip pain	3	6
Lip pruritus		8
Lip swelling	20	78
Liquid product physical issue		4
Listless		1
Livedo reticularis		2
Liver disorder		1
Liver function test abnormal		1
Liver function test increased	1	3
Liver injury		1
Localised infection		2
Localised oedema		2
Loss of consciousness	39	102
Loss of personal independence in daily activities	9	40
Low density lipoprotein increased	1	1
Lower limb fracture		1
Lower respiratory tract congestion		1
Lower respiratory tract infection	1	3
Lung carcinoma cell type unspecified stage I		1
Lung disorder	5	7
Lung opacity		2
Lyme disease	1	1
Lymphadenitis		5
Lymphadenopathy	59	293
Lymph node pain	8	64
Lymphoblast count		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	3		
		1	1		1
			1		1
			1		
		1	2		1
					1
		3	6		
			3		5
		14	54	6	24
			4		
			1		
			1		1
					1
					1
		1	3		
					1
			2		
			2		
				39	102
		7	34	2	6
		1	1		
					1
			1		
				1	3
					1
		2	3	3	4
			2		
				1	1
			3		2
	1	52	265	7	28
		6	55	2	9
			1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lymphocyte count abnormal		2
Lymphocyte count decreased	3	4
Lymphocyte count increased	2	3
Lymphoedema		3
Lymphoma		1
Macroglossia		1
Macular hole		1
Macule	1	1
Maculopathy		1
Madarosis		1
Major depression	1	1
Malaise	89	440
Mammogram abnormal		1
Mania	1	1
Mass	9	21
Mastication disorder		2
Mastoid disorder		1
Mean cell haemoglobin increased	1	1
Mean cell volume increased	2	3
Mean platelet volume decreased		2
Measles	1	2
Medication error		1
Meibomian gland dysfunction		1
Memory impairment	8	24
Meniere's disease		3
Meningitis	1	2
Meningitis viral		1
Menstrual disorder	8	9
Menstruation irregular		1
Mental disorder	2	5
Mental fatigue	1	2
Mental impairment	4	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
		1	2	2	2
		1	2	1	1
			3		
					1
					1
					1
		1	1		
					1
			1		
				1	1
		85	417	4	23
			1		
		1	1		
		7	18	2	3
			2		
			1		
		1	1		
		2	3		
			2		
				1	2
			1		
					1
		8	18		6
					3
				1	2
					1
		5	6	3	3
			1		
		2	4		1
		1	2		
				4	9

* I=Interval, C=Cumulative

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mental status changes		1
Meralgia paraesthetica		1
Mesenteric artery aneurysm		1
Mesenteric panniculitis		1
Metamorphopsia	1	1
Metastases to meninges		1
Methylenetetrahydrofolate reductase gene mutation		1
Micturition urgency	1	2
Middle insomnia	2	12
Migraine	21	87
Migraine with aura		1
Miliaria	1	1
Miosis		1
Mitral valve prolapse		1
Moaning	1	1
Mobility decreased	8	30
Monoplegia	3	5
Mood altered	1	2
Mood swings		1
Morning sickness		1
Motion sickness		5
Motor dysfunction	1	4
Mouth haemorrhage		1
Mouth swelling	1	8
Mouth ulceration	3	5
Movement disorder	15	43
Mucosal disorder	1	3
Mucosal dryness	1	2
Mucosal inflammation	1	1
Mucosal pain	1	1
Mucosa vesicle		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
					1
					1
				1	1
					1
			1		
		1	1		1
		2	11		1
		18	76	3	11
			1		
		1	1		
			1		
					1
		1	1		
		6	25	2	5
				3	5
		1	2		
			1		
					1
			5		
		1	3		1
			1		
		1	5		3
		3	5		
		14	37	1	6
		1	1		2
		1	2		
				1	1
		1	1		
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mucous stools		2
Multi-organ disorder		1
Multiple fractures		1
Multiple organ dysfunction syndrome		1
Multiple sclerosis		1
Multiple sclerosis relapse	2	5
Muscle atrophy		2
Muscle contractions involuntary		3
Muscle contracture		2
Muscle discomfort		3
Muscle disorder		6
Muscle fatigue	2	7
Muscle injury		1
Muscle mass		1
Muscle rigidity	3	4
Muscle rupture		1
Muscle spasms	31	111
Muscle spasticity	1	3
Muscle strain	3	5
Muscle swelling	2	5
Muscle tightness	10	36
Muscle twitching	9	29
Muscular weakness	23	83
Musculoskeletal chest pain	6	17
Musculoskeletal discomfort	5	27
Musculoskeletal disorder	2	3
Musculoskeletal pain	1	6
Musculoskeletal stiffness	21	76
Myalgia	100	525
Myasthenia gravis		2
Mydriasis		3
Myelitis transverse		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
					1
					1
					1
				2	5
			2		
			3		
			2		
			3		
			6		
		2	6		1
			1		
			1		
		3	4		
					1
		29	96	2	15
		1	3		
		3	4		1
		2	3		2
		10	33		3
		9	25		4
		12	58	11	25
		4	14	2	3
		3	22	2	5
		2	2		1
		1	4		2
		21	75		1
		93	484	7	41
			3		2
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myelopathy		1
Myocardial infarction	7	22
Myocardial necrosis marker increased		2
Myocarditis		2
Myoclonus	1	3
Myokymia		1
Myosclerosis	1	1
Myositis	2	2
Nail discolouration		2
Narcolepsy		1
Nasal congestion	15	85
Nasal discomfort	3	12
Nasal disorder		1
Nasal dryness	1	2
Nasal injury		1
Nasal oedema	2	6
Nasal pruritus	3	4
Nasopharyngitis	16	84
Nausea	152	823
Near death experience	4	10
Neck injury		1
Neck mass	1	5
Neck pain	35	152
Necrotising retinitis		1
Needle issue		1
Neoplasm		1
Neoplasm malignant		1
Nephrolithiasis	1	10
Nerve compression		5
Nerve injury	5	9
Nervousness	15	44
Nervous system disorder	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1	7	21
					2
					2
				1	3
			1		
				1	1
		2	2		
			2		
					1
		14	78	1	7
		3	10		2
					1
		1	2		
			1		
		1	3	1	3
		3	4		
		15	81	1	3
		138	738	14	85
				4	10
			1		
		1	5		
		33	139	2	13
					1
					1
			1		
					1
				1	10
			4		1
		2	5	3	4
		14	43	1	1
		1	1		3

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neuralgia	11	34
Neuritis	1	3
Neurological procedural complication	1	1
Neurological symptom	2	8
Neuropathy peripheral	8	22
Neutropenia		1
Neutrophil count abnormal		1
Neutrophil count decreased	1	1
Neutrophil count increased	1	1
Nightmare		9
Night sweats	7	33
Nipple pain		1
No adverse event	3	7
Nodule	2	11
Noninfective encephalitis		1
Noninfective gingivitis		1
Non-pitting oedema		1
Nonspecific reaction		1
Norepinephrine increased		1
Nuchal rigidity		1
Nucleated red cells	1	1
Nystagmus		1
Obstructive airways disorder		1
Occipital neuralgia		1
Occupational exposure to SARS-CoV-2		2
Ocular discomfort	5	16
Ocular hyperaemia	6	33
Ocular icterus		1
Ocular ischaemic syndrome	1	1
Ocular vascular disorder		1
Odynophagia		7
Oedema		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		8	26	3	8
		1	3		
		1	1		
			5	2	3
				8	22
					1
					1
		1	1		
		1	1		
			8		1
		7	31		2
			1		
		3	7		
		2	11		
					1
			1		
					1
			1		
			1		
		1	1		
			1		
					1
					1
			2		
		5	16		
		5	27	1	6
			1		
				1	1
					1
			6		1
			4		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oedema mucosal	1	1
Oedema peripheral	3	7
Oesophageal disorder		1
Oesophageal irritation	1	1
Oesophageal spasm	1	1
Oesophagitis	1	1
Off label use	23	89
Oligomenorrhoea	2	2
Onychalgia		1
Onychoclasia		2
Ophthalmic herpes zoster	1	1
Ophthalmic migraine		2
Optic nerve disorder		1
Optic neuritis		1
Oral blood blister		1
Oral candidiasis	1	3
Oral discomfort	3	11
Oral disorder		3
Oral herpes	9	21
Oral mucosal blistering	4	7
Oral mucosal eruption		2
Oral mucosal erythema	1	5
Oral mucosal exfoliation		1
Oral mucosal roughening		1
Oral pain	5	17
Oral pruritus	2	6
Oral viral infection		1
Organising pneumonia		1
Oropharyngeal blistering	1	2
Oropharyngeal discomfort	5	22
Oropharyngeal pain	21	133
Oropharyngeal spasm		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		3	6		1
					1
		1	1		
		1	1		
		1	1		
		23	89		
		2	2		
			1		
			2		
				1	1
			2		
					1
					1
					1
		1	3		
		1	7	2	4
			2		1
		9	20		1
		4	7		
			2		
			3	1	2
			1		
			1		
		5	16		1
		2	4		2
			1		
					1
				1	2
		4	21	1	1
		19	124	2	9
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Orthostatic heart rate response increased		1
Orthostatic hypotension		3
Osteoarthritis		2
Osteogenesis imperfecta		1
Osteomyelitis		1
Osteopenia	1	1
Otitis media		1
Overdose	4	25
Overweight	1	3
Ovulation disorder	1	1
Oxygen consumption decreased	1	1
Oxygen saturation abnormal		1
Oxygen saturation decreased	4	21
Pain	231	1,093
Painful respiration		2
Pain in extremity	263	1,092
Pain in jaw	5	36
Pain of skin	3	11
Palatal disorder		1
Palatal swelling	2	6
Pallor	4	18
Palmar erythema		1
Palpitations	30	139
Pancreatic disorder		2
Pancreatitis	1	3
Pancreatitis acute	2	4
Pancreatitis relapsing		1
Panic attack	1	10
Panic disorder		1
Panic reaction	1	5
Panniculitis	1	1
Papule		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2		1
			2		
					1
					1
		1	1		
			1		
		4	24		1
		1	3		
		1	1		
				1	1
			1		
		2	12	2	9
		214	1018	17	75
			1		1
	1	239	1020	24	72
	1	4	31	1	5
		3	9		2
			1		
		1	3	1	3
		4	15		3
			1		
		25	117	5	22
			1		1
				1	3
				2	4
					1
		1	9		1
			1		
		1	5		
				1	1
			2		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Paraesthesia	65	280
Paraesthesia oral	10	81
Paralysis	3	7
Paranasal sinus discomfort	2	6
Paranasal sinus hypersecretion	2	5
Paranasal sinus hyposcretion		1
Paranoia	1	3
Paranoid personality disorder		1
Parkinson's disease	1	2
Parosmia	3	18
Parotitis	1	1
Patient elopement	1	1
Pelvic inflammatory disease		1
Pelvic pain	2	6
Pemphigoid		1
Pericardial effusion	4	6
Pericarditis	7	9
Periorbital cellulitis		1
Periorbital discomfort		1
Periorbital disorder		2
Periorbital oedema		1
Periorbital pain		1
Periorbital swelling	2	12
Peripheral artery thrombosis		1
Peripheral coldness	7	29
Peripheral ischaemia		1
Peripheral paralysis		1
Peripheral sensory neuropathy		1
Peripheral swelling	45	178
Peroneal nerve palsy	1	4
Personality change	1	2
Pertussis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		55	236	10	44
		8	66	2	15
				3	7
		1	5	1	1
		2	5		
			1		
		1	3		
			1		
				1	2
		2	15	1	3
		1	1		
		1	1		
					1
		1	5	1	1
					1
				4	6
				7	9
					1
			1		
			2		
					1
					1
		1	9	1	3
			1		
		5	24	2	5
					1
					1
			1		
	1	33	150	12	28
		1	4		
		1	2		
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Petechiae	4	11
Pharyngeal erythema		4
Pharyngeal haemorrhage		1
Pharyngeal hypoaesthesia		4
Pharyngeal inflammation		1
Pharyngeal mass		3
Pharyngeal oedema		1
Pharyngeal paraesthesia		6
Pharyngeal swelling	13	60
Pharyngitis streptococcal	1	4
Phlebitis superficial	1	1
Photophobia	4	22
Photopsia	2	4
Photosensitivity reaction	2	7
Physical deconditioning		1
Piloerection	2	4
Platelet count abnormal		1
Platelet count decreased	2	14
Platelet count increased	1	2
Pleural effusion	2	5
Pleurisy	1	2
Pneumonia	5	21
Pneumonia aspiration	2	3
Pneumonia bacterial	1	1
Pneumonia viral	1	2
Pneumonitis	2	4
PO2 decreased		1
Pollakiuria	2	10
Polymyalgia rheumatica		1
Polymyositis		1
Polyneuropathy		1
Polyuria	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4	3	7
			4		
					1
			2		2
			1		
			3		
					1
			3		3
		8	37	5	23
		1	3		1
		1	1		
		4	21		1
		2	3		1
		2	6		1
			1		
		2	4		
			1		
		1	7	1	7
		1	1		1
				2	5
			1	1	1
1	1			5	21
				2	3
				1	1
				1	2
		1	2	1	2
					1
		2	10		
					1
					1
					1
		1	4		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Poor peripheral circulation		2
Poor quality product administered	8	27
Poor quality sleep	2	13
Portal vein thrombosis		2
Post concussion syndrome	1	1
Postmenopausal haemorrhage	8	14
Post-traumatic neck syndrome		2
Postural orthostatic tachycardia syndrome		2
Posture abnormal		1
Posturing		1
Potentiating drug interaction	3	10
Pre-existing condition improved		2
Premenstrual syndrome		1
Prescr bed overdose		1
Presyncope	10	41
Prinzmetal angina		2
Procedural pain		1
Proctalgia		1
Product administered at inappropriate site	2	16
Product administration error		4
Product dispensing issue		1
Product dose omission issue	6	15
Productive cough	3	19
Product leakage		1
Product odour abnormal		1
Product preparation error	2	12
Product preparation issue	2	13
Product quality issue		4
Product storage error	4	10
Product supply issue	1	5
Product temperature excursion issue	4	8
Product use issue	3	40

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
		8	27		
		2	13		
					2
		1	1		
				8	14
					2
			1		1
			1		
					1
		3	10		
			2		
			1		
			1		
		7	27	3	14
					2
			1		
			1		
		2	16		
			4		
			1		
		6	15		
		2	17	1	2
			1		
			1		
		2	12		
		2	11		2
			4		
		4	10		
		1	5		
		4	8		
		3	40		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Prostate infection	1	2
Prostatitis	1	1
Protein total decreased		2
Prothrombin time prolonged		1
Pruritus	106	380
Pruritus genital		1
Pseudomonas infection		1
Psoriasis	1	3
Psoriatic arthropathy		3
Psychiatric symptom		1
Psychomotor hyperactivity		2
Psychotic disorder	1	2
Pulmonary congestion	2	7
Pulmonary embolism	8	28
Pulmonary fibrosis		1
Pulmonary oedema	2	7
Pulmonary pain	6	12
Pulmonary thrombosis	8	14
Pulse abnormal	1	4
Pulse absent		1
Pulse pressure increased	2	2
Pupillary disorder		2
Purpura	1	2
Pustule		4
Pyrexia	216	1,173
Quality of life decreased		1
Radial nerve palsy		1
Radial pulse abnormal	1	1
Rash	93	352
Rash erythematous	9	53
Rash macular	9	42
Rash maculo-papular	1	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
				1	1
			2		
			1		
		85	316	21	64
					1
					1
		1	3		
					3
			1		
			1		1
		1	2		
				2	7
				8	28
					1
		1	1	1	6
		6	8		4
				8	14
		1	4		
					1
		2	2		
			2		
		1	2		
			3		1
		197	1084	19	89
			1		
			1		
				1	1
		68	288	25	64
		7	46	2	7
		9	40		2
		1	6		1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rash morbilliform		3
Rash papular	8	21
Rash pruritic	12	48
Rash pustular	1	1
Rash vesicular	3	10
Raynaud's phenomenon	2	5
Reaction to excipient		1
Reactogenicity event		1
Rectal haemorrhage	1	4
Rectal tenesmus		1
Red blood cell count decreased	1	2
Red blood cell count increased	1	2
Red blood cell sedimentation rate increased		1
Red cell distribution width decreased		1
Red ear syndrome	1	1
Reduced facial expression	1	2
Reflux gastritis	1	1
Renal cyst		1
Renal disorder	1	3
Renal failure	1	2
Renal function test abnormal	1	1
Renal impairment	2	3
Renal pain	3	12
Repetitive speech	1	1
Respiration abnormal	1	7
Respiratory arrest	1	3
Respiratory disorder	3	9
Respiratory distress		14
Respiratory failure		1
Respiratory rate decreased	1	2
Respiratory rate increased	1	7
Respiratory symptom		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		
		7	20	1	1
		10	41	2	7
				1	1
		3	10		
		2	5		
					1
			1		
				1	4
			1		
			1	1	1
		1	2		
			1		
			1		
		1	1		
				1	2
		1	1		
			1		1
				1	2
		1	1		
				2	3
		2	10	1	2
		1	1		
		1	7		
				1	3
		3	6		3
					14
					1
		1	1		1
		1	4		3
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory tract congestion	2	7
Respiratory tract infection		2
Respiratory tract oedema	1	3
Restless legs syndrome		4
Restlessness		12
Retching	4	10
Retinal aneurysm	1	1
Retinal detachment	1	3
Retinal tear		3
Retinal vascular thrombosis		1
Retinal vein occlusion	2	2
Retinitis		1
Rhabdomyolysis	1	1
Rheumatoid arthritis	3	15
Rhinalgia		4
Rhinorrhoea	17	89
Rhinovirus infection		1
Rib fracture		1
Road traffic accident	1	2
Root canal infection		1
Rosacea	1	4
Rotator cuff syndrome	1	1
Rubella		1
Salivary gland enlargement	1	1
Salivary gland pain	1	3
Salivary hypersecretion		4
Sarcoidosis		1
SARS-CoV-2 ant body test		1
SARS-CoV-2 ant body test negative		13
SARS-CoV-2 ant body test positive	1	4
SARS-CoV-2 test		1
SARS-CoV-2 test false positive		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	7		
					2
				1	3
			4		
			10		2
		1	6	3	4
				1	1
		1	1		2
					3
					1
				2	2
					1
				1	1
3	4			3	15
			3		1
		17	82		7
			1		
					1
		1	1		1
			1		
			3	1	1
				1	1
			1		
				1	1
		1	3		
			1		3
					1
			1		
			12		1
		1	4		
			1		
			1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
SARS-CoV-2 test positive	6	39
Scab	3	6
Scar	1	2
Schwannoma		1
Sciatica		3
Scleral haemorrhage		1
Scleritis		1
Scleroderma		1
Scratch	1	8
Screaming		2
Scrotal dermatitis		1
Scrotal infection		1
Seasonal allergy	1	1
Seborrhoea		1
Secretion discharge	4	9
Sedation		1
Seizure	12	32
Seizure like phenomena		1
Sensation of blood flow		1
Sensation of foreign body	1	8
Sensitisation		1
Sensitive skin	1	3
Sensitivity to weather change		1
Sensory disturbance	3	8
Sensory level abnormal		1
Sensory loss	2	12
Sepsis	1	4
Serotonin syndrome		1
Serum ferritin decreased		1
Serum ferritin increased		1
Shock		4
Shock hypoglycaemic	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	16	1	23
		3	5		1
		1	1		1
					1
			3		
					1
					1
					1
			6	1	2
			1		1
			1		
					1
		1	1		
			1		
		1	4	3	5
			1		
				12	32
					1
			1		
		1	7		1
			1		
		1	3		
			1		
		3	8		
			1		
		2	9		3
				1	4
					1
					1
			1		
					4
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Shoulder injury related to vaccine administration		1
Sialoadenitis		1
Sickle cell anaemia with crisis		2
Sinus congestion	3	17
Sinus disorder	2	16
Sinus headache	1	10
Sinusitis	5	24
Sinus pain	2	8
Sinus tarsi syndrome		1
Sitting disability		1
Skeletal injury		1
Skin abrasion	1	1
Skin atrophy	1	1
Skin bacterial infection	1	1
Skin burning sensation	4	18
Skin discolouration	7	23
Skin disorder	6	20
Skin erosion		1
Skin exfoliation	4	11
Skin fissures	1	2
Skin haemorrhage		3
Skin irritation	2	9
Skin laceration	2	2
Skin lesion	3	7
Skin lesion removal		1
Skin mass	5	7
Skin odour abnormal	1	2
Skin reaction	2	4
Skin sensitisation	1	3
Skin swelling	2	4
Skin tightness		4
Skin ulcer	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
					2
		3	16		1
		1	15	1	1
		1	10		
		3	19	2	5
		2	8		
			1		
			1		
			1		
		1	1		
		1	1		
		1	1		
		4	18		
		6	19	1	4
		5	16	1	4
			1		
		2	8	2	3
		1	2		
			3		
		2	9		
		2	2		
		3	7		
			1		
		4	6	1	1
		1	2		
		2	4		
		1	3		
		1	3	1	1
			4		
		1	2		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin warm		1
Skin wrinkling		1
Sleep attacks		1
Sleep deficit		3
Sleep disorder	8	36
Sleep disorder due to a general medical condition	1	4
Sleep disorder due to general medical condition, insomnia type	1	1
Sleep talking		1
Sleep terror		1
Slow speech		1
Sluggishness	1	11
Small intestinal obstruction		2
Sneezing	9	42
Snoring		1
Soft tissue injury		1
Somnolence	31	111
Speech disorder	7	31
Speech disorder developmental	2	2
Spinal cord disorder	2	2
Spinal disorder		1
Spinal pain		6
Spleen disorder	1	1
Splenomegaly		2
Splinter		1
Spondylitis		1
Sputum discoloured		2
Staphylococcal skin infection		1
Staring	1	1
Status asthmaticus		1
Stevens-Johnson syndrome	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
			1		
			3		
		8	35		1
		1	4		
		1	1		
			1		
			1		
		1	10		1
					2
		7	38	2	4
			1		
			1		
		28	104	3	7
		5	21	2	10
		2	2		
				2	2
			1		
			4		2
		1	1		
			1		1
			1		
					1
			1		1
					1
				1	1
					1
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Stiff tongue		1
Stomatitis	7	18
Streptococcal infection		1
Streptococcal urinary tract infection	1	1
Stress	1	13
Stress urinary incontinence	1	1
Stridor		7
Subarachnoid haemorrhage	1	1
Subclavian vein thrombosis	1	1
Subcutaneous abscess		2
Subdural haemorrhage		1
Sudden hearing loss		2
Sudden visual loss		1
Suicidal behaviour	1	1
Suicidal ideation	2	8
Sunburn	2	4
Supraventricular extrasystoles		2
Supraventricular tachycardia		2
Surgery	1	1
Suspected counterfeit product		1
Suspected COVID-19	10	34
Sweating fever		1
Swelling	32	141
Swelling face	36	134
Swelling of eyelid	8	20
Swollen tongue	9	57
Syncope	19	61
Syndactyly	1	1
Systemic lupus erythematosus		1
Tachycardia	5	59
Tachyphrenia		3
Tachypnoea		10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		5	14	2	4
			1		
				1	1
		1	13		
		1	1		
			4		3
				1	1
				1	1
					2
					1
					2
					1
				1	1
		1	1	1	7
		1	3	1	1
			1		1
					2
		1	1		
			1		
		5	14	5	20
					1
		22	113	10	28
		24	98	12	36
		4	14	4	6
	1	6	30	3	27
		1	1	18	60
				1	1
					1
		3	38	2	21
			3		
			8		2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Taste disorder	3	31
Tearfulness		2
Temperature intolerance		2
Temporomandibular joint syndrome		1
Tenderness	4	27
Tendonitis	1	3
Tendon pain		1
Tendon rupture	1	1
Tenosynovitis		1
Tension		1
Tension headache	4	8
Testicular disorder	1	1
Testicular pain	2	5
Testicular swelling	1	1
Therapeutic product effect prolonged		1
Therapeutic response unexpected	7	27
Thermal burn	2	3
Thinking abnormal	6	19
Thirst	5	25
Thirst decreased		1
Thoracic outlet syndrome		1
Throat clearing	1	1
Throat irritation	12	45
Throat tightness	9	76
Thrombocytopenia	5	10
Thrombophlebitis superficial		3
Thrombosis	42	79
Thyroid disorder	3	5
Thyroid function test abnormal		2
Thyroiditis acute		1
Thyroiditis subacute		1
Thyroid mass	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	28		3
			2		
			2		
					1
		4	25		2
		1	2		1
			1		
				1	1
			1		
			1		
		4	8		
		1	1		
		2	4		1
		1	1		
			1		
		7	27		
		2	3		
		6	19		
		5	24		1
			1		
			1		
		1	1		
		10	34	2	11
		6	43	3	33
				5	10
			2		1
				42	79
		1	3	2	2
			2		
					1
			1		
		1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Thyroid pain		2
Thyroxine decreased		1
Tinnitus	41	155
Tongue blistering	1	3
Tongue coated	1	2
Tongue discolouration		3
Tongue discomfort	3	11
Tongue disorder	4	10
Tongue dry		3
Tongue erythema	1	2
Tongue injury		1
Tongue oedema		1
Tongue paralysis		2
Tongue pruritus	2	6
Tongue ulceration		3
Tonsillar disorder	1	2
Tonsillitis		2
Tooth abscess	1	2
Toothache	6	23
Tooth disorder		2
Tooth fracture	1	3
Tooth infection	1	4
Tooth loss		1
Torticollis		1
Tracheal obstruction		1
Tracheal stenosis	1	1
Tracheitis		1
Tracheomalacia		1
Transient ischaemic attack	3	12
Transverse sinus thrombosis	1	1
Tremor	26	143
Trigeminal nerve disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
			1		
		30	110	11	45
		1	2		1
		1	2		
			2		1
		2	9	1	2
		4	8		2
			3		
			1	1	1
			1		
					1
					2
		1	4	1	2
			2		1
			1	1	1
			2		
				1	2
		6	20		3
			2		
		1	3		
		1	4		
					1
			1		
					1
				1	1
			1		
					1
				3	12
				1	1
		22	114	4	29
					1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Trigeminal neuralgia	1	2
Trigger finger	1	3
Tri-iodothyronine decreased		1
Trismus		1
Troponin abnormal		1
Troponin I decreased		1
Troponin increased		6
Tumour pain	1	1
Tunnel vision	1	6
Type 1 diabetes mellitus	1	2
Type 2 diabetes mellitus		1
Type I hypersensitivity	1	1
Type III immune complex mediated reaction		1
Ulcer	1	2
Underdose	4	17
Underweight	1	1
Unresponsive to stimuli		3
Upper-airway cough syndrome		8
Upper airway obstruction		2
Upper limb fracture		2
Upper respiratory tract congestion	3	19
Upper respiratory tract infection		3
Urethritis noninfective	1	1
Urge incontinence		1
Urinary bladder haemorrhage	1	1
Urinary incontinence		5
Urinary retention	4	5
Urinary tract disorder		1
Urinary tract infection	7	19
Urinary tract infection bacterial		1
Urine analysis abnormal		3
Urine odour abnormal	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
		1	3		
			1		
			1		
					1
			1		
			3		3
				1	1
				1	6
				1	2
					1
				1	1
					1
			1	1	1
		4	16		1
		1	1		
					3
			8		
					2
			1		1
		3	19		
			3		
		1	1		
			1		
				1	1
			5		
				4	5
			1		
		4	12	3	7
					1
			3		
		2	2		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Urine output decreased	1	2
Urticaria	73	229
Use of accessory respiratory muscles		3
Uterine inflammation		1
Uterine pain	1	1
Uveitis		3
Vaccination complication		1
Vaccination failure	7	22
Vaccination site bruising	6	22
Vaccination site cellulitis		4
Vaccination site coldness		1
Vaccination site cyst	1	1
Vaccination site discharge	2	2
Vaccination site discolouration	5	7
Vaccination site discomfort	5	11
Vaccination site erythema	22	115
Vaccination site exfoliation	1	2
Vaccination site extravasation	1	1
Vaccination site haemorrhage	5	13
Vaccination site hyperaesthesia	1	1
Vaccination site hypoaesthesia	1	5
Vaccination site induration		7
Vaccination site infection		3
Vaccination site inflammation	1	4
Vaccination site injury		1
Vaccination site irritation		3
Vaccination site joint movement impairment		6
Vaccination site joint pain	1	3
Vaccination site lymphadenopathy		2
Vaccination site macule		2
Vaccination site mass	6	34
Vaccination site movement impairment	2	19

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
		57	166	16	63
			1		2
					1
		1	1		
					3
			1		
				7	22
		6	22		
			2		2
			1		
		1	1		
		2	2		
		5	7		
		5	11		
		20	106	2	9
		1	2		
		1	1		
		4	11	1	2
		1	1		
			3	1	2
			7		
			3		
		1	4		
			1		
			3		
			5		1
		1	3		
			2		
			2		
		4	32	2	2
		1	17	1	2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site nerve damage	1	1
Vaccination site nodule	3	5
Vaccination site oedema		2
Vaccination site pain	121	733
Vaccination site pallor		1
Vaccination site papule	1	1
Vaccination site paraesthesia	1	5
Vaccination site pruritus	7	53
Vaccination site pustule		1
Vaccination site rash	7	24
Vaccination site reaction	4	9
Vaccination site swelling	20	128
Vaccination site urticaria	2	9
Vaccination site vesicles		3
Vaccination site warmth	10	54
Vaginal discharge		1
Vaginal haemorrhage	4	13
Vaginal infection		1
Vaginal lesion	1	1
Varicella	1	2
Varicella zoster virus infection	1	2
Varicose vein		1
Vascular injury	1	1
Vascular occlusion		1
Vasculitic rash		1
Vasculitis		1
Vasodilatation	1	1
Vein disorder	5	6
Vein rupture		1
Vein wall hypertrophy	1	1
Ventricular extrasystoles	1	10
Vertigo	25	112

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		2	4	1	1
					2
	1	119	714	2	19
			1		
		1	1		
			4	1	1
		5	49	2	4
			1		
		5	19	2	5
		4	9		
		19	124	1	4
		2	9		
			3		
		8	50	2	4
			1		
		2	9	2	4
					1
				1	1
		1	2		
		1	2		
					1
				1	1
					1
			1		
			1		
		1	1		
		5	6		
					1
				1	1
		1	5		5
		21	96	4	16

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vertigo positional		2
Vestibular disorder	1	1
Vestibular migraine		1
Vibratory sense increased		1
Viral infection	3	4
Vision blurred	22	81
Visual acuity reduced		3
Visual field defect	1	4
Visual impairment	12	39
Vitamin D decreased		2
Vitamin D deficiency		2
Vlth nerve paralysis	1	4
Vitreous detachment		1
Vitreous floaters	3	6
Vocal cord disorder		1
Vocal cord inflammation	1	1
Vocal cord paresis		1
Vomiting	62	263
Vulvovaginal burning sensation		1
Vulvovaginal mycotic infection		1
Vulvovaginal pain		1
Vulvovaginal pruritus		1
Vulvovaginal rash		1
Vulvovaginal swelling		1
Wa king aid user		1
Wa king disability		1
Weight bearing difficulty	1	3
Weight decreased	12	39
Weight fluctuation	1	4
Weight increased	3	10
Wheezing	10	52
White blood cell count decreased	2	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		1	1		
			1		
			1		
		1	2	2	2
		17	59	5	22
			2		1
		1	3		1
		8	29	4	10
			2		
			2		
				1	4
					1
		2	4	1	2
					1
				1	1
			1		
		48	204	14	59
					1
			1		
			1		
					1
					1
					1
			1		
		1	2		1
		11	31	1	8
		1	4		
		3	9		1
		9	35	1	17
		1	5	1	2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
White blood cell count increased	4	13			3	11	1	2
White blood cells urine	1	1			1	1		
Wound		3				3		
Wound haemorrhage		3				2		1
Wound infection		1						1
Wrong product administered	6	10			6	10		
Wrong technique in product usage process	3	15			3	15		
Yawning	1	1			1	1		
Yellow skin		1				1		
	7,094	31,042	21	37	5588	25235	1506	5807

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal abscess		1						1
Abdominal discomfort	18	107			17	102	1	5
Abdominal distension	3	24			3	22		2
Abdominal infection		1						1
Abdominal pain	8	62			7	51	1	11
Abdominal pain lower	1	4				1	1	3
Abdominal pain upper	21	119			18	108	3	11
Abdominal rigidity		1				1		
Abdominal symptom		1				1		
Abdominal tenderness	1	2			1	2		
Abdominal wall haematoma		1						1
Abdominal wall haemorrhage		1						1
Abnormal behaviour	1	4			1	4		
Abnormal clotting factor		1						1
Abnormal dreams	1	12			1	10		2
Abnormal faeces	1	3				2	1	1
Abnormal sensation in eye		3				3		
Abscess		1						1
Acarodermatitis		1						1
Accident		1						1
Accidental exposure to product		5				5		
Accidental overdose		3				3		
Accidental underdose		1				1		
Achlorhydria		1				1		
Acidosis		1						1
Acne	3	8			3	8		
Acoustic neuritis		1						1
Activated partial thromboplastin time prolonged		2				2		
Acute febrile neutrophilic dermatosis		1						1
Acute hepatic failure		1						1
Acute kidney injury		5						5
Acute myeloid leukaemia		1						1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acute myocardial infarction		2
Acute respiratory distress syndrome		1
Acute respiratory failure	1	2
Acute stress disorder	1	1
Adhesion		1
Administration site irritation		1
Adnexa uteri pain		1
Adrenal insufficiency		2
Adrenocortical insufficiency acute		1
Adverse drug reaction		1
Adverse event	1	3
Affective disorder		1
Ageusia	8	48
Agitation	1	5
Agnosia	1	1
Agonal respiration	1	1
Alanine aminotransferase abnormal		1
Alanine aminotransferase increased	1	4
Allergic reaction to excipient	1	4
Allergy to arthropod sting		2
Allergy to vaccine	1	16
Allodynia		1
Alopecia	2	16
Altered state of consciousness		2
Altered visual depth perception		1
Ammonia increased		1
Amnesia	1	13
Anaemia	2	5
Anaemia vitamin B12 deficiency		1
Anal haemorrhage		1
Anal incontinence	1	4
Anal infection		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
				1	2
		1	1		
					1
			1		
			1		
					2
					1
			1		
		1	3		
			1		
		7	42	1	6
		1	5		
		1	1		
				1	1
			1		
			3	1	1
		1	4		
			2		
			13	1	3
			1		
		2	14		2
					2
			1		
					1
		1	9		4
		1	2	1	3
			1		
			1		
		1	4		
			1		

* I=Interval, C=Cumulative

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anaphylactic reaction	10	42
Anaphylactic shock		3
Anaphylactoid reaction		1
Aneurysm	1	2
Anger	2	3
Angina pectoris	2	18
Angina unstable		1
Angioedema	1	14
Angiokeratoma		1
Angiolymphoid hyperplasia with eosinophilia		1
Angiopathy		1
Angle closure glaucoma		1
Angular cheilitis		1
Ankle fracture		1
Anorectal discomfort		2
Anosmia	3	29
Antibody test abnormal		1
Antibody test negative		2
Anxiety	14	67
Apathy	1	4
Aphasia	3	14
Aphonia	2	10
Aphthous ulcer	2	2
Apnoea		1
Appendicitis	1	9
Appendicitis perforated		2
Appetite disorder		2
Apraxia	1	1
Aptyalism		1
Arachnoid cyst		1
Areflexia		1
Arrhythmia		18

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				10	42
					3
					1
				1	2
		2	3		
				2	18
					1
				1	14
			1		
			1		
			1		
					1
			1		
					1
			2		
		3	24		5
			1		
			2		
		13	61	1	6
		1	3		1
		1	6	2	8
		1	6	1	4
		2	2		
					1
				1	9
					2
			2		
		1	1		
			1		
					1
					1
					18

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arrhythmia supraventricular		1
Arterial thrombosis		1
Arteriospasm coronary		1
Arthralgia	120	667
Arthritis	8	42
Arthropathy	6	14
Arthropod bite	2	5
Arthropod infestation		1
Arthropod sting		4
Aspartate aminotransferase increased		2
Aspiration		1
Asthenia	90	501
Asthenopia	1	7
Asthma	7	27
Asthma prophylaxis		1
Asymptomatic COVID-19	2	10
Ataxia	1	3
Atelectasis		2
Atrial fibrillation	14	65
Atrial flutter		5
Atrioventricular block	1	2
Atrioventricular block complete		1
Atypical pneumonia	1	1
Aura	1	2
Autoimmune disorder	1	7
Autoimmune haemolytic anaemia		1
Autoimmune thyroiditis		2
Autonomic nervous system imbalance		1
Autoscopy		2
Axillary mass	1	2
Axillary pain	4	23
Back disorder	5	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
		106	606	14	61
		5	37	3	5
		5	13	1	1
		2	5		
					1
			4		
			2		
					1
	1	81	425	9	76
		1	7		
		7	21		6
					1
			1	2	9
			1	1	2
			1		1
				14	65
			2		3
				1	2
					1
				1	1
		1	2		
				1	7
					1
					2
			1		
			1		1
		1	2		
		4	23		
		4	8	1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Back injury	2	4
Back pain	37	213
Bacteraemia		1
Bacterial infection		2
Bacterial test positive		1
Balance disorder	16	73
Band neutrophil count increased		1
Basal cell carcinoma		1
Basal ganglia haemorrhage		1
Basophil count abnormal		1
Bed rest		1
Bedridden	1	15
Bell's palsy	11	68
Biliary colic		1
Biliary tract disorder		1
Biopsy		1
Bipolar disorder		1
Bite		1
Bladder discomfort	1	1
Bladder disorder		2
Bladder pain		1
Blast cell count increased		1
Blepharitis		1
Blepharospasm		3
Blindness	4	15
Blindness transient	1	6
Blindness unilateral		5
Blister	7	34
Blood albumin decreased		1
Blood albumin increased		1
Blood bilirubin decreased		2
Blood bilirubin increased		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	4		
		33	183	4	30
					1
			2		
			1		
		15	63	1	10
					1
					1
					1
			1		
			1		
		1	13		2
				11	68
			1		
			1		
			1		
					1
			1		
		1	1		
			2		
			1		
					1
			1		
			3		
				4	15
				1	6
					5
		7	29		5
			1		
			1		
			2		
			2		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood blister	1	4
Blood calcium increased	1	2
Blood chloride decreased		1
Blood cholesterol		1
Blood cholesterol abnormal		1
Blood cholesterol increased		6
Blood copper increased		1
Blood count abnormal		1
Blood creatine phosphokinase increased		2
Blood creatinine increased	1	7
Blood disorder		3
Blood fibrinogen decreased		1
Blood folate decreased		1
Blood folate increased		1
Blood glucose	1	1
Blood glucose abnormal		5
Blood glucose decreased	1	15
Blood glucose increased	3	40
Blood immunoglobulin E increased		1
Blood immunoglobulin G decreased		1
Blood insulin increased		1
Blood iron decreased		2
Blood magnesium decreased		2
Blood parathyroid hormone decreased	1	1
Blood phosphorus increased	1	1
Blood potassium decreased	1	3
Blood potassium increased		1
Blood pressure abnormal	2	7
Blood pressure decreased	6	27
Blood pressure fluctuation	4	23
Blood pressure increased	23	106
Blood pressure measurement		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4		
		1	2		
			1		
			1		
			1		
			6		
			1		
			1		
					2
		1	6		1
			3		
			1		
			1		
		1	1		
			4		1
		1	9		6
		2	29	1	11
					1
			1		
			1		
			1		1
					2
		1	1		
		1	1		
		1	1		2
					1
		1	3	1	4
		5	16	1	11
		2	15	2	8
		14	62	9	44
			2		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood pressure orthostatic increased		1
Blood pressure systolic increased	2	3
Blood sodium decreased	1	3
Blood sodium increased	1	1
Blood test abnormal	1	5
Blood thyroid stimulating hormone abnormal	1	1
Blood thyroid stimulating hormone increased	1	1
Blood triglycerides increased		1
Blood urea increased		1
Blood uric acid increased		2
Blood urine present	3	12
Blue toe syndrome		1
B-lymphocyte count decreased		1
Body height decreased	2	18
Body temperature abnormal	4	12
Body temperature decreased	1	10
Body temperature fluctuation	3	6
Body temperature increased	6	56
Body tinea		1
Bone disorder		3
Bone marrow disorder	1	2
Bone pain	12	45
Bone swelling		4
Bowel movement irregularity	1	12
Bradycardia		2
Bradykinesia	1	2
Bradyphrenia	1	3
Brain death		1
Brain injury		1
Brain neoplasm	1	1
Brain oedema	1	3
Breast cancer		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	2	1	1
		1	2		1
		1	1		
		1	4		1
		1	1		
				1	1
					1
			1		1
		3	8		4
					1
			1		
		2	17		1
		4	12		
			8	1	2
		3	6		
		3	51	3	5
			1		
			2		1
		1	2		
		10	41	2	4
			3		1
		1	12		
					2
		1	2		
		1	3		
					1
					1
				1	1
				1	3
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Breast cellulitis	1	1
Breast discomfort	1	2
Breast disorder		1
Breast mass		4
Breast pain	7	32
Breast swelling		6
Breast tenderness	2	2
Bronchitis	2	15
Bronchospasm		5
Bruxism	1	1
Burning mouth syndrome		1
Burning sensation	25	85
Burn oral cavity		1
Bursa disorder		1
Bursitis	2	6
Butterfly rash		1
Candida infection		1
Capillary disorder		1
Capillary nail refill test abnormal		1
Carbohydrate antigen 125 increased		1
Carcinoembryonic antigen increased	1	1
Cardiac arrest	1	14
Cardiac discomfort		3
Cardiac disorder	2	17
Cardiac failure		1
Cardiac failure chronic		1
Cardiac failure congestive		4
Cardiac fibrillation	1	1
Cardiac flutter	6	10
Cardiac valve disease		1
Cardiomegaly	1	1
Cardiomyopathy		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	2		
			1		
			3		1
		7	31		1
			6		
		2	2		
		1	10	1	5
			3		2
		1	1		
			1		
		21	74	4	11
					1
			1		
		2	4		2
					1
			1		
			1		
			1		
				1	1
				1	14
			3		
		1	9	1	8
					1
					1
					4
				1	1
				6	10
			1		
		1	1		
					2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardio-respiratory arrest		2
Carpal tunnel syndrome		1
Cataract	4	6
Cataract nuclear		1
Cellulitis	2	15
Cerebellar haemorrhage	1	1
Cerebellar stroke		1
Cerebral artery stenosis	1	1
Cerebral atrophy	1	1
Cerebral disorder	1	3
Cerebral haematoma	1	1
Cerebral haemorrhage	2	7
Cerebral infarction		2
Cerebral palsy		1
Cerebral thrombosis	2	3
Cerebral venous sinus thrombosis	1	2
Cerebrospinal fluid leakage		1
Cerebrovascular accident	20	86
Cervical spinal stenosis	1	1
Cervicogenic vertigo	1	1
Chalazion		1
Chapped lips	1	4
Chest discomfort	19	118
Chest pain	24	133
Chillblains	1	4
Chills	186	1,119
Choking		8
Choking sensation		4
Cholelithiasis		1
Chondritis		1
Chromatopsia		3
Chromaturia		6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
			1		
				4	6
					1
				2	15
				1	1
					1
				1	1
				1	1
		1	3		
				1	1
				2	7
					2
					1
				2	3
				1	2
					1
				20	86
				1	1
		1	1		
			1		
		1	4		
		15	95	4	23
		17	89	7	44
		1	4		
1	1	175	1021	11	98
	1				8
			4		
			1		
			1		
			3		
			6		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chronic fatigue syndrome	1	1
Chronic kidney disease		1
Chronic lymphocytic leukaemia		1
Chronic obstructive pulmonary disease	2	6
Chronic sinusitis	1	2
Circadian rhythm sleep disorder		1
Circulatory collapse		2
Circumoral swelling	1	1
Circumstance or information capable of leading to device use error		1
Circumstance or information capable of leading to medication error	9	174
Clostridium difficile infection	2	2
Cluster headache		2
Coagulopathy		3
Cognitive disorder	1	7
Cold sweat	6	37
Colitis		6
Colitis ischaemic		1
Colitis ulcerative		1
Communication disorder	2	4
Concussion	3	4
Condition aggravated	35	172
Confusional state	9	45
Conjunctival haemorrhage		6
Conjunctival hyperaemia		1
Conjunctivitis		2
Conjunctivitis allergic		2
Constipation	5	26
Contraindicated product administered		1
Contraindication to medical treatment		1
Contraindication to vaccination		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
					1
	1	1	3	1	3
		1	2		
					1
					2
		1	1		
			1		
		8	173	1	1
				2	2
			1		1
			1		2
		1	4		3
		6	34		3
			5		1
					1
					1
		1	2	1	2
		1	2	2	2
		27	137	8	35
		7	30	2	15
					6
					1
			2		
			2		
		5	26		
			1		
			1		
			4		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Contrast media allergy		1
Contusion	7	56
Conversion disorder		1
Coordination abnormal	2	6
Coronary artery disease		2
Coronavirus infection		1
Costochondritis	2	2
Cough	41	232
COVID-19	91	377
COVID-19 immunisation		1
COVID-19 pneumonia	2	15
C-reactive protein increased	2	9
Crepitations	1	2
Crohn's disease	1	1
Crying		5
CSF oligoclonal band present		1
CSF protein increased		2
Cutaneous T-cell lymphoma	1	1
Cutaneous vasculitis	1	4
Cyanopsia	1	1
Cyanosis		3
Cystitis	1	10
Cytokine storm		1
Daydreaming		1
Deafness	3	15
Deafness bilateral		1
Deafness neurosensory		5
Deafness transitory		1
Deafness unilateral	8	23
Death	3	27
Decreased activity		1
Decreased appetite	39	175

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		6	47	1	9
			1		
		1	4	1	2
					2
			1		
				2	2
	1	33	210	8	22
1	2	22	104	69	273
			1		
				2	15
		1	5	1	4
		1	2		
1	1			1	1
			4		1
					1
					2
				1	1
				1	4
				1	1
			2		1
		1	8		2
					1
			1		
				3	15
					1
					5
					1
			1	8	22
	1			3	27
			1		
		34	146	5	29

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Decreased immune responsiveness	1	2
Decreased interest		1
Deep vein thrombosis	11	31
Defaecation disorder		1
Defaecation urgency		1
Deformity		1
Degenerative bone disease	1	1
Dehydration	10	49
Delirium	1	9
Delusion		4
Delusional disorder, unspecified type	1	1
Dementia		6
Demyelinating polyneuropathy		1
Dental caries		2
Dental discomfort		1
Dental paraesthesia		2
Dental restoration failure		1
Depressed level of consciousness		3
Depressed mood	3	18
Depression	1	10
Dermatitis	1	10
Dermatitis acneiform		1
Dermatitis allergic		1
Dermatitis atopic	1	2
Dermatitis contact		3
Dermatomyositis		2
Dermatophytosis of nail		1
Dermoid cyst		1
Device leakage		1
Diabetes mellitus	2	7
Diabetes mellitus inadequate control	1	1
Diabetic wound		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
			1		
				11	31
			1		
			1		
			1		
		1	1		
		3	21	7	28
				1	9
			2		2
				1	1
					6
					1
			2		
			1		
			2		
			1		
					3
	1	3	17		1
		1	9		1
		1	9		1
			1		
					1
		1	2		
			3		
					2
			1		
					1
			1		
				2	7
				1	1
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Diaphragmalgia		2
Diaphragmatic disorder		1
Diarrhoea	61	427
Diarrhoea haemorrhagic		4
Differential white blood cell count abnormal		1
Diplegia		1
Diplopia	4	16
Discomfort	11	49
Discontinued product administered		1
Disease progression		1
Disease recurrence	5	52
Disorientation	5	27
Disseminated intravascular coagulation		1
Dissociation		1
Distract bility	1	1
Disturbance in attention	2	18
Disturbance in social behaviour		1
Diverticulitis	2	11
Diverticulum intestinal		1
Dizziness	121	738
Dizziness exertional	1	1
Dizziness postural	1	15
Drainage	2	2
Drooling		3
Drowning		1
Drug abuser	1	1
Drug effective for unapproved indication		3
Drug eruption		4
Drug hypersensitivity	2	18
Drug ineffective	55	236
Drug interaction	4	13
Dry eye	2	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
			1		
	1	53	378	8	49
					4
					1
					1
		1	8	3	8
		11	49		
			1		
			1		
		4	21	1	31
		3	19	2	8
					1
			1		
		1	1		
		2	16		2
			1		
		1	1	1	10
					1
1	1	106	650	15	88
		1	1		
			12	1	3
		2	2		
			3		
					1
			3		
			3		1
		1	15	1	3
1	2			55	236
		4	10		3
		2	10		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dry mouth	8	47
Dry skin	9	23
Dry throat	2	8
Dumping syndrome		1
Dupuytren's contracture		1
Dysaesthesia	1	1
Dysarthria	4	15
Dyschezia	2	2
Dysentery		1
Dysgeusia	13	66
Dysgraphia		1
Dyskinesia		9
Dyslexia	1	1
Dyslipidaemia		1
Dyspepsia	2	27
Dysphagia	8	50
Dysphemia	3	5
Dysphonia	9	47
Dyspnoea	63	336
Dyspnoea at rest		2
Dyspnoea exertional		6
Dysstasia	8	38
Dysuria	1	8
Ear congestion	1	2
Ear discomfort	12	35
Ear disorder	2	8
Ear infection	2	9
Ear infection viral		1
Ear pain	12	46
Ear pruritus		6
Ear swelling	2	8
Eating disorder	4	22

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		8	45		2
		9	20		3
		2	8		
			1		
					1
		1	1		
		2	10	2	5
		1	1	1	1
					1
		10	60	3	6
			1		
			9		
		1	1		
			1		
		2	26		1
		6	40	2	10
		1	2	2	3
		7	33	2	14
	1	41	226	22	110
					2
			5		1
		6	25	2	13
		1	8		
		1	2		
		11	32	1	3
		2	8		
		2	9		
			1		
		11	40	1	6
			6		
		2	8		
		4	18		4

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eating disorder symptom		1
Ebola disease		1
Ecchymosis		1
Eczema		6
Ejection fraction decreased		2
Electric shock sensation	2	5
Electrocardiogram abnormal	2	2
Electrocardiogram ST segment elevation		1
Electrocardiogram T wave abnormal		1
Electrolyte imbalance		1
Embolic stroke	2	3
Embolism		1
Emotional disorder	2	7
Emphysema		2
Encephalitis		2
Encephalomalacia		1
Encephalopathy		1
Endocarditis		1
Endometriosis		1
Energy increased		4
Enlarged uvula		3
Enuresis	1	1
Eosinophil count increased		1
Eosinophilia		1
Epicondylitis	1	1
Epistaxis	9	38
Eructation		7
Erythema	49	244
Erythema multiforme	2	3
Erythema nodosum		1
Erythema of eyelid		2
Erythrospia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
			1		
			5		1
					2
		2	5		
				2	2
					1
			1		
					1
				2	3
					1
		2	7		
			1		1
					2
					1
					1
					1
			4		
			3		
		1	1		
					1
					1
		1	1		
		7	26	2	12
			7		
		43	218	6	26
				2	3
			1		
			2		
		1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Escherichia infection	1	1
Essential hypertension		1
Eustachian tube disorder		1
Eustachian tube dysfunction		1
Excessive cerumen production		3
Exercise tolerance decreased		1
Exophthalmos		1
Expired product administered	3	7
Exposure to SARS-CoV-2		13
Exposure to toxic agent		1
Exposure via skin contact		4
Extra dose administered	1	1
Extraocular muscle disorder		1
Extraocular muscle paresis		1
Extrasystoles	2	4
Eye colour change		1
Eye contusion	1	5
Eye discharge	1	4
Eye disorder	1	16
Eye haemorrhage	1	7
Eye infection		2
Eye inflammation		1
Eye irritation	3	13
Eyelid disorder		1
Eyelid function disorder		3
Eyelid oedema		2
Eyelid pain		4
Eyelid ptosis	1	5
Eyelid rash	1	1
Eyelids pruritus		2
Eye movement disorder		3
Eye oedema	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		
			1		
					1
			3		
			1		
					1
		3	7		
			13		
			1		
			4		
		1	1		
			1		
					1
		2	4		
					1
		1	5		
		1	4		
		1	13		3
				1	7
			2		
					1
		2	12	1	1
			1		
			1		2
			2		
			4		
		1	3		2
		1	1		
			2		
					3
		2	4		1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye pain	7	44
Eye pruritus	3	28
Eye swelling	6	31
Face injury		2
Face oedema		2
Facial bones fracture		1
Facial discomfort	2	5
Facial neuralgia		1
Facial pain	7	22
Facial paralysis	2	24
Facial paresis		2
Faecaloma		1
Faeces discoloured	1	9
Faeces soft	1	2
Fall	22	103
Fatigue	254	1,374
Fear	3	16
Fear of falling		1
Feeding disorder	3	17
Feeling abnormal	79	399
Feeling cold	11	90
Feeling drunk	1	7
Feeling hot	22	142
Feeling jittery	2	10
Feeling of body temperature change	6	27
Fibrin D dimer increased	1	4
Fibroblast growth factor 23 increased	1	1
Fibromyalgia	1	5
Finger deformity		1
Fistula		1
Flank pain		3
Flatulence	4	29

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		7	38		6
		3	26		2
		5	20	1	11
			2		
			2		
					1
		2	5		
			1		
		6	19	1	3
				2	24
					2
					1
		1	8		1
		1	2		
1	1	13	63	9	40
	2	238	1271	16	103
		2	14	1	2
			1		
		2	12	1	5
		74	371	5	28
		10	76	1	14
		1	6		1
		21	129	1	13
		2	9		1
		5	23	1	4
		1	3		1
		1	1		
		1	4		1
			1		
			1		
			3		
		3	27	1	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Flea infestation	1	1
Fluid intake reduced		3
Fluid overload	1	2
Fluid retention		4
Flushing	10	78
Foaming at mouth		1
Food allergy	2	2
Food aversion		1
Food poisoning		2
Foot deformity	1	2
Foot fracture		3
Foreign body in throat		2
Foreign body sensation in eyes		2
Formication	1	4
Fracture		1
Freezing phenomenon		2
Frequent bowel movements		3
Frustration tolerance decreased	1	4
Full blood count abnormal		1
Functional gastrointestinal disorder		2
Fungal infection		3
Furuncle	1	1
Gait disturbance	27	137
Gait inability	13	43
Gallbladder disorder		2
Gangrene		1
Gastric disorder	3	16
Gastric haemorrhage		1
Gastric ulcer		1
Gastritis		1
Gastritis bacterial		1
Gastroenteritis viral	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
			2		1
		1	1		1
			2		2
		8	69	2	9
			1		
		2	2		
			1		
			2		
		1	2		
			1		2
					2
			2		
		1	3		1
					1
			2		
			2		1
		1	4		
					1
			2		
			3		
		1	1		
		19	100	8	37
		7	22	6	21
			1		1
					1
		2	14	1	2
					1
					1
			1		
					1
		1	2		2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastrointestinal disorder	2	13
Gastrointestinal haemorrhage	2	7
Gastrointestinal hypomotility		1
Gastrointestinal motility disorder		1
Gastrointestinal pain		11
Gastrointestinal sounds abnormal		2
Gastrointestinal stoma complication		1
Gastroesophageal reflux disease	5	22
Generalised anxiety disorder		1
Generalised tonic-clonic seizure	2	4
General physical health deterioration	2	2
Genital herpes		1
Gingival abscess	1	1
Gingival bleeding	1	2
Gingival blister	1	1
Gingival discomfort		2
Gingival disorder	1	1
Gingival erythema		1
Gingival pain		3
Gingival swelling		1
Gingivitis		3
Glare		1
Glassy eyes		1
Glaucoma		2
Glomerular filtration rate decreased	1	3
Glomerulonephritis minimal lesion		1
Glossitis	1	3
Glossodynia	4	15
Glycosylated haemoglobin decreased	1	1
Glycosylated haemoglobin increased	1	3
Goitre		1
Gout	2	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	12		1
				2	7
					1
			1		
			11		
			2		
			1		
		4	21	1	1
			1		
				2	4
		1	1	1	1
			1		
		1	1		1
		1	1		
			2		
		1	1		
			1		
			3		
			1		
			3		
			1		
			1		
					2
				1	3
					1
			2	1	1
		4	14		1
		1	1		
			1	1	2
			1		
		1	6	1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Granuloma annulare		1
Grip strength decreased		1
Groin pain	3	10
Guillain-Barre syndrome	1	9
Haemarthrosis	1	1
Haematemesis		6
Haematochezia	1	16
Haematocrit increased		1
Haematoma		4
Haematuria		5
Haemoglobin abnormal		1
Haemoglobin decreased		3
Haemoglobin increased		1
Haemoptysis	1	9
Haemorrhage	7	24
Haemorrhage urinary tract	1	5
Haemorrhagic stroke		4
Haemorrhagic urticaria		1
Haemorrhoids		5
Hair texture abnormal	1	1
Hallucination	4	20
Hallucination, auditory		1
Hallucination, visual		4
Hand fracture		3
Hangover	1	3
Haptoglobin increased		1
Headache	311	1,590
Head deformity		2
Head discomfort	11	45
Head injury	6	19
Hearing disability		1
Heart injury		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
		2	7	1	3
				1	9
				1	1
					6
				1	16
			1		
			4		
			2		3
					1
			1		2
			1		
		1	5		4
				7	24
				1	5
					4
					1
			3		2
		1	1		
				4	20
					1
					4
					3
		1	2		1
			1		
		300	1464	11	126
			1		1
		10	40	1	5
1	1	4	10	2	9
			1		
					4

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Heart rate		1
Heart rate abnormal		11
Heart rate decreased	1	11
Heart rate increased	32	163
Heart rate irregular	1	19
Heart rate normal		1
Heart valve incompetence		1
Hemiparesis	1	8
Hemiplegia		3
Henoch-Schonlein purpura		2
Heparin-induced thrombocytopenia		1
Hepatic cyst		2
Hepatic enzyme abnormal	1	1
Hepatic enzyme increased	3	7
Hepatic function abnormal		1
Hepatic pain		2
Hepatitis		3
Hepatitis acute		1
Hepatomegaly		1
Hereditary haemorrhagic telangiectasia		1
Herpes simplex	1	7
Herpes simplex reactivation		2
Herpes virus infection		2
Herpes zoster	68	127
Herpes zoster oticus	2	3
Herpes zoster reactivation	3	4
Hiatus hernia	1	2
Hiccups		5
Hip fracture	1	5
HIV infection		1
Hordeolum		1
Hot flush	6	35

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			9		2
		1	8		3
		26	132	6	31
			14	1	5
			1		
					1
				1	8
					3
					2
					1
			1		1
			4	3	3
					1
					2
					3
					1
			1		
			1		
			5	1	2
			2		
			1		1
1	1	62	107	6	20
				2	3
		3	4		
			1	1	1
			4		1
				1	5
			1		
					1
		6	34		1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hydrothorax	1	1
Hyperactive pharyngeal reflex		1
Hyperacusis	1	6
Hyperaesthesia	1	8
Hyperaesthesia teeth		1
Hyperchlorhydria		1
Hyperglycaemia	1	3
Hyperhidrosis	27	148
Hyperlipidaemia		1
Hypernatraemia		1
Hyperphagia	1	1
Hyperpyrexia		2
Hyperreflexia		1
Hypersensitivity	25	107
Hypersensitivity vasculitis		1
Hypersomnia	9	53
Hypertension	22	118
Hypertensive crisis		2
Hypertensive emergency		1
Hyperthermia		1
Hypertonia		2
Hyperventilation	2	8
Hypoacusis	6	22
Hypoaesthesia	41	191
Hypoaesthesia eye		2
Hypoaesthesia oral	10	45
Hypoaesthesia teeth		1
Hypogammaglobulinaemia		1
Hypogeusia	1	5
Hypoglycaemia	1	5
Hypokalaemia		1
Hypokinesia	1	14

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		
		1	5		1
		1	8		
			1		
					1
		1	1		2
		25	129	2	19
					1
					1
		1	1		
					2
			1		
		22	85	3	22
					1
		9	49		4
	1	11	65	11	53
					2
					1
			1		
			1		1
		1	7	1	1
		5	18	1	4
		35	158	6	33
			2		
		7	39	3	6
			1		
					1
		1	4		1
		1	3		2
					1
		1	10		4

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyponatraemia		1
Hypophagia	1	5
Hypopnoea	1	9
Hyporesponsive to stimuli		1
Hyposmia		1
Hypotension	3	29
Hypothermia	1	5
Hypothyroidism		1
Hypovolaemic shock		2
Hypoxia		7
IIIrd nerve paralysis	2	3
Ileus		1
III-defined disorder		2
Illness	34	195
Immobile	2	4
Immune-mediated neuropathy	1	1
Immune system disorder	5	12
Immune thrombocytopenia	3	5
Immunisation		1
Immunodeficiency	1	1
Impaired driving ability	1	5
Impaired healing		2
Impaired self-care		1
Impaired work ability	2	6
Imperception		1
Inappropriate affect		1
Inappropriate schedule of product administration	43	215
Incision site haemorrhage		1
Incoherent		5
Incomplete course of vaccination		4
Incontinence	1	6
Incorrect dosage administered		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	3		2
		1	5		4
					1
			1		
		3	13		16
				1	5
					1
					2
					7
				2	3
					1
			2		
	1	31	180	3	15
				2	4
				1	1
		3	8	2	4
				3	5
			1		
1	1			1	1
		1	4		1
			2		
					1
		2	4		2
			1		
			1		
		43	214		1
					1
			3		2
			4		
		1	4		2
			2		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Incorrect dose administered	3	11
Incorrect dose administered by device		1
Incorrect product administration duration		1
Incorrect route of product administration	3	27
Increased appetite	1	2
Increased bronchial secretion		1
Increased tendency to bruise	1	1
Increased upper airway secretion		3
Increased viscosity of upper respiratory secretion		1
Induration	2	2
Infarction	1	1
Infection	1	11
Infection reactivation	1	1
Inflammation	9	30
Inflammatory bowel disease		1
Inflammatory marker increased	1	2
Inflammatory pain		1
Influenza	5	40
Influenza like illness	27	163
Initial insomnia		4
Injected limb mobility decreased	1	5
Injection site abscess		1
Injection site bruising		1
Injection site discolouration		2
Injection site discomfort		2
Injection site erythema	5	35
Injection site haematoma		1
Injection site haemorrhage	1	2
Injection site induration		2
Injection site infection		1
Injection site joint pain		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	10		1
			1		
			1		
		3	26		1
		1	2		
			1		
		1	1		
			2		1
					1
		2	2		
				1	1
			4	1	7
		1	1		
		7	26	2	4
					1
		1	2		
			1		
		5	35		5
		25	150	2	13
			4		
		1	5		
			1		
			2		
			2		
		5	35		
					1
		1	2		
			2		
			1		
			1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site mass		2
Injection site nodule		1
Injection site oedema		1
Injection site pain	5	100
Injection site papule		1
Injection site paraesthesia		1
Injection site pruritus		7
Injection site rash		9
Injection site reaction		4
Injection site swelling	3	26
Injection site urticaria		3
Injection site vesicles		1
Injection site warmth		4
Injury		1
Inner ear disorder		1
Insomnia	41	170
Intentional dose omission		2
Intentional product misuse		2
Internal haemorrhage		1
International normalised ratio decreased		2
International normalised ratio increased	1	4
Intervertebral disc protrusion	1	2
Intestinal haemorrhage		1
Intestinal obstruction		1
Intra-abdominal haematoma		1
Intracranial hypotension	1	1
Intracranial mass		1
Intranasal paraesthesia		2
Intraocular pressure increased		2
Intraocular pressure test abnormal		1
Iridocyclitis		2
Iron deficiency	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
			1		
			1		
		5	99		1
			1		
			1		
			7		
			9		
			4		
		3	26		
			3		
			1		
			4		
			1		
			1		
		36	152	5	18
			2		
			2		
					1
			2		
		1	2		2
			1	1	1
					1
					1
		1	1		
					1
			2		
			1		1
			1		
					2
		1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Irritability	3	7
Irritability postvaccinal		1
Irritable bowel syndrome	2	6
Ischaemic stroke	1	9
IVth nerve paralysis		2
Jaundice		4
Jaw clicking		1
Jaw disorder	1	2
Joint dislocation	1	1
Joint effusion	1	2
Joint injury	2	9
Joint instability		1
Joint lock	1	5
Joint noise		1
Joint range of motion decreased	2	15
Joint stabilisation		1
Joint stiffness	5	13
Joint swelling	10	59
Kawasaki's disease	1	1
Keratosis pilaris	1	1
Kidney infection		6
Laboratory test abnormal		1
Labyrinthitis		2
Lack of spontaneous speech	1	1
Lack of vaccination site rotation	1	1
Lacrimal disorder	1	1
Lacrimation increased	6	22
Lactose intolerance	1	1
Lacunar infarction		1
Large intestine polyp		1
Laryngeal oedema		1
Laryngeal pain		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	5	2	2
			1		
		2	4		2
				1	9
					2
			3		1
			1		
		1	2		
				1	1
		1	2		
		2	8		1
			1		
			4	1	1
			1		
		1	12	1	3
					1
		5	12		1
		8	52	2	7
				1	1
		1	1		
					6
					1
			1		1
				1	1
		1	1		
		1	1		
		6	20		2
		1	1		
					1
			1		
					1
			1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Laryngitis	1	5
Laziness		1
Lethargy	17	78
Leukaemia		4
Leukocytosis		3
Lichenoid keratosis		1
Ligament injury		1
Ligamentitis	1	1
Ligament pain	1	1
Ligament sprain		4
Limb discomfort	16	70
Limb injury	3	15
Limb mass		3
Lipase increased		1
Lip blister		1
Lip discolouration		1
Lip disorder		5
Lip dry		1
Lip erythema		2
Lip exfoliation	1	1
Lip haemorrhage		1
Lipids increased		1
Lip injury		2
Lip oedema		3
Lipoma		1
Lip pain	1	3
Lip swelling	7	58
Liquid product physical issue		1
Listless		2
Liver disorder		1
Liver function test increased		2
Liver injury		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		2
			1		
		17	72		6
					4
			1		2
					1
			1		
				1	1
				1	1
			4		
		16	66		4
1	1	3	15		
			3		
			1		
			1		
					1
			5		
			1		
			2		
		1	1		
					1
			1		
			2		
			2		1
					1
		1	3		
		5	44	2	14
			1		
			2		
			1		
			2		
			1		2

* I=Interval, C=Cumulative

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Localised infection	1	6
Loss of consciousness	14	92
Loss of personal independence in daily activities	9	48
Low density lipoprotein increased		2
Lower gastrointestinal haemorrhage		2
Lower limb fracture		1
Lower respiratory tract congestion		1
Lower respiratory tract infection		1
Lumbar puncture abnormal		1
Lumbar radiculopathy		2
Lung abscess	1	1
Lung disorder	1	12
Lung hyperinflation		1
Lung infiltration		1
Lung neoplasm malignant		1
Lung opacity		1
Lupus-like syndrome	1	1
Lyme disease	1	1
Lymphadenitis	1	2
Lymphadenopathy	29	167
Lymph node pain	10	37
Lymph node palpable		1
Lymphocyte count abnormal		1
Lymphocyte count decreased		2
Lymphocyte count increased		2
Lymphocytosis		1
Lymphoedema	1	3
Lymphoma	1	2
Lymphopenia		1
Macular oedema		1
Macule		1
Major depression		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	6		
			1	14	91
		5	36	4	12
			2		
					2
			1		
			1		
					1
					1
			2		
				1	1
		1	12		
			1		
					1
					1
			1		
				1	1
				1	1
				1	2
		27	159	2	8
		10	35		2
			1		
			1		
			2		
			2		
			1		
		1	3		
				1	2
					1
			1		
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Malaise	82	561
Malnutrition	1	1
Mania	1	1
Mass	5	20
Mastication disorder		5
May-Thurner syndrome		1
Measles	1	1
Mechanical urticaria		1
Mediastinal mass	1	1
Medication error		1
Melaena		1
Memory impairment	9	31
Meniere's disease		1
Meningitis		3
Meningitis aseptic		2
Meningitis viral		2
Meniscus injury		2
Mental disorder		4
Mental impairment	2	13
Mental status changes	2	6
Metabolic acidosis		1
Metamyelocyte count increased		1
Microembolism		1
Micturition disorder		1
Micturition frequency decreased		1
Micturition urgency		2
Middle insomnia	1	7
Migraine	8	50
Migraine without aura		1
Miliaria	1	4
Mitral valve disease		1
Mitral valve incompetence	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		72	508	10	53
				1	1
		1	1		
		4	18	1	2
			3		2
					1
				1	1
			1		
		1	1		
			1		
					1
		7	28	2	3
					1
					3
					2
					2
			1		1
			3		1
				2	13
		1	4	1	2
			1		
					1
					1
			1		
			1		
			2		
		1	7		
		6	38	2	12
			1		
		1	4		
					1
				1	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mixed connective tissue disease	1	2
Moaning		2
Mobility decreased	6	32
Monocyte count abnormal		1
Monocyte count increased		3
Mononeuropathy multiplex	1	1
Monoplegia		2
Mood altered		1
Mood swings		1
Motor dysfunction	1	2
Mouth haemorrhage		3
Mouth injury		3
Mouth swelling	4	19
Mouth ulceration	1	6
Movement disorder	13	51
Mucosal disorder	1	2
Mucosal inflammation		1
Mucous stools		1
Multi-organ disorder		2
Multiple organ dysfunction syndrome		2
Multiple sclerosis	2	6
Multiple sclerosis relapse		1
Muscle contractions involuntary		2
Muscle discomfort	1	10
Muscle disorder	2	8
Muscle fatigue		3
Muscle injury		2
Muscle rigidity		3
Muscle rupture	1	1
Muscle spasms	22	117
Muscle spasticity		1
Muscle strain	3	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
			1		1
		3	26	3	6
			1		
			2		1
				1	1
					2
			1		
					1
		1	1		1
			1		2
			3		
		4	15		4
		1	6		
		10	42	3	9
		1	2		
			1		
			1		
			2		
					2
				2	6
					1
			1		1
		1	10		
		1	5	1	3
			3		
			2		
			2		1
				1	1
		18	101	4	16
					1
		3	7		2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle swelling		2
Muscle tightness	6	35
Muscle twitching	2	18
Muscular weakness	17	90
Musculoskeletal chest pain	3	20
Musculoskeletal discomfort	10	36
Musculoskeletal disorder	2	7
Musculoskeletal pain		7
Musculoskeletal stiffness	35	136
Myalgia	93	554
Myasthenia gravis		1
Mydriasis		1
Myelitis transverse		4
Myelocyte count increased		1
Myocardial infarction	8	48
Myocardial necrosis marker increased	1	1
Myocarditis		2
Myoclonus		1
Myositis	2	3
Nail discolouration		1
Nasal congestion	15	84
Nasal crusting		1
Nasal discomfort	2	8
Nasal disorder		1
Nasal dryness		2
Nasal injury		1
Nasal oedema		4
Nasal pruritus		1
Nasopharyngitis	18	108
Nausea	138	832
Near death experience	2	7
Neck injury	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		5	29	1	6
		2	14		4
		12	66	5	24
		3	18		2
		9	33	1	3
		2	5		2
			6		1
		28	117	7	19
	1	86	511	7	43
					1
			1		
					4
					1
			1	8	47
				1	1
					2
			1		
		1	2	1	1
			1		
		13	79	2	5
			1		
			6	2	2
			1		
			2		
			1		
			4		
			1		
		18	106		2
	1	132	762	6	70
				2	7
		1	2		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neck mass	1	4
Neck pain	23	142
Necrosis		1
Needle issue	1	2
Neglect of personal appearance		1
Neoplasm	1	5
Neoplasm malignant		4
Neoplasm progression		2
Neoplasm recurrence	1	1
Neoplasm skin	1	2
Nephritis	1	1
Nephrolithiasis	1	10
Nephropathy		3
Nephrotic syndrome		1
Nerve compression		7
Nerve injury	3	6
Nervousness	10	52
Nervous system disorder	4	13
Neuralgia	2	26
Neuritis	1	2
Neurological symptom	4	5
Neuromyelitis optica spectrum disorder		2
Neuropathy peripheral	5	27
Neutropenia	2	3
Neutrophil count abnormal		1
Neutrophil count decreased	1	3
Neutrophil count increased		2
Neutrophilia		1
Nightmare	3	12
Night sweats	6	33
Nipple pain	1	3
Nipple swelling		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3	1	1
		20	125	3	17
					1
		1	2		
			1		
		1	5		
					4
			1		1
		1	1		
		1	2		
				1	1
				1	10
					3
					1
			6		1
		1	4	2	2
		10	49		3
		2	9	2	4
		2	22		4
		1	2		
		2	3	2	2
					2
		1	1	4	26
				2	3
					1
			1	1	2
			2		
			1		
		3	11		1
		6	30		3
		1	3		
			2		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nitrite urine present		1
No adverse event	2	18
Nocturia		1
Nodal rhythm		1
Nodule		5
Non-cardiac chest pain		1
Non-Hodgkin's lymphoma		2
Noninfective gingivitis	1	1
Normocytic anaemia		1
Nystagmus		1
Obesity		1
Obsessive-compulsive personality disorder	1	1
Obstructive airways disorder		1
Obstructive shock		1
Occipital neuralgia	1	2
Ocular discomfort	3	13
Ocular hyperaemia	5	25
Ocular icterus		1
Oculofacial paralysis		1
Odynophagia	1	5
Oedema	1	7
Oedema peripheral	3	5
Oesophageal pain		3
Off label use	28	158
Oligodipsia		1
Omphalitis		1
Ophthalmic herpes zoster	3	4
Ophthalmic migraine		5
Ophthalmoplegia	1	1
Optic ischaemic neuropathy		3
Optic neuritis		2
Oral blood blister	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		2	18		
			1		
			1		
			5		
			1		
					2
		1	1		
			1		
			1		
			1		
		1	1		
					1
					1
		1	2		
		3	12		1
		5	22		3
			1		
					1
		1	5		
		1	5		2
		1	3	2	2
			3		
		28	157		1
					1
					1
				3	4
			5		
				1	1
					3
					2
		1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral candidiasis		2
Oral discomfort	5	18
Oral disorder		5
Oral fungal infection		2
Oral herpes	5	22
Oral lichen planus		1
Oral mucosal blistering		2
Oral mucosal eruption	1	1
Oral pain	3	9
Oral pruritus	2	9
Orchitis		1
Orchitis noninfective		1
Organising pneumonia	1	1
Oromandibular dystonia		1
Oropharyngeal blistering	1	1
Oropharyngeal candidiasis		1
Oropharyngeal discomfort	3	21
Oropharyngeal pain	30	138
Oropharyngeal spasm	1	1
Orthostatic hypotension		3
Osteitis	1	1
Osteoarthritis	1	7
Osteolysis	1	1
Osteomyelitis		1
Osteoporosis		1
Otitis media	1	1
Ovarian cancer		1
Overdose	3	28
Overweight		1
Oxygen consumption decreased		1
Oxygen saturation		1
Oxygen saturation abnormal	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		4	16	1	2
			3		2
			2		
		5	18		4
			1		
			1		1
				1	1
		3	9		
		2	8		1
			1		
			1		
				1	1
			1		
				1	1
			1		
		3	17		4
		26	127	4	11
				1	1
			1		2
		1	1		
		1	7		
		1	1		
					1
			1		
		1	1		
					1
		3	28		
					1
			1		
			1		
		1	5		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oxygen saturation decreased	4	25
Pain	173	945
Painful respiration		5
Pain in extremity	235	1,221
Pain in jaw	9	36
Pain of skin	5	15
Palatal disorder		1
Pallor	1	7
Palmar erythema		2
Palpitations	28	132
Pancreatic carcinoma metastatic	1	1
Pancreatic disorder		1
Pancreatic enzymes increased		1
Pancreatitis		3
Pancreatitis acute	1	2
Pancytopenia		2
Panic attack	2	9
Panic disorder		1
Panic reaction	1	5
Papule	2	2
Paraesthesia	39	177
Paraesthesia oral	5	60
Paralysis	6	25
Paranasal sinus discomfort	4	8
Paranasal sinus hypersecretion		1
Paranoia	1	3
Paraplegia		1
Paresis		1
Parkinsonism		1
Parkinson's disease		1
Parosmia	4	19
Parotitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			8	4	17
	1	148	851	25	94
			2		3
		214	1138	21	83
		9	31		5
		4	14	1	1
					1
		1	5		2
			2		
		24	109	4	23
				1	1
			1		
			1		
					3
				1	2
					2
		2	7		2
			1		
		1	5		
		2	2		
		35	155	4	22
		4	49	1	11
			1	6	24
		4	8		
			1		
		1	3		
					1
					1
			1		
					1
		3	18	1	1
			1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Paroxysmal sympathetic hyperactivity		1
Patient elopement		1
Pelvic fracture		1
Pelvic pain	1	3
Pemphigoid	1	2
Penile haemorrhage		1
Penile rash	1	1
Penis disorder		1
Periarthritis	1	1
Pericardial effusion	1	5
Pericarditis	2	10
Periodontitis		1
Periorbital oedema		1
Periorbital swelling	1	12
Peripheral artery thrombosis	1	1
Peripheral coldness	3	21
Peripheral ischaemia		1
Peripheral sensory neuropathy	1	3
Peripheral swelling	53	222
Peripheral vascular disorder		1
Peripheral venous disease	2	2
Peritonitis	1	1
Peroneal nerve palsy	1	3
Petechiae		3
Pharyngeal disorder	2	2
Pharyngeal erythema	1	6
Pharyngeal hypoaesthesia	1	2
Pharyngeal inflammation		1
Pharyngeal paraesthesia		1
Pharyngeal swelling	9	48
Pharyngeal ulceration	1	1
Pharyngitis		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
					1
		1	3		
				1	2
					1
		1	1		
			1		
		1	1		
				1	5
				2	10
			1		
			1		
		1	11		1
				1	1
		2	20	1	1
			1		
				1	3
		43	187	10	35
			1		
		2	2		
				1	1
				1	3
			1		2
		2	2		
		1	6		
		1	2		
			1		
			1		
		7	32	2	16
		1	1		
			3		1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pharyngitis streptococcal	1	3
Phlebitis		3
Photophobia	1	13
Photopsia	1	8
Photosensitivity reaction	1	3
Pigmentation disorder		3
Piloerection	1	2
Pituitary tumour benign		1
Plantar erythema		1
Plantar fasciitis		1
Plasma cell myeloma	1	1
Platelet count decreased	8	23
Platelet count increased	1	3
Platelet disorder		1
Pleural effusion		1
Pleurisy	2	2
Pleuritic pain		2
Plicated tongue	1	2
Pneumonia	12	42
Pneumonia aspiration		2
Pneumonia bacterial		1
Pneumonia staphylococcal		1
Pneumonia viral		2
Pneumonitis		2
Pneumothorax	1	4
Poisoning		1
Pollakiuria	2	16
Polychondritis		1
Polycythaemia		1
Polydipsia		1
Polymyalgia rheumatica	1	6
Polyuria		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		
			3		
		1	12		1
			5	1	3
1	1	1	2		1
			3		
		1	2		
					1
			1		
			1		
				1	1
		2	5	6	18
		1	3		
					1
					1
				2	2
			1		1
		1	2		
			2	12	40
					2
					1
					1
					2
					2
				1	4
					1
		2	16		
					1
			1		
			1		
				1	6
			2		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Poor quality product administered	12	32
Poor quality sleep	3	16
Portal vein thrombosis	2	2
Post-acute COVID-19 syndrome	1	1
Post herpetic neuralgia		1
Postictal state		1
Post inflammatory pigmentation change		1
Post lumbar puncture syndrome		1
Post procedural complication		
Post procedural haemorrhage		1
Post procedural infection		1
Post procedural oedema		1
Post-traumatic neuralgia		1
Post-traumatic stress disorder		1
Postural orthostatic tachycardia syndrome		1
Posture abnormal	1	2
Potentiating drug interaction	1	11
Pre-existing condition improved	1	4
Presyncope	6	35
Procedural haemorrhage		1
Proctalgia		1
Product administered at inappropriate site	5	26
Product administration error		4
Product colour issue		2
Product communication issue		1
Product dose omission issue	5	37
Productive cough	4	24
Product leakage	1	3
Product preparation error	2	16
Product preparation issue	1	12
Product quality issue		1
Product storage error	8	14

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		12	32		
		3	15		1
				2	2
				1	1
			1		
					1
			1		
			1		
	1				
					1
					1
			1		
			1		
			1		
					1
		1	2		
		1	11		
		1	4		
		3	25	3	10
					1
			1		
		5	26		
			3		1
			2		
			1		
		5	36		1
		4	23		1
		1	3		
		2	16		
		1	12		
			1		
		8	14		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Product substitution error		1
Product supply issue	1	5
Product temperature excursion issue	4	11
Product use in unapproved indication		1
Product use issue	1	53
Prostate cancer		2
Prostate examination abnormal	1	1
Prostatic specific antigen increased		1
Prostatomegaly		1
Protein total decreased		1
Protein total increased		1
Proteinuria		3
Protein urine	1	1
Prothrombin level increased		1
Prothrombin time prolonged		1
Pruritus	96	432
Pseudofolliculitis	1	1
Psoriasis		8
Psoriatic arthropathy		1
Psychomotor hyperactivity		2
Psychotic disorder	1	2
Pulmonary artery thrombosis		1
Pulmonary congestion		8
Pulmonary embolism	11	38
Pulmonary fibrosis		3
Pulmonary hypertension		2
Pulmonary mass		2
Pulmonary oedema	3	9
Pulmonary pain	2	6
Pulmonary thrombosis	2	20
Pulmonary venous thrombosis		1
Pulse abnormal		5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	5		
		4	11		
			1		
		1	52		1
					2
		1	1		
			1		
			1		
			1		
			2		1
				1	1
					1
			1		
		90	389	6	43
		1	1		
			6		2
1	1				1
			2		
		1	1		1
					1
			1		7
				11	38
1	1				3
	1				2
			2		
				3	9
		2	6		
				2	20
					1
			1		4

* I=Interval, C=Cumulative

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pulse absent		1
Pulseless electrical activity	1	2
Pulse pressure increased		1
Pulse volume decreased		1
Purpura	2	3
Pustule		3
Pyrexia	181	969
Quality of life decreased		1
Radiation injury	1	1
Rash	97	422
Rash erythematous	17	64
Rash macular	20	57
Rash maculo-papular	1	3
Rash morbilliform	1	4
Rash papular	2	25
Rash pruritic	21	74
Rash pustular		1
Rash vesicular	2	8
Reaction to excipient		3
Reaction to preservatives		1
Rectal discharge		1
Rectal haemorrhage	2	7
Red blood cell count abnormal		1
Red blood cell count decreased		2
Red blood cell count increased		1
Red blood cell sedimentation rate abnormal		1
Red blood cell sedimentation rate increased	2	6
Red cell distribution width increased		1
Reduced facial expression		1
Reflux gastritis		1
Regurgitation		1
Renal atrophy		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	2
			1		
			1		
		1	2	1	1
			1		2
1	1	167	874	14	95
					1
		1	1		
		88	371	9	51
		13	52	4	12
		17	51	3	6
		1	3		
			1	1	3
		2	22		3
		19	65	2	9
			1		
		2	7		1
			1		2
			1		
				2	7
			1		
			1		1
			1		
		2	4		2
					1
					1
			1		
			1		
					1

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* AE=Adverse Event

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Renal cyst		1
Renal disorder		8
Renal failure	3	6
Renal haemorrhage		1
Renal impairment	3	7
Renal pain	1	7
Renal tubular disorder		1
Renal tubular injury		1
Respiration abnormal	1	3
Respiratory arrest	2	9
Respiratory disorder	1	11
Respiratory distress	1	14
Respiratory failure		3
Respiratory rate decreased		3
Respiratory rate increased		6
Respiratory symptom		1
Respiratory tract congestion		16
Respiratory tract infection	1	5
Respiratory tract inflammation		1
Respiratory tract irritation		2
Respiratory tract oedema		2
Restless legs syndrome		2
Restlessness		12
Retching	3	26
Retinal artery occlusion		2
Retinal detachment	1	2
Retinal disorder		1
Retinal vascular thrombosis		1
Retinal vein occlusion		3
Retinitis pigmentosa		1
Retinogram abnormal	1	1
Retinopathy hypertensive		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			6		2
				3	6
					1
				3	7
		1	6		1
					1
					1
		1	2		1
				2	9
		1	8		3
				1	14
					3
			2		1
			2		4
					1
			13		3
				1	5
			1		
			1		1
					2
			2		
			11		1
	1	2	21	1	5
					2
				1	2
			1		
			1		
					3
					1
				1	1
					1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rhabdomyolysis	1	2
Rheumatic disorder		1
Rheumatoid arthritis		14
Rhinalgia	1	2
Rhinitis		3
Rhinorrhoea	20	126
Rib fracture		2
Right ventricular dilatation		1
Rotator cuff syndrome	2	3
Ruptured cerebral aneurysm	1	1
Salivary gland disorder		1
Salivary gland enlargement		1
Salivary gland mass	1	1
Salivary hypersecretion	1	6
Sarcoidosis	1	1
SARS-CoV-1 test positive		1
SARS-CoV-2 ant body test negative		11
SARS-CoV-2 ant body test positive		4
SARS-CoV-2 test		1
SARS-CoV-2 test negative	1	3
SARS-CoV-2 test positive	6	41
Scab	3	6
Scar	2	7
Sciatica	2	18
Scleral discolouration		1
Scratch	1	4
Screaming		1
Scrotal disorder		1
Scrotal erythema		1
Scrotal inflammation		1
Scrotal pain		2
Seasonal allergy	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
			1		
2	2				14
		1	2		
			2		1
		20	122		4
					2
			1		
		2	3		
				1	1
					1
			1		
				1	1
		1	5		1
				1	1
			1		
			9		2
			4		
			1		
		1	3		
		3	17	3	24
		3	6		
		2	4		3
			11	2	7
			1		
		1	4		
			1		
			1		
			1		
			2		
		2	5		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Secretion discharge	3	8
Sedation		1
Seizure	11	43
Seizure like phenomena	1	2
Sensation of blood flow		1
Sensation of foreign body		8
Sensitive skin		7
Sensitivity to weather change		1
Sensory disturbance	1	10
Sensory level abnormal		1
Sensory loss	1	4
Sepsis	2	6
Septic shock	1	1
Serratia infection	1	1
Shock		5
Shock symptom		1
Sialoadenitis		2
Sinus bradycardia		2
Sinus congestion	1	12
Sinus disorder	3	19
Sinus headache		9
Sinusitis	5	21
Sinusitis bacterial		2
Sinus pain	1	6
Sinus tachycardia	1	2
Sitting disability		1
Sjogren's syndrome	2	2
Skin abrasion		2
Skin bacterial infection		1
Skin burning sensation	7	18
Skin cancer	1	1
Skin discolouration	4	35

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	8		
			1		
				11	43
				1	2
					1
			8		
			7		
			1		
		1	10		
			1		
			2	1	2
				2	6
				1	1
				1	1
					5
					1
					2
					2
			10	1	2
		3	16		3
			9		
		5	21		
					2
		1	6		
			1	1	1
			1		
				2	2
			2		
					1
		5	16	2	2
				1	1
		4	29		6

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin disorder	7	24
Skin exfoliation	4	16
Skin fissures		1
Skin haemorrhage	1	5
Skin hypertrophy	1	1
Skin indentation		1
Skin infection		1
Skin injury		1
Skin irritation	3	9
Skin laceration	1	11
Skin laxity		1
Skin lesion	1	13
Skin mass	2	6
Skin odour abnormal		1
Skin reaction	2	4
Skin swelling	1	5
Skin tightness	1	2
Skin turgor decreased		1
Skin warm	1	6
Skin weeping	1	1
Skin wrinkling		1
Sleep deficit		1
Sleep disorder	7	46
Sleep disorder due to a general medical condition	2	6
Sleep disorder due to general medical condition, insomnia type		1
Slow speech		1
Sluggishness	3	14
Small fibre neuropathy		1
Small intestinal obstruction		1
Snapping hip syndrome		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		7	22		2
		4	16		
					1
			3	1	2
		1	1		
			1		
					1
			1		
		3	9		
			3	1	8
			1		
		1	12		1
		2	5		1
			1		
		1	2	1	2
		1	4		1
		1	2		
					1
		1	6		
		1	1		
			1		
			1		
		7	43		3
		2	6		
			1		
			1		
		3	14		
			1		
					1
			1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sneezing	13	51
Soft tissue disorder		1
Soft tissue swelling		1
Solar lentigo		1
Somatic symptom disorder		2
Somnolence	31	148
Speech disorder	8	38
Spinal cord disorder		1
Spinal fusion surgery		1
Spinal osteoarthritis		2
Spinal pain	1	8
Spinal stenosis	1	2
Spleen disorder		1
Splenic infarction		1
Splenic vein thrombosis		1
Splinter haemorrhages		1
Spondylitis	1	1
Sputum discoloured	1	2
Sputum purulent	1	1
Staphylococcal bacteraemia		1
Staphylococcal infection		3
Staring		2
Stenosis		1
Stevens-Johnson syndrome	1	2
Stoma site pruritus		1
Stomatitis	1	6
Strabismus		3
Streptococcus test positive		1
Stress	6	18
Stridor		1
Subarachnoid haemorrhage		3
Submaxillary gland enlargement	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		13	50		1
			1		
			1		
			2		1
		31	138		10
		5	29	3	9
					1
					1
			2		
		1	8		
			1	1	1
					1
					1
			1		
		1	1		
				1	2
				1	1
					1
			1		2
					2
					1
				1	2
			1		
		1	5		1
			1		2
			1		
		6	17		1
			1		
					3
				1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sudden cardiac death		1
Sudden death		2
Sudden hearing loss	2	5
Suffocation feeling		1
Suicidal ideation	1	2
Sunburn	3	5
Superficial vein prominence		1
Superior sagittal sinus thrombosis		1
Supraventricular extrasystoles		1
Supraventricular tachycardia		2
Suspected counterfeit product		1
Suspected COVID-19	10	37
Swelling	24	122
Swelling face	15	109
Swelling of eyelid	2	12
Swollen tongue	8	48
Syncope	7	56
Synovitis		1
Systemic inflammatory response syndrome	1	2
Systemic lupus erythematosus	1	4
Tachycardia	7	34
Tachypnoea		8
Tanning		1
Tardive dyskinesia	1	1
Taste disorder	5	36
Temperature intolerance		3
Temporomandibular joint syndrome		1
Tenderness	8	31
Tendon discomfort		1
Tendonitis	3	6
Tendon pain	1	4
Tenosynovitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					2
				2	5
			1		
				1	2
		3	5		
			1		
					1
					1
			1		1
			1		
		7	17	3	20
		22	104	2	18
		10	82	5	27
		2	11		1
		6	32	2	16
				7	56
			1		
				1	2
1	1			1	4
		2	16	5	18
			4		4
			1		
				1	1
		4	30	1	6
			3		
			1		
		8	31		
			1		
		1	4	2	2
			2	1	2
			1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tension	1	1
Tension headache		4
Terminal insomnia		1
Testicular pain		1
Testicular swelling		1
Tetanus		1
Thalamic infarction		1
Therapeutic product effect decreased	1	1
Therapeutic product effect incomplete		1
Therapeutic response unexpected	5	33
Thermal burn		2
Thermal burns of eye	1	1
Thinking abnormal	2	17
Thirst	3	20
Throat clearing		2
Throat irritation	8	41
Throat lesion	1	1
Throat tightness	13	48
Thrombocytopenia	1	8
Thrombocytopenic purpura	1	1
Thrombophlebitis superficial		4
Thrombosis	25	74
Thrombotic stroke	1	2
Thyroid disorder	1	4
Thyroid hormones increased		1
Thyroiditis		1
Thyroiditis subacute		1
Tibia fracture		1
Tic		1
Tinea infection	1	1
Tinnitus	36	112
Tobacco user	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
			2		2
			1		
			1		
			1		
					1
					1
		1	1		
					1
		5	33		
			1		1
				1	1
		2	15		2
		3	18		2
			2		
		8	35		6
		1	1		
		9	33	4	15
				1	8
				1	1
			1		3
1	1			25	74
				1	2
		1	4		
			1		
			1		
			1		
					1
			1		
		1	1		
		28	95	8	17
		1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tongue blistering	1	2
Tongue coated		2
Tongue cyst		1
Tongue discolouration		3
Tongue discomfort	4	14
Tongue disorder	1	10
Tongue eruption		1
Tongue erythema	1	5
Tongue haematoma		1
Tongue injury		1
Tongue movement disturbance		2
Tongue oedema	1	2
Tongue pruritus		4
Tongue ulceration	2	2
Tonsillar hypertrophy		1
Tonsillar inflammation		1
Tooth abscess	1	3
Toothache	4	23
Tooth discolouration		1
Tooth disorder	1	6
Tooth infection	1	7
Tooth injury		3
Total lung capacity decreased		1
Tourette's disorder		1
Toxicity to various agents		1
Transaminases decreased		1
Transaminases increased		1
Transient global amnesia		1
Transient ischaemic attack	1	12
Transplant failure		1
Traumatic haemorrhage		1
Tremor	27	142

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
			2		
			1		
			3		
		4	14		
		1	10		
			1		
		1	5		
			1		
			1		
			2		
			1	1	1
			4		
		1	1	1	1
			1		
		1	3		
		4	21		2
			1		
		1	6		
		1	6		1
			1		2
			1		
					1
					1
					1
			1		
			1		
				1	12
					1
					1
1	2	23	114	4	28

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Trichorrhexis	1	1
Trigeminal nerve disorder		3
Trigeminal neuralgia		1
Trigger finger		3
Trismus	1	2
Troponin I increased		1
Troponin increased		4
Tumour marker abnormal		1
Tumour marker increased	1	1
Tunnel vision		1
Type 1 diabetes mellitus		1
Type IV hypersensitivity reaction	1	1
Type V hyperlipidaemia		1
Ulcer	2	3
Underdose	5	29
Unevaluable event		2
Unresponsive to stimuli	3	14
Upper-airway cough syndrome	1	7
Upper limb fracture	1	3
Upper respiratory tract congestion	3	11
Upper respiratory tract infection		3
Ureteric stenosis		1
Urinary bladder haemorrhage		1
Urinary incontinence	2	10
Urinary retention		2
Urinary tract infection	5	32
Urinary tract infection bacterial		2
Urine abnormality		2
Urine analysis abnormal	1	4
Urine leukocyte esterase positive		2
Urine output decreased		3
Urine output increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
			2		1
			1		
			3		
		1	2		
			1		
			1		3
					1
				1	1
					1
					1
		1	1		
					1
		2	3		
		4	28	1	1
			2		
				3	14
		1	6		1
				1	3
		3	11		
			3		
					1
					1
		2	8		2
					2
		3	22	2	10
					2
			2		
		1	4		
			2		
			3		
			1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Urobilinogen urine increased		1
Urticaria	57	188
Urticaria thermal		1
Vaccination complication	1	3
Vaccination failure	7	30
Vaccination site bruising	4	24
Vaccination site cellulitis		5
Vaccination site coldness		4
Vaccination site dermatitis	1	1
Vaccination site discolouration	1	7
Vaccination site discomfort	4	20
Vaccination site erythema	21	130
Vaccination site extravasation		1
Vaccination site haematoma		3
Vaccination site haemorrhage	4	23
Vaccination site hypoaesthesia	3	6
Vaccination site induration	1	8
Vaccination site infection		4
Vaccination site inflammation		5
Vaccination site injury		1
Vaccination site irritation	1	3
Vaccination site joint movement impairment	1	3
Vaccination site joint pain		2
Vaccination site lymphadenopathy		1
Vaccination site macule		2
Vaccination site mass	13	48
Vaccination site movement impairment	1	10
Vaccination site nodule	1	5
Vaccination site oedema	1	2
Vaccination site pain	103	646
Vaccination site papule		1
Vaccination site paraesthesia	1	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		51	164	6	24
			1		
1	2	1	2		1
			1	7	29
		4	21		3
			1		4
			4		
		1	1		
		1	7		
		3	19	1	1
		21	121		9
			1		
			2		1
		3	21	1	2
		3	6		
		1	8		
			4		
			4		1
			1		
		1	3		
		1	3		
			2		
			1		
			2		
		13	44		4
			9	1	1
		1	4		1
		1	2		
	1	98	617	5	29
			1		
		1	6		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site pruritus	13	86
Vaccination site rash	13	43
Vaccination site reaction		9
Vaccination site scab	1	1
Vaccination site scar		1
Vaccination site streaking		1
Vaccination site swelling	28	125
Vaccination site urticaria	2	16
Vaccination site vesicles	1	3
Vaccination site warmth	6	52
Vaginal discharge		1
Vaginal haemorrhage	1	3
Varicella		1
Varicose vein	1	6
Vascular injury	1	1
Vascular pain		1
Vasculitis	1	1
Vein discolouration		1
Vein disorder		6
Venous thrombosis limb		2
Ventricular arrhythmia		1
Ventricular extrasystoles		3
Ventricular fibrillation		2
Ventricular tachycardia		2
Vertigo	24	104
Vertigo positional		3
Vestibular disorder	1	4
Viral infection	1	1
Viral rash		1
Viral test positive		1
Viral upper respiratory tract infection		1
Vision blurred	15	84

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		13	79		7
		13	40		3
1	1		8		1
		1	1		
			1		
			1		
		27	116	1	9
		2	14		2
		1	3		
		6	45		7
			1		
		1	1		2
			1		
		1	6		
		1	1		
			1		
		1	1		
			1		
			5		1
					2
					1
					3
					2
					2
		22	91	2	13
			3		
		1	3		1
		1	1		
			1		
			1		
			1		
		13	71	2	13

* I=Interval, C=Cumulative

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Visual acuity reduced	1	1
Visual field defect		5
Visual impairment	6	42
Vitamin B12 decreased		1
Vitamin B12 increased		1
Vitamin D decreased		3
Vitamin D deficiency		1
Vlth nerve paralysis		3
Vitreous degeneration		1
Vitreous detachment	2	2
Vitreous floaters	3	8
Vocal cord disorder		1
Vomiting	47	282
Vomiting projectile		4
Vulvovaginal burning sensation	2	2
Vulvovaginal dryness	1	1
Vulvovaginal erythema	1	1
Vulvovaginal pain	2	2
Vulvovaginal pruritus	1	1
Vulvovaginal rash	1	1
Wa king aid user	1	3
Wa king disability	1	2
Weight decreased	18	64
Weight fluctuation		1
Weight increased	3	14
Wheezing	5	30
White blood cell count decreased	2	7
White blood cell count increased	6	20
White blood cells urine positive		2
White matter lesion		2
Wound		3
Wound haemorrhage	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			4		1
		2	30	4	12
			1		
			1		
			3		
			1		
					3
					1
				2	2
		3	6		2
					1
1	2	40	235	7	47
			4		
		1	1	1	1
		1	1		
		1	1		
		2	2		
		1	1		
		1	1		
		1	3		
			1	1	1
		15	52	3	12
			1		
		3	14		
		4	21	1	9
1	1	1	6	1	1
		3	13	3	7
			2		
					2
			1		2
		1	2		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Wrist fracture		1						1
Wrong product administered	6	14			6	14		
Wrong schedule		4				4		
Wrong technique in device usage process		1				1		
Wrong technique in product usage process	4	18			4	18		
	1	4			1	4		
	6,073	32,073	23	47	4879	25913	1194	6160

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* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	1	26			1	25		1
Abdominal distension		5				5		
Abdominal pain	2	13			2	10		3
Abdominal pain lower		2				2		
Abdominal pain upper	5	42			5	38		4
Abnormal behaviour		2				2		
Abnormal dreams	1	3			1	2		1
Abnormal faeces		2				2		
Abnormal loss of weight	1	1			1	1		
Acarodermatitis		1				1		
Accident	1	1					1	1
Accidental exposure to product		2				2		
Accidental overdose		1				1		
Acne		3				3		
Acute hepatic failure		1						1
Acute kidney injury		5				1		4
Acute myeloid leukaemia		2						2
Acute myocardial infarction		1						1
Acute respiratory distress syndrome		1						1
Administration site bruise	1	1			1	1		
Administration site joint erythema		1				1		
Adrenal disorder		1				1		
Ageusia	4	15			4	15		
Aggression	1	3				1	1	2
Agitation	1	4			1	3		1
Allergy to vaccine	2	6				3	2	3
Alopecia	2	4			2	4		
Altered state of consciousness		2						2
Amnesia	2	7			2	6		1
Amyloidosis		1						1
Anaemia		3				1		2
Anal haemorrhage		1				1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anal incontinence	1	2
Anaphylactic reaction	1	5
Anger	2	5
Angina pectoris		2
Angioedema		2
Anorectal discomfort		1
Anosmia	1	4
Antibody test abnormal		1
Anxiety	5	20
Aortic arteriosclerosis		1
Aortic valve disease		1
Apathy		1
Aphasia		4
Aphonia	1	3
Apnoea		1
Appetite disorder		1
Application site erythema		1
Application site swelling		1
Arrhythmia		9
Arterial occlusive disease		1
Arterial stenosis	1	1
Arteriosclerosis		1
Arteriosclerosis coronary artery		1
Arthralgia	33	159
Arthritis	3	14
Arthropathy		6
Asthenia	27	165
Asthenopia		2
Asthma	2	4
Asymptomatic COVID-19		4
Atelectasis		1
Atrial fibrillation	4	29

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	1
				1	5
		2	3		2
					2
					2
			1		
		1	4		
			1		
		5	16		4
			1		
					1
			1		
			3		1
		1	2		1
					1
			1		
			1		
			1		
					9
					1
				1	1
					1
			1		
		29	146	4	13
		2	13	1	1
			6		
		22	136	5	29
			2		
		2	2		2
			1		3
					1
				4	29

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Autoimmune disorder	1	1
Autoimmune haemolytic anaemia	1	2
Autoimmune thyroiditis		1
Axillary pain		2
Back disorder	1	3
Back injury		1
Back pain	11	44
Bacterial infection	2	3
Balance disorder	5	29
Barrett's oesophagus		1
Basal ganglia stroke		1
Bedridden	1	8
Behaviour disorder		1
Belligerence		1
Bell's palsy	1	5
Bladder disorder		1
Bladder dysfunction		1
Blast cell crisis		1
Blindness		4
Blindness transient		1
Blister	3	14
Blood albumin decreased		1
Blood blister	2	4
Blood calcium decreased		1
Blood calcium increased		1
Blood chloride decreased		1
Blood chloride increased		2
Blood cholesterol increased		1
Blood count abnormal		2
Blood creatine increased		1
Blood creatinine increased		1
Blood disorder	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	2
					1
			2		
		1	3		
					1
		9	39	2	5
		2	3		
		5	22		7
					1
					1
		1	6		2
					1
					1
				1	5
			1		
			1		
					1
					4
					1
		3	12		2
			1		
		2	2		2
			1		
					1
			1		
			1		1
					1
			1		
		1	2		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood glucose abnormal		2
Blood glucose decreased		3
Blood glucose fluctuation		1
Blood glucose increased		10
Blood immunoglobulin G increased		1
Blood immunoglobulin M increased		1
Blood iron decreased		1
Blood iron increased		1
Blood lactic acid increased		1
Blood potassium decreased		5
Blood potassium increased		2
Blood pressure abnormal	1	5
Blood pressure decreased		4
Blood pressure fluctuation		4
Blood pressure increased	5	44
Blood pressure systolic increased		3
Blood sodium decreased		1
Blood test abnormal		1
Blood urea increased		1
Blood urine		1
Blood urine present		3
Body height decreased	2	17
Body temperature		1
Body temperature abnormal	1	2
Body temperature decreased		1
Body temperature increased	1	18
Bone density abnormal		1
Bone neoplasm		1
Bone pain		7
Bowel movement irregularity		5
Bradycardia		1
Bradykinesia	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
			3		
			1		
			7		3
			1		
			1		
					1
			1		
					1
			3		2
			1		1
		1	5		
			2		2
			4		
		3	29	2	15
			1		2
			1		
			1		
			1		
			3		
		2	17		
			1		
		1	2		
			1		
		1	17		1
			1		
			1		
			6		1
			5		
					1
		1	2		

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* AE=Adverse Event

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Brain injury		2
Brain natriuretic peptide increased		1
Brain stem stroke		1
Breast cancer		1
Breast mass		1
Breast pain	1	4
Breast swelling		1
Breath sounds abnormal		1
Bronchitis	1	5
Bronchospasm		1
Bundle branch block left		1
Burning sensation	1	17
Bursitis		2
Cardiac arrest	3	11
Cardiac disorder	1	9
Cardiac failure		2
Cardiac failure congestive	1	4
Cardiac flutter		2
Cardiac valve disease		1
Cardiogenic shock		1
Cardiomyopathy		1
Carpal tunnel syndrome	1	1
Cataract		2
Catatonia		1
Cellulitis	1	5
Central nervous system lesion		1
Cerebral artery embolism		1
Cerebral haemorrhage		2
Cerebral infarction		1
Cerebral thrombosis	1	4
Cerebrovascular accident	6	31
Chest discomfort	6	16

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
			1		
					1
					1
			1		
		1	4		
			1		
			1		
		1	5		
			1		
					1
		1	15		2
			2		
				3	11
			4	1	5
					2
				1	4
					2
			1		
					1
					1
				1	1
					2
			1		
				1	5
					1
					1
					2
					1
				1	4
				6	31
		6	12		4

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chest injury		1
Chest pain	3	30
Chills	43	226
Choking		1
Choking sensation		3
Cholecystitis		1
Cholelithiasis	1	2
Chorea		1
Chromaturia		3
Chronic myeloid leukaemia recurrent		1
Chronic obstructive pulmonary disease		1
Circumstance or information capable of leading to device use error		2
Circumstance or information capable of leading to medication error	2	68
Clostridium difficile infection	1	2
Coagulopathy		1
Coccidioidomycosis		1
Cognitive disorder	1	8
Cold sweat	3	6
Colitis		1
Colitis microscopic		1
Colitis ulcerative		1
Colon cancer		1
Coma	1	3
Communication disorder		2
Concussion		1
Condition aggravated	11	51
Confusional state	7	38
Conjunctivitis		1
Constipation		7
Contraindicated product administered		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		3	22		8
		42	208	1	18
					1
			2		1
					1
				1	2
					1
			3		
					1
					1
			2		
		2	68		
				1	2
					1
					1
			4	1	4
		3	6		
					1
					1
					1
				1	3
			1		1
					1
		9	39	2	12
		5	26	2	12
			1		
			7		
			1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Contraindication to vaccination		2
Contusion	1	15
Coordination abnormal	1	1
Coronary artery occlusion		1
Coronary artery thrombosis	1	1
Cor pulmonale acute		1
Cough	15	67
COVID-19	20	123
COVID-19 pneumonia		12
C-reactive protein increased		3
Crying		3
Culture urine positive		1
Cutaneous vasculitis		1
Cyanosis		1
Cystitis	1	4
Cystitis bacterial	1	1
Cytogenetic analysis abnormal	1	1
Deafness	2	14
Deafness bilateral		1
Deafness neurosensory	1	1
Deafness unilateral	1	3
Death	2	33
Decreased appetite	4	65
Decreased interest	1	2
Deep vein thrombosis	2	8
Degenerative bone disease		1
Dehydration	3	17
Delirium		6
Delusion	1	3
Delusional perception		4
Dementia	2	9
Dementia Alzheimer's type	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		1	14		1
		1	1		
					1
				1	1
					1
		13	56	2	11
	2	4	27	16	96
					12
			1		2
			2		1
			1		
					1
					1
				1	4
				1	1
				1	1
				2	14
					1
				1	1
1	1			1	3
				2	33
		3	55	1	10
		1	1		1
				2	8
			1		
			7	3	10
					6
		1	2		1
			3		1
				2	9
				1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dental discomfort		1
Depressed level of consciousness		1
Depressed mood		2
Depression	2	5
Dermatitis	1	6
Dermatitis allergic		1
Dermatitis contact		1
Dermatitis diaper		1
Device issue		1
Diabetes mellitus		1
Diabetes mellitus inadequate control		3
Diarrhoea	20	128
Diarrhoea haemorrhagic		2
Diet refusal		1
Diplopia		3
Discomfort	3	15
Disease recurrence	4	15
Disorganised speech		1
Disorientation		17
Disturbance in attention		3
Diverticulitis		2
Dizziness	26	212
Dizziness postural		1
Dreamy state		1
Drooling	1	2
Drug hypersensitivity		5
Drug ineffective	15	88
Drug interaction		4
Dry eye		1
Dry mouth	5	11
Dry skin	1	6
Dry throat		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
			2		
		2	5		
		1	5		1
			1		
			1		
					1
			1		
					1
					1
					3
		20	117		11
					2
					1
			3		
		3	14		1
		3	7	1	8
					1
			9		8
			1		2
					2
		23	187	3	25
			1		
			1		
		1	1		1
			5		
	1			15	88
			3		1
			1		
		4	9	1	2
		1	6		
			3		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysarthria	1	9
Dysentery		2
Dysgeusia	2	9
Dysgraphia		2
Dyskinesia		7
Dyspepsia	2	7
Dysphagia	2	17
Dysphemia	1	2
Dysphonia	1	10
Dyspnoea	21	107
Dyspnoea exertional		2
Dysstasia	2	21
Dysuria	1	8
Ear discomfort	1	3
Ear disorder		2
Ear haemorrhage		1
Ear infection		1
Ear infection bacterial		1
Ear pain	7	17
Ear swelling		2
Eating disorder	1	12
Eating disorder symptom		1
Eczema	1	1
Electrolyte imbalance	1	2
Embolic stroke		1
Emotional disorder		3
Emotional distress		1
Emphysema	1	1
Encephalitis	1	1
Endometrial cancer	1	2
Energy increased		1
Enterovesical fistula	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3	1	6
					2
		2	8		1
			2		
			5		2
		2	7		
		2	14		3
		1	1		1
			9	1	1
		12	68	9	39
			2		
		1	12	1	9
			5	1	3
		1	3		
					2
			1		
			1		
					1
		7	16		1
			2		
			7	1	5
			1		
		1	1		
				1	2
					1
			2		1
			1		
		1	1		
				1	1
				1	2
			1		
				1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eosinophil count decreased		1
Eosinophil count increased		2
Epistaxis	1	16
Eructation		2
Erythema	6	55
Erythema multiforme		1
Erythema of eyelid		1
Essential tremor	1	1
Euphoric mood	1	2
Exaggerated startle response	1	1
Excessive cerumen production		1
Exposure during pregnancy	1	1
Exposure to SARS-CoV-2		3
Exposure via skin contact		2
Extra dose administered		1
Extrasystoles	1	5
Eye discharge		1
Eye disorder	2	5
Eye haemorrhage		1
Eye infection		1
Eye inflammation		1
Eye irritation	1	3
Eyelid disorder	1	1
Eyelid haematoma		1
Eye movement disorder		1
Eye pain		9
Eye pruritus		5
Eye swelling		6
Face injury		2
Face oedema		1
Facial pain		4
Facial paralysis	1	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		1
		1	9		7
			2		
		5	49	1	6
					1
			1		
		1	1		
		1	2		
		1	1		
					1
		1	1		
			3		
			2		
			1		
		1	4		1
			1		
		1	3	1	2
					1
			1		
			1		
		1	3		
		1	1		
			1		
					1
			9		
			4		1
			5		1
			2		
					1
			4		
				1	7

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Faeces discoloured		1
Faeces soft		2
Fall	10	50
Fatigue	55	334
Fear		3
Feeding disorder	2	9
Feeling abnormal	20	135
Feeling cold	4	22
Feeling drunk	1	2
Feeling hot	2	31
Feeling jittery	1	1
Feeling of body temperature change		3
Femur fracture		1
Fibromyalgia		1
Flank pain		1
Flat affect	1	1
Flatulence		4
Fluid intake reduced		1
Fluid retention		3
Flushing	1	8
Food allergy		2
Food aversion		1
Foot deformity		1
Freezing phenomenon	1	1
Frequent bowel movements		3
Frustration tolerance decreased	1	3
Functional gastrointestinal disorder		1
Fungal peritonitis		1
Furuncle		1
Gait disturbance	9	72
Gait inability	3	23
Gallbladder disorder		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		1
		4	23	6	27
		49	303	6	31
			3		
		2	9		
		19	129	1	6
		4	21		1
		1	2		
		2	31		
		1	1		
			2		1
					1
			1		
					1
		1	1		
			3		1
					1
			1		2
		1	7		1
			2		
			1		
			1		
		1	1		
			3		
		1	2		1
			1		
					1
			1		
		7	54	2	18
		1	13	2	10
					2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastric disorder	1	5
Gastric ulcer		1
Gastroenteritis viral		1
Gastrointestinal bacterial infection	1	1
Gastrointestinal disorder	2	5
Gastrointestinal haemorrhage		2
Gastrointestinal motility disorder		1
Gastrointestinal pain	1	2
Gastrointestinal sounds abnormal	1	2
Gastrooesophageal reflux disease	1	5
General physical health deterioration		6
Genital herpes		1
Gingival bleeding		2
Gingival swelling		1
Gingivitis	1	1
Glassy eyes		2
Glaucoma		1
Glomerular filtration rate decreased		2
Glossitis		1
Glossodynia	1	2
Goitre	1	2
Gout	1	6
Grip strength decreased		1
Groin pain	1	5
Grunting		2
Guillain-Barre syndrome		2
Haematochezia		3
Haematocrit decreased		3
Haematoma		4
Haemoglobin decreased	1	9
Haemoptysis		5
Haemorrhage		6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	5		
					1
					1
				1	1
		2	2		3
					2
			1		
		1	2		
		1	2		
		1	4		1
			1		5
			1		
			2		
			1		
		1	1		
			1		1
					1
			2		
			1		
		1	2		
				1	2
			4	1	2
			1		
		1	4		1
			2		
					2
					3
			2		1
			3		1
		1	6		3
			3		2
					6

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haemorrhage subcutaneous		1
Haemorrhage urinary tract		1
Haemorrhagic varicella syndrome		1
Hair growth abnormal		1
Hallucination	2	12
Hallucination, auditory		3
Hallucination, visual		4
Hangover	1	2
Headache	44	253
Head discomfort	5	12
Head injury		6
Hearing disability		1
Heart injury		1
Heart rate abnormal	1	5
Heart rate decreased		1
Heart rate increased	3	32
Heart rate irregular	1	6
Hemiparesis	1	2
Hepatic enzyme increased		1
Hepatic failure		1
Herpes simplex	1	1
Herpes zoster	23	38
Hiatus hernia		1
Hip fracture		4
Hostility		1
Hot flush	4	13
Hunger		1
Hyperacusis		1
Hyperaesthesia		1
Hyperexplexia	1	1
Hyperhidrosis	6	26
Hyperpyrexia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
			1		
				2	12
					3
					4
		1	2		
		41	227	3	26
		4	9	1	3
			3		3
			1		
					1
		1	4		1
					1
		1	25	2	7
		1	5		1
				1	2
					1
					1
				1	1
		21	34	2	4
			1		
					4
					1
		4	11		2
			1		
			1		
			1		
		1	1		
		6	25		1
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypersensitivity	1	20
Hypersomnia	2	15
Hypertension	2	33
Hyperventilation	2	2
Hypoacusis	3	19
Hypoaesthesia	3	20
Hypoaesthesia oral		4
Hypokalaemia		1
Hypokinesia		3
Hypophagia		1
Hypopnoea		1
Hypotension		8
Hypothyroidism	1	2
Hypotonia		1
Hypoxic-ischaemic encephalopathy		1
Illrd nerve paralysis		1
Illness	9	53
Illusion	1	1
Immobile		2
Immune system disorder	1	2
Immune thrombocytopenia	1	4
Immunodeficiency		2
Impaired driving ability		1
Inappropriate schedule of product administration	11	71
Incoherent		3
Incontinence	1	3
Incorrect dose administered	2	10
Increased viscosity of bronchial secretion	1	1
Infection		3
Inflammation		11
Inflammatory marker increased		1
Influenza		7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			15	1	5
		2	13		2
		2	20		13
		1	1	1	1
		3	16		3
		3	16		4
			4		
					1
			1		2
					1
					1
			4		4
				1	2
			1		
					1
					1
		8	47	1	6
		1	1		
					2
		1	1		1
				1	4
1	1				2
			1		
		11	71		
			1		2
			1	1	2
		2	10		
		1	1		
			3		
			11		
			1		
			7		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Influenza like illness	4	23
Injected limb mobility decreased	2	2
Injection site discomfort		1
Injection site erythema		16
Injection site haemorrhage		2
Injection site induration		1
Injection site injury		1
Injection site joint pain		1
Injection site pain		20
Injection site pruritus	1	7
Injection site rash		1
Injection site reaction		1
Injection site scab		1
Injection site swelling		9
Injection site urticaria		1
Injection site warmth		6
Inner ear disorder		1
Insomnia	9	57
Instillation site pain		1
Intentional product misuse		1
Intentional product use issue	1	1
Internal haemorrhage		1
International normalised ratio decreased		1
International normalised ratio increased		2
Intervertebral disc degeneration		1
Intervertebral discitis		1
Intestinal ischaemia		1
Intestinal perforation		1
Irritability	1	3
Irritable bowel syndrome	1	1
Ischaemic stroke	1	3
Jaundice		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	23		
		2	2		
			1		
			16		
			2		
			1		
			1		
			1		
			20		
		1	7		
			1		
			1		
			1		
			9		
			1		
			6		
			1		
		9	47		10
			1		
			1		
		1	1		
					1
					1
			1		1
			1		
					1
					1
					1
		1	2		1
		1	1		
				1	3
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Jaw disorder		2
Joint effusion		1
Joint injury	1	3
Joint lock		1
Joint range of motion decreased	1	6
Joint stiffness	1	5
Joint swelling	6	21
Joint warmth	1	1
Kidney infection		1
Lacrimation increased		6
Lactic acidosis		1
Large intestinal haemorrhage		1
Laryngeal oedema		1
Laryngeal pain	1	1
Laryngitis	3	3
Laziness		1
Lead dislodgement	1	1
Lethargy	4	28
Leukocytosis		1
Ligament rupture	1	1
Ligament sprain		1
Limb discomfort	1	19
Limb injury		5
Limb mass		1
Lip blister		1
Lip discolouration		1
Lip dry		1
Lip injury	1	1
Lip swelling	3	20
Localised infection		2
Localised oedema		1
Loss of consciousness	3	26

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
					1
			2	1	1
			1		
		1	5		1
		1	5		
		4	18	2	3
		1	1		
					1
			6		
			1		
					1
					1
		1	1		
		3	3		
			1		
				1	1
		3	22	1	6
			1		
		1	1		
			1		
		1	17		2
			5		
			1		
			1		
			1		
		1	1		
		2	14	1	6
			1		1
					1
				3	26

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Loss of control of legs		4
Loss of personal independence in daily activities	5	16
Lung disorder	1	3
Lung infiltration		2
Lung opacity		1
Lymphadenopathy	7	24
Lymph node pain		5
Lymphocyte count decreased		2
Lymphoedema	1	3
Macular degeneration		3
Macule		1
Maculopathy	1	1
Malaise	16	145
Mass		7
Mastication disorder		3
Mechanical urticaria	1	1
Medication error		2
Memory impairment	3	13
Meniere's disease		1
Meningitis viral		1
Mental disorder		4
Mental impairment	1	5
Mental status changes	1	2
Micturition disorder		1
Micturition urgency		1
Middle ear effusion		1
Middle insomnia		1
Migraine	2	7
Migraine with aura		1
Moaning		1
Mobility decreased	1	10
Monoclonal gammopathy		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					4
		4	14	1	2
		1	3		
			1		1
					1
		7	23		1
			5		
			2		
		1	3		
					3
			1		
				1	1
		16	123		22
			6		1
			3		
		1	1		
			2		
		3	11		2
					1
					1
			3		1
				1	5
		1	2		
					1
			1		
			1		
		1	5	1	2
					1
			1		
			6	1	4
			1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Monocyte count increased		1
Monoparesis		1
Motion sickness		1
Motor dysfunction		2
Mouth haemorrhage		2
Mouth injury	1	1
Mouth swelling	1	2
Movement disorder	2	10
Mucosal disorder		1
Mucous stools		1
Muscle contractions involuntary	1	1
Muscle contusion	1	1
Muscle discomfort	1	4
Muscle disorder		4
Muscle rigidity		1
Muscle spasms	4	21
Muscle strain	1	2
Muscle swelling		1
Muscle tightness	1	6
Muscle twitching	2	3
Muscular weakness	6	32
Musculoskeletal chest pain	2	8
Musculoskeletal discomfort		7
Musculoskeletal disorder		3
Musculoskeletal pain		1
Musculoskeletal stiffness	6	40
Mutism		2
Myalgia	21	101
Myasthenia gravis		1
Myocardial infarction	2	17
Myocarditis		1
Nail discolouration		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
			1		
			2		
			2		
				1	1
		1	2		
		2	10		
			1		
			1		
		1	1		
		1	1		
		1	4		
			3		1
					1
		4	17		4
		1	2		
			1		
		1	4		2
		2	2		1
		2	19	4	13
		2	6		2
			7		
			1		2
			1		
		5	34	1	6
			1		1
		20	95	1	6
					1
				2	17
					1
			1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nasal congestion	2	20
Nasal discomfort		3
Nasal mucosal disorder		1
Nasal oedema		1
Nasal pruritus		1
Nasopharyngitis	4	23
Nausea	15	172
Near death experience	1	5
Neck mass		1
Neck pain	5	39
Needle issue		1
Neoplasm		2
Neoplasm malignant	1	2
Neoplasm progression	1	1
Nerve compression	1	2
Nerve injury		3
Nervousness	2	14
Nervous system disorder	1	2
Neuralgia		2
Neurological symptom		1
Neuropathy peripheral		6
Neutrophil count decreased	1	2
Nightmare	1	5
Night sweats	3	7
Nipple pain		2
Nipple swelling		1
No adverse event	1	5
Nocturia		2
Nose deformity		2
Nystagmus		1
Obsessive thoughts		1
Obstructive airways disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	16		4
			3		
			1		
					1
			1		
		4	22		1
		15	155		17
				1	5
			1		
		3	33	2	6
			1		
			1		1
				1	2
				1	1
		1	2		
			3		
		2	12		2
		1	2		
			2		
			1		
					6
		1	2		
		1	5		
		3	7		
			2		
			1		
		1	5		
			2		
			2		
					1
					1
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ocular discomfort	1	3
Ocular hyperaemia	1	5
Ocular vascular disorder		1
Oedema		2
Oedema peripheral		3
Oesophageal achalasia		1
Oesophageal stenosis		1
Off label use	4	41
Oliguria		1
Ophthalmic vein thrombosis	1	1
Oral discomfort	1	3
Oral disorder	1	1
Oral herpes	2	7
Oral mucosal blistering	2	4
Oral pain		5
Oropharyngeal discomfort		7
Oropharyngeal pain		21
Osteoarthritis		1
Overdose	3	17
Oversensing		1
Oxygen consumption decreased		1
Oxygen saturation abnormal		1
Oxygen saturation decreased	2	15
Pain	38	217
Painful respiration		2
Pain in extremity	58	307
Pain in jaw	2	3
Pain of skin		2
Pallor		4
Palpable purpura		1
Palpitations	3	20
Pancreatitis acute		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		
		1	5		
			1		
			2		
			1		2
			1		
					1
		4	41		
			1		
				1	1
		1	3		
		1	1		
		2	7		
		2	4		
			5		
			7		
			18		3
			1		
		3	17		
			1		
					1
			1		
			4	2	11
		35	200	3	17
					2
		52	280	6	27
		1	2	1	1
			1		1
			1		3
			1		
		2	15	1	5
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Panic reaction		2
Paraesthesia	2	27
Paraesthesia oral	1	5
Paralysis	1	1
Paranasal sinus discomfort		1
Paranasal sinus hypersecretion		1
Paranoia	2	3
Parkinsonism		1
Parkinson's disease		1
Parosmia	2	5
Pelvic pain		1
Pemphigus		2
Pericardial effusion		1
Periorbital swelling		2
Peripheral artery thrombosis	1	1
Peripheral coldness		7
Peripheral swelling	12	60
Peripheral venous disease		2
Perivascular dermatitis		1
Personality change		1
Pertussis	1	1
Petechiae		4
Pharyngeal disorder		1
Pharyngeal enanthema		1
Pharyngeal erythema		1
Pharyngeal hypoaesthesia		1
Pharyngeal swelling		3
Phlebitis superficial		1
Photopsia		1
Piloerection	1	1
Plasma cell myeloma		1
Platelet count decreased		8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		2	24		3
		1	3		2
				1	1
			1		
			1		
		2	3		
					1
					1
		1	3	1	2
			1		
					2
					1
			1		1
				1	1
			7		
		7	49	5	11
			2		
			1		
					1
				1	1
			2		2
			1		
			1		
			1		
			1		
			3		
			1		
					1
		1	1		
					1
1	1		4		4

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Platelet count increased	1	1
Pleurisy		2
Pneumonia	3	24
Pneumonia aspiration		1
Pneumonia bacterial		1
Pneumonitis	1	1
Pneumothorax		1
Pollakiuria		3
Polydipsia		1
Polymyalgia rheumatica		2
Polyuria		1
Poor peripheral circulation		2
Poor quality product administered	2	10
Poor quality sleep		6
Post herpetic neuralgia		1
Potentiating drug interaction		1
Pre-existing condition improved	1	1
Presyncope	1	8
Product administered at inappropriate site		3
Product administration error		1
Product dose omission issue	1	8
Productive cough	3	9
Product leakage		1
Product preparation error	1	4
Product preparation issue	1	8
Product prescribing error		1
Product quality issue	1	2
Product storage error	1	6
Product supply issue	2	2
Product use issue	1	15
Pruritus	11	113
Psoriasis		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		1
				3	24
					1
					1
				1	1
					1
			3		
			1		
					2
			1		
			2		
		2	10		
			6		
			1		
			1		
		1	1		
		1	6		2
			3		
			1		
		1	8		
		3	9		
			1		
		1	4		
		1	8		
			1		
		1	2		
		1	6		
		2	2		
		1	15		
		10	98	1	15
			2		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Psychomotor hyperactivity		1
Psychotic disorder		2
Pulmonary congestion		1
Pulmonary embolism	2	9
Pulmonary fibrosis		2
Pulmonary oedema	2	6
Pulmonary pain		1
Pulmonary thrombosis	2	2
Pulse abnormal		2
Pulse absent		1
Pulse pressure decreased		1
Purpura		1
Pustule		1
Pyrexia	25	180
Rash	18	108
Rash erythematous	1	16
Rash macular	3	23
Rash maculo-papular		1
Rash morbilliform		1
Rash papular	1	7
Rash pruritic	5	21
Rash vesicular		1
Reaction to excipient		2
Red blood cell count decreased	3	5
Red blood cell sedimentation rate increased		2
Regurgitation	1	2
Renal atrophy		1
Renal disorder		3
Renal failure		5
Renal impairment	1	5
Renal infarct		1
Renal injury		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		1
					1
				2	9
					2
				2	6
			1		
				2	2
			2		
					1
					1
					1
					1
		24	160	1	20
		17	101	1	7
		1	16		
		3	21		2
			1		
					1
		1	5		2
		4	18	1	3
			1		
			2		
		2	4	1	1
					2
		1	2		
					1
			2		1
					5
				1	5
					1
					1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Renal pain	1	1
Respiration abnormal		1
Respiratory arrest		3
Respiratory disorder		3
Respiratory distress		4
Respiratory failure		2
Respiratory rate decreased		1
Respiratory rate increased		2
Respiratory tract congestion		2
Restless legs syndrome		2
Restlessness		4
Retching		9
Rheumatoid arthritis		1
Rhinitis allergic		1
Rhinorrhoea	5	27
Road traffic accident	1	1
Rosacea		1
Rotator cuff syndrome	1	2
Salivary gland disorder		1
SARS-CoV-2 ant body test negative		4
SARS-CoV-2 test false positive		1
SARS-CoV-2 test positive	2	11
Scab		3
Sciatica	1	4
Scratch		4
Screaming	1	1
Secretion discharge		2
Sedation		1
Seizure	2	9
Senile dementia	1	1
Sensation of foreign body		3
Sensitive skin	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
			1		
					3
			1		2
					4
					2
			1		
					2
			2		
			2		
			3		1
			6		3
					1
			1		
		5	25		2
				1	1
			1		
		1	1		1
			1		
			4		
					1
			3	2	8
			3		
			2	1	2
			3		1
		1	1		
			2		
					1
				2	9
				1	1
			3		
		1	3		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sensory disturbance		2
Sensory loss	1	2
Sepsis		5
Seronegative arthritis		2
Serum sickness		1
Shock		3
Sinus bradycardia		1
Sinus disorder		6
Sinus headache	1	4
Sinusitis	2	8
Sinus pain	1	1
Sitting disability		1
Sjogren's syndrome		1
Skin burning sensation	1	2
Skin depigmentation		2
Skin discolouration		10
Skin disorder	1	4
Skin exfoliation		2
Skin fissures		1
Skin haemorrhage		2
Skin hypertrophy	1	1
Skin injury		1
Skin irritation	1	3
Skin laceration	1	1
Skin laxity		1
Skin lesion		4
Skin reaction		3
Skin swelling		1
Skin weeping	1	1
Sleep disorder	2	18
Small intestinal haemorrhage		1
Sneezing	2	17

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		1	1		1
					5
					2
					1
					3
			1		
			5		1
		1	4		
		2	6		2
		1	1		
					1
					1
		1	2		
			2		
			9		1
		1	3		1
			2		
			1		
			2		
		1	1		
			1		
		1	3		
		1	1		
			1		
			4		
			2		1
			1		
		1	1		
		1	17	1	1
					1
		2	16		1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Somnolence	4	39
Speech disorder	4	15
Spinal fracture	1	1
Spinal pain		1
Spinal stenosis		1
Splenic rupture	1	1
Stoma site haemorrhage	1	2
Stomatitis	1	3
Stress	3	4
Stupor	1	1
Subdural haematoma		1
Sunburn		1
Superficial injury of eye		1
Supraventricular tachycardia		1
Suspected COVID-19	2	10
Swelling	4	29
Swelling face	3	34
Swelling of eyelid		3
Swollen tongue		6
Symptom recurrence		1
Syncope	1	13
Syringe issue		1
Systemic lupus erythematosus	1	1
Systolic hypertension		1
Tachycardia	1	6
Tachypnoea		2
Taste disorder	2	5
Temperature regulation disorder	1	1
Temporomandibular joint syndrome		1
Tenderness	1	4
Tendonitis	1	2
Terminal insomnia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	32		7
		2	8	2	7
				1	1
			1		
			1		
				1	1
				1	2
		1	3		
		3	4		
		1	1		
					1
			1		
			1		
					1
			3	2	7
		4	26		3
		2	29	1	5
			3		
			5		1
			1		
				1	13
			1		
				1	1
					1
			4	1	2
			2		
		2	5		
		1	1		
			1		
		1	4		
			1	1	1
			1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Therapeutic response unexpected	2	10
Thinking abnormal		3
Thirst		2
Thoracic vertebral fracture		1
Throat irritation	1	11
Throat tightness	1	12
Thrombocytopenia	1	2
Thrombosis	13	31
Thyroid disorder		2
Tic		1
Tinnitus		12
T-lymphocyte count increased		1
Tongue biting		1
Tongue blistering	1	2
Tongue discomfort	1	3
Tongue disorder		2
Tongue dry	1	1
Tongue erythema		2
Tongue ulceration		1
Tonsillar hypertrophy		1
Tooth abscess	1	2
Toothache	2	4
Tooth infection		1
Tooth injury		1
Transient ischaemic attack	1	12
Tremor	7	38
Trigger finger		1
Trismus		1
Troponin increased	1	3
Tumour marker decreased		1
Type V hyperlipidaemia		1
Ulcer		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	10		
			3		
			2		
					1
		1	10		1
		1	9		3
				1	2
	1			13	31
			1		1
					1
			6		6
			1		
					1
		1	2		
		1	3		
			2		
		1	1		
			2		
			1		
			1		
		1	2		
		2	4		
			1		
			1		
				1	12
		7	26		12
			1		
			1		
				1	3
			1		
					1
			1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ulcer haemorrhage		1
Underdose		5
Unresponsive to stimuli		11
Upper respiratory tract congestion		1
Urge incontinence		1
Urinary incontinence	2	5
Urinary retention		2
Urinary tract infection	3	15
Urinary tract infection bacterial		1
Urine output decreased		1
Urine output increased		1
Urosepsis		1
Urticaria	12	39
Vaccination complication		1
Vaccination failure		12
Vaccination site bruising		8
Vaccination site discolouration	1	6
Vaccination site discomfort		7
Vaccination site dryness		1
Vaccination site erythema	8	45
Vaccination site haematoma		1
Vaccination site haemorrhage	1	6
Vaccination site hypoaesthesia		2
Vaccination site induration	1	5
Vaccination site inflammation		1
Vaccination site irritation		1
Vaccination site mass		7
Vaccination site movement impairment		1
Vaccination site pain	17	133
Vaccination site pruritus	3	22
Vaccination site rash		6
Vaccination site reaction	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			5		
					11
			1		
			1		
		2	5		
					2
		1	6	2	9
					1
			1		
			1		
					1
		11	35	1	4
			1		
	1				12
			8		
		1	5		1
			6		1
			1		
		7	43	1	2
			1		
		1	4		2
			1		1
		1	4		1
			1		
			1		
			6		1
			1		
		15	124	2	9
		3	19		3
			6		
			1	1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site scab		1
Vaccination site swelling	7	29
Vaccination site warmth	2	17
Varicella		1
Vascular dementia		1
Vascular pain		1
Venous thrombosis limb	1	1
Vertigo	2	23
Vessel puncture site bruise		1
Vestibular neuronitis		1
Viral infection	3	3
Viral myocarditis		1
Viral upper respiratory tract infection		1
Vision blurred	1	17
Visual acuity reduced		2
Visual field defect		1
Visual impairment	3	16
Vitamin B12 decreased		1
Vitamin D decreased		1
Volvulus		1
Vomiting	8	82
Vulvovaginal pain	1	1
Vulvovaginal swelling	1	1
Wa king aid user	1	3
Wa king disability	2	4
Weight abnormal		1
Weight decreased	1	21
Weight fluctuation		1
Weight increased	1	3
Wheezing	1	6
White blood cell count abnormal	1	1
White blood cell count decreased	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		6	27	1	2
		1	15	1	2
			1		
			1		1
				1	1
		2	19		4
			1		
					1
		3	3		
					1
			1		
		1	15		2
			2		
			1		
		3	11		5
					1
					1
					1
		8	69		13
		1	1		
		1	1		
		1	3		
		1	3	1	1
			1		
		1	18		3
			1		
		1	3		
			3	1	3
				1	1
		1	3		1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Wound		2				2		
Wound complication		1				1		
Wound haemorrhage		1				1		
Wound secretion		1						1
Wrong product administered	2	5			2	5		
Wrong schedule		2				2		
Wrong technique in device usage process		1				1		
Wrong technique in product usage process		4				4		
	1,304	8,346	3	8	1019	6396	285	1950

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	11	49	11	49		
Abdominal distension	2	7	1	6	1	1
Abdominal mass		1		1		
Abdominal pain	5	20	5	19		1
Abdominal pain lower		2		2		
Abdominal pain upper	11	53	11	51		2
Abdominal rigidity		2		2		
Abnormal dreams	1	5	1	5		
Abnormal faeces		1		1		
Abnormal sensation in eye		2		2		
Abortion spontaneous	2	4			2	4
Abscess		2		2		
Accident		3		1		2
Accidental exposure to product		31		31		
Accidental overdose	2	28	2	28		
Accidental underdose		2		2		
Acne	2	4	2	4		
Acute myeloid leukaemia		1				1
Adnexa uteri pain		1		1		
Adverse event	5	12	4	11	1	1
Adverse reaction		1		1		
Affective disorder		1		1		
Ageusia	7	37	7	33		4
Aggression		1		1		
Agitation		3		3		
Alanine aminotransferase increased		1		1		
Allergic cough		1		1		
Allergic reaction to excipient	1	2	1	2		
Allergy to chemicals	1	1	1	1		
Allergy to vaccine	3	14	2	12	1	2
Alopecia	1	5	1	5		
Amenorrhoea		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amnesia	1	4	1	4		
Anaemia		3		2		1
Anaesthesia		2		2		
Anal incontinence		2		2		
Anaphylactic reaction	4	98		1	4	97
Anaphylactic shock		3				3
Anger	2	3	2	3		
Angina pectoris	4	10			4	10
Angioedema		5				5
Angiopathy		1		1		
Anhedonia		1		1		
Animal bite		2		2		
Ankylosing spondylitis		1				1
Anosmia	6	32	6	29		3
Antibody test abnormal	1	4	1	4		
Antibody test negative	1	3		2	1	1
Anti-neutrophil cytoplasmic antibody positive vasculitis	1	1			1	1
Anxiety	12	50	12	48		2
Aphasia	1	6	1	5		1
Aphonia		5		5		
Aphthous ulcer		3		3		
Apnoea	1	1			1	1
Appendicitis		4				4
Appetite disorder		3		3		
Application site acne	1	1	1	1		
Application site pain		1		1		
Arrhythmia	2	8			2	8
Arthralgia	57	315	57	310		5
Arthritis	3	14	3	14		
Arthritis infective	1	1			1	1
Arthropathy		7		7		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropod bite	1	6	1	6		
Aspartate aminotransferase increased		1		1		
Aspiration		1				1
Asthenia	38	155	36	150	2	5
Asthenopia		1		1		
Asthma	5	21	4	18	1	3
Asymptomatic COVID-19	7	23	1	6	6	17
Atrial f brillation	4	18			4	18
Atrioventricular block	1	1	1	1		
Attention deficit hyperactivity disorder	1	1	1	1		
Atypical pneumonia		1				1
Auditory disorder		1		1		
Autoimmune disorder	2	5			2	5
Axillary mass	1	4	1	4		
Axillary pain	1	16	1	16		
Back disorder	2	8	1	7	1	1
Back injury	2	3		1	2	2
Back pain	37	141	36	134	1	7
Bacterial disease carrier		1		1		
Bacterial infection	1	1	1	1		
Bacterial vaginosis		1		1		
Balance disorder	4	13	3	11	1	2
Basedow's disease		1				1
Bed rest		1		1		
Bedridden	1	6	1	6		
Bell's palsy	6	43			6	43
Bite		1		1		
Bladder discomfort		1		1		
Bladder disorder		2		2		
Bladder pain		1		1		
Blepharospasm		2		2		
Blindness	3	9			3	9

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blister	2	12	1	10	1	2
Blood bilirubin increased	1	2	1	1		1
Blood blister		1		1		
Blood cholesterol abnormal		1		1		
Blood cholesterol increased	2	3	2	3		
Blood count abnormal		2		2		
Blood creatinine increased		1		1		
Blood disorder	1	5		2	1	3
Blood glucose abnormal		1		1		
Blood glucose decreased		5		4		1
Blood glucose fluctuation		1		1		
Blood glucose increased	2	19	1	16	1	3
Blood immunoglobulin G abnormal		1		1		
Blood immunoglobulin G decreased		1		1		
Blood immunoglobulin M abnormal		1		1		
Blood immunoglobulin M increased	2	2	2	2		
Blood magnesium decreased		1				1
Blood potassium decreased		2		1		1
Blood potassium increased		1				1
Blood pressure abnormal	1	8	1	8		
Blood pressure decreased		5		5		
Blood pressure fluctuation	5	6	5	6		
Blood pressure increased	9	45	6	29	3	16
Blood pressure systolic increased		1		1		
Blood sodium decreased		2		1		1
Blood test abnormal		1		1		
Blood testosterone decreased		1		1		
Blood triglycerides increased		1		1		
Blood urea increased		1		1		
Blood urine present		4		3		1
B-lymphocyte abnormalities	1	1	1	1		
Body temperature abnormal		8		8		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Body temperature decreased	1	8	1	7		1
Body temperature increased	4	23	4	23		
Bone development abnormal		1		1		
Bone marrow disorder	1	1	1	1		
Bone neoplasm		1				1
Bone pain	4	29	4	29		
Bone swelling		2		2		
Booster dose missed		1		1		
Bowel movement irregularity		2		2		
Bradycardia		1				1
Bradyphrenia		1		1		
Brain injury		2				2
Brain oedema	1	2			1	2
Breast abscess		1		1		
Breast cancer metastatic		1				1
Breast discharge		1		1		
Breast discomfort	1	1	1	1		
Breast engorgement		1		1		
Breast induration		2		2		
Breast mass		1		1		
Breast milk discolouration		1		1		
Breast pain	3	10	3	10		
Breast swelling	2	3	2	3		
Breast tenderness	1	1	1	1		
Breath odour		1				1
Breath sounds abnormal		1		1		
Bronchitis	1	8	1	4		4
Bronchospasm		1				1
Burning sensation	11	39	9	36	2	3
Burning sensation mucosal		1		1		
Bursitis		1		1		
Candida infection	1	2	1	2		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiac arrest	2	8
Cardiac discomfort		1
Cardiac disorder	7	21
Cardiac failure congestive		2
Cardiac fibrillation		1
Cardiac flutter		7
Cardiac valve disease		1
Cardiospasm		1
Cardiovascular disorder	1	1
Carpal tunnel syndrome		1
Cataract	2	4
Cellulitis		10
Cerebral arteriosclerosis	1	1
Cerebral artery occlusion	1	2
Cerebral disorder	2	3
Cerebral haemorrhage	1	4
Cerebral thrombosis	2	2
Cerebrovascular accident	6	24
Chapped lips		2
Cheilitis	1	1
Chest discomfort	12	57
Chest pain	26	67
Chillblains	1	2
Chills	134	701
Choking		1
Chromaturia	2	3
Chronic kidney disease		1
Chronic lymphocytic leukaemia	1	2
Chronic obstructive pulmonary disease	2	8
Circumoral swelling		1
Circumstance or information capable of leading to device use error		4

Spontaneous			
Nonserious		Serious	
I	C	I	C
		2	8
			1
4	14	3	7
			2
			1
			7
			1
	1		
1	1		
	1		
		2	4
			10
		1	1
		1	2
2	3		
		1	4
		2	2
		6	24
	2		
1	1		
11	47	1	10
20	50	6	17
1	2		
131	692	3	9
			1
2	3		
			1
		1	2
2	5		3
	1		
	4		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circumstance or information capable of leading to medication error	31	621	30	620	1	1
Clumsiness		2		2		
Cluster headache		1		1		
Coagulopathy		2				2
Cognitive disorder	1	6	1	6		
Cold sweat	3	19	3	19		
Colitis	1	2	1	2		
Colitis ulcerative		1				1
Coma	1	1			1	1
Completed suicide	1	2			1	2
Complication associated with device		1				1
Compression fracture	1	1			1	1
Computerised tomogram normal		1		1		
Computer vision syndrome		1		1		
Concussion		1		1		
Condition aggravated	13	44	13	38		6
Confusional state	4	16	3	14	1	2
Congenital anomaly	1	1			1	1
Conjunctivitis		1		1		
Conjunctivitis allergic		1		1		
Conjunctivitis bacterial	1	1			1	1
Conjunctivitis viral	1	1			1	1
Constipation	1	8	1	8		
Contraceptive diaphragm		1		1		
Contraindicated product administered		3		3		
Contraindication to vaccination		5		5		
Contusion	11	36	10	34	1	2
Coordination abnormal		3		2		1
Coronavirus infection	1	1			1	1
Coronavirus test positive		2				2
Cough	34	143	33	139	1	4

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Counterfeit product administered		1		1		
COVID-19	289	1,361	89	343	200	1018
COVID-19 pneumonia		6				6
Cranial nerve disorder		1		1		
C-reactive protein increased		1		1		
Crepitations		1		1		
Crohn's disease		4				4
Crying		4		4		
Cyanosis	2	4	2	4		
Cystitis	4	12	3	11	1	1
Daydreaming		1		1		
Deafness	3	12			3	12
Deafness bilateral	1	1			1	1
Deafness unilateral		2				2
Death	9	49			9	49
Decreased appetite	5	40	5	40		
Decreased immune responsiveness	1	1	1	1		
Deep vein thrombosis		4				4
Defaecation urgency	1	2	1	2		
Dehydration		5		4		1
Delirium	1	3			1	3
Dementia	1	6			1	6
Dental discomfort		6		6		
Dental restoration failure	1	2	1	2		
Depressed mood	1	7	1	7		
Depression	1	3	1	3		
Derealisation		1		1		
Dermatitis	1	2	1	2		
Dermatitis acneiform		1		1		
Dermatitis allergic	1	3		2	1	1
Dermatitis contact	2	4	2	4		
Diabetes mellitus		4				4

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diabetic foot infection		1		1		
Diabetic neuropathy		1		1		
Diaphragmalgia		1		1		
Diarrhoea	34	198	33	192	1	6
Diarrhoea haemorrhagic		2				2
Diastolic hypotension		1				1
Diplopia		2		2		
Discomfort	7	23	7	23		
Disease progression		1				1
Disease recurrence	7	14	5	10	2	4
Disorganised speech	1	1	1	1		
Disorientation	1	6	1	6		
Dissociation		1		1		
Disturbance in attention	1	4	1	4		
Diverticulitis		9				9
Dizziness	69	329	67	312	2	17
Dizziness exertional	1	1	1	1		
Dizziness postural	1	5	1	5		
Dose calculation error		1		1		
Drainage		1		1		
Drooling		1		1		
Drug effective for unapproved indication		1		1		
Drug hypersensitivity	1	14	1	13		1
Drug ineffective	215	1,111	1	1	214	1110
Drug interaction	1	9	1	6		3
Drug intolerance	1	2		1	1	1
Dry eye	1	4	1	4		
Dry mouth	3	11	3	10		1
Dry skin		2		2		
Dry throat	2	10	2	10		
Dysacusis		1		1		
Dysaesthesia		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysarthria		2		1		1
Dysgeusia	5	43	5	43		
Dyskinesia	1	9	1	9		
Dyspepsia	4	17	4	17		
Dysphagia	3	18	2	13	1	5
Dysphemia		1		1		
Dysphonia	1	14	1	11		3
Dyspnoea	29	150	25	121	4	29
Dyspnoea exertional	2	2	1	1	1	1
Dysstasia	2	13	2	9		4
Dystonia	1	1			1	1
Dysuria		3		3		
Ear congestion		1		1		
Ear discomfort	5	11	4	10	1	1
Ear disorder		3		3		
Ear infection	3	9	3	8		1
Ear neoplasm		1		1		
Ear pain	5	23	5	20		3
Ear pruritus	1	4	1	4		
Ear swelling	1	3	1	3		
Eating disorder	2	6	2	5		1
Ecchymosis		4		4		
Eczema	1	3	1	3		
Ejection fraction decreased	1	2			1	2
Electric shock sensation		1		1		
Emotional disorder		1		1		
Encephalitis	1	3			1	3
Endocrine ophthalmopathy		1				1
Endodontic procedure	1	1	1	1		
Energy increased		3		3		
Eosinophil count increased		1		1		
Eosinophilic oesophagitis		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Epigastric discomfort		1		1		
Epilepsy		2				2
Epistaxis	3	25	3	22		3
Epstein-Barr viraemia		1		1		
Epstein-Barr virus infection	1	1	1	1		
Erectile dysfunction		3				3
Erosive oesophagitis		1				1
Eructation		1		1		
Erythema	17	90	16	86	1	4
Erythema multiforme	1	1			1	1
Erythema of eyelid	1	2	1	2		
Escherichia infection		1				1
Euphoric mood		2		2		
Eustachian tube dysfunction	1	1	1	1		
Eustachian tube obstruction	1	1	1	1		
Expired product administered	15	62	15	62		
Exposure during pregnancy	13	36	11	31	2	5
Exposure to SARS-CoV-2	6	49	5	43	1	6
Exposure via breast milk	7	65	7	65		
Exposure via eye contact	1	4	1	4		
Exposure via skin contact		24		24		
Extra dose administered	1	3	1	3		
Extraocular muscle disorder	1	1	1	1		
Eye allergy		1		1		
Eye colour change		2		1		1
Eye contusion		2		2		
Eye discharge		2		2		
Eye disorder	2	14	2	12		2
Eye haemorrhage	1	4			1	4
Eye infection		3		3		
Eye injury		1				1
Eye irritation		8		8		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid infection		1		1		
Eyelid oedema		2		2		
Eyelid pain	1	3	1	3		
Eyelid ptosis		1		1		
Eyelid vascular disorder		1		1		
Eye oedema		1		1		
Eye pain	7	23	6	22	1	1
Eye pruritus		12		12		
Eye swelling	4	24	2	22	2	2
Face oedema		2		2		
Facial asymmetry		1		1		
Facial bones fracture		1				1
Facial discomfort	1	2	1	2		
Facial pain	1	11	1	11		
Facial paralysis	3	10			3	10
Facial spasm		1		1		
Faeces discoloured		2		2		
Faeces pale		1		1		
Faeces soft		2		2		
Fall	9	38	6	26	3	12
Fasciitis		1				1
Fatigue	155	767	152	759	3	8
Fear	2	6	2	6		
Fear of injection		1		1		
Febrile neutropenia		1				1
Feeding disorder	1	12	1	12		
Feeling abnormal	51	228	51	220		8
Feeling cold	6	52	6	52		
Feeling drunk	2	7	2	6		1
Feeling hot	13	60	12	56	1	4
Feeling jittery	1	6	1	6		
Feeling of body temperature change	3	11	3	11		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling of relaxation	1	1	1	1		
Femur fracture		1				1
Fibrin D dimer increased		2				2
Fibromyalgia	3	6	3	5		1
Flank pain		1		1		
Flat affect	1	1	1	1		
Flatulence		4		4		
Fluid intake reduced		1		1		
Fluid retention		4		4		
Flushing	5	42	4	37	1	5
Foetal cystic hygroma	1	2			1	2
Foetal death	2	2			2	2
Foetal exposure during pregnancy	1	2	1	1		1
Foetal growth restriction	3	4			3	4
Foetal heart rate abnormal		1				1
Foetal heart rate decreased		1				1
Foetal hypokinesia		1				1
Food allergy	1	5		3	1	2
Food poisoning	1	3	1	3		
Foreign body sensation in eyes		1		1		
Formication	1	4	1	4		
Freezing phenomenon		1		1		
Frustration tolerance decreased	2	6	2	6		
Fungal infection		3		3		
Furuncle		2		2		
Gait disturbance	6	33	5	31	1	2
Gait inability	3	13	3	11		2
Gallbladder disorder	1	2	1	2		
Gallbladder injury		1		1		
Gastric disorder		4		4		
Gastric haemorrhage		2				2
Gastritis		2		2		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastroenteritis viral		4		3		1
Gastrointestinal disorder	2	15	1	14	1	1
Gastrointestinal haemorrhage		1				1
Gastrointestinal infection	1	1			1	1
Gastrointestinal pain	2	4	2	4		
Gastrointestinal sounds abnormal		1		1		
Gastrooesophageal reflux disease		4		4		
Generalised tonic-clonic seizure	1	2			1	2
Genital haemorrhage		1				1
Gingival discomfort	1	2	1	2		
Gingival disorder	1	1	1	1		
Gingival pain	1	2	1	2		
Gingival swelling		5		5		
Gingivitis	3	4	3	4		
Glare		1		1		
Glassy eyes		1		1		
Glaucoma		4		1		3
Glomerular filtration rate decreased		1		1		
Glossitis	2	4	2	4		
Glossodynia	2	9	2	9		
Gout		8		8		
Granulocytes abnormal		1		1		
Grip strength decreased		2		2		
Groin pain		4		4		
Growing pains	1	1	1	1		
Guillain-Barre syndrome		3				3
Gun shot wound	1	1			1	1
Haemangioma		1				1
Haematemesis	1	2			1	2
Haematochezia	7	13			7	13
Haematoma		1		1		
Haematospermia		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematuria		2		1		1
Haemodialysis		1		1		
Haemolytic anaemia		1				1
Haemoptysis		2		2		
Haemorrhage	3	14			3	14
Haemorrhage urinary tract	1	1			1	1
Haemorrhoidal haemorrhage		1		1		
Haemorrhoids		1		1		
Hallucination	1	5			1	5
Hallucination, visual		1				1
Hand deformity		1				1
Hangover	1	4	1	4		
Headache	236	1,044	231	1024	5	20
Head banging	1	1	1	1		
Head discomfort	7	18	7	18		
Head injury	5	10	3	8	2	2
Head titubation		2		2		
Heart rate abnormal	4	7	4	7		
Heart rate decreased	1	5		3	1	2
Heart rate increased	22	110	17	94	5	16
Heart rate irregular		5		4		1
Heavy menstrual bleeding	5	6	5	6		
Hemiparesis		4				4
Hepatic cirrhosis		1				1
Hepatic enzyme abnormal		1				1
Hepatic enzyme increased		2		1		1
Hepatic haemorrhage		1				1
Hepatic lesion		1				1
Hepatitis A virus test positive		1		1		
Hepatitis D		1				1
Hernia		1				1
Hernia repair		1				1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes simplex		2		2		
Herpes virus infection	3	8	3	8		
Herpes zoster	83	127	79	122	4	5
Herpes zoster oticus		1				1
Herpes zoster reactivation	1	1	1	1		
Hiccups		2		2		
Hip fracture	2	4			2	4
HIV test false positive	1	2	1	2		
Hordeolum		1		1		
Hot flush	2	12	2	12		
Hunger	1	2	1	2		
Hyperacusis		1		1		
Hyperaesthesia	1	5		4	1	1
Hyperhidrosis	19	66	17	63	2	3
Hyperphagia		1		1		
Hyperpyrexia	1	1			1	1
Hypersensitivity	28	115	21	94	7	21
Hypersensitivity vasculitis		1				1
Hypersomnia	1	11		10	1	1
Hypertension	6	34	6	26		8
Hyperventilation		1				1
Hypoacusis	3	15	3	15		
Hypoaesthesia	24	105	22	91	2	14
Hypoaesthesia eye		1		1		
Hypoaesthesia oral	5	28	4	25	1	3
Hypogeusia		3		3		
Hypokinesia		4		4		
Hypophagia		1		1		
Hyposmia		1		1		
Hypotension	5	12	3	6	2	6
Hypothermia	1	2			1	2
Hypotonia		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoxia		3				3
Illness	47	207	41	192	6	15
Immune system disorder	3	11	3	11		
Immune thrombocytopenia		4				4
Immunodeficiency		1				1
Immunoglobulins abnormal		1		1		
Immunoglobulins decreased		2		2		
Impaired driving ability	1	4	1	4		
Impaired gastric emptying		1				1
Impaired work ability	1	4	1	4		
Implant site pain	1	1	1	1		
Inappropriate schedule of product administration	67	469	66	468	1	1
Incoherent	2	2	1	1	1	1
Incomplete course of vaccination	1	12	1	12		
Incorrect dosage administered		2		2		
Incorrect dose administered	19	56	18	55	1	1
Incorrect dose administered by product		1		1		
Incorrect route of product administration	5	67	5	66		1
Increased appetite		2		2		
Increased viscosity of upper respiratory secretion		1		1		
Induration		2		1		1
Infection	2	14		10	2	4
Infection parasitic		1		1		
Infectious mononucleosis		4		4		
Inflammation	2	14	2	14		
Inflammatory carcinoma of the breast	1	1			1	1
Inflammatory pain	1	1	1	1		
Influenza	6	48	5	47	1	1
Influenza like illness	16	107	16	107		
Infrequent bowel movements		1		1		
Initial insomnia		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site bruising		5		5		
Injection site discomfort		5		5		
Injection site erythema	3	11	3	11		
Injection site extravasation	1	4	1	4		
Injection site haematoma		1		1		
Injection site haemorrhage		3		3		
Injection site infection		1		1		
Injection site mass		2		2		
Injection site nodule		1		1		
Injection site pain	8	76	7	75	1	1
Injection site pruritus		5		5		
Injection site rash	1	6	1	6		
Injection site reaction		1		1		
Injection site swelling	1	11	1	11		
Injection site urticaria	1	1	1	1		
Injection site warmth		1		1		
Injury		6		3		3
Inner ear inflammation	1	1			1	1
Insomnia	13	67	12	65	1	2
Intentional dose omission		7		7		
Intentional overdose		1		1		
Intentional product misuse	1	6	1	6		
Intentional product use issue		1		1		
Intercepted medication error		2		2		
Intermenstrual bleeding		2		2		
Internal haemorrhage		2				2
International normalised ratio decreased		1		1		
International normalised ratio increased		3		3		
Intervertebral disc protrusion		2		1		1
Intranasal paraesthesia	1	1	1	1		
Intraocular pressure increased		1		1		
Iron deficiency	1	1	1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Irregular breathing		1		1		
Irritability	1	6		5	1	1
Irritable bowel syndrome		1		1		
Jaundice		1				1
Jaw disorder		1		1		
Joint effusion		1		1		
Joint injury	2	8	1	7	1	1
Joint lock		2		2		
Joint range of motion decreased		7		7		
Joint stiffness		3		3		
Joint swelling	4	26	4	23		3
Kidney infection	2	7			2	7
Knee deformity		1		1		
Laboratory test abnormal		3		3		
Laboratory test normal		1		1		
Lacrimation increased	2	17	2	17		
Laryngitis		1		1		
Laryngospasm		1		1		
Laziness	1	1	1	1		
Lethargy	7	49	7	48		1
Leukaemia	1	2			1	2
Leukaemia recurrent		1				1
Leukocytosis		1				1
Lichen planus		1		1		
Ligament sprain	1	3	1	3		
Limb discomfort	2	44	2	43		1
Limb injury	2	16	2	15		1
Limb mass	1	4	1	3		1
Lip blister		2		2		
Lip disorder		1		1		
Lip dry		1		1		
Lip oedema		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lip pain	1	3	1	3		
Lip pruritus		2		2		
Lip swelling	6	23	4	20	2	3
Liquid product physical issue		6		6		
Liver contusion		1				1
Localised infection		2		2		
Loss of consciousness	19	45			19	45
Loss of personal independence in daily activities	8	29	8	27		2
Lower limb fracture		2				2
Lower respiratory tract congestion		1		1		
Lower respiratory tract infection		1				1
Lung carcinoma cell type unspecified recurrent	1	1			1	1
Lung disorder		5		3		2
Lung neoplasm malignant		2				2
Lyme disease		3				3
Lymphadenitis	1	5	1	5		
Lymphadenopathy	23	151	20	143	3	8
Lymph node pain	2	17	2	17		
Lymphoedema	1	4	1	4		
Macular degeneration		2				2
Macule		2		2		
Malaise	68	372	64	357	4	15
Malignant melanoma	1	1			1	1
Mass	3	10	3	10		
Mastication disorder	1	2	1	2		
Maternal exposure before pregnancy	1	2	1	2		
Maternal exposure during breast feeding	2	4	2	4		
Maternal exposure during pregnancy	10	68	7	60	3	8
Maternal exposure timing unspecified	2	4	1	3	1	1
Mean cell haemoglobin decreased	1	1	1	1		
Mean platelet volume decreased	1	1	1	1		
Medication error		6		6		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Melanocytic naevus	1	1	1	1		
Memory impairment	5	14	5	14		
Meniere's disease	1	1			1	1
Meningitis bacterial	1	1			1	1
Meningitis viral		3				3
Menopause		1		1		
Menstrual discomfort		1		1		
Menstrual disorder	6	10	6	10		
Menstruation irregular	6	11	6	11		
Mental disorder	1	2		1	1	1
Mental fatigue		1		1		
Mental impairment	6	10			6	10
Mental status changes		1		1		
Microembolism		1				1
Micturition urgency		3		2		1
Middle insomnia	1	5	1	5		
Migraine	9	56	8	48	1	8
Miliaria		1		1		
Mobility decreased	4	13	4	10		3
Monocyte count increased		1		1		
Monoplegia	1	1			1	1
Motion sickness		1		1		
Motor dysfunction		1				1
Mouth cyst	1	1	1	1		
Mouth haemorrhage		1		1		
Mouth injury		2		2		
Mouth swelling		4		4		
Mouth ulceration		1		1		
Movement disorder	4	28	4	25		3
Mucosal dryness		1		1		
Mucous stools		1		1		
Multiple allergies		2		2		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Multiple sclerosis		2				2
Multiple sclerosis relapse		1				1
Mumps		1		1		
Muscle discomfort		2		2		
Muscle disorder		4		4		
Muscle fatigue		2		2		
Muscle rigidity	1	1	1	1		
Muscle spasms	13	49	12	47	1	2
Muscle strain		4		4		
Muscle swelling	1	1	1	1		
Muscle tightness	1	9	1	9		
Muscle twitching	6	16	6	16		
Muscular weakness	3	24	3	22		2
Musculoskeletal chest pain		6		6		
Musculoskeletal discomfort	2	12	2	12		
Musculoskeletal disorder		3		3		
Musculoskeletal pain		3		3		
Musculoskeletal stiffness	6	36	6	36		
Myalgia	45	297	45	296		1
Mydriasis	1	2	1	2		
Myelitis transverse		1				1
Myocardial infarction	9	22			9	22
Myocardial necrosis marker increased	1	1			1	1
Myocarditis	2	2			2	2
Nail discolouration		1		1		
Nail infection		1		1		
Nasal congestion	14	72	14	70		2
Nasal discomfort		7		7		
Nasal disorder	1	3	1	3		
Nasal oedema		1		1		
Nasopharyngitis	26	110	26	110		
Nausea	73	368	71	361	2	7

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Near death experience	3	8			3	8
Neck deformity	1	1	1	1		
Neck injury		2		2		
Neck mass	2	6	2	6		
Neck pain	15	80	15	76		4
Needle issue		8		8		
Neoplasm malignant	4	9			4	9
Nephrolithiasis	4	8			4	8
Nephropathy	1	1	1	1		
Nerve compression		5		5		
Nerve injury	2	4	1	3	1	1
Nervousness	3	21	3	20		1
Nervous system disorder	1	8	1	7		1
Neuralgia	1	15	1	15		
Neuritis		1		1		
Neurological examination normal		1		1		
Neurological symptom	1	3		2	1	1
Neuropathy peripheral	2	10			2	10
Neutropenia		2				2
Neutrophil count decreased		1		1		
Neutrophil count increased		1		1		
Nightmare	3	9	3	9		
Night sweats	2	13	1	12	1	1
No adverse event	5	29	5	29		
Noninfective gingivitis		3		3		
Occupational exposure to product	1	11	1	11		
Occupational exposure to SARS-CoV-2	1	3	1	2		1
Ocular discomfort	2	6	2	6		
Ocular hyperaemia	2	16	2	16		
Ocular icterus	1	1	1	1		
Odynophagia	1	5	1	5		
Oedema		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oedema peripheral		2		2		
Oesophageal disorder		1		1		
Off label use	49	331	49	331		
Ophthalmic migraine	1	1	1	1		
Optic neuritis		1				1
Oral discomfort	1	4	1	4		
Oral disorder	1	6	1	6		
Oral dysaesthesia		1				1
Oral fungal infection		1		1		
Oral herpes	4	18	4	18		
Oral mucosal blistering		3		3		
Oral mucosal eruption	1	1			1	1
Oral pain	1	5	1	5		
Oral pruritus		2		1		1
Oral viral infection		1		1		
Organ failure		1				1
Oropharyngeal discomfort	1	13	1	12		1
Oropharyngeal pain	23	134	23	131		3
Oropharyngeal spasm		1				1
Orthostatic hypotension		1		1		
Osteoarthritis		1		1		
Osteoporosis		2		2		
Overdose	500	672	500	672		
Oxygen consumption		1		1		
Oxygen saturation abnormal	1	3	1	3		
Oxygen saturation decreased	3	15	2	8	1	7
Pain	110	695	104	678	6	17
Pain in extremity	169	865	166	858	3	7
Pain in jaw	3	14	3	13		1
Pain of skin		5		4		1
Palatal swelling		1		1		
Pallor	2	5	1	4	1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Palmar erythema		1		1		
Palpitations	16	50	15	45	1	5
Pancreatic cyst		1		1		
Pancreatic disorder		1				1
Pancreatitis		2				2
Pancytopenia		1				1
Panic attack	2	7	1	5	1	2
Panic disorder		1		1		
Panic reaction		1		1		
Papule		1		1		
Paraesthesia	18	113	18	107		6
Paraesthesia oral	1	33		30	1	3
Paralysis	3	8			3	8
Paranasal sinus discomfort		3		3		
Paranasal sinus hypersecretion		2		2		
Paranoia		1		1		
Parkinsonism	1	1			1	1
Parkinson's disease		1				1
Parosmia	2	7	2	7		
Paternal exposure timing unspecified	1	1	1	1		
Pelvic discomfort		1		1		
Pelvic fracture	1	1			1	1
Pelvic pain		3		3		
Periarthritis	1	1	1	1		
Pericardial effusion	2	5			2	5
Pericarditis	1	3			1	3
Periorbital swelling		3		3		
Peripheral artery thrombosis		1				1
Peripheral coldness		9		9		
Peripheral swelling	29	131	27	127	2	4
Peripheral vascular disorder		1		1		
Peripheral venous disease		1		1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Petechiae	1	2	1	2		
Phantom limb syndrome		1		1		
Pharyngeal disorder		3		3		
Pharyngeal erythema		1		1		
Pharyngeal hypoaesthesia		1		1		
Pharyngeal inflammation		3		3		
Pharyngeal oedema		1				1
Pharyngeal paraesthesia	3	7	2	4	1	3
Pharyngeal swelling	5	20	5	16		4
Pharyngitis		2		2		
Pharyngitis streptococcal		1		1		
Photophobia	1	4	1	4		
Photopsia		2		1		1
Photosensitivity reaction	1	1	1	1		
Piloerection	1	2	1	2		
Plantar erythema		1		1		
Platelet count decreased	3	12	3	10		2
Platelet count increased		1		1		
Platelet disorder		1		1		
Pleural effusion	1	2			1	2
Pleurisy		2		1		1
Pneumonia	8	36			8	36
Pneumonia aspiration		1				1
Poisoning		1				1
Pollakiuria	1	5	1	5		
Polymenorrhoea	1	1	1	1		
Polyneuropathy		1				1
Poor quality product administered	222	530	222	530		
Poor quality sleep	4	10	4	10		
Postmenopausal haemorrhage	3	3			3	3
Post procedural complication		1				1
Potentiating drug interaction	1	14	1	14		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pre-existing condition improved		1		1		
Premature baby	1	6			1	6
Premenstrual syndrome		1		1		
Presyncope	2	12	1	9	1	3
Product administered at inappropriate site	5	35	5	35		
Product administered to patient of inappropriate age	1	2	1	2		
Product administration error	4	24	4	24		
Product colour issue		3		3		
Product complaint	1	6	1	6		
Product compounding quality issue		1		1		
Product confusion		1		1		
Product container issue		2		2		
Product dose omission in error		2		2		
Product dose omission issue	18	125	18	125		
Product expiration date issue	1	1	1	1		
Productive cough		4		3		1
Product label confusion		1		1		
Product label issue	1	1	1	1		
Product leakage	3	14	3	14		
Product lot number issue		1		1		
Product packaging issue	1	1	1	1		
Product packaging quantity issue		4		4		
Product preparation error	41	142	41	142		
Product preparation issue	341	519	341	519		
Product prescribing error	1	9	1	9		
Product quality issue	2	13	2	13		
Product storage error	71	114	71	114		
Product supply issue	2	27	2	27		
Product temperature excursion issue	114	298	114	298		
Product use complaint		1		1		
Product use issue	18	180	18	180		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Prostate cancer		3				3
Prostatic disorder	1	1	1	1		
Protein total increased		1		1		
Pruritus	41	174	37	165	4	9
Psoriasis	1	2	1	2		
Psoriatic arthropathy		1				1
Psychomotor hyperactivity		1		1		
Pulmonary congestion		4				4
Pulmonary embolism		7				7
Pulmonary fibrosis		1				1
Pulmonary mass		1				1
Pulmonary oedema	1	4		1	1	3
Pulmonary pain	5	7	5	6		1
Pulmonary thrombosis	5	8			5	8
Pulse abnormal		3		2		1
Purpura		1		1		
Pustule		2		2		
Pyrexia	170	846	163	829	7	17
Quality of life decreased		1		1		
Rash	50	235	43	222	7	13
Rash erythematous	9	22	9	22		
Rash macular	8	20	8	18		2
Rash morbilliform	1	3	1	3		
Rash papular		3		3		
Rash pruritic	7	30	7	30		
Rash vesicular		2		2		
Raynaud's phenomenon		1		1		
Reaction to excipient	2	4	1	3	1	1
Reaction to preservatives		1		1		
Reading disorder	1	1	1	1		
Rectal haemorrhage		1				1
Red blood cell abnormality		1				1

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Red blood cell count abnormal		1		1		
Red blood cell count decreased		2				2
Red ear syndrome		1		1		
Renal disorder	1	6	1	3		3
Renal failure	1	5			1	5
Renal pain	1	6	1	5		1
Respiration abnormal		2		2		
Respiratory arrest		2				2
Respiratory disorder	1	10		8	1	2
Respiratory disorder neonatal		1				1
Respiratory distress		1				1
Respiratory symptom		2		2		
Respiratory tract congestion	2	7	2	7		
Respiratory tract infection		2				2
Restless legs syndrome		1		1		
Restlessness		2		2		
Retching	1	9	1	9		
Retinal haemorrhage		1				1
Rheumatic disorder	1	1	1	1		
Rheumatoid arthritis	4	10			4	10
Rhinalgia	1	3	1	3		
Rhinitis		1		1		
Rhinitis allergic	1	2	1	2		
Rhinorrhoea	11	93	11	93		
Rib fracture		2				2
Road traffic accident	1	2	1	2		
Root canal infection		1		1		
Rubber sensitivity		1		1		
Sacroiliitis		1		1		
Saliva discolouration		1				1
Salivary hypersecretion		1		1		
Sarcoidosis		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
SARS-CoV-1 test positive		1		1		
SARS-CoV-2 ant body test negative		18		18		
SARS-CoV-2 ant body test positive		7		6		1
SARS-CoV-2 test false positive		1		1		
SARS-CoV-2 test negative		4		4		
SARS-CoV-2 test positive	8	138	2	20	6	118
Scar		1		1		
Sciatica	1	2	1	2		
Sciatic nerve neuropathy		1		1		
Scratch	1	5	1	4		1
Screaming		1		1		
Seasonal allergy	2	12	2	12		
Secretion discharge		3		3		
Sedation		4		4		
Seizure	7	27			7	27
Sensation of foreign body		7		7		
Sensitive skin	2	4	1	3	1	1
Sensitivity to weather change		1		1		
Sensory disturbance	2	9	2	8		1
Sensory loss	1	3	1	3		
Sepsis		5				5
Shock symptom		1				1
Shoulder injury related to vaccine administration	1	1			1	1
Sinus congestion	1	4	1	4		
Sinus disorder	2	17	2	17		
Sinus headache		6		6		
Sinusitis	4	31	4	28		3
Sinus operation		1		1		
Sinus pain		4		4		
Sitophobia		1		1		
Sitting disability		1		1		
Skin abrasion	1	1	1	1		

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Age Range

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin burning sensation	1	7	1	7		
Skin cancer	1	1			1	1
Skin depigmentation	1	1	1	1		
Skin discolouration	4	10	4	7		3
Skin disorder	1	10	1	10		
Skin erosion	1	1	1	1		
Skin exfoliation	1	2	1	1		1
Skin fissures		1		1		
Skin haemorrhage		1		1		
Skin infection		1		1		
Skin injury	1	1			1	1
Skin irritation	2	8	2	8		
Skin laceration		2		2		
Skin lesion	1	1	1	1		
Skin mass		1		1		
Skin odour abnormal		1		1		
Skin reaction		3		2		1
Skin swelling	1	2	1	2		
Skin warm	1	2	1	2		
Sleep apnoea syndrome		1		1		
Sleep deficit	1	1	1	1		
Sleep disorder	6	20	6	20		
Sleep disorder due to a general medical condition	1	1	1	1		
Sluggishness	1	6	1	6		
Sneezing	7	38	7	38		
Soft tissue swelling		1		1		
Somatic symptom disorder		1		1		
Somnambulism		1		1		
Somnolence	14	47	14	46		1
Speech disorder	3	17	2	15	1	2
Spinal compression fracture		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Spinal cord disorder		1				1
Spinal pain	1	5	1	5		
Spinal stenosis		1		1		
Sputum discoloured		2		2		
Staphylococcal infection		1				1
Stevens-Johnson syndrome	1	1			1	1
Stomatitis	1	4		3	1	1
Streptobacillus infection		1				1
Streptococcal infection	1	4	1	4		
Streptococcus test positive		2				2
Stress		6		6		
Suicidal ideation	2	3			2	3
Sunburn		1		1		
Suppressed lactation		1		1		
Supraventricular tachycardia		3		2		1
Suspected COVID-19	36	74	9	25	27	49
Swelling	16	85	14	82	2	3
Swelling face	14	52	11	45	3	7
Swelling of eyelid	1	4	1	4		
Swollen tongue	3	24	2	19	1	5
Syncope	9	30	1	1	8	29
Syphilis		1				1
Syringe issue		4		4		
Systemic inflammatory response syndrome		1				1
Systemic lupus erythematosus		3				3
Tachycardia	3	30	3	24		6
Tachycardia foetal		1				1
Tachypnoea		1		1		
Taste disorder	1	12	1	11		1
Teeth brittle		1		1		
Teething	1	1	1	1		
Temperature intolerance		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tenderness	4	8	4	8		
Tendonitis		3		3		
Tendon pain		1		1		
Tension		1		1		
Tension headache		1		1		
Thanatophobia		1		1		
Therapeutic product effect decreased	1	1	1	1		
Therapeutic response increased		1		1		
Therapeutic response unexpected	6	28	6	28		
Thermal burn	1	1	1	1		
Thinking abnormal	2	5	2	5		
Thirst	2	3	2	3		
Throat irritation	8	37	7	33	1	4
Throat tightness	4	28	2	21	2	7
Thrombocytopenia	1	5			1	5
Thrombosis	22	51			22	51
Thyroid cancer	1	2			1	2
Thyroid disorder		1		1		
Thyroid function test abnormal		1		1		
Thyroid hormones increased		1		1		
Thyroid mass		1		1		
Thyroid pain		1		1		
Tinnitus	27	64	26	60	1	4
Tongue biting		1		1		
Tongue blistering		1		1		
Tongue discolouration	2	2	2	2		
Tongue discomfort		2		2		
Tongue disorder	2	4	2	4		
Tongue dry		1		1		
Tongue erythema	1	1	1	1		
Tongue fungal infection		1		1		
Tongue paralysis		2				2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue pruritus		2		1		1
Tongue spasm		1		1		
Tongue ulceration		1		1		
Tonic clonic movements		1				1
Tonsillar erythema		1		1		
Tonsillar hypertrophy		1		1		
Tooth abscess		1		1		
Toothache	5	26	5	24		2
Tooth disorder		12		12		
Tooth extraction		4		4		
Tooth fracture	1	2	1	2		
Tooth infection	1	2	1	2		
Tooth injury	1	2	1	2		
Transaminases increased	1	2	1	2		
Transient global amnesia		1		1		
Transient ischaemic attack	1	2			1	2
Tremor	8	68	6	62	2	6
Trigeminal nerve disorder		1		1		
Trigger finger	1	1			1	1
Tuberculosis		2				2
Tumour pain	1	1			1	1
Tunnel vision	1	2			1	2
Type 2 diabetes mellitus	1	1			1	1
Ulcer		1		1		
Ulcer haemorrhage	1	1			1	1
Underdose	34	188	34	188		
Unresponsive to stimuli		1				1
Upper airway obstruction		1				1
Upper limb fracture		2				2
Upper respiratory tract congestion	2	6	2	6		
Upper respiratory tract infection	1	3	1	3		
Urethral haemorrhage		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urinary assistance device user		1		1		
Urinary incontinence	1	1	1	1		
Urinary retention	1	3			1	3
Urinary tract infection	11	51	9	44	2	7
Urine abnormality	1	2	1	2		
Urine analysis abnormal	1	1	1	1		
Urine odour abnormal	2	3	2	2		1
Urine output decreased	1	1	1	1		
Urticaria	40	122	39	116	1	6
Vaccination complication		3		3		
Vaccination error	1	6	1	6		
Vaccination failure	13	35			13	35
Vaccination site bruising	5	13	5	12		1
Vaccination site discharge		4		4		
Vaccination site discolouration	3	6	3	6		
Vaccination site discomfort	2	14	2	14		
Vaccination site erythema	4	55	4	55		
Vaccination site extravasation		11		11		
Vaccination site haemorrhage	2	22	1	21	1	1
Vaccination site hypersensitivity	1	2	1	2		
Vaccination site hypoaesthesia		4		4		
Vaccination site induration		10		9		1
Vaccination site inflammation		4		4		
Vaccination site injury		1		1		
Vaccination site irritation	1	3	1	3		
Vaccination site joint movement impairment	1	1	1	1		
Vaccination site joint pain	1	3	1	3		
Vaccination site lymphadenopathy		1		1		
Vaccination site mass	4	28	4	26		2
Vaccination site movement impairment	2	7	2	7		
Vaccination site nodule	1	1	1	1		
Vaccination site oedema		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	50	349	49	346	1	3
Vaccination site paraesthesia		7		5		2
Vaccination site pruritus	3	22	3	21		1
Vaccination site rash		16		16		
Vaccination site reaction	5	17	5	17		
Vaccination site scab		1		1		
Vaccination site scar	1	2	1	2		
Vaccination site swelling	7	57	7	56		1
Vaccination site urticaria		4		4		
Vaccination site vesicles		2		2		
Vaccination site warmth	3	22	3	22		
Vaginal disorder		1		1		
Vaginal haemorrhage	2	5	2	5		
Vagus nerve disorder		1				1
Varicella		1		1		
Vasculitis	1	2	1	2		
Vasodilatation	1	2	1	2		
Vein disorder		1		1		
Ventricular extrasystoles		1				1
Vertigo	10	45	10	40		5
Vessel puncture site haemorrhage		1		1		
Vessel puncture site injury		1		1		
Vestibular neuronitis		1		1		
Viral infection	4	10	4	7		3
Vision blurred	8	26	8	26		
Visual impairment	8	21	8	19		2
Vitamin D deficiency		1		1		
Vitreous degeneration		1				1
Vitreous detachment		1				1
Vitreous floaters		3		3		
Vomiting	30	136	27	132	3	4
Vomiting projectile		2		2		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Von Willebrand's disease		1				1
Water pollution		1		1		
Weight decreased	3	11	3	10		1
Wheezing	1	11	1	8		3
White blood cell count abnormal		1		1		
White blood cell count decreased		3		1		2
White blood cell count increased	3	5	2	2	1	3
Wound haemorrhage		1				1
Wrong dose		1		1		
Wrong product administered	11	40	10	39	1	1
Wrong schedule		7		7		
Wrong technique in product usage process	17	84	17	84		
Yawning	1	1	1	1		
Yellow skin	1	2	1	1		1
	5,679	24,665	4762	20546	917	4119

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred
UNITED STATES MINOR OUTLYING ISLA

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal pain upper		1		1
Diarrhoea		1		1
Dizziness		1		1
Pain in extremity		1		1
Vaccination site pain		1		1
		5		5

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

URUGUAY

Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Paraesthesia	1	1	1	1
Pruritus	1	1	1	1
	2	2	2	2

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fatigue	1	1	1	1
Headache	1	1	1	1
Pain	1	1	1	1
Pyrexia	1	1	1	1
	4	4	4	4

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inflammation		1		1
Maternal exposure during pregnancy	2	2	2	2
Pain		1		1
Synovial cyst		1		1
	2	5	2	5

* I=Interval, C=Cumulative

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

APPENDIX 2.5.3: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per Gender by Preferred Term per Country

Cumulative Reporting Period: Through 31-MAY-2021

Interval Reporting Period: 30-APR-2021 Through 31-MAY-2021

Total Number of Cases: 47,174 (Interval) / 167,956 (Cumulative)

Total Number of Adverse Events (PT): 174,177 (Interval) / 631,356 (Cumulative)

MedDRA Version: v.24.0J

Country Where Event Occurred

AFGHANISTAN

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills		1		1		
Erythema		1		1		
Facial paralysis		1				1
Feeling of body temperature change		1		1		
Muscle tightness		1		1		
Paraesthesia		1		1		
Pruritus		1		1		
Rash		1		1		
Swelling face		1		1		
		9		8		1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ALBANIA

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19		2		2
Off label use		1		1
Product use issue		1		1
		4		4

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

AMERICAN SAMOA

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills		1		1
Pain		1		1
		2		2

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Feeling cold	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ANDORRA

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product administered to patient of inappropriate age		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ANGOLA

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inappropriate schedule of product administration		1		1		
Nasopharyngitis		1				1
Pyrexia		1				1
Swollen tongue		1				1
Vomiting		1				1
		5		1		4

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ARGENTINA

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	1	1	1	1		
Blood immunoglobulin G decreased		1		1		
Blood immunoglobulin M decreased		1		1		
Blood pressure increased	1	1			1	1
Circumstance or information capable of leading to medication error		1		1		
Cognitive disorder	1	1			1	1
Confusional state	1	1			1	1
COVID-19	2	2	2	2		
Diabetes mellitus	1	2			1	2
Dizziness	1	1			1	1
Drug ineffective	1	1			1	1
Gait disturbance	1	1	1	1		
Gait inability	1	1	1	1		
Headache	1	1			1	1
Hot flush	1	1			1	1
Hyperhidrosis	1	1			1	1
Hypersensitivity		1		1		
Hypertension	1	1	1	1		
Influenza	1	1	1	1		
Injection site erythema	1	1	1	1		
Intentional product misuse		1		1		
Intervertebral disc protrusion	1	1			1	1
Lung disorder	1	1	1	1		
Malaise	1	1	1	1		
Memory impairment	1	1			1	1
Mobility decreased	1	1	1	1		
Motor dysfunction	1	1			1	1
Nausea	1	1			1	1
Pain	1	1	1	1		
Pain in extremity		1		1		
Pruritus	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary thrombosis	1	1			1	1
Pyrexia	2	2	1	1	1	1
Rash papular	1	1	1	1		
Suspected COVID-19	1	1			1	1
Thunderclap headache	1	1			1	1
Thyroid disorder	1	1	1	1		
Vertigo	1	1			1	1
	34	41	16	22	18	19

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	1			1	1
Drug ineffective	1	1			1	1
SARS-CoV-2 ant body test negative		1		1		
	2	3		1	2	2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

AUSTRALIA

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	2	1	2		
Abdominal pain	13	25	13	24		1
Abdominal pain lower		1		1		
Abdominal pain upper		1		1		
Abdominal sepsis	1	1			1	1
Abdominal tenderness		1		1		
Abortion spontaneous	2	2			2	2
Accidental overdose		1		1		
Acute coronary syndrome		1				1
Acute kidney injury	1	3			1	3
Acute macular outer retinopathy	1	1			1	1
Adverse event following immunisation	2	3			2	3
Ageusia	3	5	3	5		
Agitation	1	1			1	1
Altered state of consciousness		1				1
Amaurosis fugax	1	1			1	1
Anaemia	1	1	1	1		
Anal haemorrhage		1		1		
Anaphylactic reaction	18	52			18	52
Angina pectoris	1	1			1	1
Angioedema	9	12			9	12
Anosmia	1	1	1	1		
Anxiety		7		2		5
Aphasia	1	2	1	1		1
Aphonia	1	1	1	1		
Aphthous ulcer	1	1	1	1		
Apnoea	1	2			1	2
Areflexia		1				1
Arrhythmia	2	4			2	4
Arthralgia	42	79	42	79		
Arthritis	1	1	1	1		
Aspiration		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	2	7	2	7		
Asthma	6	7	6	7		
Atrioventricular block complete	1	1			1	1
Axillary pain		1		1		
Back pain	1	2	1	2		
Balance disorder		1				1
Bell's palsy	4	6			4	6
Bicytopenia	1	1			1	1
Blister	1	1	1	1		
Blood blister	1	1	1	1		
Blood creatine phosphokinase increased		1				1
Blood pressure decreased		2		2		
Blood pressure immeasurable	1	1			1	1
Blood pressure increased	3	7	3	5		2
Body temperature decreased	1	1			1	1
Body temperature increased	1	1			1	1
Bradycardia	3	4			3	4
Bronchitis	1	1	1	1		
Bronchospasm	1	2	1	2		
Burning sensation	1	1	1	1		
Cardiac arrest	1	4			1	4
Cardiac fibrillation	1	1			1	1
Cellulitis	3	4			3	4
Cerebral venous sinus thrombosis	1	1			1	1
Cerebrovascular accident	4	4			4	4
Chest discomfort	17	28	17	27		1
Chest pain	7	10	7	10		
Chills	27	60	27	59		1
Circulatory collapse		1				1
Circumstance or information capable of leading to medication error		1		1		
Cognitive disorder		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat	1	8	1	5		3
Coma scale abnormal	2	3			2	3
Concomitant disease progression	3	3	1	1	2	2
Condition aggravated	2	4	1	1	1	3
Confusional state	1	6	1	5		1
Conjunctival haemorrhage	2	3			2	3
Consciousness fluctuating		1				1
Contusion	3	7	2	5	1	2
Cough	43	67	43	67		
Crying		1		1		
Cyanosis		2		1		1
Deafness	1	2			1	2
Deafness neurosensory	1	1			1	1
Death	8	11			8	11
Decreased appetite	2	7	1	5	1	2
Deep vein thrombosis	14	15			14	15
Delirium		2				2
Demyelination		1				1
Depressed level of consciousness	3	5			3	5
Depressed mood		1		1		
Dermatitis allergic		1		1		
Dermatitis bullous	1	1			1	1
Diabetes mellitus		1				1
Diabetic ketoacidosis	1	2			1	2
Diarrhoea	12	21	12	21		
Disease progression	1	1	1	1		
Disorientation		1		1		
Disseminated intravascular coagulation	1	1			1	1
Dizziness	24	60	24	55		5
Drooling		1				1
Dry eye	1	1	1	1		
Dry mouth		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry throat	1	3	1	3		
Dysarthria	1	4			1	4
Dysgeusia	2	4	2	4		
Dyskinesia		1		1		
Dysphagia	1	5		2	1	3
Dysphonia	2	4	2	4		
Dyspnoea	53	72	50	63	3	9
Dysuria	1	1	1	1		
Ear pain	2	3	2	3		
Endometriosis	1	1			1	1
Epilepsy	1	1			1	1
Epistaxis	1	2	1	2		
Erythema	6	14	6	14		
Extensive swelling of vaccinated limb	4	5	4	4		1
Eye pain		2		2		
Eye pruritus		2		2		
Eye swelling	1	1	1	1		
Face oedema	1	2	1	2		
Facial pain		1		1		
Facial paralysis	2	7			2	7
Facial paresis	1	1	1	1		
Fall	6	9	3	4	3	5
Fatigue	42	96	42	96		
Febrile neutropenia	1	1			1	1
Feeling abnormal	1	4	1	3		1
Feeling cold	1	2	1	2		
Feeling hot	3	10	3	9		1
Feeling jittery		1		1		
Feeling of body temperature change	1	5	1	5		
Feeling of despair	1	1	1	1		
Fibrin D dimer increased	2	2	2	2		
Fine motor skill dysfunction	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Flushing	8	18
Foaming at mouth		1
Food refusal		1
Gait disturbance	3	5
Gastrointestinal disorder	1	1
Generalised tonic-clonic seizure	2	2
General physical health deterioration	1	2
Haematemesis		1
Haemorrhage	3	3
Haemorrhage intracranial	1	1
Hallucination	2	4
Hallucination, tactile		1
Hangover	1	1
Headache	93	194
Head discomfort		1
Heart rate increased	2	4
Heart rate irregular		1
Hemiparesis	1	2
Hemiplegia	1	1
Herpes zoster	1	3
Hot flush	3	5
Hyperaldosteronism	1	1
Hyperglycaemia		1
Hyperglycaemic hyperosmolar nonketotic syndrome		1
Hyperhidrosis	2	9
Hyperkalaemia	1	1
Hypersensitivity	3	6
Hypertension	7	28
Hypoaesthesia	3	9
Hypoaesthesia oral	2	2
Hypoglycaemia		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
8	18		
			1
	1		
3	5		
1	1		
		2	2
		1	2
			1
		3	3
		1	1
		2	4
			1
1	1		
93	193		1
	1		
2	4		
			1
		1	2
		1	1
1	3		
3	5		
		1	1
			1
2	8		1
		1	1
3	6		
7	27		1
3	9		
2	2		
	1		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hypophagia	1	2
Hypopnoea		1
Hypotension	5	14
Hypoxia	1	3
Illness		1
Inadequate aseptic technique in use of product		1
Incoherent	1	1
Incontinence		1
Inflammation		1
Influenza like illness	3	5
Injected limb mobility decreased		1
Injection site discomfort	1	1
Injection site hypersensitivity	1	1
Injection site pain		2
Injection site reaction		2
Insomnia	1	4
Ischaemic stroke		2
Joint stiffness		1
Joint swelling	1	2
Lacunar infarction	1	1
Laryngitis	1	2
Lethargy	66	102
Limb discomfort	2	4
Lip oedema	1	1
Lip swelling	6	9
Liver function test abnormal	1	1
Liver function test increased		1
Localised oedema		1
Local reaction	1	1
Loss of consciousness	3	6
Lower respiratory tract infection	12	12
Lymphadenopathy	7	24

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	2
	1		
3	10	2	4
		1	3
	1		
	1		
		1	1
	1		
	1		
3	5		
	1		
1	1		
1	1		
	2		
	2		
1	4		
			2
	1		
1	2		
		1	1
1	2		
65	99	1	3
2	4		
1	1		
6	9		
1	1		
	1		
	1		
1	1		
		3	6
		12	12
7	23		1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphoedema	1	1	1	1		
Malaise	5	18	4	14	1	4
Maternal exposure during pregnancy	1	1	1	1		
Menstruation irregular	2	2	1	1	1	1
Migraine	3	5	3	5		
Migraine with aura		1		1		
Miliaria	1	1	1	1		
Monoplegia	1	2			1	2
Mouth ulceration	1	1	1	1		
Multiple organ dysfunction syndrome	1	1			1	1
Multiple sclerosis	1	3			1	3
Multiple sclerosis relapse		1				1
Muscle spasms		1		1		
Muscle tightness		1		1		
Muscular weakness	1	2	1	2		
Musculoskeletal stiffness		2		2		
Myalgia	77	138	77	137		1
Myalgia intercostal	1	1	1	1		
Mydriasis		2				2
Myocardial infarction	1	2			1	2
Nasal congestion	5	7	5	7		
Nasopharyngitis	1	2	1	2		
Nausea	38	99	37	96	1	3
Neck pain		4		4		
Nerve injury		1		1		
Nervousness		2		1		1
Neuropathy peripheral		1				1
Neutrophil count decreased		1		1		
Night sweats		2		2		
Nystagmus	1	1	1	1		
Occipital neuralgia		1		1		
Ocular discomfort		1		1		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular hyperaemia	1	3	1	3		
Odynophagia		1		1		
Oedema	1	1	1	1		
Off label use		2		2		
Oral herpes	1	2	1	2		
Oropharyngeal pain	17	28	17	28		
Orthostatic tremor		1		1		
Oxygen saturation decreased	2	5	2	3		2
Oxygen saturation immeasurable	1	1			1	1
Pain	3	10	2	9	1	1
Pain in extremity	4	9	4	9		
Pallor	1	3	1	2		1
Palpitations	2	11	2	11		
Pancreatitis		1				1
Panic reaction		1		1		
Paraesthesia	3	19	3	19		
Paraesthesia oral	8	18	8	17		1
Pelvic fracture		1				1
Pelvic pain	1	1	1	1		
Peripheral circulatory failure		1				1
Peripheral coldness		1		1		
Peripheral swelling	1	2		1	1	1
Peritonsillar abscess	1	1			1	1
Petit mal epilepsy	1	1			1	1
Pharyngeal swelling	2	4	2	2		2
Pharyngitis	2	2	2	2		
Photophobia	1	2	1	2		
Photosensitivity reaction		1		1		
Platelet count increased	1	1	1	1		
Pleuritic pain		2		2		
Pneumonia	1	4			1	4
Pneumonia aspiration	2	4			2	4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumothorax	1	1			1	1
Poor quality product administered		1		1		
Presyncope	2	16	2	16		
Product preparation error		1		1		
Product use issue		2		2		
Pruritus	13	28	12	27	1	1
Pulmonary congestion	1	2			1	2
Pulmonary embolism	3	7			3	7
Pulmonary sepsis		1				1
Pupil fixed		3				3
Pupils unequal		1				1
Pyrexia	57	109	56	107	1	2
Rash	46	65	46	64		1
Rash macular		1				1
Rash maculo-papular	1	1	1	1		
Rash pruritic	4	7	4	7		
Rectal haemorrhage	2	3			2	3
Renal impairment	2	2			2	2
Respiratory distress		1				1
Respiratory rate increased		1				1
Respiratory symptom	1	1	1	1		
Respiratory tract infection		1				1
Restlessness	1	1	1	1		
Retching	2	2	2	2		
Rhinorrhoea	6	14	6	14		
Rhinovirus infection		1		1		
Rotator cuff syndrome	1	1	1	1		
Scar		1		1		
Seizure	5	7			5	7
Sensitive skin		1		1		
Sensory disturbance		1		1		
Sensory loss		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sepsis	5	8			5	8
Sinusitis	1	1	1	1		
Sinus pain		1		1		
Sinus tachycardia		1		1		
Skin sensitisation		1		1		
Somatic symptom disorder		1				1
Somnolence	1	4	1	3		1
Speech disorder		1		1		
Speech disorder developmental	1	1	1	1		
Spinal pain		1		1		
Splenomegaly	1	1	1	1		
Stridor	2	2	2	2		
Sweating fever	1	1			1	1
Swelling	7	9	7	9		
Swelling face		3		3		
Swelling of eyelid	1	1	1	1		
Swollen tongue	5	8	5	7		1
Syncope	36	62			36	62
Systemic lupus erythematosus	1	1			1	1
Tachycardia	14	29	14	26		3
Tachypnoea		2		1		1
Tendon rupture	1	1	1	1		
Terminal state	2	2			2	2
Thirst	1	1	1	1		
Throat irritation	9	15	9	15		
Throat tightness	6	12	6	10		2
Thrombocytopenia	4	4			4	4
Thrombophlebitis		1		1		
Thrombosis	1	1			1	1
Thrombotic stroke	1	1			1	1
Thunderclap headache	1	1	1	1		
Tinnitus	1	2	1	2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue oedema	1	1	1	1		
Tonsillitis	1	2	1	2		
Transient ischaemic attack	1	2			1	2
Transverse sinus thrombosis	1	1			1	1
Tremor	1	6	1	6		
Trigeminal neuralgia		1		1		
Unresponsive to stimuli	3	8			3	8
Urinary tract infection	1	1			1	1
Urosepsis		1				1
Urticaria	16	28	16	28		
Vaccination site bruising	1	2	1	2		
Vaccination site cellulitis		1		1		
Vaccination site discomfort	2	3	2	3		
Vaccination site erythema		6		5		1
Vaccination site hypersensitivity	1	1	1	1		
Vaccination site pain	10	30	10	29		1
Vaccination site pruritus		2		2		
Vaccination site rash	1	1	1	1		
Vaccination site reaction	49	87	49	87		
Vaccination site swelling	1	7	1	6		1
Vaccination site vesicles		1		1		
Vaccination site warmth		1		1		
Vaginal haemorrhage	1	1	1	1		
Vasculitis	1	1	1	1		
Vertigo		3		3		
Vertigo positional		1				1
Vision blurred	5	7	4	6	1	1
Visual acuity reduced	1	1	1	1		
Visual impairment		3		3		
Vomiting	12	38	11	29	1	9
Weight decreased		1				1
Wheezing	8	12	7	11	1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
White blood cell count decreased		1		1		
	1,288	2,592	1047	2099	241	493

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	2	4	2	4		
Accidental overdose		1		1		
Acute pulmonary oedema		1				1
Adrenocortical insufficiency acute		1				1
Adverse event following immunisation	1	2			1	2
Ageusia	1	1	1	1		
Agitation		1		1		
Anaphylactic reaction		3				3
Angioedema	1	1			1	1
Anxiety		1		1		
Aphonia	2	2	2	2		
Arthralgia	4	14	4	14		
Asthenia	1	1	1	1		
Back pain	2	3	2	3		
Balance disorder	1	2	1	2		
Bell's palsy	2	2			2	2
Blood pressure increased	1	2	1	2		
Body temperature increased		2		2		
Bradycardia	1	4			1	4
Brain stem stroke	2	2			2	2
Burning sensation		1		1		
Cardiac arrest	1	3			1	3
Cardiogenic shock	2	2			2	2
Cellulitis		1				1
Cerebral haemorrhage	1	2			1	2
Cerebrovascular accident	1	3			1	3
Chest discomfort	5	7	5	7		
Chest pain	4	7	3	6	1	1
Chills	2	10	2	10		
Cold sweat	1	3	1	3		
Concomitant disease aggravated	1	2			1	2

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Concomitant disease progression	3	3
Condition aggravated		1
Confusional state	1	1
Conjunctival haemorrhage	1	2
Contusion	1	4
Cough	8	15
COVID-19		1
Cyanosis	1	1
Deafness		1
Deafness neurosensory	1	1
Deafness unilateral	1	1
Death	5	8
Decreased appetite		1
Deep vein thrombosis	8	9
Depressed level of consciousness	1	3
Diarrhoea	3	6
Disease progression		1
Disorientation		1
Dizziness	4	10
Dry mouth	1	1
Dysgeusia	1	1
Dysphonia		1
Dyspnoea	14	22
Ear pain	1	1
Epistaxis	1	1
Exposure via breast milk		1
Extensive swelling of vaccinated limb		1
Eye discharge		1
Eye pain		2
Eye pruritus	1	1
Facial paralysis		1
Fall	1	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
		3	3
			1
1	1		
		1	2
1	4		
8	13		2
	1		
		1	1
			1
		1	1
		1	1
		5	8
			1
		8	9
		1	3
3	6		
			1
	1		
4	9		1
1	1		
1	1		
	1		
10	13	4	9
1	1		
1	1		
	1		
	1		
	2		
1	1		
			1
	1	1	2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fatigue	10	20	10	19		1
Feeling abnormal		2		2		
Feeling hot	1	1	1	1		
Fibrin D dimer increased	1	1	1	1		
Flushing	2	4	2	4		
Foaming at mouth	1	1	1	1		
Gait disturbance		1		1		
Gastrointestinal haemorrhage		1				1
Generalised tonic-clonic seizure	1	1			1	1
General physical health deterioration		3				3
Headache	15	34	15	33		1
Heart rate increased		1				1
Hot flush	1	1	1	1		
Hyperhidrosis	1	5	1	5		
Hypertension	2	4	2	4		
Hypoaesthesia	2	3	2	3		
Hypoaesthesia oral	1	2	1	1		1
Hyporesponsive to stimuli		1				1
Hypotension	1	5		3	1	2
Hypoxia		1				1
Influenza like illness		2		2		
Insomnia	1	2	1	2		
Intestinal obstruction	1	1			1	1
Lethargy	8	13	8	13		
Limb discomfort	1	1	1	1		
Loss of consciousness	1	6			1	6
Lymphadenopathy	2	5	2	5		
Lymphocyte count increased	1	1	1	1		
Malaise	7	12	7	9		3
Migraine		2		2		
Multiple organ dysfunction syndrome		1				1
Muscle spasms		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	7	19	7	19		
Myocardial infarction	1	1			1	1
Myokymia	1	1	1	1		
Nasal congestion	2	2	2	2		
Nasal pruritus	1	1	1	1		
Nasopharyngitis		1		1		
Nausea	5	13	5	13		
Nephrolithiasis	1	1			1	1
Ocular hyperaemia		1		1		
Oedema peripheral	1	2			1	2
Oral contusion	1	1	1	1		
Oropharyngeal pain	2	6	2	6		
Oxygen saturation decreased	2	4	2	2		2
Pain	2	3	1	2	1	1
Pain in extremity	4	6	4	6		
Pallor	1	1			1	1
Paraesthesia		6		6		
Pericarditis	1	1			1	1
Peripheral swelling	2	2	1	1	1	1
Petechiae	1	1	1	1		
Pneumonia	3	10			3	10
Pneumonia aspiration	1	2			1	2
Pneumonia viral		1				1
Presyncope	1	9	1	7		2
Product preparation error		1		1		
Pruritus	2	3	2	3		
Pulmonary congestion	1	1			1	1
Pulmonary embolism	1	1			1	1
Pyrexia	13	26	11	20	2	6
Rales	1	2	1	1		1
Rash	9	12	9	11		1
Rectal haemorrhage		2				2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory distress		1				1
Respiratory failure	1	4			1	4
Respiratory rate increased	1	2	1	1		1
Retinal artery occlusion		1				1
Rhinorrhoea	1	6	1	6		
Seizure	2	5			2	5
Septic shock		1				1
Soft tissue inflammation		1		1		
Somnolence	2	5	1	3	1	2
Subdural haemorrhage	1	1			1	1
Swelling		1		1		
Syncope	9	16			9	16
Tachycardia	2	2	1	1	1	1
Terminal state	1	1			1	1
Throat irritation	2	2	2	2		
Throat tightness	3	3	3	3		
Thrombocytopenia	3	3			3	3
Thrombosis	7	7			7	7
Transient ischaemic attack		1				1
Tremor	1	3	1	3		
Unresponsive to stimuli	1	5			1	5
Urinary incontinence		1				1
Urosepsis		1				1
Urticaria	4	7	4	7		
Vaccination site bruising		1		1		
Vaccination site discomfort	1	1	1	1		
Vaccination site hypersensitivity	1	1	1	1		
Vaccination site pain	3	11	3	11		
Vaccination site reaction	7	16	7	16		
Vaccination site swelling		1		1		
Vasoconstriction		1		1		
Venous thrombosis		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vertigo		1		1		
Vision blurred	2	2	2	2		
Vomiting	2	6	2	4		2
Wheezing	2	5	2	4		1
	285	608	199	415	86	193

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	3	1	3		
Anaphylactic reaction	8	25			8	25
Angioedema	1	1			1	1
Appendicitis		1				1
Arthralgia	2	4	2	4		
Asthenia	1	4	1	4		
Back pain		1		1		
Blood disorder		1		1		
Blood pressure increased	1	2	1	2		
Blood thyroid stimulating hormone increased	1	1	1	1		
Burning sensation	1	1	1	1		
Cerebrovascular accident		5				5
Chest discomfort		1		1		
Chest pain		4		4		
Chills	6	8	6	8		
Chronic obstructive pulmonary disease	1	1	1	1		
Circumstance or information capable of leading to medication error	1	1	1	1		
Cold sweat		1		1		
Cough	2	6	2	6		
COVID-19	1	2			1	2
Deafness		1				1
Deafness unilateral		2				2
Decreased appetite		1		1		
Deep vein thrombosis	1	2			1	2
Demyelination	1	1			1	1
Depressed level of consciousness		1				1
Diarrhoea	2	3	2	3		
Dizziness	5	11	5	11		
Drug ineffective	1	2			1	2
Dysphonia	1	1	1	1		
Dyspnoea	8	11	8	10		1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema		1		1		
Facial paralysis		1				1
Facial paresis	1	6	1	2		4
Fatigue	9	13	9	13		
Feeling hot	1	2	1	2		
Flushing	1	3	1	3		
Headache	10	17	10	17		
Heart rate increased	1	2	1	2		
Hot flush		1		1		
Hyperhidrosis		3		3		
Hypersensitivity	1	2	1	2		
Hypertension	1	6	1	6		
Hyperthyroidism	2	4			2	4
Hypoaesthesia		1		1		
Hypopnoea		1		1		
Influenza like illness	2	3	2	3		
Iridocyclitis		1				1
Lethargy	4	10	4	10		
Lip swelling	1	1	1	1		
Liver injury		1				1
Loss of consciousness	1	2			1	2
Lymphadenopathy	3	3	3	3		
Lymph node pain	1	1	1	1		
Malaise		1		1		
Mobility decreased		1		1		
Monoplegia		1				1
Muscle injury	1	1	1	1		
Muscle tightness		1		1		
Muscle twitching		1		1		
Musculoskeletal stiffness	1	1	1	1		
Myalgia	8	11	8	11		
Nasal congestion		1		1		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	4	9	4	9		
Neck pain	2	2	2	2		
Ocular hyperaemia		1		1		
Oropharyngeal pain	2	3	2	3		
Pain	2	2	2	2		
Pain in extremity		2		2		
Pain in jaw	1	1	1	1		
Palpitations	3	5	3	5		
Paraesthesia	1	4	1	4		
Paraesthesia ear		1		1		
Paraesthesia oral	1	2	1	2		
Pharyngeal swelling	1	1	1	1		
Photophobia		2		2		
Pneumonia		1				1
Postural orthostatic tachycardia syndrome	1	1	1	1		
Presyncope		1		1		
Productive cough	1	1	1	1		
Product use issue		1		1		
Pruritus	3	5	3	5		
Pulmonary embolism		1				1
Pulmonary oedema		1				1
Pyrexia	11	18	11	18		
Rash	7	13	7	13		
Rash erythematous		1		1		
Rash pruritic	1	1	1	1		
Retching		1		1		
Rhinorrhoea	1	1	1	1		
Seizure	2	7			2	7
Seizure like phenomena	1	1			1	1
Sensation of foreign body		1		1		
Sinus congestion	2	2	2	2		
Somnolence	1	1	1	1		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling	2	2	2	2		
Swelling face	2	2	2	2		
Swollen tongue	1	2	1	2		
Syncope	2	8			2	8
Tachycardia	4	5	4	5		
Tachypnoea		1		1		
Taste disorder	1	1	1	1		
Throat irritation		2		2		
Thrombophlebitis		1		1		
Tinnitus		2		2		
Tremor		3		3		
Urticaria	4	5	4	5		
Vaccination site erythema		1		1		
Vaccination site pain		2		2		
Vaccination site reaction	5	8	5	8		
Vaccination site swelling	1	1	1	1		
Vomiting		5		5		
Wheezing	1	1	1	1		
	166	359	145	282	21	77

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Country Where Event Occurred

AUSTRIA

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1		1		
Abdominal pain	3	7	2	3	1	4
Abdominal pain lower		2				2
Abdominal pain upper		3		2		1
Activated partial thromboplastin time prolonged		1				1
Acute coronary syndrome		1				1
Acute disseminated encephalomyelitis	1	4			1	4
Acute kidney injury		1				1
Acute left ventricular failure		1				1
Acute macular outer retinopathy		1				1
Acute myocardial infarction		1				1
Administration site hypoaesthesia		1		1		
Ageusia	2	4	1	3	1	1
Agitation	1	2	1	2		
Alanine aminotransferase increased	1	2		1	1	1
Allergy to vaccine	2	2	1	1	1	1
Alopecia	1	3	1	3		
Altered visual depth perception		1		1		
Amenorrhoea		1				1
Analgesic drug level above therapeutic		1				1
Anaphylactic reaction	2	10			2	10
Anaphylactic shock		3				3
Anaphylactoid reaction		2				2
Aneurysm ruptured		1				1
Angina pectoris	2	5			2	5
Angioedema		1				1
Anosmia	2	3	1	2	1	1
Antiphospholipid syndrome		1				1
Anxiety	1	4	1	2		2
Apathy		2		2		
Aphasia	2	4	1	2	1	2
Aphonia		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apnoea		1				1
Application site pain		1		1		
Arrhythmia	4	10			4	10
Arterial occlusive disease		1				1
Arterial thrombosis	1	1			1	1
Arteriosclerosis		1				1
Arteriosclerosis coronary artery		1				1
Arthralgia	58	108	56	83	2	25
Arthritis	1	1	1	1		
Aspartate aminotransferase increased	1	2		1	1	1
Aspiration		1				1
Asthenia	8	27	6	21	2	6
Asthma		2				2
Asymptomatic COVID-19	10	18			10	18
Atelectasis	1	2	1	1		1
Atrial fibrillation	1	5			1	5
Autoimmune thyroiditis		1				1
Axillary pain		1				1
Back pain	1	9	1	4		5
Balance disorder	1	3	1	2		1
Basilar migraine		1				1
Bedridden		1		1		
Beta globulin increased		1		1		
Biliary colic		1				1
Blepharospasm	1	2	1	1		1
Blister	1	1	1	1		
Blood albumin decreased		1		1		
Blood creatine phosphokinase MB increased		1				1
Blood fibrinogen increased	1	1	1	1		
Blood glucose fluctuation	1	2			1	2
Blood glucose increased	1	2	1	1		1
Blood lactate dehydrogenase increased	1	2		1	1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood lactic acid increased	1	1			1	1
Blood pressure abnormal		2				2
Blood pressure decreased	1	3			1	3
Blood pressure fluctuation	1	1			1	1
Blood pressure immeasurable		1				1
Blood pressure increased	3	10	3	6		4
Blood pressure systolic increased		1				1
Blood urea increased		1		1		
Body temperature increased	4	16	3	14	1	2
Bone marrow oedema		1				1
Bone pain	2	3	2	3		
Bradycardia		3				3
Breast pain		1		1		
Breath sounds		1		1		
Breath sounds abnormal		1				1
Bronchial obstruction		1				1
Bronchiolitis		1				1
Bundle branch block left		1				1
Bundle branch block right		1				1
Burning feet syndrome	1	1	1	1		
Burning sensation		2		1		1
Bursitis		2		1		1
Cachexia		1				1
Cardiac arrest		3				3
Cardiac death		1				1
Cardiac failure		6				6
Cardiac hypertrophy		1				1
Cardiomegaly	1	2		1	1	1
Cardiomyopathy		1				1
Cardiopulmonary failure		1				1
Cardio-respiratory arrest		2				2
Cardiovascular disorder	6	17	6	15		2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral haemorrhage		3				3
Cerebral infarction		2				2
Cerebral venous sinus thrombosis	2	3			2	3
Cerebrovascular accident	3	6			3	6
Chapped lips		1				1
Chest discomfort	2	10		3	2	7
Chest pain	5	13	1	5	4	8
Chills	1	1			1	1
Chills	48	121	47	93	1	28
Choking		1				1
Cholestasis		1				1
Chromaturia	1	1			1	1
Chronic kidney disease		1				1
Chronic obstructive pulmonary disease		1				1
Circulatory collapse	9	27			9	27
Coagulation factor increased	1	1			1	1
Coagulopathy		1				1
Cognitive disorder	1	1			1	1
Cold sweat		1				1
Concomitant disease aggravated		2				2
Concussion		1				1
Condition aggravated	3	5	1	1	2	4
Confusional state		2				2
Congestive hepatopathy		1				1
Conjunctival haemorrhage		2				2
Conjunctival hyperaemia	1	1	1	1		
Conjunctivitis		1				1
Contusion		1				1
Cough	6	16	4	13	2	3
COVID-19	45	65	2	6	43	59
COVID-19 pneumonia	1	4			1	4
C-reactive protein increased	3	6	2	3	1	3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cutaneous vasculitis	1	1			1	1
Deafness	1	1			1	1
Death	1	12			1	12
Decreased appetite	2	6	1	5	1	1
Deep vein thrombosis	7	13			7	13
Defaecation urgency		1		1		
Dehydration		1				1
Delirium		1				1
Depressed level of consciousness		1				1
Depression	1	1			1	1
Dermatitis allergic	1	3			1	3
Device related infection		1				1
Diarrhoea	14	37	12	30	2	7
Diarrhoea haemorrhagic		2				2
Diplopia	1	3		1	1	2
Discomfort	1	2	1	2		
Disease progression		1				1
Disease recurrence	2	4			2	4
Disorganised speech		1		1		
Disorientation		2		1		1
Disseminated varicella zoster virus infection		1				1
Disturbance in attention	2	8	2	5		3
Dizziness	28	86	23	61	5	25
Drug eruption		2				2
Drug ineffective	22	31			22	31
Dry mouth	1	6		3	1	3
Dry throat		1		1		
Dysacusis	1	1	1	1		
Dysaesthesia	2	6		1	2	5
Dysarthria		1				1
Dyschromatopsia	1	1			1	1
Dysgeusia	3	11	3	7		4

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysgraphia		1		1		
Dysphagia		7		3		4
Dyspnoea	16	51	5	12	11	39
Dyspnoea at rest	1	1			1	1
Dyspnoea exertional	2	7		1	2	6
Dysstasia		1		1		
Dysuria		1		1		
Ear discomfort		2		2		
Ear infection		1				1
Ear pain		1		1		
Ear pruritus	1	1	1	1		
Ear swelling	1	1	1	1		
Eczema	1	3	1	2		1
Electrocardiogram abnormal		1		1		
Emphysema		2		1		1
Endocrine ophthalmopathy		1				1
Epilepsy		2				2
Epistaxis	1	4	1	3		1
Erysipelas		1				1
Erythema	1	13	1	7		6
Exercise tolerance decreased		1		1		
Exposure during pregnancy		1		1		
External ear pain		1				1
Extrasystoles	2	5	1	2	1	3
Eye contusion		1				1
Eye haemorrhage		1				1
Eye irritation		1				1
Eyelid contusion		1				1
Eyelid oedema		1				1
Eye movement disorder		1				1
Eye pain	1	4		2	1	2
Eye pruritus		2		2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye swelling	1	2	1	2		
Face oedema		3				3
Facial asymmetry		1				1
Facial bones fracture		1				1
Facial pain	1	1			1	1
Facial paralysis	4	8			4	8
Facial paresis		9				9
Facial spasm		1				1
Faecal calprotectin increased		1				1
Faeces pale	1	1			1	1
Fall	1	6		1	1	5
Fatigue	92	189	86	161	6	28
Fear of disease	1	1			1	1
Febrile convulsion	1	1			1	1
Feeling abnormal	2	7	2	6		1
Feeling cold	3	8	3	4		4
Feeling drunk		2		2		
Feeling hot	1	10	1	5		5
Feeling of body temperature change	1	3	1	3		
Fibrin D dimer increased	3	4	3	4		
Flank pain		1				1
Flatulence		1		1		
Fluid retention	1	1	1	1		
Flushing	1	10		1	1	9
Foreign body aspiration		1				1
Formication		1		1		
Gait disturbance	3	10	3	7		3
Gastroenteritis		1		1		
Gastrointestinal disorder		2		2		
Gastrointestinal hypermotility		1		1		
Gastrointestinal motility disorder		1		1		
Generalised oedema		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Generalised tonic-clonic seizure		3				3
General physical health deterioration	5	14	1	3	4	11
Genital discomfort	1	1	1	1		
Gingivitis		1		1		
Glossopharyngeal nerve disorder		1				1
Groin pain		1		1		
Grunting		1		1		
Haematoma		1				1
Haematuria		1				1
Haemorrhage		1				1
Haemorrhage intracranial	1	1			1	1
Hallucination		1				1
Hand dermatitis		1		1		
Hangover		1		1		
Headache	113	243	105	196	8	47
Head discomfort	1	2	1	2		
Heart rate decreased		2				2
Heart rate increased	1	4	1	2		2
Heavy menstrual bleeding	2	3	1	1	1	2
Helicobacter infection		1				1
Helplessness	1	1	1	1		
Hemianaesthesia		1				1
Hemidysaesthesia		2				2
Hemiparaesthesia	2	4			2	4
Hemiparesis	1	4			1	4
Hemiplegia	1	1			1	1
Hepatic pain		2		1		1
Hepatic steatosis		1		1		
Herpes zoster	10	17	7	12	3	5
Herpes zoster cutaneous disseminated		1				1
Hirsutism		1		1		
Histamine intolerance		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hot flush		4		2		2
Hyperaesthesia		1				1
Hypereosinophilic syndrome	1	1			1	1
Hyperglycaemia		1				1
Hyperhidrosis	2	4	2	3		1
Hyperkalaemia	1	1			1	1
Hypernatraemia		1				1
Hypersensitivity	4	17	1	2	3	15
Hypersomnia		1		1		
Hypertension	4	13	1	2	3	11
Hypertensive crisis	3	10			3	10
Hypertensive emergency	1	2			1	2
Hyperventilation	1	3			1	3
Hypoacusis	2	2	1	1	1	1
Hypoaesthesia	3	23	2	10	1	13
Hypoaesthesia oral	2	9	2	4		5
Hypogeusia		2		1		1
Hypoglossal nerve paresis		1				1
Hypoglycaemia	1	2			1	2
Hypokalaemia		1				1
Hypokinesia		1		1		
Hyponatraemia	2	2			2	2
Hypophagia		1				1
Hypopnoea		1				1
Hyposmia		1				1
Hypotension	3	10	3	4		6
Hypothermia	3	3			3	3
Hypotonia		4		3		1
Illness		1				1
Immobilisation syndrome	1	1			1	1
Immunisation anxiety related reaction	1	1			1	1
Impaired driving ability		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Impaired work ability	3	11	1	5	2	6
Inappropriate schedule of product administration	2	3	2	3		
Incontinence		1				1
Incorrect dose administered		1		1		
Incorrect route of product administration	2	9	2	9		
Inflammation		1				1
Inflammatory bowel disease	1	1			1	1
Influenza like illness	4	8	4	7		1
Injected limb mobility decreased		1				1
Injection site bruising		1		1		
Injection site pain		2		2		
Injection site paraesthesia		1		1		
Injury		1				1
Insomnia		5		4		1
Intentional overdose		1				1
Interleukin level increased		1				1
Intermenstrual bleeding	1	2	1	1		1
International normalised ratio fluctuation	1	1			1	1
Intervertebral disc protrusion	1	2			1	2
Intraventricular haemorrhage		1				1
Ischaemic cerebral infarction		1				1
Ischaemic stroke		1				1
Jaundice	1	1			1	1
Joint swelling	1	4	1	2		2
Lacrimation increased		1		1		
Language disorder		1		1		
Laryngeal oedema		1				1
Laryngeal pain		1				1
Laryngospasm		1				1
Leukocytosis		1				1
Leukoencephalopathy		1				1
Leukopenia		2				2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Limb discomfort		1				1
Lip dry		2		1		1
Lip erythema		1				1
Lip pruritus		1				1
Lip swelling		6				6
Listless	1	1			1	1
Lividity		1		1		
Localised oedema		1				1
Locked-in syndrome		1				1
Loss of consciousness		6				6
Loss of personal independence in daily activities	1	3			1	3
Low density lipoprotein increased	1	1			1	1
Lung disorder		1		1		
Lung infiltration		1				1
Lymphadenopathy	13	37	10	20	3	17
Lymph node pain	5	7	5	7		
Lymphoedema	2	2			2	2
Lymphopenia		1		1		
Malaise	6	14	5	9	1	5
Marasmus	1	2			1	2
Mass	1	1	1	1		
Maternal exposure during pregnancy		1		1		
Memory impairment	1	4		1	1	3
Meningism		1				1
Menstruation irregular	2	3	1	1	1	2
Mesenteric vein thrombosis	1	1			1	1
Migraine	1	4		3	1	1
Monoparesis	1	3			1	3
Monoplegia	1	3			1	3
Mouth swelling		2				2
Mouth ulceration	1	1			1	1
Movement disorder		2		2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Multiple organ dysfunction syndrome		1				1
Multiple sclerosis	1	3			1	3
Muscle atrophy		1		1		
Muscle contractions involuntary		1		1		
Muscle disorder		1				1
Muscle rigidity	1	1	1	1		
Muscle spasms		6		3		3
Muscle twitching	1	2	1	2		
Muscular weakness		8		2		6
Musculoskeletal chest pain		1				1
Musculoskeletal disorder	1	2	1	1		1
Myalgia	54	97	53	82	1	15
Myasthenia gravis	1	1			1	1
Myocardial infarction	2	5			2	5
Myocarditis	1	3			1	3
Myosclerosis	1	1			1	1
Narcolepsy		1				1
Nasal congestion	1	1	1	1		
Nasopharyngitis	1	1	1	1		
Nausea	42	104	39	78	3	26
Neck pain	4	10	4	9		1
Neoplasm malignant		1				1
Nerve conduction studies abnormal		1				1
Neuralgia		3		1		2
Neuralgic amyotrophy		1				1
Neuritis		1				1
Neuropathy peripheral		1				1
Night sweats		2		1		1
Nuchal rigidity		2		1		1
Obstructive airways disorder		1		1		
Ocular hyperaemia		2		2		
Oedema		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oedema mucosal		1		1		
Oedema peripheral		2				2
Off label use	3	9	3	9		
Onychoclasia		1		1		
Ophthalmoplegia	1	1			1	1
Opiates positive		1				1
Optic neuritis	1	1			1	1
Oral discomfort		2				2
Oral herpes	2	2			2	2
Oral mucosal erythema		1				1
Oral pruritus		2				2
Oral pustule		1		1		
Oropharyngeal pain	5	13	3	8	2	5
Oropharyngeal swelling	1	1	1	1		
Oxygen saturation		1				1
Oxygen saturation decreased		6		2		4
Oxygen saturation immeasurable		1				1
Pain	7	20	6	13	1	7
Painful respiration	1	2		1	1	1
Pain in extremity	28	86	26	67	2	19
Pain in jaw	2	2	2	2		
Pain of skin	1	1			1	1
Palatal swelling		1				1
Pallor		7		2		5
Palmar erythema		1				1
Palpitations	5	24	4	10	1	14
Pancytopenia	1	1			1	1
Panic attack		1				1
Panic reaction		1		1		
Paraesthesia	8	43	3	16	5	27
Paraesthesia oral	3	8	2	3	1	5
Paralysis	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paresis		1				1
Pelvic venous thrombosis	1	1			1	1
Performance status decreased	1	1			1	1
Pericardial effusion		2				2
Pericarditis		1				1
Periorbital swelling	1	2	1	1		1
Peripheral coldness		1		1		
Peripheral swelling	4	10	2	4	2	6
Peroneal nerve palsy		1				1
Personality change		1				1
Petechiae	2	4		1	2	3
Pharyngeal swelling		3		1		2
Phlebitis superficial	1	1			1	1
Phobic postural vertigo	1	1	1	1		
Photophobia	1	5		4	1	1
Platelet count decreased	1	1			1	1
Platelet count increased		1		1		
Pleural effusion		2				2
Pleurisy		1				1
Pneumonia	1	7			1	7
Pneumonia aspiration		1				1
Pollakiuria		1		1		
Poor peripheral circulation		1		1		
Presyncope	4	23	3	8	1	15
Product administered at inappropriate site		1		1		
Productive cough		1		1		
Product use issue	1	6	1	6		
Prohormone brain natriuretic peptide increased	1	1	1	1		
Prurigo		1				1
Pruritus	5	35	2	8	3	27
Pruritus allergic		1				1
Pulmonary congestion		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary embolism	8	22			8	22
Pulmonary hypertensive crisis		1				1
Pulmonary infarction		1				1
Pulmonary oedema		3				3
Pulmonary pain	1	1			1	1
Pupils unequal		1				1
Pustule		1		1		
Pyrexia	110	216	103	171	7	45
Radiculopathy		1				1
Rales		2		1		1
Rash	7	35	5	12	2	23
Rash erythematous	1	1			1	1
Rash macular		5		1		4
Rash morbilliform		1				1
Rash papular	1	1			1	1
Rash pruritic	1	6	1	2		4
Rash pustular		3		1		2
Red blood cell sedimentation rate increased		1		1		
Reduced facial expression		1		1		
Renal disorder		1		1		
Renal failure	1	3			1	3
Renal pain		3				3
Respiratory depression		1				1
Respiratory disorder	2	3		1	2	2
Respiratory distress	1	2			1	2
Respiratory failure		1				1
Respiratory rate decreased	1	2	1	1		1
Respiratory symptom	1	1	1	1		
Restlessness	1	3		2	1	1
Retching		1		1		
Retinal artery occlusion	1	2			1	2
Retinal tear		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Retrograde amnesia	1	1	1	1		
Rhabdomyolysis		1				1
Rheumatoid arthritis		1				1
Rhinitis		2		2		
Rhinitis allergic		1				1
Rhinorrhoea	1	1	1	1		
Ruptured cerebral aneurysm		1				1
SARS-CoV-2 ant body test negative		2				2
SARS-CoV-2 test positive	15	18			15	18
Sciatica	2	2			2	2
Seizure		1				1
Sensation of foreign body	2	8	1	1	1	7
Sense of oppression		1				1
Sensory disturbance		2				2
Sensory level abnormal		2				2
Septic shock		1				1
Serum ferritin decreased		1		1		
Serum ferritin increased	1	2		1	1	1
Shock		1				1
Sinus congestion		1		1		
Sinus tachycardia		2				2
Skin burning sensation		1				1
Skin discolouration		1				1
Skin exfoliation		1				1
Skin indentation		1		1		
Skin irritation	1	1	1	1		
Skin lesion		1				1
Skin striae		1		1		
Skin tightness		1				1
Sleep attacks		1		1		
Sleep disorder	1	2	1	1		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sleep disorder due to general medical condition, hypersomnia type		1		1		
Somatic symptom disorder		1				1
Somnolence	8	27	5	20	3	7
Speech disorder	1	5	1	2		3
Spinal pain		4		2		2
Stomatitis		1		1		
Strabismus	1	2		1	1	1
Subarachnoid haemorrhage		2				2
Subdural haemorrhage		1				1
Supraventricular tachycardia		1				1
Suspected COVID-19		1				1
Swelling	1	5		2	1	3
Swelling face	1	9	1	3		6
Swelling of eyelid		1				1
Swollen tongue	1	9		2	1	7
Syncope	5	21			5	21
Syringe issue		1		1		
Tachycardia	7	21	2	4	5	17
Tachycardia paroxysmal		1				1
Tachypnoea		1		1		
Taste disorder		2		1		1
Tendon disorder		1		1		
Tension		1		1		
Tension headache		2		1		1
Thalamic infarction		1				1
Therapeutic response unexpected	1	1	1	1		
Thinking abnormal		1				1
Thirst		1		1		
Throat irritation	1	7	1	4		3
Throat tightness	1	4			1	4
Thrombocytopenia	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thrombophlebitis		1				1
Thrombosed varicose vein		1				1
Thrombosis	1	4			1	4
Thrombosis mesenteric vessel		1				1
Tinnitus	2	4		1	2	3
Tongue discomfort		3		1		2
Tonsillitis	1	1	1	1		
Tonsillitis bacterial	1	2			1	2
Toothache		1				1
Toxicity to various agents		1				1
Transaminases increased	1	3		1	1	2
Transferrin increased		1		1		
Transient ischaemic attack	1	1			1	1
Tremor	1	4		2	1	2
Trichoglossia		1		1		
Trigeminal neuralgia		2				2
Troponin I increased		1				1
Tunnel vision		2				2
Type I hypersensitivity		1				1
Underdose		1		1		
Unresponsive to stimuli	1	5			1	5
Urinary retention		1				1
Urinary tract infection		1				1
Urticaria	3	14			3	14
Urticaria pressure		1				1
Use of accessory respiratory muscles		1		1		
Uterine abscess	1	1			1	1
Vaccination complication		1				1
Vaccination failure	34	47	1	1	33	46
Vaccination site abscess	1	1			1	1
Vaccination site discolouration		2				2
Vaccination site dysaesthesia		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site erythema	10	24	9	17	1	7
Vaccination site haematoma	1	1	1	1		
Vaccination site haemorrhage		1		1		
Vaccination site hypoaesthesia		4		2		2
Vaccination site induration	4	8	3	5	1	3
Vaccination site inflammation	2	3	1	1	1	2
Vaccination site joint pain	1	3	1	2		1
Vaccination site lymphadenopathy	5	9	5	8		1
Vaccination site movement impairment	2	7	2	6		1
Vaccination site pain	67	139	65	123	2	16
Vaccination site paraesthesia		1		1		
Vaccination site pruritus	6	11	5	7	1	4
Vaccination site rash		3		2		1
Vaccination site reaction	3	7	2	6	1	1
Vaccination site swelling	21	35	20	29	1	6
Vaccination site urticaria	1	3	1	2		1
Vaccination site warmth	1	7	1	5		2
Vaginal discharge		1		1		
Vaginal haemorrhage		2				2
Varicophlebitis	1	1			1	1
Vascular encephalopathy		1				1
Vascular occlusion	1	1			1	1
Venous thrombosis limb	1	1			1	1
Ventricular extrasystoles		1				1
Ventricular fibrillation		1				1
Vertigo	6	28	6	16		12
Vertigo positional	1	1			1	1
Vestibular neuronitis		1				1
Viral rash		1				1
Vision blurred	2	7	2	5		2
Visual acuity reduced	1	1			1	1
Visual field defect	1	2			1	2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Visual impairment	4	9		1	4	8
Vitreous detachment	1	1			1	1
Vitreous haemorrhage		2				2
Vomiting	11	33	10	26	1	7
Weight bearing difficulty	1	1			1	1
Weight increased	1	1	1	1		
White blood cell count increased		1		1		
White blood cells urine		1				1
Wound haemorrhage		1				1
Wrong technique in product usage process		2		2		
	1,331	3,614	896	1946	435	1668

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	2			1	2
Accommodation disorder	2	2	2	2		
Acute coronary syndrome		1				1
Acute myocardial infarction	1	1			1	1
Ageusia	1	2	1	2		
Agitation		1		1		
Agranulocytosis		1				1
Allodynia		1		1		
Amnesia		1		1		
Anaemia	3	5			3	5
Anaphylactic reaction	1	1			1	1
Anaphylactic shock		3				3
Angina pectoris	1	4			1	4
Angioedema		1				1
Anti-platelet ant body		1				1
Anxiety		1		1		
Aphasia		2				2
Arrhythmia	1	2			1	2
Arteriosclerosis coronary artery		1				1
Arthralgia	20	27	19	24	1	3
Arthritis	1	1	1	1		
Arthritis infective	1	1			1	1
Asthenia	6	19	3	13	3	6
Asymptomatic COVID-19	5	6			5	6
Atrial f brillation		4				4
Autoimmune disorder		1				1
Autoimmune haemolytic anaemia		1				1
Axillary pain		1		1		
Back pain	2	5		1	2	4
Bacterial sepsis		1				1
Balance disorder	1	1	1	1		
Basal ganglia stroke		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bell's palsy		1				1
Benign prostatic hyperplasia	1	1			1	1
Bleeding time prolonged	1	1			1	1
Blepharospasm	1	1	1	1		
Blindness unilateral	1	1			1	1
Blister		1				1
Blood creatine phosphokinase increased		4		2		2
Blood creatine phosphokinase MB increased		1		1		
Blood creatinine increased		1		1		
Blood glucose decreased	2	2			2	2
Blood glucose fluctuation	1	1			1	1
Blood glucose increased		1		1		
Blood pressure abnormal		1				1
Blood pressure decreased		1		1		
Blood pressure increased		4		2		2
Blood sodium decreased		1		1		
Body temperature abnormal	1	1	1	1		
Body temperature increased	1	4	1	3		1
Bradycardia		1				1
Bradykinesia		2		1		1
Brain natriuretic peptide increased		1				1
Bronchitis		1				1
Burning sensation		1		1		
Cachexia		1				1
Cardiac arrest		1				1
Cardiac failure	3	6			3	6
Cardiac failure acute		1				1
Cardiopulmonary failure	1	2			1	2
Cardiovascular disorder	1	2	1	2		
Central nervous system infection		1				1
Cerebellar stroke		1				1
Cerebral artery occlusion		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral infarction		1				1
Cerebral ischaemia		1				1
Cerebrovascular accident	2	6			2	6
Chest discomfort	1	4			1	4
Chest pain	1	7		1	1	6
Chills	11	28	9	21	2	7
Chromaturia	1	1	1	1		
Chronic obstructive pulmonary disease	1	2	1	1		1
Circulatory collapse	2	8			2	8
Clonus		1				1
Colitis		1				1
Coma	1	1			1	1
Complication associated with device		1		1		
Concomitant disease progression		1				1
Condition aggravated	1	2		1	1	1
Confusional state	2	7	2	3		4
Coronary artery stenosis		1				1
Coronary artery thrombosis	1	1			1	1
Cough	2	4	1	1	1	3
COVID-19	21	36	2	3	19	33
COVID-19 pneumonia	4	5			4	5
Craniocerebral injury		1				1
C-reactive protein increased		1		1		
Cyanosis	1	1			1	1
Daydreaming		1				1
Death	1	7			1	7
Decreased appetite	3	5	3	4		1
Deep vein thrombosis	5	7			5	7
Dehydration		1		1		
Dermatitis bullous		1				1
Diarrhoea	4	8	4	6		2
Diarrhoea haemorrhagic		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diffuse alveolar damage	1	1			1	1
Diplopia	1	1			1	1
Discomfort	1	1			1	1
Disorientation	1	2	1	2		
Disturbance in attention	1	2	1	1		1
Dizziness	7	20	6	14	1	6
Dizziness postural		1		1		
Drug ineffective	9	18			9	18
Dry mouth		3		3		
Dysaesthesia	1	3	1	1		2
Dysarthria	1	2			1	2
Dysgeusia	1	1			1	1
Dyskinesia		1				1
Dysphagia		3				3
Dyspnoea	9	20			9	20
Dyspnoea at rest	1	1			1	1
Dyspnoea exertional	1	6		1	1	5
Dysstasia		1				1
Ear pain		1		1		
Eczema		1				1
Electrocardiogram change		1				1
Electrocardiogram ST segment elevation		1				1
Electrocardiogram ST-T change		1				1
Epididymal tenderness	1	1			1	1
Epilepsy	1	3			1	3
Epistaxis		1		1		
Epstein-Barr virus infection	1	1			1	1
Erythema		3		3		
Escherichia infection	1	1			1	1
Escherichia sepsis	1	2			1	2
Eyelid oedema	1	1	1	1		
Eyelid ptosis	1	2			1	2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Face oedema		1		1		
Facial paralysis	1	3			1	3
Facial paresis	4	6			4	6
Fall	1	4	1	1		3
Fatigue	37	68	31	54	6	14
Febrile convulsion	2	3		1	2	2
Feeling abnormal		2		1		1
Feeling cold		1				1
Feeling jittery	1	2		1	1	1
Fibrin D dimer increased		1				1
Flushing		2				2
Formication	1	1			1	1
Gait disturbance	2	3	1	2	1	1
Gastrointestinal pain		1				1
General physical health deterioration	3	6	1	1	2	5
Glossodynia		1				1
Guillain-Barre syndrome	2	2			2	2
Haematemesis		2				2
Haematoma		1				1
Haematuria		1				1
Haemolytic anaemia	1	1			1	1
Haemorrhage subcutaneous	1	1			1	1
Headache	32	62	30	50	2	12
Head banging		1				1
Head discomfort		1				1
Head injury		1				1
Heart rate increased		1		1		
Hemiataxia	1	1			1	1
Hemiparesis	3	3			3	3
Hemiplegia		1				1
Hereditary angioedema with normal C1 esterase inhibitor		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Herpes simplex encephalitis		1
Herpes zoster	3	5
Hot flush		1
Hyperchromic anaemia		1
Hyperhidrosis	2	5
Hyperkalaemia	1	1
Hyperreflexia		1
Hypersensitivity		3
Hypersomnia	1	2
Hypertension		3
Hypertensive crisis	1	4
Hypertonia		1
Hyperventilation		1
Hypoacusis	1	2
Hypoaesthesia	2	6
Hypoaesthesia oral		2
Hypoglycaemia	1	1
Hyponatraemia	1	1
Hypotension		5
Hypoxia	1	1
Idiopathic angioedema		1
Ileus	1	1
Immune thrombocytopenia		1
Impaired healing	1	1
Impaired quality of life		1
Impaired work ability	3	7
Inappropriate schedule of product administration	1	2
Incorrect route of product administration		2
Infection	1	3
Inflammation	1	1
Inflammatory marker increased	3	3
Influenza		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
3	3		2
			1
			1
	3	2	2
		1	1
			1
			3
1	2		
			3
		1	4
			1
	1		
1	1		1
	2	2	4
	2		
		1	1
		1	1
	2		3
		1	1
		1	1
			1
1	1		
			1
			1
	1	3	6
1	2		
	2		
		1	3
		1	1
		3	3
	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Influenza like illness	1	8	1	7		1
Insomnia	1	2			1	2
Intraocular pressure increased		1				1
Ischaemic cardiomyopathy	1	1			1	1
Joint effusion	1	1			1	1
Joint range of motion decreased		1				1
Joint swelling		3		1		2
Lack of spontaneous speech		1				1
Left ventricular failure		2				2
Leukocytosis		1				1
Leukopenia	2	4			2	4
Lip oedema	1	1	1	1		
Loss of consciousness	2	4			2	4
Lymphadenopathy	4	13	4	11		2
Lymph node pain	3	8	3	6		2
Lymph node palpable		1		1		
Lymphocyte count increased		2		1		1
Lymphocytosis		1				1
Malaise	2	7	2	5		2
Mania		1				1
Mean platelet volume decreased		1		1		
Mechanical ventilation	1	1			1	1
Memory impairment		2		1		1
Meningitis bacterial		1				1
Migraine		3		1		2
Migraine with aura	1	1	1	1		
Mitral valve incompetence	1	1			1	1
Mouth haemorrhage		1				1
Movement disorder		1				1
Multiple organ dysfunction syndrome	1	3			1	3
Muscle contractions involuntary		2				2
Muscle spasms	2	5		2	2	3

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle spasticity		1				1
Muscular weakness	1	4		1	1	3
Musculoskeletal disorder		1				1
Musculoskeletal stiffness	1	1			1	1
Myalgia	16	26	16	21		5
Myelosuppression		1				1
Myocardial infarction	2	2			2	2
Myocarditis	2	4			2	4
Myoclonus		1				1
Nasopharyngitis		1		1		
Nausea	10	27	7	18	3	9
Necrosis	1	1			1	1
Nervous system disorder		1				1
Neurological symptom		1				1
Neutropenia		1				1
Night sweats	1	1	1	1		
Occipital neuralgia		1		1		
Ocular myasthenia	1	1			1	1
Oculofacial paralysis	1	1			1	1
Oedema genital	1	1			1	1
Oedema peripheral	1	1			1	1
Off label use	1	3	1	3		
Oral disorder		1		1		
Oral herpes	1	1	1	1		
Oral mucosa erosion		1		1		
Organising pneumonia	1	1			1	1
Oropharyngeal pain	2	5	1	4	1	1
Oxygen saturation abnormal	1	1	1	1		
Oxygen saturation decreased	1	2			1	2
Pain	1	6		4	1	2
Pain in extremity	5	17	4	12	1	5
Pain of skin		2		1		1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Palpitations		3		2		1
Pancreatitis	1	1			1	1
Pancytopenia		1				1
Paraesthesia		7		3		4
Paralysis	1	1			1	1
Parosmia		2		2		
Pemphigus		1				1
Performance status decreased		3		2		1
Peripheral coldness		2		1		1
Peripheral embolism	1	1			1	1
Peripheral swelling	2	6	1	3	1	3
Petechiae		2				2
Petit mal epilepsy		1				1
Pharyngeal lesion		1		1		
Pharyngeal swelling	1	4	1	1		3
Platelet count decreased		1		1		
Pleural effusion	3	4			3	4
Pneumonia	1	5			1	5
Pneumonia aspiration		3				3
Pneumonia bacterial		2				2
Pneumothorax spontaneous		1				1
Poor quality product administered		1		1		
Post herpetic neuralgia		1				1
Presyncope	2	4	1	1	1	3
Product preparation error		1		1		
Product use issue		1		1		
Pruritus	2	4		1	2	3
Psoriasis		1				1
Psychotic disorder		1				1
Pulmonary congestion	1	1			1	1
Pulmonary embolism	6	14			6	14
Pulmonary function test decreased		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary infarction	2	3			2	3
Pulpitis dental	1	1			1	1
Pupillary reflex impaired		1				1
Pyrexia	34	70	27	46	7	24
Radial nerve palsy		1				1
Rash	1	4			1	4
Rash pruritic		2		1		1
Renal function test abnormal	1	1	1	1		
Respiratory acidosis		1				1
Respiratory disorder	1	1			1	1
Respiratory failure	4	5			4	5
Restlessness		3		2		1
Resuscitation	1	1			1	1
Retching		1		1		
Retinal vein thrombosis	1	1			1	1
Rhinitis	1	1			1	1
Rib fracture		1				1
Road traffic accident		1				1
SARS-CoV-2 ant body test negative		1				1
SARS-CoV-2 test positive	6	8	1	1	5	7
Seizure	1	5			1	5
Sepsis	1	3			1	3
Shift to the left		1				1
Sinus tachycardia		1				1
Skin exfoliation		1		1		
Skin laxity		1		1		
Skin reaction		1		1		
Sleep disorder	1	1			1	1
Somnolence	4	12	2	5	2	7
Sopor		1				1
Speech disorder		1				1
Splenic vein thrombosis		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Splenomegaly		1		1		
Spontaneous haematoma		1				1
Status epilepticus	1	2			1	2
Stress		1		1		
Subcutaneous haematoma		1				1
Sudden cardiac death	1	1			1	1
Sudden hearing loss		2				2
Suspected COVID-19	1	2	1	1		1
Swelling		4		3		1
Swollen tongue		2				2
Syncope	3	9			3	9
Systemic inflammatory response syndrome		1				1
Tachycardia	1	3			1	3
Tachypnoea	1	1			1	1
Taste disorder	1	2	1	2		
Thalamic infarction	1	1			1	1
Thinking abnormal		1		1		
Throat tightness		1				1
Thrombocytopenia	2	6			2	6
Thrombophlebitis	1	1			1	1
Thrombosis		1				1
Tinnitus	1	3	1	3		
Tongue discomfort	1	2	1	1		1
Transient ischaemic attack		1				1
Tremor	2	3	1	1	1	2
Trismus	1	1			1	1
Troponin increased		1				1
Troponin T increased		3				3
Tunnel vision	1	1	1	1		
Urinary retention	1	1			1	1
Urinary tract infection	1	1			1	1
Urine ketone body present		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria	4	10		2	4	8
Vaccination failure	17	21			17	21
Vaccination site anaesthesia		1				1
Vaccination site erythema	2	2	2	2		
Vaccination site hypoaesthesia		2		1		1
Vaccination site induration	1	1	1	1		
Vaccination site inflammation	1	1	1	1		
Vaccination site lymphadenopathy	2	4	2	3		1
Vaccination site movement impairment	1	2	1	2		
Vaccination site pain	19	38	19	36		2
Vaccination site paraesthesia		1				1
Vaccination site pustule		1		1		
Vaccination site rash		1		1		
Vaccination site reaction	2	3	2	3		
Vaccination site swelling	3	8	3	6		2
Vasculitis		1				1
Venous thrombosis limb		5		1		4
Vertigo	2	4		1	2	3
Viral infection		1		1		
Vision blurred		1		1		
Visual field defect		2		1		1
Visual impairment	1	5	1	1		4
Vomiting	2	9		3	2	6
Weight bearing difficulty		1		1		
White blood cell count increased		1		1		
	519	1,279	251	555	268	724

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Antibody test abnormal		1		1		
Arthralgia	1	1	1	1		
Asthenia		1				1
Asymptomatic COVID-19	1	1	1	1		
Balance disorder		1				1
Coronavirus infection		1				1
COVID-19		12				12
Dizziness	2	2	2	2		
Drug ineffective		13				13
Fatigue		1				1
General physical health deterioration		1				1
Headache	2	4	2	3		1
Hemianaesthesia		1				1
Herpes simplex reactivation	1	1			1	1
Hyperglycaemia		1				1
Lymphadenopathy		1				1
Nausea	2	3	2	2		1
Neck pain	1	1	1	1		
Neutralising antibodies negative		1		1		
Pain in extremity		1		1		
Pulmonary embolism		1				1
Pyrexia	1	2	1	1		1
Rash		1				1
Underdose	1	1	1	1		
Vaccination failure	1	1			1	1
Vaccination site hypoaesthesia		1		1		
Vaccination site lymphadenopathy	1	2	1	1		1
Vaccination site pain		1				1
Wrong technique in product usage process		1		1		
	15	61	13	19	2	42

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

BAHRAIN

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Anaphylactic reaction	2	2			2	2
Anosmia	1	1	1	1		
Atrioventricular block	1	1			1	1
Cerebrovascular accident	1	1			1	1
Chills		2		2		
Cough	1	1	1	1		
COVID-19	1	1			1	1
Dizziness	1	1	1	1		
Drug ineffective	1	1			1	1
Dysarthria	1	1			1	1
Dyspnoea	1	1	1	1		
Fatigue	2	2	2	2		
Guillain-Barre syndrome	1	1			1	1
Headache	3	3	2	2	1	1
Hot flush		1		1		
Hypoaesthesia	1	1			1	1
Limb discomfort	1	1	1	1		
Lymphadenopathy		1		1		
Myalgia		1		1		
Nasal congestion	1	1	1	1		
Nausea	1	2		1	1	1
Neck pain		1		1		
Oropharyngeal pain	1	1	1	1		
Pain		1		1		
Photophobia	1	1			1	1
Pruritus		1		1		
Pyrexia	2	4	2	4		
Secretion discharge	1	1	1	1		
Syncope	1	1			1	1
Vomiting	1	1			1	1
	29	40	15	26	14	14

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	1			1	1
Axillary pain		1				1
Cerebral artery occlusion	1	1			1	1
Cerebrovascular accident	1	1			1	1
Chest pain	1	1			1	1
Chills		1				1
Dyspnoea		1				1
Headache	2	3	1	2	1	1
Heart rate increased		1				1
Hyperhidrosis	1	2			1	2
Hypoaesthesia	2	2	1	1	1	1
Muscle spasms		1				1
Muscular weakness	2	2	2	2		
Myalgia		1		1		
Pain		1				1
Paraesthesia		1				1
Pyrexia		1				1
Sensory loss	1	1	1	1		
Swelling		1				1
Troponin increased	1	1			1	1
Vaccination site pain		1		1		
	13	26	5	8	8	18

* I=Interval, C=Cumulative
* AE=Adverse Event

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Country Where Event Occurred

BELGIUM

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	3	6	2	4	1	2
Abdominal distension		2		1		1
Abdominal pain	3	10		1	3	9
Abdominal pain upper	8	16	1	3	7	13
Abdominal symptom		1		1		
Abnormal dreams	1	2			1	2
Acute kidney injury	2	4			2	4
Acute macular outer retinopathy		1				1
Acute pulmonary oedema		1				1
Acute respiratory failure		3				3
Ageusia	1	2	1	2		
Agitation		4		1		3
Alanine aminotransferase increased		1		1		
Allergic reaction to excipient		1				1
Allergy to vaccine		1				1
Allodynia		1				1
Altered state of consciousness		4				4
Anal incontinence		1		1		
Anaphylactic reaction	2	32			2	32
Anaphylactic shock		5				5
Anaphylactoid reaction		1				1
Angina pectoris	2	5			2	5
Angioedema	1	5			1	5
Anosmia	1	2	1	1		1
Anxiety		7		1		6
Apathy		1				1
Aphasia	4	6			4	6
Aphonia	1	1	1	1		
Aphthous ulcer	1	3	1	1		2
Appendicitis	1	3			1	3
Arrhythmia		3				3
Arthralgia	73	223	25	37	48	186

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthritis		4		1		3
Arthropathy	1	1	1	1		
Aspartate aminotransferase increased		1		1		
Asthenia	12	40	3	9	9	31
Asthenopia	1	1			1	1
Asthma		2				2
Asthma exercise induced		1				1
Atrial fibrillation		1				1
Atrioventricular block complete		1				1
Autoimmune disorder	1	7			1	7
Axillary mass		1				1
Axillary pain	12	18	8	8	4	10
Back pain	15	21	8	10	7	11
Balance disorder		7				7
Bedridden	1	1			1	1
Bell's palsy	2	3			2	3
Biliary colic		1				1
Blindness		3				3
Blood alkaline phosphatase increased	1	1			1	1
Blood glucose decreased		1		1		
Blood lactic acid increased		2				2
Blood pressure abnormal		3		1		2
Blood pressure decreased	5	15	4	5	1	10
Blood pressure increased	1	7		1	1	6
Blood pressure systolic increased		1		1		
Blood test abnormal	1	2	1	1		1
Blood urine present		1				1
Body temperature decreased		1				1
Body temperature increased	4	13	4	8		5
Bone pain	1	6			1	6
Bone swelling	1	1	1	1		
Bradycardia		9				9

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bradypnoea		1				1
Brain contusion	1	1			1	1
Breast pain		3		1		2
Breath odour		1				1
Bronchitis	1	1			1	1
Bronchospasm	1	4			1	4
Bundle branch block left		1				1
Burning sensation	3	9	1	3	2	6
Cardiac arrest		5				5
Cardiac discomfort	1	1			1	1
Cardiac disorder		2				2
Cardiac failure		2				2
Cardiogenic shock		1				1
Cardio-respiratory arrest		3				3
Cardiovascular disorder	3	47	2	9	1	38
Carotid artery occlusion	2	2			2	2
Carotid artery thrombosis	1	1			1	1
Carpal tunnel syndrome	1	1			1	1
Cerebral haemorrhage		1				1
Cerebral ischaemia		1				1
Cerebral thrombosis	1	2			1	2
Cerebrovascular accident	4	11			4	11
Chest discomfort	2	12		2	2	10
Chest injury	1	1			1	1
Chest pain	12	32	6	11	6	21
Cheyne-Stokes respiration		1				1
Chillblains		1				1
Chills	122	448	45	73	77	375
Cholelithiasis	1	1			1	1
Chromaturia	1	1			1	1
Coagulopathy	13	26	2	5	11	21
Coccydynia	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat		1				1
Coma		1				1
Concussion		1				1
Condition aggravated	2	4		1	2	3
Confusional state	1	2		1	1	1
Conjunctival hyperaemia	1	1			1	1
Contusion	2	5	1	2	1	3
Cough	4	18		2	4	16
COVID-19	15	46	4	9	11	37
COVID-19 pneumonia		1				1
C-reactive protein increased	2	4		1	2	3
Crying		2				2
Cutaneous vasculitis	1	2			1	2
Cyanosis	1	4			1	4
Deafness		2				2
Deafness unilateral		1				1
Death	3	7			3	7
Decreased appetite	7	18	2	3	5	15
Decreased vibratory sense		1				1
Deep vein thrombosis	6	9			6	9
Dehydration		1				1
Delirium		1				1
Depressed level of consciousness		7				7
Dermatitis	1	1	1	1		
Dermo-hypodermatitis		1				1
Diaphragmalgia		1				1
Diarrhoea	11	36	3	8	8	28
Diarrhoea haemorrhagic		1				1
Diplopia	1	2			1	2
Discomfort	4	8		1	4	7
Disease recurrence		2				2
Disorientation	1	2			1	2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbance in attention	1	3		1	1	2
Dizziness	16	65	11	20	5	45
Dizziness postural		1				1
Drug administered in wrong device		1		1		
Drug ineffective	7	24			7	24
Drug resistance		1				1
Dry mouth		3				3
Dry throat		2		1		1
Dysacusis		1				1
Dysaesthesia		1				1
Dysgeusia	5	11	2	4	3	7
Dyspepsia	1	2	1	1		1
Dysphagia	1	6		2	1	4
Dysphonia	4	6	3	3	1	3
Dyspnoea	15	62	6	9	9	53
Dyspnoea exertional	1	5	1	1		4
Dyspraxia		1				1
Dysstasia	2	3	2	2		1
Dystonia		1				1
Ear discomfort	1	3		2	1	1
Ear pain	2	7	1	2	1	5
Eczema	3	3	2	2	1	1
Electric shock sensation		2				2
Endocrine ophthalmopathy		1				1
Endolymphatic hydrops		2				2
Epicondylitis	1	1			1	1
Epilepsy	4	14			4	14
Epistaxis	1	2	1	1		1
Erythema	10	26	7	9	3	17
Eschar		1				1
Exercise tolerance decreased		2				2
Expired product administered		2		1		1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Extensive swelling of vaccinated limb	13	21
Extrasystoles	1	1
Eye irritation		1
Eye pain	2	5
Eye swelling	1	4
Face oedema		3
Facial asymmetry		1
Facial bones fracture		1
Facial nerve disorder	1	1
Facial pain		2
Facial paralysis	5	17
Facial paresis	3	9
Facial spasm		2
Faeces discoloured	1	2
Fall	2	9
Fasciitis	1	1
Fatigue	182	587
Feeding disorder	1	1
Feeling abnormal	8	18
Feeling cold	7	13
Feeling drunk		1
Feeling hot	9	14
Feeling of body temperature change	4	9
Fibrin D dimer increased	3	5
Flatulence		2
Flushing		1
Folate deficiency	1	1
Food allergy		1
Formication		1
Gait disturbance	1	2
Gait inability	1	1
Gamma-glutamyltransferase increased		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1	13	20
		1	1
			1
1	1	1	4
1	1		3
	2		1
			1
			1
		1	1
	1		1
		5	17
		3	9
	2		
		1	2
	1	2	8
		1	1
74	126	108	461
		1	1
3	6	5	12
3	3	4	10
	1		
6	8	3	6
3	3	1	6
1	1	2	4
	2		
			1
1	1		
			1
			1
		1	2
		1	1
	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastric dilatation	1	1			1	1
Gastric disorder		1				1
Gastritis	1	1			1	1
Gastroenteritis viral	1	1			1	1
Gastrointestinal disorder	2	4	2	2		2
Gastrointestinal pain	3	6	1	1	2	5
Gastrooesophageal reflux disease	1	2	1	1		1
Generalised tonic-clonic seizure	1	3			1	3
General physical health deterioration	1	12		1	1	11
Gingival pain		1				1
Haematoma	2	4	1	2	1	2
Haemophagocytic lymphohistiocytosis	1	1			1	1
Haemoptysis	1	1			1	1
Haemorrhage intracranial		1				1
Haemorrhagic transformation stroke	1	1			1	1
Hallucination	1	2			1	2
Hallucination, visual		1				1
Hangover	2	2	1	1	1	1
Headache	197	633	95	155	102	478
Head discomfort		1				1
Heart rate decreased		2				2
Heart rate increased	3	12	2	5	1	7
Heart rate irregular		1		1		
Hemianaesthesia		1				1
Hemiparaesthesia	1	2			1	2
Hemiparesis	1	3			1	3
Hemiplegia	3	5			3	5
Hepatic cytolysis	1	1			1	1
Hepatic enzyme increased		1		1		
Hepatic failure		1				1
Hepatic pain	1	1	1	1		
Hepatitis	1	3			1	3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes ophthalmic		1				1
Herpes simplex		1				1
Herpes virus infection		1				1
Herpes zoster	6	9	6	8		1
Herpes zoster meningoradiculitis	1	1			1	1
Hot flush	3	11	1	3	2	8
Hunger	1	1	1	1		
Hyperacusis		2				2
Hyperaesthesia	1	2	1	1		1
Hyperaesthesia teeth		1				1
Hyperferritinaemia	1	1			1	1
Hyperglycaemia	1	1			1	1
Hyperhidrosis	14	25	10	12	4	13
Hyperresponsive to stimuli	1	1			1	1
Hypersensitivity	3	22		2	3	20
Hypersomnia		2				2
Hypertension	4	36	1	4	3	32
Hypertensive crisis		1				1
Hyperthermia		1		1		
Hyperventilation	1	5	1	2		3
Hypoacusis		1				1
Hypoaesthesia	8	17	5	7	3	10
Hypoaesthesia oral		1		1		
Hypoglycaemia	1	5	1	1		4
Hypokalaemia		1				1
Hyponatraemia		1				1
Hyporeflexia		1				1
Hyporesponsive to stimuli		1				1
Hypotension	4	16	3	4	1	12
Hypothermia		3				3
Hypoxia		1				1
Illness	1	5	1	4		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Illusion		1				1
Immobile		1				1
Impaired work ability		1		1		
Inappropriate schedule of product administration	1	2	1	2		
Incorrect route of product administration		2		2		
Infection		3		2		1
Inflammation	2	4			2	4
Influenza	7	11	6	8	1	3
Influenza like illness	30	87	18	30	12	57
Injection site discomfort		1		1		
Injection site erythema		1				1
Injection site haematoma		1		1		
Injection site hypersensitivity		1				1
Injection site pain	1	3	1	3		
Injection site reaction	1	7	1	3		4
Injection site swelling	1	1	1	1		
Injection site warmth	1	1	1	1		
Insomnia	7	25	2	6	5	19
Intestinal dilatation		1				1
Intestinal ischaemia		1				1
Iridocyclitis	1	1			1	1
Irritability		1				1
Ischaemic stroke	2	2			2	2
Jaw disorder		1		1		
Joint range of motion decreased	1	3	1	1		2
Joint stiffness		1				1
Joint swelling		1				1
Ketoacidosis		3				3
Lacrimation increased	1	2			1	2
Lactic acidosis		1				1
Laryngeal oedema		1				1
Laryngitis		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Laryngospasm		1				1
Lethargy		2				2
Leukocytosis	1	2			1	2
Leukocyturia		1		1		
Limb discomfort	3	8	2	3	1	5
Lip swelling		5		1		4
Livedo reticularis		1				1
Liver disorder	3	7		2	3	5
Liver function test abnormal		1				1
Localised infection		1				1
Local reaction	1	1	1	1		
Loss of consciousness	3	12			3	12
Loss of personal independence in daily activities	2	3		1	2	2
Lower respiratory tract congestion		1				1
Lung disorder		1				1
Lung infiltration		1				1
Lymphadenitis		2		1		1
Lymphadenopathy	17	43	11	15	6	28
Lymph node pain	2	9	1	1	1	8
Lymphoedema		1				1
Malaise	74	319	26	53	48	266
Mastication disorder	1	1			1	1
Maternal exposure during pregnancy	2	4	2	4		
Memory impairment		2		1		1
Meniere's disease	1	1			1	1
Microangiopathic haemolytic anaemia	1	1			1	1
Middle insomnia	4	4	3	3	1	1
Migraine	10	23	5	5	5	18
Migraine with aura		1				1
Mobility decreased	1	5	1	2		3
Monoplegia	2	2			2	2
Motor dysfunction	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Movement disorder	1	1	1	1		
Multiple organ dysfunction syndrome		2				2
Mumps	1	1	1	1		
Muscle contractions involuntary		1				1
Muscle disorder	1	1			1	1
Muscle fatigue		1				1
Muscle spasms	2	4	1	1	1	3
Muscle strain	7	16	3	5	4	11
Muscle tightness		1				1
Muscular weakness	3	6	3	3		3
Musculoskeletal chest pain		2		1		1
Musculoskeletal discomfort		1				1
Musculoskeletal pain	2	2	2	2		
Musculoskeletal stiffness	21	52	15	28	6	24
Myalgia	156	493	71	112	85	381
Myosclerosis		1				1
Nasal congestion	3	4	2	3	1	1
Nasopharyngitis	6	8	2	2	4	6
Nausea	106	375	47	74	59	301
Neck pain	9	21	8	9	1	12
Nerve compression	1	1			1	1
Nerve injury	2	2	1	1	1	1
Nervous system disorder	10	39	2	7	8	32
Neuralgia		3		1		2
Neuritis		1				1
Neurogenic shock		1				1
Neuropathic muscular atrophy	1	1			1	1
Neuropathy peripheral		1				1
Nightmare		1				1
Night sweats	1	2			1	2
Noninfective encephalitis	1	1			1	1
Noninfective gingivitis	1	2	1	1		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
N-terminal prohormone brain natriuretic peptide increased		1				1
Oedema peripheral		1				1
Off label use	3	7	3	7		
Ophthalmic herpes zoster	1	1			1	1
Oral herpes	3	6	2	2	1	4
Oropharyngeal discomfort	1	1	1	1		
Oropharyngeal pain	5	16	3	7	2	9
Orthostatic hypotension	1	1	1	1		
Orthostatic intolerance		1				1
Oxygen saturation decreased		19		1		18
Pain	14	33	9	14	5	19
Painful respiration		3				3
Pain in extremity	41	89	20	43	21	46
Pain in jaw		1				1
Pain of skin	1	4	1	1		3
Pallor		2				2
Palmoplantar pustulosis		1		1		
Palpitations	7	21	1	6	6	15
Pancreatitis acute	1	1			1	1
Papule		1				1
Paraesthesia	12	29	9	17	3	12
Paraesthesia oral	2	8	1	2	1	6
Paralysis		1				1
Parapharyngeal space infection		1				1
Paresis		1				1
Parkinson's disease		2				2
Parosmia	1	3	1	2		1
Parotid gland enlargement	1	1			1	1
Pelvic pain	1	1	1	1		
Pericardial effusion	1	2			1	2
Pericarditis	3	4			3	4

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral coldness	1	1			1	1
Peripheral motor neuropathy		1				1
Peripheral swelling	11	50	10	17	1	33
Peripheral venous disease	1	1			1	1
Petechiae	2	3	1	2	1	1
Pharyngeal erythema		1				1
Pharyngeal inflammation	1	1	1	1		
Pharyngeal swelling		6				6
Phlebitis	2	3	1	1	1	2
Phlebitis superficial	1	1			1	1
Photophobia	1	4			1	4
Photopsia		1				1
Platelet count decreased	1	1			1	1
Pleural effusion		2				2
Pleuritic pain	1	1	1	1		
Pneumonia		3				3
Pneumonia aspiration	1	2			1	2
Pneumonia bacterial		1				1
Pneumonitis		2				2
Polyneuropathy		1				1
Polyuria	1	1			1	1
Poor quality sleep	1	3	1	1		2
Posture abnormal		1		1		
Presyncope	1	10	1	3		7
Procedural pain		1				1
Product administered at inappropriate site		1				1
Productive cough	2	3			2	3
Product use issue	3	7	3	7		
Pruritus	5	27	2	9	3	18
Pruritus allergic		1				1
Pulmonary arterial hypertension		1				1
Pulmonary embolism	6	11			6	11

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary oedema		2				2
Pyelonephritis		2				2
Pyrexia	134	463	69	118	65	345
Rales		1				1
Rash	6	16	4	8	2	8
Rash erythematous	2	6	2	5		1
Rash macular	1	3	1	1		2
Rash maculo-papular	1	2	1	1		1
Rash papular	1	1	1	1		
Rash pruritic		1				1
Red blood cell sedimentation rate increased		1		1		
Renal disorder	2	5			2	5
Renal failure		1				1
Renal pain	1	4			1	4
Respiration abnormal		2				2
Respiratory arrest	1	2			1	2
Respiratory disorder	3	53	1	4	2	49
Respiratory distress		1				1
Respiratory failure	1	2			1	2
Respiratory rate increased		1				1
Respiratory tract infection		1				1
Restless legs syndrome		1		1		
Restlessness		2		1		1
Retching		4				4
Retinal vein thrombosis	1	1	1	1		
Rhinitis	1	1	1	1		
Rhinitis allergic	1	1			1	1
Rhinolaryngitis	1	1	1	1		
Rhinorrhoea	5	11	2	5	3	6
Rhythm idioventricular		1				1
Salivary gland pain	1	1			1	1
Salivary hypersecretion	1	3		1	1	2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
SAPHO syndrome		1				1
SARS-CoV-2 ant body test negative	1	1			1	1
SARS-CoV-2 ant body test positive		1		1		
SARS-CoV-2 test positive		1				1
Scarlet fever		1				1
Scleral discolouration		1				1
Sedation		2				2
Seizure	2	12			2	12
Sensation of foreign body		2		1		1
Sense of oppression		4		2		2
Sensitive skin	2	6	2	3		3
Sensory disturbance		2		2		
Sensory loss		1				1
Sepsis		1				1
Sinus headache		1				1
Sinusitis	2	3	1	1	1	2
Sinus pain		1				1
Sinus tachycardia		1				1
Skin burning sensation		1				1
Skin disorder	19	56	7	12	12	44
Skin haemorrhage	1	1	1	1		
Skin odour abnormal	1	1	1	1		
Skin sensitisation		1				1
Sleep disorder	1	4		1	1	3
Sleep disorder due to a general medical condition		1		1		
Sleep disorder due to general medical condition, insomnia type	1	1			1	1
Sneezing	2	5	1	2	1	3
Somnolence	5	15	1	2	4	13
Speech disorder	2	4		2	2	2
Spinal pain	2	4	1	3	1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stomatitis		1				1
Stress cardiomyopathy		1		1		
Subcutaneous abscess	1	1	1	1		
Sudden death	2	10			2	10
Sudden hearing loss		1				1
Suffocation feeling		1				1
Suppressed lactation		1				1
Supraventricular tachycardia		1				1
Suspected COVID-19		1				1
Swelling	3	5	2	2	1	3
Swelling face		5		1		4
Swelling of eyelid	1	2			1	2
Swollen tongue		7		1		6
Syncope	5	29			5	29
Synovial cyst	1	1	1	1		
Tachyarrhythmia		1				1
Tachycardia	4	30	3	5	1	25
Tachypnoea	1	2			1	2
Taste disorder	2	3	1	2	1	1
Tendonitis	1	1			1	1
Tension	1	1			1	1
Tension headache	1	1	1	1		
Tetany		1				1
Thinking abnormal		1				1
Thirst	3	4	1	2	2	2
Thoracic outlet syndrome		1				1
Throat tightness		3				3
Thrombocytopenia	4	6			4	6
Thrombophlebitis superficial	1	1	1	1		
Thrombosis	3	4			3	4
Tinnitus	1	6			1	6
Tongue discomfort		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue oedema	1	1			1	1
Tonsillitis		1				1
Tooth disorder	1	1	1	1		
Tracheitis	1	1	1	1		
Transient ischaemic attack	1	2			1	2
Tremor	4	14	3	3	1	11
Trigeminal neuralgia	2	2			2	2
Troponin increased	1	2			1	2
Unresponsive to stimuli		3				3
Upper airway obstruction		1				1
Urinary retention		1				1
Urosepsis		1				1
Urticaria	5	11	3	3	2	8
Vaccination failure	1	2			1	2
Vaccination site bruising	1	1	1	1		
Vaccination site discomfort	4	4	3	3	1	1
Vaccination site erythema	17	49	13	35	4	14
Vaccination site haematoma	1	6	1	4		2
Vaccination site hypersensitivity		1				1
Vaccination site hypertrophy		1				1
Vaccination site induration	8	18	7	13	1	5
Vaccination site inflammation	1	2		1	1	1
Vaccination site joint pain	1	1			1	1
Vaccination site lymphadenopathy	1	3			1	3
Vaccination site movement impairment	4	7	1	2	3	5
Vaccination site oedema	1	1	1	1		
Vaccination site pain	41	106	29	48	12	58
Vaccination site pruritus	3	6	2	3	1	3
Vaccination site rash		1		1		
Vaccination site reaction	79	269	23	50	56	219
Vaccination site swelling	7	27	5	15	2	12
Vaccination site warmth	5	14	3	6	2	8

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaginal abscess	1	1			1	1
Vaginal haemorrhage	1	2	1	1		1
Vasculitis		2		1		1
Vasodilatation	2	2	1	1	1	1
Vein disorder	1	1	1	1		
Venous thrombosis	1	1			1	1
Venous thrombosis limb	1	1			1	1
Ventricular tachycardia		1				1
Vertigo	8	29	7	11	1	18
Vertigo positional	1	1	1	1		
Vestibular disorder	1	1			1	1
Vestibular neuronitis		1				1
Vision blurred	2	9	2	4		5
Visual acuity reduced	1	1			1	1
Visual field defect	1	3			1	3
Visual impairment	3	7	1	2	2	5
Vitamin B complex deficiency	1	1	1	1		
Vitamin D deficiency		1				1
Vomiting	15	55	6	9	9	46
Vulval abscess	1	1			1	1
Weight decreased	1	2			1	2
Wheezing		2				2
White blood cell count decreased	1	2		1	1	1
Wrong product administered		1		1		
Yellow skin		1				1
	2,133	6,906	941	1670	1192	5236

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal distension	1	1	1	1		
Abdominal pain	3	6	2	2	1	4
Abdominal pain upper	2	2	1	1	1	1
Acute kidney injury	1	2			1	2
Acute psychosis		1				1
Acute respiratory failure		1				1
Aggression	1	1			1	1
Agitation	1	3	1	1		2
Allergic reaction to excipient		1		1		
Altered state of consciousness		1				1
Amnesia		1				1
Anaphylactic reaction		3				3
Angina pectoris	1	1			1	1
Angle closure glaucoma		1				1
Anxiety		2		1		1
Apathy		2		1		1
Aphthous ulcer		1				1
Arrhythmia	1	2			1	2
Arthralgia	26	54	10	15	16	39
Asthenia	9	17	7	10	2	7
Asthenopia		2		2		
Asthma	1	1	1	1		
Asymptomatic COVID-19		1				1
Atrial fibrillation		2				2
Atrioventricular block complete		1				1
Auditory disorder	1	1	1	1		
Autoimmune disorder	1	1			1	1
Axillary pain	1	1	1	1		
Back pain	7	9	4	4	3	5
Balance disorder	2	3			2	3
Blepharospasm	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood glucose increased		1		1		
Blood pressure increased	2	4			2	4
Body temperature fluctuation		1				1
Body temperature increased	2	4	1	1	1	3
Bone pain	1	1	1	1		
Bradycardia		1				1
Brain injury		1				1
Breath odour		1				1
Bronchial disorder		1				1
Burning sensation	1	1			1	1
Cardiac arrest		4				4
Cardiac failure		2				2
Cardiogenic shock		1				1
Cardiomegaly	1	2			1	2
Cardio-respiratory arrest	1	1			1	1
Cardiovascular disorder	4	17		1	4	16
Cerebral thrombosis		1				1
Cerebrovascular accident	2	6			2	6
Chest discomfort		3				3
Chest pain	2	6	1	2	1	4
Chills	35	94	12	20	23	74
Circadian rhythm sleep disorder	1	1	1	1		
Coagulopathy	10	14	2	2	8	12
Cold sweat		1				1
Confusional state		4		1		3
Constipation		1				1
Contusion	1	1	1	1		
Coronary artery thrombosis		1				1
Cough	2	4		1	2	3
COVID-19	13	28	1	4	12	24
COVID-19 pneumonia		2				2
C-reactive protein increased	2	3	1	1	1	2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Death	5	5			5	5
Decreased appetite	2	4	1	3	1	1
Deep vein thrombosis	3	5			3	5
Delirium	1	1			1	1
Delusion	1	1			1	1
Depressed level of consciousness		3				3
Depressive symptom	1	1	1	1		
Diabetic complication		1				1
Diaphragmalgia	1	1	1	1		
Diarrhoea	5	8	1	1	4	7
Diplopia	1	1			1	1
Disorientation		1				1
Disturbance in attention	1	1			1	1
Diverticulitis	1	1			1	1
Dizziness	7	12	6	7	1	5
Drug ineffective	8	16			8	16
Dry skin		1				1
Dysgeusia	1	5	1	2		3
Dyskinesia	1	1			1	1
Dyspepsia	1	1	1	1		
Dyspnoea	9	16	3	4	6	12
Dyspnoea exertional	1	2			1	2
Dysstasia		1				1
Ear infection	1	1	1	1		
Ear pain		1				1
Eczema		1		1		
Epistaxis		1				1
Erysipelas	1	2			1	2
Erythema	3	7	2	5	1	2
Erythema multiforme	1	1			1	1
Exercise tolerance decreased		1				1
Exposure via breast milk	1	1	1	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposure via skin contact		1		1		
Extensive swelling of vaccinated limb	3	4			3	4
Eye movement disorder		1				1
Eye pain		3		3		
Facial paralysis	1	1			1	1
Faecal vomiting		1				1
Fall	1	5		1	1	4
Fatigue	65	145	29	48	36	97
Feeling abnormal	3	4	2	3	1	1
Feeling cold		4		3		1
Feeling hot	2	3	2	3		
Feeling of body temperature change	3	4	3	3		1
Fibrin D dimer increased		1				1
Flatulence	1	1			1	1
Fluid retention	1	1	1	1		
Gait disturbance		2				2
Gastric dilatation		2		1		1
Gastrointestinal disorder	1	1			1	1
Gastrointestinal pain	2	2	1	1	1	1
Generalised tonic-clonic seizure		1				1
General physical health deterioration	1	6			1	6
Glaucoma		1				1
Haematoma	1	1	1	1		
Haematuria	2	2	1	1	1	1
Haemorrhage		1				1
Haemorrhagic stroke		1				1
Hallucination		3				3
Headache	82	157	52	67	30	90
Head discomfort	1	1			1	1
Heart rate increased	1	4	1	2		2
Hemiplegia	2	3			2	3
Herpes ophthalmic		2				2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes zoster	4	6	3	5	1	1
Hot flush	1	5		1	1	4
Hyperaesthesia	1	1			1	1
Hyperglycaemia	1	1			1	1
Hyperhidrosis	6	7	5	5	1	2
Hypersensitivity	1	3		1	1	2
Hypersomnia	2	2	2	2		
Hypertension	2	6	1	1	1	5
Hyperthermia		1		1		
Hypoglycaemia	1	2			1	2
Hypotension		5				5
Hypothermia		1				1
Hypovolaemic shock		1				1
Illness	1	2	1	2		
Incorrect dose administered		1		1		
Influenza	2	2			2	2
Influenza like illness	19	35	16	16	3	19
Injection site pain		1		1		
Injection site reaction		2				2
Insomnia	3	6	2	4	1	2
International normalised ratio increased	1	1			1	1
Intestinal ischaemia		1				1
Intestinal obstruction		1				1
Ischaemic cerebral infarction	1	1			1	1
Ischaemic stroke	1	1			1	1
Joint range of motion decreased	1	1			1	1
Lacrimation increased		1		1		
Lactic acidosis		1				1
Laryngeal discomfort	1	1			1	1
Lethargy		1		1		
Limb discomfort	4	5	2	2	2	3
Lipase increased	1	1	1	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lip swelling	1	1	1	1		
Liver disorder	1	1			1	1
Liver function test abnormal		2				2
Loss of consciousness	2	2			2	2
Lymphadenopathy	5	12	5	5		7
Lymph node pain	1	2	1	1		1
Malaise	28	72	11	12	17	60
Maternal exposure during pregnancy	1	1			1	1
Metabolic acidosis		1				1
Middle insomnia	1	1	1	1		
Migraine	1	3			1	3
Migraine with aura		1				1
Mobility decreased	1	1	1	1		
Muscle contracture		1				1
Muscle fatigue		1		1		
Muscle strain	1	3	1	1		2
Muscle tightness	1	1	1	1		
Muscular weakness	1	3	1	2		1
Musculoskeletal chest pain		1		1		
Musculoskeletal discomfort	1	1	1	1		
Musculoskeletal stiffness	16	33	16	28		5
Myalgia	48	99	26	34	22	65
Myocardial infarction		1				1
Myocarditis	2	2			2	2
Nasopharyngitis	1	1			1	1
Nausea	28	63	10	11	18	52
Neck pain	3	4	3	3		1
Nervous system disorder	4	13	1	2	3	11
Neurogenic shock		1				1
Neutropenia		1				1
Neutrophilia		1				1
Night sweats		1				1

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MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Occupational exposure to product		1		1		
Ocular discomfort	1	3	1	3		
Ocular hyperaemia		1		1		
Odynophagia		1		1		
Oedema peripheral	1	1			1	1
Oral herpes		2		1		1
Oral pruritus		1				1
Oropharyngeal pain		2		2		
Oxygen saturation abnormal		1				1
Oxygen saturation decreased	2	8			2	8
Pain	6	7	3	4	3	3
Painful respiration	1	1	1	1		
Pain in extremity	17	22	11	14	6	8
Pain in jaw	1	1	1	1		
Pallor		1				1
Pancreatitis	1	1			1	1
Papule		1		1		
Paraesthesia	4	4	3	3	1	1
Paralysis	1	1			1	1
Patient elopement		1				1
Peripheral coldness		1				1
Peripheral swelling	2	5	1	1	1	4
Pharyngeal inflammation	1	1			1	1
Pharyngitis	1	1			1	1
Phlebitis superficial	1	1			1	1
Pneumonia	1	2			1	2
Pneumonitis		1				1
Polyuria	1	1	1	1		
Poor quality sleep	1	3	1	3		
Presyncope	1	4	1	1		3
Prohormone brain natriuretic peptide increased		1				1
Pruritus	3	5	2	3	1	2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Psychomotor hyperactivity	1	1			1	1
Pulmonary embolism	6	10			6	10
Pulmonary infarction		1				1
Pulmonary oedema		1				1
Pyrexia	62	132	43	59	19	73
Rales		1				1
Rash	1	2	1	2		
Rectal haemorrhage	1	1			1	1
Renal disorder		2				2
Renal failure		2				2
Respiratory acidosis		1				1
Respiratory disorder	4	11		1	4	10
Respiratory distress		3				3
Respiratory tract infection		2				2
Restlessness		1				1
Retinal pigment epitheliopathy	1	1			1	1
Retinal vein occlusion	1	1			1	1
Rhinitis		1				1
Rhinorrhoea		1				1
Screaming	1	1	1	1		
Seizure		2				2
Sense of oppression	1	3	1	2		1
Sepsis		1				1
Septic shock		2				2
Serum ferritin increased		1		1		
Skin discolouration	1	1	1	1		
Skin disorder	4	4	2	2	2	2
Skin mass		1				1
Sleep deficit		1				1
Sleep disorder		3		1		2
Sneezing		1		1		
Somnolence	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Speech disorder	1	2		1	1	1
Staring		1				1
Subdural haematoma	1	1			1	1
Sudden death	3	10			3	10
Swelling face	1	1	1	1		
Swollen tongue		1				1
Syncope	1	7			1	7
Tachycardia	1	4			1	4
Tachypnoea		1				1
Taste disorder	1	1			1	1
Therapeutic response unexpected		1		1		
Thirst	1	2	1	1		1
Thrombocytopenia	3	3			3	3
Thrombophlebitis		1				1
Thrombosis	1	3			1	3
Thrombotic stroke	1	1			1	1
Tinnitus		2		1		1
Tonsillar inflammation		1				1
Tonsillitis		1		1		
Tremor	2	4	2	3		1
Troponin increased		2				2
Troponin T increased		1				1
Tumour thrombosis	1	1			1	1
Type III immune complex mediated reaction	1	1			1	1
Urinary tract infection		1		1		
Vaccination failure		2				2
Vaccination site discomfort		1		1		
Vaccination site erythema	2	4	2	4		
Vaccination site induration	1	1	1	1		
Vaccination site movement impairment		1				1
Vaccination site pain	16	34	14	25	2	9
Vaccination site reaction	28	58	9	11	19	47

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site swelling		2		1		1
Vertigo	1	8	1	3		5
Vision blurred	1	3	1	3		
Visual impairment	2	3			2	3
Vomiting	7	10	4	4	3	6
Weight decreased	1	1	1	1		
Wheezing		1				1
	782	1,718	388	575	394	1143

* I=Interval, C=Cumulative
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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	3	3	3	3		
Arthralgia	3	3	3	3		
Asthenia	3	3	3	3		
Asymptomatic COVID-19		24				24
Aversion	1	1	1	1		
Axillary pain	2	2	2	2		
Back pain	1	1	1	1		
Body temperature increased		1		1		
Chest discomfort	1	1	1	1		
Chills	9	9	9	9		
Cough	1	2	1	2		
COVID-19	13	59		9	13	50
C-reactive protein increased		1		1		
Decreased appetite		1		1		
Diarrhoea	2	2	2	2		
Dizziness	1	2	1	2		
Drug ineffective	13	57			13	57
Dry mouth	1	1	1	1		
Erythema	1	1	1	1		
Exposure via breast milk	1	3	1	3		
Fatigue	12	13	12	13		
Feeling abnormal	1	1	1	1		
Feeling cold	1	1	1	1		
Feeling drunk	1	1	1	1		
Feeling hot	2	2	2	2		
Feeling of body temperature change	2	2	2	2		
General physical health deterioration		1				1
Headache	26	26	26	26		
Hyperhidrosis	3	3	3	3		
Hypoaesthesia	1	1	1	1		
Incorrect route of product administration	78	125	78	125		
Inflammation		1		1		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Influenza	3	3	3	3		
Influenza like illness	11	11	11	11		
Injection site reaction		1		1		
Insomnia	1	1	1	1		
Lymphadenopathy	4	5	4	5		
Malaise		1		1		
Migraine	1	1	1	1		
Muscle strain	1	1	1	1		
Muscular weakness	1	1	1	1		
Musculoskeletal stiffness	4	6	4	6		
Myalgia	21	21	21	21		
Mydriasis		1		1		
Nausea	8	11	8	10		1
Neck pain	3	4	3	4		
Night sweats	2	2	2	2		
Ocular hyperaemia	1	1	1	1		
Orthostatic hypotension	1	1	1	1		
Pain	3	3	3	3		
Pain in extremity	10	11	10	11		
Poor quality sleep	1	1	1	1		
Product preparation issue		1		1		
Pyrexia	22	24	22	24		
Skin reaction	1	1	1	1		
Sudden death		1				1
Syringe issue		1		1		
Underdose		1		1		
Vaccination failure		14				14
Vaccination site discolouration	1	1	1	1		
Vaccination site erythema		1		1		
Vaccination site induration		1		1		
Vaccination site movement impairment	1	1	1	1		
Vaccination site pain	6	6	6	6		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vision blurred		1		1		
Visual impairment		1		1		
Vomiting	1	1	1	1		
Wrong product administered		1		1		
Wrong technique in product usage process	77	112	77	112		
	368	610	342	462	26	148

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Country Where Event Occurred

BERMUDA

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Balance disorder		1		1		
Chills		1		1		
Diarrhoea		1		1		
Dizziness		1		1		
Dyspnoea		1				1
Ear congestion		1		1		
Ear discomfort		1		1		
Erythema		1				1
Feeling cold		1		1		
Lymphadenopathy	1	1	1	1		
Maternal exposure during pregnancy	1	1	1	1		
Night sweats		1		1		
Pain		1				1
Pain in extremity	1	1	1	1		
Paraesthesia		1		1		
Peripheral swelling	1	2	1	1		1
Pyrexia		1		1		
Rash		1		1		
Sudden visual loss		1				1
	5	21	5	16		5

* I=Interval, C=Cumulative

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Country Where Event Occurred

BOLIVIA

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased	1	1	1	1		
Cough	1	1	1	1		
Dizziness	1	1	1	1		
Feeling hot	1	1	1	1		
Heart rate increased	1	1	1	1		
Hypertension	1	1			1	1
Oropharyngeal pain	1	1	1	1		
Pancreatitis	1	1			1	1
Tachycardia	1	1	1	1		
	9	9	7	7	2	2

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* AE=Adverse Event

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Country Where Event Occurred

BOSNIA AND HERZEGOVINA

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Axillary pain	1	1	1	1
Lymphadenopathy	1	1	1	1
Oedema	1	1	1	1
	3	3	3	3

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19		1		1
		1		1

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Country Where Event Occurred

BRAZIL

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Ageusia	1	1	1	1		
Agitation	1	1	1	1		
Anxiety	1	1	1	1		
Arthralgia	3	3	3	3		
Asthenia	5	5	5	5		
Asthenopia	1	1	1	1		
Back pain	2	2	2	2		
Blood glucose increased	1	1	1	1		
Body temperature increased	1	1	1	1		
Bone pain	1	1	1	1		
Burning sensation	1	1	1	1		
Cardio-respiratory arrest	1	1			1	1
Chest discomfort	1	1	1	1		
Chills	8	8	8	8		
Contusion	1	1	1	1		
Cough	3	3	3	3		
COVID-19	3	3	2	2	1	1
Decreased appetite	2	2	2	2		
Diarrhoea	5	5	5	5		
Dizziness	2	2	2	2		
Drug ineffective	1	1			1	1
Dry mouth	1	1	1	1		
Dry throat	1	1	1	1		
Dysphonia	1	1	1	1		
Epistaxis	1	1	1	1		
Erythema	2	2	2	2		
Exposure during pregnancy	1	1			1	1
Eyelid oedema	1	1	1	1		
Eyelid pain	1	1	1	1		
Eye pain	1	1	1	1		
Eye swelling	1	1	1	1		

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fatigue	8	8	8	8		
Feeling abnormal	2	2	2	2		
Feeling hot	1	1	1	1		
Foetal death	1	1			1	1
Haemorrhage	1	1			1	1
Headache	14	14	14	14		
Head discomfort	2	2	2	2		
Heart rate increased	1	1	1	1		
Hyperhidrosis	1	1	1	1		
Hypersensitivity	5	5	4	4	1	1
Hypotension	1	1	1	1		
Influenza like illness	3	3	3	3		
Limb discomfort	2	2	2	2		
Lymphadenopathy	2	2	2	2		
Lymphocyte count decreased	1	1	1	1		
Lymphopenia	1	1	1	1		
Malaise	4	4	4	4		
Maternal exposure during pregnancy	3	3	2	2	1	1
Maternal exposure timing unspecified	1	1	1	1		
Menstrual disorder	1	1	1	1		
Myalgia	9	9	9	9		
Nasal congestion	2	2	2	2		
Nausea	6	6	6	6		
Neck pain	1	1	1	1		
Neutrophil count decreased	1	1	1	1		
Off label use	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Overdose	2	2	2	2		
Pain	7	8	7	8		
Painful respiration	1	1	1	1		
Pain in extremity	13	13	13	13		
Pain in jaw	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Papule	1	1			1	1
Peripheral coldness	1	1	1	1		
Peripheral swelling	1	1	1	1		
Pollakiuria	1	1	1	1		
Polymenorrhoea	1	1	1	1		
Premature labour	1	1			1	1
Productive cough	1	1	1	1		
Product preparation error	1	1	1	1		
Product use issue	1	1	1	1		
Pruritus	3	3	2	2	1	1
Pyrexia	11	11	11	11		
Rash	2	2	1	1	1	1
Rhinitis	1	1	1	1		
Rhinorrhoea	1	1	1	1		
SARS-CoV-2 test positive	2	2	1	1	1	1
Seizure	1	1			1	1
Sleep disorder	1	1	1	1		
Sluggishness	2	2	2	2		
Somnolence	1	1	1	1		
Speech disorder	1	1	1	1		
Tachycardia	2	2	2	2		
Thirst	1	1	1	1		
Throat irritation	2	2	2	2		
Thrombosis	1	1			1	1
Tremor	1	1	1	1		
Urticaria	2	2	1	1	1	1
Vaccination site bruising	1	1	1	1		
Vaccination site haematoma	1	1	1	1		
Vaccination site haemorrhage	2	2	1	1	1	1
Vaccination site inflammation	1	1			1	1
Vaccination site mass	1	1			1	1
Vaccination site pain	19	19	18	18	1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site swelling	2	2	2	2		
Visual impairment	1	1	1	1		
White blood cell count decreased	1	1	1	1		
	230	231	210	211	20	20

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	2	2	2	2		
Appetite disorder	1	1	1	1		
Arthralgia	1	1	1	1		
Asthenia	2	2	2	2		
Back pain	1	1	1	1		
Burning sensation	1	1	1	1		
Chills	8	8	8	8		
Cough	2	2	2	2		
Dizziness	1	1	1	1		
Drug ineffective	1	1			1	1
Dry mouth	2	2	2	2		
Dyskinesia	1	1	1	1		
Dyspnoea	2	2	1	1	1	1
Erythema	1	1	1	1		
Fatigue	5	5	4	4	1	1
Gait disturbance	1	1	1	1		
Headache	12	12	12	12		
Hyperhidrosis	1	1	1	1		
Hypoaesthesia oral	1	1	1	1		
Hypokinesia	1	1	1	1		
Incorrect dose administered	1	1	1	1		
Influenza like illness	1	1	1	1		
Insomnia	1	1	1	1		
Lymphadenopathy	2	2	2	2		
Malaise	2	2	2	2		
Mobility decreased	1	1	1	1		
Myalgia	2	2	2	2		
Nausea	3	3	3	3		
Overdose	2	2	2	2		
Pain	6	6	6	6		
Pain in extremity	4	4	4	4		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pleural effusion	1	1			1	1
Poor quality product administered	1	1	1	1		
Product administered at inappropriate site	1	1	1	1		
Pruritus	1	1	1	1		
Pyrexia	10	10	9	9	1	1
Somnolence	2	2	2	2		
Suspected COVID-19	1	1			1	1
Swelling face	1	1	1	1		
Thirst	1	1	1	1		
Tremor	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site mass	1	1	1	1		
Vaccination site pain	9	9	8	8	1	1
Vomiting	1	1	1	1		
Wrong technique in product usage process	1	1	1	1		
	106	106	99	99	7	7

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposure via breast milk	1	1	1	1		
Maternal exposure during pregnancy	1	1			1	1
Premature baby	1	1			1	1
Therapeutic response unexpected	1	1	1	1		
	4	4	2	2	2	2

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Country Where Event Occurred

BULGARIA

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- * AE=Adverse Event
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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Abdominal pain upper		1				1
Agitation		1		1		
Anaphylactoid reaction		1				1
Angina pectoris		1				1
Anosmia		1		1		
Antibody test abnormal		1		1		
Anti-thyroid antibody positive		1				1
Arrhythmia		1				1
Arthralgia	7	25	5	23	2	2
Arthritis		1		1		
Asthenia	2	12	2	11		1
Axillary pain	1	1	1	1		
Back pain	4	7	3	6	1	1
Blood fibrinogen increased	1	1			1	1
Blood glucose increased	1	2		1	1	1
Blood pressure ambulatory increased	1	1	1	1		
Blood pressure decreased		1				1
Blood pressure diastolic decreased		1		1		
Blood pressure inadequately controlled		1		1		
Blood pressure increased	1	6	1	4		2
Body temperature abnormal	1	2	1	2		
Body temperature increased	17	32	16	29	1	3
Bone pain		1		1		
Breast pain	1	2	1	2		
Bronchitis		1		1		
Chest discomfort	1	1	1	1		
Chest pain		1		1		
Chills	8	27	7	23	1	4
Coccydynia	1	1			1	1
Communication disorder	1	1	1	1		
Condition aggravated		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Confusional state	1	1	1	1		
Conjunctivitis allergic		1		1		
Cough		3		3		
COVID-19		7				7
COVID-19 pneumonia		2				2
Cystitis	1	1			1	1
Deafness unilateral		1				1
Decreased appetite	2	3	2	2		1
Dental discomfort		1		1		
Discomfort	2	4	2	4		
Disturbance in attention	1	2	1	2		
Dizziness	4	14	4	13		1
Dizziness postural		1		1		
Drug ineffective		7				7
Drug interaction	1	1			1	1
Dry mouth		1		1		
Dysphagia	1	1	1	1		
Dyspnoea	2	6	2	5		1
Epistaxis	1	1	1	1		
Erythema	3	7	3	7		
Extrasystoles		2		2		
Eye irritation	1	1	1	1		
Eye pain	1	3	1	3		
Facial paralysis		1				1
Fatigue	8	25	8	25		
Fear	1	1	1	1		
Feeling abnormal	1	1	1	1		
Gait disturbance		2		1		1
Gastrointestinal disorder		1		1		
Grip strength decreased		1		1		
Haematoma		1				1
Headache	14	41	13	36	1	5

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Head discomfort		2		1		1
Heart rate increased	1	1	1	1		
Heart rate irregular		1		1		
Herpes simplex		1		1		
Herpes zoster	1	1	1	1		
Hyperglycaemia	1	1			1	1
Hyperhidrosis		2				2
Hypersensitivity	3	3	1	1	2	2
Hypertension	2	3	1	2	1	1
Hypoaesthesia	2	2	2	2		
Hypothermia		1				1
Influenza like illness	2	3	2	3		
Injection site pain		3		3		
Injection site swelling		1		1		
Insomnia	1	2	1	2		
Interstitial lung disease		1				1
Joint swelling	1	1	1	1		
Joint warmth	1	1	1	1		
Lacrimation increased	1	2	1	2		
Leukopenia		1				1
Limb discomfort		2		2		
Lip swelling	1	2	1	1		1
Lymphadenopathy	2	10	2	10		
Lymph node pain		2		2		
Lymphocyte count decreased		1		1		
Malaise	2	7	2	7		
Mastication disorder		1		1		
Mobility decreased		1		1		
Movement disorder		2		1		1
Muscle spasms	2	2	2	2		
Musculoskeletal pain		1		1		
Musculoskeletal stiffness	2	4	1	2	1	2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	11	34	11	34		
Myelitis transverse		1				1
Nasopharyngitis		2		2		
Nausea	5	15	5	14		1
Neck pain		1		1		
Neuralgia	1	1	1	1		
Neuromyelitis optica spectrum disorder		1				1
Oedema peripheral	1	3	1	3		
Oropharyngeal discomfort	1	1	1	1		
Oropharyngeal pain	2	4	2	4		
Overdose		2		2		
Pain		3		3		
Painful respiration		1		1		
Pain in extremity	8	16	6	14	2	2
Pallor		1		1		
Palpitations	1	4	1	3		1
Paraesthesia	2	6	1	4	1	2
Paraesthesia oral		1		1		
Paranasal sinus discomfort		1		1		
Peripheral coldness		1		1		
Peripheral sensory neuropathy		1		1		
Peripheral swelling		2		2		
Photophobia	1	2	1	2		
Pneumonia		1				1
Polymenorrhoea	1	1	1	1		
Poor peripheral circulation	1	1	1	1		
Presyncope		1		1		
Pruritus	1	4		2	1	2
Pyrexia	13	33	13	31		2
Rash	3	7	2	6	1	1
Rash erythematous	1	2		1	1	1
Rash macular		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash papular	1	1			1	1
Rash pruritic		1		1		
Renal pain	1	2	1	2		
Rheumatoid arthritis		1				1
Rheumatoid factor increased		1				1
Rheumatoid factor positive		1		1		
Rhinorrhoea		1		1		
SARS-CoV-2 test positive		1				1
Seizure		1				1
Sensitive skin	1	1	1	1		
Sinusitis		1		1		
Somnolence	2	2	2	2		
Spinal pain		1		1		
Swelling		2		2		
Swelling face	1	1	1	1		
Swollen tongue		1				1
Syncope		1				1
Tachycardia	1	2	1	1		1
Thirst		1		1		
Throat irritation		1		1		
Tinnitus		1		1		
Tracheitis		1		1		
Tremor		3		2		1
Trismus		1		1		
Urticaria	2	4	1	2	1	2
Vaccination site erythema	5	19	5	16		3
Vaccination site induration	1	2	1	1		1
Vaccination site oedema	1	2	1	2		
Vaccination site pain	16	63	15	61	1	2
Vaccination site paraesthesia	1	2	1	2		
Vaccination site reaction		1				1
Vaccination site swelling	3	20	3	18		2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vasodilatation		1		1		
Vasospasm		1				1
Vertigo	1	10	1	6		4
Vision blurred	1	1	1	1		
Vomiting	3	6	3	5		1
	212	668	187	559	25	109

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		1		1		
Abdominal pain upper	1	1	1	1		
Ageusia		1		1		
Agitation		1		1		
Allergy to vaccine		1		1		
Anosmia		1		1		
Application site erythema	1	1	1	1		
Application site swelling	1	1	1	1		
Arthralgia	1	11	1	11		
Asthenia	2	10	2	9		1
Axillary pain		1		1		
Back pain	1	2	1	2		
Blood glucose increased		1				1
Blood pressure ambulatory increased		1				1
Blood pressure fluctuation		1		1		
Blood pressure increased		2		2		
Body temperature increased	2	11	2	11		
Chills	1	9	1	9		
Circulatory collapse		1				1
Cold sweat		1		1		
Condition aggravated		1		1		
Cough	3	4	3	4		
COVID-19	4	8	2	4	2	4
C-reactive protein increased		1				1
Decreased appetite	1	2	1	2		
Diarrhoea	1	3	1	3		
Dizziness	1	4	1	4		
Drug eruption		1		1		
Drug ineffective	2	4			2	4
Dry mouth		1		1		
Dysphonia		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea	1	3	1	2		1
Epigastric discomfort		1		1		
Epistaxis		1		1		
Erectile dysfunction		1				1
Erythema		1		1		
Eye pain	2	2	2	2		
Facial bones fracture		1				1
Facial paralysis		2				2
Fatigue	5	15	5	15		
Feeling cold		1		1		
Feeling hot		1		1		
Gait disturbance	1	2	1	2		
Groin abscess		1				1
Headache	6	21	6	21		
Heart alternation		1		1		
Heart rate increased		1		1		
HIV test positive		1		1		
Hot flush		1		1		
Hyperhidrosis	1	4	1	4		
Hypersensitivity	1	1			1	1
Hypertension	1	3	1	2		1
Hypoaesthesia		1		1		
Inappropriate schedule of product administration		1		1		
Influenza like illness	1	2	1	2		
Injection site pain	1	2	1	2		
Injection site swelling		2		2		
Iron deficiency anaemia	1	1	1	1		
Joint injury		1				1
Jugular vein distension		1				1
Lacrimation increased		1		1		
Lymphadenopathy	3	11	2	9	1	2
Lymph node pain		2		2		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise	2	7	2	7		
Meningism		1		1		
Mouth swelling	1	1			1	1
Muscular weakness	1	1	1	1		
Musculoskeletal stiffness	1	1	1	1		
Myalgia	1	12	1	12		
Nasopharyngitis		1		1		
Nausea	1	5	1	5		
Neck pain	1	1	1	1		
Neuralgia		1		1		
Off label use		1		1		
Oropharyngeal pain	1	3	1	3		
Pain		2		2		
Pain in extremity	1	6	1	6		
Palpitations		1		1		
Panic attack		2		2		
Paraesthesia	1	5	1	5		
Peripheral swelling	2	2	1	1	1	1
Pneumonia	1	1			1	1
Productive cough		1		1		
Pruritus	1	1	1	1		
Pyrexia	5	16	5	16		
Rash	1	1	1	1		
Rhinorrhoea		1		1		
Sweating fever		1				1
Swelling		1		1		
Syncope		1				1
Tachycardia		2		1		1
Tinnitus		1		1		
Tremor		2		2		
Urticaria	1	2		1	1	1
Vaccination site erythema	2	5	2	5		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site extravasation		1		1		
Vaccination site induration		1		1		
Vaccination site pain	6	19	6	19		
Vaccination site pruritus	1	1	1	1		
Vaccination site reaction		1		1		
Vaccination site swelling	1	3	1	3		
Ventricular extrasystoles		1				1
Vertigo	1	3	1	3		
Vomiting		1		1		
	79	300	69	267	10	33

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Body temperature increased	1	1	1	1		
COVID-19		3		1		2
Dizziness		1		1		
Drug ineffective		2				2
Fatigue	1	1	1	1		
Headache	1	1	1	1		
Lethargy		1		1		
Swelling face	1	1	1	1		
Vertigo		1		1		
	4	12	4	8		4

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Country Where Event Occurred

CANADA

090177e19749cf15\Approved\Approved On: 14-Jun-2021 14:01 (GMT)

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2		2		
Abdominal pain	3	6	2	4	1	2
Abdominal pain lower	1	3	1	3		
Abdominal pain upper	5	12	4	10	1	2
Abnormal dreams		1		1		
Abnormal sensation in eye	1	1			1	1
Abortion spontaneous		3				3
Accidental exposure to product		1		1		
Acne		1		1		
Affect lability	1	2	1	2		
Ageusia		3		3		
Agitation	1	1	1	1		
Alanine aminotransferase decreased		1		1		
Allergy to vaccine		1		1		
Amenorrhoea	1	1	1	1		
Anaphylactic reaction	4	21			4	21
Anaphylactic shock		2				2
Anger	1	1	1	1		
Angioedema	2	4			2	4
Angiopathy		1		1		
Anosmia	1	2	1	2		
Anxiety	1	7	1	6		1
Aphasia		2		2		
Aphthous ulcer		2		2		
Arrhythmia	5	7			5	7
Arthralgia	25	56	19	46	6	10
Arthritis	7	8	3	4	4	4
Arthritis reactive	1	1			1	1
Asthenia	5	26	4	20	1	6
Asthma		1		1		
Asymptomatic COVID-19		1				1
Ataxia	1	2		1	1	1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Atrial f brillation		3
Autoimmune disorder	2	3
Axillary mass	1	2
Axillary pain	2	6
Back pain	7	13
Balance disorder	3	5
Bedridden	1	1
Bell's palsy	3	10
Beta haemolytic streptococcal infection		1
Bladder spasm		1
Blindness transient	1	1
Blister	2	2
Blood creatinine abnormal		1
Blood glucose decreased	2	4
Blood glucose increased		1
Blood immunoglobulin G increased		1
Blood iron decreased	1	1
Blood pressure decreased	3	6
Blood pressure fluctuation	1	2
Blood pressure increased		4
Blood pressure orthostatic abnormal	1	1
Blood pressure systolic increased	1	1
Blood urine present		1
Body temperature increased	3	4
Bradycardia		1
Bradyphrenia	1	1
Breast pain	2	4
Breast swelling		1
Breast tenderness		1
Bronchitis		1
Bronchospasm		1
Burning sensation	9	11

Spontaneous			
Nonserious		Serious	
I	C	I	C
			3
		2	3
1	2		
2	6		
6	10	1	3
3	4		1
		1	1
		3	10
			1
	1		
		1	1
		2	2
	1		
1	1	1	3
	1		
1	1		
2	3	1	3
	1	1	1
	3		1
		1	1
1	1		
	1		
3	4		
			1
1	1		
2	3		1
	1		
	1		
			1
7	9	2	2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bursitis		1		1		
Candida infection	1	1	1	1		
Cardiac arrest	1	1			1	1
Cardiac disorder		1				1
Cardiac flutter	1	3			1	3
Cardiovascular disorder		1		1		
Carotid artery dissection		1				1
Carotid artery thrombosis		1				1
Cerebral artery occlusion	1	1			1	1
Cerebral haemorrhage	1	1			1	1
Cerebrovascular accident	5	8			5	8
Cerumen impaction		1		1		
Change of bowel habit		1		1		
Chapped lips		1		1		
Chest discomfort	2	14	1	7	1	7
Chest pain	12	17	10	14	2	3
Chillblains	1	1	1	1		
Chills	21	65	19	61	2	4
Chronic obstructive pulmonary disease		1				1
Coeliac disease		1				1
Cognitive disorder	1	2	1	2		
Cold sweat		4		3		1
Colitis ischaemic	1	1			1	1
Coma	1	1			1	1
Communication disorder	1	1			1	1
Condition aggravated	5	11	3	4	2	7
Confusional state	4	6	3	5	1	1
Conjunctival haemorrhage	1	1			1	1
Conjunctivitis	1	2	1	2		
Connective tissue disorder		1				1
Constipation	1	1	1	1		
Contusion	4	10	2	6	2	4

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Costochondritis	1	1	1	1		
Cough	4	15	4	12		3
COVID-19	6	17	1	2	5	15
COVID-19 pneumonia		1				1
C-reactive protein increased	1	1	1	1		
Crying	1	1	1	1		
Cystitis		1		1		
Deafness	2	3			2	3
Deafness neurosensory	1	1			1	1
Deafness unilateral	2	2			2	2
Death		1				1
Decreased appetite	2	6	1	5	1	1
Deep vein thrombosis		1				1
Defaecation urgency	1	2	1	2		
Dehydration	2	3	2	3		
Depressed level of consciousness	1	2			1	2
Depression		2		2		
Dermatitis	1	1	1	1		
Dermatitis infected		1		1		
Dermatochalasis		1		1		
Diabetes mellitus		1				1
Diarrhoea	11	33	8	27	3	6
Diplopia		2		1		1
Discomfort	2	5	1	4	1	1
Disease recurrence	5	10	1	3	4	7
Disseminated varicella zoster virus infection	1	1			1	1
Distract bility		1		1		
Disturbance in attention	3	9	2	7	1	2
Diverticulitis	1	1			1	1
Dizziness	35	80	24	58	11	22
Dizziness postural	1	1	1	1		
Drug hypersensitivity		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug ineffective	6	15			6	15
Drug interaction	1	1	1	1		
Dry eye		1		1		
Dry mouth		4		3		1
Dysarthria		1				1
Dysgeusia	1	11	1	11		
Dyskinesia	1	2	1	2		
Dysmenorrhoea	4	6	4	6		
Dysphagia	1	10	1	9		1
Dysphonia	1	4	1	3		1
Dyspnoea	9	37	7	25	2	12
Dysuria		1				1
Ear discomfort		5		5		
Ear pain	1	1	1	1		
Ear pruritus	2	3	2	3		
Ear swelling	2	2	2	2		
Eating disorder	1	1	1	1		
Ectopic pregnancy		1				1
Eczema		1		1		
Electric shock sensation	1	3			1	3
Eosinophil count increased		1		1		
Epistaxis		1		1		
Erythema	7	21	6	17	1	4
Erythema multiforme		1				1
Euphoric mood	1	1	1	1		
Excessive cerumen production		1		1		
Exposure during pregnancy	4	14	4	14		
Exposure via breast milk	1	8	1	8		
Extrasystoles		1		1		
Eye haemorrhage	1	1			1	1
Eyelid function disorder		1				1
Eyelid oedema		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid ptosis		1				1
Eyelid sensory disorder		1		1		
Eyelids pruritus	1	2	1	1		1
Eye movement disorder	1	1			1	1
Eye pain	4	5	2	3	2	2
Eye pruritus	2	3	2	3		
Eye swelling	3	6	2	4	1	2
Face oedema		1				1
Facial pain	2	5	1	4	1	1
Facial paralysis		2				2
Faeces discoloured		1		1		
Faeces soft		1		1		
Fall	1	5	1	2		3
Fatigue	52	143	44	124	8	19
Fear	1	2	1	2		
Feeling abnormal	14	26	12	24	2	2
Feeling cold	1	6	1	4		2
Feeling drunk	1	2		1	1	1
Feeling hot	8	17	8	16		1
Feeling of body temperature change		2		2		
Fibrin D dimer increased	2	2	1	1	1	1
Fibromyalgia		1		1		
Fluid retention	1	4	1	4		
Flushing	4	8	3	6	1	2
Frequent bowel movements	1	1	1	1		
Gait disturbance	9	10	9	9		1
Galactostasis	1	1	1	1		
Gastric disorder		1		1		
Gastric ulcer		1				1
Gastroenteritis		1		1		
Gastroenteritis viral		1		1		
Gastrointestinal disorder	1	2	1	2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal pain	1	2	1	2		
Gastroesophageal reflux disease		1		1		
Generalised tonic-clonic seizure		1				1
Gestational diabetes		1				1
Gout	1	1	1	1		
Grip strength decreased		1		1		
Haematemesis		1				1
Haematochezia		1				1
Haemoglobin decreased	1	1			1	1
Haemoglobin increased		1		1		
Haemorrhage	1	1			1	1
Hallucination	1	1			1	1
Hand deformity	1	1	1	1		
Headache	51	147	41	128	10	19
Head discomfort	4	5	4	5		
Heart rate decreased		2				2
Heart rate increased	7	15	4	8	3	7
Heart rate irregular	1	1			1	1
Heavy menstrual bleeding	14	17	10	12	4	5
Hepatic enzyme increased		1				1
Herpes ophthalmic	1	1			1	1
Herpes zoster	12	18	11	15	1	3
Herpes zoster oticus		1				1
Hip fracture		1				1
Hot flush	3	6	3	5		1
Hunger	2	2	1	1	1	1
Hyperacusis	1	1	1	1		
Hyperaesthesia	1	3	1	3		
Hyperaesthesia teeth	2	3	1	2	1	1
Hyperhidrosis	9	12	9	10		2
Hypersensitivity	6	16	5	10	1	6
Hypersomnia		2		2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertension	7	20	2	5	5	15
Hypertensive crisis		1				1
Hypoacusis	1	4	1	4		
Hypoaesthesia	27	53	17	31	10	22
Hypoaesthesia eye	1	2	1	2		
Hypoaesthesia oral	4	12	3	5	1	7
Hypomenorrhoea	1	1	1	1		
Hypopnoea	1	2	1	2		
Hypotension	4	12	2	7	2	5
Idiopathic angioedema	1	1			1	1
Illness	2	4	2	4		
Impaired driving ability	2	2	2	2		
Impaired quality of life	1	2	1	2		
Impaired work ability		2		2		
Inappropriate schedule of product administration	5	22	5	22		
Incomplete course of vaccination		1		1		
Incorrect dose administered	1	2	1	2		
Incorrect route of product administration		1		1		
Infection		1		1		
Inflammation	2	3	2	3		
Inflammatory pain	1	1			1	1
Influenza like illness		9		7		2
Infusion site warmth		1		1		
Injection site bruising	1	1	1	1		
Injection site erythema	1	3	1	3		
Injection site haemorrhage	1	1	1	1		
Injection site pain	1	7	1	7		
Injection site scar		1		1		
Insomnia	5	9	3	7	2	2
Intermenstrual bleeding	3	3	3	3		
Intraocular pressure increased	1	1			1	1
Ischaemic stroke	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
IVth nerve paralysis		1				1
Joint noise		1		1		
Joint stiffness	2	2	1	1	1	1
Joint swelling	4	8	2	4	2	4
Joint warmth	2	2	1	1	1	1
Labyrinthitis	1	1			1	1
Lacrimation increased		1		1		
Language disorder	1	1	1	1		
Laryngeal oedema	1	1			1	1
Laryngospasm		1				1
Lethargy	3	5	3	5		
Leukoplakia		1		1		
Ligament sprain		1		1		
Limb discomfort	6	8	4	6	2	2
Lip blister		1		1		
Lip haemorrhage		1		1		
Lip oedema	1	1	1	1		
Lip pain		1		1		
Lip pruritus		1		1		
Lip swelling	4	11	3	8	1	3
Livedo reticularis	2	2	2	2		
Liver function test increased		1				1
Loss of consciousness	3	7			3	7
Loss of personal independence in daily activities	1	4	1	3		1
Lung disorder		2				2
Lymphadenopathy	10	33	9	27	1	6
Lymph node pain		3		3		
Lymphoedema	1	1	1	1		
Malaise	14	37	11	33	3	4
Mass		1		1		
Mastitis	1	1			1	1
Maternal exposure before pregnancy		3		3		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Maternal exposure during pregnancy	1	20
Maternal exposure timing unspecified		2
Mean cell haemoglobin concentration increased		1
Menstrual disorder	7	8
Menstruation delayed	1	2
Menstruation irregular	18	20
Mental disorder	1	1
Mental impairment	1	2
Micturition urgency	1	2
Migraine	5	14
Migraine with aura		1
Miosis	1	1
Mobility decreased	2	4
Monocyte count increased		1
Monocyte percentage increased		1
Motion sickness	1	1
Mouth swelling	2	3
Movement disorder	3	4
Mucosal discolouration		1
Multiple organ dysfunction syndrome	1	1
Multiple sclerosis		1
Multiple sclerosis relapse		1
Muscle injury		1
Muscle rigidity	1	1
Muscle spasms	4	6
Muscle tightness	1	2
Muscle twitching	2	4
Muscular weakness	6	12
Musculoskeletal chest pain	1	1
Musculoskeletal discomfort	1	1
Musculoskeletal pain	1	2
Musculoskeletal stiffness	2	10

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	20		
	2		
	1		
5	6	2	2
1	2		
17	19	1	1
1	1		
		1	2
1	2		
5	13		1
			1
1	1		
	2	2	2
	1		
	1		
1	1		
1	1	1	2
3	4		
	1		
		1	1
			1
	1		
1	1		
2	3	2	3
1	2		
2	4		
3	8	3	4
1	1		
1	1		
1	2		
2	10		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	15	54	13	48	2	6
Myocardial infarction	3	4			3	4
Myocarditis	1	2			1	2
Myositis	1	1	1	1		
Nasal congestion		2		1		1
Nasopharyngitis	1	3	1	3		
Nausea	34	87	28	72	6	15
Neck pain	3	11	3	10		1
Necrosis		1				1
Needle issue		1		1		
Nervousness	1	2	1	1		1
Neuralgia	1	3	1	1		2
Neurogenic shock	2	2			2	2
Neurological symptom	1	2	1	1		1
Neuropathy peripheral	2	2			2	2
Neutropenia	1	1			1	1
Neutrophil count decreased		1		1		
Nightmare	1	1			1	1
Night sweats		2		1		1
Ocular discomfort	2	2	1	1	1	1
Ocular hyperaemia	1	1			1	1
Odynophagia	1	2	1	2		
Oedema		1				1
Oedema peripheral		1		1		
Oesophageal disorder		1				1
Off label use	20	60	20	59		1
Ophthalmic herpes zoster	2	2			2	2
Optic nerve disorder	1	1	1	1		
Oral candidiasis		1		1		
Oral discomfort		3		3		
Oral herpes	1	3		2	1	1
Oral mucosal blistering		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral pain		1		1		
Oropharyngeal discomfort		1		1		
Oropharyngeal pain	4	12	4	12		
Osteoarthritis	1	1	1	1		
Overdose		4		4		
Oversensing	1	1	1	1		
Oxygen saturation decreased		1				1
Pain	20	50	19	46	1	4
Pain in extremity	43	83	38	72	5	11
Pain in jaw		3		2		1
Pain of skin		2		2		
Palatal swelling	1	1	1	1		
Pallor	2	5	2	4		1
Palmar erythema	1	1			1	1
Palpitations	5	10	3	7	2	3
Panic reaction	1	1	1	1		
Paraesthesia	18	46	12	28	6	18
Paraesthesia oral	5	17	2	10	3	7
Paralysis		1				1
Parvovirus infection		1		1		
Pelvic pain	1	1			1	1
Pericardial effusion	1	2			1	2
Pericarditis	2	3			2	3
Periorbital swelling	1	3	1	3		
Peripheral coldness	3	5	2	3	1	2
Peripheral swelling	7	17	5	13	2	4
Petechiae		2		2		
Pharyngeal hypoaesthesia	1	4	1	3		1
Pharyngeal oedema	1	1	1	1		
Pharyngeal paraesthesia		1				1
Pharyngeal swelling	2	6	1	3	1	3
Phlebitis	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Photophobia	2	2	2	2		
Photosensitivity reaction	2	2	1	1	1	1
Platelet count decreased	1	1			1	1
Platelet count increased	1	1	1	1		
Pleural effusion	1	2			1	2
Pneumonia	1	1			1	1
Polydipsia		1		1		
Polymenorrhoea	6	7	6	7		
Polyuria		1		1		
Poor peripheral circulation		1		1		
Poor quality sleep	1	1			1	1
Portal vein thrombosis	1	1			1	1
Postmenopausal haemorrhage	1	1			1	1
Postpartum haemorrhage		1		1		
Postural orthostatic tachycardia syndrome	1	1			1	1
Premenstrual pain	1	1	1	1		
Presyncope	2	9	2	6		3
Product administered at inappropriate site	1	4	1	4		
Productive cough		2		1		1
Product preparation issue		2		2		
Product supply issue	1	3	1	3		
Product use issue	16	48	16	47		1
Pruritus	11	34	5	22	6	12
Psychomotor hyperactivity	1	1			1	1
Psychotic disorder due to a general medical condition		1				1
Pulmonary congestion	1	1			1	1
Pulmonary embolism	5	7			5	7
Pulmonary infarction		1				1
Pulmonary oedema		1				1
Pulmonary pain		1				1
Pulse volume decreased		2		1		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Purpura		2		2		
Pyrexia	23	70	21	64	2	6
Rash	7	31	4	27	3	4
Rash erythematous	2	7	1	5	1	2
Rash macular	3	5	3	5		
Rash maculo-papular		2		2		
Rash papular	1	3	1	2		1
Rash pruritic	4	8	1	3	3	5
Rash vesicular	1	1			1	1
Raynaud's phenomenon		1				1
Rectal haemorrhage		1				1
Rectal polyp		1				1
Reflexes abnormal		1				1
Renal failure	1	1			1	1
Respiratory disorder	1	2		1	1	1
Respiratory distress		1				1
Respiratory rate increased	1	1			1	1
Restless arm syndrome	1	1	1	1		
Restless legs syndrome	1	1	1	1		
Retinal vascular thrombosis	1	1			1	1
Rheumatoid arthritis	1	3			1	3
Rhinorrhoea	2	6	1	4	1	2
Rib fracture		1				1
Roseola		1		1		
SARS-CoV-2 test positive	1	1			1	1
Scar	1	1			1	1
Scleral disorder	1	1	1	1		
Screaming		1		1		
Seasonal allergy	1	1	1	1		
Secretion discharge		1		1		
Seizure		1				1
Sensitisation	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensory disturbance		1				1
Sensory loss	2	3	1	2	1	1
Shock	1	1			1	1
Sinus disorder	1	1	1	1		
Sinus pain	1	2		1	1	1
Skin burning sensation	3	5	3	5		
Skin discolouration	2	3	2	3		
Skin disorder	1	2	1	2		
Skin exfoliation	1	2		1	1	1
Skin induration	1	1	1	1		
Skin laceration		1		1		
Skin lesion		1		1		
Skin reaction		2		2		
Skin warm		1		1		
Sleep disorder	4	5	3	4	1	1
Sluggishness	1	1	1	1		
Small fibre neuropathy	1	1	1	1		
Sneezing	1	3	1	3		
Somnolence	5	10	4	6	1	4
Speech disorder	3	5	3	5		
Spinal pain	2	2	2	2		
Stevens-Johnson syndrome		1				1
Stomatitis	1	2	1	2		
Stress	2	4	2	4		
Sudden death	1	1			1	1
Sudden hearing loss	1	1			1	1
Superior sagittal sinus thrombosis		1				1
Suspected COVID-19		2		1		1
Swelling	7	12	4	8	3	4
Swelling face	7	17	5	11	2	6
Swelling of eyelid	2	4	2	4		
Swollen tongue	2	10	1	7	1	3

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Syncope	6	15
Synovitis	2	2
Systemic lupus erythematosus		1
Tachycardia	5	18
Tachypnoea		2
Taste disorder		2
Temporomandibular joint syndrome		1
Tenderness		1
Tendon disorder	1	2
Tendonitis		1
Tension headache		1
Therapeutic product effect decreased	1	1
Therapeutic response unexpected	2	5
Thirst	2	4
Threatened labour		1
Throat irritation		2
Throat tightness	2	9
Thrombocytopenia		2
Thrombophlebitis	1	1
Thrombosis	7	11
Thyroid disorder		1
Thyroiditis	1	1
Tinnitus	6	15
Tongue discomfort	1	1
Tongue disorder		5
Tongue oedema	1	1
Tongue pruritus		2
Transient ischaemic attack		2
Tremor	2	9
Trigeminal nerve disorder	1	1
Troponin increased		1
Type I hypersensitivity		2

Spontaneous			
Nonserious		Serious	
I	C	I	C
		6	15
		2	2
			1
2	9	3	9
	2		
	2		
	1		
	1		
	1	1	1
	1		
	1		
1	1		
2	5		
2	4		
	1		
	2		
	2	2	7
			2
		1	1
		7	11
	1		
1	1		
5	11	1	4
		1	1
	4		1
1	1		
	2		
			2
2	8		1
		1	1
	1		
			2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Type IV hypersensitivity reaction		1		1		
Underdose		2		2		
Unresponsive to stimuli	1	1			1	1
Upper-airway cough syndrome		1		1		
Urinary incontinence		1				1
Urinary tract infection		1		1		
Urticaria	13	37	11	29	2	8
Uveitis		1				1
Vaccination failure		2				2
Vaccination site cellulitis	1	1	1	1		
Vaccination site discomfort	1	4	1	3		1
Vaccination site erythema	3	9	1	7	2	2
Vaccination site hyperaesthesia	1	1	1	1		
Vaccination site hypersensitivity	1	1	1	1		
Vaccination site hypoaesthesia	1	1	1	1		
Vaccination site induration	2	4	1	3	1	1
Vaccination site inflammation		1		1		
Vaccination site joint movement impairment		1		1		
Vaccination site lymphadenopathy		1		1		
Vaccination site mass	1	2	1	2		
Vaccination site movement impairment		1		1		
Vaccination site nodule	1	1			1	1
Vaccination site oedema		3		3		
Vaccination site pain	31	78	27	72	4	6
Vaccination site paraesthesia	1	1	1	1		
Vaccination site pruritus		1		1		
Vaccination site rash		2		2		
Vaccination site reaction	1	2	1	2		
Vaccination site swelling	3	11	2	10	1	1
Vaccination site urticaria	1	6	1	4		2
Vaccination site warmth	2	7		5	2	2
Vaginal discharge		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaginal haemorrhage	6	9	1	4	5	5
Venous bruit	1	1	1	1		
Venous thrombosis limb	1	1			1	1
Ventricular tachycardia		1				1
Vertebral artery dissection		1				1
Vertigo	10	15	4	8	6	7
Viral rash		1		1		
Vision blurred	6	11	3	6	3	5
Visual acuity reduced	1	1	1	1		
Visual impairment	1	2			1	2
Vitamin B12 increased	1	1	1	1		
Vitreous detachment		1				1
Vitreous floaters		1		1		
Vomiting	12	30	10	22	2	8
Vomiting projectile		1		1		
Vulval disorder		1				1
Vulvitis		1		1		
Weight decreased	1	3		2	1	1
Weight increased		1		1		
Wheezing	2	6		3	2	3
White blood cell count decreased		1		1		
White blood cell count increased	2	2	2	2		
White coat hypertension		1				1
	1,265	3,170	894	2333	371	837

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal distension		1		1		
Abdominal pain	1	2	1	2		
Abdominal pain upper	2	3	2	3		
Acne	1	1	1	1		
Acute kidney injury		1				1
Ageusia	1	1	1	1		
Agitation		1		1		
Alanine aminotransferase increased		3		2		1
Amyloidosis	1	1			1	1
Anal incontinence	1	1			1	1
Anaphylactic reaction		2				2
Anaphylactic shock	2	2			2	2
Aneurysm	1	2			1	2
Angioedema	1	1			1	1
Anosmia	1	1	1	1		
Anxiety	3	4		1	3	3
Arrhythmia	2	3			2	3
Arthralgia	3	6	1	4	2	2
Arthritis	1	2		1	1	1
Aspartate aminotransferase increased		1				1
Asthenia	5	11	5	10		1
Asthma	1	1			1	1
Atrial fibrillation	1	2			1	2
Axillary pain		2		2		
Back pain	2	3	1	2	1	1
Balance disorder		2		1		1
Bell's palsy		6				6
Blood cholesterol decreased		1		1		
Blood creatine phosphokinase increased		1				1
Blood pressure decreased		1				1
Blood urine		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood urine present		1		1		
Burning sensation	1	1	1	1		
Cardiac failure		1				1
Cardiac flutter	1	2			1	2
Cellulitis		1				1
Cerebral haemorrhage	1	1			1	1
Cerebrovascular accident	2	3			2	3
Chest discomfort	2	4		2	2	2
Chest pain	1	2	1	2		
Chills	3	10	2	9	1	1
Choking	1	1			1	1
Chromaturia		1		1		
Cold sweat	1	1			1	1
Colitis ulcerative		1				1
Coma	1	1			1	1
Condition aggravated	1	4			1	4
Contusion	1	1	1	1		
Conversion disorder	1	1			1	1
Cough	1	2	1	2		
COVID-19	1	7			1	7
C-reactive protein increased		2		1		1
Deafness	2	3			2	3
Deafness unilateral		1				1
Death	1	1			1	1
Decreased appetite	1	5		3	1	2
Deep vein thrombosis	1	1			1	1
Delirium		1				1
Depressed level of consciousness		1				1
Depressed mood	1	1			1	1
Dermatitis		1				1
Diarrhoea	3	7	2	6	1	1
Discomfort	1	1	1	1		

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Disease recurrence	1	3
Disseminated varicella zoster virus infection		1
Disturbance in attention		1
Dizziness	7	14
Dizziness postural	1	2
Drug ineffective	1	5
Drug interaction	1	3
Drug level increased		2
Dry mouth	1	1
Dry throat		1
Dysgeusia	2	3
Dysphagia	2	3
Dysphonia		1
Dyspnoea	3	8
Dysstasia		1
Dysuria		1
Ear discomfort	1	1
Ear swelling		1
Encephalitis autoimmune	1	1
Eructation		1
Erythema	3	5
Exposure via breast milk		4
Eye irritation		1
Eyelid disorder		1
Eye movement disorder	1	1
Eye pain	1	1
Eye swelling		1
Face oedema	1	1
Fall		2
Fatigue	12	22
Feeling abnormal		2
Feeling hot	3	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		2
			1
	1		
5	12	2	2
1	2		
		1	5
		1	3
	1		1
1	1		
	1		
1	2	1	1
1	1	1	2
	1		
1	5	2	3
	1		
	1		
		1	1
	1		
		1	1
2	3	1	2
	4		
			1
	1		
		1	1
		1	1
	1		
		1	1
			2
9	17	3	5
	2		
3	3		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Flatulence		2		2		
Flushing	1	1	1	1		
Frustration tolerance decreased	1	1			1	1
Fungal skin infection		1		1		
Gait disturbance	1	3	1	2		1
Gastric ulcer		1				1
Gout	3	3	2	2	1	1
Haematocrit decreased		1		1		
Haemoglobin decreased		2		2		
Haemorrhage urinary tract		4				4
Headache	10	24	8	22	2	2
Head discomfort	2	2	2	2		
Heart rate decreased	1	2	1	2		
Heart rate increased		1		1		
Hemiparesis		1				1
Hepatic enzyme increased		1				1
Herpes simplex	1	2			1	2
Herpes zoster	10	12	10	12		
Hiatus hernia		1		1		
Hiccups	1	1			1	1
Hot flush		1		1		
Hyperaesthesia		1				1
Hyperhidrosis	2	3	1	2	1	1
Hypersensitivity	3	4	2	3	1	1
Hypersomnia		2		2		
Hypertension		1		1		
Hyperuricaemia		1		1		
Hypoaesthesia	2	4	2	3		1
Hypokinesia		1		1		
Hypotension	2	2	2	2		
Hypoxia		1				1
Iliac artery occlusion		1				1

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Illness	1	1
Inappropriate schedule of product administration		3
Incoherent	1	1
Incontinence		1
Incorrect route of product administration		1
Injection site pain		1
Insomnia	3	4
Irritability		1
Ischaemic stroke		1
Joint range of motion decreased		1
Joint stiffness	1	1
Joint swelling	1	2
Lack of spontaneous speech		1
Lacrimation increased		2
Lateral medullary syndrome	1	1
Lethargy		2
Limb discomfort	2	2
Lip disorder		1
Lip pain		1
Lip swelling	1	1
Loss of consciousness	3	7
Loss of personal independence in daily activities		1
Lung disorder		1
Lymphadenopathy		4
Lymphocyte count decreased		1
Lymphoedema	2	2
Malaise	3	8
Mean cell haemoglobin		1
Mean cell volume increased		1
Melaena		1
Memory impairment		1
Meningitis aseptic		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
	3		
1	1		
			1
	1		
	1		
3	4		
	1		
			1
	1		
1	1		
1	2		
	1		
	2		
		1	1
	2		
2	2		
	1		
	1		
		1	1
		3	7
	1		
			1
	4		
	1		
2	2		
3	8		
	1		
	1		
			1
	1		
			1

* I=Interval, C=Cumulative
* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Monocyte count increased		1		1		
Monoparesis		1				1
Mucosal disorder		1		1		
Multiple sclerosis	1	1			1	1
Muscle spasms		1		1		
Muscle twitching	1	1	1	1		
Muscular weakness	1	2	1	2		
Musculoskeletal chest pain	1	1	1	1		
Musculoskeletal stiffness	2	4	2	4		
Myalgia	1	10	1	10		
Myelocyte count increased		1		1		
Myocardial infarction		1				1
Myocarditis		1				1
Nausea	4	9	3	8	1	1
Neck mass	1	1	1	1		
Neck pain	1	3	1	3		
Nervous system disorder		1				1
Neuropathy peripheral	1	1			1	1
No adverse event		1		1		
Ocular hyperaemia		1		1		
Oesophagitis		1				1
Off label use		2		2		
Oropharyngeal pain		1		1		
Overdose		2		2		
Pain	3	13	3	11		2
Pain in extremity	5	13	4	12	1	1
Palpitations	2	3		1	2	2
Paraesthesia	3	3	3	3		
Paraparesis		1				1
Penis disorder		1				1
Pericarditis	2	2			2	2
Periorbital swelling		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral arterial occlusive disease		1		1		
Peripheral artery thrombosis	1	1			1	1
Peripheral swelling	4	5	2	3	2	2
Pharyngeal swelling		1		1		
Photosensitivity reaction	1	1	1	1		
Platelet count decreased		1		1		
Pneumonia		2				2
Pneumonia aspiration		1				1
Product administered at inappropriate site		2		2		
Productive cough		1		1		
Product preparation error		1		1		
Product preparation issue		1		1		
Pruritus	2	7	1	5	1	2
Pulmonary embolism		1				1
Pyrexia	5	16	3	13	2	3
Rash	3	8	2	6	1	2
Rash erythematous		1		1		
Rash macular		1		1		
Rash maculo-papular		1				1
Rash pruritic		2		2		
Rash pustular		1		1		
Red blood cell count decreased		1		1		
Respiratory failure		2				2
Rheumatoid arthritis		1				1
Rhinorrhoea		2		2		
Road traffic accident		1				1
Secretion discharge		1		1		
Seizure		3				3
Seizure like phenomena	1	1			1	1
Sensory loss		1		1		
Sepsis		2				2
Shoulder injury related to vaccine administration		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin burning sensation	1	1	1	1		
Skin injury		1		1		
Sleep disorder		2		2		
Sneezing		1		1		
Somnolence	1	4	1	3		1
Speech disorder	1	1	1	1		
Spinal pain	1	1			1	1
Splenitis		1				1
Suicidal ideation		1				1
Suspected COVID-19		1		1		
Swelling	1	3	1	3		
Syncope	1	6			1	6
Tachycardia	1	1			1	1
Tachypnoea		1		1		
Tenderness		1		1		
Tendonitis		1		1		
Testicular pain		1		1		
Testicular retraction		1				1
Therapeutic response unexpected		2		2		
Thirst		1		1		
Throat irritation		1		1		
Throat tightness	1	2		1	1	1
Thrombosis	6	8	1	1	5	7
Tinnitus	2	4		1	2	3
Toothache	1	1			1	1
Toxicity to various agents		1				1
Tremor	1	1			1	1
Troponin increased		1		1		
Underdose		1		1		
Urinary incontinence	1	1			1	1
Urinary retention	1	1			1	1
Urinary tract infection	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria	4	10	2	7	2	3
Vaccination failure		1				1
Vaccination site bruising	1	2	1	2		
Vaccination site mass		1		1		
Vaccination site pain	4	9	3	8	1	1
Vaccination site reaction		1		1		
Vaccination site swelling		1		1		
Varicella		1		1		
Vascular anastomosis	1	1			1	1
Vertigo		1		1		
Vision blurred	1	2		1	1	1
Visual impairment		1		1		
Vital functions abnormal		1				1
Vitamin B12 increased		1				1
Vitreous floaters	1	1			1	1
Vomiting	1	6		4	1	2
Weight decreased	2	2	2	2		
Wrong product administered	1	2	1	2		
	243	643	136	413	107	230

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose	1	1	1	1		
Adverse event	1	1	1	1		
Ageusia		1		1		
Anaphylactic reaction		21				21
Anaphylactic shock		1				1
Arthralgia		2		2		
Asthenia	1	1	1	1		
Chills	3	3	3	3		
Circumstance or information capable of leading to medication error		3		3		
Condition aggravated		1		1		
COVID-19	3	32	2	2	1	30
Diarrhoea	1	2	1	2		
Disease recurrence		1		1		
Dizziness	1	1	1	1		
Drug ineffective	1	31			1	31
Dysphonia	1	1	1	1		
Ear infection		1				1
Exposure during pregnancy		2				2
Exposure via breast milk	13	21	13	21		
Fatigue	5	8	5	8		
Feeling abnormal	1	1	1	1		
Foetal growth restriction		3				3
Headache	3	5	3	5		
Herpes zoster	3	4	2	2	1	2
Hyperhidrosis	1	1	1	1		
Hypersensitivity		7				7
Hypertension		3		3		
Inappropriate schedule of product administration		28		28		
Incomplete course of vaccination		1		1		
Incorrect dose administered		2		2		
Intentional product misuse		1		1		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lethargy		2		2		
Limb discomfort	1	1	1	1		
Malaise	1	2	1	2		
Maternal exposure before pregnancy		1				1
Migraine	1	1	1	1		
Musculoskeletal stiffness		1		1		
Myalgia	1	3	1	3		
Nasopharyngitis		1		1		
Nausea		1		1		
Neck pain		1		1		
No adverse event	2	3	2	3		
Off label use		26		26		
Overdose		6		6		
Pain in extremity	1	3	1	3		
Pallor	1	1	1	1		
Product complaint		4		4		
Product container issue		1		1		
Product preparation error	1	3	1	3		
Product preparation issue		11		11		
Product quality issue		1		1		
Pyrexia	3	6	3	5		1
Rash	2	2	2	2		
Rheumatoid arthritis		1				1
Rhinorrhoea		1		1		
SARS-CoV-2 test positive		1				1
Stress		1		1		
Syncope	1	2			1	2
Taste disorder		1		1		
Therapeutic response unexpected		1		1		
Thrombosis		1				1
Underdose		10		10		
Vaccination site pain	1	2	1	2		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site rash		1		1		
	55	294	51	189	4	105

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Country Where Event Occurred

CAYMAN ISLANDS

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Back pain	1	1	1	1
Decreased appetite		1		1
Dyspepsia		1		1
Fatigue		1		1
Headache		1		1
Irritability		1		1
Muscle spasms		1		1
Muscle twitching		1		1
Pain in extremity	1	1	1	1
Palpitations		1		1
	2	10	2	10

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Back pain	5	5	5	5
Pain in extremity	5	5	5	5
	10	10	10	10

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Country Where Event Occurred

CHILE

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		2		2		
Abdominal pain upper	2	6	2	5		1
Abnormal faeces		1		1		
Anaphylactic reaction		2				2
Anxiety		1		1		
Aphasia		1				1
Arrhythmia		1				1
Arthralgia	1	8	1	7		1
Arthritis	1	2			1	2
Asthenia	1	3	1	3		
Aversion		1		1		
Axillary mass		1		1		
Axillary pain		1		1		
Back pain	3	6	3	6		
Blood glucose decreased		1		1		
Blood pressure increased	1	1	1	1		
Blood test abnormal		1		1		
Bone pain		2		2		
Breast engorgement		1		1		
Breast pain	1	2	1	2		
Breast swelling	1	1	1	1		
Bronchitis	1	1	1	1		
Burning sensation	1	2	1	2		
Chest discomfort	1	2	1	2		
Chest pain	1	3	1	2		1
Chills	1	12	1	11		1
Choking		1				1
Circumstance or information capable of leading to medication error	1	1	1	1		
Colitis		1		1		
Complement factor C3 decreased		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Contusion	1	1	1	1		
Cough		1		1		
C-reactive protein decreased		1		1		
Crying		1				1
Cyst		1		1		
Decreased appetite	1	2	1	2		
Depressed mood	1	2	1	2		
Dermatitis acneiform	1	1	1	1		
Dermatitis allergic		1				1
Diarrhoea		6		6		
Discomfort	2	3	2	3		
Discouragement		1		1		
Disease recurrence		1		1		
Dizziness	1	4	1	4		
Drug-induced liver injury		1				1
Dry mouth		1				1
Dry skin		1		1		
Dysbiosis		1				1
Dysgeusia		1				1
Dyspepsia	2	2	2	2		
Dyspnoea	1	4	1	2		2
Ear discomfort		1		1		
Emotional distress		1		1		
Erythema	2	4	1	3	1	1
Erythema nodosum		1				1
Eye discharge		1		1		
Eye inflammation	1	1			1	1
Eyelid oedema	1	1			1	1
Eyelids pruritus	1	1			1	1
Eye movement disorder		1				1
Eye swelling	1	2		1	1	1
Face oedema		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial paralysis		1				1
Fatigue	4	13	4	13		
Fear		1		1		
Fear of disease	1	1	1	1		
Feeling abnormal	2	3	2	3		
Feeling cold	2	5	2	5		
Flatulence	1	1	1	1		
Gait disturbance		3		2		1
Gait inability		1				1
Galactostasis		1		1		
General physical health deterioration	1	1	1	1		
Glossitis		1		1		
Guillain-Barre syndrome		1				1
Haemorrhoids	1	1	1	1		
Headache	9	35	9	34		1
Head discomfort		1		1		
Hemiparesis		1				1
Hemiplegia		1				1
Herpes zoster	1	1	1	1		
Hot flush	1	1	1	1		
Hyperaesthesia		2		2		
Hyperhidrosis		1		1		
Hypersensitivity	2	9	2	9		
Hypertension		1		1		
Hyperventilation		1				1
Hypoaesthesia	1	4	1	3		1
Hypotension		1				1
Incomplete course of vaccination		1		1		
Inflammation		1		1		
Injected limb mobility decreased	1	1	1	1		
Insomnia	2	4	2	4		
Joint swelling		2		1		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Limb discomfort		1		1		
Loss of consciousness		2				2
Loss of personal independence in daily activities	1	2	1	2		
Lymphadenitis	1	1	1	1		
Lymphadenopathy	2	8	2	7		1
Lymph node pain		3		3		
Malaise	4	17	4	17		
Mass		1		1		
Maternal exposure during pregnancy		1		1		
Maternal exposure timing unspecified		1		1		
Mobility decreased	1	1	1	1		
Monocyte count decreased		1		1		
Muscle discomfort		1		1		
Muscle spasms		3		3		
Muscular weakness		1		1		
Musculoskeletal pain		1		1		
Myalgia	1	18	1	17		1
Myocardial infarction	1	1			1	1
Myocardial ischaemia	1	1			1	1
Nasal congestion		1		1		
Nausea	4	14	4	13		1
Neck pain		2		2		
Neuralgia		1				1
Nipple pain	1	1	1	1		
Ocular discomfort	1	1			1	1
Oedema	1	1			1	1
Oedema peripheral		1		1		
Off label use	1	3	1	3		
Overdose		1		1		
Oxygen saturation decreased		1		1		
Pain	3	15	3	14		1
Pain in extremity	7	14	7	14		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pallor		1				1
Pancreatitis		1				1
Panic attack		1		1		
Panic reaction	1	2	1	2		
Paraesthesia		6		4		2
Peripheral swelling		3		2		1
Pharyngeal swelling	1	1			1	1
Photophobia		1				1
Proctalgia	1	1	1	1		
Product preparation error		1		1		
Product use issue	1	3	1	3		
Pruritus	1	3		2	1	1
Pyrexia	4	26	4	25		1
Rash	1	3		1	1	2
Rash papular	1	1			1	1
Rash pruritic		1				1
Respiratory disorder	1	2	1	1		1
Rhabdomyolysis		1				1
Rhinorrhoea		1		1		
SARS-CoV-2 ant body test negative		1		1		
Seizure		1				1
Sensory loss		1		1		
Skin burning sensation		1		1		
Skin discomfort	1	1	1	1		
Skin swelling	1	1	1	1		
Somnolence		2		2		
Stenosis		1		1		
Stress		1		1		
Suspected COVID-19		1				1
Swelling	1	1			1	1
Swelling face	1	1			1	1
Swollen tongue		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Synovial cyst		1		1		
Tachycardia	1	2	1	1		1
Therapeutic response unexpected	1	1	1	1		
Thirst	2	2	2	2		
Throat irritation		2		2		
Tinnitus		1		1		
Tongue movement disturbance		1				1
Transaminases increased		1		1		
Urine analysis abnormal		1				1
Urticaria	1	2			1	2
Vaccination site discomfort		1		1		
Vaccination site erythema		2		2		
Vaccination site inflammation		3		3		
Vaccination site pain	3	14	3	12		2
Vaccination site paraesthesia		1		1		
Vaccination site swelling		1		1		
Vasculitis		1				1
Vein disorder	1	1	1	1		
Venous thrombosis		1				1
Vestibular disorder		1		1		
Vomiting	1	3	1	3		
Wheezing	1	1	1	1		
Wrong product administered		2		2		
	119	464	102	387	17	77

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	1	1	1	1		
Anaphylactic reaction		1				1
Angina pectoris		1				1
Angioedema		1				1
Arthralgia	1	2	1	2		
Asthenia	1	1	1	1		
Axillary pain	1	1	1	1		
Blood glucose increased		1				1
Blood pressure increased		1		1		
Chest pain		1				1
Chills	1	2	1	2		
Coronavirus infection		1		1		
Costochondritis	1	1	1	1		
Cough	1	3	1	2		1
COVID-19		1				1
Decreased appetite		1		1		
Depressed mood	2	2	2	2		
Diarrhoea		3		3		
Dizziness	1	2	1	2		
Drug ineffective		1				1
Dyspnoea	1	3	1	2		1
Exposure via breast milk	1	2	1	2		
Eye irritation		1		1		
Eye pain		1		1		
Eye pruritus		1				1
Eye swelling		1				1
Fall		1				1
Fatigue		5		5		
Fear	1	1	1	1		
Headache	4	15	4	14		1
Head injury		1				1
Hemiparaesthesia		1				1

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* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hepatic enzyme increased		1				1
Hepatic steatosis		1		1		
Hypertension		1		1		
Hypertonia		1		1		
Hypoaesthesia		1		1		
Inappropriate schedule of product administration		2		2		
Incorrect route of product administration		1		1		
Insomnia		1		1		
Internal haemorrhage		1				1
Laboratory test interference	1	1	1	1		
Lymphadenitis	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Malaise	4	7	4	6		1
Muscle spasms	1	1	1	1		
Myalgia	1	9	1	8		1
Nasal congestion		1		1		
Nausea		4		3		1
Ocular hyperaemia		1				1
Off label use		1		1		
Oropharyngeal pain		1				1
Pain		1		1		
Pain in extremity		3		3		
Paraesthesia		1		1		
Product supply issue		1		1		
Pruritus	1	1	1	1		
Pyrexia	5	10	5	9		1
Respiratory distress		1				1
Rhinorrhoea		2		2		
Seizure		1				1
Skin burning sensation		1		1		
Somnolence		1		1		
Splenic rupture		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Splenomegaly		1				1
Swelling face		1				1
Tachycardia		2		1		1
Throat irritation		1		1		
Toothache		1		1		
Type 2 diabetes mellitus		1		1		
Vaccination site pain	5	12	5	11		1
Vomiting		1				1
Wound haemorrhage		1				1
	37	144	37	112		32

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		2		2		
Adverse event	1	1	1	1		
Angioedema		1				1
Blood pressure fluctuation		1		1		
Burning sensation		1		1		
Chest discomfort		1		1		
Chest pain		1		1		
Cold sweat		1		1		
Contusion		2		2		
COVID-19	1	1	1	1		
Dermatitis allergic		4		4		
Discomfort		1		1		
Dizziness	1	2	1	2		
Dyspnoea		1		1		
Erythema		1		1		
Face oedema		1				1
Fatigue		4		4		
Feeling cold		1		1		
Gait disturbance		1		1		
Guillain-Barre syndrome		1				1
Headache		5		5		
Hot flush		1		1		
Hypersensitivity		1		1		
Inappropriate schedule of product administration	1	1	1	1		
Incomplete course of vaccination		8		8		
Localised oedema		1				1
Loss of personal independence in daily activities	1	2	1	2		
Lymphadenopathy		1		1		
Malaise		2		2		
Mental disorder		1		1		
Musculoskeletal chest pain		1		1		
Myalgia		4		4		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea		1		1		
Oropharyngeal pain		1		1		
Pain		1		1		
Pain in extremity	1	2	1	2		
Peripheral swelling		1		1		
Polydipsia		1		1		
Product supply issue	1	1	1	1		
Pyrexia		3		3		
Syncope		1				1
Tachycardia		1		1		
Therapeutic response unexpected		1		1		
Urticaria		1		1		
Vaccination site erythema		1		1		
Vaccination site inflammation		1		1		
Vaccination site mass		1		1		
Vaccination site pain		3		3		
Vaccination site pruritus		1		1		
	7	79	7	74		5

* I=Interval, C=Cumulative
* AE=Adverse Event
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Country Where Event Occurred

COLOMBIA

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	1	1	1	1		
Abdominal pain upper		1		1		
Anal rash	1	1	1	1		
Anaphylactic reaction		2				2
Anaphylactic shock		1				1
Aphonia	1	1	1	1		
Arthralgia	3	7	3	7		
Arthritis	1	1	1	1		
Asphyxia	1	2			1	2
Asthenia	3	6	3	5		1
Asthenopia	1	1	1	1		
Axillary mass	1	1			1	1
Axillary pain	1	1			1	1
Back pain		1		1		
Blister	1	2	1	2		
Blood pressure increased		1		1		
Body temperature decreased	2	2	2	2		
Bone pain	2	3	2	3		
Bowel movement irregularity	1	1			1	1
Burning sensation	2	3	2	3		
Chest pain		1		1		
Chills	3	8	3	7		1
Choking sensation	1	1			1	1
Cough	2	7	2	6		1
COVID-19	8	8	4	4	4	4
Cyanosis		1		1		
Death		1				1
Diarrhoea	1	3	1	2		1
Diplopia	1	1			1	1
Discomfort	3	4	3	3		1
Dizziness	4	5	3	4	1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug hypersensitivity		1		1		
Drug ineffective	4	4			4	4
Dysgeusia	1	1			1	1
Dysphonia		1		1		
Dyspnoea	2	5	1	3	1	2
Erythema	2	5	2	5		
Exposure during pregnancy		1		1		
Eye inflammation	1	1	1	1		
Eye pain	1	2	1	2		
Facial paralysis	1	1			1	1
Fatigue	3	4	3	3		1
Feeling hot		2		2		
Gait disturbance	1	1	1	1		
Gait inability		1		1		
Headache	8	18	8	17		1
Herpes virus infection	1	1	1	1		
Herpes zoster	2	2	2	2		
Hyperhidrosis		1		1		
Hypersensitivity	2	4		2	2	2
Hypertension		2		1		1
Hypoaesthesia		1		1		
Hypokinesia	1	1	1	1		
Inappropriate schedule of product administration		1		1		
Inflammation	1	1	1	1		
Influenza		2		2		
Influenza like illness		1		1		
Joint swelling	1	1	1	1		
Limb discomfort	1	1	1	1		
Lip dry	1	1			1	1
Lymphadenopathy	2	3	2	3		
Lymph node palpable	1	1	1	1		
Malaise	5	10	5	9		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mobility decreased	1	1			1	1
Muscle spasms		1		1		
Musculoskeletal pain	1	1	1	1		
Myalgia	4	8	4	8		
Nasal congestion	1	1	1	1		
Nausea	2	3	1	2	1	1
Neck pain	1	1	1	1		
Neuralgia	1	1	1	1		
Odynophagia	1	1	1	1		
Oedema		1		1		
Oropharyngeal pain	2	4	2	4		
Oxygen saturation decreased	1	2		1	1	1
Pain	3	5	3	5		
Pain in extremity	3	3	3	3		
Papule	1	1	1	1		
Paraesthesia	1	4	1	4		
Pharyngeal swelling	1	1	1	1		
Post herpetic neuralgia	1	1	1	1		
Product use issue	1	1	1	1		
Pruritus		1		1		
Puncture site pain		1		1		
Pyrexia	3	7	3	7		
Rash	5	7	3	4	2	3
Respiratory distress		1				1
Secretion discharge		1		1		
Sedation	1	1			1	1
Skin discolouration		1		1		
Skin plaque		1		1		
Sneezing		1		1		
Suffocation feeling		1		1		
Suspected COVID-19	1	1	1	1		
Swelling	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling face	1	1	1	1		
Syncope		1				1
Tachycardia	1	2	1	2		
Thrombophlebitis	1	1	1	1		
Thrombosed varicose vein	1	1	1	1		
Tremor	1	1			1	1
Urticaria		2		2		
Vaccination site pain	2	4	2	4		
Vertigo	3	4	3	3		1
Vision blurred	1	1			1	1
Vomiting	3	6	3	5		1
		1		1		
	139	253	110	204	29	49

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	1			1	1
Aphthous ulcer	1	1	1	1		
Arthralgia	1	3	1	3		
Asthenia		1		1		
Asymptomatic COVID-19	2	3			2	3
Candida infection		1		1		
Cardiac disorder	1	1			1	1
Chills	2	4	2	4		
Cough		1		1		
COVID-19	7	11	4	6	3	5
COVID-19 pneumonia	1	1			1	1
Decreased appetite		1		1		
Diarrhoea	1	1	1	1		
Discomfort	1	1			1	1
Dizziness	2	4	2	4		
Drug ineffective	4	5			4	5
Dry mouth	1	1	1	1		
Dry throat	1	1	1	1		
Dyspnoea		1		1		
Erythema		1		1		
Eye pain	1	1	1	1		
Fatigue	1	1	1	1		
Feeling hot		1		1		
General physical health deterioration	1	1	1	1		
Gingivitis		1		1		
Headache	4	7	4	7		
Herpes zoster	1	1	1	1		
Hypersensitivity	1	3	1	3		
Inappropriate schedule of product administration	1	1	1	1		
Insomnia	1	1	1	1		
Leukocytosis		1		1		
Lung disorder	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy		1		1		
Malaise	1	6	1	6		
Muscle spasms	1	1	1	1		
Myalgia	1	1	1	1		
Myocardial infarction	1	1			1	1
Nausea		1		1		
Neck pain	1	1	1	1		
Ocular hyperaemia		1		1		
Odynophagia	1	1	1	1		
Off label use		1		1		
Oral candidiasis		1		1		
Oxygen saturation abnormal	1	1			1	1
Oxygen saturation decreased	1	2		1	1	1
Pain	1	1	1	1		
Pharyngeal erythema		1		1		
Pharyngeal oedema	1	1			1	1
Pharyngitis	1	1	1	1		
Pneumonia	1	1			1	1
Product use issue		1		1		
Pruritus	1	1	1	1		
Pruritus allergic	1	1	1	1		
Pyrexia	2	3	2	3		
Renal disorder	1	1			1	1
Rhinitis allergic	1	1	1	1		
Rhinorrhoea		1		1		
Stomatitis		1		1		
Thirst	1	1	1	1		
Tinnitus	1	1	1	1		
Underdose		1		1		
Urticaria		2		2		
Vaccination failure	1	1			1	1
Vaccination site erythema		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	2	7	2	7		
Vomiting	1	1	1	1		
	62	113	41	88	21	25

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Anxiety		1				1
Headache		1				1
Pyrexia		1				1
Rash		3		2		1
Seizure		1				1
		8		2		6

* I=Interval, C=Cumulative
* AE=Adverse Event
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Country Where Event Occurred

COSTA RICA

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal distension		1				1
Abdominal pain	1	2	1	2		
Abdominal pain upper	1	5	1	2		3
Abortion spontaneous		1				1
Adnexa uteri pain		2		2		
Anaphylactic reaction		1				1
Anaphylactic shock		2				2
Aphonia		1		1		
Aphthous ulcer		1		1		
Application site inflammation		1		1		
Application site pain	2	3	2	3		
Arthralgia	2	7	2	7		
Asthenia	3	9	3	7		2
Axillary pain	1	2	1	2		
Back pain	1	2	1	2		
Bacterial test positive	1	1	1	1		
Blood cholesterol increased	1	1	1	1		
Blood pressure increased		1		1		
Bowel movement irregularity	1	1	1	1		
Breast discomfort		1		1		
Bronchospasm		1		1		
Burning sensation		2		2		
Cerebrovascular accident		2				2
Chest discomfort		1				1
Chest pain		1				1
Chills	4	11	4	9		2
Cold sweat		1		1		
Colitis	1	1	1	1		
Condition aggravated		1				1
Constipation		1		1		
Contusion		1				1

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	1	2	1	2		
COVID-19	5	10		1	5	9
Death	1	2			1	2
Depression		1		1		
Dermatitis allergic		1				1
Diarrhoea	3	8	3	7		1
Discomfort	1	3	1	2		1
Dizziness	3	10	3	7		3
Drug ineffective	2	5			2	5
Dry mouth		1				1
Dysgeusia		1				1
Dyspepsia		2				2
Dysphonia		2		2		
Dyspnoea	1	7	1	5		2
Dysstasia	1	1	1	1		
Ear pain	1	1	1	1		
Ecchymosis		1		1		
Encephalopathy		1				1
Energy increased		1		1		
Epistaxis		2		1		1
Erythema	1	2	1	2		
Euphoric mood		1		1		
Extensive swelling of vaccinated limb		1		1		
Eye allergy		1		1		
Eye inflammation		1		1		
Eye pain	2	3	2	3		
Eye pruritus		2		2		
Face oedema	1	1	1	1		
Fall		1				1
Fatigue	13	36	13	34		2
Feeling abnormal	1	4	1	3		1
Feeling cold	1	2	1	2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling hot	2	3	2	3		
Gastric disorder		1		1		
Gastritis		2		1		1
Haemorrhage		1				1
Headache	17	44	17	41		3
Heart rate increased	1	2			1	2
High density lipoprotein decreased	1	1	1	1		
Hyperaesthesia	1	1	1	1		
Hyperhidrosis	3	5	3	4		1
Hypertension		1				1
Hypertensive crisis		1				1
Hyperthermia		1		1		
Hypoaesthesia	1	2	1	2		
Hyposmia		1		1		
Hypothermia		1				1
Immune thrombocytopenia		1				1
Immunology test abnormal		1		1		
Impaired work ability	1	2		1	1	1
Incoherent		1		1		
Incorrect route of product administration		2		2		
Infection		1		1		
Influenza	2	2	2	2		
Influenza like illness	1	2	1	1		1
Insomnia		1		1		
Intentional product use issue		1		1		
Ischaemia		1		1		
Joint swelling		1		1		
Lacrimation increased	1	1	1	1		
Limb discomfort		2		2		
Loss of personal independence in daily activities		1		1		
Low density lipoprotein increased	1	1	1	1		
Lung disorder		2		1		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy	1	4	1	4		
Lymphangitis		1				1
Lymph node pain		2		2		
Malaise	2	4	2	4		
Migraine	2	5	2	4		1
Miosis		1				1
Mobility decreased	1	1	1	1		
Multiple organ dysfunction syndrome	1	1			1	1
Muscle contracture		1		1		
Muscle spasms		2		2		
Myalgia	6	17	6	16		1
Myocardial infarction		1				1
Nasal congestion		1		1		
Nasal discomfort	1	1	1	1		
Nasopharyngitis		1		1		
Nausea	1	10	1	8		2
Nervous system disorder		1		1		
Ocular hyperaemia		2		2		
Odynophagia		1		1		
Oropharyngeal discomfort		1				1
Oropharyngeal pain		3		3		
Oxygen saturation decreased		3		1		2
Pain	12	20	12	20		
Pain in extremity	6	30	6	30		
Paraesthesia	1	3	1	3		
Peripheral swelling	1	3	1	3		
Petechiae		2		1		1
Photopsia		1		1		
Platelet count abnormal		2				2
Poor quality product administered		1		1		
Pruritus	1	4	1	4		
Pyrexia	6	20	6	19		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash	2	5	2	5		
Rash macular	1	1	1	1		
Rash papular		1		1		
Renal disorder		1		1		
Respiratory disorder		1				1
Respiratory distress		1				1
Rhinorrhoea	1	2	1	2		
SARS-CoV-2 ant body test negative		1		1		
Seizure		1				1
Sensation of foreign body		1		1		
Skin burning sensation		1		1		
Skin discolouration		1		1		
Skin lesion		1		1		
Somnolence	2	6	2	6		
Swelling	1	1	1	1		
Tachycardia	1	4	1	4		
Tachypnoea		2		2		
Thirst		2				2
Throat irritation		1		1		
Throat tightness		1				1
Thrombophlebitis	1	1	1	1		
Thrombosis	1	1			1	1
Tinnitus		2		2		
Urticaria		1		1		
Vaccination failure	3	4			3	4
Vaccination site erythema	1	2	1	2		
Vaccination site induration	1	2	1	2		
Vaccination site mass		1		1		
Vaccination site movement impairment		1		1		
Vaccination site nodule		1		1		
Vaccination site pain	12	40	12	40		
Vaccination site swelling	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site urticaria		1		1		
Vaccination site warmth	1	1	1	1		
Venous thrombosis		1				1
Vertigo	2	2	2	2		
Vision blurred	1	1	1	1		
Vomiting		4		3		1
	164	528	149	433	15	95

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Arthralgia	1	4	1	4		
Asthenia		4		4		
Axillary pain		1		1		
Back pain		2		2		
Bone pain		1		1		
Cardiac arrest	1	1			1	1
Cerebrovascular accident		1				1
Chills	1	6	1	6		
Communication disorder		1		1		
Condition aggravated		1		1		
Constipation		1		1		
Contusion		1		1		
Cough		3		3		
COVID-19	2	8		1	2	7
Deafness		1				1
Death		1				1
Dermatitis allergic		1		1		
Diarrhoea	2	5	2	4		1
Discomfort	1	2	1	2		
Dizziness	1	2	1	2		
Drug ineffective	1	3			1	3
Drug reaction with eosinophilia and systemic symptoms	1	1			1	1
Dry eye		1		1		
Dysgeusia		2		2		
Dyspnoea		2		2		
Ear discomfort		1		1		
Erythema of eyelid		1		1		
Eyelid irritation		1		1		
Faeces soft		1		1		
Fatigue	3	12	3	12		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling abnormal		1		1		
Feeling cold		3		3		
Fibrin D dimer increased		1		1		
Flatulence		1		1		
Gastrointestinal pain		1		1		
Gastrointestinal sounds abnormal		1		1		
Gingival bleeding		1		1		
Gingival disorder		1		1		
Gingival pain		1		1		
Gingivitis		1		1		
Headache	4	13	4	13		
Head discomfort		1		1		
Heart rate irregular		1		1		
Hepatic enzyme increased		1				1
Hyperhidrosis	1	1	1	1		
Hypersensitivity		1		1		
Hypersomnia		1		1		
Infarction	1	1			1	1
Infection		1		1		
Influenza		1		1		
Joint range of motion decreased		1				1
Lethargy		2		2		
Limb discomfort		2		2		
Loss of personal independence in daily activities		1		1		
Malaise	2	6	2	5		1
Migraine	1	2	1	2		
Mobility decreased		2		1		1
Mouth swelling		1		1		
Muscle spasms		1		1		
Muscle tightness	1	1	1	1		
Musculoskeletal chest pain		1		1		
Myalgia	1	13	1	12		1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myocardial infarction		1				1
Nausea		1		1		
Neck pain		1		1		
Ocular hyperaemia		1		1		
Oropharyngeal pain		1		1		
Oxygen saturation abnormal		1				1
Oxygen saturation decreased		1				1
Pain	4	11	4	11		
Pain in extremity	2	9	2	9		
Pain of skin	1	1	1	1		
Peripheral coldness		1		1		
Peripheral swelling		1		1		
Pleural effusion		1				1
Pleuritic pain		1		1		
Pneumonitis		1				1
Pruritus		4		4		
Pyrexia	1	12	1	11		1
Rash	1	3	1	3		
Red blood cell sedimentation rate increased		1		1		
Renal disorder	1	1			1	1
Respiratory symptom	1	1	1	1		
Respiratory tract congestion		1		1		
Sleep disorder		2		2		
Splenomegaly		1				1
Suspected COVID-19		1		1		
Swelling face		1		1		
Syncope		1				1
Throat clearing		1		1		
Throat irritation		1		1		
Toothache	1	1	1	1		
Tooth disorder		1		1		
Tremor		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria		1		1		
Vaccination complication		1		1		
Vaccination failure	1	2			1	2
Vaccination site discomfort		1		1		
Vaccination site pain	2	21	2	21		
Vasculitis		1		1		
Vision blurred		1		1		
Vomiting	1	2	1	1		1
	41	237	33	203	8	34

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	1			1	1
Diarrhoea		1		1		
Drug ineffective	1	1			1	1
Drug reaction with eosinophilia and systemic symptoms	1	1			1	1
Exposure via breast milk	1	1	1	1		
Fatigue	1	1	1	1		
Headache	1	1	1	1		
Malaise		1		1		
Pain		1		1		
Pyrexia	1	1	1	1		
Somnolence	1	1	1	1		
	8	11	5	8	3	3

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* AE=Adverse Event

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Country Where Event Occurred

CROATIA

090177e19749cf15\Approved\Approved On: 14-Jun-2021 14:01 (GMT)

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- * AE=Adverse Event
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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Abdominal pain upper	1	3		2	1	1
Abortion spontaneous		1				1
Ageusia	2	2			2	2
Altered state of consciousness		1				1
Anaphylactic reaction		2				2
Anaphylactic shock		2				2
Angioedema		2				2
Anosmia	2	2			2	2
Aphthous ulcer		1		1		
Application site oedema		1		1		
Aptyalism		1				1
Arrhythmia		4				4
Arthralgia	2	15	2	14		1
Arthritis	1	1			1	1
Arthritis reactive		1				1
Asthenia	10	34	8	28	2	6
Asthma		1				1
Asymptomatic COVID-19	21	21			21	21
Atrial f brillation		2				2
Axillary mass	1	1	1	1		
Axillary pain	2	2	2	2		
Back pain		5		3		2
Balance disorder		2				2
Blister		1				1
Blood creatine phosphokinase increased		1		1		
Blood creatinine increased	1	1			1	1
Blood glucose increased		1		1		
Blood pressure decreased		2		2		
Blood pressure increased		12		5		7
Body temperature increased	6	18	5	16	1	2
Bone pain	3	10	2	9	1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast pain		1		1		
Breath sounds abnormal		1				1
Bronchitis		1				1
Bronchospasm		4				4
Burning sensation		2				2
Capillary fragility		1		1		
Cardiac arrest		1				1
Cardiac disorder		1				1
Cardiac failure		2				2
Cardiac failure acute		1				1
Cardiac failure congestive		1				1
Cardiomyopathy		1				1
Cerebral haemorrhage		2				2
Cerebrovascular accident		1				1
Chest discomfort	1	6		1	1	5
Chest pain	3	8	1	4	2	4
Chills	14	55	13	47	1	8
Choking sensation		1				1
Cold sweat		1		1		
Coma		1				1
Condition aggravated		1				1
Confusional state	1	3	1	2		1
Conjunctival haemorrhage		3				3
Conjunctivitis allergic		1				1
Contusion	1	1			1	1
Cough	3	9	1	3	2	6
COVID-19	25	39		2	25	37
C-reactive protein increased	1	1	1	1		
Cyanosis		2				2
Deafness bilateral		1				1
Deafness unilateral		1				1
Decreased appetite	1	4	1	4		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deep vein thrombosis		1				1
Defaecation urgency		1		1		
Dermatitis	1	1			1	1
Dermatitis allergic		1				1
Diabetes mellitus		1				1
Diaphragmatic spasm		1				1
Diarrhoea	2	5	2	4		1
Disturbance in attention	1	2	1	2		
Dizziness	1	10		8	1	2
Dizziness postural	1	1	1	1		
Drug ineffective	2	4			2	4
Dry eye		1				1
Dry mouth		2		1		1
Dysgeusia		2		1		1
Dyskinesia		1				1
Dysphagia		3				3
Dysphonia		1				1
Dyspnoea	3	16	1	4	2	12
Dyspnoea exertional		1		1		
Ear infection		1				1
Encephalitis post immunisation		1				1
Erythema	4	23	3	6	1	17
Escherichia urinary tract infection		1				1
Exposure during pregnancy		1		1		
Extensive swelling of vaccinated limb	2	19			2	19
Extensor plantar response		1		1		
Extrapyramidal disorder		1				1
Eye haematoma		1				1
Eye haemorrhage		1				1
Eyelid oedema		2		1		1
Eyelid pain		1		1		
Eyelid ptosis		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye opacity		1		1		
Eye pain		2		2		
Face oedema	1	1			1	1
Facial nerve disorder		1		1		
Facial pain		1		1		
Facial paresis		5		1		4
Fall	1	3			1	3
Fatigue	16	39	14	32	2	7
Fear		1				1
Feeding disorder		1		1		
Feeling abnormal	1	2	1	2		
Feeling cold		1		1		
Feeling hot		8		4		4
Gait disturbance	1	2			1	2
Gastrointestinal pain		1		1		
General physical health deterioration		1				1
Gingival bleeding		1		1		
Haematoma		1		1		
Haemorrhage subcutaneous		1				1
Headache	22	82	18	64	4	18
Head discomfort		1				1
Head titubation		1				1
Heart rate increased	2	4	1	2	1	2
Heavy menstrual bleeding	1	1	1	1		
Hemiparesis		2				2
Hemiplegia		1				1
Hepatic enzyme abnormal	1	1			1	1
Herpes zoster	1	1	1	1		
Hot flush		1				1
Hyperaesthesia		1		1		
Hyperhidrosis		8		6		2
Hypersensitivity		4				4

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertension	1	9		1	1	8
Hypoacusis		1		1		
Hypoaesthesia		4		2		2
Hypoaesthesia oral		1				1
Hypogeusia		1		1		
Hypokinesia		1				1
Hypopnoea		1				1
Hypotension		2		1		1
Illness		1		1		
Incorrect dose administered		1				1
Influenza like illness	1	1	1	1		
Insomnia	1	5	1	5		
Intraocular pressure increased		1		1		
Irritable bowel syndrome		1		1		
Ischaemic cerebral infarction		1				1
Ischaemic stroke		1				1
Joint effusion		1				1
Lacrimation increased		1		1		
Lip disorder		1				1
Lip oedema	1	3			1	3
Lip swelling		1				1
Livedo reticularis		1				1
Localised oedema		1		1		
Loss of consciousness	2	5			2	5
Loss of personal independence in daily activities		2				2
Lymphadenitis		2		1		1
Lymphadenopathy	2	8	2	7		1
Lymph node pain	3	6	3	5		1
Malaise	3	17	2	14	1	3
Melaena		1				1
Menstrual disorder		1		1		
Migraine		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Moaning		1				1
Monoparesis		1				1
Movement disorder	1	1			1	1
Multi-organ disorder		1				1
Multiple organ dysfunction syndrome	1	1			1	1
Muscle contractions involuntary		1		1		
Muscle spasms		3		2		1
Muscle tightness		1		1		
Muscular weakness		4		2		2
Musculoskeletal stiffness		1		1		
Myalgia	15	52	14	47	1	5
Myocardial infarction	1	1			1	1
Myosclerosis		1				1
Nasal congestion	2	2			2	2
Nasopharyngitis	2	2			2	2
Nausea	6	31	6	25		6
Neck pain	2	7	2	7		
Neuritis		1		1		
Neurological symptom		1		1		
Neutrophil count increased		1		1		
Night sweats		1		1		
Nystagmus		1				1
Ocular hyperaemia		1		1		
Oedema mouth		1				1
Oedema peripheral		2		1		1
Off label use		1		1		
Oral mucosal erythema		1		1		
Oral pain		1		1		
Organic brain syndrome		1				1
Oropharyngeal discomfort		1		1		
Oropharyngeal pain	1	4		3	1	1
Overdose	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oxygen saturation decreased	1	1			1	1
Pain	3	9	3	9		
Pain in extremity	8	24	7	19	1	5
Pallor		2				2
Palpitations		10		5		5
Panic attack		2				2
Paraesthesia	2	12	1	6	1	6
Paraesthesia oral	1	6		2	1	4
Paresis		1				1
Parosmia	1	1			1	1
Peripheral coldness		2		1		1
Peripheral swelling	1	4		2	1	2
Pharyngeal paraesthesia		1				1
Pharyngeal swelling		1		1		
Pleural effusion		1				1
Pneumonia		2				2
Pneumonia klebsiella		1				1
Pneumonia staphylococcal		1				1
Polymenorrhoea	1	2	1	2		
Poor peripheral circulation		1				1
Presyncope		1				1
Product preparation error	1	1	1	1		
Product use issue		1		1		
Pruritus	4	15	4	6		9
Pulmonary embolism		1				1
Pulmonary pain		1		1		
Pulse absent		1				1
Pyrexia	16	81	14	59	2	22
Rales		1				1
Rash	2	15	2	4		11
Rash erythematous		2		1		1
Rash macular	1	4	1	1		3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash maculo-papular		4				4
Rectal haemorrhage		1				1
Renal pain		1		1		
Respiratory failure		1				1
Respiratory rate decreased		1		1		
Respiratory symptom	1	1			1	1
Respiratory tract oedema		1				1
Restlessness		1				1
Retching		1		1		
Rhinorrhoea	1	2		1	1	1
Salivary hypersecretion		1				1
Sensory disturbance		1				1
Sensory loss		1				1
Sepsis syndrome	1	1			1	1
Serum sickness		1				1
Sinusitis	1	1			1	1
Skin burning sensation		2		1		1
Skin discolouration		1				1
Skin oedema		1		1		
Skin reaction		1				1
Skin tightness		2				2
Sleep paralysis		1		1		
Sleep terror		1		1		
Sneezing		1				1
Somnolence	1	4	1	2		2
Speech disorder		1				1
Spinal pain	1	1			1	1
Stress cardiomyopathy		1				1
Stridor		2				2
Suffocation feeling		1				1
Swelling face		2				2
Swollen tongue		3				3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Syncope	1	4			1	4
Synovitis		1				1
Tachycardia	1	14	1	7		7
Tachypnoea		2				2
Tension		1		1		
Tension headache	1	1	1	1		
Thirst	1	1			1	1
Throat tightness		2				2
Thrombophlebitis		1				1
Thrombosis		1				1
Tinnitus	1	6		2	1	4
Tongue disorder		1				1
Tongue oedema	1	4			1	4
Transient ischaemic attack	1	1			1	1
Tremor	3	11	2	8	1	3
Trismus	1	1	1	1		
Type I hypersensitivity		19				19
Underdose		1				1
Unresponsive to stimuli		1				1
Urinary incontinence		1				1
Urinary tract infection		1				1
Urine odour abnormal		1		1		
Urticaria	4	9	4	4		5
Use of accessory respiratory muscles		2				2
Vaccination failure	45	55			45	55
Vaccination site erythema	5	40	5	31		9
Vaccination site haematoma		3		3		
Vaccination site hypersensitivity		1		1		
Vaccination site induration		7		5		2
Vaccination site joint erythema		1		1		
Vaccination site joint movement impairment		1		1		
Vaccination site lymphadenopathy		2		2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site mass		1				1
Vaccination site oedema	2	10	2	7		3
Vaccination site pain	15	98	15	85		13
Vaccination site paraesthesia	1	1	1	1		
Vaccination site pruritus	1	5	1	4		1
Vaccination site reaction		1		1		
Vaccination site swelling	3	20	3	16		4
Vaccination site warmth		1		1		
Vertigo	1	5	1	4		1
Vision blurred		1				1
Visual impairment	1	2	1	1		1
Vitreous detachment		1				1
Vomiting	2	12	2	9		3
Wheezing		3				3
White blood cell count increased		1		1		
Wrong technique in product usage process		1		1		
	351	1,429	189	787	162	642

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Allergy to chemicals		1		1		
Anaemia		1				1
Angina pectoris		1				1
Anosmia		1				1
Anxiety	1	1	1	1		
Arrhythmia		3				3
Arthralgia	2	7	2	5		2
Asthenia		7		3		4
Asymptomatic COVID-19	5	5			5	5
Axillary pain		1				1
Bell's palsy		1				1
Blood creatine phosphokinase increased		1		1		
Blood glucose increased		2		1		1
Blood pressure increased		5				5
Body temperature increased	1	4	1	3		1
Burning sensation	2	3	1	1	1	2
Cardiac failure	1	2			1	2
Cardio-respiratory arrest		1				1
Catarrh		1				1
Cerebral artery thrombosis		1				1
Cerebral infarction		1				1
Cerebrovascular disorder		1				1
Chest discomfort		1				1
Chest pain	2	3			2	3
Chills	1	10	1	10		
Cold sweat		1				1
Communication disorder		1				1
Condition aggravated		1				1
Confusional state	2	2	1	1	1	1
Coordination abnormal	1	1	1	1		
Cough		2		2		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	10	15		1	10	14
Cyanosis		2				2
Death		3				3
Decreased appetite		2		1		1
Deep vein thrombosis	1	2			1	2
Dermatitis allergic		1		1		
Diarrhoea	1	3	1	2		1
Discomfort		1		1		
Disorientation	1	2	1	1		1
Dizziness	2	5	1	2	1	3
Drug eruption	1	1			1	1
Drug ineffective	2	2			2	2
Dry mouth		1				1
Dysarthria		1		1		
Dyspepsia		1		1		
Dyspnoea	2	8		1	2	7
Dyspnoea exertional	1	1			1	1
Ear canal erythema		1				1
Ear pain		3		1		2
Ear pruritus		1				1
Epilepsy		1				1
Eructation		1		1		
Erythema	1	2			1	2
Extensive swelling of vaccinated limb		4				4
Eyelid function disorder		1				1
Eyelid ptosis		1				1
Eye pain		1		1		
Facial paresis	1	5			1	5
Fall		1				1
Fatigue	5	15	4	12	1	3
Feeling abnormal		2		1		1
Feeling hot		2		2		

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* AE=Adverse Event

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Fibromyalgia		1
Flushing	1	1
Gait disturbance	2	3
Gastritis		1
Headache	5	26
Heart rate increased		1
Hot flush		1
Hyperhidrosis		1
Hypertension	1	4
Hypertensive crisis		1
Hypoacusis		1
Hypoaesthesia		1
Hypoaesthesia oral		1
Hyporesponsive to stimuli		1
Hypotension		2
Hypoxia		1
Immune system disorder		1
Incorrect route of product administration		1
Increased appetite		1
Insomnia		2
Joint swelling		1
Lacrimation increased		1
Loss of consciousness	1	3
Lymphadenopathy	1	4
Lymphopenia		1
Malaise	2	7
Memory impairment		1
Monoparesis	1	1
Motor dysfunction	1	1
Muscle contractions involuntary		1
Muscular weakness	1	2
Musculoskeletal stiffness		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
1	1		
1	1	1	2
	1		
5	19		7
	1		
	1		
			1
1	1		3
			1
			1
	1		
	1		
			1
			2
			1
	1		
	1		
	1		
	2		
	1		
	1		
		1	3
1	3		1
	1		
1	5	1	2
	1		
1	1		
		1	1
			1
	1	1	1
			1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	5	15	5	12		3
Nasal congestion		1		1		
Nasopharyngitis		2		2		
Nausea	1	5	1	4		1
Neck pain	1	2	1	1		1
Ocular discomfort		2		2		
Oedema peripheral	1	2			1	2
Oral herpes	1	1	1	1		
Oropharyngeal pain		1		1		
Overdose		1		1		
Oxygen saturation decreased		1				1
Pain	1	1			1	1
Pain in extremity	2	7	1	4	1	3
Pain of skin		1				1
Pallor		1				1
Palpitations		2				2
Paraesthesia	2	5	2	4		1
Paraesthesia oral		1				1
Peripheral coldness		1				1
Peripheral swelling	1	1			1	1
Photophobia	1	1	1	1		
Pneumonia		1				1
Presyncope		2		1		1
Product preparation error		1		1		
Pruritus	1	1			1	1
Psoriasis		1		1		
Pulmonary embolism	3	4			3	4
Pyrexia	7	30	7	25		5
Rash	2	2			2	2
Rash maculo-papular	2	2	1	1	1	1
Rash pruritic	1	1	1	1		
Respiratory distress		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Retching		2		2		
Rheumatoid factor positive		1		1		
Rhinorrhoea		3		2		1
Sensation of foreign body		1		1		
Sensory disturbance	1	1			1	1
Sensory loss	1	1			1	1
Skin burning sensation		1				1
Skin hypertrophy		1				1
Skin sensitisation		1		1		
Snoring		2		1		1
Somnolence		1		1		
Speech disorder		1				1
Spinal pain		1		1		
Syncope		1				1
Throat tightness		1				1
Thrombocytopenia		1				1
Tinnitus		1		1		
Transient ischaemic attack		1				1
Tremor		3		3		
Type I hypersensitivity		1				1
Vaccination error		1		1		
Vaccination failure	13	17			13	17
Vaccination site erythema		3		2		1
Vaccination site lymphadenopathy		1		1		
Vaccination site movement impairment		1				1
Vaccination site oedema		2		2		
Vaccination site pain	4	22	4	19		3
Vaccination site swelling	2	4	2	2		2
Vertigo	2	3	1	1	1	2
Viral infection		1		1		
Vomiting		3		1		2
Wheezing		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	117	427	54	215	63	212

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Country Where Event Occurred

CYPRUS

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- * AE=Adverse Event
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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Abdominal pain upper		1		1		
Acute kidney injury		1				1
Acute respiratory distress syndrome		1				1
Amenorrhoea	1	1	1	1		
Anaphylactic reaction		1				1
Angina pectoris		1				1
Aortic aneurysm		1				1
Arthralgia	3	12	3	12		
Asthenia	6	9	6	9		
Asymptomatic COVID-19	1	1			1	1
Axillary pain		2		2		
Back pain		1		1		
Bacterial sepsis		1				1
Balance disorder		1		1		
Blood pressure increased		1				1
Body temperature increased	1	2	1	2		
Bone pain		1		1		
Bradycardia		1				1
Cerebrovascular accident		1				1
Cervix oedema		1		1		
Chest pain	1	2	1	2		
Chills	7	20	7	20		
Cold sweat	1	1	1	1		
Condition aggravated	1	2	1	2		
Contusion		2		2		
Cough	2	2	2	2		
COVID-19	2	4			2	4
C-reactive protein increased		1		1		
Death		1				1
Dehydration		1				1
Diarrhoea		2		2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	3	10	3	10		
Drug ineffective	2	4			2	4
Drug interaction		1		1		
Dry mouth	1	1	1	1		
Dysgeusia		2		2		
Dysphagia		1		1		
Dyspnoea	5	9	3	5	2	4
Ear discomfort		1		1		
Erythema		1		1		
Eye disorder		1		1		
Eyelid ptosis		1		1		
Face oedema		2		1		1
Facial paralysis		1				1
Facial paresis		4				4
Fatigue	4	16	4	16		
Feeling of relaxation	1	1	1	1		
Fibrin D dimer increased		1		1		
Gait disturbance		2		2		
Gait inability		1		1		
Gastrointestinal infection		1				1
Guillain-Barre syndrome		1				1
Headache	5	18	5	18		
Herpes zoster	2	2	2	2		
Hyperhidrosis	2	5	2	5		
Hypersensitivity		1		1		
Hypertension		1				1
Hypoacusis		1		1		
Hypoaesthesia	1	4	1	3		1
Hypoaesthesia eye		1				1
Hypoaesthesia oral		2		1		1
Hyponatraemia		2		2		
Hypotension		2				2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inappropriate schedule of product administration		2		2		
Inflammation		1		1		
Influenza like illness		2		2		
Injection site pain		1		1		
Insomnia		1		1		
Jaw disorder	1	1	1	1		
Lymphadenopathy		5		4		1
Malaise	1	8	1	8		
Migraine		1		1		
Mobility decreased		1		1		
Multiple organ dysfunction syndrome		1				1
Muscle contracture		1		1		
Muscle spasms	1	1	1	1		
Muscular weakness		2		1		1
Musculoskeletal stiffness	1	1	1	1		
Myalgia	9	27	9	27		
Myelitis		1				1
Nasal congestion		1		1		
Nasopharyngitis	1	1	1	1		
Nausea		9		9		
Oedema	1	1	1	1		
Off label use		2		2		
Oropharyngeal discomfort	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Oxygen saturation decreased		2				2
Pain		3		3		
Pain in extremity	1	2	1	2		
Pallor		1		1		
Peripheral swelling		1		1		
Pharyngeal oedema		1		1		
Product use issue		1		1		
Pulmonary embolism		5				5

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary oedema		1				1
Pyrexia	3	13	3	13		
Rash		2		2		
Rash erythematous		1		1		
Respiratory tract oedema		1				1
SARS-CoV-2 ant body test negative		1				1
Shock		1				1
Sinus congestion	1	1	1	1		
Sluggishness		1		1		
Somnolence	2	2	2	2		
Swelling face	1	1	1	1		
Swollen tongue		2		2		
Syncope		2				2
Tachyarrhythmia		1				1
Tachycardia	3	4	3	3		1
Therapeutic response unexpected		1		1		
Thirst	1	1	1	1		
Tongue rough	1	1	1	1		
Unresponsive to stimuli		1				1
Upper respiratory tract congestion	1	1	1	1		
Urinary retention		1				1
Vaccination failure	1	1			1	1
Vaccination site oedema		3		3		
Vaccination site pain	4	13	4	13		
Vaccination site swelling		2		2		
Vasculitis		2		1		1
Vertigo		1		1		
Viral sepsis		1				1
Vomiting	1	8	1	7		1
	90	341	82	278	8	63

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Arthralgia	1	4	1	4		
Asthenia		2		2		
Back pain		1		1		
Chills	1	5	1	5		
Confusional state		2		2		
COVID-19		3		1		2
Dermatitis atopic		1		1		
Discomfort		1		1		
Drug ineffective		2				2
Dysaesthesia		1				1
Dyspnoea		3		3		
Ear pain		1		1		
Eczema		1		1		
Epistaxis		1				1
Eye pain		1		1		
Facial paresis	1	3	1	1		2
Fatigue		3		3		
Generalised tonic-clonic seizure		1				1
Headache	1	5	1	5		
Head titubation		1		1		
Herpes zoster	1	1	1	1		
Hypertension		1		1		
Hypoaesthesia	1	3	1	3		
Hypoaesthesia oral		1				1
Hypotension		1				1
Influenza		1		1		
Influenza like illness	1	2	1	2		
Insomnia	1	3	1	3		
Lymphadenopathy	1	2	1	2		
Malaise		2		2		
Migraine		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	1	9	1	9		
Myocardial infarction		2				2
Nasopharyngitis		1		1		
Nausea		1		1		
Neck pain		1		1		
Overdose		1		1		
Oxygen saturation decreased		1		1		
Pulmonary embolism		1				1
Pyrexia	3	11	3	11		
Respiratory distress		1				1
Sialoadenitis		1				1
Syncope		1				1
Tachycardia		1		1		
Tremor		1		1		
Vaccination site pain	1	8	1	8		
	14	102	14	84		18

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse event	1	1	1	1		
Arthralgia		5		5		
COVID-19	1	9			1	9
Drug ineffective		2				2
Facial paralysis		1				1
Gastric haemorrhage		1				1
Headache	1	2	1	2		
Malaise		5		5		
Myalgia		5		5		
Paraesthesia		1		1		
Vaccination failure		1				1
Vision blurred	1	1	1	1		
	4	34	3	20	1	14

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Country Where Event Occurred

CZECH REPUBLIC

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	4			1	4
Abdominal pain	2	16	2	9		7
Abdominal pain lower	2	4	2	3		1
Abdominal pain upper	5	10	5	8		2
Abnormal dreams		1		1		
Abortion spontaneous		1				1
Acne	1	2		1	1	1
Acquired haemophilia	1	1			1	1
Acute kidney injury	1	2			1	2
Acute respiratory failure		2				2
Acute vestibular syndrome		1				1
Ageusia	1	6		3	1	3
Airway burns		2				2
Akathisia		1		1		
Akinesia		1				1
Alanine aminotransferase increased	1	1	1	1		
Allergic oedema		1				1
Allergy to vaccine		6		1		5
Alopecia	1	3		1	1	2
Altered state of consciousness		4				4
Amenorrhoea	1	1			1	1
Amnesia	1	2			1	2
Anaemia		3		1		2
Anaesthesia oral		1				1
Anaphylactic reaction		16				16
Aneurysm		1				1
Angina pectoris	2	3			2	3
Angioedema		1				1
Anosmia	1	8		5	1	3
Antibody test abnormal		1		1		
Anuria		1				1
Anxiety	1	11	1	8		3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic stenosis		1				1
Apathy	3	8	2	4	1	4
Aphasia		2		1		1
Aphonia		1				1
Aphthous ulcer		4				4
Apnoea		1				1
Application site coldness		1				1
Application site erythema		1		1		
Arrhythmia		4				4
Arteriosclerosis		1				1
Arthralgia	86	219	81	179	5	40
Arthritis	2	2			2	2
Aspartate aminotransferase increased	1	1	1	1		
Asthenia	33	98	29	73	4	25
Asthma	2	4		1	2	3
Asymptomatic COVID-19	1	1			1	1
Atrial fibrillation	1	3			1	3
Attention deficit hyperactivity disorder		1		1		
Axillary mass		1		1		
Axillary pain	6	16	4	12	2	4
Back pain	17	36	16	33	1	3
Bacterial rhinitis		1				1
Balance disorder	1	2			1	2
Biliary colic	1	1	1	1		
Blepharospasm	1	1			1	1
Blindness		2				2
Blister		1				1
Blood chloride increased		1		1		
Blood glucose fluctuation	1	1	1	1		
Blood glucose increased		2		2		
Blood lactic acid increased		1		1		
Blood pressure abnormal		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased	1	3	1	1		2
Blood pressure diastolic increased		1		1		
Blood pressure fluctuation	2	4	1	2	1	2
Blood pressure increased	7	18	5	11	2	7
Blood pressure systolic increased	1	3			1	3
Blood urea increased		1		1		
Blood urine present		1		1		
Body temperature decreased		1		1		
Body temperature fluctuation	1	1	1	1		
Body temperature increased	6	13	6	10		3
Bone pain	2	4	1	3	1	1
Borrelia infection		1				1
Bradycardia		1				1
Bradyphrenia	1	3	1	2		1
Brain oedema		2				2
Breast pain	3	7	2	4	1	3
Breast swelling	1	3		1	1	2
Bronchitis		1				1
Bronchitis chronic		1		1		
Bronchospasm		2		1		1
Bundle branch block right	1	1			1	1
Burning sensation	4	10	2	6	2	4
Burning sensation mucosal		2		2		
Bursitis	1	1			1	1
Cardiac arrest		1				1
Cardiac failure		1				1
Cardiac failure congestive		1				1
Cardiac hypertrophy		1				1
Cardiomegaly	1	1	1	1		
Cardiomyopathy		1				1
Cardio-respiratory arrest		2				2
Cerebral atrophy		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral haemorrhage		1				1
Cerebral thrombosis		1				1
Cerebrovascular accident		7				7
Chest discomfort	5	21	3	9	2	12
Chest pain	9	21	1	7	8	14
Chills	95	248	93	226	2	22
Choking sensation		1				1
Circulatory collapse		9				9
Circumoral swelling	1	1			1	1
Clostridium difficile colitis	1	1			1	1
Clumsiness	1	1	1	1		
Coagulopathy		1				1
Cognitive disorder		1				1
Cold sweat	1	2	1	2		
Coma	1	2			1	2
Communication disorder		1				1
Concussion	1	2	1	1		1
Condition aggravated	2	3		1	2	2
Conductive deafness		1				1
Confusional state	2	8	1	2	1	6
Conjunctivitis	1	1	1	1		
Conjunctivitis allergic		1		1		
Contusion	1	4	1	1		3
Coordination abnormal	1	2			1	2
Cor pulmonale		1				1
Cough	8	34	7	27	1	7
Cough decreased	1	1	1	1		
COVID-19	15	50	3	13	12	37
COVID-19 pneumonia	1	5			1	5
Cranial nerve palsies multiple		1				1
C-reactive protein increased	3	6	2	4	1	2
Cyanosis		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cystitis noninfective		1		1		
Cytomegalovirus test positive		1		1		
Deafness	1	1			1	1
Deafness neurosensory	1	2			1	2
Deafness unilateral		2				2
Death		2				2
Decreased activity		2		2		
Decreased appetite	4	25	3	18	1	7
Deep vein thrombosis	6	6			6	6
Defect conduction intraventricular	1	1			1	1
Dehydration		2		1		1
Delirium		1				1
Depression		3		1		2
Dermatitis		2		1		1
Dermatitis allergic	3	10	1	2	2	8
Dermatitis atopic	1	1			1	1
Diarrhoea	12	45	10	33	2	12
Diplopia	2	5	1	3	1	2
Discomfort		1		1		
Disease recurrence		4				4
Disorientation	3	8	2	4	1	4
Disturbance in attention	4	8	3	5	1	3
Diverticulitis		1				1
Dizziness	23	56	16	42	7	14
Dizziness postural		1				1
Drug eruption		3				3
Drug hypersensitivity		2		1		1
Drug ineffective	8	19			8	19
Drug interaction	1	2	1	1		1
Dry eye		1				1
Dry mouth	3	9	2	5	1	4
Dry skin		2				2

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry throat		1		1		
Dysaesthesia	1	2			1	2
Dysarthria		2				2
Dysgeusia	1	5	1	3		2
Dyskinesia		1				1
Dysmenorrhoea	1	1			1	1
Dyspepsia		7		4		3
Dysphagia	2	10	1	2	1	8
Dysphemia		1				1
Dysphonia	1	2	1	2		
Dyspnoea	22	78	5	17	17	61
Dyspnoea at rest		1				1
Dyspnoea exertional	1	3		1	1	2
Dysstasia		1				1
Dysuria	1	2	1	1		1
Ear discomfort	3	13	1	6	2	7
Ear infection	1	1			1	1
Ear pain	4	6	3	5	1	1
Ear pruritus		1				1
Ear swelling		1				1
Eating disorder		2		1		1
Eczema	2	3			2	3
Eczema herpeticum		1				1
Electrocardiogram abnormal		1		1		
Endolymphatic hydrops	1	1			1	1
Enterococcal infection		1				1
Epilepsy		1				1
Epistaxis	2	7	2	4		3
Erysipelas		2				2
Erythema	3	36	2	21	1	15
Erythema nodosum		1				1
Extensive swelling of vaccinated limb	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Extrasystoles		1		1		
Eye disorder		1		1		
Eye haemorrhage		2				2
Eye inflammation		1		1		
Eye irritation	2	6	1	1	1	5
Eyelid function disorder		1				1
Eyelid oedema	3	7			3	7
Eye movement disorder		1		1		
Eye pain	5	13	4	10	1	3
Eye pruritus		3		2		1
Eye swelling		3		2		1
Face oedema		1				1
Facial asymmetry		1				1
Facial pain	1	3		1	1	2
Facial paralysis	1	7			1	7
Facial paresis		5				5
Fall	2	10		3	2	7
Fatigue	150	340	147	303	3	37
Fear		1		1		
Fear of death		1		1		
Febrile convulsion		1				1
Feeling abnormal	3	10	1	7	2	3
Feeling cold		3		3		
Feeling hot	3	16	1	8	2	8
Feeling of body temperature change	2	2	2	2		
Femur fracture	1	1			1	1
Fibrin D dimer increased	1	1	1	1		
Flank pain		1		1		
Flatulence	1	5	1	4		1
Fluid intake reduced		1		1		
Flushing	2	6		2	2	4
Foetal death		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Food intolerance		1				1
Formication	2	5	2	4		1
Frequent bowel movements		1		1		
Functional gastrointestinal disorder		1		1		
Gait disturbance	1	7		2	1	5
Gait inability	1	3		1	1	2
Gastric ulcer		1				1
Gastroenteritis		1		1		
Gastrointestinal hypermotility		1				1
Gastrointestinal necrosis	1	1			1	1
Gastrointestinal pain		1		1		
Gastrooesophageal reflux disease		1				1
Generalised oedema		1		1		
Generalised onset non-motor seizure	1	1			1	1
General physical health deterioration	3	11	1	4	2	7
Gingival bleeding	1	1	1	1		
Gingival pain		1		1		
Glomerular filtration rate decreased		1		1		
Gout		1		1		
Grip strength decreased	1	1			1	1
Groin pain		1		1		
Grunting		1		1		
Haemarthrosis	1	1			1	1
Haematochezia		1				1
Haematoma	1	5		1	1	4
Haemoglobin decreased	1	1	1	1		
Haemorrhage intracranial		1				1
Hallucination	1	2			1	2
Hallucinations, mixed		1				1
Headache	116	297	110	266	6	31
Head discomfort	1	3	1	2		1
Heart rate decreased		1		1		

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Gender

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate increased	4	6	3	4	1	2
Heart rate irregular		2		2		
Heavy menstrual bleeding	3	3	2	2	1	1
Hemiparesis		1				1
Hemiplegia		1				1
Hepatic function abnormal		1				1
Hepatic infarction		1				1
Hepatitis		1				1
Herpes dermatitis		1				1
Herpes simplex		2				2
Herpes virus infection		1		1		
Herpes zoster	9	18			9	18
Hot flush	3	20	3	13		7
Humerus fracture		1				1
Hyperaemia		1		1		
Hyperaesthesia	1	2	1	2		
Hypercoagulation	1	1			1	1
Hyperglycaemia	1	2		1	1	1
Hyperhidrosis	5	24	5	19		5
Hyperlipidaemia		1		1		
Hyperphagia		1		1		
Hypersensitivity	9	51	3	17	6	34
Hypersomnia	1	4	1	1		3
Hypertension	8	41		8	8	33
Hyperventilation	3	4	2	3	1	1
Hypoacusis		3		1		2
Hypoaesthesia	3	10		3	3	7
Hypoaesthesia oral		3		1		2
Hypokalaemia		5				5
Hypokinesia	1	3	1	3		
Hypomagnesaemia		1		1		
Hypophagia	1	2		1	1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypotension	6	23	2	5	4	18
Hypotonia		1		1		
Hypotonic-hyporesponsive episode		1				1
Ileus	1	1			1	1
Illusion		1		1		
Immune system disorder		1				1
Immune thrombocytopenia	1	1			1	1
Inappropriate schedule of product administration	1	8	1	8		
Incontinence	1	1	1	1		
Incorrect route of product administration	1	5	1	5		
Induration	1	2		1	1	1
Infection		1		1		
Inflammation	1	2			1	2
Influenza	2	3	2	3		
Influenza like illness	48	120	43	93	5	27
Injected limb mobility decreased		2		2		
Injection site erythema		1				1
Insomnia	10	22	9	18	1	4
Intermenstrual bleeding	4	5	2	3	2	2
International normalised ratio increased		2		1		1
Intestinal haemorrhage	1	1			1	1
Intraocular pressure increased	1	1	1	1		
Irritability	1	2	1	2		
Ischaemic stroke	2	3			2	3
Joint instability		1				1
Joint range of motion decreased	2	6	2	5		1
Joint stiffness		2		1		1
Joint swelling	3	8	2	6	1	2
Joint warmth		1		1		
Jugular vein distension		1		1		
Klebsiella infection	1	1			1	1
Lacrimation increased	2	4	2	3		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lagophthalmos		1		1		
Language disorder		1				1
Laryngeal oedema		1				1
Laryngospasm		1				1
Lethargy		1		1		
Leukocytosis	1	2	1	2		
Leukopenia		1				1
Ligament sprain	1	2			1	2
Limb discomfort	2	3			2	3
Limb immobilisation		1		1		
Lip dry		1		1		
Lip oedema		1				1
Lip swelling	3	9		1	3	8
Livedo reticularis		1		1		
Localised oedema	1	5	1	1		4
Local reaction		1		1		
Logorrhoea		1		1		
Loss of consciousness	4	12			4	12
Loss of personal independence in daily activities	1	3		2	1	1
Lymphadenitis		5		1		4
Lymphadenopathy	29	102	23	58	6	44
Lymph node pain	7	21	5	15	2	6
Malaise	17	41	17	38		3
Mass		1		1		
Maternal exposure during pregnancy		1		1		
Mean cell haemoglobin concentration increased	1	1	1	1		
Mean cell haemoglobin decreased	1	1	1	1		
Melaena		1				1
Memory impairment	3	4			3	4
Menstrual disorder	2	3	1	2	1	1
Menstruation delayed		1		1		
Menstruation irregular	8	8	5	5	3	3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mental disorder		1		1		
Mental fatigue	1	1	1	1		
Mental impairment	2	2			2	2
Middle insomnia	1	1	1	1		
Migraine	3	15	3	9		6
Migraine with aura		1		1		
Mobility decreased	3	7	1	5	2	2
Monoparesis	1	3	1	1		2
Monoplegia	1	1			1	1
Motor dysfunction	1	1	1	1		
Movement disorder	3	4			3	4
Mucosal disorder		1				1
Mucosal dryness		1				1
Multiple organ dysfunction syndrome		1				1
Multiple sclerosis relapse		1				1
Muscle atrophy		1				1
Muscle spasms	5	9	4	6	1	3
Muscle tightness		1		1		
Muscle twitching	1	5		2	1	3
Muscular weakness	6	19	3	13	3	6
Musculoskeletal chest pain		2		2		
Musculoskeletal disorder	2	3	2	3		
Musculoskeletal pain		1		1		
Musculoskeletal stiffness	6	17	6	13		4
Myalgia	74	169	71	143	3	26
Nasal congestion	3	8		5	3	3
Nasal discomfort		1				1
Nasal dryness		1		1		
Nasal oedema		1		1		
Nasopharyngitis	2	3	2	3		
Nausea	58	150	53	126	5	24
Neck pain	4	11	4	9		2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Necrosis ischaemic	1	1			1	1
Nephrosclerosis		1				1
Nervousness	2	3	1	1	1	2
Neuralgic amyotrophy	1	1			1	1
Neuropathy peripheral		4				4
Neutropenia		1				1
Neutrophil count increased	1	1	1	1		
Night sweats	1	5	1	4		1
Nodule	1	2	1	1		1
Nuchal rigidity		1		1		
Nystagmus		2		2		
Ocular discomfort		2				2
Ocular hyperaemia		1		1		
Oedema	1	4		3	1	1
Oedema mouth		1				1
Oedema peripheral	5	16	2	8	3	8
Oesophageal irritation		1		1		
Off label use	1	10	1	10		
Oligomenorrhoea	1	1			1	1
Oral discomfort		4		2		2
Oral herpes	1	3		1	1	2
Oral mucosal blistering		1		1		
Oral pruritus		1		1		
Orbital oedema		1				1
Oropharyngeal discomfort		3		2		1
Oropharyngeal pain	6	16	6	14		2
Overdose	2	6	2	6		
Oxygen saturation decreased		4		1		3
Pain	19	41	15	32	4	9
Pain in extremity	89	173	78	144	11	29
Pain in jaw		1		1		
Pain of skin		3		2		1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Palatal swelling	1	3
Pallor		5
Palpitations	8	27
Pancreatic infarction		1
Paraesthesia	37	92
Paraesthesia mucosal		1
Paraesthesia oral	6	33
Paralysis		3
Paraparesis		1
Paresis		2
Paresis cranial nerve		1
Parosmia		2
Patient uncooperative		1
Pemphigoid	1	1
Peripheral coldness	1	10
Peripheral nerve palsy		1
Peripheral swelling	8	22
Peripheral venous disease		1
Petechiae		2
Pharyngeal oedema		2
Pharyngeal swelling	1	7
Photophobia		4
Photopsia		2
Photosensitivity reaction	1	2
Platelet count decreased	1	1
Pneumobilia	1	1
Pneumoconiosis		1
Pneumonia		1
Polyarthrits		2
Polymenorrhoea	1	1
Poor peripheral circulation	1	1
Poor quality product administered		60

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	3
	2		3
5	11	3	16
			1
15	33	22	59
			1
	2	6	31
			3
			1
			2
			1
	1		1
	1		
		1	1
1	8		2
			1
4	10	4	12
			1
			2
			2
		1	7
	4		
	1		1
1	2		
		1	1
		1	1
			1
			2
		1	1
		1	1
	60		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Posture abnormal		1		1		
Premature menarche	1	1	1	1		
Presyncope	6	13		1	6	12
Procalcitonin increased	1	1	1	1		
Product administered at inappropriate site		2		2		
Productive cough	1	4	1	2		2
Product preparation error		60		60		
Product preparation issue		1		1		
Product use issue		5		5		
Prolonged expiration		1		1		
Pruritus	8	45	3	16	5	29
Pulmonary embolism	3	6			3	6
Pulmonary hypoperfusion	1	1			1	1
Pulmonary oedema		1				1
Pulmonary pain		2		1		1
Pulmonary sensitisation		2		1		1
Pulpitis dental		1				1
Pulse abnormal		1		1		
Puncture site erythema	1	1	1	1		
Puncture site oedema		1		1		
Pyrexia	146	369	125	264	21	105
Quadripareisis		1				1
Radiculitis brachial		1				1
Radiculopathy		1				1
Rash	14	60	7	24	7	36
Rash erythematous		3				3
Rash macular	2	10	1	1	1	9
Rash maculo-papular	2	4			2	4
Rash pruritic	4	14	1	3	3	11
Rash pustular		1		1		
Red blood cell sedimentation rate increased		1		1		
Reduced facial expression	1	1			1	1

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			Nonserious		Serious	
			I	C	I	C
Renal cyst		1				1
Renal disorder		1		1		
Renal failure		2				2
Renal impairment		1				1
Renal pain		2		2		
Respiration abnormal		1				1
Respiratory depression		1				1
Respiratory disorder		1				1
Respiratory distress		1				1
Respiratory failure	1	3			1	3
Respiratory tract oedema	2	3			2	3
Restlessness	1	5	1	4		1
Retching	3	10	3	6		4
Rheumatoid arthritis	1	2			1	2
Rhinalgia		2		2		
Rhinitis	1	8	1	7		1
Rhinorrhoea	4	18	4	16		2
Right ventricular dilatation		1				1
Salivary hypersecretion		1				1
SARS-CoV-2 ant body test negative		1				1
SARS-CoV-2 test positive		2		2		
Scab		2		2		
Sciatica	1	1			1	1
Seizure	2	6			2	6
Sensation of foreign body		6		1		5
Sensory loss	1	1			1	1
Shock		1				1
Sinus bradycardia		1		1		
Sinus pain		1		1		
Sinus tachycardia	1	2	1	1		1
Sitting disability		1				1
Skin burning sensation	2	8	1	4	1	4

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			Nonserious		Serious	
			I	C	I	C
Skin discolouration	1	2		1	1	1
Skin disorder		1				1
Skin exfoliation		2		1		1
Skin laceration		1				1
Skin mass		1		1		
Skin reaction		1		1		
Skin warm	1	1			1	1
Sleep deficit		1				1
Sleep disorder	1	3	1	2		1
Sleep talking		1		1		
Sneezing		2		2		
Somnolence	6	27	6	21		6
Speech disorder		3		2		1
Spinal disorder	1	2	1	1		1
Spinal pain	5	11	4	6	1	5
Splenic infarction		1				1
Sputum purulent		1				1
Starvation	1	1			1	1
Stridor		2		2		
Subarachnoid haemorrhage	1	1			1	1
Sudden death		1				1
Supraventricular extrasystoles		1		1		
Supraventricular tachycardia		1				1
Swelling	3	10	1	6	2	4
Swelling face	3	26	1	4	2	22
Swelling of eyelid	2	4			2	4
Swollen tongue		6				6
Syncope	3	19			3	19
Tachycardia	4	36		16	4	20
Tachypnoea		8		1		7
Taste disorder		1				1
Tenderness		1				1

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			Nonserious		Serious	
			I	C	I	C
Tendon pain		1				1
Tension headache		3		1		2
Tetany	1	1			1	1
Thirst		3		3		
Throat irritation		4		2		2
Throat tightness	3	13		2	3	11
Thrombocytopenia	1	2			1	2
Thrombophlebitis	1	1			1	1
Thrombophlebitis superficial		1				1
Thrombosis	4	5			4	5
Tinnitus	2	11		3	2	8
Tongue discomfort		3		1		2
Tongue erythema	1	1	1	1		
Tongue oedema	1	7			1	7
Toothache	2	6	2	5		1
Tooth infection		1				1
Tracheal pain	1	1	1	1		
Transient ischaemic attack		1				1
Tremor	4	17	2	8	2	9
Truncus coeliacus thrombosis		1				1
Underdose	1	1	1	1		
Urinary incontinence		2				2
Urinary tract disorder	1	1	1	1		
Urinary tract infection		3		1		2
Urinary tract infection enterococcal		1				1
Urinary tract inflammation		3		1		2
Urogenital infection bacterial		1				1
Urosepsis		1				1
Urticaria	5	14		2	5	12
Urticarial dermatitis	1	1	1	1		
Vaccination complication		3		2		1
Vaccination failure	3	12			3	12

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			Nonserious		Serious	
			I	C	I	C
Vaccination site atrophy		2		1		1
Vaccination site bruising	1	3	1	2		1
Vaccination site cellulitis		1				1
Vaccination site discolouration		1		1		
Vaccination site discomfort	2	5	2	4		1
Vaccination site erythema	27	102	22	61	5	41
Vaccination site extravasation		1		1		
Vaccination site haematoma	2	5	2	3		2
Vaccination site hypersensitivity	3	3	2	2	1	1
Vaccination site induration	5	15	5	10		5
Vaccination site joint movement impairment		2		1		1
Vaccination site joint pain	1	3	1	3		
Vaccination site joint swelling	1	1			1	1
Vaccination site lymphadenopathy		1		1		
Vaccination site mass	1	4	1	2		2
Vaccination site movement impairment	4	10	2	6	2	4
Vaccination site oedema	17	52	16	35	1	17
Vaccination site pain	122	260	120	226	2	34
Vaccination site papule		1				1
Vaccination site paraesthesia	1	3		2	1	1
Vaccination site pruritus	6	22	5	18	1	4
Vaccination site pustule		1		1		
Vaccination site rash	1	6	1	3		3
Vaccination site reaction		6		4		2
Vaccination site swelling	14	46	13	32	1	14
Vaccination site urticaria		4		1		3
Vaccination site warmth	4	16	4	12		4
Vascular pain	1	2	1	1		1
Ventricular tachycardia		1				1
Vertigo	12	51	7	33	5	18
Vertigo positional	1	1			1	1
Vestibular neuritis		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Viral infection		2		1		1
Vision blurred	8	21	4	8	4	13
Visual acuity reduced	1	1			1	1
Visual field defect		2				2
Visual impairment	1	4		1	1	3
Vomiting	13	64	13	50		14
Weight decreased		1		1		
Wheezing		2		2		
White blood cell count decreased	1	1			1	1
White blood cell count increased	1	1	1	1		
White coat hypertension		1		1		
Wound	1	1	1	1		
Yellow skin		1				1
	1,917	5,804	1444	3732	473	2072

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2		2		
Abdominal pain		2		1		1
Abdominal pain upper		2		2		
Abnormal dreams	1	2	1	2		
Acute myocardial infarction		2				2
Altered state of consciousness		1				1
Amnesia		1				1
Anal incontinence		1		1		
Anaphylactic reaction		2				2
Anaphylactoid reaction		1				1
Angina pectoris	1	4			1	4
Angioedema		1				1
Anosmia		2		1		1
Anxiety	2	2	1	1	1	1
Aortic arteriosclerosis		1				1
Apathy	1	3			1	3
Aphasia		3		1		2
Application site erythema		1				1
Arrhythmia	2	3			2	3
Arteriosclerosis		1				1
Arthralgia	42	70	37	58	5	12
Asthenia	8	29	7	23	1	6
Asymptomatic COVID-19	1	1	1	1		
Atrial fibrillation		3				3
Atrial flutter		1				1
Auditory disorder	1	1			1	1
Autoimmune haemolytic anaemia	1	1			1	1
Axillary pain	2	2	2	2		
Back pain	2	6		3	2	3
Bacterial sepsis	1	1			1	1
Bacterial test positive		1		1		
Balance disorder	4	4	3	3	1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Basal ganglia haemorrhage		1				1
Bell's palsy		2				2
Bladder pain	1	1			1	1
Blister		1				1
Blood pressure decreased	2	2	1	1	1	1
Blood pressure increased	1	5		1	1	4
Blood pressure systolic increased		2		2		
Blood urine	1	1			1	1
Blood urine present		1		1		
Body temperature increased	1	2	1	2		
Bone pain	1	2	1	1		1
Bradycardia	1	5			1	5
Brain oedema		1				1
Bundle branch block right		1				1
Cardiac arrest		2				2
Cardiac disorder		1				1
Cardiac failure	1	4			1	4
Cardiac failure acute	1	1			1	1
Carpal tunnel syndrome		1				1
Cerebral ischaemia		1				1
Cerebral venous sinus thrombosis		1				1
Cerebrovascular accident		7				7
Chest discomfort		3		2		1
Chest pain	2	6	1	4	1	2
Chills	42	72	41	66	1	6
Choking	1	1			1	1
Circulatory collapse		1				1
Cognitive disorder	1	1			1	1
Cold sweat		1		1		
Communication disorder	1	1			1	1
Condition aggravated		1				1
Confusional state	3	6	1	3	2	3

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Constipation		3		2		1
Cough	10	18	8	14	2	4
COVID-19	18	30	6	7	12	23
COVID-19 pneumonia	1	4			1	4
C-reactive protein increased	1	3	1	1		2
Deafness		1				1
Deafness neurosensory		1				1
Death	1	2			1	2
Decreased appetite	2	15	2	12		3
Decreased interest		1		1		
Deep vein thrombosis	5	7			5	7
Dehydration	1	1	1	1		
Delirium		2				2
Dementia		1				1
Dermatitis allergic		2				2
Diarrhoea	4	14	3	10	1	4
Discomfort	1	1			1	1
Disease progression	1	1			1	1
Disease recurrence		2		1		1
Disorganised speech		1				1
Disorientation	1	3			1	3
Disturbance in attention		2				2
Dizziness	4	8	3	5	1	3
Drug eruption	1	2			1	2
Drug hypersensitivity		1				1
Drug ineffective	4	9			4	9
Dry mouth	1	1	1	1		
Duodenal ulcer		1				1
Dysarthria		1		1		
Dyspepsia		2		1		1
Dysphagia		1				1
Dyspnoea	6	24	2	8	4	16

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysstasia	1	1	1	1		
Dysuria	1	1	1	1		
Ear pain	1	2	1	2		
Electrocardiogram abnormal		1				1
Embolism	1	1			1	1
Epilepsy		1				1
Epistaxis	2	4		1	2	3
Erythema		1				1
Escherichia infection		1				1
Eye haemorrhage	1	2			1	2
Eye irritation	2	2	2	2		
Eyelid oedema	1	1			1	1
Eye pain	2	4	2	4		
Eye swelling		1				1
Face oedema		1				1
Facial paralysis		1				1
Facial paresis	2	2			2	2
Fall		2				2
Fatigue	55	94	55	83		11
Feeling abnormal	1	1			1	1
Feeling cold	1	1	1	1		
Feeling hot	2	6	1	4	1	2
Formication	1	1			1	1
Gait disturbance	2	5			2	5
Gait inability		2		1		1
Gallbladder disorder		1		1		
Gastric ulcer		1				1
Gastrointestinal disorder		2		2		
Gastrointestinal necrosis		1				1
Gaze palsy		1				1
General physical health deterioration		1				1
Genital pain	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gingival bleeding	1	1			1	1
Glaucoma		1				1
Groin pain	1	1			1	1
Grunting		1				1
Guillain-Barre syndrome		1				1
Haematochezia		1				1
Haematoma	2	2			2	2
Haematuria	1	1	1	1		
Haemoptysis		1				1
Haemorrhage	1	2			1	2
Hallucination		1				1
Hangover	1	1	1	1		
Headache	35	55	35	50		5
Heart rate increased		3				3
Hemiparesis		1				1
Hemiplegia		1				1
Hepatic infarction	1	1			1	1
Herpes ophthalmic	1	1			1	1
Herpes zoster	4	8			4	8
Herpes zoster reactivation	1	1			1	1
Hordeolum		1				1
Hot flush	1	1			1	1
Hyperacusis		1				1
Hyperglycaemia		4				4
Hyperhidrosis	3	9	3	9		
Hyperpyrexia	1	2			1	2
Hypersensitivity	3	7	2	2	1	5
Hypersomnia		1				1
Hypertension	3	6		1	3	5
Hypertensive crisis	1	1			1	1
Hypoacusis	2	3		1	2	2
Hypoaesthesia	2	7	1	3	1	4

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypogeusia	1	1	1	1		
Hypoglycaemia		2		1		1
Hypokalaemia		1				1
Hypokinesia		1		1		
Hypotension	1	7		2	1	5
Hypoxia		2				2
Immunoglobulins increased		1		1		
Impaired work ability		1				1
Increased bronchial secretion	1	1	1	1		
Inflammation		1		1		
Inflammatory marker increased	2	2	1	1	1	1
Influenza	1	1	1	1		
Influenza like illness	22	43	18	34	4	9
Insomnia	1	8	1	5		3
Intermittent claudication	1	1	1	1		
Intestinal infarction		1				1
Ischaemic stroke	1	3			1	3
Jaundice		1		1		
Joint effusion		1				1
Joint range of motion decreased	1	1			1	1
Joint stiffness	1	1			1	1
Joint swelling	2	3	1	2	1	1
Klebsiella infection		1				1
Laboratory test abnormal		1		1		
Lacrimation increased		1		1		
Leukocytosis		1		1		
Leukopenia		1				1
Limb discomfort		2		1		1
Lip swelling		1				1
Localised oedema		1				1
Loss of consciousness	4	11			4	11
Lymphadenitis	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy	8	13	5	6	3	7
Lymph node pain	2	3	1	2	1	1
Lymphoedema		1		1		
Malaise	6	11	6	8		3
Mass		1				1
Memory impairment	1	1			1	1
Mesenteric arterial occlusion		1				1
Mesenteric vascular insufficiency		1				1
Micturition disorder	1	1	1	1		
Micturition urgency	1	1			1	1
Mineral metabolism disorder	1	1			1	1
Mobility decreased	2	2			2	2
Monoplegia		2				2
Mood swings	1	1			1	1
Movement disorder	1	1			1	1
Mucosal dryness		1		1		
Mucosal haemorrhage	1	1			1	1
Multiple organ dysfunction syndrome		1				1
Multiple sclerosis		1				1
Muscle spasms		1				1
Muscle spasticity		1		1		
Muscle strain	1	1	1	1		
Muscle twitching	1	1	1	1		
Muscular weakness	1	3	1	1		2
Musculoskeletal chest pain	1	1			1	1
Musculoskeletal stiffness		1		1		
Myalgia	24	44	21	35	3	9
Mydriasis		1				1
Myelitis		1				1
Myocardial infarction	1	4			1	4
Myocarditis		1				1
Myoclonic epilepsy	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myosclerosis		1				1
Myositis		1				1
Narcolepsy		2				2
Nasal congestion	1	1			1	1
Nasopharyngitis	1	1	1	1		
Nausea	7	17	5	14	2	3
Nervousness		1		1		
Neuralgia	1	2			1	2
Nuchal rigidity	1	1			1	1
Ocular discomfort	1	1	1	1		
Oedema peripheral	2	4	1	1	1	3
Off label use		1		1		
Oropharyngeal pain	1	2	1	2		
Oxygen saturation decreased		2		1		1
Pain	2	8	2	6		2
Pain in extremity	26	37	21	30	5	7
Pallor		4		3		1
Palpitations		2		1		1
Panic attack	1	1			1	1
Panic reaction	1	1	1	1		
Paraesthesia	8	13	3	5	5	8
Paraesthesia oral		1				1
Peripheral coldness	1	2		1	1	1
Peripheral ischaemia	1	1			1	1
Peripheral swelling		1		1		
Petechiae		2				2
Pharyngeal paraesthesia		1				1
Photophobia		1				1
Pigmentation disorder	1	1	1	1		
Pleurisy	1	1			1	1
Pneumonia	1	6			1	6
Pneumonitis		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Polyarthrititis		1				1
Poor quality product administered		23		23		
Poor quality sleep	2	2	2	2		
Presyncope	1	6		1	1	5
Product administered at inappropriate site		1		1		
Productive cough		1				1
Product preparation error		23		23		
Product use issue		1		1		
Prostate cancer		1				1
Pruritus	1	7		2	1	5
Psychomotor hyperactivity		1				1
Pulmonary embolism	2	3			2	3
Purpura		1				1
Pyrexia	51	104	43	76	8	28
Rash	3	8		1	3	7
Rash macular		3		1		2
Rash maculo-papular		1				1
Rash papular	1	1			1	1
Rash pruritic	4	7	3	4	1	3
Rash vesicular		1		1		
Reduced facial expression	1	1	1	1		
Renal colic	1	1			1	1
Renal failure		1				1
Renal impairment		1				1
Renal infarct	1	1			1	1
Renal mass	1	1			1	1
Renal pain	1	1			1	1
Renal transplant failure		1				1
Respiratory acidosis		1		1		
Respiratory depression		1				1
Respiratory failure		3				3
Respiratory tract oedema		2				2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Restlessness	1	2	1	2		
Retching		1		1		
Retinal artery thrombosis	1	1			1	1
Rheumatoid arthritis		1				1
Rhinitis	1	2	1	2		
Rhinorrhoea	3	3	3	3		
Salivary gland pain	1	1	1	1		
SARS-CoV-2 ant body test negative		1				1
SARS-CoV-2 test positive		2				2
Scratch	1	1			1	1
Seizure		3				3
Sepsis		2				2
Shock		2				2
Skin disorder		1				1
Sleep disorder		1		1		
Somnolence	4	11	4	7		4
Sopor		1				1
Speech disorder	1	2			1	2
Spinal pain	2	2	2	2		
Splenic infection		1				1
Sputum discoloured		1				1
Sudden death		2				2
Suicidal ideation	1	1			1	1
Swelling face	1	3			1	3
Syncope	4	10			4	10
Tachycardia		3		1		2
Tenderness		1		1		
Tension headache		1		1		
Throat irritation		1				1
Thrombocytopenia	1	1			1	1
Thrombosis	1	1			1	1
Tinnitus	1	5		1	1	4

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue oedema		2				2
Toothache	1	2		1	1	1
Transient ischaemic attack		1				1
Transverse sinus thrombosis		1				1
Tremor	2	5	1	3	1	2
Troponin I increased		1				1
Urinary straining	1	1			1	1
Urinary tract infection		1				1
Urosepsis	1	1			1	1
Urticaria	2	4			2	4
Vaccination complication		1		1		
Vaccination failure	1	5			1	5
Vaccination site anaesthesia		1				1
Vaccination site discomfort	1	2	1	2		
Vaccination site erythema	6	10	4	4	2	6
Vaccination site hyperaesthesia	2	2	2	2		
Vaccination site hypersensitivity		1				1
Vaccination site induration	1	2		1	1	1
Vaccination site joint movement impairment		1				1
Vaccination site lymphadenopathy	1	1	1	1		
Vaccination site mass		1				1
Vaccination site oedema	1	5	1	3		2
Vaccination site pain	68	85	67	79	1	6
Vaccination site pruritus	2	4	2	2		2
Vaccination site rash	2	2	1	1	1	1
Vaccination site swelling	5	7	5	6		1
Vaccination site warmth		1				1
Vena cava thrombosis		1				1
Venous thrombosis	1	1			1	1
Venous thrombosis limb		1				1
Ventricular tachycardia		1				1
Vertigo	4	9	3	6	1	3

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vision blurred	4	8	1	2	3	6
Visual impairment	1	1			1	1
Vomiting	3	11	2	6	1	5
Wheezing		1				1
White blood cell count decreased	1	1	1	1		
	691	1,534	484	891	207	643

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abscess of salivary gland		1				1
Arthralgia		1				1
Asthenia		1		1		
Chills	2	2	2	2		
Deep vein thrombosis	1	1			1	1
Dysphagia	1	1	1	1		
Exposure via breast milk		1		1		
Fatigue	1	2	1	1		1
Headache	1	1	1	1		
Hyperhidrosis	1	1	1	1		
Ligament pain		1		1		
Lymphadenopathy		1				1
Myalgia	1	1	1	1		
Oral pruritus	1	1	1	1		
Palpitations	1	1	1	1		
Pulmonary embolism	1	1			1	1
Pyrexia	2	3	2	3		
Rash maculo-papular		1				1
Tachycardia	1	1	1	1		
Throat tightness	1	1	1	1		
Vomiting		1				1
	15	25	13	17	2	8

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Country Where Event Occurred

DENMARK

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2		2		
Abdominal distension		1		1		
Abdominal lymphadenopathy	1	1	1	1		
Abdominal pain	3	18	2	10	1	8
Abdominal pain lower	1	2	1	1		1
Abdominal pain upper	2	9	1	5	1	4
Abdominal tenderness		1				1
Abdominal wall abscess		1				1
Abortion missed	1	3			1	3
Abortion spontaneous	1	1			1	1
Accidental exposure to product		1		1		
Acute kidney injury		3				3
Acute leukaemia		1				1
Acute myocardial infarction	2	6			2	6
Acute respiratory failure		1				1
Adrenal insufficiency		1				1
Adrenocortical insufficiency acute	1	1			1	1
Ageusia		1		1		
Alanine aminotransferase increased		1		1		
Allergy to vaccine	2	3			2	3
Altered state of consciousness		3				3
Amnesia		3				3
Anaemia		1		1		
Anaphylactic reaction		19				19
Anaphylactic shock	1	7			1	7
Angina pectoris		1				1
Angioedema	1	7			1	7
Anosmia		1		1		
Anti-glomerular basement membrane disease		1				1
Anxiety		4		1		3
Aphasia	3	4			3	4
Appendicitis		3				3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	27	79	20	52	7	27
Arthritis		1		1		
Arthritis reactive	1	2			1	2
Asthenia	2	20	1	6	1	14
Asthma		5		1		4
Atrial fibrillation		6				6
Atrial flutter		2				2
Auricular swelling		1		1		
Axillary pain	1	5	1	5		
Azotaemia		1				1
Back pain	2	8	1	6	1	2
Bacterial infection		1				1
Balance disorder	2	3			2	3
Blindness	1	1			1	1
Blood bilirubin decreased		1		1		
Blood count abnormal		1		1		
Blood creatine phosphokinase increased		1				1
Blood glucose increased		1		1		
Blood iron decreased		1		1		
Blood lactate dehydrogenase abnormal		1		1		
Blood lactic acid increased	1	2	1	2		
Blood potassium decreased		1		1		
Blood potassium increased		1		1		
Blood pressure abnormal		1				1
Blood pressure decreased	4	6	2	2	2	4
Blood pressure fluctuation		1		1		
Blood pressure increased	1	10		3	1	7
Blood pressure systolic increased		1				1
Blood prolactin increased	1	1	1	1		
Blood sodium decreased		1		1		
Blood test abnormal	1	1	1	1		
Blood urea decreased		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood uric acid abnormal		1		1		
Body temperature increased		6		5		1
Bradycardia		4				4
Breast pain		1		1		
Breath sounds abnormal		1				1
Bronchospasm		2				2
Burning sensation	3	9		4	3	5
Bursitis		1				1
Carbon monoxide poisoning		1				1
Cardiac arrest	3	5			3	5
Cardiac disorder		1				1
Cardiogenic shock		1				1
Cardiovascular disorder		1				1
Cerebellar embolism	1	1			1	1
Cerebral haemorrhage	1	1			1	1
Cerebral infarction	2	2			2	2
Cerebral ischaemia		1				1
Cerebral thrombosis		2				2
Cerebral vascular occlusion	1	1			1	1
Cerebral venous sinus thrombosis	1	1			1	1
Cerebrovascular accident	5	16			5	16
Chest discomfort	3	24	1	8	2	16
Chest pain	3	22		5	3	17
Chills	15	71	8	47	7	24
Choking sensation		1				1
Chorioretinitis		1				1
Chronic obstructive pulmonary disease	1	5			1	5
Cold sweat	4	10	2	6	2	4
Colitis		1				1
Condition aggravated	1	9	1	1		8
Confusional state	3	10			3	10
Conjunctival haemorrhage		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival hyperaemia		1		1		
Conjunctival oedema	1	1			1	1
Constipation	2	2	1	1	1	1
Contusion		1		1		
Coordination abnormal	1	4			1	4
Coronary artery thrombosis		2				2
Cough	5	26	2	14	3	12
COVID-19		12		3		9
C-reactive protein increased	2	15	1	5	1	10
Crying		1				1
Cystitis		1		1		
Death		9				9
Decreased appetite	3	5	1	2	2	3
Deep vein thrombosis	3	8			3	8
Dehydration	3	3			3	3
Delirium	1	3			1	3
Delusion		1				1
Dementia		1				1
Depressed level of consciousness	2	9			2	9
Depressed mood	2	2	2	2		
Derealisation		5		4		1
Dermatitis allergic		2				2
Diarrhoea	11	42	3	23	8	19
Diplopia	2	5			2	5
Discomfort	3	16	2	6	1	10
Disease recurrence	1	2		1	1	1
Disorientation		1				1
Disseminated intravascular coagulation		1				1
Disturbance in attention	1	5	1	2		3
Dizziness	35	166	16	87	19	79
Dizziness exertional		1		1		
Dizziness postural	1	3			1	3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug ineffective		4				4
Dry eye		1		1		
Dry mouth		5		4		1
Dry skin		1		1		
Dry throat		1		1		
Dysaesthesia	1	3		1	1	2
Dysarthria	1	3			1	3
Dysgeusia		4		2		2
Dyspepsia		1		1		
Dysphagia	1	9		2	1	7
Dysphonia	2	8	1	5	1	3
Dyspnoea	22	98	5	25	17	73
Dyspnoea at rest		1				1
Dyspnoea exertional		5		4		1
Dysstasia		1				1
Ear discomfort	1	2	1	2		
Ear pruritus		1				1
Eating disorder		1		1		
Eczema	1	2	1	2		
Electrocardiogram QT prolonged		1				1
Electrocardiogram ST segment depression		1				1
Embolic stroke	1	1			1	1
Encephalitis	1	1			1	1
Epilepsy	1	1			1	1
Epistaxis		4		1		3
Erysipelas	2	2			2	2
Erythema	7	43	3	24	4	19
Exfoliative rash	1	1	1	1		
Exposure via skin contact		1		1		
Extensive swelling of vaccinated limb	1	1			1	1
Extravasation	1	1			1	1
Eye irritation		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid oedema		1		1		
Eyelid ptosis		2				2
Eye pain	2	8	1	7	1	1
Eye pruritus		5		4		1
Eye swelling	1	2		1	1	1
Face oedema		2				2
Facial paralysis	1	4			1	4
Facial paresis	1	3	1	1		2
Faeces soft		1		1		
Fall	2	8	1	1	1	7
Fatigue	54	210	42	148	12	62
Feeling abnormal	3	8	2	5	1	3
Feeling cold	4	16	2	10	2	6
Feeling hot	2	26	1	12	1	14
Feeling of body temperature change	1	4	1	1		3
Femur fracture		1				1
Fibrin D dimer increased		1				1
Flatulence		1		1		
Fluid intake reduced		1		1		
Flushing		8		3		5
Foaming at mouth		2		1		1
Gait disturbance		3		1		2
Gait inability	1	1			1	1
Gastric ulcer		1				1
Gastrointestinal disorder		1		1		
Gastrointestinal necrosis		1				1
Gastrooesophageal reflux disease		2		1		1
Generalised tonic-clonic seizure	1	1			1	1
General physical health deterioration	2	13	1	2	1	11
General symptom	1	1	1	1		
Glossodynia		1		1		
Groin pain		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Guillain-Barre syndrome		1				1
Haematemesis		1				1
Haematochezia		1				1
Haematology test abnormal		1				1
Haematoma		1		1		
Haematuria		1		1		
Haemoconcentration	1	1	1	1		
Haemodynamic instability		1				1
Haemoglobin decreased		3				3
Haemoptysis	1	1			1	1
Haemorrhage		1				1
Hallucination	1	1			1	1
Hallucination, visual		1				1
Hand dermatitis		1		1		
Headache	77	343	60	249	17	94
Head discomfort	2	6	1	4	1	2
Head injury	1	2	1	1		1
Heart rate abnormal		1		1		
Heart rate decreased	1	4	1	4		
Heart rate increased	2	16	1	10	1	6
Heart rate irregular		1				1
Heavy menstrual bleeding	1	1	1	1		
Hemiparesis	2	6			2	6
Hemiplegia	1	2			1	2
Hepatic enzyme increased	1	2	1	2		
Hepatic vein thrombosis	1	1			1	1
Herpes simplex meningoencephalitis	1	1			1	1
Herpes zoster	3	4	3	4		
Hot flush	1	5		4	1	1
Hyperacusis	1	3		1	1	2
Hyperaesthesia	1	1			1	1
Hyperchlorhydria		1		1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hyperglycaemia		1
Hyperhidrosis	2	15
Hypersensitivity	6	28
Hypersomnia		4
Hypertension	1	20
Hyperthyroidism	1	1
Hypertonia		1
Hyperventilation	1	7
Hypoacusis		3
Hypoaesthesia	1	6
Hypoaesthesia oral		2
Hypoglycaemia		2
Hypokalaemia	1	3
Hypokinesia	1	1
Hyponatraemia	1	1
Hypophagia		1
Hypotension	1	8
Hypothermia		2
Hypotonia		1
Hypoxia		1
Idiopathic intracranial hypertension		1
Idiopathic pulmonary fibrosis		1
IIIrd nerve paresis		1
Illness		1
Immune-mediated adverse reaction		1
Immunisation reaction	1	1
Inappropriate schedule of product administration	2	6
Incorrect route of product administration	1	4
Infarction		1
Infection	3	6
Influenza	2	11
Influenza like illness	10	29

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
2	9		6
3	8	3	20
	1		3
	7	1	13
		1	1
			1
		1	7
	1		2
	3	1	3
			2
	1		1
		1	3
1	1		
		1	1
	1		
		1	8
			2
	1		
			1
			1
			1
	1		
			1
1	1		
2	6		
1	3		1
			1
	2	3	4
2	7		4
10	20		9

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Gender

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Initial insomnia		1		1		
Injected limb mobility decreased		1		1		
Injection site pain		1		1		
Inner ear disorder	1	1	1	1		
Insomnia		4		4		
Intestinal ischaemia		1				1
Intracardiac thrombus	1	3			1	3
Joint stiffness		2		1		1
Joint swelling	2	7		2	2	5
Joint warmth		1		1		
Jugular vein thrombosis	1	1			1	1
Ketoacidosis		1				1
Lacrimation increased		2		2		
Lethargy	1	4	1	4		
Leukocytosis		1		1		
Leukopenia	1	2			1	2
Limb discomfort		9		4		5
Lip pruritus		1				1
Lip swelling	1	4	1	1		3
Livedo reticularis		1				1
Loss of consciousness	3	10			3	10
Loss of personal independence in daily activities	1	2			1	2
Lung disorder		2				2
Lung infiltration	2	2			2	2
Lymphadenitis		2		1		1
Lymphadenopathy	4	28	4	20		8
Lymph node pain	1	5	1	5		
Lymphopenia		3		1		2
Malaise	19	140	11	76	8	64
Maternal exposure during pregnancy	3	4	2	2	1	2
Melaena		1				1
Memory impairment	1	2			1	2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Meniere's disease		1				1
Meningitis	1	1			1	1
Menstruation delayed	1	1	1	1		
Mesenteric artery thrombosis		1				1
Metabolic acidosis		1				1
Metabolic alkalosis		1		1		
Micturition urgency		1				1
Migraine	4	10	2	6	2	4
Mobility decreased	1	3	1	3		
Monoparesis		2				2
Monoplegia		2				2
Motor dysfunction		1				1
Mouth swelling		1				1
Movement disorder	1	1	1	1		
Multimorbidity		1				1
Muscle discomfort		1				1
Muscle fatigue		3		3		
Muscle spasms	4	10	1	4	3	6
Muscle tightness	1	2	1	1		1
Muscle twitching		1		1		
Muscular weakness	4	15	1	6	3	9
Musculoskeletal chest pain	1	1	1	1		
Musculoskeletal discomfort		1				1
Musculoskeletal pain	1	1			1	1
Musculoskeletal stiffness		2		1		1
Myalgia	37	142	29	108	8	34
Mydriasis		1		1		
Myelitis		1				1
Myelitis transverse	1	1			1	1
Myelosuppression		1				1
Myocardial infarction		1				1
Myocardial ischaemia	1	1			1	1

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Gender

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nasal congestion		5		5		
Nasal discomfort		1				1
Nasal pruritus		3		1		2
Nasopharyngitis	2	5	2	5		
Nausea	40	176	26	113	14	63
Neck pain	1	9		6	1	3
Nervous system disorder		1				1
Neuralgia		2		1		1
Neurological symptom	1	1			1	1
Neuropathy peripheral	1	1			1	1
Neutrophil count increased		1		1		
Night sweats		1		1		
Nodular rash	1	1	1	1		
Obliterative bronchiolitis		1				1
Obstructive airways disorder		2				2
Ocular hyperaemia		1		1		
Odynophagia		2		1		1
Oedema	1	3			1	3
Oedema mucosal		1				1
Oedema peripheral	1	6		3	1	3
Oesophageal spasm		1		1		
Off label use	2	9	2	9		
Oral discomfort		2		1		1
Oral fungal infection		1		1		
Oral mucosal blistering		1		1		
Oral mucosal eruption		1		1		
Oral pruritus		2		2		
Oropharyngeal discomfort		3		2		1
Oropharyngeal pain	2	17	2	15		2
Oxygen saturation decreased	1	7		1	1	6
Pain	10	33	10	26		7
Painful respiration		2		2		

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FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in extremity	16	59	11	48	5	11
Pain of skin	2	6	1	3	1	3
Pallor		11		3		8
Palpable purpura	1	1			1	1
Palpitations	6	32	3	17	3	15
Pancreatitis acute		1				1
Pancytopenia		1				1
Panic attack		1				1
Paraesthesia	9	46	3	25	6	21
Paraesthesia mucosal		1				1
Paraesthesia oral	3	17	2	9	1	8
Paresis		1				1
Parkinson's disease		1				1
Periarthritis		1		1		
Pericarditis		1				1
Periorbital swelling	2	3		1	2	2
Peripheral coldness	2	3	1	1	1	2
Peripheral swelling	2	10	1	6	1	4
Petechiae	3	3			3	3
Pharyngeal haemorrhage	1	1			1	1
Pharyngeal oedema		1				1
Pharyngeal paraesthesia		1		1		
Pharyngeal swelling	1	12		2	1	10
Photophobia		5		1		4
Photopsia		3		1		2
Photosensitivity reaction		1		1		
Pityriasis rosea	1	1	1	1		
Platelet count decreased	3	3	2	2	1	1
Pleural effusion		2				2
Pleurisy	1	1			1	1
Pleuritic pain		1		1		
Pneumonia	7	15			7	15

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonia bacterial		1				1
Polycythaemia vera		1				1
Polymenorrhoea	1	1	1	1		
Poor quality sleep		1		1		
Postmenopausal haemorrhage		1				1
Presyncope	2	26		8	2	18
Productive cough	1	2		1	1	1
Product use issue		6		6		
Prolonged expiration		1				1
Protein total decreased	1	1	1	1		
Pruritus	8	46	6	32	2	14
Pulmonary arterial hypertension		1				1
Pulmonary arterial pressure increased		1		1		
Pulmonary embolism	3	17			3	17
Pulmonary fibrosis		1				1
Pulmonary oedema		4				4
Pulmonary pain		1		1		
Pulse abnormal	1	2			1	2
Pyrexia	59	247	45	168	14	79
Radiculitis brachial	1	1			1	1
Rash	8	40	6	25	2	15
Rash erythematous	2	19	2	12		7
Rash macular	1	3	1	3		
Rash morbilliform		1		1		
Rash papular		1		1		
Rash pruritic	2	10	2	8		2
Rash vesicular		1		1		
Renal colic		1		1		
Renal failure		3				3
Renal pain		1				1
Respiration abnormal		2				2
Respiratory acidosis		4				4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory arrest	1	1			1	1
Respiratory disorder	1	1	1	1		
Respiratory distress		1				1
Respiratory failure		7				7
Respiratory tract infection bacterial		1				1
Restlessness	2	10	2	7		3
Rhabdomyolysis		1				1
Rheumatoid arthritis	1	2			1	2
Rhinalgia		1		1		
Rhinorrhoea	1	8	1	6		2
Salivary gland enlargement		1		1		
Salivary gland pain		1		1		
Salivary hypersecretion		1				1
SARS-CoV-2 test positive		1				1
Scratch		1				1
Seizure	3	5			3	5
Sensation of foreign body		4				4
Sensitive skin	1	1	1	1		
Sensory disturbance	8	17	4	11	4	6
Sensory loss	1	3			1	3
Sepsis		1				1
Severe acute respiratory syndrome		1				1
Sinus node dysfunction	1	1			1	1
Sinus tachycardia		2		2		
Skin burning sensation	1	2	1	1		1
Skin lesion		1		1		
Sleep disorder	1	4	1	4		
Sneezing		5		5		
Somnolence	4	11	3	7	1	4
Speech disorder	1	3			1	3
Splenic infarction		1				1
Staphylococcal infection		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stomatitis		1		1		
Strabismus	1	1			1	1
Stress cardiomyopathy		1				1
Stridor		1				1
Subarachnoid haemorrhage	1	1			1	1
Sudden cardiac death		1				1
Sudden death		3				3
Swelling	3	10	2	8	1	2
Swelling face	1	19	1	7		12
Swelling of eyelid		2		1		1
Swollen tongue		10		2		8
Syncope	9	23			9	23
Systemic immune activation		1				1
Systemic inflammatory response syndrome		1				1
Tachycardia	2	9	1	2	1	7
Tachypnoea		1				1
Taste disorder		3		2		1
Tenderness	3	15	3	11		4
Therapeutic response unexpected	1	1	1	1		
Throat irritation	2	10		3	2	7
Throat tightness		5		2		3
Thrombocytopenia	2	5			2	5
Thrombophlebitis superficial		1				1
Thrombosis	1	6			1	6
Tinnitus	2	6	1	3	1	3
Tongue discomfort	1	2		1	1	1
Tongue pruritus	1	3			1	3
Tonic convulsion		1				1
Tonsillar hypertrophy		1		1		
Toxicity to various agents		1				1
Transient ischaemic attack	4	6			4	6
Tremor	2	20	2	7		13

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Troponin I increased		2		1		1
Troponin increased		2				2
Tunnel vision		2				2
Type I hypersensitivity		1				1
Underdose		2		2		
Upper respiratory tract infection		1		1		
Urinary tract infection		3				3
Urinary tract infection bacterial		1				1
Urine odour abnormal		1				1
Urosepsis		1				1
Urticaria	15	45	6	23	9	22
Vaccination complication		2		1		1
Vaccination site abscess		1				1
Vaccination site discolouration	1	2	1	1		1
Vaccination site discomfort		2		2		
Vaccination site erythema	16	51	16	48		3
Vaccination site haematoma	2	5	1	4	1	1
Vaccination site haemorrhage	1	2	1	2		
Vaccination site hypoaesthesia		1		1		
Vaccination site induration		2		2		
Vaccination site infection	1	1	1	1		
Vaccination site inflammation		4		4		
Vaccination site irritation	1	3	1	2		1
Vaccination site lymphadenopathy		1		1		
Vaccination site movement impairment	1	2	1	2		
Vaccination site necrosis		1				1
Vaccination site nodule		1		1		
Vaccination site pain	50	220	46	200	4	20
Vaccination site paraesthesia		3		3		
Vaccination site pruritus	1	11	1	10		1
Vaccination site rash	3	8	3	5		3
Vaccination site reaction		1		1		

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FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site swelling	13	60	13	55		5
Vaccination site thrombosis		1				1
Vaccination site warmth	3	21	3	20		1
Vaginal discharge		1		1		
Vaginal haemorrhage		2		1		1
Vascular rupture	2	2	2	2		
Vasodilatation		1				1
Ventricular fibrillation	1	1			1	1
Ventricular tachycardia		1				1
Vertigo		3		1		2
Viral infection		1		1		
Vision blurred	2	6		1	2	5
Visual impairment	2	4	1	2	1	2
Vlth nerve paralysis		1				1
Vomiting	16	57	5	26	11	31
Vulvovaginal pain		1		1		
Vulvovaginal pruritus		1		1		
Weight increased		1		1		
Wheezing		1				1
White blood cell count increased	2	4	2	4		
White blood cells urine positive	1	1			1	1
White matter lesion		1		1		
Wound		1				1
Yawning		1		1		
	1	1	1	1		
	954	4,277	552	2396	402	1881

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1			1	1
Abdominal pain	2	5	2	3		2
Abdominal pain upper	1	3			1	3
Abnormal dreams	1	1			1	1
Acute coronary syndrome	2	2			2	2
Acute kidney injury		1				1
Acute myocardial infarction		1				1
Acute respiratory distress syndrome		1				1
Ageusia	1	1	1	1		
Aggression		2				2
Altered state of consciousness		3				3
Amnesia		2				2
Anaemia		1				1
Anaphylactic reaction		1				1
Anaphylactic shock	1	1			1	1
Angioedema		1				1
Anosmia	1	1	1	1		
Anxiety	1	2		1	1	1
Aortic aneurysm rupture		1				1
Aphasia		2				2
Arthralgia	6	9	3	5	3	4
Aspiration		1				1
Asthenia	1	6	1	2		4
Asthma	1	1			1	1
Atrial fibrillation	1	4			1	4
Autoimmune neuropathy	1	1			1	1
Autonomic nervous system imbalance	1	1			1	1
Back pain		3		2		1
Bacteraemia		1				1
Balance disorder		1				1
Basilar artery occlusion		1				1
Bell's palsy	2	2			2	2

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Beta haemolytic streptococcal infection	1	1
Blindness	1	1
Blood albumin decreased		1
Blood alkaline phosphatase increased		1
Blood chloride increased		1
Blood creatinine abnormal	1	1
Blood creatinine increased		1
Blood glucose increased		1
Blood pressure decreased		1
Blood pressure increased	1	1
Blood pressure systolic increased		2
Body temperature increased		1
Bradycardia	1	1
Brain injury	1	1
Bronchitis		1
Bronchospasm		1
Burning sensation	1	1
Calcium ionised increased		1
Cardiac arrest	2	8
Cardiac failure	1	3
Cardiogenic shock		2
Cardiovascular disorder		1
Cardiovascular symptom	1	1
Cerebral haemorrhage		1
Cerebral infarction	3	4
Cerebral thrombosis	1	2
Cerebrovascular accident	8	14
Chest discomfort	1	2
Chest pain	8	8
Chills	4	12
Chronic obstructive pulmonary disease		4
Circulatory collapse	2	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	1
	1		
	1		
	1		
		1	1
			1
	1		
	1		
		1	1
			1
		1	1
	1		
		1	1
			1
			1
		1	1
	1		
		2	8
		1	3
			2
			1
		1	1
			1
		3	4
		1	2
		8	14
		1	2
1	1	7	7
3	9	1	3
			4
		2	3

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Clonic convulsion		1				1
Cognitive disorder		1				1
Cold sweat	1	1			1	1
Colitis		1		1		
Coma		1				1
Condition aggravated		4				4
Confusional state	1	6		1	1	5
Contusion		1				1
Coordination abnormal	1	1			1	1
Cough	1	5		1	1	4
COVID-19		9		1		8
C-reactive protein abnormal		1				1
C-reactive protein increased		4		1		3
Death		7				7
Decreased appetite	1	7	1	2		5
Deep vein thrombosis	3	8			3	8
Dehydration	1	3			1	3
Delirium		6				6
Depressed level of consciousness		4				4
Diabetic complication		1				1
Diarrhoea	6	12	3	5	3	7
Diplopia	1	1			1	1
Discomfort	4	5	3	3	1	2
Disease progression	1	1			1	1
Disease recurrence		1		1		
Disorientation	1	1			1	1
Disturbance in attention		2		1		1
Dizziness	8	17	2	6	6	11
Drug ineffective		4				4
Drug interaction		1				1
Dysarthria	1	3			1	3
Dysphonia		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea	8	29		1	8	28
Dyspnoea exertional		3		1		2
Dysuria		1				1
Embolic stroke	1	1			1	1
Emphysema		1				1
Endocarditis bacterial	1	1			1	1
Endophthalmitis	1	1			1	1
Epilepsy	1	3			1	3
Epistaxis	1	1			1	1
Erysipelas		1				1
Erythema	1	1	1	1		
Eye pain		1		1		
Facial pain		1		1		
Facial paralysis		1				1
Facial paresis	1	3		1	1	2
Fall	2	6			2	6
Fatigue	12	39	4	22	8	17
Feeling cold		2		1		1
Feeling drunk		1		1		
Feeling hot	3	6	2	5	1	1
Femoral neck fracture	1	1			1	1
Fibrin D dimer increased		2		1		1
Flatulence	1	1			1	1
Fluid intake reduced	1	3			1	3
Flushing		3		2		1
Functional gastrointestinal disorder	1	1			1	1
Gait disturbance	1	2			1	2
Gastrointestinal sounds abnormal	1	1			1	1
Gastroesophageal reflux disease		1		1		
Generalised tonic-clonic seizure		4				4
General physical health deterioration		6				6
Glomerular filtration rate decreased		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Groin pain		1		1		
Haematuria		1				1
Haemoglobin abnormal	1	1			1	1
Haemoglobin decreased	1	1	1	1		
Haemolysis		1				1
Haemoptysis	1	1			1	1
Haemorrhage intracranial	1	2			1	2
Haemorrhagic cerebral infarction	1	1			1	1
Haemorrhagic diathesis		1				1
Hallucination, visual	2	2			2	2
Headache	13	39	7	26	6	13
Head discomfort	1	1	1	1		
Head injury		1				1
Heart rate increased	1	1			1	1
Hemiparesis	1	3			1	3
Hemiplegia		1				1
Hepatic cyst		1		1		
Herpes zoster	2	3	2	2		1
Hot flush		2		2		
Hyperhidrosis		2		1		1
Hypermetabolism	1	1	1	1		
Hypersensitivity		2		1		1
Hypersomnia	1	1			1	1
Hypertension	1	1			1	1
Hypoacusis		1		1		
Hypoaesthesia	2	4			2	4
Hypokinesia	1	1	1	1		
Hypophagia	1	2		1	1	1
Hypotension		4		1		3
Ileus paralytic		1				1
Immune-mediated hepatitis		1				1
Immune thrombocytopenia		1				1

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Impaired work ability	1	1
Inappropriate schedule of product administration		1
Incorrect route of product administration		1
Infection	1	1
Influenza		2
Influenza like illness	2	9
Insomnia	1	3
Intracardiac thrombus	1	1
Ischaemic stroke	1	1
Joint range of motion decreased	1	1
Joint swelling	1	1
Lacrimation increased		1
Limb discomfort		1
Lip swelling		2
Livedo reticularis		1
Liver function test increased		1
Loss of consciousness		1
Loss of control of legs		1
Low density lipoprotein increased		1
Lung infiltration		1
Lymphadenopathy		5
Lymphangitis		1
Malaise	10	25
Micturition urgency		1
Middle insomnia	1	1
Migraine		1
Mobility decreased		3
Muscle discomfort		1
Muscle spasms	1	1
Muscle twitching	2	3
Muscular weakness	2	4
Musculoskeletal stiffness	1	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
	1		
	1		
		1	1
	1		1
	7	2	2
	2	1	1
		1	1
		1	1
1	1		
1	1		
	1		
	1		
			2
			1
	1		
			1
			1
	1		
			1
	4		1
			1
3	8	7	17
			1
1	1		
			1
			3
	1		
		1	1
1	1	1	2
		2	4
1	1		1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	5	22	2	12	3	10
Myocarditis		1				1
Nasal obstruction		1		1		
Nausea	9	20	5	11	4	9
Neck pain	3	4	1	1	2	3
Neutrophil count increased		1		1		
Obstructive airways disorder	1	2			1	2
Odynophagia		1		1		
Oedema	1	1			1	1
Oedema peripheral		2				2
Off label use		3		3		
Oropharyngeal pain	1	7		4	1	3
Orthostatic hypotension	1	1	1	1		
Oxygen saturation decreased		2				2
Pain	3	10	2	6	1	4
Painful respiration		1				1
Pain in extremity		5		3		2
Pain of skin		1				1
Pallor		1				1
Palpitations	1	2		1	1	1
Pancreatitis acute	1	1			1	1
Paraesthesia	2	2	1	1	1	1
Paraesthesia oral	1	2	1	1		1
Paralysis		1				1
Parosmia		1		1		
Partial seizures	1	1			1	1
Periarthritis		1		1		
Pericarditis	1	2			1	2
Periorbital swelling		2				2
Peripheral coldness		2				2
Peripheral swelling	1	3	1	1		2
Petit mal epilepsy	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal paraesthesia	1	1	1	1		
Pharyngeal swelling		1				1
Pharyngitis		1				1
Phlebitis deep		1				1
Platelet count abnormal		1				1
Pneumonia	2	14			2	14
Pneumonia aspiration		1				1
Pneumonitis		1				1
Presyncope	1	3			1	3
Productive cough	1	3			1	3
Product use issue		2		2		
Pruritus	2	4	1	2	1	2
Pulmonary congestion	1	1			1	1
Pulmonary embolism	7	16			7	16
Pulmonary fibrosis		1				1
Pulmonary oedema		2				2
Pyrexia	9	44	4	26	5	18
Rales		1				1
Rash	2	8	2	8		
Rash erythematous		1		1		
Rash papular	1	1			1	1
Rash pruritic	2	4	2	2		2
Renal failure	1	2			1	2
Respiratory alkalosis	1	1			1	1
Respiratory arrest		4				4
Respiratory distress	1	1			1	1
Respiratory failure	1	8			1	8
Respiratory rate decreased		1				1
Respiratory rate increased	1	1	1	1		
Restless arm syndrome	1	1			1	1
Restless legs syndrome	1	1			1	1
Restlessness		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Retinal vascular thrombosis		1				1
Rhabdomyolysis	1	1			1	1
Rheumatoid factor increased		1				1
Rhinitis		1		1		
Scratch	1	1			1	1
Seasonal allergy		1		1		
Seizure		2				2
Sensory disturbance	1	1	1	1		
Sepsis		1				1
Septic embolus	1	1			1	1
Septic shock		1				1
Skin abrasion		1				1
Skin haemorrhage		1				1
Sneezing		1		1		
Somnolence		5		4		1
Speech disorder		1		1		
Splenic haemorrhage		1				1
Sputum discoloured		1				1
Sudden death		1				1
Swelling	1	1	1	1		
Swollen tongue		1				1
Syncope		4				4
Systemic immune activation		1				1
Tachypnoea		1				1
Taste disorder		1		1		
Temporomand bular joint syndrome		1				1
Tenderness	1	1	1	1		
Thinking abnormal		1				1
Throat irritation		2		2		
Thrombocytopenia		1				1
Thrombocytosis		1				1
Thrombophlebitis	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thrombosis	1	6			1	6
Tinnitus		1		1		
Tooth infection	1	1			1	1
Tracheal stenosis		1				1
Transplant failure		1				1
Tremor	1	2	1	2		
Unresponsive to stimuli		1				1
Urinary incontinence	1	2			1	2
Urticaria	3	7	2	4	1	3
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	1	2	1	2		
Vaccination site haemorrhage	2	2			2	2
Vaccination site movement impairment	1	2	1	2		
Vaccination site pain	10	37	9	35	1	2
Vaccination site paraesthesia	1	1	1	1		
Vaccination site rash		1		1		
Vaccination site swelling	1	4	1	3		1
Vasculitis	1	2		1	1	1
Visual field defect	1	1			1	1
Visual impairment	1	1			1	1
Vomiting	4	13	1	5	3	8
Wound complication		1		1		
Wound infection		1				1
Wrong product administered	1	1	1	1		
	297	937	97	340	200	597

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		3				3
Anencephaly	1	1			1	1
Cleft palate	1	1			1	1
Congenital absence of cranial vault	1	1			1	1
COVID-19		1				1
Drug ineffective		1				1
Exposure via breast milk		1		1		
Fatigue	1	2	1	2		
Headache	1	2	1	2		
Hypoaesthesia		1		1		
Influenza like illness	1	2	1	2		
Maternal exposure during pregnancy	1	1			1	1
Myalgia	1	2	1	2		
No adverse event	1	1	1	1		
Product administration error		1		1		
Product preparation issue		1		1		
Reaction to excipient		2				2
	9	24	5	13	4	11

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Country Where Event Occurred

ECUADOR

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- * AE=Adverse Event
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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Angina pectoris		1				1
Anxiety	2	2	2	2		
Autoimmune myocarditis	1	1			1	1
Blood pressure increased		1		1		
Chronic pigmented purpura	1	1	1	1		
Cough	1	1			1	1
COVID-19	1	4	1	1		3
Depressed mood		1		1		
Diarrhoea		3		3		
Discomfort	1	4	1	4		
Dizziness	2	4	1	3	1	1
Drug ineffective	1	3			1	3
Dysphagia	1	1			1	1
Dysphonia	1	1			1	1
Erythema	1	1	1	1		
Face oedema		1		1		
Fatigue	1	2	1	2		
Feeling hot	1	1	1	1		
Headache	1	1	1	1		
Head discomfort	1	1			1	1
Hyperhidrosis	1	1			1	1
Influenza	1	1	1	1		
Insomnia	1	1			1	1
Lip oedema		1		1		
Lymphadenitis		1		1		
Malaise	2	2	1	1	1	1
Muscular weakness	1	1			1	1
Myalgia	1	2		1	1	1
Nasopharyngitis	1	1	1	1		
Neck pain	1	1			1	1
Oropharyngeal pain	1	2		1	1	1

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain	2	3		1	2	2
Paraesthesia	1	1			1	1
Pericarditis	2	2			2	2
Pyrexia	1	5	1	5		
Respiratory disorder	1	1			1	1
Rhinorrhoea	1	1			1	1
SARS-CoV-2 test positive		1		1		
Sitting disability	1	1			1	1
Suffocation feeling	1	1			1	1
Supraventricular extrasystoles	1	1			1	1
Suspected COVID-19	1	2			1	2
Tachycardia	1	1	1	1		
Transient ischaemic attack	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site oedema	1	1	1	1		
Vaccination site pain		1		1		
Vaccination site swelling	1	1	1	1		
Vaccination site urticaria	1	1	1	1		
Ventricular extrasystoles	1	1			1	1
Vomiting		1		1		
	47	78	19	43	28	35

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	2	1	2		
Blood pressure increased		1		1		
Chills		1		1		
Cough		1		1		
COVID-19	2	5		2	2	3
Diarrhoea		1		1		
Discomfort	1	2	1	2		
Drug ineffective	1	2			1	2
Eye pain		1		1		
Fatigue		1		1		
Headache		1		1		
Laryngitis		1		1		
Limb discomfort		1		1		
Lung infiltration		1		1		
Myalgia	2	2	2	2		
Pyrexia	1	3	1	3		
Rhinorrhoea	1	1	1	1		
Thrombotic stroke		1				1
Vaccination failure	1	1			1	1
Vaccination site pain	1	5	1	5		
	11	34	7	27	4	7

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	22	23			22	23
Drug ineffective	22	23			22	23
Laryngitis		1		1		
Musculoskeletal disorder		1		1		
Tracheitis		1		1		
Vaccination site pain		1		1		
	44	50		4	44	46

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Country Where Event Occurred

EGYPT

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19		1		1
Drug ineffective		1		1
		2		2

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Country Where Event Occurred

EL SALVADOR

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Atypical pneumonia	1	1			1	1
Back pain	1	1	1	1		
Bronchospasm	1	1	1	1		
Cerebrovascular accident	1	1			1	1
Insomnia	1	1	1	1		
Pleural effusion	1	1			1	1
Pneumonia	1	1			1	1
Pulmonary oedema	1	1			1	1
	8	8	3	3	5	5

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Pleural effusion	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

ESTONIA

090177e19749cf15\Approved\Approved On: 14-Jun-2021 14:01 (GMT)

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	3		2	1	1
Abdominal pain upper		1				1
Acute disseminated encephalomyelitis		1				1
Ageusia		2		2		
Altered state of consciousness	1	1			1	1
Anaphylactic shock	1	1			1	1
Angina pectoris	2	2			2	2
Anxiety		1				1
Aphonia		1				1
Arrhythmia	2	2			2	2
Arthralgia	4	18	4	18		
Asthenia	7	29	5	22	2	7
Asymptomatic COVID-19	1	2			1	2
Atrial f brillation	1	1			1	1
Back pain		3		1		2
Balance disorder	1	3	1	3		
Basilar artery thrombosis	1	1			1	1
Bell's palsy	1	1			1	1
Blood creatine phosphokinase increased		1		1		
Blood pressure increased	1	2	1	1		1
Body temperature decreased		1		1		
Bone contusion		1				1
Bone pain		2		1		1
Bradycardia		1				1
Bronchitis	1	1	1	1		
Cerebral haemorrhage		1				1
Cerebrovascular accident		1				1
Chest discomfort		1		1		
Chest pain		5		3		2
Chills	5	26	5	25		1
Cognitive disorder		1		1		
Cold sweat		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Condition aggravated		1		1		
Contusion		1				1
Cough	3	6	3	6		
COVID-19	25	49		1	25	48
COVID-19 pneumonia		1				1
C-reactive protein increased		1		1		
Cystitis	1	1			1	1
Decreased appetite	1	3		2	1	1
Demyelination		1				1
Diarrhoea	1	4		3	1	1
Disease recurrence		1		1		
Dizziness	4	16	3	11	1	5
Drug hypersensitivity		1				1
Drug ineffective	6	11			6	11
Dry mouth	1	1			1	1
Dysgeusia	1	7	1	5		2
Dyspepsia		1		1		
Dysphagia		1				1
Dyspnoea	1	13	1	11		2
Dyspnoea exertional	1	1	1	1		
Dysuria		1				1
Ear disorder		1		1		
Ear pain	1	2	1	2		
Electrocardiogram ST segment depression	1	1			1	1
Epistaxis	1	1			1	1
Erythema	1	1	1	1		
Exposure during pregnancy	1	6	1	6		
Exposure to SARS-CoV-2	1	1	1	1		
Extensive swelling of vaccinated limb		1		1		
Facial nerve disorder		1		1		
Facial pain		2		2		
Facial paralysis		1				1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Fall	1	3
Fatigue	8	22
Feeling hot		2
Fine motor skill dysfunction	1	1
Flushing		1
Fracture		1
General physical health deterioration	1	1
Glossodynia	1	1
Haematoma		1
Haemorrhage in pregnancy		1
Headache	12	49
Heart rate increased		1
Herpes zoster	1	1
Hot flush	1	1
Hyperhidrosis	3	6
Hypersensitivity		4
Hypertension	1	5
Hypoaesthesia	1	5
Hypoaesthesia oral		1
Hypopnoea		1
Hypotension	2	4
Hypothermia		5
Immunisation anxiety related reaction		9
Immunisation reaction		1
Increased appetite		1
Influenza like illness		1
Insomnia		5
Intranasal paraesthesia		1
Ischaemic cerebral infarction	1	1
Joint range of motion decreased		1
Joint stiffness		1
Joint swelling		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	2	1	1
8	21		1
	2		
1	1		
	1		
			1
		1	1
1	1		
	1		
			1
12	45		4
			1
1	1		
1	1		
2	5	1	1
	1		3
	3	1	2
	4	1	1
	1		
			1
1	1	1	3
			5
	8		1
			1
	1		
	1		
		1	1
	1		
	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lacrimation increased	1	1	1	1		
Laryngeal oedema	1	3			1	3
Lip swelling		1				1
Loss of consciousness	1	2			1	2
Lymphadenopathy	1	6	1	6		
Malaise	3	11	2	8	1	3
Maternal exposure during pregnancy	3	6	3	5		1
Migraine with aura		1		1		
Mouth swelling		1				1
Muscle spasms		1		1		
Muscular weakness		3		3		
Musculoskeletal pain		1		1		
Musculoskeletal stiffness	1	2	1	1		1
Myalgia	9	24	9	23		1
Myelitis transverse		1				1
Nasal congestion		1		1		
Nausea	3	17	1	11	2	6
Neck pain		2				2
Nervousness		1				1
Ocular discomfort		1		1		
Off label use		1		1		
Oral herpes		2		2		
Oropharyngeal discomfort		1				1
Oropharyngeal pain	5	8	5	8		
Pain		2		1		1
Pain in extremity	4	12	4	12		
Pallor		1				1
Palpitations		3		3		
Panic attack		1		1		
Paraesthesia		16		13		3
Paraesthesia oral		3		3		
Peripheral swelling		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal paraesthesia		1		1		
Pharyngeal swelling		1		1		
Photopsia		1		1		
Pneumonia		1				1
Presyncope		1				1
Product use issue		1		1		
Pruritus	1	2	1	2		
Pulmonary embolism	1	1			1	1
Pulse absent	1	1			1	1
Pyrexia	12	45	11	43	1	2
Respiration abnormal		1				1
Respiratory failure		1				1
Respiratory symptom		1		1		
Restlessness		3		3		
Retching		1				1
Reversed hot-cold sensation	1	1	1	1		
Rhinitis	1	2	1	2		
Rhinorrhoea	3	6	3	6		
Road traffic accident		1		1		
Skull fractured base	1	1			1	1
Somnolence	5	14	4	12	1	2
Speech disorder	1	2			1	2
Spinal cord injury		1				1
Sputum increased		1		1		
Subdural haematoma	1	1			1	1
Supraventricular tachycardia		1				1
Suspected COVID-19	1	1			1	1
Syncope	3	13			3	13
Syringe issue		1		1		
Tachycardia		3		3		
Tendon pain		1		1		
Throat irritation	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Throat tightness		1				1
Thrombophlebitis		1		1		
Tinnitus		2		1		1
Tremor		2		2		
Type I hypersensitivity		1				1
Type IV hypersensitivity reaction		1				1
Underdose		1		1		
Urinary retention		1				1
Vaccination failure	21	39			21	39
Vaccination site erythema	2	6	2	6		
Vaccination site extravasation		1		1		
Vaccination site induration	1	3	1	3		
Vaccination site oedema	2	7	2	7		
Vaccination site pain	6	33	6	33		
Vaccination site paraesthesia		1		1		
Vaccination site pruritus		1		1		
Vaccination site rash		2		2		
Vaccination site swelling	1	5	1	5		
Vaccine breakthrough infection		1				1
Ventricular extrasystoles		1				1
Vision blurred	1	2	1	2		
Visual impairment		1				1
Vomiting	2	4	1	3	1	1
Wound		1				1
	216	765	120	511	96	254

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction		1				1
Asthenia	1	2	1	1		1
Balance disorder	1	1	1	1		
Blindness unilateral		1				1
Cardiac arrest	1	1			1	1
Cardiac failure congestive		1				1
Cellulitis	1	1			1	1
Cerebral infarction		1				1
Chills		1		1		
Chronic obstructive pulmonary disease		1				1
Condition aggravated	2	2			2	2
COVID-19	9	12			9	12
Death		2				2
Decreased appetite	1	1			1	1
Deep vein thrombosis		1				1
Diplopia		1		1		
Disease recurrence		1				1
Dizziness	2	3	2	3		
Drug ineffective	1	2			1	2
Dysgeusia	1	1			1	1
Dysphagia	1	2		1	1	1
Dyspnoea	1	1			1	1
Fall	1	1			1	1
Fatigue	1	1	1	1		
Feeling hot	1	1	1	1		
Femoral artery embolism	1	1			1	1
Headache	2	4	2	4		
Hypertension	1	1	1	1		
Hypertensive heart disease		1				1
Hypoaesthesia oral	1	2	1	2		
Hypoglycaemia		1				1
Hypotension	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Illrd nerve disorder		1				1
Immunisation anxiety related reaction		1		1		
Insomnia	1	1	1	1		
Limb discomfort	1	1	1	1		
Lymphadenopathy	1	2	1	2		
Malaise	1	3	1	2		1
Myocardial infarction	1	1			1	1
Nausea	1	3	1	3		
Paraesthesia		2		2		
Peripheral sensory neuropathy		1				1
Peripheral swelling	2	2			2	2
Pharyngeal hypoaesthesia		1		1		
Pruritus	1	1	1	1		
Psoriasis		1				1
Pulmonary embolism	1	3			1	3
Pulmonary oedema		1				1
Pyrexia		4		3		1
Respiratory failure		2				2
Retinal vascular thrombosis		1				1
Seizure		1				1
Skin ulcer	1	1			1	1
Somnolence	1	1	1	1		
Suspected COVID-19		1				1
Syncope		1				1
Thrombophlebitis superficial	1	1			1	1
Trigeminal nerve disorder		1				1
Urticaria	1	1	1	1		
Vaccination failure	8	11			8	11
Vaccination site erythema	1	2	1	2		
Vaccination site oedema		1		1		
Vaccination site pain	2	8	2	8		
Vomiting	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	57	117	21	47	36	70

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills		1		1
Myalgia		1		1
Pyrexia		1		1
Vaccination site erythema		1		1
Vaccination site pain		1		1
		5		5

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Country Where Event Occurred

FINLAND

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	3	5	2	2	1	3
Abdominal distension		3		2		1
Abdominal pain	7	18	4	7	3	11
Abdominal pain lower		3		1		2
Abdominal pain upper	4	9	2	2	2	7
Abdominal symptom		2		1		1
Abortion spontaneous		1				1
Acquired haemophilia		2				2
Acute hepatic failure	1	1			1	1
Acute myocardial infarction		1				1
Ageusia	1	2			1	2
Alanine aminotransferase increased		1				1
Allergy to vaccine	1	3			1	3
Amaurosis fugax	1	2			1	2
Amnesia	1	2			1	2
Anaesthesia		1		1		
Anal incontinence	1	1			1	1
Anaphylactic reaction	10	26			10	26
Anaphylactic shock	2	5			2	5
Angina pectoris	2	2			2	2
Anosmia	3	3	1	1	2	2
Anti factor VIII ant body positive		2				2
Anuria		2				2
Anxiety	2	3			2	3
Aortitis		1				1
Aphasia		1				1
Aphonia	2	5		1	2	4
Apnoea	1	3			1	3
Appendicitis		1				1
Appendicitis perforated	1	1			1	1
Arrhythmia	8	27			8	27
Arthralgia	21	81	10	31	11	50

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthritis		1				1
Arthritis reactive		1				1
Asthenia	19	69	11	19	8	50
Asthenopia		2				2
Asthma	1	2			1	2
Asymptomatic COVID-19	1	1			1	1
Atelectasis	1	1			1	1
Atrial f brillation	4	10			4	10
Atrial flutter	1	1			1	1
Atypical pneumonia	1	1			1	1
Axillary pain	4	18	4	10		8
Back pain	4	18	3	10	1	8
Bacterial test positive		3				3
Balance disorder	2	4	1	1	1	3
Bedridden		1				1
Bell's palsy	1	2			1	2
Bladder dysfunction	1	1			1	1
Blepharitis		1				1
Blindness unilateral	1	1			1	1
Blister		2		1		1
Blood alkaline phosphatase increased		1				1
Blood bilirubin increased		1				1
Blood cholesterol increased	1	1			1	1
Blood glucose increased	1	2			1	2
Blood lactic acid decreased		1		1		
Blood potassium decreased	1	1			1	1
Blood pressure decreased	4	11	4	5		6
Blood pressure diastolic decreased		1				1
Blood pressure diastolic increased		2				2
Blood pressure fluctuation	4	5	1	1	3	4
Blood pressure increased	16	37	4	7	12	30
Blood pressure systolic decreased		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood uric acid increased		1				1
Body temperature decreased		2				2
Body temperature fluctuation		1				1
Body temperature increased	1	3		1	1	2
Bone pain		3		1		2
Breast cyst	1	2	1	1		1
Breast pain		1				1
Breast swelling		1				1
Breast tenderness		1				1
Breath sounds abnormal	1	3		1	1	2
Bronchitis		2				2
Burning sensation	4	13	1	4	3	9
Cardiac arrest		1				1
Cardiac disorder	2	2			2	2
Cardiac failure		2				2
Cardiac flutter		1				1
Cardiac hypertrophy		1				1
Carotid artery thrombosis	1	1			1	1
Central nervous system inflammation		1				1
Cerebral artery thrombosis		1				1
Cerebral haematoma	1	1			1	1
Cerebral haemorrhage	1	1			1	1
Cerebral infarction	5	15			5	15
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident		1				1
Cervical spinal stenosis		1				1
Cheilitis		1		1		
Chest discomfort	5	20		4	5	16
Chest pain	2	11		2	2	9
Chest X-ray abnormal		1				1
Chills	27	65	20	36	7	29
Choking sensation		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholelithiasis		1				1
Chromatopsia	1	1			1	1
Circulatory collapse		2				2
Clumsiness	1	2		1	1	1
Cognitive disorder		3		1		2
Cold sweat	1	4		1	1	3
Coma scale abnormal		2				2
Concussion	1	1			1	1
Condition aggravated	2	5			2	5
Confusional state	4	8	1	1	3	7
Congestive cardiomyopathy		1				1
Conjunctival hyperaemia		1				1
Contusion	2	4	1	2	1	2
Coordination abnormal		1		1		
Corneal infection		1				1
Cough	9	27		1	9	26
COVID-19		2				2
C-reactive protein	1	1			1	1
C-reactive protein abnormal	1	1			1	1
C-reactive protein increased	5	16	2	4	3	12
CREST syndrome		1				1
Crohn's disease		1				1
CSF immunoglobulin increased		1				1
CSF protein increased		1				1
Cyanosis		1				1
Cystitis		1				1
Deafness	1	1			1	1
Deafness bilateral	1	1			1	1
Deafness unilateral		2				2
Death	4	12			4	12
Decreased appetite	1	10	1	1		9
Deep vein thrombosis	5	8			5	8

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dehydration		1				1
Delusion		2		2		
Dementia Alzheimer's type		2				2
Demyelination		1				1
Depressed level of consciousness	1	6			1	6
Depressed mood	1	1			1	1
Derealisation	1	2		1	1	1
Diarrhoea	15	33	7	14	8	19
Diplopia	1	3		2	1	1
Discomfort		3		1		2
Disease recurrence	3	8	1	1	2	7
Disorganised speech	1	1			1	1
Disturbance in attention		1				1
Diverticulitis		2				2
Dizziness	35	84	14	28	21	56
Dizziness postural	1	1			1	1
Drug ineffective		1				1
Drug interaction	2	2			2	2
Dry eye		1				1
Dry mouth		2				2
Dysarthria		7		1		6
Dysgeusia	3	6	1	2	2	4
Dyskinesia		1		1		
Dysmetria		1				1
Dyspepsia		1				1
Dysphagia		7		2		5
Dysphonia	7	11	2	4	5	7
Dyspnoea	19	86	4	11	15	75
Dyspnoea exertional		4				4
Dysstasia		2				2
Dysuria		2		1		1
Ear discomfort		2		2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear pain		4		3		1
Ear pruritus		1		1		
Eating disorder		1		1		
Eczema		1				1
Electric shock sensation		2		1		1
Electrocardiogram ST segment depression		1				1
Electrocardiogram T wave inversion		1				1
Emphysema	1	1			1	1
Encephalitis		1				1
Epilepsy		2				2
Epistaxis		3		1		2
Erysipelas	2	4			2	4
Erythema	9	46	2	13	7	33
Erythema multiforme		1				1
Erythema of eyelid		2				2
Escherichia infection	1	1			1	1
Exercise tolerance decreased		2				2
Extensive swelling of vaccinated limb		2		2		
Extrasystoles	2	7		3	2	4
Eye disorder		1				1
Eye irritation		1		1		
Eyelid irritation		1				1
Eyelid oedema	2	7	1	2	1	5
Eye movement disorder		1		1		
Eye oedema	2	2	1	1	1	1
Eye pain	2	10	2	5		5
Eye swelling	1	1			1	1
Face oedema	4	15	2	3	2	12
Facial pain		4		2		2
Facial paralysis	1	11			1	11
Facial paresis	3	5	1	1	2	4
Fall	5	16		1	5	15

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Fatigue	41	150
Fear		1
Feeding disorder		1
Feeling abnormal	7	21
Feeling cold	10	23
Feeling drunk		1
Feeling hot	5	29
Female genital tract fistula		1
Fibrin D dimer increased		1
Fixed eruption		2
Flank pain	1	2
Flatulence		1
Fluid retention	1	1
Flushing		8
Food allergy		2
Food aversion		1
Fracture	1	1
Gait disturbance	2	7
Gait inability	1	2
Gastric disorder		1
Gastrointestinal necrosis		1
Gaze palsy		2
General physical health deterioration	7	25
Giant cell arteritis		1
Gingival swelling		1
Glomerular filtration rate decreased	1	1
Glossodynia	2	3
Grip strength decreased		1
Groin pain		1
Haematochezia		1
Haematoma	1	4
Haematuria		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
24	61	17	89
	1		
			1
2	4	5	17
6	9	4	14
			1
3	12	2	17
			1
	1		
	2		
1	1		1
	1		
		1	1
	2		6
			2
			1
		1	1
	1	2	6
		1	2
	1		
			1
			2
1	3	6	22
			1
	1		
1	1		
1	1	1	2
			1
			1
			1
	2	1	2
			1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemodynamic instability		1				1
Haemoglobin decreased		1				1
Haemorrhagic fever with renal syndrome	1	1			1	1
Hallucination	1	2			1	2
Hallucination, auditory		2				2
Hallucination, visual	1	1			1	1
Headache	63	189	33	71	30	118
Head discomfort	3	10	1	4	2	6
Head injury	2	4		1	2	3
Heart rate abnormal	1	1			1	1
Heart rate decreased		2		1		1
Heart rate increased	14	34	3	4	11	30
Heart rate irregular	3	7		1	3	6
Heavy menstrual bleeding	2	2	2	2		
Helplessness		1		1		
Hemianaesthesia	4	23			4	23
Hemihyperaesthesia		1				1
Hemiparaesthesia		3				3
Hemiparesis	1	5			1	5
Hemiplegia		1				1
Hepatic steatosis	1	1	1	1		
Herpes ophthalmic		1				1
Herpes simplex	1	1	1	1		
Herpes virus infection	1	1			1	1
Herpes zoster	6	17	2	8	4	9
Herpes zoster oticus		1				1
Hip fracture		1				1
Hot flush		2				2
Human herpesvirus 6 infection	1	1			1	1
Hyperacusis	1	1			1	1
Hyperaesthesia	1	5	1	1		4
Hyperhidrosis	5	16	2	5	3	11

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperlactacidaemia		1				1
Hypersensitivity	8	25	2	3	6	22
Hypersomnia		2		1		1
Hypertension	4	11	1	2	3	9
Hyperventilation	2	2	1	1	1	1
Hypoacusis	3	6	2	5	1	1
Hypoaesthesia	18	53	8	20	10	33
Hypoaesthesia oral	4	17	3	8	1	9
Hypoaesthesia teeth		1		1		
Hypogeusia	1	1	1	1		
Hypokalaemia	1	6			1	6
Hyponatraemia		1				1
Hyposmia		1		1		
Hypotension		2				2
Hypothermia		3				3
Hypotonia		2				2
Illness		1				1
Immune-mediated adverse reaction	1	1			1	1
Immune thrombocytopenia		1				1
Impaired reasoning		1				1
Impaired work ability	3	16			3	16
Inappropriate affect	1	1			1	1
Inappropriate schedule of product administration	4	5	4	5		
Incorrect route of product administration		10		10		
Increased bronchial secretion	1	1			1	1
Increased tendency to bruise		1				1
Increased upper airway secretion	1	6			1	6
Infection		2				2
Infectious mononucleosis	1	1			1	1
Inflammation		1				1
Inflammatory marker increased	1	2			1	2
Influenza		3		1		2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Influenza like illness		2				2
Initial insomnia	1	2			1	2
Insomnia	4	14	2	4	2	10
International normalised ratio decreased		3		1		2
Intestinal ischaemia	1	2			1	2
Iritis		1				1
Irritability		2				2
Jaundice		1				1
Joint effusion		1				1
Joint injury		1				1
Joint range of motion decreased		3		2		1
Joint stiffness	1	2		1	1	1
Joint swelling	1	2		1	1	1
Keratitis		1				1
Ketoacidosis	1	1			1	1
Klebsiella infection	1	1			1	1
Laryngeal pain		1				1
Lethargy	1	2			1	2
Limb discomfort	2	3	1	2	1	1
Limb injury		1				1
Lip exfoliation	1	1			1	1
Lip oedema	1	5		3	1	2
Lip pain		2		2		
Lip pruritus		1				1
Lip swelling	1	3		1	1	2
Localised oedema	3	7	2	4	1	3
Loss of consciousness	7	13			7	13
Loss of control of legs		2				2
Loss of personal independence in daily activities	3	5	1	1	2	4
Lung disorder		2				2
Lymphadenitis	1	1			1	1
Lymphadenopathy	14	62	10	32	4	30

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymph node pain		8		3		5
Lymph nodes scan abnormal		1				1
Macular oedema	1	1			1	1
Malaise	29	83	10	24	19	59
Malignant lymphoid neoplasm		1				1
Maternal exposure during pregnancy		1		1		
Memory impairment	3	5		1	3	4
Meniere's disease	1	1			1	1
Menstrual disorder		1				1
Mental impairment		2				2
Mesenteric artery stenosis	1	1			1	1
Mesenteric artery stent insertion	1	1			1	1
Mesenteric artery thrombosis		1				1
Mesenteric vein thrombosis	1	1			1	1
Middle insomnia		5		2		3
Migraine	1	13		1	1	12
Migraine with aura		1				1
Mobility decreased	1	4		1	1	3
Monoparesis	1	2			1	2
Mouth haemorrhage		1				1
Mouth swelling	1	3			1	3
Movement disorder		1				1
Multiple sclerosis relapse	2	2			2	2
Mumps	1	1			1	1
Muscle disorder		1				1
Muscle fatigue	1	3	1	1		2
Muscle spasms	6	12	1	2	5	10
Muscle spasticity		2				2
Muscle strain		1				1
Muscle tightness		2		1		1
Muscle twitching	3	11	2	4	1	7
Muscular weakness	3	24	1	4	2	20

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal discomfort		1				1
Musculoskeletal disorder		2		1		1
Musculoskeletal pain		3		1		2
Musculoskeletal stiffness	2	15	1	7	1	8
Myalgia	31	124	20	45	11	79
Mydriasis		1		1		
Myelitis transverse	1	1			1	1
Myocardial infarction		2				2
Myocarditis		1				1
Myokymia	1	1			1	1
Narcolepsy		1				1
Nasal congestion	1	5	1	3		2
Nasal pruritus		1		1		
Nasopharyngitis	1	9		1	1	8
Nausea	37	106	20	42	17	64
Neck pain	7	20	3	5	4	15
Neuralgia	4	15	2	4	2	11
Neurological symptom		2				2
Nightmare	1	1			1	1
Night sweats	1	2	1	2		
Nodule		2		2		
Noninfective sialoadenitis		1				1
Nuchal rigidity	1	3		2	1	1
Obstruction		1				1
Ocular discomfort		1		1		
Ocular hyperaemia		2				2
Oedema mouth	1	1			1	1
Oedema peripheral		7		2		5
Off label use	4	5	4	5		
Opisthotonus		1				1
Oral discomfort	1	3	1	3		
Oral mucosal blistering		2		2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral pruritus	1	5			1	5
Oropharyngeal discomfort	1	6		1	1	5
Oropharyngeal oedema		2		1		1
Oropharyngeal pain	7	22	3	11	4	11
Oxygen saturation decreased		3				3
Pain	5	32	1	3	4	29
Pain in extremity	30	112	15	43	15	69
Pain in jaw	1	1			1	1
Pain of skin	2	6	2	3		3
Palatal swelling	1	1			1	1
Pallor	1	5	1	2		3
Palpitations	11	31	5	11	6	20
Papule	2	3	1	2	1	1
Paraesthesia	12	45	5	15	7	30
Paraesthesia oral	8	26	1	10	7	16
Paraparesis		1				1
Paronychia	1	1	1	1		
Peak expiratory flow rate decreased		3				3
Perichondritis		1		1		
Peripheral coldness		1				1
Peripheral swelling	1	3		1	1	2
Peritonitis	1	1			1	1
Pharyngeal hypoaesthesia		4		1		3
Pharyngeal oedema	3	10		1	3	9
Pharyngeal paraesthesia	1	4		1	1	3
Pharyngeal swelling	5	11	1	1	4	10
Photophobia	2	5	1	2	1	3
Photopsia	1	3			1	3
Photosensitivity reaction	1	2			1	2
Platelet count decreased	1	1			1	1
Platelet disorder		1				1
Pleural effusion	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonia	2	6			2	6
Polymyalgia rheumatica	2	3			2	3
Porphyria		1				1
Portal vein thrombosis	1	1			1	1
Post herpetic neuralgia	1	1	1	1		
Post procedural haemorrhage		1				1
Presyncope		5		1		4
Productive cough		2				2
Product use issue		1		1		
Pruritus	13	28	6	15	7	13
Pulmonary embolism	3	9			3	9
Pulmonary haemorrhage		1				1
Pulmonary oedema		1				1
Pulmonary pain	1	6			1	6
Pyelonephritis	2	4			2	4
Pyrexia	57	193	37	76	20	117
Rales		1				1
Rash	8	19	3	6	5	13
Rash erythematous		4		2		2
Rash macular	2	5	1	2	1	3
Rash pruritic		4		3		1
Rash vesicular	3	3	3	3		
Rectal haemorrhage		1				1
Rectal ulcer		1				1
Red blood cell sedimentation rate increased		1				1
Red blood cells urine		1				1
Red blood cells urine positive		1				1
Reduced facial expression		1		1		
Renal disorder		1		1		
Renal failure	1	2			1	2
Respiratory arrest		1				1
Respiratory rate decreased		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory rate increased		1				1
Respiratory tract congestion	1	1			1	1
Respiratory tract irritation		1				1
Resuscitation		1				1
Retinal haemorrhage		1				1
Retinal tear		1				1
Retinal vein occlusion	1	1			1	1
Retinal vein thrombosis		1				1
Rheumatoid arthritis		1				1
Rhinitis		2				2
Rhinorrhoea	4	7	2	4	2	3
Rhonchi	1	1			1	1
Right ventricular failure		2				2
Salivary gland enlargement		1				1
Salivary hypersecretion		1				1
SARS-CoV-2 test negative	4	7	2	3	2	4
Scab		1				1
Secretion discharge		1				1
Seizure	2	3			2	3
Self-injurious ideation		1				1
Sensation of foreign body	7	15	1	2	6	13
Sensory disturbance		1		1		
Sensory loss		1				1
Sialoadenitis		1				1
Sinusitis	1	1			1	1
Sinus tachycardia		2				2
Skin burning sensation	2	2	1	1	1	1
Skin discolouration	1	1			1	1
Skin mass	1	1			1	1
Skin reaction		1		1		
Skin sensitisation		1				1
Skin striae		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin warm		2		1		1
Sneezing	1	2	1	1		1
Snoring		1				1
Somnolence	6	10	2	3	4	7
Speech disorder	1	3			1	3
Spinal pain	1	3		1	1	2
Splenic infarction	1	1			1	1
Sputum discoloured		1				1
Stiff tongue	1	2			1	2
Stomatitis	1	1			1	1
Strabismus		1				1
Stridor		2				2
Stupor		1				1
Sudden death		1				1
Sudden hearing loss		1				1
Suffocation feeling		2				2
Suicidal ideation	1	1			1	1
Swelling	1	7		3	1	4
Swelling face	1	4		1	1	3
Swelling of eyelid	1	3			1	3
Swollen tongue	5	7	1	1	4	6
Syncope	4	19			4	19
Synovial fluid white blood cells positive		1				1
Tachycardia	2	11		1	2	10
Taste disorder	1	1			1	1
Tension headache	1	1			1	1
Thirst	4	4	2	2	2	2
Throat irritation	5	16	1	4	4	12
Throat tightness	3	8			3	8
Thrombocytopenia	2	2			2	2
Thrombocytosis		1				1
Thrombolysis	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thrombophlebitis superficial	4	5	1	1	3	4
Thrombosis		3				3
Thrombotic cerebral infarction		1				1
Tinnitus	6	11	2	6	4	5
Tongue discolouration		1				1
Tongue discomfort		3		1		2
Tongue disorder		1				1
Tongue erythema		1				1
Tongue oedema		4				4
Tongue pruritus	2	2			2	2
Toothache		1		1		
Transient aphasia		2				2
Transient ischaemic attack	3	5			3	5
Traumatic intracranial haemorrhage	1	1			1	1
Tremor	4	14	1	2	3	12
Trigeminal palsy		1				1
Trismus		1		1		
Troponin I increased		1				1
Tubulointerstitial nephritis	1	1			1	1
Type IV hypersensitivity reaction		1		1		
Ulcerative keratitis		1				1
Unresponsive to stimuli	1	3			1	3
Urinary incontinence	1	1			1	1
Urinary retention		1				1
Urinary tract infection	3	9		1	3	8
Urine porphobilinogen increased		1				1
Urogenital haemorrhage		1				1
Urticaria	10	34	5	12	5	22
Vaccination failure	1	2			1	2
Vaccination site abscess		1				1
Vaccination site bruising	1	3	1	1		2
Vaccination site erythema	6	36	4	25	2	11

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site haematoma		5		5		
Vaccination site hyperaesthesia	2	7		1	2	6
Vaccination site hypersensitivity	1	1			1	1
Vaccination site hypoaesthesia	1	2		1	1	1
Vaccination site induration	1	6		4	1	2
Vaccination site joint movement impairment		1		1		
Vaccination site macule		1		1		
Vaccination site mass	2	7	2	3		4
Vaccination site movement impairment	4	10	2	3	2	7
Vaccination site oedema	3	19	2	17	1	2
Vaccination site pain	21	77	15	45	6	32
Vaccination site paraesthesia	1	1	1	1		
Vaccination site plaque	1	2	1	2		
Vaccination site pruritus		7		5		2
Vaccination site rash		1		1		
Vaccination site reaction		4		2		2
Vaccination site swelling		7		2		5
Vaccination site urticaria		1		1		
Vaccination site warmth	5	20	5	14		6
Vaginal infection		1				1
Venous thrombosis	1	3			1	3
Venous thrombosis limb	2	2			2	2
Ventricular fibrillation		1				1
Vertigo	3	6		1	3	5
Vertigo positional	1	1			1	1
Vestibular neuritis		1				1
Viral infection		2				2
Vision blurred	2	6	2	3		3
Visual impairment	4	8	1	2	3	6
Vitreous detachment	1	1			1	1
Vomiting	10	41	5	13	5	28
Vulvovaginal inflammation		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Weight increased	1	1			1	1
Wheezing	1	6		1	1	5
White blood cell count decreased	1	1	1	1		
White blood cell count increased		2				2
White blood cells urine		1				1
White blood cells urine positive		1				1
Wrong technique in product usage process		1		1		
	1,177	3,935	455	1212	722	2723

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	2	1	1		1
Abdominal pain	1	2			1	2
Abdominal pain lower	2	3		1	2	2
Abdominal pain upper	2	2			2	2
Accommodation disorder		1		1		
Acne	1	1			1	1
Acute myocardial infarction		1				1
Acute respiratory failure		1				1
Amaurosis fugax	1	1			1	1
Ankylosing spondylitis		1				1
Apathy	1	1			1	1
Aphasia	2	3			2	3
Apnoea		1				1
Areflexia		1				1
Arrhythmia	1	3			1	3
Arteriosclerosis	1	1			1	1
Arthralgia	4	12	2	5	2	7
Arthritis reactive		1				1
Aspiration		1				1
Asthenia	6	12		3	6	9
Atrial f brillation		1				1
Autoimmune arthritis		1				1
Back injury	1	1			1	1
Back pain	1	6		3	1	3
Bacterial infection	1	1			1	1
Balance disorder	1	1			1	1
Bell's palsy	2	2			2	2
Biopsy muscle abnormal	1	1			1	1
Blindness transient	1	1			1	1
Blindness unilateral	2	2			2	2
Blister	1	2		1	1	1
Blood creatine increased		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood creatinine increased		1				1
Blood glucose decreased		1				1
Blood glucose increased	2	2			2	2
Blood pressure decreased	2	4			2	4
Blood pressure increased	3	6	2	2	1	4
Blood pressure systolic increased	1	1			1	1
Body temperature decreased	1	1	1	1		
Borrelia infection		1				1
Breath sounds abnormal	1	1			1	1
Bronchiolitis		1				1
Burning sensation	1	1			1	1
Cardiac death	1	1			1	1
Cardiac disorder	1	1			1	1
Cardiac failure	2	7			2	7
Cardiovascular disorder	1	1			1	1
Cerebral haemorrhage		1				1
Cerebral infarction	5	6			5	6
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident		1				1
Cerebrovascular disorder	1	2			1	2
Chest discomfort	1	3		1	1	2
Chest pain		1				1
Chills	4	10	2	2	2	8
Chronic obstructive pulmonary disease		1				1
Clumsiness	1	2		1	1	1
Condition aggravated	2	3			2	3
Confusional state	2	4		2	2	2
Coordination abnormal	1	1			1	1
Coronary artery thrombosis		1				1
Cough	3	6		2	3	4
C-reactive protein increased	1	4	1	2		2
Cyanosis	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness unilateral		1				1
Death		5				5
Deep vein thrombosis	5	6			5	6
Dehydration	1	1	1	1		
Delirium		1				1
Dementia Alzheimer's type		2				2
Depressed level of consciousness		1				1
Diarrhoea	2	3		1	2	2
Diplopia	1	1			1	1
Discomfort		1				1
Disease recurrence	1	1			1	1
Disseminated varicella zoster virus infection	2	2			2	2
Disturbance in attention	1	1			1	1
Dizziness	3	19		2	3	17
Dry mouth		1				1
Dysarthria		4				4
Dysphagia		2				2
Dysphonia	2	2			2	2
Dyspnoea	6	20	1	3	5	17
Ear canal erythema		1		1		
Ear discomfort	1	3		1	1	2
Ear pain		3		3		
Eczema		1				1
Embolic cerebellar infarction	1	1			1	1
Embolic cerebral infarction	1	1			1	1
Encephalitis		1				1
Eosinophil count increased		1				1
Epilepsy	1	3			1	3
Epistaxis		1				1
Erysipelas	1	1			1	1
Erythema	1	2	1	2		
Extrasystoles		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye haematoma		1				1
Eye infection		1				1
Eyelid ptosis		1				1
Eye pain		1				1
Face oedema		1				1
Facial paralysis	2	5			2	5
Fall	2	3			2	3
Fatigue	12	27	3	6	9	21
Feeling abnormal	4	4	1	1	3	3
Feeling cold	3	5	1	1	2	4
Feeling hot	1	2			1	2
Fibrin D dimer increased		1		1		
Fine motor skill dysfunction	1	1			1	1
Flank pain		2				2
Fluid intake reduced		1				1
Foaming at mouth		1				1
Gait deviation	1	1			1	1
Gait disturbance	1	4		1	1	3
Gastrointestinal viral infection		1				1
General physical health deterioration	4	14			4	14
Giant cell arteritis	1	1			1	1
Gout	2	2			2	2
Grip strength decreased	1	1			1	1
Haematoma		2		1		1
Haemoglobin decreased		1				1
Haemorrhage	1	1			1	1
Hallucination, visual	1	1			1	1
Headache	15	25	7	11	8	14
Head discomfort		1				1
Head injury	1	1			1	1
Heart rate increased		2		1		1
Heart rate irregular		1				1

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hemiparesis	2	3
Hemiplegia		1
Herpes virus infection		1
Herpes zoster	1	2
Herpes zoster cutaneous disseminated	1	2
Hyperacusis		1
Hyperhidrosis	2	2
Hypernatraemia		1
Hypersensitivity	1	1
Hypertension		1
Hyperventilation		1
Hypoacusis		1
Hypoaesthesia	2	7
Hypoaesthesia oral	1	1
Hypophagia		1
Hypopnoea		1
Hyporeflexia		1
Hypotension		1
Hypothermia		1
Hypotonia	1	2
Illusion	1	1
Impaired work ability		3
Inappropriate schedule of product administration	2	2
Incorrect route of product administration		1
Increased upper airway secretion		1
Inflammation	1	1
Influenza like illness		1
Insomnia	2	3
Intervertebral disc disorder		1
Intestinal ischaemia	1	1
Irritability	1	1
Irritability postvaccinal		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		2	3
			1
	1		
1	1		1
		1	2
			1
1	1	1	1
			1
		1	1
			1
			1
1	3	1	4
		1	1
			1
			1
			1
		1	2
		1	1
	1		2
2	2		
	1		
			1
1	1		
			1
	1	2	2
	1		
		1	1
		1	1
	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
IVth nerve paralysis	1	1			1	1
Joint injury	1	1			1	1
Joint range of motion decreased	2	2	1	1	1	1
Laboratory test abnormal	1	1			1	1
Lacunar infarction	1	1			1	1
Lethargy		1				1
Limb discomfort		1		1		
Limb injury		1				1
Lip swelling		1				1
Loss of consciousness	2	3			2	3
Loss of control of legs		1				1
Loss of personal independence in daily activities	1	1			1	1
Lymphadenopathy	2	4	1	1	1	3
Lymph node pain		1				1
Macular oedema		1				1
Malaise	6	11	4	6	2	5
Mechanical ventilation		1				1
Meniere's disease		1				1
Mesenteric vein thrombosis	1	1			1	1
Middle insomnia		2		1		1
Migraine	1	1	1	1		
Mobility decreased	1	2			1	2
Movement disorder	1	1			1	1
Muscle rigidity	1	1			1	1
Muscle spasms	1	1			1	1
Muscle twitching	1	2		1	1	1
Muscular weakness	1	7			1	7
Musculoskeletal stiffness	2	4		2	2	2
Myalgia	10	20	6	9	4	11
Nasal congestion	1	2			1	2
Nasal oedema		2				2
Nasopharyngitis		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	4	14	1	5	3	9
Neck injury	1	1			1	1
Neck pain	1	3		2	1	1
Nephrolithiasis	1	1			1	1
Neuralgia		2		2		
Neuritis		1				1
Neutropenia		1				1
Nightmare	1	1			1	1
Nodule		1				1
Obstruction		1				1
Oedema		1		1		
Oedema peripheral	2	5	1	3	1	2
Off label use	1	1	1	1		
Ophthalmic artery thrombosis	1	1			1	1
Ophthalmic vein thrombosis		1				1
Oral disorder		1				1
Oral herpes		1		1		
Oropharyngeal pain	1	3		2	1	1
Osteoarthritis		1		1		
Pain	1	4	1	2		2
Painful respiration		1				1
Pain in extremity	7	17	1	7	6	10
Pain of skin	1	2			1	2
Pallor		2				2
Palpitations	1	1			1	1
Paraesthesia		1				1
Paranasal sinus discomfort		1				1
Paresis		1				1
Pelvic venous thrombosis		1				1
Peripheral coldness	1	1			1	1
Peripheral embolism		1				1
Peripheral swelling	3	3	1	1	2	2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Petit mal epilepsy	1	2			1	2
Pharyngeal oedema	1	1			1	1
Pigmentary glaucoma		1				1
Pneumonia	1	8			1	8
Pneumonia aspiration		1				1
Polyarthrititis		1				1
Polycythaemia	1	1	1	1		
Poor quality sleep		1				1
Productive cough		1				1
Pruritus	4	4	2	2	2	2
Pseudomonal sepsis		1				1
Pulmonary embolism	1	5			1	5
Pulmonary infarction		1				1
Pulmonary pain		1		1		
Pyelonephritis	1	1			1	1
Pyrexia	18	37	8	13	10	24
Radiculopathy	1	1			1	1
Rash		1				1
Rash erythematous		1				1
Rash macular		1				1
Rash papular	1	1			1	1
Rash vesicular	1	1			1	1
Respiratory arrest		1				1
Respiratory rate increased	1	1			1	1
Respiratory tract infection		1				1
Retinal artery occlusion	1	1			1	1
Retinal ischaemia	1	1			1	1
Retinal vascular occlusion	1	2			1	2
Retinal vascular thrombosis		1				1
Retinal vein thrombosis		1				1
Rhinorrhoea	1	1	1	1		
Rhonchi		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rinne tuning fork test abnormal		1		1		
SARS-CoV-2 test negative		1				1
Secretion discharge		1		1		
Seizure	1	4			1	4
Sensation of foreign body		1		1		
Sepsis	1	1			1	1
Sinus disorder		1				1
Skin discolouration	1	1			1	1
Skin ulcer	1	1			1	1
Skull fractured base		1				1
Sleep disorder	1	1	1	1		
Slow speech		1				1
Sluggishness	1	1			1	1
Small intestinal resection	1	1			1	1
Somnolence	2	4			2	4
Speech disorder	2	3			2	3
Spinal disorder	1	1			1	1
Stertor	1	1			1	1
Stress		1				1
Subcutaneous abscess		1				1
Sudden death		2				2
Swelling		2		1		1
Swelling face		1				1
Syncope	3	3			3	3
Tachycardia	1	1			1	1
Tendon pain		2				2
Thrombophlebitis superficial	2	2	1	1	1	1
Thrombosis		1				1
Tinnitus		1				1
Transient ischaemic attack		1				1
Tremor	1	6		1	1	5
Tympanic membrane hyperaemia		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urinary tract infection		1				1
Urticaria	4	6	3	3	1	3
Vaccination site erythema	1	4	1	1		3
Vaccination site hyperaesthesia		1				1
Vaccination site hypoaesthesia		1				1
Vaccination site movement impairment	1	3			1	3
Vaccination site oedema	1	4	1	3		1
Vaccination site pain	2	12	1	5	1	7
Vaccination site warmth	1	1	1	1		
Venous thrombosis limb	1	1			1	1
Vertigo		2				2
Vertigo positional		1				1
Visual acuity reduced	1	2			1	2
Visual impairment	1	3			1	3
Vomiting	2	7	1	3	1	4
Weber tuning fork test abnormal		1		1		
Weight decreased		1		1		
Wheezing	1	2			1	2
White blood cell count increased		1				1
	312	755	71	174	241	581

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amputation stump pain	1	1	1	1		
Cerebral infarction		1				1
Chills	1	1	1	1		
COVID-19		1				1
Drug ineffective		1				1
Hemiparesis		1				1
Myalgia	2	2	2	2		
Off label use		2		2		
Poor quality product administered	1	13	1	13		
Product preparation error		12		12		
Product quality issue		1		1		
Product temperature excursion issue	1	1	1	1		
	6	37	6	33		4

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Country Where Event Occurred

FRANCE

090177e19749cf15\Approved\Approved On: 14-Jun-2021 14:01 (GMT)

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	7	1	4		3
Abdominal mass	1	1	1	1		
Abdominal pain	28	101	14	42	14	59
Abdominal pain lower		1				1
Abdominal pain upper	13	42	5	12	8	30
Abdominal rigidity		1				1
Abdominal wall haematoma	1	1			1	1
Abnormal behaviour		1		1		
Abnormal faeces		1		1		
Abnormal loss of weight	2	2			2	2
Abnormal sensation in eye		1		1		
Abnormal uterine bleeding	1	1	1	1		
Abortion spontaneous	6	15			6	15
Abscess of salivary gland	1	1			1	1
Accelerated hypertension		1		1		
Accidental exposure to product	1	1	1	1		
Accidental overdose		2		2		
Accommodation disorder		1				1
Acne		1		1		
Acquired haemophilia		1				1
Activated partial thromboplastin time prolonged	1	2			1	2
Activated partial thromboplastin time shortened		1				1
Acute coronary syndrome	4	15			4	15
Acute febrile neutrophilic dermatosis		1				1
Acute kidney injury	5	17			5	17
Acute myeloid leukaemia		2				2
Acute myocardial infarction	1	5			1	5
Acute polyneuropathy	1	1			1	1
Acute pulmonary oedema	5	24			5	24
Acute respiratory distress syndrome	3	15			3	15
Acute respiratory failure		12				12
Acute sinusitis		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute vestibular syndrome		3				3
Adrenal insufficiency		1				1
Adrenal mass		1		1		
Adrenocortical insufficiency acute	1	2			1	2
Aerococcus urinae infection		1				1
Aerophagia		1				1
Affective disorder		1		1		
Age-related macular degeneration		1				1
Ageusia	6	11	4	7	2	4
Aggression		4				4
Agitation	2	14		4	2	10
Alanine aminotransferase increased	2	5		3	2	2
Albuminuria		1				1
Alexia		1				1
Allergy to vaccine		5		2		3
Allodynia	1	1	1	1		
Altered state of consciousness		9				9
Amaurosis	1	2			1	2
Amaurosis fugax	1	3			1	3
Amenorrhoea	1	2	1	1		1
Amnesia	6	11	1	1	5	10
Amnesic disorder		2				2
Anaemia	6	12	2	3	4	9
Anaemia macrocytic		1				1
Anaesthesia		1				1
Anaesthesia oral	2	4	2	2		2
Anaphylactic reaction	10	44			10	44
Anaphylactic shock	4	17			4	17
Anaphylactoid reaction	1	2			1	2
Aneurysm	1	1			1	1
Angina pectoris	1	10			1	10
Angina unstable		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	13	60			13	60
Ankylosing spondylitis	2	7			2	7
Anosmia	3	8	2	4	1	4
Antinuclear ant body positive	1	2	1	1		1
Antisynthetase syndrome		1				1
Anuria		2				2
Anxiety	6	24	4	10	2	14
Anxiety disorder		1		1		
Aortic aneurysm	1	1	1	1		
Aortic arteriosclerosis	2	3	1	1	1	2
Aortic bruit		1		1		
Aortic dissection	1	2			1	2
Aortic stenosis		1				1
Aortic valve calcification		1				1
Aortic valve incompetence		3				3
Apathy		3		1		2
Aphasia	8	25		5	8	20
Aphonia		2				2
Apthous ulcer	1	4	1	3		1
Aplastic anaemia		1				1
Apnoea	1	3			1	3
Appendicitis	2	3			2	3
Application site warmth		1		1		
Areflexia	1	1			1	1
Arrested labour	1	1			1	1
Arrhythmia	15	49			15	49
Arrhythmia supraventricular		3				3
Arterial disorder		1				1
Arterial thrombosis	1	1			1	1
Arteriosclerosis		1				1
Arteritis	1	1			1	1
Arthralgia	53	214	33	93	20	121

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthritis	1	9		3	1	6
Arthritis reactive		2				2
Aspartate aminotransferase increased	1	5		4	1	1
Asphyxia	1	2			1	2
Aspiration	1	3			1	3
Asthenia	159	671	109	284	50	387
Asthma	4	17	1	2	3	15
Asthmatic crisis	8	14			8	14
Asymptomatic COVID-19	1	14			1	14
Ataxia	2	7	1	3	1	4
Atrial fibrillation	33	98			33	98
Atrial flutter		3		1		2
Atrial thrombosis	1	1			1	1
Atrioventricular block		2		1		1
Atrioventricular block complete	2	4			2	4
Auditory disorder		1				1
Aura		2				2
Autoimmune hepatitis		1				1
Autoimmune thyroiditis	1	2			1	2
Axillary mass	1	1	1	1		
Axillary pain	4	14	2	7	2	7
Back pain	10	51	3	18	7	33
Bacterial pyelonephritis		1				1
Bacterial sepsis		1				1
Bacterial test positive		2		1		1
Bacteriuria	1	1			1	1
Balance disorder	5	23	5	10		13
Basedow's disease		1				1
Bed rest		1				1
Bedridden	2	2			2	2
Behaviour disorder	1	7		1	1	6
Bell's palsy	2	3			2	3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Benign breast neoplasm		1		1		
Biliary colic	1	1	1	1		
Bipolar disorder		1				1
Bladder dilatation	1	2	1	1		1
Bladder dysfunction	1	1	1	1		
Blastocystis infection		1				1
Blepharitis	1	1			1	1
Blindness	2	3			2	3
Blindness cortical	1	1			1	1
Blindness unilateral	1	2			1	2
Blister	1	3			1	3
Block vertebra	1	1			1	1
Blood albumin decreased		1		1		
Blood alkaline phosphatase increased		1		1		
Blood blister	1	1			1	1
Blood calcium decreased		1		1		
Blood chloride increased	1	1			1	1
Blood cholesterol increased	1	1			1	1
Blood creatinine abnormal		1				1
Blood creatinine decreased		1				1
Blood creatinine increased	1	2		1	1	1
Blood culture positive		1				1
Blood fibrinogen increased	1	1	1	1		
Blood folate decreased		1				1
Blood glucose decreased	1	1			1	1
Blood glucose fluctuation		1		1		
Blood glucose increased	1	5		4	1	1
Blood immunoglobulin G decreased	1	1	1	1		
Blood lactate dehydrogenase increased	2	2	2	2		
Blood lactic acid increased	1	1			1	1
Blood loss anaemia		1				1
Blood osmolarity increased	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure abnormal	1	4	1	2		2
Blood pressure decreased	5	24	4	8	1	16
Blood pressure diastolic decreased	1	3		1	1	2
Blood pressure fluctuation	2	6		3	2	3
Blood pressure inadequately controlled	1	2			1	2
Blood pressure increased	22	38	9	13	13	25
Blood pressure systolic decreased	1	3	1	2		1
Blood pressure systolic increased	1	6		1	1	5
Blood sodium decreased		1		1		
Blood thyroid stimulating hormone decreased		1		1		
Blood thyroid stimulating hormone increased		4		2		2
Blood urea increased	2	2	1	1	1	1
Blood urine present	1	2	1	2		
Blue toe syndrome		1		1		
Body temperature decreased		2		1		1
Body temperature increased	3	11	3	3		8
Bone abscess		1				1
Bone pain	1	6	1	2		4
Bone swelling		1		1		
Bradyarrhythmia	1	1	1	1		
Bradycardia	5	35			5	35
Brain contusion		1				1
Brain natriuretic peptide increased		2		1		1
Brain oedema	2	2			2	2
Brain scan abnormal		1				1
Breast abscess		1				1
Breast haematoma	1	1			1	1
Breast induration		1				1
Breast mass		1				1
Breast pain		4		1		3
Breast swelling	1	2		1	1	1
Breath sounds abnormal	2	3	2	2		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchial obstruction		1				1
Bronchial secretion retention		1		1		
Bronchiectasis	1	1			1	1
Bronchiolitis		1				1
Bronchitis	6	8	2	2	4	6
Bronchopneumopathy		2		1		1
Bronchospasm	3	10			3	10
Bruxism	1	1	1	1		
Bundle branch block		1				1
Bundle branch block left	1	4			1	4
Bundle branch block right		5		2		3
Burning sensation	7	22	4	9	3	13
Burn oesophageal	2	2	1	1	1	1
Burn oral cavity		2				2
Bursitis	1	4		1	1	3
Calculus bladder	1	1	1	1		
Capillary fragility	1	1			1	1
Capillary leak syndrome	1	1			1	1
Carcinoembryonic antigen increased		1				1
Cardiac arrest	3	13			3	13
Cardiac discomfort		2		1		1
Cardiac disorder		2				2
Cardiac failure	13	61			13	61
Cardiac failure acute	1	5			1	5
Cardiac failure congestive		3				3
Cardiac fibrillation		1				1
Cardiac flutter	1	3			1	3
Cardiac tamponade		1				1
Cardiogenic shock	3	8			3	8
Cardiomegaly	2	3			2	3
Cardiopulmonary failure	2	4			2	4
Cardio-respiratory arrest	5	24			5	24

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardio-respiratory distress		1				1
Cardiovascular disorder	2	6	1	1	1	5
Carotid arteriosclerosis	1	1			1	1
Carotid artery thrombosis		2				2
Catatonia	1	1			1	1
Cell death		4				4
Cellulitis		1				1
Central nervous system lesion		1				1
Cerebellar infarction		1				1
Cerebellar stroke	1	2			1	2
Cerebral amyloid angiopathy	1	1			1	1
Cerebral artery stenosis		1				1
Cerebral atrophy	1	2			1	2
Cerebral disorder	1	1	1	1		
Cerebral haematoma	2	7			2	7
Cerebral haemorrhage		1				1
Cerebral hyperperfusion syndrome		1				1
Cerebral infarction	2	6			2	6
Cerebral ischaemia	1	2			1	2
Cerebral thrombosis		2				2
Cerebral venous thrombosis	2	4			2	4
Cerebrovascular accident	20	47			20	47
Cervical radiculopathy	3	4	1	1	2	3
Cervicobrachial syndrome	2	3	1	2	1	1
Chest discomfort	19	70	6	27	13	43
Chest injury	2	3			2	3
Chest pain	29	112	6	22	23	90
Chest X-ray abnormal	1	3			1	3
Chillblains	8	11	8	10		1
Chills	55	273	40	117	15	156
Choking	2	6			2	6
Choking sensation	1	2		1	1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholecystitis		2				2
Cholelithiasis	1	1	1	1		
Cholestasis	2	6			2	6
Cholestatic liver injury	2	3			2	3
Chondrocalcinosis	1	2			1	2
Choroidal neovascularisation	1	1			1	1
Chromaturia		1				1
Chronic kidney disease	2	2			2	2
Chronic obstructive pulmonary disease		7				7
Circadian rhythm sleep disorder		1		1		
Circulatory collapse	1	6			1	6
Claudication of jaw muscles		1				1
Clinomania		1		1		
Clonus	1	3		1	1	2
Clumsiness	2	3	2	2		1
Cognitive disorder	4	8	2	4	2	4
Cold sweat	4	9	2	4	2	5
Colitis		1				1
Colitis ulcerative	1	1			1	1
Coma		9				9
Coma scale abnormal		1				1
Communication disorder	2	2			2	2
Condition aggravated	25	73	5	16	20	57
Conduction disorder		1				1
Conductive deafness	1	1			1	1
Confusional state	9	39	1	4	8	35
Conjunctival haemorrhage	3	14			3	14
Conjunctival oedema		1		1		
Conjunctivitis	1	7	1	4		3
Conjunctivitis bacterial		1				1
Constipation	6	11	6	10		1
Contraindicated product administered		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Contusion	3	4	1	2	2	2
Coordination abnormal		1		1		
Coronary artery disease	1	1	1	1		
Coronary artery insufficiency		1				1
Coronary artery stenosis		2				2
Coronavirus infection		3		2		1
Costovertebral angle tenderness		1				1
Cough	19	81	14	36	5	45
COVID-19	120	333	2	49	118	284
COVID-19 pneumonia	8	17			8	17
C-reactive protein increased	9	37	3	18	6	19
Creatinine renal clearance decreased	1	2	1	1		1
Crepitations		2		1		1
Crying	1	1	1	1		
Cryoglobulins present	1	1	1	1		
Culture urine positive		1		1		
Cutaneous lupus erythematosus		1				1
Cutaneous vasculitis	1	3			1	3
Cyanosis	2	11	1	3	1	8
Cystitis	1	2			1	2
Cystitis klebsiella		1				1
Cytomegalovirus test positive		1		1		
Daydreaming		2				2
Deafness	5	10			5	10
Deafness unilateral	3	9			3	9
Death	12	69			12	69
Decreased appetite	18	63	10	30	8	33
Decreased interest		1				1
Decubitus ulcer		1				1
Deep vein thrombosis	54	83			54	83
Degenerative mitral valve disease	1	1			1	1
Dehydration	4	19		4	4	15

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Delirium		3				3
Delusion		3		1		2
Dementia	1	4			1	4
Demyelination		1				1
Dependent rubor		1				1
Depressed level of consciousness	4	18			4	18
Depressed mood	1	1	1	1		
Depression		1				1
Dermal cyst		2		1		1
Dermatitis allergic	1	1			1	1
Dermatitis bullous		1				1
Dermatomyositis		2				2
Dermatosis	1	1	1	1		
Dermo-hypodermatitis		3				3
Detachment of retinal pigment epithelium	1	1			1	1
Diabetes insipidus		1				1
Diabetes mellitus	3	7			3	7
Diabetes mellitus inadequate control	2	9			2	9
Diabetic coma		1				1
Diabetic hyperosmolar coma	1	2			1	2
Diabetic ketoacidosis		1				1
Diabetic ketosis		1				1
Diabetic metabolic decompensation		1				1
Diarrhoea	33	169	18	64	15	105
Diarrhoea haemorrhagic	1	5			1	5
Dilatation ventricular	1	1	1	1		
Diplegia		1				1
Diplopia	5	12		1	5	11
Discomfort	16	58	11	23	5	35
Disease recurrence	22	66		3	22	63
Disinhibition		1				1
Disorientation	4	21	1	5	3	16

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbance in attention	6	15	5	7	1	8
Diverticulitis		2				2
Dizziness	63	211	34	77	29	134
Dizziness postural	1	4	1	1		3
Drooling		1		1		
Drop attacks	1	1			1	1
Dropped head syndrome		1				1
Drug eruption	2	2			2	2
Drug hypersensitivity		2				2
Drug ineffective	53	135		1	53	134
Drug interaction	1	1	1	1		
Dry eye		3		2		1
Dry mouth	4	9	3	5	1	4
Dry skin	1	2		1	1	1
Dry throat		2		1		1
Dysaesthesia	4	14	1	6	3	8
Dysarthria	7	19	5	7	2	12
Dyschromatopsia	1	1			1	1
Dysgeusia	15	35	12	20	3	15
Dysgraphia	1	2	1	1		1
Dyshidrotic eczema		2		2		
Dyskinesia	3	5		1	3	4
Dyslipidaemia	1	2	1	2		
Dysmetria	1	1			1	1
Dyspepsia	4	9	1	1	3	8
Dysphagia	10	29	3	9	7	20
Dysphemia		2				2
Dysphonia	2	9	1	3	1	6
Dyspnoea	74	211	27	50	47	161
Dyspnoea at rest		4				4
Dyspnoea exertional	5	17	3	7	2	10
Dysstasia	2	9		2	2	7

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Gender

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysuria		2		1		1
Ear discomfort		1		1		
Ear disorder		1		1		
Ear haemorrhage	1	1			1	1
Ear pain	3	17	1	6	2	11
Ear swelling		3		1		2
Eating disorder		2		1		1
Ecchymosis	5	5	2	2	3	3
Eczema	1	3		1	1	2
Ejection fraction decreased		1				1
Electric shock sensation	2	5	1	2	1	3
Electrocardiogram abnormal	1	2			1	2
Electrocardiogram PR prolongation		1				1
Electrocardiogram QRS complex prolonged	1	1			1	1
Electrocardiogram QRS complex shortened		1				1
Electrocardiogram QT interval abnormal		1				1
Electrocardiogram repolarisation abnormality		1				1
Electrocardiogram ST segment depression		1				1
Electrocardiogram ST segment elevation	1	2			1	2
Electrocardiogram ST-T segment abnormal		1				1
Electrocardiogram T wave inversion		2				2
Embolic stroke	1	3			1	3
Embolism		1				1
Embolism venous		1				1
Emphysema		1				1
Encephalitis	4	6			4	6
Encephalitis viral		1				1
Endocrine ophthalmopathy		1				1
Enlarged uvula		1				1
Enteritis	1	1			1	1
Enterococcal infection		1				1
Enterocolitis haemorrhagic	1	1			1	1

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FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Enthesopathy	1	1			1	1
Eosinophil count increased		1		1		
Eosinophilia	1	3			1	3
Eosinophilic bronchitis		1				1
Epicondylitis	1	1	1	1		
Epilepsy	10	25			10	25
Epistaxis	17	27	6	8	11	19
Epstein-Barr virus infection		1				1
Epstein-Barr virus infection reactivation	1	2			1	2
Epstein-Barr virus test positive	1	2		1	1	1
Erectile dysfunction		1				1
Eructation	1	4	1	1		3
Erysipelas	5	7			5	7
Erythema	28	99	21	48	7	51
Erythema multiforme	2	4			2	4
Erythema nodosum		2				2
Erythema of eyelid		2		1		1
Erythrosis	1	1	1	1		
Escherichia infection		1				1
Escherichia pyelonephritis	1	1			1	1
Escherichia test positive		2		2		
Escherichia urinary tract infection	2	4			2	4
Euphoric mood		1		1		
Exophthalmos		1				1
Exposure during pregnancy	3	4	1	2	2	2
Exposure via breast milk		2		1		1
Exposure via skin contact		1		1		
Extensive swelling of vaccinated limb		11		9		2
Extensor plantar response		1				1
Extradural haematoma		1				1
Extrapyramidal disorder		1				1
Extrasystoles	1	18	1	7		11

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Extremity contracture	1	1			1	1
Extremity necrosis	1	2		1	1	1
Eye discharge		1				1
Eye disorder		1				1
Eye haemorrhage	1	4			1	4
Eye inflammation	1	1			1	1
Eye injury		2				2
Eye irritation	2	4		1	2	3
Eyelid disorder		1				1
Eyelid injury	1	1			1	1
Eyelid irritation		1		1		
Eyelid myoclonus		1				1
Eyelid oedema	2	15	2	5		10
Eyelid ptosis		2				2
Eye movement disorder	1	2		1	1	1
Eye oedema	1	3		1	1	2
Eye pain	2	11	2	8		3
Eye swelling		2				2
Face injury	3	5			3	5
Face oedema	5	36	1	3	4	33
Facial asymmetry	1	2			1	2
Facial bones fracture	1	2			1	2
Facial pain	2	5	2	3		2
Facial paralysis	40	110			40	110
Facial paresis		4		3		1
Factor II mutation		1		1		
Faecaloma	1	3			1	3
Faecal vomiting		2				2
Faeces discoloured	1	1	1	1		
Failure to thrive		1				1
Fall	24	83	7	18	17	65
Familial mediterranean fever	1	2			1	2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fatigue	82	358	54	174	28	184
Fear		2		1		1
Fear of death		1				1
Febrile convulsion	2	2			2	2
Feeding disorder	5	5			5	5
Feeling abnormal	6	25	4	14	2	11
Feeling cold	7	26	3	10	4	16
Feeling drunk	2	10	1	4	1	6
Feeling hot	10	31	6	13	4	18
Feeling jittery	1	1	1	1		
Feeling of body temperature change	1	5	1	3		2
Femur fracture		3				3
Fibrin D dimer increased	6	11			6	11
Fibroma		1		1		
Fine motor skill dysfunction		1		1		
Flank pain	1	2			1	2
Flatulence		1				1
Fluid overload	2	2	1	1	1	1
Fluid retention		1				1
Flushing	4	16	2	5	2	11
Foaming at mouth		1				1
Focal dyscognitive seizures		1				1
Food aversion		2		1		1
Food craving		1				1
Food refusal	1	1	1	1		
Foot deformity		1		1		
Foot fracture	1	1			1	1
Formication	2	12	1	5	1	7
Frostbite		1		1		
Functional gastrointestinal disorder	1	4			1	4
Gait disturbance	10	23	8	14	2	9
Gait inability	5	13	3	4	2	9

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gamma-glutamyltransferase increased	1	5
Gangrene		1
Gastric pH decreased		1
Gastric volvulus		1
Gastritis		1
Gastroenteritis	2	2
Gastrointestinal disorder	10	18
Gastrointestinal haemorrhage		1
Gastrointestinal hypermotility		1
Gastrointestinal inflammation		1
Gastrointestinal motility disorder		2
Gastrointestinal pain		6
Gastrooesophageal reflux disease		2
Gaze palsy		1
Generalised anxiety disorder		1
Generalised oedema		1
Generalised onset non-motor seizure		1
Generalised tonic-clonic seizure	2	8
General physical health deterioration	17	52
Genital haemorrhage		1
Genital herpes		2
Genital herpes zoster		1
Giant cell arteritis	1	8
Gingival bleeding	1	2
Gingival discomfort		2
Gingival pain	1	1
Glaucoma		1
Glomerular filtration rate decreased	2	7
Glossitis		2
Glossodynia	2	4
Glycosylated haemoglobin increased	2	2
Goitre		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	3	1	2
			1
	1		
			1
			1
1	1	1	1
10	12		6
			1
	1		
			1
	1		1
	4		2
			2
			1
			1
			1
		2	8
5	10	12	42
			1
			2
			1
		1	8
1	1		1
	1		1
1	1		
			1
	1	2	6
	1		1
1	3	1	1
1	1	1	1
	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gout	1	3		1	1	2
Groin pain		1		1		
Guillain-Barre syndrome	1	3			1	3
Haemarthrosis		2				2
Haematemesis		3				3
Haematochezia		5				5
Haematoma	6	20	1	3	5	17
Haematoma muscle	1	2			1	2
Haematuria	3	6	1	1	2	5
Haemodynamic instability		1		1		
Haemoglobinaemia	1	1			1	1
Haemoglobin decreased		3		2		1
Haemoglobinuria		1				1
Haemolytic anaemia		1				1
Haemophagocytic lymphohistiocytosis		1				1
Haemoptysis		2				2
Haemorrhagic disorder		1				1
Haemorrhagic stroke	3	17			3	17
Haemorrhagic transformation stroke		1				1
Haemorrhoids thrombosed	1	2			1	2
Haemothorax		1				1
Hair colour changes		1		1		
Hallucination	1	13			1	13
Hallucination, auditory		4				4
Hallucination, olfactory		1				1
Hallucinations, mixed	1	3			1	3
Hallucination, visual	1	8			1	8
Hand fracture	1	1			1	1
Headache	218	790	133	336	85	454
Head discomfort	2	6	2	5		1
Head injury	3	15		1	3	14
Heart rate decreased	1	7		4	1	3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate increased	6	17	3	8	3	9
Heart rate irregular		3				3
Heart sounds abnormal	2	4	2	3		1
Heavy menstrual bleeding	1	2	1	1		1
Hemianaesthesia		1				1
Hemianopia		1				1
Hemianopia homonymous		1				1
Hemiapraxia		1				1
Hemiparaesthesia		2				2
Hemiparesis	8	19			8	19
Hemiplegia	3	15			3	15
Hepatic cyst		1				1
Hepatic cytolysis	4	16			4	16
Hepatic enzyme increased		1				1
Hepatic failure	1	1			1	1
Hepatic function abnormal	1	3		2	1	1
Hepatic haematoma		1				1
Hepatic infarction	1	2			1	2
Hepatic lesion		1		1		
Hepatic pain		1		1		
Hepatic steatosis	1	1	1	1		
Hepatitis		1				1
Hepatitis acute	1	3			1	3
Hepatitis cholestatic		1				1
Hepatitis E	1	1			1	1
Hepatitis infectious mononucleosis		1				1
Hepatitis viral		1				1
Hepatocellular injury	2	3			2	3
Hepatomegaly	2	3	1	1	1	2
Herpangina		1		1		
Herpes ophthalmic		1				1
Herpes pharyngitis		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes simplex	4	6	3	4	1	2
Herpes simplex test positive	1	2		1	1	1
Herpes virus infection		1		1		
Herpes zoster	84	147	52	74	32	73
Herpes zoster cutaneous disseminated		1				1
Herpes zoster meningoencephalitis		2				2
Herpes zoster meningoradiculitis	1	1			1	1
Herpes zoster reactivation	2	3	2	3		
High-pitched crying		1		1		
Hippocampal atrophy		1				1
Hormone level abnormal		1				1
Hostility		1				1
Hot flush	10	53	5	24	5	29
Hyperacusis		1		1		
Hyperaesthesia	4	9	2	3	2	6
Hyperaesthesia eye	1	1	1	1		
Hyperbilirubinaemia		2				2
Hypercapnia		1				1
Hyperchlorhydria	1	1	1	1		
Hypercholesterolaemia		1		1		
Hyperferritinaemia	1	1			1	1
Hyperglycaemia	3	7	1	3	2	4
Hyperhidrosis	9	58	3	14	6	44
Hyperkalaemia	1	4			1	4
Hyperleukocytosis	4	16			4	16
Hypermetabolism	1	1			1	1
Hypermetropia	1	1			1	1
Hypernatraemia	1	5		2	1	3
Hypersensitivity	16	77	2	22	14	55
Hypersomnia		4		1		3
Hypertension	158	522	20	67	138	455
Hypertensive crisis	27	133			27	133

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertensive encephalopathy	1	2			1	2
Hyperthermia	18	63	4	19	14	44
Hyperthyroidism		5				5
Hypertonia		1				1
Hypertriglyceridaemia	1	1			1	1
Hyperuricaemia	1	2		1	1	1
Hyperventilation	1	3		1	1	2
Hypoacusis	2	7		1	2	6
Hypoaesthesia	18	50	7	21	11	29
Hypoaesthesia eye	1	1	1	1		
Hypoaesthesia oral	1	7		1	1	6
Hypoalbuminaemia	1	2			1	2
Hypocalcaemia	1	2			1	2
Hypogammaglobulinaemia	1	1			1	1
Hypoglycaemia	3	15	1	3	2	12
Hypokalaemia	1	5			1	5
Hypokinesia		5		1		4
Hyponatraemia	3	4		1	3	3
Hypoperfusion		2		1		1
Hypophosphataemia	1	1	1	1		
Hypotension	20	116	3	22	17	94
Hypothermia	4	17			4	17
Hypothyroidism	2	3			2	3
Hypotonia	1	6	1	2		4
Hypoventilation		1				1
Hypoxia	7	23			7	23
Hypoxic-ischaemic encephalopathy	1	1			1	1
IIIrd nerve paralysis	1	2			1	2
III-defined disorder		1				1
Illness	2	6	2	3		3
Illusion		1				1
Immune reconstitution inflammatory syndrome	1	1			1	1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Immune thrombocytopenia	6	10
Immunodeficiency		1
Immunoglobulin G4 related disease	1	1
Immunoglobulins increased	2	3
Impaired driving ability		1
Impaired work ability	5	23
Impetigo	1	1
Inappropriate schedule of product administration	8	21
Incoherent		3
Incorrect dose administered	3	6
Incorrect route of product administration	3	13
Increased bronchial secretion		3
Induration	1	3
Infarction	1	3
Infection	3	8
Infectious mononucleosis		1
Inflammation	10	30
Inflammatory pain		2
Influenza	14	57
Influenza like illness	109	484
Inhibitory drug interaction		1
Initial insomnia		1
Injected limb mobility decreased	7	32
Injection site erythema		4
Injection site haematoma	1	1
Injection site haemorrhage	1	1
Injection site hyperaesthesia		1
Injection site oedema		1
Injection site pain	1	6
Injection site paraesthesia		1
Injection site pruritus		2
Injection site rash		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		6	10
			1
		1	1
2	3		
			1
1	4	4	19
		1	1
8	19		2
	3		
2	5	1	1
3	12		1
			3
1	1		2
		1	3
1	2	2	6
			1
6	15	4	15
			2
6	17	8	40
49	109	60	375
	1		
			1
3	7	4	25
	4		
1	1		
1	1		
	1		
	1		
1	6		
	1		
	2		
			1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site reaction		2		1		1
Injection site swelling		1		1		
Inner ear disorder		2		1		1
Insomnia	11	53	4	19	7	34
Insulin-requiring type 2 diabetes mellitus		1				1
Intercostal neuralgia		1				1
Intermenstrual bleeding	1	3			1	3
Intermittent claudication	1	1			1	1
International normalised ratio abnormal		2		1		1
International normalised ratio increased	4	7	2	2	2	5
Interstitial lung disease	2	6			2	6
Intervertebral disc compression		1				1
Intestinal ischaemia	2	4			2	4
Intestinal obstruction		2				2
Intracardiac thrombus	1	3			1	3
Intracranial aneurysm	1	1			1	1
Intracranial haematoma		1				1
Intracranial pressure increased		1				1
Iridocyclitis	1	2			1	2
Iron binding capacity total abnormal	1	1			1	1
Iron deficiency anaemia		1				1
Irritability		1				1
Ischaemic cardiomyopathy		1				1
Ischaemic stroke	43	88			43	88
Jaundice		2				2
Jaw fracture	1	1			1	1
Joint ankylosis	1	2	1	1		1
Joint dislocation		1				1
Joint effusion	2	5	1	2	1	3
Joint injury		1				1
Joint range of motion decreased	2	4			2	4
Joint stiffness	1	5		1	1	4

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint swelling	3	10	2	4	1	6
Joint warmth		1				1
Jugular vein distension		1				1
Jugular vein thrombosis	2	3			2	3
Ketoacidosis	1	1			1	1
Klebsiella infection		2				2
Labile blood pressure	1	2			1	2
Labyrinthitis	1	1	1	1		
Lacrimation increased		6		3		3
Lactic acidosis	1	2			1	2
Lactobacillus infection		1				1
Lacunar infarction		1				1
Lacunar stroke		2				2
Language disorder	2	5	1	1	1	4
Large intestine infection		2				2
Laryngeal discomfort	4	9	1	2	3	7
Laryngeal dyspnoea		2				2
Laryngeal oedema	4	15			4	15
Laryngeal stenosis	2	2			2	2
Laryngitis		2				2
Laryngitis allergic		1				1
Laryngospasm	1	1			1	1
Left atrial dilatation	1	2	1	1		1
Left ventricular dysfunction	1	1	1	1		
Left ventricular end-diastolic pressure increased		1				1
Left ventricular failure	1	2			1	2
Left ventricular hypertrophy		2				2
Lethargy	2	2	2	2		
Leukocyte alkaline phosphatase increased	1	1			1	1
Leukocytosis	1	4		2	1	2
Leukocyturia	4	6	1	2	3	4
Leukoencephalopathy		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Leukopenia	1	5			1	5
Lichenoid keratosis	1	1			1	1
Lichen planus		1				1
Ligament sprain	1	2			1	2
Limb discomfort	10	22	6	14	4	8
Lipase increased		2		2		
Lip blister	1	1	1	1		
Lip dry	2	2	2	2		
Lip erythema	1	1	1	1		
Lip injury	1	1			1	1
Lip oedema	2	17		3	2	14
Lipoma		2				2
Lip pain	1	3			1	3
Lip pruritus	1	2	1	1		1
Lip swelling	5	11	4	4	1	7
Listless		1				1
Livedo reticularis	2	8	1	2	1	6
Liver disorder	1	1			1	1
Liver function test abnormal	2	2	1	1	1	1
Liver function test increased	1	1			1	1
Liver injury	2	3			2	3
Lividity		1				1
Localised oedema	1	8		3	1	5
Local reaction		3		3		
Logorrhoea		1				1
Loss of consciousness	32	99			32	99
Loss of personal independence in daily activities	7	14	1	3	6	11
Low density lipoprotein increased	1	2			1	2
Lower respiratory tract congestion	2	4			2	4
Lower respiratory tract infection		1				1
Lung disorder	6	28	1	3	5	25
Lung opacity	1	3			1	3

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Lymphadenitis	3	13
Lymphadenopathy	33	126
Lymphangitis		1
Lymph node pain	1	7
Lymphocyte count decreased		2
Lymphoedema	2	3
Lymphopenia	4	12
Macroglossia		2
Macule		1
Major depression	1	2
Malaise	62	318
Malignant peritoneal neoplasm	1	1
Malnutrition	1	3
Maternal exposure during pregnancy	10	13
Maternal exposure timing unspecified	2	3
Mean cell volume decreased		2
Melaena	1	2
Memory impairment		7
Meniere's disease		1
Meningeal disorder	1	1
Meningitis		2
Meningitis aseptic	2	4
Meningoencephalitis herpetic	1	3
Meningoradiculitis		1
Meningorrhagia		1
Menstruation delayed	3	4
Mental disorder	1	1
Mental fatigue		1
Mental impairment	1	3
Mesenteric vein thrombosis	2	2
Metabolic acidosis	2	2
Metamorphopsia	1	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
	8	3	5
25	65	8	61
			1
	2	1	5
	1		1
1	2	1	1
1	5	3	7
			2
	1		
		1	2
24	97	38	221
		1	1
1	1		2
6	8	4	5
1	2	1	1
	1		1
		1	2
	1		6
			1
1	1		
			2
		2	4
		1	3
			1
			1
3	3		1
		1	1
			1
		1	3
		2	2
		2	2
1	2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Metastases to peritoneum		1				1
Microcytic anaemia	2	2	1	1	1	1
Microembolism		1				1
Middle insomnia	2	7		3	2	4
Migraine	7	34	6	17	1	17
Migraine with aura		3		2		1
Miosis		1				1
Mitral valve calcification		2				2
Mitral valve disease		1				1
Mitral valve incompetence		3				3
Mitral valve stenosis		1				1
Mixed liver injury	1	1			1	1
Mobility decreased	3	16	1	7	2	9
Monoclonal immunoglobulin increased		1				1
Monocytosis	1	3		1	1	2
Mononeuropathy multiplex		1				1
Mononucleosis syndrome		1				1
Monoparesis	1	3	1	2		1
Monoplegia	3	6	1	1	2	5
Morning sickness		1		1		
Motor dysfunction	11	21	7	9	4	12
Mouth haemorrhage	2	3	2	2		1
Mouth ulceration		2		2		
Movement disorder	2	5	2	3		2
Mucosal discolouration		1				1
Mucosal pain		1		1		
Mucous stools	1	1			1	1
Multiple organ dysfunction syndrome	1	5			1	5
Multiple sclerosis	2	2			2	2
Multiple sclerosis relapse	1	1			1	1
Muscle contractions involuntary		1		1		
Muscle contracture		6		2		4

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle discomfort	1	1			1	1
Muscle disorder		1		1		
Muscle fatigue	1	3	1	1		2
Muscle hypertrophy	1	1			1	1
Muscle rigidity	1	1	1	1		
Muscle spasms	7	21	4	9	3	12
Muscle spasticity	1	1			1	1
Muscle tightness	2	4	2	4		
Muscle twitching	2	2	1	1	1	1
Muscular weakness	8	35	3	12	5	23
Musculoskeletal chest pain	2	8	2	3		5
Musculoskeletal discomfort		1		1		
Musculoskeletal disorder		2		1		1
Musculoskeletal pain	3	4		1	3	3
Musculoskeletal stiffness	19	92	10	26	9	66
Myalgia	75	347	57	158	18	189
Myalgia intercostal		1				1
Myasthenia gravis	3	4			3	4
Myasthenia gravis crisis		1				1
Mydriasis		2		1		1
Myelitis	1	1			1	1
Myocardial infarction	6	24			6	24
Myocardial ischaemia	1	2			1	2
Myocardial necrosis		1				1
Myocarditis	3	7			3	7
Myoclonus	1	2			1	2
Myokymia		1		1		
Myositis		2		1		1
Nasal congestion	3	4	1	2	2	2
Nasal injury	1	1			1	1
Nasopharyngitis	5	10	4	7	1	3
Nausea	96	405	63	170	33	235

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Near death experience		1				1
Neck mass	1	1	1	1		
Neck pain	14	34	7	14	7	20
Necrosis	1	2			1	2
Necrotising colitis		1				1
Needle issue		2		2		
Nephropathy		1				1
Nephrotic syndrome	2	2			2	2
Nerve compression		1		1		
Nerve injury	1	2			1	2
Nervousness		1				1
Nervous system disorder	1	5		1	1	4
Neuralgia	13	46	7	16	6	30
Neuralgic amyotrophy	1	1			1	1
Neuritis		2		1		1
Neurological examination abnormal		1				1
Neurological symptom	1	2			1	2
Neuromuscular pain		2		1		1
Neuromyelitis optica spectrum disorder	1	1			1	1
Neuromyopathy		2				2
Neuropathy peripheral	4	8			4	8
Neutropenia	2	8			2	8
Neutrophil count abnormal		1				1
Neutrophil count decreased		2		1		1
Neutrophil count increased	1	5		3	1	2
Neutrophilia	1	2	1	2		
Neutrophilic dermatosis		1				1
Nightmare	1	2	1	2		
Night sweats	2	6	1	2	1	4
Nitrite urine present		1		1		
Nocturia		1		1		
Nocturnal dyspnoea		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Noninfective gingivitis		2		1		1
Normal pressure hydrocephalus		1				1
Normochromic anaemia		1				1
Normochromic normocytic anaemia		1		1		
Normocytic anaemia		1				1
N-terminal prohormone brain natriuretic peptide increased	2	6	2	3		3
Nystagmus	1	4		1	1	3
Obstructive airways disorder		1		1		
Occipital neuralgia	1	4			1	4
Occupational exposure to product		2		2		
Ocular discomfort	2	6	1	4	1	2
Ocular hyperaemia	1	4			1	4
Ocular myasthenia		1				1
Ocular vascular disorder		1				1
Odynophagia	2	4		1	2	3
Oedema	6	15	3	5	3	10
Oedema mouth	1	2			1	2
Oedema peripheral	16	47	10	16	6	31
Oesophageal discomfort	1	1			1	1
Oesophageal pain		1				1
Oesophageal spasm		1				1
Off label use	8	27	7	25	1	2
Oliguria		1		1		
Ophthalmic herpes zoster	18	35	1	1	17	34
Ophthalmic migraine		3		1		2
Oppositional defiant disorder	1	1			1	1
Optic ischaemic neuropathy		1				1
Optic neuritis	1	1			1	1
Optic neuropathy	1	1			1	1
Oral blood blister		1				1
Oral discomfort	1	2	1	2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral disorder		1		1		
Oral dysaesthesia		3		2		1
Oral fungal infection		1		1		
Oral herpes	3	5	3	4		1
Oral pain	2	4	2	4		
Oral pruritus	1	4	1	2		2
Orbital haematoma	1	2			1	2
Oropharyngeal discomfort	3	6	2	4	1	2
Oropharyngeal pain	7	19	7	17		2
Oropharyngeal swelling		1				1
Orthopnoea	1	2	1	1		1
Orthostatic hypertension	1	1			1	1
Orthostatic hypotension	1	5		1	1	4
Osteoarthritis	2	3		1	2	2
Otitis externa		1		1		
Otolithiasis		1				1
Ovarian cancer	1	1			1	1
Ovarian neoplasm	1	1			1	1
Overdose	2	7	2	7		
Oxygen saturation abnormal		1				1
Oxygen saturation decreased	29	111	8	13	21	98
Oxygen saturation increased		1				1
Pain	44	179	24	79	20	100
Painful respiration	1	1			1	1
Pain in extremity	53	162	30	70	23	92
Pain in jaw	3	11	1	3	2	8
Pain of skin		4		2		2
Palatal disorder	1	1	1	1		
Palatal oedema		3				3
Pallor	5	22	3	4	2	18
Palpitations	22	68	8	29	14	39
Pancreatic steatosis	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pancreatitis	4	4			4	4
Pancreatitis acute	4	8			4	8
Pancytopenia	1	4			1	4
Panic attack		2		1		1
Papule		3		2		1
Paraesthesia	53	169	27	63	26	106
Paraesthesia ear		1				1
Paraesthesia oral	9	26	6	12	3	14
Paralysis	5	11			5	11
Paraplegia	1	1			1	1
Paresis		1				1
Parkinsonism		1				1
Parkinson's disease	1	1			1	1
Parophthalmia		1				1
Parosmia	1	3		2	1	1
Parotitis	1	2			1	2
Partial seizures		3				3
Parvovirus B19 test positive	1	1			1	1
Pathological fracture	1	1			1	1
PCO2 increased	1	1			1	1
Peau d'orange		1		1		
Pelvic fracture	2	2			2	2
Pelvic haematoma	1	1	1	1		
Pelvic pain		4				4
Pelvic venous thrombosis	1	1			1	1
Pemphigoid	1	4			1	4
Peptic ulcer		1				1
Periarthritis	1	5			1	5
Pericardial effusion	5	9			5	9
Pericardial haemorrhage		1				1
Pericarditis	12	27			12	27
Periorbital haematoma	2	3	2	2		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Periorbital oedema	1	1			1	1
Periorbital pain		2		1		1
Periorbital swelling		1				1
Peripheral arterial occlusive disease	1	1			1	1
Peripheral artery occlusion	1	1			1	1
Peripheral artery thrombosis	5	7			5	7
Peripheral coldness	4	11	3	7	1	4
Peripheral ischaemia	4	9	2	2	2	7
Peripheral sensorimotor neuropathy	1	1			1	1
Peripheral swelling	7	23	5	9	2	14
Peripheral venous disease	1	2	1	1		1
Peritonitis	2	2			2	2
Pernio-like erythema		1		1		
Persecutory delusion		2		1		1
Persistent depressive disorder		1				1
Persistent postural-perceptual dizziness		1				1
Petechiae	4	9	2	5	2	4
Petit mal epilepsy		7				7
Phaeochromocytoma		1				1
Pharyngeal disorder		1				1
Pharyngeal oedema	1	2			1	2
Pharyngeal paraesthesia	3	9	3	5		4
Pharyngeal swelling	1	2	1	2		
Pharyngitis	3	4	2	3	1	1
Phlebitis	5	13	1	3	4	10
Phlebitis superficial	1	3	1	3		
Phonophobia		2		1		1
Photophobia		7		2		5
Photopsia	2	5		1	2	4
Photosensitivity reaction		1		1		
Physical examination abnormal	1	1	1	1		
Piloerection		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Platelet count decreased		2		2		
Platelet count increased	1	2			1	2
Pleural effusion	6	9	1	1	5	8
Pleurisy	1	2	1	1		1
Pleuropericarditis	2	2			2	2
Pneumonia	2	18			2	18
Pneumonia aspiration	2	21			2	21
Pneumonia bacterial	1	1			1	1
Pneumonitis	1	5		1	1	4
Pneumoperitoneum		1				1
Pneumothorax	1	2			1	2
Pollakiuria	1	2	1	2		
Polyarthrits	3	5			3	5
Polychondritis		1				1
Polydipsia		1				1
Polymenorrhoea	2	2	2	2		
Polymyalgia rheumatica	4	4			4	4
Polyneuropathy	1	4			1	4
Polyserositis		1				1
Poor quality product administered	1	83	1	83		
Portal hypertension	1	1			1	1
Portal vein phlebitis	1	1			1	1
Portal vein thrombosis	4	4			4	4
Posterior revers ble encephalopathy syndrome		1				1
Post lumbar puncture syndrome	1	1	1	1		
Post vaccination syndrome	1	1			1	1
Pre-existing condition improved	1	1	1	1		
Prerenal failure		1				1
Presyncope	14	45	6	18	8	27
Proctitis		1		1		
Proctitis haemorrhagic	1	1			1	1
Product administered at inappropriate site	2	3	2	2		1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Product administration error		1
Productive cough	3	9
Product preparation error		4
Product preparation issue	3	9
Product temperature excursion issue		82
Product use issue	2	13
Progressive supranuclear palsy		1
Prohormone brain natriuretic peptide increased	1	1
Prostatic specific antigen increased	1	1
Proteinuria	1	4
Prothrombin time prolonged	1	1
Prothrombin time shortened		2
Pruritus	30	86
Pseudomonal bacteraemia	1	1
Psoriasis		2
Psychomotor hyperactivity		1
Psychomotor retardation		1
Psychomotor skills impaired	1	4
Pulmonary alveolar haemorrhage		1
Pulmonary arterial hypertension	3	5
Pulmonary arterial pressure increased	1	3
Pulmonary artery dilatation		1
Pulmonary congestion	1	3
Pulmonary embolism	75	148
Pulmonary infarction	2	5
Pulmonary oedema	2	8
Pulmonary pain		1
Pulmonary sepsis	1	2
Pulpitis dental		1
Pulse absent		2
Punctate keratitis	1	1
Purpura	6	11

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
2	5	1	4
	4		
3	9		
	82		
1	12	1	1
			1
		1	1
		1	1
1	2		2
		1	1
	1		1
17	37	13	49
		1	1
	1		1
			1
1	2		2
			1
		3	5
1	1		2
			1
		1	3
		75	148
		2	5
		2	8
	1		
		1	2
			1
	1		1
		1	1
	1		10

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pyelonephritis	5	10
Pyelonephritis acute	2	2
Pyrexia	143	596
Quadripareisis	1	2
Quadriplegia		2
Radiculitis brachial	1	1
Rales	3	10
Rash	18	57
Rash erythematous	5	20
Rash macular		5
Rash maculo-papular	8	17
Rash papular		2
Rash pruritic	4	14
Rash pustular		1
Rash vesicular		2
Raynaud's phenomenon	2	3
Rebound effect		1
Rectal haemorrhage	3	9
Red blood cell sedimentation rate increased		2
Red blood cells urine positive		1
Renal colic	1	2
Renal cyst haemorrhage		1
Renal failure	4	15
Renal impairment	1	3
Renal infarct		1
Renal pain		2
Respiration abnormal		1
Respiratory alkalosis	1	4
Respiratory arrest	1	3
Respiratory depression		3
Respiratory disorder	5	14
Respiratory distress	7	35

Spontaneous			
Nonserious		Serious	
I	C	I	C
		5	10
		2	2
89	244	54	352
		1	2
			2
		1	1
3	4		6
7	24	11	33
1	4	4	16
	1		4
1	5	7	12
	1		1
1	6	3	8
			1
			2
2	3		
			1
		3	9
	2		
			1
1	1		1
			1
		4	15
		1	3
			1
			2
			1
		1	4
		1	3
			3
	1	5	13
		7	35

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory failure	2	8			2	8
Respiratory fatigue		1				1
Respiratory rate decreased	1	2			1	2
Respiratory tract congestion		1				1
Respiratory tract infection	2	3			2	3
Restlessness	1	10		4	1	6
Retinal artery occlusion	2	3			2	3
Retinal artery thrombosis	1	1			1	1
Retinal detachment	2	2			2	2
Retinal haemorrhage	3	3			3	3
Retinal vein occlusion	1	3			1	3
Rheumatic disorder		2		1		1
Rheumatic fever		1				1
Rheumatoid arthritis	8	20			8	20
Rhinalgia		1				1
Rhinitis	3	10	3	7		3
Rhinorrhoea	3	12	2	4	1	8
Rhonchi		1				1
Rib fracture	2	4			2	4
Right ventricular dilatation	1	2	1	1		1
Right ventricular failure	1	1			1	1
Road traffic accident		1				1
Rotator cuff syndrome	1	1	1	1		
Salivary gland disorder		1		1		
Salivary hypersecretion	2	5	2	3		2
SARS-CoV-2 ant body test negative		6		6		
SARS-CoV-2 ant body test positive	1	3	1	3		
SARS-CoV-2 test positive	4	23		5	4	18
Scan abnormal	1	1			1	1
Sciatica	2	5	2	3		2
Scleritis	2	3			2	3
Secretion discharge	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sedation		1		1		
Seizure	4	17			4	17
Seizure anoxic		1				1
Sense of oppression	1	3			1	3
Sensorimotor disorder		4		1		3
Sensory disturbance	2	6	1	3	1	3
Sensory loss	2	10	1	5	1	5
Sepsis	1	4			1	4
Septic shock	3	5			3	5
Serum ferritin increased	2	3		1	2	2
Shock	3	7			3	7
Shock haemorrhagic	1	1			1	1
Shoulder injury related to vaccine administration	1	2			1	2
Sialoadenitis		1				1
Sickle cell anaemia with crisis	1	1			1	1
Sinusitis	2	5	1	1	1	4
Sinus pain		1				1
Sinus tachycardia	1	15	1	3		12
Sjogren's syndrome		3				3
Skin abrasion	1	1	1	1		
Skin discolouration	1	3		1	1	2
Skin disorder		1		1		
Skin exfoliation	1	1	1	1		
Skin fissures		1				1
Skin hyperpigmentation		1				1
Skin lesion	1	6	1	3		3
Skin necrosis		1				1
Skin plaque	1	5	1	4		1
Skin reaction	1	6	1	4		2
Skin tightness	1	1	1	1		
Skin ulcer		1				1
Skin warm	2	4	1	3	1	1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
SLE arthritis		1
Sleep apnoea syndrome	1	2
Sleep disorder	5	15
Sleep disorder due to general medical condition, insomnia type	1	3
Sleep talking		1
Sluggishness		2
Snoring		1
Somnolence	10	37
Speech disorder	7	18
Spinal compression fracture		2
Spinal osteoarthritis	1	2
Spinal pain		2
Splenic artery aneurysm	1	1
Splenic infarction		1
Splenic vein thrombosis	1	1
Spondylitis		1
Spondyloarthropathy		1
Staphylococcal bacteraemia		1
Status epilepticus	1	6
Status migrainosus		1
Stereotypy		1
Stertor		1
Stomatitis		2
Strabismus	1	1
Stress	1	6
Stress cardiomyopathy	1	4
Stridor	1	1
Stupor	1	1
Subarachnoid haemorrhage		2
Subcutaneous haematoma	1	1
Subdural haematoma		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
		1	2
3	6	2	9
1	3		
	1		
	2		
	1		
6	16	4	21
2	2	5	16
			2
	1	1	1
			2
		1	1
		1	1
			1
	1		
			1
		1	6
			1
			1
	1		1
	4	1	2
		1	4
		1	1
1	1		
			2
1	1		
			1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Subileus	1	2			1	2
Subretinal haematoma	1	1			1	1
Sudden death	6	42			6	42
Sudden hearing loss	1	6			1	6
Sudden onset of sleep		2				2
Suffocation feeling	1	5			1	5
Suicidal ideation	1	2			1	2
Sunburn		1				1
Superinfection	2	2			2	2
Supraventricular extrasystoles	1	3	1	1		2
Supraventricular tachyarrhythmia		1				1
Supraventricular tachycardia	2	10			2	10
Suspected COVID-19	3	7		2	3	5
Swelling	3	10	3	7		3
Swelling face	3	8	2	3	1	5
Swelling of eyelid		1				1
Swollen tongue	3	9	1	3	2	6
Symmetrical drug-related intertriginous and flexural exanthema	1	1			1	1
Syncope	9	34			9	34
Synovial cyst	4	6	3	3	1	3
Syringe issue	1	1	1	1		
Systemic inflammatory response syndrome	1	2	1	1		1
Systemic lupus erythematosus		1				1
Systolic hypertension	1	2			1	2
Tachyarrhythmia	5	9	1	3	4	6
Tachycardia	58	245	13	60	45	185
Tachycardia paroxysmal		1				1
Tachypnoea	1	12	1	3		9
Temporal lobe epilepsy		1				1
Tendon disorder	1	2	1	1		1
Tendonitis	4	10	2	4	2	6

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tendon pain		2		2		
Tenosynovitis	1	2		1	1	1
Tension	4	8	3	5	1	3
Tension headache	1	2			1	2
Tetany		1				1
Therapeutic response unexpected	1	2	1	2		
Thermal burns of eye		1				1
Thermohypoaesthesia		1		1		
Thirst		6		3		3
Throat irritation	2	10	2	6		4
Throat tightness	4	9	4	4		5
Thrombocytopenia	13	22			13	22
Thrombocytopenic purpura	1	1			1	1
Thrombolysis		1				1
Thrombophlebitis	6	9			6	9
Thrombophlebitis superficial	16	21	1	4	15	17
Thrombosed varicose vein		1				1
Thrombosis	7	14			7	14
Thrombotic stroke	1	1			1	1
Thymoma	1	1			1	1
Thyroiditis subacute	1	1			1	1
Thyroid mass	1	2	1	2		
Thyroxine free decreased		1		1		
Tinnitus	23	56	10	20	13	36
Tongue biting	1	1			1	1
Tongue coated		2				2
Tongue discolouration	1	2			1	2
Tongue discomfort		1				1
Tongue disorder		1				1
Tongue dry		1				1
Tongue injury		1		1		
Tongue movement disturbance		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue oedema	3	10		2	3	8
Tongue pruritus	1	1			1	1
Tongue spasm	1	1	1	1		
Tonic clonic movements		4				4
Tonsillitis	2	4			2	4
Tooth abscess		2		1		1
Toothache	1	3	1	2		1
Tooth infection		1		1		
Tooth loss	1	1			1	1
Torticollis		1				1
Toxicity to various agents		1				1
Toxic skin eruption	2	3			2	3
Transaminases increased	1	1			1	1
Transcription medication error		1		1		
Transient aphasia	1	1			1	1
Transient global amnesia	3	5	1	1	2	4
Transient ischaemic attack	20	46			20	46
Tremor	15	59	9	22	6	37
Tricuspid valve incompetence	1	1			1	1
Trigeminal neuralgia	1	3	1	1		2
Tri-iodothyronine free decreased		1		1		
Trismus		2		2		
Troponin increased	2	11		2	2	9
Tumour perforation		1				1
Type 1 diabetes mellitus		1				1
Type I hypersensitivity	2	4			2	4
Type II hypersensitivity		1				1
Type III immune complex mediated reaction	1	2			1	2
Ulcer	1	1			1	1
Underdose	5	13	5	13		
Unresponsive to stimuli		2				2
Upper respiratory tract congestion	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urinary incontinence		4				4
Urinary retention	1	4			1	4
Urinary tract candidiasis		1				1
Urinary tract discomfort		1		1		
Urinary tract infection	3	8	1	2	2	6
Urinary tract infection bacterial		3				3
Urine odour abnormal		1		1		
Urosepsis		1				1
Urticaria	30	81	16	35	14	46
Urticaria chronic		1				1
Urticarial vasculitis	1	1			1	1
Uterine contractions abnormal	1	1			1	1
Uterine contractions during pregnancy	1	1			1	1
Uterine spasm	1	1			1	1
Uveitis	1	1			1	1
Uvulitis		1				1
Vaccination complication	1	6		2	1	4
Vaccination failure	87	162			87	162
Vaccination site abscess		2		1		1
Vaccination site bruising		1		1		
Vaccination site cellulitis		1				1
Vaccination site coldness		1		1		
Vaccination site discharge		1				1
Vaccination site discolouration		1				1
Vaccination site discomfort		1				1
Vaccination site dysaesthesia		1				1
Vaccination site erythema	12	54	9	35	3	19
Vaccination site exfoliation		1				1
Vaccination site granuloma		1				1
Vaccination site haematoma	3	15	1	7	2	8
Vaccination site haemorrhage		2		1		1
Vaccination site hyperaesthesia	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site hypersensitivity	1	10	1	10		
Vaccination site hypoaesthesia		1				1
Vaccination site induration	2	18	2	14		4
Vaccination site inflammation	10	32	6	14	4	18
Vaccination site joint movement impairment		1				1
Vaccination site joint pain	1	3	1	2		1
Vaccination site lymphadenopathy		1				1
Vaccination site macule	1	1	1	1		
Vaccination site mass		3		2		1
Vaccination site movement impairment	4	18	1	7	3	11
Vaccination site nodule		3		1		2
Vaccination site oedema	1	16		5	1	11
Vaccination site pain	86	379	69	205	17	174
Vaccination site papule		1		1		
Vaccination site paraesthesia	4	13	3	7	1	6
Vaccination site plaque		1				1
Vaccination site pruritus	7	27	7	16		11
Vaccination site rash		4		2		2
Vaccination site reaction	9	25	5	16	4	9
Vaccination site recall reaction		1		1		
Vaccination site swelling	7	26	6	17	1	9
Vaccination site thrombosis		1				1
Vaccination site urticaria	2	3	2	3		
Vaccination site warmth		16		7		9
Vagus nerve disorder		1				1
Varicella virus test positive	1	2			1	2
Varicella zoster virus infection	1	1			1	1
Vascular encephalopathy		1				1
Vascular graft thrombosis	1	1			1	1
Vascular pain	1	1	1	1		
Vascular purpura	6	11		2	6	9
Vascular rupture	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular stenosis		1				1
Vasculitis	4	6	3	4	1	2
Vasoconstriction		1		1		
Vasodilatation		1		1		
Vasoplegia syndrome	1	2			1	2
Vein rupture		1				1
Vena cava thrombosis		1				1
Venous oxygen saturation decreased		2				2
Venous thrombosis	3	3			3	3
Venous thrombosis limb	2	4	1	1	1	3
Ventricular arrhythmia	1	2			1	2
Ventricular extrasystoles		9		2		7
Ventricular failure		1				1
Ventricular f brillation	1	3			1	3
Ventricular hypokinesia		1				1
Ventricular tachycardia		1				1
Vertigo	45	134	18	46	27	88
Vertigo positional	1	12	1	1		11
Vestibular disorder	2	5	1	2	1	3
Vestibular neuritis	2	7			2	7
Viral infection	2	5		2	2	3
Viral pharyngitis	2	2			2	2
Vision blurred	10	25	5	10	5	15
Visual acuity reduced	2	3			2	3
Visual acuity reduced transiently		1				1
Visual field defect	2	5			2	5
Visual impairment	10	25	6	8	4	17
Vitamin D deficiency		1		1		
Vlth nerve paralysis	1	1			1	1
Vitreous detachment	1	1			1	1
Vitreous floaters	1	1			1	1
Vocal cord paralysis	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vomiting	62	232	38	79	24	153
Vomiting projectile	2	2			2	2
Von Willebrand's factor activity decreased		1				1
Vulval haemorrhage	1	1			1	1
Walking disability		2				2
Weight decreased	2	8	1	2	1	6
Weight increased	4	7	2	3	2	4
Wheezing	1	5	1	2		3
White blood cell count decreased	1	3	1	3		
White blood cell count increased	2	3	1	2	1	1
Withdrawal hypertension	1	2		1	1	1
Wrist fracture	2	2			2	2
Wrong patient received product		1		1		
Wrong technique in product usage process	1	4	1	4		
	5,022	17,337	1924	5391	3098	11946

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		3		2		1
Abdominal distension	1	3		2	1	1
Abdominal mass		1		1		
Abdominal pain	9	30	6	14	3	16
Abdominal pain lower		2		2		
Abdominal pain upper	6	14	3	9	3	5
Abdominal rigidity		1				1
Abnormal behaviour		2		1		1
Abscess		1		1		
Acidosis hyperchloraemic		1				1
Acne		1		1		
Acquired haemophilia		1				1
Activated partial thromboplastin time abnormal		1				1
Activated partial thromboplastin time prolonged	1	1			1	1
Acute abdomen		1				1
Acute coronary syndrome	5	14			5	14
Acute generalised exanthematous pustulosis	1	1			1	1
Acute kidney injury	8	19			8	19
Acute myocardial infarction		1				1
Acute pulmonary oedema	2	6			2	6
Acute respiratory distress syndrome	6	11			6	11
Acute respiratory failure	2	6			2	6
Acute vestibular syndrome	1	3			1	3
Adult failure to thrive		1				1
Affective disorder	1	1			1	1
Ageusia	1	7	1	6		1
Aggression	1	3		1	1	2
Agitation	3	10		2	3	8
Agnosia		1				1
Agranulocytosis		2				2
Air embolism		1				1
Alanine aminotransferase increased		2		1		1

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Altered state of consciousness	2	7
Amaurosis		1
Amnesia		2
Amnesic disorder	1	1
Amyotrophy		1
Anaemia	4	10
Anal incontinence	1	1
Anaphylactic reaction	1	6
Anaphylactic shock	1	1
Anaphylactoid shock	1	1
Aneurysm ruptured	1	2
Angina pectoris	4	8
Angina unstable		1
Angioedema	5	16
Ankylosing spondylitis	1	1
Anosmia	1	3
Anterograde amnesia	1	2
Anticoagulation drug level below therapeutic		2
Anti-neutrophil cytoplasmic antibody positive vasculitis		1
Anuria	1	1
Anxiety	4	8
Aortic dilatation	1	1
Aortic dissection		1
Aortic stenosis	1	1
Aortic valve incompetence		1
Apathy	2	6
Aphasia	5	13
Aphonia		1
Aphthous ulcer	1	4
Aplasia		1
Appendicitis	2	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
		2	7
			1
	1		1
		1	1
			1
	1	4	9
1	1		
		1	6
		1	1
		1	1
		1	2
		4	8
			1
1	1	4	15
		1	1
	2	1	1
		1	2
	1		1
			1
		1	1
2	4	2	4
		1	1
			1
		1	1
			1
1	4	1	2
2	3	3	10
			1
	1	1	3
			1
		2	3

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appendicitis perforated		1				1
Arrhythmia	16	51			16	51
Arrhythmia supraventricular		2				2
Arterial disorder	1	1			1	1
Arterial occlusive disease	1	1			1	1
Arterial thrombosis	1	3			1	3
Arteriosclerosis	2	3	1	1	1	2
Arteriosclerosis coronary artery	1	2	1	1		1
Arteriovenous fistula thrombosis	1	2			1	2
Arteriovenous malformation	1	1			1	1
Artery dissection	2	2			2	2
Arthralgia	18	63	10	31	8	32
Arthritis	2	5		1	2	4
Arthritis reactive		2				2
Arthropathy		1		1		
Aspartate aminotransferase increased		1				1
Aspiration		2				2
Asthenia	48	199	28	77	20	122
Asthma		1				1
Asthmatic crisis		2				2
Asymptomatic COVID-19	2	12		3	2	9
Ataxia	1	6	1	4		2
Atelectasis		1				1
Atrial fibrillation	22	63			22	63
Atrial flutter	2	5			2	5
Atrial thrombosis		1				1
Atrioventricular block	2	7			2	7
Atrioventricular block complete	2	3			2	3
Atrioventricular block first degree	1	1			1	1
Atrioventricular block second degree	1	2			1	2
Atypical pneumonia		1				1
Autoimmune haemolytic anaemia		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmune thyroiditis		2				2
Axillary pain	2	5	2	5		
Axillary vein thrombosis		1		1		
Back pain	7	15	6	10	1	5
Bacteraemia	1	1			1	1
Bacterial infection		1				1
Bacterial sepsis		1				1
Balance disorder	8	16	2	3	6	13
B-cell lymphoma		1				1
Bedridden		1		1		
Behaviour disorder	1	5			1	5
Bell's palsy	1	1			1	1
Benign prostatic hyperplasia	2	4	2	3		1
Beta 2 microglobulin increased		1		1		
Bicytopenia	2	2			2	2
Bilirubin conjugated increased		1		1		
Bladder disorder	1	1	1	1		
Blindness	1	2			1	2
Blindness transient		1				1
Blindness unilateral		3				3
Blister		2		1		1
Blood alkaline phosphatase increased	1	4		3	1	1
Blood bicarbonate decreased		1				1
Blood bilirubin abnormal		1		1		
Blood bilirubin increased	2	3	1	2	1	1
Blood bilirubin unconjugated increased		1		1		
Blood creatine phosphokinase increased		1				1
Blood creatinine increased	3	4	2	3	1	1
Blood fibrinogen increased	1	1	1	1		
Blood glucose increased	1	5		2	1	3
Blood immunoglobulin G increased	1	1	1	1		
Blood lactate dehydrogenase increased	1	3		2	1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood parathyroid hormone increased		1		1		
Blood potassium increased		1		1		
Blood pressure decreased	3	7	2	3	1	4
Blood pressure diastolic decreased		1		1		
Blood pressure fluctuation	1	3			1	3
Blood pressure inadequately controlled	1	1			1	1
Blood pressure increased	4	17	2	5	2	12
Blood pressure systolic decreased		1		1		
Blood pressure systolic increased		2				2
Blood sodium increased		3		1		2
Blood thyroid stimulating hormone increased		1		1		
Blood uric acid increased		1		1		
Blood urine present	1	1	1	1		
Body temperature decreased		1				1
Body temperature increased	1	4	1	3		1
Bone pain		1				1
Bone swelling	2	3	1	2	1	1
Bradycardia	5	24			5	24
Bradykinesia	1	1	1	1		
Bradyphrenia		2				2
Brain hypoxia		1				1
Brain natriuretic peptide increased	1	3		1	1	2
Brain oedema	1	1			1	1
Brain stem haemorrhage		1				1
Brain stem stroke	1	1			1	1
Bronchiolitis		1				1
Bronchitis	3	12	1	4	2	8
Bronchopneumopathy		2				2
Bronchospasm	1	1	1	1		
Bundle branch block left		2		1		1
Bundle branch block right	1	3		1	1	2
Burning sensation	3	8	1	5	2	3

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bursal fluid accumulation		1		1		
Bursal haematoma	1	2			1	2
Bursitis		1				1
Camptocormia	1	1	1	1		
Cardiac arrest	6	19			6	19
Cardiac discomfort		1				1
Cardiac disorder		1		1		
Cardiac failure	9	48			9	48
Cardiac failure acute		1				1
Cardiac fibrillation		1				1
Cardiogenic shock	1	1			1	1
Cardiomyopathy		1				1
Cardiopulmonary failure	1	2			1	2
Cardio-respiratory arrest	9	28			9	28
Cardio-respiratory distress		1				1
Carotid artery occlusion	1	4			1	4
Carotid artery stenosis	1	2			1	2
Carotid artery thrombosis		1				1
Cataract		1				1
Cerebellar ataxia		1		1		
Cerebellar haematoma		1				1
Cerebellar infarction	1	2			1	2
Cerebellar stroke	1	1			1	1
Cerebellar syndrome	3	6			3	6
Cerebral amyloid angiopathy	1	2			1	2
Cerebral arteriosclerosis	1	2	1	1		1
Cerebral atrophy		1				1
Cerebral disorder		1				1
Cerebral haematoma		2				2
Cerebral haemorrhage	2	11			2	11
Cerebral infarction	4	10			4	10
Cerebrovascular accident	14	34			14	34

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cervical cord compression		1				1
Cervical radiculopathy		1		1		
Cervicobrachial syndrome		2				2
Chest discomfort	7	15	2	6	5	9
Chest pain	29	71	11	19	18	52
Chillblains	2	2	2	2		
Chills	24	78	17	41	7	37
Choking		1				1
Choking sensation	1	1	1	1		
Cholecystitis		1				1
Cholecystitis acute	1	1			1	1
Cholelithiasis	1	1			1	1
Cholestasis	5	6			5	6
Chorioretinitis	1	1			1	1
Chromaturia		1		1		
Chronic kidney disease	2	3			2	3
Chronic obstructive pulmonary disease	1	9		2	1	7
Circulatory collapse		1				1
Citrobacter infection		1				1
Clonic convulsion	1	1			1	1
Cluster headache		1				1
Cognitive disorder	1	1			1	1
Cold sweat		4		3		1
Colitis		2		1		1
Colitis ulcerative		1				1
Coma	3	9			3	9
Complex regional pain syndrome		1		1		
Condition aggravated	8	25	2	5	6	20
Confusional state	10	28		5	10	23
Congestive cardiomyopathy		1				1
Conjunctival haemorrhage	1	5			1	5
Conjunctival hyperaemia		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival irritation		1		1		
Conjunctivitis	1	2	1	1		1
Constipation	5	9	4	8	1	1
Contusion	2	3	2	3		
Coordination abnormal	1	2	1	1		1
Coronary artery disease		2				2
Coronary artery occlusion	3	4			3	4
Coronary artery stenosis	2	4			2	4
Cough	4	33	3	13	1	20
COVID-19	78	209	5	23	73	186
COVID-19 pneumonia	10	23			10	23
Cranial nerve paralysis	1	1			1	1
C-reactive protein increased	7	30	3	12	4	18
Crepitations		1		1		
Crohn's disease		1				1
Cutaneous vasculitis	1	1			1	1
Cyanosis	2	3	1	1	1	2
Cystic lymphangioma		1				1
Cytomegalovirus infection		2				2
Dacryocystitis	1	1			1	1
Deafness		3				3
Deafness neurosensory		2				2
Deafness unilateral		4				4
Death	3	48			3	48
Decreased appetite	15	38	8	17	7	21
Decubitus ulcer		2		1		1
Deep vein thrombosis	53	69			53	69
Defect conduction intraventricular		1				1
Dehydration	6	18		4	6	14
Delirium	1	6			1	6
Delusion		1		1		
Depressed level of consciousness		3				3

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Depression		1		1		
Dermabrasion		1		1		
Dermatitis bullous	3	5			3	5
Dermatitis exfoliative generalised		2				2
Dermo-hypodermatitis		3				3
Diabetes insipidus	1	1			1	1
Diabetes mellitus	2	7			2	7
Diabetes mellitus inadequate control	1	6			1	6
Diabetic ketoacidosis	1	4			1	4
Diabetic ketosis	1	1			1	1
Diabetic metabolic decompensation	1	2			1	2
Diarrhoea	26	82	11	30	15	52
Diarrhoea haemorrhagic		1				1
Diarrhoea infectious		2				2
Diplopia	3	10			3	10
Discomfort	7	22	3	7	4	15
Disease progression	1	2			1	2
Disease recurrence	11	38	1	2	10	36
Disorientation	2	9		3	2	6
Disseminated intravascular coagulation		1				1
Disseminated varicella zoster virus infection	1	1			1	1
Disturbance in attention	1	3		1	1	2
Diverticulum intestinal	1	3		1	1	2
Dizziness	19	61	11	28	8	33
Drooling		1		1		
Drop attacks		1				1
Drug eruption		1		1		
Drug ineffective	31	85	1	1	30	84
Drug interaction		2		1		1
Drug reaction with eosinophilia and systemic symptoms		1				1
Dry eye		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry mouth		2		1		1
Dysaesthesia	2	6	1	3	1	3
Dysarthria	4	12	1	2	3	10
Dysgeusia	1	6	1	3		3
Dysgraphia		1				1
Dyskinesia	2	4	1	2	1	2
Dyslipidaemia		1		1		
Dysmetria		1				1
Dyspepsia		2		1		1
Dysphagia	6	11	4	5	2	6
Dysphemia		1				1
Dysphonia	1	6	1	4		2
Dyspnoea	27	85	7	17	20	68
Dyspnoea at rest	1	4			1	4
Dyspnoea exertional	5	16		2	5	14
Dysstasia	1	3	1	1		2
Dysuria	1	5	1	2		3
Ear discomfort		1				1
Ear disorder		1		1		
Ear haemorrhage		1		1		
Ear infection		2				2
Ear pain	1	8		3	1	5
Ecchymosis	1	1	1	1		
Eczema		3		1		2
Eczema nummular		1				1
Ejection fraction abnormal	1	1			1	1
Ejection fraction decreased	2	2	1	1	1	1
Electric shock sensation	1	2	1	1		1
Electrocardiogram QRS complex prolonged	1	2			1	2
Electrocardiogram repolarisation abnormality	1	2			1	2
Electrocardiogram ST segment elevation	1	1			1	1
Electrocardiogram T wave abnormal		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Electroencephalogram abnormal		1				1
Embolic stroke		2				2
Embolism	1	1			1	1
Emotional distress		1		1		
Encephalopathy	1	1			1	1
Enterocolitis haemorrhagic		1				1
Enthesopathy	1	1			1	1
Enuresis		1				1
Eosinophilia		3				3
Epicondylitis	1	1			1	1
Epilepsy	5	18			5	18
Epistaxis	6	22		7	6	15
Epstein-Barr virus infection reactivation	1	1			1	1
Erectile dysfunction		2				2
Eructation		1				1
Erysipelas	1	9			1	9
Erythema	3	22		9	3	13
Erythema multiforme		1				1
Erythema nodosum		1		1		
Escherichia bacteraemia		1				1
Escherichia urinary tract infection	1	2			1	2
Euphoric mood	1	1	1	1		
Exposure to SARS-CoV-2		1				1
Extensive swelling of vaccinated limb		1		1		
Extrapyramidal disorder		2		1		1
Extrasystoles	3	7			3	7
Extremity necrosis		1				1
Eye contusion		1		1		
Eye haemorrhage		3				3
Eye irritation	1	2	1	2		
Eyelid disorder	1	1	1	1		
Eyelid function disorder		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid haematoma		1		1		
Eyelid oedema		3		1		2
Eye movement disorder	2	2	1	1	1	1
Eye pain	4	6	3	3	1	3
Eye swelling	2	4		1	2	3
Face oedema	1	9	1	2		7
Facial asymmetry		1				1
Facial bones fracture		1				1
Facial neuralgia	1	1			1	1
Facial pain		3				3
Facial paralysis	17	59			17	59
Facial paresis	1	3			1	3
Faeces discoloured		1		1		
Faeces soft		2		2		
Fall	18	48	5	11	13	37
Fatigue	25	108	19	66	6	42
Fat tissue increased		1		1		
Febrile bone marrow aplasia	1	1			1	1
Febrile convulsion		1				1
Feeling abnormal	3	6	3	4		2
Feeling cold		5		3		2
Feeling drunk		1				1
Feeling hot	1	7	1	4		3
Femoral neck fracture		1				1
Femur fracture		1				1
Fibrin D dimer increased	5	6	1	1	4	5
Flank pain		1		1		
Flatulence	2	3	2	3		
Flushing	1	5	1	3		2
Focal discognitive seizures		1				1
Folate deficiency	3	3	2	2	1	1
Fracture		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Functional gastrointestinal disorder		1				1
Gait disturbance	3	16	1	6	2	10
Gait inability		2		1		1
Gamma-glutamyltransferase increased	1	7		5	1	2
Gastric ulcer	2	2			2	2
Gastric ulcer haemorrhage	1	1			1	1
Gastritis	1	1			1	1
Gastritis erosive		1				1
Gastroenteritis	2	5		1	2	4
Gastrointestinal disorder	1	5	1	3		2
Gastrointestinal haemorrhage	1	3			1	3
Gastrointestinal motility disorder		1		1		
Gastrointestinal pain	1	1			1	1
Gastrointestinal sounds abnormal		1		1		
Gastrointestinal wall thickening		1		1		
Gastroesophageal reflux disease	1	3	1	3		
Gaze palsy		1				1
Generalised tonic-clonic seizure	3	8			3	8
General physical health deterioration	6	24	2	7	4	17
Giant cell arteritis	2	3			2	3
Gingival bleeding	1	1	1	1		
Gingivitis		1				1
Glomerular filtration rate decreased	1	1	1	1		
Glomerulonephritis		1				1
Glycosylated haemoglobin increased		1		1		
Goitre	1	1			1	1
Gout	1	3	1	2		1
Gross motor delay		1				1
Guillain-Barre syndrome	3	6			3	6
Guttate psoriasis		1		1		
Gynaecomastia	1	1	1	1		
Haemarthrosis	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematemesis		3				3
Haematochezia	1	1			1	1
Haematoma	1	4		1	1	3
Haematoma muscle		1				1
Haematuria	1	4			1	4
Haemodynamic instability	1	2		1	1	1
Haemoglobin decreased		5		2		3
Haemolysis	1	1			1	1
Haemolytic anaemia		1				1
Haemophagocytic lymphohistiocytosis		3				3
Haemoptysis		3				3
Haemorrhage		1				1
Haemorrhagic diathesis		1				1
Haemorrhagic stroke	1	6			1	6
Haemorrhagic transformation stroke	3	3			3	3
Haemorrhoids		1				1
Hallucination	1	2			1	2
Hallucination, auditory		1				1
Hallucination, visual	1	5			1	5
Headache	66	180	47	97	19	83
Head discomfort	1	3		1	1	2
Head injury	3	10			3	10
Heart rate decreased	4	6	2	3	2	3
Heart rate increased	1	7	1	4		3
Heart rate irregular		2				2
Heart sounds abnormal		2				2
Heart valve incompetence	1	1	1	1		
Hemianopia		2				2
Hemianopia homonymous		2				2
Hemiataxia	1	1			1	1
Hemiparaesthesia	1	2			1	2
Hemiparesis	1	6			1	6

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hemiplegia	4	11
Henoch-Schonlein purpura		1
Hepatic cyst infection		1
Hepatic cytolysis	4	6
Hepatic enzyme abnormal	1	1
Hepatic enzyme increased	1	3
Hepatic pain	1	1
Hepatic steatosis	1	3
Hepatitis	1	1
Hepatitis acute	1	1
Hepatitis B		1
Hepatitis cholestatic		1
Hepatitis E	1	1
Hepatocellular injury		2
Hepatjugular reflux		1
Hepatomegaly	1	2
Herpes ophthalmic	1	3
Herpes simplex		2
Herpes virus infection	1	1
Herpes zoster	52	96
Herpes zoster cutaneous disseminated	1	1
High density lipoprotein decreased	1	1
Hippocampal atrophy		1
Hoffmann's sign		1
Horner's syndrome		1
Hot flush	1	8
Humerus fracture		1
Hyperaesthesia	3	7
Hyperbilirubinaemia	1	3
Hypercalcaemia		1
Hypercalcaemia of malignancy		1
Hypercapnia		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		4	11
	1		
			1
		4	6
		1	1
1	2		1
		1	1
1	2		1
		1	1
		1	1
			1
			1
		1	1
			2
	1		
		1	2
		1	3
	1		1
1	1		
35	49	17	47
		1	1
1	1		
	1		
	1		
			1
1	6		2
			1
2	5	1	2
		1	3
	1		
	1		
			1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperchloraemia		1				1
Hyperferritinaemia	1	2	1	1		1
Hypergammaglobulinaemia	1	1	1	1		
Hyperglycaemia	1	9	1	4		5
Hyperglycinaemia		1				1
Hyperhidrosis	10	32	5	14	5	18
Hyperhomocysteinaemia	1	1	1	1		
Hyperkalaemia	2	6			2	6
Hyperlactacidaemia	2	3			2	3
Hyperleukocytosis		6				6
Hypernatraemia	2	5	1	2	1	3
Hyperpathia	1	1	1	1		
Hypersensitivity	3	16	1	7	2	9
Hypersensitivity pneumonitis	1	1			1	1
Hypersensitivity vasculitis		1				1
Hypersomnia	1	3	1	3		
Hypertension	50	165	6	22	44	143
Hypertensive crisis	8	52			8	52
Hypertensive encephalopathy	1	1			1	1
Hypertensive urgency		1				1
Hyperthermia	8	25	3	6	5	19
Hypertonia		1				1
Hypertriglyceridaemia	1	1	1	1		
Hypertrophic cardiomyopathy		2				2
Hyperventilation	1	2		1	1	1
Hypervitaminosis B12		1				1
Hypoacusis		4		1		3
Hypoesthesia	8	19	4	9	4	10
Hypoesthesia oral		1				1
Hypoalbuminaemia	2	2	1	1	1	1
Hypocalcaemia	1	1			1	1
Hypocapnia	1	1	1	1		

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			Nonserious		Serious	
			I	C	I	C
Hypogammaglobulinaemia	1	2			1	2
Hypoglycaemia	1	1			1	1
Hypokalaemia	2	5			2	5
Hyponatraemia	2	2	2	2		
Hypophagia		1		1		
Hypotension	13	57	3	13	10	44
Hypotensive crisis		1				1
Hypothermia		3				3
Hypotonia	1	4		1	1	3
Hypoventilation	1	1			1	1
Hypovitaminosis	1	1	1	1		
Hypovolaemic shock		2				2
Hypoxia	1	8			1	8
Idiopathic pulmonary fibrosis	1	1			1	1
Illrd nerve paralysis	1	2			1	2
Illness	1	1	1	1		
Immune thrombocytopenia	6	10			6	10
Impaired driving ability	1	1			1	1
Impaired work ability	1	4			1	4
Inappropriate schedule of product administration	3	7	3	7		
Incoherent	2	5	1	1	1	4
Incontinence	1	2			1	2
Incorrect dose administered		2		2		
Incorrect route of product administration	2	8	2	8		
Induration		1		1		
Infarction		2				2
Infection		3		2		1
Inflammation	8	21	2	7	6	14
Inflammatory marker increased	1	1			1	1
Influenza	9	20	6	8	3	12
Influenza like illness	38	138	20	46	18	92
Injected limb mobility decreased	3	5	2	2	1	3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site erythema		1		1		
Injection site pruritus		1		1		
Injury	1	1	1	1		
Insomnia	5	22	4	15	1	7
International normalised ratio abnormal		1				1
International normalised ratio increased	1	5		1	1	4
Interstitial lung disease	4	5			4	5
Intervertebral disc disorder		1		1		
Intervertebral disc protrusion		1		1		
Intestinal ischaemia		3				3
Intestinal obstruction	1	1			1	1
Intracranial artery dissection	1	1			1	1
Irritability		1		1		
Ischaemia		1				1
Ischaemic limb pain		1				1
Ischaemic stroke	37	73			37	73
IVth nerve paralysis	1	1			1	1
Jaundice		2				2
Jaundice cholestatic		1				1
Joint effusion		1				1
Joint stiffness		1				1
Joint swelling		2		2		
Jugular vein thrombosis		1				1
Ketonuria	1	1			1	1
Laboratory test abnormal	1	2	1	1		1
Lacrimation increased	1	2	1	2		
Lactic acidosis		1				1
Laryngeal discomfort	1	1			1	1
Laryngeal oedema		1				1
Larynx irritation		1				1
Left atrial dilatation	2	2			2	2
Left ventricular dilatation		2		2		

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			Nonserious		Serious	
			I	C	I	C
Left ventricular dysfunction		1				1
Left ventricular failure	1	3			1	3
Left ventricular hypertrophy	1	1	1	1		
Leukocyturia		2		2		
Leukoencephalopathy		4				4
Leukopenia		1				1
Limb discomfort	1	2			1	2
Lip erosion		1				1
Lip haematoma		1				1
Lip haemorrhage		1				1
Lip oedema	1	3	1	1		2
Lip swelling	1	2		1	1	1
Lithiasis		1		1		
Livedo reticularis	3	7	3	5		2
Liver abscess	1	1			1	1
Liver function test increased		1				1
Localised oedema		1				1
Loss of consciousness	20	54			20	54
Loss of libido		1		1		
Loss of personal independence in daily activities	1	3	1	1		2
Lower respiratory tract congestion		3				3
Lumbar puncture	1	1			1	1
Lung abscess	1	2			1	2
Lung cancer metastatic	1	1			1	1
Lung disorder	3	16		4	3	12
Lyme disease		2				2
Lymphadenitis	2	5	1	2	1	3
Lymphadenopathy	5	30	3	17	2	13
Lymphadenopathy mediastinal		1		1		
Lymphangitis	1	2			1	2
Lymphoedema		3		2		1
Lymphopenia	4	13	2	4	2	9

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Macroglossia		1				1
Macular oedema		1				1
Madarosis		1				1
Major depression	1	1			1	1
Malaise	34	125	11	40	23	85
Malignant hypertension		1				1
Malignant peritoneal neoplasm	1	1			1	1
Malnutrition	3	5		2	3	3
Mass		1				1
Mastitis	1	1			1	1
Mediastinitis	1	1			1	1
Medication error		1		1		
Melaena	2	2			2	2
Memory impairment		2		1		1
Meniere's disease	1	1			1	1
Meningeal disorder		1				1
Meningioma	1	1			1	1
Meningitis aseptic	1	1			1	1
Mental impairment	1	2			1	2
Mesenteric artery thrombosis	1	1			1	1
Mesenteric vein thrombosis		1				1
Metabolic acidosis	2	2			2	2
Metamorphopsia		1				1
Microangiopathy	1	1			1	1
Middle insomnia		3				3
Migraine	1	4	1	2		2
Migraine with aura		1		1		
Mitral valve incompetence	1	2			1	2
Moaning		1				1
Mobility decreased	1	3			1	3
Monoclonal gammopathy		2				2
Monocytosis	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mononeuropathy multiplex	1	1			1	1
Monoparesis	2	5	2	2		3
Monoplegia	1	2			1	2
Mood altered	1	1			1	1
Moraxella infection		1				1
Motor dysfunction	4	13	1	1	3	12
Mouth haemorrhage		1		1		
Mouth ulceration		1		1		
Movement disorder	1	4	1	2		2
Mucous stools		1		1		
Multiple organ dysfunction syndrome	2	4			2	4
Muscle contractions involuntary		2				2
Muscle contracture		1		1		
Muscle fatigue		2		2		
Muscle rigidity		1		1		
Muscle spasms	7	11	4	6	3	5
Muscle strength abnormal		1				1
Muscle tightness	1	1	1	1		
Muscle twitching	2	2			2	2
Muscular weakness	3	11	1	3	2	8
Musculoskeletal chest pain	1	2	1	2		
Musculoskeletal disorder	1	1	1	1		
Musculoskeletal pain		2		2		
Musculoskeletal stiffness	5	26	5	10		16
Mutism		2		1		1
Myalgia	37	103	28	57	9	46
Myasthenia gravis		1				1
Myasthenia gravis crisis		1				1
Mydriasis		3		1		2
Myelitis		1				1
Myelocytosis		1				1
Myelodysplastic syndrome		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myelofibrosis		1				1
Myocardial infarction	11	29			11	29
Myocardial ischaemia		3				3
Myocardial necrosis marker increased		2				2
Myocarditis	4	8			4	8
Myoclonus	1	5			1	5
Myositis		1				1
Nasal congestion	2	5	1	3	1	2
Nasal discomfort	1	1			1	1
Nasal herpes		1				1
Nasopharyngitis		4		4		
Nausea	24	83	12	36	12	47
Near death experience		2				2
Neck injury		1				1
Neck pain	5	13	4	8	1	5
Needle issue		1		1		
Neoplasm		1				1
Nephrotic syndrome	1	2			1	2
Nerve conduction studies abnormal		1		1		
Nervous system disorder	2	4	1	1	1	3
Neuralgia	1	9		4	1	5
Neuralgic amyotrophy	2	3			2	3
Neuritis		1		1		
Neuroleptic malignant syndrome	1	1			1	1
Neurological decompensation	1	3		1	1	2
Neurological symptom	1	1	1	1		
Neuropathy peripheral	1	1			1	1
Neutropenia	2	5			2	5
Neutrophil count decreased	1	2	1	1		1
Neutrophil count increased		1		1		
Neutrophilia		1		1		
Nightmare		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Night sweats		3		2		1
Nocturnal dyspnoea	1	1	1	1		
Noninfective chorioretinitis		1				1
N-terminal prohormone brain natriuretic peptide increased	2	3	1	1	1	2
Nystagmus	1	2	1	2		
Obstruction gastric		1				1
Occipital neuralgia	3	3	1	1	2	2
Ocular discomfort	1	2	1	2		
Ocular hyperaemia	1	4	1	1		3
Odynophagia		2		2		
Oedema		2		2		
Oedema genital		1				1
Oedema mucosal	1	1	1	1		
Oedema peripheral	8	21	2	5	6	16
Oedematous pancreatitis	1	1			1	1
Off label use	2	8	2	8		
Oligoarthritis	1	1			1	1
Oliguria	1	1			1	1
Ophthalmic herpes zoster	6	12			6	12
Optic ischaemic neuropathy		1				1
Optic neuritis		1				1
Organising pneumonia	1	1			1	1
Oropharyngeal candidiasis		1				1
Oropharyngeal discomfort		1		1		
Oropharyngeal oedema		1				1
Oropharyngeal pain	3	9	3	8		1
Orthopnoea		2				2
Osteoarthritis		4		2		2
Otitis externa	1	3	1	2		1
Overdose	4	9	4	9		
Oxygen saturation decreased	11	42	3	10	8	32

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			Nonserious		Serious	
			I	C	I	C
Pain	8	59	2	26	6	33
Painful respiration	1	2			1	2
Pain in extremity	22	50	12	28	10	22
Pain in jaw	1	4	1	1		3
Pain of skin		2				2
Palatal oedema	1	3	1	1		2
Pallor	2	10		1	2	9
Palpitations	6	26	2	7	4	19
Pancreatic cyst	1	1			1	1
Pancreatitis	1	3			1	3
Pancreatitis acute	4	7			4	7
Pancytopenia	1	2			1	2
Papilloedema	1	1			1	1
Paraesthesia	9	37	4	10	5	27
Paraesthesia oral		2		1		1
Paresis		2				2
Parkinsonism		1				1
Parkinson's disease		1				1
Parosmia		1		1		
Parotitis	1	1			1	1
Partial seizures		3				3
Pelvic fracture		1				1
Pelvic venous thrombosis	1	1			1	1
Pemphigoid		1				1
Pericardial effusion	3	7			3	7
Pericarditis	6	16			6	16
Periorbital oedema		1				1
Peripheral artery thrombosis		1				1
Peripheral coldness	2	5	1	4	1	1
Peripheral embolism		1				1
Peripheral ischaemia	2	6	1	1	1	5
Peripheral sensory neuropathy		1				1

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			Nonserious		Serious	
			I	C	I	C
Peripheral swelling	6	12	2	5	4	7
Peripheral venous disease		1		1		
Peritonitis	1	1			1	1
Pernio-like erythema		1		1		
Petechiae	3	6	2	4	1	2
Petit mal epilepsy		1				1
Pharyngeal paraesthesia	1	1	1	1		
Pharyngitis		1		1		
Phlebitis	8	15	1	5	7	10
Phlebitis superficial	1	1			1	1
Photophobia	1	6	1	1		5
Photopsia		1				1
Pituitary tumour benign	1	1	1	1		
Platelet count decreased	1	3	1	1		2
Platelet count increased	1	1	1	1		
Pleural effusion	3	7		2	3	5
Pleuropericarditis	1	1			1	1
Pneumocephalus	1	1			1	1
Pneumococcal sepsis		1				1
Pneumonia	4	22			4	22
Pneumonia aspiration	2	10			2	10
Pneumonia bacterial		4				4
Pneumonia moraxella		1				1
Pneumonia mycoplasmal	1	1			1	1
Pneumonia pneumococcal		1				1
Pneumonia respiratory syncytial viral	1	1			1	1
Pneumonia viral	1	1			1	1
Pneumothorax		2				2
Pollakiuria	1	2	1	2		
Polyarthrits	1	2			1	2
Polydipsia		1		1		
Polymyalgia rheumatica	2	4			2	4

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Polyneuropathy	1	3
Polyp		1
Poor quality product administered		37
Portal vein thrombosis	1	2
Post herpetic neuralgia	1	1
Prerenal failure		2
Presbycusis		1
Presyncope	7	16
Priapism		1
Procalcitonin increased	2	3
Proctitis	1	1
Product administered at inappropriate site	1	1
Productive cough		2
Product preparation error		1
Product preparation issue	2	9
Product temperature excursion issue		34
Product use issue		5
Prostatitis		4
Protein C increased		1
Proteinuria	1	1
Prothrombin level abnormal		1
Pruritus	4	26
Pseudodementia		1
Pseudomonal sepsis	1	1
Psoriasis		1
Psoriatic arthropathy		1
Psychomotor skills impaired	2	3
Pulmonary embolism	61	99
Pulmonary hypertension		1
Pulmonary infarction	1	2
Pulmonary oedema		7
Pulmonary pain		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	3
	1		
	37		
		1	2
1	1		
			2
	1		
3	6	4	10
			1
	1	2	2
1	1		
1	1		
			2
	1		
2	9		
	34		
	5		
	2		2
			1
		1	1
			1
2	12	2	14
			1
		1	1
			1
1	2	1	1
		61	99
			1
		1	2
			7
			1

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			Nonserious		Serious	
			I	C	I	C
Pulse abnormal		1		1		
Pulse absent	2	3		1	2	2
Pupils unequal		1		1		
Purpura	5	9	2	3	3	6
Pyrexia	71	222	47	97	24	125
Quadrantanopia	1	1			1	1
Radial nerve palsy		1				1
Rales	1	7	1	1		6
Rash	5	26	4	14	1	12
Rash erythematous	1	5	1	4		1
Rash macular		2				2
Rash maculo-papular	1	8	1	4		4
Rash papular		5		2		3
Rash pruritic	1	3	1	1		2
Rash vesicular		1		1		
Raynaud's phenomenon		2		1		1
Recalled product administered		1		1		
Rectal haemorrhage	1	3			1	3
Red blood cell count decreased	1	1	1	1		
Renal artery stenosis		1				1
Renal artery thrombosis	1	1			1	1
Renal colic	2	3			2	3
Renal cyst		1				1
Renal disorder	1	1			1	1
Renal failure	3	11			3	11
Renal impairment		1				1
Renal infarct	1	1			1	1
Renal tubular necrosis	1	1			1	1
Respiration abnormal		1				1
Respiratory acidosis		1				1
Respiratory alkalosis	1	1	1	1		
Respiratory depression		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory disorder	1	6	1	1		5
Respiratory distress	1	11			1	11
Respiratory failure	1	8			1	8
Respiratory rate increased		3		2		1
Respiratory tract infection		2				2
Respiratory tract infection bacterial		1				1
Respiratory tract oedema		1				1
Restlessness	1	3	1	2		1
Retinal artery occlusion	1	5			1	5
Retinal detachment	1	1			1	1
Retinal fovea disorder		1				1
Retinal infarction	1	1			1	1
Retinal vein occlusion		5				5
Retinal vein thrombosis	2	2	1	1	1	1
Retrograde amnesia		1				1
Rhabdomyolysis	1	6			1	6
Rheumatoid arthritis	1	1			1	1
Rheumatoid factor increased		1				1
Rheumatoid factor positive	1	1	1	1		
Rhinitis		1		1		
Rhinorrhoea	1	7		3	1	4
Rhonchi		2		1		1
Rib fracture		1				1
Road traffic accident		5		1		4
Romberg test positive		1		1		
Rotator cuff syndrome		2		1		1
Salivary hypersecretion	2	2	1	1	1	1
SARS-CoV-2 ant body test negative		7		7		
SARS-CoV-2 ant body test positive		2		2		
SARS-CoV-2 test false positive		1		1		
SARS-CoV-2 test positive		10		4		6
Scan abdomen abnormal	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sciatica	1	1	1	1		
Scleral disorder		1				1
Seizure	5	17			5	17
Sensory disturbance	1	4			1	4
Sensory loss		3				3
Sepsis	3	10			3	10
Septic shock		4				4
Serum sickness		1				1
Shock	1	2			1	2
Shock haemorrhagic		2				2
Sinus arrest		1				1
Sinus arrhythmia	1	1	1	1		
Sinus bradycardia	2	4			2	4
Sinus disorder		1				1
Sinus tachycardia	1	6	1	3		3
Skin discolouration		1		1		
Skin exfoliation		1				1
Skin induration		1				1
Skin lesion	2	4		1	2	3
Skin mass		2		1		1
Skin necrosis	1	1			1	1
Skin reaction	1	1	1	1		
Skin ulcer		1		1		
Skin warm		1		1		
Sleep apnoea syndrome		1		1		
Sleep disorder	1	3	1	2		1
Sleep disorder due to general medical condition, insomnia type		1				1
Snoring	1	1	1	1		
Somnolence	2	17		8	2	9
Speech disorder	3	11	2	3	1	8
Spinal cord infarction		2				2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Spinal cord ischaemia		1				1
Spinal pain		2		1		1
Sputum abnormal		1				1
Staphylococcal bacteraemia		2				2
Staphylococcal sepsis		1				1
Staring		1				1
Status epilepticus		3				3
Stereotypy		1				1
Sternal fracture		1				1
Stress		1		1		
Subarachnoid haemorrhage	1	2			1	2
Subclavian vein thrombosis	1	2			1	2
Subdural haematoma	3	5			3	5
Subileus		1				1
Sudden death	8	28			8	28
Sudden hearing loss	1	3			1	3
Suffocation feeling	2	4	2	3		1
Superinfection	1	2	1	1		1
Superinfection bacterial		1				1
Superinfection viral		1				1
Superior vena cava syndrome		1				1
Supraventricular extrasystoles	2	5	1	1	1	4
Supraventricular tachycardia	2	4			2	4
Suspected COVID-19	3	7			3	7
Swelling face	4	5	1	1	3	4
Swelling of eyelid	1	1	1	1		
Syncope	7	21			7	21
Synovitis	1	1			1	1
Systemic inflammatory response syndrome		1				1
Systolic hypertension	1	1			1	1
Tachyarrhythmia	1	4		1	1	3
Tachycardia	23	76	6	19	17	57

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachypnoea	1	6	1	1		5
Target skin lesion		1				1
Taste disorder		1		1		
Temporomandibular joint syndrome		1		1		
Tenderness		1		1		
Tendon disorder	1	2			1	2
Tendonitis	1	3			1	3
Tendon pain	1	1	1	1		
Tendon rupture		1				1
Tension		1		1		
Tension headache	1	1	1	1		
Terminal state		1				1
Testicular pain		1		1		
Tetany	1	1			1	1
Therapeutic response unexpected		1		1		
Thirst		2		1		1
Throat irritation		1		1		
Thrombocytopenia	11	31			11	31
Thrombocytopenic purpura		1				1
Thrombocytosis	1	2		1	1	1
Thrombophlebitis	5	11	2	3	3	8
Thrombophlebitis superficial	8	17		2	8	15
Thrombosis	9	14			9	14
Thrombosis mesenteric vessel		1				1
Thyroid disorder		1		1		
Thyroiditis	1	1			1	1
Tinnitus	4	19	4	8		11
Tongue biting	1	4		1	1	3
Tongue haematoma		2		2		
Tongue oedema		1		1		
Tongue paralysis		1				1
Tonic clonic movements		3				3

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tonic convulsion		2				2
Tonsillar hypertrophy		1		1		
Tonsillitis	1	1			1	1
Torticollis	1	3	1	2		1
Toxicity to various agents		1				1
Toxic skin eruption		1				1
Toxocariasis		1				1
Toxoplasmosis		1		1		
Tracheal pain	1	1			1	1
Transaminases increased		1				1
Transient ischaemic attack	15	25			15	25
Transplant rejection	1	1			1	1
Tremor	10	25	6	9	4	16
Tricuspid valve incompetence		1				1
Trigeminal neuralgia	1	1			1	1
Troponin abnormal	1	1			1	1
Troponin increased	4	9	2	4	2	5
Type 1 diabetes mellitus		1				1
Type 2 diabetes mellitus		1				1
Type I hypersensitivity		1				1
Ulnar nerve palsy		1				1
Ultrasound scan abnormal	1	1			1	1
Underdose	2	10	2	10		
Upper-airway cough syndrome		1				1
Urinary incontinence	4	7	2	3	2	4
Urinary retention		1				1
Urinary tract infection	2	5	1	1	1	4
Urine odour abnormal		1		1		
Urticaria	4	19	3	6	1	13
Uveitis		1				1
Vaccination complication	1	2		1	1	1
Vaccination failure	54	99			54	99

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site bruising	1	1	1	1		
Vaccination site dermatitis		1		1		
Vaccination site discomfort	1	1	1	1		
Vaccination site eczema		1				1
Vaccination site erythema	6	16	4	12	2	4
Vaccination site haematoma		1				1
Vaccination site hyperaesthesia		1				1
Vaccination site hypersensitivity		9		9		
Vaccination site induration	1	4	1	3		1
Vaccination site infection		1				1
Vaccination site inflammation	1	5	1	2		3
Vaccination site joint inflammation		1				1
Vaccination site joint pain		1				1
Vaccination site lymphadenopathy		1		1		
Vaccination site movement impairment	1	5	1	2		3
Vaccination site oedema	2	6	2	4		2
Vaccination site pain	21	107	19	76	2	31
Vaccination site paraesthesia		1		1		
Vaccination site pruritus		3		1		2
Vaccination site rash		1				1
Vaccination site reaction	1	5	1	2		3
Vaccination site swelling	3	6	2	4	1	2
Vaccination site urticaria		1				1
Vaccination site warmth		2		2		
Vaginal haemorrhage		1				1
Varicose vein		1		1		
Vascular graft thrombosis	2	2			2	2
Vascular occlusion	1	1			1	1
Vascular pain		1		1		
Vascular purpura	4	7	2	2	2	5
Vascular stent stenosis	1	1			1	1
Vascular stent thrombosis		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vasculitis	1	1			1	1
Vein rupture		1				1
Vena cava thrombosis		1				1
Venous thrombosis	1	4			1	4
Venous thrombosis limb	3	8		1	3	7
Ventricular extrasystoles	3	9		2	3	7
Ventricular f brillation	2	5			2	5
Ventricular hypokinesia	2	3			2	3
Ventricular tachycardia	5	11			5	11
Vertigo	15	47	7	16	8	31
Vertigo positional	2	2			2	2
Vestibular disorder		2				2
Vestibular neuritis	3	6			3	6
Vestibulitis		1				1
Viral infection		1		1		
Visceral venous thrombosis	1	1			1	1
Vision blurred	4	11	1	2	3	9
Visual acuity reduced		4				4
Visual brightness		1				1
Visual field defect	1	1			1	1
Visual impairment	3	7	2	3	1	4
Vitamin D deficiency		1				1
Vlth nerve paralysis	1	3			1	3
Vitreous floaters		1				1
Volvulus of small bowel	1	1			1	1
Vomiting	20	70	13	28	7	42
Weight decreased	3	11	2	3	1	8
Weight increased	1	2	1	1		1
Wheezing		3				3
White blood cell count decreased	1	4	1	1		3
White blood cell count increased		3		1		2
White matter lesion		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Withdrawal hypertension		1				1
Wound	1	2	1	1		1
Wrong product administered	1	1	1	1		
Yellow skin		1		1		
	2,343	7,302	755	2145	1588	5157

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute vestibular syndrome		1		1		
Adult failure to thrive	1	1			1	1
Ageusia		1				1
Allergy to vaccine		1		1		
Anaphylactoid reaction		1				1
Anosmia		1				1
Aphasia	1	1			1	1
Arthralgia	1	2	1	2		
Asthenia	1	3	1	1		2
Asymptomatic COVID-19		8				8
Autoimmune thyroiditis	1	2			1	2
Bronchospasm		1				1
Cachexia	1	1			1	1
Cerebral haematoma		1				1
Chills	1	1	1	1		
Circumstance or information capable of leading to medication error		1		1		
Coma	1	1			1	1
COVID-19	7	83		2	7	81
Death		5				5
Deformity		1		1		
Diarrhoea		1		1		
Diplopia		1		1		
Disease recurrence	1	2			1	2
Drug ineffective	7	78			7	78
Dyspnoea exertional		1				1
Exposure during pregnancy	1	2			1	2
Exposure via breast milk		2		2		
Eyelid oedema		2		2		
Eyelid ptosis		1		1		
Face oedema		2		2		
Fall	1	4			1	4

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Foetal growth restriction	1	1
Foetal heart rate disorder	1	1
General physical health deterioration		2
Glaucoma	1	1
Haematemesis		1
Haematoma	1	1
Headache	1	3
Herpes zoster		2
Hypertension		4
Hyperthermia		1
Immune thrombocytopenia		2
Inappropriate schedule of product administration		2
Incorrect dose administered	1	1
Influenza like illness		4
Injection site pain		1
Insomnia		1
Intercepted product preparation error		1
Ischaemic stroke	1	1
Lip oedema		2
Liquid product physical issue	4	4
Lymphadenopathy		2
Maternal exposure during pregnancy	3	3
Musculoskeletal stiffness		2
Myalgia	2	3
Myocardial ischaemia		1
Neonatal respiratory acidosis	1	1
Nervous system disorder	1	1
No adverse event		2
Off label use		2
Overdose	6	6
Pain in extremity		2
Pancreatitis acute		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	1
			2
		1	1
			1
		1	1
1	2		1
	2		
	4		
	1		
			2
	2		
1	1		
	2		2
	1		
			1
	1		
		1	1
	2		
4	4		
			2
1	1	2	2
	2		
2	2		1
			1
		1	1
		1	1
	2		
	2		
6	6		
	2		
			1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonia aspiration		1				1
Poor quality product administered	189	254	189	254		
Premature baby	2	2	1	1	1	1
Product administered at inappropriate site		1		1		
Product complaint		15		15		
Product contamination physical	2	3	2	3		
Product label confusion		1		1		
Product physical issue	6	7	6	7		
Product preparation error	34	34	34	34		
Product preparation issue		6		6		
Product quality issue	1	2	1	2		
Product storage error	6	7	6	7		
Product temperature excursion issue	143	189	143	189		
Pulmonary embolism	1	2			1	2
Pyrexia	1	4		3	1	1
Radius fracture	1	1			1	1
Rash		1				1
Respiratory distress		1				1
Rhinitis	1	1	1	1		
SARS-CoV-2 ant body test negative		1		1		
SARS-CoV-2 test positive		2				2
Serology negative		1		1		
Small for dates baby		1				1
Somnolence	1	1			1	1
Speech disorder		1		1		
Spine malformation	1	1			1	1
Swelling face		2		2		
Tachycardia		1				1
Trisomy 21	1	1			1	1
Umbilical cord thrombosis	1	1			1	1
Underdose	1	6	1	6		
Vaccination failure		12				12

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site dysaesthesia		1		1		
Vaccination site erythema		1		1		
Vaccination site haemorrhage		1		1		
Vaccination site pain		1		1		
Vaccination site pruritus		1		1		
Vaccination site swelling		1		1		
Vertigo		1		1		
Wrong technique in product usage process		1		1		
	441	846	402	601	39	245

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Country Where Event Occurred

FRENCH GUIANA

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cerebral venous sinus thrombosis	1	1	1	1
Ischaemic stroke	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

FRENCH POLYNESIA

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Arthralgia		1		1
Asthenia		1		1
Confusional state		1		1
Dysstasia		1		1
Hyperaesthesia		1		1
Hyperthermia		1		1
Memory impairment		1		1
Movement disorder		1		1
Oxygen saturation decreased		1		1
		9		9

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute respiratory distress syndrome		1		1
Apraxia	1	1	1	1
Asthenia	1	2	1	2
Cardiopulmonary failure		1		1
Dermatitis bullous		1		1
Dermatosis		1		1
Dyspnoea	1	2	1	2
Dysstasia	1	1	1	1
Facial paralysis	1	1	1	1
Haemoptysis		1		1
Pulmonary embolism		1		1
Staphylococcal sepsis		1		1
Toxic epidermal necrolysis		1		1
	5	15	5	15

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Country Where Event Occurred
FRENCH SOUTHERN TERRITORIES

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Death		1		1
		1		1

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Country Where Event Occurred

GAMBIA

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Blood creatinine increased		1		1
Hypertension		1		1
Oedema peripheral		1		1
		3		3

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Country Where Event Occurred

GEORGIA

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Sepsis		1		1
		1		1

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Liquid product physical issue	1	1	1	1		
Pneumonia		1				1
Poor quality product administered	1	1	1	1		
	2	3	2	2		1

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Country Where Event Occurred

GERMANY

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	1	6			1	6		
Abdominal distension	1	2			1	2		
Abdominal pain	18	36		1	17	28	1	8
Abdominal pain lower	3	8			3	7		1
Abdominal pain upper	7	22			6	15	1	7
Abnormal behaviour	1	1			1	1		
Abnormal faeces	8	15			8	14		1
Abortion missed		1						1
Abortion spontaneous		4						4
Abscess		1						1
Abscess limb		1						1
Abscess rupture	1	1					1	1
Accidental exposure to product	1	2			1	2		
Accidental overdose		11				9		2
Acidosis		1						1
Acne	1	1			1	1		
Acute coronary syndrome		5						5
Acute febrile neutrophilic dermatosis		2						2
Acute kidney injury	5	14					5	14
Acute myeloid leukaemia		1				1		
Acute myocardial infarction	3	13					3	13
Acute phase reaction		1				1		
Acute respiratory distress syndrome	1	3					1	3
Acute respiratory failure	1	3					1	3
Acute stress disorder		2						2
Adverse event	2	2			2	2		
Ageusia	4	12			4	12		
Aggression		1						1
Agitation		4				1		3
Agranulocytosis		1						1
Alanine aminotransferase increased	1	3			1	1		2
Allergic oedema		2				1		1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Allergy to vaccine	4	7
Allodynia		1
Alopecia		3
Altered state of consciousness		4
Amenorrhoea	1	1
Amino acid level decreased		1
Amnesia	1	5
Amnesic disorder		1
Anaemia	2	3
Anaesthesia		1
Anaesthesia oral	1	1
Anaphylactic reaction	15	93
Anaphylactic shock	9	23
Anaphylactoid reaction		2
Anger	1	1
Angina pectoris	7	22
Angioedema	5	32
Anorectal disorder		1
Anosmia	1	5
Anxiety	4	9
Aortic aneurysm		2
Aortic dissection		1
Aortic valve stenosis		1
Apathy		4
Aphasia	2	16
Aphthous ulcer	1	1
Appendicitis		
Application site erythema	1	1
Application site pain	1	1
Application site vesicles		1
Application site warmth	1	1
Arrhythmia	13	40

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3	2	4
			1		
			1		2
	1				4
				1	1
			1		
		1	2		3
					1
		2	3		
					1
		1	1		
				15	93
	1			9	23
					2
		1	1		
				7	22
				5	32
					1
		1	5		
		4	7		2
					2
					1
					1
			1		3
		2	7		9
		1	1		
	1				
		1	1		
		1	1		
					1
		1	1		
	1			13	40

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Arterial occlusive disease	2	3
Arterial thrombosis		2
Arteriosclerosis		2
Arthralgia	61	148
Arthritis		1
Arthropathy	1	2
Ascites	1	2
Aspartate aminotransferase increased	2	4
Aspiration		2
Asthenia	88	210
Asthenopia		1
Asthma	6	24
Asymptomatic COVID-19	2	7
Ataxia		5
Atrial fibrillation	4	18
Atrial flutter		1
Atrial tachycardia		1
Atrioventricular block complete		3
Atrioventricular block first degree		1
Autoimmune disorder	3	4
Autoimmune thyroiditis		1
Autonomic nervous system imbalance		2
Axillary pain	4	14
Back pain	16	36
Balance disorder	4	5
Basal ganglia infarction		1
Basedow's disease	1	1
Basilar artery thrombosis		2
Bedridden		2
Bell's palsy	1	2
Beta haemolytic streptococcal infection	1	1
Bladder discomfort	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	3
					2
			1		1
	17	59	135	2	13
					1
		1	1		1
				1	2
		2	3		1
					2
		83	183	5	27
			1		
		5	16	1	8
			1	2	6
					5
				4	18
			1		
					1
			1		3
				3	4
					1
			1		1
		4	13		1
		16	34		2
		4	5		
					1
				1	1
					2
			1		1
				1	2
				1	1
		1	2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bladder dysfunction		1
Bladder irritation	1	1
Bladder pain	1	2
Blepharitis		1
Blindness transient	1	1
Blister		5
Blood blister	1	1
Blood calcium decreased		2
Blood calcium increased		1
Blood count abnormal	1	1
Blood creatine phosphokinase increased	1	1
Blood creatinine increased		1
Blood disorder		1
Blood glucose abnormal		1
Blood glucose decreased		4
Blood glucose fluctuation		2
Blood glucose increased		3
Blood immunoglobulin M increased		1
Blood lactate dehydrogenase increased	1	3
Blood methaemoglobin present		1
Blood potassium decreased		3
Blood pressure abnormal	1	3
Blood pressure decreased	3	13
Blood pressure fluctuation	1	4
Blood pressure immeasurable	1	3
Blood pressure increased	8	40
Blood pressure systolic increased	1	1
Blood sodium decreased		2
Blood test abnormal	1	2
Blood thyroid stimulating hormone increased		1
Blood urine present		2
Bloody discharge		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1		
		1	2		
			1		
				1	1
			3		2
		1	1		
			1		1
		1	1		
				1	1
					1
					1
			1		
			2		2
			1		1
			3		
			1		
		1	1		2
			1		
					3
		1	3		
	1		3	3	10
			3	1	1
				1	3
	2	5	22	3	18
				1	1
			1		1
		1	2		
			1		
					2
			1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Body temperature decreased	1	3
Body temperature fluctuation	1	1
Body temperature increased	41	88
Bone pain	11	33
Booster dose missed	1	1
Borrelia infection	1	1
Bradycardia		3
Bradyphrenia	1	1
Brain death		1
Brain injury		1
Brain oedema		3
Brain stem infarction	2	3
Brain stem ischaemia	1	1
Breast abscess	1	1
Breast cancer	2	2
Breast cancer recurrent	1	1
Breast inflammation	1	1
Breast pain		2
Breast swelling	1	1
Bronchial disorder		1
Bronchial irritation	1	1
Bronchial obstruction		2
Bronchitis	1	3
Bronchitis bacterial		1
Bronchospasm	1	7
Burning sensation	4	21
Burning sensation mucosal	1	1
Bursitis		1
Capillary nail refill test abnormal		2
Carbon dioxide decreased		1
Cardiac aneurysm		1
Cardiac arrest	2	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		
		1	1		
1	1	41	79		9
		11	31		2
		1	1		
				1	1
					3
		1	1		
					1
					1
					3
				2	3
				1	1
				1	1
				2	2
				1	1
				1	1
	1		2		
				1	1
			1		
		1	1		
					2
		1	2		1
					1
			2	1	5
		3	11	1	10
		1	1		
	1				1
			1		1
					1
					1
				2	12

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiac death		1
Cardiac discomfort	1	3
Cardiac failure	2	28
Cardiac failure acute	2	3
Cardiac failure congestive		3
Cardiac valve disease	1	1
Cardiogenic shock	1	5
Cardiomyopathy		1
Cardio-respiratory arrest		1
Cardiovascular disorder	15	48
Cardiovascular insufficiency	3	9
Carotid artery occlusion		1
Cerebellar ataxia		1
Cerebellar syndrome		1
Cerebral artery embolism	1	1
Cerebral haemorrhage	6	13
Cerebral infarction	8	18
Cerebral ischaemia	1	3
Cerebral thrombosis	1	3
Cerebral venous sinus thrombosis	9	12
Cerebral venous thrombosis		2
Cerebral ventricle collapse		1
Cerebrovascular accident	7	38
Cerebrovascular disorder	1	2
Cervical vertebral fracture	1	1
Cervix haematoma uterine		1
Chest discomfort	16	29
Chest pain	14	39
Chills	204	388
Chronic idiopathic pain syndrome	1	1
Chronic kidney disease		1
Chronic lymphocytic leukaemia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	2		1
				2	28
				2	3
					3
				1	1
				1	5
					1
					1
		12	36	3	12
				3	9
					1
					1
					1
				1	1
				6	13
				8	18
				1	3
				1	3
				9	12
					2
					1
				7	38
				1	2
				1	1
					1
		13	21	3	8
		12	28	2	11
1	21	195	355	9	33
		1	1		
					1
				1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chronic obstructive pulmonary disease	1	6
Circulatory collapse	13	48
Circumoral oedema		1
Cluster headache		1
Coagulation time prolonged		1
Coagulopathy	2	3
Cold sweat	2	10
Colitis ulcerative		4
Coma		1
Complement factor C3 increased		1
Condition aggravated	9	18
Confusional state	3	14
Conjunctival haemorrhage	1	3
Conjunctival hyperaemia		1
Conjunctivitis	2	6
Constipation	3	5
Contusion	1	2
Coordination abnormal		1
Coronary artery disease	1	1
Coronary artery dissection		1
Coronary artery stenosis		1
Coronary artery thrombosis	1	2
Coronavirus infection		1
Coronavirus test positive	1	3
Cor pulmonale	1	2
Cough	18	60
COVID-19	51	240
COVID-19 pneumonia		9
Cranial nerve decompression		1
Cranial nerve disorder		1
C-reactive protein increased	5	13
Crepitations		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		5
	1			13	48
			1		
			1		
			1		
		1	1	1	2
		2	5		5
					4
					1
			1		
		3	9	6	9
		3	6		8
				1	3
					1
		2	4		2
		3	5		
				1	2
					1
				1	1
					1
					1
				1	2
			1		
			1	1	2
				1	2
	1	17	47	1	13
	1	16	70	35	170
					9
					1
			1		
		3	8	2	5
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Creutzfeldt-Jakob disease		2
Crying	1	1
Cutaneous vasculitis		1
Cyanosis	3	9
Cystitis	2	3
Cystitis haemorrhagic		1
Dark circles under eyes		1
Deafness		6
Deafness transitory		1
Deafness unilateral		2
Death	32	141
Decreased appetite	10	27
Deep vein thrombosis	14	28
Defaecation urgency		1
Dehydration	1	4
Delirium	1	5
Delusion		1
Dementia	1	7
Depressed level of consciousness		6
Depressed mood	2	3
Depression	2	6
Depressive symptom	1	1
Dermatitis allergic	2	11
Dermatitis contact	1	1
Diabetes mellitus		1
Diaphragmalgia		1
Diarrhoea	53	144
Diarrhoea haemorrhagic	3	3
Diet refusal		3
Digestive enzyme abnormal		1
Diplopia	1	4
Discomfort	3	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		1	1		
					1
		2	5	1	4
		2	3		
					1
			1		
					6
					1
					2
				32	141
		10	24		3
				14	28
			1		
		1	1		3
				1	5
					1
				1	7
			1		5
		2	2		1
		2	5		1
		1	1		
		2	7		4
		1	1		
					1
			1		
	10	48	122	5	22
				3	3
					3
			1		
		1	2		2
	1	3	3		1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Disease progression		1
Disease recurrence	3	10
Disorientation		5
Disseminated intravascular coagulation		1
Disturbance in attention	11	37
Diverticulitis	2	3
Dizziness	113	325
Drug eruption	2	3
Drug hypersensitivity	1	1
Drug ineffective	34	143
Drug interaction	3	5
Dry age-related macular degeneration		1
Dry eye	1	2
Dry mouth	4	16
Dry skin	1	2
Dry throat		1
Dysaesthesia	2	10
Dysarthria	2	6
Dysgeusia	5	16
Dysgraphia	1	2
Dyskinesia		1
Dyslalia		1
Dysmenorrhoea	4	4
Dyspepsia		2
Dysphagia	4	19
Dysphemia	1	1
Dysphonia	2	14
Dyspnoea	41	167
Dyspnoea at rest	1	3
Dyspnoea exertional	7	18
Dysstasia	1	3
Dysuria		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	6	2	4
			1		4
					1
		11	29		8
				2	3
	36	105	254	8	71
		2	3		
				1	1
				34	143
		2	3	1	2
					1
		1	2		
		4	11		5
		1	2		
			1		
		2	6		4
		1	1	1	5
		4	13	1	3
		1	2		
					1
					1
		4	4		
			2		
			7	4	12
		1	1		
		2	10		4
	2	28	83	13	84
				1	3
		6	10	1	8
			2	1	1
					2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ear congestion	1	1
Ear discomfort	4	8
Ear pain	4	9
Ear swelling	1	1
Eczema	4	9
Eczema asteatotic	1	1
Electric shock sensation		1
Electrocardiogram QT prolonged		1
Electrocardiogram ST segment depression		1
Electrocardiogram T wave inversion		1
Electroencephalogram abnormal	1	1
Electrolyte depletion		1
Electrolyte imbalance		1
Embedded device		1
Embolism cerebral infarction	1	2
Embolism stroke		1
Embolism		1
Embolism arterial		1
Emotional disorder		1
Enanthema	1	2
Encephalitis		1
Endocrine ophthalmopathy	1	1
Endometriosis	1	1
Enteritis	1	2
Eosinophil count decreased		1
Epicondylitis	1	1
Epilepsy	4	29
Epistaxis	3	8
Epstein-Barr virus infection reactivation		3
Eructation	1	1
Erysipelas	3	6
Erythema	26	81

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		4	6		2
		3	8	1	1
		1	1		
		4	8		1
		1	1		
			1		
					1
					1
					1
		1	1		
			1		
					1
					1
				1	2
					1
					1
					1
		1	1		1
					1
				1	1
		1	1		
		1	1		1
			1		
		1	1		
				4	29
		3	7		1
					3
		1	1		
				3	6
		24	62	2	19

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Erythema migrans	1	1
Erythema multiforme		1
Euphoric mood	1	1
Evans syndrome		1
Exercise tolerance decreased	1	1
Expired product administered	1	1
Exposure during pregnancy	8	10
Exposure via breast milk		4
Exposure via skin contact	1	1
Extrapyramidal disorder		1
Extrasystoles		1
Eye discharge	1	1
Eye haemorrhage	1	4
Eye infection	1	1
Eye irritation	3	8
Eyelid exfoliation	1	1
Eyelid function disorder	1	1
Eyelid haematoma	1	1
Eyelid irritation	1	1
Eyelid oedema		3
Eye oedema	1	1
Eye pain	5	9
Eye pruritus	3	12
Eye swelling	5	9
Face oedema	2	3
Facial discomfort	2	2
Facial nerve disorder		1
Facial pain	1	4
Facial paralysis	10	34
Facial paresis	13	37
Factor VIII inhibition		1
Faecaloma	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
		1	1		
					1
				1	1
		1	1		
		8	10		
			4		
		1	1		
					1
			1		
		1	1		
				1	4
		1	1		
		3	7		1
		1	1		
				1	1
		1	1		
		1	1		
			1		2
		1	1		
		5	9		
		3	6		6
		5	8		1
		2	3		
		2	2		
					1
		1	4		
				10	34
		4	17	9	20
					1
				1	1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Fall	8	18
Fatigue	262	581
Fear	1	2
Febrile infection		1
Feeling abnormal	7	21
Feeling cold	30	59
Feeling drunk		1
Feeling hot	12	39
Feeling of body temperature change	3	12
Feeling of despair		1
Femoral artery embolism		1
Fibrin D dimer increased		2
Fibromyalgia	3	3
Fistula		1
Flank pain	1	2
Flatulence	1	4
Fluid retention		1
Flushing	15	54
Food refusal		3
Formication	2	3
Fracture		1
Freezing phenomenon	1	1
Frequent bowel movements	1	1
Gait disturbance	8	18
Gait inability		2
Gamma-glutamyltransferase increased	2	3
Gastric dilatation	1	1
Gastritis		1
Gastrointestinal disorder	1	2
Gastrointestinal haemorrhage	1	1
Gastrointestinal inflammation	1	1
Gastrointestinal motility disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2	7	16
1	44	258	551	4	30
		1	1		1
					1
		6	19	1	2
		29	52	1	7
			1		
		12	29		10
		3	12		
			1		
					1
			2		
		3	3		
					1
		1	2		
		1	4		
			1		
		14	31	1	23
			1		2
		2	3		
					1
				1	1
		1	1		
		4	10	4	8
			1		1
		2	2		1
		1	1		
			1		
		1	1		1
				1	1
		1	1		
			1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastrointestinal necrosis		2
Gastrointestinal pain	2	5
Generalised tonic-clonic seizure		3
General physical condition abnormal		6
General physical health deterioration	5	41
Genital haemorrhage		1
Genital herpes	2	2
Giant cell arteritis		1
Gingival bleeding		3
Gingival pain	1	1
Gingival swelling	1	3
Gingivitis	1	3
Glomerular filtration rate decreased		1
Glossitis	1	1
Gout		1
Groin pain	1	2
Guillain-Barre syndrome	4	5
Guttate psoriasis	1	1
Haematemesis		1
Haematochezia	2	3
Haematocrit decreased		1
Haematoma	7	17
Haematoma infection		1
Haematuria	1	2
Haemoglobin decreased		2
Haemolytic uraemic syndrome	1	1
Haemoptysis	1	5
Haemorrhage	3	6
Haemorrhagic diathesis	1	1
Haemothorax		1
Hallucination	4	7
Hand dermatitis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		2	2		3
					3
					6
		3	14	2	27
					1
		2	2		
					1
			1		2
		1	1		
		1	2		1
		1	1		2
			1		
		1	1		
			1		
		1	2		
				4	5
		1	1		
					1
				2	3
			1		
		6	10	1	7
					1
		1	2		
			1		1
				1	1
		1	4		1
				3	6
				1	1
					1
				4	7
		1	1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Headache	348	791
Head discomfort	6	16
Head injury		1
Heart rate increased	9	20
Heavy menstrual bleeding	7	8
Hemiataxia	1	1
Hemiparaesthesia		2
Hemiparesis	4	16
Hemiplegia		1
Hepatic enzyme increased	1	5
Hepatic failure		3
Hepatitis	2	2
Herpes dermatitis		1
Herpes ophthalmic	1	1
Herpes simplex		3
Herpes virus infection	1	2
Herpes zoster	60	97
Herpes zoster infection neurological		1
Herpes zoster meningitis	1	2
Herpes zoster oticus		2
Herpes zoster reactivation		1
Histiocytosis	1	1
Hordeolum		1
Hot flush	5	17
Huntington's disease		3
Hyperaesthesia	3	6
Hypercalcaemia		2
Hyperglycaemia		2
Hyperhidrosis	23	47
Hyperkalaemia		1
Hypersensitivity	21	96
Hypersensitivity vasculitis		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	47	335	710	13	81
		4	12	2	4
					1
		6	13	3	7
		6	7	1	1
				1	1
					2
				4	16
					1
			2	1	3
					3
				2	2
			1		
				1	1
			2		1
		1	2		
		55	84	5	13
					1
				1	2
					2
			1		
				1	1
			1		
		4	14	1	3
					3
		3	5		1
					2
					2
		22	42	1	5
					1
	3	15	43	6	53
					3

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hypersomnia	3	7
Hypertension	15	74
Hypertensive crisis	2	15
Hypertensive emergency		1
Hypertensive heart disease	1	1
Hyperthermia		1
Hyperventilation	1	10
Hypoacusis	1	3
Hypoaesthesia	24	57
Hypoaesthesia oral	4	16
Hypoglycaemia		1
Hypokalaemia	1	1
Hypokinesia	1	2
Hyponatraemia	1	5
Hypophagia		2
Hyporesponsive to stimuli		1
Hypotension	10	43
Hypothermia		3
Hypothyroidism	1	2
Hypotonia	7	21
Hypoventilation		1
Hypoxia		2
Idiopathic intracranial hypertension		2
IIIrd nerve paresis	1	2
Ileus		1
Ileus paralytic	1	3
Illness	3	6
Immune thrombocytopenia	2	7
Immunisation reaction		
Impaired driving ability	1	1
Impaired healing		1
Impaired work ability	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	5		2
	2	10	30	5	44
				2	15
					1
				1	1
					1
		1	5		5
		1	2		1
	2	20	45	4	12
		3	12	1	4
			1		
				1	1
		1	2		
			3	1	2
					2
					1
		7	22	3	21
					3
				1	2
		7	16		5
					1
					2
					2
				1	2
					1
				1	3
		3	5		1
				2	7
1	1				
		1	1		
					1
		1	2		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Inadequate aseptic technique in use of product		1
Inappropriate schedule of product administration	11	27
Incomplete course of vaccination	1	5
Incontinence	1	1
Incorrect dose administered	2	2
Incorrect route of product administration	19	73
Increased upper airway secretion		1
Induration	1	1
Infarction		1
Infection	2	7
Infection susceptibility increased	1	1
Infective exacerbation of chronic obstructive airways disease		1
Inflammation	4	5
Inflammatory marker increased	1	2
Influenza	12	17
Influenza like illness	62	118
Initial insomnia	1	1
Injected limb mobility decreased	1	2
Injection site hypoaesthesia	1	1
Injection site pain	2	4
Injection site swelling	1	1
Insomnia	10	19
Intentional product misuse		1
International normalised ratio decreased		1
Intestinal gangrene		1
Intestinal haemorrhage	1	1
Intestinal infarction	1	2
Intestinal ischaemia	1	2
Intestinal obstruction		1
Intracardiac thrombus	2	2
Intraocular pressure increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		11	27		
		1	5		
				1	1
		2	2		
		18	71	1	2
			1		
		1	1		
					1
	1	1	3	1	4
				1	1
					1
		3	3	1	2
		1	1		1
		12	17		
		61	114	1	4
		1	1		
		1	2		
		1	1		
		2	4		
		1	1		
		10	18		1
			1		
			1		
					1
				1	1
				1	2
				1	2
					1
				2	2
			1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Iridocyclitis		2
Iron deficiency	1	1
Irregular breathing		2
Ischaemia	1	2
Ischaemic cerebral infarction		2
Ischaemic stroke	1	3
Jaundice		2
Jaw clicking		1
Joint range of motion decreased	2	6
Joint stiffness	2	2
Joint swelling	2	4
Jugular vein thrombosis	2	2
Koebner phenomenon	1	1
Lack of spontaneous speech	1	1
Lacrimation increased	3	11
Language disorder	1	2
Large intestine perforation	1	1
Laryngeal oedema		5
Laryngospasm		1
Leukocytosis		1
Leukopenia	3	4
Lhermitte's sign		1
Limb deformity	1	1
Limb discomfort	37	63
Limb injury	1	1
Lipase increased		1
Lipid metabolism disorder		1
Lipids increased		1
Lip oedema		2
Lip pain	1	1
Lip swelling	4	11
Listless	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		1	1		
					2
				1	2
					2
				1	3
			2		
					1
		1	4	1	2
		2	2		
		2	2		2
				2	2
		1	1		
		1	1		
		3	8		3
				1	2
				1	1
					5
					1
					1
				3	4
			1		
		1	1		
		35	55	2	8
		1	1		
					1
			1		
			1		
			1		1
		1	1		
		4	4		7
		2	3		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Livedo reticularis		1
Liver function test increased		2
Localised infection		1
Local reaction	7	21
Loss of consciousness	8	27
Loss of control of legs	1	1
Loss of personal independence in daily activities	1	1
Lower respiratory tract congestion		1
Lung disorder	1	3
Lymphadenitis	2	8
Lymphadenopathy	62	119
Lymphangitis	1	2
Lymphatic disorder	2	2
Lymph node pain	17	34
Lymphocyte count decreased		1
Lymphocyte count increased	1	1
Lymphocytic infiltration		1
Lymphoedema	3	5
Lymphopenia	1	3
Macular degeneration		
Macular hole		
Malaise	50	127
Marasmus		1
Mastitis	1	1
Maternal exposure before pregnancy	1	2
Maternal exposure during pregnancy	31	68
Maternal exposure timing unspecified		1
Memory impairment		5
Meningism		3
Meningitis	1	2
Meningitis aseptic		1
Meningitis viral		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					2
			1		
		7	18		3
				8	27
				1	1
		1	1		
			1		
		1	3		
		2	6		2
	1	61	115	1	4
				1	2
		2	2		
		17	34		
			1		
				1	1
					1
		2	4	1	1
			1	1	2
1	1				
1	1				
	37	48	105	2	22
					1
				1	1
		1	2		
		30	66	1	2
			1		
			2		3
			1		2
				1	2
					1
					1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Menstrual cycle management	2	2
Menstrual disorder	3	9
Menstruation irregular	3	4
Mental disorder	1	4
Mental impairment	1	2
Mesenteric vascular occlusion	1	1
Mesenteric vein thrombosis	1	1
Metabolic acidosis		1
Microcytic anaemia		2
Microembolism		1
Micturition disorder		1
Micturition urgency		1
Middle insomnia		2
Migraine	13	23
Migraine with aura	1	1
Migraine without aura	1	1
Mobility decreased	4	17
Monocyte count decreased		1
Monocytosis		1
Monoparesis	1	1
Monoplegia	3	5
Motion sickness	1	1
Mouth haemorrhage		1
Mouth swelling	1	3
Movement disorder	6	12
Multimorbidity		1
Multiple organ dysfunction syndrome		4
Multiple sclerosis	2	3
Multiple sclerosis relapse	1	5
Muscle contractions involuntary		1
Muscle discomfort	1	2
Muscle mass		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2		
		3	9		
		2	3	1	1
		1	3		1
				1	2
				1	1
				1	1
					1
					2
					1
			1		
			1		
			2		
		12	20	1	3
		1	1		
		1	1		
		3	14	1	3
			1		
					1
		1	1		
				3	5
		1	1		
		1	1		2
		5	9	1	3
					1
					4
1	1			2	3
1	1			1	5
					1
		1	2		
			1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Muscle spasms	9	18
Muscle spasticity	1	2
Muscle strain		
Muscle swelling	1	2
Muscle tightness	3	5
Muscle twitching	2	9
Muscular weakness	12	26
Musculoskeletal chest pain	1	6
Musculoskeletal discomfort	1	1
Musculoskeletal disorder	1	2
Musculoskeletal pain	2	6
Musculoskeletal stiffness	4	7
Myalgia	91	237
Myasthenia gravis		1
Mycoplasma infection		1
Myelitis	1	2
Myocardial infarction	9	15
Myocardial ischaemia		1
Myocarditis	5	11
Myoclonus		2
Myofascial spasm	1	1
Myosclerosis		2
Myositis		1
Nasal congestion	1	6
Nasal discomfort	1	1
Nasopharyngitis	15	41
Nausea	112	275
Neck pain	17	34
Neoplasm		1
Neoplasm malignant	1	1
Nervousness		1
Nervous system disorder	3	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		8	14	1	4
		1	1		1
	1				
		1	2		
	1	2	4	1	1
		2	7		2
		11	19	1	7
		1	3		3
		1	1		
		1	2		
		2	4		2
		3	6	1	1
	28	89	221	2	16
					1
			1		
				1	2
				9	15
					1
				5	11
			1		1
		1	1		
					2
			1		
		1	5		1
		1	1		
	1	15	37		4
	29	105	234	7	41
		16	32	1	2
					1
				1	1
			1		
		1	1	2	6

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Neuralgia	15	21
Neuralgic amyotrophy		2
Neuritis		3
Neurodermatitis	2	5
Neurological symptom	1	1
Neuropathy peripheral	1	3
Neutropenia		2
Neutrophil count increased		1
Night sweats	5	11
Nodule		1
Normocytic anaemia	1	1
Nuchal rigidity	1	3
Nystagmus		1
Obstructive airways disorder		1
Obstructive pancreatitis		1
Occipital neuralgia		1
Occupational exposure to product		1
Ocular discomfort	3	7
Ocular hyperaemia	3	9
Ocular icterus		1
Ocular myasthenia	1	1
Odynophagia		
Oedema		2
Oedema peripheral	2	7
Oesophageal irritation		1
Off label use	14	40
Oligoarthritis		1
Oliguria		1
Onychoclasia		1
Ophthalmic herpes simplex	1	1
Ophthalmic herpes zoster	2	4
Ophthalmic vein thrombosis	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		15	21		
					2
			3		
		2	5		
		1	1		
				1	3
					2
			1		
		5	11		
			1		
				1	1
		1	2		1
					1
					1
			1		
			1		
		3	6		1
		3	7		2
			1		
				1	1
	1				
			1		1
		2	5		2
					1
		14	40		
					1
					1
			1		
				1	1
				2	4
				2	4

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Optic nerve disorder		
Optic neuritis	1	3
Optic neuropathy		1
Oral discomfort	4	5
Oral herpes	4	8
Oral mucosa erosion		1
Oral mucosal blistering		1
Oral mucosal erythema	1	1
Oral pain		1
Organ failure		1
Organising pneumonia	1	1
Oropharyngeal blistering		2
Oropharyngeal discomfort		1
Oropharyngeal pain	16	37
Oropharyngeal swelling		1
Orthopnoea		2
Orthostatic hypotension		1
Orthostatic intolerance		2
Otitis media		1
Overdose	2	3
Overweight	1	1
Oxygen saturation decreased	3	15
Pain	28	71
Painful respiration	4	6
Pain in extremity	220	452
Pain in jaw	1	3
Pain of skin	3	5
Pallor	1	5
Palpitations	20	74
Pancreatitis acute		1
Panic attack	1	5
Panic disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1				
				1	3
					1
		4	5		
		4	7		1
			1		
			1		
		1	1		
					1
					1
				1	1
					2
			1		
	1	16	34		3
					1
					2
			1		
			1		1
			1		
		2	2		1
		1	1		
		2	4	1	11
		28	60		11
		3	5	1	1
		216	426	4	26
		1	3		
		3	5		
		1	1		4
	1	19	55	1	19
					1
			1	1	4
			1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Panic reaction	1	2
Papilloedema		1
Paraesthesia	40	121
Paraesthesia oral	10	28
Paralysis	3	7
Paranoia		1
Paresis		3
Parkinsonian rest tremor		1
Parkinson's disease		2
Parosmia	2	5
Partial seizures		2
Pathogen resistance		1
Pelvic fracture		1
Pelvic pain		1
Pelvic venous thrombosis	2	2
Pemphigus		2
Performance status decreased	4	6
Pericardial effusion	1	3
Perioral dermatitis		1
Peripheral circulatory failure	1	6
Peripheral coldness	3	5
Peripheral embolism		2
Peripheral swelling	14	31
Peripheral vascular disorder	9	35
Peritonitis		1
Personality change		6
Petechiae	4	14
Petit mal epilepsy		1
Pharyngeal erythema	1	1
Pharyngeal hypoaesthesia		2
Pharyngeal inflammation	1	2
Pharyngeal oedema		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
					1
	3	35	80	5	41
		8	22	2	6
				3	7
					1
			2		1
			1		
					2
		2	4		1
					2
					1
					1
			1		
				2	2
					2
		4	6		
				1	3
			1		
		1	4		2
		3	5		
			1		1
		13	23	1	8
	1	9	20		15
					1
			1		5
		2	7	2	7
					1
		1	1		
			2		
		1	2		
					1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pharyngeal paraesthesia		1
Pharyngeal swelling	1	11
Pharyngitis		2
Phlebitis		1
Photophobia	2	2
Photopsia		2
Photosensitivity reaction	1	2
Physical deconditioning	1	1
Pituitary tumour benign	1	1
Platelet count decreased	1	2
Platelet count increased	1	1
Platelet function test abnormal	1	1
Pleocytosis		1
Pleural effusion	2	4
Pleuritic pain		1
Pneumonia	6	26
Pneumonia aspiration		3
Pneumonia bacterial		1
Pneumonia viral		1
Pneumonitis	1	1
Pollakiuria	1	1
Polyarthrits	1	2
Polycythaemia	1	1
Polydipsia		1
Polymenorrhoea	1	1
Polymyalgia rheumatica		2
Polyneuropathy	1	4
Polyuria		1
Poor peripheral circulation	1	1
Poor quality product administered	10	39
Poor quality sleep	2	8
Post herpetic neuralgia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
	1		3	1	8
			2		
			1		
		2	2		
			2		
		1	2		
		1	1		
				1	1
		1	1		1
				1	1
		1	1		
			1		
				2	4
			1		
				6	26
					3
					1
					1
				1	1
		1	1		
				1	2
				1	1
					1
		1	1		
					2
1	1			1	4
					1
		1	1		
		10	37		2
		2	6		2
		1	1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Postictal state		1
Postoperative wound infection	1	1
Pregnancy with contraceptive device		1
Presyncope	5	18
Product administered at inappropriate site	2	3
Product administration error	1	1
Product dose omission issue		2
Productive cough	1	1
Product preparation issue		2
Product storage error	6	7
Product supply issue		1
Product temperature excursion issue	6	34
Product use issue	6	23
Protein urine present		1
Pruritus	32	95
Pruritus allergic		2
Psoriasis	1	3
Psychogenic seizure	1	1
Psychological factor affecting medical condition		1
Psychomotor hyperactivity		2
Psychomotor retardation	1	2
Psychomotor skills impaired	1	1
Pulmonary artery thrombosis		1
Pulmonary embolism	22	53
Pulmonary hypertension		1
Pulmonary infarction	2	3
Pulmonary oedema		3
Pulmonary pain	2	4
Pulmonary vasculitis		1
Pulse absent		1
Pulse waveform abnormal		1
Pupillary disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
					1
		5	13		5
		2	3		
		1	1		
			1		1
		1	1		
			2		
		6	7		
			1		
		6	32		2
		6	23		
			1		
	1	32	71		24
			1		1
		1	2		1
				1	1
					1
					2
		1	1		1
		1	1		
					1
				22	53
					1
				2	3
					3
		2	3		1
					1
					1
			1		
			1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pustule	3	9
Pyelonephritis acute	1	1
Pyrexia	214	450
Quadripareisis		2
Quality of life decreased	1	1
Radiculopathy		2
Rash	34	98
Rash erythematous	4	6
Rash macular	5	10
Rash maculo-papular	2	4
Rash papular		2
Rash pruritic	7	18
Rash pustular	2	3
Rash vesicular	5	8
Raynaud's phenomenon		1
Reaction to excipient		1
Red blood cell count decreased		1
Red blood cell sedimentation rate increased	1	2
Reduced facial expression	1	1
Renal failure	2	11
Renal impairment		1
Renal pain	2	5
Respiration abnormal	2	5
Respiratory disorder	2	2
Respiratory distress	8	81
Respiratory failure		7
Respiratory fume inhalation disorder		1
Respiratory rate decreased		1
Respiratory rate increased		1
Respiratory symptom		1
Respiratory tract infection		4
Respiratory tract infection viral		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	7		2
				1	1
	19	208	398	6	52
					2
		1	1		
			1		1
	4	31	64	3	34
		4	6		
		4	9	1	1
		2	4		
			2		
		6	15	1	3
		2	3		
		5	8		
			1		
			1		
			1		
		1	2		
		1	1		
				2	11
					1
		2	3		2
		2	5		
		2	2		
				8	81
					7
					1
			1		
			1		
			1		
					4
			1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory tract oedema		1
Resting tremor		1
Restlessness	6	14
Resuscitation		1
Retching	1	5
Retinal artery occlusion	1	2
Retinal detachment	1	1
Retinal disorder		1
Retinal tear		2
Retinal vein thrombosis	1	1
Retinopathy		1
Retrograde amnesia		2
Revers ble cerebral vasoconstriction syndrome		1
Rheumatic disorder	1	3
Rheumatoid arthritis	3	5
Rhinalgia		2
Rhinitis	1	3
Rhinitis allergic		1
Rhinorrhoea	7	29
Rhonchi		2
Rib fracture	1	1
Rosacea		1
Salivary gland enlargement		2
Salivary hypersecretion	2	2
SARS-CoV-2 ant body test		1
SARS-CoV-2 ant body test negative	1	11
SARS-CoV-2 ant body test positive	3	25
SARS-CoV-2 sepsis		1
SARS-CoV-2 test positive	3	19
Scratch		2
Seasonal allergy	2	3
Secondary hypertension		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
		4	11	2	3
					1
			4	1	1
				1	2
				1	1
					1
					2
				1	1
					1
			1		1
					1
		1	2		1
				3	5
			2		
		1	3		
					1
		7	26		3
					2
				1	1
					1
			2		
		2	2		
			1		
		1	11		
		2	24	1	1
					1
		2	12	1	7
			2		
		2	3		
			1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Seizure	6	26
Sensation of blood flow		1
Sensation of foreign body	1	19
Sense of oppression		1
Sensitive skin	2	3
Sensorimotor disorder	1	1
Sensory disturbance	16	36
Sensory level abnormal		4
Sensory loss		1
Sepsis	1	4
Septic arthritis staphylococcal		1
Septic shock	1	2
Shock		2
Sialoadenitis		1
Sinus congestion	1	3
Sinusitis	1	2
Sinus tachycardia	1	7
Skin abrasion		1
Skin burning sensation	6	10
Skin cancer	1	1
Skin discolouration	6	10
Skin disorder	1	2
Skin exfoliation		3
Skin haemorrhage	2	2
Skin irritation		1
Skin lesion		1
Skin necrosis	1	2
Skin reaction	3	4
Skin sensitisation	1	1
Skin swelling		2
Skin warm		1
Sleep disorder	8	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				6	26
			1		
		1	5		14
			1		
		2	3		
		1	1		
		14	30	2	6
			3		1
					1
				1	4
					1
				1	2
					2
					1
		1	3		
		1	2		
		1	2		5
					1
		6	9		1
				1	1
		6	9		1
		1	1		1
			1		
					1
				1	2
		3	4		
		1	1		
			2		
			1		
		8	13		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Slow speech	1	1
Sneezing		6
Snoring		2
Soft tissue infection		1
Somatic symptom disorder		1
Somnolence	21	46
Sopor		1
Speech disorder	1	5
Spinal cord ischaemia		1
Spinal disorder	1	2
Spinal pain	3	6
Staphylococcal sepsis		1
Status epilepticus		4
Stomatitis		3
Stress	1	3
Stress cardiomyopathy	1	1
Stridor	1	5
Stupor		1
Subarachnoid haemorrhage		3
Subclavian vein thrombosis		1
Subileus		2
Sudden cardiac death		2
Sudden death	7	23
Sudden visual loss		1
Suffocation feeling	1	1
Suicidal ideation	1	1
Superinfection bacterial		2
Superior sagittal sinus thrombosis	1	2
Supraventricular extrasystoles		4
Supraventricular tachycardia	1	3
Suspected counterfeit product		1
Suspected COVID-19	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
			5		1
			2		
					1
					1
		18	32	3	14
					1
			1	1	4
					1
		1	1		1
		3	4		2
					1
					4
					3
		1	3		
				1	1
				1	5
					1
					3
					1
			1		1
					2
				7	23
					1
		1	1		
				1	1
					2
				1	2
			2		2
		1	2		1
			1		
				2	4

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Swelling	6	26
Swelling face	9	32
Swelling of eyelid	4	7
Swollen tongue	4	23
Syncope	12	60
Systemic inflammatory response syndrome		1
Systemic lupus erythematosus		1
Tachyarrhythmia	1	3
Tachycardia	21	102
Tachycardia induced cardiomyopathy		1
Tachypnoea	1	4
Taste disorder	2	8
Temporomand bular joint syndrome		1
Tenderness	2	3
Tendonitis	1	2
Tendon pain	1	2
Tenosynovitis	1	1
Tension	1	1
Tension headache		2
Therapeutic response unexpected	6	10
Thermal burn	1	1
Thinking abnormal	1	1
Thirst	2	4
Throat clearing	1	1
Throat irritation	2	14
Throat tightness	3	27
Thrombocytopenia	3	9
Thrombophlebitis		3
Thrombophlebitis superficial	3	6
Thrombosis	7	14
Thrombotic microangiopathy	1	1
Thyroiditis acute		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	22		4
	3	9	20		12
		4	6		1
		3	12	1	11
	1			12	60
					1
					1
			1	1	2
	5	17	58	4	44
					1
			1	1	3
		2	6		2
			1		
		2	3		
		1	1		1
		1	1		1
		1	1		
		1	1		
			1		1
		6	10		
		1	1		
		1	1		
	1	2	4		
		1	1		
	1	2	13		1
		3	14		13
				3	9
			2		1
		1	3	2	3
				7	14
				1	1
					1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Tinnitus	6	13
Tongue coated	1	2
Tongue discomfort	3	4
Tongue disorder	1	2
Tongue oedema		1
Tongue pruritus		1
Tonsillar disorder	1	1
Tonsillar hypertrophy		1
Tonsillitis	1	1
Tonsillitis bacterial		1
Toothache		1
Transaminases increased	2	3
Transient global amnesia	1	2
Transient ischaemic attack	1	3
Tremor	8	40
Trichoglossia	2	3
Trigeminal neuralgia	1	2
Trismus	2	2
Tryptase increased		1
Type 1 diabetes mellitus		2
Type IV hypersensitivity reaction	1	1
Underdose	2	6
Unresponsive to stimuli		7
Upper respiratory tract infection		5
Urea urine	1	1
Urinary incontinence	1	1
Urinary tract infection		2
Urinary tract inflammation		1
Urine odour abnormal		1
Urticaria	17	49
Urticaria physical	1	1
Vaccination complication	6	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	10	1	3
		1	2		
		2	3	1	1
			1	1	1
					1
					1
		1	1		
			1		
		1	1		
					1
			1		
		1	1	1	2
				1	2
				1	3
		2	17	6	23
		1	2	1	1
		1	2		
		1	1	1	1
					1
					2
				1	1
		2	6		
					7
			1		4
		1	1		
				1	1
			1		1
			1		
		17	37		12
		1	1		
		4	4	2	4

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination failure	6	25
Vaccination site abscess	1	1
Vaccination site bruising		1
Vaccination site dermatitis		1
Vaccination site discolouration		1
Vaccination site discomfort	7	12
Vaccination site erythema	28	65
Vaccination site granuloma		1
Vaccination site haematoma	1	7
Vaccination site haemorrhage		2
Vaccination site hyperaesthesia		3
Vaccination site hypersensitivity		1
Vaccination site hypoaesthesia		1
Vaccination site induration	3	10
Vaccination site inflammation	1	1
Vaccination site irritation		1
Vaccination site joint movement impairment		3
Vaccination site joint pain		1
Vaccination site lymphadenopathy	4	7
Vaccination site movement impairment	5	15
Vaccination site oedema		1
Vaccination site pain	189	547
Vaccination site papule		1
Vaccination site paraesthesia	1	7
Vaccination site pruritus	13	26
Vaccination site pustule		1
Vaccination site rash	2	6
Vaccination site reaction	10	20
Vaccination site swelling	33	89
Vaccination site urticaria	1	4
Vaccination site warmth	17	39
Vaginal haemorrhage	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				6	25
				1	1
			1		
			1		
			1		
		7	12		
	1	27	61	1	4
			1		
		1	6		1
			2		
			3		
			1		
					1
		3	10		
	1	1	1		
			1		
			2		1
			1		
		4	7		
		5	15		
			1		
	41	187	533	2	14
			1		
		1	7		
		13	25		1
			1		
		2	5		1
		10	18		2
	8	33	85		4
		1	3		1
	1	17	37		2
		1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Varicella		1
Varicella zoster virus infection		1
Varicophlebitis	1	1
Varicose vein		1
Vascular dementia		1
Vascular occlusion		1
Vasculitis		2
Venous occlusion		1
Venous thrombosis	3	5
Venous thrombosis in pregnancy		1
Venous thrombosis limb	8	10
Ventricle rupture	1	1
Ventricular extrasystoles	1	2
Ventricular f brillation		2
Vertigo	2	10
Viral rash		1
Visceral venous thrombosis		1
Vision blurred		9
Visual field defect	2	5
Visual impairment	9	32
VLth nerve paralysis		1
Vitreous disorder		1
Vomiting	37	113
Vulvitis		1
Vulvovaginal discomfort		1
Vulvovaginal mycotic infection	1	2
Vulvovaginal pain		1
Vulvovaginal swelling		1
Weight bearing difficulty	1	1
Weight decreased	2	3
Weight increased		1
Wheezing		5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
				1	1
			1		
					1
					1
			1		1
					1
				3	5
					1
		1	1	7	9
				1	1
				1	2
					2
		1	9	1	1
			1		
					1
			5		4
		1	2	1	3
		8	16	1	16
					1
					1
	6	30	75	7	38
					1
					1
		1	1		1
			1		1
		1	1		
		1	1	1	2
			1		
			1		4

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
White blood cell count decreased	1	3			1	3		
White blood cell count increased	1	3			1	2		1
Wrong product administered		2				2		
Wrong technique in product usage process	1	2			1	2		
	4,624	12,570	11	406	3809	8624	815	3946

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	1	1					1	1
Abdominal pain	3	15			2	9	1	6
Abdominal pain lower	5	6			5	5		1
Abdominal pain upper	2	5			1	4	1	1
Abnormal faeces	2	9			2	9		
Abscess neck		1						1
Accidental overdose		3				2		1
Acne	1	2			1	2		
Acute abdomen		3						3
Acute generalised exanthematous pustulosis		1						1
Acute kidney injury	1	7					1	7
Acute myeloid leukaemia		1						1
Acute myocardial infarction	2	13					2	13
Acute respiratory distress syndrome		3						3
Acute respiratory failure		2						2
Acute right ventricular failure		1						1
Age-related macular degeneration	1	1					1	1
Ageusia	1	4			1	3		1
Aggression		2						2
Agitation		1						1
Allergy to vaccine		1						1
Alopecia	1	1			1	1		
Alopecia areata		1				1		
Altered state of consciousness		2						2
Amaurosis fugax		1						1
Amnesia	2	5					2	5
Anaemia	1	3					1	3
Anaphylactic reaction	3	14					3	14
Anaphylactic shock		2						2
Angina pectoris	3	4					3	4
Angioedema	1	7					1	7
Anosmia	1	4			1	3		1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Antibody test abnormal		3
Antibody test negative	1	1
Anxiety		1
Aortic aneurysm		1
Aortic arteriosclerosis	1	1
Aortic dissection		1
Apathy	2	7
Aphasia	1	4
Aphthous ulcer		1
Arrhythmia	8	22
Arterial disorder	2	2
Arterial occlusive disease	1	1
Arthralgia	13	42
Arthritis reactive		1
Aspartate aminotransferase increased	1	1
Aspermia	1	1
Aspiration		2
Asthenia	21	64
Asthma	1	3
Asymptomatic COVID-19	3	4
Ataxia		2
Atrial fibrillation	1	9
Atrioventricular block complete		2
Atypical pneumonia		1
Autoimmune thyroiditis		1
Automatism		1
Axillary pain	2	2
Axillary vein thrombosis	1	1
Back pain	9	15
Balance disorder	2	3
Basal ganglia haemorrhage		1
Basedow's disease		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		
				1	1
			1		
					1
		1	1		
					1
		2	5		2
				1	4
					1
				8	22
		1	1	1	1
				1	1
	5	13	39		3
					1
				1	1
		1	1		
					2
		17	51	4	13
		1	2		1
		1	1	2	3
					2
				1	9
					2
					1
					1
		2	2		
				1	1
		9	14		1
		2	2		1
					1
					1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Basilar artery occlusion		1
Bell's palsy	1	2
Bladder discomfort		1
Blindness	1	1
Blindness unilateral		1
Blister		2
Blister infected		1
Blood blister	1	1
Blood calcium decreased		1
Blood cholesterol increased		1
Blood count abnormal		1
Blood creatine phosphokinase increased	3	5
Blood creatine phosphokinase MB increased		1
Blood glucose decreased	1	1
Blood glucose fluctuation		1
Blood glucose increased	1	1
Blood lactate dehydrogenase increased	1	1
Blood potassium decreased		1
Blood potassium increased	1	1
Blood pressure decreased	1	6
Blood pressure fluctuation		2
Blood pressure increased	4	6
Blood pressure systolic increased		1
Blood uric acid increased	2	2
Body temperature increased	10	21
Bone pain		1
Bowel movement irregularity		1
Bradyarrhythmia		1
Bradycardia	1	4
Brain death		1
Brain oedema	1	1
Brain stem ischaemia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	2
			1		
				1	1
					1
			2		
			1		
		1	1		
			1		
			1		
					1
		2	3	1	2
			1		
				1	1
				1	1
			1		
				1	1
			3	1	3
			2		
		3	4	1	2
					1
		2	2		
		10	20		1
			1		
			1		
					1
				1	4
					1
				1	1
				1	1

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Breast pain	2	2
Bronchitis		2
Bronchitis bacterial		1
Bronchitis chronic		1
Bundle branch block right		2
Burning sensation	1	3
Bursitis		1
Cardiac arrest	5	14
Cardiac disorder	2	2
Cardiac failure	1	15
Cardiac failure congestive	1	2
Cardiac fibrillation		2
Cardiac hypertrophy	2	2
Cardiac procedure complication	1	1
Cardiac ventricular thrombosis	1	1
Cardiogenic shock	3	6
Cardiomyopathy	2	2
Cardiopulmonary failure		1
Cardio-respiratory arrest		1
Cardiovascular disorder	3	8
Cardiovascular insufficiency		2
Cellulitis		1
Cerebellar syndrome		1
Cerebral artery occlusion	1	1
Cerebral atrophy		1
Cerebral haemorrhage	5	13
Cerebral infarction	1	5
Cerebral ischaemia		4
Cerebral venous sinus thrombosis	6	10
Cerebrovascular accident	13	30
Cerebrovascular disorder	1	1
Cervical radiculopathy	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	1
			1		1
			1		1
			1		2
		1	3		
			1		
				5	14
		1	1	1	1
				1	15
				1	2
					2
		1	1	1	1
				1	1
				3	6
				2	2
					1
					1
		2	4	1	4
					2
					1
				1	1
					1
				5	13
				1	5
					4
				6	10
				13	30
				1	1
		1	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chest discomfort	1	4
Chest pain	4	7
Chest X-ray abnormal		1
Chills	57	124
Cholelithiasis		1
Chronic inflammatory demyelinating polyradiculoneuropathy		1
Chronic kidney disease		1
Chronic obstructive pulmonary disease		3
Circulatory collapse	2	16
Circumstance or information capable of leading to medication error		1
Clonus		1
Coagulopathy		1
Cognitive disorder	1	4
Cold sweat	1	5
Colitis ulcerative	2	2
Coma	1	2
Communication disorder		1
Condition aggravated		5
Confusional state	2	7
Conjunctivitis		1
Contusion	2	5
Coordination abnormal	1	1
Coronary artery disease	1	2
Coronavirus infection	1	1
Cough	7	19
COVID-19	37	172
COVID-19 pneumonia	1	13
Cranial nerve disorder		1
Craniocerebral injury		1
C-reactive protein increased	2	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	1	2
		3	5	1	2
					1
	5	57	119		5
			1		
					1
			1		2
				2	16
			1		
					1
					1
		1	2		2
		1	3		2
				2	2
				1	2
			1		
					5
			1	2	6
					1
			1	2	4
		1	1		
				1	2
				1	1
		6	13	1	6
		16	53	21	119
				1	13
			1		
					1
		2	5		1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
CSF cell count increased	1	1
CSF protein increased	1	1
Cutaneous vasculitis		2
Cyanosis	2	5
Deafness	2	2
Deafness bilateral		1
Deafness unilateral	1	1
Death	26	103
Decreased appetite	4	10
Deep vein thrombosis	17	34
Dehydration	2	4
Delirium		2
Delusion		1
Dementia		1
Dementia of the Alzheimer's type, with delirium		1
Demyelinating polyneuropathy	1	1
Depressed level of consciousness	1	4
Depression		2
Dermatitis allergic	2	3
Dermatitis atopic		1
Dermatitis bullous	1	2
Diabetes mellitus	1	2
Diabetes mellitus inadequate control		1
Diabetic nephropathy	1	1
Diarrhoea	10	41
Diet refusal		2
Diplopia	1	4
Discomfort	2	2
Disease recurrence	1	7
Disorientation	2	5
Disturbance in attention	5	17
Diverticulitis	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
					2
		1	1	1	4
				2	2
					1
				1	1
				26	103
		3	7	1	3
				17	34
		2	3		1
					2
					1
					1
					1
				1	1
				1	4
			2		
		2	3		
			1		
				1	2
				1	2
					1
		1	1		
	1	8	33	2	8
					2
			2	1	2
	2	2	2		
				1	7
			3	2	2
		5	13		4
				1	2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dizziness	27	66
Dizziness postural		2
Drug eruption		1
Drug ineffective	21	94
Drug interaction		3
Dry eye		1
Dry throat	1	1
Dysaesthesia	1	2
Dysarthria		1
Dysgeusia	1	4
Dyskinesia	1	1
Dyspepsia		2
Dysphagia		3
Dyspnoea	18	56
Dyspnoea exertional	1	4
Dysuria	1	1
Ear discomfort	1	1
Ear pain	2	4
Eastern Cooperative Oncology Group performance status worsened		1
Eating disorder		2
Eczema	1	3
Effusion		1
Embolism	1	1
Emphysema		1
Encephalitis		2
Encephalitis autoimmune	1	2
Enteritis		1
Enuresis	1	1
Eosinophilia		1
Epilepsy	1	7
Episcleritis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	5	25	54	2	12
			1		1
					1
				21	94
			2		1
			1		
		1	1		
		1	1		1
					1
		1	3		1
		1	1		
			2		
			1		2
		9	22	9	34
		1	2		2
		1	1		
				1	1
		2	4		
			1		
			2		
			2	1	1
					1
				1	1
					1
					2
				1	2
					1
				1	1
					1
				1	7
			1		

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Epistaxis	1	3
Erectile dysfunction	3	3
Erysipelas	2	3
Erythema	3	16
Escherichia infection		1
Essential tremor		1
Exercise tolerance decreased		
Exposure via breast milk	1	1
Extrapyramidal disorder		1
Extrasystoles		1
Eye disorder	1	1
Eye haemorrhage	1	2
Eye infarction	1	1
Eye inflammation	1	1
Eye irritation	2	3
Eyelid oedema		1
Eyelid ptosis	1	1
Eye pain	1	3
Eye swelling		1
Face oedema		2
Facial discomfort	1	1
Facial nerve disorder		1
Facial paralysis	5	17
Facial paresis	5	13
Faeces discoloured		1
Fall	2	12
Fatigue	91	219
Febrile infection		2
Feeling abnormal	1	3
Feeling cold	7	15
Feeling hot	4	14
Feeling jittery		

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1		1	1	2
				3	3
				2	3
	2	3	12		4
					1
					1
	1				
		1	1		
			1		
					1
				1	1
				1	2
				1	1
		1	1		
		2	3		
					1
		1	1		
		1	3		
			1		
			1		1
		1	1		
			1		
				5	17
		2	5	3	8
			1		
		1	2	1	10
	12	88	208	3	11
					2
		1	2		1
		7	15		
		3	9	1	5
	1				

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Feeling of body temperature change	2	4
Femoral neck fracture		1
Femur fracture		1
Fibrin D dimer increased	4	6
Flatulence		3
Flushing	4	6
Functional gastrointestinal disorder		1
Gait disturbance	8	11
Gastric disorder	1	1
Gastritis	1	1
Gastrointestinal disorder		1
Gastrointestinal haemorrhage	1	1
Gastrointestinal necrosis		1
Gastrointestinal pain	1	1
General physical condition abnormal		3
General physical health deterioration	2	27
Genital herpes		1
Giant cell arteritis	1	1
Glomerular filtration rate decreased		1
Glomerulonephritis minimal lesion		1
Glycosylated haemoglobin increased	1	1
Granulocyte count increased		1
Guillain-Barre syndrome	1	2
Haematemesis		3
Haematochezia	2	5
Haematocrit decreased		1
Haematocrit increased	1	1
Haematology test abnormal	1	1
Haematoma		1
Haemoglobin decreased	1	4
Haemoglobin increased	1	1
Haemolytic uraemic syndrome		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	4		
					1
					1
		3	4	1	2
	1		2		1
		4	6		
			1		
		5	5	3	6
		1	1		
		1	1		
			1		
				1	1
					1
	1	1	1		
					3
		1	7	1	20
			1		
				1	1
			1		
		1	1		1
			1		
				1	2
					3
				2	5
			1		
				1	1
				1	1
			1		
		1	2		2
				1	1
					1

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Haemoptysis	1	1
Haemorrhage	1	5
Haemorrhagic diathesis	1	1
Hair disorder	1	1
Hallucination		1
Hallucination, auditory		1
Hallucinations, mixed		1
Hallucination, visual	2	2
Headache	107	247
Head discomfort	1	2
Head injury		2
Heart rate decreased	2	4
Heart rate increased	1	4
Hemiparaesthesia		1
Hemiparesis	3	11
Hemiplegia		3
Heparin-induced thrombocytopenia test positive		1
Hepatic cirrhosis		1
Hepatic failure		1
Hepatic pain		1
Hepatitis cholestatic		2
Herpes simplex encephalitis		1
Herpes simplex reactivation		1
Herpes zoster	36	46
Herpes zoster infection neurological		1
Herpes zoster meningitis	1	2
Herpes zoster meningoencephalitis	1	1
Herpes zoster oticus		1
HIV test positive		1
Hot flush	2	4
Hunger	1	2
Huntington's disease	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				1	5
				1	1
		1	1		
					1
					1
					1
				2	2
	10	102	234	5	13
			1	1	1
					2
		1	1	1	3
		1	2		2
					1
				3	11
					3
			1		
					1
					1
			1		
					2
					1
					1
					1
					1
		33	39	3	7
					1
				1	2
				1	1
					1
					1
		2	4		
		1	2		
		1	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyperacusis		1
Hyperaesthesia		2
Hyperglycaemia	1	1
Hyperhidrosis	4	15
Hypernatraemia	1	1
Hyperpyrexia	1	2
Hypersensitivity	7	22
Hypersomnia		1
Hypertension	5	19
Hypertensive crisis		5
Hyperthyroidism		2
Hypertonia		2
Hyperventilation		2
Hypoacusis	1	1
Hypoesthesia	3	16
Hypoesthesia eye	1	1
Hypoesthesia oral	1	2
Hypogeusia	1	1
Hypoglycaemia		1
Hyponatraemia		2
Hyposmia	1	1
Hypotension	3	13
Hypotonia	3	4
Hypoxia		1
Ileectomy		1
Illness	1	4
Immature granulocyte count increased		1
Immune thrombocytopenia	2	6
Impaired work ability		1
Inappropriate schedule of product administration	5	17
Incomplete course of vaccination	1	1
Incontinence	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2		
		1	1		
	1		10	4	5
				1	1
				1	2
	1	6	11	1	11
			1		
	1	2	8	3	11
					5
					2
			1		1
					2
				1	1
		2	13	1	3
		1	1		
		1	2		
				1	1
			1		
					2
				1	1
		2	7	1	6
		1	2	2	2
					1
					1
		1	4		
			1		
				2	6
					1
		5	17		
		1	1		
		1	1		1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Incorrect dose administered		2
Incorrect route of product administration	11	31
Induration		1
Infarction		1
Infection		3
Infective exacerbation of chronic obstructive airways disease		1
Inflammation	1	3
Inflammatory marker increased	1	1
Influenza	4	7
Influenza like illness	21	45
Initial insomnia		2
Injected limb mobility decreased		1
Injection site discomfort		1
Injection site pain	2	3
Injection site swelling	1	1
Insomnia	5	7
Intentional product misuse		1
Internal haemorrhage		1
International normalised ratio increased	1	2
Intestinal haemorrhage		1
Intestinal ischaemia		1
Intestinal obstruction		1
Intracranial aneurysm		1
Intraocular pressure increased	1	1
Ischaemia		1
Ischaemic cardiomyopathy		1
Ischaemic cerebral infarction		2
Ischaemic stroke		3
IVth nerve disorder		1
IVth nerve paresis		1
Jaundice		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		11	31		
			1		
					1
			1		2
					1
		1	1		2
		1	1		
		4	5		2
		21	43		2
			2		
			1		
			1		
		2	3		
		1	1		
		4	6	1	1
			1		
					1
		1	2		
					1
					1
					1
					1
				1	1
					1
					1
					2
					3
					1
					1
					1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Joint effusion	1	1
Joint range of motion decreased	1	1
Joint swelling		1
Jugular vein thrombosis	2	2
Keratoconus		1
Klippel-Trenaunay syndrome	1	1
Lacrimation increased		1
Language disorder		1
Laryngeal obstruction		1
Laryngeal oedema	1	2
Left ventricular failure		1
Leukaemia		1
Leukopenia	1	1
Limb discomfort	6	17
Lipase increased	1	1
Lipids increased	1	1
Lip swelling	1	3
Listless		1
Liver disorder		1
Liver function test abnormal	1	1
Local reaction	1	4
Loss of consciousness		6
Loss of personal independence in daily activities	1	3
Low density lipoprotein increased		1
Lung infiltration		1
Lyme disease	1	1
Lymphadenitis	3	3
Lymphadenopathy	13	29
Lymph node pain	6	10
Lymphocyte count decreased		1
Lymphoedema	1	1
Lymphopenia		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1		
			1		
				2	2
					1
				1	1
			1		
					1
					1
				1	2
					1
					1
				1	1
		6	16		1
		1	1		
		1	1		
		1	1		2
					1
					1
		1	1		
			2	1	2
					6
		1	3		
			1		
					1
				1	1
		2	2	1	1
		13	28		1
		6	10		
			1		
		1	1		
					2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Malaise	24	50
Malignant melanoma		1
Malignant pleural effusion		1
Mean cell volume decreased	1	1
Medical induction of coma	1	1
Medication error		1
Meningoencephalitis herpetic	2	2
Mental disorder		1
Mesenteric vein thrombosis	1	5
Metabolic disorder		1
Microscopic polyangiitis		2
Middle insomnia		1
Migraine	2	2
Miller Fisher syndrome	1	1
Misleading laboratory test result	1	1
Mobility decreased		5
Monocyte count increased	1	2
Monoparesis	1	4
Monoplegia		2
Mood altered	1	1
Motor dysfunction		1
Mouth swelling		1
Movement disorder	4	10
Multi-organ disorder		1
Multiple organ dysfunction syndrome		5
Multiple sclerosis		1
Muscle spasms	1	4
Muscle strength abnormal		1
Muscle tightness		1
Muscle twitching		5
Muscular weakness	3	7
Musculoskeletal chest pain		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	13	22	40	2	10
					1
					1
		1	1		
				1	1
			1		
				2	2
					1
				1	5
					1
					2
			1		
		2	2		
				1	1
		1	1		
			2		3
		1	2		
			1	1	3
					2
		1	1		
					1
					1
		2	4	2	6
					1
					5
					1
			1	1	3
			1		
			1		
			4		1
		2	5	1	2
					1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Musculoskeletal discomfort		2
Musculoskeletal stiffness	1	1
Myalgia	37	97
Myelitis		1
Myocardial infarction	10	14
Myocarditis	21	28
Myocarditis infectious		1
Myocarditis septic		1
Myoglobin blood increased		1
Myositis	1	2
Nasal congestion	1	2
Nasopharyngitis	8	14
Natural killer T cell count decreased		1
Nausea	23	58
Neck pain	8	18
Nephrolithiasis		1
Nephrotic syndrome		1
Nerve injury	1	1
Nervous system disorder		1
Neuralgia	5	8
Neuralgic amyotrophy		3
Neuritis		1
Neurodermatitis		1
Night sweats	1	1
No adverse event	1	1
Obesity	2	2
Obstructive airways disorder		2
Ocular discomfort	1	2
Ocular hyperaemia	1	1
Odynophagia	1	2
Oedema		2
Off label use	1	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		1	1		
	7	36	95	1	2
					1
				10	14
				21	28
					1
					1
					1
		1	1		1
		1	2		
		8	12		2
			1		
	6	22	49	1	9
		8	17		1
					1
					1
			1	1	1
			1		
		5	8		
			1		2
					1
			1		
		1	1		
		1	1		
		2	2		
					2
		1	2		
		1	1		
		1	2		
					2
		1	9		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Open angle glaucoma	1	1
Ophthalmic herpes zoster	1	1
Ophthalmic vein thrombosis	3	5
Optic atrophy	1	1
Optic ischaemic neuropathy		1
Oral candidiasis		1
Oral fungal infection		1
Oral herpes	1	1
Oral mucosal eruption		1
Oral mucosal erythema	1	1
Organising pneumonia	1	1
Oropharyngeal blistering	1	1
Oropharyngeal pain	6	11
Orthostatic hypotension		1
Osteoporosis		1
Overdose	2	3
Oxygen saturation decreased	1	4
Pain	13	36
Pain in extremity	72	159
Pain of skin		1
Palatal swelling		1
Pallor		4
Palpitations	3	10
Pancreatitis acute	1	1
Pancreatitis necrotising	1	1
Pancytopenia	1	3
Paraesthesia	2	9
Paraesthesia oral		1
Paresis		4
Paresis cranial nerve	1	1
Parkinsonism		1
Parkinson's disease	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
				3	5
				1	1
					1
					1
					1
		1	1		
			1		
		1	1		
				1	1
				1	1
		6	11		
			1		
			1		
		2	2		1
		1	1		3
		11	27	2	9
		67	149	5	10
			1		
					1
			2		2
	3	2	5	1	5
				1	1
				1	1
				1	3
		1	7	1	2
			1		
			1		3
				1	1
					1
				1	1

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Parosmia	1	1
Pelvic pain		1
Pelvic venous thrombosis		2
Performance status decreased	1	3
Pericardial effusion	1	1
Pericarditis	1	2
Peripheral circulatory failure	1	5
Peripheral coldness	3	4
Peripheral swelling	3	8
Peripheral vascular disorder	3	10
Peroneal nerve injury		1
Personality change		2
Petechiae	2	4
Pharyngeal swelling		2
Pharyngitis bacterial	1	1
Phobia	1	1
Photophobia	1	1
Platelet count decreased	4	6
Platelet count increased	1	1
Pleocytosis		2
Pleurisy		1
Pneumonia	8	26
Pneumonia bacterial		1
Pneumonia streptococcal	1	1
Pneumonitis	1	1
PO2 decreased		1
Poisoning		1
Pollakiuria	1	3
Polymyositis	1	1
Polyneuropathy		2
Poor quality product administered	4	12
Poor quality sleep		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		
					2
				1	3
				1	1
				1	2
		1	2		3
		3	4		
		1	6	2	2
		3	4		6
					1
					2
		1	1	1	3
					2
				1	1
		1	1		
		1	1		
			1	4	5
				1	1
					2
					1
				8	26
					1
				1	1
				1	1
					1
					1
		1	3		
				1	1
					2
		4	12		
			1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Presbycusis		1
Presyncope		3
Product administration error	1	1
Product complaint		1
Product dose omission issue		1
Productive cough	1	1
Product preparation error		1
Product prescribing error	1	1
Product storage error	3	4
Product supply issue		1
Product temperature excursion issue	3	10
Product use issue	1	2
Prostatic specific antigen increased	1	1
Prostatitis	1	1
Proteinuria	1	2
Prurigo		1
Pruritus	7	17
Pseudoallergic reaction		2
Pulmonary artery thrombosis	1	1
Pulmonary embolism	30	63
Pulmonary fibrosis		1
Pulmonary haemorrhage	1	2
Pulmonary infarction		1
Pulmonary oedema	1	2
Pulmonary pain	2	2
Pulmonary sarcoidosis		1
Pulmonary sepsis		2
Pulmonary thrombosis	2	2
Pupils unequal		1
Purpura		1
Pustule	2	2
Pyramidal tract syndrome		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			2		1
		1	1		
			1		
			1		
		1	1		
			1		
		1	1		
		3	4		
			1		
		3	10		
			1	1	1
		1	1		
		1	1		
		1	1		1
			1		
	1	5	12	2	5
			1		1
				1	1
				30	63
					1
				1	2
					1
				1	2
		1	1	1	1
					1
					2
				2	2
					1
					1
	1	2	2		
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pyrexia	75	202
Rash	10	29
Rash erythematous	1	5
Rash macular	1	2
Rash maculo-papular	1	5
Rash papular	1	1
Rash pruritic	5	8
Rash vesicular	1	2
Rectal polyp		1
Red blood cell count decreased		1
Red blood cell count increased	1	1
Red blood cell sedimentation rate increased		1
Red cell distribution width decreased	2	2
Renal disorder	1	3
Renal failure	1	5
Renal function test abnormal	1	1
Renal pain		1
Respiratory arrest	1	2
Respiratory disorder	1	1
Respiratory distress	3	24
Respiratory failure	3	17
Respiratory rate increased	1	3
Respiratory tract infection		2
Respiratory tract inflammation		1
Restlessness	3	8
Retching		2
Retinal vein thrombosis	1	2
Rhabdomyolysis	2	5
Rheumatoid arthritis	3	3
Rhinalgia	1	1
Rhinitis	3	4
Rhinorrhoea		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	7	70	156	5	46
		9	18	1	11
		1	4		1
		1	2		
		1	4		1
		1	1		
		4	6	1	2
		1	2		
			1		
			1		
				1	1
			1		
		1	1	1	1
		1	1		2
				1	5
		1	1		
			1		
				1	2
		1	1		
				3	24
				3	17
		1	3		
					2
					1
		3	6		2
			1		1
				1	2
				2	5
				3	3
		1	1		
		3	4		
			3		

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* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Right ventricular failure	1	2
SARS-CoV-2 ant body test negative	1	8
SARS-CoV-2 ant body test positive	1	10
SARS-CoV-2 test positive	2	15
Seizure	1	15
Sensation of foreign body		1
Sensory disturbance	4	10
Sensory loss		1
Sepsis	1	1
Septic shock		2
Shock		1
Shock haemorrhagic		1
Sinusitis	1	2
Skin burning sensation		1
Skin haemorrhage		1
Skin laceration		1
Skin ulcer		1
Sleep apnoea syndrome	2	2
Sleep disorder	1	7
Sneezing		2
Somnolence	11	20
Speech disorder	1	4
Spinal pain	2	2
Splenomegaly	1	1
Spontaneous haematoma	1	1
Staphylococcal sepsis		1
Status epilepticus		3
Stress	2	3
Stridor	1	2
Subclavian artery thrombosis		1
Subclavian vein thrombosis	2	3
Subcutaneous abscess		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
		1	7		1
		1	9		1
		1	8	1	7
				1	15
			1		
		4	10		
			1		
				1	1
					2
					1
					1
		1	2		
					1
					1
			1		
		1	1	1	1
		1	7		
			2		
		6	12	5	8
		1	3		1
		2	2		
				1	1
				1	1
					1
					3
		2	2		1
				1	2
					1
				2	3
					1

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* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Subdural haematoma		1
Sudden cardiac death	2	3
Sudden death	5	16
Sudden hearing loss	2	10
Sudden onset of sleep		1
Superinfection bacterial		1
Suspected COVID-19	2	4
Swelling	1	3
Swelling face	3	5
Swollen tongue	1	1
Syncope	6	23
Tachyarrhythmia		2
Tachycardia	6	24
Tachypnoea		1
Taste disorder		1
Tenderness	2	2
Tendon pain	1	1
Tendon rupture		1
Tenosynovitis		1
Tension		1
Tetany		1
Thalamic infarction		1
Therapeutic response unexpected	1	6
Thirst	1	2
Throat irritation	2	7
Throat tightness		3
Thrombectomy		1
Thrombocytopenia	8	10
Thrombophlebitis	1	1
Thrombophlebitis superficial	2	2
Thrombosis	11	19
Tinnitus	4	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				2	3
				5	16
				2	10
					1
					1
		2	2		2
			2	1	1
		3	4		1
		1	1		
				6	23
					2
	1	5	12	1	12
					1
			1		
		2	2		
		1	1		
					1
			1		
			1		
					1
					1
		1	6		
		1	2		
		2	7		
			2		1
					1
				8	10
		1	1		
		1	1	1	1
				11	19
		3	4	1	3

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* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tongue discomfort		1
Tongue oedema		1
Tonic convulsion		1
Tonsillitis bacterial		1
Toxicity to various agents		1
Transaminases increased	1	3
Transient aphasia		1
Transient global amnesia		1
Transient ischaemic attack	1	4
Tremor	1	3
Trigeminal nerve paresis	1	1
Trigeminal neuralgia		1
Trigeminal neuritis	1	1
Tumour marker increased	1	1
Type 2 diabetes mellitus	1	1
Ulnar nerve injury	1	1
Underdose		1
Unresponsive to stimuli	1	4
Upper gastrointestinal haemorrhage		2
Urinary retention		1
Urinary tract infection		1
Urosepsis		1
Urticaria	6	17
Vaccination complication		2
Vaccination failure	3	21
Vaccination site abscess	1	1
Vaccination site bruising		3
Vaccination site discomfort	1	4
Vaccination site dysaesthesia	1	2
Vaccination site erythema	4	8
Vaccination site haematoma		3
Vaccination site haemorrhage		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
					1
					1
		1	3		
					1
			1		
				1	4
		1	2		1
				1	1
			1		
		1	1		
				1	1
				1	1
		1	1		
			1		
				1	4
					2
					1
					1
					1
	1	5	13	1	4
					2
				3	21
				1	1
			3		
		1	4		
		1	2		
		4	7		1
			3		
			1		

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* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site hypersensitivity		1
Vaccination site induration		1
Vaccination site joint pain	1	2
Vaccination site lymphadenopathy		1
Vaccination site movement impairment		1
Vaccination site pain	81	236
Vaccination site pruritus	1	2
Vaccination site rash	2	2
Vaccination site reaction	3	6
Vaccination site swelling	10	19
Vaccination site warmth	2	4
Varicella zoster virus infection	1	1
Vascular encephalopathy		1
Vasculitis	1	3
Venous thrombosis	3	5
Venous thrombosis limb	5	6
Ventricular extrasystoles		1
Ventricular f brillation	2	4
Ventricular tachycardia	1	3
Vertebral wedging		1
Vertigo	1	4
Vestibular neuronitis		1
Viral rash		1
Vision blurred		2
Visual acuity reduced	2	3
Visual impairment	4	10
Vomiting	7	27
Weight bearing difficulty		1
Weight decreased	2	3
Wheezing		1
White blood cell count decreased	1	2
White blood cell count increased		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
		1	2		
			1		
			1		
	12	81	234		2
		1	2		
		2	2		
		3	6		
	4	10	18		1
		2	4		
		1	1		
					1
				1	3
				3	5
		1	1	4	5
			1		
				2	4
				1	3
					1
		1	3		1
			1		
			1		
			1		1
		1	1	1	2
		3	3	1	7
	2	4	19	3	8
					1
		1	1	1	2
			1		
			1	1	1
			1		1

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* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Wound	1	1			1	1		
Wrong product administered	1	1			1	1		
Wrong technique in product usage process		1				1		
	1,693	4,666		108	1145	2724	548	1942

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* I=Interval, C=Cumulative
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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain lower		1		1		
Acute myocardial infarction	1	1			1	1
Ageusia		1		1		
Allergic oedema		1				1
Allergy to vaccine		1		1		
Anaphylactic reaction		2				2
Anaphylactic shock	1	1			1	1
Angina pectoris	1	1			1	1
Angioedema		1				1
Anxiety		1				1
Aphasia		1				1
Arthralgia	3	3	3	3		
Asthenia	1	2	1	2		
Asthma		1				1
Asymptomatic COVID-19		1				1
Autoimmune pancreatitis	1	1			1	1
Balance disorder	1	1	1	1		
Blood pressure decreased		1				1
Body temperature increased	1	2	1	2		
Borrelia infection	1	1			1	1
Cardiac arrest		1				1
Cardiac failure	1	1			1	1
Cardiovascular disorder	1	3	1	1		2
Cerebrovascular accident	1	1			1	1
Chills	2	24	2	24		
Circulatory collapse	2	3			2	3
Circumstance or information capable of leading to medication error	1	2	1	2		
Coronary artery disease	1	1			1	1
Coronavirus infection		10		7		3
Cough		3		3		
COVID-19	36	163	10	43	26	120

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness		1				1
Death	2	22			2	22
Decreased appetite		1				1
Deep vein thrombosis		2				2
Dehydration		1				1
Dermatitis	1	1			1	1
Diarrhoea		4		3		1
Diet refusal		1				1
Disturbance in attention		2		1		1
Dizziness	1	4		2	1	2
Drug ineffective	26	117		1	26	116
Dysarthria		1		1		
Dysgeusia	1	1	1	1		
Dysphagia		4		4		
Dyspnoea		3		1		2
Eczema		4		4		
Electrocardiogram ST segment depression	1	1			1	1
Erythema	1	4	1	4		
Exposure via breast milk	5	9	5	9		
Facial paralysis		1				1
Facial paresis		1		1		
Fall		1				1
Fatigue	3	18	3	18		
Feeling cold		1		1		
Femur fracture		1				1
Fine motor skill dysfunction	1	1	1	1		
Gait inability	1	1	1	1		
Haemorrhage	1	1			1	1
Headache	3	30	3	29		1
Herpes zoster	7	9	6	8	1	1
Hyperaesthesia		1		1		
Hypersensitivity	2	4	2	3		1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertensive crisis		1				1
Hypoacusis	3	3	3	3		
Hypoaesthesia	1	2	1	2		
Hypotension		1				1
Hypothermia		1				1
Hypotonia		1				1
Inappropriate schedule of product administration		1		1		
Incorrect dose administered	2	3	2	3		
Incorrect route of product administration	4	6	4	6		
Increased appetite	1	1	1	1		
Influenza like illness	6	7	6	7		
Ischaemia		1				1
Limb discomfort	1	1	1	1		
Lip swelling		1		1		
Liquid product physical issue	3	3	3	3		
Listless		1		1		
Local reaction		1		1		
Loss of consciousness	1	1			1	1
Lymphadenopathy		2		2		
Malaise		12		12		
Maternal exposure during pregnancy	1	1			1	1
Mobility decreased	1	1	1	1		
Muscular weakness	2	2	2	2		
Myalgia	3	15	3	14		1
Nasal congestion	1	1	1	1		
Nasopharyngitis		1		1		
Nausea	2	6	2	6		
Neck pain		1		1		
Necrosis		1				1
Neuralgia		1		1		
No adverse event		2		2		
Oculogyric crisis		1				1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Off label use	1	4
Pain		1
Pain in extremity	3	14
Paraesthesia		3
Paraesthesia oral		3
Parosmia	2	2
Peripheral embolism		1
Peripheral ischaemia		1
Peripheral swelling		1
Polyneuropathy		1
Poor quality product administered	7	11
Premature separation of placenta	1	1
Product administered to patient of inappropriate age		1
Product leakage		1
Product preparation error	1	3
Product preparation issue	2	8
Product quality issue	1	3
Product storage error	1	1
Product temperature excursion issue		1
Product use issue		2
Pruritus	1	1
Pyrexia	3	21
Rales		1
Rash		1
Raynaud's phenomenon		1
Rhinorrhoea	1	1
SARS-CoV-2 ant body test negative		3
SARS-CoV-2 ant body test positive	1	2
SARS-CoV-2 test false positive		4
SARS-CoV-2 test positive		16
Stridor		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	4		
	1		
3	14		
	2		1
	3		
2	2		
			1
			1
	1		
			1
7	11		
		1	1
	1		
	1		
1	3		
2	8		
1	3		
1	1		
	1		
	2		
1	1		
3	18		3
			1
	1		
	1		
1	1		
	3		
1	2		
	4		
	13		3
			1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sudden hearing loss		1				1
Swelling	1	2	1	2		
Swelling face	1	1	1	1		
Syncope		1				1
Thrombosis		1				1
Tinnitus	3	3	3	3		
Tongue disorder	1	2	1	2		
Tremor		1		1		
Type IV hypersensitivity reaction		4		4		
Underdose	1	17	1	17		
Urinary incontinence	1	1	1	1		
Vaccination site hyperaesthesia		1		1		
Vaccination site pain	2	9	2	9		
Vaccination site swelling		1		1		
Venous thrombosis limb	1	1			1	1
Vestibular neuronitis	1	1			1	1
Visual impairment		1		1		
Vomiting		4		2		2
Weight increased	1	1	1	1		
Wound		1		1		
Wrong product administered	1	1	1	1		
Wrong technique in product usage process	1	2	1	2		
	184	745	110	410	74	335

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Country Where Event Occurred

GREECE

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- * AE=Adverse Event
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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	2		1	1	1
Abdominal pain	7	16	5	9	2	7
Abdominal pain upper	4	9	2	6	2	3
Abortion spontaneous		1				1
Abscess	1	1	1	1		
Accident	1	1			1	1
Acne	2	3	2	3		
Acute myocardial infarction	2	2			2	2
Acute respiratory failure		1				1
Ageusia	2	3	1	1	1	2
Alanine aminotransferase increased		2		2		
Allergy to vaccine		4		1		3
Alopecia		1		1		
Anaemia		1				1
Anaphylactic reaction	1	11			1	11
Anaphylactic shock		7				7
Anaphylactoid reaction		2				2
Angina pectoris	1	1			1	1
Angioedema		13				13
Ankylosing spondylitis		1				1
Anosmia		2		1		1
Anxiety		2		2		
Aphasia		1				1
Aphonia	1	1			1	1
Arrhythmia	2	8			2	8
Arteriovenous graft thrombosis		1				1
Arthralgia	13	69	11	39	2	30
Arthritis		1		1		
Arthritis enteropathic		1				1
Aspartate aminotransferase increased		1		1		
Aspiration		1				1
Asthenia	13	36	10	22	3	14

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma	1	1			1	1
Asthmatic crisis		1				1
Asymptomatic COVID-19		4				4
Atrial fibrillation	4	8			4	8
Atypical pneumonia	1	1			1	1
Auscultation		1		1		
Autonomic nervous system imbalance		1				1
Axillary pain	1	1	1	1		
Back pain	1	8		5	1	3
Balance disorder	1	3		1	1	2
Bell's palsy	1	1			1	1
Blepharospasm		1		1		
Blindness	1	1			1	1
Blister	1	3	1	3		
Blood gases abnormal		1				1
Blood glucose abnormal		2		1		1
Blood glucose decreased	1	1	1	1		
Blood parathyroid hormone increased	1	1	1	1		
Blood pressure abnormal		1				1
Blood pressure decreased		5		1		4
Blood pressure diastolic increased		1		1		
Blood pressure fluctuation		1		1		
Blood pressure increased	12	53	8	26	4	27
Blood pressure systolic		1				1
Blood pressure systolic increased		4		1		3
Blood triglycerides increased		1				1
Body dysmorphic disorder		1				1
Body temperature decreased	1	1	1	1		
Bone pain	3	7	3	5		2
Bradycardia	1	1			1	1
Breast pain		1		1		
Breast swelling	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchial hyperreactivity		1				1
Bronchospasm	1	9	1	1		8
Bruxism	1	1			1	1
Burning sensation	3	31	3	22		9
Burning sensation mucosal		1				1
Bursitis		1				1
Cachexia		2				2
Cardiac arrest	1	4			1	4
Cardiac discomfort		1				1
Catarrh	1	1	1	1		
Cerebral haemorrhage	1	1			1	1
Cerebral ischaemia	1	1			1	1
Cerebrovascular accident		1				1
Cervix erythema		1				1
Chest discomfort	1	7		2	1	5
Chest pain	6	21	2	7	4	14
Chills	18	74	17	42	1	32
Choking sensation		1				1
Cholelithiasis		1				1
Cholinergic syndrome		4				4
Circumoral oedema		1				1
Clonus		1				1
Cold sweat	1	2			1	2
Coma		1				1
Complex regional pain syndrome		4		1		3
Condition aggravated	1	4	1	1		3
Confusional state	1	7	1	2		5
Conjunctival hyperaemia		2		2		
Contusion	2	3	2	3		
Cough	4	24	2	8	2	16
COVID-19	7	24	2	7	5	17
C-reactive protein increased		2		2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
CSF polymorphonuclear cell count increased		1				1
Cyanosis		1				1
Deafness	1	2			1	2
Deafness unilateral		1				1
Death	3	5			3	5
Decreased appetite		1				1
Deep vein thrombosis	1	2			1	2
Defaecation urgency		1				1
Dehydration		1				1
Dermatitis allergic	2	5			2	5
Dermatomyositis		1				1
Diabetes mellitus inadequate control		1				1
Diarrhoea	8	28	7	19	1	9
Diastolic hypertension		1				1
Diplegia	1	3			1	3
Diplopia		2				2
Discomfort		4		2		2
Disease recurrence	1	5			1	5
Disorientation	1	2	1	2		
Diverticulitis		1				1
Dizziness	16	77	14	50	2	27
Dizziness postural	1	1			1	1
Drowning		1				1
Drug ineffective	5	17			5	17
Drug interaction		1				1
Dry eye		2		2		
Dry mouth		6		5		1
Dry throat	1	12		2	1	10
Dysarthria	1	3	1	1		2
Dysgeusia	9	20	9	14		6
Dyskinesia	2	6	2	5		1
Dysmenorrhoea	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspepsia		3		1		2
Dysphagia	3	20	1	4	2	16
Dysphonia	1	14	1	3		11
Dysphoria		3				3
Dyspnoea	8	39	5	14	3	25
Dysstasia		2				2
Ear pain	1	4		2	1	2
Eating disorder		1				1
Eating disorder symptom		1		1		
Eczema	1	1	1	1		
Electric shock sensation		1		1		
Electrocardiogram repolarisation abnormality		1				1
Electromyogram abnormal		1		1		
Embolic stroke	1	1			1	1
Encephalitis	1	1			1	1
Enlarged uvula	1	4			1	4
Epigastric discomfort		1				1
Epilepsy		1				1
Episcleritis		1				1
Epistaxis	2	2	2	2		
Eructation		3		2		1
Erythema	10	60	7	41	3	19
Extrasystoles		4		2		2
Eye haemorrhage		1				1
Eye irritation	1	1	1	1		
Eyelid irritation		1				1
Eyelid oedema		4		3		1
Eyelid ptosis	1	3			1	3
Eyelids pruritus		2		1		1
Eye oedema		1				1
Eye pain		1				1
Eye pruritus	1	2		1	1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Face oedema		4		1		3
Facial paralysis	1	2			1	2
Facial paresis	2	7	1	3	1	4
Fall	2	3	1	1	1	2
Fatigue	36	112	30	71	6	41
Feeling abnormal		1				1
Feeling cold		2		2		
Feeling drunk		1				1
Feeling hot	1	4		2	1	2
Femur fracture	1	2			1	2
Fibrin D dimer increased		2		1		1
Fibromyalgia		1		1		
Fibrosis	1	1			1	1
Flatulence		2				2
Flushing	1	28	1	11		17
Gait disturbance		7		4		3
Gait inability		1				1
Gamma-glutamyltransferase increased		1				1
Gastric pH decreased	1	1			1	1
Gastroenteritis		1				1
Gastrointestinal disorder	1	7	1	6		1
Gastrointestinal hypermotility		1				1
Gastrointestinal pain	1	1	1	1		
Genital herpes zoster		1				1
Glossodynia		2				2
Goitre		1				1
Granuloma annulare		1		1		
Guillain-Barre syndrome		3				3
Haematochezia		1				1
Haematocrit decreased		1		1		
Haemoptysis		1				1
Headache	44	142	37	99	7	43

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Head discomfort	3	5	3	5		
Heart rate abnormal		1				1
Heart rate decreased		3				3
Heart rate increased		19		13		6
Heavy menstrual bleeding	1	2			1	2
Hemiparesis		1				1
Hepatic function abnormal	1	1	1	1		
Hepatic pain	1	1	1	1		
Hepatitis		1				1
Herpes dermatitis		1				1
Herpes simplex reactivation		1		1		
Herpes zoster	4	15	3	7	1	8
Hordeolum		1		1		
Hydrocephalus	1	1			1	1
Hyperhidrosis	3	17	2	9	1	8
Hyperpyrexia	1	1			1	1
Hypersensitivity	5	35	1	12	4	23
Hypersensitivity vasculitis		1				1
Hypertension	4	30	4	17		13
Hypertensive crisis		12				12
Hypertensive emergency		1				1
Hypoacusis		1				1
Hypoaesthesia	19	86	12	48	7	38
Hypoaesthesia oral	8	29	6	12	2	17
Hypoalbuminaemia		1		1		
Hypoglycaemia	1	1			1	1
Hypokalaemia		1				1
Hyponatraemia		2		1		1
Hyporeflexia		1				1
Hypotension	2	18		5	2	13
Hypothermia	1	3			1	3
Hypotonia	1	4		1	1	3

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Gender

FEMALE

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
			1
	1		
3	5		
1	2		
			3
	2		
1	1		
	1		
1	1		
2	2		
	1		
1	1		
			1
	1		
1	2		
	1		
	1		
			1
	1		
			1
		1	1
1	1		
	1		
			1
1	2		
2	3		
			5
			1
			5
3	7		1
	1		1

Immunoglobulins increased
 Impaired gastric emptying
 Incomplete course of vaccination
 Incorrect route of product administration
 Infection
 Inflammation
 Influenza like illness
 Injection site erythema
 Injection site hypoaesthesia
 Injection site mass
 Injection site pain
 Injury
 Inner ear disorder
 Insomnia
 Intercostal neuralgia
 Intermenstrual bleeding
 Intervertebral disc degeneration
 Intervertebral disc protrusion
 Iridocyclitis
 Irritability
 Ischaemic cerebral infarction
 Ischaemic stroke
 Jaw disorder
 Joint range of motion decreased
 Joint stiffness
 Joint swelling
 Lacrimation increased
 Laryngeal oedema
 Laryngeal pain
 Laryngospasm
 Lethargy
 Leukaemia

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Leukocytosis		1		1		
Lichenoid keratosis		1		1		
Limb discomfort	1	4	1	3		1
Limb injury		1		1		
Limb mass	2	2	2	2		
Lip oedema	2	10		2	2	8
Lip pain		2				2
Lip swelling	3	7	2	5	1	2
Liquid product physical issue		1		1		
Listeriosis	1	1			1	1
Livedo reticularis		1		1		
Localised oedema	1	3		1	1	2
Local reaction		2		2		
Loss of consciousness	2	4			2	4
Lower limb fracture	1	1			1	1
Lymphadenitis	4	23	4	9		14
Lymphadenopathy	10	40	8	24	2	16
Lymph node pain		4		3		1
Lymphoedema		1				1
Lymphopenia		1		1		
Malaise	9	32	8	21	1	11
Mastication disorder	1	1	1	1		
Maternal exposure during pregnancy	1	5	1	5		
Memory impairment		1				1
Meningism		1		1		
Meningomyelitis herpes		1				1
Menstruation delayed	1	2	1	2		
Menstruation irregular	1	3	1	2		1
Migraine	2	9	1	6	1	3
Monoparesis		2				2
Monoplegia	1	1			1	1
Mouth swelling	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mouth ulceration		2		2		
Mucosal dryness		1				1
Muscle discomfort		1				1
Muscle fatigue		1		1		
Muscle spasms	2	6	1	2	1	4
Muscle strain		1		1		
Muscle tightness	1	2	1	2		
Muscular weakness	2	7	1	3	1	4
Musculoskeletal chest pain		1		1		
Musculoskeletal discomfort	1	1	1	1		
Musculoskeletal stiffness		1		1		
Myalgia	37	127	34	90	3	37
Myelitis		2				2
Myocardial infarction	1	2			1	2
Myocarditis	2	2			2	2
Myoclonus	1	1			1	1
Nail discolouration		1		1		
Nasal congestion		2		2		
Nasal pruritus		1		1		
Nausea	3	41	2	28	1	13
Neck pain	1	5	1	4		1
Neoplasm progression	1	1	1	1		
Nervousness		1				1
Neuralgia		1				1
Neuropathy peripheral		1				1
Neutrophil count decreased	1	1			1	1
Nystagmus		1		1		
Ocular hyperaemia		3				3
Oedema	1	4		1	1	3
Oedema peripheral	2	5	2	4		1
Off label use		3		3		
Ophthalmic herpes zoster	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral disorder	1	1			1	1
Oral herpes		4		3		1
Oral mucosal erythema		1		1		
Oropharyngeal pain	2	13	1	6	1	7
Orthostatic hypotension		1		1		
Osteoarthritis	1	1	1	1		
Oxygen saturation decreased		8		1		7
Pain	9	32	4	15	5	17
Pain in extremity	12	41	11	36	1	5
Pain in jaw		2		1		1
Palpitations	3	24	3	14		10
Pancreatitis		1				1
Panic attack	1	1	1	1		
Panic reaction		1				1
Paraesthesia		3		1		2
Paralysis		1				1
Paratracheal lymphadenopathy		1				1
Parosmia	1	2	1	1		1
Parotid gland enlargement		2		1		1
Periorbital swelling		1		1		
Peripheral coldness	1	9	1	3		6
Peripheral swelling	4	6	3	5	1	1
Peripheral venous disease		1		1		
Petechiae		1				1
Pharyngeal abscess	1	1			1	1
Pharyngeal oedema	1	2		1	1	1
Pharyngitis		1		1		
Photophobia		1				1
Platelet count increased		1		1		
Pleural effusion	1	1			1	1
Polyarthritits		1				1
Polydipsia		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Polymenorrhoea	2	2	2	2		
Polyneuropathy		2				2
Polyuria		1		1		
Poor quality product administered		1		1		
Portal vein thrombosis	1	1			1	1
Post herpetic neuralgia		1				1
Presyncope		9		5		4
Productive cough	1	1			1	1
Product use issue		2		2		
Pruritus	13	67	9	38	4	29
Pruritus allergic		1				1
Pulmonary embolism	2	4			2	4
Pulmonary fibrosis		1				1
Pulmonary mass		1				1
Pulmonary oedema	1	1			1	1
Pulmonary pain	1	1			1	1
Pulmonary thrombosis		2				2
Pulse abnormal		1		1		
Pulse absent		1				1
Purpura		1				1
Pyrexia	62	184	50	123	12	61
Rash	7	65	5	29	2	36
Rash erythematous	1	3	1	3		
Rash macular	1	2	1	2		
Rash maculo-papular	1	4	1	2		2
Rash morbilliform	1	1	1	1		
Rash papular	2	3	1	1	1	2
Rash pruritic	2	12	2	8		4
Raynaud's phenomenon		1				1
Reflexes abnormal		1				1
Renal failure		1				1
Respiratory failure		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory tract infection		2				2
Retinal artery thrombosis	1	1			1	1
Retinal vein thrombosis	1	1			1	1
Rheumatoid arthritis		2				2
Rhinitis		1		1		
Rhinitis allergic		1		1		
Rhinorrhoea	1	3	1	2		1
Salivary gland enlargement		1				1
Salivary gland pain		2		2		
Sarcoidosis		1				1
Seizure		1				1
Sensation of foreign body		1				1
Sensory loss		1				1
Sjogren's syndrome		1				1
Skin burning sensation	1	4	1	3		1
Skin papilloma	1	1			1	1
Skin reaction		1				1
Soft tissue swelling		1		1		
Somnolence	1	19	1	14		5
Speech disorder		2				2
Spinal pain		3				3
Stomatitis	1	1			1	1
Stress		1		1		
Sudden death		1				1
Suffocation feeling	1	1	1	1		
Suspected COVID-19	1	3	1	2		1
Swelling	2	5	1	2	1	3
Swelling face		3		1		2
Swollen tongue	2	3	1	2	1	1
Syncope	3	7			3	7
Systolic dysfunction	1	1			1	1
Tachycardia	10	58	7	27	3	31

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachypnoea		2		2		
Taste disorder		3				3
Teething		1				1
Temporomand bular joint syndrome		2		2		
Tension		1		1		
Tension headache	1	1	1	1		
Terminal state		1				1
Therapeutic response unexpected		1		1		
Throat irritation		12		8		4
Throat tightness		1				1
Thrombosis	4	6			4	6
Thrombosis in device	1	1			1	1
Thrombotic stroke	1	1			1	1
Thyroid cyst		1				1
Thyroiditis		2		1		1
Thyroiditis acute		1				1
Tinnitus	1	6		3	1	3
Tongue discomfort		1				1
Tongue oedema	1	5			1	5
Tongue ulceration		1		1		
Tonsillitis		1		1		
Toothache	1	1	1	1		
Tooth fracture	1	1	1	1		
Transaminases increased	1	1	1	1		
Transient ischaemic attack	2	2			2	2
Tremor		15		10		5
Trigeminal neuralgia	1	2	1	1		1
Trismus		1		1		
Underdose	1	1	1	1		
Urinary tract infection		2		1		1
Urine analysis abnormal	1	1	1	1		
Urticaria	8	13	7	10	1	3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Uveitis		3				3
Vaccination failure		1				1
Vaccination site bruising	2	2	2	2		
Vaccination site discomfort		2		2		
Vaccination site erythema	2	5	2	3		2
Vaccination site haemorrhage		1		1		
Vaccination site hypoaesthesia		2		1		1
Vaccination site induration		1		1		
Vaccination site inflammation	1	2	1	2		
Vaccination site irritation	1	2	1	1		1
Vaccination site movement impairment		1		1		
Vaccination site oedema	3	6	3	6		
Vaccination site pain	60	130	59	119	1	11
Vaccination site pruritus	2	4	2	3		1
Vaccination site rash	2	4	1	3	1	1
Vaccination site reaction		1		1		
Vaccination site swelling		1		1		
Vaccination site warmth		3		2		1
Vasculitis		1				1
Vasoconstriction		1				1
Venous thrombosis	2	2			2	2
Venous thrombosis limb		1				1
Ventricular arrhythmia		1				1
Vertigo	3	14	2	10	1	4
Viral infection		2		2		
Vision blurred	2	4	1	3	1	1
Visual impairment		1				1
Vitiligo	1	1	1	1		
Vomiting	7	26	4	13	3	13
Walking disability		1				1
Water pollution		1				1
White blood cell count decreased	1	2		1	1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Wrong technique in product usage process	1	1	1	1		
	764	3,065	538	1656	226	1409

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	4		2	1	2
Abdominal pain upper		3		3		
Activated partial thromboplastin time prolonged	1	1	1	1		
Acute coronary syndrome	1	1			1	1
Acute kidney injury	1	1			1	1
Acute myocardial infarction	1	4			1	4
Acute respiratory distress syndrome		1				1
Acute respiratory failure	1	1			1	1
Aggression		1				1
Agitation		1				1
Amylase decreased	1	1	1	1		
Anaphylactic reaction	3	7			3	7
Angina pectoris		1				1
Angioedema		2				2
Arrhythmia		4				4
Arteriosclerosis		1				1
Arthralgia	12	26	11	17	1	9
Asthenia	2	18	2	13		5
Asymptomatic COVID-19		1				1
Ataxia	1	1			1	1
Atrial f brillation	3	6			3	6
Audiogram abnormal		1		1		
Axillary pain		2		1		1
Back pain	3	6	3	6		
Bell's palsy	1	3			1	3
Blepharitis		1		1		
Blister		2		2		
Blood calcium decreased		1		1		
Blood creatine phosphokinase increased	1	2	1	2		
Blood creatine phosphokinase MB increased	1	1	1	1		
Blood creatinine decreased	1	1	1	1		
Blood fibrinogen increased	1	1	1	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood glucose abnormal		1		1		
Blood glucose increased	1	2	1	2		
Blood iron decreased		1		1		
Blood lactate dehydrogenase increased	1	1	1	1		
Blood magnesium increased	1	1	1	1		
Blood phosphorus decreased	1	1	1	1		
Blood potassium decreased	1	2	1	2		
Blood pressure abnormal		1				1
Blood pressure decreased		2		2		
Blood pressure diastolic increased		1		1		
Blood pressure inadequately controlled		1		1		
Blood pressure increased	3	15	3	9		6
Blood pressure systolic abnormal		1				1
Blood pressure systolic decreased	1	1	1	1		
Blood pressure systolic increased		1				1
Blood sodium increased	1	1	1	1		
Blood urea increased		1		1		
Body temperature increased	1	1	1	1		
Bone pain	2	3	2	3		
Bradycardia	1	3			1	3
Brain death		2				2
Bronchospasm		1				1
Burning sensation	3	5	2	4	1	1
Bursitis		1		1		
Cachexia		2				2
Capillary disorder		1		1		
Carbohydrate antigen 125 increased		1		1		
Carcinoembryonic antigen increased		1				1
Cardiac arrest	3	8			3	8
Cardiac failure		1				1
Cardiac valve disease		1				1
Carotid artery occlusion		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Carpal tunnel syndrome	1	1	1	1		
Catarrh		2		2		
Central nervous system stimulation		1				1
Cerebral haemorrhage	2	3			2	3
Cerebral ischaemia		1				1
Cerebral venous thrombosis		1				1
Cerebrovascular accident	4	7			4	7
Cervical radiculopathy		1				1
Chest discomfort		2				2
Chest pain	3	6	2	4	1	2
Chills	5	37	3	20	2	17
Cholecystitis	1	1			1	1
Cholestasis	1	1			1	1
Coma	1	1			1	1
Communication disorder		1		1		
Complex regional pain syndrome		1				1
Condition aggravated		1				1
Confusional state	1	5		1	1	4
Conjunctivitis		1		1		
Constipation		1		1		
Coronary artery stenosis	1	2			1	2
Coronary artery thrombosis		1				1
Cough		6		4		2
COVID-19	5	22		5	5	17
Cranial nerve palsies multiple	1	1			1	1
C-reactive protein increased	3	3	3	3		
Cyanosis		2		2		
Deafness unilateral		1				1
Death	2	5			2	5
Decreased appetite	2	5	1	4	1	1
Deep vein thrombosis	2	5			2	5
Depression	1	2		1	1	1

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Diabetes mellitus inadequate control		3
Diarrhoea	2	9
Diplegia		1
Diplopia	1	2
Discomfort		3
Disease recurrence	1	1
Disorientation		1
Disturbance in attention		1
Dizziness	3	24
Drug ineffective	6	15
Dry mouth		3
Dry throat		1
Dysarthria		1
Dysgeusia		2
Dyskinesia		1
Dysphagia	1	7
Dysphonia		3
Dysphoria		1
Dyspnoea	2	18
Dysstasia		2
Ear, nose and throat examination abnormal		1
Ear pain		1
Eczema		1
Electric shock sensation	1	1
Eosinophil count decreased	1	1
Epistaxis		2
Eructation		2
Erythema		13
Extrasystoles		1
Eye irritation		1
Eyelid oedema		1
Eye pruritus		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			3
1	6	1	3
			1
		1	2
	2		1
		1	1
			1
			1
2	16	1	8
		6	15
	2		1
	1		
			1
	2		
	1		
	3	1	4
	2		1
			1
1	7	1	11
	1		1
	1		
	1		
1	1		
1	1		
	2		
	1		1
	8		5
	1		
	1		
	1		
			1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye swelling		1				1
Face oedema		1		1		
Facial paralysis		3				3
Facial paresis	2	9	1	1	1	8
Fall		5		2		3
Fatigue	13	42	11	29	2	13
Feeding disorder		1		1		
Feeling cold		1		1		
Feeling hot	1	3	1	2		1
Fibrin D dimer increased	1	1	1	1		
Fine motor skill dysfunction		1				1
Flushing	1	5		3	1	2
Foot deformity		1				1
Formication	1	1			1	1
Gait disturbance	2	5		1	2	4
Gait inability	1	2	1	1		1
Gastrointestinal disorder		4		4		
Gastrointestinal haemorrhage		1				1
Glycosylated haemoglobin decreased		1		1		
Granulocytopenia	1	1			1	1
Guillain-Barre syndrome		4				4
Haematocrit decreased	1	2	1	1		1
Haematoma		1				1
Haematuria	1	2			1	2
Haemodynamic instability	1	1			1	1
Haemoglobin decreased	1	2	1	2		
Haemolysis	1	1			1	1
Haemoptysis		1		1		
Headache	18	52	14	36	4	16
Head discomfort		2		2		
Heart rate decreased		2				2
Heart rate increased	1	5		2	1	3

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate irregular		1				1
Hemianaesthesia	1	1			1	1
Hemiparesis	1	3			1	3
Hepatorenal syndrome	1	1			1	1
Herpes ophthalmic		2				2
Herpes zoster	2	8	1	6	1	2
Hiccups	1	1	1	1		
Hot flush	1	3	1	1		2
Hyperbilirubinaemia	1	1			1	1
Hyperhidrosis	2	13		5	2	8
Hypersensitivity		4		2		2
Hypertension	4	13	1	4	3	9
Hypertensive crisis		3				3
Hypertrophic cardiomyopathy		1				1
Hypoaesthesia	5	22	3	11	2	11
Hypoaesthesia oral	1	3	1	3		
Hypoglycaemia		4		3		1
Hypokalaemia		1				1
Hyponatraemia		1				1
Hypotension		4		1		3
Hypothermia	1	1			1	1
Hypotonia	1	4	1	3		1
Illness		2		1		1
Impaired self-care		1				1
Impaired work ability		1				1
Incorrect route of product administration		1		1		
Inflammation		1		1		
Influenza	1	1	1	1		
Injection site pain	2	3	2	3		
Insomnia		5		4		1
Insulin resistance		1				1
International normalised ratio decreased	1	1	1	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Intervertebral disc protrusion	1	1			1	1
Ischaemic cerebral infarction	1	1			1	1
Ischaemic stroke		1				1
Jaundice	2	2			2	2
Joint effusion		1				1
Laryngeal oedema		1				1
Left ventricular hypertrophy		1				1
Lethargy		1				1
Leukocytosis		1				1
Limb discomfort	1	2			1	2
Lip oedema		1		1		
Lip swelling	1	1	1	1		
Liquid product physical issue		1		1		
Localised oedema		1				1
Loss of consciousness		7				7
Loss of personal independence in daily activities		1		1		
Lower respiratory tract infection		1				1
Lymphadenitis	1	5	1	2		3
Lymphadenopathy	2	11	2	7		4
Lymph node pain	3	4	3	4		
Lymph node palpable	1	1	1	1		
Lymphocyte count decreased	1	1	1	1		
Malaise	2	12	2	9		3
Mechanical urticaria		1		1		
Memory impairment		1				1
Mental impairment	1	1			1	1
Middle insomnia		1		1		
Migraine		1		1		
Miller Fisher syndrome	1	1			1	1
Mobility decreased	3	3	1	1	2	2
Movement disorder		1		1		
Muscle injury		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle spasms	1	2			1	2
Muscle tightness		1				1
Muscular weakness		7		2		5
Musculoskeletal discomfort	1	2	1	2		
Musculoskeletal stiffness		2		1		1
Myalgia	15	41	14	29	1	12
Myocardial infarction	3	6			3	6
Myocarditis	1	2			1	2
Nail discolouration		1		1		
Nasopharyngitis		1		1		
Nausea	2	10	1	6	1	4
Neck mass	1	1	1	1		
Neck pain		2		1		1
Nervous system disorder	1	1			1	1
Neuritis		1				1
Neuritis cranial		1				1
Neuropathy peripheral		1				1
No adverse event		1		1		
Occupational exposure to product		1		1		
Ocular hyperaemia		1		1		
Oedema peripheral		1				1
Off label use		1		1		
Onycholysis		1		1		
Ophthalmic artery thrombosis	1	2			1	2
Ophthalmoplegia	1	1			1	1
Oropharyngeal pain	2	4	2	4		
Orthostatic hypotension		1				1
Overdose		1		1		
Oxygen saturation abnormal		1				1
Pain	4	11	2	7	2	4
Pain in extremity	9	19	7	15	2	4
Pallor		3		2		1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Palpitations	1	8	1	3		5
Pancreatic carcinoma	1	1			1	1
Pancreatitis		1				1
Papilloedema		1				1
Paralysis	1	2			1	2
Paraparesis		1				1
Paresis		2				2
Parotitis		1		1		
Pericarditis	1	1			1	1
Periorbital oedema		1		1		
Peripheral coldness		1				1
Peripheral swelling	1	1	1	1		
Petechiae		1		1		
Petit mal epilepsy		1				1
Pharyngeal swelling	1	1			1	1
Platelet count decreased	1	1	1	1		
Pneumonia	1	2			1	2
Pollakiuria		1		1		
Polyneuropathy		1				1
Poor quality product administered		1		1		
Poor quality sleep		1		1		
Presyncope	1	5			1	5
Priapism	1	1			1	1
Product preparation error		1		1		
Product use issue		1		1		
Protein total decreased	1	2	1	2		
Prothrombin time prolonged	1	2	1	2		
Pruritus	3	12	2	8	1	4
Psoriasis		1		1		
Psoriatic arthropathy		1				1
Pulmonary embolism	1	1			1	1
Pulmonary oedema		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulse abnormal		1				1
Pupillary reflex impaired	1	1			1	1
Pupils unequal	1	1			1	1
Purpura	1	1			1	1
Pyrexia	22	75	19	52	3	23
Rash	1	14	1	7		7
Rash maculo-papular	2	3	1	1	1	2
Rash pruritic		2		2		
Red blood cell count decreased	1	1	1	1		
Renal impairment		1				1
Respiratory tract infection		1				1
SARS-CoV-2 ant body test positive		2		2		
SARS-CoV-2 test positive	1	2		1	1	1
Sciatica		1				1
Scleritis		1				1
Shock		1				1
Skin irritation		1		1		
Skin lesion	1	2	1	1		1
Soft tissue swelling		1				1
Somnolence	4	6	4	5		1
Speech disorder		3		2		1
Sputum increased		1				1
Sputum purulent		1				1
Sudden death		2				2
Supraventricular tachycardia	1	1			1	1
Suspected COVID-19	2	2	1	1	1	1
Swelling	1	3		1	1	2
Swelling face		1				1
Syncope	1	10			1	10
Tachyarrhythmia	1	1			1	1
Tachycardia	2	14	1	7	1	7
Tendon pain	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tension		1		1		
Therapeutic response unexpected		2		2		
Thirst		1		1		
Thrombocytopenia	1	1			1	1
Thrombosis	2	3			2	3
Tinnitus		4		3		1
Tongue oedema		1				1
Tonsillar hypertrophy		1				1
Transient ischaemic attack		1				1
Tremor		3		2		1
Trigeminal neuritis	1	1			1	1
Troponin increased	1	1	1	1		
Urinary incontinence		2		1		1
Urinary tract infection		1				1
Urticaria	1	1			1	1
Uveitis		2				2
Vaccination failure		3				3
Vaccination site discomfort		3		3		
Vaccination site erythema		2		2		
Vaccination site hyperaesthesia		1		1		
Vaccination site hypoaesthesia		2		2		
Vaccination site lymphadenopathy		1				1
Vaccination site oedema		4		3		1
Vaccination site pain	22	50	21	46	1	4
Ventricular f brillation	1	1			1	1
Vertigo	1	2	1	1		1
Vision blurred	1	1			1	1
Visual impairment	1	2		1	1	1
Vomiting		5		2		3
Wheezing		1		1		
White blood cell count increased	1	1	1	1		
	339	1,227	197	641	142	586

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Anaphylactic reaction		1				1
Asthenia		1		1		
Blood pressure increased		2		2		
Bronchospasm		1				1
Burning sensation		2		2		
Chills	2	3	2	3		
Circumstance or information capable of leading to medication error		2		2		
Cough		4		3		1
COVID-19		1				1
Crying		1		1		
Dizziness	1	4	1	3		1
Drug ineffective		1				1
Dysgeusia		2		1		1
Dyspepsia		2		2		
Dysphagia		2		1		1
Erythema	1	3	1	2		1
Expired product administered		1		1		
Exposure via breast milk		1		1		
Eye irritation		1		1		
Haematoma	1	1	1	1		
Headache		3		2		1
Heart rate increased		1		1		
Hyperhidrosis		1		1		
Hypersensitivity		2		2		
Hypertension		2		1		1
Hypoaesthesia oral		5		4		1
Incorrect route of product administration		1		1		
Lip oedema	1	1	1	1		
Liquid product physical issue		2		2		
Muscle spasms	1	1			1	1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	1	1			1	1
No adverse event	1	3	1	3		
Oedema		1		1		
Oral discomfort		1		1		
Oropharyngeal discomfort		2		2		
Pain in extremity	3	4	3	4		
Palpitations		1		1		
Periorbital oedema		1		1		
Poor quality product administered		2		2		
Product quality issue		1		1		
Pruritus		1				1
Pyrexia	4	4	4	4		
Rash		2		1		1
Rash macular		1		1		
Reaction to excipient		1				1
Restlessness		1		1		
Skin burning sensation	1	1	1	1		
Swelling	1	1	1	1		
Tachycardia		3		3		
Therapeutic response unexpected	1	2	1	2		
Thrombosis	1	1			1	1
Urticaria		1		1		
Vaccination site bruising		1		1		
Vaccination site pain	2	2	2	2		
Vomiting	1	2		1	1	1
Wrong technique in product usage process		2		2		
	23	99	19	80	4	19

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Country Where Event Occurred

GUINEA

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Headache		1		1
Hypertension		1		1
		2		2

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Country Where Event Occurred

HAITI

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia		1		1
Dizziness		1		1
Dyskinesia		1		1
Vertigo		1		1
		4		4

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Country Where Event Occurred
HOLY SEE (VATICAN CITY STATE)

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia		1		1
Extensive swelling of vaccinated limb		1		1
Injected limb mobility decreased		1		1
Oedema peripheral		2		2
Pain in extremity		1		1
Periorbital oedema		1		1
Vaccination site pain		1		1
		8		8

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Country Where Event Occurred

HONDURAS

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19	1	1	1	1
Illness	1	1	1	1
	2	2	2	2

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19	1	1	1	1
Illness	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

HONG KONG

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Abortion spontaneous		1				1
Allergy to vaccine	1	3	1	2		1
Anaphylactic reaction		1				1
Anaphylactoid reaction	1	2			1	2
Aortic dissection	1	1			1	1
Arthralgia	1	2		1	1	1
Asthenia		2		1		1
Axillary pain	1	1	1	1		
Bell's palsy	7	7			7	7
Blood pressure increased	3	8	1	4	2	4
Burning sensation		1		1		
Cardiac arrest	1	1			1	1
Chest discomfort	4	10	2	6	2	4
Chest pain	5	12	2	4	3	8
Coma	2	2			2	2
Death	1	1			1	1
Dermatitis allergic	1	1	1	1		
Dizziness	13	31	6	14	7	17
Drug hypersensitivity		1				1
Dyspnoea	4	8	2	4	2	4
Epilepsy	1	1			1	1
Essential hypertension		1				1
Fatigue		2		2		
Headache	3	7	1	3	2	4
Hyperhidrosis		1		1		
Hypersensitivity	1	1			1	1
Hypertension	7	17	2	4	5	13
Hypertensive crisis	1	1			1	1
Hyperventilation		2				2
Hypoaesthesia	5	12		2	5	10
Lip swelling	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Loss of consciousness	3	6			3	6
Lower respiratory tract infection	1	1			1	1
Lung opacity	1	1			1	1
Malaise	1	2		1	1	1
Muscle twitching		1		1		
Musculoskeletal chest pain	1	1	1	1		
Musculoskeletal stiffness	1	2	1	2		
Myocardial infarction	1	1			1	1
Nausea	1	4	1	2		2
Neck pain	1	1			1	1
Neuralgia		1		1		
Pain	1	1	1	1		
Palpitations	13	22	4	6	9	16
Pharyngeal swelling		1		1		
Pneumonia	1	1			1	1
Presyncope		1		1		
Pruritus	1	2		1	1	1
Pyrexia	2	4	1	2	1	2
Rash	8	22	3	12	5	10
Seizure	4	4			4	4
Swelling face	1	1			1	1
Swelling of eyelid	2	2	2	2		
Syncope	4	6			4	6
Tachycardia	1	1			1	1
Tenderness	1	1	1	1		
Transient ischaemic attack	1	1			1	1
Urticaria	1	1	1	1		
Vaccination site erythema	1	2	1	2		
Vaccination site pain		3		2		1
Vaccination site pruritus		1		1		
Vaccination site swelling		1		1		
Vomiting		1				1

* I=Interval, C=Cumulative

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* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	118	243	37	94	81	149

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* I=Interval, C=Cumulative
* AE=Adverse Event
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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Acute haemorrhagic conjunctivitis	1	1	1	1		
Back pain		1				1
Bell's palsy	6	8			6	8
Blood pressure increased	1	3	1	3		
Cardiac arrest	1	1			1	1
Cerebrovascular accident	1	2			1	2
Chest discomfort	2	4	1	1	1	3
Chest pain	3	5			3	5
Conjunctival haemorrhage	1	1			1	1
Contusion		1				1
Coronary artery disease	2	4			2	4
Dizziness	8	16	2	5	6	11
Dysphagia	1	1	1	1		
Dyspnoea	1	2			1	2
Erythema	1	1			1	1
Essential hypertension	1	1			1	1
Fall		2				2
Headache	1	2		1	1	1
Hyperhidrosis		1		1		
Hypersensitivity		4		2		2
Hypertension	3	7	2	3	1	4
Hyperventilation	1	1			1	1
Hypoaesthesia	2	7		2	2	5
Injury		1				1
Ischaemic stroke		1				1
Lip injury		1				1
Loss of consciousness	6	13			6	13
Muscular weakness		1				1
Myalgia		1		1		
Myocardial ischaemia		1				1
Nausea	1	1	1	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Palpitations	4	11	1	4	3	7
Paresis		1				1
Presyncope	4	5			4	5
Pruritus	1	1			1	1
Rash	4	7		2	4	5
Seizure	7	12			7	12
Swelling	1	1	1	1		
Syncope	9	14			9	14
Tachycardia	1	1			1	1
Urticaria		1				1
Vaccination site hypoaesthesia	1	1			1	1
Vomiting		1		1		
	76	153	11	30	65	123

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* AE=Adverse Event
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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphasia		1		1		
Arthralgia		1		1		
Asthenia		1		1		
Chills	1	1	1	1		
Decreased appetite		1		1		
Dizziness		1		1		
Facial paralysis		1				1
Fatigue		1		1		
Hypoaesthesia		1		1		
Injection site pain		1		1		
Loss of consciousness		1				1
Lymphadenopathy		2		2		
Migraine		1		1		
Movement disorder		1		1		
Myalgia	1	1	1	1		
Paraesthesia		1		1		
Paralysis		1				1
Pyrexia	1	1	1	1		
Rash pruritic	1	1	1	1		
Seizure		1				1
Syncope		1				1
Tremor		1		1		
	4	23	4	18		5

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Country Where Event Occurred

HUNGARY

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	2	1	2		
Abdominal distension		3		3		
Abdominal pain	5	11	3	9	2	2
Abdominal pain upper		4		4		
Abortion		1				1
Abortion missed		2				2
Acute respiratory distress syndrome	1	1			1	1
Adnexa uteri pain		1		1		
Ageusia	1	3	1	3		
Aggression		1				1
Alanine aminotransferase increased		1		1		
Allergic oedema	1	1			1	1
Allergy to vaccine		1				1
Alopecia		1		1		
Anaemia	1	1			1	1
Anaphylactic reaction	2	4			2	4
Anaphylactic shock	1	1			1	1
Angina pectoris	2	6			2	6
Angioedema	1	3			1	3
Anosmia		3		3		
Antibody test normal		1		1		
Anuria	1	1			1	1
Aphthous ulcer		1		1		
Arrhythmia		1				1
Arteriosclerosis	1	2			1	2
Arthralgia	17	35	17	31		4
Arthritis reactive		1				1
Arthropathy		1		1		
Aspartate aminotransferase increased		1		1		
Asphyxia	1	4			1	4
Asthenia	22	81	20	69	2	12
Asthenopia	1	2	1	2		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Atrial f brillation	1	3
Autoimmune thyroiditis		1
Axillary mass		1
Axillary pain	2	6
Back pain	6	13
Balance disorder	1	1
B-cell type acute leukaemia		1
Bezold-Jarisch reflex		1
Biliary tract disorder		1
Blepharospasm		1
Blindness		1
Blister		1
Blood glucose decreased		1
Blood glucose increased		3
Blood pressure ambulatory increased		1
Blood pressure decreased	1	5
Blood pressure fluctuation	5	8
Blood pressure increased	7	23
Blood pressure systolic increased		1
Blood test abnormal	1	1
Body temperature increased		2
Bone pain	2	4
Bradycardia	2	3
Bradyphrenia		1
Brain injury	1	1
Breast discomfort		2
Breast mass		1
Bronchitis		1
Bronchospasm	1	1
Bruxism	1	1
Burning sensation	2	11
Cachexia	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	3
			1
	1		
2	6		
5	12	1	1
1	1		
			1
	1		
			1
	1		
	1		
	3		
	1		
1	5		
4	5	1	3
5	14	2	9
			1
1	1		
	2		
2	4		
	1		
		1	1
	2		
			1
			1
		1	1
1	1		
2	10		1
		1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Capillaritis		1		1		
Cardiac arrest	2	2			2	2
Cardiac disorder	1	2			1	2
Cardiac failure	3	8			3	8
Cardiomegaly		1				1
Cardiopulmonary failure	2	3			2	3
Cardiovascular disorder	1	2			1	2
Cartilage injury		1				1
Cerebral ischaemia		1				1
Cerebrovascular accident	1	2			1	2
Cervical neuritis		1		1		
Chest discomfort	3	8	3	7		1
Chest pain	5	16	3	12	2	4
Chills	15	70	15	69		1
Cholecystitis		1				1
Cholinergic syndrome	1	1			1	1
Chromaturia		1		1		
Chronic obstructive pulmonary disease		1		1		
Circulatory collapse	1	2			1	2
Clostridium difficile infection	1	1			1	1
Cold sweat		2		2		
Condition aggravated	2	6	1	3	1	3
Confusional state		2		1		1
Congestive hepatopathy	1	1			1	1
Cough	4	13	2	10	2	3
COVID-19	14	34	1	5	13	29
COVID-19 pneumonia	7	7			7	7
Craniofacial fracture		1				1
Cutaneous symptom		1				1
Cyanosis	1	1			1	1
Dark circles under eyes		1		1		
Death	8	11			8	11

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	6	12	6	12		
Deep vein thrombosis	2	4			2	4
Defaecation urgency		1		1		
Dehydration	1	2			1	2
Dementia	1	2			1	2
Depressed mood		1		1		
Depression		1		1		
Diarrhoea	9	28	7	25	2	3
Discomfort		1		1		
Disease recurrence	3	4	2	2	1	2
Disturbance in attention		2		1		1
Dizziness	17	56	16	49	1	7
Drug hypersensitivity		2		2		
Drug ineffective	9	26			9	26
Drug interaction		1		1		
Dry eye		3		3		
Dry mouth	2	4	2	3		1
Dry throat	1	1	1	1		
Dysgeusia	2	9	2	8		1
Dyspepsia		2		2		
Dysphagia	1	10		3	1	7
Dysphemia		1				1
Dysphonia	1	5		2	1	3
Dyspnoea	13	23	5	12	8	11
Dyspnoea exertional	1	3	1	2		1
Dysstasia	1	1			1	1
Ear discomfort		3		2		1
Ear pain	1	4	1	4		
Ear pruritus		2		2		
Ear swelling		1				1
Eczema		1		1		
Emphysema		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Enteritis		1				1
Erythema	3	17	2	15	1	2
Erythema multiforme		1				1
Exposure during pregnancy	1	4	1	4		
Exposure to SARS-CoV-2	1	1	1	1		
Exposure via breast milk	17	35	17	35		
Extrasystoles	1	2	1	1		1
Eye disorder	1	1	1	1		
Eye haemorrhage	1	2			1	2
Eye inflammation		2		1		1
Eye irritation		2		2		
Eyelid oedema		1		1		
Eye movement disorder	1	1	1	1		
Eye oedema		2				2
Eye pain	1	4	1	4		
Eye pruritus	1	2		1	1	1
Face oedema		3		1		2
Facial neuralgia	1	1	1	1		
Facial pain	1	2	1	2		
Facial paralysis		2				2
Facial paresis	2	5	2	4		1
Fall		4		1		3
Fatigue	17	53	17	53		
Fear of death	2	4	2	4		
Feeding disorder		1				1
Feeling abnormal	1	11	1	9		2
Feeling cold		2		2		
Feeling hot	2	9	2	7		2
Feeling of body temperature change	1	2	1	2		
Feeling of despair	1	1	1	1		
Femoral neck fracture		1				1
Fibrin D dimer increased	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Flushing	1	4	1	3		1
Foaming at mouth		1				1
Foetal death	1	1			1	1
Food aversion	1	1	1	1		
Frequent bowel movements	1	1	1	1		
Gait disturbance	1	3		2	1	1
Gait inability	1	1			1	1
Gamma-glutamyltransferase increased		1		1		
Gastric disorder	1	1	1	1		
Gastroesophageal reflux disease		1		1		
General symptom	1	1	1	1		
Glossitis	1	2	1	2		
Glossodynia	1	2		1	1	1
Haematemesis	1	1			1	1
Haematoma		2				2
Haematuria		1				1
Haemorrhage	1	3			1	3
Headache	36	110	36	104		6
Head discomfort	1	2	1	2		
Heart rate decreased		1		1		
Heart rate increased	6	16	3	11	3	5
Heart rate irregular		1		1		
Heavy menstrual bleeding	1	1	1	1		
Hemiparesis		1				1
Hepatic enzyme increased		1		1		
Hepatic function abnormal	1	1	1	1		
Herpes virus infection		1		1		
Herpes zoster	4	6	4	6		
Hot flush	1	5	1	4		1
Hyperaemia		1		1		
Hyperaesthesia		2		2		
Hyperhidrosis	3	10	3	10		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hypersensitivity	1	8
Hypertension	1	4
Hypertensive crisis	1	2
Hyperthyroidism	1	1
Hypoaesthesia	11	29
Hypoaesthesia oral	2	8
Hypoglycaemia		1
Hypokinesia	1	2
Hyporeflexia		2
Hypotension	1	5
Ileus	1	1
Ileus paralytic	1	1
Illness		3
Inappropriate schedule of product administration		1
Incorrect route of product administration	1	3
Increased appetite	1	1
Induration		1
Inflammation		1
Influenza		1
Influenza like illness		3
Initial insomnia	1	1
Injected limb mobility decreased	1	1
Injection site pain	1	1
Injection site urticaria		1
Injection site warmth	1	1
Insomnia	1	7
Irritability	1	1
Ischaemic stroke	1	2
Joint range of motion decreased	1	2
Joint swelling	2	2
Lacrimation increased		4
Lactation disorder		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	4	1	4
	2	1	2
		1	2
		1	1
9	24	2	5
1	6	1	2
	1		
		1	2
	2		
	2	1	3
		1	1
		1	1
	3		
	1		
	2	1	1
1	1		
	1		
	1		
	1		
	3		
1	1		
1	1		
1	1		
1	1		
1	7		
1	1		
		1	2
1	2		
2	2		
	4		
	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Left ventricular failure		1				1
Lethargy	1	3	1	2		1
Limb discomfort	1	2	1	2		
Lip oedema		1				1
Lip swelling		3		1		2
Listless		1				1
Liver function test increased	1	1	1	1		
Localised oedema		1		1		
Local reaction		2		2		
Loss of consciousness	3	5			3	5
Lower limb fracture		1				1
Lymphadenitis	2	5	1	4	1	1
Lymphadenopathy	13	45	11	36	2	9
Lymph node pain	4	14	4	13		1
Macular oedema		1				1
Malaise	10	49	10	46		3
Mastication disorder		1		1		
Maternal exposure during breast feeding		1		1		
Maternal exposure during pregnancy		2		1		1
Meibomian gland dysfunction		1		1		
Memory impairment		2		1		1
Menstruation delayed	1	2	1	2		
Menstruation irregular	2	3	2	3		
Micturition urgency		1		1		
Migraine	2	8	2	7		1
Mobility decreased	1	1	1	1		
Monoplegia		2				2
Mood altered		2		2		
Mouth swelling		2		1		1
Movement disorder	1	1	1	1		
Mucosal inflammation		1				1
Multiple organ dysfunction syndrome	2	2			2	2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle fatigue		1		1		
Muscle spasms	3	3	2	2	1	1
Muscle strain		1		1		
Muscle twitching		2		1		1
Muscular weakness	3	9	3	9		
Musculoskeletal chest pain		2		2		
Musculoskeletal stiffness	2	6	1	4	1	2
Myalgia	20	58	20	57		1
Nasal congestion	2	4	2	4		
Nasopharyngitis	5	7	5	7		
Nausea	24	65	23	60	1	5
Neck pain	3	5	3	5		
Neoplasm malignant	1	1			1	1
Neoplasm progression		1				1
Nervous system disorder	1	1	1	1		
Neuralgia		2		2		
Night sweats		1		1		
Nipple pain		1		1		
Noninfective gingivitis		1		1		
Ocular hyperaemia	1	1			1	1
Odynophagia		1		1		
Oedema blister		1				1
Oedema peripheral		2		1		1
Oesophageal varices haemorrhage	1	1			1	1
Off label use	48	90	48	90		
Ophthalmic herpes zoster		1				1
Oral herpes	1	2	1	2		
Oropharyngeal pain	3	16	2	14	1	2
Overdose		1		1		
Overfeeding of infant		1		1		
Oxygen consumption increased		1		1		
Oxygen saturation decreased	1	3	1	2		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain	2	8	2	8		
Painful respiration	1	2		1	1	1
Pain in extremity	24	76	22	72	2	4
Pain of skin	2	5	2	5		
Pallor		4		4		
Palpitations	5	12	5	10		2
Pancreatitis acute	1	1			1	1
Panic attack		1		1		
Paraesthesia	1	5	1	3		2
Paralysis		1				1
Pelvic inflammatory disease	1	1			1	1
Performance status decreased	1	1	1	1		
Periarthritis		1		1		
Pericarditis		1				1
Peripheral coldness		2		2		
Peripheral nerve paresis		1				1
Peripheral swelling	5	12	5	10		2
Peripheral venous disease		1				1
Pharyngeal oedema	2	2	1	1	1	1
Pharyngeal swelling		3		2		1
Pharyngitis		1		1		
Photopsia		1		1		
Pneumonia	1	3			1	3
Pollakiuria		1				1
Polyarthritis		2				2
Polymenorrhoea	1	1	1	1		
Polyneuropathy		1				1
Poor peripheral circulation		1		1		
Poor quality sleep	1	2	1	2		
Post-acute COVID-19 syndrome		1		1		
Potentiating drug interaction		1		1		
Presyncope	2	2	2	2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product administered at inappropriate site		1		1		
Productive cough	1	1	1	1		
Product use in unapproved indication		1		1		
Product use issue	48	89	48	89		
Progressive multifocal leukoencephalopathy	1	1			1	1
Pruritus	5	16	4	14	1	2
Psychiatric symptom		1				1
Pulmonary arterial pressure increased		1				1
Pulmonary embolism	4	4			4	4
Pulpitis dental		1		1		
Pyrexia	41	123	38	117	3	6
Rash	4	12	4	9		3
Rash erythematous		6		5		1
Rash macular	1	3		2	1	1
Rash maculo-papular		2		2		
Rash pruritic	1	7		5	1	2
Renal cyst		1		1		
Renal impairment	1	1			1	1
Renal pain		1		1		
Respiratory distress	1	3			1	3
Respiratory failure	2	2			2	2
Respiratory muscle weakness	1	1			1	1
Restlessness		1		1		
Retching		2		2		
Retinal vascular thrombosis	1	1			1	1
Rheumatoid arthritis	1	1			1	1
Rhinorrhoea	4	8	4	8		
Salivary gland enlargement		1		1		
SARS-CoV-2 ant body test positive		1		1		
SARS-CoV-2 test positive	3	8		2	3	6
Sensation of foreign body		5		2		3
Sensitive skin	1	4	1	4		

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensory loss		1		1		
Sepsis	1	1			1	1
Shock	1	1			1	1
Sinus tachycardia	1	1			1	1
Sjogren's syndrome		1				1
Skin burning sensation		7		6		1
Skin discolouration	2	3	1	2	1	1
Skin disorder		1		1		
Skin haemorrhage	1	1	1	1		
Skin hypertrophy		1		1		
Skin ulcer	1	2	1	1		1
Skin warm		1		1		
Sleep disorder	1	4	1	4		
Sleep disorder due to general medical condition, insomnia type	1	1	1	1		
Somnolence	2	11	2	10		1
Speech disorder	2	2	1	1	1	1
Status epilepticus	1	1			1	1
Stress	1	2	1	2		
Sudden death	2	2			2	2
Suspected COVID-19	2	3	1	1	1	2
Swelling	1	2	1	2		
Swelling face	2	3		1	2	2
Swelling of eyelid		2		2		
Swollen tongue		1		1		
Syncope	4	8			4	8
Tachycardia	3	11	1	6	2	5
Tachypnoea	1	1			1	1
Taste disorder		1		1		
Therapeutic response unexpected		1		1		
Thirst	1	4	1	3		1
Throat irritation	2	2	2	2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Throat tightness	3	6	1	2	2	4
Thrombophlebitis	1	2		1	1	1
Thrombophlebitis superficial	1	2			1	2
Thrombotic stroke		1				1
Tinnitus		2		2		
Tongue oedema	1	1			1	1
Tonsillar hypertrophy		1		1		
Toothache		1		1		
Total lung capacity decreased	1	1	1	1		
Tremor	5	15	5	12		3
Tricuspid valve incompetence		1				1
Type 1 diabetes mellitus	1	1			1	1
Type IV hypersensitivity reaction		1				1
Upper respiratory tract infection		2		2		
Urinary tract infection	1	1	1	1		
Urinary tract pain		1		1		
Urine output increased	1	1	1	1		
Urticaria	7	14	5	10	2	4
Uveitis		1				1
Vaccination complication	1	2	1	2		
Vaccination failure		2				2
Vaccination site coldness	1	1	1	1		
Vaccination site discolouration	1	2	1	2		
Vaccination site discomfort	2	3	2	3		
Vaccination site erythema	7	36	7	36		
Vaccination site haematoma		1		1		
Vaccination site haemorrhage		1		1		
Vaccination site hypoaesthesia	1	2	1	2		
Vaccination site induration		2		2		
Vaccination site inflammation		1		1		
Vaccination site joint movement impairment	1	1			1	1
Vaccination site lymphadenopathy	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site macule		1		1		
Vaccination site mass	1	2	1	2		
Vaccination site movement impairment	2	7	2	7		
Vaccination site nodule		4		4		
Vaccination site oedema	1	2	1	2		
Vaccination site pain	23	76	23	75		1
Vaccination site paraesthesia		1		1		
Vaccination site pruritus	3	8	3	8		
Vaccination site rash	1	2	1	2		
Vaccination site swelling	6	26	6	26		
Vaccination site vesicles	1	2	1	2		
Vaccination site warmth	2	7	2	7		
Vaginal discharge		1		1		
Vaginal infection	1	1	1	1		
Varicose vein		2		2		
Vascular pain	1	1	1	1		
Vasculitis		1		1		
Vasoconstriction		1				1
Vasodilatation	1	1			1	1
Vision blurred	1	3	1	3		
Visual impairment		2		1		1
Vomiting	5	17	5	15		2
Weight decreased	2	2	1	1	1	1
White blood cell count decreased	1	1	1	1		
White coat hypertension		1		1		
Wound		3		2		1
Wound complication		1		1		
	848	2,470	648	1962	200	508

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour		1		1		
Acute kidney injury	1	1			1	1
Acute myocardial infarction	1	2			1	2
Acute respiratory distress syndrome	1	1			1	1
Acute respiratory failure		2				2
Akinesia	1	1			1	1
Anaemia		1				1
Anal incontinence		1				1
Anaphylactic reaction		1				1
Anaphylactic shock		1				1
Angina pectoris		1				1
Anosmia		1		1		
Antibody test negative		1		1		
Anuria		1				1
Anxiety		1		1		
Arrhythmia	1	1			1	1
Arthralgia	4	6	4	6		
Asphyxia	1	2			1	2
Asthenia	8	19	7	12	1	7
Ataxia	1	2		1	1	1
Atrial f brillation	1	3			1	3
Atrioventricular block complete	1	1			1	1
Back pain	2	2	2	2		
Balance disorder	1	1	1	1		
Bell's palsy	1	2			1	2
Bilirubin conjugated increased	1	1			1	1
Blister		1		1		
Blood bilirubin increased	1	1			1	1
Blood glucose increased		1				1
Blood pressure decreased	1	2			1	2
Blood pressure fluctuation		1		1		
Blood pressure increased	3	10	1	5	2	5

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Blood thyroid stimulating hormone decreased		1
Bradycardia	2	2
Bronchial neoplasm	1	1
Bronchitis		1
Burning sensation		1
Bursitis		1
Cachexia	1	1
Cardiac arrest	2	2
Cardiac disorder		1
Cardiac failure	3	5
Cardiac failure congestive	1	1
Cardiogenic shock	1	1
Cardiomegaly		1
Cardiopulmonary failure	3	3
Cardiovascular insufficiency	1	1
Catarrh	1	1
Cellulitis		1
Cerebral infarction		1
Cerebrovascular accident	1	2
Chest discomfort	1	4
Chest pain		1
Chills	7	13
Choking		1
Chromaturia		1
Circulatory collapse	3	5
Cold sweat		1
Condition aggravated		3
Confusional state	1	3
Constipation		1
Coordination abnormal		1
Cough	3	7
COVID-19	20	38

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
		2	2
		1	1
	1		
	1		
	1		
		1	1
		2	2
			1
		3	5
		1	1
		1	1
	1		
		3	3
		1	1
1	1		
			1
			1
		1	2
1	4		
	1		
6	12	1	1
			1
	1		
		3	5
	1		
			3
	1	1	2
	1		
	1		
	3	3	4
2	3	18	35

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19 pneumonia	7	8			7	8
Cyanosis		1				1
Cystitis	1	1	1	1		
Death	4	7			4	7
Decreased appetite	1	4	1	3		1
Decubitus ulcer		1				1
Deep vein thrombosis	1	2			1	2
Depression		1		1		
Dermal cyst	1	1	1	1		
Dermatitis herpetiformis		1		1		
Diarrhoea	1	6		4	1	2
Diarrhoea haemorrhagic		1				1
Disease recurrence	1	1			1	1
Dizziness	6	11	3	8	3	3
Drug ineffective	16	27			16	27
Drug interaction	1	1	1	1		
Dysarthria	1	1			1	1
Dysgeusia		1		1		
Dysphagia		3				3
Dysphonia		1				1
Dyspnoea	6	15	1	3	5	12
Dysuria	1	1	1	1		
Ear pruritus		1		1		
Eczema infantile	1	1	1	1		
Eosinophilia	1	1	1	1		
Epistaxis		1		1		
Erysipelas		1				1
Erythema	1	4	1	4		
Exposure via breast milk	22	39	21	38	1	1
Eye haemorrhage	1	2			1	2
Facial paresis	1	1	1	1		
Fall		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fatigue	5	18	5	17		1
Feeding disorder		1				1
Feeling abnormal	1	3	1	3		
Feeling hot	1	3	1	3		
Feeling of despair		1		1		
Fibrin D dimer increased		1				1
Flushing		1		1		
Functional gastrointestinal disorder		1		1		
Gait disturbance		2		2		
Gastritis erosive		1				1
Gastrointestinal disorder	1	1	1	1		
Gastrointestinal haemorrhage		1				1
General physical health deterioration	1	2		1	1	1
Gingival pain		1		1		
Glomerular filtration rate decreased		1		1		
Guillain-Barre syndrome		1				1
Haematochezia	1	2			1	2
Haematoma		2		1		1
Haemoptysis		1				1
Headache	6	23	5	21	1	2
Head injury	1	1			1	1
Heart rate increased	4	5	3	4	1	1
Heat stroke	1	1	1	1		
Hepatic enzyme abnormal	1	1			1	1
Herpes zoster	1	5	1	5		
Hot flush		1		1		
Hyperaesthesia		1		1		
Hyperhidrosis	2	3	1	1	1	2
Hypersensitivity		4		4		
Hypertension	1	1	1	1		
Hypertensive encephalopathy	1	1			1	1
Hyperthyroidism	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia	2	6		4	2	2
Hypoaesthesia oral		2		1		1
Hypotension		3				3
Hypotonia		1				1
Hypovolaemic shock	1	1			1	1
Immune-mediated adverse reaction	1	1	1	1		
Incontinence	1	1	1	1		
Incorrect product formulation administered		1		1		
Incorrect route of product administration	1	1	1	1		
Inflammation	1	2	1	2		
Influenza like illness		1		1		
Insomnia	1	4	1	4		
Intervertebral disc protrusion		1		1		
Iodine uptake decreased		1		1		
Irritability		1		1		
Ischaemic cardiomyopathy	1	1			1	1
Ischaemic stroke	1	1			1	1
Lack of spontaneous speech	1	1	1	1		
Laryngeal oedema		1				1
Left ventricular failure	1	1			1	1
Lethargy		3		3		
Lhermitte's sign		1		1		
Lip disorder	1	1			1	1
Liquid product physical issue		1		1		
Loss of consciousness	1	4			1	4
Lung disorder	1	1	1	1		
Lung neoplasm	1	1			1	1
Lymphadenopathy	1	6	1	6		
Lymph node pain		1		1		
Lymphocyte count decreased		1		1		
Malaise	7	15	7	15		
Megacolon		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Melaena		1				1
Metabolic acidosis		1				1
Micturition urgency	1	1	1	1		
Mobility decreased		1		1		
Monocyte count increased		1		1		
Monocytosis		1				1
Movement disorder	1	1			1	1
Muscle spasms		1		1		
Muscle strain		1		1		
Muscle tightness		1		1		
Muscular weakness	2	4	2	4		
Musculoskeletal stiffness	1	1	1	1		
Myalgia	3	13	3	13		
Myelopathy		1				1
Myocardial infarction	2	2			2	2
Nausea	4	10	3	9	1	1
Neoplasm	1	1			1	1
Neoplasm progression	1	1			1	1
Nervous system disorder	1	1			1	1
Neuralgia		1				1
Oedema peripheral		1				1
Oesophageal haemorrhage	1	1			1	1
Oropharyngeal pain		3		1		2
Pain	2	4	2	4		
Pain in extremity	3	13	2	12	1	1
Pain of skin		2		2		
Pallor		1				1
Palpitations	1	2	1	2		
Paranasal sinus discomfort		1		1		
Paraplegia	1	1			1	1
Peripheral coldness		1		1		
Peripheral swelling	1	2	1	2		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Petechiae	1	2		1	1	1
Pharyngeal oedema		1		1		
Pityriasis rosea		1		1		
Pneumonia	3	5			3	5
Pneumonitis	1	1			1	1
Poor quality product administered		1		1		
Poor quality sleep	1	1			1	1
Post-acute COVID-19 syndrome	1	1			1	1
Presyncope	1	1	1	1		
Product complaint		1		1		
Productive cough		2		2		
Prostatomegaly	1	1	1	1		
Pruritus	1	2	1	2		
Psychiatric symptom		1				1
Pulmonary embolism	2	3			2	3
Pulmonary oedema	2	2			2	2
Pulseless electrical activity		1				1
Pyrexia	12	37	7	26	5	11
Radiculopathy		1		1		
Rash		3		3		
Rash erythematous		2		2		
Rash maculo-papular		1				1
Rash pruritic		1		1		
Rash vesicular		1		1		
Red blood cell sedimentation rate increased		1		1		
Renal impairment		1				1
Renal pain		1		1		
Respiratory arrest	1	1			1	1
Respiratory disorder		1		1		
Respiratory failure	2	3			2	3
Respiratory symptom	1	1	1	1		
Restlessness	1	2		1	1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Retinal artery thrombosis	1	1			1	1
Retinal vein thrombosis	1	1			1	1
Rhinorrhoea	1	6	1	6		
Sarcoidosis	1	1			1	1
SARS-CoV-2 ant body test negative		1		1		
SARS-CoV-2 ant body test positive		1		1		
SARS-CoV-2 test positive	1	5		3	1	2
Sciatica		1				1
Sensation of foreign body		2				2
Serum ferritin increased		1		1		
Sinusitis		1		1		
Skin burning sensation	1	1	1	1		
Skin disorder	1	1	1	1		
Skin lesion		1		1		
Skin sensitisation		1		1		
Skin swelling	1	1	1	1		
Sleep deficit	1	1	1	1		
Sleep disorder		1		1		
Somnolence	1	5	1	3		2
Speech disorder		1		1		
Spinal osteoarthritis		1		1		
Stress		1		1		
Stridor		1				1
Sudden death	3	3			3	3
Suspected counterfeit product		1		1		
Suspected COVID-19	2	2			2	2
Swelling		1		1		
Swelling face		2		2		
Syncope	2	5			2	5
Tachycardia	1	2			1	2
Tachypnoea		1				1
Tenosynovitis	1	1	1	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tension		2		2		
Tension headache		1		1		
Therapeutic response unexpected		1		1		
Throat irritation		1		1		
Thrombocytopenia	1	1			1	1
Thrombophlebitis		1				1
Thrombosis	1	1			1	1
Thyroiditis subacute		1		1		
Thyroxine free increased		1		1		
Tinnitus	1	4	1	4		
Tooth disorder		1				1
Transient ischaemic attack	1	2			1	2
Tremor	1	2		1	1	1
Tri-iodothyronine free increased		1		1		
Urinary incontinence		1		1		
Urinary tract inflammation	1	1	1	1		
Urosepsis	1	1			1	1
Urticaria	2	4	2	4		
Vaccination failure	4	6			4	6
Vaccination site coldness		1		1		
Vaccination site pain	2	12	2	12		
Vaccination site swelling	1	1	1	1		
Vascular dementia	1	1			1	1
Vein disorder		1		1		
Vomiting		2		1		1
Weight decreased	1	2			1	2
Wheezing		1				1
White matter lesion		1		1		
	305	759	135	435	170	324

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		1		1		
Back pain		1		1		
Chills		1		1		
Condition aggravated	1	2	1	2		
COVID-19		1				1
Dermatitis allergic		1		1		
Drug ineffective		1				1
Exposure via breast milk	8	11	8	11		
Full blood count abnormal		1				1
Headache		1		1		
Herpes zoster		4		4		
Inflammation	1	2	1	2		
Lymphadenopathy		1		1		
Lymphoedema		1		1		
Neuralgia	1	1	1	1		
Off label use	1	2	1	2		
Oropharyngeal pain		1		1		
Pain in extremity		1		1		
Product use issue	1	2	1	2		
Pyrexia		2		2		
	13	38	13	35		3

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Country Where Event Occurred

ICELAND

090177e19749cf15\Approved\Approved On: 14-Jun-2021 14:01 (GMT)

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anal incontinence		1		1		
Aortic aneurysm		1				1
Aphasia	1	3		1	1	2
Arrhythmia	2	2			2	2
Arthralgia	2	5	2	5		
Arthritis	1	1	1	1		
Asthenia		5		5		
Asthma		1				1
Axillary pain		3		3		
Back pain	1	4		3	1	1
Balance disorder		1				1
Blood pressure increased	1	2	1	2		
Bone pain	1	2	1	2		
Bradycardia		1				1
Breast inflammation		1		1		
Breath sounds abnormal		1				1
Cardiac failure		1				1
Chest discomfort	1	3	1	3		
Chest pain	1	3		2	1	1
Chills	4	14	4	14		
Cold sweat		1		1		
Confusional state		1				1
Contusion		1				1
Cough		5		4		1
Death		4				4
Decreased appetite		4		4		
Deep vein thrombosis		1				1
Delirium		1				1
Discomfort	1	1	1	1		
Disease progression		1				1
Disease recurrence		1		1		
Disorientation	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	4	14	4	14		
Dry mouth		1		1		
Dry throat		1		1		
Dysgeusia		1		1		
Dyspnoea	1	7	1	5		2
Dyspraxia	1	1			1	1
Ear pain		1		1		
Electrocardiogram QT prolonged	1	1			1	1
Erythema		4		4		
Fall		1		1		
Fatigue	2	17	2	16		1
Feeling abnormal		3		3		
Feeling cold		1		1		
Feeling hot		1		1		
Fibrin D dimer increased		1				1
Fluid overload		1				1
Gastrointestinal pain		1		1		
Headache	11	45	11	45		
Head discomfort	1	2	1	2		
Heart rate increased	3	5	3	5		
Hepatic enzyme increased		2		1		1
Hot flush		1		1		
Hypercapnia		1				1
Hyperhidrosis		2		2		
Hypersomnia		1		1		
Hypertension		1		1		
Hypoaesthesia	2	7	1	6	1	1
Hypoperfusion		1				1
Hypoxia		1				1
Influenza like illness		1		1		
Injection site pain		1		1		
Injection site swelling	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Insomnia		2		2		
Joint stiffness		1		1		
Limb discomfort		1		1		
Loss of consciousness		2				2
Lung infiltration		1				1
Lymphadenopathy	1	6	1	6		
Malaise	6	27	6	23		4
Maternal exposure during pregnancy		1		1		
Memory impairment		1		1		
Migraine		1		1		
Motor dysfunction		1				1
Muscle twitching		2		2		
Muscular weakness		1		1		
Myalgia	9	31	9	31		
Nasopharyngitis		5		5		
Nausea	5	15	5	15		
Neck pain	1	1	1	1		
Noninfective sialoadenitis		1		1		
Ocular discomfort		1		1		
Off label use	1	3	1	3		
Oropharyngeal pain		5		5		
Oxygen saturation decreased		1				1
Pain	1	2		1	1	1
Painful respiration		1		1		
Pain in extremity	3	11	3	9		2
Pallor		2		2		
Palpitations	1	1	1	1		
Periorbital swelling		1		1		
Peripheral artery thrombosis		1				1
Peripheral embolism		1				1
Peripheral swelling		1				1
Personality change		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal swelling		1		1		
Pneumonia		3				3
Poor quality sleep		1		1		
Productive cough		1		1		
Product use issue	1	3	1	3		
Pruritus	1	6	1	6		
Pulmonary embolism	1	1			1	1
Pulmonary oedema		1				1
Pulmonary pain	1	2	1	2		
Pyrexia	11	44	11	42		2
Rash	1	4	1	4		
Respiratory arrest		1				1
Rhinorrhoea		2		2		
Salivary gland enlargement		1		1		
Sensitive skin		2		2		
Sensory loss		1		1		
Skin burning sensation		1		1		
Skin discolouration		1		1		
Sleep disorder	1	2	1	1		1
Sluggishness		1		1		
Speech disorder	1	1			1	1
Sudden death	1	2			1	2
Syncope	1	2			1	2
Tachycardia		2		1		1
Thirst		1		1		
Throat tightness	1	1	1	1		
Transient ischaemic attack		2				2
Tremor	1	2	1	2		
Urinary incontinence		1		1		
Urine flow decreased		1				1
Vaccination site erythema		6		6		
Vaccination site inflammation		3		3		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site irritation	1	1	1	1		
Vaccination site pain	6	24	6	24		
Vaccination site reaction		1		1		
Vaccination site swelling		2		2		
Vaccination site warmth	1	3	1	3		
Vomiting	2	3	2	3		
	104	475	90	406	14	69

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction		2				2
Anaphylactic reaction	1	1			1	1
Arthralgia		2		2		
Arthritis		1		1		
Asthenia		2		2		
Atrial f brillation		1				1
Bell's palsy	1	1			1	1
Blood pressure decreased		1				1
Bone pain		1		1		
Cardiac failure		1				1
Cerebrovascular accident		1				1
Chest pain		1				1
Chills	2	5	2	5		
Chronic obstructive pulmonary disease		1				1
Cold sweat	1	1	1	1		
Death		2				2
Delirium		2				2
Depressed level of consciousness		1				1
Discomfort		2		2		
Dizziness	1	1	1	1		
Dysgeusia	1	1	1	1		
Dysphoria	1	1			1	1
Erythema		1		1		
Exposure via breast milk	1	1			1	1
Fatigue		2		2		
Feeling abnormal	1	1	1	1		
Feeling cold		1		1		
Headache	4	7	4	7		
Hyperhidrosis		1				1
Hypoaesthesia	1	1	1	1		
Hypotension	1	1	1	1		
Hypoxia		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Influenza like illness	1	1	1	1		
Injection site pain		1		1		
Joint swelling		2		2		
Loss of consciousness		1				1
Malaise	1	5	1	4		1
Muscular weakness	1	1	1	1		
Myalgia	4	7	4	7		
Myocardial infarction		1				1
Nasopharyngitis	1	1	1	1		
Nausea	1	3	1	3		
Oedema peripheral		1		1		
Off label use		2		2		
Oropharyngeal pain		1		1		
Oxygen saturation decreased		1				1
Pain		1		1		
Pain in extremity	1	1	1	1		
Pneumonia		1				1
Pneumonia aspiration		1				1
Presyncope	1	1	1	1		
Product use in unapproved indication		2		2		
Product use issue		1		1		
Pyrexia	4	13	3	10	1	3
Respiration abnormal		1				1
Respiratory failure		1				1
Sepsis		1				1
Sudden death		1				1
Swelling		1		1		
Syncope		1				1
Tachycardia	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination site pain	3	6	3	6		
Vaccination site swelling		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ventricular tachycardia		1				1
Visual impairment		1		1		
	36	115	31	81	5	34

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anencephaly		1				1
Maternal exposure during pregnancy		1		1		
Rhinorrhoea		1		1		
		3		2		1

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Country Where Event Occurred

INDIA

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		1				1
COVID-19		1				1
Dizziness		1				1
Drug ineffective		1				1
Fatigue		1				1
Headache		1				1
Inappropriate schedule of product administration		1		1		
Loss of consciousness		1				1
Off label use		1		1		
Oxygen saturation decreased		1				1
Pain		1				1
Vaccination site pain		1				1
Vomiting		1				1
		13		2		11

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19	2	2	2	2
COVID-19 pneumonia	1	1	1	1
Drug ineffective	2	2	2	2
Myocardial infarction	1	1	1	1
	6	6	6	6

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	1			1	1
Drug ineffective	1	1			1	1
Suspected counterfeit product		1		1		
	2	3		1	2	2

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Country Where Event Occurred

IRAQ

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough		1		1		
COVID-19	2	2	2	2		
Headache		1		1		
Lymphadenopathy	1	1	1	1		
Mastitis	1	1			1	1
Myalgia		1		1		
Nausea		1		1		
Pyrexia		1		1		
Vaccination site pain		1		1		
	4	10	3	9	1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Cerebrovascular accident	2	2			2	2
Chest pain	1	1			1	1
COVID-19	2	2	2	2		
Gait disturbance	1	1	1	1		
Hyperhidrosis	1	1			1	1
Lacunar infarction	1	1			1	1
Limb discomfort	1	1	1	1		
Myocardial infarction	1	1			1	1
Oxygen saturation decreased	1	1	1	1		
Pain in extremity	1	1	1	1		
Paraesthesia	1	1	1	1		
Pyrexia	2	2	2	2		
Tremor	1	1	1	1		
Vaccination site pain	1	1	1	1		
	18	18	12	12	6	6

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	1			1	1
Decreased appetite		1		1		
Deep vein thrombosis	1	1			1	1
Drug ineffective	1	1			1	1
Fatigue		1		1		
Insomnia		1		1		
Pyrexia		1		1		
Vaccination site pain		1		1		
	3	8		5	3	3

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Country Where Event Occurred

IRELAND

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	5		2	2	3
Abdominal distension		3		1		2
Abdominal infection		1				1
Abdominal pain	3	9		1	3	8
Abdominal pain lower	1	1	1	1		
Abdominal pain upper	3	8	1	3	2	5
Abortion spontaneous	1	4			1	4
Abortion threatened	1	1			1	1
Accidental overdose		1		1		
Acute myocardial infarction	2	2			2	2
Acute respiratory distress syndrome	1	1			1	1
Ageusia	2	6	1	2	1	4
Agitation	2	2	1	1	1	1
Allergy to vaccine		1				1
Amenorrhoea		1				1
Amnesia	1	1			1	1
Anaemia		1				1
Anaphylactic reaction	1	8			1	8
Anaphylactic shock		1				1
Anaphylactoid reaction	1	1			1	1
Aneurysm	1	1	1	1		
Angina pectoris	1	1			1	1
Angioedema	1	4			1	4
Ankylosing spondylitis	1	1			1	1
Anosmia	1	1			1	1
Anxiety	4	9	3	3	1	6
Aortic aneurysm		1				1
Aphasia	2	3			2	3
Arrhythmia	2	2			2	2
Arthralgia	36	72	13	24	23	48
Arthritis	1	1			1	1
Aspiration		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aspiration joint	1	1	1	1		
Asthenia	18	65	3	13	15	52
Asthenopia	1	1			1	1
Asthma		1				1
Atrial tachycardia	1	1			1	1
Axillary mass		1				1
Axillary pain	4	11	2	3	2	8
Back pain	11	31	3	7	8	24
Balance disorder	2	2	2	2		
Bedridden	4	5			4	5
Bell's palsy	5	12			5	12
Blindness		1				1
Blindness transient		1				1
Blister		1				1
Blood bilirubin increased		1				1
Blood glucose fluctuation		1				1
Blood lactic acid increased		1				1
Blood pressure decreased	1	1			1	1
Blood pressure diastolic increased		1				1
Blood pressure increased		9				9
Blood pressure systolic increased	1	2		1	1	1
Blood sodium decreased		1				1
Blood urine present		1				1
Bloody discharge		1				1
Body temperature decreased		1				1
Body temperature increased		2		1		1
Bone pain	3	9	1	2	2	7
Bradycardia		1				1
Brain injury	1	1			1	1
Breast mass		1				1
Breast pain		4				4
Breast swelling		4				4

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast tenderness		1		1		
Burning sensation	3	9		1	3	8
Cardiac failure		1				1
Cardiac failure congestive		1				1
Cardiac flutter	1	1			1	1
Cardio-respiratory arrest	1	1			1	1
Cellulitis	1	4			1	4
Cerebral disorder		1				1
Cerebral infarction	1	2			1	2
Cerebrovascular accident	3	5			3	5
Cerebrovascular insufficiency		1				1
Cheilitis		1				1
Chest discomfort	4	20	1	3	3	17
Chest pain	10	25	1	3	9	22
Chillblains	1	2			1	2
Chills	33	80	17	23	16	57
Choking sensation		1		1		
Chromaturia		3		1		2
Cluster headache		1		1		
Cold sweat		3				3
Coma		1				1
Complicated appendicitis		1				1
Condition aggravated	4	5	2	2	2	3
Confusional state	3	7	1	1	2	6
Constipation		1				1
Contusion		1		1		
Corneal reflex decreased		1				1
Cough	4	14	3	4	1	10
COVID-19	3	10	1	1	2	9
C-reactive protein increased	1	1	1	1		
Cyanosis	1	3	1	2		1
Cyst		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dark circles under eyes		1				1
Deafness		2				2
Deafness unilateral	1	1			1	1
Death	1	5			1	5
Decreased activity		1				1
Decreased appetite	9	19	1	3	8	16
Deep vein thrombosis		5				5
Dehydration		1				1
Delirium	1	1			1	1
Dental paraesthesia	1	1	1	1		
Depressed level of consciousness	1	2			1	2
Depression	2	2	1	1	1	1
Dermatitis	1	3	1	2		1
Dermatitis allergic	1	2			1	2
Diarrhoea	13	31	6	9	7	22
Diplopia		2		1		1
Discomfort	3	13		1	3	12
Disease recurrence	1	6			1	6
Disorientation	1	5			1	5
Disturbance in attention	1	5		2	1	3
Dizziness	40	101	13	24	27	77
Dizziness postural	1	1			1	1
Drug ineffective	2	4			2	4
Dry eye	1	3			1	3
Dry mouth		1				1
Dry skin	1	1	1	1		
Dry throat		2				2
Dysarthria	1	3	1	1		2
Dysgeusia	6	12	5	7	1	5
Dyskinesia	1	2		1	1	1
Dysphagia	1	3			1	3
Dysphonia		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea	10	30		1	10	29
Dyspnoea at rest		1				1
Dyspnoea exertional	2	4			2	4
Dysstasia		2				2
Ear discomfort		1				1
Ear infection		1				1
Ear pain	3	4	1	1	2	3
Eating disorder	1	1	1	1		
Eczema		1				1
Electrocardiogram change	1	1			1	1
Emotional distress	2	3			2	3
Encephalitis		1				1
Encephalopathy		1				1
Eosinophil count increased		1				1
Epicondylitis	1	1			1	1
Epilepsy		1				1
Epistaxis		2				2
Eructation	1	1	1	1		
Erythema	2	8		3	2	5
Erythema nodosum	1	1			1	1
Erythema of eyelid		1				1
Excessive eye blinking		1				1
Exposure during pregnancy	2	4	1	3	1	1
Extensive swelling of vaccinated limb		1		1		
Extra dose administered	1	1	1	1		
Eye discharge		1				1
Eye infection	1	1			1	1
Eye irritation	1	2			1	2
Eyelid ptosis		1				1
Eyelid rash	1	1			1	1
Eyelids pruritus		1				1
Eye movement disorder		2				2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye pain	2	6			2	6
Eye pruritus	2	3			2	3
Eye swelling		2				2
Face injury		1				1
Facial neuralgia	1	1			1	1
Facial pain	4	6	2	3	2	3
Facial paralysis	4	9			4	9
Facial paresis	1	2			1	2
Faeces discoloured		1				1
Faeces pale		1				1
Fall	2	2			2	2
Fatigue	52	144	27	56	25	88
Feeding disorder	2	3			2	3
Feeling abnormal	10	21	4	6	6	15
Feeling cold	1	11	1	3		8
Feeling drunk		2				2
Feeling hot	12	27	6	7	6	20
Feeling jittery	1	1			1	1
Feeling of body temperature change	4	7	2	2	2	5
Flank pain		4				4
Flatulence		2		1		1
Flushing	2	7	1	1	1	6
Formication		1				1
Furuncle		1				1
Gait disturbance	1	6			1	6
Gait inability		2				2
Gastric disorder		1				1
Gastrointestinal sounds abnormal	1	1	1	1		
Gastroesophageal reflux disease		1				1
Generalised tonic-clonic seizure	1	1			1	1
General physical health deterioration		2				2
Glossodynia		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematemesis		1				1
Haematochezia		1				1
Haemoglobin decreased		1				1
Hallucination		1				1
Hangover		1		1		
Headache	76	207	33	58	43	149
Head injury	1	1			1	1
Heart rate decreased		1				1
Heart rate increased	6	17	2	3	4	14
Heart rate irregular		2				2
Heavy menstrual bleeding	2	3	2	3		
Hemiparaesthesia	1	1			1	1
Hemiparesis	1	3			1	3
Hepatic pain	1	1			1	1
Herpes zoster	1	3	1	1		2
Herpes zoster oticus	1	1			1	1
Herpes zoster reactivation		1				1
Hordeolum	1	2			1	2
Hot flush	2	2	1	1	1	1
Hyperaesthesia		1				1
Hyperaesthesia teeth	1	1	1	1		
Hyperhidrosis	6	25	1	3	5	22
Hyperpyrexia		1				1
Hypersensitivity	1	7	1	2		5
Hypersomnia	3	4			3	4
Hypertension	7	22	1	2	6	20
Hyperventilation		1				1
Hypoaesthesia	13	38	6	14	7	24
Hypoaesthesia oral	2	11	2	3		8
Hypoglycaemia		1				1
Hypopnoea	1	2			1	2
Hypotension	1	10		3	1	7

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypotonia		1				1
Illness		3		2		1
Impaired driving ability		3				3
Impaired work ability	17	34	5	7	12	27
Inappropriate schedule of product administration	1	5	1	5		
Incorrect dose administered	1	2		1	1	1
Infection		1		1		
Inflammation	1	2			1	2
Influenza	1	3	1	2		1
Influenza like illness	6	21	4	10	2	11
Injected limb mobility decreased	2	4	1	2	1	2
Injection site movement impairment		1				1
Injection site pain	1	4		1	1	3
Injury	1	2			1	2
Injury associated with device		1		1		
Insomnia	14	27	4	5	10	22
Intermenstrual bleeding		3				3
Intervertebral disc disorder	1	1	1	1		
Irritable bowel syndrome		1				1
IVth nerve paralysis		1				1
Jaundice		1				1
Jaw disorder	1	1	1	1		
Joint range of motion decreased		1				1
Joint stiffness	1	5	1	1		4
Joint swelling	1	1			1	1
Joint warmth	1	1			1	1
Kidney infection	1	1			1	1
Lacrimation decreased		1				1
Lacrimation increased		1				1
Lethargy	9	20	1	2	8	18
Limb discomfort	4	11	3	5	1	6
Lip discolouration		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lip dry		1				1
Lip swelling	1	11			1	11
Liver function test increased		1				1
Localised infection	1	1	1	1		
Loss of consciousness	4	9			4	9
Loss of control of legs		1				1
Loss of personal independence in daily activities	7	12		2	7	10
Lower respiratory tract infection		1				1
Lymphadenopathy	11	31	1	4	10	27
Lymph node pain	3	9	2	2	1	7
Malaise	22	59	9	15	13	44
Mass		1				1
Mastitis		2				2
Maternal exposure during breast feeding		2		2		
Maternal exposure during pregnancy	3	11	2	9	1	2
Melaena		1				1
Memory impairment	1	3			1	3
Menstrual disorder	1	3		1	1	2
Menstruation irregular	1	1			1	1
Metabolic acidosis		1				1
Micturition urgency		1		1		
Migraine	5	11	2	4	3	7
Mobility decreased	3	7	1	1	2	6
Muscle fatigue		1		1		
Muscle spasms	1	7		2	1	5
Muscle tightness	1	1	1	1		
Muscle twitching	1	8		1	1	7
Muscular weakness	3	9			3	9
Musculoskeletal chest pain	1	3			1	3
Musculoskeletal discomfort		1				1
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	5	12	2	5	3	7

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	33	84	18	29	15	55
Mydriasis		1		1		
Myelitis transverse		1				1
Myocardial infarction		2				2
Myocarditis	2	2			2	2
Nasal congestion	1	3	1	2		1
Nasopharyngitis	2	2	2	2		
Nausea	40	132	18	42	22	90
Neck pain	8	15	5	6	3	9
Nerve compression		1				1
Nerve injury	1	2			1	2
Nervousness		1				1
Neuralgia	2	5			2	5
Neuritis cranial		1				1
Neuropathy peripheral		1				1
Night sweats	2	4	2	3		1
Normal pressure hydrocephalus		1				1
Nystagmus		1				1
Off label use	2	11	2	11		
Oligomenorrhoea		1		1		
Oral herpes		4		2		2
Oral hyperaesthesia	1	1			1	1
Oral pain	1	1			1	1
Oral pruritus		1		1		
Oropharyngeal discomfort	1	2	1	1		1
Oropharyngeal pain	2	11		2	2	9
Oxygen saturation decreased	1	7			1	7
Pain	27	82	13	24	14	58
Pain in extremity	21	69	14	28	7	41
Pain in jaw	3	3	2	2	1	1
Pallor	1	9	1	3		6
Palpitations	6	22	1	2	5	20

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pancreatitis relapsing		1				1
Panic attack		3				3
Paraesthesia	17	52	8	15	9	37
Paraesthesia ear	1	1			1	1
Paraesthesia oral	4	14	2	5	2	9
Paranasal sinus discomfort		1				1
Periarthritis		1				1
Pericardial effusion	1	1			1	1
Periorbital discomfort		1		1		
Periorbital oedema		1		1		
Periorbital swelling		1				1
Peripheral coldness	3	3	2	2	1	1
Peripheral swelling	3	9			3	9
Pharyngeal hypoaesthesia		1		1		
Pharyngeal paraesthesia		2		1		1
Pharyngeal swelling	2	5	1	1	1	4
Photophobia		1				1
Photosensitivity reaction	1	1			1	1
Platelet count decreased		2				2
Pneumonia		1				1
Pollakiuria		1				1
Polymenorrhoea	1	1	1	1		
Poor quality product administered		1		1		
Poor quality sleep		1		1		
Presyncope	3	9	2	6	1	3
Productive cough	1	1			1	1
Product preparation error	1	2		1	1	1
Product preparation issue		3		3		
Product use issue	1	6	1	6		
Pruritus	14	32	7	12	7	20
Psoriasis	1	1	1	1		
Psychomotor hyperactivity		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary embolism		2				2
Pulmonary pain	1	1			1	1
Pulmonary sepsis		1				1
Pulse abnormal		1				1
Pupils unequal		1		1		
Purpura	1	1			1	1
Pyrexia	56	142	25	45	31	97
Quality of life decreased		1				1
Rash	21	44	6	11	15	33
Rash erythematous	4	10		1	4	9
Rash macular	2	3	1	1	1	2
Rash papular	1	1			1	1
Rash pruritic	3	7	1	3	2	4
Rectal haemorrhage	1	1			1	1
Red blood cell sedimentation rate increased	1	1	1	1		
Respiratory arrest	1	1			1	1
Respiratory rate increased		1				1
Respiratory tract infection		1				1
Retching		2				2
Retroplacental haematoma	1	1			1	1
Rhinitis		2				2
Road traffic accident		1				1
Salivary hypersecretion		2		2		
SARS-CoV-2 test positive		1				1
Sciatica	2	2	1	1	1	1
Seizure	1	3			1	3
Sensation of foreign body		2				2
Sensitive skin		1				1
Sensory disturbance	3	4	1	2	2	2
Sensory loss		2				2
Sinus congestion		1				1
Sinus headache	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sinusitis	1	1			1	1
Sinus pain	1	2	1	1		1
Skin burning sensation	1	3	1	1		2
Skin discolouration		1				1
Skin exfoliation		1				1
Skin laceration		1		1		
Skin papilloma		1				1
Skin tightness		1				1
Skin warm		1				1
Skin wrinkling		1				1
Sleep disorder	2	3			2	3
Sneezing	1	1	1	1		
Somnolence	3	8	1	2	2	6
Speech disorder	1	3	1	2		1
Spinal pain	1	1			1	1
Stridor		3				3
Sudden death		1				1
Sudden onset of sleep		1				1
Supraventricular extrasystoles	1	1			1	1
Supraventricular tachycardia		2				2
Suspected product quality issue		3		3		
Swelling	2	9	1	2	1	7
Swelling face	2	9	1	2	1	7
Swelling of eyelid	2	4		1	2	3
Swollen tongue	1	6			1	6
Syncope	13	29			13	29
Syringe issue	1	1	1	1		
Tachycardia	4	24		1	4	23
Taste disorder		2				2
Tenderness	1	4			1	4
Tension headache		1				1
Tetany	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thinking abnormal	1	1	1	1		
Thirst	2	3	1	1	1	2
Throat irritation		4		2		2
Throat tightness		4		1		3
Thrombosis		2				2
Thyroiditis acute	1	1			1	1
Tinnitus	2	5		1	2	4
Tongue biting		1				1
Tongue disorder		1				1
Tongue rough	1	1			1	1
Toothache	2	2	1	1	1	1
Transient ischaemic attack	1	3			1	3
Tremor	2	12	1	2	1	10
Trigeminal nerve disorder		2				2
Trigeminal neuralgia	1	2			1	2
Troponin increased	1	2			1	2
Type III immune complex mediated reaction		1				1
Underdose		3		3		
Unresponsive to stimuli	1	3			1	3
Upper-airway cough syndrome	1	1	1	1		
Upper gastrointestinal haemorrhage		1				1
Upper respiratory tract infection		1		1		
Urinary incontinence	1	3			1	3
Urinary retention		1				1
Urinary tract infection		1		1		
Urine odour abnormal		1		1		
Urticaria	6	19	3	6	3	13
Urticaria chronic	1	1			1	1
Urticarial vasculitis		1				1
Urticaria papular		1		1		
Uveitis	1	1			1	1
Vaccination error		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination failure		1				1
Vaccination site bruising	1	2	1	1		1
Vaccination site cellulitis	1	1			1	1
Vaccination site discolouration		1				1
Vaccination site discomfort		1				1
Vaccination site erythema	7	16	3	5	4	11
Vaccination site induration	2	2	1	1	1	1
Vaccination site inflammation	2	3	1	2	1	1
Vaccination site irritation		1				1
Vaccination site joint movement impairment		1				1
Vaccination site mass	3	6	2	2	1	4
Vaccination site movement impairment	1	1			1	1
Vaccination site pain	16	43	6	21	10	22
Vaccination site paraesthesia		2		1		1
Vaccination site pruritus	5	10	1	2	4	8
Vaccination site rash	1	1			1	1
Vaccination site swelling	5	10	1	2	4	8
Vaccination site urticaria		1		1		
Vaccination site warmth	3	8	3	4		4
Vaginal haemorrhage		3				3
Ventricular extrasystoles	1	1			1	1
Vertigo	4	6	2	3	2	3
Viral labyrinthitis	1	1	1	1		
Vision blurred	3	6	1	2	2	4
Visual field defect	1	1	1	1		
Visual impairment		4		1		3
Vitreous floaters	1	4	1	1		3
Vomiting	17	53	6	10	11	43
Vomiting projectile	1	1	1	1		
Weight bearing difficulty		1				1
Weight decreased		1				1
Wheezing		6				6

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FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
White blood cell count decreased	1	1			1	1
White blood cell count increased		1		1		
	1,142	3,213	426	853	716	2360

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	4	2	3		1
Abdominal distension	1	1			1	1
Abdominal pain	1	1			1	1
Abdominal pain upper	1	2	1	1		1
Acute cardiac event		1				1
Ageusia	1	2		1	1	1
Agitation		1				1
Alanine aminotransferase increased		1				1
Allergy to vaccine		1				1
Anaphylactic reaction	1	3			1	3
Angioedema		1				1
Angiopathy	1	1			1	1
Angiotensin converting enzyme increased		1				1
Anosmia		2		1		1
Aphasia		1				1
Arthralgia	5	15	4	8	1	7
Arthritis	1	1			1	1
Asthenia	2	8	1	3	1	5
Asthma		1				1
Atrial f brillation		1				1
Axillary mass		1		1		
Axillary pain		1		1		
Balance disorder		1		1		
Bedridden	1	1			1	1
Bell's palsy		4				4
Blepharospasm		1				1
Blood pH decreased		1				1
Blood pressure increased		1				1
Breath odour		1				1
Carbon dioxide increased		1				1
Cardiac arrest	1	4			1	4
Cellulitis		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebrovascular accident	2	3			2	3
Chest discomfort		3		1		2
Chest pain	1	5	1	1		4
Chills	8	15	3	5	5	10
Cold sweat	2	4	2	3		1
Colitis ulcerative	1	1			1	1
Condition aggravated	3	3	3	3		
Confusional state		3				3
Conjunctivitis		1		1		
Constipation	1	1	1	1		
Contusion	1	1	1	1		
Coronary artery occlusion		1				1
Coronary artery thrombosis		1				1
Cough	2	3	1	1	1	2
COVID-19		3				3
C-reactive protein increased		2				2
Cyanosis	2	3			2	3
Death	1	6			1	6
Decreased appetite	2	4	2	2		2
Deep vein thrombosis	1	2			1	2
Dehydration		1		1		
Depressed level of consciousness		1				1
Depressed mood		1				1
Diarrhoea	1	3	1	1		2
Diplopia		1				1
Discomfort		1				1
Disseminated varicella zoster virus infection	1	1			1	1
Dizziness	1	5		2	1	3
Drug ineffective	1	2			1	2
Dysarthria		2				2
Dyspepsia	1	1	1	1		
Dyspnoea	1	4			1	4

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			Nonserious		Serious	
			I	C	I	C
Dyspnoea at rest		1				1
Ear pain		2		1		1
Emotional distress		1				1
Epistaxis		1		1		
Erythema	1	2	1	1		1
Exfoliative rash	1	1			1	1
Exposure via breast milk		1				1
Eye irritation		1		1		
Eye movement disorder		1				1
Eye pruritus		1		1		
Eye swelling		1		1		
Facial nerve disorder		1		1		
Fall	3	4			3	4
Fatigue	13	28	10	18	3	10
Feeling abnormal		2		1		1
Feeling hot		3		1		2
Flushing		1				1
Frequent bowel movements	1	1	1	1		
Gait inability		1		1		
General physical health deterioration	1	3			1	3
Groin pain	1	1			1	1
Headache	14	29	9	11	5	18
Head injury	1	1			1	1
Heart rate irregular		1				1
Hemiparesis		1				1
Herpes zoster	1	1			1	1
Hyperhidrosis	2	5			2	5
Hypersensitivity		1				1
Hypersomnia	1	1	1	1		
Hypertension	1	3	1	1		2
Hypoaesthesia	2	5	2	3		2
Hypoaesthesia oral	1	1			1	1

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			Nonserious		Serious	
			I	C	I	C
Hypoglycaemia		1				1
Hypopnoea		1				1
Hypotension		1				1
Hypotonia		1				1
Hypoxia		1				1
Impaired work ability	3	6	1	1	2	5
Inappropriate schedule of product administration		1		1		
Inflammation		1				1
Influenza like illness	1	1	1	1		
Insomnia	2	5	2	2		3
Irritability		1				1
Joint stiffness		1		1		
Joint swelling		2				2
Lethargy	1	1	1	1		
Limb discomfort	1	1	1	1		
Lip swelling	1	2	1	1		1
Loss of consciousness		5				5
Loss of control of legs	1	1			1	1
Lower respiratory tract infection	1	1			1	1
Lymphadenopathy		4				4
Lymph node pain		1				1
Malaise	7	14	4	6	3	8
Migraine	2	3	2	2		1
Migraine with aura		1				1
Mobility decreased	1	1			1	1
Mood swings		1				1
Muscle spasms	1	1	1	1		
Muscle tightness		1				1
Musculoskeletal discomfort	1	1	1	1		
Musculoskeletal stiffness		3		3		
Myalgia	9	15	6	7	3	8
Myocardial ischaemia		1				1

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			Nonserious		Serious	
			I	C	I	C
Myocarditis		1				1
Myokymia		1				1
Nasal congestion		1				1
Nasal discomfort		1		1		
Nausea	6	13	3	4	3	9
Neck mass		1				1
Neck pain		3		1		2
Negative thoughts		1				1
Nervousness		1		1		
Nervous system disorder		1				1
Neuralgia		1				1
Neutropenia	1	2			1	2
Night sweats		1		1		
Off label use		1		1		
Oropharyngeal pain	1	2	1	1		1
Orthostatic hypotension		1				1
Otitis media	1	1			1	1
Oxygen saturation decreased		3				3
Pain	3	12	2	4	1	8
Pain in extremity	4	11	3	9	1	2
Pain in jaw		1		1		
Pallor		3		1		2
Palpitations		1		1		
Paraesthesia		6		3		3
Paraesthesia oral	1	2		1	1	1
Pericarditis	2	2			2	2
Peripheral swelling	2	3	1	1	1	2
Pharyngeal paraesthesia		3		2		1
Photophobia		1				1
Photopsia		1				1
Pneumonia	3	4			3	4
Pneumonitis		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Presyncope		2				2
Product leakage	1	1	1	1		
Product preparation issue		2		2		
Pruritus		2		1		1
Psoriasis	1	1	1	1		
Pulmonary embolism	1	1			1	1
Pulse abnormal		1				1
Pulseless electrical activity	1	1			1	1
Pyrexia	9	24	4	7	5	17
Rales		1				1
Rash	2	6	2	4		2
Rash erythematous		2				2
Rash macular		1				1
Rash vesicular	1	1	1	1		
Respiration abnormal		1				1
Respiratory arrest	2	2			2	2
Respiratory distress		1				1
Respiratory failure		1				1
Respiratory rate decreased		3				3
Respiratory rate increased		1				1
Respiratory tract infection		2				2
Retching		2				2
Rheumatoid arthritis	1	1			1	1
Seizure		1				1
Seizure like phenomena	1	1			1	1
Sinusitis		1				1
Skin discolouration		1		1		
Sneezing		1		1		
Somnolence	1	2			1	2
Stress		1		1		
Sudden death		2				2
Supraventricular tachycardia		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Suspected COVID-19	2	3	1	2	1	1
Suspected product quality issue		2		2		
Swelling		1		1		
Swelling face		1				1
Swollen tongue		1				1
Syncope	3	8			3	8
Syringe issue	1	1	1	1		
Tachycardia	1	2			1	2
Tardive dyskinesia		1				1
Thrombotic stroke	1	1			1	1
Tidal volume decreased		1				1
Tinnitus		1		1		
Tongue movement disturbance		1				1
Tonic clonic movements		1				1
Transient ischaemic attack	1	2			1	2
Tremor	1	1			1	1
Tympanic membrane perforation	1	1			1	1
Type IV hypersensitivity reaction		1				1
Underdose	1	4	1	4		
Unresponsive to stimuli	1	3			1	3
Urticaria	1	5	1	2		3
Vaccination site discomfort		1		1		
Vaccination site pain	1	10	1	6		4
Vaccination site reaction	1	1	1	1		
Varicella zoster virus infection	1	1			1	1
Vertigo		2		1		1
Vomiting	3	6			3	6
Wheezing		1				1
	192	565	95	193	97	372

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal loss of weight	1	1			1	1
Accidental exposure to product		3		3		
Anal incontinence	1	1			1	1
Arthralgia		1		1		
Asthenia	1	1			1	1
Bell's palsy	1	1			1	1
Chills	2	3	1	2	1	1
Circumstance or information capable of leading to medication error		1		1		
Confusional state	1	1			1	1
COVID-19	4	5			4	5
Decreased appetite	1	1			1	1
Decubitus ulcer	1	1			1	1
Diabetes mellitus inadequate control	1	1			1	1
Dizziness		1		1		
Drug ineffective	4	6			4	6
Dysarthria	1	1			1	1
Dysphonia	1	1			1	1
Expired product administered		1		1		
Exposure via breast milk		5		5		
Exposure via skin contact		2		2		
Facial paralysis	1	2			1	2
Fall	1	1			1	1
Fatigue	1	2		1	1	1
Fluid intake reduced	1	1			1	1
Headache	2	5	2	5		
Hypoaesthesia		1				1
Hypoaesthesia oral		1				1
Inappropriate schedule of product administration	2	2	2	2		
Incorrect dose administered	5	7	5	7		
Influenza like illness	1	1	1	1		
Injury associated with device		1		1		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lethargy	1	1	1	1		
Limb discomfort	1	1	1	1		
Loss of personal independence in daily activities	1	1			1	1
Lymphadenopathy		1		1		
Malaise	2	3	2	3		
Migraine	1	1	1	1		
Nausea	1	1			1	1
No adverse event		1		1		
Off label use	1	1	1	1		
Overdose	1	1	1	1		
Oxygen saturation decreased	1	1			1	1
Pain	1	3		2	1	1
Pain in extremity	1	1	1	1		
Paraesthesia	3	3	2	2	1	1
Poor quality product administered	1	12	1	12		
Product packaging quantity issue		1		1		
Product preparation error	1	1	1	1		
Product preparation issue	4	6	4	6		
Product temperature excursion issue	1	2	1	2		
Pyrexia		1		1		
Respiratory rate increased	1	1			1	1
Restlessness	1	1			1	1
Seizure	1	1			1	1
Skin disorder	1	1			1	1
Suspected COVID-19		1				1
Underdose		4		4		
Urinary tract infection	1	1			1	1
Urine output decreased	1	1			1	1
Vaccination site discharge		1		1		
Vaccination site pain	1	1	1	1		
Vomiting	1	4		3	1	1
Weight bearing difficulty	1	1			1	1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Weight increased	1	1			1	1
Wound		1		1		
Wrong technique in product usage process		11		11		
	66	136	29	92	37	44

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Country Where Event Occurred

ISRAEL

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- * AE=Adverse Event
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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal pain	2	8			2	7		1
Abdominal pain upper		3				3		
Abortion missed	1	1					1	1
Abortion spontaneous		2						2
Activated partial thromboplastin time shortened		1						1
Adnexa uteri pain		1				1		
Ageusia		2				2		
Allergy to vaccine		4				2		2
Alopecia	1	1			1	1		
Amenorrhoea	2	2			2	2		
Anaemia	1	2				1	1	1
Anal haemorrhage		2				2		
Anaphylactic reaction	1	7					1	7
Anaphylactic shock		1						1
Aneurysm ruptured	1	1					1	1
Anger		1				1		
Angina pectoris		2						2
Angioedema		1						1
Anorectal discomfort		1				1		
Anosmia		2				2		
Antinuclear ant body positive		1				1		
Antiphospholipid antibodies positive		1						1
Anxiety	1	3			1	1		2
Aphasia		2				1		1
Aphonia		1						1
Arrhythmia		4						4
Arthralgia	12	31			10	27	2	4
Arthritis	1	2			1	2		
Arthritis infective	1	1					1	1
Arthropathy		1				1		
Aspiration		1						1
Asthenia	37	112			34	100	3	12

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Asthenopia		1
Asthma		1
Asymptomatic COVID-19		3
Atrial fibrillation	1	3
Axillary pain	1	2
Back pain	5	19
Bell's palsy	1	6
Blindness transient		1
Blister	1	2
Blood chloride increased		1
Blood creatine phosphokinase increased	1	1
Blood fibrinogen increased	1	1
Blood glucose increased		2
Blood immunoglobulin M increased		1
Blood iron decreased	1	2
Blood pressure abnormal		1
Blood pressure decreased		1
Blood pressure fluctuation		1
Blood pressure increased	5	13
Body temperature decreased	1	2
Bone pain	5	9
Brain death		1
Brain injury		1
Brain oedema		1
Breast engorgement		1
Breast inflammation		1
Breast pain		1
Breast tenderness		1
Burning sensation	1	2
Cardiac arrest		5
Cardiac death		1
Cardiac disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
					3
				1	3
		1	2		
		5	17		2
				1	6
					1
		1	1		1
					1
				1	1
				1	1
					2
			1		
				1	2
					1
			1		
		4	10	1	3
		1	2		
		5	9		
					1
					1
					1
			1		
			1		
			1		
			1		
		1	1		1
					5
					1
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiac failure		2
Cardiac failure chronic		1
Cardiogenic shock		1
Cerebellar haemorrhage		1
Cerebral ischaemia		1
Cerebrovascular accident		5
Cheilitis		1
Chest discomfort		3
Chest pain	7	25
Chills	26	77
Choking		3
Cold sweat	1	4
Condition aggravated	1	2
Conduction disorder	1	1
Confusional state	2	3
Contusion	1	3
Coronavirus infection	1	3
Cough	1	8
COVID-19	3	27
C-reactive protein increased	1	2
Crying	1	3
Deafness neurosensory		2
Deafness unilateral		2
Death		13
Decreased activity	1	1
Decreased appetite	1	8
Deep vein thrombosis		2
Depressed level of consciousness		1
Depressed mood		4
Depression		1
Diabetic ketoacidosis		1
Diarrhoea	3	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
					1
					1
					1
					5
			1		
			2		1
		5	15	2	10
		26	73		4
					3
		1	4		
		1	2		
		1	1		
		2	3		
		1	2		1
				1	3
		1	6		2
	1		4	3	23
			1	1	1
		1	2		1
					2
					2
					13
		1	1		
		1	8		
					2
					1
			4		
			1		
					1
		3	12		1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Discomfort	3	4
Disease recurrence		4
Disturbance in attention	1	1
Dizziness	17	42
Drug hypersensitivity		2
Drug-induced liver injury		1
Drug ineffective	4	22
Dry mouth		1
Dry throat	1	1
Dysaesthesia		1
Dysgeusia	1	9
Dyskinesia		2
Dysmenorrhoea	2	3
Dyspepsia	1	6
Dysphagia		5
Dysphemia		1
Dysphonia	1	1
Dyspnoea	6	38
Dyspnoea exertional		2
Dysstasia	1	2
Ear discomfort		2
Ear infection		1
Ear pain	1	4
Eczema	1	1
Electric shock sensation		1
Emotional disorder	1	1
Endocarditis		1
Eosinophilic oesophagitis		1
Epistaxis		1
Erythema	2	10
Erythema nodosum	1	1
Expired product administered	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	4		
			3		1
		1	1		
		17	36		6
			1		1
					1
	1			4	22
			1		
		1	1		
			1		
		1	9		
			1		1
		2	3		
		1	6		
			3		2
					1
		1	1		
		3	15	3	23
			2		
		1	1		1
			2		
			1		
		1	4		
		1	1		
			1		
		1	1		
					1
			1		
					1
		2	10		
				1	1
		1	1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Exposure during pregnancy	3	8
Exposure to SARS-CoV-2		
Exposure via breast milk		1
Extensive swelling of vaccinated limb		2
Eyelid oedema		1
Eye pain	2	5
Eye swelling	1	4
Face injury		1
Facial asymmetry		1
Facial nerve disorder		1
Facial pain	1	3
Facial paralysis	2	12
Facial paresis		1
Faeces soft	1	1
Fall		5
Fatigue	20	68
Feeling abnormal	3	13
Feeling cold	3	11
Feeling hot	2	8
Feeling of body temperature change		1
Finger deformity	1	1
Flushing	1	1
Foetal death		1
Food craving		1
Formication	1	3
Frustration tolerance decreased	1	1
Gait disturbance		4
Gastric haemorrhage		1
Gastrointestinal necrosis		1
General physical health deterioration		3
Gingival bleeding		1
Glomerular filtration rate decreased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	6		2
	1				
			1		
			2		
			1		
		2	4		1
		1	2		2
					1
			1		
			1		
		1	2		1
				2	12
					1
		1	1		
			2		3
		19	65	1	3
		2	9	1	4
		3	11		
		2	8		
			1		
				1	1
		1	1		
					1
			1		
		1	3		
		1	1		
			1		3
					1
					1
					3
					1
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Guillain-Barre syndrome	1	3
Haematemesis	1	1
Haematochezia		1
Haemorrhage		2
Hallucination		1
Hallucination, auditory		1
Hangover		1
Headache	38	112
Head discomfort		1
Heart rate increased	2	7
Heavy menstrual bleeding	12	15
Hemiparaesthesia		1
Hemiparesis	1	1
Hemiplegia		1
Hepatic failure		1
Hepatic function abnormal		1
Hepatitis		1
Hepatitis acute		1
Hepatomegaly	1	1
Herpes simplex		1
Herpes virus infection		1
Herpes zoster	2	15
High risk pregnancy	1	1
Hip fracture		1
Hormone level abnormal	1	2
Hot flush	3	3
Hyperbilirubinaemia		1
Hyperhidrosis	1	8
Hypersensitivity	2	15
Hypersomnia		1
Hypertension		2
Hypoaesthesia	8	34

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
				1	1
					1
					2
					1
					1
			1		
		38	109		3
			1		
		1	5	1	2
		12	15		
					1
				1	1
					1
					1
					1
				1	1
			1		
			1		
		1	12	1	3
		1	1		
					1
		1	8		
		1	4	1	11
			1		
			1		1
		8	31		3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypoaesthesia oral		10
Hypomenorrhoea	1	3
Hypotension	1	4
Illrd nerve paralysis		1
Illness		1
Impaired gastric emptying	1	1
Impaired quality of life		1
Inappropriate schedule of product administration	1	6
Incomplete course of vaccination	1	1
Infective tenosynovitis	1	1
Inflammation of wound		1
Influenza	1	4
Influenza like illness	1	9
Insomnia	3	10
Intermenstrual bleeding	6	7
International normalised ratio decreased		1
International normalised ratio increased		1
Joint noise		1
Joint range of motion decreased	2	2
Joint swelling		2
Leukocytosis		3
Leukopenia		1
Ligament sprain	1	1
Limb discomfort	1	2
Limb injury		1
Lip pruritus		1
Lip swelling	1	4
Liver function test abnormal	1	1
Liver function test increased		1
Loss of consciousness		6
Loss of personal independence in daily activities	1	2
Lung disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			8		2
		1	3		
		1	2		2
					1
			1		
				1	1
			1		
		1	6		
		1	1		
				1	1
			1		
		1	4		
		1	9		
		2	9	1	1
		6	7		
					1
					1
			1		
				2	2
			2		
					3
					1
		1	1		
		1	2		
			1		
			1		
		1	3		1
		1	1		
			1		
					6
		1	2		
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lymphadenopathy	3	16
Lymphopenia		1
Malaise	4	22
Maternal exposure during pregnancy	7	12
Maternal exposure timing unspecified		1
Mean cell haemoglobin decreased		2
Mean platelet volume increased		1
Mechanical urticaria		1
Menstrual disorder	9	11
Menstruation delayed	4	4
Menstruation irregular	13	15
Mental disorder	1	2
Migraine	1	3
Migraine with aura	1	1
Miliaria		1
Mobility decreased		3
Mood altered		1
Mood swings	1	1
Motor dysfunction		1
Movement disorder	1	3
Multiple sclerosis		2
Multiple sclerosis relapse		2
Muscle contractions involuntary		4
Muscle disorder		1
Muscle rigidity		1
Muscle spasms	2	2
Muscular weakness	3	8
Musculoskeletal chest pain	1	1
Musculoskeletal disorder	1	1
Musculoskeletal stiffness		1
Myalgia	34	72
Myasthenia gravis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	14		2
					1
		4	20		2
		6	11	1	1
			1		
			1		1
			1		
			1		
		8	10	1	1
		4	4		
		13	15		
		1	2		
		1	3		
		1	1		
			1		
			2		1
			1		
		1	1		
					1
		1	3		
					2
					2
			4		
			1		
			1		
		2	2		
		3	6		2
		1	1		
				1	1
			1		
		32	67	2	5
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myocardial infarction		6
Myocarditis	2	9
Nasal congestion	1	1
Nasopharyngitis	1	3
Nausea	17	54
Neck pain	3	7
Nervous system disorder	1	2
Neuralgia		1
Neuralgic amyotrophy		1
Neuritis		1
Neutrophil count decreased		1
Neutrophil count increased		1
Nightmare	1	1
Night sweats	1	1
Noninfective encephalitis	1	1
Ocular discomfort	2	2
Ocular hyperaemia		1
Odynophagia	1	2
Oedema mouth		1
Oedema peripheral		1
Off label use		5
Ophthalmic herpes zoster		2
Oral discomfort		1
Oral herpes	1	4
Oropharyngeal discomfort		1
Oropharyngeal pain	5	9
Overdose		1
Ovulation delayed	1	1
Oxygen saturation decreased		2
Pain	12	36
Pain in extremity	19	58
Pain in jaw	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					6
				2	9
		1	1		
		1	3		
		15	50	2	4
		1	5	2	2
		1	2		
			1		
			1		
			1		
			1		
					1
		1	1		
		1	1		
				1	1
		1	1	1	1
			1		
		1	2		
					1
			1		
			5		
					2
			1		
		1	3		1
			1		
		5	9		
			1		
		1	1		
			1		1
		11	30	1	6
		18	54	1	4
		1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pallor		2
Palmar erythema		1
Palpitations	2	11
Paraesthesia	7	39
Paraesthesia oral	1	13
Paralysis		1
Paraplegia		1
Parosmia	1	4
Pelvic fracture		1
Pelvic pain		1
Pericardial effusion	5	6
Pericarditis	3	16
Peripheral artery occlusion		1
Peripheral coldness		3
Peripheral ischaemia		1
Peripheral swelling	1	6
Personality change		1
Pharyngeal swelling		4
Pleural effusion	1	2
Pleurisy	1	1
Pleuritic pain		1
Pneumonia aspiration		2
Pneumonia pseudomonal	1	1
Polymenorrhoea	2	2
Polyneuropathy		1
Poor quality product administered	1	3
Poor quality sleep	1	2
Premature labour		1
Premenstrual syndrome	1	2
Presyncope	1	5
Product administered at inappropriate site		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
			1		
		2	9		2
		7	34		5
		1	11		2
					1
					1
		1	4		
					1
			1		
				5	6
				3	16
					1
			3		
					1
		1	5		1
			1		
			2		2
				1	2
				1	1
			1		
					2
				1	1
		2	2		
					1
		1	3		
		1	2		
					1
		1	2		
		1	4		1
			2		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Product administered to patient of inappropriate age		2
Product colour issue	1	1
Productive cough	1	1
Product packaging quantity issue		1
Product preparation error		1
Product preparation issue		2
Product use issue		4
Pruritus	3	13
Psoriatic arthropathy		1
Pulmonary embolism		5
Pulmonary oedema		2
Pulse abnormal		1
Pulseless electrical activity		1
Pupil fixed		1
Purpura		1
Pyrexia	38	105
Rash	6	21
Rash macular		1
Rash maculo-papular		1
Rash pruritic	2	3
Rash vesicular		1
Reduced facial expression		1
Respiratory arrest		1
Respiratory disorder		3
Respiratory rate increased		1
Restlessness		1
Rhinalgia		1
Rhinorrhoea		1
Rib fracture		1
Right ventricular enlargement		1
SARS-CoV-2 ant body test negative		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		1	1		
				1	1
			1		
			1		
			2		
			4		
		3	9		4
					1
					5
					2
					1
					1
					1
			1		
		36	96	2	9
		5	15	1	6
			1		
			1		
		2	3		
					1
			1		
					1
			1		2
					1
			1		
			1		
			1		
					1
			1		
			2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Schizophrenia		1
Seizure		7
Sensory disturbance		3
Sensory loss		3
Skin burning sensation		2
Skin discolouration		2
Skin disorder		1
Skin tightness	1	1
Sleep disorder		1
Somnolence		2
Speech disorder		5
Still birth		1
Stress		1
Subarachnoid haemorrhage	1	1
Sudden hearing loss		3
Suffocation feeling		1
Superior sagittal sinus thrombosis		1
Swelling		2
Swelling face	2	3
Swollen tongue		4
Syncope		4
Systemic inflammatory response syndrome		1
Tachycardia		5
Taste disorder	1	2
Tenderness		1
Therapeutic response unexpected	3	5
Thinking abnormal		1
Thirst		2
Throat irritation	1	2
Throat tightness	1	2
Thrombosis	1	2
Tic	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					7
			2		1
			1		2
			2		
			2		
			1		
		1	1		
			1		
			2		
			3		2
					1
			1		
				1	1
					3
					1
					1
			2		
		2	3		
					4
					4
					1
			4		1
		1	2		
			1		
		3	5		
			1		
			1		1
		1	1		1
				1	2
				1	2
		2	2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tinnitus		7
Tongue oedema		1
Tonic convulsion		1
Toothache	1	1
Tracheal oedema		1
Transaminases increased	1	1
Transient ischaemic attack		3
Tremor	2	5
Troponin increased		1
Twin pregnancy		1
Ultrasound breast abnormal	1	1
Underdose		2
Unresponsive to stimuli		1
Urinary tract infection	1	2
Urticaria	1	6
Uterine contractions abnormal		1
Uterine haemorrhage		1
Uterine pain	1	2
Vaccination failure		4
Vaccination site bruising		1
Vaccination site cellulitis		2
Vaccination site discomfort	1	1
Vaccination site erythema	5	14
Vaccination site haematoma	1	1
Vaccination site haemorrhage	1	1
Vaccination site hypersensitivity		1
Vaccination site induration	1	1
Vaccination site inflammation		1
Vaccination site joint movement impairment		1
Vaccination site lymphadenopathy		2
Vaccination site movement impairment	1	3
Vaccination site oedema	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		5
					1
					1
		1	1		
					1
				1	1
					3
		2	5		
					1
			1		
				1	1
			2		
					1
			1	1	1
		1	3		3
			1		
					1
		1	2		
					4
			1		
			1		1
		1	1		
		4	12	1	2
		1	1		
		1	1		
			1		
		1	1		
			1		
			1		
			2		
		1	3		
				1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site pain	28	95			28	95		
Vaccination site paraesthesia		1				1		
Vaccination site pruritus	1	2			1	2		
Vaccination site reaction	1	2			1	2		
Vaccination site swelling	4	13			3	11	1	2
Vaccination site vesicles		1				1		
Vaccination site warmth	1	1			1	1		
Vaginal haemorrhage	8	18			8	13		5
Vaginal ulceration	1	1			1	1		
Vein discolouration		1				1		
Vertigo	1	3			1	1		2
Vision blurred	1	4			1	4		
Vitamin B12 decreased		1						1
Vomiting	6	15			4	13	2	2
Vulval ulceration	1	1			1	1		
Walking disability	1	1			1	1		
Weight decreased	2	3			2	2		1
Wheezing	1	3			1	2		1
Wrong technique in product usage process		1				1		
	646	2,234		3	557	1671	89	563

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		1		1		
Abdominal pain upper		1		1		
Abnormal faeces	1	1	1	1		
Acute kidney injury	2	4			2	4
Acute myocardial infarction		4				4
Acute respiratory distress syndrome		1				1
Acute respiratory failure		1				1
Adverse event		1		1		
Agitation		1		1		
Alanine aminotransferase increased	1	1	1	1		
Alcohol intolerance		1		1		
Alopecia		1		1		
Amylase increased	1	1			1	1
Anaemia		1				1
Anaesthesia	1	1	1	1		
Anaesthesia oral		1		1		
Anaphylactic shock		1				1
Angina pectoris		2				2
Angioedema		3				3
Anxiety		4		4		
Aphthous ulcer		1		1		
Arrhythmia	1	1			1	1
Arterial thrombosis		1				1
Arthralgia	4	18	4	15		3
Arthritis reactive		1				1
Aspartate aminotransferase increased	1	1	1	1		
Asthenia	14	56	13	49	1	7
Asthma		1				1
Asymptomatic COVID-19		2				2
Atelectasis		1				1
Atrial fibrillation		6				6

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Atrioventricular block	1	1			1	1
Autoimmune haemolytic anaemia		1				1
Back pain	1	7		5	1	2
Bell's palsy		10				10
Blood chloride increased		1		1		
Blood creatine phosphokinase increased	2	3			2	3
Blood creatinine abnormal		1		1		
Blood glucose increased		1		1		
Blood iron decreased	1	1			1	1
Blood lactate dehydrogenase increased		1				1
Blood phosphorus decreased	1	1			1	1
Blood pressure abnormal	1	1	1	1		
Blood pressure decreased		1				1
Blood pressure fluctuation	1	1			1	1
Blood pressure increased	2	7	1	2	1	5
Blood pressure systolic increased		1		1		
Blood triglycerides increased	1	1			1	1
Body temperature decreased		2		2		
Bone pain	1	2	1	2		
Bradycardia	1	1			1	1
Bruxism	1	1			1	1
Cardiac arrest		7				7
Cardiac disorder		1				1
Cardiac dysfunction	1	1			1	1
Cardiac failure	1	6			1	6
Cardiac flutter		1				1
Cardiac tamponade		1				1
Cardiomegaly	1	1			1	1
Cartilage injury		1				1
Cerebral haemorrhage		1				1
Cerebrovascular accident		7				7
Chest discomfort	3	7	1	4	2	3

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest pain	5	19	5	14		5
Chills	10	27	9	25	1	2
Choking		1				1
Cholelithiasis		1		1		
Chronic lymphocytic leukaemia		1				1
Chronic obstructive pulmonary disease		2				2
Circulatory collapse		1				1
Condition aggravated		1		1		
Confusional state	1	4	1	2		2
Conjunctival disorder		1				1
Conjunctivitis	1	1	1	1		
Constipation	1	1	1	1		
Coronavirus infection	1	2			1	2
Cough	3	8	2	6	1	2
COVID-19	4	34		4	4	30
C-reactive protein increased	2	5	1	2	1	3
Deafness		3				3
Deafness neurosensory		2				2
Deafness unilateral		1				1
Death	2	20			2	20
Decreased appetite	1	5	1	4		1
Deep vein thrombosis	1	2			1	2
Depressed mood		1				1
Depression		1				1
Diarrhoea	1	12	1	11		1
Discomfort	1	3	1	3		
Disease recurrence		1				1
Disseminated intravascular coagulation		1				1
Disturbance in attention	1	1	1	1		
Diverticulitis		1				1
Dizziness	4	21	4	17		4
Drug hypersensitivity		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug ineffective	3	31			3	31
Dysarthria		1				1
Dyschromatopsia		1		1		
Dysgeusia	2	4	2	4		
Dyskinesia		4		3		1
Dyspepsia		1		1		
Dysphagia		1		1		
Dyspnoea	2	19	2	7		12
Dyspnoea exertional	1	2	1	2		
Dysstasia		3		2		1
Ear discomfort	1	5	1	3		2
Ear pain		2		2		
Electrocardiogram abnormal		2		1		1
Electrocardiogram T wave inversion		1				1
Encephalitis		1				1
Eosinophilic pneumonia acute		1				1
Epilepsy	1	2			1	2
Epistaxis	1	1			1	1
Erythema	2	10	2	7		3
Erythromelalgia	1	1			1	1
Expired product administered	1	1	1	1		
Exposure to contaminated water		1		1		
Eye infection		2		1		1
Eye irritation		2		1		1
Eyelid function disorder		1		1		
Eye pain	1	3	1	3		
Eye swelling		1				1
Facial paralysis		13				13
Facial paresis		1				1
Faeces soft	1	1	1	1		
Fall		2		1		1
Fatigue	4	26	4	24		2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling abnormal	3	11	3	7		4
Feeling cold	1	7	1	7		
Feeling hot	1	1	1	1		
Food refusal		1				1
Formication		1		1		
Gait disturbance		3		1		2
Gastroenteritis viral		1		1		
Generalised oedema	1	1			1	1
Generalised tonic-clonic seizure	1	1			1	1
General physical health deterioration		1				1
Gingival pain		1		1		
Gingivitis		1		1		
Glomerulonephritis minimal lesion	2	2			2	2
Guillain-Barre syndrome		2				2
Haematemesis		1				1
Haemolytic anaemia		1				1
Headache	13	51	13	45		6
Head injury		1				1
Heart rate increased	3	7	3	7		
Heart rate irregular	1	1	1	1		
Hepatic enzyme increased		1				1
Hepatic function abnormal		1				1
Herpes virus infection	1	1	1	1		
Herpes zoster	2	7	2	5		2
Hyperacusis	1	1	1	1		
Hyperhidrosis		4		4		
Hypersensitivity		2		2		
Hypertension	1	5		2	1	3
Hyperventilation		1		1		
Hypoacusis	1	3	1	2		1
Hypoaesthesia	2	16	2	15		1
Hypoaesthesia oral		3		3		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia teeth		1		1		
Hyponatraemia		1				1
Hypotension		2		1		1
Hypothermia		1				1
Hypoventilation		1				1
Illness		1		1		
Immune thrombocytopenia		2				2
Inappropriate schedule of product administration		1		1		
Incorrect dose administered		2		2		
Incorrect route of product administration	1	1	1	1		
Infection		1		1		
Inflammation	1	5		2	1	3
Inflammatory marker increased		1				1
Influenza like illness	2	6	2	6		
Injection site erythema	1	1	1	1		
Insomnia	2	2	2	2		
Intentional dose omission		1		1		
International normalised ratio increased		1		1		
Ischaemic stroke		1				1
Jaundice		1		1		
Joint range of motion decreased	1	1	1	1		
Joint swelling	1	2	1	1		1
Lacrimation increased		2		1		1
Laryngeal inflammation		1		1		
Laryngitis bacterial		1				1
Leukocytosis		4				4
Limb discomfort		1		1		
Lip disorder		1		1		
Lip pruritus		1		1		
Liquid product physical issue		1		1		
Liver injury		1				1
Localised infection		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Loss of consciousness		6				6
Loss of libido		1		1		
Loss of personal independence in daily activities		1		1		
Lung disorder		1		1		
Lung infiltration		1				1
Lymphadenopathy		6		4		2
Lymphocyte count decreased	1	1			1	1
Lymphocyte count increased		1		1		
Lymphocytosis		1		1		
Malaise	1	12		8	1	4
Mean cell haemoglobin concentration decreased		1		1		
Mean cell haemoglobin decreased		1		1		
Mean cell volume decreased		1		1		
Mobility decreased	1	3	1	2		1
Movement disorder		3		2		1
Multiple organ dysfunction syndrome		1				1
Multiple sclerosis relapse		2				2
Muscle spasms		3		3		
Muscle twitching		1		1		
Muscular weakness	1	4		1	1	3
Musculoskeletal chest pain		2		2		
Musculoskeletal discomfort		1		1		
Musculoskeletal disorder	1	1	1	1		
Musculoskeletal stiffness	1	2		1	1	1
Myalgia	11	33	9	29	2	4
Myasthenia gravis		1				1
Myocardial infarction		1				1
Myocarditis	12	75			12	75
Myositis	1	1			1	1
Nasopharyngitis		3		3		
Nausea	1	12		7	1	5
Neck pain	2	6	1	5	1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nephrolithiasis		1				1
Nephrotic syndrome	2	2			2	2
Nervousness		1		1		
Neuralgia		1				1
Neuralgic amyotrophy		1				1
Neutropenia		1				1
Non-Hodgkin's lymphoma		1				1
Odynophagia		2		1		1
Oedema		1				1
Oedema peripheral		1				1
Off label use	2	3	2	3		
Oral discomfort		1		1		
Oral herpes		3		3		
Oral pain		1		1		
Oropharyngeal pain	1	9		7	1	2
Osteomyelitis		1				1
Otitis media		1		1		
Overdose		4		4		
Pain	3	20	2	16	1	4
Pain in extremity	6	18	6	18		
Pain in jaw	1	4	1	4		
Palpitations		3		3		
Pancreatitis		1				1
Pancreatitis chronic	1	1			1	1
Pancytopenia		1				1
Paraesthesia	6	21	5	16	1	5
Paraesthesia oral		4		4		
Paralysis		2				2
Pericardial effusion		1				1
Pericarditis		30				30
Peripheral coldness		1		1		
Pharyngeal paraesthesia		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pleural effusion	1	2	1	1		1
Pleuritic pain		1				1
Pneumonia	1	6			1	6
Poor quality product administered	1	4	1	4		
Poor quality sleep		1		1		
Presyncope	2	2	1	1	1	1
Product administered at inappropriate site	1	2	1	2		
Product deposit		1		1		
Productive cough		1		1		
Product preparation error		3		3		
Product temperature excursion issue	1	1	1	1		
Product use issue	2	2	2	2		
Pruritus	1	4	1	4		
Pseudomonas infection		1				1
Psychomotor hyperactivity		1		1		
Pulmonary congestion	1	1			1	1
Pulmonary embolism	1	2			1	2
Pulpitis dental		1		1		
Purpura		1				1
Pyrexia	15	50	14	36	1	14
Rash	4	6	4	5		1
Rash macular		1		1		
Recall phenomenon		2		2		
Red blood cell count increased		1		1		
Respiratory arrest		1				1
Respiratory disorder		1				1
Respiratory distress		1				1
Restlessness		1				1
Rhabdomyolysis		1				1
Rhinorrhoea		3		3		
Ruptured cerebral aneurysm		1				1
SARS-CoV-2 ant body test negative		1				1

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
SARS-CoV-2 test positive		2
Seizure		3
Sensory disturbance	1	2
Sensory loss	1	1
Sepsis		1
Septic shock		1
Shock		1
Sinus bradycardia	1	1
Sinus tachycardia	1	3
Skin burning sensation		1
Skin discolouration		1
Skin exfoliation		1
Skin reaction		1
Sleep attacks	1	1
Sleep disorder due to general medical condition, insomnia type		1
Slow speech		1
Sneezing		3
Somnolence	1	2
Speech disorder		3
Streptococcal infection		1
Stress		1
Sudden cardiac death		1
Sudden death		1
Sudden hearing loss		1
Suffocation feeling		2
Suicidal ideation		1
Suspected COVID-19		1
Swelling		1
Swelling face		2
Syncope	1	7
Systemic inflammatory response syndrome		9

Spontaneous			
Nonserious		Serious	
I	C	I	C
			2
			3
1	2		
1	1		
			1
			1
			1
		1	1
1	2		1
	1		
	1		
	1		
	1		
1	1		
	1		
			1
	2		1
1	2		
	1		2
			1
	1		
			1
			1
			1
			2
			1
			1
	1		
	1		1
		1	7
			9

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia	1	4		1	1	3
Taste disorder		1		1		
Testicular pain		1		1		
Therapeutic response unexpected	3	4	3	4		
Thrombocytopenia		1				1
Thrombosis		2				2
Tinnitus	2	6	2	4		2
Tongue discomfort		1		1		
Tonsillitis		1				1
Toothache		2		2		
Tooth injury		1		1		
Transient ischaemic attack	1	4			1	4
Tremor		4		3		1
Trigeminal neuralgia	1	1	1	1		
Troponin increased		1				1
Underdose		1		1		
Urine sodium increased	1	1			1	1
Urosepsis		1				1
Urticaria		2		2		
Uveitis		2				2
Vaccination failure	2	5			2	5
Vaccination site discomfort		1		1		
Vaccination site erythema		2		2		
Vaccination site hypersensitivity		1		1		
Vaccination site movement impairment	1	1	1	1		
Vaccination site pain	8	32	8	32		
Vaccination site swelling		4		4		
Ventricular f brillation		2				2
Vertigo		5		3		2
Vestibular neuronitis		1				1
Vision blurred		2		2		
Vlth nerve paralysis		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vomiting	2	11	1	6	1	5
Walking disability	1	1	1	1		
Weight decreased		2		1		1
Wrong technique in product usage process		1		1		
Yawning		2		1		1
Yellow skin	1	1	1	1		
	266	1,338	182	733	84	605

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Anosmia		1		1		
Anxiety		1		1		
Arthralgia	1	6		3	1	3
Asthenia	5	20	5	20		
Back pain		1		1		
Balance disorder		1		1		
Basedow's disease		1				1
Bell's palsy		2				2
Body temperature increased	1	1	1	1		
Burning sensation	1	1	1	1		
Chest discomfort	1	1	1	1		
Chills	7	17	7	17		
Chronic inflammatory demyelinating polyradiculoneuropathy		1				1
Condition aggravated		1				1
Coronavirus infection	1	1			1	1
Cough	2	3	2	3		
COVID-19	2	11		2	2	9
Cyanosis	1	1	1	1		
Decreased appetite	1	1	1	1		
Diarrhoea		1		1		
Discomfort		1		1		
Dizziness	2	7	2	7		
Drug ineffective	3	8			3	8
Dysgeusia		1		1		
Dyspnoea	1	3	1	2		1
Ear pain	2	2	2	2		
Epistaxis		1				1
Exposure via breast milk	4	8	4	8		
Eye haemorrhage		1				1
Eye infection		1		1		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye irritation	1	1	1	1		
Eye pain	1	3	1	1		2
Facial paralysis		1				1
Fatigue	4	15	4	15		
Fear of injection	1	1	1	1		
Feeling abnormal	2	2	2	2		
Feeling cold	1	3	1	3		
Foetal death		2				2
Foetal exposure during pregnancy		1				1
Foetal heart rate abnormal		1				1
Foetal movement disorder		1				1
Headache	7	17	7	16		1
Head discomfort		2		2		
Heart rate increased	1	1	1	1		
Heavy menstrual bleeding	2	2	2	2		
Herpes zoster		6		6		
Hot flush	1	1	1	1		
Hypersensitivity	1	1	1	1		
Hypertension		1				1
Hypoaesthesia		1		1		
Inappropriate schedule of product administration		1		1		
Incomplete course of vaccination		1		1		
Influenza like illness	1	2	1	2		
Initial insomnia		1		1		
Intermenstrual bleeding	1	1	1	1		
Joint range of motion decreased		1				1
Liquid product physical issue	3	17	3	17		
Lymphadenopathy		1		1		
Malaise	1	2	1	1		1
Menstruation irregular	1	1	1	1		
Migraine	1	1	1	1		
Monoplegia		1				1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Multiple sclerosis		1				1
Muscle spasms	1	1	1	1		
Myalgia	5	19	5	18		1
Nausea	1	4	1	4		
Neck pain	1	3		1	1	2
Neuralgia		1				1
Neuralgic amyotrophy		1		1		
Night sweats	1	1	1	1		
Ocular discomfort		1		1		
Off label use		1		1		
Oral herpes		1				1
Oropharyngeal pain	1	3	1	3		
Pain	7	8	7	8		
Pain in extremity	2	8	1	6	1	2
Pancreatitis acute	1	1			1	1
Paraesthesia	2	3	2	3		
Paralysis		1				1
Peripheral coldness	1	2	1	2		
Peripheral swelling		1				1
Photopsia		1		1		
Polymenorrhoea	1	1	1	1		
Poor quality product administered	5	32	5	32		
Premenstrual syndrome	1	1	1	1		
Product complaint		1		1		
Product packaging quantity issue		11		11		
Product quality issue	2	2	2	2		
Product use issue	1	2	1	2		
Pruritus		1		1		
Pyrexia	6	18	6	17		1
Rash	1	3	1	3		
Seizure		7				7
Sleep disorder		1				1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Syncope		1				1
Syndactyly		1				1
Therapeutic response unexpected	3	6	3	6		
Tooth loss	1	1	1	1		
Tremor		3		3		
Urticaria		1				1
Vaccination failure		2				2
Vaccination site erythema	1	2	1	2		
Vaccination site pain	2	18	2	17		1
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling		1		1		
Vertigo		1		1		
Vision blurred		1		1		
Vomiting	3	5	3	5		
Wheezing		1				1
Wrong technique in product usage process		1		1		
	116	388	106	319	10	69

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Country Where Event Occurred

ITALY

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	8	19			5	15	3	4
Abdominal distension	2	18			2	14		4
Abdominal migraine		1				1		
Abdominal pain	45	345	3	3	39	294	6	51
Abdominal pain lower	2	5			1	3	1	2
Abdominal pain upper	38	156		2	27	119	11	37
Abdominal rigidity		4				4		
Abnormal dreams	1	1			1	1		
Abortion		2						2
Abortion missed	1	1					1	1
Abortion spontaneous	2	7					2	7
Abscess		1						1
Acarodermatitis	1	1					1	1
Accidental overdose	2	2			1	1	1	1
Accommodation disorder		1				1		
Acidosis	1	1					1	1
Acne	1	1			1	1		
Acquired haemophilia			1	1				
Acquired macroglossia		1						1
Acute abdomen		1						1
Acute coronary syndrome		6						6
Acute kidney injury	2	3		1			2	3
Acute myocardial infarction	5	10					5	10
Acute polyneuropathy	1	1					1	1
Acute pulmonary oedema	1	2					1	2
Acute respiratory failure	2	5					2	5
Adenoviral conjunctivitis		1				1		
Administration site erythema		3				3		
Administration site induration	1	1			1	1		
Administration site joint pain	1	1			1	1		
Administration site oedema		8				8		
Administration site pain	2	56			2	56		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Administration site paraesthesia		2
Administration site pruritus		3
Administration site rash		1
Administration site reaction		5
Administration site swelling		2
Administration site warmth		1
Adnexa uteri pain	1	2
Adrenomegaly	1	3
Age-related macular degeneration		1
Ageusia	12	44
Agitation	5	26
Akathisia		1
Alanine aminotransferase increased	1	4
Allergic cough		1
Allergic reaction to excipient		1
Allergy to vaccine	3	12
Alopecia	1	4
Altered state of consciousness	1	4
Amenorrhoea	6	8
Amnesia	11	18
Amylase increased	1	3
Anaemia	5	7
Anaemia macrocytic		1
Anaesthesia	4	41
Anaesthesia oral		6
Anal erythema		1
Anal haemorrhage	1	1
Anal sphincter atony		1
Anamnestic reaction	1	1
Anaphylactic reaction	9	70
Anaphylactic shock	2	14
Anaphylactoid reaction	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
			3		
			1		
			4		1
			2		
			1		
		1	2		
		1	3		
					1
1	3	7	29	5	15
	1	3	16	2	10
			1		
		1	3		1
					1
1	1	1	3	2	9
		1	2		2
				1	4
		4	6	2	2
		3	8	8	10
			1	1	2
1	1		2	5	5
					1
		4	36		5
			5		1
					1
				1	1
					1
		1	1		
1	2			9	70
	1			2	14
				2	4

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Aneurysm ruptured		1
Angina pectoris	3	8
Angioedema	14	61
Angiomyolipoma		1
Angular cheilitis		1
Anosmia	14	38
Anterograde amnesia		1
Antibody test abnormal		1
Antinuclear ant body positive		1
Anti-thyroid antibody positive		2
Anuria	1	4
Anxiety	6	36
Aortic arteriosclerosis	1	1
Aortic dissection		1
Aortic valve calcification	1	1
Aortic valve stenosis		1
Apallic syndrome	1	1
Apathy	1	4
Aphasia	12	26
Aphonia	1	10
Aphthous ulcer	3	16
Appendicitis	1	1
Appetite disorder	1	1
Application site coldness		1
Application site oedema		1
Application site paraesthesia		1
Aptyalism	1	3
Areflexia	1	1
Arrhythmia	5	22
Arterial occlusive disease	1	1
Arterial thrombosis		
Arteriosclerosis	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				3	8
				14	61
					1
			1		
1	3	11	28	3	10
					1
			1		
					1
			2		
1	1			1	4
		3	23	3	13
				1	1
					1
				1	1
				1	1
		1	2		2
2	2		2	12	24
			5	1	5
	1	3	14		2
				1	1
		1	1		
			1		
			1		
			2	1	1
				1	1
				5	22
				1	1
1	1				
		1	1	1	2

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Arteriosclerotic retinopathy		1
Arteriovenous fistula		1
Arthralgia	349	2,672
Arthritis	4	9
Arthropod sting		1
Aspartate aminotransferase increased	1	1
Asphyxia		1
Asthenia	320	1,903
Asthenopia		11
Asthma	4	27
Asthma exercise induced		1
Asthmatic crisis	3	13
Asymptomatic COVID-19	25	42
Ataxia	1	3
Atelectasis	1	2
Atrial fibrillation	10	22
Atrial flutter	1	4
Atrial tachycardia	1	1
Atrioventricular block	1	1
Atrioventricular block complete		1
Atrioventricular block first degree		1
Atrioventricular block second degree	1	1
Auditory disorder		1
Aura	1	4
Autoimmune arthritis	1	1
Autoimmune disorder	2	2
Autoimmune hepatitis	1	1
Autoimmune thyroiditis		2
Axillary mass		1
Axillary pain	19	145
Azotaemia	1	3
Back disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
1	10	303	2379	46	293
		1	5	3	4
			1		
		1	1		
					1
2	9	278	1645	42	258
			9		2
		2	10	2	17
					1
1	3			3	13
		3	4	22	38
				1	3
				1	2
1	1			10	22
			1	1	3
				1	1
				1	1
					1
			1		
		1	1		
					1
		1	4		
				1	1
				2	2
				1	1
					2
			1		
	3	18	134	1	11
				1	3
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Back pain	40	182
Balance disorder	9	26
Band sensation		5
Basedow's disease		1
Bedridden		1
Behaviour disorder	1	1
Bell's palsy	7	25
Benign hydatidiform mole	1	1
Biliary colic		1
Binocular eye movement disorder		1
Bladder dysfunction		1
Blepharitis	1	1
Blepharospasm		3
Blindness	2	6
Blister	2	10
Blister infected		1
Blood alkaline phosphatase increased		1
Blood calcium decreased		1
Blood creatinine increased	1	2
Blood disorder	1	1
Blood fibrinogen increased		1
Blood glucose abnormal	1	2
Blood glucose decreased		1
Blood glucose increased		2
Blood lactate dehydrogenase increased		1
Blood potassium decreased		1
Blood pressure abnormal	3	5
Blood pressure decreased	5	19
Blood pressure diastolic increased	1	2
Blood pressure fluctuation	1	8
Blood pressure increased	25	116
Blood pressure systolic decreased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	2	33	146	7	36
1	2	3	14	6	12
1	1		3		2
			1		1
				1	1
1	2			7	25
				1	1
					1
					1
		1	1		
			2		1
				2	6
		1	6	1	4
			1		
					1
			1		
			1	1	1
				1	1
			1		
				1	2
			1		
			1		1
					1
			1		
		2	4	1	1
	1	4	13	1	6
			1	1	1
			4	1	4
4	4	13	66	12	50
			1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood pressure systolic increased		6
Blood thyroid stimulating hormone increased	1	3
Body temperature abnormal	1	2
Body temperature decreased	2	3
Body temperature fluctuation	1	1
Body temperature increased	6	33
Bone marrow oedema		1
Bone pain	29	184
Bowel movement irregularity	1	1
Bradycardia	1	14
Bradykinesia	2	5
Bradyphrenia		2
Brain stem stroke		1
Breast abscess		1
Breast cyst		1
Breast discomfort		3
Breast disorder	1	1
Breast enlargement		1
Breast inflammation	1	1
Breast oedema		5
Breast pain	4	21
Breast swelling	1	4
Breath odour	1	2
Breath sounds		2
Breath sounds abnormal	1	4
Bronchial disorder	1	1
Bronchial wall thickening		1
Bronchiectasis		1
Bronchitis	1	3
Bronchitis chronic	1	1
Bronchospasm	7	41
Bronchostenosis	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		4
			2	1	1
		1	2		
		1	2	1	1
		1	1		
1	2	6	31		2
					1
		27	150	2	34
		1	1		
1	1			1	14
		2	4		1
			2		
					1
					1
			1		
			2		1
				1	1
			1		
		1	1		
			4		1
		3	14	1	7
		1	2		2
		1	2		
			1		1
			1	1	3
		1	1		
					1
					1
		1	2		1
		1	1		
	1	2	13	5	28
				1	2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Brow ptosis		1
Bundle branch block right		1
Burning mouth syndrome		1
Burning sensation	8	31
Burn oral cavity		1
Bursitis	1	1
Butterfly rash		2
Capillary fragility	1	3
Cardiac arrest	9	19
Cardiac failure	6	13
Cardiac failure congestive	1	2
Cardiac murmur	1	1
Cardiac valve disease	1	1
Cardio-ankle vascular index		1
Cardiomegaly	1	1
Cardiopulmonary failure	1	1
Cardio-respiratory arrest	3	5
Cardiovascular disorder		1
Carotid arteriosclerosis	1	1
Carotid artery thrombosis	1	1
Catarrh	2	7
Catheter site pain		2
Cauda equina syndrome	1	1
Central cord syndrome		1
Central nervous system lesion	1	1
Central nervous system vasculitis	2	2
Central pain syndrome		1
Cerebellar haemorrhage		1
Cerebellar stroke	1	1
Cerebral artery embolism	1	1
Cerebral artery occlusion		1
Cerebral artery thrombosis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
					1
		7	22	1	9
					1
				1	1
			1		1
		1	2		1
				9	19
				6	13
				1	2
				1	1
				1	1
			1		
		1	1		
				1	1
				3	5
			1		
				1	1
				1	1
		1	5	1	2
			2		
				1	1
					1
				1	1
				2	2
			1		
					1
				1	1
				1	1
					1
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebral disorder		1
Cerebral haematoma	1	1
Cerebral haemorrhage	6	10
Cerebral infarction	1	2
Cerebral ischaemia	7	15
Cerebral thrombosis	1	1
Cerebral venous sinus thrombosis	2	3
Cerebral venous thrombosis		1
Cerebrovascular accident	11	21
Cerebrovascular disorder		
Cerebrovascular insufficiency	1	1
Cervical radiculopathy		2
Cervicobrachial syndrome	3	9
Change of bowel habit	1	1
Chest discomfort	17	85
Chest expansion decreased		1
Chest pain	38	147
Chillblains		1
Chills	319	2,054
Choking		1
Choking sensation	1	5
Cholecystitis acute		1
Cholelithiasis		2
Chorioretinopathy	1	1
Chromaturia	1	2
Chronic fatigue syndrome	2	2
Chronic kidney disease	1	1
Chronic respiratory failure		1
Circadian rhythm sleep disorder		1
Circulatory collapse	1	4
Circumoral oedema	1	6
Circumoral swelling		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
				6	10
				1	2
				7	15
2	2			1	1
				2	3
					1
	1			11	21
1	1				
				1	1
			1		1
		1	6	2	3
				1	1
2	4	12	50	5	35
			1		
4	5	17	87	21	60
			1		
	7	278	1772	41	282
					1
			1	1	4
					1
			1		1
			1	1	1
		2	2		
				1	1
					1
			1		
				1	4
		1	6		
					2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Clonus		5
Clostridial infection	1	1
Cluster headache		2
Coagulation factor increased		1
Coagulation test abnormal	1	1
Coagulopathy		1
Cognitive disorder		2
Cold burn		1
Cold sweat	3	28
Cold urticaria		1
Colitis	2	3
Colitis ischaemic		1
Coma	2	5
Coma scale abnormal		1
Compulsions		1
Condition aggravated	5	21
Confusional state	29	132
Conjunctival haemorrhage	4	10
Conjunctival hyperaemia	2	5
Conjunctival irritation		2
Conjunctivitis	6	32
Conjunctivitis allergic	1	2
Connective tissue disorder		1
Connective tissue inflammation		1
Constipation	4	10
Contraindicated product administered		1
Contusion	3	9
Convulsions local		1
Coordination abnormal		1
Corneal bleeding		1
Corneal dystrophy		1
Corneal opacity	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		3
				1	1
			2		
					1
		1	1		
					1
	1		1		1
			1		
		2	20	1	8
			1		
		1	2	1	1
					1
				2	5
					1
					1
		1	6	4	15
3	7	13	82	16	50
	1			4	10
		1	2	1	3
					2
		3	22	3	10
			1	1	1
					1
			1		
		3	9	1	1
					1
		1	6	2	3
					1
					1
					1
				1	2

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Coronary artery disease	1	2
Coronary artery dissection		1
Coronary artery stenosis		1
Cough	55	229
COVID-19	110	240
COVID-19 pneumonia	5	9
Cramp-fasciculation syndrome		2
Cranial nerve disorder	1	2
Cranial nerve paralysis	2	3
Craniocerebral injury	1	1
C-reactive protein abnormal		1
C-reactive protein increased	2	4
Crying	1	3
Cyanosis	3	12
Cyst		1
Cystitis	2	6
Cystitis haemorrhagic	1	6
Dark circles under eyes	1	1
Deafness	2	5
Deafness neurosensory		2
Deafness unilateral	1	2
Death	4	7
Decreased appetite	23	104
Deep vein thrombosis	23	31
Defaecation urgency		1
Dehydration	1	4
Delirium	2	3
Delirium febrile	1	1
Delusion	1	3
Dementia Alzheimer's type		1
Demyelinating polyneuropathy		2
Demyelination		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
					1
					1
3	4	32	130	23	99
2	3	18	46	92	194
	1			5	9
			1		1
			1	1	1
				2	3
				1	1
					1
		2	4		
		1	3		
			2	3	10
			1		
		2	5		1
				1	6
		1	1		
				2	5
					2
				1	2
				4	7
1	2	14	80	9	24
				23	31
			1		
				1	4
				2	3
				1	1
			1	1	2
					1
					2
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dental discomfort	1	1
Depersonalisation/derealisation disorder		1
Depressed level of consciousness	9	42
Depressed mood	1	2
Depression	3	4
Dermal cyst	1	3
Dermatitis	3	11
Dermatitis allergic		4
Dermatitis atopic		1
Dermatitis bullous	3	13
Dermatitis exfoliative generalised		2
Device issue		1
Diaphragmatic disorder	1	1
Diaphragmatic spasm		2
Diarrhoea	120	629
Diarrhoea haemorrhagic	1	1
Diastolic hypertension		1
Diastolic hypotension		1
Dilatation atrial		1
Diplegia		1
Diplopia	10	21
Discomfort	11	28
Disease recurrence	4	22
Disorientation	3	24
Disseminated varicella zoster virus infection		1
Dissociation		2
Distract bility	1	1
Disturbance in attention	4	33
Diverticulitis		1
Diverticulum	1	1
Dizziness	86	430
Drooling		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
			1		
	1			9	42
		1	2		
		1	2	2	2
		1	3		
		2	9	1	2
			3		1
			1		
	1			3	13
					2
			1		
			1		
1	4	103	525	17	104
				1	1
			1		
					1
					1
		3	11	7	10
		9	23	2	5
	1		4	4	18
1	3	1	13	2	11
					1
			2		
		1	1		
	1	1	19	3	14
					1
				1	1
	2	64	304	22	126
			1		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Drug eruption		1
Drug hypersensitivity		5
Drug ineffective	43	106
Drug interaction		1
Dry eye	1	7
Dry mouth	16	93
Dry skin	1	5
Dry throat		6
Duodenal ulcer haemorrhage	1	1
Dysaesthesia	7	31
Dysaesthesia pharynx		2
Dysarthria	9	15
Dysbiosis		1
Dysentery	13	164
Dysgeusia	22	139
Dysgraphia	2	4
Dyskinesia	1	4
Dyslalia	1	2
Dyslexia		1
Dysmetria		2
Dyspepsia	3	28
Dysphagia	10	102
Dysphemia		1
Dysphonia	11	55
Dyspnoea	81	372
Dyspnoea at rest		3
Dyspnoea exertional	4	17
Dysstasia	4	7
Dystonia		1
Dysuria		6
Ear discomfort	1	14
Ear disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		4
1	2			43	106
1	1				1
		1	5		2
	1	14	68	2	25
				1	5
			5		1
				1	1
		4	23	3	8
			2		
5	5		2	9	13
					1
1	6			13	164
	2	20	124	2	15
		1	2	1	2
			2	1	2
				1	2
					1
					2
		3	26		2
1	4	5	58	5	44
					1
	1	4	24	7	31
6	11	35	156	46	216
					3
1	1	2	10	2	7
		2	3	2	4
					1
			3		3
		1	11		3
			1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Ear haemorrhage	1	2
Ear infection		10
Ear pain	12	52
Ear pruritus		4
Ear swelling	2	5
Eating disorder	1	1
Ecchymosis	5	8
Ectopic pregnancy		1
Eczema	2	2
Effusion		1
Electric shock		1
Electric shock sensation	1	2
Electrocardiogram abnormal		4
Embolic stroke	1	1
Embolism	1	2
Embolism venous		1
Emotional disorder		1
Emphysema		1
Enanthema		1
Encephalitis		1
Encephalopathy		1
Endometriosis		1
Enteritis	1	3
Enterococcal infection		1
Enthesopathy		2
Enuresis	1	1
Eosinophil count decreased		1
Eosinophil count increased		1
Epilepsy	3	9
Episcleritis		1
Epistaxis	9	27
Erectile dysfunction	3	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	1
			8		2
		5	34	7	18
			4		
		1	3	1	2
				1	1
		2	4	3	4
					1
		2	2		
					1
					1
		1	2		
			1		3
				1	1
1	1			1	2
					1
			1		
					1
					1
					1
					1
1	1	1	3		
					1
			1		1
				1	1
					1
				3	9
					1
		4	19	5	8
				3	4

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Eructation	1	4
Erysipelas	2	3
Erythema	59	404
Erythema multiforme	2	6
Erythema nodosum	1	7
Erythema of eyelid		3
Erythematotelangiectatic rosacea		1
Euphoric mood	1	4
Exophthalmos	1	1
Exposure during pregnancy	8	10
Exposure to SARS-CoV-2		2
Exposure via breast milk		2
Extensive swelling of vaccinated limb		6
Extra dose administered	1	1
Extraocular muscle paresis		1
Extrasystoles	2	17
Extravasation		1
Eye colour change		1
Eye disorder		2
Eye haematoma	1	2
Eye haemorrhage	2	3
Eye infection		1
Eye irritation	11	72
Eyelid function disorder		1
Eyelid myoclonus		2
Eyelid oedema	2	28
Eyelid pain		1
Eyelid ptosis	3	11
Eyelids pruritus	1	2
Eye movement disorder		2
Eye oedema	3	11
Eye pain	6	55

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3	1	1
				2	3
4	5	44	291	15	113
			4	1	3
			2		1
			1		
		1	4		
				1	1
		8	10		
			2		
			2		
			4		2
				1	1
					1
1	1	1	10	1	7
			1		
					1
			1		1
				1	2
				2	3
					1
	1	11	65		7
					1
					2
	1	1	15	1	13
			1		
			3	3	8
		1	2		
			1		1
		2	7	1	4
	1	4	43	2	12

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye paraesthesia	2	7
Eye pruritus	2	23
Eye swelling	2	8
Face injury	1	3
Face oedema	10	48
Facial asymmetry		2
Facial bones fracture	1	2
Facial discomfort		2
Facial nerve disorder		6
Facial neuralgia		4
Facial pain	1	15
Facial paralysis	12	37
Facial paresis	8	32
Facial spasm	1	4
Faeces hard		1
Faeces pale	1	1
Faeces soft		2
Fall	5	14
Fasciitis		1
Fatigue	297	2,122
Febrile convulsion		10
Feeling abnormal	8	36
Feeling cold	27	195
Feeling hot	27	178
Feeling jittery		5
Feeling of body temperature change	2	12
Feeling of despair	1	1
Female sexual dysfunction		1
Fibrin D dimer increased	4	5
Fibromuscular dysplasia		1
Fibromyalgia	1	3
Flank pain	2	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	5		2
		1	12	1	11
		2	5		3
				1	3
1	1	6	21	4	27
					2
				1	2
			2		
			3		3
			2		2
			8	1	7
				12	37
1	1	4	19	4	13
			2	1	2
			1		
				1	1
			1		1
		1	2	4	12
			1		
2	6	249	1884	48	238
			6		4
		8	30		6
	1	24	171	3	24
		17	123	10	55
			4		1
		1	7	1	5
		1	1		
			1		
1	1	2	2	2	3
					1
		1	2		1
		2	6		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Flat affect		3
Flatulence	4	9
Fluid retention		2
Flushing	14	139
Foaming at mouth		2
Focal dyscognitive seizures		1
Foetal death	1	1
Foetal growth restriction		1
Folliculitis		1
Food allergy		1
Food aversion		1
Foreign body in throat		1
Foreign body sensation in eyes		1
Frequent bowel movements		3
Full blood count increased		1
Functional gastrointestinal disorder		1
Fungal infection		1
Gait disturbance	9	32
Gait inability	3	6
Gallbladder disorder	1	1
Gamma-glutamyltransferase increased		1
Gastritis	3	4
Gastroenteritis	1	6
Gastrointestinal disorder	9	43
Gastrointestinal haemorrhage		1
Gastrointestinal hypermotility		1
Gastrointestinal motility disorder	1	1
Gastrointestinal pain	7	15
Gastrointestinal sounds abnormal	2	4
Gastrooesophageal reflux disease	1	6
Gaze palsy	1	1
Generalised oedema		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		1
		3	8	1	1
			2		
1	1	12	117	2	22
					2
					1
				1	1
					1
			1		
					1
			1		
					1
			1		
			3		
			1		
			1		
			1		
		5	17	4	15
				3	6
				1	1
					1
		3	4		
		1	5		1
	1	9	39		4
					1
					1
		1	1		
		6	13	1	2
		2	4		
		1	6		
				1	1
			1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Generalised tonic-clonic seizure	1	4
General physical health deterioration		3
General symptom	1	1
Genital discomfort		1
Genital pain	1	1
Gilbert's syndrome	1	1
Gingival bleeding	2	3
Gingival discolouration		1
Gingival discomfort	1	1
Gingival pain		2
Gingival swelling		1
Gingivitis		3
Glare		1
Glaucoma	1	1
Gliositis		1
Glomerulonephritis		1
Glossitis		6
Glossodynia	2	7
Glottal incompetence		1
Goitre	1	3
Grip strength decreased		2
Groin pain		3
Grunting		1
Guillain-Barre syndrome	2	4
Guttate psoriasis		1
Haematemesis		2
Haematochezia	2	4
Haematocrit decreased	1	2
Haematoma	6	18
Haematoma muscle	1	1
Haematuria		5
Haemochromatosis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	4
					3
		1	1		
					1
		1	1		
		1	1		
			1	2	2
					1
	1	1	1		
			2		
			1		
			3		
			1		
				1	1
			1		
					1
			4		2
		2	4		3
					1
		1	2		1
			1		1
	2		3		
					1
				2	4
					1
1	1				2
				2	4
		1	2		
		1	10	5	8
		1	1		
			3		2
			1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Haemodynamic instability	1	1
Haemoglobin decreased	3	5
Haemolysis	1	1
Haemoperitoneum		1
Haemorrhage	2	4
Haemorrhage subcutaneous		1
Haemorrhagic cerebral infarction		1
Haemorrhagic infarction	1	1
Haemorrhagic stroke	2	2
Haemorrhoids	1	1
Haemorrhoids thrombosed	2	2
Hallucination	3	8
Hallucination, auditory		3
Hallucination, olfactory		2
Hallucinations, mixed		1
Hallucination, visual		6
Hand deformity		1
Hand dermatitis		1
Haptoglobin increased		1
Headache	917	4,654
Head discomfort	6	24
Head injury		1
Heart rate abnormal		1
Heart rate decreased	1	5
Heart rate increased	1	21
Heart rate irregular		2
Heat stroke		3
Heavy menstrual bleeding	13	18
Hemianaesthesia	2	11
Hemianopia		1
Hemianopia heteronymous		1
Hemianopia homonymous		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	2	2	3
				1	1
					1
				2	4
					1
					1
				1	1
				2	2
		1	1		
				2	2
				3	8
1	1				3
					2
					1
					6
			1		
			1		
					1
9	26	830	4108	87	546
		6	20		4
1	1				1
					1
			2	1	3
		1	9		12
					2
			2		1
		10	11	3	7
				2	11
					1
					1
					1

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FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hemidysaesthesia		4
Hemihyperaesthesia	1	2
Hemiparaesthesia	6	29
Hemiparesis	6	21
Hemiplegia	2	6
Hepatic encephalopathy		
Hepatic enzyme increased	1	1
Hepatic pain		2
Hepatic steatosis	1	1
Hepatitis A antibody positive		1
Hepatitis acute		2
Hepatitis B antibody positive		1
Hepatitis cholestatic	1	1
Herpes ophthalmic	2	8
Herpes simplex	3	7
Herpes simplex encephalitis		1
Herpes virus infection	3	10
Herpes zoster	33	58
Herpes zoster cutaneous disseminated	1	1
Herpes zoster infection neurological	1	1
Herpes zoster oticus	1	2
Herpes zoster reactivation	3	4
Hiatus hernia	1	1
Hiccups		1
Hidradenitis		1
Histamine intolerance		1
Hormone level abnormal	1	1
Hot flush	24	100
Hyperacusis	1	2
Hyperaemia	3	8
Hyperaesthesia	3	17
Hyperbilirubinaemia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					4
				1	2
				6	29
				6	21
				2	6
1	1				
				1	1
			2		
				1	1
			1		
					2
			1		
				1	1
				2	8
		3	6		1
					1
		2	9	1	1
		28	46	5	12
				1	1
				1	1
				1	2
		3	3		1
				1	1
			1		
					1
			1		
				1	1
		17	79	7	21
		1	2		
		1	5	2	3
		3	16		1
					1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hypercapnia	1	1
Hypergammaglobulinaemia benign monoclonal	1	1
Hyperglycaemia	2	8
Hyperhidrosis	26	180
Hyperkinesia		1
Hyperpyrexia	16	196
Hyperreflexia	1	1
Hypersensitivity	14	72
Hypersomnia	1	6
Hypertension	31	140
Hypertensive crisis	22	84
Hypertensive heart disease		2
Hyperthermia	4	33
Hyperthyroidism		1
Hypertonia	1	3
Hypertransaminasaemia		2
Hypertrophy of tongue papillae	2	3
Hyperventilation		7
Hypoacusis	2	10
Hypoaesthesia	18	133
Hypoaesthesia oral	5	47
Hypogeusia	1	2
Hypoglycaemia	1	4
Hypoglycaemic unconsciousness	1	1
Hypokalaemia		3
Hypokinesia		2
Hyponatraemia	1	2
Hyporeflexia	1	3
Hyporesponsive to stimuli	1	5
Hyposmia	1	1
Hypotension	23	140
Hypotensive crisis		5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
		2		2	6
	1	20	141	6	39
			1		
	2			16	196
				1	1
3	5	5	29	9	43
		1	6		
1	2	14	68	17	72
				22	84
					2
		4	26		7
					1
1	1		2	1	1
1	1				2
		2	2		1
	1		3		4
1	1		4	2	6
	2	14	106	4	27
		3	37	2	10
		1	2		
			3	1	1
				1	1
					3
			1		1
				1	2
		1	1		2
			3	1	2
				1	1
1	3	12	80	11	60
					5

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hypothermia	6	25
Hypothyroidism	1	1
Hypotonia		10
Hypotonic-hyporesponsive episode		1
Hypovolaemia		1
Hypoxia	2	9
Idiopathic urticaria		1
Idiosyncratic drug reaction	1	1
IIIrd nerve disorder		1
Illness	7	13
Immobile		1
Immune system disorder		1
Immune thrombocytopenia	1	1
Immunisation	1	2
Immunisation anxiety related reaction		1
Impaired fasting glucose	1	1
Impaired gastric emptying		1
Impaired quality of life	5	7
Impaired work ability		1
Inappropriate schedule of product administration	4	13
Incomplete course of vaccination	1	1
Incontinence	1	3
Incorrect dosage administered		1
Incorrect dose administered	1	5
Incorrect route of product administration	5	28
Increased upper airway secretion		1
Increased viscosity of bronchial secretion		1
Induration		10
Infantile vomiting		1
Infected cyst		1
Infection	1	2
Inflammation		9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	5	24
				1	1
			6		4
			1		
					1
				2	9
			1		
		1	1		
					1
		7	11		2
					1
			1		
				1	1
		1	2		
			1		
				1	1
					1
		1	3	4	4
					1
		4	12		1
		1	1		
		1	1		2
			1		
		1	5		
		5	28		
			1		
					1
			10		
			1		
					1
		1	2		
			8		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Inflammatory pain		2
Influenza	4	27
Influenza like illness	22	135
Infusion site lymphadenopathy		1
Infusion site pain		2
Infusion site paraesthesia		1
Initial insomnia	2	21
Injected limb mobility decreased	1	30
Injection		1
Injection related reaction		1
Injection site discharge		1
Injection site discomfort		2
Injection site erythema	5	148
Injection site haematoma	1	10
Injection site haemorrhage		2
Injection site hypersensitivity		3
Injection site hypoaesthesia		3
Injection site induration		9
Injection site infection		9
Injection site inflammation		1
Injection site joint erythema		2
Injection site joint pain	1	2
Injection site joint swelling		1
Injection site lymphadenopathy		2
Injection site muscle weakness		1
Injection site oedema	2	232
Injection site pain	49	1,572
Injection site paraesthesia		11
Injection site pruritus		47
Injection site rash	1	5
Injection site reaction		23
Injection site swelling	1	51

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
		4	24		3
	1	22	123		12
			1		
			2		
			1		
		1	17	1	4
		1	29		1
			1		
			1		
			2		
		5	148		
		1	10		
			2		
			3		
			3		
			9		
			9		
			1		
			2		
		1	2		
			1		
			2		
			1		
		2	232		
		49	1570		2
			11		
			47		
		1	5		
			23		
		1	51		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site urticaria		31
Injection site warmth	1	9
Injury	1	4
Insomnia	39	253
Inspiratory capacity abnormal		1
Instillation site bruise		1
Intentional product misuse		1
Intermenstrual bleeding	1	8
Intermittent claudication	1	2
Internal haemorrhage	1	1
International normalised ratio increased	1	1
Interstitial lung disease	3	5
Intervertebral disc degeneration	1	1
Intestinal congestion		1
Intestinal infarction	1	1
Intestinal obstruction	1	1
Intestinal pseudo-obstruction		1
Intra-abdominal haemorrhage	1	1
Intracranial pressure increased	1	1
Intranasal hypoaesthesia		1
Intranasal paraesthesia		2
Intraocular pressure increased	1	1
Iridocyclitis		1
Irritability	4	13
Irritable bowel syndrome	1	1
Ischaemia	4	5
Ischaemic stroke	8	13
IVth nerve disorder		1
IVth nerve paralysis	1	1
Jaundice	2	3
Jaw fracture		1
Joint ankylosis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			30		1
		1	9		
			2	1	2
		33	224	6	29
			1		
			1		
			1		
		1	5		3
			1	1	1
				1	1
				1	1
				3	5
				1	1
			1		
				1	1
				1	1
					1
				1	1
				1	1
			1		
			2		
		1	1		
				4	5
1	1			8	13
					1
				1	1
			1	2	2
					1
			1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Joint contracture		1
Joint dislocation		1
Joint effusion		2
Joint hyperextension		1
Joint instability		1
Joint lock	2	4
Joint range of motion decreased	3	12
Joint stabilisation	1	1
Joint stiffness		2
Joint swelling	3	6
Joint warmth		2
Klebsiella infection	1	1
Laboratory test abnormal		1
Labyrinthitis	1	8
Lacrimation disorder		1
Lacrimation increased	4	27
Lactic acidosis	1	1
Lactose intolerance	1	1
Lacunar stroke		1
Lagophthalmos		2
Language disorder		1
Laryngeal discomfort		2
Laryngeal dyspnoea		4
Laryngeal obstruction		1
Laryngeal oedema	13	77
Laryngeal pain		1
Laryngeal stenosis		1
Laryngospasm	2	17
Larynx irritation		1
Lateropulsion		1
Left ventricular hypertrophy		1
Lethargy	2	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
			1		1
			1		
			1		
		1	2	1	2
		1	5	2	7
		1	1		
			2		
		3	4		2
					2
				1	1
					1
			3	1	5
					1
		3	20	1	7
				1	1
		1	1		
					1
			1		1
			1		
			1		1
					4
					1
				13	77
			1		
					1
			4	2	13
			1		
					1
					1
		1	5	1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Leukocytosis	1	3
Leukopenia		4
Lichen sclerosus	1	1
Limb discomfort	16	69
Limb immobilisation	1	2
Lipase increased	1	4
Lip disorder		2
Lip dry		1
Lip erythema	1	5
Lipodystrophy acquired		1
Lip oedema	13	72
Lip pain		4
Lip pruritus	2	17
Lip swelling	9	41
Livedo reticularis	1	1
Liver abscess	1	1
Liver disorder	1	1
Localised infection	1	1
Localised oedema	3	27
Local reaction	3	10
Logorrhoea	1	2
Loss of consciousness	22	91
Loss of control of legs		1
Loss of personal independence in daily activities	2	6
Lung opacity	1	1
Lymphadenitis	7	41
Lymphadenopathy	179	1,390
Lymphangitis		8
Lymphatic obstruction		1
Lymph node pain	13	106
Lymph node palpable		2
Lymphocyte count increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1		2	1	1
	1				4
				1	1
		13	59	3	10
			1	1	1
			2	1	2
					2
			1		
		1	4		1
					1
	1	8	38	5	34
			4		
			6	2	11
	1	5	26	4	15
				1	1
				1	1
				1	1
		3	22		5
		3	10		
				1	2
				22	91
					1
			4	2	2
		1	1		
		7	30		11
1	12	160	1223	19	167
					8
					1
1	6	12	93	1	13
			2		
					1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Lymphocytosis		2
Lymphoedema		7
Lymphopenia		1
Macroglossia	2	3
Macule	1	1
Maculopathy		2
Madarosis		1
Malaise	160	1,293
Mastitis	1	7
Maternal exposure before pregnancy		1
Maternal exposure during pregnancy	10	27
Maternal exposure timing unspecified		1
Mean cell haemoglobin concentration decreased		1
Mean cell haemoglobin decreased		1
Mechanical urticaria		7
Mechanical ventilation	1	1
Mediastinal disorder	1	1
Medication error		1
Melaena	1	2
Memory impairment	1	6
Menstrual cycle management		1
Menstrual disorder	10	11
Menstruation delayed	5	5
Menstruation irregular	15	16
Mental disorder		2
Mental impairment	1	4
Metabolic acidosis	1	1
Metamorphopsia	1	1
Micturition disorder		1
Micturition urgency	1	3
Middle insomnia		6
Migraine	25	201

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
			5		2
					1
				2	3
				1	1
					2
					1
7	9	138	1182	22	111
				1	7
			1		
		10	26		1
					1
			1		
			1		
	2		4		3
				1	1
		1	1		
			1		
				1	2
			2	1	4
			1		
		9	10	1	1
		5	5		
		15	16		
			1		1
				1	4
				1	1
		1	1		
			1		
		1	1		2
			5		1
1	3	22	167	3	34

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Gender

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Migraine with aura	3	6
Miosis		1
Mitral valve incompetence		2
Mitral valve stenosis		1
Mobility decreased	4	12
Monoclonal gammopathy	1	1
Monocyte count decreased		1
Mononeuritis	2	2
Monoparesis	9	12
Monoplegia	1	7
Mood altered		2
Mood swings	1	2
Morning sickness		1
Motion sickness		2
Motor dysfunction	2	27
Mouth swelling	1	6
Mouth ulceration		1
Movement disorder	1	20
Mucosal dryness		2
Mucosal hyperaemia		1
Mucosal inflammation		1
Mucous stools		1
Multi-organ disorder	1	1
Multiple organ dysfunction syndrome		3
Multiple sclerosis	2	4
Multiple sclerosis relapse	2	2
Muscle contractions involuntary	3	11
Muscle contracture		9
Muscle discomfort	1	1
Muscle disorder		1
Muscle fatigue		4
Muscle oedema		5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	6		
			1		
					2
					1
		3	9	1	3
				1	1
					1
		1	1	1	1
		8	10	1	2
				1	7
			1		1
			1	1	1
			1		
			2		
			18	2	9
		1	3		3
					1
1	1		8	1	12
			2		
					1
			1		
			1		
				1	1
					3
				2	4
				2	2
		1	8	2	3
	1		6		3
		1	1		
			1		
			3		1
			3		2

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Muscle rigidity	7	23
Muscle spasms	7	54
Muscle strain		1
Muscle strength abnormal	1	1
Muscle swelling		1
Muscle tightness	1	5
Muscle twitching	2	8
Muscular weakness	21	101
Musculoskeletal chest pain	1	21
Musculoskeletal discomfort		1
Musculoskeletal disorder	1	5
Musculoskeletal pain	46	380
Musculoskeletal stiffness	11	45
Myalgia	444	3,171
Myalgia intercostal		2
Myasthenia gravis		3
Myasthenia gravis crisis	1	2
Mydriasis		1
Myelitis	1	1
Myocardial infarction	3	6
Myocardial ischaemia	3	4
Myocarditis	1	2
Myoclonus		4
Myokymia		1
Myositis	1	5
Myringitis		1
Narcolepsy		3
Nasal congestion	14	28
Nasal discomfort	3	6
Nasal herpes	1	3
Nasal obstruction	2	5
Nasal oedema	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	17	2	6
	1	4	39	3	15
			1		
		1	1		
			1		
		1	4		1
		1	5	1	3
		10	67	11	34
		1	15		6
					1
		1	4		1
	1	43	328	3	52
		8	29	3	16
	8	406	2876	38	295
			1		1
					3
				1	2
					1
				1	1
				3	6
				3	4
				1	2
					4
			1		
		1	2		3
					1
					3
		7	18	7	10
		2	5	1	1
		1	3		
		2	4		1
		1	1		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nasal pruritus		1
Nasopharyngitis	27	76
Nausea	260	1,809
Neck pain	30	152
Neoplasm	1	1
Nephropathy	1	1
Nerve compression	1	3
Nerve injury		1
Nervousness	2	5
Nervous system disorder	2	5
Neuralgia	8	31
Neuritis	1	8
Neurodermatitis		1
Neurological symptom	2	4
Neurologic neglect syndrome		1
Neuromuscular pain	2	2
Neuropathy peripheral	3	16
Neurosensory hypoacusis		1
Neurotoxicity		1
Neutropenia		1
Neutrophil count increased		2
Neutrophilia		2
Neutrophil percentage increased		1
Nightmare	2	3
Night sweats	4	22
Nocturnal dyspnoea	1	1
Nodule		1
Non-Hodgkin's lymphoma	1	1
Noninfective gingivitis	1	3
Non-pitting oedema		1
Normal pressure hydrocephalus	1	1
Nuchal rigidity		19

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		22	59	5	17
3	14	222	1527	38	282
	2	22	121	8	31
		1	1		
				1	1
		1	2		1
			1		
		2	5		
				2	5
	1	6	23	2	8
		1	7		1
			1		
1	2		1	2	3
					1
		1	1	1	1
				3	16
1	1				1
					1
	1				1
			1		1
					2
					1
		1	2	1	1
		4	21		1
		1	1		
			1		
				1	1
		1	2		1
					1
				1	1
			11		8

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Gender

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nystagmus		2
Obstruction		1
Obstructive airways disorder	1	3
Occipital neuralgia		1
Occult blood positive	1	1
Occupational exposure to product		1
Ocular discomfort	4	9
Ocular hyperaemia	4	40
Oculogyric crisis		1
Odynophagia	1	6
Oedema	7	32
Oedema mouth	1	7
Oedema mucosal	1	3
Oedema peripheral	11	46
Oedematous pancreatitis		1
Oesophageal pain		2
Oesophageal spasm		2
Off label use	16	38
Oligomenorrhoea	1	1
Oliguria		2
Ophthalmic herpes simplex		1
Ophthalmic herpes zoster		1
Ophthalmic migraine		1
Optic neuritis	1	6
Optic neuropathy		1
Oral candidiasis	1	2
Oral discomfort	7	30
Oral disorder	1	2
Oral dysaesthesia	1	7
Oral herpes	8	56
Oral mucosal erythema		2
Oral pain	2	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
			1		
			1	1	2
					1
		1	1		
			1		
		4	9		
		4	30		10
					1
	1	1	4		2
		7	28		4
	1	1	5		2
				1	3
1	2	5	31	6	15
					1
			1		1
					2
		15	35	1	3
				1	1
					2
					1
					1
				1	6
					1
			1	1	1
	1	6	25	1	5
		1	2		
			6	1	1
		8	44		12
			1		1
		2	5		1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Oral pruritus	1	13
Orbital oedema		1
Oropharyngeal discomfort	2	26
Oropharyngeal oedema		2
Oropharyngeal pain	30	129
Oropharyngeal plaque		1
Oropharyngeal spasm		1
Oropharyngeal swelling	1	4
Orthopnoea		1
Orthostatic hypotension		4
Osteitis	1	1
Osteoarthropathy		1
Otitis externa		1
Otitis media acute	1	1
Ovarian cyst	1	1
Overdose	16	54
Ovulation pain	1	1
Oxygen saturation decreased	12	56
Pain	96	617
Painful respiration		1
Pain in extremity	218	1,185
Pain in jaw	2	14
Pain of skin	1	6
Palatal oedema	2	16
Palatal swelling		5
Palatal ulcer	1	1
Pallor	2	19
Palpable purpura		2
Palpitations	6	44
Pancreatitis acute		1
Panic attack	3	9
Panic reaction		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	5		8
					1
		1	17	1	9
					2
	1	26	102	4	27
					1
					1
		1	3		1
					1
			3		1
		1	1		
			1		
			1		
		1	1		
		1	1		
		14	50	2	4
				1	1
2	3	1	10	11	46
1	2	83	520	13	97
			1		
3	5	187	1042	31	143
		2	9		5
		1	5		1
		1	10	1	6
			3		2
		1	1		
2	3	2	13		6
			1		1
		5	28	1	16
					1
		2	6	1	3
			2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Panniculitis		1
Papilloedema	1	3
Papule		3
Paraesthesia	120	750
Paraesthesia ear		2
Paraesthesia mucosal		1
Paraesthesia oral	37	265
Parainfluenzae virus infection	1	1
Paralysis		3
Paraparesis		2
Paratracheal lymphadenopathy		1
Paresis	1	5
Parosmia	2	10
Partial seizures	1	2
Partner stress		1
Parvovirus B19 test positive		1
Pelvic fracture	1	1
Pelvic pain	1	3
Pemphigoid	1	2
Performance status decreased	1	1
Pericardial effusion	3	13
Pericarditis	5	10
Perineal pain		1
Perioral dermatitis		1
Periorbital oedema	2	15
Periorbital pain		2
Periorbital swelling	3	14
Peripheral coldness	6	21
Peripheral ischaemia	2	2
Peripheral paralysis	1	1
Peripheral sensorimotor neuropathy		1
Peripheral sensory neuropathy		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	3
			2		1
3	6	87	549	33	201
			1		1
					1
1	4	25	174	12	91
				1	1
					3
					2
			1		
		1	2		3
		1	7	1	3
				1	2
			1		
			1		
				1	1
		1	3		
				1	2
		1	1		
				3	13
				5	10
			1		
			1		
		2	10		5
			2		
		2	12	1	2
1	2	2	12	4	9
				2	2
				1	1
					1
			1		

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* AE=Adverse Event

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Peripheral swelling	26	112
Peripheral venous disease	1	2
Peristalsis vis ble		1
Petechiae	5	10
Petit mal epilepsy	1	2
Pharyngeal disorder		2
Pharyngeal erythema	1	6
Pharyngeal hypoaesthesia		1
Pharyngeal mass	1	2
Pharyngeal oedema	2	11
Pharyngeal paraesthesia	4	28
Pharyngeal swelling	1	16
Pharyngitis	2	8
Pharyngitis streptococcal	1	1
Phlebitis	2	9
Phlebitis superficial		2
Photophobia	5	38
Photopsia	2	9
Photosensitivity reaction	3	6
Piloerection		1
Pityriasis rosea		3
Platelet count decreased	2	2
Platelet disorder	1	1
Pleural effusion	2	8
Pleurisy	1	1
Pleuropericarditis	1	1
Plicated tongue	1	2
Pneumonia	4	12
Pneumonia aspiration	1	1
Pneumonia bacterial		1
Pneumonitis	2	3
PO2 decreased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1	21	91	5	21
		1	2		
			1		
	1	2	6	3	4
				1	2
			1		1
		1	3		3
					1
			1	1	1
	1		2	2	9
		3	12	1	16
		1	6		10
	1	1	5	1	3
		1	1		
		2	7		2
			1		1
		4	31	1	7
		2	6		3
		3	4		2
					1
			3		
				2	2
				1	1
		1	2	1	6
		1	1		
				1	1
		1	1		1
				4	12
				1	1
					1
				2	3
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pollakiuria		4
Polyarthrits		2
Polydipsia		3
Polymenorrhoea	6	6
Polymyalgia rheumatica	1	2
Polyneuropathy		1
Polyuria	1	4
Poor quality product administered	1	1
Poor quality sleep	1	2
Post thrombotic syndrome	1	1
Post-traumatic neck syndrome	1	1
Premenstrual pain		2
Presyncope	20	130
Procalcitonin increased	1	1
Product administered at inappropriate site		5
Product administered to patient of inappropriate age	1	2
Product administration error	1	1
Productive cough	1	5
Product preparation error	2	2
Product preparation issue	2	4
Product use in unapproved indication	1	1
Product use issue	9	22
Protein C increased	1	1
Proteinuria		2
Prurigo		1
Pruritus	62	451
Pruritus allergic		1
Pruritus genital		2
Psoriasis		2
Psoriatic arthropathy		1
Psychiatric decompensation	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		1
					2
			3		
		6	6		
				1	2
					1
			2	1	2
		1	1		
			1	1	1
				1	1
		1	1		
			2		
2	3	7	71	13	59
		1	1		
			5		
		1	2		
		1	1		
				1	5
		2	2		
		2	4		
		1	1		
		9	20		2
				1	1
			2		
			1		
2	4	46	352	16	99
			1		
			2		
			1		1
					1
		1	1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Psychomotor hyperactivity	3	7
Pulmonary air leakage	1	1
Pulmonary artery thrombosis	2	2
Pulmonary congestion	1	1
Pulmonary embolism	24	42
Pulmonary hypertension	1	2
Pulmonary hypoperfusion		1
Pulmonary mass		1
Pulmonary oedema	1	1
Pulmonary pain		3
Pulmonary thrombosis	1	1
Pulse abnormal		1
Pulse volume decreased		1
Puncture site induration		4
Puncture site pain		1
Pupils unequal	2	2
Purpura	2	2
Pustular psoriasis		1
Pustule		4
Pyrexia	777	4,662
Q fever		8
Quality of life decreased	1	8
Radiculitis brachial		3
Radiculopathy		3
Rales	1	3
Rash	47	310
Rash erythematous	5	26
Rash macular	6	16
Rash maculo-papular	1	7
Rash maculovesicular		1
Rash morbilliform		2
Rash papular	1	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	5	1	2
		1	1		
				2	2
				1	1
3	3		1	24	41
				1	2
					1
					1
				1	1
			2		1
				1	1
					1
					1
			4		
			1		
		1	1	1	1
	1			2	2
					1
			2		2
5	35	682	3944	95	718
					8
		1	4		4
			3		
			2		1
			1	1	2
	3	39	218	8	92
	1	4	17	1	9
		6	14		2
		1	7		
			1		
			2		
		1	6		1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Rash pruritic	6	48
Rash pustular	1	1
Rash scarlatiniform		1
Rash vesicular	1	8
Raynaud's phenomenon	1	2
Reaction to excipient		1
Rectal haemorrhage	5	7
Red blood cell count increased		1
Red blood cell sedimentation rate increased	1	3
Reduced facial expression		1
Regurgitation		1
Renal colic	2	2
Renal failure	4	7
Renal infarct	1	1
Renal pain	2	9
Respiration abnormal	1	1
Respiratory arrest		3
Respiratory depression	1	2
Respiratory disorder	1	15
Respiratory distress	2	21
Respiratory failure	10	19
Respiratory fatigue	2	8
Respiratory rate increased		2
Respiratory tract haemorrhage		1
Respiratory tract infection	1	1
Respiratory tract oedema	2	6
Restless legs syndrome		3
Restlessness	5	12
Retching	4	36
Retinal artery occlusion	1	3
Retinal degeneration		1
Retinal detachment		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	31	1	17
		1	1		
			1		
		1	6		2
			1	1	1
					1
				5	7
			1		
		1	1		2
					1
					1
				2	2
				4	7
				1	1
		2	9		
		1	1		
					3
				1	2
		1	6		9
	1			2	21
1	1			10	19
		1	3	1	5
			1		1
					1
				1	1
				2	6
					3
		5	10		2
1	1	4	26		10
				1	3
					1
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Retinal disorder		1
Retinal drusen		1
Retinal oedema		1
Retinal vascular thrombosis		
Retinal vein occlusion		1
Retinal vein thrombosis	1	2
Retrograde amnesia		1
Reynold's syndrome	1	1
Rhabdomyolysis		1
Rheumatic disorder		1
Rheumatoid arthritis		5
Rhinalgia		3
Rhinitis	8	26
Rhinitis allergic	1	2
Rhinorrhoea	8	30
Root canal infection		1
Rosacea		1
Salivary gland pain		1
Salivary hypersecretion	1	11
Sarcoidosis	1	1
SARS-CoV-2 ant body test		1
SARS-CoV-2 ant body test negative		3
SARS-CoV-2 ant body test positive	1	8
SARS-CoV-2 test		2
SARS-CoV-2 test positive	9	21
Scab		1
Scalloped tongue	1	1
Scarlet fever		
Sciatica	3	8
Scintillating scotoma	1	4
Scleral discolouration	2	3
Scleral hyperaemia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
	1				
					1
				1	2
			1		
				1	1
					1
			1		
					5
			2		1
1	1	6	21	2	5
		1	2		
		5	21	3	9
			1		
					1
			1		
			8	1	3
				1	1
					1
			2		1
			6	1	2
					2
		4	5	5	16
					1
		1	1		
	1				
		2	7	1	1
		1	4		
		2	2		1
			1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Seasonal allergy		1
Seborrhoeic dermatitis		1
Secretion discharge	1	1
Sedation		3
Seizure	4	13
Sensation of foreign body	3	21
Sense of oppression		6
Sensitive skin		2
Sensory disturbance	1	3
Sensory loss	2	9
Sepsis	2	4
Septic shock		3
Seroconversion test negative	1	4
Shock	1	5
Sinus bradycardia		1
Sinus headache		1
Sinusitis		1
Sinus pain	1	4
Sinus tachycardia		12
Sjogren's syndrome		1
Skin burning sensation	2	17
Skin discolouration	1	7
Skin discomfort		1
Skin exfoliation	1	4
Skin hypertrophy	2	3
Skin induration	1	2
Skin irritation	1	3
Skin laceration	1	4
Skin lesion	2	10
Skin mass	1	3
Skin oedema		1
Skin reaction	3	29

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
		1	1		
			1		2
				4	13
		1	12	2	9
1	1		3		3
			2		
		1	2		1
			3	2	6
				2	4
					3
			2	1	2
1	1			1	5
			1		
			1		
			1		
			2	1	2
			5		7
					1
			14	2	3
		1	4		3
			1		
			2	1	2
		1	2	1	1
		1	1		1
		1	2		1
			2	1	2
		1	7	1	3
		1	3		
			1		
		3	20		9

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin striae		1
Skin swelling	1	2
Skin tightness		2
Skin warm		5
Skull fractured base	1	1
Sleep disorder	1	15
Sluggishness	1	2
Sneezing	2	7
Soft tissue infection		1
Soliloquy		1
Somnolence	46	257
Sopor	2	8
Speech disorder	7	22
Spinal compression fracture	1	1
Spinal epidural haematoma	1	1
Spinal pain	6	28
Splenomegaly		1
Spontaneous haematoma	1	1
Status epilepticus	1	1
Stenosis	2	2
Stertor		1
Stoma site pain		1
Stomatitis	2	6
Strabismus	1	1
Stress		1
Stridor	1	4
Stupor		12
Subarachnoid haemorrhage	2	2
Subcutaneous haematoma		1
Subdural haematoma	1	1
Submaxillary gland enlargement		1
Sudden death		8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	1		1
			1		1
			2		3
				1	1
		1	13		2
		1	1		1
		1	5	1	2
					1
			1		
	1	38	215	8	42
1	2		1	2	7
	1	1	7	6	15
				1	1
				1	1
		5	26	1	2
					1
1	1	1	1		
				1	1
				2	2
					1
			4	2	2
				1	1
			1		
			1	1	3
			7		5
				2	2
					1
				1	1
			1		
	1				8

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Sudden hearing loss	1	1
Sudden onset of sleep		2
Suffocation feeling	2	10
Suicidal ideation	1	1
Superinfection bacterial		1
Supraventricular extrasystoles		1
Supraventricular tachycardia	1	2
Suspected COVID-19	5	7
Swelling	19	83
Swelling face	10	55
Swelling of eyelid		8
Swollen tongue	5	41
Syncope	32	136
Systemic lupus erythematosus		1
Systolic hypertension		1
Tachyarrhythmia		4
Tachycardia	78	426
Tachycardia paroxysmal	2	7
Tachypnoea	6	28
Takayasu's arteritis	1	1
Taste disorder	4	25
Temperature intolerance		2
Temperature regulation disorder	1	1
Temporomandibular joint syndrome		2
Tenderness	1	7
Tendon disorder	1	1
Tendonitis	1	2
Tendon pain	1	2
Tenosynovitis		1
Tension	1	4
Tension headache	1	12
Terminal insomnia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					2
			4	2	6
				1	1
					1
					1
		1	1		1
				5	7
		15	66	4	17
	1	5	33	5	22
			6		2
		4	22	1	19
3	7			32	136
					1
					1
1	1		4		
3	7	48	265	30	161
	1		2	2	5
		2	13	4	15
				1	1
		3	18	1	7
			2		
		1	1		
			1		1
		1	6		1
		1	1		
			1	1	1
			1	1	1
			1		
		1	3		1
		1	10		2
			1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tetany		2
Therapeutic response unexpected	2	2
Thirst	2	9
Thirst decreased	1	1
Thought blocking		1
Throat irritation	10	65
Throat tightness	12	107
Thromboangiitis obliterans		1
Thrombocytopenia	6	17
Thrombocytosis	1	1
Thrombophlebitis	5	7
Thrombophlebitis superficial	4	11
Thrombosis	10	18
Thrombotic stroke	1	1
Thyroglobulin increased		1
Thyroglossal cyst		1
Thyroid disorder	1	2
Thyroiditis acute	2	2
Thyroiditis subacute		3
Thyroid mass	1	2
Thyroid pain		2
Tinnitus	7	32
Tongue biting	1	1
Tongue blistering	1	1
Tongue coated		2
Tongue discolouration	1	3
Tongue discomfort		13
Tongue disorder		3
Tongue dry		5
Tongue erythema		3
Tongue geographic	1	1
Tongue movement disturbance		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
		2	2		
		2	9		
		1	1		
					1
		8	38	2	27
1	3	5	48	7	59
					1
1	2			6	17
				1	1
		5	6		1
	1	1	2	3	9
1	1			10	18
				1	1
					1
		1	2		
				2	2
			3		
		1	1		1
			1		1
		6	23	1	9
				1	1
		1	1		
			2		
		1	2		1
			11		2
			2		1
			4		1
			2		1
		1	1		
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tongue oedema	9	43
Tongue paralysis		1
Tongue pruritus	3	14
Tongue ulceration		3
Tonic clonic movements		1
Tonic convulsion		1
Tonsillar hypertrophy	2	7
Tonsillitis		2
Toothache		2
Tooth infection		1
Torticollis	3	9
Toxic skin eruption		2
Tracheal pain		2
Tracheitis	1	4
Transaminases increased	1	2
Transient ischaemic attack	4	6
Tremor	30	150
Tricuspid valve incompetence		1
Trigeminal nerve disorder		7
Trigeminal neuralgia		8
Trigeminal palsy	1	1
Trigger finger		1
Trismus	2	2
Troponin I increased		1
Troponin increased	1	2
Troponin T increased		1
Type 1 diabetes mellitus		1
Type I hypersensitivity	5	13
Type IV hypersensitivity reaction		1
Umbilical haematoma		1
Underdose	2	10
Undersensing		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	5	19	4	24
					1
		2	8	1	6
			2		1
					1
					1
		2	7		
			2		
			2		
			1		
		3	9		
					2
			1		1
		1	3		1
				1	2
				4	6
2	4	21	91	9	59
					1
			3		4
			6		2
				1	1
			1		
		2	2		
					1
				1	2
					1
					1
				5	13
					1
					1
		2	10		
					1

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FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Unresponsive to stimuli		2
Upper airway obstruction	1	3
Upper limb fracture		1
Upper respiratory tract inflammation		2
Urinary incontinence	1	3
Urinary retention	1	4
Urinary tract infection	2	2
Urinary tract infection bacterial		1
Urine flow decreased		1
Urine odour abnormal		1
Urine output decreased		2
Urosepsis		1
Urticaria	49	345
Urticaria chronic		1
Urticaria papular		1
Urticaria physical		1
Urticaria thermal		1
Urticaria vesiculosa		1
Use of accessory respiratory muscles		7
Uterine leiomyoma	1	1
Uveitis		7
Vaccination complication	30	135
Vaccination error		1
Vaccination failure	73	130
Vaccination site bruising		4
Vaccination site cellulitis		1
Vaccination site discharge		1
Vaccination site discolouration		1
Vaccination site discomfort	4	5
Vaccination site eczema		1
Vaccination site erythema	48	173
Vaccination site extravasation		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
				1	3
					1
			1		1
			1	1	2
				1	4
				2	2
					1
			1		
			1		
					2
					1
1	1	40	248	9	97
			1		
			1		
			1		
			1		
					1
			2		5
				1	1
					7
	2	30	120		15
			1		
2	3		5	73	125
			3		1
					1
			1		
			1		
		4	5		
			1		
		41	130	7	43
			1		1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination site haematoma	5	15
Vaccination site hypersensitivity	1	2
Vaccination site hypoaesthesia		9
Vaccination site induration	10	25
Vaccination site infection	1	1
Vaccination site inflammation	4	13
Vaccination site irritation		1
Vaccination site ischaemia		1
Vaccination site joint erythema		3
Vaccination site joint movement impairment	1	8
Vaccination site joint pain	4	16
Vaccination site joint swelling	4	23
Vaccination site joint warmth		1
Vaccination site lymphadenopathy	2	23
Vaccination site mass	2	5
Vaccination site movement impairment	2	25
Vaccination site nerve damage	1	1
Vaccination site nodule		2
Vaccination site oedema	36	359
Vaccination site pain	577	2,828
Vaccination site pallor		1
Vaccination site paraesthesia	11	36
Vaccination site phlebitis		1
Vaccination site pruritus	19	68
Vaccination site rash	2	12
Vaccination site reaction	17	85
Vaccination site swelling	59	218
Vaccination site ulcer	1	1
Vaccination site urticaria	6	33
Vaccination site vesicles		4
Vaccination site warmth	4	32
Vaginal haemorrhage	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	15		
		1	1		1
			8		1
		10	22		3
		1	1		
		4	11		2
			1		
					1
			3		
		1	7		1
		4	16		
		4	23		
			1		
		2	18		5
		2	5		
		2	24		1
		1	1		
			2		
	1	35	341	1	18
	4	551	2608	26	220
			1		
		8	28	3	8
			1		
		14	53	5	15
		2	11		1
		17	77		8
	1	56	174	3	44
				1	1
		6	24		9
			3		1
		4	23		9
			2	2	3

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaginal infection		2
Varicella	1	1
Vascular calcification	1	1
Vascular purpura		2
Vascular rupture		1
Vascular skin disorder	1	1
Vasculitic rash		2
Vasculitis	5	13
Vasculitis necrotising		1
Vasoconstriction		8
Vasodilatation		2
Vasomotor rhinitis		1
Vena cava thrombosis	1	1
Venous arterialisation	1	1
Venous occlusion	1	1
Venous thrombosis	6	8
Venous thrombosis limb	2	2
Ventricular dysfunction	1	1
Ventricular extrasystoles	2	8
Ventricular f brillation		1
Vertigo	56	405
Vertigo positional		2
Vessel puncture site swelling		1
Vestibular neuronitis	1	3
Viral corneal ulcer		1
Viral infection	1	1
Virologic failure	1	1
Vision blurred	15	58
Visual acuity reduced	2	4
Visual field defect		3
Visual impairment	10	38
Vitamin D decreased	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		1	1		
		1	1		
			1		1
					1
				1	1
			1		1
		2	8	3	5
					1
			3		5
			1		1
			1		
				1	1
				1	1
		2	2	4	6
		1	1	1	1
				1	1
			4	2	4
					1
3	5	45	328	11	77
	1		1		1
			1		
			1	1	2
					1
				1	1
		1	1		
1	1	10	41	5	17
	1	1	2	1	2
			2		1
	2	6	22	4	16
		1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vitamin D deficiency		1				1		
Vitreoretinal traction syndrome	1	2					1	2
Vitreous detachment		3						3
Vitreous disorder		2				1		1
Vitreous floaters	1	3					1	3
Vitritis		1						1
Vocal cord dysfunction		1						1
Vocal cord paralysis		1						1
Vomiting	103	524	2	8	68	368	35	156
Vomiting projectile		3				1		2
Vulvovaginal burning sensation		1				1		
Vulvovaginal candidiasis	1	2			1	2		
Vulvovaginal pain		1				1		
Weight decreased		3				2		1
Wheezing	6	19			2	9	4	10
White blood cell count decreased	1	1			1	1		
White blood cell count increased		3				1		2
Withdrawal hypertension	1	1			1	1		
Wrong product administered	4	4			4	4		
Wrong technique in product usage process	1	2			1	2		
Xanthopsia		1						1
Xerophthalmia		2						2
Yellow skin		2				2		
	9,450	53,904	169	456	6987	42309	2463	11595

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	2	3			2	2		1
Abdominal distension	3	10			1	5	2	5
Abdominal pain	17	67			12	52	5	15
Abdominal pain upper	1	29	2	2	1	26		3
Abdominal tenderness	1	1			1	1		
Abnormal behaviour		1				1		
Abscess limb		1				1		
Accommodation disorder	1	2					1	2
Activated partial thromboplastin time shortened	1	1			1	1		
Acute abdomen		1						1
Acute coronary syndrome	3	5					3	5
Acute kidney injury	1	4					1	4
Acute motor axonal neuropathy		1						1
Acute myocardial infarction	5	9					5	9
Acute polyneuropathy		1						1
Acute pulmonary oedema		1						1
Acute respiratory distress syndrome		2						2
Acute respiratory failure	2	9					2	9
Administration site movement impairment		2				1		1
Administration site oedema		11				11		
Administration site pain	1	33			1	33		
Administration site reaction		2				2		
Administration site swelling		2				2		
Ageusia	6	12	1	1	3	8	3	4
Aggression			1	1				
Agitation	2	11				7	2	4
Akinesia		1						1
A bumin CSF increased	1	1					1	1
Allergic respiratory symptom		1						1
Allergy to vaccine	1	2				1	1	1
Allodynia		2				1		1
Alopecia	1	2					1	2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Alpha globulin increased		1
Alpha tumour necrosis factor increased		1
Altered pitch perception		1
Amaurosis fugax	1	2
Amnesia	2	4
Amylase increased		2
Anaemia	3	5
Anaesthesia		2
Anaesthesia oral		1
Anal incontinence		3
Anaphylactic reaction	1	12
Anaphylactic shock	1	3
Anaphylactoid reaction		2
Angina unstable	1	1
Angioedema	1	11
Angiopathy		1
Ankylosing spondylitis	1	1
Anosmia	4	8
Anterograde amnesia		1
Antibody test abnormal		1
Anuria		2
Anxiety	3	10
Anxiety disorder due to a general medical condition		1
Aortic dilatation		1
Aphasia	5	13
Aphonia	2	3
Aphthous ulcer		3
Apical granuloma	1	1
Apnoea		1
Application site oedema		1
Areflexia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
			1		
				1	2
		1	2	1	2
			1		1
		1	1	2	4
			2		
					1
			1		2
	2			1	12
				1	3
					2
				1	1
				1	11
					1
				1	1
1	1	2	4	2	4
					1
			1		
					2
		1	7	2	3
			1		
			1		
	1			5	13
		2	2		1
			3		
		1	1		
					1
			1		
				1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arrhythmia	1	13
Arterial occlusive disease	1	1
Arterial thrombosis	1	1
Arteriosclerosis	1	1
Arteriospasm coronary		1
Arthralgia	101	702
Arthritis	1	1
Arthritis reactive		
Arthropathy	1	1
Arthropod sting		1
Asphyxia	1	1
Aspiration	1	1
Asthenia	95	531
Asthenopia		3
Asthma		4
Asthmatic crisis		2
Asymptomatic COVID-19	8	18
Ataxia	1	2
Atrial fibrillation	4	16
Atrial flutter		2
Atrial tachycardia		2
Atrioventricular block		
Auditory disorder	1	3
Aura	1	1
Autoimmune disorder	1	1
Autoimmune thyroiditis		3
Axillary pain	10	36
Back injury	1	1
Back pain	9	47
Balance disorder	1	13
Band sensation		1
Barotrauma		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	13
				1	1
				1	1
				1	1
					1
	1	85	629	16	73
		1	1		
	1				
				1	1
			1		
				1	1
				1	1
3	7	74	449	21	82
			3		
			3		1
	1				2
		2	2	6	16
				1	2
				4	16
					2
			2		
1	1				
			2	1	1
		1	1		
				1	1
					3
	3	9	32	1	4
				1	1
	1	6	35	3	12
	1	1	9		4
			1		
			1		

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Basedow's disease	1	1
Basilar artery occlusion	1	1
Basophil percentage increased		1
Bell's palsy	8	15
Bladder obstruction		1
Blepharospasm		1
Blindness	1	2
Blindness unilateral	2	3
Blister	3	6
Blood alcohol increased	1	1
Blood bilirubin increased		1
Blood creatinine increased	1	1
Blood fibrinogen increased	1	2
Blood glucose increased	2	3
Blood pressure decreased	2	5
Blood pressure increased	12	33
Blood pressure systolic increased		3
Blood urea increased	1	1
Bloody discharge		1
Body temperature decreased		2
Body temperature increased		17
Bone marrow disorder	1	1
Bone pain	10	42
Bradycardia		7
Bradykinesia		2
Bradyphrenia		1
Brain compression		1
Brain neoplasm		1
Brain oedema		1
Brain stem haemorrhage		1
Breakthrough pain		1
Breast enlargement		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
			1		
				8	15
					1
			1		
				1	2
				2	3
		2	5	1	1
				1	1
					1
		1	1		
		1	2		
		1	2	1	1
		1	2	1	3
		4	17	8	16
			2		1
		1	1		
					1
			1		1
			14		3
				1	1
		7	35	3	7
2	3				7
1	1				2
1	1				1
					1
					1
					1
					1
			1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Breast pain	1	2
Breath sounds abnormal	1	1
Bronchitis	1	2
Bronchospasm		2
Bullous haemorrhagic dermatosis	1	1
Burning mouth syndrome		1
Burning sensation	2	7
Bursitis infective		1
Capillary fragility	1	1
Cardiac arrest	5	14
Cardiac disorder	1	3
Cardiac dysfunction	1	1
Cardiac failure	1	6
Cardiac failure congestive		2
Cardiac fibrillation		1
Cardiogenic shock		1
Cardiomyopathy	1	1
Cardiopulmonary failure	1	2
Cardio-respiratory arrest	2	8
Cardioversion	1	1
Carotid artery dissection		1
Carotid artery occlusion	1	1
Carotid artery stenosis	1	1
Carotid artery thrombosis	1	1
Catarrh		2
Central nervous system lesion	1	2
Cerebellar ataxia		1
Cerebellar haemorrhage	1	1
Cerebral artery occlusion	1	2
Cerebral haematoma		1
Cerebral haemorrhage	8	15
Cerebral infarction		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
				1	1
		1	1		1
			1		1
				1	1
			1		
		1	6	1	1
					1
				1	1
				5	14
				1	3
				1	1
1	1			1	6
					2
					1
					1
				1	1
				1	2
				2	8
		1	1		
					1
				1	1
				1	1
			1		1
		1	1		1
				1	1
				1	2
					1
				8	15
					1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebral ischaemia	3	7
Cerebral thrombosis		1
Cerebral venous sinus thrombosis		
Cerebral venous thrombosis	1	1
Cerebral ventricle collapse		1
Cerebrovascular accident	2	9
Cervicobrachial syndrome		3
Chest discomfort	4	18
Chest injury		
Chest pain	20	50
Chillblains	1	6
Chills	80	486
Choking		1
Choking sensation		1
Cholangitis		1
Chromaturia	1	2
Chronic obstructive pulmonary disease		1
Circulatory collapse	1	2
Circumstance or information capable of leading to medication error		1
Clonic convulsion	2	2
Clonus		1
Cluster headache		1
Cognitive disorder	1	1
Cold burn		1
Cold sweat	3	9
Colitis	1	1
Coma	2	3
Complicated appendicitis	1	1
Condition aggravated	1	8
Confusional state	4	33
Conjunctival haemorrhage	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	7
					1
1	1				
				1	1
					1
1	1			2	9
			2		1
		3	14	1	4
1	1				
1	1	7	23	13	27
			4	1	2
		69	428	11	58
					1
			1		
					1
		1	1		1
					1
				1	2
			1		
				2	2
					1
			1		
			1		
		1	1	2	8
		1	1		
				2	3
				1	1
1	1		1	1	7
1	3	3	17	1	16
	1			1	4

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Conjunctival hyperaemia		2
Conjunctival irritation		2
Conjunctivitis	4	5
Constipation	1	2
Contusion	1	2
Coordination abnormal	1	1
Coronary artery disease		1
Coronary artery stenosis		1
Cough	12	54
COVID-19	42	119
COVID-19 pneumonia	4	10
Cranial nerve disorder	1	2
Cranial nerve paralysis	3	3
Craniocerebral injury	1	1
C-reactive protein abnormal	1	2
C-reactive protein increased	1	7
Crying		1
Cyanosis	2	5
Cystitis	1	2
Dactylitis		1
Deafness		1
Deafness neurosensory	3	3
Death	3	10
Decreased appetite	8	29
Deep vein thrombosis	13	22
Defect conduction intraventricular		1
Dehydration	2	4
Delusion	1	1
Dental dysaesthesia	1	1
Depressed level of consciousness	4	16
Depression		1
Dermatitis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
			2		
		2	2	2	3
				1	2
		1	2		
	1			1	1
					1
					1
		6	30	6	24
5	6	8	19	34	100
	1			4	10
				1	2
				3	3
				1	1
		1	2		
			2	1	5
1	1				1
		1	1	1	4
		1	2		
					1
					1
		1	1	2	2
				3	10
		6	20	2	9
	1			13	22
					1
				2	4
				1	1
				1	1
				4	16
			1		
				1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dermatitis acneiform	2	2
Dermatitis allergic	1	6
Dermatitis atopic		1
Dermatitis bullous	1	2
Dermatitis exfoliative		1
Dermatitis herpetiformis		3
Dermatitis psoriasiform		1
Diabetes mellitus	1	1
Diaphragmalgia		1
Diarrhoea	30	160
Diarrhoea haemorrhagic		1
Diplegia		2
Diplopia	5	15
Discomfort	3	8
Discouragement	1	1
Disease progression	2	2
Disease recurrence	3	8
Disorientation	2	9
Disturbance in attention	1	4
Dizziness	20	93
Dizziness postural	1	1
Drug abuse		1
Drug hypersensitivity		2
Drug ineffective	13	56
Dry eye		1
Dry mouth	2	15
Dry skin		2
Dry throat		2
Dysaesthesia	2	8
Dysarthria	7	12
Dyschezia		1
Dysentery	2	28

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2		
		1	3		3
			1		
				1	2
					1
			1		2
			1		
				1	1
			1		
2	2	22	130	8	30
					1
					2
		1	8	4	7
		2	5	1	3
		1	1		
				2	2
		1	1	2	7
1	1		2	2	7
		1	4		
	1	10	67	10	26
				1	1
					1
					2
1	1	1	1	12	55
			1		
		1	11	1	4
			1		1
			1		1
		1	6	1	2
	1	1	1	6	11
					1
1	2			2	28

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysgeusia	2	28
Dyskinesia	1	2
Dyspepsia	1	5
Dysphagia	9	20
Dysphonia		6
Dyspnoea	33	115
Dyspnoea at rest	1	1
Dyspnoea exertional	1	3
Dyspraxia	1	1
Dysstasia	3	4
Dysuria	1	5
Ear discomfort		4
Ear disorder		2
Ear infection		1
Ear pain		5
Ear pruritus		1
Ecchymosis	2	5
Eczema	2	3
Eczema asteatotic	1	1
Eczema eyelids	1	1
Eczema nummular		1
Electrocardiogram change	1	1
Electrocardiogram repolarisation abnormality		1
Electrocardiogram T wave inversion		
Electrolyte imbalance		1
Embolic stroke		1
Embolism	2	4
Emotional disorder	1	1
Emotional distress	1	1
Emphysema		1
Encephalitis	2	3
Encephalopathy		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	1	22	1	6
		1	1		1
		1	3		2
1	1	3	6	6	14
			2		4
3	5	9	38	24	77
				1	1
			1	1	2
				1	1
1	1	1	1	2	3
				1	5
			3		1
			1		1
			1		
			3		2
			1		
				2	5
		1	2	1	1
		1	1		
		1	1		
			1		
				1	1
					1
	1				
					1
					1
				2	4
		1	1		
		1	1		
					1
				2	3
					1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Endothelial dysfunction	1	1
Enterocolitis		1
Enthesopathy	1	2
Epicondylitis		2
Epididymitis	1	1
Epilepsy	4	11
Epistaxis	5	8
Erectile dysfunction	1	4
Erysipelas		1
Erythema	14	73
Erythema multiforme		1
Escherichia sepsis	1	1
Essential hypertension		
Exophthalmos	2	2
Exposure via breast milk		4
Extrasystoles		9
Extremity contracture		1
Eye allergy		1
Eye discharge	1	1
Eye disorder		2
Eye haemorrhage	1	2
Eye irritation	2	12
Eyelid bleeding	1	1
Eyelid function disorder	1	1
Eyelid oedema		2
Eyelid pain		1
Eyelid ptosis	3	4
Eyelid retraction		1
Eyelids pruritus		1
Eye movement disorder	1	1
Eye pain	4	10
Eye pruritus	3	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
				1	2
			2		
				1	1
1	1			4	11
		3	5	2	3
				1	4
1	1				1
1	2	9	51	5	22
					1
				1	1
1	1				
				2	2
			1		3
			6		3
			1		
			1		
		1	1		
			1		1
				1	2
		2	11		1
				1	1
		1	1		
			1		1
					1
		1	2	2	2
					1
			1		
				1	1
		3	8	1	2
		1	2	2	3

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Eye swelling	1	4
Face oedema	1	6
Facial asymmetry	2	2
Facial discomfort		2
Facial paralysis	9	29
Facial paresis	5	15
Fall	8	14
Fatigue	81	561
Fear-related avoidance of activities	1	1
Febrile convulsion		2
Feeding disorder		1
Feeling abnormal		3
Feeling cold	6	46
Feeling drunk		1
Feeling hot	7	42
Feeling jittery		1
Feeling of body temperature change		4
Femur fracture	1	1
Fibrin D dimer increased	3	10
Flank pain		2
Flatulence		2
Fluid retention		2
Flushing	4	19
Foaming at mouth	1	1
Frequent bowel movements		1
Full blood count abnormal	1	1
Furuncle		1
Gait disturbance	5	20
Gait inability		2
Gastric dilatation		1
Gastritis	2	2
Gastroenteritis		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4		
1	1		2	1	4
				2	2
			2		
	1			9	29
			2	5	13
2	2	2	2	6	12
	1	68	513	13	48
		1	1		
					2
					1
			1		2
		4	42	2	4
			1		
		6	35	1	7
					1
			3		1
				1	1
		2	6	1	4
			2		
			2		
					2
1	1	3	15	1	4
				1	1
			1		
		1	1		
			1		
1	1	3	10	2	10
					2
			1		
		1	1	1	1
			3		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastrointestinal disorder	3	11
Gastrointestinal motility disorder		1
Gastrointestinal pain	2	4
Gaze palsy	1	2
Generalised tonic-clonic seizure	1	2
General physical health deterioration	2	4
Genital herpes zoster		1
Genital rash	1	1
Gingival bleeding	2	4
Gingival oedema		2
Gingival swelling		1
Gingivitis		1
Glossitis		1
Goitre	1	1
Gravitational oedema	1	1
Groin pain	3	4
Guillain-Barre syndrome	2	4
Haematemesis	1	1
Haematochezia	1	1
Haematoma	2	5
Haematospermia	1	1
Haematuria	1	4
Haemoglobin decreased		2
Haemorrhagic diathesis	2	2
Haemorrhagic infarction		1
Haemorrhagic stroke	2	3
Hallucination	3	6
Hand dermatitis	1	2
Headache	208	1,107
Head discomfort	1	5
Head injury		1
Heart rate decreased	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	10		1
					1
		2	4		
				1	2
				1	2
			1	2	3
					1
		1	1		
				2	4
			1		1
					1
			1		
			1		
		1	1		
		1	1		
		1	2	2	2
				2	4
				1	1
				1	1
			1	2	4
				1	1
			1	1	3
			1		1
				2	2
					1
				2	3
2	2			3	6
		1	2		
1	5	186	996	22	111
		1	5		
					1
			1	1	2

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Heart rate increased	4	9
Heat stroke		1
Hemianopia	1	1
Hemianopia homonymous	1	1
Hemidysaesthesia	1	1
Hemiparaesthesia		2
Hemiparesis	5	14
Hemiplegia	3	8
Hepatic enzyme increased		
Hepatic pain		1
Hepatitis acute	1	1
Herpes ophthalmic		1
Herpes simplex		2
Herpes virus infection	2	6
Herpes zoster	18	37
Herpes zoster infection neurological	1	2
Herpes zoster oticus		1
HIV infection		1
Hot flush	3	20
Hydrocephalus		1
Hyperacusis		3
Hyperaemia		3
Hyperaesthesia		1
Hypercapnia	1	2
Hypercholesterolaemia		1
Hypercreatininaemia		1
Hyperglycaemia	2	4
Hyperhidrosis	10	86
Hyperpyrexia	5	50
Hyperreflexia		1
Hypersensitivity	3	14
Hypersensitivity vasculitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	7	1	2
			1		
				1	1
				1	1
				1	1
					2
				5	14
				3	8
	1				
			1		
				1	1
					1
			2		
		1	2	1	4
	1	15	21	3	16
				1	2
					1
					1
		3	17		3
					1
			2		1
			1		2
					1
				1	2
					1
					1
			1	2	3
		6	60	4	26
1	3			5	50
					1
	1	2	6	1	8
					1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypertension	8	40
Hypertensive crisis	7	31
Hypertensive heart disease		1
Hyperthermia	2	8
Hyperthyroidism	1	2
Hypertonia		1
Hypertrophic cardiomyopathy		1
Hyperventilation		3
Hypoacusis	2	6
Hypoaesthesia	5	42
Hypoaesthesia oral	3	8
Hypoglossal nerve disorder		1
Hypoglycaemia		2
Hypokinesia	1	3
Hyponatraemia		
Hypoperfusion	1	1
Hypopituitarism	1	1
Hyposmia		3
Hypotension	9	41
Hypotensive crisis	1	3
Hypothermia		2
Hypotonia		1
Hypoxia	4	5
Illrd nerve paralysis	1	2
Illness	3	5
Immobilisation prolonged	1	1
Immune-mediated adverse reaction	1	1
Immune thrombocytopenia	1	2
Immunodeficiency common variable	1	1
Impaired quality of life	2	4
Inappropriate affect		1
Inappropriate schedule of product administration	3	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	17	6	23
	2			7	31
					1
		2	6		2
				1	2
			1		
					1
			1		2
				2	6
		3	30	2	12
		2	5	1	3
					1
			1		1
			1	1	2
1	1				
		1	1		
		1	1		
			2		1
1	2	2	15	7	26
				1	3
					2
			1		
				4	5
				1	2
		2	3	1	2
				1	1
				1	1
	1			1	2
				1	1
		1	2	1	2
			1		
		3	7		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Incontinence		1
Incorrect route of product administration	2	8
Increased upper airway secretion		1
Induration	1	1
Infarction		1
Infection		1
Inflammation	1	5
Inflammatory bowel disease	1	1
Influenza	8	18
Influenza like illness	8	41
Infusion site joint swelling		1
Infusion site pain		2
Initial insomnia		4
Injected limb mobility decreased	1	2
Injection site discomfort	1	1
Injection site erythema		26
Injection site hyperaesthesia		1
Injection site induration		4
Injection site infection	1	3
Injection site inflammation		1
Injection site joint pain		1
Injection site muscle weakness		1
Injection site oedema		75
Injection site pain	11	474
Injection site paraesthesia		2
Injection site pruritus		2
Injection site reaction		5
Injection site swelling		12
Injection site urticaria		3
Injection site warmth		2
Injury		1
Insomnia	12	66

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		2	8		
					1
		1	1		
					1
					1
		1	2		3
				1	1
		8	18		
		7	36	1	5
			1		
			2		
			4		
	1		1	1	1
		1	1		
			26		
			1		
			4		
		1	3		
			1		
			1		
			1		
			75		
		10	473	1	1
			2		
			2		
			5		
			12		
			3		
			2		
			1		
		6	56	6	10

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Intentional product use issue	1	1
Intermittent claudication	1	1
International normalised ratio increased	2	5
Interstitial lung disease	2	6
Intervertebral discitis		1
Intestinal ischaemia	2	6
Intestinal obstruction		1
Intracardiac thrombus	1	1
Intraventricular haemorrhage		2
Irritability		1
Ischaemia	3	4
Ischaemic stroke	5	12
Jaundice	1	3
Jaundice cholestatic		1
Joint lock		1
Joint range of motion decreased		3
Joint swelling	1	4
Labyrinthitis		2
Lacrimation increased	3	7
Lagophthalmos		1
Laryngeal obstruction		1
Laryngeal oedema	1	11
Laryngeal pain	1	1
Laryngospasm	1	3
Left ventricular dysfunction		1
Left ventricular failure		1
Lens disorder	1	1
Lethargy	1	1
Leukaemia		1
Leukocytosis	1	1
Leukopenia		1
Ligament sprain	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				1	1
			1	2	4
				2	6
					1
				2	6
					1
				1	1
					2
			1		
				3	4
				5	12
				1	3
					1
			1		
			1		2
		1	2		2
			2		
		1	5	2	2
					1
					1
				1	11
		1	1		
		1	2		1
			1		
					1
		1	1		
		1	1		
					1
				1	1
					1
				1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Limb discomfort	1	15
Limb injury	1	1
Lipase increased		2
Lip dry		1
Lip oedema		12
Lipoma	1	1
Lip pruritus		3
Lip swelling		4
Listeriosis		1
Livedo reticularis		1
Localised oedema	3	9
Local reaction		2
Loss of consciousness	14	41
Loss of libido		1
Loss of personal independence in daily activities		1
Lung cancer metastatic	1	1
Lung disorder		1
Lung neoplasm malignant		1
Lung opacity	1	1
Lymphadenitis	3	10
Lymphadenopathy	37	292
Lymphadenopathy mediastinal	1	1
Lymphangitis		2
Lymph node abscess		1
Lymph node pain	3	23
Lymph node palpable		1
Lymphocyte count decreased		1
Lymphocyte count increased	1	1
Lymphocytosis	1	1
Lymphoedema		2
Lymphopenia		2
Macroglossia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	13		2
				1	1
			1		1
			1		
			10		2
		1	1		
			3		
			4		
					1
	1		1		
	1	2	7	1	2
			2		
				14	41
			1		
					1
				1	1
					1
				1	1
		3	8		2
	3	34	258	3	34
				1	1
					2
					1
		3	19		4
			1		
			1		
		1	1		
		1	1		
			2		
					2
1	1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Macular rupture		1
Malaise	49	364
Mastication disorder		2
Mean cell volume increased		1
Mechanical urticaria	1	2
Memory impairment		1
Meningeal disorder		1
Mesenteric vein thrombosis	1	1
Metabolic acidosis		1
Metamorphopsia		1
Micturition urgency	1	1
Middle insomnia	1	6
Migraine	5	38
Migraine with aura		1
Miller Fisher syndrome	1	1
Mitral valve incompetence		2
Mobility decreased		2
Monocyte count increased		1
Monoparesis	1	1
Monoplegia	1	2
Mood altered	2	2
Motion sickness		1
Motor dysfunction	2	9
Mouth haemorrhage		2
Mouth swelling		1
Mouth ulceration		1
Movement disorder	2	4
Mucosal dryness		1
Mucosal ulceration		1
Multiple organ dysfunction syndrome		
Muscle contractions involuntary		2
Muscle contracture		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
	1	40	324	9	40
			1		1
			1		
			1	1	1
					1
			1		
				1	1
					1
					1
		1	1		
			5	1	1
1	1	4	32	1	6
			1		
				1	1
					2
			1		1
			1		
		1	1		
				1	2
		2	2		
			1		
1	1		4	2	5
			1		1
			1		
			1		
			2	2	2
			1		
					1
	1				
			1		1
			2		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle discomfort		1
Muscle fatigue		3
Muscle rigidity	1	4
Muscle spasms	3	16
Muscle swelling		2
Muscle tightness		2
Muscle twitching	1	4
Muscular weakness	4	15
Musculoskeletal chest pain	2	12
Musculoskeletal discomfort		1
Musculoskeletal pain	10	123
Musculoskeletal stiffness		4
Myalgia	126	868
Myasthenia gravis crisis		1
Mydriasis	1	1
Myeloid leukaemia	1	1
Myocardial infarction	2	4
Myocardial ischaemia	1	2
Myocardial necrosis marker increased		1
Myocarditis	2	7
Myoclonus		1
Myositis	2	2
Nasal congestion	4	8
Nasal discomfort		1
Nasal obstruction	1	1
Nasal oedema		1
Nasopharyngitis	4	14
Nausea	56	306
Neck pain	5	26
Necrotising fasciitis	1	2
Nervousness		1
Nervous system disorder	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2		1
			2	1	2
		3	15		1
					2
			1		1
		1	4		
		1	11	3	4
		1	9	1	3
			1		
		8	107	2	16
			2		2
	5	111	797	15	71
					1
		1	1		
				1	1
				2	4
				1	2
					1
				2	7
			1		
	1	1	1	1	1
		3	6	1	2
			1		
		1	1		
					1
		2	10	2	4
2	2	47	262	9	44
		3	20	2	6
				1	2
					1
				2	2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neuralgia	3	8
Neuralgic amyotrophy		1
Neuritis		3
Neurogenic bladder		1
Neuropathy peripheral		2
Neutropenia	1	1
Nightmare	1	1
Night sweats		5
Nipple disorder	1	1
Nipple pain		1
No adverse event		1
Nocturia		1
Nocturnal dyspnoea	1	1
Non-cardiac chest pain		1
Non-pitting oedema		1
Nuchal rigidity		2
Nystagmus	1	2
Obstructive airways disorder	1	3
Occult blood positive	1	1
Occupational exposure to product	1	1
Ocular discomfort	1	3
Ocular hyperaemia	1	3
Oculogyric crisis	1	1
Odynophagia		3
Oedema	2	8
Oedema mouth		3
Oedema mucosal		1
Oedema peripheral	5	13
Oesophageal oedema		1
Off label use	7	14
Oliguria		1
Oncologic complication	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3	1	5
	1		1		
			1		2
					1
					2
				1	1
		1	1		
			5		
		1	1		
			1		
			1		
			1		
		1	1		
			1		
					1
			1		
			2		
				1	2
				1	3
				1	1
		1	1		
			2	1	1
			1	1	2
				1	1
			2		1
		1	6	1	2
			2		1
					1
3	4	1	7	4	6
					1
		7	14		
					1
		1	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ophthalmic herpes simplex		1
Ophthalmic herpes zoster	2	4
Optic disc haemorrhage	1	1
Optic ischaemic neuropathy		1
Optic neuritis		1
Oral discomfort	1	2
Oral dysaesthesia	1	1
Oral herpes	2	9
Oral pruritus		3
Orbital haematoma		1
Orchitis		1
Organic brain syndrome		1
Oropharyngeal discomfort	1	2
Oropharyngeal pain	4	28
Orthostatic hypotension		1
Osteoarthritis	1	1
Otitis media		1
Otolithiasis	1	1
Overdose	8	18
Oxygen saturation abnormal		
Oxygen saturation decreased	8	25
Pain	29	137
Pain in extremity	48	282
Pain of skin		1
Palatal disorder		1
Palatal oedema		8
Pallor	4	11
Palpitations	6	13
Pancreatitis		4
Panic attack		1
Papule		3
Paraesthesia	29	154

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				2	4
				1	1
					1
				1	2
		1	1		
		1	5	1	4
			3		
					1
					1
					1
		1	2		
		3	24	1	4
			1		
		1	1		
					1
				1	1
		8	17		1
	1				
		1	3	7	22
		27	124	2	13
1	1	37	249	11	33
			1		
			1		
			5		3
		3	7	1	4
		3	7	3	6
					4
					1
			2		1
3	4	20	110	9	44

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Paraesthesia mucosal	1	1
Paraesthesia oral	6	37
Paralysis		2
Paraparesis	1	4
Paresis		2
Paresis cranial nerve		2
Parosmia		4
Parotid gland enlargement		2
Paroxysmal arrhythmia		1
Partial seizures		1
Penile erythema		1
Penile ulceration		1
Pericardial effusion	2	4
Pericarditis	2	8
Periorbital discomfort		1
Periorbital oedema		1
Periorbital swelling		2
Peripheral artery thrombosis		1
Peripheral coldness		5
Peripheral embolism		1
Peripheral ischaemia		2
Peripheral nerve palsy	1	1
Peripheral paralysis	1	1
Peripheral swelling	7	24
Peritonsillar abscess		1
Persecutory delusion	1	1
Petechiae	5	7
Petit mal epilepsy		1
Pharyngeal erythema	1	3
Pharyngeal hypoaesthesia		1
Pharyngeal mass	1	2
Pharyngeal oedema		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		2	26	4	11
					2
				1	4
			1		1
			1		1
			2		2
			1		1
					1
			1		
			1		
				2	4
				2	8
					1
					1
			1		1
			5		
					1
					2
		1	1		
				1	1
		5	16	2	8
					1
				1	1
			1	5	6
					1
		1	2		1
			1		
				1	2
					2

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pharyngeal paraesthesia	1	2
Pharyngeal swelling		1
Pharyngitis	1	8
Pharyngotonsillitis	1	1
Phlebitis superficial	1	1
Photophobia		6
Photopsia	1	2
Pityriasis rosea		3
Plantar fasciitis		1
Platelet count decreased		1
Platelet count increased	1	2
Pleural effusion		3
Pleurisy		1
Pleuropericarditis		1
Pneumatoxis		1
Pneumonia	3	12
Pneumonia bacterial	1	2
Pneumonia legionella		1
Pneumonitis	1	4
Pneumothorax		1
Pollakiuria		1
Polyarthrits		2
Polydipsia	1	1
Polyneuropathy	1	1
Polyneuropathy in malignant disease	1	1
Polyuria	3	5
Portal hypertension	1	1
Portal vein thrombosis	2	2
Post herpetic neuralgia		1
Posture abnormal	1	1
Presyncope	11	64
Procalcitonin increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		1
			1		
		1	6		2
				1	1
				1	1
			5		1
				1	2
			2		1
			1		
			1		
		1	1		1
					3
					1
					1
					1
				3	12
				1	2
					1
				1	4
					1
					1
					2
		1	1		
				1	1
				1	1
		3	4		1
				1	1
				2	2
					1
				1	1
		5	35	6	29
			1		

* I=Interval, C=Cumulative
* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Product administered at inappropriate site		2
Product dose omission issue		1
Product label confusion		1
Product leakage	1	1
Product preparation error	2	2
Product preparation issue	1	3
Product use issue	2	6
Proteinuria	1	1
Pruritus	12	73
Pseudomembranous colitis	1	1
Psoriasis	1	2
Psoriatic arthropathy		2
Psychogenic pseudosyncope	1	1
Psychomotor hyperactivity	1	1
Psychomotor skills impaired		1
Psychotic disorder		1
Pulmonary congestion		1
Pulmonary embolism	20	25
Pulmonary infarction		1
Pulmonary microemboli		1
Pulmonary oedema		3
Pulmonary thrombosis	1	1
Pulse volume decreased		1
Puncture site pain		1
Purpura		1
Pyrexia	243	1,334
Q fever		1
Quadripareisis	2	3
Quality of life decreased	5	5
Radial nerve palsy	1	1
Rales		2
Rash	10	63

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
			1		
			1		
		1	1		
		2	2		
		1	3		
		2	6		
		1	1		
		9	56	3	17
				1	1
			1	1	1
					2
		1	1		
				1	1
					1
					1
1	3			20	25
					1
					1
					3
				1	1
			1		
			1		
1	1				1
6	15	195	1088	48	246
					1
				2	3
		1	1	4	4
				1	1
					2
		8	45	2	18

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Rash erythematous	2	8
Rash macular	2	5
Rash maculo-papular		2
Rash morbilliform	1	1
Rash papular	1	2
Rash papulosquamous		1
Rash pruritic	4	8
Rash vesicular	1	2
Raynaud's phenomenon	1	2
Red blood cell count decreased		1
Red blood cell sedimentation rate increased		2
Red cell distribution width increased		1
Renal colic	1	1
Renal failure	2	2
Renal impairment	2	3
Renal pain	2	7
Respiratory acidosis	1	1
Respiratory alkalosis	1	1
Respiratory disorder	1	4
Respiratory distress	1	6
Respiratory failure	6	16
Respiratory fatigue	1	4
Respiratory tract infection		1
Restlessness		4
Retching	2	7
Retinal artery embolism	1	1
Retinal artery occlusion	1	1
Retinal detachment		1
Retinal ischaemia	1	1
Retinal vein occlusion	1	1
Retinal vein thrombosis	1	3
Retrograde amnesia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	6		2
		1	3	1	2
			1		1
				1	1
		1	1		1
			1		
		4	6		2
		1	2		
			1	1	1
					1
			1		1
			1		
				1	1
				2	2
				2	3
			4	2	3
				1	1
				1	1
		1	1		3
				1	6
				6	16
				1	4
					1
			2		2
		1	5	1	2
				1	1
				1	1
					1
				1	1
				1	1
				1	3
					1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rhabdomyolysis	1	1
Rheumatic disorder		1
Rhinalgia	1	1
Rhinitis	1	6
Rhinitis allergic		1
Rhinorrhoea	4	9
Rhonchi		1
Rib fracture	1	1
Right ventricular dilatation		1
Right ventricular dysfunction	1	1
Rosai-Dorfman syndrome	1	1
Sacroiliitis		1
Sarcoidosis		1
SARS-CoV-2 ant body test		1
SARS-CoV-2 ant body test negative		3
SARS-CoV-2 test false positive		1
SARS-CoV-2 test negative	1	2
SARS-CoV-2 test positive	4	16
Scab		1
Sciatica	2	4
Sciatic nerve neuropathy	1	1
Scratch	1	1
Scrotal erythema		1
Secretion discharge		1
Sedation		4
Seizure	3	5
Seizure like phenomena		1
Senile dementia	1	1
Sensation of foreign body	1	6
Sense of oppression		1
Sensitisation		1
Sensitive skin	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
		1	1		
		1	3		3
			1		
		3	7	1	2
			1		
				1	1
			1		
				1	1
			1		
					1
					1
			3		
			1		
			1	1	1
4	4	2	5	2	11
			1		
		1	2	1	2
		1	1		
		1	1		
					1
					1
			4		
				3	5
					1
				1	1
		1	3		3
			1		
			1		
				1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sensorimotor disorder		1
Sensory disturbance	4	6
Sensory loss	1	3
Sepsis	1	2
Septic shock	2	3
Seroconversion test negative		1
Serratia test positive		1
Severe acute respiratory syndrome		3
Shift to the left	1	1
Shock	1	1
Sinusitis	1	2
Sinus rhythm		1
Sinus tachycardia		5
Sitting disability		1
Skin burning sensation		2
Skin discolouration	2	3
Skin discomfort	1	1
Skin exfoliation		1
Skin irritation	2	3
Skin laceration		1
Skin lesion		1
Skin oedema		1
Skin reaction	4	8
Skin tightness		1
Sleep disorder		3
Slow speech		1
Sneezing	1	1
Somnolence	8	55
Sopor		4
Speech disorder	2	7
Spider vein		1
Spinal pain		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		3	3	1	3
			1	1	2
				1	2
				2	3
			1		
					1
					3
		1	1		
				1	1
		1	1		1
			1		
	1		4		1
			1		
			1		1
		1	1	1	2
		1	1		
			1		
		2	3		
					1
					1
			1		
		3	7	1	1
			1		
			3		
					1
		1	1		
	1	6	46	2	9
	1		2		2
				2	7
			1		
			4		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Squamous cell carcinoma	1	1
Status epilepticus		1
Stenotrophomonas test positive		1
Stomatitis		1
Strabismus	1	1
Strangury		
Stress	1	1
Stridor		1
Stupor		3
Subarachnoid haemorrhage		3
Subclavian vein thrombosis	1	1
Subcutaneous abscess		1
Subdural haematoma		1
Sudden death	6	16
Sudden hearing loss	1	2
Suffocation feeling	1	1
Superinfection bacterial		1
Supraventricular extrasystoles		1
Supraventricular tachycardia		1
Suspected COVID-19	1	2
Swelling	6	23
Swelling face	2	10
Swelling of eyelid		1
Swollen tongue	2	7
Syncope	15	44
Systemic lupus erythematosus		1
Tachyarrhythmia	2	2
Tachycardia	17	79
Tachycardia paroxysmal		2
Tachypnoea		5
Taste disorder	3	5
Telangiectasia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
					1
					1
				1	1
1	1				
				1	1
					1
			1		2
					3
				1	1
					1
					1
				6	16
				1	2
		1	1		
					1
			1		
			1		
				1	2
		3	18	3	5
		1	7	1	3
			1		
			2	2	5
3	3			15	44
					1
		1	1	1	1
	1	8	50	9	29
			2		
			4		1
		1	1	2	4
		1	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Temporomand bular joint syndrome	1	2
Tenderness		2
Tendonitis		1
Tendon pain		1
Tenosynovitis		1
Tension headache	1	1
Terminal insomnia		2
Testicular neoplasm		1
Testicular pain	2	2
Thalamus haemorrhage	1	1
Therapeutic response unexpected		1
Thermal burns of eye		1
Throat irritation	1	6
Throat tightness	4	17
Thrombocytopenia	14	24
Thrombophlebitis	6	9
Thrombophlebitis superficial	4	6
Thrombosis	5	6
Thrombotic thrombocytopenic purpura	1	1
Thyroid hormones increased		1
Tinnitus	5	17
Tongue biting	2	2
Tongue discolouration		1
Tongue dry		2
Tongue eruption		1
Tongue oedema		4
Tongue pruritus		2
Tonic clonic movements		1
Tonsillar erythema		1
Tonsillar hypertrophy		1
Tonsillar inflammation	1	1
Tonsillitis		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
			2		
			1		
					1
					1
		1	1		
			2		
					1
				2	2
				1	1
			1		
					1
		1	3		3
		2	8	2	9
				14	24
		4	6	2	3
		1	1	3	5
				5	6
				1	1
					1
1	1	2	7	3	10
				2	2
			1		
			1		1
			1		
			1		3
			2		
					1
			1		
			1		
		1	1		
			1		1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Toothache	1	3
Torticollis		2
Transaminases increased		1
Transient ischaemic attack	3	6
Traumatic fracture		1
Tremor	7	42
Tricuspid valve incompetence		1
Trigeminal nerve disorder		1
Trigeminal neuralgia	1	1
Trigeminal neuritis		1
Troponin		1
Troponin increased	1	1
Troponin T increased		2
Underdose	1	4
Unresponsive to stimuli		1
Upper respiratory tract infection		1
Urinary incontinence	1	4
Urinary retention	1	2
Urinary tract infection	1	3
Urine output decreased	1	1
Urticaria	7	54
Urticaria papular	1	1
Vaccination complication	9	24
Vaccination failure	25	56
Vaccination site anaesthesia		1
Vaccination site bruising	1	1
Vaccination site dermatitis		1
Vaccination site discomfort	1	4
Vaccination site erythema	4	17
Vaccination site haematoma		3
Vaccination site hypoaesthesia		5
Vaccination site induration	5	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	1	1
			2		
			1		
				3	6
					1
		2	22	5	20
					1
			1		
				1	1
					1
					1
				1	1
					2
		1	4		
					1
					1
		1	1		3
				1	2
			2	1	1
				1	1
		5	39	2	15
				1	1
		9	24		
3	4		1	25	55
					1
				1	1
					1
		1	4		
		4	15		2
			3		
			4		1
		4	6	1	2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site inflammation	1	4
Vaccination site joint inflammation		1
Vaccination site joint movement impairment		1
Vaccination site joint swelling		3
Vaccination site lymphadenopathy		3
Vaccination site movement impairment		6
Vaccination site oedema	9	79
Vaccination site pain	192	880
Vaccination site paraesthesia		7
Vaccination site pruritus	1	9
Vaccination site rash	2	5
Vaccination site reaction	3	19
Vaccination site swelling	16	43
Vaccination site urticaria		2
Vaccination site vesicles		1
Vaccination site warmth	1	6
Vascular device infection	1	1
Vasculitis		2
Vasculitis necrotising	1	2
Vasodilatation		1
Venous thrombosis	2	4
Venous thrombosis limb	4	6
Ventricular arrhythmia	1	3
Ventricular extrasystoles		4
Ventricular fibrillation	1	2
Ventricular tachycardia		2
Vertebral artery occlusion	1	1
Vertebrobasilar insufficiency	1	1
Vertigo	8	81
Vertigo CNS origin	1	1
Vertigo positional		1
Vestibular disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		1
			1		
			1		
			3		
			3		
			6		
		9	77		2
	3	181	842	11	38
			5		2
			7	1	2
		2	3		2
		3	19		
	1	13	34	3	9
			2		
			1		
	1	1	5		1
				1	1
			1		1
		1	1		1
					1
				2	4
	2		1	4	5
				1	3
			3		1
				1	2
					2
				1	1
				1	1
1	2	5	62	3	19
				1	1
			1		
					1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vestibular neuritis	1	4				1	1	3
Vision blurred	6	25			3	15	3	10
Visual field defect	1	3				2	1	1
Visual impairment	3	8			2	4	1	4
Vitamin B12 deficiency	1	1			1	1		
Vlth nerve paralysis		2						2
Vlth nerve paresis		1				1		
Vitreous detachment	1	2		1			1	2
Vitreous disorder		1						1
Vitreous floaters		1						1
Vitreous haemorrhage		1						1
Vocal cord paralysis		1						1
Volvulus		1						1
Vomiting	22	95	1	2	11	65	11	30
Wandering pacemaker		1						1
Weight decreased	1	3					1	3
Wheezing	1	3				2	1	1
White blood cell count decreased		1				1		
White blood cell count increased	1	1					1	1
Wound	1	2	1	1			1	2
Wrong product administered	1	1			1	1		
Wrong technique in product usage process	1	1			1	1		
Xerosis		1						1
Yolk sac tumour site unspecified	1	1					1	1
	2,892	14,344	86	176	1789	10658	1103	3686

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1	1	1		
Abdominal pain	1	2	1	2		
Abdominal pain lower	1	1	1	1		
Abscess	1	1	1	1		
Anaphylactic reaction		3				3
Anaphylactic shock		1				1
Aphasia	1	1			1	1
Arthralgia	8	24	8	21		3
Asthenia	7	24	6	20	1	4
Asthenopia		1		1		
Axillary pain	1	2	1	2		
Back pain		4		4		
Bell's palsy		1				1
Bladder spasm	1	1			1	1
Blood pressure increased	3	3	1	1	2	2
Bone pain		3		3		
Bradycardia		1				1
Breakthrough pain		1		1		
Carotid artery dissection		1				1
Catarrh		1				1
Chest discomfort		1				1
Chills	2	21	2	19		2
Clonic convulsion	1	1			1	1
Confusional state	1	4		3	1	1
Constipation	1	1	1	1		
Cough	1	2		1	1	1
COVID-19	23	31		1	23	30
COVID-19 pneumonia	2	2			2	2
Cranial nerve disorder		1		1		
Deafness bilateral		1				1
Decreased appetite		2		2		
Deep vein thrombosis	1	1			1	1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Depressed level of consciousness		1
Dermatitis bullous		1
Diarrhoea	1	3
Diplegia		1
Diplopia		1
Disease recurrence	1	2
Dizziness	3	4
Drug ineffective	23	29
Dry mouth		1
Dry throat	1	1
Dysphagia		2
Dyspnoea	3	7
Ear pain		1
Ear pruritus		1
Epiglottic oedema		1
Epilepsy	1	1
Erectile dysfunction	1	1
Erythema	2	9
Exposure via breast milk	4	4
Eyelid oedema	1	1
Eyelid ptosis		1
Eye pain	1	3
Eye paraesthesia		1
Facial paralysis		1
Fall	1	1
Fatigue	3	16
Febrile convulsion		1
Feeling cold		2
Feeling hot	2	3
Flushing		1
Gait inability		2
Gastrointestinal disorder		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
			1
1	3		
			1
	1		
1	1		1
3	4		
		23	29
	1		
1	1		
	1		1
	1	3	6
	1		
	1		
			1
		1	1
		1	1
2	6		3
4	4		
1	1		
	1		
1	3		
	1		
			1
		1	1
3	14		2
	1		
	2		
2	3		
	1		
	2		
	1		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Glossitis		1		1		
Groin pain		1		1		
Hallucination		1				1
Headache	11	39	11	34		5
Head discomfort		1		1		
Hemiparaesthesia		1				1
Hemiparesis		2				2
Hemiplegia		1				1
Herpes zoster		1				1
Hyperhidrosis	1	2	1	2		
Hyperpyrexia	1	6			1	6
Hypersensitivity		1				1
Hypertensive crisis		1				1
Hyperthermia		1		1		
Hypoacusis		1				1
Hypoaesthesia oral		1		1		
Hypotension		2		1		1
Illrd nerve paralysis		1				1
Inappropriate schedule of product administration	1	2	1	2		
Incorrect dose administered	1	2	1	2		
Influenza	1	1	1	1		
Influenza like illness		1		1		
Injection site infection		1		1		
Injection site joint pain		1		1		
Injection site oedema		2		2		
Injection site pain		18		18		
Insomnia		3		3		
Ischaemia		2				2
Lacrimation increased	1	1	1	1		
Laryngeal oedema		3				3
Lip oedema		3		3		
Lip swelling		1				1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lymphadenitis		1
Lymphadenopathy	2	17
Lymph node pain	1	2
Magnetic resonance imaging head abnormal	1	1
Malaise	1	8
Migraine		3
Musculoskeletal pain	1	4
Myalgia	3	19
Nausea	4	12
Neck pain		1
No adverse event	1	2
Nuchal rigidity		1
Ocular discomfort		1
Oedema		1
Oedema peripheral		1
Off label use	1	1
Oral herpes		1
Oral pain		1
Oropharyngeal pain		2
Overdose	1	1
Pain		7
Pain in extremity	3	10
Palatal oedema		1
Pallor		1
Palpitations		1
Papule	1	1
Paraesthesia	3	9
Paraesthesia oral	1	2
Parosmia		1
Periorbital swelling	1	1
Peripheral coldness		1
Petechiae		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
2	16		1
1	2		
		1	1
1	8		
	2		1
1	4		
3	16		3
4	11		1
	1		
1	2		
	1		
	1		
	1		
			1
1	1		
	1		
			1
	1		1
1	1		
	7		
3	9		1
			1
	1		
	1		
1	1		
3	9		
1	2		
	1		
1	1		
	1		
	1		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Photophobia	1	2
Poor quality product administered	6	8
Presyncope		2
Product administered at inappropriate site		1
Product administration error	4	6
Product preparation error	1	1
Product preparation issue	1	2
Pruritus	1	5
Pulmonary embolism	2	2
Pyrexia	7	41
Radiculopathy		1
Rash	2	5
Respiratory failure	1	1
Rhinitis	1	1
Seizure		1
Skin tightness		1
Sleep disorder		1
Sneezing	1	1
Somnolence	1	3
Sopor		1
Swelling face		2
Syncope		1
Tachycardia	1	6
Tenderness		1
Tinnitus		1
Tongue dry	1	1
Tongue oedema		1
Underdose		1
Urinary incontinence		1
Urticaria	1	7
Vaccination failure	1	2
Vaccination site erythema		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	2		
6	8		
	2		
	1		
4	6		
1	1		
1	2		
1	4		1
		2	2
7	36		5
	1		
2	4		1
		1	1
1	1		
			1
			1
	1		
1	1		
1	3		
	1		
	1		1
			1
	3	1	3
	1		
	1		
1	1		
	1		
	1		
1	6		1
		1	2
			1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site hyperaesthesia		1				1
Vaccination site lymphadenopathy		1		1		
Vaccination site oedema		4		4		
Vaccination site pain	3	22	3	21		1
Vaccination site paraesthesia		1		1		
Vaccination site pruritus	1	2	1	2		
Vaccination site reaction		1		1		
Vaccination site swelling	1	3	1	2		1
Vertigo		3		2		1
Visual field defect	1	1	1	1		
Vomiting		2		2		
Wrong technique in product usage process		1		1		
	186	624	116	450	70	174

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Country Where Event Occurred

JAPAN

090177e19749cf15\Approved\Approved On: 14-Jun-2021 14:01 (GMT)

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- * AE=Adverse Event
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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	16	39	4	14	12	25
Abdominal distension	1	2	1	2		
Abdominal pain	46	88	24	44	22	44
Abdominal pain lower	3	6	1	2	2	4
Abdominal pain upper	15	25	8	13	7	12
Abdominal symptom	1	2			1	2
Abnormal behaviour	1	1	1	1		
Abnormal sensation in eye	3	7	1	4	2	3
Accidental overdose	1	1	1	1		
Acidosis		1				1
Acoustic neuroma		1				1
Acute abdomen	1	1			1	1
Acute disseminated encephalomyelitis	4	4			4	4
Acute febrile neutrophilic dermatosis		1				1
Acute kidney injury	1	1			1	1
Acute myocardial infarction	2	2			2	2
Administration site movement impairment		1		1		
Affective disorder		1		1		
Agitation	1	2		1	1	1
Allergic gastroenteritis	1	1			1	1
Allergic pharyngitis	1	1			1	1
Allergic reaction to excipient		2				2
Allergy to vaccine	8	18	3	11	5	7
Alopecia	1	1	1	1		
Altered state of consciousness	21	31			21	31
Amnesia	6	7	3	3	3	4
Anaemia	2	7		3	2	4
Anal incontinence		1		1		
Anaphylactic reaction	383	1,016	1	4	382	1012
Anaphylactic shock	17	36			17	36
Anaphylactoid reaction	2	12			2	12
Aneurysm	1	2			1	2

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Aneurysm ruptured	2	2
Angina pectoris	3	4
Angina unstable		1
Angioedema	4	12
Antiphospholipid antibodies positive		1
Anxiety	11	20
Anxiety disorder	3	3
Aortic dissection	2	2
Aphasia	4	4
Aphonia	1	2
Apnoea	5	8
Apnoeic attack		1
Apraxia		1
Arrhythmia	9	16
Arrhythmia supraventricular	1	1
Arterial occlusive disease	1	1
Arthralgia	129	187
Arthritis	6	8
Arthritis reactive	1	1
Arthropathy	1	1
Ascites		1
Asphyxia	2	2
Asthenia	39	66
Asthenopia	2	3
Asthma	68	119
Asthmatic crisis	1	1
Atrial tachycardia	1	2
Atrioventricular block complete	1	1
Autonomic dysreflexia	1	1
Autonomic nervous system imbalance		1
Autonomic neuropathy		1
Autophony		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		2	2
		3	4
			1
	2	4	10
			1
6	9	5	11
		3	3
		2	2
1	1	3	3
	1	1	1
		5	8
			1
			1
		9	16
		1	1
1	1		
98	137	31	50
3	4	3	4
		1	1
		1	1
			1
		2	2
18	28	21	38
2	2		1
18	36	50	83
		1	1
		1	2
		1	1
		1	1
			1
			1
	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Axillary pain	5	8	5	7		1
Back pain	21	32	14	22	7	10
Balance disorder	1	2			1	2
Basilar artery occlusion	1	1			1	1
Bilirubinuria		1				1
Blepharospasm	6	9	4	4	2	5
Blindness unilateral	1	1			1	1
Blister	1	2	1	1		1
Blood alkaline phosphatase decreased		1		1		
Blood creatine phosphokinase increased	1	1			1	1
Blood creatinine decreased		1		1		
Blood creatinine increased	1	1			1	1
Blood disorder	1	1	1	1		
Blood glucose decreased		1				1
Blood pressure abnormal	5	8		1	5	7
Blood pressure ambulatory abnormal	1	1			1	1
Blood pressure decreased	52	85	9	25	43	60
Blood pressure diastolic decreased	5	6	2	3	3	3
Blood pressure diastolic increased	1	1	1	1		
Blood pressure fluctuation	1	2	1	2		
Blood pressure immeasurable	2	3	1	2	1	1
Blood pressure increased	271	402	68	123	203	279
Blood pressure measurement		1		1		
Blood pressure systolic decreased	5	5	3	3	2	2
Blood pressure systolic increased	12	21	5	10	7	11
Blood urea increased	1	1			1	1
Body temperature abnormal		1		1		
Body temperature decreased	2	2	2	2		
Body temperature increased	13	21	7	15	6	6
Bowel movement irregularity	1	1	1	1		
Bradycardia	5	12			5	12
Bradykinesia	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Brain compression		1				1
Brain herniation	2	2			2	2
Brain neoplasm		1				1
Brain oedema		1		1		
Brain stem infarction	2	2			2	2
Breast cancer		1				1
Breath sounds abnormal	4	6	1	1	3	5
Bronchial disorder	1	1			1	1
Bronchial obstruction		1				1
Bronchitis	2	2	2	2		
Bronchitis bacterial	1	1			1	1
Bronchospasm	8	10	1	1	7	9
Bronchostenosis	1	3			1	3
Bundle branch block right	1	2	1	2		
Burning sensation	7	9	4	4	3	5
Burnout syndrome	1	1	1	1		
Cardiac arrest	4	4			4	4
Cardiac discomfort		1		1		
Cardiac failure	2	4			2	4
Cardiac failure acute	4	5			4	5
Cardiac failure congestive	1	1			1	1
Cardiac hypertrophy	1	1	1	1		
Cardiac tamponade	1	1			1	1
Cardiomyopathy	1	1			1	1
Cardio-respiratory arrest	11	14			11	14
Cardiovascular disorder	2	4	1	3	1	1
Carotid artery dissection	1	1			1	1
Carotid artery stenosis	1	1			1	1
Cellulitis	3	5			3	5
Cerebellar ataxia	1	1			1	1
Cerebral artery embolism	1	1			1	1
Cerebral artery stenosis	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral congestion		1				1
Cerebral haemorrhage	11	16			11	16
Cerebral infarction	14	17			14	17
Cerebral venous sinus thrombosis	1	1			1	1
Cerebrovascular accident	1	1			1	1
Cerebrovascular disorder	2	2			2	2
Cheilitis		1		1		
Chest discomfort	43	65	18	28	25	37
Chest pain	6	12	2	4	4	8
Chillblains	2	2	1	1	1	1
Chills	139	226	93	143	46	83
Choking		1				1
Choking sensation	3	4	1	1	2	3
Cholinergic syndrome		1				1
Chromatopsia		1				1
Chromaturia	3	3	1	1	2	2
Circulatory collapse		3				3
Circumoral oedema	1	1			1	1
Circumoral swelling	2	2			2	2
Clonus	1	1	1	1		
Cold sweat	28	58	8	21	20	37
Colitis		1				1
Colitis ischaemic	1	2			1	2
Colitis ulcerative	2	3			2	3
Colour blindness		1		1		
Coma	2	2			2	2
Coma scale abnormal		1				1
Communication disorder	1	1			1	1
Completed suicide	1	1			1	1
Complex regional pain syndrome	1	3			1	3
Condition aggravated	6	11		1	6	10
Confusional state	2	3	2	3		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival haemorrhage	1	2			1	2
Conjunctival hyperaemia	10	26	4	12	6	14
Conjunctival oedema	2	2	2	2		
Contusion	2	2	2	2		
Convulsions local		1				1
Coronary artery occlusion	1	1			1	1
Coronary artery stenosis	1	1			1	1
Coronavirus infection	2	2			2	2
Cough	181	378	61	119	120	259
Cough variant asthma	1	2	1	1		1
COVID-19	12	18	4	5	8	13
C-reactive protein increased	2	2	1	1	1	1
CSF cell count increased	1	1			1	1
Cutaneous symptom	2	6		2	2	4
Cyanosis	4	7		1	4	6
Cystitis	4	4	1	1	3	3
Daydreaming		1				1
Deafness	3	3			3	3
Deafness neurosensory	2	3			2	3
Death	2	3			2	3
Decreased appetite	28	41	12	16	16	25
Decreased vibratory sense		2				2
Deep vein thrombosis	1	2			1	2
Dehydration	5	9		1	5	8
Delirium	1	2			1	2
Depressed level of consciousness	29	53	1	1	28	52
Depressed mood	2	2			2	2
Dermatitis	2	4	1	3	1	1
Dermatitis allergic	8	13	6	10	2	3
Dermatitis atopic		2		1		1
Dermatitis bullous	1	1			1	1
Dermatitis contact		1		1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Diarrhoea	88	141
Diastolic hypotension		1
Diplopia		2
Discomfort	14	30
Disease recurrence	7	9
Disorientation	1	1
Disseminated intravascular coagulation		1
Dissociative disorder	2	3
Disturbance in attention	1	2
Diverticulitis		2
Diverticulum		1
Dizziness	154	262
Dizziness postural	8	13
Drug eruption	7	15
Drug hypersensitivity	7	13
Drug-induced liver injury	1	1
Drug ineffective	5	9
Dry mouth		2
Dry skin	2	4
Dry throat	1	3
Duodenal ulcer	1	1
Dysaesthesia	2	5
Dysarthria	2	2
Dysgeusia	9	10
Dyskinesia	5	6
Dyslalia		1
Dysmenorrhoea	1	1
Dyspepsia		3
Dysphagia	5	10
Dysphonia	23	50
Dysphoria	37	44
Dyspnoea	199	370

Spontaneous			
Nonserious		Serious	
I	C	I	C
51	77	37	64
			1
	1		1
10	21	4	9
1	2	6	7
		1	1
			1
2	3		
1	1		1
			2
			1
68	131	86	131
6	9	2	4
3	8	4	7
2	3	5	10
		1	1
		5	9
	1		1
	2	2	2
	2	1	1
		1	1
1	2	1	3
		2	2
7	8	2	2
2	2	3	4
	1		
1	1		
	1		2
	1	5	9
9	22	14	28
15	18	22	26
54	111	145	259

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysstasia	14	15	5	5	9	10
Dysuria	1	2			1	2
Ear discomfort	8	15	6	10	2	5
Ear pain	1	1	1	1		
Ear pruritus	1	2			1	2
Ear swelling	1	2	1	1		1
Eating disorder	1	3	1	1		2
Eczema	10	14	3	5	7	9
Eczema herpeticum		1				1
Electrocardiogram change	1	1			1	1
Electrocardiogram P wave abnormal	1	1	1	1		
Electrocardiogram T wave inversion	1	1			1	1
Electrolyte imbalance	1	1	1	1		
Embolic cerebral infarction	1	1			1	1
Embolism venous	1	1			1	1
Emotional distress	1	1	1	1		
Enanthema	1	1			1	1
Encephalitis	2	2			2	2
Enteritis infectious		1				1
Enterocolitis	1	1			1	1
Epigastric discomfort	1	3		1	1	2
Epilepsy	6	7			6	7
Epistaxis	1	3	1	1		2
Eructation		1		1		
Erythema	275	511	106	241	169	270
Erythema multiforme	2	3			2	3
Erythema of eyelid	6	7	4	4	2	3
Erythrospia	1	1	1	1		
Excessive eye blinking	1	2	1	1		1
Exposure during pregnancy	2	3		1	2	2
Extrasystoles	2	2	1	1	1	1
Eye disorder	2	6	1	1	1	5

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye haemorrhage	2	3			2	3
Eyelid function disorder		1				1
Eyelid irritation	1	2	1	1		1
Eyelid oedema	9	29	5	15	4	14
Eyelid pain	1	1			1	1
Eyelid ptosis	1	2			1	2
Eyelid rash	2	2			2	2
Eyelids pruritus	2	2	1	1	1	1
Eye movement disorder	4	6	3	3	1	3
Eye oedema		1				1
Eye pain	3	6	2	3	1	3
Eye pruritus	10	20	3	8	7	12
Eye swelling	1	4		1	1	3
Face oedema	10	18	1	4	9	14
Facial pain		4		2		2
Facial paralysis	9	20			9	20
Faeces discoloured	1	1			1	1
Faeces soft	3	5	2	3	1	2
Fall	15	21	5	9	10	12
Fatigue	54	66	45	54	9	12
Fear	1	1			1	1
Feeding disorder	7	11	3	3	4	8
Feeling abnormal	219	361	102	170	117	191
Feeling cold	31	51	14	21	17	30
Feeling drunk	2	2	2	2		
Feeling hot	73	126	37	67	36	59
Feeling jittery		1				1
Female reproductive tract disorder	1	1	1	1		
Fibrin degradation products increased		1				1
Fibromyalgia	1	1	1	1		
Fluid intake reduced	1	1			1	1
Flushing	40	73	14	32	26	41

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Foaming at mouth	1	1	1	1		
Foreign body in respiratory tract	1	1			1	1
Foreign body in throat		2				2
Foreign body sensation in eyes	1	1	1	1		
Gait disturbance	9	20	4	6	5	14
Gait inability		1				1
Gastric ulcer	2	2			2	2
Gastric ulcer haemorrhage	2	2			2	2
Gastroenteritis bacterial		1				1
Gastroenteritis viral	1	1	1	1		
Gastrointestinal disorder	5	7	2	2	3	5
Gastrointestinal haemorrhage	1	2			1	2
Gastrointestinal hypermotility		3				3
Gastrointestinal hypomotility	1	1			1	1
Gastrointestinal motility disorder		1		1		
Gastrointestinal mucosal disorder		1				1
Gastrointestinal oedema	3	4			3	4
Gastrooesophageal reflux disease	1	1			1	1
Gaze palsy	1	4			1	4
Generalised oedema		1				1
General physical condition abnormal	1	1			1	1
General physical health deterioration	2	2	1	1	1	1
General symptom	1	1	1	1		
Genital haemorrhage	3	3			3	3
Gingivitis	1	1	1	1		
Glare	2	2	2	2		
Glassy eyes	1	1			1	1
Glomerulonephritis	1	1			1	1
Glossodynia	2	2	2	2		
Grip strength decreased		2		2		
Groin pain	1	2			1	2
Grunting		2		1		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Guillain-Barre syndrome	3	7			3	7
Haemarthrosis		1				1
Haematemesis	1	1			1	1
Haematochezia	3	7			3	7
Haematoma	1	1			1	1
Haematuria	3	3			3	3
Haemolytic anaemia	1	1			1	1
Haemorrhage	3	5			3	5
Haemorrhage subcutaneous	7	14			7	14
Haemorrhagic disorder	1	1			1	1
Hallucination	1	1			1	1
Hallucination, visual	1	2			1	2
Hand dermatitis	1	1			1	1
Headache	379	609	239	387	140	222
Head discomfort	29	54	17	31	12	23
Heart rate decreased	10	15	2	5	8	10
Heart rate increased	58	95	23	44	35	51
Heavy menstrual bleeding	3	3	2	2	1	1
Hemiparesis	1	2			1	2
Hemiplegia	5	6			5	6
Henoch-Schonlein purpura	5	6	3	4	2	2
Hepatic function abnormal	5	10	1	2	4	8
Hepatitis	1	1			1	1
Hepatitis acute	3	3			3	3
Herpes simplex	2	2	2	2		
Herpes zoster	5	7	4	4	1	3
Herpes zoster oticus		1				1
Hiccups	1	1			1	1
Hordeolum	1	1			1	1
Hot flush	52	95	28	53	24	42
Hyperaemia	2	3	1	1	1	2
Hyperaesthesia	1	2	1	1		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperglycaemia		1		1		
Hyperhidrosis	44	80	26	42	18	38
Hyperpyrexia	1	3			1	3
Hyperreflexia	1	2	1	1		1
Hypersensitivity	74	117	17	38	57	79
Hypertension	28	48	4	8	24	40
Hypertensive emergency	2	4			2	4
Hypertensive urgency		1				1
Hyperthermia	3	4	1	1	2	3
Hyperthyroidism	1	1			1	1
Hypertonia	1	2		1	1	1
Hyperventilation	36	58	7	15	29	43
Hypoacusis	3	5	1	2	2	3
Hypoaesthesia	150	243	85	141	65	102
Hypoaesthesia oral	29	48	16	28	13	20
Hypochromic anaemia	1	1			1	1
Hypoglycaemia	2	2			2	2
Hypokalaemia	2	5			2	5
Hyponatraemia	1	1	1	1		
Hypophagia	2	3	1	1	1	2
Hypopnoea	1	2	1	1		1
Hyporeflexia	1	1			1	1
Hypotension	3	3	1	1	2	2
Hypothermia	2	4			2	4
Hypotonia		1				1
Hypoventilation		1				1
Hypoxia	2	4			2	4
Ileus paralytic	1	2			1	2
Illusion	5	5	4	4	1	1
Imaging procedure abnormal	1	1			1	1
Immobile	1	1			1	1
Immune system disorder	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Immunisation reaction	2	2	1	1	1	1
Impaired work ability	1	1	1	1		
Inappropriate schedule of product administration	3	4	3	4		
Incorrect dose administered	2	3	2	3		
Incorrect route of product administration	1	4	1	4		
Induration	2	3	2	3		
Infarction	1	1			1	1
Inflammation	2	3	1	2	1	1
Injected limb mobility decreased	2	6	2	6		
Injection site erythema	1	2	1	1		1
Injection site hypoaesthesia	1	2	1	2		
Injection site pain		3		3		
Injection site pruritus	1	3		2	1	1
Injection site rash		1		1		
Injection site warmth		1		1		
Insomnia	8	10	5	7	3	3
Intermenstrual bleeding	2	2	1	1	1	1
Internal haemorrhage	13	24	1	1	12	23
Interstitial lung disease	1	1			1	1
Intestinal ischaemia	1	1			1	1
Intestinal ulcer	1	1			1	1
Intracranial aneurysm	3	3			3	3
Intraventricular haemorrhage	2	2			2	2
Irregular breathing		1				1
Irritability	1	1			1	1
Joint range of motion decreased	3	8	2	3	1	5
Joint swelling	3	5	3	5		
Joint warmth	1	1	1	1		
Lacrimation increased	8	13	2	5	6	8
Lacunar infarction		1				1
Laryngeal discomfort	11	18	4	8	7	10
Laryngeal obstruction		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Laryngeal oedema	5	11	1	2	4	9
Laryngeal pain		1		1		
Laryngospasm		1				1
Larynx irritation	3	6	1	2	2	4
Lethargy		1				1
Leukopenia		1				1
Lid margin discharge		1		1		
Limb discomfort	12	24	6	15	6	9
Lip erythema		1				1
Lip oedema	3	5	1	2	2	3
Lip pruritus	2	5	1	2	1	3
Lip swelling	8	22	2	10	6	12
Listless	1	3		2	1	1
Livedo reticularis		1		1		
Liver disorder		1				1
Liver function test abnormal	1	1			1	1
Local reaction		1		1		
Loss of consciousness	36	55			36	55
Lymphadenitis	1	2	1	2		
Lymphadenitis bacterial		1				1
Lymphadenopathy	18	29	14	23	4	6
Lymph node pain	3	5	2	3	1	2
Lymphocyte count increased	1	1	1	1		
Lymphocyte percentage decreased		1		1		
Lymphoedema		1				1
Lymphoma	1	2			1	2
Malaise	282	470	186	316	96	154
Marasmus	2	2			2	2
Mass	1	1	1	1		
Maternal exposure during pregnancy		1		1		
Melaena	1	3			1	3
Memory impairment	3	5	2	3	1	2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Meniere's disease	2	2			2	2
Meningitis	1	2			1	2
Meningitis aseptic	1	7			1	7
Menstrual disorder	2	2	2	2		
Menstruation irregular	1	1	1	1		
Mental disorder	1	1	1	1		
Mesenteric artery thrombosis	1	1			1	1
Middle insomnia		1				1
Migraine	3	4			3	4
Mobility decreased	6	9	4	5	2	4
Monocyte percentage increased		1		1		
Monoparesis	2	2			2	2
Monoplegia	3	3			3	3
Mood altered	1	1			1	1
Motion sickness		1				1
Mouth swelling	1	6	1	5		1
Movement disorder	10	16	8	10	2	6
Mucocutaneous disorder		1		1		
Mucocutaneous rash	1	1			1	1
Mucosal disorder		1		1		
Mucosal haemorrhage		1		1		
Mucosal inflammation	1	1			1	1
Multi-organ disorder		2		1		1
Multiple organ dysfunction syndrome	1	1			1	1
Muscle fatigue	2	2	1	1	1	1
Muscle spasms	11	23	6	11	5	12
Muscle tightness	8	10	4	5	4	5
Muscle twitching	4	6	2	3	2	3
Muscular weakness	31	56	14	20	17	36
Musculoskeletal chest pain		1		1		
Musculoskeletal discomfort	3	6	2	4	1	2
Musculoskeletal disorder	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal stiffness	9	15	5	9	4	6
Mutism		1				1
Myalgia	102	162	88	134	14	28
Mydriasis		1		1		
Myocardial infarction	4	4			4	4
Myocardial ischaemia	1	1			1	1
Myopathy	1	1	1	1		
Myositis	1	2	1	1		1
Nasal congestion	12	16	8	8	4	8
Nasal mucosal disorder	1	1	1	1		
Nasal obstruction	6	11	1	2	5	9
Nasal oedema	1	1			1	1
Nasal pruritus	1	2	1	1		1
Nasopharyngitis	5	7	3	5	2	2
Nausea	352	568	158	261	194	307
Neck pain	9	16	5	8	4	8
Needle issue	1	2	1	2		
Nephropathy	1	1	1	1		
Neuralgia	3	3			3	3
Neuritis		1		1		
Neurological symptom	4	5	1	1	3	4
Neuropathy peripheral	30	53			30	53
Neutrophilic dermatosis		1		1		
Nightmare	1	1	1	1		
Night sweats		1		1		
Norovirus infection	1	1	1	1		
Nystagmus	5	5	2	2	3	3
Obstructive airways disorder	3	6			3	6
Ocular hyperaemia	10	31	5	20	5	11
Oculomucocutaneous syndrome	6	13			6	13
Odynophagia		1				1
Oedema	5	9	2	2	3	7

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oedema mouth	2	3			2	3
Oedema mucosal	2	3	1	1	1	2
Oedema peripheral	9	10	6	7	3	3
Off label use	3	4	3	4		
Opisthotonus		1				1
Optic neuritis	1	1			1	1
Oral allergy syndrome	1	1	1	1		
Oral discomfort	10	19	5	11	5	8
Oral herpes	1	1	1	1		
Oral mucosa erosion		1		1		
Oral mucosal blistering		1		1		
Oral mucosal roughening	1	1	1	1		
Oral pain		1		1		
Oral pruritus	9	14	3	5	6	9
Orbital oedema	1	1			1	1
Oropharyngeal discomfort	171	327	64	123	107	204
Oropharyngeal pain	21	45	12	28	9	17
Orthopnoea	1	1			1	1
Orthostatic hypotension		1				1
Orthostatic intolerance		1				1
Otorrhoea		1				1
Ovarian haemorrhage	1	1			1	1
Overdose		1		1		
Oxygen saturation decreased	28	45	4	9	24	36
Oxygen saturation increased	1	2			1	2
Pain	68	95	44	64	24	31
Pain in extremity	56	88	42	65	14	23
Pain of skin	1	1	1	1		
Palatal oedema	1	1			1	1
Pallor	50	69	15	22	35	47
Palmar erythema	3	4		1	3	3
Palpitations	162	293	82	151	80	142

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pancreatitis acute	1	1			1	1
Panic attack	4	4	1	1	3	3
Panic disorder	2	2			2	2
Papule	1	2		1	1	1
Paraesthesia	20	35	11	24	9	11
Paraesthesia oral	12	20	4	10	8	10
Paralysis	2	3			2	3
Parasympathetic nerve injury	1	1			1	1
Paresis	2	2			2	2
Parosmia	3	4	1	2	2	2
Parotitis	1	3	1	3		
Paroxysmal sympathetic hyperactivity	1	1			1	1
Pemphigoid	1	1			1	1
Periorbital oedema		1				1
Periorbital swelling	1	6		2	1	4
Peripheral circulatory failure	1	3			1	3
Peripheral coldness	26	49	13	27	13	22
Peripheral nerve palsy	2	2	2	2		
Peripheral swelling	14	19	8	13	6	6
Peritonitis		1				1
Petechiae	1	1	1	1		
Petit mal epilepsy		2				2
Pharyngeal disorder		1				1
Pharyngeal erythema	1	2		1	1	1
Pharyngeal hypoaesthesia	1	1	1	1		
Pharyngeal inflammation	1	1	1	1		
Pharyngeal oedema	7	7	3	3	4	4
Pharyngeal paraesthesia	3	5		1	3	4
Pharyngeal stenosis	2	4			2	4
Pharyngeal swelling	7	15		5	7	10
Pharyngitis	1	1	1	1		
Phlebitis		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Photopsia	8	12	4	7	4	5
Physical deconditioning	5	14	2	9	3	5
Pigmentation disorder		1		1		
Piloerection		2				2
Platelet aggregation abnormal	1	1	1	1		
Platelet count decreased	1	3	1	1		2
Pleural effusion		1				1
Pneumonia	3	4			3	4
Pneumonia aspiration	2	2			2	2
Pneumonia viral		1				1
Pollakiuria	2	3			2	3
Polyuria	1	1			1	1
Poor peripheral circulation	1	1	1	1		
Poor quality sleep	2	3	2	3		
Postmenopausal haemorrhage	1	1			1	1
Postural tremor		1				1
Posturing	1	1	1	1		
Presyncope	78	126	32	69	46	57
Primary hyperaldosteronism	1	2		1	1	1
Product administered at inappropriate site	3	4	3	4		
Product container issue	1	1	1	1		
Productive cough	5	9	3	6	2	3
Product leakage		2		2		
Product preparation error	1	1	1	1		
Prolonged expiration	1	1			1	1
Protein total decreased		1		1		
Proteinuria	1	1			1	1
Protein urine present	1	1			1	1
Prurigo	1	1			1	1
Pruritus	346	629	135	297	211	332
Pulmonary artery thrombosis	1	2			1	2
Pulmonary embolism	4	6			4	6

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary thrombosis	1	1			1	1
Pulse abnormal	3	5	1	1	2	4
Puncture site pain	1	2		1	1	1
Pupils unequal		1		1		
Purpura	5	6	5	6		
Putamen haemorrhage	2	2			2	2
Pyelonephritis	2	2			2	2
Pyrexia	369	622	250	433	119	189
Quadripareisis	1	1			1	1
Radial pulse abnormal	2	6	1	2	1	4
Radial pulse increased		1				1
Radiation pneumonitis	1	1	1	1		
Rash	219	381	92	181	127	200
Rash erythematous	22	32	11	17	11	15
Rash macular	2	2	1	1	1	1
Rash papular	1	2		1	1	1
Rash pruritic	4	5	3	4	1	1
Raynaud's phenomenon		1		1		
Reaction to excipient		2				2
Rectal tenesmus		1				1
Red blood cells urine positive	1	1			1	1
Reduced facial expression		1				1
Renal disorder	1	1			1	1
Respiration abnormal	2	2			2	2
Respiratory alkalosis	1	2		1	1	1
Respiratory arrest	2	2			2	2
Respiratory disorder	8	13	2	3	6	10
Respiratory distress	2	12		1	2	11
Respiratory failure	3	3			3	3
Respiratory rate decreased		2		1		1
Respiratory rate increased	6	11	2	3	4	8
Respiratory symptom	1	7		1	1	6

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Restless legs syndrome	1	1	1	1		
Restlessness	3	3			3	3
Retching	1	1			1	1
Retinal haemorrhage	1	2			1	2
Rheumatoid arthritis	2	2			2	2
Rhinorrhoea	25	47	13	26	12	21
Rotator cuff syndrome	1	1			1	1
Ruptured cerebral aneurysm	2	2			2	2
Salivary gland calculus	1	1	1	1		
Salivary gland pain	2	2	2	2		
Salivary hypersecretion	3	4	1	1	2	3
Scleritis		1				1
Scratch	1	1	1	1		
Sedation	1	1	1	1		
Seizure	12	28		1	12	27
Sensation of blood flow		1		1		
Sensation of foreign body	15	22	5	11	10	11
Sensitisation	1	1			1	1
Sensory disturbance	16	21	9	13	7	8
Sensory loss	1	1	1	1		
Septic shock	1	1			1	1
Serum sickness		1				1
Shock	4	7			4	7
Shock symptom		1				1
Shoulder injury related to vaccine administration		1				1
Sialoadenitis		1				1
Sinus bradycardia		1		1		
Sinus rhythm		2				2
Sinus tachycardia	12	16	2	4	10	12
Sitting disability		1		1		
Sjogren's syndrome	1	1			1	1
Skin discolouration	1	1	1	1		

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Gender

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin erosion	1	1	1	1		
Skin exfoliation	2	2	1	1	1	1
Skin haemorrhage	1	1			1	1
Skin laceration	1	1			1	1
Skin plaque		1				1
Skin reaction	1	1	1	1		
Sleep disorder	1	2			1	2
Slow response to stimuli		1				1
Slow speech	1	1	1	1		
Sneezing	4	11	2	6	2	5
Soft tissue atrophy		1				1
Somatic symptom disorder	2	3	1	2	1	1
Somnolence	27	42	15	24	12	18
Speech disorder	3	5	1	2	2	3
Speech sound disorder	1	2		1	1	1
Spinal column injury		1		1		
Sputum retention	2	3	1	2	1	1
Status asthmaticus	1	1			1	1
Stenosis		2				2
Stomatitis	2	3	2	3		
Strabismus	1	1			1	1
Stress		3		2		1
Stress cardiomyopathy	1	1			1	1
Stridor	1	7	1	4		3
Subarachnoid haemorrhage	14	20			14	20
Subdural haematoma	1	1			1	1
Submaxillary gland enlargement		1		1		
Sudden cardiac death	1	1			1	1
Sudden death	1	1			1	1
Sudden hearing loss		6				6
Suffocation feeling	1	3		1	1	2
Sunburn		1		1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Supraventricular extrasystoles	1	1
Supraventricular tachyarrhythmia	1	1
Supraventricular tachycardia	1	1
Swelling	22	34
Swelling face	15	34
Swelling of eyelid	10	22
Swollen tongue	1	1
Sympathicotonia	1	3
Syncope	8	21
Systemic lupus erythematosus	1	1
Tachyarrhythmia	1	1
Tachycardia	70	108
Tachypnoea	11	23
Taste disorder	6	7
Tearfulness	1	1
Temperature intolerance		1
Tenderness		1
Tension	7	9
Tension headache		1
Tetany	1	2
Thalamic infarction	1	1
Thirst	7	11
Throat clearing	1	1
Throat irritation	49	85
Throat tightness	43	70
Thrombocytopenia	1	1
Thrombocytopenic purpura	1	2
Thrombophlebitis superficial		1
Thrombosis		1
Thrombotic thrombocytopenic purpura	1	1
Thyroid function test abnormal	1	1
Thyroiditis acute	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
		1	1
1	1		
18	26	4	8
9	16	6	18
6	12	4	10
1	1		
1	2		1
		8	21
		1	1
1	1		
29	41	41	67
3	10	8	13
4	5	2	2
1	1		
			1
			1
4	5	3	4
			1
		1	2
		1	1
2	4	5	7
1	1		
24	42	25	43
13	26	30	44
		1	1
		1	2
	1		
			1
		1	1
1	1		
		1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thyroiditis subacute	1	1	1	1		
Tic	1	1			1	1
Tinnitus	4	9	1	4	3	5
Tongue discomfort	1	1			1	1
Tongue disorder		1				1
Tongue erythema	2	2	1	1	1	1
Tongue oedema	1	1	1	1		
Tongue paralysis	1	1			1	1
Tongue pruritus	1	1	1	1		
Tonsillar disorder		1		1		
Tonsillar hypertrophy	1	1	1	1		
Toothache	1	2	1	2		
Toxic skin eruption	2	5			2	5
Tracheal obstruction		1				1
Tracheal stenosis	1	3			1	3
Transient global amnesia	1	1			1	1
Transient ischaemic attack	1	1			1	1
Tremor	44	67	20	25	24	42
Trigeminal nerve disorder	1	4	1	1		3
Trigeminal neuralgia	1	2		1	1	1
Type I hypersensitivity	2	10			2	10
Type IV hypersensitivity reaction	2	3	1	2	1	1
Underdose		2		2		
Unresponsive to stimuli		2				2
Upper airway obstruction		1				1
Upper respiratory tract inflammation	1	1	1	1		
Urinary incontinence	1	1			1	1
Urinary occult blood	1	1			1	1
Urinary occult blood positive	3	3			3	3
Urinary retention	3	5			3	5
Urinary tract infection	2	2			2	2
Urine abnormality		1				1

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FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urine analysis abnormal	1	1			1	1
Urine output decreased	1	1			1	1
Urticaria	201	395	74	196	127	199
Use of accessory respiratory muscles	1	1			1	1
Uterine haemorrhage	1	1			1	1
Uveitis	1	1			1	1
Vaccination complication		1		1		
Vaccination site bruising	3	4	3	3		1
Vaccination site coldness	2	2	1	1	1	1
Vaccination site discolouration		1		1		
Vaccination site discomfort	3	3	3	3		
Vaccination site erythema	32	53	26	41	6	12
Vaccination site haematoma	1	1	1	1		
Vaccination site haemorrhage	3	5	3	5		
Vaccination site hypoaesthesia	6	8	4	6	2	2
Vaccination site induration	6	8	4	6	2	2
Vaccination site joint discomfort		1		1		
Vaccination site joint pain	1	1	1	1		
Vaccination site lymphadenopathy	1	1	1	1		
Vaccination site mass	3	4	2	3	1	1
Vaccination site movement impairment	1	7	1	6		1
Vaccination site necrosis		2				2
Vaccination site pain	199	306	155	244	44	62
Vaccination site papule	1	1	1	1		
Vaccination site paraesthesia	2	5	1	4	1	1
Vaccination site pruritus	26	48	18	36	8	12
Vaccination site rash	4	9	4	9		
Vaccination site reaction	1	3		2	1	1
Vaccination site swelling	66	83	55	68	11	15
Vaccination site urticaria	4	9	2	6	2	3
Vaccination site vesicles		1				1
Vaccination site warmth	12	15	9	10	3	5

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaginal discharge	1	1	1	1		
Vaginal haemorrhage	3	3			3	3
Vagus nerve disorder		1				1
Vascular injury		1		1		
Vascular occlusion	1	1			1	1
Vasculitis	3	4	3	4		
Vasodilatation		1		1		
Vasospasm		1				1
Ventricular extrasystoles	1	3	1	2		1
Ventricular tachycardia	1	1			1	1
Vertigo	12	22	5	6	7	16
Vertigo positional	1	1	1	1		
Viral infection		1				1
Vision blurred	5	10	2	6	3	4
Visual brightness	1	1			1	1
Visual field defect	1	1	1	1		
Visual impairment	15	22	8	12	7	10
Vlth nerve disorder		1				1
Vitreous floaters		1		1		
Vocal cord disorder		1				1
Vomiting	131	230	50	97	81	133
Wheezing	35	68	9	13	26	55
White blood cell count decreased	3	4	2	2	1	2
White blood cell count increased	2	3	1	2	1	1
White blood cells urine positive	1	1			1	1
White matter lesion	1	1			1	1
Yawning	1	7	1	5		2
	8,683	15,131	3814	6742	4869	8389

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* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	3	7	2	5	1	2
Abdominal distension	3	3			3	3
Abdominal pain	12	18	8	12	4	6
Abdominal pain lower	2	2	2	2		
Abdominal pain upper	1	2	1	1		1
Abdominal tenderness	2	2	2	2		
Abnormal sensation in eye	1	2			1	2
Accident		1				1
Acidosis	1	1			1	1
Acute coronary syndrome		2				2
Acute endocarditis		1				1
Acute lymphocytic leukaemia		1				1
Acute myocardial infarction	6	7			6	7
Acute respiratory distress syndrome		2				2
Alanine aminotransferase increased		1				1
Allergy to vaccine		1				1
Altered state of consciousness	5	6			5	6
Amnesia		1				1
Anaemia	1	2		1	1	1
Anaesthesia dolorosa		1				1
Anaphylactic reaction	49	108			49	108
Anaphylactic shock	2	3			2	3
Anaphylactoid reaction	1	1			1	1
Angioedema		1				1
Angiopathy	1	1			1	1
Anxiety	1	2		1	1	1
Aortic dissection	1	2			1	2
Aphasia	1	2			1	2
Areflexia	1	1			1	1
Arrhythmia	1	4			1	4
Arthralgia	23	34	16	25	7	9
Arthritis		1				1

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Asphyxia	1	1
Aspiration	1	1
Asthenia	11	16
Asthenopia	1	1
Asthma	8	10
Atrial f brillation	2	3
Atrial septal defect	1	1
Autonomic dysreflexia	1	1
Axillary pain	1	1
Back pain	4	9
Bile duct cancer	1	1
Bile duct stone	1	1
Biliary dilatation	1	1
Blister	1	1
Blood creatine phosphokinase increased	2	3
Blood pressure decreased	16	23
Blood pressure diastolic increased	1	3
Blood pressure immeasurable	2	2
Blood pressure increased	23	32
Blood pressure systolic		1
Blood pressure systolic increased	4	5
Body temperature increased	2	3
Bone pain	1	1
Bradycardia	5	6
Bradyphrenia		1
Brain herniation	1	1
Brain stem haemorrhage	1	2
Bronchostenosis		1
Burning sensation	1	2
Calculus urinary	1	2
Capillaritis		1
Cardiac arrest	4	4

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	1
2	5	9	11
1	1		
3	3	5	7
		2	3
		1	1
		1	1
1	1		
2	6	2	3
		1	1
		1	1
1	1		
	1	2	2
3	9	13	14
	1	1	2
		2	2
5	11	18	21
	1		
2	2	2	3
2	3		
		1	1
	1	5	5
			1
		1	1
		1	2
			1
	1	1	1
1	2		
	1		
		4	4

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac death		1				1
Cardiac failure	4	6			4	6
Cardiac failure chronic		1				1
Cardiac tamponade	1	2			1	2
Cardiomyopathy	1	1			1	1
Cardio-respiratory arrest	12	16			12	16
Cardiovascular disorder		1		1		
Cellulitis		2				2
Cerebral haemorrhage	1	2			1	2
Cerebral infarction	4	5			4	5
Cerebral mass effect	1	1			1	1
Cerebral palsy	1	1			1	1
Cerebral venous sinus thrombosis		1				1
Cerebral venous thrombosis	1	1			1	1
Cerebral ventricular rupture	1	1			1	1
Chest discomfort	6	16	2	8	4	8
Chest pain	3	6	1	2	2	4
Chills	26	45	21	34	5	11
Choking	2	2			2	2
Choking sensation	1	1	1	1		
Cholecystitis	1	1			1	1
Chromaturia	1	1	1	1		
Chronic obstructive pulmonary disease	2	2	1	1	1	1
Chronic respiratory disease	1	1	1	1		
Circulatory collapse		1				1
Clonic convulsion	1	1			1	1
Coccydynia	1	1	1	1		
Cold sweat	6	16	3	9	3	7
Completed suicide	1	1			1	1
Complex regional pain syndrome		1				1
Condition aggravated	2	2	1	1	1	1
Conjunctival haemorrhage		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival hyperaemia	3	5	1	2	2	3
Coronary artery stenosis	1	1			1	1
Cough	15	29	8	14	7	15
COVID-19	5	5	4	4	1	1
COVID-19 pneumonia	1	1			1	1
C-reactive protein increased	2	3	1	1	1	2
CSF protein increased		1				1
Cubital tunnel syndrome	1	1			1	1
Cyanosis	3	4	1	2	2	2
Deafness	3	5			3	5
Deafness neurosensory	1	1			1	1
Death	3	3			3	3
Decreased appetite	10	13	7	10	3	3
Deep vein thrombosis	1	2			1	2
Dehydration	4	4	1	1	3	3
Dementia	1	1			1	1
Depressed level of consciousness	8	11			8	11
Derealisation	1	1	1	1		
Dermatitis atopic	1	2	1	2		
Diabetes insipidus	1	1			1	1
Diabetes mellitus	2	2			2	2
Diarrhoea	15	23	9	16	6	7
Discomfort		3				3
Disseminated intravascular coagulation	1	1			1	1
Diverticulum intestinal haemorrhagic	1	1			1	1
Dizziness	24	40	13	23	11	17
Dizziness postural	2	5	2	4		1
Drowning		1				1
Drug ineffective	1	1			1	1
Dry mouth		1				1
Dysarthria	1	1			1	1
Dyschezia	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyskinesia	1	1	1	1		
Dysphagia	3	3	2	2	1	1
Dysphonia	4	6	4	5		1
Dysphoria	3	4	2	2	1	2
Dyspnoea	29	46	11	20	18	26
Dysstasia	3	3			3	3
Dysuria	1	1			1	1
Ear discomfort	2	2	1	1	1	1
Eczema		1		1		
Electrocardiogram QRS complex shortened	1	1			1	1
Electrocardiogram ST segment elevation	2	2			2	2
Embolic stroke	1	1			1	1
Embolism venous		1				1
Enteritis		1				1
Enterocolitis	2	6			2	6
Enzyme level increased	1	1			1	1
Epigastric discomfort		1		1		
Epistaxis	1	1	1	1		
Erythema	27	49	9	23	18	26
Erythema ab igne		1		1		
Erythema multiforme	1	1			1	1
Eustachian tube dysfunction	1	1	1	1		
Extrasystoles		1		1		
Eye discharge	1	1	1	1		
Eye disorder	1	2	1	2		
Eyelid oedema		1				1
Eyelid ptosis		1				1
Eye oedema	1	1	1	1		
Eye pain	1	1	1	1		
Eye pruritus	2	4	2	4		
Face oedema	3	5	1	2	2	3
Facial paralysis	5	9			5	9

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Faeces soft		3		3		
Fall	8	11	2	3	6	8
Fatigue	8	9	7	7	1	2
Febrile convulsion	1	1			1	1
Feeding disorder	2	3	2	3		
Feeling abnormal	28	47	16	28	12	19
Feeling cold	9	11	3	4	6	7
Feeling hot	8	14	3	7	5	7
Fibrin D dimer increased	1	1	1	1		
Flatulence	2	2			2	2
Flushing	6	9	3	3	3	6
Foreign body sensation in eyes	1	1	1	1		
Fracture		1		1		
Frequent bowel movements		1		1		
Gait disturbance	4	4	1	1	3	3
Gallbladder enlargement	1	1			1	1
Gamma-glutamyltransferase increased	1	1	1	1		
Gastroenteritis		1		1		
Gastrointestinal motility disorder	1	1			1	1
Gastrointestinal necrosis	1	1			1	1
Gaze palsy		1				1
General physical health deterioration	1	1			1	1
Gingival bleeding	1	1			1	1
Glossodynia		1		1		
Grip strength decreased	2	6	1	3	1	3
Guillain-Barre syndrome	2	4	1	1	1	3
Haematochezia	3	4			3	4
Haematoma	1	1			1	1
Haemoptysis		1				1
Haemorrhage	1	1			1	1
Haemorrhage subcutaneous	1	1			1	1
Haemorrhagic cerebral infarction	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hallucination, visual	1	1			1	1
Headache	52	96	34	62	18	34
Head discomfort	5	8	3	6	2	2
Head injury	1	1			1	1
Heart rate decreased	1	1			1	1
Heart rate increased	8	9	3	4	5	5
Hemiplegia	1	2			1	2
Hepatic enzyme increased	1	1			1	1
Hepatic function abnormal	2	3	1	1	1	2
Herpes simplex	1	1	1	1		
Herpes virus infection		1				1
Herpes zoster	2	3	2	3		
Herpes zoster oticus		1				1
Hot flush	3	6	1	4	2	2
Hyperaemia		1				1
Hyperaesthesia		1				1
Hyperhidrosis	14	22	4	10	10	12
Hyperpyrexia		1				1
Hyperreflexia	1	1			1	1
Hypersensitivity	7	13	5	9	2	4
Hypertension	4	7	1	2	3	5
Hyperthermia	1	3	1	3		
Hyperventilation	4	4	1	1	3	3
Hypoaesthesia	16	30	11	17	5	13
Hypoaesthesia oral	1	3	1	3		
Hypokinesia		1		1		
Hypophagia	1	2		1	1	1
Hypoxia	1	2			1	2
IIIrd nerve paralysis		1				1
Illusion		1				1
Impaired driving ability	1	1			1	1
Impaired work ability	1	1	1	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inappropriate schedule of product administration	1	1	1	1		
Incorrect route of product administration	1	2	1	2		
Induration		1		1		
Infection		1		1		
Inflammatory marker increased	1	1	1	1		
Injection site muscle weakness		1		1		
Injection site swelling		1		1		
Injection site vesicles		1				1
Insomnia	1	1	1	1		
Intention tremor	1	1			1	1
Internal haemorrhage	2	4			2	4
Interstitial lung disease	1	2			1	2
Intracranial aneurysm		1				1
Irregular breathing	1	1			1	1
Joint range of motion decreased	1	2	1	2		
Laryngeal obstruction	1	1			1	1
Laryngeal oedema	3	3	1	1	2	2
Limb discomfort	3	6	2	4	1	2
Lip discolouration	1	1			1	1
Lip haemorrhage	1	1	1	1		
Lip swelling	1	1			1	1
Listless		1		1		
Loss of consciousness	7	15			7	15
Lung infiltration		1				1
Lymphadenopathy	4	4	3	3	1	1
Malaise	65	121	48	87	17	34
Melaena	1	1			1	1
Meningitis		1				1
Meningitis aseptic	1	1			1	1
Mental disorder	1	1			1	1
Mesenteric arterial occlusion	1	1			1	1
Middle insomnia	1	1	1	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Migraine		1				1
Mobility decreased		2		2		
Monoplegia	1	1			1	1
Motion sickness		1		1		
Movement disorder	2	2	1	1	1	1
Mucous stools	1	1	1	1		
Multiple sclerosis		1				1
Muscle atrophy		1		1		
Muscle spasms	3	3	1	1	2	2
Muscle strain		1		1		
Muscle swelling	2	2	1	1	1	1
Muscle tightness		1		1		
Muscular weakness	10	18	3	7	7	11
Musculoskeletal discomfort	1	2	1	2		
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	2	2	1	1	1	1
Myalgia	41	70	35	62	6	8
Myelitis		1				1
Myocardial infarction	2	4			2	4
Myocardial ischaemia	2	2			2	2
Myocardial rupture	1	1			1	1
Myocarditis	2	6			2	6
Myositis	1	2		1	1	1
Nail discolouration	1	1			1	1
Nasal congestion	2	2	2	2		
Nasal mucosal disorder		1				1
Nasal obstruction	1	1	1	1		
Nasal oedema	1	1	1	1		
Nasopharyngitis	1	1	1	1		
Nausea	54	84	24	36	30	48
Neck pain	2	3	1	1	1	2
Neoplasm	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nephrotic syndrome	1	2			1	2
Nervous system disorder	1	1	1	1		
Neuralgia	1	1	1	1		
Neurological symptom	1	1			1	1
Neuropathy peripheral	8	12			8	12
Nystagmus		1				1
Obstructive airways disorder	1	1			1	1
Ocular hyperaemia	2	2	2	2		
Oculomucocutaneous syndrome	1	2			1	2
Odynophagia	1	1	1	1		
Oedema	1	1			1	1
Oedema mucosal	1	1			1	1
Oedema peripheral		2				2
Off label use	1	1	1	1		
Oliguria	1	1			1	1
Oral discomfort	1	2	1	2		
Oral disorder	1	1	1	1		
Oral herpes	1	1			1	1
Oral mucosa haematoma		1		1		
Oropharyngeal discomfort	13	29	9	17	4	12
Oropharyngeal pain	3	9	3	8		1
Orthostatic hypotension	1	1			1	1
Oxygen saturation decreased	14	17	4	4	10	13
Oxygen saturation immeasurable	1	1			1	1
Pain	11	19	5	12	6	7
Pain in extremity	10	25	7	21	3	4
Pallor	9	11	4	5	5	6
Palpitations	15	26	5	12	10	14
Panic attack		1				1
Paraesthesia	5	8	3	3	2	5
Paraesthesia oral	1	2	1	2		
Paralysis	2	3			2	3

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Parotid gland enlargement	1	1	1	1		
Pericardial effusion	2	2			2	2
Pericarditis	1	3			1	3
Periorbital swelling	1	2	1	2		
Peripheral coldness	5	11	2	7	3	4
Peripheral nerve paresis		1				1
Peripheral swelling	1	3	1	3		
Peripheral vascular disorder	1	1			1	1
Petechiae	1	1	1	1		
Pharyngeal oedema	1	1	1	1		
Pharyngeal paraesthesia	1	2	1	2		
Pharyngeal swelling	2	3	2	2		1
Pharyngitis	3	3	3	3		
Pharyngitis bacterial	1	2			1	2
Photophobia	1	1			1	1
Physical deconditioning	4	5	1	1	3	4
Pneumonia	3	5			3	5
Pneumonia aspiration	2	2			2	2
Pneumothorax		2				2
Pollakiuria		1				1
Polydipsia	1	1	1	1		
Polyuria	1	1	1	1		
Portal vein embolism	1	1			1	1
Portal vein thrombosis	1	1			1	1
Post thrombotic syndrome		1				1
Posture abnormal	1	1			1	1
Presyncope	12	21	5	11	7	10
Product administered at inappropriate site	1	1	1	1		
Productive cough	1	4	1	2		2
Prostatitis		1				1
Prostatomegaly		1				1
Protein urine present		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Prurigo	1	1	1	1		
Pruritus	25	47	9	24	16	23
Pulmonary artery thrombosis	1	1			1	1
Pulmonary oedema	1	1			1	1
Pulse abnormal	3	3	1	1	2	2
Pulseless electrical activity	1	1			1	1
Purpura	1	1	1	1		
Putamen haemorrhage	1	1			1	1
Pyrexia	82	148	53	102	29	46
Rash	16	35	8	21	8	14
Rash erythematous	2	3	1	2	1	1
Rash papular	1	1			1	1
Rash pruritic	1	1	1	1		
Renal impairment	1	1			1	1
Respiration abnormal	1	1			1	1
Respiratory acidosis	1	1	1	1		
Respiratory arrest	2	2			2	2
Respiratory disorder	1	4	1	2		2
Respiratory distress	1	1			1	1
Respiratory failure	1	1			1	1
Retinal haemorrhage	2	2			2	2
Retinal vein occlusion	2	2			2	2
Rhinalgia	1	1	1	1		
Rhinorrhoea	3	6	2	4	1	2
Road traffic accident		1		1		
Scar pain	1	1	1	1		
Sciatica	1	1	1	1		
Scleral haemorrhage	1	1			1	1
Seizure	7	9			7	9
Sensation of foreign body	4	5	1	2	3	3
Sensory disturbance	6	7	2	3	4	4
Sepsis	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Septic shock	1	1
Serum ferritin increased	1	1
Shock	3	4
Shock haemorrhagic	1	1
Shock symptom	1	1
Sinus rhythm	1	1
Skin abrasion		1
Skin discomfort	1	1
Skin fissures		1
Sleep disorder due to general medical condition, insomnia type		1
Sneezing	2	2
Somatic symptom disorder		1
Somnolence	3	4
Sputum discoloured		1
Sputum increased	2	2
Sputum purulent		2
Stenosis	1	1
Stomatitis	1	2
Streptococcal infection		1
Stridor		1
Subarachnoid haemorrhage	1	2
Sudden cardiac death	1	1
Sudden death	1	1
Sudden hearing loss	1	3
Supraventricular extrasystoles	1	1
Supraventricular tachycardia	1	1
Swelling	2	4
Swelling face	1	2
Swelling of eyelid		1
Syncope	5	7
Tachycardia	12	19

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
1	1		
		3	4
		1	1
		1	1
		1	1
			1
		1	1
	1		
			1
2	2		
	1		
2	3	1	1
	1		
		2	2
			2
		1	1
	1	1	1
			1
			1
		1	2
		1	1
		1	1
		1	3
		1	1
		1	1
1	2	1	2
1	2		
	1		
		5	7
5	9	7	10

* I=Interval, C=Cumulative
* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachypnoea	2	3	1	2	1	1
Tetany	1	1	1	1		
Thalamus haemorrhage	1	1			1	1
Thirst	1	5	1	4		1
Throat irritation	3	5	2	4	1	1
Throat tightness	1	5		1	1	4
Thrombosis mesenteric vessel	1	1			1	1
Thrombotic cerebral infarction	1	1			1	1
Tinnitus	2	2	1	1	1	1
Tongue oedema		1		1		
Tonic convulsion	1	1			1	1
Toxic skin eruption		1				1
Tracheal obstruction		1				1
Trance		1		1		
Transient ischaemic attack	1	1			1	1
Tremor	7	10	3	5	4	5
Troponin increased	1	1			1	1
Ulnar nerve palsy	1	1			1	1
Upper gastrointestinal haemorrhage		1				1
Urinary tract infection	2	2			2	2
Urinary tract infection bacterial	1	1	1	1		
Urine abnormality	1	1			1	1
Urticaria	19	39	10	22	9	17
Vaccination complication		1				1
Vaccination site coldness		1		1		
Vaccination site erythema	2	7	1	3	1	4
Vaccination site haemorrhage		1				1
Vaccination site hypoaesthesia		2		1		1
Vaccination site induration	1	2	1	2		
Vaccination site movement impairment	3	5	1	1	2	4
Vaccination site pain	58	115	43	94	15	21
Vaccination site papule		1		1		

* I=Interval, C=Cumulative

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site rash		1		1		
Vaccination site swelling	7	14	7	11		3
Vaccination site warmth		2		1		1
Vasodilatation		1		1		
Ventricular extrasystoles		1		1		
Ventricular fibrillation	2	3			2	3
Ventricular hypokinesia		1				1
Ventricular tachycardia	1	1			1	1
Vertebral artery dissection		2				2
Vertigo	3	5		1	3	4
Vestibular neuronitis		1				1
Viral pericarditis		1				1
Visual acuity reduced	1	1			1	1
Visual impairment	3	3	2	2	1	1
Vomiting	15	23	5	7	10	16
Wheezing	4	5	1	1	3	4
White blood cell count increased	1	2			1	2
Wrong technique in product usage process		1				1
	1,493	2,544	673	1243	820	1301

* I=Interval, C=Cumulative
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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	2	1	1		1
Acute respiratory distress syndrome		1				1
Anaphylactic reaction	10	36			10	36
Anaphylactic shock	2	6			2	6
Anxiety		1				1
Aortic dissection		1				1
Appendicitis	1	1			1	1
Arrhythmia	1	1			1	1
Arthralgia	6	6	5	5	1	1
Arthritis	1	1	1	1		
Arthritis reactive		1				1
Asthenia	1	1	1	1		
Asthma	1	3	1	2		1
Asymptomatic COVID-19		2				2
Atrioventricular block complete	1	1			1	1
Back pain	1	1	1	1		
Blood glucose increased	1	1	1	1		
Blood pressure fluctuation		1				1
Blood pressure increased	4	7	1	3	3	4
Blood pressure systolic increased	1	1			1	1
Bradycardia	1	1			1	1
Cardiac failure	1	2			1	2
Cerebral haemorrhage	8	8			8	8
Cerebral infarction	2	3			2	3
Chillblains	1	1	1	1		
Chills	1	3	1	3		
Choking sensation	1	1			1	1
Condition aggravated		1				1
Convulsions local	1	1			1	1
Cough		4		2		2
COVID-19	15	17	4	5	11	12
Decreased appetite		1				1

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* AE=Adverse Event

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dementia Alzheimer's type	1	1			1	1
Dermatitis allergic		1				1
Diarrhoea	5	9	4	7	1	2
Discomfort	1	1	1	1		
Disease recurrence	1	1			1	1
Dizziness	3	7	2	4	1	3
Drug eruption	1	2		1	1	1
Drug hypersensitivity		1		1		
Drug ineffective	11	14			11	14
Dysgeusia		1				1
Dyspnoea	5	8	4	5	1	3
Ear discomfort	1	1	1	1		
Eczema	1	5		4	1	1
Erythema	4	5	3	3	1	2
Erythema multiforme		1				1
Exposure via breast milk	1	1	1	1		
Eye oedema	1	1	1	1		
Face oedema		1		1		
Facial paralysis	2	2			2	2
Fatigue	1	3	1	2		1
Feeling abnormal	1	10	1	10		
Feeling hot	2	2	2	2		
Flushing		1				1
Gait disturbance	1	1	1	1		
Gastrointestinal disorder	1	2	1	1		1
General physical health deterioration	1	2			1	2
Glucose urine present	1	1	1	1		
Guillain-Barre syndrome	1	1			1	1
Haematuria	1	1			1	1
Haemorrhage subcutaneous	1	2			1	2
Headache	11	18	10	15	1	3
Head discomfort	1	1	1	1		

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* AE=Adverse Event

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate increased	1	1	1	1		
Hepatic function abnormal		1		1		
Herpes virus infection	1	1			1	1
Herpes zoster	4	4	3	3	1	1
HIV antibody positive		2		2		
Hot flush		1		1		
Hyperhidrosis	1	3	1	1		2
Hyperpyrexia		1				1
Hypersensitivity	3	7	2	4	1	3
Hypertension	2	2	2	2		
Hyperthermia	2	3	1	1	1	2
Hypoaesthesia	3	5	3	5		
Hypoaesthesia oral		1				1
Hypothyroidism		1				1
Incoherent	1	1	1	1		
Incorrect dose administered		2		2		
Incorrect route of product administration	1	2	1	2		
Injected limb mobility decreased		1		1		
Injury associated with device	1	1			1	1
Interstitial lung disease	1	1			1	1
Joint range of motion decreased		1		1		
Joint swelling	1	1	1	1		
Limb discomfort	3	3	3	3		
Loss of consciousness	1	2			1	2
Lymphadenitis	1	1	1	1		
Lymphadenopathy	3	4	3	4		
Lymph node pain	1	1	1	1		
Malaise	10	20	8	17	2	3
Meningitis		1				1
Meningitis aseptic		1				1
Mobility decreased	1	2	1	2		
Muscle abscess	1	1			1	1

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* AE=Adverse Event

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle tightness		1
Muscular weakness		1
Musculoskeletal stiffness	1	1
Myalgia	9	21
Nausea	5	10
Needle issue		1
No adverse event	1	1
Occupational exposure to product	1	1
Ocular hyperaemia	1	1
Optic atrophy		1
Oral discomfort	1	2
Oropharyngeal discomfort	1	7
Oropharyngeal pain	1	5
Pain	5	11
Pain in extremity	2	2
Pallor		1
Palpitations	1	3
Paralysis	1	1
Parosmia	1	1
Peripheral swelling	1	1
Pharyngeal stenosis	1	1
Pharyngeal swelling		1
Physical deconditioning	1	2
Physical disability	1	1
Piloerection	1	1
Platelet count decreased	1	2
Pneumonia	1	1
Presyncope	1	3
Product preparation issue		2
Pruritus	1	4
Purpura		1
Pyrexia	24	49

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	1		
1	1		
9	21		
3	8	2	2
	1		
1	1		
1	1		
1	1		
			1
1	1		1
	4	1	3
1	5		
4	9	1	2
2	2		
			1
1	2		1
		1	1
		1	1
1	1		
		1	1
			1
		1	2
1	1		
1	1		
		1	2
		1	1
1	2		1
	2		
	3	1	1
	1		
20	44	4	5

* I=Interval, C=Cumulative

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash	6	15	3	12	3	3
Rash erythematous	1	1	1	1		
Rash papular	1	1	1	1		
Respiratory distress		1				1
Respiratory failure	1	1			1	1
Retinal haemorrhage		1				1
Rhinorrhoea	2	2	1	1	1	1
Seizure	1	2			1	2
Shock		1				1
Skin disorder		1		1		
Sneezing	1	1			1	1
Somnolence	1	2	1	1		1
Sudden hearing loss	1	2			1	2
Suspected COVID-19	2	3	1	1	1	2
Swelling	2	4	2	4		
Swelling face	1	1	1	1		
Tachycardia	1	4	1	4		
Tachypnoea	1	1	1	1		
Taste disorder	1	1			1	1
Thrombosis	1	2			1	2
Tinnitus	1	1	1	1		
Tremor		1				1
Underdose	1	4	1	4		
Upper respiratory tract inflammation	1	1	1	1		
Urticaria	4	16	2	12	2	4
Vaccination failure		1				1
Vaccination site bruising	1	1	1	1		
Vaccination site erythema	2	3	2	3		
Vaccination site haemorrhage	1	1			1	1
Vaccination site movement impairment		1		1		
Vaccination site pain	11	30	11	29		1
Vaccination site pruritus	1	1	1	1		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site rash	1	1	1	1		
Vaccination site reaction		1		1		
Vaccination site swelling	4	6	4	6		
Vaccination site urticaria		1		1		
Vasculitis	1	1	1	1		
Vertigo	2	3	2	3		
Visual field defect		1		1		
Visual impairment	1	1	1	1		
Vomiting	3	5	1	2	2	3
Wheezing	1	1	1	1		
White blood cell count increased	1	1			1	1
	292	576	179	359	113	217

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* AE=Adverse Event
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Country Where Event Occurred

JORDAN

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose	1	1	1	1		
Animal attack		1		1		
Arthralgia		1		1		
Asthenia	1	1	1	1		
Blood pressure increased		1				1
Burning sensation	1	1	1	1		
COVID-19	1	1			1	1
Drug ineffective	1	1			1	1
Dysgeusia		1		1		
Erythema		1				1
Fatigue		2		2		
Feeling cold	1	1	1	1		
Gangrene		1				1
Haematemesis		1				1
Headache		2		2		
Mesenteric vein thrombosis		1				1
Muscle spasms		1		1		
Myalgia		1		1		
Obstructive airways disorder		1				1
Pain		2		2		
Pain in extremity		2		2		
Swelling		1				1
Swelling face		1		1		
Syncope		1				1
Vaccination site pain	1	2	1	2		
Weight decreased		1		1		
	7	31	5	21	2	10

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Acne	1	1	1	1		
Anosmia		1		1		
Asthenia		1				1
Cerebral thrombosis		1				1
Cerebrovascular accident		1				1
Condition aggravated		1				1
Confusional state		1				1
Cough		1		1		
COVID-19	1	3			1	3
COVID-19 pneumonia		1				1
Dizziness		1		1		
Dyspnoea		1				1
Fatigue	1	3	1	3		
Headache	1	1	1	1		
Hypoxia		1				1
Increased bronchial secretion		1				1
Increased viscosity of upper respiratory secretion		1				1
Inflammatory marker increased	1	1	1	1		
Influenza		1		1		
Influenza like illness		1		1		
Injection site pain		1		1		
Loss of consciousness		1				1
Lung disorder		1				1
Myalgia	1	2	1	2		
Pain in extremity		1		1		
Pruritus	2	2	2	2		
Pyrexia	1	1	1	1		
Respiratory failure		1				1
Scratch	1	1	1	1		
Sputum retention		1				1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling		1		1		
Syncope		1				1
Tachypnoea		1				1
Testicular swelling		1		1		
Tongue disorder		1		1		
Vaccination failure		1				1
Vaccination site pain		1		1		
	10	44	9	23	1	21

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma		1		1		
Chills		1		1		
COVID-19		1		1		
Myalgia		1		1		
Pneumonia		1				1
Pyrexia		1		1		
		6		5		1

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Country Where Event Occurred
KOREA, REPUBLIC OF (SOUTH KOREA)

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Brain oedema	1	1	1	1
Cerebral infarction	1	1	1	1
	2	2	2	2

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint swelling		1		1
Lymphadenopathy	1	1	1	1
Swelling	1	1	1	1
	2	3	2	3

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Country Where Event Occurred

KUWAIT

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthma		1		1
Fatigue		1		1
Headache		2		2
Lymphocyte percentage increased		1		1
Maternal exposure during pregnancy	1	1	1	1
Mean cell haemoglobin concentration increased		1		1
Musculoskeletal stiffness		1		1
Pain		1		1
Polyp		1		1
Pyrexia		1		1
Splenomegaly		1		1
	1	12	1	12

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* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1			1	1
Axillary pain	1	1			1	1
Back pain	1	1			1	1
Breast pain	1	1			1	1
COVID-19		1		1		
Ear pain	1	1			1	1
Fatigue		1		1		
Hyperhidrosis	1	1			1	1
Hypoaesthesia	1	1			1	1
Lymphadenopathy	1	2		1	1	1
Muscle tightness	1	1			1	1
Musculoskeletal chest pain	1	1			1	1
Myalgia		1		1		
Neck pain		1		1		
Pain in extremity		1		1		
Paraesthesia	1	1			1	1
Peripheral swelling		1		1		
Pyrexia		1		1		
Swelling		1		1		
Tenderness		2		2		
Vaccination site pain		1		1		
Vaccination site swelling		1		1		
	11	24		13	11	11

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
COVID-19		1		1
		1		1

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Country Where Event Occurred

LATVIA

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		5		5		
Abdominal pain lower	1	2	1	2		
Abdominal pain upper		2				2
Abortion missed		1				1
Anaphylactic reaction		1				1
Anxiety		2				2
Arrhythmia		2				2
Arthralgia	5	45	5	41		4
Asthenia	3	23	3	21		2
Asthma		2		1		1
Asymptomatic COVID-19	1	1			1	1
Atrial fibrillation		1				1
Bacille Calmette-Guerin scar reactivation		1		1		
Back pain		1		1		
Bell's palsy		1				1
Blood creatine phosphokinase increased		1		1		
Blood pressure increased		3		1		2
Body temperature decreased		1		1		
Body temperature increased	9	49	9	48		1
Bone pain		2		2		
Bradycardia		1				1
Bradyphrenia		1		1		
Burning sensation		4		1		3
Chest discomfort		1				1
Chest pain		2		2		
Chills	6	52	6	52		
Cold sweat		2		1		1
Condition aggravated		2		1		1
Confusional state		1		1		
Conjunctival haemorrhage		1				1
Coordination abnormal		1		1		
Costovertebral angle tenderness		1		1		

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	1	9	1	9		
COVID-19	1	6		2	1	4
C-reactive protein increased		3		3		
Deafness		1				1
Decreased appetite	1	8	1	8		
Depressed mood		1		1		
Depression		1		1		
Dermatitis allergic	1	1	1	1		
Diarrhoea	1	7	1	7		
Diplopia		1				1
Disease recurrence		2				2
Disturbance in attention		5		5		
Dizziness	1	20		16	1	4
Drug ineffective	1	3			1	3
Dry mouth		2		1		1
Dry skin		1		1		
Dysgeusia		4		2		2
Dysphonia		2		2		
Dyspnoea	1	7	1	4		3
Dyspnoea exertional		2		2		
Ear discomfort		1				1
Ear pain		2		1		1
Epistaxis		1				1
Erythema	1	3	1	2		1
Exposure during pregnancy		2		1		1
Extrasystoles		1				1
Eye pain	1	10	1	10		
Face oedema		1				1
Facial paresis		2				2
Fatigue	9	65	8	61	1	4
Feeling hot		2		2		
Flushing	1	1	1	1		

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gait disturbance		2		2		
Generalised oedema		1				1
Generalised tonic-clonic seizure		1				1
Glomerular filtration rate decreased		1		1		
Headache	12	82	11	73	1	9
Head injury	1	1			1	1
Heart rate increased		2		1		1
Herpes zoster		1				1
Hot flush	1	4	1	3		1
Hyperacusis	1	1	1	1		
Hyperaesthesia		7		4		3
Hyperhidrosis	4	9	4	9		
Hypersensitivity	1	1	1	1		
Hypertension		2		1		1
Hypertensive crisis		2				2
Hypoacusis		1		1		
Hypoaesthesia		1				1
Hypotension		1		1		
Hypothyroidism		1				1
Illness		2		2		
Inappropriate schedule of product administration	1	2	1	2		
Influenza like illness		1		1		
Initial insomnia		3		3		
Insomnia		2		1		1
Joint range of motion decreased		1		1		
Joint stiffness		2		1		1
Lacrimation increased		2		1		1
Loss of proprioception		1				1
Lymphadenitis		2		1		1
Lymphadenopathy	2	23	2	19		4
Lymph node pain		6		3		3
Malaise	1	4	1	4		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Menstrual disorder	1	1	1	1		
Mental impairment		1				1
Migraine		1				1
Muscle spasms	1	3	1	2		1
Muscular weakness	1	4	1	3		1
Musculoskeletal discomfort	1	3	1	3		
Musculoskeletal stiffness	2	4	2	3		1
Myalgia	10	55	10	52		3
Nasal congestion	2	4	2	4		
Nasal oedema		1		1		
Nasopharyngitis		1		1		
Nausea	5	29	5	28		1
Neck pain		3		2		1
Neuralgia		3				3
Neutrophil count increased		1		1		
Night sweats		1		1		
Oedema mucosal		1				1
Oedema peripheral		1				1
Off label use		2		2		
Oral discomfort		1		1		
Oral herpes	1	1	1	1		
Oropharyngeal pain		3		3		
Pain	1	5	1	4		1
Pain in extremity	3	10	3	8		2
Palatal swelling		1		1		
Palpitations		3				3
Paraesthesia	2	9	1	2	1	7
Paraesthesia oral	2	4	2	2		2
Peripheral coldness	1	3	1	2		1
Peripheral sensory neuropathy		1				1
Peripheral swelling		1		1		
Pharyngeal oedema		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal paraesthesia	1	1	1	1		
Photophobia	2	5	2	4		1
Polymenorrhoea	1	2	1	2		
Presyncope		1				1
Product use issue		1		1		
Pruritus		3		1		2
Pulse volume decreased		1		1		
Purpura		2				2
Pyrexia	14	88	14	76		12
Rash		3		2		1
Rash macular		1		1		
Rash pruritic		3		3		
Respiratory distress		1				1
Restless legs syndrome		1		1		
Rhabdomyolysis		1				1
Rhinorrhoea		1		1		
SARS-CoV-2 test positive		1				1
Sensitive skin	1	1	1	1		
Skin burning sensation		1				1
Skin tightness		1				1
Sleep disorder		1		1		
Sleep disorder due to general medical condition, insomnia type		1		1		
Somatic dysfunction		1				1
Somnolence	1	9	1	7		2
Stomatitis		1				1
Swelling face	2	2	1	1	1	1
Syncope	1	3			1	3
Tachycardia		6		1		5
Thirst		2		1		1
Throat irritation		4		4		
Throat tightness	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue spasm		1				1
Toothache		1		1		
Upper respiratory tract congestion		1		1		
Vaccination failure	1	2			1	2
Vaccination site discolouration		1		1		
Vaccination site erythema		12		10		2
Vaccination site haematoma		1				1
Vaccination site hyperaesthesia	1	1	1	1		
Vaccination site hypoaesthesia		1				1
Vaccination site inflammation		1		1		
Vaccination site lymphadenopathy		1		1		
Vaccination site mass		2				2
Vaccination site oedema	1	9	1	7		2
Vaccination site pain	11	76	11	73		3
Vaccination site pruritus		4		3		1
Vaccination site rash		2				2
Vaccination site reaction		2		2		
Vaccination site swelling	1	2	1	2		
Vaccination site warmth	1	6	1	5		1
Vertigo		3		3		
Vision blurred		1				1
Vomiting		7		6		1
	142	1,013	131	825	11	188

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal sensation in eye		1		1		
Angina pectoris		1				1
Anosmia		1				1
Arthralgia	2	13	1	12	1	1
Asthenia		5		3		2
Back pain		1		1		
Blepharitis		1		1		
Blood pressure decreased		1		1		
Body temperature increased	2	11	2	11		
Bundle branch block left		1				1
Chills		8		8		
COVID-19	1	4			1	4
Death	1	1			1	1
Disturbance in attention		3				3
Dizziness		2		1		1
Drug ineffective	1	2			1	2
Eye pain	1	4		3	1	1
Fatigue	2	16	1	10	1	6
Glossodynia	1	1	1	1		
Headache	2	11	1	9	1	2
Head discomfort		1		1		
Hyperhidrosis		2		2		
Hypertension		1		1		
Increased appetite		1		1		
Insomnia	1	1			1	1
Lymphadenopathy		1		1		
Migraine	1	2		1	1	1
Muscular weakness		2				2
Myalgia	2	15	1	13	1	2
Nausea		1		1		
Oropharyngeal pain		3		2		1
Pain	1	1	1	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in extremity		1		1		
Pruritus	1	1	1	1		
Pyrexia	1	8	1	5		3
Rash		1		1		
Rash maculo-papular	1	1	1	1		
Rhinorrhoea		1				1
Sleep disorder		1		1		
Somnolence		1		1		
Tachycardia		1				1
Thrombosis	1	1			1	1
Transient ischaemic attack		1				1
Tunnel vision		1				1
Urticaria	1	2		1	1	1
Urticaria papular	1	1			1	1
Vaccination failure		2				2
Vaccination site pain	1	9	1	8		1
Vasculitic rash		1		1		
Vertebrobasilar stroke		1				1
Vertigo		1		1		
	25	155	12	108	13	47

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
Axillary pain	1	1	1	1
Chills	1	1	1	1
COVID-19		1		1
Lymphadenopathy	1	1	1	1
Pyrexia	1	1	1	1
	5	6	5	6

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Country Where Event Occurred

LEBANON

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Back pain		1		1		
Cerebrovascular accident		1				1
Chest discomfort		1		1		
Chills		3		3		
Confusional state	1	1	1	1		
COVID-19	1	2		1	1	1
Decreased appetite		1		1		
Dermatitis allergic		1		1		
Dizziness		1		1		
Dysarthria	1	1	1	1		
Dysphonia		1				1
Dyspnoea		1		1		
Erythema		1				1
Extrasystoles		1				1
Eyelid ptosis	1	1			1	1
Fatigue	1	2		1	1	1
Headache	1	5		4	1	1
Hyperhidrosis		1		1		
Hypersensitivity		1				1
Hypertension	1	3	1	2		1
Hypoaesthesia		1		1		
Incorrect route of product administration		1		1		
Influenza		1		1		
Insomnia		1		1		
Irritable bowel syndrome		1		1		
Limb discomfort		1		1		
Loss of consciousness		1				1
Malaise		1		1		
Menstruation delayed	4	4	4	4		
Mood altered		1		1		
Muscle twitching		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscular weakness	1	1	1	1		
Myalgia		2		2		
Oropharyngeal pain		2		2		
Pain		1		1		
Pain in extremity		2		2		
Paraesthesia		2		2		
Paralysis	1	1			1	1
Pruritus		1				1
Pyrexia		3		3		
Rash		2				2
Respiratory tract oedema		1				1
Throat tightness		1				1
Thrombocytopenia	1	1			1	1
Urticaria		1		1		
Vaccination failure	1	1			1	1
Vaccination site pain		1		1		
Vision blurred		1		1		
Vomiting	1	1			1	1
	16	70	8	50	8	20

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Arthralgia		1		1		
Back pain		1		1		
Chills		1				1
Dyspnoea		1		1		
Facial paresis		1				1
Fatigue		1		1		
Flushing		1		1		
Hypertension		1				1
Panic attack		1		1		
Paraesthesia		1		1		
Pyrexia		1				1
Sciatica		1		1		
Speech disorder		1		1		
Tachycardia		1		1		
		15		10		5

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse event	1	1	1	1		
Allergic reaction to excipient		1		1		
Aphasia	1	1			1	1
Bell's palsy		1				1
Chest pain	1	1	1	1		
Chills		2		2		
COVID-19	3	16		3	3	13
Death		11				11
Dehydration		1		1		
Diarrhoea		1		1		
Drug ineffective	3	7			3	7
Embolism venous	1	1			1	1
Feeling cold		1		1		
Hypertension		2		2		
Hypoaesthesia	1	1	1	1		
Hypotension		1		1		
Incorrect route of product administration		1		1		
Inflammation	1	1	1	1		
Lack of spontaneous speech	1	1			1	1
Lung disorder		1				1
Myalgia	1	1	1	1		
Neurological symptom	2	2			2	2
Paraesthesia	1	2	1	2		
Product container issue	1	1	1	1		
Pyelonephritis		1				1
Pyrexia		2		2		
Rhinorrhoea		2		2		
Swelling face	1	1	1	1		
Tachycardia		1		1		
Throat irritation		2		2		
Vaccination failure		4				4
	19	72	8	29	11	43

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Country Where Event Occurred

LIECHTENSTEIN

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes zoster	1	1			1	1
Incorrect dose administered		1		1		
Neuralgia	1	1			1	1
Wrong product administered	1	1	1	1		
	3	4	1	2	2	2

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Country Where Event Occurred

LITHUANIA

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Abdominal pain upper		3		2		1
Accidental overdose		1				1
Anaphylactic reaction		2				2
Anaphylactic shock		1				1
Angina pectoris	1	4			1	4
Anxiety	1	2	1	1		1
Arrhythmia	3	4			3	4
Arthralgia	5	16	5	15		1
Asthenia	9	36	6	27	3	9
Atrial f brillation	1	1			1	1
Axillary pain		5		4		1
Back pain		1		1		
Balance disorder		1		1		
Bell's palsy		1				1
Blister	1	1			1	1
Blood pressure abnormal		1		1		
Blood pressure ambulatory increased		1		1		
Blood pressure decreased		2				2
Blood pressure fluctuation	1	3	1	2		1
Blood pressure increased	2	9		2	2	7
Body temperature increased	1	5	1	4		1
Bone pain	2	7	2	7		
Cardiogenic shock		1				1
Chest discomfort	1	2	1	1		1
Chest pain		1		1		
Chills	3	21	3	19		2
Chronic sinusitis		1		1		
Cognitive disorder		1				1
Cold sweat	1	2		1	1	1
Condition aggravated	1	3	1	1		2
Confusional state		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Convulsions local		1				1
Coordination abnormal		1				1
Cough	1	3	1	3		
COVID-19 pneumonia		1				1
Death		1				1
Decreased appetite	1	3	1	3		
Deep vein thrombosis		1				1
Depressed level of consciousness	1	2			1	2
Diarrhoea	1	7	1	5		2
Discomfort	1	1	1	1		
Disorientation		2				2
Dizziness	5	17	5	13		4
Dry mouth	2	2	1	1	1	1
Dysgeusia		1		1		
Dyspepsia		1		1		
Dysphagia	1	2			1	2
Dyspnoea	5	9	4	6	1	3
Dyspraxia	1	1	1	1		
Ear disorder	1	1			1	1
Ear pain	1	2	1	2		
Epilepsy		1				1
Epistaxis	1	1	1	1		
Erythema		3		2		1
Exposure during pregnancy		1		1		
Extrasystoles	1	1	1	1		
Eye disorder	1	2	1	2		
Eye irritation	1	1	1	1		
Eyelid function disorder		1				1
Eye pain		3		3		
Eye swelling	1	1	1	1		
Facial asymmetry		1				1
Facial nerve disorder		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial paralysis		4				4
Fatigue	2	8	2	7		1
Feeling abnormal	2	3	1	2	1	1
Feeling drunk		1		1		
Feeling hot	1	3		1	1	2
Flatulence		1		1		
Gait disturbance	1	2			1	2
Groin pain	1	1	1	1		
Haemorrhagic stroke	1	1			1	1
Headache	9	38	9	31		7
Head discomfort	1	2	1	2		
Heart rate increased	1	9		5	1	4
Heart rate irregular		1		1		
Heavy menstrual bleeding	1	1	1	1		
Herpes simplex		1		1		
Hot flush		1		1		
Hyperhidrosis	2	4	1	3	1	1
Hypersensitivity	1	2			1	2
Hypertension	1	3		1	1	2
Hypertensive crisis		1				1
Hypoacusis		1		1		
Hypoaesthesia	1	10		8	1	2
Hypoaesthesia oral		1				1
Hypotension	1	2			1	2
Injected limb mobility decreased		1		1		
Injection site pain		1		1		
Insomnia	2	4	2	4		
Irritability		1				1
Lacrimation increased		1				1
Limb discomfort	1	1	1	1		
Lip swelling		1		1		
Local reaction		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Loss of consciousness	3	7			3	7
Lymphadenopathy	1	8	1	7		1
Lymph node abscess	6	15			6	15
Lymph node pain		1				1
Lymph node palpable		1				1
Malaise	1	4	1	2		2
Memory impairment	1	2	1	2		
Menstrual disorder	1	1	1	1		
Menstruation delayed	1	1	1	1		
Mental impairment	1	1			1	1
Mobility decreased		1		1		
Muscle spasms		1		1		
Muscle twitching		1		1		
Muscular weakness	1	3	1	3		
Musculoskeletal chest pain	1	1	1	1		
Musculoskeletal stiffness		1		1		
Myalgia	3	17	3	15		2
Myositis		1		1		
Nasal congestion	1	3		2	1	1
Nasopharyngitis	3	6	3	6		
Nausea	7	21	7	17		4
Neck pain		3		3		
Neuralgia		1				1
Night sweats	1	1	1	1		
Non-cardiac chest pain		1		1		
Oropharyngeal pain	1	2	1	2		
Pain	1	3	1	2		1
Pain in extremity	5	21	5	20		1
Pain of skin		1		1		
Pallor	1	2			1	2
Palpitations	2	2			2	2
Panic attack	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia	2	6	1	4	1	2
Paraesthesia oral	1	1	1	1		
Paralysis	1	1			1	1
Paresis		1				1
Peripheral coldness	1	2		1	1	1
Peripheral swelling	2	6	2	5		1
Peritonitis		1				1
Pharyngeal disorder	1	1			1	1
Phlebitis	1	1			1	1
Photophobia	1	1	1	1		
Pneumonia		1				1
Polymyositis		1				1
Product preparation issue		1				1
Pruritus	3	5	2	4	1	1
Pulmonary embolism	1	1			1	1
Pulse abnormal	1	1			1	1
Pyrexia	10	34	10	33		1
Rash	3	3	2	2	1	1
Rash papular		1				1
Respiratory rate increased	1	1			1	1
Rhinorrhoea	1	2	1	2		
Seizure		5				5
Sensation of foreign body		1				1
Skin mass		1				1
Somnolence	1	5	1	5		
Speech disorder	1	1			1	1
Stress		1		1		
Swelling	2	2	1	1	1	1
Swelling face	1	2		1	1	1
Swollen tongue	1	1	1	1		
Syncope	1	7			1	7
Tachycardia	4	6	2	3	2	3

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Taste disorder		1				1
Tendon pain		1		1		
Thermal burns of eye	1	1			1	1
Throat tightness	1	1			1	1
Thrombophlebitis	1	1			1	1
Thrombosis	1	2			1	2
Tinnitus		2		1		1
Tongue dry	1	1			1	1
Tongue movement disturbance	1	1			1	1
Tremor	3	7		3	3	4
Underdose		1		1		
Urinary incontinence		1		1		
Urticaria	2	2	1	1	1	1
Vaccination failure		1				1
Vaccination site erythema	3	14	3	13		1
Vaccination site induration		1		1		
Vaccination site inflammation		1		1		
Vaccination site mass	1	1	1	1		
Vaccination site pain	8	28	7	26	1	2
Vaccination site pruritus		1		1		
Vaccination site reaction		1		1		
Vaccination site swelling		10		9		1
Vaccination site warmth		3		2		1
Visual impairment		1		1		
Vomiting	2	8	2	4		4
	197	660	128	445	69	215

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Angina pectoris		1				1
Apathy		1		1		
Arthralgia		4		4		
Asthenia	3	4	1	2	2	2
Back pain		1		1		
Blood pressure decreased	1	1			1	1
Body temperature increased	1	1			1	1
Cardiac arrest	1	1			1	1
Chills		1		1		
Cold sweat	1	1			1	1
Cough		2		2		
COVID-19		1		1		
Death	1	3			1	3
Dizziness	1	2		1	1	1
Dry eye		1		1		
Dyspnoea	1	2		1	1	1
Ear pain	1	2	1	2		
Eye irritation		1		1		
Eye pain		2		2		
Feeling of body temperature change		1		1		
Headache		3		3		
Induration	1	1			1	1
Joint swelling	1	1			1	1
Lacrimation increased		2		2		
Lymphopenia	1	1	1	1		
Malaise	1	1			1	1
Mucosal disorder		1		1		
Myalgia		6		6		
Off label use		1		1		
Overdose		1		1		
Pain in extremity	1	3		2	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pallor	1	1			1	1
Peripheral swelling	1	1			1	1
Peritonsillar abscess		1				1
Pneumonia	1	1			1	1
Product use issue		1		1		
Pulmonary oedema		1				1
Pyrexia		6		6		
Rash	1	2		1	1	1
Rash maculo-papular	1	2		1	1	1
Sensitive skin		1		1		
Skin discolouration	1	1			1	1
Slow response to stimuli		1		1		
Sneezing		1		1		
Somnolence		1		1		
Syncope	1	1			1	1
Tonsillar hypertrophy		1		1		
Tremor		1		1		
Vaccination complication		1		1		
Vaccination site pain		2		2		
	24	82	3	56	21	26

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		1		1		
Bone pain		1		1		
Chronic gastritis		1		1		
Diverticulum		1		1		
Haemolytic anaemia		1				1
Headache		1		1		
Myalgia		1		1		
Pruritus		1		1		
Pyrexia		1		1		
Vaccination site erythema		1		1		
		10		9		1

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Country Where Event Occurred

LUXEMBOURG

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- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1				1
Abdominal pain upper		1				1
Acute coronary syndrome		1				1
Allergic oedema		1		1		
Anaphylactic reaction	1	1			1	1
Anxiety		3		2		1
Apathy	1	1			1	1
Arrhythmia		1				1
Arthralgia	4	16	3	6	1	10
Asthenia	1	3			1	3
Asthmatic crisis		1				1
Back pain	1	1	1	1		
Blood pressure fluctuation	1	1	1	1		
Blood pressure increased		1				1
Bradyphrenia		1				1
Cerebrovascular accident	1	1			1	1
Chest discomfort	3	6			3	6
Chest pain	1	2			1	2
Chillblains		1		1		
Chills	3	19	3	6		13
Coma	1	1			1	1
Confusional state	1	1			1	1
Cough		1				1
C-reactive protein	1	1	1	1		
Decreased appetite	1	2			1	2
Dermatitis allergic		1				1
Dermatitis bullous		1				1
Diarrhoea		7		1		6
Diplopia		1				1
Dizziness	1	6	1	1		5
Dry mouth		1				1
Dry skin		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysaesthesia		1				1
Dysgeusia		1				1
Dysphonia		1				1
Dyspnoea	2	6			2	6
Dyspnoea exertional	2	3			2	3
Epilepsy		3				3
Epistaxis	1	2	1	1		1
Erythema	2	2			2	2
Erythema nodosum		1				1
Eyelid oedema		2		1		1
Eye movement disorder		1				1
Eye swelling	1	1			1	1
Face oedema		2				2
Facial pain	1	1	1	1		
Facial paralysis	1	1			1	1
Fall		1				1
Fatigue	11	32	7	9	4	23
Feeding disorder		1				1
Feeling abnormal		1				1
Feeling cold	1	1			1	1
Feeling hot		1				1
Gait disturbance	1	1			1	1
General physical health deterioration		1				1
Haematoma		1		1		
Headache	11	39	9	12	2	27
Hemiparaesthesia		1				1
Hemiparesis	1	1			1	1
Herpes zoster		1		1		
Hyperhidrosis		1				1
Hypersensitivity		3				3
Hypersomnia	1	1			1	1
Hypertension	2	8		1	2	7

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperthermia		1		1		
Hypoaesthesia		1				1
Hypotension	3	6	2	2	1	4
Hypotonia	1	1	1	1		
Illness	1	1	1	1		
Influenza		4				4
Insomnia	1	1	1	1		
Joint swelling	1	1			1	1
Laryngeal discomfort		1				1
Limb discomfort	1	1			1	1
Lip pain	1	1	1	1		
Loss of consciousness	1	2			1	2
Lymphadenitis	1	1	1	1		
Lymphadenopathy	2	5		3	2	2
Lymph node pain	1	1			1	1
Malaise	2	11	2	3		8
Migraine		1				1
Musculoskeletal stiffness		2				2
Myalgia	7	26	4	7	3	19
Nausea	4	13	4	5		8
Neck pain	2	3		1	2	2
Oral herpes		1		1		
Oropharyngeal discomfort	1	2			1	2
Oxygen saturation decreased		1				1
Pain	2	3	1	1	1	2
Pain in extremity	2	6	2	4		2
Palpitations		1				1
Panic attack		1		1		
Panic reaction	1	1	1	1		
Paraesthesia	1	3			1	3
Paraesthesia oral		1		1		
Paresis		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral coldness		1				1
Peripheral swelling	1	4	1	3		1
Pharyngeal paraesthesia	1	1			1	1
Pneumonia		1				1
Presyncope	2	2	2	2		
Productive cough		1				1
Pruritus	2	7	1	2	1	5
Psoriasis	1	1	1	1		
Pulmonary embolism		1				1
Pulmonary pain		1				1
Pyrexia	7	22	4	5	3	17
Rash		2				2
Respiratory failure		1				1
SARS-CoV-2 ant body test negative		1				1
Skin haemorrhage		1				1
Skin plaque	1	1	1	1		
Somnolence		1				1
Swelling		1				1
Swelling face	1	3		1	1	2
Tachycardia		4				4
Tetany		1		1		
Therapeutic response unexpected		1		1		
Throat tightness		1				1
Tinnitus		1				1
Tongue ulceration		1				1
Tremor		2		1		1
Urinary incontinence		1				1
Urinary tract infection		1		1		
Urticaria	1	2	1	2		
Uveitis	1	1			1	1
Vaccination complication		3				3
Vaccination site induration	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	3	5	3	3		2
Vaccination site reaction	6	23	6	18		5
Vaccination site swelling	1	1	1	1		
Venous thrombosis limb	1	1			1	1
Vertigo	1	2	1	2		
Vitamin B12 deficiency		1				1
Vlth nerve paralysis		1				1
Vomiting		4				4
Wheezing		2				2
	127	428	72	130	55	298

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1				1
Acute kidney injury		1				1
Altered state of consciousness		1				1
Arrhythmia		1				1
Arthralgia	3	7		1	3	6
Asthenia	1	2		1	1	1
Atrial f brillation		1				1
Back pain		1		1		
Bone pain	1	1			1	1
Cardiac arrest	1	1			1	1
Carotid arteriosclerosis	1	1	1	1		
Cerebral haemorrhage		1				1
Cervical radiculopathy	1	1			1	1
Chest pain		1		1		
Chills	2	2			2	2
Claudication of jaw muscles	1	1			1	1
Confusional state	1	1			1	1
Conjunctivitis		1				1
COVID-19 pneumonia		1				1
C-reactive protein increased	2	2	1	1	1	1
Deafness	1	1			1	1
Deep vein thrombosis	2	3			2	3
Dizziness		1				1
Dry mouth		1				1
Dysphonia		1				1
Dyspnoea	1	2			1	2
Eye pain		1				1
Fall		1				1
Fatigue	5	11	4	4	1	7
Formication		1				1
Generalised tonic-clonic seizure	1	1			1	1
Haematoma	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemoglobin decreased		1				1
Headache	5	13	1	4	4	9
Heart rate increased		1				1
Hot flush		1				1
Hyperhidrosis		1				1
Hypernatraemia		1				1
Hypersomnia		1		1		
Hypertension		1				1
Hypertensive crisis	1	1			1	1
Hyperthermia		1				1
Hypotension		1				1
Hypoxia		1				1
Inflammation	1	1			1	1
Influenza		1		1		
Injected limb mobility decreased		1				1
Injection site reaction		1		1		
Insomnia	1	2			1	2
Loss of consciousness		1				1
Lung disorder		1				1
Lymphadenopathy	2	3	1	1	1	2
Lymphoedema	1	1			1	1
Malaise	1	2			1	2
Muscular weakness	1	2			1	2
Myalgia	3	9	1	3	2	6
Nasopharyngitis		1		1		
Nausea		2				2
Neck pain	1	2			1	2
Pain in extremity	1	3	1	1		2
Pallor		1				1
Palpitations		2				2
Paraesthesia		1				1
Phlebitis	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonia	1	1			1	1
Pneumonia aspiration	1	1			1	1
Presyncope		1				1
Pruritus		1				1
Pulmonary embolism	1	3			1	3
Pulse abnormal		1				1
Pyrexia	6	9	4	5	2	4
Rash	1	2			1	2
Rectal haemorrhage		1				1
Sepsis		1				1
Speech disorder	1	1			1	1
Subdural haematoma	1	1			1	1
Tachycardia	1	1			1	1
Tonsillitis bacterial	1	1			1	1
Tremor		1				1
Vaccination complication	1	2			1	2
Vaccination site pain	2	3			2	3
Vaccination site reaction	2	8	2	6		2
Weight decreased	1	1			1	1
	64	156	16	34	48	122

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19		1				1
Drug ineffective		1				1
Fear of injection		1		1		
Influenza		1		1		
Lymphadenopathy		1		1		
Myalgia		1		1		
Vaccination complication		1		1		
		7		5		2

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* AE=Adverse Event
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Country Where Event Occurred

MACAO

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute coronary syndrome		1		1
Bell's palsy	1	1	1	1
	1	2	1	2

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Facial paralysis	3	3	3	3
	3	3	3	3

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Country Where Event Occurred
MACEDONIA, THE FORMER YUGOSLAV

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		1		1		
Asthenia		1		1		
Body temperature increased	1	2	1	2		
COVID-19	1	1			1	1
Eye oedema	1	1	1	1		
Headache		3		3		
Hypersensitivity	1	1	1	1		
Incorrect route of product administration		1		1		
Lip oedema	1	1	1	1		
Loss of consciousness		1				1
Malaise	1	2	1	2		
Myalgia	1	2	1	2		
Nasopharyngitis		1		1		
Pneumonia	1	1			1	1
Pyrexia	1	1	1	1		
Rhinorrhoea		1		1		
Vaccination site pain		1		1		
	9	22	7	19	2	3

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Body temperature increased		1		1
Headache	1	1	1	1
Malaise	1	2	1	2
Myalgia	1	1	1	1
Pyrexia	2	3	2	3
Rash maculo-papular		1		1
Vaccination site pain	1	1	1	1
	6	10	6	10

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Country Where Event Occurred

MALAYSIA

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- * AE=Adverse Event
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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1			1	1
Abdominal pain upper	1	1			1	1
Abdominal sepsis	1	1			1	1
Asthenia		1		1		
Blood uric acid increased	1	1			1	1
Cardiac disorder	1	1			1	1
Cellulitis		1				1
Death	1	2			1	2
Fatigue		1		1		
Gastrointestinal necrosis	1	1			1	1
Headache		1		1		
Heavy menstrual bleeding	1	1	1	1		
Hepatic function abnormal	1	1			1	1
Hypoaesthesia		1		1		
Intestinal ischaemia	1	1			1	1
Labile blood pressure	1	1			1	1
Loss of consciousness	1	1			1	1
Malaise	1	2		1	1	1
Maternal exposure during pregnancy	2	3	2	3		
Nausea	1	1			1	1
Perforation	1	1			1	1
Pityriasis rosea		1		1		
Pyrexia		1		1		
Rash	1	1	1	1		
Rash erythematous		1		1		
Rash papular		1		1		
Renal impairment	1	1			1	1
Septic shock	1	1			1	1
Skin discolouration	1	1	1	1		
Skin necrosis		1				1
Speech disorder	1	1			1	1
Thrombosis	1	1			1	1

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site erythema		1		1		
Vaccination site pain	1	2	1	2		
Vaccination site swelling	1	1	1	1		
Vaccination site warmth		1		1		
Vomiting	1	1			1	1
	26	42	7	20	19	22

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amnesia	1	1	1	1		
Cerebral infarction	1	1			1	1
Dizziness		1		1		
Haemorrhagic stroke	1	1			1	1
Haemorrhagic transformation stroke	1	1			1	1
Memory impairment	1	1	1	1		
Saliva altered	1	1	1	1		
Seizure		1				1
Vaccination site pain		1		1		
	6	9	3	5	3	4

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* AE=Adverse Event

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactoid reaction	1	1			1	1
Bronchospasm	1	1			1	1
Constipation		1		1		
Contusion	1	1	1	1		
COVID-19		1		1		
Disseminated intravascular coagulation	1	1			1	1
Hair texture abnormal		1		1		
Headache		1		1		
Musculoskeletal stiffness		1		1		
Neuropathy peripheral		2				2
No adverse event	4	5	4	5		
Platelet count decreased	1	1	1	1		
Product complaint	1	1	1	1		
Urticaria	1	1	1	1		
	11	19	8	14	3	5

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Country Where Event Occurred

MALTA

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		2		2		
Activated partial thromboplastin time prolonged		2		2		
Activated partial thromboplastin time ratio increased		1		1		
Acute kidney injury	1	1			1	1
Alanine aminotransferase increased		1		1		
Altered state of consciousness	1	2			1	2
Anaphylactic reaction		7				7
Angioedema		2				2
Arrhythmia	1	1			1	1
Arthralgia	1	3	1	3		
Arthritis infective		1				1
Asthenia		3		2		1
Asthma		2				2
Atrial f brillation	1	1			1	1
Bell's palsy		1				1
Blood alkaline phosphatase increased		2		2		
Blood calcium decreased		1		1		
Blood osmolarity increased		1		1		
Blood urea increased		1		1		
Bone pain		1		1		
Bronchospasm		3				3
Burning sensation		2		1		1
Cardiac arrest		2				2
Cardiac failure congestive	1	1			1	1
Cerebellar atrophy		1				1
Cerebral atrophy		1				1
Chest discomfort		2				2
Chest pain		2		1		1
Chills	4	10	4	10		
Cough		2		1		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	6		1	1	5
COVID-19 pneumonia		1				1
C-reactive protein increased		2		2		
Decreased appetite		1		1		
Deep vein thrombosis	2	2			2	2
Defaecation urgency		1		1		
Dehydration		1		1		
Diarrhoea		3		2		1
Dizziness		4		4		
Drug ineffective		2				2
Dysgeusia		2		1		1
Dysphagia		1				1
Dysphonia		3				3
Dyspnoea		6				6
Ear swelling		1		1		
Erythema	1	7	1	4		3
Eye swelling		1				1
Facial paralysis		2				2
Fatigue	2	14	2	14		
Feeling abnormal		1		1		
Feeling of body temperature change		1				1
Flushing		2				2
Gait disturbance		1		1		
Gait inability		1		1		
Generalised tonic-clonic seizure		1				1
Goitre		1		1		
Haematemesis		1				1
Haematocrit decreased		2		2		
Haemoglobin decreased		2		2		
Headache	1	4	1	4		
Heart rate increased		2		1		1
Hot flush		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperhidrosis	1	3	1	3		
Hypersensitivity	2	8	2	4		4
Hypertension		2		1		1
Hypoaesthesia		3		3		
Hypothermia		1				1
Hypoxia		2				2
Impaired healing	1	1			1	1
Influenza like illness	1	1	1	1		
Injection		1		1		
Insomnia	2	3	2	3		
International normalised ratio increased		1		1		
Lethargy	2	7	1	6	1	1
Limb discomfort	3	5	3	4		1
Lip swelling		1				1
Loss of consciousness		2				2
Lymphadenopathy	2	3	2	3		
Lymphocyte count decreased		2		2		
Malaise	1	5	1	5		
Mean cell haemoglobin concentration decreased		1		1		
Mean cell haemoglobin concentration increased		1		1		
Mean cell volume increased		1		1		
Mean platelet volume decreased		1		1		
Migraine		1		1		
Mobility decreased		1		1		
Monocyte count decreased		1		1		
Musculoskeletal stiffness	1	3	1	3		
Myalgia	2	8	2	8		
Nausea	1	6	1	3		3
Neck pain		2		2		
Neoplasm progression		1				1
Neutrophil count increased		2		2		
Night sweats		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Normochromic normocytic anaemia		1		1		
Off label use		2		2		
Overdose		1		1		
Oxygen saturation decreased		1		1		
Pain	3	9	3	9		
Pain in extremity	3	10	3	9		1
Palpitations		5		1		4
Panic reaction		1		1		
Paraesthesia	3	8	3	8		
Paraesthesia oral		2		2		
Pericardial effusion	1	1			1	1
Peripheral coldness	1	2	1	2		
Peripheral swelling		1		1		
Pigmentation disorder	1	1	1	1		
Platelet count decreased		1		1		
Platelet count increased		1		1		
Poor peripheral circulation		1		1		
Product administered at inappropriate site		1		1		
Product use issue		1		1		
Prothrombin time prolonged		1		1		
Pruritus		8		4		4
Pulmonary artery thrombosis	1	1			1	1
Pulmonary embolism	1	1			1	1
Pyrexia	4	16	4	16		
Rash	1	7	1	3		4
Rash erythematous		3		1		2
Rash pruritic		2				2
Red blood cell count decreased		2		2		
Red cell distribution width increased		1		1		
Respiratory arrest		2				2
Respiratory depression		1				1
Respiratory distress		3				3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory failure		1				1
Restlessness	1	1	1	1		
Reticulocyte count increased		1		1		
Sepsis		1				1
Septic shock		1				1
Sinus tachycardia		1				1
Somnolence		3		3		
Swelling		2				2
Swelling face		4		1		3
Swollen tongue		1				1
Syncope		3				3
Tachycardia		4				4
Tachypnoea		3				3
Throat tightness		1				1
Thrombocytopenia	1	2			1	2
Traumatic haemorrhage	1	1			1	1
Tremor		1				1
Ulcer		1		1		
Urticaria		1				1
Use of accessory respiratory muscles		2				2
Vaccination failure	1	3			1	3
Vaccination site discomfort		1		1		
Vaccination site erythema		1		1		
Vaccination site induration		1		1		
Vaccination site movement impairment		1		1		
Vaccination site pain	2	6	2	6		
Vaccination site pruritus		2		2		
Vaccination site rash		1		1		
Vaccination site urticaria		2		1		1
Vertigo	1	1	1	1		
Vision blurred		2				2
Vomiting	1	4	1	3		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Wheezing		2				2
	63	384	47	237	16	147

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	3			1	3
Altered state of consciousness	1	1			1	1
Anaphylactic reaction		1				1
Arthralgia	1	3	1	3		
Arthritis reactive	1	1			1	1
Atrial f brillation		1				1
Basophil count increased		1		1		
Bell's palsy		2				2
Blood creatinine increased		1		1		
Blood glucose increased		1		1		
Blood magnesium decreased		1		1		
Blood phosphorus decreased		1		1		
Blood urea increased		1		1		
Bone pain		1		1		
Cardiac failure	1	1			1	1
Cardiac failure congestive	1	1			1	1
Cerebral atrophy		1				1
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident	1	2			1	2
Chills	1	3	1	3		
Cough		1		1		
COVID-19	1	5			1	5
COVID-19 pneumonia		1				1
C-reactive protein increased		1		1		
Deafness	1	1			1	1
Deep vein thrombosis	1	2			1	2
Diarrhoea	1	1	1	1		
Discomfort	1	1	1	1		
Drug ineffective	1	3			1	3
Dyspnoea	1	1			1	1
Ear swelling		1		1		
Eosinophil count decreased		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema		2		2		
Fatigue		4		2		2
Fine motor skill dysfunction	1	1	1	1		
Flushing		1		1		
Fungal skin infection		1		1		
Grip strength decreased	1	1	1	1		
Haematocrit decreased		1		1		
Haemoglobin decreased		1		1		
Headache	1	4	1	4		
Hemiplegia	1	1			1	1
Hot flush		1		1		
Hypersensitivity		2		2		
Hypertension		1				1
Hypoaesthesia	1	2	1	1		1
Hypoxia	1	2			1	2
Immature granulocyte count increased		1		1		
Inappropriate schedule of product administration	1	1	1	1		
Influenza like illness		1		1		
Lethargy	1	7		6	1	1
Lymphadenopathy	1	2	1	2		
Lymphocyte count decreased		1		1		
Malaise		2		2		
Monocyte count increased		1		1		
Mouth ulceration		1		1		
Muscle spasms		1		1		
Muscle twitching		1		1		
Myalgia		3		3		
Nausea	1	2	1	2		
Neck pain		1		1		
Neutrophil count increased		1		1		
Nucleated red cells		1		1		
Ocular hyperaemia		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral pain		1		1		
Oropharyngeal pain		1		1		
Pain		1		1		
Pain in extremity		2		1		1
Parosmia		1		1		
Periorbital swelling		1		1		
Platelet count increased		1		1		
Pulmonary embolism		1				1
Pyrexia	2	11	2	9		2
Rash	1	2	1	2		
Red blood cell count decreased		1		1		
Red cell distribution width increased		1		1		
Renal failure	1	1			1	1
Respiratory failure	1	1			1	1
Retinal vein occlusion		1				1
Sepsis	1	2			1	2
Soft tissue swelling	1	1	1	1		
Speech disorder	1	1	1	1		
Swelling		1				1
Swelling face		1		1		
Tachypnoea	1	1			1	1
Taste disorder		1		1		
Thrombocytopenia	1	1			1	1
Thrombosis		1				1
Tinnitus	2	2			2	2
Tongue ulceration		1		1		
Toothache		1		1		
Urinary retention	1	1			1	1
Urinary tract infection	1	2		1	1	1
Urosepsis		1				1
Urticaria		1		1		
Vaccination failure		2				2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	1	9	1	9		
White blood cell count increased		1		1		
	41	158	17	102	24	56

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Asthenia	1	1	1	1		
Fatigue	1	1	1	1		
Fear of injection		1		1		
Headache	1	1	1	1		
Hot flush		1		1		
Lip swelling	1	1	1	1		
Periorbital swelling	1	1			1	1
Pruritus	1	1	1	1		
Syncope		1				1
Urticaria	1	1	1	1		
Vaccination site pain	1	1	1	1		
	9	12	8	10	1	2

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Country Where Event Occurred

MEXICO

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	5	2	4		1
Abdominal distension	3	4	3	4		
Abdominal pain	208	342	187	303	21	39
Abdominal pain lower	1	2	1	2		
Abdominal pain upper	4	10	4	9		1
Abdominal symptom		1		1		
Abnormal faeces	2	6	2	4		2
Abnormal sensation in eye	1	1	1	1		
Abscess	5	9	5	8		1
Accidental overdose	1	1			1	1
Acne		2		2		
Advanced sleep phase	1	1	1	1		
Ageusia	2	6	2	5		1
Aggression		2		2		
Agitation	7	8	5	6	2	2
Akathisia		1		1		
Allergy to vaccine		4		3		1
Allodynia	1	3	1	3		
Altered state of consciousness	1	1			1	1
Amnesia	1	2	1	1		1
Anaesthesia	1	1			1	1
Analgesic therapy	1	1	1	1		
Anaphylactic reaction		24				24
Anaphylactic shock	3	43			3	43
Angina pectoris		1				1
Angina unstable	1	1			1	1
Angioedema	1	11			1	11
Anosmia	27	46	27	43		3
Antibody test abnormal		1		1		
Antibody test negative		1		1		
Anxiety	38	70	31	54	7	16
Aphasia		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphonia	4	6	4	6		
Aphthous ulcer		2		2		
Application site hypoaesthesia	1	1	1	1		
Application site induration	1	1	1	1		
Application site oedema	1	1	1	1		
Application site pain	8	8	8	8		
Areflexia	1	1			1	1
Arrhythmia		6				6
Arthralgia	845	1,276	788	1164	57	112
Arthritis	1	2		1	1	1
Arthropathy	1	1	1	1		
Asphyxia	1	1			1	1
Asterix		1				1
Asthenia	1,151	1,757	1053	1581	98	176
Asthma	3	5	3	5		
Asthmatic crisis	1	2			1	2
Asymptomatic COVID-19		1				1
Ataxia		1		1		
Atrial f brillation	1	2			1	2
Atrophy		1		1		
Auricular swelling	1	2	1	2		
Axillary pain	7	11	7	11		
Axonal neuropathy		1				1
Back pain	43	70	36	60	7	10
Balance disorder	1	5	1	3		2
Bell's palsy	1	6			1	6
Blepharitis	1	2	1	2		
Blepharospasm		1		1		
Blindness		1				1
Blindness transient		1				1
Blister	3	5	3	5		
Blood glucose abnormal	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood glucose increased	3	6	1	4	2	2
Blood pressure abnormal	17	17	10	10	7	7
Blood pressure ambulatory abnormal	1	1			1	1
Blood pressure ambulatory increased	1	1	1	1		
Blood pressure decreased	2	3	2	2		1
Blood pressure diastolic increased	2	3	1	2	1	1
Blood pressure fluctuation	6	6	6	6		
Blood pressure increased	107	148	68	93	39	55
Blood pressure systolic increased	6	6	3	3	3	3
Body temperature abnormal	1	1			1	1
Body temperature decreased		1		1		
Body temperature fluctuation		1				1
Body temperature increased	196	323	180	294	16	29
Bone pain	2	4	1	2	1	2
Bowel movement irregularity	1	1	1	1		
Bradycardia	1	14			1	14
Bradykinesia	1	1			1	1
Brain oedema		1				1
Brain stem ischaemia		2				2
Breast pain	4	5	3	4	1	1
Bronchial disorder		2		2		
Bronchitis	1	1	1	1		
Bronchospasm	27	90	18	48	9	42
Bruxism	1	1			1	1
Burning sensation	8	14	8	10		4
Cardiac failure	1	1			1	1
Cardio-respiratory arrest		1				1
Cardiovascular disorder		1		1		
Cellulitis	8	43			8	43
Cerebral infarction		1				1
Cerebral ischaemia		1				1
Cerebral small vessel ischaemic disease	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebrovascular accident		2				2
Cheilitis	3	4	2	3	1	1
Chest discomfort	33	51	32	45	1	6
Chest pain	74	150	61	121	13	29
Chest X-ray abnormal	1	1	1	1		
Chills	808	1,220	759	1110	49	110
Choking sensation		1				1
Choluria	1	2	1	1		1
Chorea	1	1			1	1
Chromaturia	1	1	1	1		
Circumoral oedema	2	2	1	1	1	1
Circumstance or information capable of leading to medication error	1	1	1	1		
Clonic convulsion		1				1
Cold sweat	1	1	1	1		
Colitis	1	2	1	2		
Condition aggravated		4		2		2
Confusional state	2	4	2	3		1
Conjunctival disorder	1	1			1	1
Conjunctival haemorrhage	1	5			1	5
Conjunctival hyperaemia	4	8	4	7		1
Conjunctival irritation	1	1	1	1		
Conjunctivitis	10	22	10	22		
Constipation	2	2	1	1	1	1
Contusion	1	4	1	4		
Conversion disorder		2		2		
Coordination abnormal	1	1	1	1		
Cough	355	598	323	524	32	74
Counterfeit product administered	1	2	1	2		
COVID-19	18	49	13	30	5	19
COVID-19 pneumonia		3				3
C-reactive protein abnormal	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
C-reactive protein increased		1		1		
Crying	33	59	31	54	2	5
Cyanosis	4	7	2	5	2	2
Cystitis		1		1		
Deafness		1				1
Deafness bilateral	1	1			1	1
Deafness unilateral		2				2
Death	1	3			1	3
Decreased activity		1		1		
Decreased appetite	95	166	91	155	4	11
Deep vein thrombosis	1	1			1	1
Dehydration	1	3	1	3		
Delirium		1				1
Demyelination		3				3
Depressed level of consciousness	3	7			3	7
Depression	1	1	1	1		
Dermatitis	1	1	1	1		
Dermatitis allergic	1	3	1	3		
Dermatosis		2		2		
Diabetic ketoacidosis		1				1
Diarrhoea	257	408	226	352	31	56
Diarrhoea haemorrhagic		1				1
Diffuse large B-cell lymphoma		1				1
Diplegia		1				1
Discharge		1		1		
Discomfort	84	111	79	103	5	8
Disease recurrence		4		2		2
Disorientation	1	6	1	5		1
Disseminated Bacillus Calmette-Guerin infection	1	8			1	8
Disturbance in attention		1		1		
Diverticulum intestinal		1				1
Dizziness	1,018	1,580	907	1359	111	221

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness postural	1	2	1	2		
Drug hypersensitivity		2				2
Drug ineffective	5	17			5	17
Dry mouth	22	38	20	30	2	8
Dry skin	1	1	1	1		
Dry throat	5	7	5	6		1
Dysaesthesia	6	9	6	8		1
Dysarthria	4	7	1	4	3	3
Dysgeusia	27	50	27	46		4
Dyskinesia	1	1	1	1		
Dyslalia	2	3	1	1	1	2
Dysmenorrhoea	1	2	1	2		
Dyspepsia		2		2		
Dysphagia	12	29	5	18	7	11
Dysphonia	11	19	6	12	5	7
Dyspnoea	77	572	57	431	20	141
Dyspnoea at rest		1				1
Dyspnoea exertional	2	7		5	2	2
Dysstasia	2	2	2	2		
Dystonia		1				1
Ear discomfort	1	3	1	3		
Ear disorder	2	3	2	3		
Ear infection		2		2		
Ear pain	13	17	11	14	2	3
Ear pruritus	1	1	1	1		
Eating disorder		1		1		
Eating disorder symptom	2	2	2	2		
Ecchymosis	1	3	1	2		1
Electric shock sensation	1	2	1	1		1
Embolism		2				2
Emotional disorder	1	1	1	1		
Encephalitis	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Encephalitis post immunisation		1				1
Enterococcal infection	1	1			1	1
Epigastric discomfort		1		1		
Epiglottic oedema		1				1
Epilepsy		1				1
Epistaxis	5	11	5	10		1
Eructation	1	1	1	1		
Erythema	230	393	209	348	21	45
Expired product administered	1	3	1	3		
Exposure during pregnancy	2	5	2	5		
Extensor plantar response	1	1			1	1
External ear inflammation		1		1		
Eye discharge	1	2	1	2		
Eye disorder	1	4	1	4		
Eye haemorrhage	2	2			2	2
Eye inflammation	1	2		1	1	1
Eye injury	18	31	15	24	3	7
Eye irritation	9	21	9	21		
Eyelid irritation	1	1	1	1		
Eyelid oedema	21	29	16	22	5	7
Eyelid pain	1	2		1	1	1
Eyelid ptosis		4		4		
Eyelid rash		1		1		
Eyelid sensory disorder	1	2	1	2		
Eyelids pruritus		1		1		
Eye oedema	1	1	1	1		
Eye pain	37	50	34	46	3	4
Eye pruritus	3	7	3	7		
Eye swelling	1	4	1	3		1
Face oedema	6	13	5	12	1	1
Facial discomfort	1	1	1	1		
Facial nerve disorder		2		2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial pain	2	2	2	2		
Facial paralysis	2	17			2	17
Facial paresis		3		3		
Facial spasm		1		1		
Faeces discoloured	1	2	1	2		
Fall	1	4		2	1	2
Fasting		1		1		
Fatigue	796	1,274	720	1140	76	134
Fear	1	1	1	1		
Febrile convulsion	11	31	8	21	3	10
Feeding intolerance	1	1	1	1		
Feeling abnormal	2	8	2	6		2
Feeling cold	10	16	9	14	1	2
Feeling drunk		1		1		
Feeling hot	27	43	26	37	1	6
Feeling of body temperature change	1	2	1	2		
Feeling of despair	2	4	2	4		
Fibrosis		1		1		
Flatulence	2	2	2	2		
Flushing	15	24	15	22		2
Foreign body sensation in eyes		1		1		
Frequent bowel movements	1	2	1	2		
Gait disturbance	11	15	6	10	5	5
Gastritis		3		3		
Gastroenteritis		1		1		
Gastrointestinal disorder	2	2	2	2		
Gastrointestinal haemorrhage		1				1
Gastrointestinal hypermotility		1		1		
Gastrointestinal hypomotility		1		1		
Gastrointestinal motility disorder		2		2		
Generalised oedema	2	2	2	2		
Generalised tonic-clonic seizure	1	4			1	4

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
General physical condition abnormal	1	2	1	1		1
General physical health deterioration	4	12	3	11	1	1
Genital paraesthesia		1		1		
Genital tract inflammation		1		1		
Gingival bleeding		1		1		
Gingival pain		1		1		
Gingival swelling		1		1		
Glabellar reflex abnormal		1		1		
Glossitis	2	2			2	2
Glossodynia	1	2	1	2		
Granuloma	2	2	2	2		
Groin pain		1		1		
Guillain-Barre syndrome	6	10			6	10
Haematochezia	1	12			1	12
Haematoma		2		2		
Haemolytic anaemia		1				1
Haemoptysis		1		1		
Haemorrhage	1	17			1	17
Haemorrhagic disorder	1	7			1	7
Hallucination	1	1			1	1
Hallucination, visual		2				2
Headache	2,163	3,053	1982	2739	181	314
Head discomfort	3	5	2	4	1	1
Heart rate abnormal	2	4	2	4		
Heart rate decreased		1		1		
Heart rate increased	8	19	3	13	5	6
Hemiparaesthesia	2	8			2	8
Hemiparesis	3	13			3	13
Hemiplegia		2				2
Hepatic pain		1		1		
Herpes zoster	2	4	2	4		
Hot flush	5	6	5	6		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hunger		2		2		
Hyperaemia	6	11	6	10		1
Hyperaesthesia	3	9	3	9		
Hyperglycaemia	1	3	1	1		2
Hyperhidrosis	55	87	47	67	8	20
Hyperoxia	1	1	1	1		
Hyperpyrexia		1				1
Hyperreflexia		1		1		
Hypersensitivity	11	43	7	33	4	10
Hypersomnia		2		2		
Hypertension	187	267	117	166	70	101
Hypertensive crisis	10	60			10	60
Hypertensive emergency	1	3			1	3
Hypertensive urgency	1	1			1	1
Hyperthermia	23	33	22	31	1	2
Hypoacusis	1	2	1	2		
Hypoaesthesia	56	85	46	64	10	21
Hypoaesthesia oral	24	38	21	32	3	6
Hypoglycaemia	4	5	1	1	3	4
Hypokinesia	11	19	9	16	2	3
Hyposmia		1		1		
Hypotension	30	45	15	23	15	22
Hypothermia	2	15			2	15
Hypotonia	1	4	1	4		
Hypoventilation		2				2
Hypovolaemic shock		19				19
Hypoxia	6	7			6	7
Immunology test abnormal		1		1		
Impaired quality of life	1	1	1	1		
Impaired work ability	1	1	1	1		
Inappropriate schedule of product administration	2	9	2	9		
Incorrect dose administered	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Incorrect route of product administration	7	8	7	8		
Increased appetite	1	1	1	1		
Induration	236	361	228	343	8	18
Infarction	1	1			1	1
Inflammation	229	356	209	324	20	32
Influenza	3	7	2	6	1	1
Influenza like illness	1	2	1	2		
Initial insomnia	1	1	1	1		
Injection site erythema	1	1	1	1		
Injection site haematoma	1	1	1	1		
Injection site haemorrhage		1		1		
Injection site hypoaesthesia	2	2	2	2		
Injection site inflammation	1	1	1	1		
Injection site pain	8	9	8	9		
Injection site reaction	1	1	1	1		
Inner ear inflammation	1	1	1	1		
Insomnia	6	9	6	9		
Intermenstrual bleeding		1		1		
Intracranial aneurysm		1				1
Intussusception		10				10
Irritability	92	181	84	157	8	24
Irritability postvaccinal	1	3	1	3		
Ischaemic stroke	1	2			1	2
Jaundice		1				1
Jaw disorder	1	1	1	1		
Joint injury	1	2		1	1	1
Joint range of motion decreased	1	2	1	2		
Joint stiffness		1		1		
Joint swelling		1		1		
Lacrimation increased	7	17	7	17		
Laryngeal discomfort	1	1	1	1		
Laryngeal inflammation		1				1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Laryngeal oedema		6
Laryngospasm		3
Larynx irritation		1
Laziness		1
Lethargy	4	7
Leukopenia		2
Limb discomfort	9	12
Lip discolouration		1
Lip disorder		1
Lip oedema	12	19
Lip pain	1	2
Lip pruritus	1	1
Listless	1	1
Livedo reticularis	1	4
Localised oedema	3	6
Local reaction	124	160
Loss of consciousness	2	17
Loss of personal independence in daily activities	4	6
Lung disorder		1
Lymphadenitis	1	3
Lymphadenopathy	78	151
Lymphangitis		1
Lymph node pain	1	2
Lymphoedema	1	1
Lymphopenia	1	2
Macule	2	2
Malaise	131	205
Mass		1
Mastication disorder	1	1
Maternal exposure during pregnancy	1	15
Mean cell haemoglobin concentration decreased		1
Mean cell haemoglobin decreased		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			6
	1		2
			1
	1		
3	4	1	3
			2
9	11		1
	1		
	1		
8	15	4	4
1	2		
1	1		
1	1		
	3	1	1
3	6		
121	156	3	4
		2	17
3	4	1	2
	1		
1	3		
72	137	6	14
			1
1	2		
1	1		
1	2		
2	2		
115	179	16	26
	1		
		1	1
1	15		
	1		
	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mean cell volume decreased		1		1		
Mean platelet volume decreased		1		1		
Mechanical urticaria	3	4	1	2	2	2
Memory impairment	1	1	1	1		
Meningitis		2				2
Menstrual disorder		1		1		
Menstruation irregular	1	1	1	1		
Metamorphopsia		1		1		
Migraine	3	4	3	4		
Mobility decreased	20	27	20	27		
Monocyte count increased		1		1		
Monocytosis	1	1	1	1		
Mononeuropathy		2				2
Monoparesis	2	5	2	3		2
Monoplegia		1				1
Motor dysfunction	1	2	1	2		
Mouth haemorrhage		1				1
Movement disorder	7	13	5	9	2	4
Mucosal dryness		1		1		
Mucous stools		1		1		
Mumps	1	1	1	1		
Muscle atrophy		1		1		
Muscle contractions involuntary	1	6	1	4		2
Muscle contracture	1	3	1	3		
Muscle fatigue	1	3	1	3		
Muscle rigidity	2	3	1	2	1	1
Muscle spasms	10	19	10	18		1
Muscle spasticity	1	2			1	2
Muscle strength abnormal	2	3	2	3		
Muscle tightness	1	2	1	2		
Muscular weakness	22	40	15	25	7	15
Musculoskeletal chest pain	3	4	3	4		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal discomfort	2	2	2	2		
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	2	4	1	3	1	1
Mutism	1	1			1	1
Myalgia	1,011	1,513	945	1389	66	124
Myelitis		1				1
Myelitis transverse		1				1
Myocardial infarction		2				2
Myoclonic epilepsy		1				1
Myoclonus	1	2	1	2		
Myopathy		1		1		
Nail discolouration		1		1		
Narcolepsy		1				1
Nasal congestion	15	29	15	29		
Nasal discomfort	1	1	1	1		
Nasal dryness	2	2	2	2		
Nasal obstruction		2		2		
Nasal oedema	1	1	1	1		
Nasal pruritus	1	3	1	3		
Nasopharyngitis	3	7	2	6	1	1
Nausea	914	1,346	813	1178	101	168
Near death experience		1				1
Neck pain	17	36	17	36		
Nerve degeneration		1				1
Nervousness	4	7	4	7		
Nervous system disorder		1				1
Neuralgia		1		1		
Neuritis		5		2		3
Neuropathy peripheral	2	4			2	4
Night sweats		1		1		
Nodule	236	375	226	351	10	24
Noninfective gingivitis		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nystagmus	2	3	2	3		
Obstruction	1	1	1	1		
Obstructive airways disorder	1	2			1	2
Ocular discomfort	1	2	1	2		
Ocular hyperaemia	2	10	2	9		1
Ocular icterus	1	1	1	1		
Odynophagia	67	114	63	100	4	14
Oedema	299	480	265	416	34	64
Oedema mouth	1	1	1	1		
Oedema peripheral	11	25	9	22	2	3
Off label use	12	21	12	21		
Optic neuritis	1	1			1	1
Oral candidiasis	1	2		1	1	1
Oral discomfort	3	4	1	1	2	3
Oral disorder		2		1		1
Oral dysaesthesia		1		1		
Oral herpes		1		1		
Oral mucosal eruption	1	1	1	1		
Oral pruritus	4	4	3	3	1	1
Oropharyngeal discomfort	7	14	7	11		3
Oropharyngeal pain	411	688	381	628	30	60
Osteoarthropathy	3	3	3	3		
Otitis externa		1		1		
Otitis media	1	2	1	2		
Otitis media acute		1		1		
Overdose	1	2	1	2		
Oxygen saturation abnormal	1	10	1	6		4
Oxygen saturation decreased	27	61	12	32	15	29
Pain	1,290	1,846	1216	1704	74	142
Pain in extremity	116	180	111	172	5	8
Pain in jaw	1	2		1	1	1
Pain of skin	3	5	3	5		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pallor	2	10
Palmar erythema	1	1
Palpitations	16	36
Panic attack	1	2
Papule		2
Paraesthesia	160	263
Paraesthesia mucosal		1
Paraesthesia oral	38	67
Paralysis	4	17
Paraparesis		1
Paresis	4	6
Parotitis	1	1
Partial seizures	1	1
Patient elopement	2	2
Pelvic discomfort		1
Pelvic pain	1	2
Pericardial disease		1
Periorbital oedema	1	2
Peripheral coldness	3	11
Peripheral motor neuropathy		1
Peripheral swelling	4	7
Peripheral vascular disorder		1
Peroneal nerve injury		1
Persistent depressive disorder		1
Petechiae	3	6
Petit mal epilepsy		1
Pharyngeal disorder	1	4
Pharyngeal erythema	1	2
Pharyngeal hypoaesthesia	1	2
Pharyngeal inflammation	1	3
Pharyngeal oedema		5
Pharyngeal paraesthesia	5	10

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	7	1	3
1	1		
12	28	4	8
1	2		
	2		
138	212	22	51
			1
27	48	11	19
		4	17
			1
4	6		
1	1		
		1	1
2	2		
			1
1	2		
	1		
1	2		
3	10		1
			1
4	5		2
			1
			1
	1		
3	3		3
			1
1	4		
1	2		
		1	2
1	1		2
			5
5	7		3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal swelling	4	4			4	4
Pharyngitis	1	1	1	1		
Pharyngotonsillitis	1	1			1	1
Photophobia	15	18	13	16	2	2
Photopsia	12	17	10	13	2	4
Photosensitivity reaction	1	2	1	2		
Pigmentation disorder		1		1		
Platelet count decreased		1				1
Platelet count increased		1		1		
Pneumonia	3	18			3	18
Pneumonia bacterial	1	1			1	1
Pollakiuria	1	1	1	1		
Polydipsia	1	1			1	1
Poor quality product administered	2	4	2	4		
Prehypertension	1	1	1	1		
Presyncope	1	5	1	3		2
Product administered at inappropriate site	1	1	1	1		
Product colour issue		1		1		
Product complaint		1		1		
Productive cough	8	11	6	8	2	3
Product use issue	11	17	11	17		
Prurigo	1	2	1	2		
Pruritus	318	475	265	389	53	86
Pulmonary embolism	1	1			1	1
Pulmonary oedema		1				1
Pulmonary pain	1	2	1	2		
Purpura	7	10	6	8	1	2
Pyelonephritis		1				1
Pyrexia	612	985	569	898	43	87
Radiculitis brachial		1				1
Radiculopathy		2				2
Rales	1	2		1	1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash	203	338	158	261	45	77
Rash erythematous	2	3	2	3		
Rash macular	1	4	1	3		1
Rash maculo-papular	1	5	1	4		1
Rash papular	2	2	2	2		
Rash pruritic	3	3	3	3		
Raynaud's phenomenon		2		2		
Reflexes abnormal		1		1		
Reflux gastritis	1	1	1	1		
Respiration abnormal	1	1	1	1		
Respiratory acidosis	1	1			1	1
Respiratory arrest		1				1
Respiratory disorder	1	3	1	3		
Respiratory distress	63	555			63	555
Respiratory failure		1				1
Respiratory rate increased	1	1	1	1		
Respiratory tract infection viral		1		1		
Restlessness		1		1		
Retching	1	1	1	1		
Rhinalgia		1		1		
Rhinitis	2	5	2	5		
Rhinorrhoea	385	593	365	558	20	35
Ruptured cerebral aneurysm		1				1
Sacroiliitis		1				1
Salivary hypersecretion	8	9	8	9		
SARS-CoV-2 ant body test negative		1		1		
SARS-CoV-2 test positive	2	3	2	3		
Sciatica		1				1
Sciatic nerve neuropathy		1				1
Screaming		1		1		
Secondary hypertension	1	1	1	1		
Secretion discharge		1		1		

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FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Seizure	10	61			10	61
Sensation of foreign body	21	39	15	21	6	18
Sensitisation		1		1		
Sensitive skin	1,306	1,746	1233	1620	73	126
Sensory disturbance	3	4	3	4		
Sensory loss	1	3		1	1	2
Sepsis		1				1
Shock	1	4			1	4
Sinusitis	1	1	1	1		
Sinus tachycardia		3		1		2
Skeletal injury		1		1		
Skin burning sensation		2		2		
Skin discolouration	1	2	1	2		
Skin disorder		1		1		
Skin exfoliation		1		1		
Skin haemorrhage		1		1		
Skin injury		1		1		
Skin lesion	1	3	1	3		
Skin mass	1	2	1	2		
Skin plaque	1	1			1	1
Skin reaction		1				1
Skin sensitisation	26	28	26	28		
Skin swelling		1		1		
Sleep deficit	1	1	1	1		
Sleep disorder		1				1
Sleep inertia		1				1
Slow response to stimuli		2		2		
Slow speech	1	2		1	1	1
Sneezing	8	10	6	8	2	2
Soft tissue swelling	1	1	1	1		
Somnolence	25	40	24	37	1	3
Speech disorder	2	4	1	3	1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Spinal pain	3	3	3	3		
Splenomegaly		1		1		
Sputum discoloured		1		1		
Sputum purulent		1				1
Stevens-Johnson syndrome		3				3
Stomatitis		1		1		
Stress		1		1		
Stridor	1	3			1	3
Subarachnoid haemorrhage		2				2
Suffocation feeling	4	6	4	6		
Suspected counterfeit product	2	3	2	3		
Suspected COVID-19	8	12	5	8	3	4
Sweating fever		1				1
Swelling	8	15	7	12	1	3
Swelling face	2	5	2	4		1
Swelling of eyelid	1	1	1	1		
Swollen tongue	1	2	1	2		
Syncope	6	61			6	61
Synovial cyst		2		2		
Systemic lupus erythematosus		1				1
Tachyarrhythmia		1		1		
Tachycardia	447	813	382	664	65	149
Tachypnoea	6	15	3	6	3	9
Taste disorder	1	2	1	2		
Temperature intolerance	1	3	1	3		
Temperature regulation disorder	2	3	2	3		
Tenderness	2	5	1	4	1	1
Tension headache	2	3	1	2	1	1
Therapeutic response unexpected	3	3	3	3		
Thermal burns of eye		2				2
Thirst	2	5	2	4		1
Throat irritation	17	31	16	28	1	3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Throat tightness	2	5		2	2	3
Thrombocytopenia		1				1
Thrombocytopenic purpura		3		2		1
Thrombosis	2	3			2	3
Tic	1	1	1	1		
Tinnitus	15	25	15	22		3
Tongue oedema	1	4	1	3		1
Tongue paralysis	1	2			1	2
Tongue pruritus	1	1	1	1		
Tonsillar hypertrophy	1	1			1	1
Toothache		2		2		
Transaminases increased		1				1
Tremor	20	37	18	34	2	3
Trismus	1	1	1	1		
Tympanic membrane disorder		1		1		
Tympanic membrane perforation	1	1			1	1
Type I hypersensitivity		1				1
Upper-airway cough syndrome		1		1		
Upper airway obstruction		1				1
Urinary incontinence	1	2	1	2		
Urinary retention	1	1			1	1
Urinary tract infection	1	2	1	2		
Urticaria	8	19	6	15	2	4
Vaccination complication	1	3	1	2		1
Vaccination error	2	2	1	1	1	1
Vaccination site abscess		3		3		
Vaccination site bruising	1	1	1	1		
Vaccination site cellulitis	2	21	2	13		8
Vaccination site dermatitis	1	1			1	1
Vaccination site discolouration	1	1	1	1		
Vaccination site discomfort	2	6	2	6		
Vaccination site erythema	27	48	24	43	3	5

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination site haematoma	1	2
Vaccination site haemorrhage	2	4
Vaccination site hyperaesthesia	2	6
Vaccination site hypersensitivity	10	44
Vaccination site hypoaesthesia	5	8
Vaccination site induration	22	51
Vaccination site inflammation	18	35
Vaccination site joint movement impairment	2	3
Vaccination site joint pain		1
Vaccination site movement impairment	7	10
Vaccination site nodule	14	26
Vaccination site oedema	31	48
Vaccination site pain	543	777
Vaccination site papule	2	2
Vaccination site paraesthesia	11	15
Vaccination site pruritus	20	25
Vaccination site rash	5	6
Vaccination site reaction	10	26
Vaccination site swelling	8	11
Vaccination site warmth	22	36
Vaginal haemorrhage	3	4
Varicella	1	1
Varicophlebitis	1	1
Varicose vein	1	1
Vascular headache	1	1
Vascular injury	1	1
Vasculitis	1	1
Vasodilatation		1
Vasospasm	1	1
Vertigo	32	59
Vestibular function test abnormal	1	1
Vestibular neuritis		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	2		
2	3		1
2	6		
8	42	2	2
5	8		
20	44	2	7
17	32	1	3
2	3		
	1		
7	10		
14	24		2
28	42	3	6
508	731	35	46
1	1	1	1
11	15		
16	21	4	4
3	4	2	2
9	24	1	2
8	11		
21	35	1	1
	1	3	3
1	1		
1	1		
		1	1
1	1		
1	1		
1	1		
1	1		
24	46	8	13
		1	1
			1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vision blurred	43	70	35	58	8	12
Visual acuity reduced	1	1			1	1
Visual impairment	2	3	1	2	1	1
Vomiting	254	428	211	347	43	81
Wheezing	2	4	2	2		2
Wrong technique in device usage process	1	1	1	1		
Wrong technique in product usage process	2	7	2	7		
Xerophthalmia		1				1
	20,295	33,030	18165	27960	2130	5070

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal distension	1	2	1	2		
Abdominal pain	62	99	58	90	4	9
Abdominal pain upper	2	5	2	5		
Abnormal faeces	2	2	2	2		
Abscess	2	6	1	5	1	1
Acute myocardial infarction		2				2
Affect lability		1		1		
Ageusia	2	5		3	2	2
Alanine aminotransferase increased		1		1		
Amnesia	1	1	1	1		
Anaesthesia oral	1	1	1	1		
Anaphylactic reaction		3				3
Anaphylactic shock		5				5
Anosmia	9	17	9	17		
Antibody test abnormal		1		1		
Antibody test negative		2		2		
Anxiety	7	18	6	13	1	5
Aphasia		1		1		
Aphonia	1	1	1	1		
Apnoeic attack	1	1			1	1
Application site pain	1	1	1	1		
Arrhythmia		2				2
Arthralgia	293	452	269	414	24	38
Arthritis	1	1	1	1		
Aspartate aminotransferase increased		1				1
Asthenia	388	597	349	534	39	63
Asthenopia	1	1	1	1		
Asthmatic crisis		1				1
Atrial fibrillation		1				1
Atypical pneumonia		1				1
Aura		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Axillary mass		1		1		
Axillary pain	3	6	2	5	1	1
Back pain	12	18	11	17	1	1
Balance disorder	2	3	1	2	1	1
Bedridden	1	1			1	1
Bell's palsy		2				2
Blepharospasm	1	1	1	1		
Blister	2	4	2	2		2
Blood glucose abnormal	1	1	1	1		
Blood glucose decreased		1				1
Blood glucose increased	1	1	1	1		
Blood pressure abnormal	8	11	5	8	3	3
Blood pressure decreased	1	2	1	1		1
Blood pressure increased	27	35	16	21	11	14
Body temperature increased	63	94	56	82	7	12
Bone disorder	1	1	1	1		
Bone pain	1	1	1	1		
Bowel movement irregularity		1		1		
Bradycardia	1	7			1	7
Bronchospasm	10	20	8	16	2	4
Burning sensation	1	2	1	2		
Burn oral cavity		1				1
Cardio-respiratory arrest	1	2			1	2
Catarrh		1		1		
Cellulitis	2	11			2	11
Cerebral haematoma		1				1
Cerebrovascular accident		1				1
Cheilitis	1	1	1	1		
Chest discomfort	8	10	6	8	2	2
Chest pain	21	38	18	33	3	5
Chills	253	386	234	351	19	35
Choking		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Choluria		1
Coagulation time prolonged		1
Cogwheel rigidity	1	1
Cold sweat		1
Colitis	1	2
Condition aggravated	1	2
Confusional state		2
Conjunctival haemorrhage		1
Conjunctivitis	2	2
Cough	105	169
Counterfeit product administered		3
COVID-19	19	47
COVID-19 pneumonia	1	3
Crying	6	12
Cyanosis	1	3
Death		1
Decreased activity	2	2
Decreased appetite	23	42
Deficiency of bile secretion		1
Dehydration	2	5
Demyelinating polyneuropathy		1
Depressed level of consciousness		3
Dermatitis exfoliative generalised	1	1
Dermatosis	2	2
Diabetes mellitus		1
Diarrhoea	99	174
Diplopia		2
Discomfort	27	43
Disease recurrence		1
Disorientation	3	6
Disseminated Bacillus Calmette-Guerin infection		5
Disturbance in attention		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
			1
1	1		
	1		
1	2		
		1	2
	2		
			1
2	2		
90	147	15	22
	3		
10	25	9	22
		1	3
6	12		
	1	1	2
			1
1	1	1	1
21	37	2	5
			1
2	3		2
			1
			3
		1	1
1	1	1	1
			1
87	149	12	25
	2		
26	40	1	3
	1		
3	5		1
			5
	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	214	350	197	314	17	36
Drug hypersensitivity		1				1
Drug ineffective	4	18			4	18
Dry mouth	7	13	7	12		1
Dysaesthesia	2	4	2	4		
Dysarthria	1	1	1	1		
Dysgeusia	8	12	8	12		
Dyskinesia	1	2	1	2		
Dyslipidaemia		1		1		
Dysphagia	2	2	1	1	1	1
Dysphonia	2	2	2	2		
Dyspnoea	39	154	23	112	16	42
Dyspnoea exertional	1	2	1	2		
Dysstasia	1	3	1	2		1
Dystonia		1				1
Ear discomfort		3		3		
Ear infection		1		1		
Ear pain	1	5		4	1	1
Ecchymosis		1		1		
Electrolyte imbalance		1				1
End stage renal disease		1				1
Epiglottic oedema		1				1
Epistaxis		4		2		2
Eructation	1	1	1	1		
Erythema	64	90	58	81	6	9
Expired product administered	1	1	1	1		
Exposure to SARS-CoV-2		1		1		
Eye injury	3	9	3	8		1
Eye irritation	4	6	4	6		
Eyelid ptosis	1	2	1	2		
Eye movement disorder		1				1
Eye oedema	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye pain	10	17	9	16	1	1
Eye paraesthesia	1	1	1	1		
Facial paralysis	2	9			2	9
Faecal volume decreased	1	1	1	1		
Faeces soft	1	1	1	1		
Fall	1	4	1	2		2
Fatigue	279	445	247	396	32	49
Febrile convulsion	3	14	1	10	2	4
Feeling abnormal	1	2	1	2		
Feeling cold	1	2	1	2		
Feeling hot	5	5	4	4	1	1
Feeling of despair	1	2	1	2		
Flank pain		1		1		
Flushing	4	5	4	5		
Foreign body in throat		1				1
Furuncle	1	1	1	1		
Gait disturbance	2	4		2	2	2
Gait inability	1	1	1	1		
Gastritis		1		1		
Gastroenteritis		1				1
Gastrointestinal disorder	1	2	1	1		1
Gastrointestinal hypermotility	1	1	1	1		
Gastrointestinal motility disorder		1		1		
Gastrointestinal pain	1	1	1	1		
Gastrooesophageal reflux disease	1	2	1	2		
Generalised oedema	2	3	1	2	1	1
Generalised tonic-clonic seizure		5				5
General physical health deterioration	2	6	1	5	1	1
General symptom		1				1
Gingival bleeding	1	1			1	1
Gingival hypertrophy	1	1	1	1		
Guillain-Barre syndrome	1	6			1	6

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematochezia		8				8
Haemorrhage		10				10
Haemorrhagic disorder	1	5			1	5
Hallucination, visual		1				1
Headache	625	889	578	816	47	73
Head discomfort	1	1	1	1		
Heart rate increased	2	5	1	4	1	1
Heart rate irregular		1				1
Hemiparaesthesia	1	3			1	3
Hemiparesis		1				1
Hepatic function abnormal		1		1		
Herpes virus infection	1	1	1	1		
Herpes zoster	2	2	2	2		
Hip fracture		1				1
Hot flush		2		2		
Hyperaemia	3	4	3	4		
Hyperaesthesia		1		1		
Hyperbilirubinaemia		1				1
Hyperglycaemia		2		2		
Hyperhidrosis	21	35	19	30	2	5
Hypernatraemia		1				1
Hypersensitivity	4	11	3	7	1	4
Hypersomnia	1	1	1	1		
Hypertension	46	68	27	37	19	31
Hypertensive crisis	2	19			2	19
Hyperthermia	11	17	10	16	1	1
Hypoacusis		2		2		
Hypoaesthesia	10	20	9	18	1	2
Hypoaesthesia oral	2	3	2	3		
Hypoglycaemia	2	2	1	1	1	1
Hypokinesia	4	5	3	4	1	1
Hypopnoea	1	1	1	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyposmia	1	2	1	2		
Hypotension	7	18	4	10	3	8
Hypothermia		4				4
Hypotonia	1	1			1	1
Hypovolaemic shock		12				12
Hypoxia	2	2			2	2
Illness	1	1	1	1		
Inappropriate schedule of product administration		4		4		
Incorrect route of product administration	1	1	1	1		
Induration	56	97	54	92	2	5
Infection	1	1	1	1		
Inflammation	55	76	50	68	5	8
Influenza	2	3	2	3		
Influenza like illness	1	3	1	3		
Injection site pain	2	2	2	2		
Injection site pruritus	1	1	1	1		
Injection site reaction	1	1	1	1		
Insomnia	5	7	4	5	1	2
Inspiratory capacity abnormal	1	1	1	1		
Intussusception		3				3
Irritability	29	52	24	42	5	10
Irritability postvaccinal		1		1		
Jaundice		1				1
Lacrimation increased	1	4	1	4		
Lacunar stroke	1	1			1	1
Laryngeal obstruction		1				1
Laryngeal oedema		1				1
Laryngospasm	1	1	1	1		
Lateropulsion		1				1
Lethargy	1	1	1	1		
Leukopenia		1				1
Limb discomfort	1	2	1	2		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lip disorder		1		1		
Livedo reticularis	1	1			1	1
Localised oedema	1	1	1	1		
Local reaction	41	58	41	56		2
Loss of consciousness	3	7			3	7
Lymphadenopathy	9	24	8	22	1	2
Lymph node pain	1	1	1	1		
Lymphopenia		1				1
Macule	1	1	1	1		
Malaise	53	84	46	74	7	10
Masticatory pain		1		1		
Measles		1				1
Melaena		1				1
Metamorphopsia	1	1	1	1		
Migraine	2	2	2	2		
Mobility decreased	4	11	3	10	1	1
Monoparesis	1	1	1	1		
Mood altered	1	1			1	1
Mouth swelling		1				1
Movement disorder	1	2	1	1		1
Mucosal dryness		1		1		
Muscle contractions involuntary	1	1	1	1		
Muscle fatigue		1		1		
Muscle spasms	1	3	1	3		
Muscle strength abnormal	1	1			1	1
Muscle tightness		1		1		
Muscular weakness	6	14	3	8	3	6
Musculoskeletal pain	1	1	1	1		
Myalgia	350	545	322	495	28	50
Myalgia intercostal		1		1		
Myoclonus	1	1	1	1		
Nasal abscess		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nasal congestion	7	10	7	10		
Nasal obstruction	1	1			1	1
Nasal turbinate hypertrophy	1	1	1	1		
Nasopharyngitis	1	4		1	1	3
Nausea	198	322	181	284	17	38
Neck pain	4	8	4	8		
Nervousness	1	3	1	2		1
Nervous system disorder		1				1
Neuralgia	1	1	1	1		
Neutrophil count increased		2		2		
Night sweats		1				1
Nodule	59	103	57	98	2	5
Nystagmus	1	1			1	1
Obstructive airways disorder	1	1			1	1
Ocular discomfort	1	2	1	2		
Ocular hyperaemia	1	4		3	1	1
Odynophagia	33	48	30	44	3	4
Oedema	74	107	65	91	9	16
Oedema peripheral	1	4		3	1	1
Off label use	3	6	3	6		
Oral administration complication		1		1		
Oral candidiasis		1		1		
Oropharyngeal discomfort		3		1		2
Oropharyngeal pain	108	168	100	154	8	14
Osteoarthritis	2	2	2	2		
Overdose	1	1	1	1		
Oxygen saturation decreased	5	11		5	5	6
Pain	397	564	379	524	18	40
Painful respiration		2		2		
Pain in extremity	26	43	25	40	1	3
Pain in jaw		1				1
Pain of skin		2		2		

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Palate injury		1
Pallor	3	4
Palmar erythema		1
Palpitations	3	7
Paraesthesia	25	50
Paraesthesia oral	3	4
Paralysis	5	18
Paraparesis		1
Parosmia		1
Parotid gland enlargement		1
Parotitis		1
Patient elopement		1
Peripheral swelling		1
Petechiae	1	3
Pharyngeal disorder	1	1
Pharyngeal erythema	2	2
Pharyngeal oedema	1	1
Pharyngeal ulceration		1
Pharyngitis		1
Phonophobia	1	1
Photophobia	3	5
Photopsia		1
Photosensitivity reaction	2	2
Piloerection	1	1
Platelet count increased		2
Pleural effusion		1
Pneumonia	5	10
Pneumonitis		1
Prehypertension	1	1
Presyncope	1	1
Productive cough	2	2
Product supply issue		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
2	3	1	1
	1		
3	7		
23	46	2	4
3	3		1
		5	18
			1
	1		
	1		
	1		
	1		
	1		
1	3		
1	1		
2	2		
1	1		
	1		
			1
1	1		
3	5		
	1		
2	2		
1	1		
	2		
	1		
		5	10
	1		
1	1		
1	1		
1	1	1	1
	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product use issue	3	5	3	5		
Prurigo		1		1		
Pruritus	51	77	45	67	6	10
Pulse absent	1	1			1	1
Purpura	4	4	3	3	1	1
Pustule	1	1	1	1		
Pyrexia	267	415	236	368	31	47
Rales	1	1	1	1		
Rash	43	71	35	54	8	17
Rash erythematous		1				1
Rash macular		1		1		
Rash maculo-papular	1	1			1	1
Rash pruritic	2	2	2	2		
Reflux gastritis	1	1	1	1		
Respiratory arrest		1				1
Respiratory disorder		1				1
Respiratory distress	29	142			29	142
Respiratory failure		2				2
Respiratory rate increased	1	2	1	2		
Rhinitis	3	3	3	3		
Rhinorrhoea	110	172	99	156	11	16
Salivary hypersecretion	3	4	3	3		1
SARS-CoV-2 ant body test negative	1	2	1	2		
SARS-CoV-2 test positive	1	4	1	2		2
Scab	1	2	1	1		1
Scratch	1	1	1	1		
Secondary hypertension	1	1	1	1		
Seizure	4	17			4	17
Sensation of foreign body	4	4	4	4		
Sensitisation		1		1		
Sensitive skin	396	530	380	497	16	33
Septic shock		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Shock		1				1
Sinus tachycardia		1		1		
Skin discolouration	1	2	1	2		
Skin lesion		1		1		
Skin plaque	1	1	1	1		
Skin sensitisation	12	12	12	12		
Sleep disorder	1	1			1	1
Sneezing	1	1	1	1		
Somnolence	8	16	8	16		
Stasis dermatitis		1		1		
Stevens-Johnson syndrome		2				2
Stridor	1	1	1	1		
Sudden infant death syndrome		1				1
Suffocation feeling		1				1
Suspected counterfeit product		3		3		
Suspected COVID-19	2	3	2	2		1
Swelling		2		2		
Swollen tongue		1		1		
Syncope	3	26			3	26
Synovial cyst	1	1	1	1		
Tachycardia	107	185	98	160	9	25
Tachycardia paroxysmal	1	1	1	1		
Tachypnoea	1	5	1	3		2
Tenderness		1		1		
Therapeutic response unexpected	1	1	1	1		
Thermal burn		1				1
Thirst		1		1		
Throat irritation	4	4	4	4		
Thrombocytopenia	1	2			1	2
Thrombocytopenic purpura	1	1			1	1
Thrombophlebitis superficial	1	1			1	1
Thrombosis	2	4			2	4

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tinnitus	4	8	4	8		
Tongue paralysis	1	1			1	1
Tongue pruritus	1	1	1	1		
Tonsillitis bacterial	1	1			1	1
Toxic epidermal necrolysis		1				1
Toxicity to various agents		1				1
Transaminases increased		1				1
Traumatic lung injury		2		2		
Tremor	2	9	2	8		1
Urinary incontinence		1		1		
Urinary tract infection		1		1		
Urticaria	5	7	3	5	2	2
Vaccination complication	1	1	1	1		
Vaccination failure	1	1			1	1
Vaccination site cellulitis		5		3		2
Vaccination site discomfort	2	5	2	5		
Vaccination site erythema	8	10	8	10		
Vaccination site haematoma		1		1		
Vaccination site haemorrhage	1	1			1	1
Vaccination site hyperaesthesia	1	1	1	1		
Vaccination site hypersensitivity	3	6	3	6		
Vaccination site hypoaesthesia	2	2	2	2		
Vaccination site induration	8	12	8	12		
Vaccination site inflammation	2	4	2	4		
Vaccination site joint movement impairment	2	2	2	2		
Vaccination site movement impairment	4	8	4	8		
Vaccination site nodule	3	5	3	5		
Vaccination site oedema	12	12	12	12		
Vaccination site pain	186	267	181	257	5	10
Vaccination site paraesthesia	3	3	3	3		
Vaccination site pruritus	4	6	4	5		1
Vaccination site rash		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site reaction	3	8	3	8		
Vaccination site swelling	6	9	6	9		
Vaccination site warmth	6	7	6	7		
Vascular test abnormal		1		1		
Vasodilatation	1	1			1	1
Vertigo	12	19	9	15	3	4
Vision blurred	6	10	5	8	1	2
Visual acuity reduced	1	1			1	1
Visual field defect	1	1	1	1		
Visual impairment	1	1			1	1
Vomiting	56	112	45	87	11	25
Wheezing	1	5		2	1	3
White blood cell count increased		1				1
White coat hypertension	1	1	1	1		
Wrong product administered	1	2	1	2		
Wrong technique in product usage process	1	2		1	1	1
	5,990	9,770	5344	8293	646	1477

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		3		3		
Abnormal faeces		1		1		
Acne	1	1	1	1		
Allergy to vaccine		3		3		
Anaphylactoid reaction		1				1
Arthralgia		25		25		
Asthenia		22		21		1
Back pain		1		1		
Blood pressure increased		1				1
Body temperature increased		5		5		
Chest discomfort		1		1		
Chest pain		1				1
Chills		10		10		
Cough	1	10	1	10		
COVID-19		4		1		3
COVID-19 pneumonia		1				1
Decreased appetite		3		3		
Diarrhoea		4		4		
Discomfort		4		4		
Dizziness	1	15	1	14		1
Drug ineffective		4				4
Dysgeusia		2		2		
Dyspnoea		7		3		4
Ear pain		1		1		
Epilepsy		1				1
Epistaxis	1	1	1	1		
Erythema		3		3		
Erythema multiforme		1				1
Exposure via breast milk		1		1		
Eye pain		1		1		
Fatigue	1	2	1	2		
Feeling hot		1		1		

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* AE=Adverse Event

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache	1	40	1	39		1
Hot flush		1		1		
Hyperacusis	1	1	1	1		
Hyperhidrosis		1		1		
Hypersensitivity		2		2		
Hypertension	1	3		1	1	2
Hypertensive crisis		2				2
Hypoaesthesia		1		1		
Inflammation		2		2		
Laryngospasm		1		1		
Local reaction		2		2		
Lymphadenopathy	1	4	1	4		
Mobility decreased		2		2		
Muscular weakness	2	2	2	2		
Myalgia	1	23	1	23		
Nausea		10		10		
Neck pain		1		1		
Nervousness		1		1		
Nodule		1		1		
Oedema		8		8		
Oropharyngeal pain	1	4	1	4		
Oxygen saturation decreased		1				1
Pain		13		12		1
Pain in extremity		2		2		
Palpitations		1		1		
Paraesthesia		4		3		1
Paraesthesia oral		2		1		1
Parotitis		1		1		
Pelvic pain		1		1		
Pneumonia		3				3
Pruritus		3		3		
Pupillary disorder	1	1	1	1		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia		20		20		
Rash		10		9		1
Rash maculo-papular		1		1		
Rhinorrhoea	1	7	1	7		
Seizure		5				5
Sensitive skin		1		1		
Sensory loss		1		1		
Suspected COVID-19		1				1
Swelling		1		1		
Syncope		2				2
Tachycardia		12		10		2
Tinnitus	1	1	1	1		
Urticaria		1		1		
Vaccination site erythema		2		2		
Vaccination site hyperaesthesia		1		1		
Vaccination site induration		2		2		
Vaccination site inflammation		1		1		
Vaccination site nodule		3		3		
Vaccination site oedema		1		1		
Vaccination site pain		31		30		1
Vaccination site rash		1		1		
Vomiting		3		3		
Wrong product administered		1		1		
	16	394	15	351	1	43

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Country Where Event Occurred

MONACO

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19		1		1
Drug ineffective		1		1
Speech disorder		1		1
		3		3

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Country Where Event Occurred

NETHERLANDS

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- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	6	19			5	17	1	2
Abdominal pain	5	17			5	15		2
Abdominal pain lower		1				1		
Abdominal pain upper	5	17			4	16	1	1
Abnormal behaviour	1	2					1	2
Abnormal dreams		2				2		
Abnormal faeces		1						1
Abnormal loss of weight		1				1		
Abortion missed		2						2
Abortion spontaneous	2	12					2	12
Accommodation disorder		1				1		
Acne		1				1		
Acute coronary syndrome		1						1
Acute kidney injury	2	3					2	3
Acute myocardial infarction	2	5					2	5
Adrenal disorder		1						1
Affect lability	1	3			1	3		
Ageusia		8				8		
Agitation		1				1		
Alanine aminotransferase increased	1	1					1	1
Allergy to vaccine		1		1				1
Allodynia	1	2			1	2		
Altered state of consciousness		1						1
Amaurosis fugax		1						1
Amnesia	2	4			2	2		2
Amylase increased		1				1		
Anal haemorrhage	1	1					1	1
Anal sphincter hypertonia		1				1		
Anamnestic reaction		1						1
Anaphylactic reaction	1	14					1	14
Anaphylactic shock	1	5					1	5
Anembryonic gestation		1						1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Aneurysm		1
Angina pectoris	1	6
Angina unstable		1
Angioedema	4	16
Ankylosing spondylitis	1	1
Anosmia	1	6
Anxiety	5	12
Aortic arteriosclerosis	1	1
Aortic dissection		1
Aortic valve stenosis		3
Apallic syndrome		2
Apathy		1
Aphasia	3	15
Aphonia	2	4
Aphthous ulcer		2
Arrhythmia	7	20
Arthralgia	115	690
Arthritis		2
Aspartate aminotransferase increased	1	1
Asthenia	5	19
Asthma	1	5
Asymptomatic COVID-19	1	1
Ataxia		2
Atrial fibrillation	9	25
Auricular swelling		1
Autonomic nervous system imbalance		2
Axillary pain	6	27
Azotaemia		2
Back pain	6	14
Bacterial infection		1
Bacterial test positive		1
Balance disorder	1	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	6
					1
				4	16
				1	1
		1	6		
		4	10	1	2
		1	1		
					1
					3
					2
			1		
		1	4	2	11
		2	2		2
			2		
				7	20
		114	681	1	9
			1		1
				1	1
		5	16		3
		1	2		3
				1	1
					2
	1	1	1	8	24
			1		
					2
		6	27		
					2
		6	14		
					1
					1
		1	6		2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Basilar artery thrombosis		1
Bedridden		2
Bell's palsy	4	6
Beta haemolytic streptococcal infection	1	1
Bleeding varicose vein	1	1
Blepharospasm	1	1
Blindness	1	7
Blindness transient	1	1
Blindness unilateral	1	4
Blister	2	5
Blood alkaline phosphatase increased		1
Blood bilirubin increased		2
Blood cholesterol increased	2	4
Blood creatinine increased	2	5
Blood glucose decreased		1
Blood glucose fluctuation	1	4
Blood glucose increased	5	11
Blood lactate dehydrogenase increased	1	1
Blood lactic acid increased	1	1
Blood potassium decreased		1
Blood pressure decreased	1	6
Blood pressure fluctuation	2	2
Blood pressure increased	1	11
Blood pressure systolic increased	1	3
Blood sodium decreased		1
Blood sodium increased	1	1
Blood urea increased	3	6
Blood uric acid increased		1
Body temperature decreased	2	3
Body temperature increased	16	126
Bradycardia		4
Bradykinesia		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		1
				4	6
				1	1
				1	1
		1	1		
	1			1	7
				1	1
				1	4
		2	4		1
			1		
			2		
		2	4		
		1	4	1	1
			1		
		1	4		
		3	8	2	3
				1	1
				1	1
			1		
		1	2		4
		1	1	1	1
			7	1	4
		1	2		1
			1		
				1	1
		2	5	1	1
			1		
		2	2		1
		16	123		3
					4
			2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bradyphrenia		2
Brain death		1
Breast disorder female		1
Breast pain		1
Bronchiectasis	1	1
Bronchitis		1
Bronchospasm	1	2
Bundle branch block right	2	3
Burning sensation	1	7
Bursitis		1
Cachexia		2
Calcium ionised decreased	1	1
Candida infection		1
Cardiac arrest	1	11
Cardiac asthma		3
Cardiac death		2
Cardiac discomfort		1
Cardiac disorder		4
Cardiac failure	6	25
Cardiac failure acute	1	1
Cardiac failure congestive		1
Cardiac fibrillation	1	1
Cardiac flutter	1	1
Cardiovascular disorder		2
Carotid arteriosclerosis		1
Carotid artery dissection	1	1
Carotid artery thrombosis	1	1
Catatonia		2
Cerebellar haematoma		1
Cerebellar infarction		1
Cerebellar ischaemia		1
Cerebral amyloid angiopathy		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
					1
			1		
			1		
				1	1
					1
				1	2
			1	2	2
		1	7		
			1		
					2
		1	1		
					1
				1	11
					3
					2
			1		
			1		3
				6	25
				1	1
					1
				1	1
				1	1
					2
					1
				1	1
				1	1
			1		1
					1
					1
					1
					1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Cerebral artery thrombosis	1	1
Cerebral atrophy	1	2
Cerebral haemorrhage	6	9
Cerebral infarction	18	33
Cerebral ischaemia	1	3
Cerebral thrombosis	1	4
Cerebral venous sinus thrombosis	1	2
Cerebrovascular accident	6	25
Cerebrovascular disorder		1
Cervical radiculopathy		1
Chest discomfort	6	28
Chest injury		1
Chest pain	9	47
Chillblains		3
Chills	191	1,059
Choking		1
Choking sensation		2
Cholecystitis		1
Cholelithiasis	1	1
Chorea		1
Chronic obstructive pulmonary disease	2	4
Circulatory collapse	2	4
Coagulopathy		1
Cognitive disorder		2
Cold sweat	1	8
Colitis ulcerative	1	1
Coma	1	1
Coma hepatic		1
Concussion		1
Condition aggravated	5	11
Confusional state	4	21
Conjunctival haemorrhage	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	2
				6	9
1	1			18	33
				1	3
				1	4
				1	2
				6	25
			1		
			1		
		4	20	2	8
					1
		7	39	2	8
			3		
		186	1043	5	16
					1
					2
					1
				1	1
					1
				2	4
				2	4
			1		
			1		1
		1	6		2
				1	1
				1	1
					1
		1	4	4	7
		2	10	2	11
				1	3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Consciousness fluctuating		1
Constipation		2
Contusion	2	7
Conversion disorder		1
Coombs negative haemolytic anaemia		1
Coordination abnormal		5
Coronary artery disease	1	1
Cough	8	27
COVID-19	23	38
C-reactive protein increased	1	7
Crying	1	2
Cutaneous vasculitis	1	2
Cyanosis		2
Cystitis	3	10
Cystitis noninfective		1
Dacryocystitis		1
Dandruff		1
Dark circles under eyes		1
Deafness	1	2
Deafness transitory		1
Deafness unilateral	1	3
Death	2	14
Decreased appetite	8	25
Deep vein thrombosis	8	25
Defaecation urgency	1	1
Dehydration	1	6
Delirium	5	16
Delirium febrile		1
Dementia		3
Depressed level of consciousness	4	12
Depressed mood		3
Depression		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		1
		1	4	1	3
					1
					1
			3		2
				1	1
		7	24	1	3
		8	12	15	26
			4	1	3
		1	2		
				1	2
			1		1
		2	7	1	3
					1
					1
			1		
			1		
				1	2
					1
				1	3
				2	14
		7	19	1	6
				8	25
		1	1		
			2	1	4
				5	16
					1
					3
1	1			4	12
			3		
			1		2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Depression suicidal	1	1
Derealisation		1
Dermatitis		1
Dermatitis allergic	1	2
Dermatitis bullous		2
Diabetes mellitus inadequate control		1
Diaphragmalgia		1
Diarrhoea	15	67
Diarrhoea haemorrhagic	1	1
Dilatation atrial		1
Diplegia	1	1
Diplopia	1	9
Discomfort	1	7
Disease recurrence	1	5
Disorganised speech		1
Disorientation		2
Disturbance in attention	3	6
Diverticulitis	2	2
Dizziness	41	181
Drug hypersensitivity		1
Drug ineffective	9	16
Dry eye	1	3
Dry mouth	1	5
Dry skin	1	1
Dry throat		1
Dysarthria		3
Dysgeusia	2	23
Dysgraphia		2
Dysmenorrhoea	1	2
Dyspepsia	1	3
Dysphagia	8	22
Dysphonia	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		
			1		
		1	2		
					2
					1
			1		
		14	64	1	3
				1	1
					1
				1	1
			7	1	2
			5	1	2
			1	1	4
			1		
			1		1
		3	6		
				2	2
		39	166	2	15
					1
				9	16
		1	3		
			4	1	1
		1	1		
			1		
			2		1
		2	23		
			1		1
		1	2		
		1	3		
		5	9	3	13
				1	4

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dyspnoea	30	133
Dyspnoea at rest	3	5
Dyspnoea exertional	1	5
Dysstasia	1	1
Ear discomfort		3
Ear pain	3	7
Ecchymosis		2
Eczema	1	4
Electric shock sensation		2
Electrocardiogram ST segment abnormal		1
Embolism		1
Embolism arterial	1	1
Emotional distress		1
Emotional poverty		1
Encephalitis autoimmune		1
Endocrine ophthalmopathy		1
Enterocolitis		1
Eosinophil count decreased		1
Epilepsy	3	19
Episcleritis		1
Epistaxis	3	15
Eructation	1	1
Erysipelas	3	6
Erythema	13	51
Erythema nodosum		1
Escherichia urinary tract infection		1
Exercise tolerance decreased	1	1
Exposure during pregnancy	1	3
Exposure to SARS-CoV-2	1	2
Exposure via breast milk		1
Extensive swelling of vaccinated limb	4	274
Extrasystoles	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	2	19	81	11	52
				3	5
		1	3		2
				1	1
			3		
		3	7		
			1		1
		1	4		
			2		
					1
					1
				1	1
			1		
					1
					1
					1
			1		
				3	19
			1		
		3	11		4
		1	1		
				3	6
		13	45		6
					1
					1
		1	1		
			2	1	1
		1	2		
			1		
		4	274		
		1	2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye contusion		1
Eye disorder		2
Eye haemorrhage		1
Eye inflammation	1	1
Eye irritation	5	6
Eyelid ptosis		1
Eye pain	1	6
Eye pruritus	1	5
Eye swelling	1	6
Eye symptom		1
Face oedema	1	2
Facial neuralgia	1	2
Facial pain	1	4
Facial paralysis	1	8
Facial paresis		3
Faeces discoloured		2
Fall	4	21
Fatigue	309	1,485
Fear		2
Febrile convulsion		1
Feeding disorder	1	3
Feeling abnormal	6	21
Feeling cold	2	10
Feeling drunk		2
Feeling hot	5	22
Feeling jittery		4
Feeling of body temperature change		1
Fibrin D dimer increased	1	2
Flank pain		1
Fluid intake reduced		1
Fluid retention	1	3
Flushing	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2		
				1	1
		5	6		
			1		
		1	5		1
		1	5		
		1	5		1
			1		
				1	2
		1	2		
		1	3		1
				1	8
			2		1
			2		
	1	2	11	2	10
		303	1445	6	40
			1		1
			1		
			2	1	1
		6	19		2
		2	9		1
			2		
		5	20		2
			4		
			1		
				1	2
			1		
					1
		1	2		1
		2	5		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Food allergy	1	2
Frequent bowel movements		1
Gait disturbance	2	12
Gait inability	1	4
Gamma-glutamyltransferase increased	1	3
Gastric pH decreased		1
Gastroenteritis		1
Gastroenteritis viral		1
Gastrointestinal disorder	1	1
Gastrointestinal haemorrhage	1	4
Gastrointestinal obstruction		1
Gastrointestinal pain	2	2
Gaze palsy		1
Generalised tonic-clonic seizure		3
General physical health deterioration		13
Genital discomfort	1	1
Genital paraesthesia		1
Giant cell arteritis		2
Gingival pain		1
Glomerular filtration rate decreased		3
Glomerulonephritis minimal lesion		1
Glossitis	1	1
Glossodynia	3	4
Glucose tolerance impaired		1
Guillain-Barre syndrome	2	3
Haematochezia	1	2
Haematocrit decreased		2
Haematocrit increased	1	2
Haematoma		4
Haemodynamic instability		1
Haemoglobin decreased	2	7
Haemoptysis		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	1
			1		
		1	8	1	4
			2	1	2
		1	3		
			1		
					1
			1		
				1	1
				1	4
					1
		2	2		
					1
					3
			4		9
		1	1		
			1		
					2
			1		
			3		
					1
		1	1		
		2	3	1	1
			1		
				2	3
				1	2
			2		
			1	1	1
			3		1
					1
		1	4	1	3
			2		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haemorrhage	1	2
Haemorrhoids		1
Hallucination	3	6
Hallucination, olfactory	2	2
Hallucination, visual	1	2
Halo vision		1
Hand deformity		1
Hand fracture		1
Hangover		1
Headache	342	1,603
Head discomfort		4
Head injury		1
Heart rate abnormal	1	2
Heart rate decreased	2	5
Heart rate increased	7	19
Heart rate irregular	1	1
Heavy menstrual bleeding	1	1
Hemianaesthesia		1
Hemianopia	1	1
Hemiparesis	2	8
Hemiplegia	2	5
Henoch-Schonlein purpura	1	1
Hepatic failure		1
Hepatic pain		1
Hepatic steatosis	1	1
Hepatitis	1	2
Hepatitis C		1
Hepatitis cholestatic		1
Herpes ophthalmic		2
Herpes simplex		1
Herpes virus infection		1
Herpes zoster	51	57

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
			1		
				3	6
				2	2
				1	2
			1		
					1
					1
			1		
		339	1582	3	21
			3		1
					1
		1	2		
		2	4		1
		6	13	1	6
				1	1
		1	1		
					1
				1	1
				2	8
				2	5
				1	1
					1
			1		
				1	1
				1	2
					1
					1
					2
			1		
			1		
		51	54		3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Herpes zoster reactivation	2	3
Hiatus hernia	2	3
Hidradenitis		1
High density lipoprotein increased	1	1
Hip fracture		1
Hot flush		6
Human epidermal growth factor receptor decreased		1
Hunger		1
Hyperacusis		1
Hyperaesthesia		1
Hyperaesthesia teeth		1
Hypercalcaemia	2	2
Hyperchlorhydria		1
Hyperglycaemia	1	2
Hyperhidrosis	6	30
Hyperkalaemia	2	3
Hypernatraemia		2
Hyperpyrexia	10	72
Hypersensitivity	10	33
Hypersomnia	1	3
Hypertension	11	43
Hypertensive crisis		1
Hypertensive urgency		1
Hyperthyroidism	2	2
Hyperventilation		4
Hypoacusis		1
Hypoaesthesia	7	18
Hypoaesthesia oral	2	6
Hypoaesthesia teeth	1	1
Hypoglycaemia	2	4
Hypokalaemia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	2
		1	1	1	2
			1		
		1	1		
					1
			5		1
					1
			1		
			1		
			1		
				2	2
			1		
		1	1		1
		6	28		2
				2	3
					2
				10	72
		6	19	4	14
		1	3		
		5	24	6	19
					1
					1
				2	2
			1		3
			1		
		4	14	3	4
		2	5		1
				1	1
		1	3	1	1
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypokinesia		1
Hyponatraemia	1	2
Hypophagia		4
Hypopnoea		1
Hyporesponsive to stimuli		1
Hypotension	9	22
Hypothermia	2	6
Hypothyroidism	1	1
Hypoxia	1	8
III-defined disorder		1
Illness	1	2
Imperception		1
Inappropriate schedule of product administration	4	11
Incontinence	1	3
Incorrect route of product administration		1
Increased tendency to bruise		1
Increased upper airway secretion		1
Infarction		2
Infection	1	3
Inflammation		3
Inflammatory marker increased	1	1
Influenza	1	1
Influenza like illness	3	11
Ingrowing nail		1
Injected limb mobility decreased	2	9
Injection site discomfort		1
Injection site erythema	1	4
Injection site haematoma	1	1
Injection site induration		1
Injection site inflammation	2	8
Injection site pain	2	14
Injection site pruritus		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	2		
			1		3
			1		
			1		
	1	4	10	5	12
				2	6
				1	1
				1	8
					1
		1	1		1
					1
		4	11		
			1	1	2
			1		
			1		
					1
					2
		1	1		2
			2		1
		1	1		
		1	1		
		2	9	1	2
			1		
		2	9		
			1		
		1	4		
		1	1		
			1		
		2	8		
		2	14		
			3		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site swelling		6
Injection site warmth	1	8
Insomnia	2	7
Intermenstrual bleeding	2	2
International normalised ratio fluctuation		1
International normalised ratio increased	1	3
Intestinal ischaemia		2
Intestinal obstruction		1
Intracranial pressure increased	1	2
Iron deficiency	1	1
Irritable bowel syndrome	1	1
Ischaemic cerebral infarction	5	18
Ischaemic stroke		1
Jaundice		3
Joint abscess		1
Joint stiffness		1
Joint swelling	1	1
Lacrimation increased		3
Lacunar infarction		1
Laryngitis		1
Left ventricular hypertrophy		1
Leukaemia	1	1
Leukopenia	1	2
Limb discomfort	6	17
Limb injury		2
Lip blister		1
Lip swelling	4	7
Listless	3	8
Livedo reticularis		1
Localised infection		1
Localised oedema	1	1
Loss of consciousness	8	37

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			6		
		1	8		
		2	7		
		2	2		
					1
		1	2		1
					2
					1
				1	2
				1	1
		1	1		
				5	18
					1
					3
					1
			1		
			3		
					1
			1		
					1
				1	1
				1	2
		6	16		1
			1		1
			1		
		1	4	3	3
		3	8		
					1
					1
				1	1
				8	37

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Loss of control of legs	2	3
Loss of personal independence in daily activities	2	5
Low density lipoprotein increased	1	1
Lung disorder		2
Lyme disease	1	1
Lymphadenitis	1	2
Lymphadenopathy	27	146
Lymphangitis	1	3
Lymph node pain	2	8
Lymph nodes scan abnormal		1
Lymphoedema	1	1
Macular degeneration		1
Malaise	300	1,534
Mastitis	1	1
Maternal exposure during pregnancy		4
Mean cell volume increased		1
Melaena		1
Memory impairment		3
Meniere's disease		2
Meningitis		1
Menstrual disorder	6	6
Menstruation delayed	2	2
Menstruation irregular	3	3
Mental disorder	1	1
Mental impairment		4
Mesenteric artery thrombosis		1
Migraine	4	8
Mobility decreased	1	1
Monoparesis	1	2
Mood altered		2
Mouth swelling		2
Mucosal dryness		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	3
		2	4		1
		1	1		
			1		1
				1	1
		1	2		
		27	146		
				1	3
		2	8		
			1		
		1	1		
					1
		288	1450	12	84
				1	1
			3		1
			1		
					1
			3		
					2
					1
		6	6		
		2	2		
		3	3		
		1	1		
					4
					1
		4	8		
				1	1
				1	2
			2		
			1		1
			1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Multiple organ dysfunction syndrome		2
Multiple sclerosis		2
Muscle contractions involuntary		2
Muscle discomfort	1	1
Muscle disorder	1	2
Muscle rigidity		1
Muscle spasms	4	15
Muscle strain	1	6
Muscle tightness		1
Muscle twitching	1	3
Muscular weakness	6	15
Musculoskeletal chest pain	1	2
Musculoskeletal discomfort	1	4
Musculoskeletal disorder		1
Musculoskeletal pain	5	19
Musculoskeletal stiffness	4	14
Mutism		1
Myalgia	346	1,573
Myelitis transverse	1	1
Myelodysplastic syndrome	1	1
Myocardial calcification	1	1
Myocardial infarction	7	21
Myoclonus		1
Nasal congestion	5	7
Nasal discomfort		1
Nasal dryness		1
Nasal inflammation		1
Nasopharyngitis	5	23
Nausea	155	806
Neck pain	4	11
Nephrolithiasis		3
Nephrotic syndrome		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					2
			2		
		1	1		
		1	2		
			1		
		1	11	3	4
		1	6		
			1		
		1	2		1
		3	9	3	6
		1	2		
		1	4		
			1		
		5	19		
		4	14		
					1
		345	1560	1	13
				1	1
				1	1
		1	1		
				7	21
			1		
		5	7		
			1		
			1		
			1		
		5	22		1
		150	771	5	35
		4	10		1
					3
					2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neuralgia	2	6
Neuritis		1
Neurologic neglect syndrome	1	2
Neuropathy peripheral	4	8
Neutrophil count increased	2	2
Nightmare		1
Night sweats	3	5
Nocturnal dyspnoea	1	1
Nodule		1
Normocytic anaemia	1	1
Nystagmus		1
Occupational exposure to product		1
Ocular discomfort	1	2
Ocular hyperaemia		4
Ocular vascular disorder	1	1
Odynophagia		1
Oedema	1	5
Oedema peripheral	4	7
Off label use	3	10
Oliguria		1
Oophoritis		1
Ophthalmic herpes zoster		1
Optic nerve infarction		1
Optic neuritis		1
Oral bacterial infection		1
Oral discomfort	1	2
Oral disorder		1
Oral herpes	2	4
Oral mucosal blistering		3
Oral mucosal erythema		1
Oral pain		1
Oral pruritus	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	6		
					1
				1	2
				4	8
		2	2		
			1		
		3	5		
		1	1		
			1		
		1	1		
			1		
			1		
		1	2		
			3		1
				1	1
			1		
			3	1	2
		2	3	2	4
		3	10		
			1		
					1
					1
					1
					1
		1	2		
			1		
		2	4		
			2		1
					1
			1		
		1	1		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oropharyngeal blistering		1
Oropharyngeal discomfort	1	3
Oropharyngeal pain	10	34
Oscillopsia		1
Osteomyelitis	1	1
Oxygen saturation abnormal		3
Oxygen saturation decreased	2	8
Pain	9	52
Painful respiration	1	3
Pain in extremity	27	107
Pain in jaw	2	9
Pain of skin	1	7
Palatal disorder	1	1
Pallor	3	16
Palpitations	10	58
Panic attack		1
Panniculitis		1
Papilloedema	1	1
Paraesthesia	26	60
Paraesthesia ear		1
Paraesthesia oral	6	36
Paralysis	2	5
Paresis		2
Parkinson's disease		1
Parosmia		2
Pelvic fracture		1
Pelvic pain		2
Pericarditis		2
Periorbital discomfort	1	1
Periorbital haematoma	1	1
Periorbital oedema		1
Periorbital swelling		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			2	1	1
		10	33		1
			1		
				1	1
			1		2
		1	2	1	6
		9	48		4
		1	3		
		25	101	2	6
		1	7	1	2
		1	7		
		1	1		
		3	9		7
		6	46	4	12
			1		
					1
				1	1
		21	53	5	7
			1		
		5	33	1	3
				2	5
			1		1
					1
			2		
			2		
					1
			2		
					2
		1	1		
		1	1		
			1		
			2		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Peripheral coldness		6
Peripheral swelling	4	15
Periventricular leukomalacia	1	1
Peroneal nerve palsy		2
Petechiae		1
Pharyngeal erythema		1
Pharyngeal oedema		1
Pharyngeal paraesthesia		2
Pharyngeal swelling	5	18
Pharyngitis	1	1
Photophobia		2
Piloerection		1
Plasma cell leukaemia	1	1
Platelet count decreased		2
Platelet count increased		1
Pleural effusion	1	2
Pneumonia	9	20
Pneumonia aspiration	1	7
PO2 increased	1	1
Pollakiuria		2
Polymenorrhoea	1	1
Polyuria		1
Poor quality sleep	1	1
Portal vein thrombosis	1	1
Post concussion syndrome		1
Posterior revers ble encephalopathy syndrome		1
Postmenopausal haemorrhage		2
Presyncope	2	21
Product administered at inappropriate site	1	1
Productive cough	1	2
Prolapse		1
Prothrombin time prolonged		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			4		2
		4	13		2
				1	1
			1		1
			1		
					1
					1
					2
		2	8	3	10
		1	1		
			2		
			1		
				1	1
			1		1
		1	1		1
1	1			9	20
				1	7
				1	1
			2		
		1	1		
			1		
		1	1		
				1	1
			1		
					1
					2
		2	18		3
		1	1		
		1	2		
			1		
			1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pruritus	17	44
Psoriasis	1	1
Psychotic symptom		2
Pulmonary embolism	19	36
Pulmonary hypertension		
Pulmonary infarction	2	4
Pulmonary mass	1	2
Pulmonary oedema		2
Pulmonary pain	1	4
Puncture site pain		1
Pupillary disorder		1
Pupillary reflex impaired	1	1
Purpura		1
Pyrexia	154	800
Rash	10	32
Rash erythematous	3	11
Rash macular	1	2
Rash maculo-papular		1
Rash papular	2	4
Rash pruritic	5	11
Rash vesicular	1	1
Raynaud's phenomenon		1
Rectal haemorrhage		2
Rectal prolapse		1
Red blood cell count decreased		1
Reduced facial expression		1
Renal disorder		1
Renal failure		2
Renal impairment	2	4
Renal infarct		1
Renal neoplasm		1
Respiration abnormal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	16	41	1	3
		1	1		
					2
				19	36
1	1				
				2	4
				1	2
					2
		1	4		
			1		
			1		
				1	1
			1		
		141	745	13	55
	1	10	28		4
		3	11		
		1	2		
			1		
		2	4		
		5	10		1
		1	1		
			1		
					2
					1
			1		
			1		
					2
				2	4
					1
					1
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory disorder		2
Respiratory failure	2	5
Respiratory rate decreased		2
Respiratory rate increased	1	4
Respiratory symptom	1	1
Respiratory tract infection		2
Respiratory tract infection viral		1
Respiratory tract irritation		2
Respiratory tract oedema		1
Resting tremor		1
Restless legs syndrome	1	1
Restlessness	1	5
Retching		3
Retinal artery embolism	1	1
Retinal artery occlusion	2	4
Retinal detachment		1
Retinal vein occlusion	1	2
Rheumatic disorder		1
Rheumatoid arthritis	3	5
Rhinitis		1
Rhinitis allergic	1	1
Rhinorrhoea	2	7
Right ventricular failure		2
Salivary gland pain		1
Salivary hypersecretion	1	2
SARS-CoV-2 ant body test positive		1
SARS-CoV-2 test positive	1	2
Secondary adrenocortical insufficiency		1
Secondary hypertension		1
Seizure	1	8
Sensation of blood flow	1	1
Sensation of foreign body	1	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
				2	5
			2		
			1	1	3
		1	1		
					2
					1
			2		
					1
			1		
		1	1		
		1	5		
			1		2
				1	1
				2	4
					1
				1	2
			1		
				3	5
			1		
		1	1		
		2	7		
					2
			1		
		1	1		1
		1	1		1
					1
				1	8
		1	1		
		1	4		2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sensitive skin		3
Sensory disturbance	1	2
Sepsis		2
Shock	1	3
Sialoadenitis		2
Sinus bradycardia		1
Sinus tachycardia		4
Skin burning sensation		3
Skin discolouration	1	6
Skin discomfort		1
Skin exfoliation	1	1
Skin induration		1
Skin irritation	3	4
Skin swelling		1
Skin warm		1
Sleep disorder		1
Slow speech		1
Sneezing	1	4
Snoring		1
Soft tissue swelling		1
Somnambulism		2
Somnolence	4	18
Speech disorder	2	9
Spinal cord injury	1	1
Splenic infarction		1
Sputum discoloured	1	1
Sputum increased		1
Status epilepticus		2
Stiff tongue		1
Stomatitis	1	2
Stress cardiomyopathy	1	1
Stridor	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		
		1	2		
					2
				1	3
					2
					1
			3		1
			3		
		1	4		2
			1		
		1	1		
			1		
		3	4		
			1		
			1		
			1		
		1	4		
			1		
					1
			2		
		3	12	1	6
		2	5		4
				1	1
					1
		1	1		
			1		
					2
			1		
		1	2		
				1	1
			1	2	3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Subarachnoid haemorrhage	2	2
Subdural haematoma		1
Sudden cardiac death		3
Sudden death	1	12
Sudden hearing loss	1	6
Suicidal ideation		1
Supraventricular tachycardia	1	2
Suspected COVID-19	1	1
Suspiciousness		1
Swelling	3	18
Swelling face	3	19
Swelling of eyelid	2	8
Swollen tongue	6	16
Syncope	19	95
Systemic lupus erythematosus	1	1
Tachycardia	4	19
Tachypnoea		3
Taste disorder	1	5
Thinking abnormal	1	2
Thirst		1
Thirst decreased		1
Throat irritation	1	2
Throat tightness	2	9
Thrombocytopenia	8	9
Thrombophlebitis	2	7
Thrombophlebitis superficial	2	4
Thrombosis	4	17
Thunderclap headache		1
Thyroid mass	1	1
Tinea versicolour	1	1
Tinnitus	2	11
Tongue discolouration		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
					1
					3
				1	12
				1	6
					1
		1	1		1
				1	1
			1		
		3	18		
		2	13	1	6
		2	7		1
		1	6	5	10
				19	95
				1	1
		3	16	1	3
			3		
		1	5		
		1	2		
			1		
					1
		1	2		
		1	5	1	4
		1	1	7	8
		1	4	1	3
		1	1	1	3
				4	17
					1
				1	1
		1	1		
1	2	1	9	1	2
			1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tongue discomfort		2
Tongue disorder	1	5
Tongue erythema	1	1
Tongue oedema		1
Tonsillitis	1	1
Toothache	2	2
Torticollis		1
Total cholesterol/HDL ratio decreased	1	1
Toxic skin eruption		1
Transient aphasia		1
Transient global amnesia		1
Transient ischaemic attack	21	49
Transverse sinus thrombosis	1	1
Traumatic haematoma		1
Tremor	3	17
Trichodynia	1	1
Trigeminal nerve disorder		1
Trigeminal neuralgia	1	1
Trismus	1	1
Troponin I increased	1	1
Troponin increased		1
Type 1 diabetes mellitus		1
Underweight		1
Unresponsive to stimuli		4
Upper limb fracture		1
Urinary incontinence	1	4
Urinary retention		3
Urinary tract infection	1	6
Urine output decreased		2
Urosepsis	1	3
Urticaria	3	18
Vaccination failure	8	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
			2	1	3
		1	1		
					1
		1	1		
		2	2		
			1		
		1	1		
					1
					1
			1		
				21	49
				1	1
					1
		2	15	1	2
		1	1		
			1		
		1	1		
		1	1		
				1	1
					1
					1
			1		
					4
					1
		1	3		1
					3
		1	3		3
			2		
				1	3
		1	11	2	7
				8	10

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination site bruising	4	38
Vaccination site coldness		1
Vaccination site discolouration		1
Vaccination site discomfort	4	16
Vaccination site erythema	86	475
Vaccination site haematoma	25	109
Vaccination site haemorrhage		1
Vaccination site induration	9	37
Vaccination site inflammation	144	509
Vaccination site irritation	1	1
Vaccination site lymphadenopathy	1	1
Vaccination site movement impairment		2
Vaccination site pain	272	1,195
Vaccination site pallor		1
Vaccination site papule		1
Vaccination site paraesthesia		2
Vaccination site pruritus	36	190
Vaccination site rash		3
Vaccination site reaction		6
Vaccination site swelling	100	574
Vaccination site urticaria		1
Vaccination site warmth	102	559
Vaginal haemorrhage	1	2
Varicose vein	1	1
Vascular calcification	1	1
Vascular parkinsonism	1	1
Vasculitis		2
Ventricular extrasystoles	1	1
Vertebrobasilar stroke	2	2
Vertigo	6	20
Vertigo positional		1
Viral infection		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	38		
			1		
			1		
		4	16		
		86	475		
		24	108	1	1
			1		
		9	37		
		144	509		
		1	1		
		1	1		
			2		
		270	1191	2	4
					1
			1		
			2		
		36	190		
			3		
			6		
		100	572		2
			1		
		102	559		
		1	2		
		1	1		
				1	1
				1	1
			2		
				1	1
				2	2
		5	18	1	2
			1		
					2

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vision blurred	2	14
Visual acuity reduced		1
Visual field defect	1	1
Visual impairment	3	15
Vitamin B12 deficiency	1	1
Vomiting	19	78
Vulvovaginal pain		1
Weight decreased		4
Weight increased		1
Wheezing		1
White blood cell count increased	2	3
Wound haemorrhage		1
Wound infection		1
Wrist fracture		1
	3,958	18,123

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	14		
			1		
				1	1
		1	6	2	9
		1	1		
		15	58	4	20
			1		
			3		1
			1		
			1		
		1	2	1	1
			1		
					1
					1
			1		
6	15	3383	16025	575	2098

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort		1						1
Abdominal distension		2				2		
Abdominal pain	3	6			3	6		
Abdominal pain upper	2	5			1	4	1	1
Abnormal dreams		1				1		
Abscess		1						1
Accommodation disorder		1				1		
Activated partial thromboplastin time prolonged	1	1					1	1
Activated partial thromboplastin time shortened		1				1		
Acute abdomen		1						1
Acute cardiac event		1						1
Acute coronary syndrome	2	2					2	2
Acute myocardial infarction	2	7					2	7
Acute respiratory failure		1						1
Ageusia		2				2		
Agitation	1	1			1	1		
Alanine aminotransferase decreased		1				1		
Alanine aminotransferase increased	1	2			1	2		
Allergy to vaccine		1				1		
Amyloidosis	1	1					1	1
Anaemia	1	2			1	2		
Anaphylactic reaction	1	3					1	3
Angina pectoris	1	4					1	4
Angioedema	2	3					2	3
Anosmia		1				1		
Anxiety		4				4		
Aortic aneurysm	1	1					1	1
Aortic arteriosclerosis		1						1
Aortic thrombosis	1	1					1	1
Aortic valve stenosis		1						1
Apathy		1						1
Aphasia	2	4			1	1	1	3

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Appendicitis		1
Apraxia	1	2
Arrhythmia	13	19
Arterial thrombosis		1
Arthralgia	20	79
Arthritis		1
Aspartate aminotransferase increased	1	3
Aspiration		1
Asthenia	1	5
Asthma	1	1
Atrial fibrillation	5	15
Atrial flutter		2
Atrioventricular block complete		1
Axillary pain	2	2
Back pain	1	4
Balance disorder		2
Basilar artery thrombosis	1	2
Basophil count decreased		1
Bell's palsy	1	3
Blindness		1
Blood alcohol decreased		1
Blood alkaline phosphatase increased		1
Blood bicarbonate decreased		2
Blood bilirubin increased		2
Blood calcium decreased		1
Blood cholesterol abnormal		1
Blood cholesterol increased		1
Blood creatine phosphokinase increased		1
Blood creatinine decreased	1	1
Blood creatinine increased	1	3
Blood fibrinogen decreased	1	1
Blood glucose decreased		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	2
1	1			13	19
					1
		18	72	2	7
					1
			2	1	1
					1
		1	3		2
		1	1		
				5	15
			1		1
					1
		2	2		
			2	1	2
			1		1
				1	2
			1		
				1	3
					1
			1		
			1		
			2		
			2		
			1		
			1		
			1		
		1	1		
		1	3		
				1	1
			2		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood glucose increased	1	3
Blood lactate dehydrogenase increased		1
Blood lactic acid increased		1
Blood loss anaemia		1
Blood potassium decreased		1
Blood pressure abnormal		1
Blood pressure decreased	1	3
Blood pressure fluctuation	1	1
Blood pressure increased		1
Blood pressure systolic increased		1
Blood sodium decreased		1
Blood urea abnormal		1
Blood urea increased		2
Body temperature decreased		3
Body temperature increased	4	18
Bradycardia	1	1
Bradyphrenia		1
Brain natriuretic peptide increased	1	2
Breath sounds abnormal	1	1
Burning sensation		1
Cachexia		1
Cardiac arrest	4	12
Cardiac asthma		4
Cardiac death	2	4
Cardiac disorder	1	3
Cardiac failure	4	15
Cardiac failure acute		4
Cardiac fibrillation	1	1
Cardiac tamponade	1	1
Cardiac ventricular thrombosis		1
Cardiogenic shock		3
Cardiopulmonary failure		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		
			1		
			1		
					1
			1		
			1		
		1	2		1
		1	1		
					1
					1
			1		
			1		
			2		
			2		1
		4	16		2
				1	1
			1		
		1	2		
		1	1		
			1		
					1
				4	12
					4
				2	4
				1	3
				4	15
					4
				1	1
				1	1
					1
					3
					1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Carotid artery thrombosis		1
Cerebral artery thrombosis	1	1
Cerebral haemorrhage	3	11
Cerebral infarction	17	25
Cerebral ischaemia	1	1
Cerebral thrombosis		1
Cerebrovascular accident	8	19
Cerebrovascular disorder		1
Chest discomfort	2	3
Chest injury		1
Chest pain	2	10
Chills	33	120
Chronic obstructive pulmonary disease		2
Circulatory collapse	1	4
Coagulation factor VIII level increased	1	1
Coagulopathy	1	1
Cognitive disorder	2	2
Cold sweat	1	2
Coma	1	1
Complement factor C1 increased	1	1
Complement factor C3 increased	1	1
Complement factor increased	1	1
Condition aggravated	2	11
Confusional state	5	12
Conjunctival haemorrhage	1	1
Conjunctival oedema		1
Constipation	1	2
Contusion	2	2
Coronary artery disease		1
Coronary artery stenosis		1
Cough	3	8
COVID-19	6	20

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
				3	11
				17	25
				1	1
					1
	1			8	19
					1
		1	2	1	1
					1
		1	3	1	7
		29	105	4	15
			1		1
				1	4
		1	1		
				1	1
		2	2		
		1	1		1
				1	1
		1	1		
		1	1		
		2	4		7
		3	6	2	6
1	1			1	1
					1
		1	2		
		2	2		
					1
					1
		2	6	1	2
		2	4	4	16

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
COVID-19 pneumonia		2
C-reactive protein increased	1	7
Cutaneous vasculitis	1	2
Cyanosis		1
Cystitis	1	4
Deafness	2	2
Deafness neurosensory		1
Deafness unilateral		1
Death	2	21
Decreased appetite		5
Decreased immune responsiveness		1
Decreased interest	1	1
Deep vein thrombosis	12	21
Defaecation urgency	1	1
Dehydration	1	2
Delirium	1	13
Delusion		1
Dementia Alzheimer's type		1
Depressed level of consciousness		7
Depressed mood		1
Depression		3
Derealisation		1
Dermatitis	1	1
Dermatitis bullous	1	1
Diabetes mellitus inadequate control		1
Diarrhoea	7	15
Diplopia		3
Disease recurrence	2	8
Dissociation		1
Disturbance in attention		2
Dizziness	6	24
Drug hypersensitivity	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		1	6		1
				1	2
					1
		1	2		2
				2	2
					1
					1
				2	21
			3		2
					1
		1	1		
				12	21
		1	1		
				1	2
				1	13
			1		
					1
					7
			1		
			3		
			1		
		1	1		
				1	1
					1
		6	13	1	2
			2		1
			1	2	7
			1		
			2		
		5	22	1	2
				1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Drug ineffective	3	10
Drug interaction	1	1
Dry eye		2
Dry mouth		1
Dysarthria		7
Dysgeusia		1
Dyskinesia	1	1
Dyspepsia		2
Dysphagia	2	10
Dysphonia	1	2
Dyspnoea	12	46
Dyspnoea exertional		2
Dysstasia		2
Ear pain	2	2
Ecchymosis		1
Electrocardiogram QT prolonged	1	1
Electrolyte imbalance		1
Emotional disorder		1
Emphysema	1	1
Encephalitis enteroviral		1
Endocarditis		1
Eosinophil count decreased		1
Epidural haemorrhage	1	1
Epilepsy	2	20
Epistaxis	1	5
Erectile dysfunction	1	2
Eructation		1
Erysipelas	2	3
Erythema	2	5
Exercise tolerance decreased	1	1
Extensive swelling of vaccinated limb	1	17
Extrasystoles	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	10
				1	1
			2		
			1		
			1		6
			1		
		1	1		
			2		
		1	4	1	6
				1	2
		8	18	4	28
			1		1
			1		1
		2	2		
					1
				1	1
					1
		1	1		
					1
			1		
				1	1
				2	20
1	1	1	2		3
				1	2
			1		
				2	3
		1	3	1	2
		1	1		
		1	16		1
		1	1		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Eye disorder	1	1
Eye haematoma		1
Eye haemorrhage	1	2
Eye infection	1	1
Eye inflammation	1	1
Eyelid ptosis		1
Eye movement disorder		1
Eye swelling	1	2
Facial bones fracture		1
Facial pain		1
Facial paralysis	2	6
Facial paresis		1
Faeces hard	1	1
Fall	3	14
Fatigue	62	204
Febrile convulsion		1
Feeding disorder		1
Feeling abnormal	1	3
Feeling cold		1
Feeling hot	1	5
Fibrin D dimer increased		2
Flank pain	1	1
Fluid intake reduced		2
Fluid retention	1	2
Fracture		1
Gait disturbance	1	4
Gait inability	1	2
Gamma-glutamyltransferase increased		1
Gastric haemorrhage		1
Gastrointestinal disorder	1	2
Gastrointestinal haemorrhage	1	4
Gastrooesophageal reflux disease		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
				1	2
				1	1
		1	1		
			1		
			1		
		1	2		
					1
			1		
				2	6
					1
		1	1		
		1	3	2	11
		57	180	5	24
			1		
					1
		1	3		
			1		
			3	1	2
			2		
				1	1
			1		1
		1	1		1
					1
			3	1	1
		1	1		1
			1		
					1
		1	2		
				1	4
			1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Generalised tonic-clonic seizure		3
General physical health deterioration	1	3
Gingival bleeding	1	1
Glomerular filtration rate decreased	1	2
Glomerulonephritis minimal lesion	1	1
Glossodynia		1
Haemarthrosis		1
Haematemesis		1
Haematocrit decreased	1	4
Haemodynamic instability	2	2
Haemoglobin abnormal		1
Haemoglobin decreased	1	6
Haemophagocytic lymphohistiocytosis		1
Haemophilia		1
Haemorrhage	1	2
Hallucination	1	2
Headache	57	183
Head discomfort	2	3
Head injury		1
Heart rate decreased		1
Heart rate increased	2	7
Heart rate irregular		2
Hemianopia	1	1
Hemiparaesthesia	1	1
Hemiparesis	2	6
Hemiplegia		1
Hepatic failure		1
Hepatitis acute		1
Hernia	1	1
Hernia pain		1
Herpes ophthalmic		1
Herpes zoster	17	19

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
		1	1		2
		1	1		
		1	2		
				1	1
			1		
					1
					1
		1	4		
		1	1	1	1
			1		
		1	5		1
					1
					1
				1	2
				1	2
		55	174	2	9
		1	2	1	1
					1
			1		
		2	5		2
			2		
				1	1
				1	1
				2	6
					1
					1
					1
		1	1		
			1		
					1
		17	19		

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* AE=Adverse Event

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Herpes zoster reactivation	1	1
Hip fracture		1
Horner's syndrome	1	1
Hydrocephalus		1
Hyperaesthesia		2
Hyperglycaemia	1	1
Hyperhidrosis	1	8
Hyperpyrexia	1	10
Hypersensitivity	4	5
Hypersomnia		1
Hypertension	5	10
Hypertriglyceridaemia		1
Hyperventilation		2
Hypoaesthesia		1
Hypoglycaemia		2
Hypokinesia	1	1
Hypophagia	1	3
Hypotension	2	9
Hypovolaemic shock		1
Hypoxia	1	9
Ileus	1	1
Immune system disorder	1	2
Immune thrombocytopenia		1
Inappropriate schedule of product administration	3	4
Incontinence		2
Infection		2
Infection susceptibility increased		1
Inflammation		2
Inflammatory marker increased		1
Injected limb mobility decreased		1
Injection site pain	1	1
Injection site pruritus		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
				1	1
					1
			1		1
		1	1		
		1	6		2
				1	10
		1	2	3	3
			1		
		2	2	3	8
					1
			2		
			1		
					2
		1	1		
				1	3
		2	4		5
					1
				1	9
				1	1
		1	1		1
					1
		3	4		
					2
					2
					1
			1		1
					1
			1		
		1	1		
			1		

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* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site swelling		1
Insomnia		1
Intentional product use issue		1
Intention tremor		1
International normalised ratio increased	1	2
Interstitial lung disease		1
Intestinal haemorrhage		2
Intestinal ischaemia	2	2
Iridocyclitis	1	2
Ischaemic cerebral infarction		11
Ischaemic stroke	1	2
IVth nerve paralysis		1
Jaundice		1
Joint swelling	2	2
Kidney infection		1
Left ventricular dysfunction		1
Left ventricular failure		1
Left ventricular hypertrophy		1
Lethargy		1
Leukocytosis	1	1
Ligament sprain	1	1
Limb discomfort		2
Lip oedema	1	1
Lip swelling	1	3
Listless	1	1
Loss of consciousness	2	5
Lung disorder		4
Lymphadenopathy	7	16
Lymphocyte count decreased		2
Macroglossia	1	1
Malaise	59	219
Mean cell haemoglobin concentration increased	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
			1		
					1
				1	2
					1
					2
				2	2
				1	2
					11
				1	2
			1		
			1		
		2	2		
					1
					1
					1
			1		
			1		
		1	1		
		1	1		
			1		1
			1		
		1	1		
				1	3
		1	1		
1	1			2	5
			1		3
		7	15		1
			1		1
				1	1
		51	182	8	37
		1	1		

* I=Interval, C=Cumulative
* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mean cell haemoglobin increased	1	1
Memory impairment	1	1
Meniere's disease		3
Mental disorder	1	1
Mesenteric vein thrombosis	1	1
Metabolic acidosis		1
Metastases to lung	1	1
Migraine		1
Mobility decreased		3
Monocyte count increased		1
Monoparesis	1	2
Monoplegia		1
Mouth swelling		1
Movement disorder		4
Muscle spasms	2	2
Muscle strain	1	3
Muscular weakness	5	10
Musculoskeletal chest pain		1
Musculoskeletal disorder		1
Musculoskeletal pain	1	6
Musculoskeletal stiffness		1
Mutism		1
Myalgia	51	194
Myelodysplastic syndrome		1
Myelopathy		1
Myocardial infarction	8	14
Nasal congestion		1
Nasopharyngitis	2	7
Nausea	17	78
Neck pain		1
Nephrotic syndrome	1	1
Neurologic neglect syndrome	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1		
					3
				1	1
				1	1
			1		
				1	1
					1
			2		1
			1		
				1	2
					1
			2		2
		1	1	1	1
		1	2		1
		3	6	2	4
					1
					1
		1	6		
			1		
					1
		51	184		10
					1
					1
				8	14
					1
		2	7		
		15	68	2	10
					1
				1	1
				1	1

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* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neuropathy peripheral		1
Neutrophil count decreased		1
Neutrophil count increased		3
Night blindness		1
Night sweats		1
Obstructive airways disorder	1	1
Ocular hyperaemia	1	2
Ocular myasthenia		1
Oedema		1
Oedema peripheral	1	3
Off label use	2	3
Oral herpes	1	1
Organ failure	1	1
Oropharyngeal pain	2	9
Oxygen saturation decreased	2	18
Pain	4	9
Painful respiration	1	1
Pain in extremity	4	14
Pain in jaw		1
Pallor		2
Palpitations	2	3
Pancytopenia		1
Paraesthesia	2	7
Paraesthesia oral		1
Paralysis		2
Parkinson's disease		1
Parosmia	1	2
Pemphigoid	1	2
Pericarditis		1
Peripheral coldness	1	3
Peripheral swelling	2	4
Personality disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
			3		
			1		
			1		
				1	1
		1	1		1
					1
					1
		1	2		1
		2	3		
		1	1		
				1	1
		1	8	1	1
			2	2	16
		4	8		1
				1	1
		4	13		1
			1		
			2		
		2	3		
					1
		2	7		
			1		
					2
					1
		1	2		
				1	2
					1
		1	3		
		2	3		1
			1		

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* AE=Adverse Event

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Petechiae		3
Pharyngeal oedema	1	1
Pharyngeal swelling	1	3
Photophobia	1	1
Pituitary apoplexy		1
Pityriasis rosea		1
Platelet count decreased	1	4
Platelet count increased		1
Pleural effusion		2
Pneumonia	8	26
Pneumonia aspiration		5
Pneumonia bacterial		1
Polymyalgia rheumatica	1	1
Polyneuropathy chronic	1	1
Poor quality product administered		1
Poor quality sleep		1
Postictal state		1
Presyncope		1
Productive cough		1
Product storage error		1
Prothrombin time prolonged	1	1
Prothrombin time ratio increased		1
Pruritus	1	4
Psoriasis	1	1
Pulmonary arterial pressure increased		1
Pulmonary embolism	15	32
Pulmonary haemorrhage		1
Pulmonary hypertension		1
Pulmonary infarction		1
Pulmonary oedema	1	1
Pulmonary sepsis	1	1
Pyelonephritis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		
				1	1
				1	3
		1	1		
					1
			1		
			3	1	1
			1		
					2
				8	26
					5
					1
				1	1
		1	1		
			1		
			1		
			1		
					1
			1		
				1	1
			1		
			2	1	2
		1	1		
					1
				15	32
					1
					1
					1
				1	1
				1	1
					1

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* AE=Adverse Event

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pyrexia	27	120
Quadriplegia		1
Rash	1	7
Rash erythematous	1	4
Rash macular	1	1
Rash papular	1	2
Rash pruritic		1
Rectal haemorrhage		1
Red blood cell count decreased	1	3
Red blood cell sedimentation rate increased	1	1
Regurgitation		1
Renal artery thrombosis	1	1
Renal disorder		1
Renal failure	3	4
Renal impairment	1	2
Renal ischaemia	1	1
Respiratory disorder		1
Respiratory failure	1	7
Respiratory rate increased		2
Restlessness	2	5
Retinal vein occlusion	1	1
Rhinitis		1
Rhinorrhoea		1
SARS-CoV-2 test positive		2
Sciatica		1
Scrotal injury		1
Seizure	1	4
Serum ferritin abnormal		1
Skin abrasion	1	1
Skin discolouration		1
Skull fracture	1	1
Small intestinal obstruction		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1	23	87	4	33
					1
		1	6		1
		1	4		
		1	1		
		1	2		
			1		
					1
		1	3		
		1	1		
			1		
				1	1
			1		
				3	4
				1	2
				1	1
					1
				1	7
			1		1
		2	4		1
				1	1
			1		
			1		
					2
					1
			1		
				1	4
					1
		1	1		
			1		
				1	1
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sneezing		1
Snoring	1	1
Soft tissue infection		1
Somnolence	1	5
Speech disorder	2	5
Spinal cord compression		1
Spinal epidural haemorrhage		1
Spinal meningeal cyst		1
Spinal osteoarthritis		1
Staphylococcal infection	1	1
Starvation	1	1
Status epilepticus		1
Stridor	1	3
Subdural haematoma		1
Sudden cardiac death	3	4
Sudden death	5	8
Sudden hearing loss		1
Supraventricular tachycardia		1
Suspected COVID-19		2
Swelling face		2
Swelling of eyelid		1
Swollen tongue	2	4
Symptom recurrence		1
Syncope	5	16
Tachycardia		2
Tachypnoea		1
Taste disorder		2
Tendonitis	1	2
Thirst		1
Throat irritation	1	1
Throat tightness	1	1
Thrombocytopenia	8	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	1		
					1
				1	5
			1	2	4
					1
					1
			1		1
				1	1
				1	1
					1
			1		
				3	4
				5	8
					1
			1		
			1		1
			1		1
			1	2	3
					1
1	2			5	16
					2
					1
			2		
		1	2		
			1		
				1	1
				1	1
		1	1	7	10

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* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Thrombophlebitis		1
Thrombophlebitis superficial	1	1
Thrombosis		8
Thrombosis mesenteric vessel		1
Tinnitus		1
Tongue biting	1	1
Tongue oedema	1	1
Tonsillitis	1	1
Toothache		1
Torsade de pointes	1	1
Torticollis	1	1
Toxic skin eruption	1	1
Transient ischaemic attack	10	31
Tremor		2
Troponin increased		1
Unresponsive to stimuli	1	5
Urinary incontinence	1	1
Urinary retention		2
Urinary tract infection	1	4
Urosepsis		2
Urticaria	5	10
Uvulitis		1
Vaccination site bruising	2	5
Vaccination site discolouration	1	1
Vaccination site discomfort	2	2
Vaccination site erythema	4	28
Vaccination site haematoma	2	5
Vaccination site induration		1
Vaccination site inflammation	12	38
Vaccination site pain	30	117
Vaccination site pruritus	1	6
Vaccination site reaction	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
					8
					1
			1		
		1	1		
				1	1
		1	1		
			1		
				1	1
				1	1
	1			10	31
			1		1
			1		
				1	5
				1	1
					2
		1	2		2
					2
		5	10		
			1		
		2	5		
		1	1		
		2	2		
		4	27		1
		2	5		
			1		
		12	38		
		30	116		1
		1	6		
		1	2		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site swelling	12	39			12	39		
Vaccination site warmth	5	24			5	24		
Vascular stent thrombosis		1						1
Vasculitis		1				1		
Ventricular fibrillation	1	4					1	4
Ventricular tachycardia	3	3					3	3
Vertigo		3				2		1
Vestibular neuronitis		1						1
Vision blurred		4				4		
Visual field defect	1	1					1	1
Visual impairment	1	3			1	2		1
Vomiting	3	14			2	8	1	6
Weight decreased		2				1		1
White blood cell count decreased		1				1		
White blood cell count increased	1	2			1	2		
Wound	1	2			1	2		
	895	3,022	6	9	572	1916	323	1106

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* AE=Adverse Event
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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion spontaneous		1				1
Anembryonic gestation		1				1
Angioedema		1				1
Circumstance or information capable of leading to medication error		1		1		
Crohn's disease		1				1
Death		1				1
Exposure via breast milk		1		1		
Headache	1	1	1	1		
Incorrect dose administered	1	1	1	1		
Maternal exposure during pregnancy		1				1
Myalgia	1	1	1	1		
Product label confusion		1		1		
Product packaging quantity issue	1	1	1	1		
Product preparation error		2		2		
Product preparation issue	1	2	1	2		
Pyrexia	1	1	1	1		
	6	18	6	12		6

* I=Interval, C=Cumulative
* AE=Adverse Event
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Country Where Event Occurred

NEW ZEALAND

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
Asthenia	1	1	1	1
Heart rate increased	1	1	1	1
Hypoglycaemia		3		3
Nausea	1	2	1	2
	4	8	4	8

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* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19		1				1
Cerebrovascular accident	1	1			1	1
Chest discomfort	1	1			1	1
Drug ineffective		1				1
Exposure to SARS-CoV-2		1				1
Headache	1	1			1	1
Heart rate increased	1	1			1	1
Hypersensitivity	20	25			20	25
Influenza like illness	1	2			1	2
Musculoskeletal stiffness	1	1			1	1
Myalgia	1	1			1	1
Product administration error	1	1	1	1		
Reactogenicity event		1				1
Seizure	1	1			1	1
Thrombosis	1	1			1	1
	30	40	1	1	29	39

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred
NORTHERN MARIANA ISLANDS

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia		1		1
Chest discomfort		1		1
Chills		1		1
Disorientation		1		1
Dizziness		1		1
Fatigue		1		1
Headache		1		1
Inappropriate schedule of product administration		2		2
Pain in extremity		1		1
Poor quality sleep		1		1
		11		11

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Country Where Event Occurred

NORWAY

090177e19749cf15\Approved\Approved On: 14-Jun-2021 14:01 (GMT)

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- * AE=Adverse Event
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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	3		2	1	1
Abdominal infection		1				1
Abdominal pain	5	16	3	9	2	7
Abdominal pain upper	3	12	1	3	2	9
Abnormal dreams		1		1		
Abnormal weight gain	1	1	1	1		
Abortion spontaneous	1	2			1	2
Acute coronary syndrome		1				1
Acute kidney injury		2				2
Acute myocardial infarction	1	6			1	6
Acute respiratory failure	1	1			1	1
Agitation		1				1
Allergy to vaccine		2				2
Altered state of consciousness		5				5
Amnesia		3		1		2
Anaphylactic reaction	15	24			15	24
Anaphylactic shock	1	1			1	1
Angina pectoris		1				1
Angioedema	4	7			4	7
Antinuclear ant body increased		1		1		
Anti-thyroid antibody		1		1		
Anxiety	2	5		1	2	4
Aortic aneurysm	1	1			1	1
Aortic arteriosclerosis		1		1		
Aortic stenosis		1				1
Apathy		2				2
Aphasia		2				2
Apnoea		2				2
Apnoeic attack		1				1
Appendicitis		2				2
Arrhythmia	3	5			3	5
Arterial haemorrhage		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arteriosclerosis coronary artery		1				1
Arthralgia	11	33	7	27	4	6
Arthritis	1	2		1	1	1
Arthritis bacterial		1				1
Asthenia	1	13		4	1	9
Asthma	2	4	1	2	1	2
Asymptomatic COVID-19	2	2			2	2
Atelectasis		1				1
Atrial fibrillation	2	3			2	3
Atrial flutter	1	1			1	1
Atrioventricular block first degree		1				1
Auditory disorder		1		1		
Axillary mass		1				1
Axillary pain		3		2		1
Back pain	2	12	2	7		5
Balance disorder	2	4	1	2	1	2
Basedow's disease		1				1
Bedridden		6		2		4
Bell's palsy	1	2			1	2
Blepharospasm		1		1		
Blindness	1	2			1	2
Blister	1	1			1	1
Blood calcium decreased		1		1		
Blood glucose decreased		1		1		
Blood glucose fluctuation		3		3		
Blood glucose increased	2	3	1	2	1	1
Blood phosphorus decreased		1		1		
Blood potassium decreased	1	2		1	1	1
Blood pressure decreased	3	11	1	3	2	8
Blood pressure diastolic decreased		1		1		
Blood pressure diastolic increased	1	1			1	1
Blood pressure increased	8	11	3	5	5	6

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure systolic increased	1	3			1	3
Body temperature decreased		1		1		
Body temperature fluctuation		1				1
Body temperature increased		1		1		
Bone pain	1	2			1	2
Brachiocephalic vein thrombosis	1	1			1	1
Bradycardia	2	5			2	5
Brain herniation	1	1			1	1
Brain injury	1	1			1	1
Brain oedema	1	1			1	1
Breast enlargement		1		1		
Breast pain		1		1		
Breast tenderness	1	1	1	1		
Breath sounds abnormal		1				1
Bronchitis		1		1		
Bronchospasm	1	1			1	1
Burning sensation	2	5	1	3	1	2
Bursitis	1	1			1	1
Cardiac arrest	2	4			2	4
Cardiac disorder	1	1			1	1
Cardiac failure		1				1
Cardiac fibrillation		1				1
Cardiac murmur	1	1	1	1		
Cardio-respiratory arrest		1				1
Cardiovascular disorder		1				1
Carotid arteriosclerosis		1		1		
Cellulitis	1	1			1	1
Cerebral artery thrombosis	1	1			1	1
Cerebral haemorrhage	1	9			1	9
Cerebral infarction	2	5			2	5
Cerebral thrombosis		1				1
Cerebrovascular accident	3	17			3	17

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebrovascular disorder		1				1
Chest discomfort	3	6	1	3	2	3
Chest pain	7	18		5	7	13
Chills	12	42	9	29	3	13
Chronic kidney disease		1				1
Chronic obstructive pulmonary disease		3				3
Circulatory collapse	1	5			1	5
Coating in mouth	1	1			1	1
Cognitive disorder	1	3		1	1	2
Cold sweat	4	15		3	4	12
Colitis	1	1			1	1
Coma		1				1
Communication disorder		1		1		
Concomitant disease aggravated		2				2
Concussion		2				2
Condition aggravated		5		1		4
Confusional state	1	17		6	1	11
Contusion		3		1		2
Coordination abnormal		2				2
Coronary artery occlusion		1				1
Cor pulmonale acute	1	1			1	1
Cough	9	21	3	11	6	10
COVID-19	6	8	1	1	5	7
COVID-19 pneumonia	1	1			1	1
C-reactive protein abnormal	1	1			1	1
C-reactive protein increased	3	17		3	3	14
Crepitations	1	1	1	1		
Cyanosis		1				1
Cystic lung disease		1		1		
Death	1	19			1	19
Decreased activity		1		1		
Decreased appetite	2	13		5	2	8

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decubitus ulcer		1		1		
Deep vein thrombosis	7	11			7	11
Dehydration	1	3	1	2		1
Delirium		1				1
Dementia		1				1
Dementia Alzheimer's type		1				1
Depressed level of consciousness	1	4			1	4
Depressed mood		1		1		
Dermatitis allergic		1				1
Diabetes mellitus inadequate control		1				1
Diarrhoea	5	25	2	14	3	11
Diarrhoea haemorrhagic	1	1			1	1
Discomfort		7		5		2
Disease recurrence	3	8	1	2	2	6
Disorientation	2	3			2	3
Disturbance in attention		1		1		
Dizziness	23	70	7	34	16	36
Drooling		1		1		
Drug ineffective	1	2			1	2
Drug interaction		2		1		1
Drug reaction with eosinophilia and systemic symptoms		1				1
Dry mouth		3		2		1
Dry skin		1		1		
Dysarthria		5		1		4
Dysgeusia	3	6	2	5	1	1
Dyskinesia		1				1
Dysphagia		3				3
Dysphonia	4	6	1	3	3	3
Dyspnoea	30	83	4	26	26	57
Dyspnoea at rest	1	1			1	1
Ear discomfort		3		3		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear pain		2		2		
Ear swelling		1		1		
Ecchymosis		1				1
Eczema		1				1
Electrolyte imbalance		1				1
Embolic cerebral infarction		1				1
Emphysema		1		1		
Encephalitis brain stem	1	1			1	1
Enthesopathy	1	1			1	1
Eosinophilia		1				1
Epilepsy		1				1
Epistaxis	1	2	1	1		1
Erysipelas	1	4			1	4
Erythema	8	18	3	9	5	9
Exfoliative rash		1				1
Exposure during pregnancy	1	2	1	2		
Extrasystoles		1				1
Eye haemorrhage	1	3			1	3
Eyelid oedema	1	1	1	1		
Eye pain		2		2		
Eye swelling	1	1	1	1		
Face oedema		1				1
Facial paralysis	1	2			1	2
Facial paresis	3	11	2	5	1	6
Faeces discoloured	1	2			1	2
Fall	1	19	1	3		16
Fatigue	30	124	22	94	8	30
Feeling abnormal		5		4		1
Feeling cold	3	4	3	4		
Feeling drunk		1		1		
Feeling hot	5	10	1	4	4	6
Feeling of body temperature change		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Femoral neck fracture		2				2
Femur fracture		1				1
Fibrin D dimer increased	3	3			3	3
Flatulence		1		1		
Flushing	3	5	2	3	1	2
Foaming at mouth		1		1		
Food refusal		1				1
Forced expiratory flow	1	1			1	1
Fracture		1				1
Frostbite	3	4	2	2	1	2
Fungal infection	1	1			1	1
Gait disturbance	1	1			1	1
Gastric haemorrhage		1				1
Gastroenteritis		1				1
Gastrointestinal haemorrhage	1	2			1	2
Gastrointestinal necrosis		1				1
Generalised tonic-clonic seizure		1				1
General physical health deterioration	5	48		10	5	38
Giant cell arteritis		1				1
Glomerulonephritis chronic		1				1
Grip strength decreased		2				2
Grunting	1	1			1	1
Haematemesis		2				2
Haematochezia	1	1			1	1
Haematoma		1				1
Haemoglobin decreased		2				2
Haemorrhage		1				1
Haemorrhage subcutaneous		2				2
Haemothorax		1				1
Hallucination	1	4			1	4
Hallucination, auditory		1				1
Hallucinations, mixed		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hallucination, visual	4	4			4	4
Headache	36	128	22	93	14	35
Head injury		1				1
Heart rate decreased	1	1			1	1
Heart rate increased	4	15	2	7	2	8
Heart rate irregular	1	4		2	1	2
Heavy menstrual bleeding	1	1	1	1		
Hemiparesis	2	6			2	6
Hemiplegia	1	2			1	2
Herpes simplex reactivation		1		1		
Herpes zoster	9	9	9	9		
Hot flush		1		1		
Hyperaesthesia		1				1
Hyperglycaemia		2		1		1
Hyperhidrosis	3	7	1	5	2	2
Hypernatraemia		1				1
Hyperpyrexia		1				1
Hypersensitivity	7	15	1	3	6	12
Hypersensitivity vasculitis	1	1			1	1
Hypersomnia	1	2	1	2		
Hypertension	5	9	2	5	3	4
Hyperthyroidism		1				1
Hyperventilation	5	10		2	5	8
Hypoaesthesia	5	12	4	9	1	3
Hypoaesthesia oral	3	8	2	5	1	3
Hypogeusia	1	2	1	2		
Hypokinesia	1	2	1	2		
Hyponatraemia		2				2
Hypophagia		1				1
Hyposmia	1	2	1	2		
Hypotension	2	13	1	1	1	12
Hypothermia		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypothyroidism	1	1			1	1
Hypoxia		1				1
Immune system disorder	1	1			1	1
Immune thrombocytopenia		2				2
Inappropriate schedule of product administration		1		1		
Incomplete course of vaccination	1	1			1	1
Incontinence		1				1
Incorrect route of product administration		3		3		
Increased bronchial secretion		2		1		1
Increased tendency to bruise		1				1
Infection	8	13	1	1	7	12
Influenza		2		2		
Influenza like illness	6	11	5	7	1	4
Injection site pain		3		3		
Insomnia		1		1		
International normalised ratio increased		1				1
Intestinal ischaemia		1				1
Intracardiac thrombus		1				1
Intranasal hypoaesthesia		1		1		
Intranasal paraesthesia		1		1		
Iridocyclitis		1				1
Iron deficiency anaemia	1	1			1	1
Ischaemic stroke		3				3
Joint swelling	2	3	1	2	1	1
Jugular vein thrombosis	1	1			1	1
Kidney fibrosis		1				1
Left ventricular failure		1				1
Lethargy	2	4	1	2	1	2
Limb discomfort		4		3		1
Lip pruritus	1	2			1	2
Lip swelling	4	4	2	2	2	2
Local reaction		1				1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Loss of consciousness	4	12
Loss of personal independence in daily activities		1
Lower respiratory tract infection		1
Lung opacity		1
Lymphadenitis		2
Lymphadenopathy		3
Lymphangitis		1
Lymphocytosis		1
Malaise	16	49
Malignant hypertension		1
Marasmus		1
Mastitis	1	1
Maternal exposure during pregnancy		1
Mechanical urticaria	1	1
Mediastinal haemorrhage		1
Melaena		1
Memory impairment		2
Menstrual discomfort	1	1
Menstrual disorder	1	1
Mental impairment		1
Mesenteric artery embolism		1
Metastases to peritoneum		1
Middle insomnia		1
Migraine		4
Migraine with aura		1
Mobility decreased		1
Monoparesis		1
Motor dysfunction		1
Mouth haemorrhage		1
Mouth swelling	1	2
Mouth ulceration		1
Multiple fractures		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		4	12
			1
			1
			1
	1		1
	2		1
			1
	1		
7	31	9	18
			1
			1
		1	1
	1		
		1	1
			1
			1
	2		
		1	1
1	1		
			1
			1
	1		
	2		2
			1
	1		
			1
	1		
			1
		1	2
			1
			1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Multiple sclerosis	1	1			1	1
Muscle contractions involuntary	1	2	1	2		
Muscle spasms		6		1		5
Muscle twitching		1		1		
Muscular weakness	2	6	1	2	1	4
Musculoskeletal pain		2		2		
Musculoskeletal stiffness	2	9	2	7		2
Myalgia	16	50	12	40	4	10
Myocardial infarction	1	1			1	1
Myopia		1				1
Nasal congestion	3	4	1	2	2	2
Nasal pruritus		1				1
Nasopharyngitis		1		1		
Nausea	25	85	13	55	12	30
Neck pain	1	7	1	6		1
Nephrolithiasis		1				1
Neuralgia	1	1			1	1
Neuroborreliosis		1				1
Neurofibromatosis	1	1			1	1
Neuropathy peripheral		2				2
Neutropenia	1	1			1	1
Night sweats		1		1		
Nocturia	1	1	1	1		
Obstructive airways disorder	2	3	1	1	1	2
Ocular hyperaemia		2		1		1
Odynophagia	1	1			1	1
Oedema peripheral		3		1		2
Ophthalmic herpes zoster		1				1
Oral mucosa haematoma		1				1
Oral pruritus	2	4			2	4
Orbital oedema		1				1
Oropharyngeal discomfort	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oropharyngeal pain		10		7		3
Oropharyngeal swelling		1				1
Orthostatic hypotension	1	2		1	1	1
Oxygen saturation decreased	2	14		1	2	13
Pain	5	17		10	5	7
Painful respiration	1	2		1	1	1
Pain in extremity	12	24	8	17	4	7
Pain of skin	1	2	1	1		1
Pallor	2	11	1	4	1	7
Palpitations	9	15	3	6	6	9
Pancytopenia		1				1
Panic attack		1		1		
Paraesthesia	7	16	5	10	2	6
Paraesthesia oral	4	6	3	4	1	2
Paranasal sinus discomfort		1		1		
Parosmia		1		1		
Pelvic venous thrombosis	2	2			2	2
Pericardial haemorrhage		1				1
Pericarditis	2	3			2	3
Peripheral coldness	1	2	1	2		
Peripheral swelling	1	8		5	1	3
Petechiae	2	7	1	2	1	5
Pharyngeal paraesthesia	2	3			2	3
Pharyngeal swelling	3	6		1	3	5
Photophobia		3		2		1
Platelet count increased	1	1			1	1
Pneumonia	4	13			4	13
Pneumonia aspiration		2				2
Pneumonitis		1				1
Polymyalgia rheumatica	1	1			1	1
Prerenal failure	1	1			1	1
Presyncope	2	10	1	3	1	7

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product administered at inappropriate site		1		1		
Productive cough	2	5	1	1	1	4
Pruritus	10	25	4	9	6	16
Psoriasis		1		1		
Psychological trauma	1	1			1	1
Psychomotor hyperactivity		2		1		1
Pulmonary embolism	15	19			15	19
Pulmonary necrosis		1				1
Pulmonary oedema		1				1
Pulmonary pain	1	1			1	1
Pupil fixed		2				2
Pyrexia	25	106	17	66	8	40
Radiculopathy	1	1			1	1
Rales		2		1		1
Rash	6	17	1	9	5	8
Rash erythematous	5	8		2	5	6
Rash macular	1	1			1	1
Rash papular	1	1	1	1		
Rash pruritic	4	7	4	5		2
Renal failure		2				2
Respiratory alkalosis		1				1
Respiratory arrest	1	4			1	4
Respiratory distress	1	1			1	1
Respiratory failure	2	5			2	5
Respiratory rate decreased		1		1		
Respiratory rate increased		7		2		5
Respiratory symptom	1	1			1	1
Respiratory tract congestion		1				1
Respiratory tract infection		1				1
Restlessness	4	13		2	4	11
Retching	2	8		3	2	5
Retinal vein occlusion	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rhinorrhoea	1	5	1	5		
Road traffic accident	1	1			1	1
Salmonella test positive		1				1
Secretion discharge		2				2
Seizure		1				1
Sensation of foreign body	1	1			1	1
Sepsis		3				3
Sinoatrial block	1	1			1	1
Skin discolouration	1	1			1	1
Skin haemorrhage		2		2		
Skin laceration		1				1
Skin warm	1	1	1	1		
Sleep disorder	1	2		1	1	1
Sleep paralysis	1	1	1	1		
Sneezing		1		1		
Snoring		1				1
Somnolence	3	14	2	9	1	5
Speech disorder	1	7		2	1	5
Staphylococcal sepsis		1				1
Status epilepticus		1				1
Status migrainosus		1				1
Stridor	1	3			1	3
Subdural haematoma		1				1
Subdural haemorrhage		1				1
Sudden death	1	7			1	7
Supraventricular extrasystoles		1				1
Swelling	3	4	1	1	2	3
Swelling face	1	6	1	3		3
Swelling of eyelid		2		1		1
Swollen tongue	6	6			6	6
Syncope	6	31			6	31
Systemic inflammatory response syndrome	1	1			1	1

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tachycardia	6	12
Tachypnoea		3
Tenderness		1
Tendon pain		1
Terminal state		1
Therapeutic product effect decreased		1
Thirst	1	3
Throat clearing		1
Throat irritation	3	6
Throat tightness	11	14
Thrombocytopenia	2	6
Thrombophlebitis	1	3
Thrombophlebitis superficial		1
Thrombosis		1
Thrombotic stroke	1	1
Time perception altered		1
Tongue disorder	1	1
Tongue pruritus	1	1
Tooth avulsion		1
Transfusion reaction		1
Transient ischaemic attack	1	3
Tremor	5	10
Upper respiratory tract congestion	1	1
Upper respiratory tract irritation	1	1
Urinary incontinence	1	2
Urinary tract infection		4
Urosepsis		2
Urticaria	15	25
Vaccination error		1
Vaccination failure	6	7
Vaccination site discomfort	1	1
Vaccination site erythema	3	12

Spontaneous			
Nonserious		Serious	
I	C	I	C
	5	6	7
	1		2
	1		
	1		
			1
	1		
1	2		1
	1		
	1	3	5
1	1	10	13
		2	6
1	3		
			1
			1
		1	1
	1		
		1	1
			1
	1		
		1	3
2	4	3	6
		1	1
		1	1
		1	2
	3		1
			2
9	12	6	13
	1		
		6	7
1	1		
3	11		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site haemorrhage	1	1	1	1		
Vaccination site hypoaesthesia		1		1		
Vaccination site movement impairment	1	2	1	1		1
Vaccination site oedema		1		1		
Vaccination site pain	12	42	12	35		7
Vaccination site paraesthesia		2		2		
Vaccination site pruritus	2	6	2	5		1
Vaccination site rash		1		1		
Vaccination site reaction	1	5		3	1	2
Vaccination site swelling	7	11	6	8	1	3
Vaccination site warmth	1	3	1	3		
Vaccine breakthrough infection		1				1
Vaginal haemorrhage	1	1			1	1
Vena cava thrombosis	1	1			1	1
Ventricular extrasystoles		1		1		
Ventricular tachycardia		1				1
Vertigo	1	2		1	1	1
Vertigo positional		1				1
Vestibular neuritis	1	1			1	1
Vision blurred		1				1
Visual field defect	1	1			1	1
Visual impairment	2	4	1	2	1	2
Vomiting	12	39	5	13	7	26
Wearing aid user	1	1	1	1		
Weight decreased		1		1		
Wheezing	4	6	1	1	3	5
White blood cell count increased		1				1
	825	2,575	305	1123	520	1452

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	5	1	3	1	2
Abdominal pain upper	2	8	1	4	1	4
Abdominal wall haemorrhage		1				1
Abnormal behaviour		1				1
Acute kidney injury	2	3			2	3
Acute myocardial infarction	5	5			5	5
Adenoma benign		1				1
Aggression		2		1		1
Alanine aminotransferase increased		1		1		
Altered state of consciousness	1	3			1	3
Anal incontinence		1				1
Anaphylactic reaction	2	5			2	5
Angina pectoris		1				1
Anxiety	1	1			1	1
Apallic syndrome		1				1
Aphasia		3				3
Apnoea	1	2			1	2
Arrhythmia	1	1			1	1
Arteriovenous fistula thrombosis		2				2
Arthralgia	9	17	6	11	3	6
Arthritis		1				1
Arthritis reactive		1				1
Aspiration		1				1
Asthenia	1	4	1	3		1
Asthma	1	1			1	1
Asymptomatic COVID-19	2	2			2	2
Atrial f brillation	2	5			2	5
Atrial flutter		1				1
Atrioventricular block	1	1			1	1
Autoimmune hepatitis	1	1			1	1
Autonomic nervous system imbalance		1				1
Back pain	1	5		3	1	2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacterial sepsis		1				1
Bacterial test positive		1		1		
Balance disorder		5		1		4
Bedridden		1				1
Bell's palsy	1	1			1	1
Blindness transient	1	1			1	1
Blood 25-hydroxycholecalciferol decreased		1		1		
Blood bilirubin increased		1		1		
Blood creatinine increased	1	1			1	1
Blood glucose increased		1		1		
Blood magnesium increased		1		1		
Blood pressure decreased	1	6	1	2		4
Blood pressure systolic decreased		1				1
Blood pressure systolic increased	1	1			1	1
Body temperature increased		1				1
Bone pain	1	2		1	1	1
Bradycardia		2				2
Brain stem infarction	1	1			1	1
Brain stem stroke		1				1
Cardiac arrest	2	3			2	3
Cardiac failure	1	4			1	4
Cardiomegaly		1				1
Carotid artery occlusion		1				1
CD4 lymphocytes decreased	1	1			1	1
Cerebellar haemorrhage	1	1			1	1
Cerebellar infarction		1				1
Cerebral artery embolism	1	2			1	2
Cerebral artery thrombosis		1				1
Cerebral haemorrhage	2	4			2	4
Cerebral infarction	1	7			1	7
Cerebral thrombosis	1	2			1	2
Cerebral venous thrombosis	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebrovascular accident	5	13			5	13
Chest discomfort		3		3		
Chest pain	6	15		2	6	13
Chills	2	8	2	5		3
Cholecystitis		1				1
Chronic obstructive pulmonary disease		3				3
Cognitive disorder	1	2	1	1		1
Cold sweat	1	4		2	1	2
Condition aggravated	2	4		1	2	3
Confusional state	5	20	2	6	3	14
Conjunctivitis		1		1		
Constipation		2		1		1
Contusion	1	1	1	1		
Coordination abnormal		1		1		
Coronary artery thrombosis	1	1			1	1
Cough	2	11	1	5	1	6
COVID-19	6	8		1	6	7
COVID-19 pneumonia	1	1			1	1
C-reactive protein increased	6	22	3	8	3	14
Cutaneous vasculitis	1	1			1	1
Cyanosis		1				1
Death	2	11			2	11
Decreased appetite	1	5	1	3		2
Deep vein thrombosis	5	7			5	7
Defaecation disorder		1				1
Defaecation urgency	1	1	1	1		
Dehydration	1	2	1	1		1
Delirium	1	6			1	6
Delusion	1	2			1	2
Dementia		1				1
Demyelinating polyneuropathy		1				1
Depressed level of consciousness	1	5			1	5

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea	2	12	1	6	1	6
Diplopia		3		1		2
Disease recurrence		1				1
Disseminated varicella zoster virus infection	1	1			1	1
Disturbance in attention	1	2	1	2		
Diverticulitis		1				1
Dizziness	3	17	3	9		8
Drug ineffective	2	3			2	3
Drug interaction	1	3		2	1	1
Dry mouth		1		1		
Duodenitis		1				1
Dysarthria		2		1		1
Dysgeusia		1				1
Dysphagia		4		2		2
Dysphonia		2		2		
Dyspnoea	11	33	4	8	7	25
Dyspnoea at rest		1				1
Dyspnoea exertional	1	1	1	1		
Epilepsy		4				4
Epistaxis	1	3	1	3		
Erysipelas	1	1			1	1
Erythema		4		4		
Erythema multiforme	1	1			1	1
Exposure to SARS-CoV-2	1	1	1	1		
Eye disorder	1	1	1	1		
Eye irritation	1	1	1	1		
Face injury	1	1			1	1
Facial paralysis	1	3			1	3
Facial paresis		1				1
Faeces discoloured		1		1		
Fall	3	8		3	3	5
Fatigue	17	45	14	33	3	12

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Fear	1	1
Fear of death		1
Febrile neutropenia	1	1
Feeling cold		2
Feeling hot	2	6
Flushing		2
Gait disturbance		2
Gastric disorder		1
Gastritis		1
Gastrointestinal haemorrhage	1	2
Generalised tonic-clonic seizure	1	1
General physical health deterioration	2	28
General symptom		1
Glomerulonephritis minimal lesion		1
Guillain-Barre syndrome		1
Haematoma		1
Haemoglobin decreased		1
Haemorrhage		2
Hallucination	1	4
Hallucination, auditory		1
Hallucination, visual	2	3
Headache	16	24
Head injury		1
Heart rate decreased	2	3
Heart rate increased	2	9
Hemianopia		1
Hemiparesis	1	2
Hemiplegia	1	4
Hepatic cyst		1
Herpes zoster	5	5
Hunger	1	1
Hyperaesthesia		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
	1		
		1	1
	2		
2	5		1
	2		
	1		1
			1
	1		
		1	2
		1	1
	8	2	20
			1
			1
			1
			1
			2
		1	4
			1
		2	3
15	20	1	4
			1
2	2		1
1	4	1	5
			1
		1	2
		1	4
			1
4	4	1	1
1	1		
			1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypercapnia		1				1
Hyperhidrosis	2	5	1	4	1	1
Hyperkalaemia		1				1
Hypertension		2		1		1
Hyperventilation		2		2		
Hypoaesthesia	1	3	1	3		
Hypoaesthesia oral	1	1	1	1		
Hypogeusia	1	1	1	1		
Hypokinesia		1				1
Hypophagia		3				3
Hypotension		6		1		5
Hypothermia		1				1
Hypoxia	1	4			1	4
Illness	1	2	1	2		
Immobile		1				1
Immune-mediated adverse reaction	1	2			1	2
Immune thrombocytopenia	2	2			2	2
Impaired driving ability	1	1			1	1
Inappropriate schedule of product administration		3		3		
Incomplete course of vaccination	1	1			1	1
Incorrect route of product administration	2	3	2	3		
Increased bronchial secretion		1				1
Increased viscosity of upper respiratory secretion		1		1		
Infection	2	5		1	2	4
Infective exacerbation of chronic obstructive airways disease		1				1
Inferior vena caval occlusion		1				1
Inflammation	1	2	1	1		1
Inflammatory marker increased		1				1
Influenza like illness	1	6	1	5		1
Injection site muscle weakness		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site pain	1	1	1	1		
Insomnia	1	1	1	1		
International normalised ratio increased		1				1
Interstitial lung disease		1				1
Intra-abdominal haematoma	1	1			1	1
Intracardiac thrombus		1				1
Iridocyclitis		1				1
Irritability postvaccinal		1				1
Lacrimation increased	1	1	1	1		
Lethargy	1	6	1	3		3
Leukocytosis	1	3		1	1	2
Listless	1	2	1	2		
Livedo reticularis		1		1		
Loss of consciousness	4	9			4	9
Loss of personal independence in daily activities		1				1
Low density lipoprotein increased		1		1		
Lung consolidation		1				1
Lung infiltration	1	1	1	1		
Lung opacity		2				2
Lymphadenopathy	1	2	1	2		
Lymph node pain	1	1	1	1		
Lymphocyte count decreased	1	1			1	1
Malaise	4	13	2	9	2	4
Malignant hypertension		1				1
Mania		1				1
Memory impairment	1	3	1	3		
Moaning		1				1
Monocytosis	1	1	1	1		
Monoplegia		1				1
Multiple sclerosis	1	1			1	1
Muscle rigidity		1				1
Muscle spasms	3	3	1	1	2	2

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Muscle spasticity		1
Muscular weakness		3
Musculoskeletal stiffness		1
Myalgia	10	20
Myocardial infarction	2	4
Nasal congestion	1	5
Nasopharyngitis		1
Nausea	9	29
Neck pain	1	4
Neutropenia	1	2
Neutrophilia	1	1
Nightmare		1
Night sweats	1	1
Nodal rhythm		1
N-terminal prohormone brain natriuretic peptide increased		2
Nystagmus		1
Obstructive airways disorder		1
Ocular hyperaemia	1	1
Oedema peripheral		2
Off label use	1	4
Ophthalmic herpes zoster	1	2
Oropharyngeal pain	4	6
Orthostatic hypotension		1
Oxygen saturation decreased	1	8
Pain	4	11
Painful respiration	2	2
Pain in extremity	2	6
Pain of skin		1
Pallor		3
Palpitations		1
Pancreatitis	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
	1		2
			1
6	11	4	9
		2	4
1	5		
			1
3	13	6	16
1	3		1
		1	2
1	1		
	1		
1	1		
			1
			2
			1
			1
1	1		
	1		1
1	4		
		1	2
2	3	2	3
			1
	1	1	7
3	6	1	5
		2	2
2	6		
	1		
	1		2
	1		
		1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paralysis	1	2			1	2
Paranoia		1				1
Paresis		1		1		
Pericardial effusion	1	3			1	3
Pericarditis	3	8			3	8
Peripheral coldness		2		1		1
Peripheral swelling	1	2	1	1		1
Personality change		1				1
Petechiae	1	1			1	1
Photophobia	1	1	1	1		
Pleural effusion	1	3			1	3
Pleurisy		1				1
Pneumonia		16				16
Pneumonia aspiration		1				1
Pneumonia bacterial		1				1
Pneumonitis		1				1
Postictal state		1		1		
Presyncope		1				1
Productive cough		2				2
Pruritus	1	3	1	2		1
Psoriasis	1	1			1	1
Psychiatric symptom	1	1	1	1		
Pulmonary congestion		1				1
Pulmonary embolism	16	25			16	25
Pulmonary infarction	2	2			2	2
Pulmonary thrombosis		1				1
Purpura	1	1			1	1
Pyelonephritis		1				1
Pyrexia	18	49	15	32	3	17
Rales		2		1		1
Rash	4	7	1	3	3	4
Rash macular	1	1	1	1		

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Rash maculo-papular	1	1
Rash pruritic		2
Rectal haemorrhage		2
Red blood cell sedimentation rate increased		2
Renal cyst		1
Renal impairment		1
Respiration abnormal		1
Respiratory acidosis		1
Respiratory arrest		1
Respiratory disorder		1
Respiratory failure	2	9
Respiratory rate increased	1	5
Restlessness		4
Retching		1
Retinal artery occlusion	1	1
Revers ble cerebral vasoconstriction syndrome	1	1
Rhinorrhoea	1	4
Rib fracture	1	1
Right ventricular failure	1	1
Road traffic accident	1	1
Seizure	2	2
Sepsis		1
Serum sickness	1	1
Shock		1
Sinoatrial block		1
Sleep disorder		2
Sleep disorder due to general medical condition, insomnia type	1	1
Soft tissue infection	1	1
Somnambulism	1	1
Somnolence	1	7
Speech disorder		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
	1		1
			2
	1		1
			1
			1
			1
			1
		2	9
	3	1	2
	3		1
			1
		1	1
		1	1
1	4		
		1	1
		1	1
		1	1
		2	2
			1
		1	1
			1
			2
1	1		
		1	1
1	1		
1	3		4
			1

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Spinal vascular disorder	1	1
Splenic infarction	1	1
Sputum increased		1
Stenosis		1
Sudden cardiac death		1
Sudden death	1	3
Sudden hearing loss	1	1
Swollen tongue	2	2
Syncope	2	10
Systemic inflammatory response syndrome	1	1
Tachycardia	2	6
Taste disorder	1	1
Tenderness		1
Thrombocytopenia		1
Thrombophlebitis		1
Thrombophlebitis superficial		2
Thrombosis	1	1
Thrombotic stroke		1
Transient ischaemic attack	1	4
Tremor		3
Troponin I increased		1
Troponin increased		1
Tubulointerstitial nephritis		1
Ulcer	1	1
Unresponsive to stimuli		4
Urinary incontinence		1
Urinary retention		2
Urinary tract infection		2
Urticaria	3	4
Vaccination failure	7	7
Vaccination site erythema	1	2
Vaccination site pain	3	11

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	1
	1		
			1
			1
		1	3
		1	1
2	2		
		2	10
		1	1
1	2	1	4
1	1		
	1		
			1
			1
	1		1
		1	1
		1	4
	1		2
	1		
			1
			1
1	1		
			4
	1		
	2		2
	2		
2	2	1	2
		7	7
1	2		
3	11		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site swelling	1	3	1	2		1
Vaccination site warmth		1				1
Ventricular extrasystoles		1				1
Vertigo		2				2
Vision blurred	1	3	1	1		2
Visual impairment	1	3		1	1	2
Vlth nerve paralysis		1				1
Vomiting	5	20	2	9	3	11
Weight decreased	1	1	1	1		
Wheezing		1				1
White blood cell count decreased	1	1			1	1
White blood cell count increased		2		2		
	391	1,172	161	438	230	734

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* AE=Adverse Event
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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	2	2			2	2
COVID-19		1				1
Dry mouth		2		2		
Fatigue		2		2		
Incorrect dose administered		5		5		
Intercepted product preparation error		1		1		
Off label use	5	6	5	6		
Poor quality product administered	5	12	5	12		
Product preparation error		2		2		
Product preparation issue		8		8		
Product temperature excursion issue	5	12	5	12		
Underdose		1		1		
Vaccination failure		1				1
Wrong technique in product usage process		1		1		
	17	56	15	52	2	4

* I=Interval, C=Cumulative
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Country Where Event Occurred

OMAN

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration		1		1
Product supply issue		1		1
		2		2

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	1			1	1
Diarrhoea		1		1		
Drug ineffective	1	1			1	1
Fatigue		1		1		
Gastritis		1		1		
Headache		1		1		
Pain		1		1		
Pyrexia		1		1		
Therapeutic response unexpected		1		1		
Thrombosis	1	1			1	1
	3	10		7	3	3

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Country Where Event Occurred
PALESTINIAN TERRITORY, OCCUPIED

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dyspnoea	1	1	1	1
Thirst	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

PANAMA

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- * AE=Adverse Event
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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Ageusia	2	2	2	2		
Agitation	3	3	3	3		
Allergy to vaccine	10	12	9	11	1	1
Anaphylactic reaction	1	2			1	2
Angioedema	1	1			1	1
Anosmia	2	2	2	2		
Arthralgia	8	9	8	9		
Asthenia	14	19	12	17	2	2
Asthmatic crisis	1	1			1	1
Axillary pain	1	1	1	1		
Back pain	4	4	4	4		
Balance disorder	1	1	1	1		
Bone pain	1	1	1	1		
Bradycardia	1	1			1	1
Bronchospasm	2	2			2	2
Burning sensation	1	1	1	1		
Chest discomfort	2	2	2	2		
Chest pain	3	3	3	3		
Chills	17	18	17	18		
Cold sweat	1	1	1	1		
Cough	5	5	3	3	2	2
COVID-19	4	4	2	2	2	2
Depressed mood	1	1			1	1
Diarrhoea	7	7	7	7		
Discomfort	1	1	1	1		
Dizziness	17	17	16	16	1	1
Drug ineffective	2	2			2	2
Dry throat		1		1		
Dysgeusia	2	2	2	2		
Dysphagia		1		1		
Dysphonia	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea	4	5	2	2	2	3
Ear pain	1	1	1	1		
Erythema	3	4	3	4		
Fatigue	5	5	5	5		
Feeling cold	1	1	1	1		
Feeling hot	7	7	6	6	1	1
Gait disturbance		1				1
Guillain-Barre syndrome	1	1			1	1
Haematoma	1	1	1	1		
Headache	37	38	36	37	1	1
Hemiparesis		1				1
Hot flush	1	1	1	1		
Hyperglycaemia	2	2	1	1	1	1
Hyperhidrosis	2	2	2	2		
Hypersensitivity	7	9	6	8	1	1
Hypertension	4	5	2	3	2	2
Hypertensive crisis	3	3			3	3
Hypertensive emergency	1	1			1	1
Hypoaesthesia	2	2	2	2		
Hypoaesthesia oral	1	2	1	1		1
Hypotension	3	3	3	3		
Hypotonia		1		1		
Hypotonic-hyporesponsive episode	3	5	1	2	2	3
Incorrect route of product administration	9	10	9	10		
Influenza like illness		1		1		
Irritability	1	2		1	1	1
Irritability postvaccinal	3	3	2	2	1	1
Lip dry		1		1		
Lip oedema	2	2	2	2		
Local reaction	5	7	3	5	2	2
Lymphadenitis	1	1	1	1		
Lymphadenopathy	2	3	2	3		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise	5	6	4	5	1	1
Monoparesis	1	1	1	1		
Muscular weakness	1	1			1	1
Musculoskeletal stiffness	1	1	1	1		
Myalgia	9	9	9	9		
Nasal congestion	1	1	1	1		
Nasal oedema	1	1	1	1		
Nausea	9	9	8	8	1	1
Neck pain	2	2	2	2		
Odynophagia	1	1	1	1		
Oedema	2	2	2	2		
Off label use	1	1	1	1		
Oropharyngeal pain	3	3	3	3		
Osteitis	1	1	1	1		
Overdose		1		1		
Pain	11	11	11	11		
Pain in extremity	2	2	2	2		
Pallor	2	3	1	2	1	1
Palpitations	4	5	4	5		
Papule	2	2	2	2		
Paraesthesia	6	7	5	5	1	2
Periorbital oedema	1	1	1	1		
Photopsia	1	1	1	1		
Presyncope	5	5	4	4	1	1
Product use issue	1	1	1	1		
Pruritus	8	8	6	6	2	2
Pulmonary pain		1				1
Pulmonary thrombosis	1	1			1	1
Pyrexia	30	32	28	29	2	3
Rash	10	10	9	9	1	1
Rash erythematous		1				1
Rash pruritic		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rhinorrhoea	3	3	3	3		
Salivary hypersecretion	1	1	1	1		
Seizure	4	4			4	4
Syncope		3				3
Tachycardia	4	4	4	4		
Tinnitus	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination site cellulitis	1	1	1	1		
Vaccination site erythema	3	3	3	3		
Vaccination site oedema	2	2	2	2		
Vaccination site pain	12	14	12	13		1
Vaccination site papule	1	1	1	1		
Vaccination site pruritus	2	2	2	2		
Vaccination site reaction	7	8	7	8		
Vaccination site warmth	1	1	1	1		
Vertigo	2	2	2	2		
Vision blurred	1	1	1	1		
Vomiting	4	4	3	3	1	1
	401	448	348	380	53	68

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	1	1	1	1		
Anaphylactic reaction	1	1			1	1
Asthenia	2	2	1	1	1	1
Back pain	2	2	1	1	1	1
Blood pressure increased	1	1	1	1		
Chest discomfort	1	1	1	1		
Chest pain	2	2	1	1	1	1
Chills	1	1	1	1		
Confusional state		1		1		
Cough	3	3	3	3		
COVID-19	2	2	2	2		
Diarrhoea	1	1			1	1
Disease progression	1	1	1	1		
Disease recurrence	1	1			1	1
Dizziness	4	4	3	3	1	1
Dyskinesia		1		1		
Dyspnoea	3	3	2	2	1	1
Eye pain	1	1	1	1		
Fatigue	2	3	2	3		
Feeling hot	2	2	2	2		
Flatulence		1		1		
Flushing	1	1	1	1		
Haematochezia	1	1			1	1
Headache	8	8	7	7	1	1
Herpes zoster	1	1	1	1		
Hyperhidrosis	2	2	2	2		
Hypertension	4	4	3	3	1	1
Hypoaesthesia	2	2	2	2		
Hypoaesthesia oral	1	1	1	1		
Hypotonia	1	1			1	1
Lip oedema	1	1	1	1		
Local reaction	1	1	1	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenitis	1	1	1	1		
Malaise	3	3	3	3		
Migraine		1		1		
Myalgia	2	2	1	1	1	1
Nasal congestion	1	1	1	1		
Nausea	1	1	1	1		
Neck pain	1	1	1	1		
Oedema	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Pain	2	2	2	2		
Pain in extremity	1	1	1	1		
Paraesthesia	2	2	2	2		
Photosensitivity reaction		1		1		
Pigmentation disorder	1	1	1	1		
Pruritus	1	1	1	1		
Pyrexia	3	3	3	3		
Rash	2	2	2	2		
Rhinorrhoea	1	1	1	1		
Sciatica	1	1	1	1		
Somnolence	1	1	1	1		
Tachycardia	1	1	1	1		
Urinary incontinence	1	1			1	1
Vaccination site pain	2	4	2	4		
Vaccination site reaction	1	1	1	1		
Vomiting	1	1	1	1		
	86	94	72	80	14	14

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arrhythmia	1	1			1	1
Cough	1	1	1	1		
Diarrhoea	1	1	1	1		
Headache	2	2	2	2		
Hyperhidrosis	1	1	1	1		
Pruritus	6	6			6	6
Rash	6	6			6	6
Rash pruritic		6				6
	18	24	5	5	13	19

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Country Where Event Occurred

PERU

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	2	2	2		
Acute respiratory failure	1	1			1	1
Arthralgia		1		1		
Back pain	2	2	2	2		
Bronchial disorder	1	1			1	1
Chest discomfort	1	1	1	1		
Chest pain	1	1	1	1		
Chills	2	2	2	2		
COVID-19		2		1		1
COVID-19 pneumonia	1	1			1	1
Diarrhoea	1	1	1	1		
Discomfort		1		1		
Drug ineffective	2	3			2	3
Dysphonia	1	1	1	1		
Fatigue	2	2	2	2		
Food intolerance	1	1	1	1		
General physical health deterioration	1	1			1	1
Headache	4	4	4	4		
Heart rate increased	1	1	1	1		
Hunger	1	1	1	1		
Hypertension	2	2	1	1	1	1
Hypotension	1	1	1	1		
Nausea	2	2	2	2		
Off label use		2		2		
Oxygen saturation decreased	1	1			1	1
Pain		1		1		
Pain in extremity	1	2	1	2		
Paraesthesia	1	1	1	1		
Pharyngeal inflammation	1	1	1	1		
Pharyngitis streptococcal	1	1	1	1		
Product use issue		2		2		
Pyrexia		2		2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Suspected COVID-19	1	1			1	1
Tongue discomfort	1	1	1	1		
Tremor	1	1	1	1		
Vaccination site pain	2	2	2	2		
	40	53	31	42	9	11

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Application site acne	1	1	1	1		
Arthralgia	1	1	1	1		
Back pain		1		1		
Chest pain		1		1		
COVID-19	1	1			1	1
Discomfort		1		1		
Drug ineffective	1	1			1	1
Epistaxis		1				1
Exposure via breast milk		1		1		
Fatigue		1		1		
Headache	1	6	1	6		
Heart rate increased		1		1		
Hyperhidrosis		1		1		
Nasal dryness		1		1		
Oropharyngeal pain	1	2	1	2		
Otitis media	1	1	1	1		
Pain in extremity	1	2	1	2		
Pyrexia	1	5	1	5		
Vaccination site hypoaesthesia	1	1	1	1		
Vaccination site pain	1	3	1	3		
Vaccination site pruritus	1	1	1	1		
	12	34	10	31	2	3

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposure via breast milk		1		1
		1		1

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Country Where Event Occurred

PHILIPPINES

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Blood pressure increased	3	3	3	3
Body temperature increased	1	1	1	1
Chills	1	1	1	1
Diarrhoea	1	1	1	1
Fatigue	1	1	1	1
Pain	1	1	1	1
Pain in extremity	1	1	1	1
Pyrexia	3	3	3	3
Sinusitis	1	1	1	1
Somnolence	1	1	1	1
Thirst	1	1	1	1
Vaccination site movement impairment	2	2	2	2
Vaccination site pain	7	7	7	7
	24	24	24	24

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	2	2	2	2		
Blood pressure increased	4	4	4	4		
Cough	1	1	1	1		
Dizziness	1	1	1	1		
Dyspnoea	2	2	1	1	1	1
Feeling cold	1	1	1	1		
Gait inability	1	1	1	1		
Headache	2	2	2	2		
Pain	3	3	3	3		
Pyrexia	2	2	2	2		
Rhinorrhoea	1	1	1	1		
Therapeutic response unexpected	1	1	1	1		
Vaccination site discomfort	1	1	1	1		
Vaccination site movement impairment	1	1	1	1		
Vaccination site pain	2	2	2	2		
Vaccination site swelling	1	1	1	1		
	26	26	25	25	1	1

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Asymptomatic COVID-19	1	1	1	1
Drug ineffective	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

POLAND

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal distension	1	2	1	1		1
Abdominal pain	1	12	1	6		6
Abdominal pain lower		1		1		
Abdominal pain upper	3	8	2	5	1	3
Acute myocardial infarction		1				1
Adnexa uteri pain		1		1		
Ageusia	1	8	1	7		1
Agitation		1				1
Alanine aminotransferase increased		1				1
Allergic reaction to excipient		1		1		
Allergic respiratory symptom		1				1
Allergy to vaccine	1	2	1	1		1
Alopecia	1	1	1	1		
Altered state of consciousness	3	3	1	1	2	2
Amnesia	1	1	1	1		
Anal incontinence		4		1		3
Anaphylactic reaction	1	10			1	10
Anaphylactic shock		9				9
Angioedema	1	9			1	9
Anosmia		9		8		1
Anuria		4				4
Anxiety	1	5	1	4		1
Aphasia		3		1		2
Aphthous ulcer		1		1		
Arrhythmia	2	7			2	7
Arterial thrombosis	1	1			1	1
Arthralgia	15	61	13	42	2	19
Arthritis		1		1		
Arthropathy	3	4	3	4		
Asphyxia		1				1
Asthenia	34	126	30	88	4	38

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma		6				6
Asymptomatic COVID-19		6				6
Atrial fibrillation	1	3			1	3
Atrial flutter		1				1
Axillary mass		1		1		
Axillary pain	3	7	2	6	1	1
Back pain	7	15	7	14		1
Balance disorder	2	3	2	3		
Basophil count decreased		1		1		
Bell's palsy	1	1			1	1
Bladder disorder	1	1	1	1		
Bleeding varicose vein		1				1
Blindness	1	1			1	1
Blood creatine phosphokinase increased		2		1		1
Blood glucose increased		1				1
Blood pressure abnormal	1	3	1	2		1
Blood pressure decreased		16		4		12
Blood pressure diastolic increased		1				1
Blood pressure fluctuation	1	1			1	1
Blood pressure increased	6	22	1	3	5	19
Blood smear test abnormal		1		1		
Blood urine present		1		1		
Body temperature decreased	1	2		1	1	1
Body temperature increased	5	11	4	8	1	3
Bone pain	2	13	1	9	1	4
Brachial plexus injury		1				1
Bradycardia		1				1
Brain stem stroke		1				1
Brain stem syndrome		1				1
Breast disorder	1	1	1	1		
Breast enlargement		1		1		
Breast pain		2		1		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breath sounds abnormal	1	2			1	2
Bronchial oedema		1				1
Burning sensation		2		2		
Cardiac arrest	3	7			3	7
Cardiac disorder	1	1	1	1		
Cardiac fibrillation	1	1			1	1
Cardiogenic shock		1				1
Cardiovascular disorder		2		1		1
Cerebellar stroke	1	1			1	1
Cerebral disorder	1	1			1	1
Cerebral haematoma		1				1
Cerebrovascular accident	1	2			1	2
Chest discomfort	2	7	2	7		
Chest pain	5	8	5	6		2
Chills	25	81	24	61	1	20
Choking		1				1
Choking sensation	1	2	1	1		1
Chorea		1		1		
Coagulopathy		2		1		1
Cognitive disorder		1		1		
Cold sweat		1				1
Confusional state	4	9	3	5	1	4
Conjunctival hyperaemia		2		1		1
Constipation	1	1	1	1		
Contraindicated product administered	1	1	1	1		
Contusion	3	9	3	4		5
Coronary artery thrombosis		1				1
Cough	4	15	3	8	1	7
COVID-19	20	67	6	12	14	55
COVID-19 pneumonia	1	1			1	1
C-reactive protein increased		1		1		
Cyanosis		2				2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cystitis		1		1		
Death	1	5			1	5
Decreased activity		1		1		
Decreased appetite	6	14	6	12		2
Decreased immune responsiveness	1	1	1	1		
Decreased nasolabial fold		1		1		
Defaecation urgency	1	1	1	1		
Delirium		1				1
Depressed level of consciousness	1	1			1	1
Depressed mood	1	1	1	1		
Derealisation	1	1	1	1		
Dermatitis allergic	1	1			1	1
Diarrhoea	8	27	7	19	1	8
Discomfort		2		2		
Disease recurrence		1				1
Disorientation		1				1
Distract bility		1		1		
Disturbance in attention	2	6	1	5	1	1
Dizziness	18	45	18	36		9
Drug hypersensitivity		1				1
Drug ineffective	12	40			12	40
Dry mouth		2		2		
Dysarthria	1	1	1	1		
Dysgeusia	2	5	2	3		2
Dysmenorrhoea	1	1	1	1		
Dysphagia		1				1
Dysphonia		1		1		
Dyspnoea	11	36	5	15	6	21
Dyspnoea exertional	1	3		1	1	2
Dysstasia		1		1		
Ear discomfort	1	1	1	1		
Ear swelling		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eating disorder		1		1		
Ecchymosis	1	2			1	2
Electrolyte imbalance		1		1		
Embolism arterial	1	1			1	1
Embolism venous	1	1			1	1
Encephalopathy		1				1
Eosinophil count decreased		1		1		
Epigastric discomfort		1				1
Episcleritis	1	1			1	1
Epistaxis	1	3	1	3		
Eructation	1	1	1	1		
Erysipelas		1				1
Erythema	4	13	3	6	1	7
Erythema multiforme		1				1
Essential hypertension		1				1
Exercise tolerance decreased		2		2		
Exposure during pregnancy		4		4		
Extensive swelling of vaccinated limb		1		1		
Extremity contracture	1	2	1	2		
Eye disorder		1		1		
Eye irritation	1	1	1	1		
Eye pain	3	9	2	4	1	5
Face oedema	1	2	1	1		1
Facial paralysis	1	9			1	9
Faeces soft		1				1
Fall	1	3	1	1		2
Fatigue	17	39	16	35	1	4
Feeling abnormal	14	23	14	23		
Feeling cold	2	14	2	9		5
Feeling hot	1	10	1	9		1
Feeling of body temperature change	1	1	1	1		
Fibrin D dimer increased		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fine motor skill dysfunction	1	1	1	1		
Flatulence		1				1
Flushing		3		2		1
Formication	1	1			1	1
Gait disturbance	1	3		2	1	1
Gait inability	1	1			1	1
Gastric disorder	1	1	1	1		
Gastrointestinal disorder		1		1		
Generalised tonic-clonic seizure		1				1
General physical health deterioration	1	1			1	1
Gingival swelling		1		1		
Guillain-Barre syndrome		1				1
Haematoma		1		1		
Haematuria		2		1		1
Haemoptysis	1	2			1	2
Haemorrhage subcutaneous		1				1
Haemorrhagic diathesis		1				1
Haemorrhagic stroke		1				1
Hallucination, olfactory		1				1
Headache	35	126	31	97	4	29
Head discomfort	1	3	1	3		
Head injury		1				1
Heart rate abnormal	1	1	1	1		
Heart rate increased	6	13	2	6	4	7
Heart rate irregular	1	1	1	1		
Helplessness		1				1
Herpes virus infection		2		2		
Herpes zoster	3	3	3	3		
Hiccups	1	1	1	1		
Hot flush		2		1		1
Hydronephrosis		1				1
Hyperacusis		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperaesthesia		5		3		2
Hyperaesthesia teeth		1		1		
Hypercoagulation	1	1			1	1
Hyperhidrosis	2	19	1	13	1	6
Hyperpyrexia		2				2
Hypersensitivity		10		1		9
Hypertension	3	7		1	3	6
Hypoacusis	1	1	1	1		
Hypoaesthesia	14	34	9	19	5	15
Hypoaesthesia oral	4	10	3	5	1	5
Hypopnoea		1				1
Hypotension	1	2	1	1		1
Hypotonia		1				1
Hypotonic-hyporesponsive episode	1	16		1	1	15
Hypoxia		1				1
Illiteracy		1				1
Illness		1		1		
Immune system disorder	1	1	1	1		
Immune thrombocytopenia	1	1			1	1
Inappropriate schedule of product administration	2	7	2	7		
Incorrect dose administered	1	2	1	2		
Incorrect route of product administration	2	5	2	5		
Infection		1		1		
Inflammation		3		3		
Influenza	1	1	1	1		
Influenza like illness	7	16	7	15		1
Initial insomnia		1		1		
Injection site pain		3		3		
Injection site swelling		1		1		
Inner ear disorder	1	1			1	1
Insomnia	6	10	5	9	1	1
International normalised ratio increased		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Iritis		1		1		
Joint range of motion decreased		1		1		
Joint stiffness	1	1	1	1		
Joint swelling	2	6	1	3	1	3
Lacrimation increased		3				3
Lagophthalmos		1		1		
Laryngeal oedema		1				1
Laryngeal pain	1	1	1	1		
Laryngospasm		3				3
Lethargy		1		1		
Limb discomfort	1	2		1	1	1
Lip blister		1				1
Lip swelling		1				1
Lividity	1	4			1	4
Localised oedema		1				1
Loss of consciousness	2	19			2	19
Lung disorder		1		1		
Lymphadenopathy	5	32	5	18		14
Lymph node pain	1	14	1	4		10
Lymphocyte count decreased		1		1		
Lymphoedema	1	1	1	1		
Macule		1				1
Malaise	24	57	20	47	4	10
Maternal exposure during pregnancy	1	3	1	3		
Memory impairment	1	4	1	3		1
Menstrual disorder	3	3	3	3		
Menstruation irregular	1	1	1	1		
Mental disorder		1		1		
Migraine	2	4	2	4		
Mobility decreased	1	1	1	1		
Monocyte count decreased		1		1		
Monoparesis		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mood altered	1	2	1	2		
Motor dysfunction	1	1	1	1		
Movement disorder		3		2		1
Muscle disorder	1	1	1	1		
Muscle injury		1				1
Muscle spasms	1	2	1	2		
Muscle tightness		1		1		
Muscular weakness	4	7	3	4	1	3
Musculoskeletal pain		2		1		1
Musculoskeletal stiffness		3		3		
Mutism		1		1		
Myalgia	23	94	21	67	2	27
Myocardial hypoxia		1				1
Myocardial infarction	2	2			2	2
Nasal congestion		2		1		1
Nasopharyngitis	2	3	2	3		
Nausea	23	62	21	47	2	15
Neck pain		8		6		2
Nervousness	1	3	1	2		1
Neuralgia	2	2	2	2		
Neuropathy peripheral		1				1
Neutrophil count increased		1		1		
Nightmare		1		1		
Night sweats	2	2	2	2		
Ocular hyperaemia	1	1			1	1
Oedema		1		1		
Oedema peripheral	2	4	1	1	1	3
Oesophageal spasm	1	1	1	1		
Off label use	2	15	2	14		1
Oliguria		1		1		
Optic neuritis		1				1
Oral candidiasis		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral herpes	1	2	1	2		
Oropharyngeal pain	1	5	1	4		1
Oxygen saturation decreased		5		1		4
Pain	8	16	7	14	1	2
Painful respiration		1		1		
Pain in extremity	37	96	35	85	2	11
Pain in jaw		1		1		
Pain of skin	2	4	2	3		1
Pallor		7		1		6
Palpitations	5	10	3	4	2	6
Pancreatitis acute		1				1
Paraesthesia	6	14	5	12	1	2
Paraesthesia oral	3	4	3	3		1
Paralysis		1				1
Paresis		1				1
Parosmia		1		1		
Peripheral coldness	1	3	1	2		1
Peripheral swelling	8	11	6	8	2	3
Petechiae	1	5	1	2		3
Pharyngeal hypoaesthesia		2				2
Pharyngeal swelling		2		1		1
Phlebitis		1		1		
Photophobia	4	6	3	4	1	2
Pneumonia	2	4			2	4
Pollakiuria	1	1	1	1		
Poor quality product administered	1	2	1	2		
Presyncope	3	7	3	5		2
Product supply issue	1	1	1	1		
Product temperature excursion issue		1		1		
Product use issue	2	12	2	11		1
Protein urine present	1	2	1	2		
Pruritus	3	7	3	5		2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Psoriatic arthropathy		1				1
Psychological trauma		1		1		
Pulmonary congestion		1				1
Pulmonary embolism	1	1			1	1
Pulmonary mass	1	1	1	1		
Pulmonary oedema		1				1
Pulmonary pain		1				1
Pulpitis dental		1		1		
Pyrexia	50	168	44	121	6	47
Radicular pain		1		1		
Radiculitis brachial		1		1		
Rash	1	4		2	1	2
Rash erythematous		2		1		1
Rash macular	2	2	1	1	1	1
Rash papular	1	3	1	2		1
Rash pruritic	2	3	2	3		
Rash vesicular		2				2
Renal failure		1				1
Renal pain		1		1		
Respiratory failure	1	2			1	2
Respiratory tract infection		1				1
Respiratory tract oedema		1				1
Restlessness		1				1
Retching		1		1		
Rheumatic disorder	1	1			1	1
Rheumatoid arthritis	1	1			1	1
Rhinitis		1				1
Rhinorrhoea	1	7	1	7		
SARS-CoV-2 ant body test negative		1				1
SARS-CoV-2 ant body test positive		1		1		
SARS-CoV-2 test positive	1	2	1	2		
Sciatica		2		1		1

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			Nonserious		Serious	
			I	C	I	C
Seizure	4	21			4	21
Sensation of foreign body		1				1
Sensory disturbance	2	3			2	3
Sensory loss	1	1	1	1		
Shock symptom		1				1
Sinus headache		1				1
Sinusitis	1	2	1	2		
Sinus pain	1	1	1	1		
Skin disorder	1	1	1	1		
Skin hypertrophy		1		1		
Skin lesion	1	2	1	1		1
Skin mass		1		1		
Skin warm	1	1			1	1
Sleep disorder	1	1	1	1		
Sluggishness		1				1
Somnolence	9	15	7	12	2	3
Speech disorder	2	9	2	3		6
Speech disorder developmental	1	1	1	1		
Spinal pain		4		3		1
Stress		1				1
Stupor		1				1
Subclavian vein thrombosis		1				1
Sudden death		1				1
Suppressed lactation		2		1		1
Supraventricular extrasystoles		1				1
Suspected COVID-19	1	3		1	1	2
Swelling	3	5	3	4		1
Swelling face	2	4	2	2		2
Swollen tongue		2				2
Syncope	4	18			4	18
Syringe issue	1	1	1	1		
Systemic lupus erythematosus		1				1

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			Nonserious		Serious	
			I	C	I	C
Tachycardia	4	19	2	5	2	14
Tachypnoea		3				3
Taste disorder	1	4	1	4		
Temperature intolerance		1		1		
Tension headache	1	1	1	1		
Therapeutic response unexpected		4		4		
Thirst		2		2		
Throat irritation	1	1			1	1
Throat tightness		1		1		
Thrombophlebitis	1	2	1	2		
Thrombophlebitis superficial	2	2	1	1	1	1
Thrombosis	3	10			3	10
Tinnitus	4	9	3	7	1	2
Toothache		2		1		1
Tracheal oedema		1				1
Transaminases increased		1				1
Tremor	2	6	1	4	1	2
Trigeminal neuralgia		1		1		
Trigeminal neuritis		1				1
Type 2 diabetes mellitus	1	2			1	2
Urinary incontinence		3				3
Urticaria		6		2		4
Vaccination complication		2		2		
Vaccination failure		11				11
Vaccination site abscess sterile		1				1
Vaccination site erythema	9	22	8	18	1	4
Vaccination site extravasation	1	3	1	3		
Vaccination site haemorrhage	1	1	1	1		
Vaccination site hypertrophy	1	1	1	1		
Vaccination site hypoaesthesia	1	1			1	1
Vaccination site induration		1		1		
Vaccination site macule		1		1		

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			Nonserious		Serious	
			I	C	I	C
Vaccination site movement impairment		3		3		
Vaccination site oedema	1	6	1	3		3
Vaccination site pain	37	109	34	98	3	11
Vaccination site pruritus	1	11	1	11		
Vaccination site reaction	1	23	1	10		13
Vaccination site swelling	4	18	3	14	1	4
Vaccination site warmth	1	5	1	5		
Vein disorder		1		1		
Venous thrombosis		1				1
Ventricular extrasystoles		1				1
Ventricular tachycardia	2	2			2	2
Vertigo		4		1		3
Viral infection		1		1		
Vision blurred	2	3	1	2	1	1
Visual acuity reduced		1				1
Visual field defect		1		1		
Visual impairment	4	7	3	4	1	3
Vomiting	6	29	5	18	1	11
Walking disability		1		1		
Wheezing	1	1	1	1		
Wrong product administered	1	1	1	1		
Yellow skin	1	1	1	1		
	809	2,694	620	1659	189	1035

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			Nonserious		Serious	
			I	C	I	C
Abdominal pain		3		3		
Abdominal pain lower		1				1
Abscess	1	1	1	1		
Accidental exposure to product	1	1	1	1		
Acute kidney injury		1				1
Acute myocardial infarction	1	2			1	2
Acute respiratory distress syndrome	1	1			1	1
Acute respiratory failure	1	1			1	1
Ageusia	1	2	1	2		
Alanine aminotransferase increased		1				1
Altered state of consciousness		2				2
Anaemia	1	1			1	1
Anaphylactic reaction		1				1
Anaphylactic shock	1	1			1	1
Angioedema		2				2
Angiopathy		1				1
Anosmia		1		1		
Anuria		1				1
Apnoea		1				1
Arrhythmia	1	3			1	3
Arteriosclerosis		2		1		1
Arthralgia	5	14	5	11		3
Arthropathy	1	1	1	1		
Aspartate aminotransferase increased		2				2
Asthenia	6	30	4	23	2	7
Asthmatic crisis		1				1
Asymptomatic COVID-19	1	3		1	1	2
Atrial f brillation	2	3			2	3
Atrial flutter		1				1
Axillary pain		1		1		
Back pain		3		3		
Balance disorder	2	4	2	3		1

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			Nonserious		Serious	
			I	C	I	C
Blister		1				1
Blood creatine phosphokinase increased		1				1
Blood glucose increased	1	2	1	1		1
Blood pressure abnormal		1				1
Blood pressure decreased	2	4		1	2	3
Blood pressure fluctuation	1	1	1	1		
Blood pressure increased	3	7	2	3	1	4
Body temperature increased	2	3	1	2	1	1
Bone density decreased		1		1		
Bone pain		4		3		1
Bradycardia		1				1
Brain oedema		1				1
Cardiac arrest	4	10			4	10
Cataract	1	1			1	1
Cerebral haematoma		1				1
Cerebral haemorrhage		1				1
Cerebrovascular accident		2				2
Cervical spinal stenosis		1				1
Chest discomfort		1				1
Chest pain	2	2	1	1	1	1
Chills	5	16	5	12		4
Chromaturia	1	1	1	1		
Circulatory collapse	1	2			1	2
Cold sweat	1	1			1	1
Coma		1				1
Contusion		1				1
Cough	4	6	4	5		1
COVID-19	15	36	2	4	13	32
COVID-19 pneumonia		1				1
Cyanosis		1				1
Deafness	1	1			1	1
Deafness unilateral		1				1

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			Nonserious		Serious	
			I	C	I	C
Death	2	8			2	8
Decreased appetite	1	2	1	1		1
Deep vein thrombosis	1	1			1	1
Delirium	1	2			1	2
Depressed level of consciousness		1				1
Diarrhoea	1	5	1	5		
Disease progression		1				1
Disease recurrence		1				1
Disturbance in attention	2	3	2	2		1
Dizziness	4	12	4	7		5
Drug ineffective	7	25			7	25
Dysarthria		2				2
Dysgeusia	1	1	1	1		
Dyskinesia	1	1	1	1		
Dysphagia		1				1
Dysphonia	1	3		2	1	1
Dyspnoea	4	9	1	1	3	8
Dysstasia	1	1	1	1		
Dysuria	1	1	1	1		
Ecchymosis	1	1			1	1
Emphysema		1		1		
Erythema	1	2		1	1	1
Erythema multiforme	1	2			1	2
Exposure via skin contact	1	1	1	1		
Eye disorder	1	1	1	1		
Eyelid oedema		1				1
Eye pain	1	1	1	1		
Facial pain	1	1	1	1		
Facial paralysis		1				1
Fall		2				2
Fatigue	2	9	2	7		2
Fear	1	1			1	1

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			Nonserious		Serious	
			I	C	I	C
Febrile convulsion		2				2
Feeling abnormal	4	5	3	3	1	2
Feeling cold		3		2		1
Feeling hot		2		2		
Feeling of relaxation		1				1
Flatulence		1		1		
Gait disturbance	1	3	1	2		1
Gait inability	1	2	1	1		1
Gastritis	1	1			1	1
Gastrointestinal disorder	1	2			1	2
Gastrointestinal haemorrhage		1				1
General physical health deterioration	1	3			1	3
Glomerulonephritis chronic	1	1			1	1
Grip strength decreased		1		1		
Haematemesis		2				2
Haemoptysis		1		1		
Haemorrhagic stroke	1	1			1	1
Headache	8	23	8	22		1
Heart rate abnormal		1		1		
Heart rate increased	2	4	2	3		1
Herpes virus infection		1		1		
Herpes zoster	1	2	1	2		
Hot flush	1	2	1	2		
Hyperhidrosis	4	7	4	5		2
Hypersensitivity	3	6	1	3	2	3
Hypertension		2				2
Hypoaesthesia	2	4	2	3		1
Hypoaesthesia oral	1	2	1	1		1
Hypotension		1		1		
Hypotonia		2				2
Hypotonic-hyporesponsive episode		1				1
Illness	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Incorrect route of product administration	2	4
Increased upper airway secretion		1
Infection	1	2
Influenza		1
Influenza like illness		1
Insomnia	2	6
Intervertebral disc protrusion		1
Iritis	1	1
Ischaemic stroke		1
Labyrinthitis		2
Lacrimation increased	1	1
Laryngospasm		1
Lethargy		1
Lip swelling	1	1
Lividity	1	1
Loss of consciousness	3	7
Loss of personal independence in daily activities	1	1
Lung disorder		1
Lung opacity		1
Lymphadenopathy	1	10
Lymph node pain		5
Malaise	9	17
Melaena		1
Memory impairment	1	1
Mental disorder	1	1
Metabolic acidosis		1
Middle insomnia		1
Mobility decreased	2	2
Monoparesis	1	1
Multiple sclerosis relapse		1
Muscle spasms		1
Muscle tightness		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	4		
	1		
1	1		1
	1		
	1		
2	6		
			1
		1	1
			1
			2
1	1		
			1
			1
1	1		
		1	1
		3	7
1	1		
	1		
	1		
1	6		4
	1		4
5	9	4	8
			1
1	1		
1	1		
			1
	1		
2	2		
		1	1
			1
	1		
	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscular weakness		2		1		1
Myalgia	8	24	7	22	1	2
Nasopharyngitis	2	4	2	4		
Nausea	2	9	2	7		2
Nerve injury	1	1	1	1		
Neuralgia	1	1	1	1		
Neuritis cranial		1				1
Night sweats		1		1		
Oedema		1				1
Oedema peripheral		1		1		
Olfactory nerve disorder	1	1	1	1		
Oxygen saturation decreased	2	7	1	2	1	5
Pain		2		2		
Pain in extremity	8	12	8	12		
Pain in jaw	1	1	1	1		
Pallor	2	3	1	1	1	2
Palpitations		1		1		
Pancreatitis acute		1				1
Paraesthesia		1		1		
Paralysis		1				1
Paraparesis		3				3
Parkinsonism	1	1			1	1
Parosmia	1	1	1	1		
PCO2 abnormal		1				1
Peripheral swelling		2				2
Petechiae	2	2			2	2
Pharyngeal erythema	1	1	1	1		
Photophobia	1	1	1	1		
Pleural effusion		1		1		
Pneumonia	3	6			3	6
Pneumonia viral		2				2
Pollakiuria	1	1	1	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Presyncope		1				1
Product administered at inappropriate site		1		1		
Product leakage	1	1	1	1		
Product supply issue	1	1	1	1		
Prostatic specific antigen increased		1				1
Prostatitis		1				1
Pruritus	2	3	2	3		
Psychomotor retardation	1	1			1	1
Pulmonary calcification		1		1		
Pulmonary mass		1		1		
Pulmonary oedema	1	1			1	1
Pulse abnormal	1	1			1	1
Pyrexia	16	49	11	28	5	21
Rash	1	4		1	1	3
Rash erythematous	1	1	1	1		
Rash macular		1		1		
Rash morbilliform	1	2			1	2
Rash papular	1	3		1	1	2
Rash pruritic		1		1		
Rash rubelliform	1	1			1	1
Reaction to excipient	1	1	1	1		
Renal disorder	1	1			1	1
Renal failure	1	2			1	2
Respiration abnormal		1		1		
Respiratory disorder		1				1
Respiratory failure	1	5			1	5
Rhabdomyolysis		1				1
Rhinorrhoea		2		2		
Rotavirus infection	1	1	1	1		
SARS-CoV-2 test positive	1	1			1	1
Seizure	2	6			2	6
Sepsis		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Shock		1				1
Somnolence		2		1		1
Speech disorder	1	3		2	1	1
Spinal cord compression		1				1
Spinal pain	2	2	2	2		
Sudden cardiac death		1				1
Sudden death		1				1
Sudden hearing loss		1				1
Suffocation feeling	1	1	1	1		
Suspected COVID-19		1				1
Swelling	1	3		1	1	2
Swollen tongue	1	2	1	1		1
Syncope	2	7			2	7
Tachycardia	4	5	2	2	2	3
Taste disorder	1	1	1	1		
Throat tightness		1				1
Thrombocytopenia		1				1
Thrombosis	1	2			1	2
Tinnitus	1	2	1	2		
Tongue oedema		1				1
Transient ischaemic attack		1				1
Tremor	1	2	1	2		
Trigeminal nerve disorder		1		1		
Trigeminal nerve paresis	1	1			1	1
Trigeminal neuralgia	1	1			1	1
Ulnar nerve palsy		1		1		
Underdose	1	1	1	1		
Urinary tract inflammation		1				1
Urticaria	2	3	1	2	1	1
Vaccination failure	3	4			3	4
Vaccination site discolouration	1	1			1	1
Vaccination site erythema	2	4	1	3	1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site hypersensitivity	1	2			1	2
Vaccination site induration		1		1		
Vaccination site infection		1		1		
Vaccination site pain	7	33	7	31		2
Vaccination site paraesthesia		1		1		
Vaccination site rash		1				1
Vaccination site reaction	1	4		1	1	3
Vaccination site scab		1		1		
Vaccination site swelling	1	2		1	1	1
Vaccination site vesicles		1		1		
Vein discolouration	1	1	1	1		
Vestibular neuronitis		1		1		
Visual acuity reduced	1	1			1	1
Visual field defect		1		1		
Visual impairment	3	4	2	3	1	1
Vomiting	1	3		1	1	2
White blood cell count increased	1	1	1	1		
Wrong product administered	2	2	2	2		
	290	797	168	403	122	394

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		4		1		3
Acute kidney injury		1				1
Acute myocardial infarction		1				1
Adverse reaction		1		1		
Ageusia		1				1
Allergic reaction to excipient		1		1		
Allergic respiratory symptom		1				1
Allergy to vaccine		1				1
Altered state of consciousness		1				1
Anaemia		1				1
Anaphylactic reaction		3				3
Anaphylactic shock		3				3
Angioedema		2				2
Anosmia		1				1
Antibody test abnormal		10		10		
Anxiety		2		1		1
Aortic aneurysm rupture		1				1
Apnoea		1				1
Arrhythmia		2				2
Arthralgia	1	27	1	15		12
Arthropathy	1	2	1	2		
Asthenia	5	40	5	12		28
Asthma		2				2
Asymptomatic COVID-19		1				1
Axillary pain		1		1		
Back pain		4		3		1
Bladder cancer		1				1
Blood pressure decreased		5				5
Blood pressure fluctuation		2				2
Blood pressure increased	1	6	1	1		5
Blood thyroid stimulating hormone decreased		1				1
Body temperature fluctuation		1		1		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Body temperature increased	4	8	4	5		3
Bone pain	2	5	2	2		3
Bradyarrhythmia		1				1
Burning sensation		1		1		
Bursitis		1		1		
Cardiac arrest		1				1
Cardiac death		1				1
Cardiogenic shock		1				1
Cardiovascular disorder		1				1
Cerebrovascular accident		1				1
Chest pain		6				6
Chills	3	29	3	16		13
Chromaturia		1				1
Circumstance or information capable of leading to medication error		1		1		
Condition aggravated		1				1
Confusional state		1				1
Conjunctival hyperaemia		1				1
Conjunctival pallor		1				1
Cough		5		1		4
COVID-19	5	13			5	13
C-reactive protein increased		3		1		2
Crying		1		1		
Cyanosis		1				1
Deafness		2				2
Death		7				7
Decreased appetite		4				4
Depressed level of consciousness		1				1
Dermatitis allergic		1				1
Diarrhoea	1	13	1	5		8
Disorientation	1	2	1	1		1
Disturbance in attention		1				1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	4	15	4	5		10
Drug hypersensitivity		1				1
Drug ineffective	5	12			5	12
Dry mouth		1				1
Dysgeusia		4		1		3
Dysphagia		1				1
Dyspnoea		12				12
Dyspnoea at rest		1				1
Ear pain		1		1		
Encephalopathy		1				1
Erythema	2	5	2	2		3
Erythema multiforme		1				1
Exposure via breast milk	1	9	1	9		
Extrasystoles		1				1
Eyelids pruritus		1				1
Eye pain		5				5
Eye pruritus		1				1
Face oedema		1				1
Facial paralysis	1	4			1	4
Fall		1				1
Fatigue	4	6	4	6		
Febrile convulsion		6				6
Feeling cold		4		1		3
Feeling hot		2				2
Formication		1				1
Goitre		1				1
Headache	9	39	9	16		23
Heart rate increased	1	4	1	1		3
Hemiparesis		1				1
Hot flush		1		1		
Hyperaesthesia		2				2
Hyperhidrosis	1	3	1	1		2

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypersensitivity		12				12
Hypertension		1				1
Hypoaesthesia		10		2		8
Hypoaesthesia eye		2				2
Hypoaesthesia oral	1	3	1	2		1
Hypopnoea		1				1
Hypotension		3				3
Hypothermia		1				1
Hypotonic-hyporesponsive episode		9		3		6
Incorrect dose administered	1	1	1	1		
Incorrect route of product administration		1		1		
Infection		1		1		
Inflammation		1				1
Insomnia	1	2	1	2		
Irregular breathing		1				1
Joint effusion		1		1		
Joint injury		1				1
Joint range of motion decreased		1		1		
Joint stiffness		1		1		
Joint swelling		1				1
Lacrimation increased		4				4
Laryngospasm		4				4
Lip pruritus		1				1
Lip swelling		1				1
Lividity		1				1
Localised oedema	1	1	1	1		
Loss of consciousness		7				7
Lymphadenopathy	2	29	2	11		18
Lymph node pain		22		6		16
Malaise		19		14		5
Maternal exposure during breast feeding		1		1		
Memory impairment	1	1	1	1		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mobility decreased		1				1
Monoplegia	1	1			1	1
Muscular weakness	1	2			1	2
Musculoskeletal pain		1				1
Musculoskeletal stiffness		1		1		
Myalgia	3	41	3	18		23
Myocardial hypoxia		1				1
Myocardial infarction		2				2
Myocarditis		1				1
Myoglobinuria		1				1
Nausea	3	17	3	8		9
Neck pain		2				2
Needle issue		1		1		
Ocular hyperaemia		1				1
Oedema		2				2
Oedema peripheral		1				1
Off label use		1		1		
Oropharyngeal pain		2		1		1
Oxygen saturation decreased		4		1		3
Pain		3		1		2
Pain in extremity		13		4		9
Pallor		2				2
Palpitations		2				2
Paraesthesia	1	7	1	1		6
Paresis		1		1		
Parosmia		3		1		2
Parotitis		1		1		
Photophobia	1	1	1	1		
Pneumonia		3				3
Poor quality product administered		3		3		
Poor quality sleep		1		1		
Presyncope	2	5	1	1	1	4

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Gender

UNKNOWN

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	2		
	1		
			3
			2
6	27		54
	1		8
			1
			2
	1		
			2
			1
			2
			2
			3
			2
			1
			1
	2		2
			1
			1
1	3		
			1
		1	10
	1		
			1
	1		12
	1		1
	1		
	1		
			1
			1

Product contamination physical

1

Product label confusion

2

Product preparation error

1

Pruritus

3

Pulmonary oedema

2

Pyrexia

6

81

Rash

9

Rash erythematous

1

Rash rubelliform

2

Reaction to excipient

1

Respiratory arrest

2

Respiratory disorder

1

Rhinitis

2

Rhinorrhoea

2

Seizure

3

Sensory disturbance

2

Skin exfoliation

1

Sleep disorder

1

Somnolence

4

Spinal pain

1

Suspected COVID-19

1

Swelling

1

3

Swelling face

1

Syncope

1

10

Synovial disorder

1

Tachyarrhythmia

1

Tachycardia

13

Taste disorder

2

Tension headache

1

Throat irritation

1

Thyroiditis

1

Thyroid pain

1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tonsillar hypertrophy		1		1		
Tremor		2				2
Trigeminal neuralgia		1				1
Underdose	1	1	1	1		
Urticaria		5				5
Vaccination failure		2				2
Vaccination site abscess sterile		1				1
Vaccination site discomfort		1				1
Vaccination site erythema	1	6	1	3		3
Vaccination site extravasation		1				1
Vaccination site hypersensitivity		1		1		
Vaccination site induration		1		1		
Vaccination site inflammation		1		1		
Vaccination site movement impairment	1	1	1	1		
Vaccination site oedema		1		1		
Vaccination site pain	5	18	5	15		3
Vaccination site pruritus		1		1		
Vaccination site reaction	1	35	1	4		31
Vaccination site swelling		3		3		
Vaccination site warmth	1	3	1	2		1
Vertigo		2				2
Visual impairment	1	2	1	1		1
Vomiting	1	13	1	3		10
Walking disability		1				1
White blood cell count increased		1				1
Yellow skin		1				1
		1		1		
	91	933	76	306	15	627

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Country Where Event Occurred

PORTUGAL

090177e19749cf15\Approved\Approved On: 14-Jun-2021 14:01 (GMT)

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	8	2	2		6
Abdominal distension		1				1
Abdominal pain	8	34	4	7	4	27
Abdominal pain lower		1				1
Abdominal pain upper	4	15	2	4	2	11
Abnormal faeces		1				1
Aborted pregnancy		1				1
Abortion	1	1			1	1
Abortion spontaneous	1	3			1	3
Acidosis		1				1
Acne		1				1
Adenopathy syphilitic		2				2
Administration site bruise		1		1		
Administration site swelling		2		2		
Administration site warmth		1		1		
Ageusia	2	4	2	2		2
Agitation		2				2
Allergy to vaccine		3				3
Altered state of consciousness		2				2
Amenorrhoea		1		1		
Amnesia		1		1		
Amylase increased		1				1
Anaemia		1		1		
Anaphylactic reaction	5	21			5	21
Anaphylactic shock		2				2
Anaphylactoid reaction		2				2
Angina pectoris		1				1
Angioedema	1	11			1	11
Anosmia	3	5	3	3		2
Anxiety	4	15	3	9	1	6
Apathy		1				1
Aphasia	1	1			1	1

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphonia		1				1
Aphthous ulcer		3				3
Apnoea		1				1
Arrhythmia	4	9			4	9
Arthralgia	39	197	30	42	9	155
Asthenia	20	127	15	28	5	99
Asthenopia		1				1
Asymptomatic COVID-19		23		2		21
Ataxia	1	1			1	1
Atelectasis		1		1		
Atrioventricular block complete		1				1
Atrioventricular block second degree	1	1			1	1
Autonomic nervous system imbalance		1				1
Autophony		1				1
Axillary lymphadenectomy		1				1
Axillary mass		1				1
Axillary pain	8	34	8	14		20
Back pain	6	21	4	5	2	16
Balance disorder	4	8	2	2	2	6
Bedridden		1				1
Behaviour disorder	1	1			1	1
Bell's palsy	1	4			1	4
Bladder disorder		1				1
Blepharospasm	1	1	1	1		
Blindness		1				1
Blister	1	1	1	1		
Blood creatinine increased	1	1	1	1		
Blood glucose increased		1				1
Blood potassium decreased	1	1			1	1
Blood pressure decreased		2				2
Blood pressure diastolic increased		1				1
Blood pressure fluctuation		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased	6	13	2	3	4	10
Body temperature decreased		1				1
Body temperature increased		7		2		5
Bone pain		2		1		1
Bradycardia	1	7			1	7
Bradyphrenia	1	3			1	3
Bradypnoea		1				1
Breast pain		5		2		3
Breast swelling		2		1		1
Bronchial hyperreactivity	1	1			1	1
Bronchospasm		6				6
Burning sensation	1	8	1	2		6
Cardiac failure		1				1
Cardio-respiratory arrest		5				5
Cerebral artery occlusion	1	1			1	1
Cerebral infarction	1	1			1	1
Cerebral thrombosis	1	1			1	1
Cerebral venous sinus thrombosis		2				2
Cerebrovascular accident	6	11			6	11
Chapped lips	1	1	1	1		
Chest discomfort	3	16	2	6	1	10
Chest pain	4	27	1	1	3	26
Chills	38	206	30	52	8	154
Choking sensation		1				1
Cholinergic syndrome		1				1
Choroiditis		1				1
Circumoral oedema		1				1
Cold sweat		4				4
Computerised tomogram thorax abnormal		1		1		
Condition aggravated	2	8	1	4	1	4
Confusional state	2	3	2	2		1
Conjunctival irritation		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Constipation		1				1
Contraindicated product administered		1		1		
Contusion	2	2			2	2
Coordination abnormal	2	2	1	1	1	1
Corneal degeneration		1				1
Corneal opacity		1				1
Cough	11	54	6	15	5	39
COVID-19	23	119	20	38	3	81
COVID-19 pneumonia	1	2			1	2
Crohn's disease		1				1
Crying		2		1		1
Cyanosis		1				1
Deafness		1				1
Deafness neurosensory	1	1			1	1
Deafness transitory		1				1
Deafness unilateral	1	2			1	2
Death	1	5			1	5
Decreased appetite	6	31	2	4	4	27
Deep vein thrombosis	4	7			4	7
Depressed level of consciousness	1	2			1	2
Depressed mood		1				1
Dermatitis allergic	1	2			1	2
Dermatitis exfoliative	2	3			2	3
Dermatitis exfoliative generalised		1				1
Dermatologic examination abnormal	1	1			1	1
Diarrhoea	21	95	13	27	8	68
Diastolic hypertension		1				1
Diplopia	2	3		1	2	2
Discomfort	6	9	5	5	1	4
Disease recurrence		1				1
Disorientation	1	2			1	2
Disturbance in attention		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	33	138	18	36	15	102
Dizziness postural		1				1
Droling		1		1		
Drug hypersensitivity		1				1
Drug ineffective	2	47			2	47
Drug interaction		1				1
Drug reaction with eosinophilia and systemic symptoms	1	1			1	1
Dry eye		1		1		
Dry mouth	2	7	2	3		4
Dry skin		1				1
Dry throat		2		1		1
Dysarthria	1	6		1	1	5
Dysgeusia	4	22	4	12		10
Dyskinesia		1				1
Dyslexia		1				1
Dyspepsia		3				3
Dysphagia		9		1		8
Dysphonia	2	11	1	3	1	8
Dyspnoea	8	49	4	10	4	39
Dyspnoea at rest		3				3
Dyspnoea exertional		2				2
Dysstasia		1				1
Dystonia	1	1			1	1
Dysuria		1				1
Ear pain	2	5	1	1	1	4
Ecchymosis	3	3	1	1	2	2
Eczema		1				1
Electric shock sensation	1	1			1	1
Electrocardiogram ST segment depression	1	1	1	1		
Embolic stroke	1	1			1	1
Emotional distress	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Epistaxis		3		2		1
Eructation		1		1		
Erythema	11	35	6	10	5	25
Exophthalmos		1				1
Exposure during pregnancy	2	11	2	10		1
Exposure to SARS-CoV-2		1				1
Exposure via breast milk		1		1		
Extrapyramidal disorder		1				1
Extrasystoles	1	3		1	1	2
Eye disorder	1	3		1	1	2
Eye haemorrhage	2	2			2	2
Eye irritation		5		4		1
Eyelid myokymia		1				1
Eyelid oedema		3				3
Eyelid sensory disorder		1		1		
Eye movement disorder		1				1
Eye pain	3	5	2	4	1	1
Eye paraesthesia		1				1
Eye pruritus	1	2	1	1		1
Eye swelling	1	2			1	2
Face oedema	4	22	1	3	3	19
Facial asymmetry		1				1
Facial nerve disorder		1				1
Facial pain	2	2	1	1	1	1
Facial paralysis	1	5			1	5
Facial paresis	1	3			1	3
Facial spasm		2		1		1
Faeces soft		1				1
Fall	1	2		1	1	1
Fatigue	46	240	36	62	10	178
Febrile convulsion		1				1
Feeling abnormal		2		1		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling cold	3	17	2	5	1	12
Feeling hot	12	38	9	16	3	22
Feeling of body temperature change		1				1
Fibrin D dimer increased		2		2		
Flatulence		3		1		2
Flushing	2	12	1	3	1	9
Food refusal		1				1
Foreign body reaction	1	1			1	1
Functional gastrointestinal disorder		2				2
Gait disturbance		2				2
Gait inability	1	4	1	2		2
Gastric disorder		1				1
Gastrointestinal disorder	3	3	1	1	2	2
Gastrointestinal pain		1				1
Generalised tonic-clonic seizure	1	3			1	3
Glossodynia		1		1		
Gonorrhoea		1				1
Haematoma	6	9	1	2	5	7
Haemoglobin decreased	1	1	1	1		
Haemoglobinuria		1				1
Haemoptysis		1				1
Haemorrhagic stroke	2	2			2	2
Hallucination		1				1
Headache	134	596	107	187	27	409
Head discomfort	2	6	1	2	1	4
Heart rate decreased	1	1			1	1
Heart rate increased	6	11	5	6	1	5
Hemiparaesthesia		1				1
Hemiparesis	1	1			1	1
Hepatic mass	1	1	1	1		
Herpes zoster	6	7	2	3	4	4
Herpes zoster cutaneous disseminated	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hot flush		4				4
Hydrocephalus		1				1
Hyperaesthesia	2	4	1	1	1	3
Hyperglycaemia		4		1		3
Hyperhidrosis	9	29	4	6	5	23
Hyperlactacidaemia		1				1
Hypersensitivity	2	7			2	7
Hypertension	6	39	1	5	5	34
Hypertensive crisis	3	8			3	8
Hyperthermia	2	13	1	2	1	11
Hyperventilation		1				1
Hypoacusis	1	3			1	3
Hypoaesthesia	9	23	1	6	8	17
Hypoaesthesia oral	2	14	1	5	1	9
Hypoglycaemia	3	6	1	1	2	5
Hypokalaemia		3				3
Hypokinesia	2	2	2	2		
Hypoperfusion		1				1
Hypopnoea		1				1
Hyposmia		1				1
Hypotension	6	25	3	4	3	21
Hypothermia		2				2
Hypothyroidism		1				1
Hypotonic-hyporesponsive episode		1				1
Hypoxia	1	1			1	1
Illness		1		1		
Immune system disorder		1		1		
Impaired work ability		2		1		1
Impetigo		1				1
Inappropriate schedule of product administration	3	7	3	6		1
Incomplete course of vaccination	1	1	1	1		
Incorrect route of product administration	4	22	4	22		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inflammation		3				3
Influenza		5		1		4
Influenza like illness	1	2	1	1		1
Injected limb mobility decreased		2		1		1
Injection site erythema		2		2		
Injection site pain	1	4	1	4		
Injection site swelling	1	1	1	1		
Insomnia	5	22	4	8	1	14
Inspiratory capacity decreased		2				2
Intermenstrual bleeding	1	2	1	1		1
Ischaemic stroke	6	7			6	7
Jaundice	1	2			1	2
Joint microhaemorrhage	1	1			1	1
Joint range of motion decreased		2				2
Joint swelling		2				2
Lacrimation increased		1				1
Lacunar stroke		1				1
Laryngeal oedema	1	7			1	7
Lethargy		1				1
Leukocytosis		1				1
Leukocyturia		1		1		
Limb discomfort	2	5		1	2	4
Lipase increased		1				1
Lip erythema	1	1			1	1
Lip oedema	2	11		1	2	10
Lip pruritus		1				1
Lip swelling		2				2
Liver function test abnormal	1	1			1	1
Liver injury	1	1			1	1
Localised oedema	1	7	1	2		5
Loss of consciousness	1	2			1	2
Loss of personal independence in daily activities		3				3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lung infiltration		1				1
Lymphadenitis	2	12	1	5	1	7
Lymphadenopathy	42	238	29	55	13	183
Lymph node pain	2	5	2	2		3
Lymph node palpable		2		1		1
Lymphoedema		1				1
Lymphoproliferative disorder		1				1
Macule	1	2			1	2
Magnetic resonance imaging head abnormal		1		1		
Malaise	16	107	13	32	3	75
Mastitis	1	3			1	3
Maternal exposure during pregnancy	2	7	2	7		
Meningioma		1				1
Meningitis viral		1				1
Menstrual disorder		1		1		
Mental fatigue		1				1
Migraine		7		2		5
Miliaria	1	1	1	1		
Mobility decreased	2	6	1	2	1	4
Motor dysfunction		2				2
Movement disorder	2	6	1	3	1	3
Muscle contractions involuntary		1				1
Muscle fatigue		4		2		2
Muscle rigidity		1				1
Muscle spasms		2		1		1
Muscle tightness		1				1
Muscular weakness	4	14	3	3	1	11
Musculoskeletal discomfort		1				1
Musculoskeletal disorder		2				2
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	2	6	1	1	1	5
Myalgia	139	663	119	198	20	465

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia intercostal		1				1
Myelitis		1				1
Myelosuppression		1				1
Myoclonus	1	3	1	1		2
Nail pigmentation	1	1			1	1
Nasal congestion	2	7		1	2	6
Nasal discomfort		1		1		
Nasal dryness		1		1		
Nasal obstruction	1	2	1	1		1
Nasopharyngitis	1	2	1	1		1
Nausea	66	278	39	81	27	197
Neck mass		1		1		
Neck pain	6	14	3	4	3	10
Necrotic lymphadenopathy		1				1
Nervousness		1				1
Neuralgia		1				1
Neurological symptom	1	1	1	1		
Neuropathy peripheral		1				1
Neutrophilia		1				1
Night sweats		3				3
Nodule	1	2	1	2		
Non-cardiac chest pain		1		1		
Nystagmus		4				4
Ocular discomfort		1		1		
Ocular hyperaemia		2				2
Odynophagia	3	16	1	4	2	12
Oedema	1	8	1	2		6
Oedema mouth		2				2
Oedema peripheral	4	16	1	5	3	11
Oesophageal disorder		1				1
Oesophageal pain		1				1
Off label use	6	18	6	18		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oliguria		2		1		1
Oral candidiasis		2				2
Oral discomfort	1	2	1	2		
Oral herpes	2	4	2	2		2
Oral pain		1				1
Oropharyngeal discomfort	1	13	1	5		8
Oropharyngeal oedema	1	2			1	2
Oropharyngeal pain	3	15	2	5	1	10
Orthopnoea		1				1
Overdose	12	28	12	27		1
Oxygen saturation decreased	2	10			2	10
Pain	22	78	15	27	7	51
Painful respiration		1				1
Pain in extremity	16	75	11	23	5	52
Pain in jaw	1	1	1	1		
Palatal disorder		1				1
Pallor	3	10	1	1	2	9
Palmar-plantar erythrodysesthesia syndrome		1				1
Palpitations	6	23	2	5	4	18
Pancreatitis		1				1
Pancytopenia		1				1
Papule	2	2	2	2		
Paraesthesia	15	84	9	28	6	56
Paraesthesia ear	1	1			1	1
Paraesthesia oral	4	20	3	6	1	14
Paralysis	1	3			1	3
Pericarditis		1				1
Perineal pain		1				1
Perioral dermatitis	1	1			1	1
Peripheral coldness	1	6			1	6
Peripheral nerve lesion	1	1	1	1		
Peripheral swelling	1	7		1	1	6

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Petechiae	1	2			1	2
Pharyngeal erythema		1				1
Pharyngeal hypoaesthesia		2		1		1
Pharyngeal inflammation		1		1		
Pharyngeal oedema		1				1
Pharyngeal paraesthesia		5				5
Pharyngeal swelling	1	2			1	2
Pharyngitis		1				1
Phlebitis	1	2			1	2
Phonophobia		1				1
Photophobia		6		2		4
Pigmentation disorder	1	1	1	1		
Piloerection		3				3
Pityriasis rosea		1				1
Platelet count increased		1		1		
Pleuritic pain		1				1
Pneumonia		1				1
Pneumonia aspiration		2				2
PO2 decreased		1				1
Polydipsia		5				5
Poor quality sleep		2				2
Postural orthostatic tachycardia syndrome		1				1
Posture abnormal	2	2			2	2
Presyncope	11	43	7	14	4	29
Product administered at inappropriate site	1	2	1	2		
Productive cough	1	2	1	1		1
Product use issue	4	16	4	16		
Proteinuria		1		1		
Pruritus	12	47	10	16	2	31
Pulmonary embolism	5	9			5	9
Puncture site haematoma		1				1
Purpura	1	5	1	2		3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyelonephritis		1				1
Pyrexia	95	472	77	126	18	346
Rash	11	56	5	14	6	42
Rash erythematous	2	7	2	5		2
Rash macular	1	9	1	1		8
Rash maculo-papular		6		1		5
Rash maculovesicular	1	1			1	1
Rash papular		3		1		2
Rash pruritic	2	11	2	6		5
Rash vesicular		1				1
Renal pain	1	1			1	1
Renal tubular necrosis		1				1
Respiratory disorder		1				1
Respiratory distress		3				3
Respiratory failure		1				1
Respiratory tract infection		1				1
Retinal artery occlusion	1	1			1	1
Retinal haemorrhage		1				1
Rhinitis		2		1		1
Rhinorrhoea	9	26	8	15	1	11
SARS-CoV-2 test positive	7	13	6	6	1	7
Scar		1		1		
Sciatica		1				1
Seizure	1	7			1	7
Sensitive skin		2		1		1
Sensory disturbance		1				1
Sensory loss		6		2		4
Shock		1				1
Sinusitis		2		2		
Sinus tachycardia		1				1
Skin burning sensation		1				1
Skin exfoliation		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin lesion		2				2
Skin reaction		1				1
Skin warm	1	5	1	2		3
Sleep disorder		2				2
Sluggishness	1	1	1	1		
Sneezing	1	4	1	2		2
Somnolence	11	66	8	34	3	32
Speech disorder		4		1		3
Spinal pain		1				1
Status epilepticus		1				1
Stiff tongue		1				1
Stomatitis		2		1		1
Stroke in evolution		1				1
Sudden death	1	1			1	1
Sudden hearing loss		2				2
Suffocation feeling	1	1			1	1
Suppressed lactation		1		1		
Supraventricular extrasystoles	1	1			1	1
Swelling	1	12		1	1	11
Swelling face	2	3			2	3
Swelling of eyelid	2	2	1	1	1	1
Swollen tongue	1	1			1	1
Syncope	2	19			2	19
Synovial cyst	3	12	3	3		9
Tachyarrhythmia		3				3
Tachycardia	16	62	11	16	5	46
Tachypnoea		3				3
Takayasu's arteritis		1				1
Taste disorder	1	6	1	1		5
Telangiectasia	1	1			1	1
Tenderness	1	1	1	1		
Tenosynovitis		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tension headache		1				1
Terminal ileitis		1				1
Throat irritation	2	10	1	3	1	7
Throat tightness	2	9	1	1	1	8
Thrombocytopenia		1				1
Thrombophlebitis		3				3
Thrombophlebitis superficial	1	1			1	1
Thrombosis	1	3			1	3
Thrombotic microangiopathy		1				1
Thyroid function test abnormal		1		1		
Thyroiditis		1				1
Thyroid mass		1				1
Tinnitus	1	5			1	5
Tongue disorder		1				1
Tongue dry		1				1
Tongue eruption		2				2
Tongue oedema		13		2		11
Tongue paralysis	1	1			1	1
Tongue pruritus		1				1
Tongue rough		1		1		
Tonic clonic movements		1				1
Tonsillar inflammation		1		1		
Tonsillitis		1				1
Transaminases increased		1				1
Tremor	8	37	5	8	3	29
Trichoglossia		1		1		
Trigeminal neuralgia		1		1		
Trigeminal palsy		1				1
Trismus		1				1
Underdose	1	1	1	1		
Urinary tract infection	1	7	1	1		6
Urticaria	8	20	5	7	3	13

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria papular		1				1
Vaccination complication	1	5	1	2		3
Vaccination failure	4	43			4	43
Vaccination site abscess		1		1		
Vaccination site cellulitis	1	1	1	1		
Vaccination site discolouration		1				1
Vaccination site eczema		2		1		1
Vaccination site erythema	17	70	15	26	2	44
Vaccination site haematoma		6		3		3
Vaccination site hypersensitivity	1	1	1	1		
Vaccination site induration	9	17	9	9		8
Vaccination site inflammation	1	14	1	3		11
Vaccination site injury		1				1
Vaccination site joint inflammation		1				1
Vaccination site joint movement impairment	1	4	1	1		3
Vaccination site lymphadenopathy	1	2	1	1		1
Vaccination site mass	1	1	1	1		
Vaccination site movement impairment	3	8	1	2	2	6
Vaccination site nodule	1	1	1	1		
Vaccination site oedema	19	82	18	31	1	51
Vaccination site pain	130	517	114	244	16	273
Vaccination site paraesthesia		3		2		1
Vaccination site pruritus	5	29	5	10		19
Vaccination site rash	2	8	2	4		4
Vaccination site reaction		7		3		4
Vaccination site swelling	7	33	6	10	1	23
Vaccination site urticaria		1				1
Vaccination site warmth	11	27	9	12	2	15
Vaginal haemorrhage		2				2
Vasculitis		2				2
Venous occlusion	1	1			1	1
Ventricular extrasystoles	1	2	1	1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vertebral artery occlusion	1	1			1	1
Vertigo	8	21	2	4	6	17
Vertigo positional		1				1
Vestibular neuronitis	1	1	1	1		
Vision blurred	6	13	2	5	4	8
Visual acuity reduced	1	2		1	1	1
Visual impairment	2	5			2	5
Vitreous floaters		1				1
Vomiting	25	88	15	21	10	67
Vulvovaginal burning sensation		2		1		1
Vulvovaginal swelling		1				1
Weight decreased		1		1		
Wheezing		4		1		3
White blood cell count increased	1	1	1	1		
Wound		1		1		
	1,599	7,161	1080	2123	519	5038

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2		2		
Abdominal pain		1		1		
Abdominal pain upper		1		1		
Abdominal symptom	1	1	1	1		
Acute kidney injury		2				2
Acute myocardial infarction		3				3
Acute pulmonary oedema		1				1
Anaphylactic reaction		4				4
Angioedema		1				1
Anti-neutrophil cytoplasmic antibody positive vasculitis	1	1			1	1
Aphasia		1				1
Aphthous ulcer		1		1		
Application site hyperaesthesia	1	1	1	1		
Arrhythmia	1	2			1	2
Arteriosclerosis		1		1		
Arthralgia	12	30	10	12	2	18
Arthritis		1				1
Arthritis reactive		1				1
Asthenia	1	29		6	1	23
Asymptomatic COVID-19	1	8			1	8
Atrial fibrillation	1	2			1	2
Atrioventricular block complete		1				1
Aura		1		1		
Axillary pain	2	6	1	1	1	5
Back pain	2	7	1	2	1	5
Bacterial infection		1				1
Balance disorder		1				1
Bell's palsy	1	1			1	1
Blindness		1				1
Blindness unilateral	2	3			2	3
Blood glucose fluctuation		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure diastolic decreased		1		1		
Blood pressure systolic increased		1		1		
Blood thyroid stimulating hormone increased		1				1
Body temperature increased	1	1	1	1		
Bradycardia	1	3			1	3
Breast discomfort		1				1
Breast swelling		1		1		
Cardiac disorder		1				1
Cardio-respiratory arrest	1	1			1	1
Cerebral artery thrombosis	1	1			1	1
Cerebral infarction	1	1			1	1
Cerebrovascular accident	3	6			3	6
Cheilitis		1		1		
Chest pain	3	6	2	3	1	3
Chillblains		1		1		
Chills	5	39	4	14	1	25
Cholangitis		1				1
Cholestasis		1				1
Chronic kidney disease		1				1
Cold sweat	1	1			1	1
Condition aggravated	1	5	1	1		4
Confusional state		1				1
Conus medullaris syndrome		1				1
Cough		7				7
COVID-19	14	46	13	20	1	26
COVID-19 pneumonia		3				3
Cutaneous vasculitis		1				1
Deafness neurosensory		1				1
Deafness unilateral		1				1
Death		4				4
Decreased appetite		8		2		6
Deep vein thrombosis	2	2			2	2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea	2	11	1	3	1	8
Discomfort	1	5	1	3		2
Disease recurrence	1	1			1	1
Disorientation		2		1		1
Disturbance in attention	1	1	1	1		
Dizziness	3	21	2	8	1	13
Drug-induced liver injury		1				1
Drug ineffective		12				12
Drug interaction		1				1
Dry mouth		2		1		1
Dysgeusia	1	2		1	1	1
Dyspepsia		1		1		
Dysphagia		2				2
Dyspnoea	2	5	2	2		3
Dyspnoea exertional	1	1			1	1
Ear congestion	1	1			1	1
Ear pain		1		1		
Ecchymosis		1				1
Eczema		1				1
Embolic stroke		1				1
Embolism	1	2			1	2
Embolism venous	1	3			1	3
Epistaxis	1	5		2	1	3
Erythema	1	6	1	4		2
Escherichia bacteraemia		1				1
Exposure via breast milk		1		1		
Eyelid oedema	1	2			1	2
Eyelids pruritus	1	1			1	1
Eye pain		1		1		
Face oedema	1	3		1	1	2
Facial paralysis		3				3
Fall	1	4	1	2		2

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* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fatigue	2	21	2	11		10
Fear of injection	1	1			1	1
Feeling cold	1	3			1	3
Feeling hot	1	4	1	2		2
Flushing		3		2		1
Functional gastrointestinal disorder		1				1
Gait inability		1		1		
Generalised tonic-clonic seizure		1				1
General symptom		1				1
Glossodynia		1		1		
Gynaecomastia		1				1
Haematoma		1				1
Haemorrhagic stroke	1	1			1	1
Haemorrhagic transformation stroke		1				1
Headache	20	98	18	45	2	53
Head injury		1				1
Heart rate decreased		1				1
Hemianaesthesia		1				1
Hemidysaesthesia		1				1
Hemiparesis		1				1
Hemiplegia		1				1
Hepatitis		1				1
Hot flush	1	1	1	1		
Hyperhidrosis		7		2		5
Hypersensitivity		1				1
Hypertension	1	4			1	4
Hypertensive crisis	1	1			1	1
Hypoacusis		1				1
Hypoaesthesia	2	5		2	2	3
Hypoaesthesia oral		2		1		1
Hypotension	1	7			1	7
Hypothermia		1				1

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Inappropriate schedule of product administration		2
Incorrect dose administered	1	1
Incorrect route of product administration		1
Influenza		2
Influenza like illness		1
Injection site pain		1
Insomnia	4	12
Intercostal neuralgia		1
International normalised ratio decreased		1
International normalised ratio increased		1
Intestinal obstruction	1	1
Ischaemic stroke	1	4
Joint range of motion decreased		3
Lacunar stroke		1
Laryngeal oedema	1	1
Lethargy		1
Leukaemoid reaction		1
Lidido decreased		1
Limb discomfort		1
Limb mass		1
Lip oedema		1
Localised oedema	2	2
Loss of consciousness		2
Loss of personal independence in daily activities		2
Lymphadenitis		2
Lymphadenopathy	6	34
Malaise	3	17
Mobility decreased		3
Monocyte count increased		1
Mood altered		1
Motor dysfunction		2
Muscle contractions involuntary	1	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
	2		
1	1		
	1		
			2
	1		
	1		
3	6	1	6
			1
	1		
			1
		1	1
		1	4
	1		2
			1
		1	1
			1
			1
	1		
	1		
	1		
			1
1	1	1	1
			2
			2
	1		1
5	15	1	19
1	5	2	12
	2		1
	1		
			1
			2
	1	1	2

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* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle fatigue		1				1
Muscle spasms		1				1
Muscle twitching		1				1
Muscular weakness	3	7	1	2	2	5
Musculoskeletal disorder	1	1	1	1		
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness		1				1
Myalgia	30	126	25	49	5	77
Myocardial infarction		1				1
Myocarditis		2				2
Myoclonus	1	1	1	1		
Nasal congestion	1	2	1	1		1
Nasal oedema		1		1		
Nausea	5	23	2	5	3	18
Neck pain	1	5	1	4		1
Nervousness		1				1
Nipple disorder		1		1		
Occupational exposure to SARS-CoV-2		1		1		
Ocular discomfort		1		1		
Odynophagia		3		1		2
Oedema		1		1		
Oedema peripheral	1	2			1	2
Off label use		3		3		
Ophthalmic artery thrombosis	1	1			1	1
Ophthalmic herpes simplex		1				1
Oropharyngeal discomfort		5		3		2
Oropharyngeal pain	2	4	2	2		2
Overdose	3	5	2	4	1	1
Oxygen saturation decreased		3				3
Pain	1	7	1	4		3
Pain in extremity	2	13	2	10		3
Pallor	1	5		1	1	4

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Palpitations		3		1		2
Papule	2	2	1	1	1	1
Paraesthesia	3	12	3	9		3
Paraesthesia oral		2		1		1
Parkinson's disease	1	1			1	1
Parosmia	1	1			1	1
Patella fracture		1				1
Pericardial effusion		1				1
Pericarditis	1	1			1	1
Peripheral artery occlusion		1				1
Peripheral artery stenosis		1				1
Peripheral swelling		1		1		
Petechiae	1	1	1	1		
Pharyngeal cyst		2				2
Pharyngeal hypoaesthesia		1				1
Pharyngeal inflammation		1				1
Piloerection		1				1
Pityriasis rosea		1				1
Pleuritic pain		1				1
Pneumonia	2	3			2	3
Presyncope		6		2		4
Procedural haemorrhage		1				1
Product administered at inappropriate site	1	2	1	2		
Productive cough		1				1
Product use issue		1		1		
Pruritus	3	11	2	4	1	7
Pulmonary embolism	2	2			2	2
Purpura	1	2			1	2
Pyrexia	17	89	16	34	1	55
Rash		10		2		8
Rash macular		3		1		2
Rash papular		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal colic		1				1
Respiratory tract congestion		1				1
Restlessness		1		1		
Rhabdomyolysis	1	2			1	2
Rhinalgia		1		1		
Rhinorrhoea		3		1		2
Salivary hypersecretion		1		1		
SARS-CoV-2 test positive	1	2			1	2
Seizure		2				2
Sensation of foreign body		1		1		
Sepsis		1				1
Sinus tachycardia		1				1
Skin burning sensation		1				1
Skin exfoliation		1				1
Skin reaction		1				1
Skin warm		3				3
Sleep disorder	1	2	1	1		1
Soft tissue haemorrhage		1		1		
Somnolence	4	14	3	8	1	6
Sudden cardiac death		1				1
Swelling		2		2		
Syncope	1	6			1	6
Systemic inflammatory response syndrome		1				1
Tachycardia		8		3		5
Tachypnoea	1	1	1	1		
Taste disorder		2				2
Throat irritation	2	4	2	3		1
Throat tightness		2		1		1
Thrombocytopenic purpura	1	1			1	1
Thrombosis	1	1			1	1
Tinnitus	2	4	1	2	1	2
Tongue coated		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue discomfort	1	2			1	2
Tongue dry		1				1
Tonsillar hypertrophy		1				1
Transient ischaemic attack	1	2			1	2
Tremor		8		1		7
Upper-airway cough syndrome		1				1
Upper gastrointestinal haemorrhage		1				1
Urinary tract infection bacterial		1				1
Urticaria	1	5		1	1	4
Urticaria cholinergic		1		1		
Vaccination failure	3	19			3	19
Vaccination site discomfort		3		2		1
Vaccination site erythema	1	11	1	9		2
Vaccination site induration		4		3		1
Vaccination site inflammation		1		1		
Vaccination site nodule		1		1		
Vaccination site oedema	2	8	1	7	1	1
Vaccination site pain	22	106	19	75	3	31
Vaccination site pruritus		5		2		3
Vaccination site reaction		1		1		
Vaccination site swelling	4	8	4	6		2
Vaccination site warmth		4		4		
Vasculitis	2	2			2	2
Venous thrombosis	1	1			1	1
Vertigo	3	6	2	3	1	3
Vision blurred	1	2	1	2		
Visual impairment	1	2	1	1		1
Vomiting	1	8		2	1	6
Wheezing		1				1
	281	1,344	178	528	103	816

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain	1	4	1	3		1
Abdominal pain upper		2		1		1
Acute myocardial infarction		1				1
Allodynia		1				1
Alopecia	1	1	1	1		
Anaphylactic reaction	1	3			1	3
Anosmia		1				1
Arthralgia	5	23	4	8	1	15
Asthenia	2	17	2	5		12
Atrial fibrillation		1				1
Axillary mass	1	1			1	1
Axillary pain	1	5		3	1	2
Back pain		2		1		1
Bedridden		1				1
Blood pressure increased		2				2
Body temperature abnormal		1				1
Bradycardia		1				1
Bronchospasm		1				1
Bursitis		1				1
Chest discomfort		1				1
Chest pain	1	6	1	3		3
Chills	5	20	5	9		11
Conjunctival haemorrhage		1				1
Contusion		1				1
Cough	2	6	2	3		3
COVID-19	6	26	4	12	2	14
Cutaneous vasculitis	1	1			1	1
Cyanosis		1				1
Decreased appetite		2		1		1
Dermatitis	1	1			1	1
Dermatitis bullous	1	1			1	1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea	2	14	2	8		6
Discomfort	1	1	1	1		
Dizziness	2	18	2	8		10
Dizziness postural		1				1
Drug ineffective	2	14			2	14
Dry mouth		1				1
Dysgeusia		5		5		
Dyspepsia		1				1
Dyspnoea	2	4			2	4
Ear pain		1				1
Episcleritis		1				1
Epistaxis		1				1
Eructation		1		1		
Erythema		4		2		2
Erythema nodosum		1				1
Exposure via breast milk	3	11	3	11		
Face oedema	1	5	1	2		3
Fatigue	5	21	4	8	1	13
Feeling hot	1	1			1	1
Flushing		5		1		4
Gastrointestinal disorder	1	1	1	1		
Groin pain		1				1
Headache	14	75	14	30		45
Hemiparaesthesia		1				1
Herpes zoster		1				1
Hyperaemia		1				1
Hyperglycaemia		1				1
Hyperhidrosis	1	4	1	3		1
Hypersensitivity	1	8		4	1	4
Hypertension		3				3
Hyperthermia		2		2		
Hypoaesthesia		2		1		1

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Gender

UNKNOWN

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
			1
	2		
2	2		
	1		
			1
	1		
7			7
2	1		1
3			3
1			1
1			1
			1
1	3		10
1	1		
4	9		2
	1		1
		1	1
			1
			1
21	42	1	53
			1
1	1		
5	15		19
2	2		
			1
1	1		
1	1		2
			1
			1
			1
		2	5
	1		

Hypoaesthesia oral

1

Hypotension

1

Incorrect dose administered

2

Incorrect route of product administration

2

2

Infant irritability

1

Inflammation

1

Irritability

1

Laryngeal oedema

7

Lethargy

2

Lip oedema

3

Lip swelling

1

Localised oedema

1

Lymphadenopathy

1

13

Lymph node pain

1

1

Malaise

4

11

Migraine

2

Moaning

1

1

Mobility decreased

1

Muscular weakness

1

Myalgia

22

95

Myoclonus

1

Nasopharyngitis

1

1

Nausea

5

34

Neck pain

2

2

Neuropathy peripheral

1

Ocular hyperaemia

1

1

Odynophagia

1

3

Oedema

1

Oedema mouth

1

Oedema mucosal

1

Oedema peripheral

2

5

Oral discomfort

1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral disorder		1				1
Oropharyngeal discomfort		1				1
Oropharyngeal oedema		1		1		
Oropharyngeal pain	2	3	2	3		
Orthopnoea		1				1
Orthostatic intolerance	1	1			1	1
Overdose	4	9	4	9		
Oxygen saturation decreased		1				1
Pain	2	9	2	4		5
Pain in extremity		2		2		
Pain in jaw		1				1
Pallor		2		1		1
Palpitations	1	1	1	1		
Paraesthesia	7	18	7	9		9
Paraesthesia oral	1	5	1	2		3
Petechiae	1	2	1	1		1
Phlebitis	1	1			1	1
Presyncope		2		1		1
Procedural nausea		1				1
Productive cough		1				1
Product preparation issue	1	1	1	1		
Pruritus	2	6		1	2	5
Purpura	1	1			1	1
Pyrexia	9	58	9	25		33
Rash	1	20		7	1	13
Rash erythematous	1	1			1	1
Rash macular		2				2
Rash maculo-papular		1		1		
Rash pruritic		2		2		
Rhinorrhoea	1	4	1	1		3
Salivary hypersecretion		1		1		
SARS-CoV-2 test positive		2				2

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensation of foreign body		1				1
Sensory loss		1				1
Skin lesion	1	1			1	1
Sleep disorder		2				2
Somnolence		7		2		5
Stomatitis		1		1		
Suspected COVID-19	1	1	1	1		
Swelling	1	1	1	1		
Syncope		6				6
Tachycardia		10		5		5
Taste disorder		2		2		
Tension headache	1	2	1	2		
Throat irritation		3		2		1
Thrombophlebitis	2	2	1	1	1	1
Tongue discomfort		1				1
Tongue disorder		1		1		
Tongue dry		1		1		
Tongue oedema		4		1		3
Tonsillitis bacterial		1				1
Tooth abscess		1		1		
Tremor		7		3		4
Urticaria	2	4	1	1	1	3
Urticaria cholinergic		1		1		
Vaccination failure		2				2
Vaccination site erythema	1	7	1	3		4
Vaccination site haemorrhage		1		1		
Vaccination site hypoaesthesia		1				1
Vaccination site inflammation		2				2
Vaccination site joint pain		1				1
Vaccination site lymphadenopathy		1				1
Vaccination site movement impairment		1				1
Vaccination site nodule	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site oedema	3	12	3	6		6
Vaccination site pain	9	56	9	43		13
Vaccination site paraesthesia	1	1	1	1		
Vaccination site swelling		2		1		1
Vaccination site warmth	1	2	1	2		
Varicella		1				1
Vertigo	1	4	1	1		3
Vomiting	1	7	1	2		5
	170	873	140	383	30	490

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

PUERTO RICO

090177e19749cf15\Approved\Approved On: 14-Jun-2021 14:01 (GMT)

- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		3		3		
Abdominal pain	1	3	1	3		
Antinuclear ant body positive		1		1		
Arthralgia	1	7	1	7		
Asthenia		1		1		
Axillary pain		1		1		
Back pain		1		1		
Balance disorder		1		1		
Blepharospasm		1		1		
Blood pressure increased		1		1		
Bone disorder		1		1		
Bone pain		1		1		
Burning sensation		3		3		
Cerebrovascular accident		1				1
Chest discomfort	1	2		1	1	1
Chest pain	1	3		2	1	1
Chills	1	6	1	6		
Contraindicated product administered	1	1	1	1		
Decreased appetite		1		1		
Dermatitis		1		1		
Diarrhoea	1	4	1	4		
Discomfort		1		1		
Dizziness		4		3		1
Dizziness postural		1		1		
Dry mouth		1		1		
Dysgeusia		1		1		
Dyskinesia		1				1
Dyspepsia		1		1		
Dysphonia		1		1		
Dyspnoea	1	1	1	1		
Erythema		3		3		
Eyelid oedema	1	1	1	1		

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Face oedema	1	1	1	1		
Facial pain		1		1		
Facial paralysis	1	4			1	4
Fatigue	1	11	1	11		
Flushing		2		2		
Gingival bleeding		1		1		
Haematoma		1		1		
Headache	3	20	2	19	1	1
Heart rate decreased		1				1
Heart rate increased		1		1		
Hot flush	1	1			1	1
Hypertension	1	3	1	2		1
Hypoaesthesia	1	9		7	1	2
Hypotension	1	1			1	1
Inappropriate schedule of product administration		1		1		
Inflammation		1		1		
Joint range of motion decreased		1		1		
Joint swelling		2		2		
Loss of personal independence in daily activities		2		2		
Lymphadenopathy	1	7	1	7		
Malaise		1		1		
Maternal exposure during pregnancy		1		1		
Migraine		1				1
Movement disorder		1		1		
Muscle spasms	2	3		1	2	2
Muscular weakness	1	1			1	1
Myalgia	1	10	1	10		
Nausea	1	7	1	7		
Neck pain	1	2	1	2		
Night sweats		1				1
Nodule		1		1		
Oedema	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral discomfort		1		1		
Oropharyngeal pain	1	1	1	1		
Pain		4		4		
Pain in extremity	1	7	1	7		
Palpitations		1		1		
Paraesthesia	3	5	1	3	2	2
Peripheral swelling		3		3		
Pharyngeal swelling	1	1			1	1
Photophobia		1		1		
Product administered at inappropriate site		1		1		
Product dose omission issue	1	1	1	1		
Productive cough		1		1		
Pruritus		2		2		
Pyrexia	1	13	1	13		
Rash		4		4		
Red blood cell sedimentation rate increased		1		1		
Rhinorrhoea		1		1		
Sensation of blood flow	1	1	1	1		
Sinus arrhythmia		1				1
Sleep disorder		1		1		
Somnolence		3		3		
Speech disorder		1		1		
Stress		1		1		
Swelling		1		1		
Swelling face		4		4		
Syncope	1	1			1	1
Tachycardia		2		2		
Taste disorder		2		2		
Urticaria		1		1		
Vaccination site discomfort		1		1		
Vaccination site erythema		1		1		
Vaccination site induration	1	2	1	2		

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site inflammation		1		1		
Vaccination site pain		7		7		
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	1	6	1	6		
Vaccination site warmth	1	1	1	1		
Vaginal haemorrhage	1	1	1	1		
	42	249	28	223	14	26

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Antibody test abnormal		1		1		
Arthralgia		2		2		
Asthenia		1		1		
Asymptomatic COVID-19		1		1		
Blood test abnormal		1		1		
Chills		1		1		
Death		1				1
Deep vein thrombosis		1				1
Dehydration		1		1		
Depression		1		1		
Dizziness		1		1		
Dyspnoea		2		1		1
Electric shock sensation		1		1		
Fatigue		5		5		
Feeling cold		1				1
Flatulence		1		1		
Gait disturbance		1		1		
Headache		4		4		
Head discomfort		1		1		
Herpes zoster		1		1		
Hyperhidrosis		1				1
Hypertension		1		1		
Illness		1				1
Inappropriate schedule of product administration		2		2		
Insomnia		1		1		
Limb discomfort		2		2		
Lymphadenitis		1		1		
Lymphadenopathy		1		1		
Muscle spasms		1		1		
Musculoskeletal discomfort		1		1		
Musculoskeletal stiffness		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea		1		1		
Neuralgia		1		1		
Off label use		1		1		
Oral herpes		1		1		
Pain		2		2		
Pain in extremity		3		3		
Photophobia		1		1		
Pneumonia		1				1
Pyrexia		5		5		
Rash		1		1		
Tachycardia		1		1		
Thirst		1		1		
Thrombosis		1				1
Urinary tract infection		1				1
		64	55		9	

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills		1		1
Fatigue		1		1
Headache		1		1
Myalgia		1		1
Poor quality product administered		10		10
Pyrexia		1		1
		15	15	

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Country Where Event Occurred

QATAR

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic shock		1				1
COVID-19		1				1
Dizziness		1				1
Dysgeusia		1		1		
Dyspepsia		2		2		
Erythema		1				1
Exposure during pregnancy		1		1		
Feeling cold		1		1		
Headache		1		1		
Mood altered		1		1		
Nausea		1				1
Peripheral coldness		1		1		
Product use issue		1		1		
Vaccination failure		1				1
		15		9		6

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		2		1		1
Back pain		1				1
Blood pressure decreased		1		1		
Confusional state		1		1		
COVID-19		1				1
Depressed mood		1		1		
Disturbance in attention		1		1		
Dizziness		1				1
Drug ineffective		1				1
Dyspnoea	1	2			1	2
Erythema		1		1		
Facial paralysis		1				1
Feeling hot		1				1
Gait disturbance		1		1		
Headache		1		1		
Heart rate decreased		1		1		
Heart rate increased		1		1		
Herpes zoster		1		1		
Hyperhidrosis		1				1
Hypertension		1		1		
Hypotension		1		1		
Middle insomnia		1		1		
Muscle spasticity		1				1
Myalgia		1		1		
Neck pain		1				1
Overdose		1		1		
Pain in extremity		1				1
Presyncope		1				1
Product preparation error		1		1		
Pulse abnormal	1	1			1	1
Pyrexia	1	2		1	1	1
Sleep disorder		1		1		

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* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Starvation		1				1
Syncope		1				1
Tachycardia	1	2		1	1	1
Vertigo		1				1
	4	40		20	4	20

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough		1				1
COVID-19		1		1		
C-reactive protein increased		1				1
Herpes zoster		1		1		
Inflammatory marker increased		1				1
Neuralgia		1		1		
Neutrophil count increased		1				1
Ocular hyperaemia		1				1
Platelet count increased		1				1
Pyrexia		1				1
Rash		1				1
Red blood cell sedimentation rate increased		1				1
Rhinovirus infection		1				1
Sexual dysfunction	1	1	1	1		
Tachycardia		1				1
White blood cell count increased		1				1
	1	16	1	4		12

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Country Where Event Occurred

ROMANIA

090177e19749cf15\Approved\Approved On: 14-Jun-2021 14:01 (GMT)

- * I=Interval, C=Cumulative
- * AE=Adverse Event
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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal pain	3	11	1	3	2	8
Abdominal pain upper	4	6	1	2	3	4
Abortion spontaneous	1	2			1	2
Acoustic neuroma		1				1
Acute coronary syndrome		1				1
Acute myocardial infarction	1	1			1	1
Administration site pain		4		3		1
Administration site reaction		4		4		
Administration site swelling		1		1		
Adnexa uteri pain		1				1
Ageusia		3		2		1
Aggression	1	1			1	1
Agitation	1	1	1	1		
Amenorrhoea		1		1		
Anaphylactic reaction	6	12			6	12
Anaphylactic shock	4	9			4	9
Anaphylactoid reaction		2				2
Angina pectoris	1	3			1	3
Angioedema		5				5
Angle closure glaucoma		1				1
Anosmia	2	4	1	3	1	1
Anxiety	1	10		1	1	9
Aphasia	1	1			1	1
Apnoea		1				1
Arrhythmia	1	2			1	2
Arthralgia	14	52	6	28	8	24
Asphyxia	1	3			1	3
Asthenia	13	42	9	28	4	14
Asthmatic crisis		1				1
Asymptomatic COVID-19		1				1
Atrial fibrillation		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Atrioventricular block		1				1
Autoimmune disorder		1				1
Autoimmune thyroiditis	1	1			1	1
Axillary pain	2	6	2	4		2
Back disorder		1		1		
Back pain	3	8	2	3	1	5
Balance disorder	1	4		1	1	3
Blister		1				1
Blood fibrinogen increased		1		1		
Blood glucose decreased		1				1
Blood glucose increased		1				1
Blood pressure abnormal	1	3	1	2		1
Blood pressure decreased		1				1
Blood pressure diastolic increased		1				1
Blood pressure fluctuation	2	5			2	5
Blood pressure increased	6	12	1	2	5	10
Blood pressure systolic increased		1				1
Blood uric acid increased		1		1		
Body temperature abnormal	1	2	1	2		
Bone pain	3	12		3	3	9
Breast inflammation	1	3	1	1		2
Breast pain	4	8	2	3	2	5
Bronchospasm		4		1		3
Bruxism	1	1	1	1		
Burning sensation	3	6	1	2	2	4
Burn of internal organs		1				1
Cardiac fibrillation		1				1
Cardio-respiratory arrest	1	1			1	1
Catarrh	1	1	1	1		
Cerebral small vessel ischaemic disease		1				1
Cerebrovascular accident	2	5			2	5
Cervical radiculopathy	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest discomfort	3	7		3	3	4
Chest pain	5	16	1	2	4	14
Chills	45	125	24	59	21	66
Circulatory collapse	1	1			1	1
Circumoral oedema		1				1
Coagulopathy	1	1			1	1
Cognitive disorder	1	1			1	1
Cold sweat		2				2
Condition aggravated		2		1		1
Confusional state	3	4	1	2	2	2
Contusion	4	4			4	4
Cough	4	13		3	4	10
COVID-19	6	47	3	8	3	39
Craniocerebral injury	1	1			1	1
Crying		1		1		
Cyanosis		3		1		2
Deafness unilateral	1	1			1	1
Death	1	2			1	2
Decreased appetite	3	9	2	4	1	5
Deep vein thrombosis		2				2
Dehydration	1	1			1	1
Delirium	1	1			1	1
Dementia		1				1
Depressed level of consciousness		1				1
Dermatitis allergic	2	7		1	2	6
Diabetes mellitus		1				1
Diarrhoea	5	16	3	6	2	10
Diplopia	1	3		1	1	2
Discomfort	1	3	1	3		
Disease recurrence	1	2	1	1		1
Disorientation	1	2	1	1		1
Disturbance in attention		2				2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	30	76	14	32	16	44
Drug eruption		2				2
Drug ineffective	3	32			3	32
Dry mouth	2	5			2	5
Dry throat	2	2			2	2
Dysgeusia		2				2
Dysmenorrhoea	1	1	1	1		
Dysphagia	3	7	2	3	1	4
Dysphonia	1	2		1	1	1
Dyspnoea	7	22		2	7	20
Dysstasia	2	3			2	3
Ear congestion	1	1			1	1
Ear discomfort	1	2	1	2		
Ear pain		1				1
Emotional distress		1		1		
Epiglottic oedema		1				1
Epistaxis		1		1		
Eructation		1				1
Erythema	6	20	3	9	3	11
Erythema nodosum		2		1		1
Exposure during pregnancy	1	2	1	2		
Extensive swelling of vaccinated limb		1				1
Eye haemorrhage		2				2
Eyelid oedema	1	2			1	2
Eyelid ptosis		1				1
Eye pain	1	3			1	3
Eye pruritus	1	2		1	1	1
Face oedema		2				2
Facial asymmetry	1	1	1	1		
Facial nerve disorder	1	1			1	1
Facial neuralgia		1				1
Facial pain		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial paralysis		7				7
Facial paresis	2	4	1	1	1	3
Faeces soft	1	2	1	1		1
Fall	2	2			2	2
Fatigue	30	88	21	59	9	29
Fear		1		1		
Feeding disorder	1	1	1	1		
Feeling abnormal	2	4	1	1	1	3
Feeling cold		2		1		1
Feeling hot	1	3	1	1		2
Flatulence		1				1
Flushing		1		1		
Foaming at mouth		1				1
Gait disturbance	1	2			1	2
Gastric pH decreased		1		1		
General physical condition abnormal		2		2		
General physical health deterioration	2	3	1	2	1	1
Goitre		1				1
Guillain-Barre syndrome	1	1			1	1
Haematuria	1	1	1	1		
Haemorrhage	1	1			1	1
Hallucination	1	1			1	1
Headache	44	162	26	82	18	80
Head discomfort		2				2
Hearing disability	1	1			1	1
Heart rate abnormal	1	2		1	1	1
Heart rate decreased	1	3			1	3
Heart rate increased	10	24	3	3	7	21
Heavy menstrual bleeding	1	1	1	1		
Hemianaesthesia		1				1
Hemiparaesthesia		1				1
Hemiparesis	1	2			1	2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hepatic cytolysis		1				1
Herpes simplex	1	1	1	1		
Herpes virus test		1		1		
Herpes zoster	6	7	3	3	3	4
High density lipoprotein decreased		1		1		
Hot flush		1		1		
Hyperaemia		1				1
Hyperaesthesia	1	2	1	2		
Hypercoagulation	1	1			1	1
Hyperglycaemia	1	1			1	1
Hyperhidrosis	1	14		4	1	10
Hyperpyrexia		1				1
Hypersensitivity	5	28		19	5	9
Hypersomnia	1	1	1	1		
Hypertension	19	57	3	8	16	49
Hypertensive crisis		2				2
Hypoacusis	1	3			1	3
Hypoaesthesia	11	28	2	7	9	21
Hypoaesthesia eye		1				1
Hypoaesthesia oral	3	6			3	6
Hypocalcaemia		1				1
Hypoglycaemia	1	1			1	1
Hypokinesia		1		1		
Hypotension	6	11	1	2	5	9
Hypothyroidism		1				1
Hypotonia		1				1
Illness		1				1
Immobile		1				1
Inappropriate schedule of product administration	2	3	2	3		
Incomplete course of vaccination		1		1		
Incorrect route of product administration		5		3		2
Induration	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inflammation	3	5	1	3	2	2
Influenza like illness		2		2		
Injected limb mobility decreased	1	4	1	4		
Insomnia	5	9	4	5	1	4
Intermenstrual bleeding	1	1	1	1		
Intertrigo	1	1	1	1		
Intervertebral disc protrusion	1	1			1	1
Intracranial pressure increased	1	2			1	2
Irregular breathing	1	1			1	1
Irritable bowel syndrome	1	1			1	1
Ischaemic stroke	1	1			1	1
Jaundice	2	2	1	1	1	1
Jaw disorder		1				1
Joint ankylosis		1				1
Joint dislocation	1	1			1	1
Joint instability	1	1			1	1
Joint stiffness		1				1
Joint swelling	2	2			2	2
Laboratory test abnormal		2		2		
Laryngeal oedema		2				2
Laryngospasm		1				1
Limb injury		1				1
Lipase increased		1		1		
Lip dry		1				1
Lip oedema		6		2		4
Lip swelling	1	2			1	2
Listeria test positive		1		1		
Loss of consciousness	7	12			7	12
Loss of personal independence in daily activities		1		1		
Lung disorder		1		1		
Lymphadenitis	1	8		4	1	4
Lymphadenopathy	12	37	6	16	6	21

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymph node pain		1		1		
Lymph node palpable		1		1		
Lymphopenia		1				1
Malaise	17	35	7	13	10	22
Maternal exposure during pregnancy		3		3		
Mean cell haemoglobin increased		1		1		
Memory impairment		1				1
Menometrorrhagia	1	1			1	1
Menstrual disorder		2		1		1
Menstruation irregular	4	5	4	4		1
Mental disorder	1	1			1	1
Mental status changes		1				1
Metamorphopsia		1				1
Migraine	3	6		1	3	5
Mobility decreased		2		1		1
Monoplegia		1				1
Mood altered	1	1			1	1
Mouth swelling		1				1
Mucosal dryness		1				1
Muscle contractions involuntary	1	2	1	2		
Muscle discomfort	1	1			1	1
Muscle rigidity		1				1
Muscle spasms	1	1			1	1
Muscle tightness	1	1	1	1		
Muscle twitching	1	1			1	1
Muscular weakness	1	3	1	2		1
Musculoskeletal chest pain		1				1
Musculoskeletal disorder	1	1	1	1		
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness		1				1
Myalgia	53	140	33	72	20	68
Myocardial infarction	1	2			1	2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myocardial ischaemia		1				1
Myoclonus	1	3			1	3
Myositis	1	1			1	1
Nasal congestion	2	3	1	1	1	2
Nasal discomfort		2		2		
Nasal dryness		3		1		2
Nasal oedema		1				1
Nausea	19	81	7	33	12	48
Neck pain	1	2		1	1	1
Nephropathy		1				1
Nervous system disorder		2		2		
Neuritis	1	1			1	1
Neurological symptom		3				3
Neuropathy peripheral	2	3			2	3
Night sweats	1	3		1	1	2
Nitrite urine present		1		1		
No adverse event		1		1		
Nodule	1	1			1	1
Nystagmus		1		1		
Obstructive airways disorder		1				1
Ocular discomfort		3		2		1
Ocular hyperaemia		1		1		
Ocular vascular disorder	1	1			1	1
Odynophagia		1		1		
Oedema		2		1		1
Oedema peripheral	4	7	1	1	3	6
Oedematous pancreatitis		1				1
Oesophageal oedema	1	1			1	1
Off label use	4	7	4	7		
Optic neuritis		1				1
Oropharyngeal discomfort		2				2
Oropharyngeal pain	4	5	1	1	3	4

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Osteoporosis	1	1
Overdose		1
Oxygen saturation decreased		4
Pain	9	21
Pain in extremity	16	49
Pain of skin	2	4
Pallor	1	3
Palpitations	3	12
Panic attack	1	1
Panic reaction	1	1
Paraesthesia	8	32
Paraesthesia oral	1	3
Paralysis		1
Paraplegia	1	2
Paratracheal lymphadenopathy		1
Parkinson's disease		1
Parosmia		3
Pelvic pain		1
Pericarditis	1	2
Peripheral coldness		2
Peripheral swelling		1
Peripheral venous disease	1	1
Petechiae		1
Pharyngitis		1
Photophobia	1	2
Photosensitivity reaction		1
Pleurisy		1
Pneumonia		1
Pollakiuria		1
Polyuria		3
Presyncope		5
Productive cough		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
	1		
			4
7	16	2	5
8	33	8	16
1	1	1	3
		1	3
	1	3	11
		1	1
		1	1
4	10	4	22
1	3		
			1
		1	2
			1
	1		2
			1
		1	1
	1		1
			1
1	1		1
			1
			1
			1
	3		2
			1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product use issue	3	5	3	5		
Protein urine present		1		1		
Pruritus	1	11		5	1	6
Pulse abnormal		4		2		2
Pulse volume decreased		2		2		
Pyrexia	55	142	29	69	26	73
Rales		1				1
Rash	4	15	3	10	1	5
Rash erythematous		3				3
Rash pruritic	1	6		3	1	3
Rash vesicular		1				1
Raynaud's phenomenon		1				1
Red blood cells urine positive		1		1		
Renal pain	1	4			1	4
Respiration abnormal		1				1
Respiratory disorder		2		1		1
Respiratory distress		3				3
Respiratory failure	1	1			1	1
Rheumatic disorder		1		1		
Rhinalgia		1				1
Rhinitis	1	1			1	1
Rhinorrhoea	1	2	1	2		
SARS-CoV-2 ant body test negative		1		1		
SARS-CoV-2 ant body test positive	1	2	1	2		
SARS-CoV-2 test positive		3		1		2
Scar pain		1		1		
Sciatica	1	1	1	1		
Seizure	1	3			1	3
Sensation of foreign body	2	2			2	2
Sensory disturbance	1	1			1	1
Sensory loss		1		1		
Shock		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sialoadenitis		1				1
Sinus tachycardia		2				2
Skin burning sensation		1				1
Skin discolouration		1		1		
Skin hypertrophy		1				1
Skin plaque		1				1
Sleep disorder		1				1
Sleep talking	1	1	1	1		
Somnolence	11	36	9	22	2	14
Speech disorder		1				1
Spinal pain		2		1		1
Stomatitis		2				2
Stress	1	1	1	1		
Stridor		1		1		
Suffocation feeling	4	8		1	4	7
Suppressed lactation		1		1		
Supraventricular tachycardia		1				1
Suspected COVID-19	1	3	1	1		2
Swelling	2	3		1	2	2
Swelling face	3	4	1	1	2	3
Swollen tongue	2	3	1	1	1	2
Syncope	8	28			8	28
Synovial cyst	1	1			1	1
Systemic inflammatory response syndrome		1				1
Systolic hypertension		1				1
Tachyarrhythmia		1				1
Tachycardia	5	29	1	8	4	21
Tachypnoea		1				1
Taste disorder		3		2		1
Teething		1				1
Tendon pain		1				1
Tetany	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thirst	1	4			1	4
Throat irritation	1	1			1	1
Throat tightness		1		1		
Thrombophlebitis	1	1			1	1
Thrombophlebitis superficial		1		1		
Thrombosis	3	3			3	3
Thyroiditis subacute		1		1		
Tinnitus	2	5		1	2	4
Tongue oedema		1				1
Tongue spasm		1				1
Toxocariasis		1				1
Toxoplasma serology positive		1		1		
Tremor	5	10		1	5	9
Type 2 diabetes mellitus		1				1
Urinary incontinence		1				1
Urine ketone body present		1		1		
Urticaria	5	18	4	7	1	11
Urticaria papular		1		1		
Use of accessory respiratory muscles		1		1		
Vaccination complication	1	1			1	1
Vaccination error	1	1			1	1
Vaccination failure		10				10
Vaccination site discolouration	1	2	1	2		
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	4	17	4	14		3
Vaccination site granuloma		1		1		
Vaccination site haemorrhage	1	1			1	1
Vaccination site induration	3	8	2	6	1	2
Vaccination site inflammation	2	3	1	1	1	2
Vaccination site joint movement impairment		2				2
Vaccination site lymphadenopathy	1	3	1	3		
Vaccination site macule		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site movement impairment		6		4		2
Vaccination site nodule		1		1		
Vaccination site oedema	2	5	1	4	1	1
Vaccination site pain	33	127	26	92	7	35
Vaccination site papule		1		1		
Vaccination site paraesthesia		2		1		1
Vaccination site pruritus	1	5	1	5		
Vaccination site reaction		16		16		
Vaccination site swelling	6	12	5	11	1	1
Vaccination site urticaria		1		1		
Vaccination site warmth	1	1	1	1		
Ventricular arrhythmia	1	1			1	1
Ventricular extrasystoles		1		1		
Vertigo	2	22	1	3	1	19
Vestibular disorder	1	2		1	1	1
Vision blurred	1	3			1	3
Visual field defect		1				1
Visual impairment	3	6		1	3	5
Vomiting	8	28	5	10	3	18
Weight decreased		1				1
Wheezing		2		1		1
White blood cells urine positive		1		1		
Wrong technique in product usage process		1		1		
	840	2,652	375	1115	465	1537

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	2	1	2		
Accidental exposure to product	1	1	1	1		
Acute pulmonary oedema		2				2
Ageusia		2		1		1
Agitation		1				1
Alanine aminotransferase increased	1	1			1	1
Allergy to vaccine		1		1		
Anaphylactic reaction		1				1
Anaphylactic shock	1	1			1	1
Angina pectoris	1	2			1	2
Anosmia		2				2
Anxiety		4		3		1
Aphonia		1		1		
Arrhythmia		2				2
Arthralgia	8	20	4	9	4	11
Aspartate aminotransferase increased	1	1			1	1
Asthenia	3	7	3	5		2
Asthma		1				1
Back pain	2	7	1	3	1	4
Balance disorder	1	2			1	2
Blepharitis		1				1
Blindness unilateral	1	1			1	1
Blood pressure increased		3		2		1
Blood pressure systolic increased		2		1		1
Body temperature abnormal		1		1		
Body temperature increased		2		1		1
Bone pain	1	2	1	1		1
Bronchitis		1				1
Bronchospasm		2		1		1
Burning sensation	1	1	1	1		
Cardiac arrest		1				1
Cardio-respiratory arrest		2				2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiovascular disorder	2	2			2	2
Cataract		1				1
Cerebrovascular accident	1	3			1	3
Chest discomfort		1		1		
Chest pain	3	6	2	4	1	2
Chills	10	37	6	21	4	16
Cold sweat		2		2		
Coma		2				2
Coma hepatic		1				1
Condition aggravated		2				2
Contusion		1		1		
Coronavirus infection		1				1
Cough	1	3	1	3		
COVID-19	6	40	2	7	4	33
C-reactive protein increased	1	1	1	1		
Death		2				2
Decreased appetite	1	4	1	2		2
Deep vein thrombosis		1				1
Dehydration	1	2			1	2
Diarrhoea		5		3		2
Disease recurrence		1				1
Disorientation	1	1	1	1		
Disturbance in attention	1	3	1	2		1
Dizziness	4	16	3	10	1	6
Drug ineffective	4	32			4	32
Dry skin	1	1			1	1
Dysphagia	1	1			1	1
Dysphonia		1		1		
Dyspnoea	1	6		1	1	5
Dyspnoea exertional		1				1
Ear pain	1	2		1	1	1
Emotional disorder	2	2	2	2		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Encephalopathy	1	1			1	1
Erythema	1	5		3	1	2
Exposure to SARS-CoV-2		1		1		
Exposure via breast milk	3	3	3	3		
Eyelid oedema		1		1		
Eyelid ptosis		1		1		
Facial pain		1		1		
Facial paralysis	2	4			2	4
Facial paresis	3	4	1	1	2	3
Fall	1	1	1	1		
Fatigue	10	24	6	17	4	7
Feeling abnormal		3		3		
Feeling cold		2				2
Feeling hot		2		1		1
Gait disturbance		1				1
General physical health deterioration		2		2		
Guillain-Barre syndrome		1				1
Headache	16	44	13	33	3	11
Head discomfort	1	1	1	1		
Heart rate increased	1	5	1	2		3
Hemiparesis	2	2			2	2
Hemiplegia		1				1
Herpes zoster		1		1		
Horner's syndrome		1				1
Hyperaesthesia	1	1	1	1		
Hyperglycaemia		3		1		2
Hyperhidrosis	3	8	2	4	1	4
Hyperkalaemia		2				2
Hypersensitivity		1		1		
Hypertension	4	11	1	2	3	9
Hypoacusis		2				2
Hypoaesthesia	5	9	4	7	1	2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia oral		1				1
Hypotension	1	3			1	3
Hypoxic-ischaemic encephalopathy		1				1
Illness	1	1	1	1		
Impaired work ability		1				1
Inappropriate schedule of product administration	2	3	2	3		
Incoherent	1	1	1	1		
Incorrect route of product administration		2		1		1
Infarction		1				1
Influenza like illness		1		1		
Insomnia	1	4	1	2		2
Ischaemic stroke		1				1
Lethargy		1		1		
Lid sulcus deepened	1	1			1	1
Lip oedema	1	1			1	1
Lip swelling		1		1		
Lividity		1				1
Localised oedema		1				1
Loss of consciousness	2	5			2	5
Loss of personal independence in daily activities		1		1		
Lymphadenitis		1				1
Lymphadenopathy	8	15	4	10	4	5
Malaise	8	14	4	7	4	7
Medication error		1		1		
Metabolic acidosis		1				1
Mobility decreased	1	1			1	1
Monoparesis	1	1			1	1
Movement disorder		1				1
Muscle contractions involuntary		1				1
Muscle contracture		1				1
Muscle swelling		1		1		
Muscular weakness	1	3		2	1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal stiffness	1	1	1	1		
Myalgia	12	37	8	20	4	17
Nasal dryness	1	1			1	1
Nasal vestibulitis		1				1
Nausea	4	11	2	6	2	5
Nephrogenic diabetes insipidus	1	1			1	1
Nervous system disorder		1		1		
Neuronal neuropathy		1				1
Nodule	1	1	1	1		
Odynophagia	1	1	1	1		
Oedema		1		1		
Oedema peripheral	1	1			1	1
Off label use	2	3	2	3		
Optic neuritis	1	1			1	1
Oral pigmentation		1		1		
Organic brain syndrome		1				1
Oropharyngeal pain		1				1
Orthostatic hypotension	1	1			1	1
Osteoarthritis	1	1	1	1		
Oxygen saturation abnormal		1				1
Oxygen saturation decreased		1		1		
Pain	3	4	2	3	1	1
Pain in extremity	5	14	2	10	3	4
Pallor		2		1		1
Palpitations	1	2	1	1		1
Panic attack		3		3		
Paraesthesia	4	12	1	6	3	6
Paraesthesia ear		1		1		
Paraesthesia oral	1	1	1	1		
Paresis	1	1			1	1
Peripheral arterial occlusive disease		1				1
Peripheral swelling	1	1	1	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonia	1	1			1	1
Polyuria	1	1			1	1
Presyncope		1		1		
Product preparation issue		1		1		
Product use issue		1		1		
Pruritus		2		1		1
Pulmonary embolism	1	1			1	1
Pulmonary infarction	1	1			1	1
Pyrexia	20	57	13	34	7	23
Rash	1	5		3	1	2
Rash erythematous		1				1
Rectal haemorrhage		1				1
Renal pain	1	1			1	1
Respiratory failure		1				1
Rheumatoid factor increased	1	1	1	1		
Rhinitis	1	1	1	1		
Rhinorrhoea	1	5	1	4		1
SARS-CoV-2 ant body test negative		2		2		
SARS-CoV-2 ant body test positive		2		2		
SARS-CoV-2 test positive		2				2
Seizure	2	3			2	3
Sensation of foreign body	1	1			1	1
Sitting disability		1				1
Skin discolouration		1		1		
Skin exfoliation	1	1			1	1
Skin irritation		2				2
Somnolence	6	13	4	8	2	5
Speech disorder	1	1			1	1
Stress cardiomyopathy	1	1			1	1
Supraventricular tachycardia		1				1
Suspected COVID-19	1	4		1	1	3
Sweating fever		1				1

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MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling		1		1		
Syncope	8	20			8	20
Syringe issue		1		1		
Tachycardia		1		1		
Thirst		1				1
Thrombophlebitis superficial	1	1			1	1
Thrombosis		1				1
Tinnitus	1	2			1	2
Transaminases increased		1		1		
Tremor	1	2		1	1	1
Urinary incontinence	2	2	2	2		
Urticaria	2	5	1	4	1	1
Vaccination failure	1	5			1	5
Vaccination site erythema		1		1		
Vaccination site joint movement impairment		1		1		
Vaccination site movement impairment		1				1
Vaccination site pain	11	44	9	36	2	8
Vaccination site reaction	1	10	1	10		
Vaccination site swelling	1	1	1	1		
Ventricular tachycardia	1	1			1	1
Vertigo	1	6	1	4		2
Viral infection		1				1
Vision blurred	1	2			1	2
Visual acuity reduced		1				1
Visual field defect	1	1	1	1		
Visual impairment	1	3			1	3
Vomiting	1	2			1	2
Walking disability	1	1	1	1		
Weight increased		1				1
White blood cell count decreased	1	1	1	1		
Wrong product administered		2		2		
Wrong technique in product usage process		2		2		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	270	840	141	414	129	426

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* I=Interval, C=Cumulative
* AE=Adverse Event
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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		2				2
Arrhythmia		2				2
Arthralgia		6		6		
Asthenia		7		7		
Asymptomatic COVID-19		1				1
Blood pressure abnormal		1		1		
Body temperature increased	1	1	1	1		
Bradycardia	16	16			16	16
Burning sensation		1				1
Chest discomfort	1	1			1	1
Chest pain	1	1			1	1
Chills	5	12	3	9	2	3
Circumstance or information capable of leading to medication error		3		3		
Cough		1		1		
COVID-19	1	108			1	108
Death	1	7			1	7
Decreased appetite		1		1		
Dizziness	1	2			1	2
Drug ineffective	1	34			1	34
Dyspnoea	2	2			2	2
Erythema		3		3		
Exposure via breast milk		1		1		
Facial paralysis		1				1
Facial paresis		2		2		
Fatigue	1	8	1	8		
Feeling cold		1		1		
Feeling hot		1		1		
Haemorrhage	1	1			1	1
Headache	14	29	12	25	2	4
Heart rate increased	1	2		1	1	1
Hyperglycaemia	1	1			1	1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyperhidrosis	16	17
Hyperpyrexia	5	5
Hypersensitivity		1
Hypertension	1	4
Hypoglycaemia	1	1
Hypotension	15	15
Incorrect route of product administration	15	16
Influenza like illness		5
Injected limb mobility decreased		1
Intercepted medication error		1
Lethargy	2	2
Liquid product physical issue	1	1
Local reaction		1
Lymphadenitis	2	2
Lymphadenopathy	6	8
Lymph node pain	1	1
Malaise	1	5
Medication error		2
Metabolic acidosis	1	1
Muscle contracture		1
Muscle spasms		1
Muscular weakness		2
Myalgia	6	21
Mydriasis	16	16
Nausea	3	4
Neuralgia		1
Neuropathy peripheral		1
Off label use		1
Pain	1	2
Pain in extremity	2	8
Pallor	15	15
Paraesthesia	1	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
16	16		1
		5	5
	1		
	2	1	2
		1	1
15	15		
	1	15	15
	5		
	1		
	1		
1	1	1	1
1	1		
	1		
1	1	1	1
5	7	1	1
		1	1
	3	1	2
	2		
		1	1
	1		
			1
	2		
4	19	2	2
10	10	6	6
2	3	1	1
			1
			1
	1		
1	2		
2	8		
15	15		
	1	1	2

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Poor quality product administered	1	1	1	1		
Product preparation error	1	13	1	13		
Product preparation issue		8		8		
Product quality issue		1		1		
Pyrexia	10	27	9	25	1	2
SARS-CoV-2 ant body test negative		4		4		
SARS-CoV-2 ant body test positive		4		4		
SARS-CoV-2 test positive		4		2		2
Skin irritation	1	1	1	1		
Sluggishness	1	1			1	1
Somnolence	2	3			2	3
Suffocation feeling	1	1			1	1
Syncope	17	19			17	19
Tachycardia	1	2		1	1	1
Thirst	1	1			1	1
Underdose		3		3		
Vaccination failure		1				1
Vaccination site discomfort		3		3		
Vaccination site erythema		13		13		
Vaccination site inflammation		1		1		
Vaccination site nodule		1		1		
Vaccination site pain	16	34	15	33	1	1
Vaccination site swelling		1		1		
Vaccination site warmth		1		1		
Wrong technique in product usage process	3	17	3	17		
	214	589	120	324	94	265

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Country Where Event Occurred

SAUDI ARABIA

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Abdominal pain upper		1				1
Abortion	1	1			1	1
Arthralgia		1		1		
Blood pressure decreased	1	1	1	1		
Cerebral haemorrhage	1	1			1	1
Cerebrovascular accident	1	1			1	1
Chills		2		2		
Death	1	1			1	1
Dizziness	1	2	1	2		
Dysstasia		1				1
Epistaxis	1	1	1	1		
Fatigue		3		2		1
Gait disturbance		2		1		1
Headache	1	6	1	6		
Heavy menstrual bleeding	1	1	1	1		
Hyperhidrosis		2		2		
Lymphadenopathy		1		1		
Lymphoma		1				1
Malaise		1		1		
Mastication disorder		1		1		
Menstruation irregular	1	2	1	2		
Mobility decreased		2		1		1
Mouth ulceration		1		1		
Movement disorder		1		1		
Musculoskeletal stiffness		1		1		
Myalgia		4		3		1
Nausea		1		1		
Off label use	2	2	2	2		
Oropharyngeal pain		1		1		
Pain		3		2		1
Pain in extremity		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in jaw		1		1		
Pain of skin		1		1		
Product administered to patient of inappropriate age	1	1	1	1		
Product use issue	2	2	2	2		
Pyrexia		3		3		
Sciatica		1		1		
Somnolence		1		1		
Stomatitis	1	1			1	1
Tremor		1		1		
Vaccination site erythema		1		1		
Vaccination site pain		2		2		
Vaccination site pruritus		1		1		
Vaccination site swelling		1		1		
Vaginal haemorrhage	1	1			1	1
Vaginal infection	1	2	1	2		
Vomiting		1				1
	19	72	12	55	7	17

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Acquired haemophilia		1				1
Anaphylactic shock		1				1
Arthralgia		1		1		
Asthenia		1		1		
Cardiac arrest		1				1
Carotid artery stenosis		1				1
COVID-19	1	4	1	4		
Death	1	1			1	1
Decreased appetite	1	1	1	1		
Disturbance in attention	1	1	1	1		
Dizziness	1	2	1	1		1
Extra dose administered	1	1	1	1		
Fatigue	1	4	1	4		
Feeling hot		1		1		
Gait inability		1				1
Headache	2	3	2	3		
Heart rate decreased		1				1
Herpes zoster		1		1		
Hot flush		1		1		
Hyperhidrosis		2		1		1
Hypotension		1				1
Infection		1		1		
Lymphadenopathy	1	2	1	2		
Malaise		1		1		
Mobility decreased		2		2		
Myalgia		2		2		
Nasopharyngitis		1		1		
Night sweats		1		1		
Overdose	1	1	1	1		
Pain		3		3		
Pain in extremity		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral coldness		1		1		
Pollakiuria		1		1		
Pyrexia		4		3		1
Respiration abnormal	1	1	1	1		
Rhinorrhoea		1		1		
Sciatica		1		1		
Seizure		2				2
Sitting disability		1				1
Sleep disorder		1		1		
Syncope		3				3
Temperature intolerance		1		1		
Vaccination site pain	1	5	1	5		
Vomiting		2				2
Weight decreased	1	1	1	1		
	14	72	13	52	1	20

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose		1		1		
Arthralgia	1	2	1	2		
Asthenia		1		1		
Axillary pain		1		1		
COVID-19	2	2			2	2
C-reactive protein increased		1		1		
Drug ineffective	2	2			2	2
Exposure via breast milk	2	2	2	2		
Fatigue		1		1		
Hypertension	1	1	1	1		
Hypoaesthesia	1	1	1	1		
Inappropriate schedule of product administration		1		1		
Lymphadenopathy		1		1		
Myalgia		1		1		
Pain in extremity	1	3	1	3		
Peripheral coldness		1		1		
Poor feeding infant	2	2	2	2		
Product preparation issue		1		1		
Pulmonary embolism		1				1
Red blood cell sedimentation rate increased		1		1		
Retching	1	1	1	1		
	13	28	9	23	4	5

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Country Where Event Occurred

SERBIA

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	4	1	3		1
Anaphylactoid reaction		1				1
Anosmia	1	3	1	3		
Anxiety		1		1		
Arthralgia	7	15	7	15		
Asphyxia		2				2
Asthenia	1	6	1	6		
Axillary pain		1		1		
Back pain	1	1	1	1		
Blepharospasm		1				1
Blood bilirubin increased	1	1	1	1		
Blood calcium decreased	1	1	1	1		
Blood creatinine increased	1	1	1	1		
Blood iron decreased	1	1	1	1		
Blood pressure increased		2		1		1
Body temperature increased	5	13	5	13		
Bone pain		1		1		
Bronchospasm		1				1
Burning sensation		1		1		
Chest pain	1	3	1	2		1
Chills	1	7	1	6		1
Circulatory collapse	1	1			1	1
Conjunctivitis		1		1		
Cough	2	3	2	2		1
COVID-19	2	9	1	5	1	4
C-reactive protein increased	1	1	1	1		
Deafness		1				1
Deafness unilateral		1				1
Death		1				1
Decreased appetite	1	2	1	2		
Diarrhoea	2	3	2	3		
Disease recurrence		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	2	7	2	6		1
Drug ineffective	1	3			1	3
Dry mouth		1		1		
Erythema	1	9	1	8		1
Exposure during pregnancy		1		1		
Eyelid oedema		1		1		
Eyelid ptosis		1				1
Eye pain		1		1		
Face oedema		1				1
Facial paralysis		1				1
Facial paresis		1				1
Fall		1		1		
Fatigue	8	14	8	13		1
Fear of death		1		1		
Feeling abnormal		1		1		
Feeling cold	1	2	1	2		
Feeling hot		2		2		
Gamma-glutamyltransferase increased	1	1	1	1		
Guillain-Barre syndrome	2	2			2	2
Haematoma		1		1		
Headache	12	25	12	24		1
Head discomfort	1	1	1	1		
Heavy menstrual bleeding	2	2	2	2		
Herpes zoster	1	2	1	2		
Huntington's disease		1				1
Hyperhidrosis		2		2		
Hypersensitivity	1	2	1	1		1
Hypertension		6		2		4
Hypoaesthesia		1		1		
Hypoaesthesia oral		2		1		1
Hypopnoea		1				1
Infection	1	1	1	1		

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Gender

FEMALE

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	2		
	1		
	1		1
		1	1
		1	1
	1		
		1	1
1	1		
1	1		
2	3		
2	9		1
	1		
	1		
	1	1	1
	1		
9	18		
	1		1
	1		1
1	2		
	1		
5	12		1
	1		
			1
1	3		
1	2		
	2		
2	12		
	2	1	1
	1		
	2	1	1
		1	1

Inflammatory marker increased
Influenza like illness
Insomnia
Joint stiffness
Laryngeal discomfort
Leukopenia
Localised oedema
Loss of consciousness
Lung disorder
Lymphadenitis
Lymphadenopathy
Malaise
Maternal exposure during pregnancy
Movement disorder
Muscular weakness
Musculoskeletal stiffness
Myalgia
Myocarditis
Myositis
Nasal congestion
Nasopharyngitis
Nausea
No adverse event
Oedema mucosal
Oedema peripheral
Oropharyngeal pain
Pain
Pain in extremity
Pallor
Palpitations
Paraesthesia
Paraesthesia mucosal

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia oral	2	2			2	2
Pruritus		1		1		
Pulmonary pain		1		1		
Pyrexia	14	35	14	34		1
Rash	1	3	1	2		1
Rash macular		2				2
Seizure	1	1			1	1
Skin burning sensation		1				1
Sleep disorder	1	2	1	2		
Somnolence		2		2		
Superficial vein prominence		1		1		
Swelling		1		1		
Swelling of eyelid		1		1		
Swollen tongue		1		1		
Syncope	1	3			1	3
Tachycardia		1				1
Thirst	1	1	1	1		
Tinnitus		1		1		
Tongue oedema		1				1
Tremor		1		1		
Tumour pseudoprogression	1	1			1	1
Urticaria	2	4	1	3	1	1
Vaccination complication	1	5	1	5		
Vaccination site erythema	2	4	2	4		
Vaccination site induration		1		1		
Vaccination site oedema		2		2		
Vaccination site pain	7	16	7	16		
Vaccination site reaction		1		1		
Vaccination site swelling		1		1		
Vertigo		1		1		
Vision blurred		2		1		1
Vomiting	1	2	1	2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Wrong product administered		1		1		
	132	387	114	319	18	68

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Abscess		1				1
Ageusia		1		1		
Anosmia		1		1		
Anxiety		1		1		
Arthralgia	1	3		1	1	2
Asthenia		4		3		1
Axillary pain		1				1
Back pain	1	2	1	1		1
Balance disorder		1				1
Blood lactate dehydrogenase increased		1				1
Body temperature increased	4	10	3	8	1	2
Bone pain		1		1		
Bronchospasm		1		1		
Chest discomfort		2		2		
Chest pain		1				1
Chills	3	8	2	5	1	3
Circulatory collapse	1	1			1	1
Confusional state	1	2	1	2		
Cough	2	4	1	2	1	2
COVID-19	4	8	3	6	1	2
COVID-19 pneumonia		1				1
C-reactive protein increased		2		1		1
Diarrhoea		1		1		
Dizziness		1		1		
Drug ineffective	1	2			1	2
Dysgeusia		1				1
Dyspnoea		4		1		3
Fall		1				1
Fatigue	6	12	6	12		
Fear		1				1
Fibrin D dimer increased		1		1		

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Headache	4	14
Heart rate increased		1
Hyperaesthesia		1
Hyperhidrosis		2
Hypersensitivity		1
Hypertension		2
Hypoaesthesia		1
Inappropriate schedule of product administration	1	2
Insomnia		1
Intraocular pressure increased		1
Irritability		1
Ischaemic stroke		1
Lacrimation increased		1
Lip disorder		1
Lip pruritus		1
Lip swelling		1
Loss of consciousness		1
Lymphadenitis		1
Lymphadenopathy	2	4
Lymphangitis	1	1
Malaise	2	15
Monocyte count increased		1
Muscular weakness		1
Myalgia	3	9
Myocardial infarction		1
Nasal congestion	1	2
Nausea	1	10
Neck pain	1	2
Nervousness		1
Oedema mouth		1
Off label use		1
Optic neuritis		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
3	11	1	3
	1		
	1		
	1		1
	1		
			2
	1		
1	2		
			1
			1
	1		
			1
	1		
	1		
	1		
			1
			1
2	3		1
		1	1
2	13		2
	1		
	1		
2	7	1	2
			1
		1	2
	8	1	2
		1	2
			1
	1		
	1		
			1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oropharyngeal pain		1		1		
Overdose		1				1
Oxygen saturation decreased		1				1
Pain		1				1
Pain in extremity	4	8	4	8		
Pain in jaw		1		1		
Palpitations		1		1		
Pancreatitis acute		1				1
Paraesthesia		1		1		
Paraesthesia oral		1		1		
Peripheral swelling		1				1
Phlebitis		1				1
Photophobia		1		1		
Pneumonia		1				1
Product supply issue	1	1	1	1		
Pruritus	1	1	1	1		
Pulmonary pain		1				1
Pyrexia	8	22	8	18		4
Rash	1	2	1	2		
Rash macular	1	1	1	1		
Rash pruritic	1	1	1	1		
Red blood cell count increased		1		1		
Red blood cell sedimentation rate increased		1				1
Rhinorrhoea		1				1
SARS-CoV-2 test positive		3		1		2
Skin burning sensation		1		1		
Skin reaction		1				1
Sneezing		1				1
Somnolence	1	2	1	1		1
Swelling		1				1
Swelling of eyelid	1	1	1	1		
Syncope		2				2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia	1	3		1	1	2
Thrombophlebitis		1				1
Thrombosis	1	2			1	2
Tremor		1		1		
Urticaria	1	2	1	2		
Vaccination complication	1	2		1	1	1
Vaccination failure		1				1
Vaccination site erythema		1		1		
Vaccination site haematoma		1				1
Vaccination site lymphadenopathy	1	1	1	1		
Vaccination site pain	3	9	3	9		
Vaccination site pruritus		1		1		
Vomiting		2		2		
Wheezing		1				1
	67	259	51	173	16	86

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposure via breast milk		1		1		
Haematemesis		1				1
Headache	1	1	1	1		
Nausea		1				1
Pyrexia	1	3	1	2		1
SARS-CoV-2 ant body test negative		1		1		
Vaccination site erythema		1		1		
Vaccination site pain		1		1		
Vomiting		1				1
	2	11	2	7		4

* I=Interval, C=Cumulative

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Country Where Event Occurred

SINGAPORE

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- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		4				4
Abdominal tenderness		1				1
Acute kidney injury		1				1
Allergy to vaccine		1				1
Anaphylactic reaction		14				14
Anaphylactic shock		3				3
Angioedema		4				4
Arthralgia		2				2
Arthritis		1				1
Asthenia		2		1		1
Asthma		1				1
Bell's palsy		1				1
Bicytopenia		1				1
Blood pressure decreased		1				1
Blood pressure increased		4		1		3
Blood pressure systolic increased		2				2
Breath sounds abnormal		1				1
Chest discomfort		12		3		9
Chest pain		2				2
Chills		5		1		4
Cough		3				3
Deafness neurosensory		1				1
Decreased appetite		1				1
Dehydration		1				1
Diarrhoea		3		1		2
Diplopia		1				1
Disease progression		1		1		
Disease recurrence		1				1
Dizziness		18		6		12
Dry eye		1				1
Dry mouth		1		1		
Dysacusis		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysgeusia	1	2	1	2		
Dyskinesia		1				1
Dysphagia		2				2
Dysphonia		8		1		7
Dyspnoea		21		1		20
Dyspnoea exertional		1		1		
Dysstasia		1				1
Ectopic pregnancy	1	1			1	1
Enlarged uvula		3				3
Erythema		2				2
Extrasystoles		1				1
Eye disorder		1				1
Eye movement disorder		2				2
Eye pruritus		2		1		1
Eye swelling		1				1
Facial asymmetry		1				1
Facial paralysis		1				1
Fall		1				1
Fatigue	3	7	3	6		1
Femoral neck fracture		1				1
Flushing		2				2
Gait disturbance		1				1
Gastroesophageal reflux disease		1				1
Generalised tonic-clonic seizure		1				1
Haematocrit increased		1				1
Haematuria		1				1
Haemoglobin increased		1				1
Headache		7		6		1
Head discomfort		1		1		
Heart rate increased		2				2
Hepatitis		1				1
Hunger		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperhidrosis		2		1		1
Hypersensitivity		3		1		2
Hypertension	1	6			1	6
Hyperthyroidism		1				1
Hypoaesthesia		5		1		4
Hypotension		4				4
Lacrimation increased		1				1
Laryngeal oedema		1				1
Lip swelling		2				2
Lymphadenopathy		1		1		
Malaise		1				1
Maternal exposure during pregnancy		1		1		
Migraine		1				1
Muscular weakness		2				2
Musculoskeletal stiffness		1				1
Myalgia		3		2		1
Nausea		9		4		5
Nerve injury		1				1
Odynophagia		1				1
Oedema peripheral		1		1		
Optic neuritis		1				1
Oropharyngeal pain		2				2
Oxygen saturation decreased		3				3
Pain	1	3	1	2		1
Pain in extremity	1	4	1	3		1
Palatal oedema		1				1
Palpitations		8		1		7
Periorbital swelling		3				3
Peripheral coldness		1		1		
Peripheral swelling		1				1
Pharyngeal mass		1		1		
Pharyngeal swelling		2				2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonia aspiration		1				1
Postural orthostatic tachycardia syndrome		1				1
Proteinuria		1				1
Pruritus		5				5
Pupillary light reflex tests abnormal		1				1
Pyrexia	1	11	1	5		6
Radiculopathy		1				1
Rash		9		2		7
Rash erythematous		1		1		
Rash macular		2				2
Rash maculo-papular		1				1
Rash papular		1				1
Renal impairment		1				1
Respiratory rate decreased		1				1
Respiratory rate increased		1				1
Respiratory tract infection		1				1
Rheumatoid arthritis		1				1
Rhinorrhoea		1				1
Secretion discharge		1		1		
Seizure		2				2
Sensation of foreign body		5				5
Sensory disturbance		1				1
Somnolence		2				2
Status epilepticus		1				1
Swelling of eyelid		1				1
Syncope		4				4
Tachycardia	1	4			1	4
Tenosynovitis		1				1
Throat irritation		4		2		2
Throat tightness		7		1		6
Tic		1				1
Tonic convulsion		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Transaminases increased		1				1
Tremor		1		1		
Troponin increased		1				1
Unresponsive to stimuli		2				2
Upper respiratory tract congestion		1		1		
Urticaria		9				9
Vaccination site erythema	1	2	1	2		
Vaccination site hypoaesthesia		1				1
Vaccination site mass		1		1		
Vaccination site pain	2	6	2	4		2
Vaccination site paraesthesia		1				1
Vaccination site pruritus	1	1	1	1		
Vaccination site rash	1	2	1	1		1
Vaccination site swelling	1	1	1	1		
Vaccination site urticaria	1	2	1	1		1
Vertigo		1		1		
Vestibular neuronitis		1				1
Vision blurred		2		1		1
Vlth nerve paralysis		1				1
Vomiting		6		1		5
Wheezing		3		1		2
	17	375	14	85	3	290

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Acute psychosis		1				1
Alanine aminotransferase increased		1				1
Anaphylactic reaction		3				3
Anaphylactic shock		1				1
Angioedema		3				3
Antineutrophil cytoplasmic antibody positive	1	1	1	1		
Aspartate aminotransferase increased		1				1
Asthma		1				1
Bell's palsy		1				1
Blepharospasm		1		1		
Blood alkaline phosphatase increased		1				1
Blood bilirubin increased		1				1
Blood pressure increased		2		1		1
Blood pressure systolic increased		1				1
Body temperature increased		1				1
Cellulitis		1				1
Chest discomfort		1				1
Chest pain		1				1
Chills		1				1
Cold sweat		1				1
Complement factor C3 increased		1				1
Confusional state		2				2
Cough		1				1
COVID-19	1	1			1	1
Cranial nerve disorder	1	1			1	1
Deep vein thrombosis		1				1
Dermatitis bullous		1				1
Diarrhoea		2				2
Diplopia	1	1			1	1
Dizziness		4		1		3
Drooling		1				1

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Drug ineffective	1	1
Drug reaction with eosinophilia and systemic symptoms		1
Dyskinesia		3
Dysphonia		1
Dyspnoea		1
Dyspnoea exertional		1
Enlarged uvula		1
Eosinophilia		1
Erythema multiforme		1
Eye colour change		1
Eye movement disorder		2
Fall		1
Fatigue	2	3
Feeding disorder		1
Feeling abnormal	1	1
Flushing		1
Generalised tonic-clonic seizure		1
Hand dermatitis		1
Headache		1
Heart rate increased		1
Herpes zoster	1	1
Hypoaesthesia		1
Hypotension		1
IIIrd nerve paralysis	1	1
Influenza like illness		1
Insomnia	1	1
IVth nerve paralysis	1	1
Lethargy		1
Limb discomfort	1	1
Lip swelling		1
Malaise		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
			1
			3
			1
			1
			1
			1
			1
	1		
			2
			1
2	3		
1	1		
			1
			1
	1		
			1
			1
1	1		
			1
			1
		1	1
	1		
1	1		
		1	1
	1		
1	1		
			1
			1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mental status changes		1				1
Myalgia		1		1		
Myocardial infarction		1				1
Nausea		2		1		1
Neck pain		1				1
Oedema peripheral	1	1	1	1		
Pain in extremity	1	2	1	2		
Palatal oedema		1				1
Pallor		1				1
Palpitations		2				2
Parosmia		2		2		
Periorbital swelling		3		1		2
Peripheral swelling	1	1	1	1		
Petit mal epilepsy		1				1
Pituitary tumour	1	1			1	1
Poor quality product administered		2		2		
Pulmonary embolism		1				1
Pyrexia	1	1	1	1		
Rash		8		5		3
Rash macular	1	3	1	1		2
Rash maculo-papular		1		1		
Rash pruritic		1				1
Seizure		2				2
Sinus tachycardia		1				1
Skin abrasion		1				1
Sleep disorder		1		1		
Somnolence		1		1		
Swelling face		1				1
Swollen tongue		1				1
Syncope		1				1
Tachycardia		1				1
Throat tightness		2				2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue biting		1				1
Tonic clonic movements		1				1
Toxic neuropathy		1				1
Transaminases increased		1				1
Unresponsive to stimuli		1				1
Urticaria	1	4	1	2		2
Vaccination complication		1				1
Vaccination site bruising	1	1	1	1		
Vaccination site erythema		1		1		
Vaccination site pruritus		1		1		
Vision blurred		2		1		1
Visual impairment		2		1		1
Vomiting		3		1		2
Wheezing		1				1
	21	149	14	44	7	105

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne		1		1		
Acute generalised exanthematous pustulosis		1				1
Anaphylactic shock		1				1
Chills		1		1		
Eye swelling		1		1		
Fibroma		1		1		
Gianotti-Crosti syndrome		1		1		
Injection site swelling		1		1		
Lip swelling		1		1		
Myalgia	1	1	1	1		
Poor quality product administered		1		1		
Product preparation issue	1	1	1	1		
Product quality issue	1	1	1	1		
Pyrexia	1	2	1	2		
Skin lesion		1		1		
Taste disorder		1		1		
Urticaria		1		1		
Vaccination site pruritus		1		1		
Vaccination site rash		1		1		
Vaccination site reaction		1		1		
Wrong technique in product usage process	1	1	1	1		
	5	22	5	20		2

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Country Where Event Occurred

SLOVAKIA

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		1		1		
Abdominal pain upper		1		1		
Abnormal dreams		1		1		
Anaphylactic reaction		2				2
Angioedema		2				2
Anosmia	1	1	1	1		
Arthralgia	2	27	2	26		1
Asthenia	2	31	2	27		4
Asymptomatic COVID-19	1	2			1	2
Axillary pain		3		3		
Axillary vein thrombosis		1				1
Back pain		3		3		
Balance disorder		1		1		
Blood glucose increased		2		2		
Blood pressure decreased		4		1		3
Blood pressure increased	2	18	1	6	1	12
Body temperature increased	4	23	4	22		1
Bone pain		2		2		
Brachial plexus injury		1				1
Brain contusion		1				1
Burning sensation	1	4	1	4		
Cardiac failure		1				1
Cervicobrachial syndrome		1				1
Chest discomfort	1	4	1	4		
Chest pain		2		2		
Chills	7	65	7	61		4
Condition aggravated		1		1		
Conjunctivitis		2		1		1
Cough	2	8	2	8		
COVID-19	1	12		3	1	9
COVID-19 pneumonia	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cyanosis		1				1
Deafness		1				1
Decreased appetite		3		3		
Dehydration		2		1		1
Dermatitis allergic		1		1		
Diarrhoea		4		4		
Diplopia		1		1		
Dizziness		13		12		1
Drug ineffective	2	8			2	8
Dry mouth		2		1		1
Dry throat		1		1		
Dysaesthesia		1		1		
Dyskinesia		1		1		
Dysphagia	1	1	1	1		
Dyspnoea	2	8	2	7		1
Epilepsy		1				1
Erysipelas		1				1
Erythema		3		3		
Exposure via breast milk		1		1		
Eye allergy		1		1		
Eye irritation	1	4	1	4		
Eyelid oedema	1	1	1	1		
Eye oedema		3		1		2
Eye pruritus		1		1		
Face oedema	1	4	1	3		1
Fall		2		1		1
Fatigue	9	45	9	45		
Feeling hot		8		8		
Feeling of body temperature change		1		1		
Flatulence		1		1		
Gait disturbance		1		1		
Headache	9	62	9	62		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Head discomfort		3		3		
Heart rate decreased		1		1		
Heart rate increased		2		2		
Hot flush	1	7	1	6		1
Hyperaemia	1	1	1	1		
Hyperhidrosis	1	8	1	6		2
Hypersensitivity		2		1		1
Hypertension		4		3		1
Hypertensive crisis		1				1
Hypoaesthesia		1		1		
Influenza like illness		2		2		
Insomnia		2		2		
Insulin resistance		1				1
Lacrimation increased		1		1		
Limb discomfort		1		1		
Lip oedema		1		1		
Loss of consciousness		3				3
Lymphadenopathy	5	11	5	11		
Lymph node pain		1		1		
Malaise	1	14	1	14		
Maternal exposure during pregnancy		3		3		
Meningeal disorder	1	1			1	1
Migraine	1	2	1	2		
Movement disorder		2		2		
Muscular weakness	1	2	1	1		1
Musculoskeletal chest pain		1		1		
Musculoskeletal discomfort		1		1		
Myalgia	4	34	4	34		
Myocardial ischaemia		1				1
Nasopharyngitis	1	1	1	1		
Nausea	4	27	4	24		3
Neck pain		2		2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular discomfort		1		1		
Ocular hyperaemia		1		1		
Oedema		1		1		
Oedema peripheral		1		1		
Off label use		2		2		
Oral discomfort		1		1		
Oropharyngeal pain		1		1		
Oxygen saturation decreased	1	1			1	1
Pain		5		5		
Painful respiration	1	1	1	1		
Pain in extremity	13	56	13	56		
Palpitations		5		5		
Pancreatitis acute		1				1
Paraesthesia	2	16	2	13		3
Paraesthesia oral		3		2		1
Peripheral coldness		2		2		
Peripheral swelling		2		2		
Photophobia		2		2		
Presyncope	1	5	1	3		2
Product administered at inappropriate site		1		1		
Product administration error		1				1
Product use issue		1		1		
Pruritus	1	3	1	3		
Pyrexia	5	47	5	45		2
Rash		2		2		
Rash pruritic		1		1		
Rectal haemorrhage	1	1			1	1
Restlessness		2				2
Retching		1		1		
Rhinalgia		1		1		
Rhinitis		2		2		
SARS-CoV-2 ant body test positive		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
SARS-CoV-2 test positive		1				1
Sinus tachycardia		2				2
Sneezing	1	1	1	1		
Somnolence		5		4		1
Subclavian vein stenosis		1				1
Subclavian vein thrombosis		1				1
Sudden hearing loss		2				2
Syncope		8				8
Synovitis		1		1		
Tachycardia		7		4		3
Tachypnoea		1				1
Tendonitis		1		1		
Tension headache		2		2		
Thirst		1		1		
Throat irritation		2		2		
Throat tightness		1		1		
Thrombosis		1				1
Tinnitus		5		5		
Tissue infiltration		1		1		
Tongue discolouration		1		1		
Tongue dry		1				1
Tremor		1				1
Tryptase decreased		1		1		
Urticaria	3	4	3	3		1
Vaccination failure	1	3			1	3
Vaccination site bruising	1	2	1	2		
Vaccination site dermatitis		1		1		
Vaccination site erythema	2	10	2	10		
Vaccination site hypersensitivity		1		1		
Vaccination site induration		3		3		
Vaccination site joint movement impairment		1		1		
Vaccination site movement impairment		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site oedema	1	11	1	11		
Vaccination site pain	13	66	13	66		
Vaccination site pruritus	1	4	1	4		
Vaccination site swelling		1		1		
Vaccination site warmth	1	2	1	2		
Venous thrombosis limb		2				2
Vertigo	1	12	1	11		1
Viral infection		1				1
Vision blurred		1		1		
Visual impairment		1				1
Vomiting		5		4		1
	122	912	112	781	10	131

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2		1		1
Abdominal pain		1				1
Abdominal pain upper		1		1		
Acute myocardial infarction		1				1
Altered state of consciousness		2				2
Amnesia		1				1
Angular cheilitis	1	1	1	1		
Aphasia		1				1
Arrhythmia	1	2			1	2
Arthralgia	1	5	1	5		
Asphyxia		1				1
Asthenia	4	14	3	11	1	3
Atrial f brillation		1				1
Axillary pain		1		1		
Back pain		1		1		
Blood glucose increased	1	1	1	1		
Blood pressure decreased	1	4	1	1		3
Blood pressure increased		4		2		2
Body temperature decreased	1	1			1	1
Body temperature increased		9		7		2
Bradycardia		1				1
Cardiac discomfort		1		1		
Cardiac failure chronic	1	1			1	1
Cardiac fibrillation		1				1
Cerebral ischaemia		1				1
Chest discomfort	1	3	1	2		1
Chest pain	1	2	1	2		
Chills	4	23	3	21	1	2
Cold sweat		1		1		
Confusional state	1	1			1	1
Coronary artery disease	1	1			1	1
Cough		2		2		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	2			1	2
Cutaneous vasculitis		1		1		
Decreased appetite	1	3	1	3		
Diarrhoea	1	5	1	3		2
Disorientation		1		1		
Dizziness	2	9	2	6		3
Drug ineffective	1	1			1	1
Dry mouth		1		1		
Dysphagia		1		1		
Dyspnoea	1	4		1	1	3
Enlarged uvula		1		1		
Erythema	1	3	1	3		
Extra dose administered		1		1		
Eyelid rash		1		1		
Eye pain		2		2		
Eye pruritus		1		1		
Facial paresis	1	2	1	1		1
Fatigue	2	5	1	4	1	1
Feeling hot	1	1	1	1		
Headache	2	13	2	13		
Heart rate increased		2		2		
Herpes zoster	1	1			1	1
Hot flush		1				1
Hyperhidrosis		2		1		1
Inflammation		1		1		
Influenza like illness	2	2	2	2		
Insomnia	1	2	1	2		
Left ventricular hypertrophy	1	1			1	1
Loss of libido	1	1	1	1		
Lymphadenitis		1		1		
Lymphadenopathy	2	6	2	6		
Lymphangitis		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise	1	3	1	2		1
Micturition urgency		1				1
Migraine	1	1	1	1		
Musculoskeletal stiffness		1		1		
Myalgia	4	15	4	15		
Mydriasis		1		1		
Nausea	3	10	3	10		
Oropharyngeal pain		1		1		
Pain		2		2		
Pain in extremity	2	6	2	6		
Pain of skin		1		1		
Pallor		3		2		1
Palpitations		1		1		
Paraesthesia	2	5	2	4		1
Peripheral coldness		1		1		
Petechiae		1		1		
Pneumonia	1	1			1	1
Presyncope		2		1		1
Product administered at inappropriate site		1		1		
Prostatitis	1	1			1	1
Pruritus		1		1		
Pyelonephritis	1	1			1	1
Pyrexia	3	19	3	18		1
Rash		2		2		
Rash papular		1		1		
Rash pruritic		1		1		
Rash pustular		1		1		
Renal colic	1	1			1	1
Retching		1		1		
SARS-CoV-2 test positive		1		1		
Speech disorder		1				1
Syncope		3				3

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia		3		3		
Thirst		1		1		
Thrombosis		1				1
Tinnitus		1		1		
Tonic convulsion		1				1
Urinary tract infection	1	1			1	1
Urosepsis	1	1			1	1
Vaccination site oedema	1	2	1	2		
Vaccination site pain	9	24	9	24		
Vaccination site urticaria		1		1		
Vertigo		3		3		
Vision blurred	1	3	1	3		
Vomiting	1	4	1	2		2
Wheezing		1				1
	75	309	56	239	19	70

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphasia		1		1		
Arthralgia	2	6	2	6		
Asthenia	2	2	2	2		
Blood pressure decreased		1		1		
Body temperature fluctuation		1		1		
Body temperature increased	2	6	2	5		1
Chills	2	6	2	5		1
COVID-19	1	2			1	2
Diarrhoea	1	1	1	1		
Drug ineffective		1				1
Dysarthria		1		1		
Erythema		1				1
Fatigue	1	7	1	7		
Feeling abnormal		1		1		
Flushing		1		1		
Headache	1	5	1	4		1
Hyperhidrosis	1	1	1	1		
Lymphadenopathy		2		2		
Malaise	1	2	1	2		
Muscular weakness		1		1		
Myalgia	1	5	1	5		
Nasopharyngitis	1	1	1	1		
Nausea		2		2		
Pain		1		1		
Pain in extremity		2		2		
Palpitations		1		1		
Paraesthesia		2		1		1
Presyncope		1		1		
Pruritus		1				1
Pyrexia	1	6	1	6		
Rash		1		1		
Rash vesicular		1		1		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination failure	1	1			1	1
Vaccination site inflammation		1		1		
Vaccination site oedema		1		1		
Vaccination site pain	1	6	1	5		1
Vaccination site swelling		1				1
	19	83	17	71	2	12

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Country Where Event Occurred

SLOVENIA

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain		3		3		
Abdominal pain lower		1		1		
Abdominal pain upper		1		1		
Acute myocardial infarction		2				2
Administration site pain	1	1	1	1		
Anaemia	1	1			1	1
Anaphylactic reaction		1				1
Angioedema		1				1
Aphasia		1				1
Arrhythmia		1				1
Arthralgia	1	6		5	1	1
Asthenia	2	4	1	3	1	1
Asymptomatic bacteriuria		1				1
Aura		1		1		
Autoimmune thyroiditis		1				1
Axillary pain		1				1
Back pain	2	2	2	2		
Bedridden		1				1
Bell's palsy		1				1
Blindness unilateral		1				1
Blood pressure increased		1		1		
Body temperature increased	3	11	3	10		1
Bradycardia		3				3
Cardiac arrest	2	3			2	3
Cardiac failure		1				1
Cardiopulmonary failure		1				1
Cerebral ischaemia	1	1			1	1
Cerebrovascular accident		1				1
Chest discomfort		3		1		2
Chest pain	2	7	1	4	1	3
Chills		6		6		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circulatory collapse		3				3
Confusional state		1		1		
Coordination abnormal		1				1
COVID-19		1				1
Decreased appetite	1	1	1	1		
Decreased insulin requirement	1	1	1	1		
Deep vein thrombosis	1	1			1	1
Dehydration	1	1	1	1		
Diabetes mellitus		1				1
Diarrhoea	3	10	3	9		1
Disease recurrence		1				1
Dizziness		5		3		2
Dysarthria		1				1
Dysgeusia		2		2		
Dyspnoea	1	3	1	2		1
Ear pain		1				1
Epistaxis	1	1			1	1
Erythema	1	3		1	1	2
Extrasystoles		1				1
Eyelid disorder		1		1		
Eyelid oedema		1		1		
Eye pruritus		1		1		
Factor VIII deficiency	1	1			1	1
Fall		3		1		2
Fatigue	4	25	4	20		5
Feeling cold	1	2	1	2		
Feeling hot		2		1		1
Gait disturbance		1				1
Gait inability		1				1
General physical health deterioration		1				1
Guillain-Barre syndrome		2				2
Haematoma	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemoptysis	1	1			1	1
Haemorrhage	1	1			1	1
Headache	7	26	6	22	1	4
Head injury		1		1		
Hot flush		1				1
Hypersensitivity		1		1		
Hypertension		5				5
Hyperventilation		1				1
Hypoaesthesia	1	3		1	1	2
Hypoglycaemia	1	1			1	1
Hyposmia		2		2		
Inappropriate schedule of product administration		1		1		
Infection	1	2	1	1		1
Insomnia		2		2		
Irritability		1				1
Ischaemic stroke	1	2			1	2
Joint injury	1	1	1	1		
Joint swelling	1	1			1	1
Lip oedema		1				1
Lip swelling		1		1		
Loss of consciousness	2	12			2	12
Lymphadenitis	1	2	1	2		
Lymphadenopathy		4		4		
Malaise	2	16	2	11		5
Maternal exposure during pregnancy		1		1		
Migraine		2		1		1
Migraine with aura		1				1
Monoparesis		1				1
Mood altered		1				1
Muscle strength abnormal	1	1			1	1
Muscular weakness		1		1		
Myalgia	3	12	3	11		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myocardial infarction	2	3			2	3
Nasopharyngitis		2		2		
Nausea	3	10	2	6	1	4
Neck pain		1		1		
Neurological symptom		1		1		
Oedema peripheral	1	2			1	2
Off label use		1		1		
Oral herpes		1				1
Oxygen saturation decreased		1				1
Pain		1		1		
Pain in extremity	3	4	3	4		
Pain of skin	1	1	1	1		
Paraesthesia		7		4		3
Paraesthesia oral		3		1		2
Paresis		1				1
Peripheral coldness		1		1		
Peripheral swelling	1	1			1	1
Pityriasis rosea		1		1		
Pneumonia		1				1
Pneumothorax spontaneous		1				1
Polymyalgia rheumatica	1	1			1	1
Presyncope		1		1		
Pyrexia	2	11	2	10		1
Rash		1		1		
Rash pruritic		2		2		
Restlessness		1		1		
Sensation of foreign body	1	2			1	2
Sensory disturbance		1		1		
Sinusitis		1		1		
Sinus tachycardia		1				1
Skin burning sensation		1		1		
Soliloquy		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Somnolence	2	10	2	7		3
Speech disorder	2	3		1	2	2
Suffocation feeling		1				1
Swollen tongue		2		2		
Syncope		2				2
Tachycardia		2		2		
Thinking abnormal		1		1		
Throat tightness		1		1		
Thrombophlebitis superficial		1				1
Tongue pruritus		2		2		
Total lung capacity decreased		1				1
Transient ischaemic attack	1	1			1	1
Tremor	1	1	1	1		
Unresponsive to stimuli		1				1
Urticaria		1				1
Uterine spasm		1				1
Vaccination failure		1				1
Vaccination site erythema		10		10		
Vaccination site oedema		4		4		
Vaccination site pain	6	51	6	47		4
Vaccination site pruritus		3		3		
Vaccination site rash	1	1	1	1		
Vaccination site swelling	1	3	1	3		
Vaccination site warmth		1				1
Ventricular extrasystoles		2		1		1
Vertigo		9		3		6
Vomiting		4		2		2
Walking disability		1				1
Wheezing		1				1
White blood cell count increased		1		1		
	85	452	53	287	32	165

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory failure		1				1
Anaemia		1				1
Angina pectoris		1				1
Aphasia		1				1
Arthralgia	1	1			1	1
Asthenia		2		1		1
Atrial f brillation		3				3
Atrial tachycardia		1				1
Basilar artery thrombosis		1				1
B-cell lymphoma		1				1
B-cell type acute leukaemia		1				1
Blood creatine phosphokinase increased		1				1
Body temperature increased	1	4		2	1	2
Bradycardia		1				1
Brain injury		1				1
Bronchial disorder		1				1
Cardiac failure		1				1
Cardiac failure congestive		1				1
Cardiac tamponade		1				1
Cardiomegaly		1				1
Cardiopulmonary failure		1				1
Cerebral haemorrhage		1				1
Cerebral thrombosis		1				1
Cerebrovascular accident	2	2			2	2
Chest discomfort		1				1
Chest pain		2				2
Confusional state	1	3			1	3
Contusion		1		1		
Cough		1				1
COVID-19		3				3
COVID-19 pneumonia		1				1
Deep vein thrombosis	1	3			1	3

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dementia		1
Diverticulum intestinal		1
Dizziness		1
Drug ineffective		1
Dry mouth		1
Dysphagia		1
Dyspnoea		5
Epilepsy		3
Fall		1
Fatigue		3
Feeling abnormal		1
Feeling hot		1
Headache	1	5
Hemiparesis	1	1
Herpes zoster	1	1
Hypersensitivity	1	1
Hypochromasia		1
Hypokalaemia		2
Hypotension		1
Immobile		2
Inappropriate schedule of product administration		2
Insomnia		1
Ischaemic cerebral infarction		1
Loss of consciousness		2
Lower respiratory tract infection		1
Malaise		4
Memory impairment	1	1
Metabolic acidosis		1
Miosis		1
Mitral valve incompetence	1	1
Myalgia	1	3
Myocardial fibrosis		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
			1
			1
			1
	1		
	1		
			5
			3
			1
	3		
	1		
			1
	3	1	2
		1	1
		1	1
	1		
	1		1
			1
			2
	2		
	1		
			1
			2
			1
	2		2
		1	1
			1
			1
		1	1
	1	1	2
			1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myocardial infarction		1				1
Myocardial rupture		1				1
Myoglobin blood increased		1				1
Nausea		1		1		
Neutropenia		1				1
Night sweats		1				1
Oedema peripheral		1				1
Off label use		2		2		
Oropharyngeal pain		1		1		
Osteopenia		1		1		
Oxygen saturation decreased		2				2
Pain in extremity		1				1
Paraesthesia	1	1			1	1
Pelvic venous thrombosis	1	1			1	1
Pharyngeal erythema		1		1		
Pneumonia		1				1
Pneumonia bacterial		1				1
Protein total increased		1		1		
Pulmonary embolism		3				3
Pulmonary hypertension	1	1			1	1
Pulmonary oedema		1				1
Pyrexia		1				1
Quadripareisis		1				1
Rash		1				1
Renal failure		1				1
Respiratory acidosis		1				1
Rhabdomyolysis		1				1
Seizure	1	2			1	2
Sensory disturbance		1				1
Skin abrasion		1		1		
Skin disorder		1				1
Speech disorder		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Subarachnoid haemorrhage		1				1
Sudden cardiac death		2				2
Sudden death		2				2
Superficial vein prominence		1				1
Suspected COVID-19		1				1
Syncope	1	4			1	4
Tachycardia		2		1		1
Thrombocytopenia		2				2
Tongue biting		1				1
Tongue movement disturbance		1		1		
Transient ischaemic attack	1	2			1	2
Tricuspid valve incompetence	1	1			1	1
Unresponsive to stimuli		2				2
Urinary incontinence		1				1
Vaccination failure		1				1
Vaccination site pain	2	8	2	7		1
Vascular stent thrombosis		1				1
Vertebral artery thrombosis		1				1
Vertigo		2		2		
	22	172	2	40	20	132

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills		1		1
Fatigue		1		1
Lymphadenopathy		1		1
Malaise		2		2
Myalgia		1		1
Nightmare		1		1
Pain		1		1
Pyrexia		1		1
		9		9

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

SOUTH AFRICA

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Aphasia	1	1			1	1
Asthenia	1	1	1	1		
Back pain	1	1	1	1		
Bone pain	1	1	1	1		
Cerebral venous thrombosis	1	1			1	1
Cerebrovascular accident	1	1			1	1
Conjunctivitis allergic	1	1	1	1		
Death	1	1			1	1
Diarrhoea	1	1	1	1		
Dizziness	2	2	2	2		
Fatigue	1	1	1	1		
Headache	3	3	3	3		
Illness	1	1			1	1
Lip swelling	1	1	1	1		
Pain	1	1	1	1		
Vomiting	1	1	1	1		
	20	20	15	15	5	5

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Asthenia	1	1	1	1		
Chills	1	1	1	1		
Death	1	1			1	1
Decreased appetite	1	1	1	1		
Dehydration	1	1	1	1		
Erythema	1	1	1	1		
Fatigue	1	1	1	1		
Feeding disorder	1	1	1	1		
Groin pain	1	1	1	1		
Headache	2	2	2	2		
Heart rate increased	1	1	1	1		
Malaise	1	1	1	1		
Pain	3	3	3	3		
Palpitations	2	2	2	2		
Pruritus	1	1	1	1		
Pyrexia	1	1	1	1		
Swelling	1	1	1	1		
Tinnitus	1	1	1	1		
Vaccination site lymphadenopathy	1	1	1	1		
Vaccination site rash	1	1	1	1		
Vision blurred	1	1	1	1		
	26	26	25	25	1	1

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headache	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

SPAIN

090177e19749cf15\Approved\Approved On: 14-Jun-2021 14:01 (GMT)

- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	5	8			4	6	1	2
Abdominal distension	1	4				3	1	1
Abdominal mass		1				1		
Abdominal pain	19	46			14	31	5	15
Abdominal pain lower	1	4			1	3		1
Abdominal pain upper	4	16			1	8	3	8
Abdominal symptom		1				1		
Abdominal wall haematoma	1	1					1	1
Abnormal behaviour	1	1					1	1
Abnormal faeces		1				1		
Abortion induced		1						1
Abortion missed	1	3					1	3
Abortion spontaneous		3						3
Accommodation disorder	1	1			1	1		
Acne	2	2			2	2		
Acoustic neuritis		1						1
Activated partial thromboplastin time prolonged		1						1
Activated partial thromboplastin time shortened	1	1			1	1		
Acute aortic syndrome	1	1					1	1
Acute coronary syndrome	1	1					1	1
Acute hepatic failure		1						1
Acute kidney injury		5						5
Acute leukaemia		1						1
Acute myocardial infarction	3	7					3	7
Acute pulmonary oedema	1	1					1	1
Acute respiratory failure	3	12					3	12
Administration site erythema		1				1		
Administration site pruritus		1				1		
Adnexa uteri pain		1				1		
Adrenal mass		1				1		
Ageusia	1	11			1	4		7
Agitation	1	4			1	1		3

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Agranulocytosis	1	1
Akathisia	1	1
Allergic cough	1	2
Allergic oedema		2
Allergic reaction to excipient	1	1
Allergy to vaccine	3	11
Allodynia		1
Alopecia		1
Altered state of consciousness	1	1
Amaurosis fugax		2
Amenorrhoea	3	4
Amino acid level increased	1	1
Amnesia		7
Anaemia	4	6
Anaesthesia oral	1	1
Anal incontinence	2	4
Anal sphincter atony		3
Anaphylactic reaction	7	50
Anaphylactic shock		4
Androgenetic alopecia		1
Anembryonic gestation	1	1
Angina pectoris	2	4
Angioedema	2	31
Angiopathy	1	1
Angular cheilitis		1
Anisocytosis	1	1
Anisometropia		1
Anosmia	1	10
Anterograde amnesia	1	1
Anxiety	8	16
Aortic aneurysm	1	1
Aortic arteriosclerosis	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1		
		1	2		
					2
				1	1
			1	3	10
			1		
					1
				1	1
					2
		1	1	2	3
		1	1		
			3		4
		2	2	2	4
		1	1		
		1	2	1	2
					3
				7	50
					4
					1
				1	1
				2	4
				2	31
		1	1		
			1		
		1	1		
			1		
		1	5		5
				1	1
		4	11	4	5
				1	1
		2	2		

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Aortic dissection		1
Aortic elongation	1	1
Aortic valve calcification		1
Aphasia	4	12
Aphonia	4	11
Aphthous ulcer	4	9
Appendicitis		3
Arrhythmia	4	6
Arteriosclerosis	2	2
Arthralgia	64	174
Arthritis	1	2
Arthritis allergic		1
Arthritis reactive		1
Asphyxia		2
Aspiration	1	1
Asthenia	62	168
Asthenopia	1	4
Asthma		3
Asthmatic crisis		1
Asymptomatic COVID-19	4	21
Ataxia		1
Atelectasis		2
Atrial fibrillation	9	22
Atrioventricular block first degree		1
Atrophic glossitis		1
Atypical haemolytic uraemic syndrome		1
Autoantibody negative		1
Autoimmune demyelinating disease		1
Autoimmune hepatitis		2
Autoimmune hypothyroidism		1
Autoimmune thyroiditis	1	1
Axillary mass	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1		
					1
		1	2	3	10
		2	4	2	7
		3	6	1	3
					3
				4	6
				2	2
		54	120	10	54
				1	2
					1
					1
					2
				1	1
		51	101	11	67
		1	1		3
			1		2
					1
			3	4	18
					1
			1		1
				9	22
			1		
					1
					1
					1
					2
					1
				1	1
		1	1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Axillary pain	3	19
Axonal neuropathy		1
Bacille Calmette-Guerin scar reactivation		1
Back pain	10	27
Bacterial test		1
Bacteriuria	1	1
Balance disorder	2	17
Basal cell carcinoma	1	1
Basal ganglia haematoma	1	1
Basal ganglia stroke	1	1
Basedow's disease	1	1
Base excess decreased		1
Bedridden		2
Bell's palsy	6	15
Bile duct stone	1	1
Biliary colic	1	3
Biliary cyst		1
Biliary sepsis	1	1
Bladder spasm		2
Bladder sphincter atony		2
Blepharospasm	2	4
Blindness	1	1
Blindness transient		1
Blindness unilateral		1
Blister	2	5
Blood bicarbonate decreased		1
Blood bicarbonate increased		1
Blood calcium decreased		1
Blood chloride increased	1	1
Blood creatine phosphokinase increased	2	2
Blood creatinine increased		1
Blood fibrinogen decreased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	14		5
			1		
			1		
		9	19	1	8
					1
		1	1		
		1	7	1	10
				1	1
				1	1
				1	1
			1		
					2
				6	15
				1	1
				1	3
			1		
				1	1
					2
					2
		2	3		1
				1	1
					1
		2	3		2
					1
			1		
			1		
		1	1		
				2	2
			1		
			1		

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* AE=Adverse Event

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Blood fibrinogen increased	3	4
Blood glucose decreased	1	2
Blood glucose increased	5	7
Blood iron decreased	1	1
Blood lactate dehydrogenase increased		2
Blood pressure abnormal		3
Blood pressure decreased	3	4
Blood pressure diastolic decreased	1	2
Blood pressure diastolic increased		1
Blood pressure increased	8	19
Blood pressure systolic increased	2	4
Blood thyroid stimulating hormone increased		1
Blood urea increased	4	5
Body temperature decreased	1	3
Body temperature increased	1	3
Bone disorder	1	1
Bowel movement irregularity	1	1
Brachial plexopathy	1	1
Brachial plexus injury		1
Bradycardia		8
Bradykinesia		2
Bradyphrenia	1	7
Breast haematoma		1
Breast mass		1
Breast oedema		1
Breast pain	3	3
Breath sounds abnormal		1
Bronchial hyperreactivity		2
Bronchiectasis		1
Bronchitis	1	2
Bronchitis bacterial		1
Bronchospasm		13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	4		
		1	1		1
		3	4	2	3
				1	1
			1		1
			2		1
		1	2	2	2
		1	1		1
					1
		4	12	4	7
		1	3	1	1
			1		
		4	4		1
		1	2		1
			2	1	1
		1	1		
		1	1		
		1	1		
					1
					8
			1		1
		1	3		4
					1
			1		
					1
				3	3
					1
					2
					1
		1	1		1
					1
					13

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Bundle branch block left	1	1
Bundle branch block right		1
Burning sensation	2	5
Burning sensation mucosal		1
Butterfly rash		1
Cachexia		1
Capillary fragility	1	1
Cardiac arrest	2	3
Cardiac disorder		2
Cardiac failure	2	12
Cardiac failure acute		3
Cardiac failure congestive	1	4
Cardiac murmur	2	2
Cardiac tamponade	1	2
Cardiomegaly	2	5
Cardio-respiratory arrest	5	11
Cardio-respiratory distress		1
Cardiothoracic ratio increased		1
Cardiovascular disorder	2	2
Carotid arteriosclerosis	1	1
Carotid bruit		2
Carpal tunnel syndrome	1	1
Castleman's disease	1	1
Catarrh		1
Cellulitis	2	9
Cellulitis staphylococcal		1
Central nervous system lesion	1	1
Cephalhaematoma		1
Cerebellar ataxia	1	1
Cerebellar stroke	1	1
Cerebellar syndrome		1
Cerebral arteriosclerosis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
		1	1	1	4
			1		
			1		
					1
		1	1		
				2	3
			1		1
				2	12
					3
				1	4
		2	2		
				1	2
		1	1	1	4
				5	11
					1
					1
		1	1	1	1
		1	1		
					2
				1	1
				1	1
			1		
				2	9
					1
				1	1
					1
		1	1		
				1	1
					1
				1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebral haematoma	1	2
Cerebral haemorrhage	2	6
Cerebral infarction		1
Cerebral ischaemia	1	2
Cerebral small vessel ischaemic disease	1	1
Cerebral venous sinus thrombosis	2	3
Cerebral venous thrombosis		2
Cerebrovascular accident	4	9
Cerebrovascular disorder		1
Cervicobrachial syndrome		1
Cheilitis		4
Chest discomfort	7	26
Chest injury		1
Chest pain	6	38
Chills	66	169
Choking		2
Choking sensation	2	9
Cholecystitis	1	1
Chromaturia		1
Chronic kidney disease	1	2
Chronic lymphocytic leukaemia		1
Chronic respiratory failure		1
Chronic sinusitis	1	1
Circumoral oedema	1	1
Circumoral swelling	1	2
Citrobacter infection		1
Claustrophobia	1	1
Clostridium difficile colitis		1
Coagulopathy	2	2
Cognitive disorder	2	4
Cold sweat	1	4
Colitis	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
				2	6
					1
				1	2
				1	1
				2	3
					2
				4	9
					1
			1		
					4
		5	10	2	16
					1
		5	14	1	24
		62	124	4	45
					2
			1	2	8
				1	1
			1		
				1	2
					1
					1
		1	1		
				1	1
			1	1	1
					1
				2	2
		1	2	1	2
			2	1	2
		1	2		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Colitis ischaemic	2	2
Colitis ulcerative		1
Coma scale abnormal	1	1
Concomitant disease aggravated		4
Condition aggravated	12	27
Confusional state	4	16
Conjunctival haemorrhage	2	10
Conjunctival hyperaemia		2
Conjunctival laceration		1
Constipation	1	8
Contraindication to vaccination	1	1
Contusion		4
Coordination abnormal	1	1
Corneal reflex decreased		1
Coronary artery stenosis	1	1
Costochondritis		1
Cough	16	54
COVID-19	18	77
COVID-19 pneumonia	2	12
Craniocerebral injury	1	6
C-reactive protein increased	4	7
Crying	1	1
CSF protein increased	1	1
Cutaneous vasculitis		1
Cyanosis		4
Cytomegalovirus test positive		1
Deafness	2	3
Deafness unilateral		1
Death		4
Decreased appetite	3	16
Deep vein thrombosis	16	23
Dehydration	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
					1
				1	1
					4
		3	5	9	22
		4	8		8
				2	10
					2
			1		
		1	6		2
		1	1		
			1		3
				1	1
					1
				1	1
					1
		10	25	6	29
		4	21	14	56
				2	12
				1	6
		3	6	1	1
		1	1		
				1	1
					1
			1		3
					1
				2	3
					1
					4
		2	7	1	9
				16	23
		1	2		1

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Delirium		2
Delirium febrile		1
Demyelination		2
Dental caries		1
Depressed level of consciousness	2	15
Depressed mood		4
Dermatitis	1	1
Dermatitis allergic	3	10
Dermatitis atopic		1
Dermatitis bullous		2
Device related thrombosis	1	1
Diabetes mellitus	1	3
Diabetes mellitus inadequate control		2
Diabetic ketoacidosis		1
Diabetic metabolic decompensation		1
Diaphragmalgia		1
Diarrhoea	50	152
Diarrhoea haemorrhagic	1	3
Dilatation atrial		1
Dilatation ventricular	1	2
Diplopia	1	6
Discomfort	7	22
Disease recurrence	4	10
Disorganised speech		1
Disorientation	6	13
Disturbance in attention	2	5
Diverticulitis intestinal haemorrhagic	1	1
Dizziness	76	236
Dizziness postural	4	7
Drowning	1	2
Drug effective for unapproved indication	1	1
Drug eruption		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
					2
			1		
				2	15
			4		
				1	1
		2	3	1	7
					1
					2
				1	1
				1	3
					2
					1
					1
					1
		45	106	5	46
				1	3
					1
				1	2
			1	1	5
		5	14	2	8
			1	4	9
					1
		3	6	3	7
		2	3		2
				1	1
		57	132	19	104
		4	6		1
				1	2
		1	1		
			1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Drug hypersensitivity	2	4
Drug ineffective	5	42
Drug interaction		1
Dry eye	1	3
Dry mouth	2	8
Dry skin	1	2
Dry throat	1	4
Duodenal ulcer haemorrhage		1
Dysaesthesia	3	10
Dysarthria	6	11
Dyschromatopsia		1
Dysgeusia	9	21
Dyskinesia		1
Dyslexia		1
Dysmenorrhoea		1
Dyspepsia	3	6
Dysphagia	7	23
Dysphonia		9
Dyspnoea	37	125
Dyspnoea at rest	1	2
Dyspnoea exertional	2	11
Dysstasia	1	2
Dystonia		1
Dysuria	1	4
Ear discomfort	1	2
Ear infection		1
Ear pain	5	10
Eating disorder		1
Ecchymosis		1
Echolalia	1	1
Eczema	1	2
Eczema herpeticum		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2		2
				5	42
			1		
		1	2		1
		2	3		5
		1	1		1
			2	1	2
					1
		1	2	2	8
		3	5	3	6
					1
		6	12	3	9
					1
					1
			1		
		2	3	1	3
		3	7	4	16
			2		7
		15	28	22	97
				1	2
			2	2	9
		1	2		
					1
		1	2		2
				1	2
					1
		5	5		5
			1		
					1
		1	1		
		1	1		1
					1

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Effusion	1	1
Electrocardiogram normal		1
Electrocardiogram QRS complex shortened		2
Electrocardiogram ST segment elevation		1
Electrocardiogram T wave inversion		1
Electrolyte imbalance		1
Embolic stroke	4	5
Embolism venous	1	1
Encephalitis		4
Encephalopathy		1
Endocarditis	1	1
Enterococcal infection	1	2
Epidermal necrosis		1
Epigastric discomfort	1	2
Epiglottitis		1
Epilepsy	1	3
Episcleritis		1
Epistaxis	3	6
Epstein-Barr virus antibody positive		1
Erythema	21	73
Erythema multiforme		1
Escherichia infection		2
Escherichia urinary tract infection	1	1
Essential hypertension		1
Essential tremor		2
Euphoric mood		3
Exercise tolerance decreased	1	1
Exposure during pregnancy	2	7
Exposure via breast milk	1	1
Extensive swelling of vaccinated limb		3
Extensor plantar response		1
Extrasystoles	3	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
					2
					1
					1
					1
				4	5
				1	1
					4
					1
				1	1
				1	2
					1
				1	2
					1
				1	3
					1
		1	1	2	5
					1
		12	32	9	41
					1
					2
				1	1
					1
			1		1
			1		2
		1	1		
		2	6		1
		1	1		
			3		
			1		
		1	1	2	4

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Eye discharge		1
Eye disorder	1	1
Eye haemorrhage		1
Eye inflammation	1	1
Eye irritation	1	1
Eyelid disorder	1	1
Eyelid oedema	2	8
Eyelid pain	1	1
Eyelids pruritus	1	1
Eye pain	3	10
Eye pruritus		5
Eye swelling	1	2
Face injury		1
Face oedema	10	21
Facial bones fracture		1
Facial neuralgia		1
Facial pain	2	4
Facial paralysis	10	36
Facial paresis		2
Faecal vomiting	1	1
Faeces discoloured		1
Faeces soft		2
Fall	5	17
Fatigue	81	191
Fear	1	1
Febrile convulsion		3
Feeling abnormal	5	11
Feeling cold	6	12
Feeling drunk		1
Feeling hot	9	25
Feeling of body temperature change	1	1
Fibrin D dimer increased	2	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1		
					1
		1	1		
		1	1		
		1	2	1	6
				1	1
				1	1
		3	5		5
			2		3
				1	2
					1
		1	1	9	20
			1		1
		2	3		1
				10	36
			1		1
				1	1
					1
			2		
		1	5	4	12
		69	129	12	62
		1	1		
					3
		5	8		3
		5	6	1	6
			1		
		4	13	5	12
		1	1		
		1	2	1	6

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Fibrinolysis		1
Fibromyalgia	1	2
Flatulence	1	5
Floppy eyelid syndrome		1
Fluid overload		1
Flushing	5	9
Focal dyscognitive seizures	1	1
Folate deficiency		1
Food allergy		1
Foreign body in throat	1	2
Foreign body sensation in eyes		3
Formication	1	5
Fracture		1
Fumbling	1	2
Fungal skin infection		1
Gait disturbance	8	14
Gait inability		5
Galactorrhoea	1	2
Gallbladder enlargement		1
Gamma-glutamyltransferase increased		1
Gastric disorder		1
Gastritis		1
Gastroenteritis	2	5
Gastrointestinal disorder	2	4
Gastrointestinal haemorrhage	1	3
Gastrointestinal pain	1	1
Gastrointestinal somatic symptom disorder		1
Gastrooesophageal reflux disease		1
Generalised oedema	1	3
Generalised tonic-clonic seizure	4	7
General physical health deterioration	3	12
Genital herpes		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	2
		1	4		1
					1
					1
		3	4	2	5
				1	1
			1		
					1
				1	2
			3		
		1	2		3
					1
				1	2
					1
		6	7	2	7
			1		4
				1	2
					1
			1		
					1
					1
		1	3	1	2
		2	4		
				1	3
		1	1		
			1		
			1		
				1	3
				4	7
		2	6	1	6
			1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Genital ulceration		1
Gingival bleeding	2	5
Gingival discolouration	1	1
Gingival erythema	1	1
Gingival swelling	1	1
Gingivitis	2	2
Glomerular filtration rate decreased	1	2
Glossitis		4
Glossodynia		1
Goitre	2	3
Granulomatous liver disease	1	2
Groin pain	1	2
Guillain-Barre syndrome		3
Haemangioma	1	1
Haemangioma of liver	1	1
Haematemesis	1	1
Haematochezia		1
Haematocrit decreased		1
Haematoma	4	11
Haematoma muscle	1	4
Haemodynamic instability	1	1
Haemoglobin decreased		3
Haemoglobin increased		1
Haemoptysis	1	3
Haemorrhage	1	3
Haemorrhage intracranial	1	2
Haemorrhagic diathesis		1
Haemorrhagic stroke	1	1
Hallucination	3	6
Hallucinations, mixed		1
Hallucination, visual	1	2
Headache	221	597

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1	2	4
		1	1		
				1	1
		1	1		
		1	1	1	1
		1	2		
					4
					1
		1	2	1	1
				1	2
		1	1		1
					3
		1	1		
		1	1		
				1	1
					1
			1		
		2	6	2	5
				1	4
				1	1
			2		1
			1		
				1	3
				1	3
				1	2
					1
				1	1
				3	6
					1
				1	2
		193	399	28	198

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Head discomfort		1
Head injury		3
Heart rate decreased		1
Heart rate increased	1	6
Heart rate irregular		1
Heavy menstrual bleeding	4	5
Hemianaesthesia	1	2
Hemidysaesthesia		1
Hemihyperaesthesia		1
Hemiparaesthesia	1	8
Hemiparesis	3	7
Hemiplegia		4
Hepatic cyst	1	3
Hepatic cytolysis	1	2
Hepatic enzyme abnormal		1
Hepatic function abnormal	1	1
Hepatitis		1
Hepatitis acute		4
Hepatitis B virus test positive		1
Hepatomegaly		1
Herpes ophthalmic	1	2
Herpes simplex		1
Herpes virus infection	1	3
Herpes zoster	23	61
Herpes zoster cutaneous disseminated	1	2
Herpes zoster oticus	2	3
Herpes zoster reactivation	1	3
Hiatus hernia		3
Hilar lymphadenopathy	1	1
Hormone level abnormal	1	1
Hot flush		3
Humerus fracture	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					3
					1
		1	4		2
					1
		4	4		1
				1	2
					1
					1
				1	8
				3	7
					4
		1	3		
				1	2
					1
				1	1
					1
					4
			1		
					1
				1	2
					1
		1	2		1
	1	6	14	17	47
				1	2
				2	3
		1	1		2
			1		2
		1	1		
		1	1		
			1		2
				1	1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hyperaemia	1	2
Hyperaesthesia	1	4
Hyperdynamic left ventricle		1
Hyperfibrinogenaemia		1
Hyperglycaemia	4	10
Hyperhidrosis	7	22
Hyperkalaemia		1
Hyperlactacidaemia	1	1
Hypernatraemia		2
Hypersensitivity	9	36
Hypersensitivity vasculitis	1	1
Hypersexuality		1
Hypersomnia	2	2
Hypertension	20	70
Hypertensive crisis	12	37
Hypertensive emergency		1
Hypertensive encephalopathy		1
Hypertensive urgency		3
Hyperthermia	1	2
Hyperthyroidism		1
Hypertonia	1	1
Hypertransaminasaemia		4
Hyperventilation	1	2
Hypoacusis	1	7
Hypoaesthesia	9	39
Hypoaesthesia eye		1
Hypoaesthesia oral	4	13
Hypocalcaemia	1	3
Hypochromasia	1	1
Hypochromic anaemia	1	1
Hypoglycaemia	5	10
Hypokalaemia	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
		1	3		1
					1
					1
		1	1	3	9
		5	9	2	13
					1
				1	1
			1		1
		4	8	5	28
				1	1
					1
		2	2		
		6	20	14	50
				12	37
					1
					1
					3
		1	1		1
					1
				1	1
			1		3
				1	2
		1	1		6
		6	14	3	25
					1
		4	7		6
		1	2		1
		1	1		
				1	1
		3	3	2	7
				1	2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypokinesia		1
Hypomagnesaemia	1	1
Hyponatraemia		2
Hypophosphataemia		1
Hyporeflexia	1	2
Hyposmia	2	2
Hypotension	8	35
Hypothermia	2	9
Hypothyroidism	1	2
Hypoventilation	1	1
Hypovolaemic shock		1
Hypoxia	2	8
Idiopathic angioedema		1
Ileus paralytic	1	3
Ill-defined disorder		1
Illness	2	2
Immobilisation syndrome		1
Immune system disorder		1
Immune thrombocytopenia	3	9
Immunisation reaction		1
Immunodeficiency	1	1
Inappropriate schedule of product administration	5	11
Incoherent	1	3
Incorrect dose administered	1	3
Incorrect route of product administration	6	10
Increased upper airway secretion	1	1
Induration		2
Infection		1
Inflammation	5	16
Inflammatory bowel disease		2
Influenza	3	8
Influenza like illness	4	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
					2
			1		
		1	1		1
				2	2
		3	9	5	26
				2	9
				1	2
				1	1
					1
				2	8
					1
				1	3
					1
		2	2		
			1		
					1
				3	9
			1		
				1	1
		5	11		
		1	1		2
		1	3		
		6	10		
		1	1		
			1		1
			1		
		4	10	1	6
					2
		2	4	1	4
		4	6		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site erythema		1
Injection site inflammation		1
Injection site paraesthesia	1	1
Injury		2
Insomnia	2	10
Insulin resistance		1
Intermenstrual bleeding	3	12
International normalised ratio increased	3	3
Interstitial lung disease		2
Intervertebral disc disorder	1	1
Intestinal angina	1	1
Intestinal ischaemia		1
Intestinal obstruction		2
Intracranial pressure increased	1	1
Intraventricular haemorrhage		1
Iridocyclitis	1	2
Iron deficiency		1
Iron deficiency anaemia	2	2
Ischaemia	1	2
Ischaemic stroke	7	21
Jaw disorder		1
Joint contracture		1
Joint injury	1	3
Joint range of motion decreased		2
Joint swelling		1
Joint warmth		1
Jugular vein thrombosis	1	1
Kaposi's sarcoma AIDS related		1
Keratitis		2
Lacrimation increased		5
Lacunar infarction	1	1
Lacunar stroke		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
		1	1		
			1		1
		2	6		4
					1
		2	3	1	9
				3	3
					2
		1	1		
				1	1
					1
					2
		1	1		
					1
				1	2
			1		
		1	1	1	1
		1	1		1
				7	21
			1		
			1		
				1	3
					2
					1
					1
				1	1
					1
			1		4
				1	1
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Laryngeal disorder		1
Laryngeal oedema	2	14
Laryngeal pain		1
Laryngitis		1
Laryngospasm		1
Larynx irritation		1
Lateral medullary syndrome	1	1
Left ventricular failure	1	1
Lethargy		1
Leukocytosis	3	5
Leukoencephalopathy	1	1
Leukopenia		1
Lichen planus		1
Limb discomfort	1	4
Limb immobilisation		1
Lipase decreased		1
Lip blister		1
Lip erythema		1
Lip oedema	4	15
Lipoma		1
Lip pruritus		5
Lip swelling	2	9
Lividity		1
Localised infection		1
Localised oedema		2
Local reaction	3	8
Loss of consciousness	5	26
Loss of personal independence in daily activities	1	2
Lower respiratory tract infection		1
Lung infiltration	2	3
Lymphadenitis	6	21
Lymphadenopathy	74	201

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				2	14
					1
					1
					1
					1
				1	1
				1	1
			1	3	4
				1	1
					1
					1
		1	3		1
					1
			1		
			1		1
			2	4	13
			1		
			3		2
			1	2	8
					1
					1
					2
		3	4		4
				5	26
		1	2		
					1
		1	1	1	2
		5	11	1	10
		57	103	17	98

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Lymphadenopathy mediastinal	1	1
Lymphangitis		2
Lymph node pain	1	2
Lymphocyte count decreased	2	3
Lymphocyte count increased		1
Lymphocytosis		1
Lymphopenia	1	2
Macroglossia		1
Macular oedema		1
Malaise	109	277
Malnutrition		1
Mass		2
Mastitis	1	1
Maternal exposure during pregnancy	4	8
Maternal exposure timing unspecified		1
May-Thurner syndrome	1	1
Mean cell haemoglobin concentration decreased	1	2
Mean cell volume decreased	1	1
Mean platelet volume increased	1	1
Mechanical urticaria		1
Medication error		1
Melaena		3
Memory impairment	2	3
Meniere's disease		1
Meningism		1
Meningitis aseptic	1	1
Meningitis herpes		1
Meningoencephalitis herpetic	1	1
Menometrorrhagia	1	2
Menstrual disorder	8	8
Menstruation delayed		2
Menstruation irregular	6	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					2
				1	2
		2	3		
			1		
			1		
		1	2		
					1
					1
		94	196	15	81
			1		
					2
				1	1
		4	8		
			1		
				1	1
		1	2		
		1	1		
		1	1		
					1
			1		
					3
		2	2		1
					1
					1
				1	1
				1	2
		8	8		
					2
		6	6		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mental impairment	1	5
Mesenteric vein thrombosis	1	1
Metabolic acidosis	1	1
Metamorphopsia	1	1
Microangiopathy	1	1
Microcytosis	1	1
Micturition urgency		2
Middle insomnia	1	1
Migraine	3	12
Migraine with aura		2
Misophonia		1
Mobility decreased	1	13
Monoparesis	2	3
Monoplegia	1	3
Mood altered		1
Morganella infection		1
Motor dysfunction	1	1
Mouth haemorrhage	2	2
Mouth injury	1	1
Mouth swelling	1	2
Mouth ulceration	1	2
Movement disorder	1	3
Mucosal disorder	1	1
Mucosal dryness		1
Multiple organ dysfunction syndrome	1	5
Muscle contractions involuntary	1	5
Muscle contracture		3
Muscle fatigue		1
Muscle rigidity	2	4
Muscle spasms	3	8
Muscle tightness		4
Muscular weakness	6	17

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	5
				1	1
				1	1
		1	1		
		1	1		
		1	1		
					2
		1	1		
		1	3	2	9
			1		1
					1
		1	4		9
		1	1	1	2
				1	3
					1
					1
				1	1
				2	2
		1	1		
				1	2
				1	2
		1	2		1
		1	1		
					1
				1	5
			2	1	3
			2		1
			1		
		1	1	1	3
		2	5	1	3
			1		3
		5	10	1	7

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Musculoskeletal chest pain		2
Musculoskeletal discomfort	2	5
Musculoskeletal disorder		1
Musculoskeletal pain	8	41
Musculoskeletal stiffness	2	7
Mutism	1	1
Myalgia	115	339
Myelitis	1	2
Myocardial infarction		1
Myocardial ischaemia		2
Myocardial rupture		1
Myocarditis		1
Myoclonic dystonia		1
Myositis		4
Nasal congestion	3	16
Nasal herpes		1
Nasal obstruction	2	2
Nasal pruritus		1
Nasopharyngitis	4	5
Nausea	93	252
Neck mass		1
Neck pain	5	19
Necrosis		1
Neoplasm		2
Neoplasm progression	1	1
Nervousness	6	12
Nervous system disorder		1
Neuralgia	2	5
Neuralgic amyotrophy		2
Neuropathy peripheral		4
Neurosensory hypoacusis		1
Neutropenia	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		2	2		3
					1
		5	16	3	25
		2	3		4
				1	1
		107	243	8	96
				1	2
					1
					2
					1
					1
					4
		2	12	1	4
					1
		1	1	1	1
					1
		4	5		
		86	184	7	68
			1		
		4	9	1	10
					1
			1		1
		1	1		
		6	8		4
					1
		2	3		2
					2
					4
					1
				1	2

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Neutrophil count decreased	1	1
Neutrophil count increased	2	5
Neutrophilia	1	2
Neutrophilic dermatosis		1
Neutrophil percentage increased	1	1
Night sweats		3
No adverse event		1
Nocturia	1	1
Nodule		1
Noninfective conjunctivitis	1	1
Noninfective gingivitis		1
Normochromic normocytic anaemia		1
Nuchal rigidity		4
Ocular discomfort	1	1
Ocular hyperaemia	1	3
Odynophagia	12	29
Oedema	4	7
Oedema mouth		2
Oedema peripheral	7	22
Off label use	8	20
Ophthalmic herpes zoster	4	5
Optic neuritis	2	2
Oral candidiasis	1	4
Oral discomfort	1	2
Oral dysaesthesia	2	2
Oral herpes	3	14
Oral mucosal blistering	1	1
Oral pain		1
Oral pruritus		3
Oropharyngeal discomfort	1	6
Oropharyngeal oedema		3
Oropharyngeal pain	11	22

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		2	5		
				1	2
					1
		1	1		
			1		2
			1		
		1	1		
			1		
		1	1		
					1
			1		
					4
		1	1		
				1	3
		7	11	5	18
		3	5	1	2
			1		1
		2	5	5	17
		8	20		
				4	5
				2	2
		1	3		1
			1	1	1
		1	1	1	1
		2	7	1	7
				1	1
			1		
			1		2
		1	1		5
					3
		8	12	3	10

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Orthopnoea	1	2
Orthostatic hypotension	1	2
Osteoarthritis		1
Ovarian cyst		1
Overdose	2	7
Oxygen saturation decreased	4	15
Pain	22	50
Pain in extremity	43	98
Pain of skin	2	2
Palatal oedema	2	11
Palatal swelling		2
Pallor	3	10
Palpitations	9	31
Pancreatitis chronic		1
Pancytopenia		2
Panic attack	1	1
Panic reaction		1
Panniculitis	1	1
Papilloedema	1	1
Papule		2
Paraesthesia	38	128
Paraesthesia mucosal		1
Paraesthesia oral	7	24
Paraparesis	1	2
Paresis		1
Parosmia		1
Parotid gland enlargement		1
Parotitis	1	3
Paroxysmal atrioventricular block	1	1
Partial seizures		2
Partial seizures with secondary generalisation	1	1
Patella fracture		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		1
		1	1		1
			1		
					1
		2	7		
			2	4	13
		19	34	3	16
		38	71	5	27
		2	2		
				2	11
			1		1
		2	4	1	6
		5	10	4	21
					1
					2
		1	1		
				1	1
		1	1		
			1		1
		22	45	16	83
					1
		6	8	1	16
		1	1		1
			1		
					1
			1		
				1	3
				1	1
					2
				1	1
					1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pelvic pain		1
Pelvic venous thrombosis	1	1
Periarthritis	1	3
Pericardial effusion	1	1
Pericardial haemorrhage		1
Pericarditis	2	7
Periorbital haematoma	1	2
Periorbital inflammation	1	1
Periorbital oedema	1	2
Periorbital pain		1
Periorbital swelling		1
Peripheral coldness	1	6
Peripheral embolism		1
Peripheral ischaemia	1	3
Peripheral paralysis		1
Peripheral swelling	6	13
Peripheral venous disease	1	1
Persistent depressive disorder	2	3
Persistent generalised lymphadenopathy		1
Pertussis		2
Petechiae	2	8
Petit mal epilepsy	1	6
Pharyngeal erythema		3
Pharyngeal hypoaesthesia		1
Pharyngeal inflammation	1	3
Pharyngeal lesion	1	1
Pharyngeal oedema	1	5
Pharyngeal swelling		4
Pharyngitis		1
Phlebitis		2
Phlebitis superficial	1	1
Phonophobia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
				1	3
				1	1
					1
				2	7
		1	1		1
				1	1
			1	1	1
					1
			1		
		1	4		2
					1
		1	1		2
					1
		2	6	4	7
				1	1
		1	1	1	2
					1
					2
		1	2	1	6
				1	6
					3
					1
				1	3
		1	1		
			1	1	4
					4
					1
			1		1
				1	1
					1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Photophobia	2	9
Photopsia		1
Pigmentation disorder		1
Pityriasis rosea		4
Platelet count decreased	3	4
Platelet count increased	1	2
Pleural effusion	1	6
Pleuritic pain		1
Pleuropericarditis	1	2
Pneumonia	2	9
Pneumonia aspiration	2	2
Pneumonitis		1
Pneumothorax		1
PO2 decreased		2
Polydipsia	1	1
Polymenorrhoea		1
Polyuria	1	2
Poor peripheral circulation	1	3
Poor quality product administered		3
Poor quality sleep		1
Portal vein thrombosis		1
Positron emission tomogram		1
Post herpetic neuralgia	3	3
Postmenopausal haemorrhage	3	3
Post-traumatic stress disorder	1	1
Post viral fatigue syndrome		1
Prerenal failure		1
Presyncope	7	29
Primary hyperthyroidism	1	1
Proctalgia		1
Proctitis		1
Product administered at inappropriate site	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3	1	6
			1		
			1		
					4
		2	2	1	2
		1	2		
			1	1	5
			1		
				1	2
				2	9
				2	2
					1
					1
			2		
				1	1
			1		
				1	2
		1	3		
			3		
					1
					1
					1
				3	3
				3	3
				1	1
					1
					1
		6	12	1	17
				1	1
			1		
					1
		1	1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Product administration interrupted	1	1
Product dose omission issue	1	1
Productive cough		3
Product preparation error		3
Product use issue	4	11
Prothrombin level decreased		1
Prothrombin level increased	1	1
Prothrombin time prolonged		2
Prothrombin time shortened	1	1
Pruritus	31	109
Pruritus allergic	1	1
Psoriasis		1
Psoriatic arthropathy		1
Psychomotor hyperactivity	1	6
Pulmonary embolism	28	53
Pulmonary haemorrhage		1
Pulmonary hypertension	2	4
Pulmonary infarction		2
Pulmonary thrombosis		4
Pulse abnormal		2
Purpura	1	2
Pustule		1
Pyelonephritis		1
Pyrexia	276	734
Rales		1
Rash	18	76
Rash erythematous	1	10
Rash macular	4	4
Rash maculo-papular	1	5
Rash papular	2	7
Rash pruritic	1	10
Rash vesicular	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1		
			1		2
			3		
		4	11		
					1
				1	1
			1		1
		1	1		
		20	44	11	65
		1	1		
					1
					1
			2	1	4
				28	53
					1
				2	4
					2
					4
					2
				1	2
					1
					1
		254	524	22	210
					1
		6	24	12	52
		1	1		9
		3	3	1	1
			1	1	4
		2	2		5
			1	1	9
		1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Raynaud's phenomenon		4
Reaction to excipient		1
Reaction to preservatives	1	1
Rectal discharge		1
Rectal haemorrhage	1	6
Rectal tenesmus		1
Red blood cell count abnormal	1	1
Red blood cell sedimentation rate increased		2
Renal cyst	1	3
Renal failure		1
Renal impairment	1	3
Respiration abnormal		1
Respiratory acidosis		2
Respiratory arrest		1
Respiratory disorder		3
Respiratory distress	4	24
Respiratory failure	3	7
Respiratory rate decreased		1
Respiratory tract infection	1	4
Resting tremor	1	1
Restless legs syndrome	2	3
Restlessness	3	7
Retinal artery occlusion		1
Retinal detachment	1	1
Retinal vein occlusion		1
Retinal vein thrombosis	1	1
Rheumatoid arthritis	1	1
Rhinitis	1	6
Rhinorrhoea	7	19
Rhonchi	1	1
Rib fracture	2	3
Right ventricular dysfunction	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					4
					1
		1	1		
					1
				1	6
					1
				1	1
			2		
		1	3		
					1
				1	3
					1
					2
					1
					3
				4	24
				3	7
					1
				1	4
				1	1
		2	2		1
		3	4		3
					1
		1	1		
					1
				1	1
				1	1
		1	5		1
		5	14	2	5
		1	1		
				2	3
				1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Right ventricular failure	1	1
Rotator cuff syndrome	3	3
Salivary hypersecretion		1
SARS-CoV-2 ant body test negative		1
SARS-CoV-2 ant body test positive	1	4
SARS-CoV-2 test positive		4
Scab		1
Scleritis		1
Scoliosis		1
Seizure	2	9
Sensation of foreign body	2	6
Sense of oppression		2
Sensory disturbance		1
Sensory loss	3	10
Sepsis	1	2
Septic shock		1
Serum ferritin abnormal	1	1
Severe acute respiratory syndrome		1
Shock	1	1
Sialoadenitis		1
Silent thyroiditis		1
Sinus bradycardia	1	2
Sinusitis		1
Sinus tachycardia	1	9
Skeletal injury		1
Skin discomfort	1	1
Skin disorder	1	1
Skin exfoliation		2
Skin lesion	3	7
Skin necrosis		2
Skin odour abnormal		1
Skin reaction	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		2	2	1	1
					1
			1		
		1	4		
			3		1
			1		
					1
					1
				2	9
		1	1	1	5
					2
					1
			3	3	7
				1	2
					1
				1	1
					1
					1
		1	2		
			1		
			1	1	8
					1
		1	1		
		1	1		
					2
		3	4		3
					2
					1
		2	3		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin sensitisation	1	1
Skin swelling	1	1
Skin tightness	1	1
Skin ulcer		4
Sleep attacks	1	1
Slow response to stimuli	1	1
Slow speech		1
Sneezing		3
Somnolence	3	23
Spasmodic dysphonia		1
Speech disorder	3	6
Spinal cord injury		1
Spinal osteoarthritis		1
Spinal pain		2
Spontaneous haematoma		1
Staphylococcal infection		1
Status epilepticus	2	3
Stomatitis	1	5
Stridor	1	2
Subarachnoid haemorrhage	3	4
Subclavian vein thrombosis	1	1
Subcutaneous abscess		1
Subcutaneous haematoma		1
Subdural haematoma	1	1
Sudden cardiac death		1
Sudden death	4	14
Sudden visual loss		1
Suffocation feeling		2
Superinfection	1	1
Superinfection bacterial		1
Superior sagittal sinus thrombosis	1	1
Supraventricular extrasystoles		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1		
		1	1		
			3		1
		1	1		
		1	1		
					1
			3		
		2	14	1	9
			1		
		1	2	2	4
					1
					1
					2
					1
					1
				2	3
		1	4		1
				1	2
				3	4
				1	1
					1
				1	1
					1
				4	14
					1
					2
		1	1		
					1
				1	1
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Supraventricular tachycardia		2
Swelling	4	7
Swelling face	3	8
Swollen tongue	3	11
Syncope	11	75
Systemic lupus erythematosus	1	2
Systemic lupus erythematosus rash		1
Tachyarrhythmia		1
Tachycardia	17	84
Tachycardia paroxysmal		1
Tachypnoea	1	7
Temperature regulation disorder	9	34
Tenderness		1
Tendon disorder		1
Tendonitis	1	2
Tenosynovitis	1	1
Tension headache		5
Thirst	1	2
Throat irritation	9	27
Throat tightness	1	5
Thrombocytopenia	6	11
Thrombophlebitis	5	9
Thrombophlebitis superficial	6	10
Thrombosed varicose vein	1	1
Thrombosis	3	5
Thrombotic microangiopathy		1
Thrombotic thrombocytopenic purpura		1
Thunderclap headache		1
Thyroiditis	1	1
Thyroiditis acute	1	1
Thyroid mass	1	1
Thyroxine decreased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		3	5	1	2
		2	4	1	4
				3	11
				11	75
				1	2
			1		
					1
		9	25	8	59
					1
		1	2		5
		7	20	2	14
					1
					1
			1	1	1
		1	1		
			2		3
		1	2		
		7	13	2	14
		1	1		4
				6	11
			1	5	8
			1	6	9
		1	1		
				3	5
					1
					1
					1
				1	1
				1	1
				1	1
			1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tic	1	3
Tinnitus	2	14
Tongue coated		1
Tongue discomfort		1
Tongue disorder	1	1
Tongue eruption	1	3
Tongue erythema		1
Tongue injury	2	2
Tongue oedema	5	16
Tongue pruritus	1	7
Tongue ulceration	1	3
Tonic clonic movements		1
Tonsillitis	1	3
Tooth avulsion		1
Toxic skin eruption		2
Tracheitis	1	1
Transferrin abnormal	1	1
Transient global amnesia	3	4
Transient ischaemic attack	1	6
Transverse sinus thrombosis	1	1
Tremor	11	18
Tricuspid valve incompetence		1
Trigeminal neuralgia		1
Trigeminal neuritis	1	1
Trismus	1	1
Troponin T increased		2
Tunnel vision		1
Ulcer	1	1
Upper limb fracture		2
Upper respiratory tract infection		1
Urinary incontinence	1	2
Urinary retention		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		2
		1	6	1	8
					1
			1		
				1	1
			2	1	1
					1
		1	1	1	1
			1	5	15
		1	3		4
		1	3		
					1
				1	3
					1
					2
				1	1
				1	1
				3	4
				1	6
				1	1
		9	10	2	8
					1
					1
		1	1		
		1	1		
					2
					1
		1	1		
			1		1
					1
		1	2		
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Urinary sediment abnormal		1
Urinary tract infection	3	15
Urinary tract infection bacterial		1
Urine output decreased		1
Urosepsis		1
Urticaria	20	75
Uterine haemorrhage		2
Uterine leiomyoma	1	1
Uvulitis	1	2
Vaccination complication	1	3
Vaccination failure	12	30
Vaccination site abscess		1
Vaccination site cellulitis		2
Vaccination site discomfort	4	7
Vaccination site erosion		1
Vaccination site erythema	7	22
Vaccination site haematoma	3	8
Vaccination site haemorrhage		1
Vaccination site hyperaesthesia		2
Vaccination site hypersensitivity		1
Vaccination site hypoaesthesia		4
Vaccination site induration	6	12
Vaccination site inflammation	8	43
Vaccination site joint discomfort		1
Vaccination site joint erythema	4	17
Vaccination site joint inflammation		2
Vaccination site joint movement impairment	1	2
Vaccination site joint pain	3	3
Vaccination site joint swelling	1	2
Vaccination site lymphadenopathy	10	34
Vaccination site macule	2	2
Vaccination site movement impairment	1	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		2	5	1	10
			1		1
					1
		7	30	13	45
					2
		1	1		
				1	2
			1	1	2
				12	30
					1
					2
		4	6		1
			1		
		5	13	2	9
		2	3	1	5
			1		
			1		1
			1		
			1		3
		5	10	1	2
		6	32	2	11
			1		
		4	11		6
					2
		1	1		1
		3	3		
		1	2		
		7	20	3	14
		2	2		
		1	5		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site oedema	5	10
Vaccination site pain	86	257
Vaccination site paraesthesia	3	7
Vaccination site phlebitis	1	1
Vaccination site pruritus	2	15
Vaccination site rash		4
Vaccination site reaction	3	6
Vaccination site swelling	2	12
Vaccination site urticaria	1	1
Vaccination site warmth	6	15
Vaginal discharge		1
Vaginal haemorrhage	1	5
Varicella zoster virus infection	1	1
Vasculitis		3
Vasoplegia syndrome		1
Venous pressure	1	1
Venous thrombosis limb	2	7
Ventricular dysfunction	1	1
Ventricular enlargement		1
Ventricular fibrillation	1	1
Vertigo	8	23
Vertigo positional		1
Vestibular migraine		1
Viral infection	1	1
Viral rash		1
Vision blurred	7	22
Visual acuity reduced		1
Visual field defect	2	2
Visual impairment	2	3
Vitamin B12 decreased	1	1
Vitamin D decreased	1	1
Vitamin D deficiency	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	6	1	4
		79	200	7	57
		2	3	1	4
				1	1
		1	8	1	7
			2		2
		3	5		1
		2	8		4
		1	1		
		5	9	1	6
			1		
			2	1	3
				1	1
					3
					1
		1	1		
				2	7
		1	1		
					1
				1	1
		5	9	3	14
					1
					1
		1	1		
					1
		4	8	3	14
					1
		1	1	1	1
				2	3
		1	1		
		1	1		
		1	2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vitreous detachment		1						1
Vitreous floaters		1						1
Vogt-Koyanagi-Harada disease	1	1					1	1
Vomiting	57	164			46	101	11	63
Vulval ulceration		1						1
Vulvovaginal candidiasis	1	2			1	1		1
Wa king disability	1	1					1	1
Wheezing		9				2		7
White blood cell count decreased		1						1
White blood cell count increased	3	4			3	4		
White matter lesion		1						1
Wound	1	2			1	1		1
Wrong technique in product usage process		1				1		
X-ray abnormal		1						1
Yawning		1				1		
Yellow fever	1	1					1	1
	3,154	9,404		1	2095	4557	1059	4847

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	6	1	4	1	2
Abdominal distension	1	1	1	1		
Abdominal pain	1	6	1	2		4
Abdominal pain lower	1	2	1	2		
Abdominal pain upper		1		1		
Activated partial thromboplastin time shortened		1		1		
Acute coronary syndrome		1				1
Acute generalised exanthematous pustulosis		1				1
Acute kidney injury	4	5			4	5
Acute myocardial infarction	9	12			9	12
Acute psychosis		1				1
Acute pulmonary oedema		1				1
Acute respiratory distress syndrome		1				1
Acute respiratory failure	2	6			2	6
Ageusia	1	2	1	1		1
Agitation	1	4		1	1	3
Alanine aminotransferase increased	1	1	1	1		
Alcohol poisoning		1				1
Allergic reaction to excipient		1				1
Allergy to vaccine		1				1
Amnesia		1		1		
Amyloidosis senile	1	1			1	1
Anaemia	1	1	1	1		
Anamnestic reaction	1	1			1	1
Anaphylactic reaction	1	7			1	7
Anaphylactic shock		2				2
Angina pectoris	1	1			1	1
Angioedema	1	7			1	7
Anosmia	1	2	1	1		1
Antibody test abnormal		1		1		
Antipsychotic drug level increased		1				1
Anuria	1	2			1	2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety		1		1		
Aortic arteriosclerosis	1	1			1	1
Aortic stenosis	1	1			1	1
Aortic valve incompetence	1	1			1	1
Apallic syndrome	1	1			1	1
Apathy		1				1
Aphthous ulcer		1				1
Apnoea		1				1
Arrhythmia		1				1
Arterial thrombosis	1	1			1	1
Arteriosclerosis	1	1			1	1
Arteriosclerosis coronary artery	1	1			1	1
Arthralgia	10	31	10	24		7
Arthritis	2	3			2	3
Arthritis reactive		1				1
Asphyxia		1				1
Aspiration	5	6			5	6
AST/ALT ratio abnormal	2	2	2	2		
Asthenia	10	35	7	15	3	20
Asthma		1				1
Asthmatic crisis		1				1
Asymptomatic bacteriuria	1	1			1	1
Asymptomatic COVID-19	2	8		2	2	6
Atelectasis	1	2	1	1		1
Atrial fibrillation	7	7			7	7
Autoimmune haemolytic anaemia		1				1
Axillary pain		1				1
Axillary vein thrombosis	1	1			1	1
Back pain	3	8	2	4	1	4
Bacteraemia	1	2			1	2
Bacterial disease carrier		1				1
Bacteriuria	1	1	1	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Balance disorder	2	3			2	3
Basal ganglia stroke		1				1
Basilar artery thrombosis		1				1
Bell's palsy	3	5			3	5
Blepharitis		2		2		
Blood chloride decreased		1		1		
Blood cholesterol decreased	1	1	1	1		
Blood creatinine decreased	2	2	2	2		
Blood creatinine increased	1	1	1	1		
Blood fibrinogen increased	5	6	4	5	1	1
Blood gases abnormal		1				1
Blood glucose increased	3	3	3	3		
Blood lactate dehydrogenase increased	1	1	1	1		
Blood lactic acid increased	2	2	2	2		
Blood parathyroid hormone increased	1	1	1	1		
Blood phosphorus increased	1	1			1	1
Blood potassium decreased	1	1	1	1		
Blood pressure abnormal		1				1
Blood pressure decreased	1	2			1	2
Blood pressure diastolic decreased	1	1	1	1		
Blood pressure fluctuation	1	1			1	1
Blood pressure increased	4	7	3	4	1	3
Blood pressure systolic increased	1	1	1	1		
Blood sodium decreased		1		1		
Blood sodium increased	1	1	1	1		
Blood urea increased	3	3	3	3		
Body temperature decreased	2	2	2	2		
Bradycardia	1	2			1	2
Bradyphrenia		1		1		
Brain oedema		1				1
Bronchitis chronic	1	1	1	1		
Bronchospasm	1	6			1	6

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bruxism		1		1		
Bulbar palsy	1	1			1	1
Bundle branch block left		1				1
Bundle branch block right	1	1			1	1
Bursitis		2				2
Cardiac amyloidosis	1	1			1	1
Cardiac arrest	1	4			1	4
Cardiac death	1	1			1	1
Cardiac failure	6	12			6	12
Cardiac failure acute	2	6			2	6
Cardiac failure congestive	2	2			2	2
Cardiogenic shock	1	1			1	1
Cardiomegaly	1	1	1	1		
Cardio-respiratory arrest	7	14			7	14
Catarrh		1				1
Cell death		1				1
Cellulitis	1	3			1	3
Cerebellar infarction		1				1
Cerebral artery embolism	1	1			1	1
Cerebral disorder		1				1
Cerebral haematoma		2				2
Cerebral haemorrhage		2				2
Cerebral infarction	1	2			1	2
Cerebral thrombosis	1	1			1	1
Cerebral venous thrombosis		1				1
Cerebrovascular accident	2	6			2	6
Cervicobrachial syndrome		1				1
Chest discomfort		4				4
Chest pain	9	17	3	3	6	14
Chest X-ray abnormal	1	1	1	1		
Chills	11	30	10	19	1	11
Cholangitis	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholelithiasis	1	1			1	1
Cholestasis		1				1
Chronic kidney disease		1				1
Chronic obstructive pulmonary disease	2	3	1	1	1	2
Chronic respiratory failure		1				1
Circadian rhythm sleep disorder		1				1
Circulatory collapse		1				1
Clostridium test positive	1	1			1	1
Cognitive disorder	1	3			1	3
Cold sweat		1				1
Colon neoplasm		1				1
Coma	1	1			1	1
Complications of transplanted kidney	1	1			1	1
Condition aggravated	4	10		1	4	9
Confusional state	3	7		1	3	6
Conjunctival haemorrhage	1	1			1	1
Constipation		1				1
Contusion	1	2		1	1	1
Coombs positive haemolytic anaemia		1				1
Coordination abnormal		2		1		1
Cough	4	12	3	6	1	6
COVID-19	9	45	1	9	8	36
COVID-19 pneumonia	3	6			3	6
Craniocerebral injury	2	3			2	3
C-reactive protein increased	2	3		1	2	2
Cyanosis		1		1		
Deafness unilateral		1				1
Death	4	7			4	7
Decreased appetite	2	4	1	1	1	3
Decreased nasolabial fold		1				1
Decubitus ulcer	1	1	1	1		
Deep vein thrombosis	16	25			16	25

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dehydration	1	2
Delayed ischaemic neurological deficit	1	1
Delirium		1
Delusion		1
Depressed level of consciousness	2	11
Depressed mood		1
Dermatitis	1	1
Dermatitis allergic		1
Dermatitis bullous		1
Dermatitis contact		1
Diabetes mellitus	1	1
Diabetes mellitus inadequate control	1	1
Diabetic metabolic decompensation		1
Diarrhoea	15	47
Diplopia	1	4
Discomfort		4
Disease recurrence	3	5
Disorientation	1	7
Disturbance in attention	1	5
Dizziness	8	23
Drowning		1
Drug ineffective	6	20
Drug interaction	1	2
Drug intolerance	1	1
Dry mouth		2
Dysaesthesia	1	2
Dysarthria	1	3
Dysgeusia	2	2
Dyshidrotic eczema	1	1
Dysphagia	1	2
Dysphonia	1	1
Dyspnoea	17	47

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1	1	1
		1	1
			1
			1
		2	11
	1		
		1	1
			1
			1
		1	1
		1	1
			1
8	22	7	25
	1	1	3
	2		2
		3	5
	2	1	5
1	1		4
5	11	3	12
			1
		6	20
		1	2
1	1		
			2
		1	2
1	2		1
2	2		
1	1		
1	1		1
		1	1
5	7	12	40

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea exertional	2	4	1	2	1	2
Dyspnoea paroxysmal nocturnal	1	1			1	1
Dyssomnia	1	1	1	1		
Dysuria		3		2		1
Ear pain	1	3		1	1	2
Ecchymosis	1	1	1	1		
Eczema		1		1		
Electrocardiogram abnormal	1	1			1	1
Electrocardiogram QRS complex prolonged		1				1
Electrocardiogram repolarisation abnormality		1				1
Electrocardiogram ST-T change		1				1
Embolic stroke		1				1
Emotional disorder	1	1			1	1
Emphysema	1	1	1	1		
Encephalitis	1	2			1	2
Encephalopathy		1				1
Eosinophil count increased	1	1	1	1		
Epididymitis	1	1			1	1
Epilepsy	2	7			2	7
Epistaxis	2	4		2	2	2
Epstein-Barr virus infection reactivation		1				1
Erythema	2	6	1	4	1	2
Erythema nodosum		1				1
Escherichia bacteraemia	1	1			1	1
Exposure via breast milk		2				2
Extrapyramidal disorder		1				1
Eye allergy	1	1	1	1		
Eyelid ptosis	1	1	1	1		
Eye pain	1	2			1	2
Face oedema		4				4
Facial bones fracture		1				1
Facial paralysis	7	18			7	18

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial paresis	1	3	1	1		2
Fall	3	9	1	4	2	5
Fatigue	13	39	10	24	3	15
Febrile convulsion		2				2
Feeling abnormal	1	3	1	2		1
Feeling cold		2		1		1
Feeling hot		3		1		2
Femur fracture		1				1
Fibrin D dimer increased	4	5	1	1	3	4
Fibrinolysis abnormal	1	1			1	1
Flushing	1	2	1	2		
Formication		1		1		
Gait disturbance	3	9	2	2	1	7
Gait inability		3		1		2
Gastric disorder		1		1		
Gastritis		1		1		
Gastroenteritis		3		2		1
Gastrointestinal haemorrhage		1				1
Gastrooesophageal reflux disease		1				1
Gaze palsy		1				1
Generalised oedema	1	1	1	1		
Generalised tonic-clonic seizure	1	5			1	5
General physical health deterioration	4	5	1	1	3	4
Genital blister		1		1		
Giant cell arteritis		1				1
Giant papillary conjunctivitis		1				1
Gingival swelling		1				1
Gingivitis		1		1		
Glomerular filtration rate decreased	2	2	1	1	1	1
Glycosylated haemoglobin increased	1	1	1	1		
Guillain-Barre syndrome	3	6			3	6
Haematemesis	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematocrit decreased	4	4	4	4		
Haematoma	2	4	1	2	1	2
Haematoma muscle	1	1			1	1
Haematuria	2	5	1	2	1	3
Haemodynamic instability	1	1			1	1
Haemoglobin decreased	2	3	1	2	1	1
Haemophagocytic lymphohistiocytosis		1				1
Haemorrhage		1				1
Haemorrhage intracranial	1	1			1	1
Haemorrhagic stroke		2				2
Haemorrhagic transformation stroke	1	1			1	1
Hallucination		1				1
Hallucination, auditory		1				1
Hallucination, visual		1				1
Headache	36	96	31	64	5	32
Head injury		1		1		
Heart rate abnormal	1	1			1	1
Heart rate increased	1	2	1	1		1
Hemiparaesthesia	1	1			1	1
Hemiplegia	1	1			1	1
Hepatic failure		1				1
Hepatic lesion	1	1			1	1
Hepatic steatosis		1				1
Hepatitis acute		1				1
Hepatitis cholestatic		1				1
Herpes ophthalmic		2				2
Herpes simplex	1	3		1	1	2
Herpes zoster	17	36	8	10	9	26
Herpes zoster cutaneous disseminated	1	2			1	2
Herpes zoster reactivation	1	2	1	1		1
Hiatus hernia	1	1	1	1		
Hot flush	1	1	1	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hydrocephalus	1	1			1	1
Hyperaesthesia		1				1
Hypercapnic coma	1	1			1	1
Hypercholesterolaemia		1		1		
Hyperglycaemia	2	5			2	5
Hyperhidrosis	1	3		1	1	2
Hyperkalaemia	1	1			1	1
Hypernatraemia		1				1
Hyperpyrexia		1				1
Hypersensitivity	1	3	1	1		2
Hypersensitivity vasculitis		1				1
Hypersomnia		1				1
Hypertension	5	9	1	1	4	8
Hypertensive crisis	2	4			2	4
Hypertrophic cardiomyopathy	1	1			1	1
Hyperuricaemia	1	1	1	1		
Hypoacusis		1				1
Hypoaesthesia	4	7	2	3	2	4
Hypocalcaemia	1	1	1	1		
Hypokalaemia	1	1			1	1
Hypokinesia		1				1
Hyponatraemia	1	2			1	2
Hypophagia	1	1	1	1		
Hypoproteinaemia	1	1	1	1		
Hyporesponsive to stimuli		1				1
Hypotension	7	13	2	4	5	9
Hypothermia	1	2			1	2
Hypotonia		1		1		
Hypoventilation	1	1			1	1
Hypoxia	2	9			2	9
Immune thrombocytopenia	2	2			2	2
Inappropriate schedule of product administration	2	5	2	5		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Incorrect dose administered	2	3	2	3		
Incorrect route of product administration	2	5	2	5		
Increased bronchial secretion		1				1
Induration	1	1	1	1		
Infant irritability		1				1
Infection		1				1
Infectious mononucleosis		1				1
Infective exacerbation of bronchiectasis		1				1
Inflammation	1	2		1	1	1
Influenza	1	3	1	2		1
Influenza like illness		1		1		
Inguinal hernia	1	1			1	1
Injection site pain		1		1		
Injury	1	1			1	1
Insomnia	2	3	1	2	1	1
International normalised ratio increased	3	3	2	2	1	1
Interstitial lung disease	1	1			1	1
Intestinal ischaemia	1	2			1	2
Intestinal obstruction	1	2			1	2
Intra-abdominal haematoma	1	1			1	1
Intraventricular haemorrhage	1	1			1	1
Iron deficiency	1	1	1	1		
Ischaemia	1	1			1	1
Ischaemic cerebral infarction		1				1
Ischaemic stroke	4	9			4	9
Jaundice	1	1	1	1		
Jaw fracture		1				1
Joint contracture		1		1		
Joint dislocation	1	1	1	1		
Joint range of motion decreased	1	1	1	1		
Jugular vein thrombosis	1	1			1	1
Labyrinthitis		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Large intestine infection		1				1
Laryngeal discomfort	1	1			1	1
Laryngeal erythema		1				1
Laryngeal oedema		2				2
Laryngospasm		1		1		
Leukoencephalopathy		1				1
Ligament sprain		1		1		
Limb discomfort	1	2	1	1		1
Lip oedema	1	2	1	1		1
Lip swelling		1				1
Liver function test abnormal		1				1
Loss of consciousness	3	8			3	8
Loss of personal independence in daily activities		1				1
Lung consolidation	1	1			1	1
Lung disorder		2				2
Lung infiltration		2		2		
Lymphadenopathy	5	15	5	6		9
Lymphadenopathy mediastinal	1	1			1	1
Lymphangitis		1				1
Lymphocyte count decreased	3	3	3	3		
Lymphocyte count increased	1	1	1	1		
Lymphocyte percentage decreased		1		1		
Lymphopenia	1	2	1	2		
Malaise	24	64	20	43	4	21
Malnutrition	1	1	1	1		
Mastication disorder	1	1	1	1		
Mean cell haemoglobin concentration decreased	1	1	1	1		
Melaena	1	1			1	1
Mental disorder		1				1
Mental impairment	1	3			1	3
Mesenteric artery thrombosis	1	1			1	1
Mesenteric panniculitis	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mesenteric vein thrombosis	2	2			2	2
Migraine with aura		1				1
Migraine without aura		1				1
Miosis		1				1
Mitral valve calcification	1	1			1	1
Mitral valve incompetence	1	1			1	1
Mitral valve stenosis	1	1			1	1
Mononeuritis	1	1			1	1
Mononeuropathy		1				1
Monoparesis		1				1
Monoplegia		1				1
Mouth swelling		1				1
Movement disorder	1	2	1	1		1
Multiple organ dysfunction syndrome	1	2			1	2
Multiple sclerosis		1				1
Muscle contractions involuntary		1		1		
Muscle contracture		2		2		
Muscle injury	1	1	1	1		
Muscle spasms		2		1		1
Muscle strain	1	1			1	1
Muscle tightness	1	1	1	1		
Muscular weakness	3	7	3	5		2
Musculoskeletal chest pain	1	1			1	1
Musculoskeletal discomfort		1				1
Musculoskeletal disorder	1	1			1	1
Musculoskeletal pain	3	8	2	3	1	5
Musculoskeletal stiffness	1	1	1	1		
Myalgia	28	67	24	47	4	20
Myocardial infarction		1				1
Myocardial ischaemia	1	1			1	1
Myocarditis		3				3
Myoclonic dystonia		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myoclonus		1				1
Nasal congestion	2	4	1	1	1	3
Nasal disorder		1		1		
Nasopharyngitis		2		2		
Nausea	9	22	7	11	2	11
Neck pain	3	5	2	3	1	2
Necrosis	1	1			1	1
Nephrotic syndrome	1	1			1	1
Nervousness		1		1		
Nervous system disorder	1	2	1	1		1
Neuralgia		2		1		1
Neuralgic amyotrophy		1				1
Neurogenic shock		1				1
Neuropathy peripheral	2	3			2	3
Neutrophil count decreased	1	1			1	1
Neutrophil count increased	4	5	4	5		
Neutrophilia		1		1		
Neutrophil percentage increased		1		1		
Night sweats		2		1		1
N-terminal prohormone brain natriuretic peptide increased	1	2	1	1		1
Obstructive shock	1	1			1	1
Ocular dysmetria		1		1		
Ocular icterus	1	1	1	1		
Oculofacial paralysis		1				1
Odynophagia	1	3		1	1	2
Oedema		2		1		1
Oedema mouth		1				1
Oedema peripheral	5	6	4	4	1	2
Off label use	2	4	2	4		
Ophthalmic herpes zoster	1	2			1	2
Ophthalmic vein thrombosis	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Optic neuritis		1				1
Oral candidiasis		1		1		
Oral discomfort		1		1		
Oral disorder		1				1
Oral dysaesthesia		1				1
Oral mucosal blistering		1		1		
Oral pruritus		1				1
Orchitis	1	1			1	1
Oropharyngeal discomfort	1	2		1	1	1
Oropharyngeal pain		1		1		
Orthopnoea	2	2	1	1	1	1
Oxygen saturation decreased	5	11	2	2	3	9
Pain	7	13	5	10	2	3
Pain in extremity	10	17	7	10	3	7
Pain in jaw		1		1		
Palatal oedema	1	5			1	5
Palatal swelling		1				1
Pallor	1	1			1	1
Palpitations	1	3			1	3
Pancytopenia	2	2			2	2
Panniculitis		1				1
Paraesthesia	5	23	3	7	2	16
Paraesthesia oral	1	4		1	1	3
Paraparesis		1				1
Parotid gland enlargement		1		1		
Parotitis		1		1		
PCO2 decreased		1		1		
PCO2 increased	2	2	2	2		
Penile discomfort		1		1		
Pericarditis	2	6			2	6
Periorbital abscess		1				1
Peripheral artery thrombosis	1	2			1	2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral coldness		1				1
Peripheral ischaemia	2	2			2	2
Peripheral sensory neuropathy		1				1
Peripheral swelling	2	3	1	1	1	2
Peripheral vascular disorder	1	1			1	1
Peripheral venous disease	1	2	1	1		1
Pernio-like erythema		2		1		1
Petechiae	1	2		1	1	1
Petit mal epilepsy		1				1
Pharyngeal inflammation		1		1		
Pharyngotonsillitis		2				2
Phlebitis superficial		2		1		1
Photopsia		1		1		
Pityriasis rosea	1	1			1	1
Platelet count decreased	4	4	4	4		
Pleural effusion	3	3	1	1	2	2
Pleuritic pain	1	3			1	3
Pleuropericarditis	1	1			1	1
Pneumonia	2	9			2	9
Pneumonia aspiration		4				4
Pneumonia bacterial	1	1			1	1
PO2 decreased	1	2	1	2		
Pollakiuria		1				1
Polyarthritis	1	2			1	2
Poor quality product administered		2		2		
Portal vein thrombosis	1	1			1	1
Portosplenomesenteric venous thrombosis	1	1			1	1
Post thrombotic syndrome		1				1
Presyncope	3	6	1	1	2	5
Procalcitonin increased	1	1			1	1
Productive cough	1	2	1	2		
Product preparation error		2		2		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product use issue		1		1		
Prothrombin time prolonged		1		1		
Prothrombin time shortened	2	2	2	2		
Pruritus	5	11	4	4	1	7
Pseudomonal bacteraemia	1	1			1	1
Psychotic disorder		1		1		
Pulmonary embolism	18	33			18	33
Pulmonary infarction	2	3			2	3
Pulmonary oedema	2	2			2	2
Pulmonary sepsis		1				1
Pulseless electrical activity	1	1			1	1
Pupils unequal	1	1	1	1		
Purpura	1	1			1	1
Pyrexia	64	184	50	115	14	69
Rash	2	7	2	3		4
Rash erythematous	2	2	1	1	1	1
Rash macular	1	2	1	1		1
Rash maculo-papular		1		1		
Rash pruritic		2		1		1
Rash vesicular		1		1		
Raynaud's phenomenon		1				1
Rectal haemorrhage	1	2			1	2
Red cell distribution width increased	1	1	1	1		
Renal failure	1	5			1	5
Renal impairment	3	4			3	4
Renal pain	1	1	1	1		
Respiratory acidosis	1	1			1	1
Respiratory alkalosis	2	2			2	2
Respiratory arrest		1				1
Respiratory disorder		1		1		
Respiratory distress	2	5			2	5
Respiratory failure	3	10			3	10

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory fatigue	1	1			1	1
Respiratory tract infection	1	4			1	4
Restlessness		1		1		
Restrictive cardiomyopathy	1	1			1	1
Retinal artery occlusion	1	2			1	2
Retinal artery thrombosis	1	1	1	1		
Retinal vein thrombosis	1	2			1	2
Rhinalgia		1		1		
Rhinitis		2		2		
Rhinitis allergic	1	1	1	1		
Rhonchi	2	2	1	1	1	1
Right ventricular dilatation	1	1			1	1
Right ventricular hypertrophy	1	1			1	1
Rotator cuff syndrome		2				2
SARS-CoV-2 ant body test negative		1		1		
SARS-CoV-2 ant body test positive		1				1
SARS-CoV-2 test positive	1	4		3	1	1
Seizure	3	8			3	8
Sensation of foreign body		1				1
Sensory disturbance	1	2	1	1		1
Sensory loss		2		1		1
Sepsis	1	2			1	2
Septic arthritis staphylococcal		1				1
Septic shock		1				1
Serology negative		1		1		
Serratia infection	1	1			1	1
Serum ferritin increased	1	1	1	1		
Shock		1				1
Shoulder injury related to vaccine administration		1		1		
Sinus arrest		1				1
Sinus bradycardia	1	1			1	1
Skin lesion		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin reaction		1				1
Skin ulcer	1	1			1	1
SLE arthritis		1				1
Slow speech		2		1		1
Sneezing	1	1			1	1
Somnolence	6	9	5	6	1	3
Speech disorder	1	2	1	1		1
Splenic vein thrombosis	1	1			1	1
Status epilepticus	1	1			1	1
Stevens-Johnson syndrome	1	1			1	1
Stupor		1				1
Subarachnoid haemorrhage	1	1			1	1
Subclavian vein thrombosis	1	1			1	1
Sudden death	6	13			6	13
Suicide attempt		1				1
Supraventricular tachycardia	1	1			1	1
Suspected COVID-19	1	2			1	2
Swelling	2	2	2	2		
Swelling face	1	2	1	1		1
Syncope	7	16			7	16
Systemic inflammatory response syndrome	1	2			1	2
Systolic dysfunction	2	2			2	2
Tachycardia	2	9	1	1	1	8
Tachypnoea	4	5	2	3	2	2
Temperature intolerance		1		1		
Temperature regulation disorder	3	7	3	5		2
Tenderness	1	1	1	1		
Tendonitis		1				1
Tenosynovitis		1				1
Tension headache		2		2		
Testicular pain		1		1		
Thalamic infarction		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thalamus haemorrhage	1	1			1	1
Therapeutic response unexpected	1	1	1	1		
Throat irritation		2		1		1
Throat tightness		1		1		
Thrombocytopenia	8	11			8	11
Thrombophlebitis	3	3			3	3
Thrombophlebitis septic	1	1			1	1
Thrombophlebitis superficial	1	4			1	4
Thrombosis mesenteric vessel	1	1			1	1
Tic		1				1
Tinnitus	1	4			1	4
Tongue disorder	1	2	1	2		
Tongue oedema		2		1		1
Toxicity to various agents		1				1
Toxic skin eruption	2	2			2	2
Tracheobronchitis bacterial	1	1			1	1
Transaminases increased	1	2			1	2
Transient ischaemic attack	2	5			2	5
Tremor		6		1		5
Trigeminal neuralgia		1				1
Troponin I increased	1	2			1	2
Troponin T increased	1	1	1	1		
Tuberculosis		1				1
Type IV hypersensitivity reaction		1				1
Underdose	4	5	4	5		
Upper gastrointestinal haemorrhage		1				1
Urinary retention		1				1
Urinary sediment present		1		1		
Urinary tract infection	2	4			2	4
Urinary tract infection pseudomonal		1				1
Urticaria	4	12	2	4	2	8
Uvulitis		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination complication		2				2
Vaccination failure	5	11			5	11
Vaccination site cellulitis	1	1			1	1
Vaccination site discomfort		1				1
Vaccination site erythema		2		2		
Vaccination site haematoma		2				2
Vaccination site hypoaesthesia		1		1		
Vaccination site induration		2		1		1
Vaccination site inflammation	3	7	3	6		1
Vaccination site joint erythema		1		1		
Vaccination site joint inflammation		1		1		
Vaccination site lymphadenopathy	1	6	1	2		4
Vaccination site movement impairment		1		1		
Vaccination site pain	14	45	14	35		10
Vaccination site paraesthesia		3		1		2
Vaccination site rash		1		1		
Vaccination site reaction	1	3	1	2		1
Vaccination site swelling		1				1
Varicella zoster virus infection	1	1	1	1		
Vascular graft thrombosis	1	1			1	1
Vasodilatation	1	1			1	1
Vasoplegia syndrome	1	1			1	1
Venous haemorrhage	1	1			1	1
Venous thrombosis limb	2	2			2	2
Ventricular dysfunction		1				1
Ventricular extrasystoles		1				1
Ventricular fibrillation		1				1
Ventricular hypokinesia	1	1			1	1
Ventricular tachycardia	1	1			1	1
Vertigo	1	5			1	5
Vestibular neuronitis	1	2			1	2
Viral keratoconjunctivitis		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vision blurred	2	4	1	1	1	3
Visual field defect	1	1	1	1		
Visual impairment		2				2
Vitamin D deficiency	1	1	1	1		
Vitreous detachment		1				1
Volvulus		1				1
Vomiting	8	29	3	11	5	18
Weight bearing difficulty	1	1			1	1
Wheezing		1		1		
White blood cell count decreased	1	1			1	1
White blood cell count increased	6	7	6	7		
White matter lesion	1	2		1	1	1
Wound	1	1			1	1
Yersinia bacteraemia	1	1			1	1
Yersinia infection	1	1			1	1
	1,002	2,453	456	916	546	1537

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Accidental overdose	1	1	1	1		
Cardiac failure acute	1	1			1	1
Chills		1		1		
Chorioretinopathy		1				1
COVID-19	1	5		2	1	3
Deep vein thrombosis	1	1			1	1
Diarrhoea		4		2		2
Dizziness	2	3	2	3		
Drug ineffective	1	3			1	3
Exposure via breast milk	3	8	3	8		
Fatigue	5	8	5	7		1
Feeling hot		1		1		
Foetal heart rate abnormal		1				1
Headache	5	9	5	8		1
Hypertension		1				1
Hypertensive crisis	1	1			1	1
Hypoaesthesia eye	1	1	1	1		
Inappropriate schedule of product administration	1	3	1	3		
Incorrect dose administered		1		1		
Injection site joint erythema	1	1	1	1		
Injection site pain	1	1	1	1		
Limb immobilisation	3	3	3	3		
Lymphadenopathy		2		1		1
Malaise	1	3	1	2		1
Maternal exposure during pregnancy		1				1
Myalgia		5		5		
Nausea	1	1	1	1		
Odynophagia		1		1		
Off label use	1	1	1	1		
Overdose		4		4		
Pain		1				1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in extremity	2	2	2	2		
Paraesthesia		1		1		
Petechiae		1		1		
Poor quality product administered	1	1	1	1		
Product preparation issue	1	5	1	5		
Pulmonary embolism	1	1			1	1
Pulmonary thrombosis	1	1			1	1
Puncture site pain	1	1	1	1		
Pyrexia	1	7	1	5		2
Rash	2	2	2	2		
Sinus tachycardia		1				1
Somnolence	1	1	1	1		
Swelling	3	3	3	3		
Syncope		2				2
Tenderness	1	1	1	1		
Thrombocytopenia	1	1			1	1
Vaccination site erythema	3	3	3	3		
Vaccination site induration	3	3	3	3		
Vaccination site joint erythema		1		1		
Vaccination site joint swelling		1		1		
Vaccination site lymphadenopathy		1		1		
Vaccination site pain	2	4	2	4		
Vaccination site swelling	2	2	2	2		
Vomiting		3		3		
Wrong technique in product usage process	1	2	1	2		
	59	130	51	102	8	28

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Country Where Event Occurred

SWEDEN

090177e19749cf15\Approved\Approved On: 14-Jun-2021 14:01 (GMT)

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	4	7	3	3	1	4
Abdominal distension	2	3			2	3
Abdominal infection		1				1
Abdominal pain	10	29	7	15	3	14
Abdominal pain lower		2				2
Abdominal pain upper	8	15	5	7	3	8
Abdominal symptom		1				1
Abdominal tenderness	1	1	1	1		
Abdominal wall haemorrhage		1				1
Abnormal dreams	1	1			1	1
Abnormal sensation in eye		1				1
Abnormal uterine bleeding	1	1	1	1		
Abortion spontaneous	1	2			1	2
Abscess limb	1	1			1	1
Acne	1	2	1	2		
Acute kidney injury		4				4
Acute left ventricular failure		1				1
Acute myocardial infarction	1	6			1	6
Acute respiratory failure	1	1			1	1
Adnexa uteri pain	1	1	1	1		
Adrenocortical insufficiency acute		1				1
Ageusia	1	7		3	1	4
Aggression		1				1
Agitation		1		1		
Akathisia	1	1			1	1
Allergy to vaccine		2		1		1
Allodynia		1		1		
Altered state of consciousness	1	2			1	2
Amenorrhoea		1		1		
Amnesia		3				3
Anaemia	1	2			1	2
Anaphylactic reaction	4	27			4	27

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic shock	2	4			2	4
Angina pectoris	2	3			2	3
Angioedema		4				4
Angiopathy	1	1	1	1		
Anosmia	1	8		3	1	5
Anxiety	4	12	3	9	1	3
Aortic aneurysm rupture		1				1
Aortic arteriosclerosis		2		1		1
Apathy	1	2			1	2
Aphasia		3				3
Apnoea		1				1
Appendicitis	1	1			1	1
Areflexia		1				1
Arrhythmia	3	8			3	8
Arterial thrombosis		1				1
Arteriosclerosis		2				2
Arthralgia	43	86	29	49	14	37
Arthritis	3	5	3	3		2
Aspiration		1				1
Asthenia	16	47	12	21	4	26
Asthenopia		3				3
Asthma	1	2			1	2
Asymptomatic COVID-19		1				1
Atelectasis		1				1
Atrial fibrillation	4	8			4	8
Atrial flutter	1	3			1	3
Atrial septal defect		1				1
Atrial thrombosis		1				1
Atrioventricular block complete		1				1
Atypical pneumonia	1	2			1	2
Autonomic nervous system imbalance		1				1
Axillary pain	6	16	6	13		3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Back pain	8	27	7	16	1	11
Balance disorder	3	10	1	2	2	8
Basedow's disease	1	2			1	2
Basilar artery thrombosis		1				1
Bedridden	1	2	1	1		1
Bell's palsy		2				2
Biliary colic	1	2			1	2
Biliary dilatation		1				1
Biliary tract disorder		1				1
Bladder dysfunction	1	1			1	1
Blepharospasm	1	1			1	1
Blindness	3	6			3	6
Blindness transient		1				1
Blister	1	3	1	2		1
Blood albumin increased	1	1			1	1
Blood alkaline phosphatase increased		1				1
Blood bilirubin increased		1				1
Blood creatinine increased		3		1		2
Blood glucose abnormal		1		1		
Blood glucose decreased		2		1		1
Blood glucose increased	1	4	1	2		2
Blood phosphorus decreased		1		1		
Blood potassium increased		2		1		1
Blood pressure abnormal		1				1
Blood pressure decreased	2	11		2	2	9
Blood pressure fluctuation	1	2			1	2
Blood pressure increased	2	9		2	2	7
Blood pressure measurement	1	1			1	1
Blood pressure systolic increased		2		1		1
Body temperature decreased		2				2
Body temperature increased	2	5	2	4		1
Bone disorder		1		1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Brain injury	1	2			1	2
Brain scan abnormal		1				1
Breast cyst	1	1			1	1
Breast pain	1	2	1	1		1
Breath sounds abnormal		1				1
Bronchospasm		1				1
Bundle branch block left		1		1		
Burning sensation	4	5	3	3	1	2
Cachexia		1				1
Cardiac arrest	1	10			1	10
Cardiac discomfort		1				1
Cardiac disorder	1	5			1	5
Cardiac failure	1	12			1	12
Cardiac failure acute		1				1
Cardiac failure chronic		1				1
Cardiac flutter	1	2			1	2
Cardiac murmur		1				1
Cardiogenic shock		1				1
Cardiopulmonary failure		1				1
Cardiovascular disorder		1				1
Central pain syndrome		1				1
Cerebral artery embolism	1	2			1	2
Cerebral atrophy		1				1
Cerebral haemorrhage	4	7			4	7
Cerebral infarction	3	8			3	8
Cerebral ischaemia	1	1			1	1
Cerebral microangiopathy		1				1
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident	14	26			14	26
Cerebrovascular disorder	1	2			1	2
Chest discomfort	8	22	3	9	5	13
Chest pain	8	35	1	11	7	24

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills	60	146	45	86	15	60
Cholecystitis		1				1
Chronic gastritis		1				1
Chronic obstructive pulmonary disease	1	5			1	5
Chronic respiratory failure		1				1
Circulatory collapse		2				2
Clostridium difficile colitis		1				1
Coeliac artery stenosis		1				1
Cognitive disorder	2	3			2	3
Cold sweat	2	11		3	2	8
Colitis	1	1			1	1
Colitis ulcerative	1	1			1	1
Coma	1	1			1	1
Concomitant disease aggravated		1				1
Concussion		1		1		
Condition aggravated	4	22		3	4	19
Confusional state	1	14	1	3		11
Constipation	1	1	1	1		
Contusion	4	6	1	1	3	5
Coordination abnormal		2				2
Coronary artery stenosis		1				1
Cor pulmonale acute		1				1
Cough	10	37	4	16	6	21
COVID-19	8	29	3	8	5	21
COVID-19 pneumonia		1				1
Cranial nerve disorder		1				1
C-reactive protein abnormal		1		1		
C-reactive protein decreased	1	1	1	1		
C-reactive protein increased	2	13		4	2	9
Crepitations		2		1		1
Crying		1		1		
Cyanosis		4		2		2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Daydreaming	1	1	1	1		
Deafness unilateral		2				2
Death	2	31			2	31
Decreased appetite	3	17	1	7	2	10
Deep vein thrombosis	5	25			5	25
Dehydration		4		2		2
Dementia		1				1
Dementia Alzheimer's type		1				1
Depressed level of consciousness	1	8			1	8
Depressed mood		3		1		2
Depression	1	2	1	2		
Depressive symptom	1	1			1	1
Derealisation		1				1
Dermatitis bullous	1	1			1	1
Dermatitis psoriasiform	1	1			1	1
Diarrhoea	18	54	10	29	8	25
Dilatation ventricular		1		1		
Discomfort	2	10	1	4	1	6
Disease recurrence	3	14		2	3	12
Disorientation		1		1		
Dissociation		1				1
Disturbance in attention	3	9	1	3	2	6
Diverticulitis		1				1
Diverticulum		1		1		
Dizziness	52	144	24	52	28	92
Drug eruption		3		2		1
Drug ineffective	1	9			1	9
Dry mouth	4	6	3	3	1	3
Dry skin		1		1		
Dysaesthesia		1		1		
Dysarthria	2	9		1	2	8
Dysgeusia		7		2		5

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspepsia		1		1		
Dysphagia	1	10		1	1	9
Dysphonia	1	10		5	1	5
Dyspnoea	27	108	6	20	21	88
Dyspnoea exertional	1	5	1	1		4
Dysstasia	1	3			1	3
Ear discomfort	2	4	1	1	1	3
Ear pain	1	4			1	4
Ear swelling		1				1
Eczema		1		1		
Electric shock sensation		1		1		
Electrocardiogram abnormal	2	2	1	1	1	1
Electrocardiogram ST segment elevation		1				1
Electrocardiogram ST-T segment depression	1	1			1	1
Electrocardiogram T wave inversion		1				1
Electrolyte imbalance		1		1		
Embolism	2	5			2	5
Embolism arterial		1				1
Encephalitis		2				2
Encephalopathy		1				1
Epilepsy	1	5			1	5
Epistaxis	5	8	1	3	4	5
Erysipelas		4				4
Erythema	7	42	2	20	5	22
Escherichia urinary tract infection		1				1
Exercise tolerance decreased	1	1			1	1
Extrasystoles	1	3	1	1		2
Eye disorder		2				2
Eye inflammation	2	3	1	1	1	2
Eye irritation	2	4	1	1	1	3
Eyelids pruritus	1	1	1	1		
Eye pain	2	9	2	2		7

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye pruritus		2				2
Eye swelling		2				2
Facial discomfort		1		1		
Facial neuralgia		1				1
Facial pain		2				2
Facial paralysis	3	12			3	12
Facial paresis	1	12			1	12
Fall	5	13	2	4	3	9
Fatigue	92	261	62	148	30	113
Fear	1	1			1	1
Feeding disorder		2		1		1
Feeling abnormal	3	16	2	7	1	9
Feeling cold	6	24	5	17	1	7
Feeling drunk	1	1	1	1		
Feeling hot	5	30	1	13	4	17
Feeling of body temperature change		3				3
Feeling of despair		1				1
Femoral neck fracture		1				1
Fibrin D dimer increased	1	1			1	1
Fibromyalgia		1				1
Flank pain		1		1		
Flatulence		1		1		
Fluid retention		1				1
Flushing	2	5	1	1	1	4
Food refusal		1				1
Formication	2	6	1	2	1	4
Furuncle		1				1
Gait disturbance	4	7		1	4	6
Gait inability		2		1		1
Gallbladder disorder		1				1
Gallbladder oedema		1				1
Gamma-glutamyltransferase increased		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastric disorder		2		1		1
Gastritis		1		1		
Gastroenteritis		1				1
Gastroesophageal reflux disease	1	1	1	1		
Generalised oedema		2				2
Generalised tonic-clonic seizure		1				1
General physical health deterioration	4	40	1	7	3	33
Genital pain	1	1			1	1
Gingival bleeding	1	1			1	1
Gingival erythema	1	1			1	1
Gingival swelling	1	1			1	1
Glomerular filtration rate decreased		2		1		1
Glossodynia		1		1		
Glucose tolerance impaired	1	1			1	1
Goitre		1				1
Grip strength decreased	1	1			1	1
Guillain-Barre syndrome		1				1
Haematochezia		1				1
Haematoma		5				5
Haemoglobin decreased		2				2
Haemolytic anaemia		1				1
Haemorrhage		2				2
Haemorrhage intracranial		1				1
Haemorrhage subcutaneous	1	2			1	2
Haemorrhagic diathesis		1				1
Hallucination	1	3			1	3
Hallucination, auditory		1				1
Hallucination, visual		3				3
Headache	139	326	104	204	35	122
Head discomfort	5	13	2	4	3	9
Head injury	1	2		1	1	1
Heart rate decreased	1	4	1	3		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate increased	12	32	1	5	11	27
Heart rate irregular		2		1		1
Heat stroke		1				1
Hemiparaesthesia		1				1
Hemiparesis	1	9			1	9
Hemiplegia	1	2			1	2
Hepatic enzyme increased	2	3			2	3
Hepatic pain	1	1			1	1
Hepatitis acute		1				1
Herpes simplex		1				1
Herpes zoster	4	15	1	3	3	12
Hot flush	1	4	1	2		2
Hydrocholecystis	1	1			1	1
Hyperacusis		1				1
Hyperaesthesia		1		1		
Hypercalcaemia		1				1
Hyperhidrosis	1	11		3	1	8
Hypernatraemia		1				1
Hyperparathyroidism primary		1		1		
Hypersensitivity	6	41		5	6	36
Hypersomnia		2		1		1
Hypersomnia-bulimia syndrome		1				1
Hypertension	5	19		3	5	16
Hypertonic bladder	1	1			1	1
Hyperventilation	2	5	1	1	1	4
Hypoacusis		6				6
Hypoaesthesia	9	69	2	20	7	49
Hypoaesthesia oral	4	17		5	4	12
Hypoalbuminaemia		1		1		
Hypoglycaemia		3				3
Hypokalaemia		2				2
Hypokinesia	1	2			1	2

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Gender

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypophagia		1				1
Hypopnoea		1				1
Hypotension		17		4		13
Hypothermia		2				2
Hypoxia		2				2
Illness	1	5	1	1		4
Immune thrombocytopenia		1				1
Immunisation reaction		1				1
Inappropriate schedule of product administration	2	3	2	3		
Incorrect route of product administration		5		5		
Increased tendency to bruise	1	1			1	1
Increased upper airway secretion		2		2		
Infection	1	9		2	1	7
Inflammation	1	4			1	4
Inflammatory marker increased	2	2			2	2
Influenza like illness	6	16	5	10	1	6
Infrequent bowel movements		1		1		
Initial insomnia		1				1
Injected limb mobility decreased	2	3	2	3		
Injection site pain	1	1	1	1		
Insomnia	2	8	2	4		4
Intention tremor		1				1
Intermenstrual bleeding	1	2	1	1		1
Internal haemorrhage	1	1			1	1
Interstitial lung disease	1	1			1	1
Intestinal haemorrhage		2				2
Intestinal ischaemia		2				2
Intracardiac thrombus	1	1			1	1
Intraventricular haemorrhage	1	1			1	1
Irregular breathing		1		1		
Ischaemic stroke	2	10			2	10
Jaundice		1				1

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FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Jaw disorder		1				1
Joint instability	1	1			1	1
Joint lock		1				1
Joint range of motion decreased		2		1		1
Joint stiffness	1	5		3	1	2
Joint swelling	1	3	1	2		1
Laryngeal oedema		1				1
Laziness	1	1	1	1		
Left ventricular hypertrophy		1				1
Lethargy		2				2
Leukocytosis		1				1
Leukopenia	1	3			1	3
Limb discomfort	4	5	2	2	2	3
Limb injury	1	2			1	2
Lipids increased	1	1			1	1
Lip pain	1	1			1	1
Lip pruritus		2				2
Lip swelling		8		2		6
Lip ulceration		1		1		
Livedo reticularis		1		1		
Liver disorder		2				2
Local reaction		1		1		
Loss of consciousness		13				13
Loss of personal independence in daily activities		2		1		1
Lower limb fracture	1	1			1	1
Lung infiltration	1	2			1	2
Lymphadenitis		1				1
Lymphadenopathy	8	30	7	19	1	11
Lymphadenopathy mediastinal		1		1		
Lymph node pain	8	16	8	14		2
Lymphoedema		1				1
Malaise	24	70	16	42	8	28

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Gender

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mania	1	1	1	1		
Mass		1				1
Maternal exposure during pregnancy	3	3	2	2	1	1
Memory impairment	3	10	1	3	2	7
Meningism		1				1
Meningitis		1				1
Meningitis herpes		1				1
Menstrual disorder	2	2	1	1	1	1
Menstruation irregular	1	1			1	1
Mental fatigue	1	8	1	2		6
Mesenteric artery embolism		1				1
Metabolic acidosis		1				1
Metabolic disorder		2		1		1
Microscopic polyangiitis	1	1			1	1
Migraine	6	17	4	8	2	9
Miosis		1		1		
Mobility decreased	1	3		1	1	2
Mononeuritis	1	1			1	1
Monoparesis		1				1
Monoplegia		1				1
Mouth swelling	2	3			2	3
Mouth ulceration		1		1		
Movement disorder	1	1			1	1
Multiple sclerosis		3				3
Muscle contractions involuntary		1				1
Muscle fatigue	1	2	1	1		1
Muscle spasms	2	15		4	2	11
Muscle tightness		1				1
Muscle tone disorder		1				1
Muscle twitching	1	5	1	1		4
Muscular weakness	8	33	2	6	6	27
Musculoskeletal chest pain		2				2

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Gender

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal discomfort	1	2			1	2
Musculoskeletal stiffness	9	26	8	16	1	10
Myalgia	56	135	39	78	17	57
Myelitis		1				1
Myelosuppression		1				1
Myocardial fibrosis		1				1
Myocardial infarction	6	15			6	15
Myocardial ischaemia		3				3
Myocardial rupture		1				1
Myocarditis		2				2
Myopia		1				1
Nail discolouration		1				1
Nasal congestion	1	11		4	1	7
Nasal dryness	1	1	1	1		
Nasal oedema	1	2		1	1	1
Nasopharyngitis	7	17	6	9	1	8
Nausea	60	149	37	78	23	71
Neck pain	9	21	6	12	3	9
Necrotising fasciitis	1	1			1	1
Neoplasm progression	1	1			1	1
Nervousness	1	3	1	2		1
Nervous system disorder	1	1	1	1		
Neuralgia		3		2		1
Neuralgic amyotrophy		1				1
Neuritis		1				1
Neurological symptom		1				1
Neuropathy peripheral	1	4			1	4
Nightmare		3				3
Night sweats	1	2		1	1	1
Nodule	1	2	1	2		
Noninfective gingivitis	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
N-terminal prohormone brain natriuretic peptide increased		1		1		
Obstructive airways disorder	1	3	1	1		2
Ocular discomfort		1				1
Ocular hyperaemia	2	2			2	2
Oedema peripheral		2		1		1
Oesophageal ulcer haemorrhage		1				1
Off label use	2	4	2	4		
Ophthalmic herpes zoster	1	2			1	2
Ophthalmic migraine	1	1			1	1
Optic ischaemic neuropathy	1	1			1	1
Oral discomfort		3				3
Oral herpes		3		2		1
Oral mucosal blistering	3	4	3	3		1
Oral pain		1		1		
Oral pruritus		7		4		3
Oral viral infection		1				1
Oropharyngeal discomfort		1		1		
Oropharyngeal pain	8	26	5	17	3	9
Oropharyngeal spasm		1				1
Oropharyngeal swelling	1	1			1	1
Orthostatic hypotension	1	1			1	1
Osteoarthritis	3	3	1	1	2	2
Overdose		2		2		
Oxygen saturation abnormal		1		1		
Oxygen saturation decreased		17		2		15
Pain	45	114	34	63	11	51
Painful respiration	2	3	1	2	1	1
Pain in extremity	70	176	48	113	22	63
Pain in jaw	2	4	1	1	1	3
Pain of skin	3	6	3	4		2
Palatal swelling		1				1

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FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pallor		7		4		3
Palpitations	10	39	1	8	9	31
Pancytopenia		2				2
Panic attack		2				2
Panic reaction		2				2
Paraesthesia	10	49	3	14	7	35
Paraesthesia ear		1				1
Paraesthesia oral	4	16	1	6	3	10
Paranasal sinus haemorrhage		1		1		
Paraparesis	1	1			1	1
Paresis		1				1
Parkinson's disease		1				1
Parosmia	4	6	2	2	2	4
PCO2 increased		1		1		
Periarthritis		1				1
Pericardial effusion		3				3
Pericardial haemorrhage		1				1
Pericarditis		1				1
Periorbital oedema		3				3
Periorbital pain		2		1		1
Periorbital swelling		2		1		1
Peripheral artery thrombosis	1	1			1	1
Peripheral coldness		4		1		3
Peripheral embolism	2	3			2	3
Peripheral motor neuropathy		1				1
Peripheral sensory neuropathy		1				1
Peripheral swelling	12	27	3	7	9	20
Petechiae	1	4		1	1	3
Petit mal epilepsy		1				1
Pharyngeal disorder		1				1
Pharyngeal erythema		2		1		1
Pharyngeal hypoaesthesia	1	4			1	4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal oedema		1				1
Pharyngeal paraesthesia		2				2
Pharyngeal swelling	9	23	3	6	6	17
Pharyngitis		1		1		
Phlebitis		1				1
Photophobia		4				4
Photosensitivity reaction	1	1	1	1		
Physical deconditioning		2		1		1
Physical disability	1	1			1	1
Platelet count decreased	1	2		1	1	1
Pleural effusion		5		1		4
Pleurisy		1				1
Pneumonia	2	8			2	8
Pneumonia aspiration		1				1
Polyarthritis		1				1
Polymyalgia rheumatica		1				1
Polyneuropathy	2	3			2	3
Poor quality product administered	4	9	4	9		
Poor quality sleep		1				1
Postoperative wound complication		1				1
Post stroke epilepsy		1				1
Post viral fatigue syndrome		1		1		
Prerenal failure	1	1			1	1
Presyncope		5		1		4
Procalcitonin decreased	1	1	1	1		
Procalcitonin increased		2				2
Product administered at inappropriate site	1	3		2	1	1
Product administration error	1	1	1	1		
Product colour issue		5		5		
Productive cough	2	5			2	5
Product preparation issue		3		3		
Product temperature excursion issue	4	4	4	4		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Product use issue	1	2
Pruritus	14	41
Psychotic disorder		2
Pulmonary artery thrombosis		1
Pulmonary embolism	15	46
Pulmonary fibrosis	1	1
Pulmonary infarction		1
Pulmonary oedema	2	7
Pulmonary pain	2	4
Pulmonary thrombosis	1	1
Pulse abnormal		3
Pulse pressure decreased		1
Purpura		1
Pyrexia	117	335
Rash	4	20
Rash erythematous	2	7
Rash macular	1	3
Rash maculo-papular		1
Rash pruritic		3
Reading disorder		1
Red blood cell sedimentation rate increased		1
Reduced facial expression		1
Renal failure		1
Renal impairment		1
Renal infarct		1
Renal pain	3	5
Renal tubular necrosis		1
Respiratory arrest	1	4
Respiratory disorder	2	4
Respiratory distress	1	12
Respiratory failure	1	4
Respiratory rate increased		5

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	2		
9	19	5	22
			2
			1
		15	46
		1	1
			1
		2	7
1	1	1	3
		1	1
	2		1
	1		
			1
97	200	20	135
3	9	1	11
	1	2	6
	2	1	1
			1
	2		1
			1
			1
			1
			1
3	4		1
			1
		1	4
	1	2	3
		1	12
		1	4
			5

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Restless legs syndrome		2				2
Retinal haemorrhage		1				1
Retinal tear	1	1			1	1
Retinal vein occlusion	1	1			1	1
Retroperitoneal haemorrhage		1				1
Rheumatoid arthritis	1	1			1	1
Rhinalgia		2		1		1
Rhinitis		1		1		
Rhinorrhoea	5	22	3	17	2	5
Rib fracture		1				1
Rotator cuff syndrome	1	1			1	1
Scapula fracture		1				1
Sciatica		2		1		1
Seizure	2	8			2	8
Seizure like phenomena		2				2
Sensation of foreign body		1				1
Sensitivity to weather change	1	1			1	1
Sensory disturbance	2	4		1	2	3
Sensory loss	2	2	1	1	1	1
Sepsis	2	4			2	4
Septic shock		2				2
Sinus congestion		1		1		
Sinus disorder		1		1		
Sinus tachycardia	1	1			1	1
Skin burning sensation		1				1
Skin discolouration	1	6		2	1	4
Skin exfoliation	1	1			1	1
Skin reaction	1	2		1	1	1
Skin swelling	1	1			1	1
Skin turgor decreased		1				1
Skin ulcer		4				4
Skin warm		1		1		

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FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sleep disorder	2	7	2	2		5
Sleep paralysis		1				1
Sleep talking		1				1
Sluggishness		1				1
Sneezing	4	5	3	4	1	1
Snoring	1	1			1	1
Somnolence	4	11	3	6	1	5
Speech disorder		2		1		1
Spinal pain	1	2	1	2		
Spinal subdural haemorrhage	1	1			1	1
Spontaneous haematoma		1				1
Stevens-Johnson syndrome		1				1
Stomatitis	1	2	1	1		1
Stress cardiomyopathy	1	1			1	1
Stroke in evolution	1	1			1	1
Subarachnoid haemorrhage		3				3
Subcutaneous haematoma	1	1			1	1
Subdural haematoma		1				1
Sudden death		5				5
Sudden hearing loss		1				1
Sudden visual loss		1				1
Supraventricular extrasystoles		1				1
Supraventricular tachycardia	1	1			1	1
Suspected COVID-19		1		1		
Swelling	6	13	5	8	1	5
Swelling face	3	14		3	3	11
Swollen tongue	2	12			2	12
Syncope	3	23			3	23
Systemic lupus erythematosus		1				1
Tachycardia	3	18	2	7	1	11
Tachypnoea		2		1		1
Taste disorder	3	7	2	3	1	4

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Temperature regulation disorder		1		1		
Tenderness	3	6	2	3	1	3
Throat irritation	5	16	3	6	2	10
Throat tightness		5		1		4
Thrombocytopenia	3	10			3	10
Thrombophlebitis	3	7	1	2	2	5
Thrombophlebitis superficial		1				1
Thrombosis	6	15			6	15
Tinnitus	6	18	1	1	5	17
Tongue discomfort		1				1
Tongue erythema		1		1		
Tongue movement disturbance		1				1
Tongue pruritus		4				4
Tonsillitis	1	1			1	1
Toothache	1	1	1	1		
Toxic epidermal necrolysis		1				1
Transaminases increased		1				1
Transient ischaemic attack	6	13			6	13
Tremor	3	14	1	2	2	12
Trigeminal nerve paresis		1				1
Troponin abnormal	1	1			1	1
Troponin increased	1	2		1	1	1
Troponin T increased	1	1			1	1
Underdose	1	4	1	4		
Unresponsive to stimuli		2				2
Upper gastrointestinal haemorrhage		1				1
Upper respiratory tract congestion		1		1		
Upper respiratory tract infection		1				1
Urinary retention		1				1
Urinary tract infection	2	11		5	2	6
Urine output decreased		2				2
Urosepsis		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria	12	47	9	22	3	25
Uterine inflammation		1		1		
Vaccination complication	1	1			1	1
Vaccination failure	4	9			4	9
Vaccination site bruising	1	3	1	2		1
Vaccination site discolouration	1	2			1	2
Vaccination site discomfort		1				1
Vaccination site erythema	16	48	10	30	6	18
Vaccination site haematoma	2	4			2	4
Vaccination site haemorrhage	3	4	1	2	2	2
Vaccination site hypoaesthesia		2		2		
Vaccination site induration	1	4	1	3		1
Vaccination site joint movement impairment		1		1		
Vaccination site joint pain	2	2			2	2
Vaccination site lymphadenopathy	1	2	1	1		1
Vaccination site mass		1		1		
Vaccination site movement impairment	5	12	4	10	1	2
Vaccination site nodule		2		2		
Vaccination site pain	71	172	57	134	14	38
Vaccination site paraesthesia	1	2	1	2		
Vaccination site phlebitis		1		1		
Vaccination site pruritus	9	18	3	9	6	9
Vaccination site rash	1	2	1	1		1
Vaccination site reaction	4	8	1	3	3	5
Vaccination site swelling	17	52	10	33	7	19
Vaccination site thrombosis		1				1
Vaccination site urticaria		1		1		
Vaccination site warmth	7	17	6	15	1	2
Vaginal haemorrhage		1				1
Varicose vein	1	1	1	1		
Vascular dementia		1				1
Vasculitis		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vasodilatation		1		1		
Venous thrombosis		1				1
Ventricular hypokinesia		1				1
Vertigo		2				2
Vertigo positional	1	2	1	2		
Vestibular disorder	1	1	1	1		
Vestibular neuronitis	1	1			1	1
Viral infection		1		1		
Vision blurred	4	11	2	3	2	8
Visual field defect	2	5			2	5
Visual impairment	4	12		1	4	11
Vitreous detachment	1	1			1	1
Vomiting	22	75	12	22	10	53
Wa king aid user	1	1			1	1
Weight decreased	1	3		1	1	2
Weight increased		1				1
Wheezing		6		1		5
White blood cell count decreased	2	3	1	2	1	1
White blood cell count increased		2		2		
Wound		2		1		1
	1,779	5,626	958	2320	821	3306

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal distension	1	2			1	2
Abdominal pain	4	6	2	3	2	3
Abdominal pain upper	1	1	1	1		
Abnormal behaviour	1	4		1	1	3
Abnormal dreams		1		1		
Acetonaemia	1	1			1	1
Acute coronary syndrome	1	1			1	1
Acute kidney injury	1	3			1	3
Acute myocardial infarction	2	5			2	5
Acute respiratory distress syndrome	1	1			1	1
Adrenal haemorrhage	1	1			1	1
Aggression	1	1			1	1
Agitation		2				2
Akinesia		1				1
Allergy to vaccine		1				1
Altered state of consciousness	1	2			1	2
Amnesia	1	3			1	3
Anaemia	1	1			1	1
Anaphylactic reaction		3				3
Anaphylactic shock		1				1
Anaphylactoid reaction		1				1
Angina pectoris	1	4			1	4
Angioedema		2				2
Anosmia	1	1			1	1
Anxiety		7				7
Aortic aneurysm	1	1			1	1
Aortic rupture	1	1			1	1
Apathy		1				1
Aphasia	1	1			1	1
Apthous ulcer	1	1	1	1		
Apnoea		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appendicitis	1	1			1	1
Arrhythmia	2	2	1	1	1	1
Arteriosclerosis	2	2			2	2
Arteriosclerosis coronary artery		1				1
Arthralgia	11	17	6	9	5	8
Arthritis		2				2
Ascites		1				1
Asthenia	3	10	2	4	1	6
Asthenopia		1				1
Atrial f brillation	2	8			2	8
Atrioventricular block complete		1				1
Axillary pain	1	3	1	2		1
Back pain	2	4	1	2	1	2
Balance disorder	3	8	1	1	2	7
Ballismus	1	1			1	1
Bell's palsy	2	5			2	5
Blepharospasm		1				1
Blindness	1	1			1	1
Blindness unilateral	1	1			1	1
Blood creatine increased	1	1	1	1		
Blood creatinine increased		2		2		
Blood fibrinogen decreased		1				1
Blood glucose decreased	1	1	1	1		
Blood glucose increased	1	1			1	1
Blood lactate dehydrogenase increased		1				1
Blood pressure decreased	3	8	1	2	2	6
Blood pressure diastolic decreased		1		1		
Blood pressure diastolic increased	1	1	1	1		
Blood pressure increased	1	3	1	2		1
Body temperature increased		2		1		1
Bradycardia		1				1
Brain herniation		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Brain stem syndrome		1				1
Bronchial haemorrhage		1				1
Bronchitis		1				1
Bundle branch block left		1				1
Bundle branch block right		1				1
Bursitis		1				1
Cardiac arrest	2	13			2	13
Cardiac death		1				1
Cardiac discomfort	1	2			1	2
Cardiac failure	2	8			2	8
Cardiac failure acute	1	2			1	2
Cardiac fibrillation	1	2			1	2
Cardiogenic shock		1				1
Catheter site haemorrhage		1		1		
Cerebellar haemorrhage		1				1
Cerebellar infarction	1	1			1	1
Cerebellar syndrome		1				1
Cerebral artery embolism	1	2			1	2
Cerebral disorder	1	1			1	1
Cerebral haemorrhage	5	10			5	10
Cerebral infarction	3	4			3	4
Cerebral small vessel ischaemic disease	1	1			1	1
Cerebral thrombosis		1				1
Cerebrovascular accident	4	13			4	13
Cerebrovascular disorder	1	1			1	1
Chest discomfort	2	7	1	3	1	4
Chest pain	3	9			3	9
Chills	12	27	6	14	6	13
Chronic fatigue syndrome		1				1
Chronic obstructive pulmonary disease	1	2			1	2
Circulatory collapse	1	5			1	5
Circumoral swelling	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coagulopathy		1				1
Cognitive disorder	1	2			1	2
Cold sweat	1	3			1	3
Condition aggravated	2	5		1	2	4
Confusional state	6	12	2	2	4	10
Constipation		2		2		
Coordination abnormal		1				1
Coronary artery disease	1	1			1	1
Coronary artery occlusion		1				1
Coronary artery thrombosis	1	1			1	1
Cough	2	9		4	2	5
COVID-19	8	14	4	5	4	9
C-reactive protein increased	1	4	1	3		1
Cutaneous vasculitis	1	1			1	1
Deafness	3	3			3	3
Death	2	13			2	13
Decreased appetite	1	5	1	3		2
Decubitus ulcer		1		1		
Deep vein thrombosis	8	11			8	11
Dehydration		4				4
Delirium		1				1
Delusional disorder, unspecified type		1				1
Depressed level of consciousness		13				13
Depressed mood		1				1
Depression		1				1
Dermatitis		2		1		1
Device related infection		1				1
Diarrhoea	3	12	1	6	2	6
Diplopia	2	3		1	2	2
Discomfort		1				1
Disease recurrence		3		1		2
Disorganised speech		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disorientation		1				1
Dizziness	12	32	3	8	9	24
Dizziness exertional		1				1
Drug ineffective	1	4			1	4
Drug intolerance	1	1			1	1
Dry eye	1	1			1	1
Dysgeusia		1				1
Dyshidrotic eczema	1	1			1	1
Dyskinesia	1	1			1	1
Dysphagia		6		3		3
Dysphonia		1				1
Dyspnoea	11	38	2	4	9	34
Dyspnoea exertional	1	1			1	1
Dysstasia	2	3	2	2		1
Dystonia		1				1
Ear pain	1	1	1	1		
Eating disorder		1				1
Ecchymosis	1	1			1	1
Eczema		1				1
Electrocardiogram ST segment elevation	1	2			1	2
Embolic cerebral infarction		1				1
Energy increased		1				1
Epilepsy		1				1
Epistaxis	1	5	1	2		3
Erysipelas	1	3			1	3
Erythema	1	2		1	1	1
Escherichia infection		1				1
Escherichia sepsis		1				1
Extrasystoles		1				1
Eye disorder		1				1
Eye haemorrhage		2				2
Eye irritation		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye pain	1	3		1	1	2
Face injury		1				1
Facial pain		1				1
Facial paralysis	1	3			1	3
Facial paresis	1	6			1	6
Fall	4	12	1	2	3	10
Fatigue	26	71	12	37	14	34
Fear of death		1				1
Feeling abnormal		2		1		1
Feeling cold	1	1	1	1		
Feeling hot		2		1		1
Fluid intake reduced		1				1
Fluid retention		1				1
Gait disturbance	5	6	1	1	4	5
Gastric haemorrhage		1				1
Gastrointestinal disorder	1	1			1	1
Gastrointestinal haemorrhage		1				1
Gaze palsy	1	1			1	1
General physical health deterioration	2	12		3	2	9
Goitre		1				1
Gout	1	2			1	2
Graft versus host disease		1				1
Haematemesis		4				4
Haematoma		1				1
Haematuria		1				1
Haemolytic anaemia		1				1
Haemoptysis		2				2
Haemorrhage		3				3
Haemorrhage subcutaneous	1	1			1	1
Hallucination	1	3			1	3
Headache	29	54	19	33	10	21
Head discomfort		1		1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Head injury		3		1		2
Heart rate increased	2	5		1	2	4
Heart rate irregular		2		2		
Helplessness		1				1
Hemiparesis	1	1			1	1
Herpes ophthalmic		1				1
Herpes virus infection	1	1			1	1
Herpes zoster	2	5	1	2	1	3
Hiccups		1				1
Hip fracture		1				1
Horner's syndrome		1				1
Hydrothorax		1				1
Hyperglycaemia	1	2			1	2
Hyperhidrosis	1	8		5	1	3
Hypersensitivity	1	5			1	5
Hypersomnia	1	2			1	2
Hypertension	1	4			1	4
Hypoacusis	2	3			2	3
Hypoaesthesia	5	19	1	4	4	15
Hypoaesthesia oral		1				1
Hypoglycaemia	1	2			1	2
Hypokinesia	1	2			1	2
Hypoperfusion		1				1
Hypophagia		1				1
Hyposmia	1	1			1	1
Hypotension	1	7	1	1		6
Hypothermia		1				1
Hypovolaemic shock	1	1			1	1
Idiopathic pulmonary fibrosis		1				1
Illness		1		1		
Immune thrombocytopenia	1	2			1	2
Inappropriate schedule of product administration	1	3	1	3		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Incontinence	1	2		1	1	1
Incorrect route of product administration		2		2		
Increased insulin requirement	1	1	1	1		
Infection	1	6			1	6
Inflammation	1	1			1	1
Influenza like illness	2	3	2	3		
Injury	1	1	1	1		
Insomnia		3		2		1
International normalised ratio increased		1				1
Intestinal haemorrhage		2				2
Intestinal ischaemia		1				1
Ischaemic stroke	5	6			5	6
Joint stiffness		1				1
Lacrimation increased		1				1
Lactic acidosis		1				1
Lacunar infarction	1	1			1	1
Lethargy		1		1		
Leukocytosis	1	1	1	1		
Ligament sprain	1	1			1	1
Loose tooth		1				1
Loss of consciousness	2	5			2	5
Loss of personal independence in daily activities	1	1			1	1
Low density lipoprotein increased	1	1			1	1
Lung disorder	1	3	1	1		2
Lung infiltration	1	1			1	1
Lung opacity	1	1			1	1
Lung transplant rejection		1				1
Lymphadenopathy	4	5	4	5		
Lymph node pain	3	3	3	3		
Malaise	13	22	5	9	8	13
Memory impairment	1	1			1	1
Mental fatigue		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Metastasis		1				1
Migraine	1	1	1	1		
Motor dysfunction		1				1
Muscle spasms	1	3		1	1	2
Muscle twitching	1	3	1	1		2
Muscular weakness		2				2
Musculoskeletal stiffness	4	13	3	4	1	9
Myalgia	13	29	8	13	5	16
Myelitis		1				1
Myocardial infarction	7	12			7	12
Myocarditis	1	2			1	2
Nasal congestion		2		1		1
Nasopharyngitis	2	3	1	1	1	2
Nausea	5	23	2	8	3	15
Neck pain	2	6	1	2	1	4
Neoplasm progression		1				1
Nephrolithiasis		1				1
Neurological symptom	1	1			1	1
Neuropsychiatric symptoms	1	1			1	1
Neutropenia	1	1			1	1
Nightmare		1		1		
Obstructive airways disorder		1				1
Ocular discomfort	1	2	1	1		1
Oedema peripheral	1	1			1	1
Off label use	1	3	1	3		
Oral mucosal blistering		1				1
Oropharyngeal pain		6		4		2
Orthostatic hypotension		1				1
Oxygen saturation decreased	3	11		2	3	9
Pain	10	22	6	11	4	11
Painful respiration		1		1		
Pain in extremity	14	25	6	15	8	10

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in jaw		1		1		
Pain of skin	1	1			1	1
Pallor		1				1
Palpable purpura	1	1			1	1
Palpitations	1	6	1	2		4
Paraesthesia	1	6		1	1	5
Paralysis		1				1
Paranoia	1	1			1	1
Parosmia		1				1
Pemphigoid		2				2
Penile haemorrhage		1				1
Periorbital discomfort		1				1
Peripheral coldness	2	2			2	2
Peripheral embolism	1	1			1	1
Peripheral swelling	5	12	1	2	4	10
Personality change	1	1			1	1
Petechiae	1	3			1	3
Petit mal epilepsy		1				1
Pharyngeal mass		1				1
Pharyngeal swelling		1				1
Platelet count decreased		1				1
Pneumonia	1	9			1	9
Pneumonia aspiration		2				2
Pneumonia bacterial		1				1
Pneumonia pneumococcal		1				1
Pneumonia streptococcal		1				1
Pneumothorax	1	1			1	1
Poor quality product administered	1	5	1	5		
Poor quality sleep		1		1		
Post-acute COVID-19 syndrome	1	1	1	1		
Product colour issue		2		2		
Productive cough		2				2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product preparation issue		1		1		
Product temperature excursion issue	1	2	1	2		
Pruritus	2	7			2	7
Psoriasis		1		1		
Psychotic disorder		1				1
Pulmonary embolism	20	38			20	38
Pulmonary fibrosis	1	1			1	1
Pulmonary haemorrhage	1	1			1	1
Pulmonary hypertension		1				1
Pulmonary oedema	1	5			1	5
Pulmonary pain	1	1	1	1		
Pulmonary thrombosis		2				2
Pyrexia	43	85	33	50	10	35
Rash	4	7		1	4	6
Rash erythematous		2				2
Rash pruritic		1				1
Renal failure	1	2			1	2
Renal haemorrhage		1				1
Renal impairment		1				1
Respiration abnormal		1				1
Respiratory arrest		2				2
Respiratory disorder	1	1			1	1
Respiratory distress		4				4
Respiratory failure	1	1			1	1
Respiratory rate increased		3		1		2
Respiratory symptom	1	1			1	1
Retinal artery occlusion		1				1
Retinal vascular thrombosis	1	1			1	1
Retinal vein occlusion		1				1
Rhinitis		1		1		
Rhinorrhoea	1	4	1	4		
Rib fracture	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Screaming		1		1		
Seizure	2	7			2	7
Sense of oppression		1				1
Sepsis	1	6			1	6
Sinus tachycardia	1	2			1	2
Skin disorder		1				1
Skin tightness		1				1
Skin wound		1				1
Skull fracture	1	1			1	1
Sleep paralysis		1		1		
Slow speech		1				1
Solar dermatitis		1				1
Somnolence	2	5	1	2	1	3
Speech disorder	1	3		1	1	2
Spleen disorder		1				1
Splenic artery thrombosis	1	1			1	1
Status epilepticus		1				1
Streptococcal bacteraemia		1				1
Stress		2		2		
Subarachnoid haemorrhage	2	3			2	3
Subdural haematoma	2	3			2	3
Sudden death		1				1
Supraventricular tachycardia		1				1
Suspected COVID-19		1				1
Swelling	3	5	1	2	2	3
Swelling face	2	5		1	2	4
Swollen tongue		2		1		1
Syncope	2	9			2	9
Systemic inflammatory response syndrome		1				1
Tachycardia	1	3			1	3
Tachypnoea		3		1		2
Tenosynovitis		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Throat irritation	1	2	1	1		1
Throat tightness		1				1
Thrombocytopenia	6	13			6	13
Thrombocytopenic purpura		1				1
Thrombophlebitis	2	3			2	3
Thrombosis	3	6			3	6
Tinnitus	2	6			2	6
Tongue discomfort		1		1		
Torticollis		1				1
Tracheal haemorrhage		1				1
Transient global amnesia	1	1			1	1
Transient ischaemic attack	2	4			2	4
Tremor	1	4		1	1	3
Troponin I increased	1	1			1	1
Underdose		2		2		
Unresponsive to stimuli		1				1
Upper respiratory tract infection		2				2
Urinary incontinence		1				1
Urinary tract infection	1	3		1	1	2
Urosepsis		2				2
Urticaria	1	5	1	2		3
Vaccination failure	2	3			2	3
Vaccination site erythema	3	4	1	1	2	3
Vaccination site induration		1		1		
Vaccination site infection		1				1
Vaccination site pain	31	56	28	50	3	6
Vaccination site paraesthesia	1	1	1	1		
Vaccination site pruritus	2	3		1	2	2
Vaccination site reaction	2	2	1	1	1	1
Vaccination site swelling	4	7	2	4	2	3
Vaccination site warmth		1		1		
Ventricular fibrillation		2				2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ventricular tachycardia		1				1
Vertigo	1	3	1	2		1
Vestibular neuronitis	1	1			1	1
Vision blurred	1	2			1	2
Visual field defect		1				1
Visual impairment		1				1
Vitreous detachment	1	1			1	1
Vomiting	5	16	1	5	4	11
Wheezing	1	5		2	1	3
White blood cells urine positive		1		1		
Wound necrosis		1				1
	598	1,595	212	475	386	1120

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1		1		
Abdominal pain upper		1		1		
Circumstance or information capable of leading to medication error		29		29		
COVID-19		19		18		1
Death		2				2
Diarrhoea		1		1		
Exposure via breast milk	1	1	1	1		
Facial paresis		1				1
Gastrointestinal pain		1		1		
Hypoaesthesia		1				1
Hypoaesthesia oral		1				1
Incorrect route of product administration		2		2		
Myalgia		2		2		
Poor quality product administered		28		28		
Product colour issue		29		29		
Product preparation issue	1	1	1	1		
Pyrexia		3		3		
Underdose	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site joint movement impairment		2		2		
Vaccination site pain		2		2		
	4	129	4	123		6

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Country Where Event Occurred

SWITZERLAND

090177e19749cf15\Approved\Approved On: 14-Jun-2021 14:01 (GMT)

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- * AE=Adverse Event
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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal pain	2	4	1	1	1	3
Abdominal pain lower		1				1
Acute kidney injury	1	3			1	3
Acute myocardial infarction		2				2
Acute pulmonary oedema		2				2
Acute stress disorder	1	3			1	3
Ageusia	1	1	1	1		
Alanine aminotransferase increased		1		1		
Allergy to vaccine	1	1			1	1
Alopecia		1				1
Altered state of consciousness		1				1
Amnesia	1	3		2	1	1
Anaemia		1				1
Anaphylactic reaction	4	16			4	16
Anaphylactic shock		1				1
Angina pectoris		1				1
Angioedema	4	11			4	11
Aphasia		1				1
Aphonia	1	1	1	1		
Aphthous ulcer		1				1
Arrhythmia	1	5			1	5
Arteriosclerosis		1				1
Arteriosclerosis coronary artery		1				1
Arthralgia	10	18	9	11	1	7
Ascites		1				1
Asthenia	7	15	5	5	2	10
Asthma	1	4			1	4
Atrial fibrillation	2	6			2	6
Atrioventricular block second degree	1	1			1	1
Atrophy		1				1
Atypical pneumonia	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autonomic nervous system imbalance	1	1	1	1		
Axillary lymphadenectomy		1				1
Back pain	2	3	1	2	1	1
Balance disorder	1	1	1	1		
Bedridden	1	1	1	1		
Bell's palsy	1	1			1	1
Blindness transient		1				1
Blister		1		1		
Blood alkaline phosphatase increased		1		1		
Blood glucose increased		1		1		
Blood pressure decreased		1		1		
Blood pressure increased	2	7	1	2	1	5
Body temperature increased	1	2	1	2		
Bone pain		1		1		
Bradycardia	3	3			3	3
Breast haematoma		1				1
Breast pain		1				1
Bronchial hyperreactivity	1	1			1	1
Burning sensation	1	1	1	1		
Cardiac arrest		2				2
Cardiac failure		4				4
Cardiac failure acute		1				1
Cardiac failure chronic		1				1
Cardiac failure congestive		1				1
Cardiac murmur	1	1			1	1
Cardiac valve disease		1				1
Cardiovascular disorder		1				1
Carotid bruit	1	1			1	1
Cerebral infarction		1				1
Cerebrovascular accident	1	5			1	5
Chest discomfort		5				5
Chest pain	2	6			2	6

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills	12	28	8	11	4	17
Cholecystitis acute		1				1
Cholestasis		2				2
Chronic obstructive pulmonary disease		2				2
Circulatory collapse	2	4			2	4
Cold sweat	1	1	1	1		
Colitis microscopic	1	1			1	1
Colitis ulcerative	1	1			1	1
Coma		1				1
Condition aggravated	4	6	2	2	2	4
Confusional state	1	3			1	3
Conjunctivitis bacterial		1				1
Contusion		1		1		
Cough	5	10	5	6		4
COVID-19	1	14			1	14
COVID-19 pneumonia		1				1
Craniocerebral injury		1		1		
C-reactive protein increased		1				1
Cystitis		1				1
Deafness unilateral	1	1			1	1
Death		2				2
Decreased appetite		3		1		2
Deep vein thrombosis	3	5			3	5
Dehydration		2				2
Delirium		3				3
Dementia		1				1
Depressed mood		1		1		
Dermatitis allergic		1		1		
Dermatitis bullous	1	1			1	1
Diabetic ketoacidosis		1				1
Diabetic metabolic decompensation		1				1
Diarrhoea	5	17	3	6	2	11

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea haemorrhagic	1	1			1	1
Diplopia		1				1
Discomfort	1	3		1	1	2
Disease recurrence	1	4			1	4
Disorientation		1				1
Dissociative disorder		1				1
Disturbance in attention	1	4	1	1		3
Dizziness	9	23	7	11	2	12
Drug eruption		1				1
Drug ineffective		5				5
Drug interaction	1	2	1	2		
Duodenal ulcer haemorrhage	1	1			1	1
Dysaesthesia	3	5	1	1	2	4
Dysarthria		1				1
Dysphagia	3	3	1	1	2	2
Dysphonia		1		1		
Dyspnoea	7	22	1	3	6	19
Dyspnoea at rest	1	1			1	1
Dyspnoea exertional	1	1			1	1
Ear pruritus		1				1
Electrocardiogram abnormal	1	1			1	1
Embolism		1				1
Encephalitis	1	1			1	1
Encephalopathy	1	1			1	1
Enthesopathy	1	1	1	1		
Enuresis		1				1
Eosinophilia		1		1		
Epigastric discomfort	1	1	1	1		
Epilepsy		4				4
Epistaxis	1	1	1	1		
Erysipelas		2				2
Erythema	2	9		2	2	7

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Extrasystoles	1	1			1	1
Extremity necrosis	1	1			1	1
Eye discharge	1	1			1	1
Eye disorder	1	1			1	1
Eye haemorrhage		1				1
Eyelid oedema		2				2
Eye pain	1	1			1	1
Facet joint syndrome	1	1	1	1		
Facial paralysis	2	4			2	4
Facial paresis		2				2
Fall	1	6		2	1	4
Fatigue	25	39	15	21	10	18
Feeding disorder		1				1
Feeling cold		1		1		
Feeling hot	1	5		1	1	4
Fluid overload		1				1
Flushing		2				2
Gait disturbance	1	3	1	1		2
Gastric disorder		1				1
Gastritis		1				1
Gastrointestinal disorder		2		2		
Gastroesophageal reflux disease		2				2
Generalised tonic-clonic seizure	1	2			1	2
General physical health deterioration	1	4	1	2		2
Genital herpes		1				1
Haematemesi		1				1
Haemophagocytic lymphohistiocytosis		1				1
Haemoptysis	1	1			1	1
Haemorrhagic stroke		1				1
Hallucination, visual		1				1
Headache	29	57	20	28	9	29
Head injury	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate increased	1	2	1	1		1
Heavy menstrual bleeding	1	1	1	1		
Hemianaesthesia	1	1			1	1
Hemiparaesthesia	1	1			1	1
Hemiplegia		1				1
Hepatic cirrhosis		1				1
Hepatocellular injury		1				1
Herpes virus infection	1	1			1	1
Herpes zoster	2	13			2	13
Hot flush	3	3			3	3
Hyperglycaemia		1				1
Hyperhidrosis	1	5	1	1		4
Hypersensitivity	3	22		4	3	18
Hypertension	5	20	1	2	4	18
Hypertensive crisis	2	4			2	4
Hypertensive emergency		1				1
Hyperthermia	1	2		1	1	1
Hypertonia	1	1			1	1
Hyperventilation	1	5			1	5
Hypoaesthesia oral		1		1		
Hypoglycaemic coma		1				1
Hypokalaemia	1	1			1	1
Hypotension	2	7	1	2	1	5
Iliac bruit	1	1			1	1
Immunisation anxiety related reaction		2				2
Inappropriate schedule of product administration	1	2	1	2		
Incorrect route of product administration	4	10	4	10		
Inflammation		2				2
Influenza	2	2	2	2		
Influenza like illness	4	7	3	4	1	3
Injection site discomfort	1	1	1	1		
Insomnia	3	4	3	4		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ischaemic cerebral infarction		2				2
Joint range of motion decreased	1	1	1	1		
Joint swelling	1	2			1	2
Keratitis	1	1			1	1
Left ventricular failure		1				1
Lethargy		1		1		
Lip oedema		1				1
Lip swelling		1				1
Liver disorder		1				1
Loss of consciousness		1				1
Loss of personal independence in daily activities	1	1	1	1		
Lower respiratory tract infection	1	1			1	1
Lung disorder		1				1
Lung infiltration	1	1			1	1
Lymphadenopathy	5	8	4	5	1	3
Lymphangiectasia		1				1
Lymph node pain	2	3	2	2		1
Lymphopenia		1				1
Malaise	9	24	2	4	7	20
Meningioma		1				1
Metabolic syndrome		1				1
Migraine	1	2	1	2		
Monocytosis		1		1		
Monoplegia		1				1
Mouth swelling	1	1			1	1
Multiple sclerosis relapse	1	1			1	1
Muscle spasms		3				3
Muscle tightness	1	1			1	1
Muscular weakness	1	3			1	3
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	2	3	2	2		1
Myalgia	23	36	17	21	6	15

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myelitis		1				1
Myoclonus	1	1			1	1
Nasal congestion	1	1	1	1		
Nasopharyngitis		1				1
Nausea	13	32	8	13	5	19
Neck pain	3	3	2	2	1	1
Neuralgia	1	3	1	1		2
Neuralgic amyotrophy		1				1
Neuropathy peripheral	1	1			1	1
Obstructive airways disorder		1				1
Ocular hyperaemia	1	1			1	1
Odynophagia	2	3	2	2		1
Oedema peripheral	1	3			1	3
Off label use	1	2	1	2		
Ophthalmic herpes zoster	1	3			1	3
Oropharyngeal oedema		1				1
Oropharyngeal pain	4	5	3	4	1	1
Otitis media	1	1			1	1
Overdose	1	1	1	1		
Oxygen saturation decreased		2				2
Pain	3	10	2	4	1	6
Pain in extremity	12	20	8	11	4	9
Pallor	2	3	2	2		1
Palpitations	1	5			1	5
Paraesthesia	5	11	2	4	3	7
Paraesthesia oral	1	4		1	1	3
Paranoia		1				1
Parotitis		1				1
Peak expiratory flow rate decreased		1				1
Pemphigoid	1	1			1	1
Performance status decreased	1	1	1	1		
Periarthritis	1	1			1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Periorbital swelling	1	1	1	1		
Peripheral coldness		2				2
Peripheral swelling	2	3			2	3
Peripheral vascular disorder		1				1
Petechiae	1	1			1	1
Pharyngeal paraesthesia		1				1
Photophobia	1	2	1	1		1
Platelet count increased		1		1		
Pleural effusion		1		1		
Pneumonia		3				3
Pneumonia aspiration		1				1
Pneumonia pneumococcal		1				1
Polyneuropathy		1				1
Presyncope	4	11	1	1	3	10
Pruritus	4	15	2	5	2	10
Psychiatric decompensation	1	1			1	1
Pulmonary congestion	1	1			1	1
Pulmonary embolism	3	5			3	5
Pulmonary fibrosis		1				1
Pulmonary oedema		1				1
Purpura		1				1
Pyelitis	1	1			1	1
Pyelonephritis	1	1			1	1
Pyrexia	27	60	18	23	9	37
Rash	4	14	2	7	2	7
Rash erythematous		2				2
Rash maculo-papular	1	3		1	1	2
Rash pruritic	2	2	2	2		
Rash pustular		1				1
Renal failure		1				1
Renal impairment		1				1
Respiratory depression		1				1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory distress	1	3			1	3
Respiratory failure		3				3
Respiratory paralysis		1				1
Respiratory tract infection		1				1
Restless legs syndrome	2	2			2	2
Rheumatoid arthritis		2				2
Rhinitis		1		1		
Rib fracture		1		1		
Road traffic accident		1				1
Salivary hypersecretion		1				1
Scratch		2		2		
Sedation		1				1
Sense of oppression		2				2
Sensory disturbance	2	5			2	5
Sepsis		1				1
Sickle cell anaemia with crisis		1				1
Sinus tachycardia		1				1
Skin infection	1	1	1	1		
Skin reaction	3	4	3	3		1
Somnolence		1				1
Speech disorder		1				1
Spinal pain	1	1			1	1
Stress cardiomyopathy		1				1
Subclavian vein thrombosis	1	1			1	1
Sudden death		2				2
Supraventricular tachycardia	1	1			1	1
Swelling face	2	4	1	3	1	1
Swelling of eyelid		1				1
Swollen tongue		1				1
Syncope	4	9			4	9
Synovitis	1	1	1	1		
Tachycardia	4	15	1	3	3	12

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachypnoea		1				1
Tendon pain		1		1		
Tendon rupture	1	1	1	1		
Tension	1	1			1	1
Throat irritation		1				1
Throat tightness		2				2
Thrombocytopenia		2				2
Tinnitus	1	1	1	1		
Tongue oedema		1				1
Transient ischaemic attack		2				2
Traumatic haematoma	1	1			1	1
Tremor	2	5	2	2		3
Trigeminal neuralgia		1				1
Troponin increased	1	1			1	1
Tumour marker increased		2		2		
Type I hypersensitivity		1				1
Type II hypersensitivity		1				1
Underdose		1		1		
Upper gastrointestinal haemorrhage	1	1			1	1
Urinary tract infection		1				1
Urinary tract infection bacterial		1				1
Urogenital haemorrhage		1				1
Urticaria	3	7	1	2	2	5
Vaccination failure	1	4			1	4
Vaccination site cellulitis	1	1	1	1		
Vaccination site erythema	5	11	5	8		3
Vaccination site haematoma	1	2	1	1		1
Vaccination site induration	2	3	2	2		1
Vaccination site lymphadenopathy		1				1
Vaccination site oedema		1		1		
Vaccination site pain	8	18	6	11	2	7
Vaccination site pruritus	4	5	4	5		

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site rash	2	3	2	3		
Vaccination site reaction	2	2	2	2		
Vaccination site swelling	3	4	3	3		1
Vaccination site urticaria		1				1
Vaccination site warmth	1	3	1	2		1
Varicella zoster virus infection		1				1
Vascular encephalopathy		1				1
Vertigo	6	6	2	2	4	4
Vertigo positional		1				1
Viral infection		1		1		
Visual field defect	1	1			1	1
Visual impairment		3				3
Vomiting	6	24	4	7	2	17
Weight decreased		1		1		
White matter lesion		1		1		
Wrong technique in product usage process		1		1		
	489	1,258	252	400	237	858

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal infection		1				1
Abdominal pain		4		1		3
Abdominal pain upper	1	1	1	1		
Acute kidney injury		1				1
Agitation		1				1
Anal haemorrhage		1		1		
Anaphylactic reaction		1				1
Angioedema		2				2
Anti-myelin-associated glycoprotein antibodies positive		1				1
Aphasia		3				3
Aphthous ulcer	1	1	1	1		
Apnoea		1				1
Appendicitis		1				1
Arthralgia	7	10	6	7	1	3
Asthenia	3	11	3	6		5
Asymptomatic COVID-19		1		1		
Atrial fibrillation	1	1			1	1
Atrioventricular block first degree	1	1			1	1
Back pain		2		1		1
Balance disorder	2	2	1	1	1	1
Blood pressure decreased		1				1
Blood pressure increased	1	1			1	1
Bone formation increased		1		1		
Bradycardia	1	1			1	1
Brain hypoxia		1				1
Bronchial wall thickening	1	1	1	1		
Burning sensation	1	1	1	1		
Cardiac disorder	1	1			1	1
Cardiac failure		1				1
Cardiac failure acute		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac fibrillation		1				1
Cardiogenic shock	1	1			1	1
Cardio-respiratory arrest		1				1
Cardiovascular disorder		1				1
Central nervous system lesion		1				1
Cerebrovascular accident	1	1			1	1
Cheilitis	1	1	1	1		
Chest injury	1	1			1	1
Chest pain	1	1	1	1		
Chills	7	12	6	8	1	4
Circulatory collapse		1				1
Cold sweat		1				1
Coma		1				1
Condition aggravated	1	1	1	1		
Confusional state	1	2	1	1		1
Contusion	1	1	1	1		
Cough		2		1		1
COVID-19	2	9		1	2	8
COVID-19 pneumonia	2	2			2	2
Craniocerebral injury	1	2			1	2
C-reactive protein increased	3	6	1	2	2	4
Crohn's disease	1	1			1	1
CSF test abnormal		1				1
Deafness unilateral		1				1
Death	2	6			2	6
Deep vein thrombosis		1				1
Delirium		2				2
Dermatitis allergic	1	1			1	1
Dermatitis psoriasiform	1	1	1	1		
Diarrhoea	3	3	3	3		
Disease recurrence	1	1			1	1
Disorientation		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbance in attention		1		1		
Dizziness	5	12	4	5	1	7
Drug ineffective	1	3			1	3
Dysarthria		1				1
Dysgeusia		1		1		
Dyskinesia	1	1	1	1		
Dyspnoea	2	4	1	3	1	1
Ear discomfort	1	1	1	1		
Ear pain		1				1
Eczema	1	1	1	1		
Embolic stroke		1				1
Encephalitis	1	2			1	2
Encephalopathy		1				1
Epilepsy	1	3			1	3
Epistaxis		1		1		
Erysipeloid		1				1
Erythema	1	2			1	2
Erythema annulare		1				1
Eye haematoma	1	1			1	1
Eyelids pruritus	1	1	1	1		
Eye pain		1		1		
Facial bones fracture	1	1			1	1
Facial paralysis		1				1
Facial paresis		1				1
Fall	4	6	1	1	3	5
Fatigue	3	13	3	8		5
Feeding disorder		1		1		
Feeling cold		2		2		
Flatulence	1	1	1	1		
Gait disturbance		2		1		1
Gastrointestinal disorder		1				1
Gaze palsy	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Generalised tonic-clonic seizure		1				1
General physical health deterioration		5		2		3
Glomerulonephritis minimal lesion		1				1
Gout		1				1
Hair growth abnormal		1		1		
Headache	8	14	7	12	1	2
Head discomfort	1	1	1	1		
Head injury	1	1			1	1
Heart rate decreased		1				1
Hemiparesis	1	1			1	1
Herpes zoster	7	14	2	2	5	12
Hypercholesterolaemia	1	1			1	1
Hypersensitivity	3	6	1	1	2	5
Hypertension		2				2
Hypertensive crisis	1	1			1	1
Hypoaesthesia oral		1				1
Hypotension		2				2
Illusion		1		1		
Immune-mediated adverse reaction		1		1		
Immune thrombocytopenia		1				1
Impaired work ability	1	2	1	2		
Incorrect route of product administration		1				1
Infection		1		1		
Inflammation		1				1
Influenza		1				1
Influenza like illness	1	2	1	2		
Insomnia		1		1		
Ischaemic cerebral infarction		1				1
Joint dislocation		1				1
Joint range of motion decreased		1				1
Joint swelling	1	1	1	1		
Language disorder	1	1			1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Leukopenia	1	1			1	1
Lip swelling	1	1	1	1		
Livedo reticularis	1	1	1	1		
Liver injury		1				1
Loss of consciousness		2				2
Lung consolidation	1	1	1	1		
Lymphadenopathy	3	4	3	3		1
Malaise	4	8	3	5	1	3
Meniere's disease		1				1
Middle insomnia		1		1		
Mobility decreased		1		1		
Monocytosis	1	1			1	1
Muscle disorder		1				1
Muscular weakness	1	1			1	1
Musculoskeletal pain		1		1		
Myalgia	3	10	2	5	1	5
Myocardial infarction		1				1
Myocarditis	1	1			1	1
Nausea	3	4	3	3		1
Neck pain	2	3	2	2		1
Nervous system disorder		1				1
Neuralgia	2	3	1	1	1	2
Neuralgic amyotrophy		1				1
Neutrophilia		1				1
NIH stroke scale score decreased		1				1
Oedema peripheral		1		1		
Oesophageal perforation		1				1
Off label use	1	1	1	1		
Oral herpes	1	2	1	1		1
Oropharyngeal pain	2	3	2	2		1
Oxygen saturation decreased		1				1
Pain	1	2	1	2		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in extremity		3		2		1
Pallor		1				1
Pancreatitis		1				1
Paraesthesia		1				1
Paraesthesia ear	1	1	1	1		
Paresis	1	1	1	1		
Pemphigoid	1	1			1	1
Performance status decreased		1				1
Pericardial effusion		1				1
Peripheral venous disease	1	1	1	1		
Pleocytosis		1				1
Pleural effusion		1				1
Pneumonia		1				1
Pneumonia aspiration	1	1			1	1
Pneumonia bacterial		1				1
Pruritus	4	7	2	2	2	5
Pulmonary embolism	2	5			2	5
Pulmonary infarction	1	1			1	1
Pyrexia	5	19	5	10		9
Rash	5	6	4	4	1	2
Rash papular		1				1
Rash papulosquamous	1	1	1	1		
Rash pruritic		1				1
Renal failure		1				1
SARS-CoV-2 ant body test negative		1		1		
Seizure		1				1
Sensory disturbance	1	1			1	1
Sepsis		1				1
Septic shock	1	2			1	2
Sinus disorder	1	1	1	1		
Skin disorder		1				1
Skin lesion	1	2	1	1		1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skull fracture		1				1
Sleep disorder		1		1		
Somnolence	1	4			1	4
Spinal cord ischaemia		1				1
Spinal disorder	1	1	1	1		
Subdural haematoma		1				1
Sudden death		2				2
Sudden hearing loss		1				1
Superinfection bacterial	1	1			1	1
Swelling of eyelid	1	1	1	1		
Syncope	1	4			1	4
Tachycardia		2				2
Tachypnoea		1				1
Tendon rupture		1				1
Therapeutic response unexpected		2		2		
Throat tightness	1	1			1	1
Thrombophlebitis superficial	1	1			1	1
Thrombosis	1	1			1	1
Tinnitus		1				1
Tongue dry	1	1			1	1
Tooth infection	1	1			1	1
Transient ischaemic attack	1	1			1	1
Underdose	1	1	1	1		
Urinary incontinence		1				1
Urinary retention	1	1			1	1
Urinary tract infection		1				1
Urticaria	1	3	1	1		2
Vaccination failure	3	4			3	4
Vaccination site erythema	1	1	1	1		
Vaccination site pain	4	9	4	7		2
Vaccination site pruritus		1				1
Vaccination site reaction	1	2	1	1		1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site swelling		1				1
Vaccination site urticaria	1	1	1	1		
Ventricular f brillation		1				1
Vertigo		4		1		3
Vomiting		1				1
	186	463	108	178	78	285

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Dizziness		2				2
Dysgeusia		1		1		
Dyspnoea		2				2
Facial paralysis	4	4			4	4
Generalised tonic-clonic seizure	1	1			1	1
Headache	4	4	4	4		
Hemianaesthesia	1	1			1	1
Hypertension	2	3	2	3		
Lymphadenopathy	1	1	1	1		
Malaise		3		1		2
Nausea		2		1		1
Product administration error		1		1		
Pruritus	1	1	1	1		
Pyrexia	2	2	2	2		
Tachycardia		2				2
Underdose		1		1		
Vomiting		2				2
Wrong product administered		1		1		
	16	35	10	17	6	18

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Country Where Event Occurred

THAILAND

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breast haematoma	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

TUNISIA

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia		2		2
Chills		1		1
Cough		1		1
COVID-19		1		1
Dizziness		1		1
Fatigue		2		2
Headache		1		1
Influenza like illness		1		1
Injection site pain		1		1
Joint range of motion decreased		1		1
Musculoskeletal stiffness		1		1
Myalgia		2		2
Pyrexia		1		1
Vaccination site pain		2		2
Vertigo		1		1
		19		19

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dizziness		1		1
Dysgeusia		1		1
Face oedema	1	1	1	1
Headache	1	1	1	1
Hypertension	1	2	1	2
Pain in extremity	1	1	1	1
Paraesthesia		1		1
Skin swelling	1	1	1	1
Vaccination site pain	1	1	1	1
Vasculitis	1	1	1	1
	7	11	7	11

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea	1	1	1	1
Herpes zoster	4	4	4	4
Influenza	1	1	1	1
	6	6	6	6

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Country Where Event Occurred

TURKEY

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose		1		1		
Adverse event	1	1	1	1		
Anaphylactic reaction		1				1
Aphasia	1	1			1	1
Arthralgia	3	5	2	4	1	1
Asthenia	4	5	4	5		
Back pain	7	7	6	6	1	1
Blister	1	1	1	1		
Blood pressure increased	1	1	1	1		
Blood pressure systolic increased	1	1			1	1
Body temperature decreased	1	1	1	1		
Bone pain	1	1	1	1		
Burning sensation	1	1	1	1		
Chills	2	2	2	2		
Contusion	1	1	1	1		
Cough		1		1		
COVID-19		2		1		1
Depressed level of consciousness	1	1			1	1
Dizziness	4	6	4	6		
Drug ineffective		1				1
Dry mouth	1	1	1	1		
Dysphagia	1	1	1	1		
Dyspnoea	2	3		1	2	2
Erythema	1	1	1	1		
Fatigue	1	2	1	2		
Feeling abnormal	1	1			1	1
Feeling cold	1	1	1	1		
Feeling hot	1	1	1	1		
Headache	13	16	12	15	1	1
Heart rate increased	1	1			1	1
Herpes zoster	1	1	1	1		
Hypertension	2	2	1	1	1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia	5	5	5	5		
Hypokinesia	2	2	1	1	1	1
Hypotension	1	1	1	1		
Incorrect dose administered		1		1		
Incorrect route of product administration	1	1	1	1		
Influenza	1	1	1	1		
Invasive ductal breast carcinoma		1				1
Joint range of motion decreased	1	1	1	1		
Limb deformity	1	1	1	1		
Lymphadenopathy	1	2	1	2		
Malaise	1	1	1	1		
Mastication disorder	1	1	1	1		
Maternal exposure during pregnancy	1	2	1	2		
Mouth ulceration	1	1	1	1		
Muscle contracture	1	1	1	1		
Myalgia	5	5	5	5		
Nasopharyngitis	1	1	1	1		
Nausea	3	3	3	3		
Neck pain	1	1	1	1		
Off label use	1	1	1	1		
Oropharyngeal pain	2	2	2	2		
Pain	2	2	2	2		
Pain in extremity	8	8	7	7	1	1
Paraesthesia	1	1	1	1		
Pelvic pain	1	1			1	1
Peripheral swelling	1	1	1	1		
Presyncope	1	1			1	1
Product preparation error		1		1		
Product use issue	1	1	1	1		
Pruritus	1	1			1	1
Pyrexia	8	9	8	9		
Rash	1	1	1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash pruritic	1	1	1	1		
Renal pain	1	1	1	1		
Restless legs syndrome	1	1	1	1		
Rhinorrhoea	1	1	1	1		
Skin texture abnormal	1	1	1	1		
Somnolence	1	1	1	1		
Suspected COVID-19		1		1		
Toothache		1		1		
Tremor	1	1	1	1		
Urine abnormality	1	1	1	1		
Vaccination site bruising	1	1	1	1		
Vaccination site cellulitis	1	1			1	1
Vaccination site hypoaesthesia	1	1	1	1		
Vaccination site pain	6	8	6	8		
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	1	1	1	1		
	131	157	114	136	17	21

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	2	2	2	2		
Asthenia	4	6	4	6		
Axillary pain	1	1	1	1		
Back pain	2	3	1	2	1	1
Blister	2	2	2	2		
Burning sensation	1	1	1	1		
Chest pain	2	2	1	1	1	1
Chills	1	2	1	2		
Concentric sclerosis	1	1			1	1
COVID-19	1	2		1	1	1
Cytomegalovirus infection	1	1			1	1
Deafness	1	1			1	1
Dizziness	1	1	1	1		
Drug ineffective	1	1			1	1
Dry skin		1		1		
Electrocardiogram abnormal	1	1			1	1
Erythema	3	5	3	5		
Eye pain	1	1	1	1		
Fatigue	2	3	2	3		
Feeling cold	1	1	1	1		
Feeling hot	1	1	1	1		
Guillain-Barre syndrome	1	1			1	1
Headache	5	7	5	7		
Head discomfort	1	1	1	1		
Heart rate increased	1	1	1	1		
Herpes zoster		1		1		
Hyperacusis	1	1	1	1		
Hyperhidrosis	1	1	1	1		
Hypersensitivity	3	3	2	2	1	1
Incorrect route of product administration	1	1	1	1		
Malaise	1	2	1	2		
Meningitis		1				1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	2	2	2	2		
Nausea		1		1		
Nightmare	1	1	1	1		
Oropharyngeal pain		1		1		
Otitis media	1	1	1	1		
Pain in extremity	4	5	4	5		
Paternal exposure during pregnancy	1	1	1	1		
Peripheral swelling	1	1	1	1		
Product use issue	1	1	1	1		
Pruritus	5	6	5	6		
Pyrexia	1	3	1	3		
Rash	2	2	2	2		
Rash erythematous	1	1	1	1		
Rash pruritic	1	1	1	1		
Sensitive skin	1	1	1	1		
Sleep disorder	1	1	1	1		
Somnolence	1	1	1	1		
Swelling	1	1	1	1		
Swelling face		1		1		
Tinnitus	3	3	3	3		
Tonsillar hypertrophy		1		1		
Toothache		1		1		
Urticaria		1		1		
Vaccination site pain	2	3	2	3		
Vein disorder	1	1	1	1		
Vomiting		1		1		
	76	102	66	91	10	11

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Asthenia	1	1	1	1		
Chills	1	1			1	1
Dizziness	1	1	1	1		
Dyspnoea	1	1	1	1		
Headache	1	1			1	1
Hypoaesthesia	1	1	1	1		
Malaise	1	1	1	1		
Muscle spasms	1	1	1	1		
Overdose		1		1		
Pain	1	1	1	1		
Presyncope	1	1	1	1		
Product preparation error		1		1		
Pyrexia	1	1			1	1
Seizure	1	1			1	1
Simple partial seizures	1	1			1	1
Syncope	1	1			1	1
Thrombosis	1	1			1	1
Vaccination site pain	1	2	1	2		
Vaccination site swelling	1	1	1	1		
	18	21	11	14	7	7

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred
TURKS AND CAICOS ISLANDS

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fatigue		1		1		
Generalised tonic-clonic seizure		1				1
Haemorrhagic stroke		1				1
Myalgia		1		1		
Neck mass		1		1		
Seizure		1				1
		6		3		3

* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

UKRAINE

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypoaesthesia		1		1
		1		1

* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

UNITED ARAB EMIRATES

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* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		4		4		
Anaphylactic shock	1	1			1	1
Arthralgia		1		1		
Asthenia		1		1		
Babesiosis		1				1
Back pain		1		1		
Bone pain		1		1		
Chest discomfort		1		1		
Chest pain		1				1
Chills		3		3		
COVID-19	1	3		1	1	2
Depressed level of consciousness		1				1
Depressed mood		1				1
Dizziness	1	4	1	3		1
Drug ineffective	1	3			1	3
Dysgeusia		2		2		
Facial paralysis		1				1
Fatigue		5		5		
Feeling abnormal		2		2		
Fibromyalgia		1		1		
Headache		4		3		1
Head discomfort	1	1	1	1		
Hyperhidrosis		1		1		
Hypertension		1				1
Hypoacusis		1				1
Hypoaesthesia		1				1
Injected limb mobility decreased		1		1		
Injection site pain		1		1		
Lyme disease		1				1
Lymphadenopathy	1	2	1	2		
Maternal exposure timing unspecified		1		1		
Muscle fatigue		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia		2		2		
Nausea		6		5		1
Neuralgia		1		1		
Neurotoxicity		1				1
Off label use		1		1		
Pain		2		2		
Pain in extremity		1		1		
Paraesthesia		1		1		
Product use issue		1		1		
Pruritus		1		1		
Pyrexia		7		7		
Rash		1		1		
Respiratory tract irritation		1		1		
SARS-CoV-2 ant body test negative		2		2		
Sciatica		1		1		
Skin irritation		1		1		
Sleep deficit		1		1		
Somnolence		1		1		
Suspected COVID-19		1				1
Swelling	1	2	1	1		1
Syncope	1	1			1	1
Tremor		1		1		
Vaccination site pain		5		5		
Vision blurred		1		1		
Vomiting		2		2		
	8	99	4	77	4	22

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		1		1		
Axillary pain	1	1	1	1		
Back pain		2		2		
Bell's palsy		1				1
Blindness unilateral		1				1
Blood pressure decreased		1				1
Chest pain		1				1
Cough		1		1		
COVID-19		5				5
Death		1				1
Decreased appetite		1		1		
Dizziness		1		1		
Drug ineffective		4				4
Dyspnoea	1	3	1	2		1
Erectile dysfunction		1				1
Erythropeia		1				1
Fatigue		2		2		
Gait disturbance		1		1		
Headache	2	5	2	5		
Head injury		1				1
Heart rate increased	1	1	1	1		
Hypertension		1		1		
Hypoxia		1				1
Inappropriate schedule of product administration	1	2	1	2		
Lethargy	1	1	1	1		
Loss of consciousness		1				1
Lymphadenopathy	1	2	1	2		
Lymph node pain		1		1		
Nausea	1	1	1	1		
Ocular vascular disorder		1				1
Ophthalmic herpes zoster		1				1
Pain	1	2	1	2		

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* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia		4		4		
Rash		2		1		1
Rectal haemorrhage		1				1
SARS-CoV-2 ant body test negative		1		1		
Sciatica		1		1		
Sudden death		1				1
Tachypnoea		1		1		
Thrombosis		2				2
Urticaria		1				1
Vaccination site pain	1	3	1	3		
Vision blurred		1		1		
	11	68	11	40		28

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	1	1	1	1		
COVID-19	2	5	1	2	1	3
Drug ineffective	1	2			1	2
Headache	1	1	1	1		
Nasopharyngitis		1		1		
Pneumonia		1				1
Pyrexia	1	1	1	1		
Vaccination failure		1				1
	6	13	4	6	2	7

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* AE=Adverse Event

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Country Where Event Occurred

UNITED KINGDOM

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- * I=Interval, C=Cumulative
- * AE=Adverse Event
- * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal adhesions		1						1
Abdominal discomfort	62	238	1	4	30	84	32	154
Abdominal distension	28	114			12	40	16	74
Abdominal lymphadenopathy		1						1
Abdominal mass		1						1
Abdominal migraine	1	2			1	1		1
Abdominal pain	106	439			42	143	64	296
Abdominal pain lower	12	36			2	7	10	29
Abdominal pain upper	170	694		2	60	201	110	493
Abdominal rigidity	1	6			1	3		3
Abdominal symptom		1						1
Abdominal tenderness	2	10				3	2	7
Abnormal behaviour	3	7			2	3	1	4
Abnormal clotting factor	1	1					1	1
Abnormal dreams	13	53			11	33	2	20
Abnormal faeces	1	8			1	6		2
Abnormal loss of weight	1	2					1	2
Abnormal sensation in eye		11				5		6
Abnormal uterine bleeding		1						1
Abnormal weight gain	1	2					1	2
Abortion missed	3	4					3	4
Abortion spontaneous	13	64	2	2			13	64
Abscess	1	6				2	1	4
Abscess jaw		1						1
Abscess oral		3				1		2
Accident	1	2				1	1	1
Accidental exposure to product	2	8			2	7		1
Accidental overdose		3				2		1
Achenbach syndrome		1				1		
Acidosis		1				1		
Acne	5	13			2	6	3	7
Acne pustular		1				1		

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acoustic neuroma		1
Acrochordon		1
Activated partial thromboplastin time prolonged	3	7
Activated partial thromboplastin time shortened		2
Acute abdomen		2
Acute aortic syndrome	1	1
Acute cardiac event		1
Acute coronary syndrome	1	3
Acute disseminated encephalomyelitis		1
Acute febrile neutrophilic dermatosis		1
Acute kidney injury	2	21
Acute motor axonal neuropathy		1
Acute myocardial infarction		9
Acute respiratory failure		1
Acute vestibular syndrome		1
Addison's disease		1
Adenomyosis	1	1
Administration site bruise	1	1
Administration site joint movement impairment		2
Adnexa uteri pain	1	5
Adrenocortical insufficiency acute	1	8
Adverse drug reaction	1	23
Adverse reaction		
Aerophagia	1	2
Affective disorder	1	2
Affect lability	1	4
African trypanosomiasis		2
Age-related macular degeneration		1
Ageusia	29	149
Aggression		5
Agitated depression		1
Agitation	6	40

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				3	7
					2
					2
				1	1
					1
				1	3
					1
					1
				2	21
					1
			1		
					1
				1	1
		1	1		
					2
				1	5
				1	8
		1	14		9
	1				
		1	1		1
				1	2
				1	4
					2
					1
	1	18	66	11	83
			1		4
					1
		5	13	1	27

* I=Interval, C=Cumulative

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Airway burns		1
Airway secretion clearance therapy		1
Akathisia		1
Alanine aminotransferase increased	1	11
Alcohol interaction		1
Alcohol intolerance		2
Alcohol poisoning		1
Allergic cough		4
Allergic oedema	2	5
Allergic reaction to excipient	1	5
Allergy to arthropod bite		2
Allergy to arthropod sting		1
Allergy to chemicals	2	2
Allergy to metals	1	1
Allergy to vaccine	3	48
Allodynia	2	5
Alopecia	14	37
Alopecia areata	3	5
Alopecia totalis		1
Altered state of consciousness	2	10
Alveolitis		1
Amblyopia		2
Amenorrhoea	26	40
Amnesia	9	39
Amylase increased		1
Anaemia	14	31
Anaemia vitamin B12 deficiency		1
Anaesthesia oral	1	1
Anal fissure		1
Analgesic drug level		1
Anal haemorrhage		5
Anal incontinence	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
		1	3		8
					1
					2
					1
					4
			1	2	4
		1	1		4
			1		1
					1
				2	2
		1	1		
		1	21	2	27
		1	1	1	4
		2	5	12	32
				3	5
					1
				2	10
					1
			1		1
		15	17	11	23
		2	7	7	32
			1		
		1	3	13	28
					1
		1	1		
					1
					1
					5
	1	1	2	1	3

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anal pruritus		1
Anal sphincter atony		1
Anaphylactic reaction	27	250
Anaphylactic shock	6	18
Anaphylactoid reaction	2	15
Anaphylactoid shock	1	2
Anaphylaxis prophylaxis		1
Aneurysm		1
Anger		3
Angina bullosa haemorrhagica		1
Angina pectoris	5	29
Angina unstable		1
Angioedema	12	99
Angiopathy	1	1
Angle closure glaucoma	1	1
Angular cheilitis		1
Anisocytosis		2
Anisomastia		1
Ankle fracture		2
Ankyloglossia congenital	1	1
Ankylosing spondylitis		4
Anorectal discomfort		1
Anorectal swelling		1
Anorgasmia	1	2
Anosmia	9	58
Anovulatory cycle	3	4
Antibody test positive		1
Anticholinergic syndrome		1
Anticoagulation drug level increased		1
Antinuclear antibody	1	1
Antinuclear ant body increased	1	1
Antiphospholipid syndrome	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
				27	250
				6	18
				2	15
				1	2
					1
					1
			1		2
					1
				5	29
					1
				12	99
				1	1
				1	1
					1
					2
			1		
					2
				1	1
					4
			1		
					1
		1	1		1
		7	28	2	30
		2	2	1	2
			1		
					1
					1
				1	1
		1	1		
				1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Antisynthetase syndrome	1	1
Anti-thyroid antibody positive		1
Anuria		3
Anxiety	30	210
Aortic aneurysm rupture	1	1
Aortic arteriosclerosis		1
Aortic embolus		2
Aortic stenosis		2
Apathy	4	13
Aphasia	9	29
Aphonia	7	30
Aphthous ulcer	1	12
Aplasia pure red cell	1	1
Apnoea		2
Appendicitis	2	5
Appendicitis perforated		1
Appetite disorder		7
Apraxia		1
Aptyalism		1
Areflexia		2
Arrhythmia	4	22
Arrhythmia supraventricular	1	4
Arterial disorder		1
Arterial occlusive disease		1
Arterial stenosis	1	2
Arterial thrombosis		2
Arteriosclerosis coronary artery		1
Arteritis	1	2
Arthralgia	607	3,324
Arthritis	21	82
Arthritis reactive	4	12
Arthritis viral		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
					3
		14	80	16	130
				1	1
					1
					2
					2
			4	4	9
		2	8	7	21
	1	2	8	5	22
			3	1	9
				1	1
					2
				2	5
					1
			1		6
			1		
			1		
					2
				4	22
			1	1	3
					1
					1
				1	2
6	22	247	1071	360	2253
		5	14	16	68
				4	12
					1

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arthropathy	3	14
Arthropod bite		2
Ascites		2
Asphyxia	1	1
Aspiration		3
Asthenia	185	908
Asthenopia	14	66
Asthma	23	135
Asthma prophylaxis		1
Asymptomatic COVID-19	2	9
Ataxia	1	3
Atelectasis		1
Atonic seizures		3
Atopy		1
Atrial fibrillation	13	68
Atrial flutter	1	2
Atrial tachycardia		1
Atrioventricular block		2
Attention deficit hyperactivity disorder		1
Atypical femur fracture		1
Auditory disorder	1	6
Aura	2	12
Auricular swelling		2
Autism spectrum disorder	1	1
Autoimmune anaemia	1	1
Autoimmune disorder	3	16
Autoimmune haemolytic anaemia	2	4
Autoimmune hepatitis	2	2
Autoimmune thyroid disorder	1	1
Autonomic nervous system imbalance	1	4
Autoscopy		3
Axillary lymphadenectomy		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	5	2	9
			1		1
					2
				1	1
					3
4	5	75	296	110	612
		8	21	6	45
		5	25	18	110
					1
				2	9
		1	1		2
					1
					3
					1
				13	68
				1	2
					1
					2
					1
					1
				1	6
		1	6	1	6
					2
				1	1
				1	1
				3	16
				2	4
				2	2
				1	1
				1	4
			1		2
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Axillary mass	31	106
Axillary pain	240	838
Axonal neuropathy		1
Bacille Calmette-Guerin scar reactivation	3	9
Back disorder	1	1
Back injury		1
Back pain	205	894
Bacterial diarrhoea		1
Bacterial infection	2	2
Balance disorder	52	174
Barotitis media	1	1
Basal cell carcinoma		1
Basedow's disease		1
Bed rest		1
Bedridden	4	20
Behcet's syndrome		5
Bell's palsy	33	168
Benign lymph node neoplasm	1	1
Biliary colic	1	2
Binocular eye movement disorder		1
Bipolar disorder	2	3
Bipolar I disorder		1
Bladder discomfort		1
Bladder disorder	1	4
Bladder dysfunction	1	2
Bladder irritation		1
Bladder pain	2	8
Bleeding time abnormal		1
Blepharitis	1	3
Blepharospasm	11	24
Blindness	5	26
Blindness transient	3	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		13	39	18	67
		78	250	162	588
					1
		1	3	2	6
		1	1		
					1
	1	85	301	120	593
					1
				2	2
		18	43	34	131
		1	1		
					1
					1
					1
		3	6	1	14
					5
				33	168
				1	1
				1	2
					1
				2	3
					1
			1		
		1	1		3
				1	2
					1
				2	8
					1
			1	1	2
		4	6	7	18
				5	26
				3	10

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Blindness unilateral	1	6
Blister	40	120
Blister rupture		1
Blood alcohol decreased	1	1
Blood alkaline phosphatase increased		4
Blood blister	3	12
Blood calcium decreased	1	1
Blood cholesterol increased	1	3
Blood count	1	1
Blood count abnormal		1
Blood creatine phosphokinase increased		2
Blood creatinine increased		2
Blood disorder	2	2
Blood fibrinogen decreased		1
Blood folate decreased	1	2
Blood follicle stimulating hormone increased	1	1
Blood glucose		1
Blood glucose abnormal	1	3
Blood glucose decreased	3	15
Blood glucose fluctuation		11
Blood glucose increased	5	43
Blood immunoglobulin G increased		1
Blood immunoglobulin M abnormal		1
Blood immunoglobulin M increased		1
Blood iron decreased	1	2
Blood iron increased		1
Blood ketone body	1	1
Blood ketone body increased		1
Blood ketone body present		1
Blood lactate dehydrogenase increased		1
Blood lactic acid increased		2
Blood luteinising hormone abnormal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	6
		19	47	21	73
			1		
				1	1
			1		3
		1	2	2	10
				1	1
				1	3
		1	1		
					1
					2
			1		1
				2	2
					1
			1	1	1
				1	1
					1
			1	1	2
			2	3	13
			4		7
			10	5	33
			1		
					1
			1		
			1	1	1
			1		
				1	1
					1
					1
			1		1
			1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood magnesium decreased		1
Blood oestrogen increased		1
Blood pH		2
Blood pH abnormal	1	1
Blood pH increased	1	4
Blood phosphorus decreased		1
Blood potassium abnormal		1
Blood potassium decreased		3
Blood potassium increased	1	3
Blood pressure abnormal	4	10
Blood pressure decreased	6	38
Blood pressure diastolic decreased		1
Blood pressure fluctuation	6	14
Blood pressure increased	31	185
Blood pressure orthostatic abnormal		1
Blood pressure orthostatic decreased	1	2
Blood pressure systolic decreased		2
Blood pressure systolic increased		5
Blood prolactin increased		1
Blood sodium decreased	3	7
Blood test	1	1
Blood test abnormal	1	7
Blood testosterone increased		1
Blood thyroid stimulating hormone increased		1
Blood urea increased		1
Blood urine	2	3
Blood urine present	3	14
Bloody discharge		1
Blue toe syndrome	2	6
Body fat disorder		1
Body temperature	5	22
Body temperature abnormal	12	71

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
					2
				1	1
			2	1	2
					1
					1
			1		2
			1	1	2
			4	4	6
		3	13	3	25
			1		
		3	5	3	9
		5	74	26	111
					1
				1	2
					2
			2		3
			1		
		1	2	2	5
				1	1
				1	7
			1		
			1		
					1
				2	3
		1	6	2	8
					1
		1	3	1	3
			1		
		4	13	1	9
		6	26	6	45

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Body temperature decreased	10	36
Body temperature fluctuation	5	26
Body temperature increased	38	243
Bone contusion		1
Bone disorder	3	4
Bone neoplasm	1	3
Bone pain	36	192
Bone swelling	3	11
Bowel movement irregularity	2	5
Brachial plexus injury		1
Bradycardia	3	22
Bradykinesia	3	9
Bradyphrenia	6	16
Brain injury	1	3
Brain neoplasm		1
Brain oedema		2
Brain stem stroke		1
Breast abscess	2	3
Breast cancer	4	13
Breast cancer stage I	1	1
Breast cancer stage III		1
Breast cellulitis		1
Breast cyst		2
Breast discomfort	3	9
Breast disorder		1
Breast engorgement		1
Breast enlargement		3
Breast haematoma	1	1
Breast inflammation	2	4
Breast mass	3	21
Breast milk discolouration		1
Breast oedema		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	10	6	26
		3	11	2	15
	2	21	110	17	133
			1		
		2	2	1	2
			1	1	2
		9	57	27	135
		1	5	2	6
		1	2	1	3
					1
				3	22
		1	2	2	7
		3	5	3	11
				1	3
					1
					2
					1
				2	3
				4	13
				1	1
					1
			1		1
		1	4	2	5
					1
					1
					3
		1	1		
		1	1	1	3
			4	3	17
			1		
					1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Breast pain	59	185
Breast prosthesis user		1
Breast swelling	16	59
Breast tenderness	12	29
Breath odour	2	8
Breath sounds abnormal		1
Bronchial disorder		1
Bronchial secretion retention		1
Bronchiectasis	3	7
Bronchitis	1	6
Bronchopulmonary aspergillosis		1
Bronchospasm	3	10
Bruxism	3	5
Burning feet syndrome		1
Burning mouth syndrome	2	2
Burning sensation	56	220
Burn oesophageal		1
Burn oral cavity		1
Burns second degree	2	5
Bursitis	5	16
Butterfly rash		3
Candida infection	1	7
Capsular contracture associated with breast implant	1	1
Cardiac arrest	1	25
Cardiac discomfort		2
Cardiac disorder	6	11
Cardiac failure	2	15
Cardiac failure congestive		4
Cardiac flutter	19	53
Cardiac murmur	1	7
Cardiogenic shock		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		21	47	38	138
			1		
		2	17	14	42
		6	10	6	19
		2	5		3
			1		
					1
			1		
				3	7
			1	1	5
					1
		1	3	2	7
		1	1	2	4
					1
				2	2
		26	74	30	146
					1
					1
			2	2	3
				5	16
			1		2
			2	1	5
				1	1
				1	25
			1		1
		2	2	4	9
				2	15
					4
				19	53
			1	1	6
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiomegaly	1	1
Cardiomyopathy		1
Cardiopulmonary failure		1
Cardiospasm	1	1
Cardiovascular disorder	1	3
Carotid artery occlusion	1	2
Carpal tunnel syndrome	1	5
Cartilage injury	1	1
Cataplexy		2
Cataract	3	3
Catarrh	1	5
Cavernous sinus thrombosis		1
Cells in urine		1
Cellulitis	11	97
Central nervous system vasculitis		1
Cerebellar stroke		3
Cerebral artery embolism	1	1
Cerebral artery occlusion		1
Cerebral artery thrombosis	1	3
Cerebral congestion	1	1
Cerebral disorder	1	3
Cerebral haemorrhage	4	20
Cerebral infarction	5	17
Cerebral small vessel ischaemic disease	1	1
Cerebral thrombosis		9
Cerebral venous sinus thrombosis	5	15
Cerebral venous thrombosis	1	2
Cerebrospinal fluid leakage		1
Cerebrovascular accident	33	155
Cerebrovascular disorder	1	1
Cervical dysplasia		1
Cervical radiculopathy		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
					1
				1	1
				1	3
				1	2
			1	1	4
				1	1
					2
				3	3
			2	1	3
					1
					1
				11	97
					1
					3
				1	1
					1
				1	3
				1	1
		1	3		
				4	20
				5	17
				1	1
					9
				5	15
				1	2
					1
				33	155
				1	1
					1
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cervicobrachial syndrome		1
Cervicogenic headache	1	2
Chalazion		2
Change of bowel habit		1
Chapped lips		7
Charles Bonnet syndrome		1
Cheilitis	3	10
Chest crushing	1	3
Chest discomfort	99	496
Chest injury	1	4
Chest pain	167	737
Chest X-ray abnormal		1
Chillblains	4	24
Chills	621	3,681
Choking	4	10
Choking sensation	1	5
Cholecystitis infective		1
Cholelithiasis		3
Chorea		1
Chorioretinopathy		1
Choroidal neovascularisation		3
Chromatopsia		1
Chromaturia	5	21
Chronic fatigue syndrome	6	34
Chronic gastritis		1
Chronic kidney disease	1	6
Chronic lymphocytic leukaemia	2	3
Chronic lymphocytic leukaemia recurrent	1	1
Chronic obstructive pulmonary disease	1	6
Chronic spontaneous urticaria	1	2
Circulatory collapse	2	25
Circumoral swelling		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1	1	1
					2
			1		
			3		4
					1
		1	5	2	5
				1	3
	1	47	161	52	335
1	4	53	176	114	561
			1		
		4	18		6
6	21	303	1386	318	2295
				4	10
			1	1	4
					1
					3
					1
					1
					3
			1		
		1	9	4	12
		3	4	3	30
					1
				1	6
				2	3
				1	1
				1	6
				1	2
				2	25
			1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Circumstance or information capable of leading to medication error		2
Clavicle fracture	1	2
Clinically isolated syndrome	1	1
Clonic convulsion		1
Clonus	1	1
Clostridium difficile colitis		1
Clostridium difficile infection		1
Clot retraction		1
Clumsiness	2	5
Cluster headache	18	74
Coagulation time prolonged		1
Coagulopathy	1	9
Coating in mouth	2	2
Coccydynia		2
Coeliac disease		4
Cognitive disorder	10	32
Coital bleeding	1	1
Cold-stimulus headache	3	6
Cold sweat	31	239
Cold urticaria		1
Colitis	5	13
Colitis ischaemic		1
Colitis microscopic		2
Colitis ulcerative	4	18
Colon cancer		1
Coma	1	3
Communication disorder		4
Complicated appendicitis	1	1
Concussion		1
Condition aggravated	63	278
Confusional arousal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		1	1		1
				1	1
					1
		1	1		
					1
					1
		1	1	1	4
1	1	5	20	13	54
					1
			1	1	8
		1	1	1	1
			2		
					4
		2	3	8	29
				1	1
		1	1	2	5
		9	74	22	165
			1		
			1	5	12
					1
					2
				4	18
					1
				1	3
			1		3
				1	1
					1
	1	14	61	49	217
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Confusional state	50	283
Congenital cystic lung		1
Congestive cardiomyopathy		1
Congestive hepatopathy		1
Conjunctival haemorrhage	3	17
Conjunctival hyperaemia		1
Conjunctival oedema		2
Conjunctivitis	1	17
Conjunctivitis bacterial		2
Conjunctivitis viral		1
Connective tissue disorder	1	1
Consciousness fluctuating		4
Constipation	6	56
Constricted affect		1
Contraindicated product administered		2
Contraindicated product prescribed	1	1
Contrast media reaction		1
Contusion	80	269
Conversion disorder	2	2
Coordination abnormal	2	24
Corneal abrasion		1
Corneal disorder		1
Corneal erosion		1
Corneal graft rejection	3	3
Corneal reflex decreased		1
Coronary artery disease		3
Coronary artery occlusion		1
Coronary artery stenosis		1
Coronavirus infection		2
Cor pulmonale		1
Cortisol decreased		1
Costochondritis	4	20

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	10	53	40	230
					1
					1
				3	17
					1
					2
			4	1	13
					2
			1		
				1	1
					4
		2	12	4	44
					1
			1		1
				1	1
					1
	1	25	93	55	176
				2	2
			6	2	18
					1
					1
				3	3
					1
					3
					1
					1
			1		1
					1
					1
		1	2	3	18

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Costovertebral angle tenderness		1
Cough	120	715
Cough variant asthma	1	1
COVID-19	70	398
COVID-19 immunisation		2
COVID-19 pneumonia		17
Cranial nerve disorder		1
Cranial nerve neoplasm benign	1	1
Cranial nerve palsies multiple		1
C-reactive protein abnormal		1
C-reactive protein increased	4	19
Creatinine renal clearance decreased		1
Crepitations	1	2
Creutzfeldt-Jakob disease		1
Crohn's disease	2	13
Crying	9	39
CT hypotension complex		1
Culture negative		1
Cutaneous sarcoidosis		2
Cutaneous symptom		1
Cutaneous vasculitis	1	2
Cyanosis	4	25
Cyanosis central		1
Cyclic vomiting syndrome		1
Cyclothymic disorder		1
Cyst	3	5
Cystitis	7	26
Cystitis interstitial		2
Cystitis-like symptom		1
Cytomegalovirus infection reactivation		1
Dairy intolerance	1	2
Dark circles under eyes	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
1	4	52	241	68	474
				1	1
1	3	20	103	50	295
					2
					17
					1
				1	1
					1
					1
		1	2	3	17
					1
		1	2		
					1
				2	13
		5	12	4	27
					1
					1
					2
					1
				1	2
		2	9	2	16
					1
					1
					1
		1	2	2	3
		2	7	5	19
					2
					1
					1
				1	2
		1	1	1	1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Deafness	15	60
Deafness bilateral	3	5
Deafness neurosensory	1	9
Deafness transitory	1	3
Deafness unilateral	3	16
Death	5	52
Decreased activity		2
Decreased appetite	119	650
Decreased embryo viability		1
Decreased immune responsiveness		2
Decreased interest	2	8
Decubitus ulcer		2
Deep vein thrombosis	26	79
Defaecation urgency		7
Deficiency anaemia		1
Dehydration	12	67
Delayed recovery from anaesthesia		2
Delirium	5	34
Delusion	1	4
Delusional perception		1
Dementia		5
Dementia Alzheimer's type		1
Demyelination	1	3
Dental caries		1
Dental discomfort	1	1
Depersonalisation/derealisation disorder		2
Depressed level of consciousness	3	19
Depressed mood	39	115
Depression	16	63
Depression suicidal		1
Derealisation		4
Dermal cyst	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				15	60
				3	5
				1	9
				1	3
				3	16
				5	52
			1		1
1	4	52	217	67	433
					1
					2
		1	3	1	5
					2
	1			26	79
					7
			1		
		4	21	8	46
			1		1
				5	34
		1	2		2
					1
					5
					1
				1	3
					1
				1	1
			1		1
				3	19
		15	30	24	85
		2	4	14	59
					1
			1		3
		1	1		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dermal filler injection		1
Dermatitis	10	37
Dermatitis allergic	7	54
Dermatitis atopic	1	7
Dermatitis bullous		5
Dermatitis contact	2	4
Dermatitis diaper		1
Dermatitis exfoliative		1
Dermatitis exfoliative generalised		1
Dermatitis infected		2
Dermatomyositis	2	5
Device connection issue	1	1
Device related infection		1
Device stimulation issue		1
Diabetes mellitus	1	11
Diabetes mellitus inadequate control	1	6
Diabetic complication		2
Diabetic diet		1
Diabetic eye disease		1
Diabetic ketoacidosis		5
Diabetic ketosis	1	1
Diaphragmalgia	1	5
Diarrhoea	311	1,622
Diarrhoea haemorrhagic		9
Diastolic hypertension		1
Diplegia	2	7
Diplopia	10	49
Discharge		2
Discoloured vomit		4
Discomfort	52	167
Disease progression	1	3
Disease recurrence	51	214

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		6	17	4	20
		3	18	4	36
		1	2		5
					5
				2	4
			1		
					1
					1
					2
				2	5
		1	1		
					1
			1		
				1	11
				1	6
					2
					1
			1		
					5
				1	1
			1	1	4
1	5	160	546	151	1076
					9
					1
				2	7
			13	10	36
					2
			2		2
	1	25	63	27	104
				1	3
1	2	11	28	40	186

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Disorganised speech		3
Disorientation	26	108
Disseminated intravascular coagulation		1
Dissociation	1	17
Dissociative amnesia		1
Disturbance in attention	43	178
Diverticulitis		4
Dizziness	639	3,131
Dizziness exertional	1	16
Dizziness postural	50	277
Dose calculation error		1
Dreamy state		1
Drooling	3	8
Drooping shoulder syndrome		1
Drug eruption	1	5
Drug hypersensitivity	2	17
Drug-induced liver injury		1
Drug ineffective	54	374
Drug interaction	2	10
Drug level decreased		1
Drug level fluctuating		1
Drug withdrawal syndrome	1	2
Dry eye	11	40
Dry lung syndrome	1	1
Dry mouth	39	189
Dry skin	22	68
Dry throat	14	68
Duodenal ulcer haemorrhage		1
Duodenogastric reflux		2
Dysaesthesia		2
Dysarthria	9	59
Dyschezia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		2
		6	21	20	87
					1
		1	9		8
			1		
		13	47	30	131
					4
2	15	270	1073	369	2058
			2	1	14
	1	21	86	29	191
			1		
			1		
		1	1	2	7
			1		
		1	2		3
			3	2	14
					1
1	2			54	374
		1	3	1	7
					1
					1
		1	1		1
		6	17	5	23
				1	1
	1	18	69	21	120
		8	29	14	39
	2	7	32	7	36
					1
			1		1
			1		1
		1	11	8	48
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dyschromatopsia	1	2
Dysgeusia	99	409
Dysgraphia		1
Dyshidrotic eczema	2	6
Dyskinesia	7	35
Dysmenorrhoea	74	103
Dysmorphism		1
Dyspepsia	18	92
Dysphagia	34	138
Dysphemia	3	6
Dysphonia	13	64
Dysphoria		1
Dyspnoea	253	1,263
Dyspnoea at rest	2	5
Dyspnoea exertional	14	56
Dysstasia	7	53
Dystonia		6
Dysuria	6	22
Ear canal erythema		1
Ear congestion	2	6
Ear discomfort	9	45
Ear disorder	2	11
Ear haemorrhage	2	3
Ear infection	4	27
Ear infection bacterial		1
Ear pain	88	321
Ear pruritus	2	8
Ear swelling	5	16
Eating disorder	4	23
Eating disorder symptom		1
Eczema	10	44
Eczema asteatotic	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	1
	1	67	222	32	187
					1
				2	6
		2	10	5	25
		30	41	44	62
					1
		9	32	9	60
		16	52	18	86
		1	1	2	5
1	1	6	25	7	39
					1
	1	81	296	172	967
				2	5
		1	12	13	44
			15	7	38
					6
		3	7	3	15
			1		
		1	1	1	5
		5	19	4	26
		1	5	1	6
		1	1	1	2
		1	7	3	20
					1
		30	94	58	227
		1	3	1	5
		4	6	1	10
			1	4	22
					1
		3	9	7	35
				1	2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eczema eyelids		2
Eczema herpeticum		1
Eczema weeping		1
Ehlers-Danlos syndrome	1	2
Electric shock		2
Electric shock sensation	2	7
Electrocardiogram abnormal		5
Electrocardiogram change		1
Electrocardiogram ST segment elevation		1
Electrocardiogram T wave inversion	1	1
Embolic stroke		4
Embolism	17	42
Emotional disorder	9	27
Emotional distress	5	19
Emphysema	1	2
Encephalitis	1	7
Encephalopathy		1
Endometriosis	6	10
Endometritis	1	1
Energy increased		2
Enlarged uvula	4	6
Enteritis		2
Enthesopathy		1
Enuresis	3	7
Eosinophil count increased		3
Eosinophilia	2	3
Ephelides		1
Epicondylitis	1	4
Epigastric discomfort		7
Epiglottitis		1
Epilepsy	17	58
Epileptic aura		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
					1
			1		
				1	2
					2
		1	5	1	2
			1		4
			1		
					1
				1	1
					4
				17	42
		1	8	8	19
		1	4	4	15
		1	1		1
				1	7
					1
		1	2	5	8
				1	1
			1		1
		3	4	1	2
					2
					1
			1	3	6
			1		2
			1	2	2
			1		
		1	2		2
			2		5
					1
				17	58
					1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Epileptic encephalopathy		1
Epinephrine increased	1	3
Epiphyses premature fusion		1
Episcleritis		4
Epistaxis	46	191
Epstein-Barr virus infection		2
Erectile dysfunction		3
Eructation	3	17
Erythema	192	834
Erythema annulare		2
Erythema induratum	1	1
Erythema multiforme	3	17
Erythema nodosum	2	6
Erythema of eyelid	1	3
Escherichia bacteraemia	1	1
Essential hypertension		1
Essential thrombocythaemia		1
Euphoric mood	3	13
Eustachian tube disorder		1
Eustachian tube dysfunction		2
Excessive cerumen production	1	3
Excessive exercise	1	1
Excessive granulation tissue		1
Exercise tolerance decreased	2	9
Exertional headache		3
Exfoliative rash	2	8
Exophthalmos		1
Expired product administered	1	3
Exposure during pregnancy	15	47
Exposure keratitis		1
Exposure to extreme temperature		1
Exposure to SARS-CoV-2		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	2		1
					1
			1		3
		23	70	23	121
					2
					3
		2	3	1	14
	2	114	437	78	397
					2
				1	1
				3	17
				2	6
				1	3
				1	1
					1
			5	3	8
					1
					2
				1	3
				1	1
					1
		1	2	1	7
			2		1
				2	8
					1
		1	2		1
	1	12	38	3	9
			1		
					1
			1		2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Exposure via breast milk	5	16
Exposure via skin contact	2	2
Extensive swelling of vaccinated limb	1	9
Extensor plantar response		1
External ear cellulitis		1
External ear disorder	1	1
External ear inflammation	1	1
External ear pain		4
Extraocular muscle disorder		1
Extraocular muscle paresis		1
Extrasystoles	11	25
Eye abscess		1
Eye allergy		2
Eye colour change	1	2
Eye complication associated with device		1
Eye contusion		9
Eye discharge	4	13
Eye disorder	8	29
Eye haematoma	1	2
Eye haemorrhage	6	13
Eye infection	3	9
Eye inflammation	3	12
Eye injury	3	5
Eye irritation	13	49
Eyelid bleeding		1
Eyelid cyst		1
Eyelid disorder	2	4
Eyelid exfoliation	1	2
Eyelid function disorder	2	4
Eyelid infection	1	1
Eyelid irritation	1	3
Eyelid margin crusting		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	6	3	10
		2	2		
			6	1	3
					1
					1
				1	1
		1	1		
			3		1
					1
					1
		1	4	10	21
					1
			1		1
		1	1		1
					1
	1		4		5
		2	3	2	10
		3	10	5	19
				1	2
				6	13
		2	2	1	7
			3	3	9
		1	1	2	4
		7	15	6	34
					1
					1
		1	2	1	2
				1	2
		2	3		1
				1	1
			1	1	2
			1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eyelid oedema	1	5
Eyelid pain	2	8
Eyelid ptosis	3	14
Eyelid rash	1	6
Eyelid skin dryness	1	1
Eyelids pruritus		7
Eye movement disorder	2	8
Eye oedema		4
Eye pain	110	397
Eye paraesthesia		1
Eye pruritus	22	97
Eye swelling	44	193
Eye symptom		1
Face crushing		1
Face injury	1	4
Face oedema	1	10
Facial discomfort	2	10
Facial nerve disorder		1
Facial neuralgia	2	9
Facial pain	16	110
Facial paralysis	25	147
Facial paresis	4	35
Facial spasm	3	11
Factitious disorder		1
Faecal calprotectin		1
Faeces discoloured	2	11
Faeces hard		1
Faeces pale		2
Faeces soft	2	4
Failed in vitro fertilisation		1
Fall	18	116
False positive investigation result		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	1	3
			1	2	7
		1	8	2	6
			2	1	4
				1	1
			2		5
		1	2	1	6
			3		1
		47	123	63	274
			1		
	2	13	44	9	53
	2	9	52	35	141
					1
					1
			1	1	3
		1	4		6
			2	2	8
			1		
		1	4	1	5
		6	33	10	77
	2			25	147
		2	13	2	22
		1	6	2	5
					1
					1
		2	6		5
					1
					2
				2	4
					1
		2	31	16	85
					1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Familial hemiplegic migraine		1
Familial periodic paralysis		1
Fatigue	1,512	7,753
Fear	4	17
Fear of falling		1
Fear of injection		1
Febrile convulsion	2	10
Febrile infection	1	1
Feeding disorder	12	49
Feeling abnormal	168	776
Feeling cold	113	627
Feeling drunk	7	37
Feeling hot	164	695
Feeling jittery	2	19
Feeling of body temperature change	52	220
Feeling of despair	1	5
Feeling of relaxation	1	2
Femoral artery embolism	1	1
Femoral neck fracture		2
Femur fracture		1
Fever neonatal	1	1
Fibrin D dimer increased	5	14
Fibromyalgia	14	44
Fine motor skill dysfunction	1	7
Finger deformity	1	2
Fingerprint loss	1	1
Flank pain	3	15
Flashback		1
Flat affect	1	4
Flatulence	15	55
Fluid imbalance		2
Fluid intake reduced		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
18	75	681	2718	831	5035
		2	5	2	12
					1
			1		
		1	7	1	3
				1	1
		8	24	4	25
2	3	72	280	96	496
1	6	48	241	65	386
		4	14	3	23
1	1	77	333	87	362
			6	2	13
		24	84	28	136
				1	5
				1	2
				1	1
					2
					1
				1	1
				5	14
	1	5	9	9	35
			1	1	6
			1	1	1
		1	1		
			9	3	6
					1
			2	1	2
		7	18	8	37
			1		1
					2

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Fluid retention	5	14
Flushing	46	232
Focal dyscognitive seizures		1
Foetal death	1	3
Foetal exposure during pregnancy		1
Foetal heart rate abnormal	1	1
Foetal hypokinesia	1	1
Follicular lymphoma	1	1
Folliculitis		3
Food allergy	2	7
Food aversion		4
Food craving	1	4
Food intolerance	1	3
Food poisoning		2
Food refusal	1	3
Forced expiratory volume increased		1
Foreign body in urogenital tract	1	1
Foreign body sensation in eyes	1	13
Formication	4	19
Fracture		1
Fracture blisters		1
Fracture pain	1	1
Freezing phenomenon	1	3
Frequent bowel movements	2	17
Frustration tolerance decreased		1
Full blood count abnormal		1
Functional gastrointestinal disorder	1	2
Fungal infection		1
Fungal skin infection		1
Furuncle	1	7
Gait disturbance	43	204
Gait inability	11	64

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3	4	11
	1	24	99	22	133
					1
				1	3
			1		
		1	1		
				1	1
				1	1
			1		2
			1	2	6
					4
			1	1	3
			1	1	2
					2
				1	3
					1
				1	1
		1	6		7
		1	5	3	14
					1
			1		
				1	1
		1	1		2
		1	4	1	13
			1		
					1
				1	2
					1
					1
		1	2		5
	1	12	41	31	163
	1	3	11	8	53

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Galactorrhoea		3
Gallbladder disorder		1
Gamma-glutamyltransferase increased	1	3
Gastric antral vascular ectasia	2	4
Gastric dilatation		2
Gastric disorder	1	13
Gastric ulcer	1	3
Gastritis	6	18
Gastroenteritis	2	10
Gastroenteritis norovirus		1
Gastroenteritis rotavirus		1
Gastroenteritis viral	1	6
Gastrointestinal disorder	2	9
Gastrointestinal haemorrhage	4	7
Gastrointestinal motility disorder		1
Gastrointestinal pain	8	43
Gastrointestinal sounds abnormal	2	13
Gastrointestinal stoma complication		1
Gastrointestinal surgery		1
Gastrointestinal wall thickening		1
Gastrooesophageal reflux disease	12	41
Generalised oedema		2
Generalised tonic-clonic seizure	4	28
General physical health deterioration	4	14
Genital haemorrhage	2	3
Genital herpes	6	10
Genital herpes simplex	1	1
Genital pain	1	1
Genital tract inflammation		1
Genital ulceration	1	2
Gestational diabetes	2	3
Giant cell arteritis		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
					1
				1	3
				2	4
					2
		1	7		6
				1	3
		2	3	4	15
		1	2	1	8
					1
					1
		1	3		3
			3	2	6
				4	7
			1		
		2	6	6	37
		1	4	1	9
					1
					1
			1		
		5	9	7	32
			1		1
				4	28
		3	6	1	8
				2	3
			2	6	8
				1	1
		1	1		
			1		
		1	1		1
		1	1	1	2
					4

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gingival abscess		1
Gingival bleeding	3	13
Gingival blister	1	2
Gingival discomfort		2
Gingival disorder	1	3
Gingival erythema		2
Gingival pain	7	39
Gingival pruritus		1
Gingival swelling	2	9
Gingivitis	2	5
Gingivitis ulcerative		2
Glaucoma	1	3
Glomerular filtration rate decreased	1	1
Glomerulonephritis minimal lesion		2
Glossitis	2	7
Glossodynia	12	83
Glucose tolerance impaired	1	2
Gluten sensitivity	1	1
Glycopenia		1
Goitre		5
Gout	4	10
Granuloma skin		1
Granulomatosis with polyangiitis	1	1
Grief reaction		1
Grip strength		1
Grip strength decreased	5	22
Groin pain	13	53
Guillain-Barre syndrome	5	19
Guttate psoriasis		1
Habit cough	1	4
Haemarthrosis	1	4
Haematemesis	2	16

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	6	2	7
		1	2		
			1		1
			1	1	2
			1		1
		2	10	5	29
					1
			2	2	7
		1	3	1	2
					2
				1	3
				1	1
					2
		1	4	1	3
		6	36	6	47
			1	1	1
				1	1
			1		
			2		3
		1	1	3	9
			1		
				1	1
					1
		1	6	4	16
		5	20	8	33
				5	19
					1
			1	1	3
				1	4
				2	16

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Haematochezia	5	20
Haematocrit increased		1
Haematoma	1	9
Haematospermia		1
Haematuria	4	16
Haemoglobin decreased	2	9
Haemoglobin increased		2
Haemolysis	1	3
Haemolytic anaemia		1
Haemoperitoneum		1
Haemoptysis	1	15
Haemorrhage	41	93
Haemorrhage in pregnancy		1
Haemorrhage intracranial		2
Haemorrhage subcutaneous		4
Haemorrhage urinary tract		4
Haemorrhagic diathesis		2
Haemorrhagic infarction		1
Haemorrhagic stroke	1	6
Haemorrhoids		7
Haemorrhoids thrombosed		1
Hair colour changes	1	2
Hair disorder		1
Hair dye user	1	1
Hair texture abnormal	1	2
Hallucination	11	83
Hallucination, auditory	3	7
Hallucination, olfactory		3
Hallucinations, mixed		1
Hallucination, tactile		1
Hallucination, visual	4	10
Halo vision	4	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				5	20
					1
		1	2		7
					1
		1	3	3	13
			2	2	7
					2
				1	3
					1
					1
			2	1	13
	1			41	93
					1
					2
					4
					4
					2
					1
				1	6
					7
					1
			1	1	1
			1		
				1	1
				1	2
				11	83
				3	7
					3
					1
					1
				4	10
		2	2	2	3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hand-arm vibration syndrome		1
Hand deformity		2
Hangover	9	25
Haptoglobin decreased		1
Headache	1,770	9,231
Head banging	1	4
Head discomfort	32	138
Head injury	2	23
Head titubation	2	3
Heart disease congenital		1
Heart injury		3
Heart rate	2	12
Heart rate abnormal	14	38
Heart rate decreased	2	23
Heart rate increased	78	376
Heart rate irregular	10	35
Heart sounds abnormal	1	1
Heat exhaustion	1	1
Heat illness	1	2
Heat oedema	1	5
Heat stroke	1	2
Heavy menstrual bleeding	194	262
Hemianopia		1
Hemianopia homonymous		1
Hemiparaesthesia		1
Hemiparesis	3	17
Hemiplegia	3	15
Hemiplegic migraine	1	6
Hepatic enzyme increased		1
Hepatic function abnormal		1
Hepatic haemorrhage	1	1
Hepatic lesion		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					2
		5	8	4	17
					1
11	46	904	3520	866	5711
			2	1	2
		13	46	19	92
			9	2	14
		1	1	1	2
					1
					3
		1	4	1	8
	1	4	11	10	27
			3	2	20
		26	125	52	251
		3	5	7	30
		1	1		
		1	1		
				1	2
			1	1	4
		1	2		
	1	97	118	97	144
					1
					1
					1
				3	17
				3	15
				1	6
			1		
					1
				1	1
					1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hepatic pain	2	8
Hepatic vascular thrombosis	1	1
Hepatitis		5
Hepatitis A		1
Hepatitis E	1	1
Hepatitis viral		1
Hepatomegaly		1
Hereditary neuropathy with liability to pressure palsies		1
Herpes ophthalmic		1
Herpes simplex	3	10
Herpes simplex reactivation		1
Herpes virus infection	2	4
Herpes zoster	275	516
Herpes zoster meningoencephalitis		1
Herpes zoster oticus	4	6
Herpes zoster reactivation	4	8
Hiatus hernia	3	3
Hiccups	1	2
Hidradenitis		1
Hilar lymphadenopathy	1	1
Hip fracture		2
Hirsutism	1	1
Histamine intolerance		1
Hodgkin's disease	1	1
Hordeolum	3	6
Hormone level abnormal	4	6
Hot flush	76	347
Humerus fracture		1
Hunger	3	9
Hydrocephalus	1	1
Hyperactive pharyngeal reflex		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	7
				1	1
					5
					1
				1	1
					1
					1
					1
					1
			3	3	7
					1
		1	1	1	3
		114	187	161	329
					1
				4	6
		3	3	1	5
		1	1	2	2
				1	2
					1
				1	1
					1
				1	1
		1	2	2	4
		2	2	2	4
		32	136	44	211
					1
		1	5	2	4
				1	1
					1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hyperacusis	2	25
Hyperaesthesia	6	52
Hyperaesthesia teeth	3	8
Hyperchlorhydria	2	8
Hypercoagulation	1	1
Hypergeusia	1	2
Hyperglycaemia	3	28
Hyperhidrosis	132	741
Hypermobility syndrome	1	1
Hyperparathyroidism	1	1
Hyperphagia		1
Hyperpyrexia	2	6
Hyperreflexia		1
Hypersensitivity	73	304
Hypersomnia	27	138
Hypertension	45	281
Hypertensive crisis	3	7
Hypertensive heart disease		2
Hypertensive urgency		1
Hyperthermia	1	2
Hyperthyroidism	1	7
Hypertonia		2
Hypertonic bladder		2
Hyperventilation	7	14
Hypervigilance	1	2
Hypervolaemia		1
Hyphaema		1
Hypnagogic hallucination		1
Hypnopompic hallucination	1	1
Hypoacusis	14	44
Hypoaesthesia	200	828
Hypoaesthesia eye	3	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			8	2	17
		3	21	3	31
		1	3	2	5
			1	2	7
				1	1
		1	1		1
			5	3	23
		47	231	85	510
				1	1
				1	1
					1
				2	6
					1
		25	85	48	219
		9	49	18	89
	1	13	81	32	200
				3	7
					2
					1
				1	2
				1	7
					2
			2		
		5	9	2	5
				1	2
					1
					1
					1
				1	1
		6	18	8	26
	4	91	318	109	510
		2	3	1	5

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypoaesthesia oral	43	198
Hypoaesthesia teeth		1
Hypocalcaemia		2
Hypogeusia	1	1
Hypoglycaemia	3	26
Hypokalaemic syndrome		2
Hypokinesia	19	63
Hypomania		1
Hypomenorrhoea	14	23
Hyponatraemia		5
Hyponatraemic syndrome		1
Hypoperfusion		1
Hypophagia	1	11
Hypopnoea	9	35
Hyporeflexia		3
Hyporesponsive to stimuli	1	2
Hyposmia	2	5
Hyposomnia		1
Hypotension	25	157
Hypothermia		11
Hypothyroidism	1	10
Hypotonia	1	6
Hypoventilation		1
Hypovitaminosis		2
Hypoxia		10
Hysteroscopy	1	1
Idiopathic intracranial hypertension	2	4
IgA nephropathy	1	1
IIIrd nerve disorder		2
IIIrd nerve paralysis		2
Ileus paralytic		1
Illness	150	693

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		23	94	20	104
			1		
					2
		1	1		
			4	3	22
					2
		4	17	15	46
					1
		10	16	4	7
					5
					1
					1
				1	11
		2	3	7	32
			1		2
				1	2
		2	3		2
					1
		11	43	14	114
					11
				1	10
			1	1	5
					1
			1		1
					10
				1	1
				2	4
				1	1
					2
					2
					1
	2	74	226	76	467

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Illusion		1
Immediate post-injection reaction		1
Immobile	3	4
Immune-mediated adverse reaction		1
Immune-mediated hepatic disorder		1
Immune system disorder	5	14
Immune thrombocytopenia	15	41
Immunisation		1
Immunisation anxiety related reaction		1
Immunisation reaction		1
Immunodeficiency	1	3
Immunodeficiency common variable		1
Immunology test		1
Immunosuppression	1	1
Impaired driving ability	2	13
Impaired gastric emptying	2	3
Impaired healing		1
Impaired quality of life		2
Impaired self-care		1
Impaired work ability	11	25
Impetigo	1	2
Implant site pain		1
Implant site swelling	1	1
Inability to crawl		1
Inappropriate affect		1
Inappropriate schedule of product administration	392	803
Incision site pain		2
Incoherent	1	6
Incomplete course of vaccination		1
Incontinence	2	16
Incorrect dose administered	3	9
Incorrect route of product administration	7	41

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
				3	4
					1
					1
		2	2	3	12
				15	41
					1
					1
					1
				1	3
					1
			1		
				1	1
		1	5	1	8
				2	3
					1
			1		1
			1		
		3	7	8	18
				1	2
					1
		1	1		
					1
					1
1	1	384	780	8	23
					2
			2	1	4
			1		
			1	2	15
		3	8		1
		6	39	1	2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Increased appetite	2	4
Increased insulin requirement		1
Increased tendency to bruise	1	8
Increased upper airway secretion		4
Increased viscosity of bronchial secretion		1
Increased viscosity of upper respiratory secretion		3
Indifference	1	3
Induration	1	6
Infant irritability		1
Infarction		1
Infected cyst	1	1
Infected dermal cyst		1
Infected skin ulcer		1
Infection	17	66
Infectious mononucleosis	2	4
Infectious pleural effusion		1
Infective pericardial effusion	1	1
Infective tenosynovitis	1	1
Infertility		1
Inflammation	25	114
Inflammatory bowel disease		1
Inflammatory marker increased		4
Inflammatory pain	2	4
Influenza	92	493
Influenza like illness	187	1,040
Infusion related reaction	1	2
Ingrown hair	1	1
Inguinal mass		1
Inhibitory drug interaction	1	1
Initial insomnia	2	7
Injected limb mobility decreased	6	20

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2	1	2
					1
			4	1	4
			1		3
					1
					3
		1	1		2
			2	1	4
			1		
					1
				1	1
					1
					1
		3	17	14	49
				2	4
					1
				1	1
				1	1
					1
		10	42	15	72
					1
			1		3
			1	2	3
2	4	40	151	52	342
3	7	91	375	96	665
				1	2
				1	1
					1
		1	1		
		2	4		3
		6	11		9

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Injection related reaction	2	16
Injection site bruising	2	2
Injection site coldness		1
Injection site erythema	15	26
Injection site hypoaesthesia	1	1
Injection site indentation	1	1
Injection site induration	1	1
Injection site inflammation	1	1
Injection site joint movement impairment		1
Injection site mass	5	7
Injection site muscle weakness		1
Injection site oedema		1
Injection site pain	32	78
Injection site paraesthesia	1	2
Injection site pruritus	6	10
Injection site pustule		1
Injection site rash	2	3
Injection site reaction		1
Injection site scab	1	1
Injection site swelling	5	13
Injection site urticaria		1
Injection site warmth	4	7
Injury	3	6
Injury associated with device		1
Injury corneal		1
Inner ear disorder		4
Inner ear inflammation	2	2
Insomnia	142	588
Insulin resistance	1	3
Insulin resistant diabetes	1	1
Intentional self-injury		3
Intermenstrual bleeding	29	39

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3	2	13
		2	2		
			1		
		13	23	2	3
		1	1		
				1	1
		1	1		
		1	1		
					1
		3	3	2	4
					1
			1		
		25	56	7	22
		1	2		
		6	9		1
					1
		1	1	1	2
					1
		1	1		
		4	11	1	2
					1
		2	3	2	4
				3	6
			1		
					1
					4
				2	2
	1	57	200	85	388
			1	1	2
				1	1
					3
		13	18	16	21

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Internal haemorrhage	1	1
International normalised ratio abnormal		3
International normalised ratio decreased	1	9
International normalised ratio fluctuation		1
International normalised ratio increased		14
Interstitial lung disease		1
Intervertebral disc compression		1
Intervertebral disc protrusion		2
Intestinal angioedema	1	1
Intestinal infarction		1
Intestinal mass		1
Intestinal obstruction		2
Intestinal perforation		1
Intracardiac thrombus	1	1
Intracranial aneurysm		1
Intracranial pressure increased		1
Intranasal hypoesthesia		1
Intranasal paraesthesia	1	3
Intraocular pressure increased		1
Intravascular haemolysis		1
Intrusive thoughts		1
Invasive ductal breast carcinoma	1	1
Iodine uptake increased		1
Iridocyclitis	2	6
Iritis		1
Iron deficiency		3
Iron deficiency anaemia	1	3
Irregular breathing		7
Irregular sleep wake rhythm disorder		1
Irritability	11	44
Irritability postvaccinal	1	1
Irritable bowel syndrome	7	31

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		2
			1	1	8
					1
			5		9
					1
					1
			1		1
				1	1
					1
					1
					2
					1
				1	1
					1
					1
		1	3		
					1
					1
			1		
				1	1
					1
				2	6
			1		
					3
			1	1	2
					7
			1		
		6	16	5	28
				1	1
		4	9	3	22

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Ischaemia	3	4
Ischaemic stroke	2	19
Itching scar		6
Jaundice		5
Jaw clicking	2	3
Jaw disorder	2	2
Joint destruction		1
Joint effusion	1	9
Joint injury		4
Joint instability	1	1
Joint laxity		1
Joint lock		2
Joint microhaemorrhage		1
Joint noise		5
Joint range of motion decreased	34	126
Joint stiffness	16	101
Joint swelling	41	174
Joint vibration		1
Joint warmth		6
Jugular vein thrombosis		2
Keratitis		2
Ketoacidosis		1
Kidney infection	2	10
Kidney small		1
Labia enlarged	1	1
Labile blood pressure		2
Labile hypertension	1	1
Labyrinthitis	8	35
Lack of spontaneous speech		2
Lacrimal disorder		1
Lacrimation increased	10	59
Lactation disorder	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	4
				2	19
			4		2
			1		4
		1	1	1	2
				2	2
					1
			3	1	6
			2		2
				1	1
					1
					2
					1
			1		4
		11	31	23	95
		4	20	12	81
		13	44	28	130
					1
			3		3
			1		1
			2		
					1
				2	10
					1
				1	1
					2
				1	1
		2	7	6	28
			1		1
					1
		6	19	4	40
				1	3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lactose intolerance		1
Lacunar infarction		1
Lacunar stroke		1
Lagophthalmos		1
Language disorder	1	3
Large intestine perforation	1	1
Laryngeal disorder		1
Laryngeal pain		3
Laryngitis		3
Learning disorder	1	1
Left ventricular dysfunction		2
Left ventricular failure		1
Lennox-Gastaut syndrome		1
Lethargy	149	826
Leukaemia		1
Leukopenia		2
Lhermitte's sign		1
L bido increased	1	2
Lichenoid keratosis		2
Lichen planus	1	1
Ligament disorder	1	1
Ligament sprain	3	8
Limbal swelling		1
Limb crushing injury	1	1
Limb deformity	1	1
Limb discomfort	151	635
Limb immobilisation	2	5
Limb injury	6	23
Limb mass	8	29
Limb operation		1
Lip blister	2	14
Lip discolouration	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
					1
					1
				1	3
				1	1
					1
			1		2
					3
				1	1
					2
					1
					1
2	9	69	305	80	521
					1
					2
					1
		1	2		
					2
				1	1
				1	1
				3	8
					1
				1	1
1	2	79	283	72	352
		1	3	1	2
		2	5	4	18
		1	9	7	20
					1
			2	2	12
				1	2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lip disorder		4
Lip dry	4	23
Lip erythema		3
Lip exfoliation	2	3
Lip haemorrhage		1
Lip injury	1	1
Lip neoplasm	1	1
Lip oedema		2
Lipoma		1
Lip pain	5	27
Lip pruritus	1	5
Lip scab		1
Lip swelling	59	295
Lip ulceration		3
Liquid product physical issue		1
Listless	1	6
Livedo reticularis		16
Liver disorder	1	1
Liver function test abnormal	6	12
Liver function test increased		7
Liver injury		5
Liver tenderness	1	2
Localised infection	1	14
Localised oedema	4	13
Local reaction	6	26
Locked-in syndrome		1
Logorrhoea	1	1
Lordosis	1	1
Loss of bladder sensation		2
Loss of consciousness	23	197
Loss of control of legs	1	7
Loss of libido		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		2
			9	4	14
			2		1
		1	1	1	2
					1
		1	1		
				1	1
					2
			1		
		1	9	4	18
			4	1	1
					1
	1	31	104	28	191
			2		1
			1		
				1	6
			4		12
				1	1
			1	6	11
			2		5
					5
				1	2
		1	3		11
		3	7	1	6
		5	14	1	12
					1
				1	1
				1	1
					2
				23	197
				1	7
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Loss of personal independence in daily activities	29	130
Lower limb fracture		2
Lower motor neurone lesion	1	1
Lower respiratory tract infection	11	69
Lung consolidation		1
Lung disorder	2	8
Lung infiltration		1
Lung neoplasm malignant		1
Lung opacity		1
Lupus-like syndrome		1
Lupus nephritis	1	1
Lymphadenitis	18	54
Lymphadenopathy	673	2,690
Lymphangioma		1
Lymphangiopathy		1
Lymphangitis	1	5
Lymphatic disorder		2
Lymph gland infection	2	7
Lymph node pain	147	568
Lymph node palpable	2	7
Lymph nodes scan abnormal		1
Lymphocyte count decreased		1
Lymphocytosis	1	3
Lymphoedema	15	58
Lymphoma	2	8
Lymphopenia		1
Macular degeneration		2
Macular hole		1
Macular oedema	1	2
Macular rupture		1
Macule		4
Maculopathy		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		8	38	21	92
					2
				1	1
				11	69
					1
		1	2	1	6
					1
					1
					1
				1	1
		13	25	5	29
3	6	253	932	420	1758
					1
					1
				1	5
			1		1
		1	2	1	5
2	3	44	154	103	414
		2	6		1
					1
					1
		1	1		2
1	2	7	17	8	41
				2	8
			1		
					2
					1
				1	2
					1
			2		2
					2

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Madarosis	1	1
MAGIC syndrome		1
Magnetic resonance imaging abnormal		1
Magnetic resonance imaging head abnormal		1
Major depression		2
Malabsorption	1	1
Malaise	499	2,691
Malignant hypertension	1	3
Mallory-Weiss syndrome	1	3
Malnutrition		1
Mandibular mass	1	1
Mania		3
Mass	8	22
Mass excision		1
Mast cell activation syndrome	1	5
Mastication disorder		4
Mastitis	3	20
Mastocytosis		1
Maternal exposure before pregnancy	1	3
Maternal exposure during breast feeding	10	23
Maternal exposure during pregnancy	33	116
Maternal exposure timing unspecified	3	6
Mean cell volume decreased		1
Measles		2
Mechanical urticaria	1	2
Mechanic's hand	1	1
Medial tibial stress syndrome	1	2
Medication error		2
Medication overuse headache	1	1
Melaena		4
Melanocytic naevus		1
Memory impairment	10	52

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
					1
					2
				1	1
3	11	229	937	270	1754
				1	3
				1	3
					1
		1	1		
					3
		3	7	5	15
			1		
				1	5
					4
				3	20
					1
		1	1		2
		5	11	5	12
5	9	16	77	17	39
		3	6		
					1
					2
		1	2		
				1	1
				1	2
			2		
		1	1		
					4
					1
		4	16	6	36

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Meniere's disease		6
Meningitis	1	5
Meningitis aseptic		1
Meningitis bacterial		1
Meningitis viral	2	4
Menometrorrhagia	1	1
Menopausal symptoms		4
Menopause	6	7
Menstrual cycle management	1	1
Menstrual discomfort	1	2
Menstrual disorder	90	108
Menstruation delayed	124	165
Menstruation irregular	104	133
Mental disorder	1	6
Mental fatigue	12	65
Mental impairment	3	17
Mesenteric vein thrombosis	2	3
Metabolic acidosis		1
Metamorphopsia	3	10
Metastases to lymph nodes	1	3
Metastasis		1
Metastatic neoplasm		1
Microvascular coronary artery disease		1
Micturition disorder		4
Micturition urgency	1	5
Middle ear disorder	1	1
Middle ear effusion		1
Middle ear inflammation		1
Middle insomnia	5	39
Migraine	201	910
Migraine prophylaxis		1
Migraine with aura	13	64

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					6
				1	5
					1
					1
				2	4
		1	1		
			2		2
		3	3	3	4
		1	1		
				1	2
	1	64	71	26	37
1	1	100	113	24	52
	1	68	77	36	56
			3	1	3
		1	11	11	54
	1			3	17
				2	3
					1
		1	2	2	8
				1	3
					1
					1
			2		2
		1	2		3
				1	1
					1
					1
		4	16	1	23
	5	68	227	133	683
					1
	1	2	15	11	49

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Migraine without aura	2	5
Miliaria	5	30
Mini mental status examination abnormal		1
Miosis	1	3
Misophonia	1	2
Mitral valve incompetence	1	2
Moaning		2
Mobility decreased	29	173
Moebius II syndrome	1	1
Monocytosis		1
Monoparesis	9	27
Monoplegia	1	26
Mood altered	3	12
Mood disorder due to a general medical condition		1
Mood swings	8	15
Morning sickness	2	10
Morton's neuralgia		1
Motion sickness	4	24
Motor dysfunction		3
Mouth breathing		3
Mouth cyst		3
Mouth haemorrhage		6
Mouth injury	1	2
Mouth swelling	12	49
Mouth ulceration	20	110
Movement disorder	18	77
Mucosal disorder	1	1
Mucosal dryness	1	1
Mucosal haemorrhage		2
Mucous stools	1	3
Multiple allergies	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	4
		3	13	2	17
					1
		1	1		2
		1	1		1
				1	2
					2
		8	47	21	126
				1	1
			1		
1	1	6	8	3	19
				1	26
		1	4	2	8
					1
		1	3	7	12
		1	1	1	9
					1
		1	9	3	15
			1		2
			2		3
			3		3
				1	2
		4	13	8	36
1	1	12	35	8	75
		11	22	7	55
		1	1		
				1	1
					2
				1	3
				1	2

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Multiple organ dysfunction syndrome		2
Multiple sclerosis	2	22
Multiple sclerosis relapse	2	16
Multiple sclerosis relapse prophylaxis		1
Mumps	1	3
Muscle atrophy		3
Muscle contractions involuntary	2	6
Muscle contracture	1	1
Muscle discomfort	1	2
Muscle disorder	2	3
Muscle fatigue	16	113
Muscle injury		1
Muscle rigidity		5
Muscle rupture	1	3
Muscle spasms	80	312
Muscle spasticity	2	4
Muscle strain	4	14
Muscle swelling	2	13
Muscle tightness	8	40
Muscle tone disorder		1
Muscle twitching	17	80
Muscular weakness	80	385
Musculoskeletal chest pain	23	101
Musculoskeletal deformity		1
Musculoskeletal discomfort	14	63
Musculoskeletal disorder	6	25
Musculoskeletal pain	4	28
Musculoskeletal stiffness	108	499
Mutism		5
Myalgia	674	3,910
Myalgia intercostal		1
Myasthenia gravis	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
				2	22
				2	16
					1
				1	3
			1		2
			2	2	4
		1	1		
			1	1	1
			1	2	2
1	1	7	30	9	83
					1
	1		1		4
				1	3
2	3	33	93	47	219
				2	4
		2	3	2	11
			4	2	9
		2	14	6	26
					1
		9	37	8	43
2	2	20	101	60	284
		5	19	18	82
					1
		6	25	8	38
		2	5	4	20
			7	4	21
		46	174	62	325
			3		2
4	25	362	1502	312	2408
					1
				1	5

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* AE=Adverse Event

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myasthenia gravis crisis		1
Mydriasis	2	6
Myelitis		3
Myelitis transverse	3	18
Myocardial infarction	13	55
Myocardial ischaemia	2	7
Myocardial oedema	1	2
Myocarditis	3	15
Myoclonus		5
Myofascial pain syndrome		3
Myopathy	3	3
Myosclerosis	1	1
Myositis	2	6
Nail avulsion		1
Nail discolouration		5
Nail ridging		1
Narcolepsy		1
Nasal congestion	23	91
Nasal crusting	1	1
Nasal discharge discolouration		1
Nasal discomfort	8	27
Nasal disorder		1
Nasal dryness	3	7
Nasal herpes		2
Nasal injury	1	1
Nasal obstruction		3
Nasal odour	1	3
Nasal oedema	3	6
Nasal pruritus		4
Nasopharyngitis	72	296
Natural killer T cell count increased		1
Nausea	906	5,086

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	2	1	4
					3
				3	18
				13	55
				2	7
				1	2
				3	15
			1		4
			1		2
				3	3
				1	1
			1	2	5
			1		
			2		3
					1
					1
		9	31	14	60
		1	1		
			1		
		5	12	3	15
			1		
		1	2	2	5
			2		
		1	1		
			2		1
			1	1	2
		1	1	2	5
			1		3
		28	113	44	183
			1		
3	21	443	1857	463	3229

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Near death experience		1
Neck mass	2	15
Neck pain	181	843
Necrotic lymphadenopathy		2
Necrotising fasciitis		1
Needle issue		2
Negative thoughts		2
Neoplasm	2	6
Neoplasm malignant	1	5
Neoplasm recurrence	1	1
Nephritis	1	1
Nephrolithiasis	1	1
Nephrotic syndrome	1	5
Nerve block	1	1
Nerve compression	4	14
Nerve injury		16
Nervousness	15	102
Nervous system disorder	1	6
Neuralgia	49	153
Neuritis	2	3
Neurogenic bladder		1
Neurogenic shock		7
Neurological symptom	4	15
Neurologic neglect syndrome		1
Neuromuscular pain		1
Neuropathy peripheral	9	38
Neuropsychiatric symptoms		1
Neutropenia	4	22
Neutropenic sepsis		2
Neutrophil count decreased	1	5
Neutrophil count increased		1
New daily persistent headache		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	6	1	9
	2	68	287	113	556
					2
					1
			1		1
					2
		1	2	1	4
				1	5
				1	1
				1	1
				1	1
				1	5
				1	1
			3	4	11
			5		11
		7	32	8	70
			4	1	2
		15	43	34	110
			1	2	2
					1
					7
			1	4	14
					1
					1
				9	38
			1		
				4	22
					2
		1	3		2
			1		
			1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Nightmare	14	50
Night sweats	43	194
Nipple exudate bloody		1
Nipple pain	2	9
Nipple swelling		1
No adverse event	1	1
Nocturia	1	2
Nocturnal dyspnoea	1	3
Nodule	1	9
Non-cardiac chest pain	1	5
Non-Hodgkin's lymphoma		1
Noninfective gingivitis		3
Noninfective sialoadenitis		1
Non-tobacco user		1
No reaction on previous exposure to drug		1
Nuchal rigidity	1	4
Numb chin syndrome		1
Nystagmus	1	4
Obstruction	1	1
Obstructive airways disorder	4	6
Obstructive pancreatitis		1
Occipital neuralgia	3	7
Occupational exposure to product	1	3
Ocular discomfort	5	18
Ocular hyperaemia	20	81
Ocular myasthenia		1
Ocular vascular disorder	2	2
Odynophagia	7	28
Oedema	7	17
Oedema mouth	1	5
Oedema mucosal	1	1
Oedema peripheral	8	36

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	17	12	33
	2	23	80	20	114
					1
		1	3	1	6
			1		
		1	1		
		1	2		
		1	1		2
		1	5		4
			1	1	4
					1
					3
					1
			1		
			1		
		1	1		3
					1
				1	4
				1	1
				4	6
					1
				3	7
		1	3		
		2	8	3	10
		10	31	10	50
					1
		1	1	1	1
		3	12	4	16
			2	7	15
			1	1	4
		1	1		
		3	12	5	24

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oesophageal pain		4
Oesophageal spasm		2
Oesophageal varices haemorrhage		1
Oesophagitis		1
Off label use	373	1,144
Oligodendroglioma		1
Oligohydramnios		1
Oligomenorrhoea	3	6
Oliguria		1
Onychalgia	1	1
Onychoclasia		2
Ophthalmic herpes simplex	1	1
Ophthalmic herpes zoster	4	7
Ophthalmic migraine	2	8
Ophthalmic vein thrombosis	1	1
Ophthalmological examination abnormal		1
Ophthalmoplegia		2
Optic ischaemic neuropathy	1	2
Optic nerve disorder		1
Optic neuritis	5	14
Oral allergy syndrome	1	2
Oral blood blister	1	5
Oral candidiasis	2	15
Oral discharge		1
Oral discomfort	9	37
Oral disorder	3	11
Oral dysaesthesia		1
Oral herpes	27	78
Oral infection	1	1
Oral lichen planus		2
Oral mucosal blistering	2	16
Oral mucosal discolouration		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		2
			1		1
			1		1
1	1	361	1091	12	53
					1
					1
		3	3		3
					1
				1	1
			1		1
				1	1
				4	7
			1	2	7
				1	1
			1		
					2
				1	2
					1
				5	14
				1	2
		1	3		2
			4	2	11
			1		
		5	13	4	24
		2	4	1	7
					1
	1	14	36	13	42
				1	1
					2
		1	9	1	7
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral mucosal eruption	1	5
Oral mucosal erythema		4
Oral mucosal exfoliation		5
Oral mucosal roughening		2
Oral pain	16	68
Oral papule		1
Oral pruritus	2	12
Oral purpura		1
Orbital oedema		1
Orbital swelling	1	1
Oropharyngeal blistering	3	13
Oropharyngeal discomfort	6	44
Oropharyngeal oedema		1
Oropharyngeal pain	189	873
Oropharyngeal plaque		1
Orthopnoea	1	1
Orthostatic hypertension	1	2
Orthostatic hypotension		8
Oscillopsia		1
Osteitis	1	1
Osteoarthritis	4	16
Osteonecrosis of jaw		1
Osteopenia	1	1
Osteoporosis	1	1
Otitis externa		1
Ovarian haemorrhage	1	1
Ovarian vein thrombosis	1	1
Overdose	4	21
Overflow diarrhoea		1
Oversensing	1	7
Ovulation disorder	1	1
Ovulation pain	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		2
			1		3
			3		2
					2
		8	27	8	41
					1
		1	5	1	7
					1
					1
				1	1
				3	13
		2	16	4	28
					1
2	5	102	343	87	530
			1		
				1	1
				1	2
			3		5
			1		
				1	1
		2	3	2	13
					1
				1	1
				1	1
					1
				1	1
				1	1
		3	19	1	2
			1		
			1	1	6
				1	1
		1	1	1	2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oxygen saturation		1
Oxygen saturation decreased	11	50
Pain	650	3,128
Painful respiration	4	32
Pain in extremity	1,033	4,578
Pain in jaw	32	130
Pain of skin	30	136
Palatal oedema		2
Palatal swelling		3
Palatal ulcer		1
Palate injury	1	1
Palindromic rheumatism		1
Pallor	18	106
Palmar erythema	1	2
Palmoplantar pustulosis	1	1
Palpitations	146	732
Pancreatic carcinoma		2
Pancreatic disorder		1
Pancreatitis	2	4
Pancreatitis acute	2	3
Pancytopenia		3
Panic attack	7	32
Panic disorder		4
Panic reaction	2	12
Papilloedema	3	5
Papule	6	21
Paraesthesia	268	1,174
Paraesthesia oral	90	531
Parainfluenzae viral laryngotracheobronchitis		1
Paralysis	9	42
Paramnesia		1
Paranasal sinus discomfort		10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	7	10	43
	6	280	1211	370	1917
		1	5	3	27
7	37	517	1867	516	2711
		13	38	19	92
1	1	15	43	15	93
					2
					3
					1
				1	1
					1
		10	40	8	66
				1	2
				1	1
	1	68	225	78	507
					2
					1
				2	4
				2	3
					3
		4	12	3	20
			2		2
		1	2	1	10
				3	5
		4	8	2	13
	3	134	484	134	690
	1	66	283	24	248
					1
	1			9	42
					1
			4		6

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Paranasal sinus hypersecretion		1
Paranasal sinus inflammation		1
Paranoia	1	4
Parapsoriasis	1	1
Paresis	1	3
Parkinsonian gait	1	1
Parkinson's disease	1	4
Paronychia	1	1
Parophthalmia		1
Parosmia	20	65
Parotid gland enlargement		3
Parotitis		5
Partial seizures	1	10
Peak expiratory flow rate		1
Peak expiratory flow rate abnormal		1
Peak expiratory flow rate decreased		2
Pelvic haemorrhage	1	4
Pelvic pain	10	29
Pelvic venous thrombosis		1
Pemphigoid	1	5
Pemphigus	2	3
Peptic ulcer haemorrhage	2	4
Perforation	1	1
Periarthritis	18	38
Pericardial effusion		5
Pericarditis	3	10
Perineal pain	1	1
Perioral dermatitis		1
Periorbital cellulitis		1
Periorbital discomfort	1	1
Periorbital haematoma		1
Periorbital infection	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				1	4
		1	1		
				1	3
		1	1		
				1	4
		1	1		
					1
		18	34	2	31
			1		2
			2		3
				1	10
					1
					1
					2
				1	4
			5	10	24
					1
				1	5
				2	3
				2	4
				1	1
		4	7	14	31
					5
				3	10
				1	1
			1		
					1
		1	1		
					1
				1	1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Periorbital oedema	1	7
Periorbital pain		2
Periorbital swelling	18	56
Peripheral arterial occlusive disease	1	1
Peripheral circulatory failure		3
Peripheral coldness	42	170
Peripheral embolism		1
Peripheral ischaemia	4	9
Peripheral sensory neuropathy	1	5
Peripheral swelling	276	1,076
Peripheral vein stenosis		1
Peripheral venous disease	1	1
Peroneal nerve palsy		4
Persistent genital arousal disorder	1	1
Persistent postural-perceptual dizziness		3
Petechiae	8	32
Petit mal epilepsy		11
Phantom limb syndrome		2
Pharyngeal disorder	2	3
Pharyngeal enanthema		1
Pharyngeal erythema		5
Pharyngeal haemorrhage	2	3
Pharyngeal hypoaesthesia	2	10
Pharyngeal inflammation		6
Pharyngeal mass	1	1
Pharyngeal oedema	1	8
Pharyngeal paraesthesia	4	32
Pharyngeal pustule		1
Pharyngeal swelling	24	124
Pharyngeal ulceration	1	6
Pharyngitis	1	8
Pharyngitis streptococcal	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		5
			1		1
		10	21	8	35
				1	1
					3
		19	59	23	111
					1
		1	3	3	6
		1	2		3
	3	116	369	160	707
					1
				1	1
			1		3
		1	1		
			1		2
		3	13	5	19
					11
					2
		1	1	1	2
					1
			2		3
				2	3
		1	6	1	4
			1		5
				1	1
				1	8
		3	14	1	18
			1		
		6	29	18	95
			1	1	5
		1	3		5
		1	1		2

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Phlebitis	5	15
Phobia		1
Phonophobia		1
Photophobia	29	164
Photopsia	13	43
Photosensitivity reaction	5	28
pH urine		1
pH urine abnormal	1	1
pH urine increased		1
Physical deconditioning		1
Physical disability	1	2
Pigmentation disorder	1	5
Piloerection	3	10
Pituitary tumour benign	1	1
Pityriasis	1	6
Pityriasis lichenoides et varioliformis acuta		1
Pityriasis rosea	3	11
Plantar fasciitis		3
Plasma viscosity abnormal		1
Platelet anisocytosis		1
Platelet count decreased	16	36
Platelet count increased		2
Pleural effusion	2	10
Pleurisy	2	13
Pleuritic pain	2	10
Plicated tongue		2
Pneumonia	7	31
Pneumonia aspiration		1
Pneumonia bacterial		1
Pneumonia fungal		1
Pneumonia staphylococcal		1
Pneumonitis	1	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			5	5	10
					1
			1		
		14	50	15	114
		4	13	9	30
		1	6	4	22
					1
				1	1
					1
					1
				1	2
			2	1	3
		3	3		7
				1	1
			3	1	3
			1		
		2	5	1	6
					3
					1
					1
		4	7	12	29
					2
				2	10
		1	1	1	12
		1	2	1	8
			1		1
				7	31
					1
					1
					1
					1
			1	1	8

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pneumothorax	1	1
Poisoning	1	4
Pollakiuria	12	29
Polyarthritis	2	6
Polychondritis		2
Polychromasia		2
Polycystic ovaries	5	5
Polydipsia	1	2
Polymenorrhoea	28	37
Polymerase chain reaction positive	6	10
Polymyalgia rheumatica	5	22
Polymyositis	1	2
Polyp		1
Polyuria	4	5
Poor peripheral circulation	1	3
Poor quality product administered	1	3
Poor quality sleep	23	100
Poor venous access	1	1
Portal vein thrombosis	1	2
Post herpetic neuralgia	9	12
Postictal state		1
Post laminectomy syndrome		1
Post lumbar puncture syndrome		1
Postmenopausal haemorrhage	15	22
Postpartum haemorrhage	1	1
Postprandial hypoglycaemia		1
Post procedural complication		1
Post procedural infection	1	1
Post stroke seizure		1
Post-traumatic stress disorder	1	3
Postural orthostatic tachycardia syndrome	2	9
Posture abnormal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	4
		6	10	6	19
				2	6
					2
					2
		3	3	2	2
				1	2
	1	16	20	12	17
		2	5	4	5
				5	22
				1	2
					1
		2	2	2	3
			2	1	1
		1	3		
	1	10	36	13	64
				1	1
				1	2
		4	6	5	6
					1
					1
					1
				15	22
				1	1
					1
					1
		1	1		
					1
				1	3
		1	2	1	7
			1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Post viral fatigue syndrome	8	39
Pouchitis		1
Pre-existing condition improved		2
Pregnancy		4
Pregnancy test positive		1
Pregnancy with contraceptive device	1	2
Pregnancy with implant contraceptive	1	1
Prehypertension		1
Premature delivery		1
Premature menarche		1
Premature menopause	1	2
Premature ovulation	1	1
Premature separation of placenta	1	1
Premenstrual dysphoric disorder	2	2
Premenstrual pain	2	2
Premenstrual syndrome	3	4
Pressure of speech		1
Presyncope	27	188
Preterm premature rupture of membranes		2
Primary cough headache		3
Procedural dizziness		3
Procedural nausea		3
Proctalgia	2	5
Proctitis ulcerative		1
Product administered at inappropriate site	3	24
Product administered to patient of inappropriate age	7	19
Product administration error	3	5
Product complaint		1
Product dose omission issue		1
Productive cough	13	55
Product leakage	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3	6	36
					1
			2		
			3		1
			1		
				1	2
				1	1
			1		
					1
			1		
		1	1		1
		1	1		
				1	1
				2	2
		1	1	1	1
		3	3		1
					1
	1	14	80	13	108
					2
			1		2
			1		2
					3
			2	2	3
					1
		3	20		4
		6	17	1	2
		2	3	1	2
					1
					1
1	1	5	16	8	39
		1	1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Product preparation error		6
Product preparation issue	1	2
Product residue present		1
Product taste abnormal		1
Product use issue	41	431
Progressive macular hypomelanosis	1	1
Prolapse		1
Prophylaxis of nausea and vomiting		1
Proteinuria		2
Protein urine present	1	1
Pruritus	324	1,343
Pseudofolliculitis		1
Pseudolymphoma		1
Psoriasis	4	26
Psoriatic arthropathy	2	11
Psychiatric symptom		1
Psychogenic seizure	1	6
Psychomotor hyperactivity	2	10
Psychotic disorder		5
Psychotic symptom		2
Pudendal canal syndrome	1	1
Pulmonary artery dilatation		1
Pulmonary cavitation	1	1
Pulmonary congestion		2
Pulmonary embolism	36	119
Pulmonary fibrosis	1	2
Pulmonary function test		1
Pulmonary hypertension		2
Pulmonary infarction	1	3
Pulmonary mass	1	1
Pulmonary oedema	2	10
Pulmonary pain	5	40

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			5		1
		1	2		
					1
			1		
		37	401	4	30
				1	1
					1
			1		1
				1	1
2	2	198	645	126	698
					1
					1
			7	4	19
				2	11
					1
			1	1	5
			2	2	8
			1		4
					2
				1	1
					1
				1	1
					2
				36	119
				1	2
					1
					2
				1	3
				1	1
				2	10
			7	5	33

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pulmonary sepsis		1
Pulmonary thrombosis	2	10
Pulpitis dental		1
Pulse abnormal		5
Pulseless electrical activity		2
Pulse pressure increased	1	1
Puncture site bruise	1	2
Puncture site discharge		1
Puncture site swelling		1
Pupil fixed		1
Pupillary disorder		1
Pupillary reflex impaired		2
Pupils unequal		3
Purging		1
Purple glove syndrome		1
Purpura	1	18
Purpura non-thrombocytopenic	1	1
Pustular psoriasis	1	2
Pustule		3
Pyelonephritis		1
Pyrexia	797	4,979
Q fever	2	7
Quadrantanopia		2
Quality of life decreased		2
Radiculitis brachial		3
Radiculopathy		2
Radioisotope uptake increased		1
Rales		2
Rash	364	1,303
Rash erythematous	90	396
Rash macular	39	182
Rash maculo-papular	5	21

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				2	10
					1
			2		3
					2
		1	1		
		1	1		1
					1
			1		
					1
					1
			1		1
					3
					1
					1
		1	9		9
				1	1
		1	1		1
			1		2
					1
7	28	394	1866	403	3113
				2	7
					2
					2
			1		2
					2
					1
					2
	1	217	636	147	667
	2	46	173	44	223
		23	95	16	87
		3	9	2	12

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Rash morbilliform	6	13
Rash neonatal	1	1
Rash papular	33	111
Rash pruritic	92	370
Rash pustular	1	3
Rash vesicular	12	30
Raynaud's phenomenon	6	25
Reaction to excipient	2	5
Reaction to preservatives		2
Reaction to previous exposure to any vaccine		1
Reading disorder	1	2
Rectal discharge	4	4
Rectal haemorrhage	9	33
Rectal injury		1
Rectal spasm		1
Red blood cell abnormality	1	1
Red blood cell sedimentation rate increased		5
Red ear syndrome	1	1
Reduced facial expression		2
Reflux gastritis	1	3
Relapsing fever		1
Renal cancer		1
Renal colic		1
Renal disorder	1	3
Renal failure	1	8
Renal haemorrhage		2
Renal impairment	4	10
Renal mass	1	1
Renal pain	23	84
Repetitive speech		1
Respiration abnormal	2	18
Respiratory acidosis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	6	3	7
		1	1		
		20	55	13	56
		59	161	33	209
				1	3
		8	15	4	15
		3	10	3	15
				2	5
					2
					1
				1	2
		1	1	3	3
				9	33
					1
			1		
		1	1		
					5
		1	1		
			1		1
		1	2		1
					1
			1		
				1	3
				1	8
					2
				4	10
				1	1
		9	30	14	54
					1
		2	6		12
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory arrest		8
Respiratory depression		1
Respiratory disorder	3	19
Respiratory distress	1	9
Respiratory failure	1	4
Respiratory rate	1	1
Respiratory rate decreased		3
Respiratory rate increased	7	31
Respiratory symptom	2	3
Respiratory tract infection	1	4
Respiratory tract irritation	2	6
Respiratory tract oedema	1	2
Resting tremor	1	1
Restless legs syndrome	4	25
Restlessness	18	75
Retching	4	44
Reticulocyte count decreased		1
Retinal artery occlusion	2	3
Retinal artery thrombosis		1
Retinal detachment	1	1
Retinal exudates		2
Retinal haemorrhage		2
Retinal injury	1	1
Retinal migraine	2	7
Retinal tear		1
Retinal toxicity		1
Retinal vasculitis		1
Retinal vein occlusion	5	10
Retinal vein thrombosis	1	1
Retinopathy		1
Retroperitoneal haemorrhage		1
Retroperitoneal lymphadenopathy	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1				8
					1
			4	3	15
				1	9
				1	4
		1	1		
					3
		4	10	3	21
	1	1	1	1	2
				1	4
		1	3	1	3
				1	2
		1	1		
		3	9	1	16
		8	24	10	51
			16	4	28
					1
				2	3
					1
				1	1
					2
					2
				1	1
			1	2	6
					1
					1
				5	10
				1	1
					1
				1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Reversed hot-cold sensation		1
Revers ble airways obstruction		1
Revers ble cerebral vasoconstriction syndrome		1
Rhabdomyolysis		2
Rheumatoid arthritis	11	61
Rheumatoid factor increased		1
Rhinalgia	1	8
Rhinitis	3	19
Rhinitis allergic		2
Rhinorrhoea	45	211
Rib fracture	1	1
Right ventricular dysfunction	1	1
Right ventricular enlargement		1
Right ventricular failure		1
Road traffic accident	2	3
Rosacea	2	4
Rotator cuff syndrome	3	8
Rubber sensitivity		1
Sacroiliitis		2
Salivary gland enlargement	1	5
Salivary gland pain		5
Salivary hypersecretion	7	23
Salt craving		1
Sarcoidosis	2	8
Sarcoma		1
SARS-CoV-2 ant body test		1
SARS-CoV-2 ant body test negative		8
SARS-CoV-2 ant body test positive		2
SARS-CoV-2 test		1
SARS-CoV-2 test negative		3
SARS-CoV-2 test positive	5	36
Scab	5	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					1
					2
	1			11	61
					1
		1	4		4
			8	3	11
					2
	5	23	78	22	133
				1	1
			1		
					1
		2	2		1
			1	2	3
		1	1	2	7
					1
			1		1
				1	5
			1		4
		3	11	4	12
					1
				2	8
					1
			1		
			4		4
			1		1
					1
			2		1
		1	10	4	26
		3	6	2	2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Scalloped tongue	1	2
Scar	4	8
Scarlet fever		1
Scar pain	2	5
Sciatica	4	17
Sciatic nerve neuropathy	1	2
Scintillating scotoma	1	2
Scleral discolouration		1
Scleritis		2
Scleroderma associated digital ulcer		1
Scratch		6
Screaming	2	4
Seasonal allergy	9	18
Seborrhoea	1	1
Seborrhoeic dermatitis	1	1
Secondary transmission		1
Secretion discharge		3
Sedation	1	4
Sedation complication		1
Seizure	25	151
Seizure cluster		3
Seizure like phenomena		1
Self-injurious ideation		2
Semen discolouration		1
Senile dementia		1
Sensation of blood flow		1
Sensation of foreign body	4	27
Sense of a foreshortened future		1
Sensitisation		2
Sensitive skin	14	70
Sensitivity to weather change		1
Sensory disturbance	13	48

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
		2	2	2	6
					1
		2	4		1
		2	5	2	12
		1	1		1
				1	2
			1		
					2
					1
			2		4
		1	2	1	2
		1	5	8	13
		1	1		
				1	1
					1
					3
			1	1	3
					1
				25	151
					3
					1
					2
					1
					1
		2	8	2	19
					1
					2
		8	33	6	37
					1
		7	25	6	23

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Sensory loss	6	32
Sensory overload	1	1
Sepsis	2	18
Septic pulmonary embolism		1
Septic shock	1	1
Serositis		2
Serum ferritin decreased	1	2
Serum ferritin increased		1
Serum sickness		1
Serum sickness-like reaction		1
Shock	4	15
Shock symptom		1
Shoulder injury related to vaccine administration	1	4
Sialoadenitis	1	2
Sight disability	1	2
Sigmoidoscopy abnormal		1
Sinonasal obstruction	1	2
Sinus arrest		2
Sinus bradycardia		1
Sinus congestion	6	17
Sinus disorder	2	7
Sinus headache	19	109
Sinusitis	5	27
Sinus node dysfunction		1
Sinus pain	11	61
Sinus tachycardia	1	21
Sitting disability		2
Sjogren's syndrome	1	5
Skin abrasion		7
Skin burning sensation	22	83
Skin depigmentation		1
Skin discharge		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			9	6	23
				1	1
				2	18
					1
				1	1
					2
				1	2
					1
					1
					1
				4	15
					1
				1	4
				1	2
		1	1		1
					1
				1	2
					2
					1
		4	7	2	10
		1	1	1	6
1	2	9	42	10	67
		4	6	1	21
					1
		5	17	6	44
		1	10		11
			1		1
				1	5
			3		4
	1	12	29	10	54
					1
					1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Skin discolouration	10	45
Skin disorder	2	11
Skin erosion	2	8
Skin exfoliation	8	31
Skin fissures		1
Skin haemorrhage	1	5
Skin hyperpigmentation	1	1
Skin hypertrophy		1
Skin indentation	2	2
Skin induration		3
Skin infection	1	7
Skin irritation	7	42
Skin laceration		1
Skin laxity		1
Skin lesion	9	21
Skin mass	1	7
Skin odour abnormal	3	5
Skin papilloma	1	1
Skin reaction	9	34
Skin sensitisation	1	11
Skin swelling	7	33
Skin temperature	1	6
Skin tightness	6	28
Skin ulcer	1	7
Skin warm	13	84
Skin weeping		2
Skull fracture		1
Sleep apnoea syndrome	1	4
Sleep attacks		1
Sleep deficit		4
Sleep disorder	39	192

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	13	6	32
		1	3	1	8
		2	4		4
		4	13	4	18
			1		
			2	1	3
		1	1		
			1		
		2	2		
			3		
		1	4		3
		6	16	1	26
					1
					1
1	1	5	11	4	10
		1	2		5
			2	3	3
		1	1		
		6	19	3	15
		1	3		8
		4	19	3	14
		1	2		4
		3	13	3	15
				1	7
		5	34	8	50
					2
					1
				1	4
					1
			1		3
		18	83	21	109

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Sleep disorder due to a general medical condition	2	12
Sleep disorder due to general medical condition, insomnia type		22
Sleep paralysis	1	2
Sleep talking	1	1
Sleep terror	2	7
Slow response to stimuli		1
Slow speech		2
Sluggishness		10
Small intestinal haemorrhage	1	2
Sneezing	23	92
Snoring	1	2
Social avoidant behaviour	2	3
Social fear		1
Soft tissue infection		1
Soft tissue inflammation	1	1
Soft tissue injury		1
Soft tissue swelling		4
Solar dermatitis	1	1
Solar lentigo	1	2
Solar urticaria	1	1
Somatic symptom disorder		1
Somnambulism	1	1
Somnolence	90	418
Speech disorder	12	51
Spina bifida	1	1
Spinal column injury		1
Spinal cord disorder		1
Spinal cord infarction	1	1
Spinal disorder		2
Spinal fracture	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			7	2	5
			8		14
		1	2		
		1	1		
		1	2	1	5
					1
					2
			3		7
				1	2
	1	10	40	13	52
				1	2
		1	1	1	2
					1
					1
		1	1		
					1
			2		2
				1	1
				1	2
				1	1
					1
				1	1
	1	39	146	51	272
	1	5	16	7	35
				1	1
					1
					1
				1	1
			1		1
				2	4

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Spinal osteoarthritis		1
Spinal pain	7	29
Spinal stenosis		1
Spleen atrophy		1
Splenic artery embolisation		1
Splenic rupture		2
Splenic vein thrombosis	1	1
Splenomegaly	1	3
Spondylitis	1	2
Sputum abnormal		1
Sputum discoloured	1	5
Sputum increased		1
Squamous cell carcinoma	1	1
Staphylococcal abscess		1
Staphylococcal infection		3
Staphylococcal sepsis		1
Staring		3
Status epilepticus	6	27
Steatorrhoea	1	2
Stereotypy		1
Stevens-Johnson syndrome	2	4
Stiff leg syndrome		1
Stiff tongue	1	3
Still birth	1	2
Stomach mass	1	1
Stoma site haemorrhage	1	1
Stomatitis	2	22
Strabismus	1	2
Streptococcal abscess		1
Streptococcal endocarditis	1	1
Streptococcal sepsis	1	1
Stress	6	26

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		3	9	4	20
					1
					1
					1
					2
				1	1
				1	3
				1	2
					1
		1	2		3
					1
				1	1
			1		
					3
					1
					3
				6	27
			1	1	1
					1
				2	4
					1
		1	2		1
				1	2
				1	1
				1	1
	1		8	2	14
		1	2		
					1
				1	1
				1	1
			7	6	19

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Stress cardiomyopathy		2
Stridor	2	9
Stroke volume decreased	1	1
Stupor	1	1
Subacute inflammatory demyelinating polyneuropathy		1
Subarachnoid haemorrhage		5
Subclavian vein thrombosis		2
Subcutaneous abscess		1
Subcutaneous haematoma		1
Subdural haematoma	1	3
Subdural haemorrhage	1	2
Submaxillary gland enlargement		2
Sudden death	1	9
Sudden hearing loss	3	10
Sudden visual loss	1	2
Suffocation feeling		1
Suicidal ideation	4	14
Suicide attempt	1	4
Sunburn	1	4
Superior sagittal sinus thrombosis		1
Suppressed lactation		2
Suprapubic pain		1
Supraventricular tachycardia	3	20
Suspected COVID-19	26	329
Suspiciousness	1	1
Sweating fever	3	44
Swelling	230	887
Swelling face	84	374
Swelling of eyelid	13	60
Swollen joint count increased		1
Swollen tongue	46	253

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
			1	2	8
				1	1
		1	1		
					1
					5
					2
					1
			1		
				1	3
				1	2
			2		
				1	9
				3	10
				1	2
			1		
				4	14
				1	4
		1	2		2
					1
					2
			1		
		1	5	2	15
		13	131	13	198
				1	1
				3	44
		85	344	145	543
	1	39	111	45	263
		4	20	9	40
					1
		16	75	30	178

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Symphysiolysis		1
Symptom recurrence	1	3
Syncope	89	525
Synovial cyst	1	4
Synovitis		2
Syringe issue	1	1
Systemic candida		1
Systemic immune activation		1
Systemic inflammatory response syndrome		2
Systemic lupus erythematosus	3	14
Systemic lupus erythematosus rash	1	5
Systolic hypertension		1
Tachyarrhythmia	1	1
Tachycardia	40	330
Tachypnea		2
Tachypnoea	3	18
Tardive dyskinesia		1
Taste disorder	22	104
Tearfulness	4	24
Teething		2
Telangiectasia		1
Temperature difference of extremities		3
Temperature intolerance		7
Temperature perception test increased		1
Temperature regulation disorder	4	10
Temporal lobe epilepsy		1
Temporomandibular joint syndrome	1	5
Tenderness	56	183
Tendon disorder	1	1
Tendon injury	1	4
Tendonitis	2	11
Tendon pain		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	2		1
	1	1	1	88	524
		1	1		3
					2
		1	1		
					1
					1
					2
	1			3	14
			1	1	4
					1
				1	1
		19	110	21	220
					2
			4	3	14
					1
		13	52	9	52
		2	8	2	16
			1		1
					1
					3
			1		6
					1
			2	4	8
					1
			3	1	2
1	3	33	111	23	72
				1	1
				1	4
		1	2	1	9
					1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Tendon rupture	1	1
Tenosynovitis stenosaurs		2
Tension	1	6
Tension headache	27	152
Terminal insomnia	3	6
Testicular pain		1
Tetany		1
Thalamic infarction		1
Therapeutic procedure		1
Therapeutic product effect increased		1
Therapeutic product ineffective		1
Therapeutic response unexpected	7	24
Thermal burn	2	9
Thermal burns of eye	1	5
Thinking abnormal	7	21
Thirst	36	138
Thoracic outlet syndrome	1	1
Throat clearing	1	5
Throat irritation	21	107
Throat tightness	22	153
Thrombocytopenia	17	57
Thrombocytopenic purpura	1	1
Thrombocytosis		1
Thrombophlebitis		7
Thrombophlebitis superficial	1	5
Thrombosis	43	109
Thrombosis in device		2
Thrombotic stroke		1
Thrombotic thrombocytopenic purpura	1	5
Thunderclap headache	1	2
Thyroid disorder		1
Thyroid function test abnormal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					2
			3	1	3
		11	51	16	101
		1	2	2	4
					1
					1
					1
			1		
					1
					1
		7	17		7
			2	2	7
				1	5
		4	7	3	14
		17	51	19	87
				1	1
				1	5
		10	34	11	73
		8	44	14	109
				17	57
				1	1
			1		
			1		6
			1	1	4
2	3			43	109
					2
					1
				1	5
				1	2
					1
			1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Thyroiditis	3	3
Thyroiditis subacute		1
Thyroid neoplasm	1	1
Thyroid pain		1
Thyroxine free increased		1
Tic		1
Tinnitus	119	389
Tongue blistering	3	9
Tongue coated	3	7
Tongue cyst		1
Tongue discolouration	4	13
Tongue discomfort	5	22
Tongue disorder	6	30
Tongue dry	1	6
Tongue eruption		5
Tongue erythema		1
Tongue exfoliation	1	1
Tongue haemorrhage		1
Tongue injury		1
Tongue movement disturbance	1	4
Tongue oedema		12
Tongue paralysis	1	2
Tongue pruritus	1	6
Tongue rough		1
Tongue spasm	1	3
Tongue ulceration	4	16
Tonic clonic movements		3
Tonic convulsion	2	8
Tonsillar disorder	1	2
Tonsillar erythema		2
Tonsillar hypertrophy	3	18
Tonsillar inflammation	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	2	2
			1		
				1	1
					1
					1
					1
		36	91	83	298
		2	3	1	6
		1	3	2	4
					1
		1	5	3	8
		2	8	3	14
		2	6	4	24
			2	1	4
			2		3
			1		
				1	1
			1		
					1
		1	2		2
			2		10
				1	2
			2	1	4
			1		
		1	1		2
		3	9	1	7
					3
				2	8
		1	1		1
			1		1
		2	9	1	9
			2	1	2

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Tonsillitis	4	19
Tonsillitis bacterial	1	3
Toothache	9	42
Tooth disorder		1
Tooth extraction		1
Tooth fracture		2
Torticollis		1
Toxic anterior segment syndrome	1	1
Toxic epidermal necrolysis		1
Toxicity to various agents		2
Toxic skin eruption		1
Tracheal inflammation		1
Tracheal pain		1
Tracheitis		2
Transaminases increased	1	1
Transferrin decreased		1
Transient global amnesia	2	4
Transient ischaemic attack	12	57
Transposition of the great vessels	1	1
Traumatic haematoma	2	2
Traumatic haemorrhage		1
Tremor	115	673
Trichodynia		1
Trichoglossia	1	1
Tricuspid valve incompetence	1	1
Trigeminal neuralgia	8	18
Trigger finger		3
Tri-iodothyronine		1
Tri-iodothyronine decreased		2
Triple negative breast cancer	1	2
Trismus	2	11
Troponin	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	3	6	1	13
				1	3
		1	11	8	31
			1		
					1
					2
					1
				1	1
	1				1
					2
					1
			1		
			1		
			1		1
			1		
		1	1	1	3
				12	57
				1	1
				2	2
					1
	3	49	210	66	463
					1
				1	1
				1	1
		2	3	6	15
			1		2
			1		
					2
				1	2
		1	2	1	9
				1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Troponin increased	1	7
Tubulointerstitial nephritis		1
Tumefactive multiple sclerosis		1
Tunnel vision	1	5
Tympanic membrane hyperaemia		1
Type 1 diabetes mellitus	1	8
Type 2 diabetes mellitus		3
Type I hypersensitivity		1
Type IV hypersensitivity reaction		4
Typical aura without headache	2	3
Ulcer		4
Ulcerative keratitis		4
Ulnar nerve injury		3
Ulnar neuritis		1
Umbilical cord abnormality	1	1
Underdose	3	9
Undersensing	1	1
Underweight		2
Unresponsive to stimuli	2	25
Upper-airway cough syndrome	2	7
Upper airway obstruction		2
Upper gastrointestinal haemorrhage		1
Upper limb fracture		5
Upper respiratory tract congestion	1	3
Upper respiratory tract infection		3
Urge incontinence	1	1
Urinary incontinence	5	28
Urinary retention	3	20
Urinary tract disorder	1	2
Urinary tract infection	9	65
Urinary tract infection bacterial		1
Urinary tract pain		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	7
					1
					1
				1	5
					1
				1	8
					3
					1
			1		3
		1	1	1	2
					4
					4
					3
					1
				1	1
		2	8	1	1
		1	1		
					2
				2	25
			2	2	5
					2
					1
					5
		1	1		2
					3
				1	1
		3	8	2	20
				3	20
		1	1		1
	1	4	11	5	54
					1
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Urine abnormality	2	3
Urine analysis abnormal		2
Urine flow decreased	1	3
Urine ketone body present	1	1
Urine odour abnormal		4
Urine output		2
Urine output decreased	2	6
Urine output increased		1
Urosepsis		1
Urticaria	94	486
Urticaria chronic		4
Urticarial vasculitis	1	1
Urticaria papular	1	2
Urticaria thermal	1	2
Uterine contractions abnormal		1
Uterine haemorrhage	2	5
Uterine leiomyoma	4	4
Uterine pain	1	3
Uterine polyp	1	1
Uterine prolapse	1	1
Uterine spasm		1
Uveitis	1	8
Uvulitis		1
Vaccination complication	2	20
Vaccination error	2	2
Vaccination failure		6
Vaccination site abscess		5
Vaccination site bruising	22	107
Vaccination site calcification		1
Vaccination site cellulitis	4	27
Vaccination site coldness	1	2
Vaccination site discharge		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	2	2
			1		1
				1	3
				1	1
			1		3
			1		1
		1	3	1	3
			1		
					1
		55	212	39	274
					4
				1	1
		1	2		
		1	2		
					1
				2	5
				4	4
				1	3
				1	1
				1	1
			1		
				1	8
			1		
			7	2	13
		2	2		
					6
			3		2
1	1	12	52	10	55
					1
		3	8	1	19
		1	1		1
					1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination site discolouration	5	13
Vaccination site discomfort	14	71
Vaccination site dryness		2
Vaccination site eczema		1
Vaccination site erythema	137	720
Vaccination site haematoma		2
Vaccination site haemorrhage	3	23
Vaccination site hyperaesthesia	1	6
Vaccination site hypersensitivity	1	5
Vaccination site hypoaesthesia	3	20
Vaccination site induration	16	84
Vaccination site infection		22
Vaccination site inflammation	11	66
Vaccination site irritation	4	12
Vaccination site joint discomfort		1
Vaccination site joint erythema	1	4
Vaccination site joint movement impairment	4	18
Vaccination site joint pain	3	12
Vaccination site joint swelling		1
Vaccination site joint warmth		1
Vaccination site lymphadenopathy	1	22
Vaccination site macule		2
Vaccination site mass	69	280
Vaccination site movement impairment	24	93
Vaccination site necrosis		2
Vaccination site nodule		1
Vaccination site oedema	4	13
Vaccination site pain	460	2,788
Vaccination site papule		1
Vaccination site paraesthesia	2	30
Vaccination site photosensitivity reaction	1	1
Vaccination site pruritus	70	297

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	5	4	8
		5	35	9	36
			1		1
			1		
1	1	92	418	45	302
					2
		1	8	2	15
			2	1	4
		1	3		2
		1	7	2	13
		9	51	7	33
			7		15
		9	40	2	26
		3	6	1	6
			1		
		1	3		1
			6	4	12
		3	6		6
			1		
			1		
		1	8		14
			2		
1	2	37	133	32	147
		3	30	21	63
					2
					1
		3	7	1	6
1	9	283	1369	177	1419
					1
			13	2	17
		1	1		
1	1	51	185	19	112

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination site rash	23	142
Vaccination site reaction	10	51
Vaccination site scab		1
Vaccination site scar		2
Vaccination site swelling	136	754
Vaccination site urticaria	4	18
Vaccination site vesicles	1	9
Vaccination site warmth	76	373
Vaccine breakthrough infection		4
Vaginal cyst		2
Vaginal discharge	3	5
Vaginal disorder		2
Vaginal haemorrhage	53	102
Vaginal ulceration		1
Varicella	3	8
Varicose vein		5
Vascular dementia		3
Vascular headache	2	9
Vascular injury	1	4
Vascular pain	1	3
Vascular stent thrombosis		1
Vasculitic rash		6
Vasculitis	3	24
Vasodilatation	1	11
Vasospasm		1
Vein discolouration		1
Vein disorder	2	6
Vein rupture		2
Venous haemorrhage		1
Venous injury		2
Venous thrombosis		3
Ventricular arrhythmia	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		15	77	8	65
1	1	7	26	3	25
					1
			1		1
		80	377	56	377
		2	10	2	8
		1	2		7
		50	197	26	176
					4
					2
		1	2	2	3
			1		1
		14	25	39	77
					1
			2	3	6
			2		3
					3
			3	2	6
				1	4
			1	1	2
					1
			2		4
		1	7	2	17
			2	1	9
			1		
			1		
				2	6
					2
					1
					2
					3
				1	3

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Ventricular extrasystoles	4	8
Ventricular f brillation		3
Ventricular flutter	1	1
Ventricular hypertrophy		1
Ventricular tachycardia	1	3
Vertebral lesion	1	2
Vertigo	81	377
Vertigo labyrinthine	1	4
Vertigo positional	9	29
Vestibular disorder		3
Vestibular migraine		6
Vestibular neuritis	2	6
Viral infection	6	16
Viral labyrinthitis		4
Viral pharyngitis	1	5
Viral rash	2	12
Viral sepsis	1	1
Viral test		1
Viral tonsillitis		1
Visceral venous thrombosis		1
Vision blurred	78	322
Visual acuity reduced	1	8
Visual brightness		1
Visual field defect	2	11
Visual impairment	30	132
Visuospatial deficit	1	1
Vital capacity		1
Vitamin B12 decreased		1
Vitamin D		1
Vitamin D decreased	1	1
Vitamin D deficiency		1
Vlth nerve paralysis	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				4	8
					3
				1	1
					1
				1	3
				1	2
	1	22	77	59	300
				1	4
			2	9	27
			1		2
			1		5
				2	6
			3	6	13
			2		2
				1	5
			4	2	8
				1	1
					1
					1
		27	97	51	225
			2	1	6
			1		
		1	3	1	8
		10	44	20	88
				1	1
					1
					1
		1	1		
					1
				2	5

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vitreous detachment	5	12
Vitreous disorder	1	1
Vitreous floaters	9	23
Vitreous haemorrhage	1	2
Vitreous haze	1	1
Vocal cord disorder		1
Vomiting	251	1,433
Vomiting projectile	4	29
Vomiting psychogenic		1
Vth nerve injury		1
Vulval abscess		1
Vulval haemorrhage		4
Vulval oedema		1
Vulval ulceration	1	2
Vulvovaginal burning sensation		1
Vulvovaginal candidiasis	2	11
Vulvovaginal dryness	1	1
Vulvovaginal injury	1	1
Vulvovaginal pain	2	7
Vulvovaginal pruritus		1
Vulvovaginal rash		1
Vulvovaginal swelling		1
Vulvovaginal ulceration		3
Wa king aid user	1	1
Wa king disability	1	1
Water pollution		1
Weight bearing difficulty	1	6
Weight decreased	14	42
Weight increased	1	3
Weight loss diet		1
Wheat-free diet		1
Wheezing	39	178

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				5	12
				1	1
		3	8	6	15
				1	2
				1	1
					1
	4	109	449	142	984
		1	7	3	22
					1
					1
					1
					4
			1		
		1	2		
					1
		1	3	1	8
				1	1
				1	1
			2	2	5
			1		
			1		
					1
					3
				1	1
				1	1
					1
			3	1	3
		3	9	11	33
		1	2		1
					1
					1
		8	48	31	130

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
White blood cell count abnormal		1						1
White blood cell count decreased	2	9			1	2	1	7
White blood cell count increased	4	15			1	5	3	10
White blood cells urine positive	1	1			1	1		
Withdrawal syndrome	2	3					2	3
Wound	1	5			1	3		2
Wound complication	3	5			2	3	1	2
Wound drainage	1	1					1	1
Wound haemorrhage		1						1
Wound secretion		1						1
Wrist fracture	1	2					1	2
Writer's cramp		1						1
Wrong product administered	10	14			10	14		
Wrong technique in product usage process	1	3			1	2		1
Xanthopsia	1	1					1	1
Yawning	1	9				1	1	8
Yellow skin		5				3		2
	17	29			17	29		
	28,610	133,689	133	544	12873	47960	15737	85729

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal adhesions		1						1
Abdominal discomfort	8	55			3	13	5	42
Abdominal distension	14	34			2	11	12	23
Abdominal infection		1						1
Abdominal lymphadenopathy		1						1
Abdominal pain	14	96		2	5	24	9	72
Abdominal pain lower	4	12			1	3	3	9
Abdominal pain upper	34	139			9	34	25	105
Abdominal rigidity		1						1
Abnormal behaviour		3				1		2
Abnormal clotting factor	1	1			1	1		
Abnormal dreams	5	22			2	12	3	10
Abnormal faeces		1						1
Abnormal loss of weight	2	3					2	3
Abnormal sensation in eye		2				1		1
Abnormal weight gain	1	3			1	1		2
Abscess		1						1
Acarodermatitis		1						1
Accidental exposure to product	1	1			1	1		
Accidental overdose		1				1		
Acidosis		2						2
Acne	3	8			2	2	1	6
Acoustic neuroma		1						1
Acquired haemophilia	1	2					1	2
Activated partial thromboplastin time prolonged	3	4			1	1	2	3
Acute abdomen		2						2
Acute cardiac event	1	3					1	3
Acute coronary syndrome		2						2
Acute disseminated encephalomyelitis	1	2					1	2
Acute hepatic failure	1	1					1	1
Acute kidney injury	3	16					3	16
Acute leukaemia		1						1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acute myocardial infarction	2	12
Acute pulmonary oedema		1
Acute respiratory distress syndrome		1
Acute respiratory failure		1
Adiposis dolorosa	1	1
Administration site discomfort		1
Adrenal haemorrhage	1	1
Adrenocortical insufficiency acute		1
Adverse drug reaction	2	7
Affect lability		1
Ageusia	8	40
Aggression	1	5
Agitation	3	13
Alanine aminotransferase increased	1	4
A buminuria		1
Alcoholic hangover		1
Alcohol interaction	1	2
Alexia		1
Alexithymia		1
Allergic cough		1
Allergic oedema		2
Allergic sinusitis		1
Allergy to vaccine		6
Allodynia		2
Alopecia	2	6
Altered state of consciousness		1
Amaurosis fugax	1	1
Amegakaryocytic thrombocytopenia		1
Ammonia abnormal		1
Amnesia	5	24
Anaemia	1	6
Anaemia megaloblastic		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	12
					1
					1
					1
				1	1
			1		
				1	1
					1
		2	7		
			1		
		2	10	6	30
			1	1	4
			4	3	9
				1	4
					1
					1
				1	2
			1		
			1		
					1
					2
					1
			4		2
					2
			1	2	5
					1
				1	1
					1
			1		
		2	6	3	18
				1	6
					1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anaemia vitamin B12 deficiency		1
Anal haemorrhage		2
Anal incontinence	2	8
Anal pruritus		1
Anaphylactic reaction	6	42
Anaphylactic shock	1	6
Anaphylactoid reaction	1	2
Anaphylactoid shock		2
Anger		2
Angina pectoris	3	18
Angioedema	4	20
Ankylosing spondylitis		2
Anorectal discomfort		1
Anosmia	5	32
Anticoagulation drug level below therapeutic		1
Anuria	1	1
Anxiety	11	53
Aortic aneurysm		1
Aortic aneurysm rupture		1
Aortic dissection		1
Aortic thrombosis	1	1
Apathy	1	8
Aphasia	2	12
Aphonia	4	7
Aphthous ulcer		2
Apnoeic attack	1	1
Apparent death		1
Appendicitis		5
Appendicitis perforated		1
Appetite disorder		1
Application site acne	1	1
Application site pain	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					2
			1	2	7
					1
				6	42
				1	6
				1	2
					2
			2		
				3	18
				4	20
					2
					1
		2	9	3	23
					1
				1	1
		4	10	7	43
					1
					1
					1
				1	1
			1	1	7
		1	1	1	11
		3	3	1	4
					2
				1	1
					1
					5
					1
					1
				1	1
				1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Application site vesicles		1
Areflexia	1	1
Arrhythmia	2	12
Arrhythmia supraventricular		3
Arterial occlusive disease		1
Arterial rupture		1
Arterial stenosis	1	1
Arterial thrombosis	1	2
Arteriosclerosis coronary artery		1
Arteriospasm coronary		1
Arthralgia	202	877
Arthritis	7	27
Arthritis bacterial		1
Arthritis reactive		6
Arthritis viral		1
Arthropathy	3	8
Ascites		1
Aspartate aminotransferase increased		2
Aspiration		3
Asthenia	66	268
Asthenopia	5	16
Asthma	7	27
Asthma late onset		1
Asymptomatic COVID-19		6
Ataxia	1	4
Atonic seizures		1
Atrial fibrillation	8	57
Atrial flutter	3	7
Atrial tachycardia		2
Atrioventricular block	1	2
Atrioventricular block complete		2
Atrioventricular block second degree	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
				2	12
					3
					1
					1
				1	1
		1	1		1
					1
					1
1	8	65	249	137	628
			2	7	25
					1
					6
			1		
		1	1	2	7
					1
					2
					3
		18	72	48	196
		4	7	1	9
		2	4	5	23
					1
			2		4
				1	4
					1
	1			8	57
				3	7
			1		1
				1	2
					2
				1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Attention deficit hyperactivity disorder		1
Auditory disorder		1
Aura		1
Auricular swelling		2
Autism spectrum disorder	1	1
Autoimmune disorder	4	6
Autoimmune haemolytic anaemia	3	4
Autoimmune neutropenia		2
Autonomic nervous system imbalance	1	1
Autoscopy		2
Axillary mass	5	14
Axillary pain	20	68
Axonal neuropathy		1
Bacille Calmette-Guerin scar reactivation		1
Back pain	43	219
Bacterial infection	1	3
Balance disorder	18	82
Basal cell carcinoma		1
Bedridden	3	8
Behaviour disorder		3
Bell's palsy	13	85
Bile duct stone		1
Biliary sepsis		1
Binge eating		1
Bipolar disorder	1	1
Bite		1
Bladder disorder	2	4
Bladder neoplasm		1
Bladder pain	2	3
Bleeding time prolonged	1	1
Blepharitis	1	2
Blepharospasm	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
					1
					2
				1	1
				4	6
				3	4
					2
				1	1
					2
		2	5	3	9
		4	28	16	40
					1
			1		
	1	13	57	30	162
		1	1		2
1	2	8	18	10	64
					1
		2	2	1	6
					3
				13	85
					1
					1
					1
				1	1
					1
				2	4
					1
				2	3
				1	1
				1	2
			1	1	3

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blindness	3	19
Blindness transient		1
Blindness unilateral		2
Blister	17	43
Blister infected		1
Blood albumin decreased		1
Blood bilirubin abnormal	1	1
Blood blister	2	7
Blood cholesterol increased		2
Blood count abnormal		2
Blood creatine phosphokinase increased	1	3
Blood electrolytes increased		1
Blood glucose		1
Blood glucose abnormal		4
Blood glucose decreased	4	12
Blood glucose fluctuation		4
Blood glucose increased	3	28
Blood growth hormone abnormal		1
Blood heavy metal increased		1
Blood immunoglobulin E increased		1
Blood immunoglobulin G increased	1	1
Blood immunoglobulin M decreased	1	1
Blood iron increased		1
Blood lactic acid increased		2
Blood pH increased		1
Blood phosphorus decreased		1
Blood potassium decreased		2
Blood pressure abnormal	1	2
Blood pressure decreased	3	17
Blood pressure diastolic decreased	1	2
Blood pressure diastolic increased		3
Blood pressure fluctuation	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	19
					1
					2
		6	11	11	32
			1		
					1
				1	1
			1	2	6
					2
					2
			1	1	2
			1		
					1
			2		2
		1	4	3	8
					4
			8	3	20
			1		
			1		
					1
				1	1
				1	1
					1
			1		1
					1
					1
					2
		1	1		1
		2	5	1	12
		1	2		
					3
				2	4

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood pressure increased	8	43
Blood pressure measurement	1	1
Blood pressure normal	1	1
Blood pressure systolic decreased		2
Blood pressure systolic increased	1	2
Blood sodium decreased		2
Blood test abnormal	1	3
Blood thrombin		1
Blood urea increased		1
Blood uric acid increased	1	1
Blood urine	1	1
Blood urine present	5	11
Blood viscosity increased		1
Blue toe syndrome	1	2
Body temperature	4	6
Body temperature abnormal	6	13
Body temperature decreased	2	7
Body temperature fluctuation	2	12
Body temperature increased	5	49
Bone pain	5	39
Bone swelling		1
Bradycardia	2	9
Bradyphrenia		2
Brain hypoxia		1
Brain neoplasm		1
Brain stem stroke		1
Brain stem syndrome		2
Breast cancer	1	1
Breast mass	2	3
Breast pain	1	1
Breath odour		4
Breath sounds abnormal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	7	6	36
				1	1
				1	1
					2
			1	1	1
			1		1
				1	3
					1
			1		
		1	1		
				1	1
		1	1	4	10
			1		
				1	2
		1	3	3	3
		2	4	4	9
		1	2	1	5
			3	2	9
1	1	3	26	2	23
	3	1	10	4	29
			1		
				2	9
					2
					1
					1
					1
					2
				1	1
		1	1	1	2
		1	1		
			2		2
					1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bronchiectasis	1	2
Bronchospasm	1	1
Bruxism		2
Bulbar palsy		1
Bulimia nervosa		1
Bundle branch block		1
Bundle branch block right		3
Burning sensation	19	39
Bursitis	2	5
Cachexia		1
Campylobacter gastroenteritis	1	1
Cardiac arrest	5	42
Cardiac discomfort		1
Cardiac disorder	2	5
Cardiac dysfunction	1	1
Cardiac failure	1	6
Cardiac failure acute		2
Cardiac failure chronic		1
Cardiac flutter	2	13
Cardiac valve disease		1
Cardiogenic shock		1
Cardiomegaly		1
Cardio-respiratory arrest		1
Cardiovascular disorder		1
Carotid artery disease		1
Carotid artery dissection		1
Carotid artery thrombosis		1
Carpal tunnel syndrome		3
Cataract		1
Catarrh	1	3
Catatonia		1
Cellulitis	3	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
				1	1
					2
					1
					1
					1
			1		2
		7	13	12	26
		2	3		2
					1
				1	1
				5	42
					1
			2	2	3
				1	1
				1	6
					2
					1
				2	13
					1
					1
			1		
					1
					1
					1
			1		2
					1
		1	3		
					1
				3	12

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Central nervous system lesion		1
Central venous pressure abnormal		1
Central vision loss		1
Cerebellar haemorrhage	1	1
Cerebellar infarction		2
Cerebral artery embolism		1
Cerebral artery thrombosis		1
Cerebral cyst	1	1
Cerebral disorder		1
Cerebral haemorrhage	4	12
Cerebral infarction		13
Cerebral palsy	1	1
Cerebral thrombosis		6
Cerebral venous sinus thrombosis	1	7
Cerebral venous thrombosis	1	2
Cerebrovascular accident	18	88
Cervicobrachial syndrome		1
Cervicogenic headache		1
Change of bowel habit	1	2
Chest discomfort	23	103
Chest pain	59	240
Chillblains	2	11
Chills	140	880
Chloropsia	1	1
Choking		4
Choking sensation		1
Cholangitis		1
Cholestasis	1	1
Chondritis		1
Chorea		1
Chromaturia	2	9
Chronic fatigue syndrome	4	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
					1
				1	1
					2
					1
					1
				1	1
					1
				4	12
					13
				1	1
					6
				1	7
				1	2
				18	88
					1
					1
		1	1		1
		5	24	18	79
	1	11	46	48	194
			7	2	4
1	3	77	312	63	568
				1	1
					4
					1
					1
				1	1
					1
			4	2	5
	1	2	3	2	6

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chronic kidney disease		2
Chronic obstructive pulmonary disease	2	10
Circulatory collapse		28
Clonic convulsion		1
Clostridium test positive		1
Clumsiness		2
Cluster headache	3	14
Coagulation time prolonged	1	2
Coagulation time shortened	1	1
Coagulopathy	1	2
Coeliac disease		1
Cognitive disorder	2	16
Cold-stimulus headache		2
Cold sweat	11	69
Colitis		4
Colitis ulcerative	2	7
Coma		2
Coma scale abnormal		3
Communication disorder		3
Concussion		1
Condition aggravated	15	71
Confusional state	29	139
Congestive hepatopathy	1	1
Conjunctival haemorrhage	1	5
Conjunctival hyperaemia		1
Conjunctivitis	2	8
Constipation	11	37
Contraindicated product prescribed		1
Contusion	21	54
Conversion disorder		1
Coordination abnormal	2	14
Corneal reflex decreased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		1	1	1	9
					28
					1
					1
					2
			2	3	12
				1	2
				1	1
		1	1		1
					1
		1	2	1	14
			1		1
		4	21	7	48
					4
	1			2	7
					2
					3
			1		2
			1		
	1	1	16	14	55
		6	26	23	113
				1	1
				1	5
					1
		1	3	1	5
		4	9	7	28
			1		
	1	6	18	15	36
					1
				2	14
			1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Coronary artery disease		3
Coronary artery occlusion	1	1
Coronary artery thrombosis	1	2
Coronavirus test positive	1	2
Cortisol decreased		1
Costochondritis		2
Cough	32	189
Cough decreased		1
COVID-19	20	185
COVID-19 immunisation		2
COVID-19 pneumonia	1	12
Cranial nerve disorder		1
C-reactive protein increased	3	16
Creutzfeldt-Jakob disease		1
Crohn's disease	2	7
Croup infectious	1	1
Crying		6
Crystal arthropathy		1
CT hypotension complex		1
Cutaneous vasculitis	2	3
Cyanopsia		1
Cyanosis	2	6
Cystitis	3	5
Dark circles under eyes		1
Deafness	10	30
Deafness neurosensory	3	6
Deafness unilateral	4	8
Death	6	58
Decreased activity	1	1
Decreased appetite	35	191
Decreased insulin requirement		1
Decreased interest		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
				1	1
				1	2
		1	2		
					1
					2
		15	71	17	118
			1		
		5	32	15	153
			1		1
				1	12
					1
			5	3	11
					1
				2	7
				1	1
			3		3
					1
					1
				2	3
					1
			2	2	4
				3	5
					1
				10	30
				3	6
				4	8
				6	58
				1	1
	1	12	50	23	141
					1
					1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Deep vein thrombosis	20	60
Dehydration	8	27
Deja vu		1
Delayed recovery from anaesthesia	1	1
Delirium	4	35
Delusion		2
Delusional perception	1	1
Dementia	1	6
Dementia with Lewy bodies		1
Demyelination	1	3
Dental discomfort		1
Dental paraesthesia	2	2
Depersonalisation/derealisation disorder		1
Depressed level of consciousness	1	8
Depressed mood	7	22
Depression	6	28
Depression suicidal		1
Derealisation	1	2
Dermatitis	3	12
Dermatitis acneiform		1
Dermatitis allergic	1	12
Dermatitis atopic	1	3
Dermatitis bullous	1	3
Dermatitis contact	1	2
Dermatitis exfoliative		1
Dermatitis exfoliative generalised	1	1
Dermatitis infected		1
Dermatosis		1
Device infusion issue		1
Device pacing issue		1
Diabetes mellitus	6	16
Diabetes mellitus inadequate control		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				20	60
		2	8	6	19
					1
				1	1
				4	35
			1		1
				1	1
				1	6
					1
				1	3
					1
				2	2
					1
				1	8
		2	3	5	19
		1	3	5	25
					1
				1	2
		1	4	2	8
					1
		1	4		8
				1	3
				1	3
				1	2
					1
				1	1
			1		
			1		
					1
					1
				6	16
					3

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Diabetic coma		1
Diabetic ketoacidosis		3
Diaphragmalgia	1	1
Diarrhoea	70	401
Diarrhoea haemorrhagic		2
Diplegia		1
Diplopia	7	26
Discoloured vomit		1
Discomfort	14	40
Disease progression	1	2
Disease recurrence	28	90
Disorganised speech		1
Disorientation	8	36
Disseminated varicella zoster virus infection		1
Dissociation	1	3
Dissociative disorder		1
Disturbance in attention	19	58
Diverticulum	1	2
Diverticulum intestinal		1
Dizziness	164	683
Dizziness exertional		7
Dizziness postural	12	48
Dreamy state		1
Drooling		4
Drug eruption		2
Drug hypersensitivity		1
Drug-induced liver injury		1
Drug ineffective	17	180
Drug interaction	5	6
Drug withdrawal syndrome	1	1
Dry eye	4	12
Dry mouth	10	35

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					3
		1	1		
		34	104	36	297
					2
					1
		1	6	6	20
					1
		4	18	10	22
				1	2
		6	12	22	78
					1
		1	6	7	30
					1
			1	1	2
			1		
	1	4	16	15	42
			1	1	1
					1
2	3	61	213	103	470
					7
		3	9	9	39
					1
			2		2
			1		1
					1
					1
				17	180
		2	3	3	3
				1	1
		3	6	1	6
		6	15	4	20

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dry skin	7	18
Dry throat	2	12
Duodenal ulcer perforation		1
Dupuytren's contracture		1
Dysarthria	1	25
Dyschezia		2
Dysdiadochokinesis		1
Dysentery		1
Dysgeusia	17	67
Dysgraphia		1
Dyskinesia	2	9
Dyspepsia	5	24
Dysphagia	8	29
Dysphemia		1
Dysphonia	2	14
Dyspnoea	82	386
Dyspnoea at rest		2
Dyspnoea exertional	5	20
Dyssomnia		1
Dysstasia	5	22
Dystonia		2
Dysuria	6	22
Ear congestion	1	2
Ear discomfort	5	11
Ear disorder	1	3
Ear haemorrhage		1
Ear infection	3	8
Ear pain	18	57
Ear pruritus	1	3
Ear swelling	4	8
Eating disorder		4
Eating disorder symptom		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	5	4	13
		1	4	1	8
					1
					1
			2	1	23
			2		
					1
					1
		12	42	5	25
					1
			1	2	8
		2	6	3	18
		3	5	5	24
			1		
		1	2	1	12
		17	68	65	318
					2
		1	7	4	13
			1		
		1	4	4	18
					2
		1	7	5	15
			1	1	1
		2	4	3	7
			1	1	2
					1
		1	3	2	5
		6	17	12	40
			1	1	2
		2	2	2	6
			3		1
					1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eczema	6	18
Eczema eyelids		1
Eczema herpeticum		1
Eczema nummular		1
Effusion	1	1
Electric shock		1
Electric shock sensation		5
Electrocardiogram abnormal		1
Electrocardiogram ST segment abnormal		1
Electrocardiogram ST segment elevation		2
Embolic cerebral infarction		1
Embolism	9	26
Embolism venous	1	1
Emotional disorder		3
Emotional distress	1	5
Emphysema		1
Encephalitis	3	5
Encephalitis viral	1	3
Encephalopathy		1
Endocarditis	1	1
Energy increased	1	3
Enlarged uvula		4
Enteritis	1	3
Enuresis	1	2
Eosinophilia	2	2
Epididymitis		2
Epigastric discomfort		1
Epiglottic oedema		1
Epiglottitis		1
Epilepsy	8	33
Epiploic appendagitis	1	1
Epistaxis	18	73

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1		4	6	14
			1		
					1
			1		
				1	1
			1		
			2		3
					1
					1
					2
					1
				9	26
				1	1
					3
			2	1	3
					1
				3	5
				1	3
					1
				1	1
				1	3
			1		3
				1	2
				1	2
		1	1	1	1
					2
					1
					1
					1
				8	33
				1	1
		8	23	10	50

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Erectile dysfunction		12
Erection increased		2
Eructation	2	7
Erythema	30	113
Erythema multiforme	1	4
Erythema nodosum	1	3
Erythema of eyelid		2
Erythrospia		2
Essential hypertension		1
Essential tremor		1
Euphoric mood	4	7
Eustachian tube disorder	1	1
Evans syndrome		1
Exercise tolerance decreased		3
Exertional headache		1
Exfoliative rash	1	1
Expired product administered		2
Exploding head syndrome	1	2
Exposure during pregnancy	1	1
Exposure via breast milk		9
Exposure via skin contact	1	1
Extensive swelling of vaccinated limb		1
External ear inflammation		1
Extraocular muscle paresis	1	1
Extrasystoles	8	16
Extremity necrosis		1
Eye contusion	2	3
Eye disorder	2	4
Eye haemorrhage	1	4
Eye infection	1	3
Eye inflammation	1	2
Eye injury	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					12
					2
		1	3	1	4
		13	44	17	69
				1	4
			1	1	2
			1		1
			1		1
					1
					1
		2	2	2	5
				1	1
					1
			2		1
					1
				1	1
			1		1
				1	2
				1	1
			2		7
		1	1		
					1
					1
				1	1
		2	2	6	14
					1
		1	2	1	1
				2	4
				1	4
		1	1		2
				1	2
				2	2

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* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye irritation	2	9
Eyelid disorder		2
Eyelid function disorder		2
Eyelid pain		1
Eyelid ptosis		3
Eyelids pruritus	1	1
Eye movement disorder	2	6
Eye pain	23	87
Eye pruritus	6	18
Eye swelling	6	25
Eye symptom	1	1
Eye ulcer	1	2
Face injury		1
Face oedema		3
Face presentation		1
Facial asymmetry		1
Facial discomfort		2
Facial nerve disorder		1
Facial neuralgia		1
Facial pain	6	25
Facial paralysis	3	39
Facial paresis	1	9
Facial spasm	2	6
Faecal calprotectin increased	3	4
Faecaloma		2
Faeces discoloured		9
Faeces hard		1
Faeces pale	1	3
Faeces soft	1	1
Fall	14	63
Fatigue	348	1,706
Fear	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	2	7
			1		1
					2
			1		
			2		1
		1	1		
		1	1	1	5
		8	20	15	67
		3	6	3	12
		4	9	2	16
		1	1		
			1	1	1
					1
			1		2
			1		
			1		
			1		1
		2	8	4	17
				3	39
			4	1	5
		1	2	1	4
		2	2	1	2
					2
			5		4
					1
		1	3		
				1	1
		6	17	8	46
5	31	142	543	206	1163
			1	2	3

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Fear of falling		1
Febrile convulsion	1	1
Feeding disorder	2	16
Feeling abnormal	45	157
Feeling cold	38	173
Feeling drunk	2	12
Feeling hot	23	103
Feeling jittery		2
Feeling of body temperature change	8	33
Feeling of despair		1
Femoral neck fracture	1	1
Fibrin D dimer increased	2	6
Fibromyalgia	2	3
Fine motor skill dysfunction	2	2
Fixed eruption		1
Flank pain	2	10
Flashback		1
Flatulence	2	26
Fluid retention	2	4
Flushing	5	27
Foaming at mouth		1
Follicular lymphoma		1
Folliculitis		1
Food craving	1	1
Food intolerance	1	1
Food poisoning		1
Food refusal		1
Forced expiratory volume increased		1
Foreign body sensation in eyes		3
Formication	1	3
Foveal reflex abnormal		1
Fractured skull depressed		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
		1	9	1	7
	2	13	40	32	117
		10	53	28	120
			3	2	9
		9	45	14	58
					2
		4	13	4	20
					1
				1	1
			2	2	4
		1	1	1	2
		2	2		
			1		
			1	2	9
					1
		1	8	1	18
				2	4
		2	13	3	14
					1
					1
			1		
				1	1
				1	1
					1
					1
					1
					3
				1	3
					1
					1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Freezing phenomenon		1
Frequent bowel movements	2	6
Frustration tolerance decreased	2	2
Full blood count increased		1
Functional gastrointestinal disorder		1
Furuncle	2	8
Gait disturbance	22	99
Gait inability	5	36
Gastric cancer		1
Gastric dilatation		1
Gastric disorder	1	3
Gastric haemorrhage		2
Gastric varices haemorrhage		1
Gastritis		3
Gastroenteritis		8
Gastroenteritis viral		1
Gastrointestinal carcinoma		1
Gastrointestinal disorder	1	6
Gastrointestinal haemorrhage		2
Gastrointestinal pain	3	11
Gastrointestinal sounds abnormal		1
Gastroesophageal reflux disease	5	13
Gastroschisis		1
Generalised tonic-clonic seizure	1	9
General physical health deterioration		3
Genital herpes	1	3
Genital herpes simplex	2	2
Genital lesion	1	2
Genital pain		1
Genitourinary symptom		1
Giant cell arteritis		1
Gingival bleeding	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1	1	5
				2	2
					1
					1
		1	2	1	6
		8	24	14	75
			6	5	30
					1
					1
		1	1		2
					2
					1
			1		2
			1		7
					1
			2	1	4
					2
			1	3	10
					1
		1	1	4	12
					1
				1	9
					3
				1	3
		1	1	1	1
		1	2		
					1
					1
					1
				2	4

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gingival blister		1
Gingival discomfort		1
Gingival disorder		2
Gingival pain	1	6
Gingival swelling	2	4
Glassy eyes		1
Glaucoma		2
Gliososis		1
Glomerulonephritis		1
Glomerulonephritis minimal lesion		2
Glomerulonephritis rapidly progressive		1
Glossodynia	2	12
Glucose urine present		1
Goitre	1	1
Gonorrhoea		1
Gout	10	30
Gouty tophus		1
Graft versus host disease		1
Grip strength decreased	4	9
Groin pain	5	15
Guillain-Barre syndrome	3	15
Guttate psoriasis	1	2
Haemangioma		1
Haemarthrosis	1	2
Haematemeses		4
Haematochezia		6
Haematoma	2	7
Haematuria	2	8
Haemodynamic instability		1
Haemoglobin decreased	2	5
Haemolysis	3	3
Haemolytic anaemia	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
			1		1
				1	6
				2	4
					1
					2
					1
					1
					2
					1
			4	2	8
					1
				1	1
					1
		2	2	8	28
					1
					1
		1	3	3	6
		2	4	3	11
				3	15
				1	2
			1		
				1	2
					4
			1		5
			3	2	4
			1	2	7
					1
			2	2	3
				3	3
				2	2

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Haemoptysis	6	12
Haemorrhage	15	32
Haemorrhage intracranial		3
Haemorrhage subcutaneous		1
Haemorrhage urinary tract		3
Haemorrhagic stroke	1	2
Haemorrhoids	3	5
Hair texture abnormal		2
Hallucination	6	19
Hallucination, auditory		1
Hallucination, olfactory		1
Hallucinations, mixed		1
Hallucination, visual	2	6
Hand-arm vibration syndrome		1
Hand-eye coordination impaired		1
Hand fracture		1
Hangover	2	11
Headache	400	1,926
Head discomfort	5	21
Head injury	5	18
Heart disease congenital		1
Heart injury	2	6
Heart rate	3	5
Heart rate abnormal	2	7
Heart rate decreased	3	17
Heart rate increased	20	79
Heart rate irregular	8	20
Heart sounds abnormal		1
Heat stroke		1
Hemianopia homonymous		1
Hemiparesis		8
Hemiplegia		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2	5	10
	1			15	32
					3
					1
					3
				1	2
		2	2	1	3
			1		1
				6	19
					1
					1
					1
				2	6
					1
					1
					1
		2	4		7
1	9	182	678	218	1248
		2	6	3	15
		2	4	3	14
					1
				2	6
		2	2	1	3
				2	7
		1	3	2	14
		2	18	18	61
1	1	2	3	6	17
					1
					1
					1
					8
					2

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Henoch-Schonlein purpura	1	1
Hepatic artery embolism		1
Hepatic cancer	1	1
Hepatic cirrhosis	1	2
Hepatic enzyme increased		3
Hepatic failure		1
Hepatic pain		2
Hepatic vein thrombosis	1	1
Hepatitis	1	2
Hepatitis viral		2
Hepatocellular carcinoma	1	1
Hernia	1	1
Herpes ophthalmic		1
Herpes simplex	2	3
Herpes simplex encephalitis		1
Herpes simplex reactivation		1
Herpes virus infection	1	5
Herpes zoster	105	197
Herpes zoster oticus	1	3
Herpes zoster reactivation	3	4
Hiccups	1	2
HIV infection	1	1
Homicidal ideation	1	1
Hordeolum		2
Horner's syndrome		1
Hot flush	14	59
Hyperacusis	5	10
Hyperaesthesia	2	11
Hyperaesthesia teeth	3	3
Hyperchlorhydria	1	1
Hypercoagulation		1
Hyperglycaemia	1	16

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
				1	1
				1	2
			2		1
					1
					2
				1	1
				1	2
					2
				1	1
				1	1
					1
		1	1	1	2
					1
			1		
			1	1	4
		53	75	52	122
				1	3
		3	3		1
				1	2
				1	1
		1	1		
					2
					1
		8	22	6	37
				5	10
		1	7	1	4
		2	2	1	1
		1	1		
					1
				1	16

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hyperhidrosis	45	239
Hyperintensity in brain deep nuclei	1	1
Hyperkalaemia		2
Hypersensitivity	11	47
Hypersensitivity pneumonitis		1
Hypersomnia	7	34
Hypertension	19	77
Hypertensive crisis		1
Hypertensive heart disease		3
Hyperthermia		3
Hyperthyroidism	1	3
Hypertonic bladder		1
Hypertrophic cardiomyopathy		1
Hyperventilation	1	7
Hypnagogic hallucination		1
Hypoacusis	6	18
Hypoaesthesia	45	153
Hypoaesthesia eye	1	1
Hypoaesthesia oral	9	20
Hypoaesthesia teeth	1	1
Hypocalcaemia		1
Hypogeusia		1
Hypoglycaemia	7	21
Hypoglycaemic coma		1
Hypokalaemia		1
Hypokinesia	3	11
Hyponatraemia		1
Hypophagia	4	9
Hypopnoea	4	9
Hyporeflexia		2
Hyposmia		2
Hypotension	11	48

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	2	15	75	30	164
				1	1
					2
		4	12	7	35
					1
		1	10	6	24
		3	12	16	65
					1
					3
					3
				1	3
			1		
					1
			2	1	5
					1
		3	8	3	10
	1	19	47	26	106
		1	1		
		6	11	3	9
				1	1
					1
					1
		3	5	4	16
					1
					1
		2	3	1	8
					1
		1	1	3	8
			1	4	8
			1		1
			1		1
		3	11	8	37

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypothermia		10
Hypothyroidism		1
Hypotonia	1	1
Hypoventilation		1
Hypovitaminosis		1
Hypovolaemia		1
Hypovolaemic shock		1
Hypoxia		9
IgA nephropathy		1
IIIrd nerve paralysis		3
Ileal perforation	1	1
Illness	26	124
Immobile	1	6
Immune-mediated adverse reaction		1
Immune system disorder	4	10
Immune thrombocytopenia	8	20
Immunisation		1
Immunisation reaction	1	1
Immunodeficiency		1
Immunology test	1	1
Impaired driving ability		6
Impaired gastric emptying	1	1
Impaired healing		1
Impaired quality of life	1	2
Impaired work ability		3
Inadequate analgesia		1
Inappropriate affect		1
Inappropriate schedule of product administration	122	208
Incision site pain		1
Incoherent	1	4
Incontinence		6
Incorrect route of product administration	1	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					10
					1
				1	1
					1
					1
					1
					1
					9
					1
					3
				1	1
		9	34	17	90
				1	6
			1		
			1	4	9
				8	20
					1
				1	1
					1
				1	1
			3		3
				1	1
					1
				1	2
					3
					1
					1
1	1	117	202	5	6
					1
		1	2		2
			2		4
		1	9		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Increased bronchial secretion		1
Increased upper airway secretion		2
Increased viscosity of upper respiratory secretion	1	3
Indifference		2
Infant irritability		1
Infarction		3
Infection	6	30
Infectious mononucleosis		1
Infective exacerbation of chronic obstructive airways disease		1
Inflammation	6	19
Inflammatory marker increased		3
Inflammatory pain	1	1
Influenza	24	123
Influenza like illness	55	279
Infusion related reaction		2
Infusion site infection		1
Inhibitory drug interaction		1
Initial insomnia	1	4
Injected limb mobility decreased		2
Injection related reaction	1	7
Injection site cellulitis		1
Injection site erythema		2
Injection site haemorrhage	1	1
Injection site hypoaesthesia	1	1
Injection site pain	5	13
Injection site rash	1	1
Injection site reaction		1
Injection site swelling	1	2
Injury	1	3
Inner ear inflammation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		1
			1	1	2
			1		1
					1
					3
		3	7	3	23
					1
					1
			3	6	16
					3
		1	1		
1	3	8	32	16	91
1	1	26	99	29	180
					2
					1
					1
			2	1	2
			1		1
			2	1	5
					1
			1		1
		1	1		
		1	1		
		5	10		3
		1	1		
			1		
		1	1		1
				1	3
					1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Insomnia	44	189
Insulin resistance	1	2
Intentional product use issue	1	1
Intermittent claudication	1	1
Internal haemorrhage	3	4
Internal hernia		1
International normalised ratio decreased		5
International normalised ratio increased	1	20
Interstitial lung disease	1	2
Intestinal haemorrhage		1
Intestinal ischaemia		3
Intestinal obstruction		4
Intestinal perforation	1	2
Intestinal pseudo-obstruction		1
Intranasal paraesthesia		1
Intraocular pressure increased	1	1
Intrusive thoughts		1
Iridocyclitis		2
Iritis		1
Irregular breathing	1	3
Irritability	6	15
Irritable bowel syndrome	1	5
Ischaemia		1
Ischaemic hepatitis	1	1
Ischaemic stroke		9
IVth nerve paralysis		1
Jaundice	5	8
Jaw disorder		1
Joint dislocation		1
Joint effusion	2	6
Joint injury	1	4
Joint laxity		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		16	71	28	118
				1	2
		1	1		
				1	1
				3	4
					1
			1		4
			3	1	17
				1	2
					1
					3
					4
				1	2
					1
			1		
				1	1
					1
					2
					1
			2	1	1
		2	6	4	9
				1	5
					1
				1	1
					9
					1
				5	8
					1
					1
		1	1	1	5
		1	2		2
					1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Joint lock		3
Joint noise	2	4
Joint range of motion decreased	12	31
Joint stiffness	7	29
Joint swelling	19	71
Jugular vein thrombosis		1
Keratitis		1
Ketoacidosis		2
Kidney infection	1	2
Kidney transplant rejection		1
Klebsiella infection		1
Laboratory test abnormal	1	1
Labyrinthitis	4	12
Lack of spontaneous speech		2
Lacrimal structural disorder	1	1
Lacrimation increased	4	19
Lacunar infarction		1
Lagophthalmos	1	2
Laryngeal obstruction		1
Laryngospasm		1
Latent autoimmune diabetes in adults		1
Lateral medullary syndrome		1
Laziness		1
Learning disability		1
Left ventricular dysfunction	1	2
Left ventricular failure		1
Left ventricular hypertrophy		1
Lethargy	42	219
L bido decreased		1
Lichen planus	1	1
Lichen sclerosus	1	1
Ligament disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
				2	4
	1	3	9	9	22
		3	7	4	22
		4	19	15	52
					1
					1
					2
				1	2
					1
					1
				1	1
		2	2	2	10
					2
				1	1
		1	5	3	14
					1
			1	1	1
					1
					1
					1
				1	2
					1
					1
		14	71	28	148
					1
				1	1
				1	1
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ligamentitis		1
Ligament sprain	1	1
Limb discomfort	21	91
Limbic encephalitis	1	1
Limb immobilisation		2
Limb injury	1	3
Limb mass		1
Lip disorder		2
Lip dry		5
Lip erythema		1
Lip exfoliation		2
Lip pain		5
Lip pruritus		1
Lip swelling	9	35
Lip ulceration		1
Listless	1	3
Livedo reticularis	1	1
Liver function test abnormal	3	7
Liver function test increased		3
Localised infection		2
Localised oedema	1	2
Local reaction		3
Logorrhoea		2
Long thoracic nerve palsy		1
Loss of consciousness	22	85
Loss of control of legs	1	2
Loss of libido	1	2
Loss of personal independence in daily activities	9	33
Lower respiratory tract infection	3	35
Lower respiratory tract infection viral		1
Lung consolidation		1
Lung disorder		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
2	5	8	43	13	48
				1	1
			2		
			1	1	2
					1
			2		
			2		3
					1
			1		1
			4		1
					1
		6	17	3	18
					1
				1	3
		1	1		
			2	3	5
					3
					2
				1	2
			1		2
					2
			1		
				22	85
				1	2
				1	2
		1	10	8	23
				3	35
					1
					1
			1		2

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Lung infiltration		1
Lung neoplasm malignant		2
Lymphadenitis	1	15
Lymphadenopathy	72	292
Lymphatic disorder	1	1
Lymph gland infection		1
Lymph node abscess		1
Lymph node pain	17	53
Lymph node palpable	1	1
Lymphocyte count decreased		1
Lymphocyte count increased		1
Lymphocytosis		1
Lymphoedema	2	7
Lymphoma		3
Lymphopenia		3
Macular oedema		1
Madarosis		1
Magnetic resonance imaging head abnormal		1
Major depression		1
Malaise	118	622
Malocclusion	1	1
Mandibular mass		1
Mania		1
Mass	1	7
Mastication disorder	1	1
Maternal exposure during breast feeding		1
Maternal exposure during pregnancy	1	1
Medication error	1	4
Medication overuse headache		1
Melaena	1	2
Memory impairment	3	17
Meniere's disease		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					2
		1	8		7
		29	113	43	179
		1	1		
			1		
					1
		7	20	10	33
				1	1
					1
					1
			2	2	5
					3
			1		2
					1
					1
2	4	50	216	68	406
				1	1
			1		
					1
			1	1	6
				1	1
					1
				1	1
				1	4
					1
				1	2
		1	4	2	13
					2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Meningitis pneumococcal		1
Meniscus injury		1
Mental disorder		5
Mental fatigue	4	13
Mental impairment		6
Mesenteric vein thrombosis		2
Metabolic acidosis		1
Metamorphopsia		2
Metastases to lymph nodes		1
Microembolism		1
Microvascular coronary artery disease		1
Micturition urgency	4	11
Middle ear effusion	1	1
Middle insomnia		9
Migraine	23	114
Migraine with aura	4	12
Migraine without aura		1
Miliaria	3	10
Misophonia	1	1
Mitral valve prolapse		1
Moaning		1
Mobility decreased	10	40
Mononeuropathy		1
Monoparesis		3
Monoplegia	1	4
Mood altered		1
Mood swings	1	4
Morose		3
Motion sickness		3
Motor dysfunction		3
Mouth haemorrhage	1	2
Mouth swelling	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
			2		3
		2	4	2	9
					6
					2
					1
					2
					1
					1
					1
		1	1	3	10
		1	1		
			5		4
		5	18	18	96
		3	5	1	7
					1
			3	3	7
				1	1
					1
					1
		2	9	8	31
					1
					3
				1	4
					1
		1	2		2
			2		1
			2		1
					3
				1	2
			2	1	3

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mouth ulceration	8	27
Movement disorder	4	17
Mucosal haemorrhage	1	1
Mucous stools		1
Multiple injuries		1
Multiple organ dysfunction syndrome	1	4
Multiple sclerosis		1
Multiple sclerosis relapse		3
Mumps		1
Muscle atrophy	1	5
Muscle contractions involuntary	2	6
Muscle discomfort	1	2
Muscle disorder		3
Muscle fatigue	6	30
Muscle haemorrhage	1	1
Muscle injury		2
Muscle mass	1	2
Muscle rigidity		4
Muscle rupture		1
Muscle spasms	24	67
Muscle spasticity	1	1
Muscle strain	3	6
Muscle tightness		10
Muscle twitching	7	23
Muscular weakness	16	123
Musculoskeletal chest pain	4	12
Musculoskeletal discomfort	5	11
Musculoskeletal disorder	4	4
Musculoskeletal pain		6
Musculoskeletal stiffness	34	121
Mutism	1	1
Myalgia	184	1,077

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	14	4	13
			3	4	14
				1	1
					1
				1	4
					1
					3
					1
			1	1	4
			1	2	5
				1	2
			1		2
		1	6	5	24
				1	1
			1		1
				1	2
					4
					1
		5	15	19	52
		1	1		
		2	3	1	3
			2		8
		6	7	1	16
		3	33	13	90
		2	4	2	8
		2	5	3	6
		1	1	3	3
			1		5
1	3	17	41	17	80
				1	1
1	6	104	419	80	658

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myasthenia gravis crisis		1
Mydriasis	2	2
Myelitis transverse		2
Myelodysplastic syndrome		1
Myocardial fibrosis		1
Myocardial haemorrhage		1
Myocardial infarction	10	53
Myocardial ischaemia		7
Myocardial oedema		1
Myocardial rupture		1
Myocarditis	4	7
Myoclonus	1	3
Myofascial pain syndrome		2
Myopathy	1	1
Myositis	1	7
Nail pigmentation		1
Narcolepsy		1
Nasal congestion	2	24
Nasal discomfort		7
Nasal dryness		3
Nasal herpes	1	1
Nasal injury		1
Nasal odour		1
Nasal oedema	1	3
Nasal pruritus		1
Nasopharyngitis	18	68
Nausea	157	785
Neck injury		1
Neck pain	50	152
Necrosis	1	1
Necrotising fasciitis		1
Neoplasm	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1	1	1
					2
					1
					1
					1
				10	53
					7
					1
					1
				4	7
			1	1	2
			1		1
				1	1
			2	1	5
					1
					1
	1	1	10	1	14
			2		5
			2		1
				1	1
					1
			2	1	1
					1
		7	23	11	45
	3	53	236	104	549
					1
		14	40	36	112
				1	1
					1
		1	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neoplasm progression	1	1
Neoplasm skin		1
Nephritis		1
Nephrolithiasis		1
Nephrotic syndrome	2	7
Nerve degeneration		1
Nerve injury		3
Nervousness	6	25
Nervous system disorder	1	6
Neuralgia	15	49
Neuritis	1	2
Neurogenic shock	1	7
Neurological symptom	1	4
Neurologic neglect syndrome		1
Neuromyelitis optica spectrum disorder		1
Neuromyopathy		1
Neuropathy peripheral	3	16
Neutropenia	1	6
Neutrophil count abnormal		1
Neutrophil count decreased	1	1
Neutrophilia		1
Nightmare	7	22
Night sweats	12	73
Nipple pain		3
Nipple swelling		3
Nodule		3
Noninfective encephalitis		1
Noninfective gingivitis	1	1
Nonspecific reaction	1	1
No reaction on previous exposure to drug		1
Nystagmus		4
Obsessive-compulsive symptom		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
					1
				2	7
					1
			1		2
			6	6	19
				1	6
		3	9	12	40
				1	2
				1	7
				1	4
					1
					1
					1
				3	16
				1	6
					1
		1	1		
					1
		4	9	3	13
	1	6	34	6	39
			1		2
			1		2
					3
					1
				1	1
		1	1		
			1		
					4
					1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Obstructive pancreatitis		1
Occupational exposure to SARS-CoV-2		1
Ocular discomfort	2	9
Ocular hyperaemia	5	25
Ocular hypertension		1
Ocular sarcoidosis		1
Ocular vascular disorder	1	2
Odynophagia	1	3
Oedema	6	11
Oedema peripheral	3	8
Oesophageal discomfort		1
Oesophageal stenosis		1
Off label use	114	267
Oliguria		1
Onychalgia	1	1
Ophthalmic herpes zoster		4
Ophthalmic migraine	2	4
Ophthalmoplegia		1
Ophthalmoplegic migraine		1
Optic nerve disorder	1	1
Optic neuritis		1
Optic neuropathy		1
Oral blood blister	1	2
Oral candidiasis	1	1
Oral discomfort	1	5
Oral disorder	1	3
Oral herpes	9	27
Oral mucosa erosion		1
Oral mucosal blistering		1
Oral mucosal eruption		1
Oral mucosal exfoliation		1
Oral pain	4	14

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
		2	6		3
		2	8	3	17
					1
					1
		1	1		1
				1	3
			3	6	8
			1	3	7
			1		
					1
1	1	111	260	3	7
					1
		1	1		
					4
				2	4
					1
			1		
				1	1
					1
					1
		1	2		
		1	1		
			1	1	4
		1	2		1
		4	9	5	18
			1		
			1		
			1		
					1
		2	4	2	10

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral pruritus		2
Orchitis		3
Oropharyngeal discomfort		1
Oropharyngeal pain	29	129
Oropharyngeal spasm		1
Orthopnoea		2
Orthostatic hypotension		2
Osmophobia		1
Osteoarthritis	4	7
Osteochondritis		1
Osteoporosis		1
Otorrhoea		1
Ovarian cyst		1
Overdose		3
Oversensing	1	2
Overweight		1
Oxygen consumption decreased		1
Oxygen saturation	1	1
Oxygen saturation decreased	4	22
Pain	190	673
Painful respiration	1	5
Pain in extremity	274	950
Pain in jaw	10	31
Pain of skin	8	21
Pallor	14	43
Palmar erythema		1
Palpitations	25	108
Pancreatic carcinoma		1
Pancreatitis		1
Pancreatitis acute		3
Pancreatitis necrotising		1
Panic attack		7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					3
			1		
		17	42	12	87
					1
			1		1
					2
					1
			1	4	6
			1		
					1
			1		
			3		
				1	2
					1
			1		
			1	4	21
1	5	81	268	109	405
			1	1	4
3	15	124	364	150	586
		5	11	5	20
		2	5	6	16
		7	20	7	23
			1		
		5	23	20	85
					1
					1
					3
					1
					7

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Panic disorder		1
Panic reaction	2	5
Papule	1	2
Paraesthesia	47	171
Paraesthesia oral	9	37
Paralysis	2	11
Paramnesia		1
Paranasal sinus discomfort		1
Paranoia		5
Paraparesis		1
Parkinsonism		3
Parkinson's disease		3
Parosmia	4	20
Parotid gland enlargement	2	2
Parotitis	2	2
Paroxysmal arrhythmia		1
Partial seizures	2	3
Patellofemoral pain syndrome		1
Paternal exposure before pregnancy		1
Paternal exposure during pregnancy	1	1
Patient-device incompatibility	1	1
Patient elopement		1
Peak expiratory flow rate decreased		1
Pelvic discomfort		1
Pelvic pain	1	2
Pelvic venous thrombosis	1	2
Pemphigoid		4
Pemphigus		1
Penile oedema	1	1
Penile swelling		3
Penis disorder	1	1
Periarthritis	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			2	2	3
				1	2
		24	69	23	102
		6	21	3	16
				2	11
					1
			1		
			1		4
					1
			1		2
					3
		2	9	2	11
		1	1	1	1
		1	1	1	1
					1
				2	3
					1
					1
		1	1		
		1	1		
					1
					1
					1
				1	2
				1	2
					4
					1
		1	1		
			1		2
		1	1		
	1			1	4

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pericardial effusion	1	2
Pericardial haemorrhage	1	3
Pericarditis	5	13
Perinatal depression	1	1
Perineal pain		1
Periorbital cellulitis		1
Periorbital oedema		2
Periorbital pain		1
Periorbital swelling		8
Peripheral artery occlusion	1	1
Peripheral circulatory failure	1	1
Peripheral coldness	14	38
Peripheral sensory neuropathy		1
Peripheral swelling	61	180
Peripheral vascular disorder		1
Peripheral vein thrombus extension		1
Periportal oedema	1	1
Peritonitis		1
Peroneal nerve palsy		3
Personality change		4
Personality disorder	1	1
Petechiae	4	15
Petit mal epilepsy		4
Pharyngeal erythema	1	1
Pharyngeal hypoaesthesia		1
Pharyngeal inflammation		2
Pharyngeal oedema		2
Pharyngeal paraesthesia		2
Pharyngeal swelling	5	19
Pharyngeal ulceration	1	3
Pharyngitis		1
Phlebitis	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
				1	3
				5	13
				1	1
			1		
					1
					2
					1
			1		7
				1	1
				1	1
	1	4	11	10	27
			1		
		15	49	46	131
			1		
					1
				1	1
					1
			1		2
			1		3
				1	1
		1	5	3	10
					4
				1	1
					1
					2
			1		1
			1		1
		1	4	4	15
		1	1		2
					1
		1	1		2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Phlebitis superficial	2	2
Photophobia	12	30
Photopsia	4	12
Photosensitivity reaction	3	8
Pigmentation disorder	2	2
Piloerection		1
Pineal gland cyst		1
Pityriasis	1	1
Pityriasis lichenoides et varioliformis acuta	2	2
Pityriasis rosea		3
Plantar fasciitis		3
Plasma cell myeloma		1
Platelet count abnormal		1
Platelet count decreased	5	25
Platelet count increased		1
Platelet disorder		1
Pleural effusion		2
Pleural rub	1	1
Pleurisy		2
Pleuritic pain	2	5
Pneumonia	5	34
Pneumonia aspiration	1	7
Pneumonitis	2	7
Pneumothorax	1	2
Pneumothorax spontaneous		1
Pollakiuria	5	12
Polyarthrits	2	5
Polydipsia	1	3
Polymerase chain reaction positive	1	1
Polymyalgia rheumatica	3	12
Polymyositis	1	1
Polyuria		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
		1	4	11	26
		2	3	2	9
		2	3	1	5
		2	2		
					1
					1
		1	1		
		1	1	1	1
			2		1
			1		2
					1
			1		
		3	7	2	18
					1
					1
					2
		1	1		
					2
				2	5
				5	34
				1	7
				2	7
				1	2
					1
		3	5	2	7
				2	5
		1	2		1
		1	1		
				3	12
				1	1
			1		

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Poor quality product administered		1
Poor quality sleep	5	22
Posterior reversible encephalopathy syndrome		1
Post herpetic neuralgia	1	3
Postictal paralysis		1
Postoperative ileus		1
Post procedural complication		2
Post procedural constipation		1
Postural orthostatic tachycardia syndrome	1	1
Posture abnormal		1
Post viral fatigue syndrome	4	8
Potentiating drug interaction		1
Pre-existing condition improved		2
Pregnancy after post coital contraception	1	1
Presyncope	11	46
Primary gastrointestinal follicular lymphoma		1
Primary headache associated with sexual activity		1
Prion disease		1
Procedural dizziness		1
Proctalgia		3
Proctitis		1
Product administered at inappropriate site	1	5
Product administered to patient of inappropriate age	2	5
Product complaint		2
Productive cough	3	25
Product use issue	1	74
Prophylaxis of nausea and vomiting	1	1
Prostate cancer	1	1
Prostatic abscess		1
Prostatic disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		3	11	2	11
					1
				1	3
					1
					1
					2
			1		
				1	1
					1
	1	1	1	3	7
					1
			1		1
				1	1
		7	19	4	27
					1
					1
					1
			1		2
			1		
		1	5		
		2	5		
			1		1
		2	9	1	16
		1	71		3
		1	1		
				1	1
					1
			1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Prostatic pain		1
Prostatic specific antigen increased	1	2
Prostatitis		2
Prostatomegaly		3
Proteinuria		1
Prothrombin time prolonged		1
Pruritus	77	223
Pruritus genital		1
Psoriasis	7	16
Psoriatic arthropathy		3
Psychiatric symptom		2
Psychomotor hyperactivity	1	2
Psychotic behaviour		1
Psychotic disorder	1	5
Pulmonary artery thrombosis		1
Pulmonary congestion	1	2
Pulmonary embolism	26	88
Pulmonary fibrosis		1
Pulmonary haemorrhage		1
Pulmonary infarction		2
Pulmonary oedema	1	9
Pulmonary pain	2	7
Pulmonary sarcoidosis		2
Pulmonary thrombosis	3	9
Pulmonary tuberculosis		1
Pulse abnormal		3
Pulseless electrical activity		1
Puncture site bruise		1
Purpura	3	5
Pustule		1
Pylorospasm		1
Pyrexia	189	1,319

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1	1	1
					2
			2		1
					1
					1
		37	88	40	135
			1		
		2	4	5	12
					3
			1		1
		1	2		
					1
				1	5
					1
				1	2
				26	88
					1
					1
					2
				1	9
			2	2	5
			1		1
	1			3	9
					1
					3
					1
					1
			1	3	4
					1
			1		
	2	81	458	108	861

* I=Interval, C=Cumulative

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Q fever		2
Radial pulse abnormal		1
Radiculitis brachial	2	2
Rales	1	1
Rash	107	317
Rash erythematous	25	89
Rash macular	20	46
Rash maculo-papular	1	9
Rash morbilliform	2	3
Rash papular	6	19
Rash pruritic	25	74
Rash pustular	1	2
Rash vesicular	3	14
Raynaud's phenomenon	1	3
Reaction to colouring		1
Reaction to excipient		1
Reaction to preservatives		1
Rectal abscess		1
Rectal discharge		1
Rectal haemorrhage	5	10
Red blood cell sedimentation rate abnormal		1
Red blood cell sedimentation rate increased		1
Red man syndrome		1
Reduced facial expression		2
Regurgitation		1
Renal cancer		1
Renal cyst		2
Renal disorder		2
Renal failure		3
Renal function test abnormal	1	1
Renal impairment	1	7
Renal infarct	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
				2	2
				1	1
		55	135	52	182
	1	14	39	11	50
		14	29	6	17
			3	1	6
				2	3
		4	9	2	10
		17	31	8	43
				1	2
		2	5	1	9
				1	3
					1
			1		
					1
					1
			1		
				5	10
					1
					1
					1
			2		
					1
					1
					2
					2
					3
				1	1
				1	7
				1	1

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Renal injury	1	1
Renal pain	2	23
Renal vasculitis		1
Respiration abnormal		7
Respiratory acidosis	1	1
Respiratory arrest		5
Respiratory disorder	2	10
Respiratory distress	1	2
Respiratory failure		4
Respiratory muscle weakness		1
Respiratory rate decreased		1
Respiratory rate increased	4	9
Respiratory symptom	1	3
Respiratory tract congestion	1	2
Respiratory tract oedema		2
Restless legs syndrome		7
Restlessness	1	17
Retching	3	14
Retinal aneurysm		1
Retinal artery occlusion	1	2
Retinal detachment		1
Retinal disorder		1
Retinal fovea disorder		1
Retinal haemorrhage	1	1
Retinal injury		1
Retinal migraine	1	5
Retinal tear	1	1
Retinal vein occlusion	2	5
Retinal vein thrombosis		1
Retinitis pigmentosa		1
Rhabdomyolysis		3
Rheumatoid arthritis	2	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			2	2	21
					1
			2		5
				1	1
					5
			2	2	8
				1	2
					4
					1
					1
				4	9
				1	3
				1	2
					2
			1		6
			2	1	15
		1	5	2	9
					1
				1	2
					1
			1		
					1
				1	1
					1
		1	2		3
				1	1
				2	5
					1
					1
				2	11

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rheumatoid factor increased	1	1
Rhinalgia	1	2
Rhinitis	1	6
Rhinorrhoea	16	56
Rib fracture		1
Road traffic accident	2	5
Rosacea	2	3
Rotator cuff syndrome		2
Sacroiliitis		2
Salivary duct obstruction		1
Salivary gland disorder	1	2
Salivary gland pain	2	3
Salivary hypersecretion	2	6
Sarcoidosis		3
SARS-CoV-2 ant body test negative		3
SARS-CoV-2 test false positive		1
SARS-CoV-2 test positive	2	14
Scab	1	4
Scar	2	2
Schizophrenia		1
Sciatica	4	11
Sciatic nerve injury	1	1
Scintillating scotoma	1	1
Scleral discolouration		3
Scleritis	1	1
Scratch	2	3
Screaming		2
Scrotal erythema		1
Scrotal exfoliation		1
Scrotal pain	1	5
Scrotal swelling		3
Seasonal allergy	6	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1	1	1
		1	3		3
		6	19	10	37
					1
			1	2	4
				2	3
					2
					2
				1	1
				1	2
		2	2		1
				2	6
					3
			3		
			1		
			1	2	13
			1	1	3
				2	2
					1
		1	3	3	8
				1	1
		1	1		
			1		2
				1	1
		1	1	1	2
			1		1
					1
		1	3		2
					3
		2	3	4	5

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Seborrhoea		1
Second primary malignancy		1
Secretion discharge	1	3
Sedation		1
Seizure	14	77
Seizure anoxic	1	1
Seizure cluster		1
Sensation of blood flow		1
Sensation of foreign body	2	6
Sense of a foreshortened future		3
Sensitive skin	2	14
Sensitivity to weather change		1
Sensory disturbance	5	10
Sensory loss		8
Sepsis	2	13
Sepsis syndrome		1
Septic shock		3
Seronegative arthritis	1	1
Serotonin syndrome		1
Serum sickness-like reaction		1
Severe acute respiratory syndrome		1
Shock		2
Sinonasal obstruction		4
Sinus bradycardia	1	1
Sinus congestion		6
Sinus disorder	1	1
Sinus headache	7	26
Sinusitis	4	10
Sinus pain	1	5
Sinus tachycardia		4
Sitting disability	1	1
Skin abrasion		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
			1	1	2
					1
				14	77
				1	1
					1
					1
		2	2		4
			2		1
		1	4	1	10
					1
		1	2	4	8
			4		4
				2	13
					1
					3
				1	1
					1
					1
					1
					2
			2		2
				1	1
			2		4
				1	1
		2	7	5	19
		1	2	3	8
			2	1	3
			1		3
				1	1
			1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin burning sensation	2	10
Skin cancer		1
Skin depigmentation		1
Skin discharge		1
Skin discolouration		20
Skin discomfort	1	1
Skin disorder	3	9
Skin erosion	2	4
Skin exfoliation	5	18
Skin fissures	2	4
Skin haemorrhage	1	2
Skin induration		1
Skin infection	2	4
Skin injury		1
Skin irritation	1	8
Skin laceration		4
Skin lesion	7	15
Skin lesion inflammation	1	1
Skin mass	1	3
Skin odour abnormal	2	2
Skin plaque		1
Skin reaction	3	5
Skin sensitisation	1	1
Skin striae	1	1
Skin swelling	4	9
Skin temperature		2
Skin test positive	1	1
Skin tightness		3
Skin ulcer	2	2
Skin warm	2	15
Skin weeping	1	4
Skin wrinkling		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1	2	5		5
					1
					1
					1
			8		12
				1	1
			1	3	8
		1	1	1	3
		1	3	4	15
		1	1	1	3
				1	2
					1
			1	2	3
			1		
		1	3		5
			2		2
		3	5	4	10
				1	1
		1	3		
				2	2
					1
			1	3	4
		1	1		
				1	1
		2	4	2	5
			1		1
		1	1		
			1		2
				2	2
	1	1	5	1	10
				1	4
			1		1

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Sleep apnoea syndrome	1	2
Sleep attacks		1
Sleep deficit	1	3
Sleep disorder	14	57
Sleep disorder due to a general medical condition	1	6
Sleep disorder due to general medical condition, insomnia type	1	5
Sleep paralysis		2
Sleep talking		1
Sleep terror	1	2
Slow response to stimuli		1
Slow speech		1
Sluggishness		1
Small intestinal haemorrhage	1	2
Small intestinal obstruction		2
Sneezing	7	38
Snoring		1
Soft tissue swelling	1	1
Solid organ transplant rejection	1	1
Somatic symptom disorder		1
Somnolence	26	113
Speech disorder	6	21
Spinal disorder		1
Spinal fracture	1	1
Spinal pain	1	9
Splenic infarction	1	1
Splenomegaly		1
Splinter haemorrhages		1
Spondylitis	1	1
Spontaneous haematoma	1	1
Sputum abnormal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
					1
			1	1	2
		2	24	12	33
			2	1	4
		1	2		3
			1		1
			1		
				1	2
					1
					1
				1	2
					2
		2	13	5	25
			1		
		1	1		
				1	1
					1
		14	44	12	69
		1	4	5	17
					1
				1	1
			1	1	8
				1	1
					1
					1
				1	1
				1	1
					1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sputum increased	1	1
Sputum purulent		1
Status epilepticus	2	2
Steatorrhoea		1
Stevens-Johnson syndrome		1
Stoma site discharge		1
Stoma site extravasation		1
Stoma site haemorrhage		1
Stomatitis	3	7
Strabismus		1
Stress	1	7
Stridor		5
Stupor		1
Subarachnoid haemorrhage	1	3
Subcutaneous abscess		1
Sudden death	3	15
Sudden hearing loss	2	7
Sudden onset of sleep	1	1
Suicidal behaviour		1
Suicidal ideation	1	5
Suicide attempt		1
Sunburn	1	1
Superficial injury of eye		1
Superficial vein prominence		1
Superior sagittal sinus thrombosis		1
Supraventricular extrasystoles		1
Supraventricular tachycardia	1	4
Suspected COVID-19	12	89
Sweating fever	2	14
Swelling	49	123
Swelling face	22	67
Swelling of eyelid	4	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
				2	2
					1
					1
					1
			1		
					1
		2	5	1	2
					1
			1	1	6
					5
					1
				1	3
			1		
				3	15
				2	7
				1	1
					1
				1	5
					1
				1	1
					1
			1		
					1
					1
			1	1	3
		7	30	5	59
				2	14
2	2	17	46	32	77
		3	16	19	51
			1	4	9

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Swollen tongue	8	25
Symptom recurrence	1	1
Syncope	37	129
Synovial cyst		4
Synovial rupture		1
Synovitis		2
Syphilis	1	1
Syringe issue	1	1
Systemic immune activation		1
Systemic lupus erythematosus rash		1
Systolic hypertension		1
Tachyarrhythmia	1	1
Tachycardia	9	67
Tachypnoea		7
Taste disorder	10	27
Tearfulness		2
Temperature difference of extremities		1
Temperature intolerance	1	7
Temperature regulation disorder		3
TEMPI syndrome		1
Temporomandibular joint syndrome	1	1
Tenderness	5	30
Tendon disorder	1	1
Tendon injury	1	3
Tendonitis		7
Tendon pain	2	5
Tendon rupture	2	2
Tenosynovitis		1
Tension		3
Tension headache	7	34
Terminal insomnia		1
Testicular pain	5	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	11	4	14
				1	1
				37	129
			1		3
			1		
					2
				1	1
		1	1		
					1
					1
					1
				1	1
	1	4	14	5	53
			2		5
		5	12	5	15
					2
					1
				1	7
			1		2
					1
				1	1
		3	18	2	12
				1	1
		1	1		2
			1		6
		1	3	1	2
				2	2
					1
			1		2
	1	2	9	5	25
					1
		2	5	3	7

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Testicular swelling	1	6
Testicular torsion		1
Testis discomfort		2
Therapeutic product effect delayed		1
Therapeutic response unexpected	4	13
Thermal burn	1	3
Thermal burns of eye		1
Thinking abnormal		2
Thirst	6	22
Throat irritation	2	15
Throat tightness	1	16
Thrombocytopenia	31	55
Thrombocytopenic purpura	1	1
Thrombocytosis		1
Thrombophlebitis	2	4
Thrombophlebitis superficial	1	3
Thrombosis	19	61
Thrombotic microangiopathy		1
Thrombotic stroke	1	1
Thrombotic thrombocytopenic purpura		1
Thunderclap headache		1
Thyroxine free increased		1
Tinnitus	50	119
Tongue biting	2	3
Tongue blistering		2
Tongue coated		1
Tongue discolouration	1	2
Tongue discomfort		2
Tongue disorder	1	3
Tongue dry	2	3
Tongue erythema		3
Tongue pruritus		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3	1	3
					1
			1		1
					1
		4	11		2
		1	2		1
					1
			1		1
		1	6	5	16
			6	2	9
		1	3		13
				31	55
				1	1
					1
			2	2	2
			2	1	1
				19	61
					1
				1	1
					1
					1
		8	21	42	98
				2	3
			1		1
			1		
			1	1	1
			1		1
			1	1	2
		1	2	1	1
			1		2
					3

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tongue ulceration		2
Tonic convulsion		3
Tonsillar cyst		1
Tonsillar haemorrhage		1
Tonsillar hypertrophy	1	5
Tonsillar inflammation		1
Tonsillar ulcer		1
Tonsillitis	1	6
Tonsillitis bacterial		1
Tooth abscess	2	3
Toothache	5	14
Tooth discolouration	1	1
Tooth infection		1
Toxic epidermal necrolysis		1
Toxicity to various agents		
Tracheitis		1
Trance	1	1
Transaminases increased		1
Transient global amnesia		2
Transient ischaemic attack	7	38
Traumatic intracranial haemorrhage		1
Treatment noncompliance		1
Tremor	35	163
Trigeminal nerve disorder		1
Trigeminal neuralgia		4
Trigger finger		1
Trismus	1	2
Troponin increased	1	3
Tunnel vision		2
Type 1 diabetes mellitus		1
Type 2 diabetes mellitus		1
Type III immune complex mediated reaction		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					3
			1		
					1
			1	1	4
			1		
					1
			1	1	5
					1
				2	3
		1	2	4	12
				1	1
					1
	1				
					1
		1	1		
					1
					2
				7	38
					1
					1
		12	36	23	127
			1		
			1		3
					1
				1	2
				1	3
					2
					1
					1
					1

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Type IV hypersensitivity reaction		2
Typical aura without headache		1
Ulcer	1	2
Ulnar nerve injury		1
Underdose		1
Unresponsive to stimuli	3	18
Upper gastrointestinal haemorrhage		2
Upper limb fracture		1
Upper respiratory tract congestion		3
Upper respiratory tract infection		3
Ureteric stenosis		1
Urethral stenosis		1
Urinary bladder haemorrhage		1
Urinary incontinence	4	20
Urinary retention	2	12
Urinary tract infection	5	20
Urine abnormality	2	5
Urine analysis abnormal		1
Urine flow decreased	1	2
Urine ketone body present		1
Urine odour abnormal		1
Urine output		1
Urine output decreased		2
Urine output increased	1	2
Urosepsis		1
Urticaria	23	82
Urticaria chronic	1	1
Urticaria contact	1	1
Urticaria papular	1	2
Uveitis	1	4
Vaccination complication	3	8
Vaccination failure		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
			1	1	1
					1
			1		
				3	18
					2
					1
			1		2
			3		
					1
					1
					1
		1	4	3	16
				2	12
		1	4	4	16
		2	4		1
					1
			1	1	1
					1
			1		
					1
					2
				1	2
					1
		12	39	11	43
				1	1
				1	1
				1	2
				1	4
		1	3	2	5
					2

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination site bruising	4	25
Vaccination site cellulitis		1
Vaccination site coldness		1
Vaccination site cyst		1
Vaccination site discolouration		3
Vaccination site discomfort	5	23
Vaccination site erythema	11	61
Vaccination site haemorrhage	1	5
Vaccination site hypoaesthesia	1	6
Vaccination site induration	2	4
Vaccination site infection		3
Vaccination site inflammation	2	7
Vaccination site joint discomfort		1
Vaccination site joint movement impairment		2
Vaccination site joint pain		4
Vaccination site lymphadenopathy		3
Vaccination site mass	5	26
Vaccination site movement impairment	5	24
Vaccination site oedema		3
Vaccination site pain	105	660
Vaccination site paraesthesia		1
Vaccination site pruritus	6	18
Vaccination site pustule		1
Vaccination site rash	5	17
Vaccination site reaction	3	14
Vaccination site scab		2
Vaccination site swelling	18	92
Vaccination site ulcer		1
Vaccination site urticaria		1
Vaccination site vesicles		3
Vaccination site warmth	4	24
Vaccine breakthrough infection		7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	14	1	11
			1		
					1
					1
			1		2
		4	15	1	8
		5	24	6	37
				1	5
			3	1	3
		1	2	1	2
					3
			3	2	4
			1		
			1		1
			3		1
			2		1
		2	14	3	12
		3	11	2	13
					3
	1	65	356	40	304
			1		
		6	13		5
					1
		2	5	3	12
		1	4	2	10
					2
		9	45	9	47
					1
			1		
			2		1
		2	8	2	16
					7

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* AE=Adverse Event

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaginal haemorrhage	1	1
Varicella	1	2
Varicella zoster virus infection		1
Varicose vein		1
Vascular dementia		1
Vascular headache	1	1
Vascular pain	1	3
Vasculitic rash	1	2
Vasculitis	3	8
Vasoconstriction		1
Vein disorder	3	6
Vena cava embolism		1
Vena cava thrombosis		1
Venous injury		1
Venous thrombosis		2
Venous thrombosis limb		1
Ventricular arrhythmia	1	1
Ventricular extrasystoles	2	9
Ventricular fibrillation		3
Ventricular hypertrophy		1
Ventricular tachycardia	1	3
Vertebral artery stenosis		1
Vertigo	29	104
Vertigo labyrinthine	3	3
Vertigo positional	1	9
Vestibular migraine		2
Vestibular neuritis		4
Viral infection	3	7
Viral labyrinthitis		1
Viral pericarditis		1
Viral rash	2	3
Viral upper respiratory tract infection		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1		1
					1
					1
					1
				1	1
			1	1	2
				1	2
				3	8
					1
		1	3	2	3
					1
					1
					1
					2
					1
				1	1
		1	2	1	7
					3
					1
				1	3
					1
		8	17	21	87
		2	2	1	1
			1	1	8
					2
					4
				3	7
			1		
					1
		2	2		1
					1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Virologic failure		1						1
Visceral pain		1				1		
Vision blurred	25	93			10	27	15	66
Visual acuity reduced		2						2
Visual field defect	2	2					2	2
Visual impairment	17	49			5	14	12	35
Visual snow syndrome		1						1
Vitamin D deficiency		1						1
Vitiligo		1						1
Vitreous detachment	3	6					3	6
Vitreous floaters	4	6			2	3	2	3
Vitreous haemorrhage	1	2					1	2
Vomiting	52	265	1	1	16	61	36	204
Vomiting projectile	3	6					3	6
Weight bearing difficulty	1	4					1	4
Weight decreased	4	19			1	4	3	15
Weight increased		3						3
Weight loss poor		1						1
Wheezing	5	35			3	6	2	29
White blood cell count decreased		1						1
White blood cell count increased		4						4
White blood cell disorder		2						2
Withdrawal syndrome	1	3				2	1	1
Wound	2	4					2	4
Wound infection		1						1
Wound secretion		1						1
Wrong product administered	3	5			3	4		1
Wrong technique in product usage process	1	1			1	1		
Yawning	1	2			1	2		
Yellow skin	1	3				2	1	1
	3	8			3	8		
	7,318	31,629	31	145	2729	9681	4589	21948

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	4	11			2	5	2	6
Abdominal distension	1	4			1	2		2
Abdominal pain	1	18			1	8		10
Abdominal pain lower	1	2				1	1	1
Abdominal pain upper	8	36			2	10	6	26
Abnormal dreams	2	4				2	2	2
Abnormal faeces		2				1		1
Abscess		2						2
Abscess drainage		1						1
Accidental overdose		15				15		
Acne pustular		1						1
Acute kidney injury		1						1
Adjustment disorder with depressed mood		1						1
Adnexa uteri pain		1						1
Adverse event	1	2			1	2		
Ageusia	1	4			1	1		3
Agitation		2						2
Alanine aminotransferase increased		1						1
Allergic oedema		1						1
Allergy to vaccine	1	1					1	1
Allodynia	1	1			1	1		
Alopecia	2	3					2	3
Anal hypoaesthesia	1	1					1	1
Anaphylactic reaction	5	15					5	15
Anaphylactic shock		1						1
Androgenetic alopecia		1						1
Angina pectoris	1	2					1	2
Angioedema		4						4
Anosmia	1	4			1	1		3
Anxiety	3	14			1	3	2	11
Aphasia		2				1		1
Aphthous ulcer	1	1			1	1		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Apnoeic attack	1	1
Arrhythmia	1	3
Arrhythmia supraventricular		1
Arthralgia	40	180
Arthritis	1	9
Arthropathy	1	2
Arthropod bite	1	1
Asthenia	13	47
Asthenopia	1	3
Asthma	1	5
Asymptomatic COVID-19		6
Atrial f brillation	1	5
Autoimmune anaemia		1
Autoimmune uveitis		1
Autoscopy		1
Axillary mass		2
Axillary pain	7	23
Back pain	13	55
Balance disorder	6	18
Bell's palsy	1	10
Bladder disorder		1
Bladder pain	1	1
Blepharitis		1
Blepharospasm		1
Blindness		2
Blister	2	4
Blood glucose increased	1	3
Blood growth hormone abnormal		1
Blood lactic acid increased		1
Blood potassium decreased		1
Blood pressure decreased	1	2
Blood pressure increased	1	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	3
					1
		14	68	26	112
				1	9
		1	2		
				1	1
		3	14	10	33
		1	2		1
		1	1		4
					6
				1	5
					1
					1
					1
					2
		1	5	6	18
	1	5	21	8	34
		1	2	5	16
				1	10
					1
				1	1
					1
					1
					2
		1	1	1	3
			1	1	2
			1		
					1
			1		
		1	1		1
		1	3		4

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood pressure systolic increased	1	1
Blood thyroid stimulating hormone increased		1
Blood urine		1
Blue toe syndrome		1
Body temperature	1	4
Body temperature abnormal		2
Body temperature decreased		3
Body temperature fluctuation	1	2
Body temperature increased	5	17
Bone pain		4
Bradycardia		1
Bradyphrenia		1
Breast cancer		1
Breast mass	1	2
Breast pain	1	3
Breast swelling	1	1
Bronchospasm		1
Burning sensation	6	10
Bursitis		1
Candida infection		1
Cardiac amyloidosis	1	1
Cardiac disorder	1	3
Cardiac failure	1	3
Cardiac flutter		3
Cardiomyopathy	1	1
Cellulitis		4
Central vision loss		1
Cerebellar haemorrhage		1
Cerebral venous sinus thrombosis	1	1
Cerebrovascular accident		5
Chest crushing		1
Chest discomfort	4	29

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
					1
					1
		1	4		
			2		
			1		2
				1	2
		2	9	3	8
			2		2
					1
			1		
					1
				1	2
			1	1	2
				1	1
					1
		1	2	5	8
					1
					1
				1	1
				1	3
				1	3
					3
				1	1
					4
					1
					1
				1	1
					5
					1
		2	9	2	20

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chest pain	7	29
Chills	33	202
Chromaturia	1	1
Circulatory collapse	1	1
Circumstance or information capable of leading to medication error		2
Cluster headache		1
Coeliac disease	1	1
Cognitive disorder	1	2
Cold sweat	3	9
Colitis	1	1
Colitis ulcerative	1	2
Condition aggravated	3	12
Confusional state	4	11
Conjunctivitis		1
Constipation	1	5
Contusion	1	10
Coordination abnormal	1	3
Coronavirus infection		1
Costochondritis	1	1
Cough	9	47
COVID-19	7	106
Crying		2
Deafness	1	4
Deafness unilateral	1	1
Death	1	7
Decreased appetite	5	22
Deep vein thrombosis	1	6
Defaecation urgency		1
Dehydration	1	3
Delirium		1
Depressed mood	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	10	5	19
	1	21	96	12	106
				1	1
				1	1
			2		
					1
				1	1
				1	2
		1	4	2	5
		1	1		
				1	2
		1	1	2	11
		2	2	2	9
					1
				1	5
		1	6		4
				1	3
					1
		1	1		
		3	18	6	29
		2	10	5	96
					2
				1	4
				1	1
				1	7
		4	11	1	11
				1	6
					1
				1	3
					1
			1	1	1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Depression		4
Dermatitis		2
Dermatitis allergic	1	1
Diabetes mellitus		1
Diaphragmatic disorder		1
Diarrhoea	17	86
Diplopia		3
Discomfort	1	12
Disease recurrence	5	7
Disorientation		2
Disturbance in attention	1	9
Dizziness	43	155
Dizziness exertional		1
Dizziness postural	2	9
Drug eruption		1
Drug ineffective	4	103
Dry eye	1	5
Dry mouth	1	10
Dry skin	1	2
Dry throat	1	2
Dysarthria	2	5
Dysgeusia	6	26
Dysgraphia	1	1
Dyskinesia		2
Dysmenorrhoea	1	1
Dyspepsia	2	6
Dysphagia		3
Dysphonia		1
Dyspnoea	11	58
Dyspnoea exertional	1	1
Dysstasia	1	5
Ear discomfort		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					4
					2
		1	1		
					1
					1
		7	29	10	57
					3
			7	1	5
		2	2	3	5
					2
			3	1	6
		20	64	23	91
					1
			5	2	4
					1
				4	103
			1	1	4
			5	1	5
			1	1	1
		1	1		1
				2	5
		5	19	1	7
				1	1
					2
				1	1
		1	3	1	3
					3
					1
		2	13	9	45
				1	1
			3	1	2
					2

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ear haemorrhage		1
Ear infection		1
Ear pain	4	21
Eczema	1	2
Electric shock		1
Electric shock sensation		2
Electrocardiogram abnormal	1	1
Encephalitis		1
Enuresis		1
Epicondylitis	1	2
Epilepsy	1	2
Epistaxis	1	8
Eructation		1
Erythema	6	29
Essential hypertension		1
Expired product administered		3
Exposure during pregnancy		1
Exposure via breast milk	15	97
Extensive swelling of vaccinated limb	1	1
Extrasystoles		1
Eye disorder	1	2
Eye haemorrhage		1
Eye irritation	1	5
Eyelid ptosis		1
Eye oedema		1
Eye pain	1	16
Eye pruritus	1	2
Eye swelling	1	3
Facial discomfort		1
Facial pain	1	6
Facial paralysis		6
Faeces soft	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
		2	9	2	12
		1	2		
			1		
			2		
		1	1		
					1
			1		
				1	2
				1	2
			2	1	6
					1
		4	18	2	11
					1
			3		
			1		
		11	80	4	17
				1	1
					1
				1	2
					1
				1	5
					1
					1
			3	1	13
		1	2		
		1	2		1
			1		
		1	4		2
					6
		1	1		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Fall	2	7
Fatigue	79	405
Fear		1
Fear of injection		1
Feeding disorder		2
Feeling abnormal	5	32
Feeling cold	7	26
Feeling drunk		1
Feeling hot	9	34
Feeling of body temperature change	2	5
Fibrin D dimer increased	1	1
Fibromyalgia		1
Flank pain		1
Flatulence	1	6
Flushing	3	9
Foetal exposure during pregnancy		1
Foetal growth restriction	1	1
Foetal heart rate abnormal	1	1
Foetal malformation		1
Food allergy		1
Food aversion		1
Food intolerance		1
Food refusal		1
Foreign body in gastrointestinal tract		1
Foreign body in mouth		1
Foreign body sensation in eyes		1
Fracture	1	1
Functional gastrointestinal disorder		1
Gait disturbance	3	6
Gait inability		1
Gastric disorder		1
Gastric haemorrhage	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	2	6
	2	27	159	52	246
			1		
			1		
			1		1
		1	11	4	21
		3	6	4	20
					1
		6	21	3	13
			1	2	4
				1	1
					1
					1
		1	2		4
		2	5	1	4
					1
				1	1
				1	1
					1
					1
					1
			1		
					1
					1
				1	1
					1
			1	3	5
					1
					1
				1	1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastritis		1
Gastrointestinal pain		3
Gastrointestinal sounds abnormal		1
Gastroesophageal reflux disease		1
Generalised tonic-clonic seizure		1
Genital pain		1
Genital rash	1	1
Gingival pain		1
Glossodynia		3
Gout		2
Groin pain	1	2
Guillain-Barre syndrome	1	1
Haematochezia		2
Haemophilia		1
Haemoptysis		1
Haemorrhage	2	4
Haemorrhage urinary tract		1
Haemorrhoids		1
Hallucination		2
Hangover		1
Headache	89	478
Head discomfort		7
Head injury		2
Heart rate	1	1
Heart rate abnormal		1
Heart rate decreased	2	3
Heart rate increased	3	20
Heart rate irregular		2
Heavy menstrual bleeding	1	2
Hepatic pain		1
Herpes zoster	18	30
Histamine level increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		2
					1
					1
					1
				1	1
					1
			2		1
					2
		1	1		1
				1	1
					2
					1
				2	4
					1
					1
					2
			1		
	1	46	217	43	261
			4		3
			1		1
		1	1		
			1		
		2	2		1
			3	3	17
					2
		1	1		1
			1		
		7	11	11	19
			1		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hordeolum	1	1
Hot flush	3	16
Hunger		2
Hyperacusis		1
Hypercapnia		1
Hyperglycaemia		1
Hyperhidrosis	5	27
Hyperintensity in brain deep nuclei		1
Hyperoxia		1
Hypersensitivity	2	17
Hypersomnia		5
Hypertension	4	16
Hypoacusis	1	2
Hypoaesthesia	12	39
Hypoaesthesia oral	3	9
Hypokinesia	1	2
Hypopnoea	1	3
Hypotension	1	6
Hypothermia		1
Illness	14	31
Immobile		1
Immune system disorder	1	1
Impaired gastric emptying		1
Inappropriate schedule of product administration	18	31
Incorrect dose administered	1	4
Incorrect route of product administration		2
Increased tendency to bruise		1
Infection		2
Inflammation	3	9
Inflammatory pain		1
Influenza	7	37
Influenza like illness	6	53

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		2	10	1	6
			1		1
			1		
					1
					1
			7	5	20
					1
					1
		1	6	1	11
			3		2
		1	5	3	11
				1	2
		7	18	5	21
		3	5		4
			1	1	1
				1	3
		1	3		3
					1
		7	12	7	19
					1
				1	1
					1
		15	28	3	3
		1	4		
			2		
					1
			2		
		2	4	1	5
			1		
		2	10	5	27
		2	25	4	28

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site pain	5	10
Injection site swelling	1	1
Insomnia	5	30
Intentional product misuse		1
Intentional product use issue		1
Intermenstrual bleeding		1
International normalised ratio decreased		1
International normalised ratio increased		1
Iritis		1
Iron deficiency anaemia		1
Irregular breathing		1
Irritability		5
Irritable bowel syndrome		3
Joint effusion		2
Joint noise	1	1
Joint prosthesis user		1
Joint range of motion decreased		5
Joint stiffness	3	6
Joint swelling	4	15
Labyrinthitis		2
Lacrimation increased		6
Lethargy	8	50
Limb crushing injury		1
Limb discomfort	8	24
Limb injury	1	1
Limb mass		1
Lip dry	1	2
Lip oedema		1
Lip pain		1
Lip swelling	3	9
Liquid product physical issue		2
Listless		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	8	1	2
		1	1		
		1	7	4	23
			1		
			1		
					1
					1
					1
					1
					1
					5
					3
			1		1
		1	1		
					1
			3		2
				3	6
			1	4	14
					2
					6
		1	27	7	23
					1
	1	6	13	2	11
				1	1
			1		
				1	2
					1
					1
		1	3	2	6
			2		
					1

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* AE=Adverse Event

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Liver function test abnormal		1
Localised infection		1
Local reaction	1	2
Loss of consciousness	2	8
Loss of libido		1
Loss of personal independence in daily activities		5
Loss of proprioception		1
Lower respiratory tract infection	1	2
Lymphadenitis		5
Lymphadenopathy	29	123
Lymph node pain	1	13
Lymphoma		2
Malaise	21	107
Mass	2	2
Mastoiditis	1	1
Maternal exposure during breast feeding	2	2
Maternal exposure during pregnancy	2	4
Medication error	2	2
Melaena		1
Memory impairment	1	3
Menstrual disorder		1
Menstruation delayed		1
Menstruation irregular	1	1
Mental fatigue	1	2
Mental impairment		1
Mental status changes		1
Metastases to lymph nodes		4
Migraine	15	52
Migraine with aura	1	4
Migraine without aura	1	1
Miliaria		1
Mobility decreased	1	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
			1	1	1
				2	8
					1
			2		3
					1
				1	2
			1		4
	1	10	52	19	71
			7	1	6
					2
	1	12	42	9	65
		1	1	1	1
				1	1
				2	2
				2	4
		2	2		
					1
			1	1	2
			1		
					1
				1	1
		1	1		1
					1
					1
					4
		4	13	11	39
			1	1	3
				1	1
			1		
		1	7		6

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Monoplegia	1	2
Mood altered		1
Motion sickness	1	4
Mouth swelling	1	1
Mouth ulceration	1	6
Movement disorder	1	4
Mucous stools		1
Multiple sclerosis		1
Muscle contractions involuntary		1
Muscle fatigue	1	6
Muscle mass	1	1
Muscle spasms	6	20
Muscle spasticity		1
Muscle strain		2
Muscle twitching		5
Muscular weakness	3	19
Musculoskeletal chest pain	2	6
Musculoskeletal discomfort		2
Musculoskeletal pain		1
Musculoskeletal stiffness	8	30
Myalgia	38	207
Myasthenia gravis		1
Myelitis transverse		1
Myelosuppression		1
Myocardial infarction	1	2
Myocardial necrosis marker increased		1
Myoclonus		1
Nasal congestion	2	7
Nasal disorder		2
Nasopharyngitis	4	17
Nausea	52	238
Neck mass		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
					1
				1	4
				1	1
		1	4		2
		1	1		3
					1
					1
					1
		1	1		5
		1	1		
		4	10	2	10
					1
					2
			2		3
		1	4	2	15
			2	2	4
					2
					1
		3	9	5	21
	1	15	97	23	110
					1
					1
					1
				1	2
					1
					1
		1	2	1	5
			1		1
		1	6	3	11
		26	98	26	140
					1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neck pain	7	42
Neonatal pneumothorax		1
Neonatal respiratory distress		1
Neoplasm progression	1	1
Nerve compression		1
Nerve injury	1	1
Nervousness		4
Neuralgia	1	3
Neurogenic shock		2
Neurological symptom		1
Neuropathy peripheral		1
Neutrophil count abnormal	4	4
Nightmare	1	5
Night sweats	3	8
No adverse event	2	7
No reaction on previous exposure to drug	1	1
Ocular hyperaemia	1	5
Oedema		1
Off label use	13	36
Ophthalmic herpes zoster	1	1
Optic disc haemorrhage	1	1
Oral candidiasis		1
Oral discomfort		1
Oral herpes	1	1
Oral mucosal blistering		1
Oral pain	2	4
Oral pruritus		1
Oropharyngeal discomfort		1
Oropharyngeal pain	11	47
Orthopnoea		2
Osteoarthritis		2
Osteonecrosis of jaw		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	16	5	26
					1
					1
		1	1		
					1
				1	1
			1		3
			1	1	2
					2
					1
					1
		4	4		
				1	5
		2	4	1	4
		2	7		
		1	1		
			2	1	3
					1
		11	33	2	3
				1	1
				1	1
					1
			1		
		1	1		
			1		
		1	1	1	3
			1		
			1		
		4	19	7	28
					2
			1		1
					1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Overdose	1	4
Oxygen saturation decreased		3
Pain	34	152
Pain in extremity	63	239
Pain in jaw	1	11
Pain of skin	2	8
Pallor	2	5
Palmar erythema		2
Palpitations	7	37
Panic attack	1	1
Panic reaction		1
Papule		1
Paraesthesia	15	49
Paraesthesia oral	4	15
Paralysis	2	3
Parkinsonism		1
Parkinson's disease		1
Parosmia		2
Peau d'orange		1
Pelvic pain		3
Periarthritis	1	5
Pericarditis	1	1
Periorbital swelling		2
Peripheral coldness	1	9
Peripheral swelling	9	42
Pharyngeal hypoaesthesia		1
Pharyngeal leukoplakia		1
Pharyngeal swelling	3	8
Pharyngitis		1
Pharyngitis streptococcal		1
Phlebitis		1
Photophobia		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4		
					3
		12	72	22	80
	2	29	106	34	133
		1	4		7
		2	5		3
		2	4		1
			1		1
		5	13	2	24
				1	1
			1		
			1		
		10	20	5	29
		2	9	2	6
				2	3
					1
					1
					2
			1		
			1		2
			1	1	4
				1	1
					2
		1	5		4
		4	13	5	29
					1
			1		
		2	4	1	4
			1		
					1
					1
			1		3

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Photopsia	1	1
Pityriasis rosea	2	3
Plantar erythema		1
Pleuritic pain		1
Pneumonia		1
Pollakiuria		2
Polymyalgia rheumatica		1
Poor feeding infant		1
Poor peripheral circulation	1	1
Poor quality product administered	10	90
Poor quality sleep	2	4
Postmenopausal haemorrhage	1	1
Post viral fatigue syndrome		1
Premature baby		2
Presyncope	3	9
Primary biliary cholangitis		1
Primary cough headache	1	1
Procedural pain	1	1
Product administered to patient of inappropriate age	1	3
Product contamination	1	1
Product contamination physical		1
Productive cough	1	6
Product label confusion		1
Product packaging quantity issue		4
Product preparation error	3	7
Product preparation issue		2
Product quality issue	1	1
Product residue present	1	1
Product storage error	7	9
Product supply issue		1
Product temperature excursion issue	1	72

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1	2	2
					1
			1		
					1
					2
					1
					1
				1	1
		10	90		
			1	2	3
				1	1
					1
					2
		2	5	1	4
					1
		1	1		
				1	1
		1	3		
		1	1		
			1		
			1	1	5
			1		
			4		
		3	7		
			2		
		1	1		
		1	1		
		7	9		
			1		
		1	72		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Product use issue		9
Pruritus	21	67
Pulmonary congestion		1
Pulmonary embolism	1	7
Pulmonary pain		2
Pyrexia	45	273
Rales		1
Rash	21	58
Rash erythematous	3	11
Rash macular	3	9
Rash maculo-papular	1	1
Rash papular	1	5
Rash pruritic	1	6
Rash vesicular	1	1
Raynaud's phenomenon	1	2
Reflux gastritis		1
Renal pain	3	9
Respiration abnormal	1	1
Respiratory disorder	1	1
Respiratory rate increased		1
Respiratory tract infection		1
Restless legs syndrome		1
Restlessness		1
Retching		3
Retinal artery occlusion	1	1
Retinal injury		1
Rheumatic disorder		1
Rheumatoid arthritis		2
Rhinitis		1
Rhinitis allergic		1
Rhinorrhoea	5	17
Rosacea	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			8		1
	1	19	42	2	25
					1
				1	7
			1		1
		22	140	23	133
					1
		14	30	7	28
			6	3	5
		3	7		2
		1	1		
		1	1		4
		1	3		3
				1	1
				1	2
			1		
		1	3	2	6
		1	1		
		1	1		
					1
					1
			1		
					1
					3
				1	1
					1
					1
					2
					1
			1		
		3	6	2	11
				1	1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rotator cuff syndrome	1	1
SARS-CoV-2 ant body test negative		1
SARS-CoV-2 test positive	1	4
Scar		1
Sciatica		1
Seasonal allergy		1
Secondary hypertension	1	1
Seizure	1	2
Sensitive skin		1
Sensory disturbance	1	1
Sensory loss	1	1
Sepsis		1
Sialoadenitis		1
Sinus bradycardia	1	1
Sinus congestion		1
Sinus disorder	1	2
Sinus headache	1	6
Sinusitis	1	2
Sinus pain		1
Sinus tachycardia		1
Skin discolouration	2	2
Skin infection		1
Skin lesion	1	3
Skin odour abnormal		1
Skin sensitisation		1
Skin temperature	1	1
Skin warm		7
Sleep apnoea syndrome		1
Sleep disorder	1	7
Sluggishness		1
Small intestinal haemorrhage		1
Sneezing	1	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		
				1	4
			1		
					1
					1
				1	1
				1	2
			1		
				1	1
				1	1
					1
					1
		1	1		
					1
				1	2
			4	1	2
		1	1		1
			1		
					1
				2	2
			1		
			2	1	1
			1		
			1		
		1	1		
			2		5
					1
		1	3		4
			1		
					1
		1	3		3

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Somnolence	7	21
Speech disorder		1
Spinal pain		2
Sputum increased	1	1
Status epilepticus		1
Stomatitis		3
Sudden visual loss		1
Suspected COVID-19	3	18
Sweating fever		1
Swelling	14	40
Swelling face	5	14
Swelling of eyelid	2	4
Swollen tongue	3	10
Syncope	3	19
Tachycardia	3	16
Taste disorder		4
Teething	1	1
Temperature regulation disorder		2
Tenderness	5	13
Tension headache	1	7
Therapeutic response unexpected	1	1
Thirst	1	4
Throat irritation	3	7
Throat tightness		6
Thrombocytopenia	1	2
Thrombosis		3
Thunderclap headache	1	1
Tic		1
Tinnitus	6	17
Tongue coated		
Tongue discomfort		1
Tongue disorder		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	11	1	10
					1
			1		1
				1	1
					1
					3
					1
		2	9	1	9
					1
		7	23	7	17
		2	4	3	10
		1	1	1	3
		1	3	2	7
				3	19
		2	8	1	8
			3		1
		1	1		
			1		1
	1	5	11		2
	1		2	1	5
		1	1		
				1	4
		2	6	1	1
			3		3
				1	2
					3
				1	1
					1
		1	3	5	14
	1				
					1
			2		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tongue eruption		1
Tongue oedema		1
Tongue pruritus	1	1
Tongue ulceration	1	1
Tonsillar disorder		1
Tonsillar hypertrophy	1	4
Tooth erosion		1
Transient ischaemic attack		2
Tremor	3	24
Trigeminal neuralgia		1
Underdose	1	6
Upper-airway cough syndrome	1	1
Upper respiratory tract infection		1
Urge incontinence	1	1
Urinary retention		1
Urinary tract infection		5
Urine odour abnormal	1	2
Urticaria	6	18
Urticaria thermal		1
Vaccination complication		1
Vaccination failure	1	2
Vaccination site bruising		4
Vaccination site cellulitis		2
Vaccination site discomfort	1	3
Vaccination site erythema	7	26
Vaccination site haemorrhage		1
Vaccination site hypoaesthesia		1
Vaccination site induration	3	5
Vaccination site infection	1	1
Vaccination site inflammation		2
Vaccination site joint erythema		1
Vaccination site joint movement impairment	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
		1	1		
		1	1		
			1		
		1	3		1
			1		
					2
		2	5	1	19
			1		
		1	6		
				1	1
					1
					5
			1	1	1
		6	11		7
			1		
					1
				1	2
			2		2
			1		1
		1	2		1
		7	21		5
					1
			1		
		3	5		
		1	1		
			2		
					1
		1	1		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site joint pain	2	2
Vaccination site joint swelling		1
Vaccination site mass	2	12
Vaccination site movement impairment		4
Vaccination site necrosis		1
Vaccination site nodule	1	1
Vaccination site pain	17	123
Vaccination site paraesthesia		2
Vaccination site pruritus	5	13
Vaccination site rash	1	2
Vaccination site reaction	2	3
Vaccination site swelling	8	30
Vaccination site urticaria	1	1
Vaccination site warmth	3	13
Vaccine breakthrough infection		6
Vaginal haemorrhage	1	2
Varicella	1	1
Vasoconstriction		1
Ventricular tachycardia	1	1
Vertigo	9	21
Vertigo positional		1
Vestibulitis	1	1
Viral infection	2	4
Viral rash	1	1
Vision blurred	5	18
Visual impairment	1	9
Visual perseveration		1
Vitamin D deficiency		1
Vlth nerve paralysis		1
Vomiting	11	50
Vomiting projectile		1
Weight decreased	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	1
					1
		1	6	1	6
			3		1
					1
		1	1		
		10	82	7	41
			1		1
		5	10		3
		1	1		1
		2	3		
		7	21	1	9
		1	1		
		2	11	1	2
					6
		1	1		1
				1	1
					1
		2	3	7	18
					1
				1	1
			2	2	2
				1	1
		1	4	4	14
			1	1	8
					1
					1
					1
		6	17	5	33
					1
				1	3

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Wheezing	2	6			2	2		4
Wrong product administered	2	2			2	2		
Wrong technique in product usage process	1	4			1	4		
		5				5		
	1,485	6,812		15	696	2900	789	3912

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Country Where Event Occurred

UNITED STATES

090177e19749cf15\Approved\Approved On: 14-Jun-2021 14:01 (GMT)

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal abscess		1						1
Abdominal discomfort	61	289			56	278	5	11
Abdominal distension	16	65			14	61	2	4
Abdominal infection		2						2
Abdominal mass		1				1		
Abdominal operation		1				1		
Abdominal pain	51	257			39	217	12	40
Abdominal pain lower	6	27			4	19	2	8
Abdominal pain upper	83	375			74	347	9	28
Abdominal rigidity		5				4		1
Abdominal symptom		1				1		
Abdominal tenderness	1	1			1	1		
Abdominal wall haematoma		1						1
Abdominal wall haemorrhage		1						1
Abnormal behaviour	3	11			2	8	1	3
Abnormal clotting factor		1						1
Abnormal dreams	4	29			4	28		1
Abnormal faeces	4	8			3	6	1	2
Abnormal loss of weight	1	1			1	1		
Abnormal sensation in eye	3	11			3	11		
Abnormal uterine bleeding	1	1					1	1
Abnormal withdrawal bleeding		1				1		
Abortion		1						1
Abortion missed		1						1
Abortion spontaneous	19	49					19	49
Abortion threatened	1	1					1	1
Abscess		1				1		
Acarodermatitis		2				1		1
Accident	2	5			1	3	1	2
Accidental exposure to product	3	34			3	34		
Accidental overdose	4	24			4	22		2
Accidental underdose		3				3		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acetonaemia		1
Achlorhydria		1
Acidosis		1
Acne	7	26
Acoustic neuritis		1
Activated partial thromboplastin time prolonged		1
Acute coronary syndrome		1
Acute disseminated encephalomyelitis		2
Acute febrile neutrophilic dermatosis		1
Acute hepatic failure		2
Acute kidney injury		7
Acute myeloid leukaemia		4
Acute myocardial infarction		3
Acute pulmonary oedema		1
Acute respiratory failure		2
Acute stress disorder	1	1
Adenoma benign		1
Adhesion		1
Administration site bruise	1	2
Administration site erythema		1
Administration site irritation		1
Administration site joint erythema		1
Administration site pain		1
Administration site pruritus		1
Administration site reaction		1
Adnexa uteri pain		3
Adrenal disorder		3
Adrenal insufficiency		2
Adrenergic syndrome		1
Adrenocortical insufficiency acute		1
Adverse drug reaction	1	3
Adverse event	2	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
					1
		6	24	1	2
			1		
			1		
					1
					2
					1
					2
					7
					4
					3
					1
					2
		1	1		
			1		
					1
		1	2		
			1		
			1		
			1		
			1		
			1		
			3		
			2		1
					2
			1		
					1
		1	3		
		2	10		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Adverse reaction		3
Affective disorder		2
Affect lability	1	3
Ageusia	29	185
Aggression	3	6
Agitation	4	24
Alanine aminotransferase		1
Alanine aminotransferase abnormal		1
Alanine aminotransferase decreased		1
Alanine aminotransferase increased	4	13
Abumin globulin ratio decreased		1
Alcohol interaction	1	1
Allergic cough	1	2
Allergic reaction to excipient	2	6
Allergic respiratory disease		1
Allergic sinusitis		2
Allergy test positive		1
Allergy to arthropod sting		1
Allergy to chemicals	1	2
Allergy to vaccine	12	70
Allodynia		1
Alopecia	8	37
Alopecia areata	1	2
Altered state of consciousness		7
Altered visual depth perception		1
Amenorrhoea	4	5
Ammonia increased		1
Amnesia	15	51
Amniotic cavity infection		1
Amyloidosis		1
Anaemia	4	9
Anaemia vitamin B12 deficiency		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		
			2		
		1	1		2
		25	166	4	19
		1	3	2	3
		4	23		1
			1		
			1		
					1
		2	9	2	4
			1		
		1	1		
		1	2		
		2	5		1
			1		
			2		
			1		
			1		
		1	2		
		5	40	7	30
			1		
		8	31		6
		1	2		
					7
			1		
		4	5		
					1
		13	39	2	12
					1
					1
		4	9		
			1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anaesthesia		2
Anal haemorrhage	1	3
Anal incontinence	1	11
Anal infection		1
Anal pruritus		2
Anal skin tags		1
Anaphylactic reaction	33	323
Anaphylactic shock	6	25
Anaphylactoid reaction		5
Aneurysm		2
Aneurysmal bone cyst	1	1
Anger	5	12
Angina pectoris	14	42
Angina unstable		1
Angioedema	8	69
Angiopathy		5
Angle closure glaucoma		1
Angular cheilitis		1
Animal bite		3
Anion gap abnormal		1
Anion gap decreased		1
Anion gap increased		1
Anisomastia		1
Ankle fracture		2
Anomalous pulmonary venous connection		1
Anorectal discomfort		2
Anosmia	21	148
Antibody test abnormal		3
Antibody test negative		3
Antibody test positive	1	1
Anti Kell antibody test positive		1
Antinuclear ant body positive	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		1	3		
			9	1	2
			1		
			2		
			1		
				33	323
				6	25
					5
					2
		1	1		
		5	10		2
				14	42
					1
				8	69
			4		1
					1
			1		
			3		
			1		
			1		
					1
			1		
					2
					1
			2		
		18	131	3	17
			3		
			3		
		1	1		
			1		
		1	1	1	1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Antiphospholipid syndrome	1	1
Anti-thyroid antibody positive	1	1
Anxiety	61	275
Anxiety disorder		1
Aortic arteriosclerosis		1
Apathy	1	6
Aphasia	10	34
Aphonia	8	31
Aphthous ulcer	4	9
Apnoea	2	3
Appendicitis	11	44
Appendicitis perforated	1	7
Appendix disorder		1
Appetite disorder		3
Application site acne	1	1
Application site erythema		1
Application site pain		1
Application site swelling		1
Apraxia	1	1
Aptyalism		2
Arachnoid cyst		1
Arrhythmia	11	48
Arrhythmia supraventricular		1
Arterial occlusive disease		1
Arterial stenosis	2	2
Arterial thrombosis		1
Arteriosclerosis		1
Arteriosclerosis coronary artery		1
Arteriospasm coronary		3
Artery dissection	1	1
Arthralgia	317	1,910
Arthritis	22	86

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1		
		58	249	3	26
					1
			1		
		1	6		
		6	17	4	17
		5	17	3	14
		3	8	1	1
				2	3
				11	44
				1	7
					1
			3		
		1	1		
			1		
			1		
		1	1		
			2		
					1
				11	48
					1
					1
				2	2
					1
					1
			1		
					3
				1	1
	1	291	1787	26	123
		15	74	7	12

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Arthritis reactive	1	1
Arthropathy	5	29
Arthropod bite	3	9
Arthropod infestation		1
Arthropod sting		5
Aspartate aminotransferase		1
Aspartate aminotransferase decreased		1
Aspartate aminotransferase increased	3	11
Asphyxia		1
Aspiration	2	3
Asthenia	202	1,150
Asthenopia	5	31
Asthma	22	93
Asthma exercise induced		1
Asthma prophylaxis		2
Asymptomatic COVID-19	5	36
Ataxia	1	5
Atelectasis	1	5
Atrial f brillation	14	88
Atrial flutter		4
Atrioventricular block	1	2
Atrioventricular block complete	1	3
Atrioventricular block second degree		1
Attention deficit hyperactivity disorder	2	2
Atypical pneumonia	1	2
Auditory disorder		1
Aura	2	5
Auricular swelling		1
Autoimmune disorder	7	23
Autoimmune haemolytic anaemia	1	1
Autoimmune thyroid disorder		1
Autoimmune thyroiditis	1	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		4	27	1	2
		3	9		
					1
			5		
			1		
			1		
		1	8	2	3
					1
				2	3
		182	1006	20	144
		5	29		2
		17	73	5	20
			1		
			1		1
			7	5	29
			3	1	2
			1	1	4
1	1			14	88
			3		1
				1	2
				1	3
					1
		2	2		
				1	2
			1		
		2	4		1
			1		
				7	23
				1	1
					1
				1	6

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Autonomic dysreflexia	1	1
Autonomic nervous system imbalance	2	6
Autonomic neuropathy	1	2
Autoscopy	1	4
Axillary mass	3	27
Axillary pain	28	169
Back disorder	5	11
Back injury	2	7
Back pain	158	661
Bacteraemia		2
Bacterial infection	5	8
Bacterial pyelonephritis		1
Bacterial test positive	2	3
Bacterial vaginosis	1	3
Bacteriuria		1
Balance disorder	30	142
Band neutrophil count increased		1
Barrett's oesophagus		1
Basal cell carcinoma		1
Basal ganglia infarction		1
Basal ganglia stroke		2
Basedow's disease	1	3
Basophil count abnormal		1
Basophil count increased		1
Bed rest	1	4
Bedridden	8	38
Bell's palsy	49	196
Bile acid malabsorption		1
Biliary colic	2	2
Biliary tract disorder		1
Binocular eye movement disorder		1
Bipolar disorder	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			2	2	4
				1	2
		1	3		1
		3	24		3
		27	163	1	6
		5	11		
		1	6	1	1
		136	574	22	87
					2
		4	6	1	2
					1
		2	3		
		1	3		
					1
		26	115	4	27
					1
					1
					1
					1
					2
				1	3
			1		
			1		
		1	4		
		6	31	2	7
			2	49	194
			1		
		2	2		
			1		
					1
				1	2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bite		2
Bladder discomfort	1	3
Bladder disorder	1	5
Bladder dysfunction		1
Bladder hypertrophy	1	1
Bladder pain		2
Bladder spasm		1
Blast cell count increased		1
Blepharitis		1
Blepharospasm	3	16
Blindness	16	36
Blindness transient	1	7
Blindness unilateral		3
Blister	27	96
Blister rupture	1	1
Blood albumin decreased		2
Blood alcohol increased	2	2
Blood alkaline phosphatase		1
Blood alkaline phosphatase increased	1	2
Blood bilirubin decreased		2
Blood bilirubin increased	1	3
Blood blister	1	7
Blood calcium decreased	1	3
Blood calcium increased	1	3
Blood chloride decreased		2
Blood chloride increased		3
Blood cholesterol		2
Blood cholesterol abnormal		4
Blood cholesterol increased	3	9
Blood chromium increased		1
Blood copper increased		2
Blood count abnormal	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		1	3		
			4	1	1
			1		
				1	1
			2		
			1		
					1
			1		
		3	16		
				16	36
				1	7
					3
		22	79	5	17
		1	1		
			2		
		1	1	1	1
			1		
		1	2		
			2		
		1	2		1
		1	4		3
		1	2		1
		1	3		
			1		1
			3		
			2		
			4		
		2	8	1	1
					1
			2		
		1	5		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood creatine increased		1
Blood creatine phosphokinase abnormal		1
Blood creatine phosphokinase increased		4
Blood creatinine abnormal		1
Blood creatinine decreased		2
Blood creatinine increased	1	11
Blood disorder	1	6
Blood electrolytes decreased	1	1
Blood folate decreased		1
Blood folate increased		1
Blood follicle stimulating hormone increased		1
Blood glucose	1	1
Blood glucose abnormal	2	7
Blood glucose decreased	5	28
Blood glucose fluctuation		2
Blood glucose increased	10	64
Blood immunoglobulin G		1
Blood immunoglobulin G increased	1	1
Blood immunoglobulin M increased	1	1
Blood iron decreased		3
Blood iron increased		1
Blood lactate dehydrogenase increased	1	1
Blood lactic acid increased		3
Blood magnesium decreased		3
Blood parathyroid hormone decreased	1	1
Blood phosphorus increased	1	1
Blood potassium decreased	1	18
Blood potassium increased		2
Blood pressure abnormal	7	30
Blood pressure decreased	9	60
Blood pressure diastolic decreased		4
Blood pressure diastolic increased		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
			1		3
					1
			1		1
		1	9		2
		1	5		1
				1	1
			1		
			1		
					1
		1	1		
		1	5	1	2
		4	20	1	8
			2		
		8	51	2	13
			1		
				1	1
		1	1		
			2		1
			1		
		1	1		
			1		2
					3
		1	1		
		1	1		
		1	9		9
			2		
		6	24	1	6
		7	36	2	24
			3		1
			1		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood pressure fluctuation	4	26
Blood pressure increased	50	345
Blood pressure measurement		2
Blood pressure systolic increased	3	15
Blood sodium decreased	2	8
Blood sodium increased	1	1
Blood test abnormal	1	6
Blood testosterone decreased		1
Blood thyroid stimulating hormone abnormal	1	1
Blood thyroid stimulating hormone decreased		1
Blood thyroid stimulating hormone increased		4
Blood triglycerides abnormal		1
Blood triglycerides decreased		2
Blood triglycerides increased		2
Blood urea increased		3
Blood uric acid increased		2
Blood urine		2
Blood urine present	10	25
Blue toe syndrome		1
B-lymphocyte count decreased		1
Body height decreased	5	27
Body mass index increased	1	1
Body temperature		1
Body temperature abnormal	8	35
Body temperature decreased	1	29
Body temperature fluctuation	2	8
Body temperature increased	21	133
Body tinea		1
Bone contusion	1	1
Bone density abnormal		1
Bone development abnormal		1
Bone disorder		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	19	1	7
		27	201	23	144
			2		
		2	7	1	8
		2	6		2
		1	1		
		1	5		1
			1		
		1	1		
					1
			3		1
			1		
			2		
			1		1
			2		1
			1		1
			2		
		9	20	1	5
					1
			1		
		5	27		
		1	1		
			1		
		7	31	1	4
		1	25		4
		2	8		
		18	127	3	6
			1		
		1	1		
			1		
			3		1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Bone marrow disorder	1	2
Bone neoplasm		2
Bone pain	31	137
Bone swelling		8
Booster dose missed		3
Bowel movement irregularity	3	17
Brachial plexopathy		2
Bradycardia		5
Bradykinesia	2	7
Bradyphrenia		6
Brain cancer metastatic		1
Brain death		1
Brain injury	1	8
Brain natriuretic peptide increased	1	1
Brain neoplasm	1	1
Brain oedema	5	9
Brain stem haemorrhage	1	2
Brain stem infarction		1
Brain stem stroke		1
Brain stem syndrome		1
Breast abscess		1
Breast cancer	1	3
Breast cancer metastatic		1
Breast cellulitis	1	1
Breast cyst		1
Breast discharge		4
Breast discomfort	3	9
Breast disorder	1	6
Breast enlargement	1	1
Breast haematoma		1
Breast induration	1	2
Breast mass	1	15

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
			1		1
		27	121	4	16
			6		2
			3		
		3	16		1
			1		1
					5
		2	7		
			3		3
					1
					1
				1	8
				1	1
				1	1
				5	9
				1	2
					1
					1
					1
			1		
				1	3
					1
				1	1
			1		
			4		
		3	8		1
			5	1	1
		1	1		
			1		
		1	2		
		1	13		2

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Breast milk discolouration		1
Breast pain	23	91
Breast swelling	5	22
Breast tenderness	7	16
Breath odour		1
Breath sounds abnormal		4
Bronchial disorder		1
Bronchial oedema		1
Bronchitis	5	25
Bronchospasm	1	33
Brown-Sequard syndrome	1	1
Bruxism	1	2
Bundle branch block left		1
Burning mouth syndrome		1
Burning sensation	89	335
Burning sensation mucosal	1	2
Burn oral cavity	1	2
Burns third degree	1	1
Bursa disorder		1
Bursitis	5	14
Butterfly rash		2
Caffeine consumption		1
Candida infection		4
Capillary fragility		1
Capillary nail refill test abnormal		2
Carbohydrate antigen 125 increased		1
Carcinoembryonic antigen increased	1	1
Cardiac arrest	4	21
Cardiac discomfort	1	6
Cardiac disorder	9	45
Cardiac dysfunction	1	1
Cardiac failure		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		20	85	3	6
		5	21		1
		7	15		1
					1
			4		
			1		
					1
		4	19	1	6
		1	18		15
				1	1
		1	2		
					1
			1		
		67	274	22	61
		1	2		
				1	2
				1	1
			1		
		5	12		2
			1		1
			1		
			4		
			1		
			2		
			1		
				1	1
				4	21
		1	5		1
		6	33	3	12
				1	1
					2

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Cardiac failure congestive	2	9
Cardiac fibrillation	1	2
Cardiac flutter	10	43
Cardiac murmur		1
Cardiac neoplasm unspecified		1
Cardiac valve sclerosis		1
Cardiac valve vegetation		1
Cardiac ventricular thrombosis		1
Cardiogenic shock		3
Cardiomegaly	3	3
Cardiomyopathy		1
Cardio-respiratory arrest		1
Cardiospasm		3
Cardiovascular disorder	3	7
Carpal tunnel syndrome	2	6
Cartilage injury		1
Cataract	7	12
Catatonia		2
Cellulitis	12	43
Central nervous system lesion		2
Central pain syndrome		1
Cerebellar ataxia		1
Cerebellar stroke		2
Cerebral artery embolism		1
Cerebral artery stenosis	1	1
Cerebral atrophy	1	1
Cerebral disorder	4	14
Cerebral haemorrhage	3	9
Cerebral infarction		2
Cerebral palsy		2
Cerebral thrombosis	4	9
Cerebral venous sinus thrombosis		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	9
				1	2
				10	43
					1
					1
					1
					1
					3
		3	3		
					1
					1
					1
					3
					1
					1
			2		1
		2	5	1	2
		2	5		1
			1		
				7	12
			1		1
				12	43
			1		1
			1		
					2
					1
				1	1
				1	1
		4	13		1
				3	9
					2
					2
				4	9
					3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebrospinal fluid leakage		1
Cerebrovascular accident	29	129
Cerebrovascular disorder		1
Cerumen impaction		1
Cervical incompetence	1	1
Cervical radiculopathy	1	2
Cervicobrachial syndrome		1
Cervicogenic vertigo	1	1
Chalazion		1
Change in sustained attention		1
Chapped lips	1	6
Cheilitis	2	6
Chest discomfort	85	486
Chest injury		2
Chest pain	114	498
Chest X-ray abnormal		1
Chillblains	1	7
Chills	674	4,006
Chloropsia	1	1
Choking	1	17
Choking sensation	1	13
Cholecystitis	1	2
Cholecystitis infective		1
Cholelithiasis	2	4
Cholestasis		2
Chondritis		1
Chromatopsia		1
Chromaturia	4	14
Chronic fatigue syndrome	2	3
Chronic kidney disease		2
Chronic lymphocytic leukaemia		1
Chronic obstructive pulmonary disease	3	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				29	129
					1
			1		
				1	1
		1	1		1
			1		
		1	1		
			1		
			1		
		1	6		
		2	5		1
		69	367	16	119
					2
		81	367	33	131
					1
		1	6		1
		639	3780	35	226
				1	1
	1			1	17
			8	1	5
				1	2
					1
				2	4
					2
			1		
			1		
		4	14		
		2	3		
					2
					1
	1	3	8		5

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Ciliary muscle spasm		1
Circadian rhythm sleep disorder		1
Circulatory collapse		6
Circumoral swelling	2	5
Circumstance or information capable of leading to device use error		4
Circumstance or information capable of leading to medication error	35	611
Clostridium difficile colitis		1
Clostridium difficile infection	2	3
Clumsiness	1	4
Cluster headache		2
Coagulation time prolonged		1
Coagulopathy	2	8
Coccidioidomycosis	1	3
Coccydynia	2	3
Coeliac disease	2	2
Cognitive disorder	7	33
Cold-stimulus headache		1
Cold sweat	20	105
Cold urticaria	1	1
Colitis	4	13
Colitis ischaemic	1	4
Colitis microscopic	1	1
Colitis ulcerative	2	8
Colon cancer		1
Coma	1	1
Communication disorder		3
Completed suicide	1	1
Complex regional pain syndrome		1
Complicated appendicitis		1
Compression fracture	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
					6
		2	5		
			4		
		34	610	1	1
					1
				2	3
		1	3		1
			2		
			1		
		1	2	1	6
				1	3
		2	3		
				2	2
		7	25		8
			1		
		20	94		11
		1	1		
		2	8	2	5
				1	4
				1	1
2	2			2	8
					1
				1	1
			2		1
				1	1
			1		
					1
				1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Concussion	4	14
Condition aggravated	105	395
Conductive deafness		1
Confusional state	18	136
Congestive cardiomyopathy		1
Conjunctival haemorrhage		6
Conjunctival hyperaemia		1
Conjunctivitis	3	14
Conjunctivitis allergic		3
Conjunctivitis viral	1	2
Consciousness fluctuating		1
Constipation	9	47
Contraceptive diaphragm		1
Contraindicated product administered		3
Contraindication to vaccination		6
Contrast media allergy		1
Contusion	54	184
Conversion disorder		1
Cooling therapy		1
Coombs negative haemolytic anaemia	1	2
Coordination abnormal	3	11
Coprolalia	1	1
Corneal infection		1
Corneal oedema		1
Corneal reflex decreased		1
Coronary artery disease		1
Coronary artery dissection	1	1
Coronary artery occlusion		1
Coronary artery thrombosis	2	2
Coronavirus infection		1
Coronavirus test positive		2
Cor pulmonale acute		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4	3	10
1	1	72	296	33	99
					1
		14	106	4	30
					1
					6
					1
		3	14		
			3		
		1	2		
					1
		9	44		3
			1		
			3		
			6		
			1		
		45	162	9	22
			1		
			1		
				1	2
		2	7	1	4
		1	1		
					1
			1		
					1
				1	1
					1
				2	2
			1		
					2
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Costochondritis	3	6
Costovertebral angle tenderness		1
Cough	134	726
COVID-19	359	1,557
COVID-19 immunisation		2
COVID-19 pneumonia	3	25
Cranial nerve disorder		2
Cranial nerve injury	1	1
Cranial nerve paralysis		1
C-reactive protein increased	2	15
Crepitations	2	3
Crohn's disease	2	7
Crying	6	40
Crystal urine		1
CSF oligoclonal band present		1
Culture urine positive		1
Cutaneous lupus erythematosus		1
Cutaneous vasculitis	1	5
Cyanopsia	1	1
Cyanosis	3	24
Cyst		4
Cystitis	7	24
Cystitis bacterial	1	2
Cyst rupture		1
Cytogenetic analysis abnormal	1	1
Cytokine storm		1
Cytomegalovirus infection reactivation	2	2
Daydreaming		3
Deafness	24	74
Deafness bilateral	2	4
Deafness neurosensory		7
Deafness transitory		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3	1	3
			1		
	1	120	627	14	99
4	7	126	478	233	1079
			2		
				3	25
			1		1
				1	1
					1
		1	10	1	5
		2	3		
1	1			2	7
		5	36	1	4
			1		
					1
			1		
					1
			1	1	4
				1	1
		1	16	2	8
			3		1
		5	18	2	6
				1	2
			1		
				1	1
					1
				2	2
			3		
				24	74
				2	4
					7
					2

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Deafness unilateral	10	36
Death	9	57
Decreased activity		1
Decreased appetite	82	419
Decreased immune responsiveness	1	2
Decreased interest		3
Deep vein thrombosis	22	59
Defaecation urgency	1	5
Deformity		1
Degenerative bone disease	1	2
Dehydration	18	102
Delirium	6	27
Delusion	1	6
Delusional disorder, unspecified type	1	1
Delusional perception		4
Dementia		12
Demyelinating polyneuropathy		2
Demyelination	1	1
Dental caries	1	2
Dental discomfort		4
Dental paraesthesia		3
Dental restoration failure	1	2
Depersonalisation/derealisation disorder		3
Depressed level of consciousness		12
Depressed mood	14	43
Depression	12	36
Derealisation		1
Dermatitis	5	21
Dermatitis acneiform	1	3
Dermatitis allergic	2	12
Dermatitis atopic	1	3
Dermatitis contact	2	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	10	35
				9	57
			1		
		76	380	6	39
		1	2		
			2		1
				22	59
		1	5		
			1		
		1	2		
		7	55	11	47
			1	6	26
		1	3		3
				1	1
			3		1
					12
					2
				1	1
		1	2		
			4		
			3		
		1	2		
			3		
					12
	1	13	40	1	3
		10	29	2	7
			1		
		4	18	1	3
			2	1	1
		1	10	1	2
		1	3		
		2	11		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dermatitis diaper		1
Dermatitis exfoliative		1
Dermatomyositis		3
Dermatophytosis of nail		1
Dermoid cyst		1
Device breakage		1
Device leakage		1
Diabetes mellitus	2	11
Diabetes mellitus inadequate control		4
Diabetic foot infection		1
Diabetic neuropathy		1
Diaphragmalgia	1	3
Diaphragmatic disorder		2
Diaphragmatic paralysis		1
Diarrhoea	213	1,198
Diarrhoea haemorrhagic	2	13
Diastolic hypotension		1
Diet refusal		1
Diffuse alopecia		1
Dilatation ventricular		1
Diplegia	3	4
Diplopia	5	24
Disability		2
Discomfort	38	168
Discontinued product administered		1
Discouragement		1
Disease progression	1	3
Disease recurrence	25	118
Disorganised speech		1
Disorientation	16	74
Disseminated intravascular coagulation	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
					3
			1		
					1
					1
			1		
				2	11
					4
			1		
			1		
		1	3		
			2		
					1
		194	1100	19	98
				2	13
					1
					1
					1
					1
				3	4
		2	13	3	11
			1		1
		35	157	3	11
			1		
			1		
			2	1	1
		18	76	7	42
					1
		9	48	7	26
				1	3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Disseminated varicella zoster vaccine virus infection	1	1					1	1
Dissociation		4				3		1
Distract bility	1	1			1	1		
Disturbance in attention	12	70			10	57	2	13
Disturbance in social behaviour		2				2		
Diverticulitis	2	17			1	1	1	16
Diverticulum intestinal		1						1
Dizziness	463	2,504	2	3	400	2143	63	361
Dizziness exertional	1	2			1	2		
Dizziness postural	5	29			4	25	1	4
Double stranded DNA antibody positive	1	1					1	1
Drainage	2	4			2	4		
Dreamy state		1				1		
Droping		4				4		
Dropped head syndrome		1						1
Drug effective for unapproved indication		6				6		
Drug eruption		4				3		1
Drug hypersensitivity	9	56			4	46	5	10
Drug ineffective	197	1,068	4	7	2	2	195	1066
Drug interaction	2	23			2	18		5
Drug intolerance	1	2				1	1	1
Drug screen positive		1				1		
Dry eye	9	35			9	33		2
Dry mouth	22	119			21	106	1	13
Dry skin	18	46			17	42	1	4
Dry throat	9	40			9	36		4
Dumping syndrome		1				1		
Duodenogastric reflux	1	3			1	3		
Dupuytren's contracture		1						1
Dysacusis	1	2				1	1	1
Dysaesthesia	3	8			3	7		1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dysarthria	19	48
Dyschezia	2	2
Dyschromatopsia		1
Dysentery		1
Dysgeusia	41	286
Dysgraphia		3
Dyskinesia	7	43
Dyslipidaemia		1
Dysmenorrhoea	17	31
Dyspareunia		1
Dyspepsia	15	83
Dysphagia	37	218
Dysphemia	4	11
Dysphonia	18	137
Dyspnoea	241	1,216
Dyspnoea at rest		3
Dyspnoea exertional	6	22
Dysstasia	16	79
Dystonia	1	7
Dysuria	6	22
Ear congestion	3	10
Ear discomfort	36	113
Ear disorder	4	20
Ear haemorrhage	1	2
Ear infection	10	31
Ear infection viral		1
Ear neoplasm		1
Ear pain	57	208
Ear pruritus	6	26
Ear swelling	7	24
Eating disorder	19	65
Eating disorder symptom		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		14	29	5	19
		1	1	1	1
			1		
					1
		36	268	5	18
			2		1
		7	35		8
			1		
		14	27	3	4
			1		
		14	82	1	1
		19	146	18	72
		3	7	1	4
		13	93	5	44
		164	792	77	424
					3
		3	15	3	7
		13	56	3	23
				1	7
		3	17	3	5
		2	6	1	4
		29	100	7	13
		4	16		4
			1	1	1
		10	27		4
			1		
			1		
		51	186	6	22
		4	22	2	4
		6	21	1	3
		16	52	3	13
			1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Ebola disease		1
Ecchymosis	1	1
Ectopic pregnancy	1	1
Eczema	8	20
Ejection fraction decreased		2
Electric shock	1	1
Electric shock sensation	8	22
Electrocardiogram abnormal	5	14
Electrocardiogram PR shortened		1
Electrocardiogram QT prolonged		2
Electrocardiogram ST segment depression		1
Electrocardiogram T wave abnormal		1
Electrocardiogram T wave peaked		1
Electrolyte imbalance	1	1
Embolic stroke	2	3
Emergency care	1	1
Emotional disorder	5	21
Emotional distress	2	6
Emphysema	1	2
Enanthema		1
Encephalitis		2
Encephalopathy		2
Endocarditis		1
Endocrine disorder	1	1
Endocrine ophthalmopathy	1	3
Endometrial cancer	1	2
Endometrial thickening		1
Endometriosis	1	2
Energy increased	2	12
Enlarged uvula	1	13
Enterovesical fistula	1	1
Eosinophil count increased		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1		
				1	1
		7	18	1	2
					2
		1	1		
		7	21	1	1
		1	8	4	6
					1
					2
					1
			1		
			1		
				1	1
				2	3
		1	1		
		5	20		1
		2	5		1
		1	1		1
			1		
					2
					2
					1
		1	1		
				1	3
				1	2
			1		
				1	2
		2	12		
			7	1	6
				1	1
			1		3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eosinophilia		1
Eosinophilic oesophagitis	1	2
Epicondylitis	1	3
Epigastric discomfort		1
Epilepsy	1	3
Epinephrine increased		1
Episcleritis		2
Epistaxis	34	113
Epstein-Barr viraemia		1
Epstein-Barr virus antibody		1
Epstein-Barr virus antibody positive		2
Epstein-Barr virus antigen positive		1
Epstein-Barr virus infection	2	2
Epstein-Barr virus infection reactivation		1
Erosive oesophagitis		1
Eructation	3	18
Erythema	135	694
Erythema multiforme	2	5
Erythema nodosum	2	3
Erythema of eyelid	1	12
Erythrodermic psoriasis	1	1
Escherichia infection		1
Essential hypertension		1
Euphoric mood	3	16
Eustachian tube disorder		1
Eustachian tube dysfunction		2
Exaggerated startle response	1	2
Excessive cerumen production		3
Excessive ocular convergence		1
Exercise electrocardiogram abnormal	1	1
Exercise lack of		1
Exercise tolerance decreased	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1	1	1
		1	3		
			1		
				1	3
			1		
			2		
		31	88	3	25
			1		
			1		
			2		
			1		
		1	1	1	1
					1
					1
		3	18		
		116	592	19	102
				2	5
		1	2	1	1
		1	9		3
		1	1		
					1
			1		
		3	15		1
			1		
			1		1
		1	2		
			3		
					1
		1	1		
			1		
			3	1	1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Exophthalmos	1	3
Expired product administered	13	26
Exposure during pregnancy	22	78
Exposure to SARS-CoV-2	7	74
Exposure via breast milk	1	12
Exposure via eye contact		1
Exposure via skin contact	1	25
Extensive swelling of vaccinated limb		1
External ear disorder		1
External ear pain	1	2
Extra dose administered	1	3
Extraocular muscle disorder	1	2
Extraocular muscle paresis		3
Extrasystoles	2	9
Extremity contracture		2
Eye allergy		1
Eye colour change	1	1
Eye contusion	1	11
Eye discharge	3	17
Eye disorder	8	54
Eye haematoma	1	1
Eye haemorrhage	7	34
Eye infection		7
Eye inflammation	1	7
Eye injury	1	5
Eye irritation	13	56
Eyelid disorder	1	6
Eyelid function disorder		2
Eyelid haematoma		1
Eyelid irritation		4
Eyelid oedema		4
Eyelid pain	1	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
		13	26		
		20	71	2	7
		6	66	1	8
		1	11		1
			1		
		1	25		
			1		
			1		
		1	2		
		1	3		
		1	2		
					3
		2	8		1
			2		
			1		
		1	1		
		1	11		
		3	17		
		6	46	2	8
				1	1
				7	34
			7		
		1	5		2
			3	1	2
		12	53	1	3
		1	6		
			1		1
			1		
			3		1
			4		
		1	10		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eyelid ptosis	1	13
Eyelid rash	1	2
Eyelid sensory disorder		2
Eyelids pruritus	2	10
Eye movement disorder	1	9
Eye oedema	4	12
Eye pain	25	143
Eye paraesthesia		2
Eye pruritus	15	94
Eye swelling	36	172
Eye ulcer		1
Face injury		8
Face oedema	2	6
Facial bones fracture		3
Facial discomfort	5	17
Facial nerve disorder		5
Facial neuralgia	1	3
Facial pain	15	80
Facial paralysis	13	72
Facial paresis	2	13
Facial spasm	2	6
Faecaloma		1
Faeces discoloured	2	19
Faeces pale		1
Faeces soft	1	9
Fall	35	184
False negative investigation result		1
Fatigue	800	4,679
Fear	3	36
Fear of death	1	1
Fear of injection		1
Febrile convulsion		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	8		5
		1	2		
			2		
		2	8		2
		1	7		2
		4	11		1
		24	132	1	11
			1		1
		12	78	3	16
		28	132	8	40
			1		
			5		3
		1	3	1	3
					3
		5	17		
			1		4
		1	2		1
		13	70	2	10
			2	13	70
		1	8	1	5
			2	2	4
					1
		2	17		2
			1		
		1	7		2
1	1	17	108	18	76
					1
	2	748	4429	52	250
		2	31	1	5
		1	1		
			1		
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Feeding disorder	14	55
Feeling abnormal	253	1,194
Feeling cold	46	268
Feeling drunk	6	21
Feeling hot	102	545
Feeling jittery	5	35
Feeling of body temperature change	20	83
Feeling of relaxation	1	2
Female reproductive tract disorder	1	1
Femur fracture		2
Fibrin D dimer increased	5	14
Fibroblast growth factor 23 increased	1	1
Fibromuscular dysplasia	1	1
Fibromyalgia	6	17
Fine motor skill dysfunction		4
Finger deformity	1	3
Fistula		1
Flank pain	1	18
Flat affect	1	1
Flatulence	6	45
Flea infestation	1	1
Fluid imbalance		1
Fluid intake reduced		5
Fluid overload	1	1
Fluid retention	1	8
Flushing	27	331
Foaming at mouth		2
Foetal death	2	6
Foetal exposure during pregnancy		1
Foetal hypokinesia		1
Folliculitis		4
Food allergy	3	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		10	45	4	10
		235	1106	18	88
		43	241	3	27
		6	20		1
		96	475	6	70
		5	30		5
		17	75	3	8
		1	2		
				1	1
					2
		3	8	2	6
		1	1		
				1	1
		6	16		1
			3		1
		1	3		
			1		
			14	1	4
		1	1		
		4	42	2	3
		1	1		
					1
			3		2
		1	1		
		1	8		
		19	262	8	69
			2		
				2	6
			1		
					1
			4		
		2	6	1	2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Food aversion		3
Food craving	1	1
Food intolerance	1	2
Food poisoning	2	6
Foot deformity	1	4
Foot fracture	2	5
Foreign body aspiration		1
Foreign body in eye		1
Foreign body in throat		4
Foreign body sensation in eyes	2	3
Formication	1	15
Fracture		1
Freezing phenomenon	1	6
Frequent bowel movements		7
Frostbite		1
Frustration tolerance decreased	4	17
Full blood count		1
Full blood count abnormal		2
Functional gastrointestinal disorder		4
Fungal infection	3	12
Fungal skin infection		1
Furuncle	1	5
Gait disturbance	74	322
Gait inability	21	89
Galactostasis	1	1
Gallbladder disorder	1	8
Gallbladder injury		1
Gallbladder polyp		1
Gastric dilatation		1
Gastric disorder	5	23
Gastric haemorrhage		1
Gastric infection		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		
		1	1		
		1	2		
		2	6		
		1	4		
			1	2	4
					1
			1		
					4
		2	3		
		1	13		2
					1
		1	6		
			7		
			1		
		4	16		1
			1		
			2		
			4		
		3	11		1
			1		
		1	5		
		48	241	26	81
		11	51	10	38
		1	1		
		1	4		4
			1		
			1		
			1		
		4	20	1	3
					1
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastric pH decreased		2
Gastric ulcer		1
Gastritis	3	7
Gastritis bacterial		1
Gastroenteritis		1
Gastroenteritis viral	1	11
Gastrointestinal bacterial infection	1	1
Gastrointestinal disorder	8	48
Gastrointestinal haemorrhage	1	9
Gastrointestinal hypomotility		1
Gastrointestinal infection	1	2
Gastrointestinal inflammation	1	1
Gastrointestinal injury		1
Gastrointestinal motility disorder	1	2
Gastrointestinal pain	6	31
Gastrointestinal sounds abnormal	1	8
Gastrointestinal stoma complication		1
Gastrointestinal viral infection		1
Gastrooesophageal reflux disease	8	43
Generalised anxiety disorder		3
Generalised tonic-clonic seizure	4	8
General physical health deterioration		5
Genital herpes	2	7
Genital herpes simplex		2
Genital lesion		1
Genital rash		1
Genital swelling		1
Genital ulceration		1
Gingival abscess	1	1
Gingival bleeding	1	11
Gingival blister		2
Gingival discomfort	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
					1
		2	6	1	1
					1
			1		
		1	7		4
				1	1
		7	44	1	4
				1	9
			1		
			1	1	1
		1	1		
			1		
		1	2		
		6	29		2
		1	8		
			1		
			1		
		7	40	1	3
			3		
				4	8
			1		4
			4	2	3
			2		
			1		
			1		
			1		
		1	1		
		1	10		1
			1		1
		1	2		1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gingival disorder	1	2
Gingival erythema		4
Gingival pain	2	15
Gingival recession		1
Gingival swelling		13
Gingival ulceration		1
Gingivitis	3	5
Glare		1
Glassy eyes		5
Glaucoma	2	8
Glomerular filtration rate abnormal		1
Glomerular filtration rate decreased	1	8
Glomerulonephritis minimal lesion		1
Glossitis	1	8
Glossodynia	10	44
Glycosylated haemoglobin decreased	1	1
Glycosylated haemoglobin increased	1	2
Goitre	4	9
Gout	2	10
Granulocytes abnormal		2
Granuloma		1
Granuloma annulare		1
Granuloma skin		1
Grip strength decreased	1	14
Groin pain	7	15
Gross motor delay	1	1
Growing pains	1	1
Grunting		8
Guillain-Barre syndrome	4	19
Gun shot wound	1	1
Haemangioma		1
Haemarthrosis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
			4		
		2	14		1
			1		
			11		2
			1		
		3	5		
			1		
			5		
		1	2	1	6
			1		
			5	1	3
					1
			7	1	1
		9	41	1	3
		1	1		
				1	2
		2	5	2	4
		1	9	1	1
			1		1
					1
			1		
		1	14		
		5	12	2	3
				1	1
		1	1		
			7		1
				4	19
				1	1
					1
				1	1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Haematemesis	2	7
Haematochezia	6	33
Haematocrit decreased		3
Haematocrit increased		2
Haematoma		9
Haematuria		3
Haemoglobin abnormal		1
Haemoglobin decreased	4	17
Haemoglobin increased		2
Haemoglobin urine present	1	1
Haemolysis		1
Haemolytic anaemia		2
Haemophagocytic lymphohistiocytosis		1
Haemoptysis	4	22
Haemorrhage	24	66
Haemorrhage intracranial	1	1
Haemorrhage subcutaneous	1	2
Haemorrhage urinary tract	4	6
Haemorrhagic diathesis	1	1
Haemorrhagic stroke	1	4
Haemorrhagic urticaria		1
Haemorrhagic varicella syndrome		1
Haemorrhoidal haemorrhage		1
Haemorrhoids	1	8
Hair disorder		1
Hair injury	1	2
Hair texture abnormal	1	1
Hallucination	11	42
Hallucination, auditory	1	10
Hallucination, visual	2	14
Hand-eye coordination impaired		1
Hand fracture		5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	7
				6	33
			3		
			2		
			8		1
			2		1
					1
		3	10	1	7
			2		
		1	1		
					1
					2
					1
		1	12	3	10
				24	66
				1	1
				1	2
				4	6
				1	1
				1	4
					1
					1
			1		
		1	6		2
			1		
		1	2		
		1	1		
		1	1	10	41
				1	10
				2	14
					1
					5

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hangover	7	19
Headache	1,098	5,838
Head banging	1	1
Head deformity		1
Head discomfort	45	173
Head injury	14	43
Head titubation	1	2
Hearing disability	1	3
Heart injury		3
Heart rate abnormal	4	31
Heart rate decreased	4	25
Heart rate increased	139	730
Heart rate irregular	8	48
Heart rate normal		1
Heart valve incompetence		2
Heat illness		2
Heavy menstrual bleeding	50	86
Helicobacter infection		1
Hemianaesthesia		
Hemiparesis	4	17
Hemiplegia	1	6
Hemiplegic migraine	1	1
Henoch-Schonlein purpura	1	2
Heparin-induced thrombocytopenia		1
Hepatic cirrhosis		1
Hepatic cyst		2
Hepatic enzyme abnormal		1
Hepatic enzyme increased	3	9
Hepatic failure	1	2
Hepatic function abnormal		1
Hepatic lesion		1
Hepatic necrosis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		7	17		2
		1042	5469	56	369
		1	1		
			1		
		43	154	2	19
1	1	9	25	5	18
		1	2		
			2	1	1
					3
		4	26		5
		3	16	1	9
		107	573	32	157
		6	37	2	11
			1		
			1		1
			2		
		36	68	14	18
					1
1	1				
1	1			4	17
				1	6
		1	1		
				1	2
					1
					1
			1		1
					1
			4	3	5
				1	2
					1
					1
					1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hepatic pain	3	5
Hepatic steatosis		1
Hepatitis acute		1
Hepatitis C	1	1
Hepatitis cholestatic		1
Hepatitis D		1
Hepatomegaly	1	2
Hernia repair		1
Herpes dermatitis	1	1
Herpes ophthalmic	1	1
Herpes simplex	3	15
Herpes simplex gastritis	1	1
Herpes simplex reactivation		3
Herpes virus infection	3	14
Herpes zoster	183	330
Herpes zoster oticus	2	4
Herpes zoster reactivation	4	5
Heterophoria		1
Hiatus hernia	1	2
Hiccups	1	3
Hidradenitis		2
Hip fracture	2	7
Histamine level increased		3
HIV test false positive	1	2
HIV test negative		1
HIV test positive	1	1
Hordeolum		7
Hormone level abnormal		2
Hospitalisation		1
Hostility	1	1
Hot flush	40	184
Human chorionic gonadotropin increased	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3	1	2
			1		
					1
				1	1
					1
					1
			1	1	1
					1
		1	1		
				1	1
		1	13	2	2
				1	1
			3		
		3	13		1
		158	278	25	52
				2	4
		4	5		
					1
			1	1	1
		1	3		
			2		
				2	7
			2		1
		1	2		
					1
		1	1		
			6		1
			1		1
					1
		1	1		
		38	168	2	16
				1	1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hunger	1	8
Huntington's disease		1
Hydrophobia		1
Hydrothorax	1	1
Hyperacusis	4	26
Hyperaemia		1
Hyperaesthesia	5	32
Hyperaesthesia teeth	2	4
Hyperbilirubinaemia		1
Hypercholesterolaemia	1	1
Hyperexplexia	1	1
Hyperglycaemia		3
Hyperhidrosis	108	555
Hyperlipidaemia		1
Hypermetropia		1
Hyperparathyroidism		1
Hyperphagia	1	2
Hyperpyrexia	2	11
Hyperreflexia		1
Hypersensitivity	109	423
Hypersexuality	1	1
Hypersomnia	16	112
Hypertension	70	319
Hypertensive crisis		3
Hypertensive emergency		3
Hyperthyroidism		2
Hypertonia		1
Hypertrichosis		1
Hyperventilation	10	29
Hypervigilance		1
Hypoacusis	19	67
Hypoaesthesia	198	911

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	8		
			1		
			1		
				1	1
		4	24		2
			1		
		4	30	1	2
		2	4		
					1
		1	1		
		1	1		
			1		2
		96	493	12	62
					1
			1		
			1		
		1	2		
				2	11
			1		
		72	295	37	128
		1	1		
		14	102	2	10
	1	29	169	41	150
					3
					3
					2
			1		
			1		
		7	21	3	8
			1		
		14	56	5	11
		158	728	40	183

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hypoaesthesia eye		8
Hypoaesthesia oral	43	251
Hypoaesthesia teeth		1
Hypobarism		1
Hypocalcaemia		1
Hypogeusia		7
Hypoglycaemia		9
Hypokalaemia	1	5
Hypokalaemic syndrome		1
Hypokinesia	4	27
Hypomagnesaemia		1
Hypomenorrhoea		1
Hyponatraemia		1
Hyponatraemic syndrome		1
Hypophagia	1	7
Hypopituitarism	1	1
Hypopnoea	3	13
Hyporeflexia		1
Hyporesponsive to stimuli		2
Hyposmia		4
Hypotension	22	94
Hypothermia	3	8
Hypothyroidism	2	8
Hypotonia		3
Hypovolaemic shock		2
Hypoxia	1	9
Hypoxic-ischaemic encephalopathy		1
Hysterectomy		1
Idiopathic intracranial hypertension	1	2
Idiopathic urticaria	1	1
Idiosyncratic drug reaction		1
Illrd nerve paralysis	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			7		1
		34	198	9	53
			1		
					1
					1
			7		
			5		4
				1	5
			1		
		2	21	2	6
					1
			1		
			1		
		1	4		3
		1	1		
		3	11		2
					1
			1		1
			4		
		13	49	9	45
				3	8
				2	8
			3		
					2
				1	9
					1
					1
				1	2
				1	1
			1		
				2	3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ileus		1
Iliotibial band syndrome		1
III-defined disorder	1	4
Illness	122	537
Illness anxiety disorder		1
Immobile	1	6
Immune-mediated arthritis		1
Immune system disorder	9	37
Immune thrombocytopenia	6	15
Immunisation		2
Immunisation reaction		1
Immunodeficiency	3	7
Immunoglobulins abnormal		1
Immunoglobulins decreased		1
Immunosuppression		1
Impaired driving ability	2	15
Impaired gastric emptying	3	4
Impaired healing		5
Impaired quality of life		1
Impaired work ability	6	18
Implant site nodule		1
Implant site pain	1	1
Impulsive behaviour		1
Inappropriate affect		1
Inappropriate schedule of product administration	121	774
Incoherent	3	10
Incomplete course of vaccination		11
Incontinence	2	7
Incorrect dosage administered		3
Incorrect dose administered	9	38
Incorrect dose administered by device		1
Incorrect product administration duration		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
		1	4		
		110	490	12	47
			1		
				1	6
					1
		6	26	3	11
				6	15
			2		
					1
1	1			3	7
			1		
			1		
					1
		2	12		3
				3	4
			4		1
					1
		4	14	2	4
			1		
		1	1		
			1		
			1		
		117	770	4	4
		1	4	2	6
			11		
		1	5	1	2
			3		
		9	36		2
			1		
			2		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Incorrect route of product administration	10	108
Increased appetite	3	7
Increased tendency to bruise	2	4
Increased upper airway secretion	1	10
Increased viscosity of bronchial secretion		1
Increased viscosity of upper respiratory secretion		3
Induration	3	8
Infant irritability		1
Infarction	1	1
Infection	7	32
Infection parasitic		1
Infection reactivation	1	1
Infectious mononucleosis	2	7
Infertility female		1
Inflammation	28	112
Inflammatory bowel disease		1
Inflammatory carcinoma of the breast	1	1
Inflammatory marker increased	3	4
Inflammatory pain		2
Influenza	21	118
Influenza B virus test positive		1
Influenza like illness	70	406
Infusion site mobility decreased		1
Initial insomnia		5
Injected limb mobility decreased	2	11
Injection site abscess		1
Injection site bruising		4
Injection site cellulitis	1	1
Injection site discolouration		1
Injection site discomfort		5
Injection site erythema	10	78

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		10	105		3
		3	7		
		1	3	1	1
			6	1	4
					1
			2		1
		3	8		
			1		
				1	1
		2	22	5	10
			1		
		1	1		
		1	6	1	1
					1
		26	103	2	9
					1
				1	1
		1	2	2	2
			2		
		19	112	2	6
			1		
		65	384	5	22
			1		
			5		
		2	11		
			1		
			4		
		1	1		
			1		
			5		
		10	78		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site extravasation	1	3
Injection site haematoma		1
Injection site haemorrhage		5
Injection site hypoaesthesia		1
Injection site indentation		1
Injection site induration		3
Injection site infection		2
Injection site inflammation		1
Injection site injury		1
Injection site joint pain		1
Injection site mass	1	12
Injection site nodule		2
Injection site oedema		1
Injection site pain	26	269
Injection site papule		1
Injection site paraesthesia		3
Injection site pruritus	2	28
Injection site rash	3	27
Injection site reaction		9
Injection site scab		1
Injection site swelling	6	64
Injection site urticaria	1	8
Injection site vesicles		1
Injection site warmth	2	19
Injury	2	11
Inner ear disorder		3
Inner ear inflammation	1	2
Insomnia	102	439
Inspiratory capacity decreased	2	2
Instillation site pain		1
Instillation site warmth	1	1
Intellectual disability	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		
					1
			5		
			1		
			1		
			3		
			2		
			1		
			1		
			1		
		1	12		
			2		
			1		
		25	266	1	3
			1		
			3		
		2	28		
		3	27		
			9		
			1		
		6	64		
		1	7		1
			1		
		2	19		
		2	8		3
			2		1
			1	1	1
		90	397	12	42
		2	2		
			1		
		1	1		
				1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Intentional dose omission		6
Intentional overdose		1
Intentional product misuse	1	5
Intercepted medication error		2
Intermenstrual bleeding	11	26
Internal haemorrhage	1	6
International normalised ratio decreased		2
International normalised ratio increased	1	7
Intervertebral disc degeneration		2
Intervertebral disc protrusion	1	4
Intestinal haemorrhage		2
Intestinal ischaemia		1
Intestinal obstruction		1
Intestinal perforation		1
Intra-abdominal haematoma		1
Intracardiac thrombus		1
Intracranial aneurysm		3
Intracranial hypotension	1	1
Intracranial pressure increased	1	5
Intranasal hypoaesthesia		1
Intranasal paraesthesia	1	4
Intraocular pressure increased		3
Intraocular pressure test abnormal	1	2
Intraventricular haemorrhage		1
Iridocyclitis		2
Iron deficiency	2	3
Irregular breathing		1
Irregular sleep wake rhythm disorder		2
Irritability	8	30
Irritability postvaccinal		1
Irritable bowel syndrome	3	8
Ischaemia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			6		
			1		
		1	5		
			2		
		10	23	1	3
				1	6
			1		1
		1	3		4
			2		
			1	1	3
					2
					1
					1
					1
					3
		1	1		
				1	5
			1		
		1	4		
			2		1
		1	2		
					1
					2
		2	3		
			1		
			2		
		7	27	1	3
			1		
		3	7		1
				1	1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Ischaemic cerebral infarction		1
Ischaemic stroke	3	10
IVth nerve paralysis		1
Jaundice	1	9
Jaw clicking		3
Jaw cyst		1
Jaw disorder	1	8
Joint contracture	1	1
Joint dislocation	1	8
Joint effusion	1	4
Joint injury	4	18
Joint instability		4
Joint lock	1	9
Joint noise	2	4
Joint range of motion decreased	11	65
Joint stabilisation		1
Joint stiffness	14	53
Joint swelling	34	146
Joint warmth		1
Jugular vein thrombosis	1	1
Kawasaki's disease	1	1
Keratitis		2
Keratosis pilaris	1	2
Kidney infection	4	14
Knee operation		1
Labile hypertension		1
Laboratory test abnormal	1	3
Labyrinthitis	1	5
Lack of spontaneous speech	1	3
Lacrimal disorder	1	1
Lacrimation decreased		1
Lacrimation increased	16	68

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				3	10
					1
			3	1	6
			3		
			1		
		1	7		1
		1	1		
		1	2		6
		1	4		
		3	16	1	2
			1		3
			8	1	1
		1	3	1	1
		10	55	1	10
					1
		12	47	2	6
		27	127	7	19
			1		
				1	1
				1	1
					2
		1	2		
				4	14
					1
			1		
		1	2		1
			1	1	4
		1	1		2
		1	1		
					1
		16	64		4

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lactic acidosis		1
Lactose intolerance	1	1
Lacunar stroke		1
Large intestinal obstruction		1
Large intestine infection		1
Large intestine perforation		1
Large intestine polyp		1
Laryngeal discomfort		1
Laryngeal oedema		4
Laryngeal pain	1	3
Laryngitis	4	14
Laryngospasm		4
Latent autoimmune diabetes in adults		1
Laziness	1	3
Lethargy	47	248
Leukaemia	1	3
Leukocytosis		2
Lichenoid keratosis		1
Lichen planus		1
Lichen sclerosus		1
Ligament disorder		1
Ligament injury	1	4
Ligamentitis	1	1
Ligament pain	1	1
Ligament rupture	2	3
Ligament sprain		8
Limb deformity		1
Limb discomfort	46	240
Limb immobilisation	1	1
Limb injury	3	34
Limb mass	3	16
Lipase decreased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1		
					1
					1
					1
			1		
			1		
					4
		1	3		
		4	12		2
			1		3
					1
		1	3		
		46	231	1	17
				1	3
			1		1
			1		
			1		
					1
		1	4		
				1	1
				1	1
		2	2		1
			8		
			1		
		46	220		20
		1	1		
1	1	3	34		
		3	15		1
			1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lipase increased		2
Lip blister	1	14
Lip discolouration	1	3
Lip disorder	4	13
Lip dry	2	6
Lip erythema	1	7
Lip exfoliation	1	2
Lip haemorrhage		1
Lipids increased		1
Lip infection		1
Lip injury	2	7
Lip oedema		6
Lipoma		1
Lip pain	6	11
Lip pruritus	1	15
Lip swelling	54	228
Lip ulceration		1
Liquid product physical issue		4
Listless		3
Livedo reticularis		7
Liver disorder		4
Liver function test abnormal		2
Liver function test increased	1	2
Liver injury		2
Liver tenderness		1
Local anaesthesia		1
Localised infection	2	8
Localised oedema	1	5
Local reaction		1
Loose body in joint		1
Loss of consciousness	90	320
Loss of control of legs		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
			9	1	5
		1	2		1
		3	12	1	1
		2	4		2
		1	6		1
		1	2		
					1
			1		
			1		
		2	5		2
			4		2
			1		
		5	10	1	1
		1	9		6
		32	155	22	73
			1		
			4		
			3		
			4		3
			2		2
			1		1
		1	2		
			1		1
			1		
			1		
		1	6	1	2
		1	5		
			1		
					1
1	1		1	90	319
					2

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Loss of employment		1
Loss of personal independence in daily activities	31	149
Loss of proprioception		1
Low density lipoprotein increased		1
Lower limb fracture		3
Lower respiratory tract congestion		2
Lower respiratory tract infection	1	9
Lower respiratory tract infection bacterial	1	1
Lumbar radiculopathy		1
Lung abscess	1	1
Lung carcinoma cell type unspecified recurrent	1	1
Lung carcinoma cell type unspecified stage I		1
Lung disorder	7	24
Lung hyperinflation		1
Lung infiltration		1
Lung neoplasm malignant		2
Lung opacity		1
Lupus-like syndrome	1	1
Lupus myositis		1
Lyme disease	2	5
Lymphadenitis	5	22
Lymphadenopathy	208	1,180
Lymph gland infection		3
Lymph node pain	43	242
Lymph node palpable		4
Lymphoblast count		1
Lymphocyte count abnormal		3
Lymphocyte count decreased	3	8
Lymphocyte count increased	2	5
Lymphocytosis		1
Lymphoedema	3	16
Lymphoma	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		24	125	7	24
					1
			1		
			1		2
			2		
				1	9
				1	1
			1		
				1	1
				1	1
		4	19	3	5
			1		
					1
					2
					1
				1	1
					1
				2	5
		3	19	2	3
		191	1108	17	72
			2		1
		39	225	4	17
			4		
			1		
			2		1
		2	7	1	1
		1	3	1	2
			1		
		3	16		
				1	4

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Lymphopenia		1
Macroglossia		2
Macular degeneration		5
Macular hole		1
Macule	1	4
Maculopathy	1	1
Major depression	1	4
Malaise	275	1,486
Malignant hypertension		1
Malignant melanoma	1	1
Mammogram abnormal		1
Mania	2	4
Mass	17	63
Mast cell activation syndrome	1	1
Mastication disorder	1	9
Mastitis	2	7
Mastoid disorder		2
Maternal exposure before pregnancy	1	2
Maternal exposure during breast feeding	1	2
Maternal exposure during pregnancy	25	151
Maternal exposure timing unspecified	2	6
May-Thurner syndrome		1
Mean cell haemoglobin decreased	1	1
Mean cell haemoglobin increased	1	1
Mean cell volume increased	1	2
Mean platelet volume decreased	1	2
Measles	3	5
Mechanical urticaria	1	2
Mediastinal mass	1	1
Medication error	1	8
Meibomian gland dysfunction		1
Melaena		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					2
					5
					1
		1	4		
				1	1
				1	4
		251	1384	24	102
					1
				1	1
			1		
		2	3		1
		14	56	3	7
				1	1
		1	7		2
				2	7
			1		1
		1	2		
		1	2		
		23	147	2	4
		2	6		
					1
		1	1		
		1	1		
		1	2		
		1	2		
				3	5
		1	2		
		1	1		
		1	8		
					1
					2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Melanocytic naevus	1	1
Memory impairment	18	75
Meniere's disease	1	6
Meningeal disorder		1
Meningism		1
Meningitis	1	5
Meningitis aseptic		1
Meningitis viral		4
Meniscus injury		2
Menopausal symptoms		1
Menopause		2
Menstrual discomfort		1
Menstrual disorder	38	65
Menstruation delayed	12	16
Menstruation irregular	44	69
Mental disorder	4	20
Mental impairment	8	44
Mental status changes		5
Meralgia paraesthetica		1
Metabolic encephalopathy		1
Metabolic function test abnormal		3
Metamyelocyte count increased		1
Metastases to meninges		1
Methylenetetrahydrofolate reductase gene mutation		1
Microangiopathic haemolytic anaemia		1
Microembolism		2
Micturition disorder	1	3
Micturition urgency	2	8
Middle ear effusion		2
Middle insomnia	2	36
Migraine	78	388

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		16	62	2	13
				1	6
			1		1
		1	1		4
					1
					4
			1		1
			1		
			2		
			1		
		34	59	4	6
		10	13	2	3
		41	66	3	3
		3	16	1	4
				8	44
			4		1
					1
					1
			2		1
					1
					1
			1		
					1
					2
		1	2		1
		1	5	1	3
			2		
		2	34		2
		60	334	18	54

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Migraine with aura	1	6
Migraine without aura		1
Miliaria	2	10
Miosis	1	2
Mitral valve disease		1
Mitral valve incompetence	1	1
Mitral valve prolapse		1
Mixed connective tissue disease	1	2
Moaning	1	2
Mobility decreased	18	95
Monocyte count abnormal		1
Monocyte count increased		4
Mononeuropathy		1
Monoparesis		1
Monoplegia	4	10
Mood altered	1	5
Mood swings		3
Morning sickness		1
Motion sickness		10
Motor dysfunction		10
Mouth cyst	1	1
Mouth haemorrhage	1	6
Mouth injury	2	6
Mouth swelling	7	41
Mouth ulceration	5	18
Movement disorder	36	136
Mucosal disorder	2	7
Mucosal dryness	1	2
Mucosal inflammation	1	2
Mucosal pain	1	1
Mucosa vesicle		1
Mucous stools		5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	5		1
			1		
		2	10		
		1	2		
					1
				1	1
					1
				1	2
		1	1		1
		13	76	5	19
			1		
			2		2
					1
					1
				4	10
		1	5		
			1		2
					1
			9		1
			4		6
		1	1		
		1	4		2
		1	5	1	1
		4	26	3	15
		5	17		1
		29	117	7	19
		2	5		2
		1	2		
			1	1	1
		1	1		
					1
			5		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Multi-organ disorder		2
Multiple allergies		2
Multiple organ dysfunction syndrome		1
Multiple sclerosis	7	16
Multiple sclerosis relapse	3	9
Multisystem inflammatory syndrome in children	1	1
Mumps		1
Muscle atrophy	1	3
Muscle contractions involuntary	2	7
Muscle contracture		1
Muscle discomfort	2	21
Muscle disorder	1	20
Muscle fatigue	5	23
Muscle injury	1	3
Muscle mass		1
Muscle rigidity	4	8
Muscle rupture	1	2
Muscle spasms	62	329
Muscle spasticity	1	4
Muscle strain	5	17
Muscle swelling	4	13
Muscle tightness	17	112
Muscle twitching	18	79
Muscular weakness	50	272
Musculoskeletal chest pain	10	58
Musculoskeletal discomfort	11	75
Musculoskeletal disorder	5	18
Musculoskeletal pain	4	22
Musculoskeletal stiffness	66	308
Mutism		3
Myalgia	290	1,856
Myasthenia gravis		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
			2		
					1
				7	16
				3	9
				1	1
			1		
			2	1	1
		1	5	1	2
			1		
		2	21		
		1	18		2
		3	21	2	2
		1	3		
			1		
		4	6		2
				1	2
		54	281	8	48
		1	3		1
		5	15		2
		4	11		2
		14	97	3	15
		17	69	1	10
		28	203	22	69
		9	52	1	6
		9	68	2	7
		5	14		4
		4	20		2
		58	283	8	25
			2		1
		273	1753	17	103
					2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mydriasis	4	10
Myelitis	1	1
Myelitis transverse	3	10
Myelocyte count increased		1
Myelopathy		1
Myocardial infarction	23	79
Myocardial necrosis marker increased	1	5
Myocardial strain		1
Myocarditis	3	10
Myoclonus	1	3
Myokymia		2
Myopathy	1	1
Myopia		1
Myosclerosis	1	1
Myositis	7	9
Nail discolouration	1	5
Nail infection		1
Narcolepsy		2
Nasal congestion	48	305
Nasal crusting		1
Nasal discharge discolouration		1
Nasal discomfort	5	28
Nasal disorder		5
Nasal dryness	3	6
Nasal injury		3
Nasal oedema	2	19
Nasal pruritus	2	6
Nasopharyngitis	48	287
Nausea	536	3,087
Near death experience	8	29
Neck deformity	1	1
Neck injury	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	10		
				1	1
				3	10
					1
					1
			1	23	78
				1	5
					1
		1	1	2	9
				1	3
			2		
				1	1
			1		
				1	1
		6	6	1	3
		1	4		1
			1		
					2
		46	280	2	25
			1		
			1		
		4	24	1	4
			4		1
		3	6		
			3		
		1	13	1	6
		2	5		1
		47	279	1	8
1	1	498	2811	38	276
				8	29
		1	1		
		1	5		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Neck mass	7	18
Neck pain	92	543
Needle issue	2	6
Neglect of personal appearance		1
Neoplasm	1	4
Neoplasm malignant	3	8
Neoplasm progression	1	4
Neoplasm skin	1	4
Nephritis	2	2
Nephrolithiasis	3	15
Nephropathy		4
Nephrotic syndrome		1
Nerve compression		17
Nerve injury	6	21
Nervousness	34	156
Nervous system disorder	9	28
Neuralgia	26	111
Neuralgic amyotrophy		3
Neuritis	2	5
Neurological infection	1	1
Neurological procedural complication	1	1
Neurological symptom	4	15
Neuromyelitis optica spectrum disorder		2
Neuropathy peripheral	17	75
Neutropenia		3
Neutrophil count abnormal		2
Neutrophil count decreased	3	6
Neutrophil count increased		6
Neutrophilia		1
Nightmare	8	39
Night sweats	15	107
Nipple exudate bloody		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	17	1	1
		81	488	11	55
		2	6		
			1		
		1	4		
				3	8
			1	1	3
		1	4		
				2	2
				3	15
			1		3
					1
			15		2
		3	14	3	7
		33	148	1	8
		8	21	1	7
		22	92	4	19
			1		2
		1	4	1	1
				1	1
		1	1		
		1	9	3	6
					2
		1	1	16	74
					3
					2
		2	3	1	3
			4		2
			1		
		8	36		3
		14	102	1	5
			1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nipple pain	1	7
Nipple swelling		2
Nitrite urine present		1
No adverse event	5	41
Nocturia		1
Nocturnal dyspnoea	1	1
Nodule	4	17
Non-Hodgkin's lymphoma		2
Noninfective encephalitis	1	4
Noninfective gingivitis	2	4
Non-pitting oedema		1
Nonspecific reaction		1
Norepinephrine increased		1
Normocytic anaemia		1
Nuchal rigidity		3
Nucleated red cells	1	1
Nystagmus	1	5
Obesity		1
Obsessive thoughts		1
Obstructive airways disorder	1	7
Obstructive shock		1
Occipital neuralgia	1	2
Occupational exposure to product		5
Occupational exposure to SARS-CoV-2		5
Ocular discomfort	8	40
Ocular hyperaemia	17	93
Ocular icterus		1
Ocular ischaemic syndrome	1	1
Ocular vascular disorder	3	5
Odynophagia	2	22
Oedema	2	20
Oedema mouth		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	7		
			2		
			1		
		5	41		
					1
		1	1		
		4	17		
					2
				1	4
		2	4		
					1
			1		
			1		
			2		1
		1	1		
		1	3		2
			1		
					1
			1	1	6
					1
		1	1		1
			5		
			5		
		8	36		4
		16	80	1	13
			1		
				1	1
			1	3	4
		2	18		4
		2	17		3
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oedema mucosal	1	1
Oedema peripheral	5	19
Oesophageal achalasia		1
Oesophageal disorder	1	3
Oesophageal pain	2	5
Oesophageal spasm	1	1
Oesophageal stenosis		1
Oesophagitis	1	2
Off label use	94	634
Oligodipsia		1
Oligomenorrhoea	5	5
Oliguria		1
Omphalitis		1
Onychoclasia		2
Ophthalmic herpes simplex		1
Ophthalmic herpes zoster	2	2
Ophthalmic migraine	3	11
Ophthalmoplegia	1	1
Optic ischaemic neuropathy		2
Optic nerve disorder		1
Optic neuritis		6
Oral blood blister		1
Oral candidiasis	1	7
Oral discomfort	10	45
Oral disorder	3	15
Oral fungal infection		2
Oral herpes	23	76
Oral lichen planus		1
Oral mucosal blistering	5	15
Oral mucosal discolouration	1	1
Oral mucosal eruption	3	8
Oral mucosal erythema	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		4	16	1	3
			1		
			1	1	2
		1	4	1	1
		1	1		
					1
		1	2		
		92	627	2	7
					1
		4	4	1	1
			1		
					1
			2		
					1
				2	2
		2	10	1	1
				1	1
					2
					1
					6
					1
		1	7		
		7	37	3	8
		3	13		2
			2		
		21	70	2	6
			1		
		4	13	1	2
		1	1		
			5	3	3
			3	1	2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral mucosal exfoliation		1
Oral mucosal roughening		1
Oral pain	9	38
Oral pruritus	5	27
Oral viral infection		2
Orbital oedema		1
Organising pneumonia	1	1
Oromandibular dystonia		1
Oropharyngeal blistering	1	4
Oropharyngeal candidiasis		1
Oropharyngeal cobble stone mucosa		1
Oropharyngeal discomfort	13	76
Oropharyngeal pain	106	585
Oropharyngeal plaque	1	1
Oropharyngeal spasm	1	3
Oropharyngeal swelling		1
Orthopnoea		1
Orthostatic heart rate response increased		1
Orthostatic hypertension	1	1
Orthostatic hypotension	1	8
Orthostatic intolerance		1
Osteitis	1	1
Osteoarthritis	1	10
Osteochondritis		1
Osteolysis	1	1
Osteomyelitis		3
Osteopenia	1	1
Osteoporosis		2
Otitis media	1	3
Otorrhoea	1	2
Ovarian cancer		1
Ovarian cyst	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
		9	36		2
		3	17	2	10
			2		
					1
				1	1
			1		
			1		
		8	61	5	15
		98	546	8	39
		1	1		
				1	3
			1		
					1
			1		
				1	1
			3	1	5
			1		
		1	1		
		1	10		
			1		
		1	1		
					3
		1	1		
			2		
		1	3		
		1	2		
					1
		2	2		1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Ovarian cyst ruptured	1	1
Ovarian disorder		1
Ovarian enlargement		1
Ovarian vein thrombosis	1	1
Overdose	22	91
Oversensing		2
Overweight	1	3
Ovulation disorder	1	1
Oxygen consumption decreased		1
Oxygen saturation		2
Oxygen saturation abnormal	1	8
Oxygen saturation decreased	10	54
Pain	648	3,714
Painful respiration	1	12
Pain in extremity	730	3,643
Pain in jaw	21	108
Pain of skin	16	53
Palatal disorder		2
Palatal swelling	2	11
Pallor	10	67
Palmar erythema		7
Palpitations	109	533
Pancreatic carcinoma metastatic	1	1
Pancreatic cyst		1
Pancreatic disorder		3
Pancreatic enzymes increased		1
Pancreatitis	2	9
Pancreatitis acute	2	5
Pancreatitis haemorrhagic	1	1
Pancreatitis relapsing		1
Pancytopenia	1	4
Panic attack	15	43

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
			1		
				1	1
		20	87	2	4
			2		
		1	3		
		1	1		
			1		
			2		
		1	8		
		4	25	6	29
1	1	586	3473	62	241
			8	1	4
	1	673	3465	57	178
		18	92	3	16
		16	50		3
			1		1
		1	8	1	3
		9	51	1	16
			6		1
1	1	90	417	19	116
				1	1
			1		
			2		1
			1		
				2	9
				2	5
				1	1
					1
				1	4
		13	36	2	7

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Panic disorder	2	7
Panic reaction	2	16
Panniculitis	1	1
Papule	4	8
Paraesthesia	170	957
Paraesthesia ear		1
Paraesthesia mucosal		1
Paraesthesia oral	30	294
Paralysis	16	45
Paranasal sinus discomfort	8	33
Paranasal sinus hypersecretion	1	4
Paranasal sinus hyposecretion		1
Paranoia	3	10
Paraplegia		1
Parkinson's disease		2
Parosmia	14	65
Paroxysmal sympathetic hyperactivity		1
Paternal exposure timing unspecified	1	1
Patient elopement	1	2
PCO2 decreased		1
Peau d'orange	1	1
Pelvic discomfort		1
Pelvic fracture	1	1
Pelvic inflammatory disease		1
Pelvic mass		2
Pelvic pain	4	17
Pemphigoid	1	1
Periarthritis	1	4
Pericardial effusion	5	13
Pericarditis	11	22
Periodontitis		1
Periorbital cellulitis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	7		
		2	15		1
				1	1
		3	7	1	1
		141	810	29	147
			1		
			1		
		20	229	10	65
			1	16	44
		7	32	1	1
		1	4		
			1		
		3	10		
					1
					2
		11	58	3	7
					1
		1	1		
		1	2		
					1
		1	1		
			1		
				1	1
					1
					2
		3	15	1	2
				1	1
		1	3		1
				5	13
				11	22
			1		
					1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Periorbital discomfort		1
Periorbital oedema		2
Periorbital pain		2
Periorbital swelling	8	38
Peripheral arterial occlusive disease		1
Peripheral artery thrombosis	2	3
Peripheral coldness	18	101
Peripheral ischaemia		2
Peripheral nerve injury		1
Peripheral sensory neuropathy	1	3
Peripheral swelling	142	596
Peripheral vascular disorder		3
Peripheral venous disease	1	4
Perivascular dermatitis		1
Peroneal nerve palsy		2
Personality change	1	3
Pertussis	1	2
Petechiae	4	28
Pharyngeal abscess	2	2
Pharyngeal disorder	2	8
Pharyngeal enanthema		2
Pharyngeal erythema		16
Pharyngeal haemorrhage		2
Pharyngeal hypoaesthesia	2	18
Pharyngeal inflammation	1	3
Pharyngeal mass		5
Pharyngeal oedema	1	9
Pharyngeal paraesthesia	3	29
Pharyngeal swelling	43	210
Pharyngeal ulceration		1
Pharyngitis	1	12
Pharyngitis streptococcal	4	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		1
			1		1
		5	31	3	7
					1
			1	2	2
		13	88	5	13
			1		1
					1
			1	1	2
		112	520	30	76
			3		
		1	4		
			1		
			2		
		1	1		2
				1	2
		2	17	2	11
				2	2
		2	7		1
			2		
			16		
					2
		1	13	1	5
			2	1	1
			4		1
			3	1	6
		2	21	1	8
		27	123	16	87
			1		
			9	1	3
		3	10	1	1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Phlebitis		4
Phlebitis superficial	1	3
Photophobia	12	65
Photopsia	4	15
Photosensitivity reaction	6	23
Phrenic nerve injury		1
Physical deconditioning		1
Physical examination abnormal		1
Pigmentation disorder		4
Piloerection	6	15
Pituitary tumour benign		1
Pityriasis		1
Pityriasis rosea	1	4
Plantar erythema		1
Plantar fasciitis		2
Platelet count abnormal		1
Platelet count decreased	11	45
Platelet count increased	3	10
Platelet disorder		2
Pleural effusion	2	12
Pleurisy	3	6
Pleuritic pain		5
Plicated tongue	1	2
Pneumocystis jirovecii pneumonia		1
Pneumonia	21	82
Pneumonia aspiration	1	4
Pneumonia bacterial	1	1
Pneumonia staphylococcal		1
Pneumonia viral	1	2
Pneumonitis	4	8
Pneumothorax		2
PO2 decreased		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			4		
		1	3		
		11	60	1	5
		3	11	1	4
		6	19		4
					1
			1		
					1
			3		1
		6	14		1
					1
			1		
		1	4		
			1		
			2		
			1		
1	1	4	19	7	26
		2	5	1	5
			1		1
			2	2	10
		1	3	2	3
			5		
		1	2		
					1
1	1			21	82
				1	4
				1	1
					1
				1	2
		3	4	1	4
					2
			1		1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Poisoning		2
Pollakiuria	7	25
Polychondritis		1
Polydipsia		2
Polymenorrhoea	8	11
Polymyalgia rheumatica		4
Polymyositis		1
Polyneuropathy		2
Polyserositis		1
Polyuria		7
Poor peripheral circulation	1	8
Poor quality product administered	35	92
Poor quality sleep	2	38
Porphyria acute		1
Portal vein thrombosis	2	5
Post-acute COVID-19 syndrome	1	1
Post concussion syndrome	1	1
Post herpetic neuralgia	2	4
Postictal state		1
Post inflammatory pigmentation change		1
Post lumbar puncture syndrome		1
Postmenopausal haemorrhage	13	20
Postoperative wound infection		1
Postpartum disorder		1
Post procedural complication		
Post-traumatic neck syndrome	1	4
Post-traumatic neuralgia		1
Post-traumatic stress disorder		2
Postural orthostatic tachycardia syndrome	4	12
Posture abnormal	1	2
Post viral fatigue syndrome		1
Potentiating drug interaction	5	26

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		5	23	2	2
					1
			2		
		7	10	1	1
					4
					1
					2
					1
			5		2
			5	1	3
		35	92		
		2	38		
					1
				2	5
				1	1
		1	1		
		1	3	1	1
			1		
			1		
				13	20
					1
			1		
	1				
		1	1		3
			1		
			2		
	1		3	4	9
		1	2		
			1		
		5	26		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pre-eclampsia	1	1
Pre-existing condition improved	2	5
Premature delivery		1
Premature labour		2
Premature rupture of membranes	1	2
Premenstrual syndrome	2	8
Pressure of speech		1
Presyncope	32	173
Primary headache associated with sexual activity		1
Prinzmetal angina		2
Procedural haemorrhage		1
Procedural pain		2
Procedural site reaction		1
Proctalgia	1	2
Product administered at inappropriate site	11	77
Product administered to patient of inappropriate age	4	12
Product administration error	4	17
Product colour issue		1
Product communication issue		1
Product complaint	1	4
Product confusion		2
Product container issue		1
Product dose omission in error		1
Product dose omission issue	24	121
Product expiration date issue	1	1
Product formulation issue		1
Productive cough	9	49
Product label issue	1	1
Product leakage	2	11
Product lot number issue		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		2	5		
					1
					2
				1	2
		2	8		
			1		
		20	126	12	47
					1
					2
			1		1
					1
		1	2		
		11	75		2
		4	12		
		4	16		1
			1		
			1		
		1	4		
			2		
			1		
			1		
		24	120		1
		1	1		
					1
		7	44	2	5
		1	1		
		2	11		
			1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Product odour abnormal		1
Product preparation error	13	43
Product preparation issue	11	42
Product prescribing error	2	9
Product quality issue		4
Product storage error	13	43
Product substitution error		1
Product supply issue	4	24
Product temperature excursion issue	16	35
Product use in unapproved indication		1
Product use issue	37	390
Protein total decreased		2
Protein total increased		1
Proteinuria		3
Protein urine	1	1
Protein urine present		1
Prothrombin time prolonged		2
Pruritus	273	1,289
Pruritus genital		1
Pseudomonas infection		1
Psoriasis	3	12
Psoriatic arthropathy		4
Psychiatric symptom		1
Psychomotor hyperactivity	1	5
Psychotic disorder	1	4
Pulmonary artery occlusion		1
Pulmonary congestion	3	20
Pulmonary embolism	23	69
Pulmonary fibrosis		3
Pulmonary hypertension		2
Pulmonary infarction	1	1
Pulmonary mass		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		13	41		2
		11	39		3
		2	9		
			4		
		13	43		
			1		
		4	24		
		16	35		
			1		
		36	384	1	6
			2		
					1
			2		1
				1	1
			1		
			1		1
		230	1116	43	173
					1
					1
1	1	3	12		
			1		4
		1	4		1
		1	2		2
					1
				3	20
				23	69
1	1				3
					2
				1	1
			2		2

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pulmonary oedema	7	20
Pulmonary pain	10	30
Pulmonary thrombosis	13	30
Pulmonary venous thrombosis		1
Pulse abnormal	3	17
Pulse absent		3
Pulseless electrical activity		1
Pulse pressure decreased		1
Pulse pressure increased	2	2
Pulse volume decreased		1
Pupil fixed		1
Pupillary disorder		2
Pupils unequal		1
Purpura	3	8
Pustule	1	7
Pyrexia	691	3,943
Quality of life decreased		3
Radial nerve injury	1	1
Radial nerve palsy		1
Radial pulse abnormal	1	1
Radiation injury	1	1
Radiculitis brachial	1	3
Rash	277	1,288
Rash erythematous	36	185
Rash macular	36	162
Rash maculo-papular	2	11
Rash morbilliform	3	11
Rash papular	15	68
Rash pruritic	52	194
Rash pustular		2
Rash vesicular	5	18
Raynaud's phenomenon	2	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	6	19
		9	24	1	6
				13	30
					1
		2	11	1	6
					3
					1
					1
		2	2		
			1		
					1
			2		
					1
		2	7	1	1
			3	1	4
		644	3690	47	253
			2		1
				1	1
			1		
				1	1
		1	1		
				1	3
		237	1100	40	188
		31	152	5	33
		34	143	2	19
		2	11		
		1	7	2	4
		14	63	1	5
		43	167	9	27
			2		
		5	16		2
		2	7		1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Reaction to excipient	2	12
Reaction to preservatives		2
Reactogenicity event		1
Reading disorder	2	2
Rectal discharge		1
Rectal haemorrhage	4	14
Rectal tenesmus		1
Red blood cell abnormality		1
Red blood cell count abnormal		2
Red blood cell count decreased	5	12
Red blood cell count increased	1	3
Red blood cell sedimentation rate abnormal		1
Red blood cell sedimentation rate increased	5	10
Red cell distribution width decreased		1
Red cell distribution width increased		1
Red ear syndrome	1	3
Reduced facial expression	1	4
Reflux gastritis		1
Regurgitation	1	3
Renal cyst		1
Renal disorder	2	10
Renal failure	3	6
Renal function test abnormal	1	1
Renal haemorrhage		1
Renal impairment	4	11
Renal infarct		1
Renal pain	11	28
Renal tubular disorder		1
Renal tubular injury		1
Respiration abnormal	2	9
Respiratory arrest	1	12
Respiratory disorder	5	41

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	8	1	4
			2		
			1		
		2	2		
			1		
				4	14
			1		
					1
			2		
		2	5	3	7
		1	3		
			1		
		4	6	1	4
			1		
					1
		1	3		
			1	1	3
			1		
		1	3		
			1		
			6	2	4
				3	6
		1	1		
					1
				4	11
					1
		8	21	3	7
					1
					1
		2	9		
				1	12
		3	23	2	18

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Respiratory distress		45
Respiratory failure		6
Respiratory rate decreased		7
Respiratory rate increased	3	25
Respiratory symptom		4
Respiratory tract congestion	4	35
Respiratory tract infection	1	4
Respiratory tract irritation		2
Respiratory tract oedema	1	8
Restless legs syndrome		12
Restlessness	3	41
Restrictive pulmonary disease		1
Retching	9	51
Retinal aneurysm	1	1
Retinal detachment	1	2
Retinal disorder		1
Retinal haemorrhage		1
Retinal tear		1
Retinal vein occlusion	2	5
Retinitis		1
Retinogram abnormal	1	1
Rhabdomyolysis	1	2
Rheumatic disorder	1	1
Rheumatoid arthritis	6	40
Rhinalgia	4	12
Rhinitis		3
Rhinitis allergic		1
Rhinorrhoea	47	343
Rhinovirus infection		2
Rib fracture		3
Right ventricular dilatation		1
Right ventricular dysfunction		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					45
					6
			5		2
		3	14		11
			2		2
		3	31	1	4
				1	4
			1		1
				1	8
			11		1
		2	35	1	6
					1
	1	5	41	4	10
				1	1
		1	1		1
			1		
					1
					1
				2	5
					1
				1	1
				1	2
		1	1		
5	6			6	40
		4	11		1
			3		
					1
		47	325		18
			2		
					3
			1		
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Road traffic accident	5	10
Root canal infection		2
Rosacea	1	7
Rotator cuff syndrome	4	6
Rubber sensitivity		1
Rubella		1
Ruptured cerebral aneurysm	1	3
Sacroiliitis		1
Saliva discolouration		1
Salivary gland disorder		1
Salivary gland enlargement	1	3
Salivary gland mass	1	1
Salivary gland neoplasm	1	1
Salivary gland pain		2
Salivary hypersecretion	2	9
Sarcoidosis		2
SARS-CoV-1 test positive		2
SARS-CoV-2 ant body test negative		31
SARS-CoV-2 ant body test positive	1	9
SARS-CoV-2 test		2
SARS-CoV-2 test false positive		1
SARS-CoV-2 test negative		2
SARS-CoV-2 test positive	13	170
Scab	6	15
Scar	3	9
Sciatica	7	18
Sciatic nerve neuropathy		1
Scleral discolouration		1
Scleral haemorrhage		1
Scleritis	1	4
Scleroderma		2
Scoliosis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	5	2	5
			2		
			6	1	1
		3	4	1	2
			1		
			1		
				1	3
			1		
			1		1
			2	1	1
				1	1
				1	1
			2		
		2	7		2
					2
			2		
			28		3
		1	9		
			2		
			1		
			2		
		6	41	7	129
		5	13	1	2
		3	6		3
		3	12	4	6
			1		
			1		
					1
				1	4
					2
		1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Scratch	5	20
Screaming		5
Seasonal allergy	4	18
Secretion discharge	4	16
Sedation		8
Seizure	40	119
Seizure like phenomena	2	6
Self-injurious ideation		1
Sensation of blood flow		3
Sensation of foreign body	3	45
Sensitisation	1	3
Sensitive skin	6	28
Sensitivity to weather change	1	6
Sensorimotor disorder		1
Sensory disturbance	4	29
Sensory level abnormal		1
Sensory loss	5	21
Sepsis	1	11
Seronegative arthritis		2
Serum ferritin decreased		1
Serum sickness		2
Shock		14
Shock hypoglycaemic	1	1
Shock symptom		4
Shoulder injury related to vaccine administration		1
Sialoadenitis		2
Sickle cell anaemia with crisis		2
Sinus arrhythmia	1	1
Sinus bradycardia		3
Sinus congestion	5	33
Sinus disorder	8	50
Sinus headache	2	26

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	17	1	3
			3		2
		4	18		
		2	13	2	3
			7		1
				40	119
				2	6
			1		
			1		2
		3	35		10
		1	3		
		5	27	1	1
		1	6		
					1
		3	26	1	3
			1		
		5	15		6
				1	11
					2
					1
					2
					14
				1	1
					4
			1		
					2
					2
		1	1		
			1		2
		4	32	1	1
		7	46	1	4
		2	26		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Sinusitis	15	86
Sinusitis bacterial		2
Sinus pain	6	20
Sinus rhythm		1
Sinus tachycardia	1	10
Sitting disability	1	8
Sjogren's syndrome	2	6
Skeletal injury		1
Skin abrasion	2	3
Skin atrophy	1	1
Skin bacterial infection		1
Skin burning sensation	16	57
Skin cancer	2	2
Skin depigmentation		3
Skin discharge	1	1
Skin discolouration	19	83
Skin discomfort		2
Skin disorder	17	61
Skin erosion	1	2
Skin exfoliation	8	30
Skin fissures		2
Skin haemorrhage	1	6
Skin hyperpigmentation	1	3
Skin hypertrophy	1	2
Skin indentation		3
Skin injury	2	5
Skin irritation	6	24
Skin laceration	4	16
Skin laxity		1
Skin lesion	5	26
Skin mass	7	11
Skin odour abnormal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		14	80	1	6
					2
		6	20		
			1		
		1	5		5
		1	7		1
				2	6
			1		
		2	3		
		1	1		
					1
		12	52	4	5
				2	2
			3		
		1	1		
		18	68	1	15
			2		
		17	54		7
		1	2		
		5	26	3	4
			1		1
			4	1	2
		1	3		
		1	2		
			3		
		1	4	1	1
		5	23	1	1
		3	9	1	7
			1		
		5	25		1
		6	10	1	1
			1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin reaction	7	15
Skin sensitisation	1	2
Skin swelling	4	13
Skin temperature		1
Skin texture abnormal		1
Skin tightness	1	12
Skin turgor decreased		1
Skin ulcer		2
Skin warm	4	14
Skin weeping	3	3
Skin wrinkling	1	3
Sleep apnoea syndrome		2
Sleep attacks		1
Sleep deficit		4
Sleep disorder	20	106
Sleep disorder due to a general medical condition	2	8
Sleep disorder due to general medical condition, insomnia type		3
Sleep paralysis		2
Sleep talking		1
Sleep terror		1
Slow speech	1	3
Sluggishness	6	28
Small fibre neuropathy	1	2
Small intestinal obstruction		2
Sneezing	30	142
Snoring		2
Soft tissue disorder		2
Soft tissue swelling	1	2
Solar lentigo		1
Soliloquy	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	12	1	3
		1	2		
		4	12		1
			1		
			1		
		1	10		2
					1
			2		
		4	14		
		2	2	1	1
		1	3		
			1		1
			1		
			4		
		20	103		3
		2	8		
			3		
			2		
			1		
			1		
		1	3		
		6	27		1
				1	2
					2
		27	135	3	7
			1		1
			2		
		1	2		
					1
		1	1		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Somatic symptom disorder		2
Somnambulism		1
Somnolence	76	331
Speech disorder	19	122
Speech disorder developmental	2	2
Speech sound disorder		1
Spinal compression fracture		1
Spinal cord disorder	1	3
Spinal disorder		3
Spinal fusion surgery		1
Spinal osteoarthritis		1
Spinal pain	5	34
Spinal stenosis		2
Spleen disorder	1	1
Splenic vein thrombosis	1	2
Splenomegaly		2
Splinter		1
Splinter haemorrhages		1
Spondylitis	2	3
Sputum discoloured	1	8
Sputum purulent	1	1
Staphylococcal infection	1	4
Staring	1	3
Starvation	1	1
Status asthmaticus		1
Status migrainosus	1	1
Stenosis		1
Stevens-Johnson syndrome	1	3
Sticky skin		1
Stiff tongue		1
Still's disease		
Stomatitis	13	44

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
			1		
		73	302	3	29
		10	75	9	47
		2	2		
			1		
					1
				1	3
			2		1
					1
			1		
		4	29	1	5
			2		
		1	1		
				1	2
			1		1
			1		
		2	2		1
			4	1	4
				1	1
				1	4
				1	3
				1	1
					1
				1	1
			1		
					1
1	1				
		10	37	3	7

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Strabismus	1	5
Strawberry tongue		1
Streptobacillus infection	1	1
Streptococcal infection	1	6
Streptococcal urinary tract infection	1	1
Streptococcus test positive		2
Stress	10	45
Stress urinary incontinence	1	2
Stridor		10
Subarachnoid haemorrhage	1	5
Subcutaneous abscess		3
Submaxillary gland enlargement	1	1
Sudden death		1
Sudden hearing loss	3	7
Sudden visual loss		1
Suffocation feeling		1
Suicidal behaviour	1	1
Suicidal ideation	5	14
Suicide attempt		1
Sunburn	3	9
Superficial vein prominence		2
Suppressed lactation		1
Supraventricular extrasystoles	1	5
Supraventricular tachycardia	3	10
Surgery	1	1
Suspected counterfeit product		1
Suspected COVID-19	25	99
Suture related complication		1
Swelling	91	446
Swelling face	84	404
Swelling of eyelid	14	51
Swollen tongue	30	208

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		3
			1		
				1	1
		1	5		1
				1	1
			1		1
		9	43	1	2
		1	2		
			5		5
				1	5
			1		2
				1	1
					1
				3	7
					1
			1		
				1	1
		1	1	4	13
					1
		2	8	1	1
			1		1
			1		
			3	1	2
		2	4	1	6
		1	1		
			1		
		13	44	12	55
					1
		77	383	14	63
		53	296	31	108
		10	43	4	8
		15	119	15	89

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Symptom recurrence		1
Syncope	72	304
Syndactyly	1	1
Synovial fluid analysis abnormal	1	1
Syringe issue		2
Systemic immune activation		1
Systemic inflammatory response syndrome	1	2
Systemic lupus erythematosus	2	12
Systemic scleroderma		1
Tachycardia	25	294
Tachyphrenia		4
Tachypnoea		34
Tardive dyskinesia	1	2
Taste disorder	15	93
Tearfulness		2
Teeth brittle		1
Teething	1	1
Temperature intolerance		7
Temperature regulation disorder	1	3
Temporomandibular joint syndrome		3
Tenderness	19	88
Tendon discomfort		1
Tendonitis	6	14
Tendon pain	1	6
Tenosynovitis		1
Tension	1	6
Tension headache	5	18
Terminal insomnia		3
Tetany		2
Thalamic infarction		1
Thanatophobia		1
Therapeutic product effect decreased	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
1	1	2	2	70	302
				1	1
				1	1
			2		
					1
				1	2
1	1			2	12
					1
		14	184	11	110
			4		
			21		13
				1	2
		14	83	1	10
			2		
			1		
		1	1		
			6		1
		1	3		
			1		2
		19	85		3
			1		
		3	11	3	3
			5	1	1
			1		
		1	6		
		5	17		1
			3		
					2
					1
			1		
		2	2		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Therapeutic product effect incomplete		1
Therapeutic product effect prolonged		1
Therapeutic response increased		1
Therapeutic response unexpected	12	58
Thermal burn		3
Thermal burns of eye	1	1
Thinking abnormal	7	38
Thirst	15	70
Thirst decreased		1
Thoracic outlet syndrome		1
Thoracic vertebral fracture		1
Throat clearing	1	10
Throat irritation	42	233
Throat lesion	1	1
Throat tightness	48	299
Thrombocytopenia	6	24
Thrombocytopenic purpura	1	1
Thrombophlebitis		2
Thrombophlebitis superficial	2	9
Thrombosis	71	175
Thrombotic microangiopathy		1
Thrombotic stroke	1	3
Thunderclap headache		1
Thyroid cancer	1	2
Thyroid disorder	4	13
Thyroid function test abnormal		4
Thyroid hormones increased		2
Thyroiditis	1	2
Thyroiditis acute		1
Thyroiditis subacute		3
Thyroid mass	1	4
Thyroid pain	2	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
			1		
		12	58		
			2		1
				1	1
		6	34	1	4
		13	65	2	5
			1		
			1		
					1
		1	6		4
		36	180	6	53
		1	1		
		29	168	19	131
				6	24
				1	1
			2		
		1	7	1	2
1	2			71	175
					1
				1	3
					1
				1	2
		2	10	2	3
			4		
			2		
		1	2		
					1
			3		
		1	2		2
		2	6		

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Thyrotoxic crisis		3
Thyroxine decreased		1
Tic	2	5
Tinea infection	1	1
Tinnitus	102	339
T-lymphocyte count increased		1
Tongue biting		2
Tongue blistering	4	12
Tongue coated	1	4
Tongue cyst		1
Tongue discolouration	1	7
Tongue discomfort	10	44
Tongue disorder	7	33
Tongue dry	1	7
Tongue eruption		2
Tongue erythema	1	7
Tongue fungal infection		1
Tongue haematoma		1
Tongue haemorrhage		1
Tongue injury		2
Tongue movement disturbance		3
Tongue oedema	1	3
Tongue pruritus	5	22
Tongue rough	1	1
Tongue spasm		1
Tongue ulceration	1	7
Tonsillar disorder	1	4
Tonsillar erythema		1
Tonsillar hypertrophy		6
Tonsillar inflammation	1	2
Tonsillar ulcer		1
Tonsillitis	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
			1		
		1	4	1	1
		1	1		
		79	260	23	79
			1		
			1		1
		4	11		1
		1	3		1
			1		
		1	7		
		8	38	2	6
		7	26		7
		1	7		
			1		1
			6	1	1
			1		
			1		
			2		
			2		1
			1	1	2
		3	16	2	6
		1	1		
			1		
			5	1	2
			2	1	2
			1		
			6		
		1	2		
			1		
		1	2		
			1		
		1	2	1	1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tonsillolith	1	2
Tooth abscess	4	9
Toothache	8	59
Tooth discolouration		1
Tooth disorder	1	13
Tooth extraction		2
Tooth fracture	2	6
Tooth infection	1	11
Tooth injury	1	7
Tooth loss		1
Torticollis		1
Tourette's disorder		1
Toxicity to various agents	1	1
Tracheal deviation		1
Tracheal stenosis	1	1
Tracheitis		1
Tracheomalacia		1
Transaminases increased		2
Transient global amnesia		1
Transient ischaemic attack	3	23
Transverse sinus stenosis		1
Transverse sinus thrombosis	1	1
Tremor	88	466
Trichorrhexis	1	1
Tricuspid valve incompetence		1
Trigeminal nerve disorder		3
Trigeminal neuralgia	2	12
Trigeminal neuritis		1
Trigger finger	2	9
Tri-iodothyronine decreased		1
Trismus	1	12
Troponin abnormal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
		3	7	1	2
		8	52		7
			1		
		1	12		1
			2		
		2	5		1
		1	10		1
		1	4		3
					1
			1		
					1
				1	1
					1
				1	1
			1		
					1
			1		1
			1		
				3	23
					1
				1	1
	1	68	370	20	96
		1	1		
					1
			1		2
		1	7	1	5
			1		
		1	8	1	1
			1		
		1	9		3
					1

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Troponin increased	3	21
Tryptase decreased		1
Tryptase increased		1
Tuberculosis		2
Tumour marker abnormal		1
Tumour marker decreased		1
Tumour marker increased	1	1
Tumour pain	2	2
Tunnel vision	1	13
Type 1 diabetes mellitus	1	3
Type 2 diabetes mellitus		1
Type I hypersensitivity	1	1
Type III immune complex mediated reaction		1
Type IV hypersensitivity reaction	1	2
Type V hyperlipidaemia		1
Ulcer	4	7
Ulcerative keratitis	1	1
Ulcer haemorrhage		1
Underdose	22	102
Underweight	1	1
Undifferentiated connective tissue disease		1
Unevaluable event		2
Unresponsive to stimuli	1	14
Upper-airway cough syndrome	2	18
Upper airway obstruction		2
Upper limb fracture	1	6
Upper respiratory tract congestion	7	40
Upper respiratory tract infection	1	6
Ureteric stenosis		1
Urethral disorder		1
Urge incontinence		2
Urinary bladder haemorrhage		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			4	3	17
			1		
			1		
					2
					1
			1		
				1	1
				2	2
				1	13
				1	3
					1
				1	1
					1
		1	2		
					1
		3	6	1	1
				1	1
					1
		21	100	1	2
		1	1		
					1
			2		
				1	14
		2	16		2
					2
				1	6
		7	38		2
		1	6		
					1
			1		
			2		
					1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Urinary incontinence	5	28
Urinary retention	4	7
Urinary tract disorder		1
Urinary tract infection	22	95
Urinary tract infection bacterial		3
Urine abnormality	1	3
Urine analysis abnormal	1	8
Urine leukocyte esterase positive		2
Urine odour abnormal	1	2
Urine output decreased	2	6
Urine output increased		3
Urobilinogen urine increased		1
Urosepsis		1
Urticaria	244	825
Urticaria chronic	2	3
Urticaria thermal		1
Use of accessory respiratory muscles		6
Uterine contractions during pregnancy		2
Uterine disorder	1	1
Uterine haemorrhage	5	7
Uterine inflammation		1
Uterine leiomyoma	1	1
Uterine pain	2	3
Uterine spasm		1
Uveitis		2
Vaccination complication	1	4
Vaccination error		3
Vaccination failure	37	113
Vaccination site bruising	16	81
Vaccination site cellulitis	2	17
Vaccination site coldness		4
Vaccination site cyst	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	21	2	7
				4	7
			1		
		16	72	6	23
					3
		1	3		
		1	8		
			2		
		1	1		1
		2	6		
			3		
			1		
					1
		198	653	46	172
		1	2	1	1
			1		
			3		3
			1		1
		1	1		
				5	7
					1
				1	1
		2	2		1
			1		
1	1				2
	1	1	4		
			3		
				37	113
		16	79		2
			4	2	13
			4		
		1	1		

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination site dermatitis	1	2
Vaccination site discharge	1	3
Vaccination site discolouration	10	28
Vaccination site discomfort	10	51
Vaccination site dryness	1	2
Vaccination site erythema	77	526
Vaccination site exfoliation	1	2
Vaccination site extravasation	2	10
Vaccination site haematoma		2
Vaccination site haemorrhage	14	59
Vaccination site hyperaesthesia	1	2
Vaccination site hypersensitivity		3
Vaccination site hypoaesthesia	4	29
Vaccination site induration	6	52
Vaccination site infection		7
Vaccination site inflammation	2	22
Vaccination site injury		4
Vaccination site irritation	1	8
Vaccination site joint erythema		1
Vaccination site joint movement impairment	1	14
Vaccination site joint pain	1	9
Vaccination site joint swelling		1
Vaccination site lymphadenopathy	1	16
Vaccination site macule		5
Vaccination site mass	21	126
Vaccination site movement impairment	2	46
Vaccination site nerve damage	1	1
Vaccination site nodule	3	15
Vaccination site oedema	1	5
Vaccination site pain	348	2,312
Vaccination site pallor		1
Vaccination site papule	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		1
		1	3		
		10	27		1
		9	48	1	3
		1	2		
		73	503	4	23
		1	2		
		2	10		
			2		
		10	52	4	7
		1	2		
			3		
		3	25	1	4
		6	51		1
			7		
		2	20		2
			4		
		1	8		
			1		
		1	11		3
		1	8		1
			1		
		1	15		1
			5		
		20	119	1	7
		1	44	1	2
		1	1		
		2	13	1	2
		1	4		1
	2	336	2241	12	71
			1		
		1	4		

* I=Interval, C=Cumulative

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site paraesthesia	4	28
Vaccination site pruritus	41	270
Vaccination site pustule	1	3
Vaccination site rash	30	135
Vaccination site reaction	5	36
Vaccination site scab	1	4
Vaccination site scar	1	3
Vaccination site streaking		1
Vaccination site swelling	79	505
Vaccination site thrombosis		1
Vaccination site urticaria	5	52
Vaccination site vesicles	2	14
Vaccination site warmth	28	229
Vaginal discharge		2
Vaginal haemorrhage	19	50
Vaginal infection		2
Vaginal lesion	1	2
Vagus nerve disorder		1
Varicella		4
Varicella zoster virus infection	1	2
Varicose vein		4
Vascular injury	3	3
Vascular occlusion		1
Vascular pain		2
Vascular rupture	1	2
Vasculitic rash	1	2
Vasculitis	2	4
Vasodilatation	2	3
Vein discolouration	1	4
Vein disorder	5	13
Vein rupture		1
Vein wall hypertrophy	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	24	1	4
		39	255	2	15
		1	3		
		28	125	2	10
		4	33	1	3
		1	4		
		1	3		
			1		
		75	482	4	23
					1
		5	47		5
		2	14		
		24	214	4	15
			2		
		13	34	6	16
			1		1
			1	1	1
					1
			4		
		1	2		
			4		
		1	1	2	2
					1
			2		
		1	2		
		1	2		
		1	3	1	1
		2	3		
		1	4		
		5	12		1
					1
				1	1

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Gender

FEMALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Venous thrombosis limb	1	1
Ventricular extrasystoles	3	20
Ventricular tachycardia		2
Vertebral artery dissection		1
Vertigo	66	308
Vertigo positional	1	9
Vessel puncture site bruise		1
Vestibular disorder	3	6
Vestibular migraine		1
Vestibular neuronitis		3
Vibratory sense increased		1
VIIIth nerve lesion		1
Viral infection	5	11
Viral myelitis	1	1
Viral myocarditis		1
Viral rash		2
Viral sepsis	1	1
Viral upper respiratory tract infection		3
Vision blurred	56	224
Visual acuity reduced	1	6
Visual field defect	1	9
Visual impairment	27	113
Vital functions abnormal	2	2
Vitamin B12 decreased		2
Vitamin B12 increased		1
Vitamin D decreased		5
Vitamin D deficiency		2
VIth nerve paralysis	1	2
Vitreous degeneration		2
Vitreous detachment	1	3
Vitreous floaters	5	13
Vocal cord disorder	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		2	11	1	9
					2
					1
		59	259	7	49
		1	6		3
			1		
		2	4	1	2
			1		
			1		2
			1		
					1
		4	8	1	3
				1	1
					1
			2		
				1	1
			2		1
		52	182	4	42
			4	1	2
		1	8		1
		22	90	5	23
		1	1	1	1
					2
			1		
			4		1
			1		1
				1	2
					2
				1	3
		4	10	1	3
				1	3

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vocal cord dysfunction		1
Vocal cord inflammation	1	1
Vocal cord paralysis		1
Vocal cord paresis		1
Volvulus		1
Vomiting	201	1,031
Vomiting projectile		10
Vulval disorder		1
Vulvovaginal burning sensation	2	3
Vulvovaginal discomfort	1	1
Vulvovaginal dryness	1	1
Vulvovaginal erythema	1	1
Vulvovaginal mycotic infection	1	4
Vulvovaginal pain	4	6
Vulvovaginal pruritus	1	2
Vulvovaginal rash	1	2
Vulvovaginal swelling	2	4
Wa king aid user	2	6
Wa king disability	2	4
Water pollution		1
Weight abnormal		1
Weight bearing difficulty	2	3
Weight decreased	27	99
Weight fluctuation	1	6
Weight increased	5	26
Wheezing	19	118
White blood cell count abnormal	1	2
White blood cell count decreased	8	24
White blood cell count increased	15	43
White blood cells urine	1	1
White blood cells urine positive		2
White matter lesion		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
					1
			1		
					1
		169	865	32	166
			10		
			1		
		1	1	1	2
				1	1
		1	1		
		1	1		
		1	4		
		3	4	1	2
		1	1		1
		1	1		1
		1	2	1	2
		2	5		1
			2	2	2
			1		
			1		
		2	2		1
		20	75	7	24
		1	6		
		5	25		1
		14	77	5	41
			1	1	1
		5	17	3	7
		9	26	6	17
		1	1		
			2		
					2

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Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Williams syndrome	1	1					1	1
Winged scapula		1				1		
Withdrawal bleed		1				1		
Wound		7				5		2
Wound closure		1				1		
Wound complication		1				1		
Wound haemorrhage	1	5			1	3		2
Wound secretion		1						1
Wrist fracture		1						1
Wrong product administered	13	39			12	38	1	1
Wrong schedule		11				11		
Wrong technique in device usage process		2				2		
Wrong technique in product usage process	14	56			13	53	1	3
Xanthopsia		1				1		
Yawning	3	3			3	3		
Yellow skin	1	2			1	2		
		4				4		
	20,840	106,974	39	64	16611	87869	4229	19105

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	23	92			23	85		7
Abdominal distension	7	25			5	19	2	6
Abdominal mass	1	1					1	1
Abdominal pain	18	67			13	46	5	21
Abdominal pain lower		4				4		
Abdominal pain upper	28	115			25	96	3	19
Abdominal rigidity		2				2		
Abdominal tenderness		1				1		
Abnormal behaviour	2	5			2	3		2
Abnormal clotting factor		1						1
Abnormal dreams	2	14			2	11		3
Abnormal faeces	1	5			1	4		1
Abnormal sensation in eye		1				1		
Abnormal sleep-related event	1	1			1	1		
Abscess		2				1		1
Abulia	1	1			1	1		
Accident		4				1		3
Accidental exposure to product	1	9			1	9		
Accidental exposure to product by child	1	1			1	1		
Accidental overdose	5	10			5	9		1
Accidental underdose		2				2		
Acne	3	8			3	8		
Acoustic neuritis		1						1
Activated partial thromboplastin time prolonged		1				1		
Acute coronary syndrome		1						1
Acute febrile neutrophilic dermatosis		1						1
Acute kidney injury	2	6				1	2	5
Acute myocardial infarction	2	6					2	6
Acute respiratory distress syndrome		3						3
Acute respiratory failure	1	1	1	1			1	1
Administration site bruise		1				1		
Adrenocortical insufficiency acute		1						1

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Adverse event	2	5
Ageusia	14	69
Aggression		2
Agitation	2	7
Agnosia	1	1
Agonal respiration	1	1
Alanine aminotransferase increased	2	4
Abumin globulin ratio decreased		1
Alcohol interaction	1	1
Allergic reaction to excipient		1
Allergy to animal	1	1
Allergy to arthropod sting	1	2
Allergy to vaccine	5	19
Alopecia	1	5
Alopecia areata		1
Alopecia universalis		2
Amaurosis fugax		1
Amnesia	4	13
Amphetamines positive	1	1
Amylase increased		1
Anaemia	1	7
Anal abscess	2	2
Anal haemorrhage		1
Anal incontinence	1	2
Anaphylactic reaction	7	31
Anaphylactic shock		7
Aneurysm	1	2
Aneurysm ruptured		1
Anger	5	8
Angina pectoris	5	9
Angioedema	2	9
Angiokeratoma		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	5		
		14	65		4
			1		1
		1	6	1	1
		1	1		
				1	1
		1	2	1	2
			1		
				1	1
			1		
		1	1		
			1	1	1
		4	14	1	5
		1	5		
			1		
			2		
					1
		1	7	3	6
		1	1		
			1		
			1	1	6
				2	2
					1
		1	2		
				7	31
					7
				1	2
					1
		5	7		1
				5	9
		1	1	1	8
			1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Angiolymphoid hyperplasia with eosinophilia		1
Anion gap increased		1
Ankle fracture		1
Ankylosing spondylitis	1	2
Anorectal discomfort		1
Anosmia	10	59
Anterior chamber cell		1
Antibody test abnormal	1	4
Antibody test negative	1	3
Anti-neutrophil cytoplasmic antibody positive vasculitis	1	1
Anxiety	23	82
Anxiety disorder		1
Aortic disorder		1
Aortic valve disease		1
Aortitis		1
Apathy		3
Aphasia	4	17
Aphonia	2	9
Aphthous ulcer	2	6
Apnoea		1
Appendectomy		1
Appendicitis	9	19
Appendicitis perforated		1
Appendix disorder		1
Appetite disorder		4
Application site haemorrhage		1
Areflexia	1	3
Arrhythmia	4	23
Arteriosclerosis		1
Arteriospasm coronary		1
Arthralgia	142	642

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
					1
				1	2
			1		
		10	53		6
					1
		1	4		
			2	1	1
				1	1
		20	72	3	10
			1		
					1
					1
					1
			2		1
		2	8	2	9
		2	9		
		1	5	1	1
					1
			1		
				9	19
					1
			1		
			4		
					1
			1	1	2
				4	23
					1
					1
		124	587	18	55

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arthritis	8	29
Arthritis infective	1	1
Arthritis reactive		1
Arthropathy	4	15
Arthropod bite		3
Aspartate aminotransferase increased	1	3
Aspiration		1
Asthenia	103	444
Asthenopia	1	2
Asthma	4	22
Asymptomatic COVID-19	4	18
Ataxia	1	3
Atelectasis	2	5
Atopy	1	1
Atrial fibrillation	16	61
Atrial flutter		4
Atrioventricular block		1
Auricular swelling		1
Autoimmune disorder	1	6
Autoimmune haemolytic anaemia		2
Autoimmune thyroiditis		1
Autoscopy		1
Axillary mass	4	10
Axillary pain	6	39
Back disorder	7	14
Back injury	4	5
Back pain	51	226
Bacteraemia	1	2
Bacterial disease carrier		1
Bacterial infection		3
Balance disorder	20	71
Basal ganglia haemorrhage		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	25	2	4
				1	1
					1
		4	15		
			3		
			2	1	1
					1
	1	88	379	15	65
		1	2		
		4	16		6
		1	7	3	11
				1	3
		1	2	1	3
		1	1		
				16	61
					4
					1
					1
				1	6
					2
					1
			1		
		4	10		
		5	38	1	1
		5	12	2	2
		3	3	1	2
		48	199	3	27
				1	2
			1		
			2		1
		14	54	6	17
					3

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Basilar artery thrombosis	1	1
Bed rest		2
Bedridden	4	12
Behaviour disorder		2
Belligerence		1
Bell's palsy	34	128
Biliary colic		1
Biliary tract disorder		1
Bilirubin urine present		1
Bite		1
Bladder discomfort		1
Bladder pain		1
Blast cell crisis		1
Blepharitis		1
Blepharochalasis		1
Blepharospasm		2
Blindness	4	17
Blindness transient	3	9
Blindness unilateral	1	9
Blister	6	31
Blood albumin decreased		2
Blood albumin increased		1
Blood alkaline phosphatase increased		1
Blood bilirubin abnormal		1
Blood bilirubin increased		5
Blood blister	2	4
Blood calcium decreased		1
Blood calcium increased		1
Blood chloride decreased		2
Blood cholesterol decreased		1
Blood cholesterol increased	2	5
Blood count abnormal		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			2		
		3	11	1	1
					2
					1
			2	34	126
			1		
					1
			1		
			1		
					1
			1		
			1		
			2		
				4	17
				3	9
				1	9
		3	23	3	8
			2		
			1		
			1		
					1
			4		1
		2	4		
			1		
					1
			2		
			1		
		2	5		
			1		1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood creatine increased		2
Blood creatine phosphokinase increased		3
Blood creatinine increased		1
Blood disorder		4
Blood electrolytes decreased		1
Blood fibrinogen decreased		1
Blood glucose abnormal	1	5
Blood glucose decreased	5	17
Blood glucose fluctuation		1
Blood glucose increased	8	49
Blood immunoglobulin E increased		1
Blood immunoglobulin G abnormal		1
Blood immunoglobulin G decreased		1
Blood immunoglobulin G increased		1
Blood immunoglobulin M abnormal		1
Blood immunoglobulin M increased		1
Blood insulin increased		1
Blood iron decreased		3
Blood ketone body increased		1
Blood lactic acid increased		1
Blood magnesium decreased	1	1
Blood osmolarity decreased		1
Blood phosphorus decreased		1
Blood potassium decreased	1	3
Blood potassium increased		3
Blood pressure abnormal	3	10
Blood pressure decreased	6	25
Blood pressure diastolic increased		2
Blood pressure fluctuation	4	14
Blood pressure increased	12	71
Blood pressure orthostatic increased		1
Blood pressure systolic increased	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
			1		2
			1		
			3		1
					1
			1		
		1	4		1
		4	11	1	6
			1		
		2	30	6	19
					1
			1		
			1		
			1		
			1		
			1		
			1		
			1		
			1		2
					1
					1
				1	1
			1		
			1		2
					3
		2	8	1	2
		3	16	3	9
			2		
		3	11	1	3
		8	48	4	23
			1		
				1	2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood sodium decreased		3
Blood test abnormal		3
Blood thyroid stimulating hormone decreased	2	2
Blood thyroid stimulating hormone increased	1	1
Blood triglycerides increased		2
Blood urea decreased		1
Blood urea increased		1
Blood urine		1
Blood urine present	4	16
Blood zinc decreased	1	1
Blue toe syndrome		2
B-lymphocyte abnormalities	1	1
Body height decreased		9
Body temperature		1
Body temperature abnormal	2	6
Body temperature decreased	1	9
Body temperature fluctuation	2	4
Body temperature increased	5	52
Bone disorder		1
Bone pain	6	33
Bone swelling		1
Bowel movement irregularity	1	7
Brachial plexopathy		1
Bradycardia		2
Bradyphrenia	1	4
Brain death		1
Brain natriuretic peptide increased		1
Brain oedema	2	3
Brain stem infarction	1	1
Brain stem syndrome		1
Breakthrough pain	1	1
Breast pain	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		2
			2		1
		1	1	1	1
				1	1
			1		1
			1		
					1
			1		
		3	11	1	5
		1	1		
					2
		1	1		
			8		1
			1		
		2	6		
			8	1	1
		2	4		
		4	48	1	4
			1		
		6	33		
			1		
		1	7		
					1
					2
		1	4		
					1
			1		
				2	3
				1	1
					1
		1	1		
		2	3		

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Breast swelling	1	1
Breast tenderness	1	1
Breath odour	1	3
Bronchitis	2	13
Bronchospasm		1
Burning sensation	27	63
Burn oesophageal		1
Burns third degree	1	1
Bursitis	1	4
Butterfly rash		1
Campylobacter infection	1	1
Candida infection	2	3
Capillary disorder		1
Carbon dioxide increased		1
Cardiac amyloidosis	1	1
Cardiac arrest	5	25
Cardiac disorder	2	23
Cardiac failure	1	4
Cardiac failure chronic		1
Cardiac failure congestive	1	4
Cardiac fibrillation		1
Cardiac flutter	3	6
Cardiac tamponade	3	3
Cardiac valve disease		3
Cardiac ventricular thrombosis	1	1
Cardiomyopathy		4
Cardio-respiratory arrest		4
Cardiospasm		1
Cardiovascular disorder	1	3
Carotid artery occlusion		1
Carpal tunnel syndrome	1	2
Cataract	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1		
		1	3		
		1	9	1	4
			1		
		22	51	5	12
			1		
				1	1
		1	2		2
			1		
				1	1
		2	3		
			1		
			1		
				1	1
				5	25
		1	9	1	14
				1	4
					1
				1	4
					1
				3	6
				3	3
			2		1
				1	1
					4
					4
			1		
			2	1	1
					1
			1	1	1
				1	2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cataract nuclear		1
CD4 lymphocytes decreased	1	1
Cell marker decreased		1
Cellulitis	5	13
Cellulitis gangrenous		1
Central nervous system lesion	1	1
Cerebellar haemorrhage	1	1
Cerebellar stroke		1
Cerebral arteriosclerosis	1	1
Cerebral artery occlusion	1	3
Cerebral disorder	1	1
Cerebral haematoma	1	1
Cerebral haemorrhage	3	11
Cerebral infarction		1
Cerebral thrombosis	4	8
Cerebral venous sinus thrombosis	1	2
Cerebrovascular accident	33	101
Cervical spinal stenosis	1	1
Cheilitis		1
Chest discomfort	24	88
Chest injury	1	2
Chest pain	65	170
Chillblains	1	2
Chills	206	1,337
Choking		5
Choking sensation		1
Cholecystitis		1
Cholelithiasis		2
Cholelithiasis obstructive		1
Cholestasis		1
Chorea		1
Chromatopsia		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
					1
				5	13
					1
				1	1
				1	1
					1
				1	1
				1	3
				1	1
				1	1
				3	11
					1
				4	8
				1	2
				33	101
				1	1
			1		
		21	68	3	20
				1	2
		35	93	30	77
		1	2		
1	1	189	1258	17	79
					5
			1		
					1
			2		
					1
					1
					1
			2		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chromaturia	3	11
Chronic inflammatory demyelinating polyradiculoneuropathy	1	3
Chronic kidney disease		3
Chronic lymphocytic leukaemia	1	1
Chronic myeloid leukaemia recurrent		1
Chronic obstructive pulmonary disease	1	4
Chronic sinusitis	1	2
Circadian rhythm sleep disorder		2
Circulatory collapse	1	1
Circumstance or information capable of leading to device use error		1
Circumstance or information capable of leading to medication error	10	272
Claustrophobia		1
Clonus	1	2
Clostridium difficile infection	1	1
Clumsiness		2
Cluster headache		2
Coagulopathy		5
Coccydynia		1
Cognitive disorder	7	16
Cold burn	1	1
Cold sweat	11	60
Colitis		2
Colitis microscopic	1	2
Colitis ulcerative		1
Coma	2	6
Communication disorder	2	5
Completed suicide	1	2
Complication associated with device		2
Computerised tomogram normal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	10	1	1
				1	3
					3
				1	1
					1
				1	4
		1	2		
			1		1
				1	1
			1		
		9	271	1	1
			1		
			1	1	1
				1	1
			2		
			1		1
			1		4
			1		
		5	9	2	7
				1	1
		10	55	1	5
			2		
				1	2
					1
				2	6
		1	2	1	3
				1	2
					2
			1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Computer vision syndrome		1
Concussion	1	4
Condition aggravated	33	127
Confusional state	17	60
Congestive cardiomyopathy	1	1
Conjunctival haemorrhage		4
Conjunctival irritation		1
Conjunctival oedema		1
Conjunctivitis	1	3
Constipation	3	27
Contraindicated product administered		3
Contraindication to medical treatment		1
Contraindication to vaccination		4
Contusion	9	40
Coordination abnormal	3	6
Corneal disorder		1
Corneal graft rejection		1
Corneal infiltrates		1
Corneal reflex decreased		1
Coronary artery disease		1
Costochondritis	1	3
Cough	72	271
COVID-19	219	945
COVID-19 immunisation		2
COVID-19 pneumonia	4	26
C-reactive protein increased	1	7
Crohn's disease	2	2
Crying	1	4
CSF glucose increased	1	1
CSF protein increased	1	3
Cutaneous T-cell lymphoma	1	1
Cutaneous vasculitis	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2	1	2
		25	96	8	31
		10	33	7	27
				1	1
					4
			1		
			1		
			2	1	1
		2	24	1	3
			3		
			1		
			4		
		8	37	1	3
		2	4	1	2
					1
					1
			1		
					1
			2	1	1
		60	240	12	31
2	4	82	271	137	674
			2		
2	2			4	26
		1	5		2
				2	2
		1	2		2
				1	1
				1	3
				1	1
				1	2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cyanosis		2
Cystitis	1	6
Cystitis escherichia		1
Deafness	14	44
Deafness bilateral	2	2
Deafness neurosensory	4	11
Deafness transitory		2
Deafness unilateral	5	19
Death	10	59
Death neonatal		1
Decreased appetite	33	147
Decreased immune responsiveness	2	2
Decreased interest	1	1
Deep vein thrombosis	17	49
Defaecation disorder		1
Defaecation urgency	1	2
Dehydration	19	64
Delirium	1	13
Delirium febrile		1
Delusion		1
Delusional perception	1	1
Dementia	3	8
Dementia Alzheimer's type	1	3
Demyelinating polyneuropathy		1
Dental caries		1
Dental discomfort		5
Dental restoration failure		1
Depressed level of consciousness		2
Depressed mood	1	8
Depression	5	14
Dermatitis	1	8
Dermatitis acneiform		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		1	4		2
					1
			1	14	43
				2	2
				4	11
					2
1	1			5	19
	1			10	59
					1
		29	131	4	16
		1	1	1	1
		1	1		
				17	49
			1		
		1	2		
		11	38	8	26
				1	13
					1
			1		
		1	1		
				3	8
				1	3
					1
			1		
			5		
			1		
					2
		1	8		
		4	12	1	2
		1	7		1
			1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dermatitis allergic		1
Dermatitis atopic		2
Dermatitis bullous	1	1
Dermatitis contact	1	3
Diabetes mellitus	1	7
Diabetes mellitus inadequate control	2	2
Diabetic coma		1
Diabetic ketoacidosis		1
Diabetic wound		1
Diaphragmalgia	1	2
Diarrhoea	64	333
Diarrhoea haemorrhagic	2	7
Diet refusal	1	1
Differential white blood cell count abnormal		1
Diplegia		1
Diplopia	5	23
Discharge		1
Discomfort	14	67
Disease progression		1
Disease recurrence	10	45
Disorganised speech		1
Disorientation	8	37
Disseminated varicella zoster virus infection		1
Dissociation		1
Distract bility	1	1
Disturbance in attention	10	27
Diverticulitis		10
Dizziness	159	694
Dizziness exertional		1
Dizziness postural	1	16
Drainage	2	2
Drooling	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			2		
				1	1
		1	3		
				1	7
				2	2
					1
					1
					1
		1	2		
	1	57	302	7	31
				2	7
				1	1
					1
					1
		4	18	1	5
			1		
		12	62	2	5
					1
		3	16	7	29
					1
		5	23	3	14
					1
			1		
		1	1		
		10	23		4
					10
		137	617	22	77
			1		
		1	15		1
		2	2		
		1	4		1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Drowning		1
Drug abuser	1	1
Drug eruption		1
Drug hypersensitivity	1	12
Drug ineffective	119	641
Drug interaction	5	16
Dry eye	5	10
Dry mouth	6	40
Dry skin	2	9
Dry throat	2	14
Ductus arteriosus premature closure		1
Dysaesthesia		2
Dysarthria	6	22
Dysentery		3
Dysgeusia	13	57
Dysgraphia		1
Dyskinesia	2	6
Dyslexia	1	2
Dyspepsia	7	26
Dysphagia	12	30
Dysphemia	1	3
Dysphonia	4	27
Dyspnoea	99	358
Dyspnoea exertional		9
Dysstasia	10	38
Dystonia		1
Dysuria	1	10
Ear congestion	1	5
Ear discomfort	7	29
Ear disorder	1	8
Ear haemorrhage		1
Ear infection	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
			1		
		1	12		
3	4			119	641
		4	12	1	4
		5	9		1
		4	33	2	7
		2	8		1
		2	13		1
					1
			2		
		3	12	3	10
					3
		11	51	2	6
			1		
		2	6		
		1	2		
		7	22		4
	1	8	20	4	10
			1	1	2
		4	22		5
	2	61	231	38	127
			7		2
		7	23	3	15
					1
		1	8		2
			3	1	2
		5	23	2	6
		1	7		1
					1
		1	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Ear infection bacterial		1
Ear injury		1
Ear pain	3	27
Ear pruritus		1
Ear swelling	1	7
Eating disorder	5	15
Eating disorder symptom		2
Ecchymosis		1
Eczema	1	5
Ejection fraction abnormal		1
Ejection fraction decreased	1	4
Electric shock sensation	2	3
Electrocardiogram abnormal		2
Electrocardiogram QT prolonged		1
Electrocardiogram ST segment elevation	2	4
Electrolyte imbalance		2
Embolic stroke	1	2
Embolism		2
Emotional disorder	1	3
Emotional distress	1	3
Encephalitis	3	7
Encephalomalacia		1
Encephalopathy	1	1
Endocarditis		1
Endodontic procedure	1	1
Energy increased		6
Enlarged uvula	1	1
Enteritis	1	2
Enterocolitis haemorrhagic	1	1
Enuresis	1	2
Eosinophil count decreased		1
Eosinophil count increased		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
		3	23		4
			1		
		1	6		1
		4	10	1	5
			2		
			1		
			4	1	1
			1		
				1	4
		1	2	1	1
			2		
					1
				2	4
					2
				1	2
					2
		1	2		1
			1	1	2
				3	7
					1
				1	1
					1
		1	1		
			6		
		1	1		
				1	2
				1	1
		1	2		
					1
			1		1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eosinophilia		1
Epididymitis	1	1
Epigastric discomfort		1
Epilepsy	1	1
Epistaxis	6	42
Epstein-Barr virus antibody positive	1	1
Erectile dysfunction	2	12
Erection increased		1
Eructation		5
Erythema	33	126
Erythema marginatum		1
Erythema multiforme	1	5
Erythema nodosum		1
Erythema of eyelid		1
Erythrospia	1	1
Escherichia bacteraemia		1
Escherichia infection	1	1
Escherichia urinary tract infection		1
Essential tremor	1	1
Euphoric mood		1
Eustachian tube dysfunction		1
Excessive cerumen production		1
Exercise electrocardiogram abnormal		1
Exercise tolerance decreased		1
Exophthalmos		1
Expired product administered	11	18
Exposure during pregnancy		1
Exposure to SARS-CoV-2	5	26
Exposure to toxic agent		1
Exposure via breast milk	4	21
Exposure via skin contact	1	6
External ear pain		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
			1		
				1	1
		5	36	1	6
				1	1
				2	12
					1
			4		1
		28	111	5	15
			1		
				1	5
			1		
			1		
		1	1		
					1
				1	1
					1
		1	1		
			1		
			1		
					1
					1
			1		
					1
		10	17	1	1
					1
		5	23		3
			1		
		2	18	2	3
		1	6		
			1		

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Extra dose administered	1	2
Extrasystoles	1	6
Extremity contracture	1	1
Eye allergy		1
Eye colour change		1
Eye contusion	1	2
Eye discharge	2	4
Eye disorder	2	18
Eye haemorrhage	2	10
Eye infection		1
Eye inflammation	1	4
Eye irritation	3	13
Eyelid disorder	1	4
Eyelid function disorder		1
Eyelid infection		1
Eyelid margin crusting		1
Eyelid oedema	1	2
Eyelid pain		3
Eyelid ptosis	2	5
Eye movement disorder	1	5
Eye oedema		2
Eye pain	8	40
Eye pruritus	3	11
Eye swelling	8	38
Face injury		3
Face oedema		4
Facet joint syndrome		1
Facial asymmetry	1	1
Facial bones fracture		1
Facial discomfort		1
Facial nerve disorder		1
Facial neuralgia		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
		1	6		
		1	1		
			1		
					1
		1	2		
		2	4		
		2	15		3
				2	10
			1		
			2	1	2
		1	9	2	4
		1	3		1
			1		
			1		
			1		
		1	2		
			3		
		1	3	1	2
		1	2		3
			2		
		7	35	1	5
		3	11		
		6	30	2	8
			2		1
			3		1
			1		
		1	1		
					1
			1		
			1		
			2		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Facial pain	1	13
Facial paralysis	4	38
Facial paresis		6
Factor V Leiden mutation		1
Faecal calprotectin decreased	1	1
Faecal calprotectin increased	1	1
Faeces discoloured	1	2
Faeces soft		3
Failure to thrive	1	1
Fall	34	103
False positive investigation result		1
Fasciitis		2
Fatigue	302	1,466
Fear	2	5
Fear of death		1
Fear of falling	1	2
Fear of injection		1
Febrile convulsion		1
Febrile neutropenia	1	1
Feeding disorder	8	25
Feeling abnormal	87	359
Feeling cold	20	82
Feeling drunk	2	13
Feeling hot	15	99
Feeling jittery		3
Feeling of body temperature change	7	19
Fever neonatal		1
Fibrin D dimer increased	2	8
Fibroblast growth factor 23	1	1
Fibromyalgia	1	4
Fine motor skill dysfunction		1
Fistula		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	11		2
				4	38
			4		2
					1
		1	1		
		1	1		
			1	1	1
			2		1
				1	1
		24	61	10	42
			1		
					2
	1	285	1391	17	75
		2	5		
					1
		1	2		
			1		
					1
				1	1
		7	21	1	4
		85	332	2	27
		19	77	1	5
		2	10		3
		12	91	3	8
			3		
		7	17		2
					1
		2	6		2
		1	1		
		1	3		1
			1		
			1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Flank pain	1	3
Flat affect	1	1
Flatulence	4	16
Fluid intake reduced		1
Fluid overload		1
Fluid retention	1	8
Flushing	8	42
Foaming at mouth	1	1
Food allergy	1	1
Food aversion	1	1
Food poisoning		1
Foreign body sensation in eyes	1	5
Formication	1	2
Freezing phenomenon		1
Frequent bowel movements		2
Frustration tolerance decreased	2	4
Full blood count abnormal		1
Functional gastrointestinal disorder		1
Fungal infection		1
Fungal peritonitis		1
Gait disturbance	26	116
Gait inability	15	42
Gallbladder disorder		2
Gallbladder oedema		1
Gangrene		1
Gastric disorder		10
Gastric haemorrhage		2
Gastric ulcer		1
Gastritis		4
Gastroenteritis		1
Gastroenteritis viral		5
Gastrointestinal disorder	7	17

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	1	1
		1	1		
		4	15		1
			1		
					1
			3	1	5
		8	38		4
				1	1
		1	1		
		1	1		
			1		
		1	5		
		1	2		
			1		
			1		1
		2	4		
					1
			1		
			1		
					1
		20	88	6	28
		7	22	8	20
			1		1
					1
					1
			10		
					2
					1
			3		1
					1
			5		
		7	13		4

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastrointestinal haemorrhage	1	2
Gastrointestinal hypomotility		1
Gastrointestinal inflammation		1
Gastrointestinal motility disorder		1
Gastrointestinal oedema		1
Gastrointestinal pain		4
Gastrointestinal sounds abnormal	1	1
Gastrointestinal tract irritation		3
Gastroesophageal reflux disease	2	9
Generalised tonic-clonic seizure	4	9
General physical health deterioration	2	4
Genital haemorrhage		1
Genital herpes		1
Gingival abscess	1	1
Gingival bleeding		2
Gingival blister	1	1
Gingival discolouration		1
Gingival discomfort		1
Gingival disorder	1	1
Gingival erythema		1
Gingival pain	3	5
Gingival swelling		4
Gingivitis	1	3
Glare		1
Glassy eyes		2
Glaucoma		1
Glossitis		2
Glossodynia	2	6
Glycosylated haemoglobin increased		3
Good syndrome		1
Gout	5	23
Grip strength decreased	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
					1
			1		
			1		
					1
			3		1
		1	1		
			3		
		1	8	1	1
				4	9
		1	1	1	3
					1
			1		
		1	1		
			1		1
		1	1		
					1
			1		
		1	1		
			1		
		3	4		1
			4		
		1	3		
			1		
			1		1
					1
			2		
		2	6		
			1		2
					1
		3	19	2	4
		1	2		1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Groin pain	3	14
Grunting		2
Guillain-Barre syndrome	7	18
Haematemesis	2	8
Haematochezia	11	33
Haematocrit decreased		1
Haematology test abnormal		1
Haematoma		5
Haematospermia		1
Haematuria	3	9
Haemoglobin decreased	1	7
Haemolytic anaemia		4
Haemoptysis	2	8
Haemorrhage	11	29
Haemorrhage intracranial		1
Haemorrhage subcutaneous		1
Haemorrhage urinary tract	4	8
Haemorrhagic stroke		3
Haemorrhoids	1	4
Hallucination	7	23
Hallucination, visual	1	3
Hand deformity		1
Hangover		7
Haptoglobin increased		1
Headache	365	1,632
Head deformity		1
Head discomfort	17	52
Head injury	8	21
Head titubation		2
Hearing disability		1
Heart injury		4
Heart rate		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	12		2
			1		1
				7	18
				2	8
1	1			11	33
					1
			1		
			5		
			1		
			2	3	7
			2	1	5
					4
			4	2	4
			2	11	27
					1
					1
				4	8
					3
		1	3		1
				7	23
				1	3
					1
			7		
			1		
		343	1526	22	106
					1
		14	44	3	8
		5	10	3	11
			2		
			1		
					4
			1		

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Heart rate abnormal	2	10
Heart rate decreased	8	19
Heart rate increased	44	156
Heart rate irregular	5	25
Hemiparesis	3	8
Hemiplegia	1	3
Henoch-Schonlein purpura	1	2
Hepatic enzyme abnormal	1	2
Hepatic enzyme increased	2	10
Hepatic failure		1
Hepatic haemorrhage		1
Hepatic pain		1
Hepatic steatosis		1
Hepatitis		4
Hepatitis acute		2
Hepatitis A virus test positive		1
Hepatitis C	1	1
Hepatomegaly		2
Hereditary haemorrhagic telangiectasia		1
Hernia	2	3
Herpes simplex		3
Herpes simplex test positive	1	1
Herpes virus infection	1	2
Herpes zoster	62	120
Herpes zoster infection neurological	1	1
Herpes zoster oticus	1	3
Herpes zoster reactivation	1	1
Hiatus hernia		1
Hiccups		6
Hip fracture	1	6
HIV infection		1
HIV test false positive		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	8		2
		4	11	4	8
		28	119	16	37
		3	19	2	6
				3	8
				1	3
				1	2
				1	2
		1	7	1	3
					1
					1
					1
			1		
					4
					2
			1		
			1	1	1
			1		1
			1		
		1	1	1	2
			2		1
		1	1		
		1	2		
		54	99	8	21
				1	1
1	1			1	3
		1	1		
			1		
			5		1
				1	6
			1		
			1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hordeolum		3
Hostility		1
Hot flush	6	34
Humerus fracture	1	1
Hunger	2	6
Hydronephrosis		1
Hyperactive pharyngeal reflex		1
Hyperacusis	2	5
Hyperaesthesia	2	8
Hyperaesthesia teeth		2
Hyperchlorhydria		1
Hyperglycaemia	2	5
Hyperhidrosis	58	243
Hypernatraemia		1
Hyperpyrexia		1
Hypersensitivity	26	90
Hypersensitivity vasculitis		2
Hypersomnia	11	38
Hypersomnia-bulimia syndrome	1	1
Hypertension	14	75
Hypertensive crisis		2
Hypertensive emergency		1
Hypertensive heart disease		1
Hyperthermia		3
Hyperthyroidism	2	2
Hypertonia		2
Hyperventilation	4	16
Hypervigilance		1
Hypoacusis	15	41
Hypoesthesia	63	202
Hypoesthesia eye	2	3
Hypoesthesia oral	7	34

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		
					1
		6	32		2
				1	1
		2	6		
					1
			1		
		2	4		1
		1	7	1	1
			2		
					1
		1	2	1	3
		53	215	5	28
					1
					1
		19	63	7	27
					2
		9	34	2	4
				1	1
		13	51	1	24
					2
					1
					1
			3		
				2	2
			1		1
		4	14		2
			1		
		10	32	5	9
		53	162	10	40
		1	2	1	1
		6	28	1	6

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypoaesthesia teeth		1
Hypogammaglobulinaemia		1
Hypogeusia	2	7
Hypoglycaemia	2	7
Hypokalaemia		1
Hypokinesia	1	10
Hypophagia	1	3
Hypopnoea	1	5
Hyposmia		2
Hypotension	10	31
Hypothermia		3
Hypoxia	1	7
IgA nephropathy	1	1
Illrd nerve paralysis		2
Illness	45	168
Illusion	1	1
Immobile	4	5
Immune-mediated neuropathy	1	1
Immune system disorder	5	12
Immune thrombocytopenia		9
Immunisation		1
Immunodeficiency	1	4
Immunoglobulins abnormal		1
Immunoglobulins decreased		1
Impaired driving ability	2	9
Impaired healing	1	2
Impaired self-care		1
Impaired work ability	3	11
Impatience	1	1
Imperception		1
Inappropriate schedule of product administration	63	357
Incision site haemorrhage		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
		2	6		1
		2	5		2
					1
		1	7		3
		1	3		
		1	2		3
			2		
		5	14	5	17
					3
				1	7
				1	1
					2
	1	39	149	6	19
		1	1		
				4	5
				1	1
		4	10	1	2
					9
			1		
1	1			1	4
			1		
			1		
		1	7	1	2
		1	2		
					1
		3	10		1
		1	1		
			1		
		62	355	1	2
					1

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Incoherent		5
Incomplete course of vaccination		6
Incontinence		2
Incorrect dose administered	5	26
Incorrect route of product administration	4	33
Increased appetite	1	2
Increased bronchial secretion		1
Increased viscosity of bronchial secretion	1	1
Infantile vomiting		1
Infant irritability		2
Infarction	1	1
Infection	2	12
Infectious mononucleosis	1	3
Inflammation	12	31
Inflammatory bowel disease		1
Inflammatory marker increased	1	2
Influenza	12	38
Influenza A virus test positive		1
Influenza like illness	45	196
Inhibitory drug interaction		1
Initial insomnia	1	5
Injected limb mobility decreased	1	1
Injection site bruising		2
Injection site discolouration		1
Injection site discomfort		4
Injection site erythema	1	19
Injection site extravasation		2
Injection site haemorrhage	1	1
Injection site joint pain		2
Injection site pain	7	100
Injection site pruritus		7
Injection site rash		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		3
			6		
					2
		5	26		
		4	32		1
		1	2		
			1		
		1	1		
			1		
			2		
				1	1
		2	5		7
		1	2		1
		9	26	3	5
					1
		1	2		
		11	33	1	5
			1		
		42	179	3	17
			1		
			4	1	1
		1	1		
			2		
			1		
			4		
		1	19		
			2		
		1	1		
			2		
		7	100		
			7		
			3		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site swelling		10
Injection site warmth		2
Injury	1	5
Inner ear inflammation		1
Insomnia	42	185
Inspiratory capacity decreased		1
Insulin resistance		1
Insulin resistant diabetes		1
Intentional dose omission		3
Intentional product misuse		3
Intentional product use issue	1	2
Intentional self-injury	1	1
International normalised ratio decreased		4
International normalised ratio increased		3
Intervertebral discitis		1
Intervertebral disc protrusion		3
Intestinal haemorrhage		
Intestinal obstruction	1	2
Intracardiac thrombus		1
Intracranial mass		1
Intraocular pressure increased		2
Intrusive thoughts		1
Investigation abnormal	1	1
Iridocyclitis		1
Iritis	1	3
Irregular breathing		1
Irritability	7	15
Irritable bowel syndrome	1	5
Ischaemic stroke	1	6
IVth nerve paralysis		1
Jaundice		5
Jaw disorder	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			10		
			2		
			1	1	4
			1		
		36	159	6	26
			1		
					1
					1
			3		
			3		
		1	2		
				1	1
			3		1
			3		
					1
			2		1
1	1				
				1	2
					1
					1
			2		
			1		
		1	1		
					1
		1	3		
			1		
		5	13	2	2
		1	4		1
				1	6
					1
			2		3
	1	2	4		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Job dissatisfaction		1
Joint adhesion	1	1
Joint dislocation	1	1
Joint effusion	1	2
Joint injury	5	12
Joint lock		2
Joint noise	1	1
Joint range of motion decreased	4	20
Joint stiffness	4	13
Joint swelling	9	46
Joint warmth	1	1
Keratic precipitates		2
Keratitis		1
Keratosis pilaris		1
Kidney infection		6
Knee deformity		1
Labile blood pressure	1	1
Laboratory test abnormal		3
Laboratory test normal		1
Lack of spontaneous speech	1	2
Lack of vaccination site rotation	1	1
Lacrimal disorder		1
Lacrimation increased	5	19
Lactic acidosis		1
Lacunar infarction		1
Large intestinal haemorrhage		1
Laryngeal oedema		1
Laryngitis	2	2
Laziness		2
Lead dislodgement	1	1
Left ventricular dysfunction	1	1
Left ventricular hypertrophy	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	1		
				1	1
		1	2		
		4	10	1	2
			2		
		1	1		
		2	15	2	5
		4	13		
		7	38	2	8
		1	1		
					2
			1		
			1		
					6
			1		
				1	1
			3		
			1		
				1	2
		1	1		
			1		
		5	17		2
			1		
					1
					1
					1
		1	1	1	1
			2		
				1	1
				1	1
		1	1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lethargy	26	100
Leukaemia		3
Leukaemia recurrent		1
Leukocytosis		3
Ligament pain		1
Ligament sprain	1	4
Limb discomfort	15	68
Limb injury	3	14
Limb mass	1	3
Lipase increased		1
Lip blister	1	3
Lip discolouration	1	1
Lip disorder		3
Lip dry		2
Lip exfoliation	1	1
Lipids increased		1
Lip injury	1	2
Lipoma		1
Lip pain		3
Lip pruritus		1
Lip swelling	7	50
Liquid product physical issue		2
Listless		1
Livedo reticularis	1	1
Liver function test abnormal		1
Liver function test increased	1	4
Liver injury		3
Localised infection	1	6
Localised oedema		1
Loss of consciousness	45	143
Loss of control of legs		2
Loss of personal independence in daily activities	21	51

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		24	90	2	10
					3
					1
			1		2
			1		
		1	4		
		15	64		4
		3	12		2
		1	3		
			1		
			2	1	1
		1	1		
			3		
			2		
		1	1		
			1		
		1	2		
					1
			3		
			1		
		6	38	1	12
			2		
			1		
				1	1
					1
			3	1	1
					3
		1	6		
					1
		2	2	43	141
					2
		12	36	9	15

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Low density lipoprotein increased	1	2
Lower gastrointestinal haemorrhage		1
Lower limb fracture		1
Lower respiratory tract congestion	1	2
Lumbar puncture abnormal		1
Lumbar radiculopathy		1
Lung disorder	3	12
Lung hyperinflation		1
Lung infiltration		3
Lung opacity		3
Lyme disease	1	1
Lymphadenitis		5
Lymphadenopathy	43	226
Lymphangitis		1
Lymph node pain	4	31
Lymphocyte count decreased	1	2
Lymphocyte count increased		1
Lymphoedema		2
Lymphoma		1
Macular oedema		1
Macule		2
Maculopathy		1
Madarosis		1
Malaise	82	542
Malnutrition	1	2
Mania		1
Mass	3	8
Mast cell degranulation present		1
Mastication disorder		3
Mastitis		1
Maternal exposure during pregnancy	1	4
Maternal exposure timing unspecified	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
					1
					1
		1	2		
					1
			1		
		1	9	2	3
			1		
			1		2
			3		
				1	1
			3		2
	1	37	207	6	19
					1
		4	29		2
			1	1	1
			1		
			2		
					1
					1
			2		
					1
		72	494	10	48
			1	1	1
			1		
		3	8		
			1		
			3		
					1
				1	4
		1	1		

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Mean cell volume increased	1	1
Mean platelet volume decreased		1
Meconium aspiration syndrome	1	1
Medication error		3
Melanoma recurrent		2
Memory impairment	12	30
Meniere's disease		1
Meningitis	1	3
Meningitis aseptic		1
Meningitis bacterial	1	1
Meningitis noninfective		1
Meningitis viral		3
Mental disorder	1	3
Mental fatigue		2
Mental impairment	5	18
Mental status changes	3	5
Mesenteric artery aneurysm		1
Mesenteric panniculitis		1
Mesenteric vein thrombosis		1
Metabolic acidosis		1
Metamorphopsia	1	2
Micturition disorder		1
Micturition frequency decreased		1
Micturition urgency		2
Middle insomnia	3	9
Migraine	15	61
Migraine with aura	1	2
Miliaria	1	1
Miosis		1
Mitral valve incompetence		1
Moaning		2
Mobility decreased	9	35

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
			1		
				1	1
			3		
					2
		9	25	3	5
					1
				1	3
					1
				1	1
					1
					3
		1	2		1
			2		
				5	18
		2	4	1	1
					1
					1
					1
			1		
				1	2
					1
			1		
			2		
		3	9		
		11	48	4	13
		1	1		1
		1	1		
			1		
					1
			2		
		5	24	4	11

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Monoclonal gammopathy		1
Monocyte count increased		2
Mononeuropathy multiplex	1	1
Monoplegia	4	6
Mood altered	2	2
Mood swings		1
Morphoea	1	1
Motion sickness		2
Motor dysfunction	6	9
Mouth haemorrhage	1	3
Mouth injury		1
Mouth swelling	3	7
Mouth ulceration		3
Movement disorder	17	40
Mucosal disorder		1
Mucosal dryness		1
Mucous stools		1
Multi-organ disorder		1
Multiple fractures		1
Multiple organ dysfunction syndrome	1	3
Multiple sclerosis	2	4
Muscle atrophy		1
Muscle contractions involuntary	1	4
Muscle contracture		1
Muscle contusion	1	1
Muscle discomfort		3
Muscle disorder	1	6
Muscle fatigue	1	5
Muscle haemorrhage	1	1
Muscle injury	1	2
Muscle rigidity		2
Muscle rupture	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2		
				1	1
				4	6
		2	2		
			1		
				1	1
			2		
		4	6	2	3
		1	3		
			1		
		3	7		
			3		
		14	31	3	9
			1		
			1		
			1		
			1		
					1
				1	3
				2	4
			1		
		1	3		1
			1		
		1	1		
			3		
			3	1	3
		1	4		1
				1	1
			1	1	1
			1		1
				1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle spasms	31	88
Muscle strain	6	10
Muscle swelling	1	2
Muscle tightness	14	32
Muscle twitching	14	30
Muscular weakness	25	103
Musculoskeletal chest pain	7	15
Musculoskeletal discomfort	7	27
Musculoskeletal disorder	2	7
Musculoskeletal pain	2	10
Musculoskeletal stiffness	27	100
Mutism		1
Myalgia	108	634
Myasthenia gravis		2
Mydriasis	1	1
Myelitis transverse	2	7
Myocardial infarction	16	57
Myocardial necrosis marker increased	3	4
Myocarditis	19	33
Myoclonus		3
Myositis		2
Nail discolouration		2
Nasal congestion	27	103
Nasal discomfort	3	9
Nasal disorder	1	3
Nasal dryness	1	4
Nasal injury	1	2
Nasal mucosal disorder		1
Nasal oedema		1
Nasal pruritus	1	2
Nasopharyngitis	39	128
Nausea	116	657

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		28	74	3	14
		5	8	1	2
		1	2		
		13	27	1	5
		14	26		4
		16	63	9	40
		6	13	1	2
		6	24	1	3
		2	4		3
		2	6		4
		24	89	3	11
			1		
	1	97	587	11	47
					2
		1	1		
				2	7
			1	16	56
				3	4
			1	19	32
			1		2
			1		1
			2		
		26	99	1	4
		2	8	1	1
		1	3		
		1	3		1
			1	1	1
			1		
					1
		1	2		
		38	126	1	2
	1	103	605	13	52

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Near death experience	7	11
Neck injury		1
Neck mass	1	3
Neck pain	30	115
Necrosis		1
Necrotising retinitis		1
Needle issue		6
Neoplasm		6
Neoplasm malignant	2	8
Neoplasm recurrence	1	1
Nephrolithiasis	3	13
Nephropathy	1	2
Nerve compression	1	7
Nerve injury	5	9
Nervousness	7	22
Nervous system disorder	5	7
Neuralgia	5	23
Neuralgic amyotrophy	3	3
Neuritis	2	2
Neurological examination normal		1
Neurological symptom	2	5
Neuropathy peripheral	8	27
Neutropenia	1	1
Neutropenia neonatal		1
Neutrophil count decreased	1	4
Neutrophil count increased	1	1
Nightmare	1	8
Night sweats	11	51
Nipple infection		1
Nipple pain		3
Nipple swelling		2
No adverse event	4	17

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				7	11
			1		
		1	3		
		26	95	4	20
					1
					1
			5		1
			5		1
				2	8
		1	1		
				3	13
		1	1		1
		1	5		2
		3	6	2	3
		6	20	1	2
		2	3	3	4
		3	17	2	6
		2	2	1	1
		2	2		
			1		
		1	2	1	3
		1	1	7	26
				1	1
					1
		1	4		
		1	1		
		1	8		
		11	45		6
			1		
			3		
			2		
		4	17		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nocturia		3
Nodal rhythm		1
Nodule	2	7
Non-cardiac chest pain		1
Noninfective encephalitis	1	3
Noninfective gingivitis		2
Nose deformity		2
Nystagmus	1	2
Obsessive-compulsive personality disorder	1	1
Obstructive airways disorder	1	2
Occipital neuralgia		2
Occupational exposure to product		2
Occupational exposure to SARS-CoV-2	1	2
Ocular discomfort	4	17
Ocular hyperaemia	2	18
Ocular icterus	1	2
Ocular vascular disorder		1
Oculofacial paralysis		1
Odynophagia	1	5
Oedema	1	3
Oedema peripheral	1	7
Oesophageal irritation	1	1
Off label use	52	193
Onychalgia		1
Ophthalmic herpes zoster	3	4
Ophthalmic migraine		1
Ophthalmic vein thrombosis	1	1
Optic ischaemic neuropathy		1
Optic neuritis	1	2
Oral blood blister	2	3
Oral discomfort	2	9
Oral disorder	2	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		
			1		
		2	5		2
			1		
				1	3
			2		
			2		
		1	2		
		1	1		
		1	1		1
			2		
			2		
		1	1		1
		4	16		1
		2	17		1
		1	2		
			1		
					1
		1	4		1
		1	3		
			3	1	4
		1	1		
		51	192	1	1
			1		
				3	4
			1		
				1	1
					1
				1	2
		2	2		1
		2	9		
		1	7	1	2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral fungal infection		1
Oral herpes	4	14
Oral mucosal blistering	3	6
Oral mucosal eruption		1
Oral pain	2	10
Oral pruritus	1	3
Orchitis		2
Orchitis noninfective		1
Organ failure		1
Organising pneumonia		1
Oropharyngeal blistering	1	1
Oropharyngeal discomfort	8	23
Oropharyngeal pain	22	135
Oropharyngeal spasm		1
Oropharyngeal swelling		1
Osteoarthritis		1
Osteogenesis imperfecta		1
Overdose	17	48
Overweight		2
Oxygen consumption decreased	1	2
Oxygen saturation abnormal	1	4
Oxygen saturation decreased	8	36
Pain	228	1,119
Painful respiration	1	6
Pain in extremity	253	1,135
Pain in jaw	5	22
Pain of skin	3	9
Pallor	7	22
Palmar erythema		1
Palpable purpura		1
Palpitations	20	82
Pancreatic disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		4	12		2
		3	6		
					1
		2	9		1
		1	3		
			1		1
			1		
					1
					1
				1	1
		8	22		1
		20	124	2	11
					1
					1
			1		
					1
		17	48		
			1		1
				1	2
		1	4		
		1	11	7	25
	1	207	1039	21	80
			2	1	4
	2	234	1060	19	75
	1	5	21		1
		2	7	1	2
		6	17	1	5
			1		
			1		
		17	72	3	10
					1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pancreatitis	1	5
Pancreatitis acute	1	5
Pancytopenia		1
Panic attack	2	12
Panic reaction	1	5
Paraesthesia	54	208
Paraesthesia oral	4	33
Paralysis	6	20
Paranasal sinus discomfort	4	13
Paranasal sinus hypersecretion	2	6
Paranoia	1	4
Paranoid personality disorder		1
Paraplegia		1
Paresis		1
Parkinsonism	1	3
Parkinson's disease	2	4
Parosmia	4	13
Parotid duct obstruction		1
Parotid gland enlargement	1	1
Parotitis	1	2
Pelvic fracture		1
Pelvic pain		2
Pemphigoid	2	4
Pemphigus	1	3
Penile erythema	1	1
Penile haemorrhage	1	2
Penile rash	1	1
Penile swelling	1	1
Penis disorder	1	2
Periarthritis	1	1
Pericardial disease		1
Pericardial effusion	3	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	5
				1	5
					1
		2	8		4
		1	5		
		46	171	8	37
		4	31		2
			1	6	19
		2	11	2	2
		2	6		
		1	3		1
			1		
					1
					1
			1	1	2
				2	4
		2	10	2	3
					1
		1	1		
		1	2		
					1
			2		
				2	4
				1	3
		1	1		
				1	2
		1	1		
		1	1		
		1	2		
		1	1		
					1
				3	7

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pericarditis	14	23
Periorbital disorder		2
Periorbital swelling	1	11
Peripheral artery thrombosis		1
Peripheral coldness	1	15
Peripheral nerve injury		1
Peripheral paralysis		1
Peripheral swelling	42	165
Peripheral venous disease	1	2
Peritonitis	1	1
Peroneal nerve palsy	2	6
Personality change		2
Petechiae	1	8
Phantom limb syndrome		1
Pharyngeal erythema	1	3
Pharyngeal hypoaesthesia		2
Pharyngeal inflammation		3
Pharyngeal mass		1
Pharyngeal oedema		2
Pharyngeal paraesthesia		1
Pharyngeal swelling	5	28
Pharyngeal ulceration	1	1
Pharyngitis streptococcal	2	3
Photophobia	5	12
Photopsia		5
Photosensitivity reaction	2	4
Piloerection		1
Pityriasis rosea	1	1
Plasma cell myeloma	1	2
Platelet count decreased	5	21
Platelet count increased		1
Platelet disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				14	23
			2		
		1	9		2
					1
		1	14		1
					1
					1
	1	33	142	9	23
		1	1		1
				1	1
		1	2	1	4
			2		
			4	1	4
			1		
		1	2		1
					2
			3		
			1		
			2		
					1
		5	18		10
		1	1		
		1	1	1	2
		5	12		
			3		2
1	1	1	3	1	1
			1		
		1	1		
				1	2
		3	7	2	14
			1		
					1

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pleural effusion	5	5
Pleurisy	1	3
Pleuritic pain	1	2
Pneumonia	10	56
Pneumonia aspiration	1	3
Pneumonia bacterial		2
Pneumonia viral		2
Pneumonitis	1	2
Pneumothorax	2	4
POEMS syndrome	1	1
Pollakiuria	1	21
Polyarthrits		1
Polycythaemia		1
Polymyalgia rheumatica	1	5
Polyneuropathy		1
Polyuria	1	5
Poor peripheral circulation		1
Poor quality product administered	39	83
Poor quality sleep	6	22
Poor venous access		1
Portal vein thrombosis	1	4
Post-acute COVID-19 syndrome	1	1
Postictal state		1
Post procedural complication		1
Post procedural haemorrhage		1
Post procedural infection		1
Post procedural oedema		1
Postural orthostatic tachycardia syndrome	1	3
Posture abnormal		1
Posturing		1
Potentiating drug interaction	1	11
Pre-existing condition improved		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	4	4
			1	1	2
				1	2
			2	10	54
				1	3
					2
					2
				1	2
				2	4
				1	1
		1	21		
					1
			1		
				1	5
					1
		1	5		
			1		
		39	83		
		6	21		1
			1		
				1	4
				1	1
					1
					1
			1		
		1	1		2
			1		
					1
		1	11		
			3		

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Premature baby	1	4
Prescr bed overdose		1
Pressure of speech		1
Presyncope	8	31
Proctalgia		1
Product administered at inappropriate site	5	30
Product administered to patient of inappropriate age	7	17
Product administration error	1	6
Product colour issue		3
Product dispensing issue		1
Product dose omission in error		1
Product dose omission issue	10	68
Productive cough	3	25
Product leakage	2	5
Product preparation error	15	39
Product preparation issue	8	27
Product prescribing error		3
Product quality issue	1	6
Product storage error	10	17
Product supply issue	3	14
Product temperature excursion issue	21	34
Product use complaint		1
Product use issue	10	75
Prostate cancer		5
Prostate examination abnormal	1	1
Prostate infection	1	2
Prostatic disorder	1	1
Prostatic specific antigen increased		1
Prostatitis	1	1
Prostatomegaly		1
Protein total decreased		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	4
			1		
					1
		6	22	2	9
			1		
		5	29		1
		7	17		
		1	5		1
			3		
			1		
			1		
		10	68		
		3	24		1
		2	5		
		15	39		
		8	27		
			3		
		1	6		
		10	17		
		3	14		
		21	34		
			1		
		10	75		
					5
		1	1		
				1	2
		1	1		
			1		
				1	1
			1		
			2		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Protein total increased		1
Prothrombin level increased		1
Prothrombin time prolonged		1
Pruritus	54	247
Pseudofolliculitis	1	1
Psoriasis	2	10
Psoriatic arthropathy		1
Psychomotor hyperactivity		3
Psychotic disorder	1	3
Pulmonary arterial pressure abnormal		1
Pulmonary artery thrombosis		1
Pulmonary congestion		2
Pulmonary embolism	18	53
Pulmonary fibrosis		4
Pulmonary hypertension		
Pulmonary infarction		2
Pulmonary oedema	3	10
Pulmonary pain	5	10
Pulmonary thrombosis	6	21
Pulse abnormal		3
Pulse absent		1
Pulseless electrical activity	1	1
Pulse pressure increased		1
Purpura		2
Pustule		5
Pyrexia	278	1,429
Radiculitis brachial	1	1
Rash	78	324
Rash erythematous	12	38
Rash macular	10	30
Rash maculo-papular	2	9
Rash morbilliform		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
			1		
		45	215	9	32
		1	1		
		2	8		2
					1
			2		1
		1	2		1
					1
					1
					2
				18	53
					4
	1				
					2
			1	3	9
		5	8		2
				6	21
			1		2
					1
				1	1
			1		
			1		1
			3		2
1	1	246	1297	32	132
				1	1
		62	282	16	42
		10	34	2	4
		9	26	1	4
		2	8		1
					3

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rash neonatal		1
Rash papular	3	13
Rash pruritic	10	53
Rash pustular	2	2
Rash vesicular	1	11
Raynaud's phenomenon	1	2
Reaction to excipient	1	1
Rectal haemorrhage		3
Red blood cell count decreased		2
Red blood cell sedimentation rate increased	1	3
Red blood cells urine positive		1
Reflux gastritis	1	1
Renal atrophy		2
Renal cyst	1	2
Renal disorder	3	14
Renal failure	4	13
Renal impairment	2	4
Renal injury		1
Renal pain	2	13
Repetitive speech	1	1
Respiration abnormal	1	7
Respiratory arrest	2	6
Respiratory disorder	2	7
Respiratory disorder neonatal		1
Respiratory distress	2	11
Respiratory failure		5
Respiratory rate decreased	1	2
Respiratory rate increased	1	5
Respiratory symptom		1
Respiratory tract congestion	1	9
Respiratory tract infection		5
Respiratory tract inflammation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		3	12		1
		7	45	3	8
				2	2
		1	9		2
		1	2		
		1	1		
					3
			2		
		1	2		1
			1		
		1	1		
					2
		1	1		1
		1	7	2	7
				4	13
				2	4
					1
		2	13		
		1	1		
		1	6		1
				2	6
		2	6		1
					1
				2	11
					5
		1	2		
		1	2		3
			1		
		1	8		1
					5
			1		

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory tract irritation		1
Restless legs syndrome	1	2
Restlessness	1	19
Retching	1	14
Retinal artery occlusion		3
Retinal detachment	1	3
Retinal tear		2
Retinal vascular thrombosis		2
Retinal vein occlusion	2	5
Retinitis pigmentosa		1
Retinopathy hypertensive		1
Rhabdomyolysis	4	6
Rheumatic disorder		1
Rheumatoid arthritis	3	8
Rhinalgia		3
Rhinitis		3
Rhinitis allergic	2	5
Rhinorrhoea	26	126
Rib fracture		2
Road traffic accident	3	4
Salivary gland disorder		1
Salivary gland enlargement	1	1
Salivary gland pain	2	2
Salivary hypersecretion	1	6
Sarcoidosis	1	1
SARS-CoV-1 test positive		1
SARS-CoV-2 ant body test		1
SARS-CoV-2 ant body test negative		19
SARS-CoV-2 ant body test positive		3
SARS-CoV-2 test false positive		3
SARS-CoV-2 test negative	1	4
SARS-CoV-2 test positive	14	96

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	2		
		1	17		2
		1	12		2
					3
				1	3
					2
			1		1
				2	5
					1
					1
				4	6
			1		
				3	8
			3		
			2		1
		2	5		
		26	122		4
					2
		1	1	2	3
					1
		1	1		
		2	2		
		1	4		2
				1	1
			1		
			1		
			18		1
			3		
			2		1
		1	4		
		8	31	6	65

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Scab	3	5
Scar	1	5
Schizophrenia		1
Schwannoma		1
Sciatica		14
Scratch	2	8
Screaming	1	2
Scrotal dermatitis		1
Scrotal disorder		1
Scrotal erythema		1
Scrotal infection		1
Scrotal inflammation		1
Scrotal pain		2
Seasonal allergy	3	5
Seborrhoea		1
Secretion discharge	4	11
Sedation		1
Seizure	29	85
Seizure like phenomena	1	1
Sensation of foreign body		5
Sensitive skin	2	8
Sensory disturbance	4	9
Sensory level abnormal		1
Sensory loss	4	10
Sepsis	2	12
Septic shock	1	1
Serotonin syndrome		1
Serratia infection	1	1
Serum ferritin decreased		1
Serum ferritin increased		1
Shock	2	5
Shock symptom	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	5		
		1	3		2
					1
					1
			9		5
		2	7		1
		1	2		
			1		
			1		
			1		
					1
			1		
			2		
		3	5		
			1		
		3	8	1	3
			1		
				29	85
				1	1
			4		1
		2	8		
		4	9		
			1		
		1	4	3	6
				2	12
				1	1
					1
				1	1
					1
			1		
				2	5
				1	1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Shoulder injury related to vaccine administration		1
Sialoadenitis		2
Sinus congestion		10
Sinus disorder	3	19
Sinus headache	1	9
Sinusitis	4	25
Sinus pain	1	8
Sinus tachycardia	2	2
Sinus tarsi syndrome		1
Sitophobia		1
Skin abrasion		1
Skin bacterial infection	1	1
Skin burning sensation	5	13
Skin depigmentation	1	1
Skin discolouration	7	27
Skin discomfort		1
Skin disorder	2	14
Skin exfoliation	4	16
Skin fissures	1	3
Skin haemorrhage		5
Skin hypertrophy	1	1
Skin infection		1
Skin injury		1
Skin irritation	4	12
Skin laceration	1	3
Skin laxity		1
Skin lesion	2	9
Skin lesion removal		1
Skin mass		5
Skin odour abnormal	1	3
Skin oedema		1
Skin reaction		5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					2
			8		2
		3	18		1
		1	9		
		3	20	1	5
		1	8		
		1	1	1	1
			1		
			1		
			1		
		1	1		
		4	11	1	2
		1	1		
		6	22	1	5
			1		
		1	12	1	2
		4	14		2
		1	3		
			5		
		1	1		
					1
			1		
		4	12		
			1	1	2
			1		
		2	9		
			1		
			4		1
		1	3		
			1		
			3		2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin sensitisation	1	2
Skin swelling	1	6
Skin tightness	1	1
Skin ulcer	1	3
Skin warm		1
Sleep deficit	1	3
Sleep disorder	14	51
Sleep disorder due to a general medical condition	1	4
Sleep disorder due to general medical condition, insomnia type	1	1
Sleep talking		1
Sleep terror	1	1
Slow response to stimuli	1	2
Slow speech		1
Sluggishness	3	18
Small fibre neuropathy		1
Small intestinal haemorrhage		1
Small intestinal obstruction		1
Snapping hip syndrome		1
Sneezing	7	34
Snoring		1
Soft tissue injury	1	2
Soft tissue swelling		1
Soliloquy	1	1
Somatic symptom disorder		1
Somnambulism	1	1
Somnolence	24	120
Speech disorder	14	36
Spinal cord disorder	1	3
Spinal disorder		1
Spinal fracture	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
			4	1	2
		1	1		
		1	3		
			1		
		1	3		
		12	47	2	4
		1	4		
		1	1		
			1		
		1	1		
		1	2		
			1		
		3	17		1
			1		
					1
					1
			1		
		7	33		1
			1		
			1	1	1
			1		
		1	1		
			1		
		1	1		
		21	113	3	7
		7	24	7	12
				1	3
					1
				1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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MALE

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		3	8		
			1	1	1
					1
					1
				1	1
			1		1
					1
			1		1
			1		
					1
			1		3
					1
			1		1
				1	1
				1	2
					1
				1	2
			1		
		2	4		
			1		1
				1	2
		2	7		1
		1	1		
					2
				1	1
					1
					1
					2
					2
				1	5

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sudden visual loss		1
Suffocation feeling		1
Suicidal ideation	4	7
Sunburn	2	4
Superficial injury of eye		1
Superior sagittal sinus thrombosis		1
Suprapubic pain	1	1
Supraventricular extrasystoles		1
Supraventricular tachycardia	1	4
Suspected counterfeit product		1
Suspected COVID-19	26	58
Sweating fever		1
Swelling	28	106
Swelling face	14	80
Swelling of eyelid	2	14
Swollen tongue	3	22
Syncope	28	88
Synovial cyst		1
Synovitis		1
Syphilis		1
Syringe issue	1	6
Systemic inflammatory response syndrome	1	3
Systolic hypertension		1
Tachycardia	3	44
Tachyphrenia		2
Tachypnoea		2
Tanning		1
Tardive dyskinesia	1	1
Taste disorder	4	28
Temperature intolerance	1	5
Temperature regulation disorder	1	2
Temporomand bular joint syndrome		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
				4	7
		2	3		1
			1		
					1
				1	1
					1
			1	1	3
			1		
		11	21	15	37
					1
		22	94	6	12
		12	64	2	16
		1	12	1	2
	1	3	14		8
		1	2	27	86
			1		
			1		
					1
		1	6		
				1	3
					1
		1	30	2	14
			2		
			2		
			1		
				1	1
		3	24	1	4
		1	4		1
		1	2		
			1		

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Gender

MALE

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Tenderness	2	18
Tendonitis	1	5
Tendon pain		1
Tendon rupture	2	2
Tenosynovitis		1
Tension	3	5
Tension headache		7
Terminal insomnia		1
Testicular disorder	2	2
Testicular pain	5	9
Testicular swelling	2	5
Tetanus		1
Therapeutic product effect delayed		1
Therapeutic response decreased	1	1
Therapeutic response unexpected	7	29
Thermal burn	3	4
Thinking abnormal	5	14
Thirst	2	14
Throat clearing		1
Throat irritation	9	35
Throat lesion	1	1
Throat tightness	9	19
Thrombocytopenia	3	14
Thrombophlebitis superficial		5
Thrombosis	56	114
Thrombotic thrombocytopenic purpura	2	2
Thyroid disorder		1
Thyroiditis	1	1
Thyroiditis subacute	1	2
Thyroxine free increased	1	1
Tibia fracture		1
Tic	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	16		2
			3	1	2
					1
		1	1	1	1
			1		
		2	4	1	1
			6		1
			1		
		2	2		
		5	8		1
		2	4		1
					1
			1		
		1	1		
		7	29		
		3	4		
		4	13	1	1
		2	13		1
			1		
		8	32	1	3
		1	1		
		5	12	4	7
				3	14
					5
				56	114
				2	2
			1		
		1	1		
		1	2		
		1	1		
					1
		1	1		1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tinea pedis		1
Tinnitus	60	177
T-lymphocyte count decreased	1	1
Tobacco user	1	1
Tongue blistering	1	1
Tongue coated		1
Tongue discolouration	2	4
Tongue discomfort	1	1
Tongue disorder		4
Tongue eruption		2
Tongue erythema	1	3
Tongue paralysis		2
Tongue pruritus		1
Tongue ulceration	2	2
Tonic clonic movements		1
Tonsillar disorder		1
Tonsillar hypertrophy	3	4
Tonsillar inflammation		1
Tonsillitis		3
Tonsillitis streptococcal	1	1
Toothache	8	24
Tooth disorder		8
Tooth extraction		2
Tooth infection	2	2
Tooth injury	1	1
Torsade de pointes		1
Total lung capacity decreased		1
Toxicity to various agents		1
Tracheal obstruction		1
Tracheitis	1	1
Transaminases decreased		1
Transaminases increased	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		41	127	19	50
				1	1
		1	1		
		1	1		
			1		
		2	2		2
		1	1		
			3		1
			1		1
		1	3		
					2
			1		
		1	1	1	1
					1
			1		
		1	2	2	2
			1		
			3		
				1	1
		8	24		
			8		
			2		
		2	2		
				1	1
					1
					1
		1	1		
					1
				1	2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Transient global amnesia		1
Transient ischaemic attack	8	24
Transplant failure		1
Traumatic haemorrhage		1
Tremor	35	138
Trigeminal nerve disorder		2
Trigeminal neuralgia		1
Trigger finger		1
Tri-iodothyronine increased	1	1
Troponin I decreased		1
Troponin I increased		1
Troponin increased	9	15
Tuberculin test positive		1
Tunnel vision	1	6
Type IV hypersensitivity reaction		1
Type V hyperlipidaemia		1
Ulcer		3
Ulcer haemorrhage	1	1
Underdose	15	49
Unresponsive to stimuli	3	19
Upper-airway cough syndrome		10
Upper airway obstruction		1
Upper gastrointestinal haemorrhage		1
Upper limb fracture	1	2
Upper respiratory tract congestion	1	6
Upper respiratory tract infection		5
Urethral haemorrhage		1
Urethritis noninfective	1	1
Urinary assistance device user		1
Urinary bladder haemorrhage	1	1
Urinary incontinence	4	7
Urinary retention	2	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				8	24
					1
					1
1	1	33	113	2	25
			2		
					1
			1		
				1	1
			1		
			1		
		1	1	8	14
			1		
				1	6
			1		
			2		1
				1	1
		15	49		
				3	19
			10		
					1
					1
			1	1	1
		1	5		1
			5		
					1
		1	1		
			1		
				1	1
		4	6		1
				2	6

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Urinary tract disorder		1
Urinary tract infection	4	31
Urinary tract infection bacterial		1
Urine abnormality		2
Urine analysis abnormal	1	1
Urine odour abnormal	2	3
Urine output decreased		1
Urticaria	43	145
Uveitis		3
Uvulitis		1
Vaccination complication		2
Vaccination error	1	1
Vaccination failure	17	54
Vaccination site bruising	4	17
Vaccination site cellulitis		1
Vaccination site coldness		5
Vaccination site discharge	2	2
Vaccination site discolouration	1	6
Vaccination site discomfort	7	23
Vaccination site erythema	10	43
Vaccination site extravasation		2
Vaccination site haematoma		2
Vaccination site haemorrhage	4	20
Vaccination site hypersensitivity	1	1
Vaccination site hypoaesthesia	1	3
Vaccination site induration		5
Vaccination site infection		2
Vaccination site inflammation		3
Vaccination site irritation		2
Vaccination site joint erythema		1
Vaccination site joint movement impairment	2	4
Vaccination site joint pain	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		2	18	2	13
					1
			2		
		1	1		
		2	3		
			1		
		37	122	6	23
					3
			1		
1	1		1		1
		1	1		
	1		1	17	53
		4	15		2
					1
			5		
		2	2		
		1	6		
		7	22		1
		10	39		4
			2		
			1		1
		4	19		1
		1	1		
		1	3		
			5		
			2		
			3		
			2		
					1
		2	4		
		2	4		1

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site joint swelling		1
Vaccination site lymphadenopathy		3
Vaccination site mass	13	30
Vaccination site movement impairment	4	14
Vaccination site nodule	1	1
Vaccination site oedema		2
Vaccination site pain	113	791
Vaccination site paraesthesia		5
Vaccination site pruritus	6	22
Vaccination site rash	4	17
Vaccination site reaction	5	12
Vaccination site scab	1	2
Vaccination site scar	1	1
Vaccination site swelling	11	56
Vaccination site ulcer		1
Vaccination site urticaria		7
Vaccination site vesicles	1	3
Vaccination site warmth	4	16
Varicella	1	1
Varicocele		1
Varicose vein	2	4
Vascular dementia		1
Vascular pain		1
Vascular test abnormal	1	1
Vasculitis	1	1
Vein disorder	2	2
Venous thrombosis limb		2
Ventricular arrhythmia	1	3
Ventricular extrasystoles		4
Ventricular fibrillation		4
Ventricular hypertrophy		1
Ventricular tachycardia		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			3		
		11	27	2	3
		3	13	1	1
		1	1		
			1		1
		111	773	2	18
			5		
		6	19		3
		3	15	1	2
1	1	5	12		
		1	2		
		1	1		
		11	54		2
			1		
			7		
		1	3		
		4	16		
		1	1		
			1		
		2	3		1
					1
					1
				1	1
		1	1		
		2	2		
					2
				1	3
			2		2
					4
					1
					2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vertigo	26	98
Vertigo positional		1
Vestibular disorder	1	1
Vestibular neuritis	1	1
Viral infection	7	11
Viral myocarditis	1	1
Viral test positive		1
Vision blurred	17	82
Visual acuity reduced		2
Visual field defect		3
Visual impairment	12	49
Vitamin B12 decreased		1
Vitamin D decreased		2
Vitamin D deficiency		3
Vlth nerve paralysis		5
Vitreous detachment	3	4
Vitreous floaters	1	4
Vocal cord disorder		1
Vomiting	62	256
Vomiting projectile		3
Wa king aid user		1
Wa king disability	2	5
Weight bearing difficulty		1
Weight decreased	16	57
Weight fluctuation		1
Weight increased	3	6
Wheezing	6	24
White blood cell count abnormal		1
White blood cell count decreased		2
White blood cell count increased	2	16
White blood cells urine	1	1
Wound	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		22	80	4	18
			1		
		1	1		
				1	1
		6	9	1	2
				1	1
			1		
		12	62	5	20
			2		
			1		2
		6	31	6	18
			1		
			2		
			3		
					5
				3	4
		1	2		2
					1
1	2	49	216	13	40
			3		
			1		
		1	3	1	2
			1		
		13	47	3	10
			1		
		3	6		
		5	17	1	7
			1		
1	1		2		
		2	11		5
		1	1		
			3	1	2

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Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Wound haemorrhage	1	4				3	1	1
Wound infection		1						1
Wrong product administered	11	27			11	27		
Wrong schedule		2				2		
Wrong technique in product usage process	4	25			4	25		
X-ray abnormal	1	1			1	1		
Yellow skin		3				2		1
	1	1			1	1		
	7,744	33,736	21	45	5736	26032	2008	7704

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	4	2	4		
Abdominal pain	1	4	1	4		
Abdominal pain upper	2	6	2	6		
Abnormal faeces		1		1		
Abnormal sensation in eye		1		1		
Acarodermatitis	1	1			1	1
Accidental exposure to product		6		6		
Accidental overdose	1	22	1	22		
Acne		1		1		
Adverse event	3	6	2	5	1	1
Ageusia	2	7	2	6		1
Aggression		2		2		
Agitation		1		1		
Alanine aminotransferase decreased		1		1		
Allergy to vaccine	5	12	1	8	4	4
Alopecia		4		4		
Anaesthesia		1		1		
Anal incontinence		1		1		
Anaphylactic reaction	1	27		1	1	26
Anger		1		1		
Angina pectoris	2	4			2	4
Angioedema		2				2
Anhedonia		1		1		
Anosmia		4		3		1
Anxiety	4	12	4	11		1
Aphasia		2		1		1
Aphthous ulcer		1		1		
Appendicitis		1				1
Arrhythmia		5				5
Arthralgia	17	71	17	70		1
Arthritis		1		1		
Asthenia	8	33	8	32		1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Asthenopia		1
Asthma	1	4
Asymptomatic COVID-19	4	10
Atrial fibrillation	2	5
Atrioventricular block	1	1
Autism spectrum disorder		1
Axillary pain		4
Back disorder	1	2
Back pain	5	20
Balance disorder	1	5
Basedow's disease		1
Bell's palsy	2	24
Biopsy		1
Bladder disorder		2
Blindness		3
Blindness unilateral		1
Blister	1	1
Blood bilirubin increased		1
Blood cholesterol increased	1	2
Blood disorder	1	1
Blood glucose decreased		1
Blood glucose increased		3
Blood immunoglobulin G decreased		1
Blood immunoglobulin M increased	1	1
Blood lactic acid decreased		1
Blood potassium decreased		3
Blood pressure decreased		1
Blood pressure fluctuation	2	2
Blood pressure increased	3	8
Blood sodium decreased		1
Blood thyroid stimulating hormone increased		1
Blood triglycerides increased	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
1	3		1
	2	4	8
		2	5
1	1		
			1
	4		
1	2		
5	20		
	4	1	1
			1
		2	24
	1		
	2		
			3
			1
		1	1
			1
1	2		
		1	1
			1
	3		
	1		
1	1		
	1		
	2		1
	1		
2	2		
1	5	2	3
	1		
	1		
1	1		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood urine present		2		2		
Body temperature abnormal	1	4	1	4		
Body temperature decreased	1	2	1	2		
Body temperature increased	4	8	4	8		
Bone marrow disorder	1	1	1	1		
Bone pain	2	5	2	5		
Bradykinesia	1	1	1	1		
Breast engorgement		1		1		
Breast induration		1		1		
Breast pain	1	3	1	3		
Burning sensation	5	11	3	9	2	2
Calcinosis	1	1	1	1		
Cardiac arrest		2				2
Cardiac disorder	3	3			3	3
Cardiac flutter		1				1
Cellulitis		1				1
Cerebral disorder	3	3	3	3		
Cerebral haemorrhage		3				3
Cerebral palsy		1				1
Cerebrovascular accident	5	11			5	11
Cervical radiculopathy		1		1		
Cheilitis	1	1	1	1		
Chest discomfort	5	15	5	14		1
Chest pain	10	16	8	14	2	2
Chillblains		1		1		
Chills	36	169	36	169		
Chronic lymphocytic leukaemia		1				1
Circumstance or information capable of leading to device use error		2		2		
Circumstance or information capable of leading to medication error	9	92	9	92		
Clostridium difficile infection		1				1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cognitive disorder		1		1		
Cold sweat	1	3	1	3		
Condition aggravated	2	12	2	11		1
Confusional state	2	6	2	6		
Congenital anomaly	1	1			1	1
Conjunctivitis		1		1		
Conjunctivitis bacterial	1	1			1	1
Conjunctivitis viral	1	1			1	1
Constipation		3		3		
Contraindication to vaccination		1		1		
Contusion	2	6	1	5	1	1
Coordination abnormal		1				1
Coronavirus infection	1	1			1	1
Cor pulmonale acute		1				1
Cough	6	26	6	24		2
Counterfeit product administered		1		1		
COVID-19	59	323	8	55	51	268
Crepitations		1		1		
Cyanosis	1	2	1	2		
Deafness		1				1
Deafness bilateral		1				1
Deafness neurosensory	1	1			1	1
Deafness unilateral		1				1
Death	3	22			3	22
Decreased appetite	2	9	2	9		
Deep vein thrombosis		3				3
Dehydration		2		1		1
Dementia		1				1
Depressed mood	1	2	1	2		
Depression		1		1		
Dermatitis	1	1	1	1		
Device issue		1		1		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diabetes mellitus		1				1
Diabetes mellitus inadequate control		1				1
Diarrhoea	8	49	8	48		1
Diplopia		1		1		
Discomfort	3	7	3	7		
Disease recurrence		1		1		
Disorganised speech	1	1	1	1		
Disturbance in attention		3		3		
Dizziness	19	73	18	70	1	3
Dizziness exertional	1	1	1	1		
Dizziness postural	1	3	1	3		
Dose calculation error		1		1		
Drug hypersensitivity		2		2		
Drug ineffective	65	316			65	316
Drug interaction	1	2	1	2		
Dry eye		2		2		
Dry mouth	1	2	1	2		
Dry skin		2		2		
Dry throat		5		5		
Dysarthria		1		1		
Dysgeusia	1	12	1	12		
Dyskinesia		3		3		
Dyspepsia	1	4	1	4		
Dysphagia	2	6	1	4	1	2
Dysphonia		2		2		
Dyspnoea	12	39	7	31	5	8
Dysstasia		4		2		2
Dystonia	1	1			1	1
Dysuria		1		1		
Ear discomfort	2	3	2	3		
Ear infection		2		2		
Ear pain	1	4		3	1	1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eating disorder		1		1		
Ecchymosis		4		4		
Electric shock sensation		1		1		
Emotional disorder		1		1		
Emphysema		1		1		
Encephalopathy		1				1
Energy increased		1		1		
Epistaxis		5		5		
Erythema	3	19	3	18		1
Euphoric mood		1		1		
Eustachian tube dysfunction	1	1	1	1		
Eustachian tube obstruction	1	1	1	1		
Expired product administered	4	43	4	43		
Exposure during pregnancy	1	3			1	3
Exposure to SARS-CoV-2		5		5		
Exposure via breast milk	8	86	8	85		1
Exposure via eye contact	1	3	1	3		
Exposure via skin contact		5		5		
Extra dose administered		1		1		
Eye colour change		2		1		1
Eye contusion		1		1		
Eye disorder		2		1		1
Eye haemorrhage		1				1
Eye irritation		3		3		
Eyelid function disorder		1				1
Eyelid oedema		1		1		
Eyelid vascular disorder		1		1		
Eye pain	2	3	2	3		
Eye pruritus	1	4	1	4		
Eye swelling		3		3		
Face oedema		1		1		
Facial asymmetry		1		1		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial pain		3		3		
Facial paralysis	2	5			2	5
Faeces discoloured		1		1		
Faeces soft	1	1	1	1		
Fall	1	6	1	6		
Fatigue	46	222	46	219		3
Fear	1	2	1	2		
Febrile neutropenia		1				1
Feeding disorder	1	2		1	1	1
Feeling abnormal	14	50	13	46	1	4
Feeling cold		12		12		
Feeling drunk	1	2	1	2		
Feeling hot	1	9	1	8		1
Feeling jittery		1		1		
Feeling of body temperature change	1	2	1	2		
Feeling of relaxation	1	1	1	1		
Fever neonatal		1				1
Fibromyalgia	1	1	1	1		
Flatulence	1	3	1	3		
Flushing	4	17	3	14	1	3
Foetal cystic hygroma	1	2			1	2
Foetal death	1	1			1	1
Foetal exposure during pregnancy	1	2	1	1		1
Foetal growth restriction	3	4			3	4
Foetal heart rate abnormal		1				1
Foetal heart rate decreased		1				1
Foetal hypokinesia		1				1
Food allergy		1		1		
Formication		1		1		
Frustration tolerance decreased	2	3	2	3		
Gait disturbance	3	8	3	8		
Gait inability	1	4		3	1	1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastric disorder		1		1		
Gastrointestinal disorder		6		6		
Gastrointestinal haemorrhage		1				1
Gastrointestinal pain	1	1	1	1		
Gingival discomfort	1	2	1	2		
Glassy eyes		1		1		
Glomerular filtration rate decreased	1	1			1	1
Glossitis	2	2	2	2		
Glossodynia	1	1	1	1		
Gout	1	3		2	1	1
Groin pain		3		2		1
Guillain-Barre syndrome		1				1
Haematochezia	1	4			1	4
Haemodialysis		1		1		
Haemorrhage	2	6			2	6
Hair growth abnormal		1		1		
Hallucination	1	2			1	2
Headache	61	264	58	257	3	7
Head discomfort	1	1	1	1		
Head injury		2		1		1
Heart rate abnormal	2	2	2	2		
Heart rate decreased		1		1		
Heart rate increased	7	32	6	29	1	3
Heart rate irregular		1		1		
Hemiparesis		1				1
Hepatic enzyme abnormal		1				1
Hepatic enzyme increased		2		1		1
Hepatic mass		1		1		
Herpes virus infection	1	1	1	1		
Herpes zoster	29	42	26	39	3	3
Hiccups		1		1		
HIV test false positive		1		1		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hot flush	1	1
Hyperacusis		1
Hyperaesthesia		1
Hyperhidrosis	6	19
Hypersensitivity	7	33
Hypersomnia		1
Hypertension	2	10
Hypoacusis	1	4
Hypoaesthesia	13	37
Hypoaesthesia eye		1
Hypoaesthesia oral	1	5
Hypokinesia		3
Hypotension	1	1
Hypothermia	1	1
Hypotonia		1
Hypoxia		1
Illness	8	44
Immune system disorder	1	2
Immune thrombocytopenia		3
Impaired driving ability	1	1
Impaired gastric emptying		1
Impetigo	1	1
Inappropriate schedule of product administration	8	67
Incomplete course of vaccination	1	2
Incorrect dosage administered		2
Incorrect dose administered	14	30
Incorrect dose administered by product		1
Incorrect route of product administration	3	23
Induration		1
Infantile vomiting		1
Infant irritability		1
Infection		3

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
	1		
	1		
6	19		
4	27	3	6
	1		
2	7		3
1	4		
9	31	4	6
	1		
	4	1	1
	3		
1	1		
		1	1
	1		
8	44		
1	2		
			3
1	1		
		1	1
8	67		
1	2		
	2		
13	29	1	1
	1		
3	22		1
			1
	1		
			1
	3		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inflammatory pain	1	1	1	1		
Influenza	2	6	2	6		
Influenza like illness	2	22	2	22		
Infrequent bowel movements		1		1		
Injection site bruising		3		3		
Injection site discomfort		2		2		
Injection site erythema	1	6	1	6		
Injection site haematoma		1		1		
Injection site haemorrhage		2		2		
Injection site nodule		1		1		
Injection site pain		16		16		
Injection site swelling		2		2		
Injection site warmth		1		1		
Injury		1		1		
Insomnia	11	26	11	26		
Intentional dose omission		1		1		
Intentional product misuse		2		2		
Intervertebral disc protrusion		1		1		
Irritability		2		2		
Joint effusion		1				1
Joint injury		1		1		
Joint range of motion decreased		2		2		
Joint stiffness		1		1		
Joint swelling	3	7	3	5		2
Kidney infection	2	2			2	2
Lacrimation increased	1	6	1	5		1
Laryngeal pain	1	1	1	1		
Lethargy	3	17	3	17		
Leukocytosis		1				1
Limb discomfort	1	10		8	1	2
Limb injury	1	3	1	3		
Limb mass		1				1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lipids abnormal		1		1		
Lip oedema		2		1		1
Lip pain	1	2	1	2		
Lip pruritus		3		2		1
Lip swelling	2	6	2	6		
Liquid product physical issue		5		5		
Liver contusion		1				1
Localised infection		1		1		
Loss of consciousness	2	8			2	8
Loss of personal independence in daily activities	2	6	2	5		1
Low density lipoprotein increased	1	2	1	2		
Lower gastrointestinal haemorrhage		1				1
Lung disorder		1				1
Lung neoplasm malignant		1				1
Lymphadenitis		1		1		
Lymphadenopathy	5	31	4	30	1	1
Lymph node pain		5		5		
Malaise	17	75	16	71	1	4
Mass	3	4	3	4		
Mastication disorder		1		1		
Maternal exposure during breast feeding	1	2	1	2		
Maternal exposure during pregnancy	3	7			3	7
Maternal exposure timing unspecified	1	2		1	1	1
Medication error		1		1		
Memory impairment	5	6	5	6		
Menstrual disorder	1	1	1	1		
Mental fatigue	1	2	1	2		
Mental impairment	3	3			3	3
Middle insomnia		1		1		
Migraine	2	12	1	10	1	2
Mobility decreased	2	4	2	4		
Mouth swelling		2		2		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mouth ulceration	1	1	1	1		
Movement disorder	1	7	1	7		
Mucous stools		1		1		
Muscle discomfort	1	1	1	1		
Muscle disorder		1		1		
Muscle fatigue		1		1		
Muscle spasms	6	17	5	16	1	1
Muscular weakness	1	5	1	5		
Musculoskeletal chest pain		3		3		
Musculoskeletal discomfort	1	3	1	3		
Musculoskeletal stiffness	2	6	2	5		1
Myalgia	13	78	13	77		1
Myocardial infarction	1	5			1	5
Myocardial necrosis marker increased	1	1			1	1
Myocarditis	4	4			4	4
Nasal congestion	2	18	2	18		
Nasal discomfort		1		1		
Nasal oedema		1		1		
Nasopharyngitis	3	9	3	9		
Nausea	20	82	20	81		1
Near death experience	1	2			1	2
Neck mass		2		2		
Neck pain	7	18	7	18		
Needle issue		4		4		
Nephrolithiasis	3	4			3	4
Nerve compression		1		1		
Nerve injury	1	1			1	1
Nervousness	1	7	1	6		1
Nervous system disorder		2		2		
Neuralgia		2		2		
Neuritis		1		1		
Neurological symptom	1	2		1	1	1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuropathy peripheral	1	4			1	4
Neutropenia	1	2			1	2
Nightmare		1		1		
Night sweats		4		4		
No adverse event	2	5	2	5		
Obstructive airways disorder	1	1			1	1
Occupational exposure to product	1	4	1	4		
Ocular hyperaemia		2		2		
Odynophagia		1		1		
Oedema peripheral	1	1	1	1		
Off label use	10	64	10	64		
Oral discomfort		1		1		
Oral disorder		1		1		
Oral dysaesthesia		1				1
Oral herpes	3	6	3	6		
Oral pruritus	1	1	1	1		
Oropharyngeal discomfort		1		1		
Oropharyngeal pain	3	20	3	20		
Orthostatic hypotension		1		1		
Osteoporosis		1		1		
Overdose	496	658	496	658		
Oxygen consumption		1		1		
Oxygen saturation decreased		3		3		
Pain	34	185	32	182	2	3
Pain in extremity	37	188	36	185	1	3
Pain in jaw		3		3		
Palpitations	4	12	4	11		1
Panic attack	1	2		1	1	1
Panic disorder		1		1		
Panic reaction		1		1		
Paraesthesia	6	21	6	20		1
Paraesthesia oral		3		3		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paralysis		1				1
Paranasal sinus discomfort	1	2	1	2		
Parosmia	1	1	1	1		
Pericardial effusion	2	2			2	2
Pericarditis		1				1
Peripheral coldness	1	2	1	2		
Peripheral sensory neuropathy		1				1
Peripheral swelling	4	35	3	34	1	1
Peripheral venous disease		1		1		
Pharyngeal disorder		1		1		
Pharyngeal hypoaesthesia		1		1		
Pharyngeal paraesthesia		2		2		
Pharyngeal swelling	1	7		5	1	2
Photophobia		1		1		
Photopsia		1		1		
Piloerection		1		1		
Plantar erythema		1		1		
Platelet count decreased	1	5	1	4		1
Platelet count increased		1		1		
Platelet disorder		1		1		
Pleurisy		1				1
Pneumonia	1	3			1	3
Pneumothorax	1	1			1	1
Poisoning		1				1
Pollakiuria		1		1		
Poor feeding infant		1		1		
Poor quality product administered	203	478	203	478		
Poor quality sleep	4	6	4	6		
Postmenopausal haemorrhage		1				1
Pre-existing condition improved		2		2		
Premature baby	1	4			1	4
Presyncope		1		1		

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UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Product administered at inappropriate site		6
Product administered to patient of inappropriate age	2	4
Product administration error	4	20
Product colour issue		1
Product complaint		3
Product compounding quality issue		1
Product container issue		1
Product dose omission issue	2	7
Productive cough		1
Product label confusion		1
Product leakage		4
Product packaging issue	1	1
Product packaging quantity issue		4
Product preparation error	38	127
Product preparation issue	337	504
Product quality issue	2	10
Product storage error	66	96
Product supply issue		3
Product temperature excursion issue	106	279
Product use issue	4	16
Protein total increased		1
Prothrombin time prolonged		1
Pruritus	14	40
Psoriatic arthropathy		1
Psychomotor hyperactivity		1
Pulmonary congestion		3
Pulmonary embolism		5
Pulmonary oedema	1	1
Pulmonary pain	3	3
Pulmonary thrombosis	2	4
Pyrexia	41	218

Spontaneous			
Nonserious		Serious	
I	C	I	C
	6		
2	4		
4	20		
	1		
	3		
	1		
	1		
2	7		
			1
	1		
	4		
1	1		
	4		
38	127		
337	504		
2	10		
66	96		
	3		
106	279		
4	16		
	1		
	1		
11	36	3	4
			1
	1		
	1		2
			5
		1	1
3	3		
		2	4
39	214	2	4

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rash	16	69
Rash erythematous	2	8
Rash macular	3	3
Rash morbilliform	1	2
Rash papular		1
Rash pruritic	2	5
Raynaud's phenomenon	1	1
Renal failure	1	3
Renal pain		1
Respiratory symptom		1
Retching		1
Rheumatoid arthritis	1	4
Rhinalgia	1	2
Rhinorrhoea	1	11
Salivary hypersecretion		1
SARS-CoV-2 ant body test negative		4
SARS-CoV-2 ant body test positive		6
SARS-CoV-2 test negative		1
SARS-CoV-2 test positive	2	46
Scab	1	1
Secretion discharge		1
Sedation		1
Seizure	4	8
Senile dementia	1	1
Sensation of foreign body		2
Sensitive skin	1	1
Sensory loss	1	1
Sepsis		1
Shoulder injury related to vaccine administration	1	1
Sinus congestion		1
Sinus disorder		2
Sinus headache		2

Spontaneous			
Nonserious		Serious	
I	C	I	C
14	64	2	5
2	8		
3	3		
1	2		
	1		
2	5		
		1	1
		1	3
	1		
	1		
	1		
		1	4
1	2		
1	10		1
	1		
	4		
	5		1
	1		
	2	2	44
		1	1
	1		
	1		
		4	8
		1	1
	2		
		1	1
1	1		
			1
		1	1
	1		
	2		
	2		

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sinusitis		4		3		1
Sinus operation		1		1		
Skin burning sensation		3		3		
Skin discolouration	1	3		1	1	2
Skin disorder	1	2	1	2		
Skin infection		1		1		
Skin irritation	1	2	1	2		
Skin laceration		1		1		
Skin lesion	2	2	1	1	1	1
Skin odour abnormal		1		1		
Skin reaction		1		1		
Sleep disorder	1	6	1	5		1
Sleep disorder due to a general medical condition	1	1	1	1		
Sneezing		6		6		
Somnolence	2	9	2	9		
Speech disorder		1		1		
Spinal pain		1		1		
Stevens-Johnson syndrome	1	1			1	1
Streptobacillus infection		1				1
Streptococcal infection		1		1		
Stress		1		1		
Suicidal ideation	1	1			1	1
Suspected COVID-19	16	26	2	5	14	21
Swelling	6	25	5	24	1	1
Swelling face	6	12	6	12		
Swollen tongue	3	5	2	4	1	1
Syncope		6				6
Synovial cyst	1	1	1	1		
Systemic lupus erythematosus		1				1
Tachycardia		8		5		3
Tachycardia foetal		1				1

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UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Taste disorder		4
Temperature intolerance		1
Tenderness	1	4
Therapeutic response unexpected	2	18
Thinking abnormal	2	3
Throat irritation	1	6
Throat tightness	2	6
Thrombocytopenia	1	2
Thrombosis	12	21
Tinnitus	8	15
Tongue discomfort		1
Tongue disorder	1	2
Tongue erythema	1	1
Tongue paralysis		2
Tongue ulceration		1
Toothache	2	6
Tooth infection		1
Transaminases increased	1	2
Transient ischaemic attack		2
Tremor	3	19
Tunnel vision	1	2
Type 2 diabetes mellitus	1	1
Underdose	20	130
Upper respiratory tract congestion	1	2
Upper respiratory tract infection	1	1
Urinary tract infection	2	2
Urine odour abnormal	1	1
Urine output decreased		1
Urticaria	8	28
Vaccination complication		2
Vaccination error		2
Vaccination failure	5	17

Spontaneous			
Nonserious		Serious	
I	C	I	C
	4		
	1		
1	4		
2	18		
2	3		
1	4		2
	4	2	2
		1	2
		12	21
7	13	1	2
	1		
1	2		
1	1		
			2
	1		
2	6		
	1		
1	2		
			2
3	19		
		1	2
		1	1
20	130		
1	2		
1	1		
1	1	1	1
1	1		
	1		
8	26		2
	2		
	2		
		5	17

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Gender

UNKNOWN

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	2		
	2		
	1		
	15		
	3		
	2		
	1		
	3		1
	1		
1	2		
	1		
1	5		
1	1		
1	1		
	1		
10	85		1
	2		
1	7		
	5		
1	5		
	1		
1	15		1
1	1		
	1		
1	5		
	1		
	1		
1	8		1
	1		
	1		
1	2		

Vaccination site bruising 1

Vaccination site discharge 2

Vaccination site discolouration 2

Vaccination site discomfort 1

Vaccination site erythema 15

Vaccination site extravasation 3

Vaccination site haemorrhage 2

Vaccination site hypersensitivity 1

Vaccination site induration 4

Vaccination site inflammation 1

Vaccination site irritation 1

Vaccination site joint pain 1

Vaccination site mass 1

Vaccination site movement impairment 1

Vaccination site nodule 1

Vaccination site oedema 1

Vaccination site pain 10

Vaccination site paraesthesia 2

Vaccination site pruritus 1

Vaccination site rash 5

Vaccination site reaction 1

Vaccination site scar 1

Vaccination site swelling 1

Vaccination site urticaria 1

Vaccination site vesicles 1

Vaccination site warmth 1

Vaginal disorder 1

Vaginal haemorrhage 1

Vertigo 1

Vessel puncture site haemorrhage 1

Vessel puncture site injury 1

Viral infection 1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vision blurred	2	7	1	6	1	1
Visual field defect		2		2		
Visual impairment	1	3	1	3		
Vitreous floaters		1		1		
Vomiting	2	25	1	23	1	2
Von Willebrand's disease		1				1
Weight decreased	2	4	2	4		
Wheezing		7		6		1
White blood cell count decreased		1				1
Wrong dose		1		1		
Wrong product administered	4	14	4	14		
Wrong technique in product usage process	10	56	10	56		
Yellow skin		1				1
	2,462	7,708	2146	6522	316	1186

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred
UNITED STATES MINOR OUTLYING ISLA

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration		1		1
Vaccination site pain		1		1
		2		2

Gender

MALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal pain upper		1		1
Diarrhoea		1		1
Dizziness		1		1
Pain in extremity		1		1
		4		4

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

URUGUAY

Gender

FEMALE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fatigue	1	1	1	1
Headache	1	1	1	1
Inflammation		1		1
Maternal exposure during pregnancy	2	2	2	2
Pain	1	2	1	2
Paraesthesia	1	1	1	1
Pruritus	1	1	1	1
Pyrexia	1	1	1	1
Synovial cyst		1		1
	8	11	8	11

* I=Interval, C=Cumulative

* AE=Adverse Event

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APPENDIX 2.5.4: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per Patient with Relevant Co-Morbidities by Preferred Term per Country

Cumulative Reporting Period: Through 31-MAY-2021

Interval Reporting Period: 30-APR-2021 Through 31-MAY-2021

Total Number of Cases: 8,621 (Interval) / 32,373 (Cumulative)

Total Number of Adverse Events (PT): 34,618 (Interval) / 141,331 (Cumulative)

MedDRA Version: v.24.0J

Country Where Event Occurred

ARGENTINA

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Circumstance or information capable of leading to medication error		1		1
SARS-CoV-2 ant body test negative		1		1
		2		2

* I=Interval, C=Cumulative
* AE=Adverse Event
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Country Where Event Occurred

AUSTRALIA

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- * I=Interval, C=Cumulative
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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose		1		1		
Acute pulmonary oedema		1				1
Arthralgia		1		1		
Body temperature increased	1	1			1	1
Cardiac arrest		2				2
Cerebral haemorrhage		1				1
Cerebrovascular accident		1				1
Condition aggravated		2				2
Contusion		1				1
Cough		1				1
Death		2				2
Depressed level of consciousness		1				1
Dizziness		1				1
Dysphagia		2				2
Dyspnoea	1	3			1	3
Fatigue		2		2		
Feeling abnormal		1		1		
General physical health deterioration		1				1
Headache		1				1
Heart rate increased		1				1
Hypoaesthesia oral		1				1
Hypophagia		1				1
Hyporesponsive to stimuli		1				1
Hypotension		2				2
Hypoxia		2				2
Loss of consciousness		2				2
Malaise		1				1
Multiple organ dysfunction syndrome		1				1
Myalgia		2		1		1
Oedema peripheral		1				1
Oxygen saturation decreased		2				2
Pneumonia		4				4
Pneumonia aspiration		1				1

* I=Interval, C=Cumulative
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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonia viral		1				1
Product preparation error		1		1		
Pruritus		1		1		
Pyrexia		2		1		1
Rales		1				1
Respiratory failure		1				1
Sepsis		1				1
Septic shock		1				1
Somnolence		3		2		1
Unresponsive to stimuli		1				1
Urinary incontinence		1				1
Urosepsis		1				1
Vaccination site erythema		1				1
Vaccination site pain		1				1
Vaccination site swelling		1				1
Vomiting		3				3
Weight decreased		1				1
Wheezing		1				1
	2	71		11	2	60

* I=Interval, C=Cumulative
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Country Where Event Occurred

AUSTRIA

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	2	1	1		1
Accommodation disorder	1	1	1	1		
Acute coronary syndrome		1				1
Acute kidney injury		1				1
Acute left ventricular failure		1				1
Acute myocardial infarction		1				1
Ageusia	1	1			1	1
Agitation	1	2	1	2		
Agranulocytosis		1				1
Alanine aminotransferase increased		1		1		
Allergy to vaccine	1	1	1	1		
Alopecia		1		1		
Altered visual depth perception		1		1		
Amnesia		1		1		
Anaemia	3	4			3	4
Anaphylactic reaction		1				1
Anaphylactic shock		2				2
Anaphylactoid reaction		1				1
Angina pectoris	1	3			1	3
Anosmia	1	1			1	1
Antiphospholipid syndrome		1				1
Aphasia		1				1
Apnoea		1				1
Application site pain		1		1		
Arrhythmia	2	5			2	5
Arterial occlusive disease		1				1
Arteriosclerosis coronary artery		1				1
Arthralgia	7	21	6	12	1	9
Arthritis	1	1	1	1		
Aspartate aminotransferase increased		1		1		
Aspiration		1				1
Asthenia	7	19	3	10	4	9
Asymptomatic COVID-19	3	4			3	4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Atrial fibrillation	1	6			1	6
Autoimmune thyroiditis		1				1
Back pain		4		1		3
Bacterial sepsis		1				1
Balance disorder	1	3	1	1		2
Basal ganglia stroke		1				1
Basilar migraine		1				1
Benign prostatic hyperplasia	1	1			1	1
Blindness unilateral	1	1			1	1
Blood creatine phosphokinase increased		2		1		1
Blood creatine phosphokinase MB increased		1				1
Blood glucose decreased	1	1			1	1
Blood glucose fluctuation	2	2			2	2
Blood glucose increased		1				1
Blood pressure decreased	1	3			1	3
Blood pressure immeasurable		1				1
Blood pressure increased	1	3	1	1		2
Blood pressure systolic increased		1				1
Body temperature increased		3		2		1
Bradycardia		1				1
Bradykinesia		1		1		
Brain natriuretic peptide increased		1				1
Breath sounds		1		1		
Breath sounds abnormal		1				1
Bronchial obstruction		1				1
Bronchitis		1				1
Bundle branch block left		1				1
Bundle branch block right		1				1
Burning sensation		1		1		
Bursitis		1		1		
Cachexia		2				2
Cardiac arrest		3				3
Cardiac death		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac failure	2	9			2	9
Cardiac failure acute		1				1
Cardiomegaly	1	1			1	1
Cardiopulmonary failure	1	3			1	3
Cardio-respiratory arrest		2				2
Cardiovascular disorder	3	7	3	6		1
Cerebral haemorrhage		1				1
Cerebral infarction		2				2
Cerebral ischaemia		1				1
Cerebral venous sinus thrombosis	1	2			1	2
Cerebrovascular accident	1	3			1	3
Chest discomfort		7		2		5
Chest pain	1	8		3	1	5
Chills	10	32	9	22	1	10
Choking		1				1
Cholestasis		1				1
Chromaturia	1	1			1	1
Chronic kidney disease		1				1
Chronic obstructive pulmonary disease	1	3	1	1		2
Circulatory collapse	1	9			1	9
Coagulation factor increased	1	1			1	1
Concomitant disease aggravated		1				1
Concomitant disease progression		1				1
Concussion		1				1
Condition aggravated	2	4		1	2	3
Confusional state	2	6	2	3		3
Conjunctival haemorrhage		1				1
Coronary artery stenosis		1				1
Cough	2	6	1	4	1	2
COVID-19	8	20			8	20
COVID-19 pneumonia	3	5			3	5
C-reactive protein increased		2		1		1
Death	1	14			1	14

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	3	7	2	5	1	2
Deep vein thrombosis	8	13			8	13
Dehydration		1				1
Depression	1	1			1	1
Device related infection		1				1
Diarrhoea	5	13	5	12		1
Diarrhoea haemorrhagic		1				1
Diffuse alveolar damage	1	1			1	1
Diplopia	1	1			1	1
Discomfort		1		1		
Disease progression		1				1
Disease recurrence		1				1
Disorientation	1	4	1	3		1
Disturbance in attention	2	3	2	3		
Dizziness	7	20	3	8	4	12
Dizziness postural		1		1		
Drug eruption		1				1
Drug ineffective	3	11			3	11
Dry mouth		2		2		
Dry throat		1		1		
Dysacusis	1	1	1	1		
Dysaesthesia	2	2	1	1	1	1
Dysarthria	1	1			1	1
Dysgeusia		3		1		2
Dyskinesia		1				1
Dysphagia		3		1		2
Dyspnoea	11	26	3	5	8	21
Dyspnoea at rest	1	1			1	1
Dyspnoea exertional	1	3			1	3
Dysstasia		1				1
Ear discomfort		1		1		
Ear pruritus	1	1	1	1		
Ear swelling	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eczema		2		1		1
Electrocardiogram ST segment elevation		1				1
Electrocardiogram ST-T change		1				1
Emphysema		1				1
Endocrine ophthalmopathy		1				1
Epilepsy		2				2
Erythema	1	3	1	2		1
Escherichia sepsis		1				1
Exercise tolerance decreased		1		1		
External ear pain		1				1
Extrasystoles	1	3		1	1	2
Eye contusion		1				1
Eye haemorrhage		1				1
Eyelid contusion		1				1
Eyelid oedema	1	1	1	1		
Eyelid ptosis	1	1			1	1
Eye pain		1				1
Eye pruritus		1		1		
Facial asymmetry		1				1
Facial paralysis	2	2			2	2
Facial paresis	2	6			2	6
Faecal calprotectin increased		1				1
Faeces pale	1	1			1	1
Fall	2	6	1	1	1	5
Fatigue	18	50	14	39	4	11
Febrile convulsion	2	2			2	2
Feeling abnormal		2		1		1
Feeling cold	1	2	1	1		1
Feeling hot	1	2	1	1		1
Feeling jittery	1	1			1	1
Fibrin D dimer increased		1				1
Flushing		3		1		2
Foreign body aspiration		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Formication		1		1		
Gait disturbance	1	5	1	3		2
Gastroenteritis		1		1		
Gastrointestinal disorder		1		1		
Generalised tonic-clonic seizure		2				2
General physical health deterioration	4	14		1	4	13
Guillain-Barre syndrome	2	2			2	2
Haematemesis		1				1
Haematoma		1				1
Haemolytic anaemia	1	1			1	1
Haemorrhage intracranial	1	1			1	1
Headache	19	53	17	39	2	14
Head banging		1				1
Head discomfort	1	1	1	1		
Head injury		1				1
Heart rate decreased		1				1
Heart rate increased		1				1
Hemiataxia	1	1			1	1
Hemiparaesthesia	1	1			1	1
Hemiparesis	1	3			1	3
Herpes zoster	2	3	1	1	1	2
Hypereosinophilic syndrome	1	1			1	1
Hyperglycaemia		2				2
Hyperhidrosis	2	2	1	1	1	1
Hyperkalaemia	1	1			1	1
Hypernatraemia		1				1
Hypersensitivity	1	4			1	4
Hypersomnia		1		1		
Hypertension	1	3			1	3
Hypertensive crisis		2				2
Hypertensive emergency		1				1
Hyperventilation		3		1		2
Hypoacusis	2	2	1	1	1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia	2	7	1	3	1	4
Hypoaesthesia oral	1	2	1	2		
Hypogeusia		1				1
Hypoglycaemia	1	1			1	1
Hypokinesia		1		1		
Hyponatraemia	1	1			1	1
Hypophagia		1				1
Hypopnoea		1				1
Hyposmia		1				1
Hypotension	1	4	1	3		1
Hypothermia	1	1			1	1
Hypotonia		3		2		1
Hypoxia	1	1			1	1
Immobilisation syndrome	1	1			1	1
Immune thrombocytopenia		1				1
Immunisation anxiety related reaction	1	1			1	1
Impaired driving ability		1				1
Impaired work ability	2	2			2	2
Inappropriate schedule of product administration		1		1		
Incontinence		1				1
Incorrect route of product administration	2	5	2	5		
Infection	1	3			1	3
Inflammatory marker increased	3	3			3	3
Influenza like illness	1	2	1	1		1
Insomnia	1	2		1	1	1
Interleukin level increased		1				1
Intermenstrual bleeding	1	1	1	1		
Intervertebral disc protrusion	1	2			1	2
Intraventricular haemorrhage		1				1
Ischaemic cardiomyopathy	1	1			1	1
Ischaemic cerebral infarction		1				1
Ischaemic stroke		1				1
Jaundice	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint swelling		4		2		2
Lack of spontaneous speech		1				1
Language disorder		1		1		
Left ventricular failure		2				2
Leukocytosis		2				2
Leukoencephalopathy		1				1
Leukopenia	2	3			2	3
Limb discomfort		1				1
Lip oedema	1	1	1	1		
Lip pruritus		1				1
Lip swelling		1				1
Locked-in syndrome		1				1
Loss of consciousness		3				3
Loss of personal independence in daily activities		1				1
Lung infiltration		1				1
Lymphadenopathy	5	8	3	6	2	2
Lymph node pain	2	3	2	3		
Lymph node palpable		1		1		
Lymphocyte count increased		2		1		1
Lymphocytosis		1				1
Lymphopenia		1		1		
Malaise	1	2			1	2
Marasmus	1	2			1	2
Meningitis bacterial		1				1
Menstruation irregular	1	1	1	1		
Mesenteric vein thrombosis	1	1			1	1
Migraine		1		1		
Mouth swelling		1				1
Multiple organ dysfunction syndrome		3				3
Muscle atrophy		1		1		
Muscle contractions involuntary		1		1		
Muscle disorder		1				1
Muscle rigidity	1	1	1	1		

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle spasms		5		4		1
Muscular weakness	1	5		2	1	3
Musculoskeletal disorder		1				1
Myalgia	8	22	8	19		3
Myasthenia gravis	1	1			1	1
Myocardial infarction	1	2			1	2
Myocarditis		2				2
Nausea	8	30	7	23	1	7
Neck pain	1	2	1	2		
Neuralgia		1				1
Neuralgic amyotrophy		1				1
Neuropathy peripheral		1				1
Neutropenia		1				1
Obstructive airways disorder		1		1		
Ocular hyperaemia		1		1		
Ocular myasthenia	1	1			1	1
Oculofacial paralysis	1	1			1	1
Oedema peripheral	1	2			1	2
Off label use		7		7		
Oral pruritus		1				1
Organising pneumonia	1	1			1	1
Oropharyngeal pain		2		2		
Oxygen saturation		1				1
Oxygen saturation abnormal	1	1	1	1		
Oxygen saturation decreased		4		1		3
Oxygen saturation immeasurable		1				1
Pain	1	5	1	3		2
Pain in extremity	6	18	4	14	2	4
Pain in jaw	1	1	1	1		
Pain of skin	1	1			1	1
Pallor		4		2		2
Palmar erythema		1				1
Palpitations	1	3	1	2		1

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* AE=Adverse Event
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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pancytopenia	1	1			1	1
Panic attack		1				1
Paraesthesia		7		3		4
Paraesthesia oral	1	3	1	1		2
Paralysis	1	1			1	1
Paresis		1				1
Pemphigus		1				1
Performance status decreased	1	1			1	1
Pericardial effusion		1				1
Pericarditis		1				1
Peripheral embolism	1	1			1	1
Peripheral swelling	1	5		1	1	4
Personality change		1				1
Petit mal epilepsy		1				1
Pharyngeal swelling		1		1		
Phlebitis superficial	1	1			1	1
Photophobia	1	3		2	1	1
Platelet count decreased	1	1			1	1
Pleural effusion	2	5			2	5
Pneumonia		7				7
Pneumonia aspiration		4				4
Pneumonia bacterial		1				1
Presyncope	1	11		2	1	9
Productive cough		1		1		
Product use issue		6		6		
Pruritus	4	16		2	4	14
Psoriasis		1				1
Pulmonary embolism	10	23			10	23
Pulmonary hypertensive crisis		1				1
Pulmonary infarction	1	2			1	2
Pulmonary oedema		2				2
Pulpitis dental	1	1			1	1
Pupillary reflex impaired		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia	21	54	18	34	3	20
Rales		2		1		1
Rash	4	12	2	4	2	8
Rash macular		2				2
Rash morbilliform		1				1
Rash papular	1	1			1	1
Rash pruritic	1	4	1	3		1
Renal failure		2				2
Renal function test abnormal	1	1	1	1		
Respiratory acidosis		1				1
Respiratory depression		1				1
Respiratory failure	2	3			2	3
Respiratory rate decreased		1				1
Restlessness		2		2		
Retinal artery occlusion		1				1
Retinal vein thrombosis	1	1			1	1
Retrograde amnesia	1	1	1	1		
Rhabdomyolysis		1				1
Rheumatoid arthritis		1				1
Rib fracture		1				1
Road traffic accident		1				1
SARS-CoV-2 ant body test negative		2				2
SARS-CoV-2 test positive	2	4			2	4
Sciatica	1	1			1	1
Seizure		3				3
Sensation of foreign body		1				1
Sepsis	1	2			1	2
Septic shock		1				1
Shock		1				1
Sinus tachycardia		1				1
Skin exfoliation		1		1		
Skin lesion		1				1
Somnolence		8		4		4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Speech disorder		2		1		1
Spinal pain		2		1		1
Splenic vein thrombosis		1				1
Status epilepticus	1	2			1	2
Subdural haemorrhage		1				1
Sudden cardiac death	1	1			1	1
Supraventricular tachycardia		1				1
Swelling		3		2		1
Swelling face	1	2	1	2		
Swollen tongue	1	1			1	1
Syncope	1	8			1	8
Systemic inflammatory response syndrome		1				1
Tachycardia	4	5			4	5
Tachycardia paroxysmal		1				1
Tachypnoea		1		1		
Thalamic infarction	1	1			1	1
Thirst		1		1		
Throat irritation	1	3	1	2		1
Thrombocytopenia	3	4			3	4
Thrombophlebitis	1	2			1	2
Thrombosed varicose vein		1				1
Thrombosis	1	4			1	4
Tinnitus	2	4		1	2	3
Tongue discomfort		1				1
Toothache		1				1
Transient ischaemic attack		1				1
Tremor	2	3	1	2	1	1
Trichoglossia		1		1		
Trigeminal neuralgia		1				1
Troponin T increased		2				2
Tunnel vision	1	1	1	1		
Type I hypersensitivity		1				1
Unresponsive to stimuli	1	3			1	3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urinary retention	1	2			1	2
Urine ketone body present		1		1		
Urticaria	5	10		1	5	9
Vaccination failure	11	14			11	14
Vaccination site discolouration		1				1
Vaccination site erythema	4	6	4	5		1
Vaccination site haemorrhage		1		1		
Vaccination site induration	2	2	2	2		
Vaccination site inflammation	1	1	1	1		
Vaccination site lymphadenopathy	3	4	3	4		
Vaccination site movement impairment		1		1		
Vaccination site pain	9	27	9	22		5
Vaccination site pruritus	2	2	2	2		
Vaccination site rash		1				1
Vaccination site reaction		1		1		
Vaccination site swelling	7	10	7	8		2
Vaccination site urticaria	1	3	1	2		1
Vaccination site warmth		1		1		
Vaginal discharge		1		1		
Vascular encephalopathy		1				1
Venous thrombosis limb		3		1		2
Ventricular extrasystoles		1				1
Vertigo	1	8	1	4		4
Vision blurred		2		2		
Visual impairment	2	5	1	1	1	4
Vomiting	2	11	2	8		3
Weight bearing difficulty	1	1			1	1
Wound haemorrhage		1				1
Wrong technique in product usage process		1		1		
	420	1,320	193	519	227	801

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Country Where Event Occurred

BAHRAIN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills		1		1
Pain		1		1
Pyrexia		1		1
		3		3

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Country Where Event Occurred

BELGIUM

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		2				2
Abdominal pain upper	1	4			1	4
Abnormal dreams	1	1			1	1
Acute kidney injury	1	4			1	4
Acute psychosis		1				1
Acute respiratory failure		3				3
Aggression	1	1			1	1
Agitation		4				4
Altered state of consciousness		2				2
Amnesia		1				1
Anaphylactic reaction	1	11			1	11
Anaphylactic shock		1				1
Angle closure glaucoma		1				1
Anxiety		2				2
Apathy		2		1		1
Aphasia	1	3			1	3
Aphonia	1	1	1	1		
Aphthous ulcer	1	2	1	1		1
Arthralgia	15	47	3	9	12	38
Arthritis		1		1		
Asthenia	1	9			1	9
Asthma	1	2	1	1		1
Asthma exercise induced		1				1
Atrioventricular block complete		1				1
Autoimmune disorder		3				3
Axillary mass		1				1
Axillary pain	2	2	1	1	1	1
Back pain	2	3	1	1	1	2
Balance disorder	1	5			1	5
Bell's palsy	1	1			1	1
Blood alkaline phosphatase increased	1	1			1	1
Blood glucose decreased		1		1		
Blood glucose increased		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood lactic acid increased		1				1
Blood pressure decreased	2	3	1	1	1	2
Blood pressure increased		2				2
Blood urine present		1				1
Body temperature increased	1	3	1	1		2
Bone pain		1				1
Bradycardia		2				2
Brain injury		1				1
Bronchial disorder		1				1
Bronchospasm	1	2			1	2
Burning sensation	1	2		1	1	1
Cardiac arrest		4				4
Cardiac failure		3				3
Cardiogenic shock		2				2
Cardiomegaly	1	2			1	2
Cardio-respiratory arrest	1	3			1	3
Cardiovascular disorder	1	18	1	2		16
Carotid artery occlusion	1	1			1	1
Cerebral haemorrhage		1				1
Cerebral ischaemia		1				1
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident		5				5
Chest discomfort		1		1		
Chest pain	1	6			1	6
Cheyne-Stokes respiration		1				1
Chills	17	67	2	4	15	63
Coagulopathy	6	10			6	10
Cold sweat		2				2
Coma		1				1
Confusional state	1	3			1	3
Conjunctival hyperaemia	1	1			1	1
Contusion		1				1
Cough	1	7		1	1	6

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	11		1	1	10
COVID-19 pneumonia		1				1
C-reactive protein increased	1	3		1	1	2
Cutaneous vasculitis	1	1			1	1
Cyanosis		1				1
Death	4	4			4	4
Decreased appetite	3	9	1	2	2	7
Deep vein thrombosis		2				2
Delirium	1	1			1	1
Depressed level of consciousness		5				5
Diabetic complication		1				1
Diaphragmalgia		1				1
Diarrhoea	1	4		1	1	3
Diplopia	1	1			1	1
Discomfort	1	1			1	1
Disease recurrence		1				1
Disorientation	1	2			1	2
Dizziness	1	15	1	4		11
Dizziness postural		1				1
Drug ineffective		5				5
Dry mouth		2				2
Dry throat		1				1
Dysphonia	1	2	1	1		1
Dyspnoea	5	24		1	5	23
Dyspnoea exertional		1				1
Dyspraxia		1				1
Dysstasia		2				2
Dystonia		1				1
Ear discomfort		1		1		
Eczema	1	1	1	1		
Endocrine ophthalmopathy		1				1
Epilepsy	1	4			1	4
Epistaxis	1	2	1	1		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erysipelas	1	1			1	1
Erythema		4		2		2
Erythema multiforme	1	1			1	1
Eschar		1				1
Exercise tolerance decreased		1				1
Extensive swelling of vaccinated limb	1	3			1	3
Eye movement disorder		1				1
Eye pain	1	4	1	2		2
Eye swelling	1	2	1	1		1
Face oedema		1				1
Facial nerve disorder	1	1			1	1
Facial paralysis	1	3			1	3
Facial paresis	1	3			1	3
Fall		5		1		4
Fatigue	33	95	7	15	26	80
Feeding disorder	1	1			1	1
Feeling abnormal	1	2			1	2
Feeling cold		1				1
Feeling of body temperature change		1				1
Fibrin D dimer increased	1	2			1	2
Flatulence	1	1			1	1
Gait disturbance		2				2
Gastric dilatation		1		1		
Gastrointestinal disorder	1	2			1	2
Gastrointestinal pain		1				1
Generalised tonic-clonic seizure		3				3
General physical health deterioration	1	11			1	11
Glaucoma		1				1
Haematoma	2	2	2	2		
Haematuria	1	1	1	1		
Haemophagocytic lymphohistiocytosis	1	1			1	1
Haemoptysis	1	1			1	1
Haemorrhagic transformation stroke	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hallucination		1				1
Hallucination, visual		1				1
Headache	28	101	4	13	24	88
Heart rate increased		3				3
Hemiparesis	1	2			1	2
Hemiplegia	1	2			1	2
Hepatic failure		1				1
Herpes ophthalmic		1				1
Herpes simplex		1				1
Herpes zoster	2	3	2	2		1
Hot flush		2		2		
Hyperglycaemia	1	1			1	1
Hyperhidrosis	1	2	1	1		1
Hypersensitivity		1				1
Hypersomnia		1				1
Hypertension	1	6			1	6
Hyperventilation	1	1	1	1		
Hypoaesthesia	1	3			1	3
Hypoglycaemia	1	5	1	1		4
Hypokalaemia		1				1
Hyponatraemia		1				1
Hypotension	2	8	2	2		6
Hypovolaemic shock		1				1
Hypoxia		1				1
Illusion		1				1
Immobile		1				1
Inappropriate schedule of product administration		1		1		
Inflammation	1	2			1	2
Influenza like illness	2	10	1	4	1	6
Injection site erythema		1				1
Injection site hypersensitivity		1				1
Insomnia	2	3		1	2	2
Intestinal ischaemia		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Iridocyclitis	1	1			1	1
Ischaemic stroke	2	2			2	2
Joint range of motion decreased		1				1
Joint stiffness		1				1
Ketoacidosis		3				3
Lacrimation increased	1	2		1	1	1
Lactic acidosis		2				2
Laryngitis		1				1
Leukocytosis	1	1			1	1
Leukocyturia		1		1		
Limb discomfort		1				1
Lip swelling	1	1	1	1		
Livedo reticularis		1				1
Liver function test abnormal		3				3
Loss of consciousness		1				1
Loss of personal independence in daily activities	1	1			1	1
Lung infiltration		1				1
Lymphadenopathy	1	4			1	4
Lymph node pain		1				1
Malaise	16	63	3	7	13	56
Mastication disorder	1	1			1	1
Memory impairment		1				1
Metabolic acidosis		1				1
Microangiopathic haemolytic anaemia	1	1			1	1
Migraine	2	2			2	2
Mobility decreased		1				1
Multiple organ dysfunction syndrome		1				1
Mumps	1	1	1	1		
Muscle contractions involuntary		1				1
Muscle disorder	1	1			1	1
Muscle spasms	1	1	1	1		
Muscle strain	1	3		1	1	2
Muscular weakness		4		1		3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal chest pain		2		1		1
Musculoskeletal stiffness	2	8	1	2	1	6
Myalgia	21	69		3	21	66
Myocardial infarction		1				1
Myocarditis	1	1			1	1
Nasopharyngitis	1	1			1	1
Nausea	20	60	4	6	16	54
Neck pain	1	6	1	1		5
Nerve compression	1	1			1	1
Nervous system disorder	4	18		3	4	15
Neuropathic muscular atrophy	1	1			1	1
Neuropathy peripheral		1				1
Neutropenia		1				1
Night sweats		1				1
Noninfective encephalitis	1	1			1	1
N-terminal prohormone brain natriuretic peptide increased		1				1
Ocular hyperaemia		1		1		
Off label use		2		2		
Oral herpes		3		1		2
Oropharyngeal discomfort	1	1	1	1		
Oropharyngeal pain		3				3
Orthostatic hypotension	1	1	1	1		
Oxygen saturation decreased		10				10
Pain	2	6	1	2	1	4
Painful respiration	1	3	1	1		2
Pain in extremity	6	16	2	4	4	12
Pain of skin		1				1
Pallor		2				2
Palmoplantar pustulosis		1		1		
Palpitations	1	2			1	2
Paraesthesia	1	4		1	1	3
Paraesthesia oral	1	3			1	3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Parapharyngeal space infection		1				1
Paresis		1				1
Parkinson's disease		1				1
Parotid gland enlargement	1	1			1	1
Patient elopement		1				1
Pelvic pain	1	1	1	1		
Peripheral swelling	1	5	1	2		3
Petechiae	1	1	1	1		
Pharyngeal swelling		1				1
Photophobia	1	1			1	1
Platelet count decreased	1	1			1	1
Pleural effusion		1				1
Pneumonia		2				2
Pneumonia aspiration	1	1			1	1
Pneumonitis		2				2
Posture abnormal		1		1		
Presyncope		3				3
Productive cough	1	2			1	2
Product use issue		2		2		
Prohormone brain natriuretic peptide increased		1				1
Pruritus	3	7	1	2	2	5
Pulmonary embolism	5	8			5	8
Pulmonary infarction		1				1
Pulmonary oedema		2				2
Pyrexia	18	69	5	11	13	58
Rales		1				1
Rash	1	1	1	1		
Rash macular	1	2	1	1		1
Rash maculo-papular	1	1	1	1		
Rectal haemorrhage	1	1			1	1
Red blood cell sedimentation rate increased		1		1		
Renal disorder		2				2
Renal failure		3				3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiration abnormal		2				2
Respiratory acidosis		1				1
Respiratory arrest	1	1			1	1
Respiratory disorder	2	17		2	2	15
Respiratory distress		3				3
Respiratory failure	1	2			1	2
Respiratory rate increased		1				1
Restlessness		2		1		1
Retching		2				2
Rhinitis		1				1
Rhinorrhoea		1				1
Rhythm idioventricular		1				1
Salivary gland pain	1	1			1	1
SAPHO syndrome		1				1
SARS-CoV-2 ant body test negative	1	1			1	1
SARS-CoV-2 ant body test positive		1		1		
SARS-CoV-2 test positive		1				1
Sedation		2				2
Seizure		3				3
Sense of oppression		1		1		
Septic shock		2				2
Sinus headache		1				1
Sinus pain		1				1
Skin discolouration	1	1	1	1		
Skin disorder	6	16	3	5	3	11
Skin haemorrhage	1	1	1	1		
Sleep disorder		1				1
Sleep disorder due to general medical condition, insomnia type	1	1			1	1
Sneezing		1		1		
Somnolence	2	6			2	6
Speech disorder		2		2		
Spinal pain	1	2		1	1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Staring		1				1
Subdural haematoma	1	1			1	1
Sudden death	5	15			5	15
Swelling face	1	3	1	2		1
Swelling of eyelid	1	1			1	1
Swollen tongue		1				1
Syncope	2	4			2	4
Tachycardia		5		1		4
Tachypnoea		2				2
Taste disorder	1	1			1	1
Tendonitis	1	1			1	1
Therapeutic response unexpected		1		1		
Thrombocytopenia	5	5			5	5
Thrombophlebitis superficial	1	1	1	1		
Thrombosis	2	3			2	3
Tonsillitis		1				1
Tremor		2				2
Trigeminal neuralgia	2	2			2	2
Troponin increased		2				2
Troponin T increased		1				1
Tumour thrombosis	1	1			1	1
Unresponsive to stimuli		2				2
Urinary tract infection		1		1		
Urticaria	1	4			1	4
Vaccination failure		1				1
Vaccination site erythema	2	5		1	2	4
Vaccination site haematoma		1		1		
Vaccination site induration	1	2			1	2
Vaccination site inflammation	1	1			1	1
Vaccination site joint pain	1	1			1	1
Vaccination site pain	4	19	1	3	3	16
Vaccination site reaction	20	49	5	7	15	42
Vaccination site swelling	1	3			1	3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site warmth	1	3			1	3
Vaginal haemorrhage	1	1	1	1		
Venous thrombosis limb	1	1			1	1
Vertigo		7		2		5
Visual impairment		2				2
Vomiting	5	13	1	1	4	12
Wheezing		2				2
White blood cell count decreased	1	2		1	1	1
Wrong product administered		1		1		
	410	1,457	87	205	323	1252

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Country Where Event Occurred

BERMUDA

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Balance disorder		1		1		
Dizziness		1		1		
Sudden visual loss		1				1
		3		2		1

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Country Where Event Occurred

BRAZIL

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	1	1	1	1		
Agitation	1	1	1	1		
Anxiety	1	1	1	1		
Arthralgia	1	1	1	1		
Asthenia	2	2	2	2		
Chills	2	2	2	2		
Cough	1	1	1	1		
Dizziness	1	1	1	1		
Dyskinesia	1	1	1	1		
Dysphonia	1	1	1	1		
Epistaxis	1	1	1	1		
Eyelid oedema	1	1	1	1		
Eyelid pain	1	1	1	1		
Eye pain	1	1	1	1		
Eye swelling	1	1	1	1		
Fatigue	3	3	3	3		
Headache	2	2	2	2		
Heart rate increased	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Lymphocyte count decreased	1	1	1	1		
Lymphopenia	1	1	1	1		
Malaise	2	2	2	2		
Myalgia	3	3	3	3		
Nausea	2	2	2	2		
Neutrophil count decreased	1	1	1	1		
Pain	2	2	2	2		
Pain in extremity	6	6	6	6		
Peripheral swelling	1	1	1	1		
Product administered at inappropriate site	1	1	1	1		
Pyrexia	5	5	5	5		
Sluggishness	2	2	2	2		
Somnolence	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia	1	1	1	1		
Throat irritation	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination site haemorrhage	1	1			1	1
Vaccination site inflammation	1	1			1	1
Vaccination site mass	1	1			1	1
Vaccination site pain	6	6	4	4	2	2
White blood cell count decreased	1	1	1	1		
	66	66	61	61	5	5

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Country Where Event Occurred

BULGARIA

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation		1		1		
Antibody test abnormal		1		1		
Arthralgia	1	5	1	5		
Asthenia		2		2		
Blood glucose increased	1	2		1	1	1
Blood pressure decreased		1				1
Blood pressure diastolic decreased		1		1		
Blood pressure increased		2		1		1
Body temperature increased	1	5	1	5		
Chest pain		1		1		
Chills		3		2		1
Cough	1	2	1	2		
COVID-19		2				2
Diarrhoea		1		1		
Dizziness		4		3		1
Dizziness postural		1		1		
Drug ineffective		2				2
Drug interaction	1	1			1	1
Dyspnoea		2		1		1
Epistaxis	1	2	1	2		
Erythema		1		1		
Extrasystoles		1		1		
Fatigue	3	7	3	7		
Feeling abnormal	1	1	1	1		
Gait disturbance		2		2		
Headache	4	9	3	7	1	2
Head discomfort		1				1
Heart rate increased	1	1	1	1		
Hyperglycaemia	1	1			1	1
Hyperhidrosis		1				1
Hypertension	1	1			1	1
Hypoaesthesia	1	1	1	1		
Lacrimation increased		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lethargy		1		1		
Limb discomfort		2		2		
Lip swelling	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Mastication disorder		1		1		
Musculoskeletal stiffness	1	1	1	1		
Myalgia	1	3	1	3		
Myelitis transverse		1				1
Nasopharyngitis		1		1		
Nausea	1	3	1	2		1
Neuromyelitis optica spectrum disorder		1				1
Oedema peripheral		1		1		
Oropharyngeal pain	1	2	1	2		
Pain		1		1		
Painful respiration		1		1		
Pallor		1		1		
Paraesthesia	1	2	1	2		
Paraesthesia oral		1		1		
Paranasal sinus discomfort		1		1		
Peripheral coldness		1		1		
Peripheral sensory neuropathy		1		1		
Peripheral swelling	1	1	1	1		
Photophobia	1	2	1	2		
Pneumonia	1	1			1	1
Poor peripheral circulation	1	1	1	1		
Pyrexia	3	4	3	4		
Rash		1		1		
Rash erythematous		1		1		
Rash pruritic		1		1		
Rhinorrhoea		1		1		
SARS-CoV-2 test positive		1				1
Seizure		1				1
Swelling		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling face	1	1	1	1		
Thirst		1		1		
Trismus		1		1		
Vaccination site erythema	1	3	1	3		
Vaccination site extravasation		1		1		
Vaccination site pain	2	7	2	7		
Vaccination site pruritus	1	1	1	1		
Vaccination site reaction		1		1		
Vaccination site swelling		2		2		
Vertigo		1				1
	37	132	31	108	6	24

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Country Where Event Occurred

CANADA

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain	1	1			1	1
Abdominal pain upper	5	7	4	5	1	2
Abnormal dreams		1		1		
Acute kidney injury		1				1
Ageusia		1		1		
Agitation		1		1		
Amyloidosis	1	1			1	1
Anal incontinence	1	1			1	1
Anaphylactic reaction	2	12			2	12
Anaphylactic shock		1				1
Anger	1	1	1	1		
Angioedema		1				1
Angiopathy		1		1		
Anosmia		1		1		
Anxiety	2	3		1	2	2
Aphthous ulcer		1		1		
Arrhythmia	3	4			3	4
Arthralgia	12	28	9	23	3	5
Arthritis	6	7	1	2	5	5
Arthritis reactive	1	1			1	1
Asthenia	3	12	2	9	1	3
Asthma	1	2		1	1	1
Ataxia	1	1			1	1
Atrial f brillation		1				1
Autoimmune disorder	2	3			2	3
Axillary pain	1	2	1	2		
Back pain	4	7	3	5	1	2
Balance disorder		1				1
Bell's palsy	1	4			1	4
Blister	1	1			1	1
Blood glucose decreased	2	2	1	1	1	1
Blood pressure decreased	1	2	1	1		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure fluctuation	1	2		1	1	1
Blood pressure increased		1		1		
Blood pressure orthostatic abnormal	1	1			1	1
Blood pressure systolic increased	1	1	1	1		
Blood urine present		1		1		
Body temperature increased	1	2	1	2		
Bradycardia		1				1
Breast pain	2	2	2	2		
Bronchitis		1		1		
Burning sensation	4	5	4	5		
Bursitis		1		1		
Cardiac arrest	1	1			1	1
Cardiac disorder		1				1
Cardiac failure		1				1
Cardiac flutter		2				2
Carotid artery dissection		1				1
Carotid artery thrombosis		1				1
Cellulitis		1				1
Cerebrovascular accident	1	3			1	3
Chest discomfort	2	7		3	2	4
Chest pain	5	7	3	5	2	2
Chills	5	20	4	18	1	2
Choking	1	1			1	1
Chronic obstructive pulmonary disease		1				1
Colitis ischaemic	1	1			1	1
Colitis ulcerative		1				1
Condition aggravated	4	8	2	2	2	6
Confusional state	2	3	1	2	1	1
Constipation	1	1	1	1		
Contusion	2	2	1	1	1	1
Conversion disorder	1	1			1	1
Cough	1	5	1	4		1
COVID-19		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness	1	2			1	2
Deafness unilateral	1	1			1	1
Death		1				1
Decreased appetite		5		4		1
Delirium		1				1
Depressed level of consciousness		1				1
Dermatitis		1				1
Diarrhoea	4	13	4	11		2
Diplopia		1				1
Discomfort	3	3	2	2	1	1
Disease recurrence	3	7	1	2	2	5
Disseminated varicella zoster virus infection		1				1
Disturbance in attention	1	2		1	1	1
Dizziness	15	33	10	23	5	10
Dizziness postural	1	2	1	2		
Drug hypersensitivity		1		1		
Drug interaction	2	3	1	1	1	2
Drug level increased		1				1
Dry eye		1		1		
Dry mouth		2		2		
Dysgeusia	1	6		5	1	1
Dyskinesia	1	1	1	1		
Dysphagia	2	5	1	3	1	2
Dysphonia		1		1		
Dyspnoea	6	16	3	10	3	6
Dysuria		2		1		1
Ear discomfort	1	3		2	1	1
Ear pruritus	1	1	1	1		
Ear swelling	1	1	1	1		
Encephalitis autoimmune	1	1			1	1
Epistaxis		1		1		
Erythema	3	7	3	5		2
Exposure during pregnancy		3		3		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye movement disorder	2	2			2	2
Eye pain	1	1			1	1
Eye swelling	1	1	1	1		
Face oedema		1				1
Faeces soft		1		1		
Fall		3		1		2
Fatigue	13	46	12	42	1	4
Feeling abnormal	5	10	4	9	1	1
Feeling cold		3		3		
Feeling hot	2	4	2	4		
Feeling of body temperature change		1		1		
Fibrin D dimer increased	1	1	1	1		
Fibromyalgia		1		1		
Flatulence		1		1		
Flushing	1	3	1	2		1
Gait disturbance	2	4	2	3		1
Galactostasis	1	1	1	1		
Gastric ulcer		2				2
Gastrointestinal disorder		1		1		
Gastrointestinal pain		1		1		
Generalised tonic-clonic seizure		1				1
Gout	3	3	2	2	1	1
Haematemesis		1				1
Haematochezia		1				1
Haemorrhage	1	1			1	1
Haemorrhage urinary tract		2				2
Hallucination	1	1			1	1
Headache	16	50	12	43	4	7
Head discomfort	2	2	2	2		
Heart rate decreased	1	3	1	2		1
Heart rate increased	2	6	1	3	1	3
Heart rate irregular	1	1			1	1
Heavy menstrual bleeding	3	3	3	3		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes simplex	1	2			1	2
Herpes zoster	11	15	11	13		2
Hiatus hernia		1		1		
Hiccups	1	1			1	1
Hot flush	2	2	2	2		
Hunger	1	1			1	1
Hyperaesthesia		1				1
Hyperhidrosis	2	3	1	1	1	2
Hypersensitivity	2	9	1	6	1	3
Hypersomnia		1		1		
Hypertension	3	8	2	3	1	5
Hypoacusis	1	2	1	2		
Hypoaesthesia	9	15	5	8	4	7
Hypoaesthesia oral		3		1		2
Hypotension	3	4	2	3	1	1
Hypoxia		1				1
Idiopathic angioedema	1	1			1	1
Illness	1	3	1	3		
Impaired work ability		1		1		
Inappropriate schedule of product administration	2	7	2	7		
Incoherent	1	1	1	1		
Incontinence		1				1
Inflammation	1	1	1	1		
Inflammatory pain	1	1			1	1
Influenza like illness		2		2		
Injection site bruising	1	1	1	1		
Injection site haemorrhage	1	1	1	1		
Injection site pain	1	3	1	3		
Insomnia	3	6	3	6		
Ischaemic stroke		1				1
IVth nerve paralysis		1				1
Joint noise		1		1		
Joint stiffness	2	2	1	1	1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint swelling	2	4	1	3	1	1
Joint warmth	1	1			1	1
Lacrimation increased		2		2		
Laryngeal oedema	1	1			1	1
Lethargy	1	2	1	2		
Leukoplakia		1		1		
Limb discomfort	4	6	3	5	1	1
Lip disorder		1		1		
Lip pain		1		1		
Lip swelling	4	7	2	5	2	2
Livedo reticularis	1	1	1	1		
Loss of consciousness	3	7			3	7
Loss of personal independence in daily activities		1		1		
Lung disorder		1				1
Lymphadenopathy	2	6	2	6		
Lymph node pain		1		1		
Lymphoedema	1	1	1	1		
Malaise	5	15	5	14		1
Mastitis	1	1			1	1
Maternal exposure during pregnancy		3		3		
Melaena		1				1
Meningitis aseptic		1				1
Menstrual disorder	1	1			1	1
Menstruation irregular	2	2	2	2		
Mental disorder	1	1	1	1		
Migraine		2		2		
Migraine with aura		1				1
Monoparesis		1				1
Mouth swelling	2	2	1	1	1	1
Movement disorder	1	2	1	2		
Mucosal discolouration		1		1		
Multiple sclerosis	1	1			1	1
Multiple sclerosis relapse		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle injury		1		1		
Muscle spasms	2	3	1	1	1	2
Muscle twitching	1	2	1	2		
Muscular weakness	1	4		2	1	2
Musculoskeletal chest pain	1	1	1	1		
Musculoskeletal discomfort	1	1	1	1		
Musculoskeletal stiffness	1	6	1	6		
Myalgia	6	20	5	17	1	3
Myocardial infarction	1	3			1	3
Myocarditis	1	2			1	2
Myositis	1	1	1	1		
Nasopharyngitis		1		1		
Nausea	10	28	7	21	3	7
Neck pain	2	4	2	3		1
Necrosis		1				1
Nervousness	1	1	1	1		
Nervous system disorder		1				1
Neuralgia	1	1	1	1		
Neurogenic shock	1	1			1	1
Neuropathy peripheral	3	3			3	3
Neutropenia	1	1			1	1
Night sweats		2		1		1
Ocular discomfort	1	1	1	1		
Oedema peripheral		1		1		
Oesophagitis		1				1
Off label use	8	19	8	19		
Oral discomfort		1		1		
Oral herpes	1	1			1	1
Oropharyngeal discomfort		1		1		
Oropharyngeal pain	1	3	1	3		
Overdose		2		2		
Oxygen saturation decreased		1				1
Pain	6	20	6	18		2

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* AE=Adverse Event

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in extremity	13	26	12	23	1	3
Pain in jaw		2		1		1
Pallor		2		2		
Palpitations	2	4	1	3	1	1
Panic reaction	1	1	1	1		
Paraesthesia	6	15	5	7	1	8
Paraesthesia oral	2	7	1	3	1	4
Paralysis		1				1
Pericarditis	2	3			2	3
Periorbital swelling		1		1		
Peripheral coldness	1	1			1	1
Peripheral swelling	4	6	3	5	1	1
Petechiae		1		1		
Pharyngeal hypoaesthesia		1				1
Pharyngeal paraesthesia		1				1
Pharyngeal swelling	2	3	1	1	1	2
Photophobia	1	1	1	1		
Pneumonia		2				2
Pneumonia aspiration		1				1
Polymenorrhoea	1	1	1	1		
Postmenopausal haemorrhage	1	1			1	1
Postural orthostatic tachycardia syndrome	1	1			1	1
Presyncope	1	2	1	2		
Productive cough		1		1		
Product preparation error		1		1		
Product use issue	7	15	7	15		
Pruritus	5	12	2	7	3	5
Psychomotor hyperactivity	1	1			1	1
Pulmonary embolism	2	3			2	3
Pulmonary oedema		1				1
Pulse volume decreased		2		1		1
Pyrexia	5	18	3	14	2	4
Rash	2	9	1	6	1	3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash erythematous	1	1			1	1
Rash macular	1	2	1	2		
Rash maculo-papular		2		1		1
Rash papular		1		1		
Rash pruritic	2	3		1	2	2
Raynaud's phenomenon		1				1
Rectal haemorrhage		1				1
Rectal polyp		1				1
Respiratory disorder	1	2		1	1	1
Respiratory failure		1				1
Respiratory rate increased	1	1			1	1
Restless arm syndrome	1	1	1	1		
Restless legs syndrome	1	1	1	1		
Rheumatoid arthritis		4				4
Rhinorrhoea	2	5	1	3	1	2
Scleral disorder	1	1	1	1		
Secretion discharge		1		1		
Seizure		1				1
Seizure like phenomena	1	1			1	1
Sensitisation	1	1	1	1		
Sensory disturbance		1				1
Sensory loss	1	1			1	1
Sepsis		1				1
Sinus pain		1		1		
Skin discolouration	1	1	1	1		
Skin disorder		1		1		
Skin injury		1		1		
Sleep disorder	1	2	1	2		
Sluggishness	1	1	1	1		
Sneezing		1		1		
Somnolence	2	3	2	3		
Stress	1	1	1	1		
Sudden death	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling	1	2			1	2
Swelling face	2	3	2	3		
Swollen tongue	1	5		2	1	3
Syncope	3	10			3	10
Synovitis	2	2			2	2
Systemic lupus erythematosus		1				1
Tachycardia	2	7		2	2	5
Tachypnoea		1		1		
Tenderness		1		1		
Tendon disorder	1	2		1	1	1
Therapeutic response unexpected		4		4		
Thirst	1	3	1	3		
Throat irritation		2		2		
Throat tightness	3	6		3	3	3
Thrombophlebitis	1	1			1	1
Thrombosis	4	4			4	4
Thyroiditis	1	1	1	1		
Tinnitus	3	6	1	4	2	2
Tongue disorder		1		1		
Toothache	1	1			1	1
Toxicity to various agents		1				1
Transient ischaemic attack		2				2
Tremor	1	5		4	1	1
Troponin increased		1		1		
Underdose		1		1		
Unresponsive to stimuli	1	1			1	1
Upper-airway cough syndrome		1		1		
Urinary incontinence	1	2			1	2
Urinary tract infection	1	1			1	1
Urticaria	6	15	6	12		3
Uveitis		1				1
Vaccination failure		1				1
Vaccination site cellulitis	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema		2		2		
Vaccination site hypersensitivity	1	1	1	1		
Vaccination site mass		1		1		
Vaccination site pain	11	28	8	23	3	5
Vaccination site rash		2		2		
Vaccination site swelling		1		1		
Vaccination site urticaria	1	2	1	1		1
Vaccination site warmth		2		2		
Vaginal haemorrhage	4	4	1	1	3	3
Varicella		1		1		
Venous bruit	1	1	1	1		
Ventricular tachycardia		1				1
Vertebral artery dissection		1				1
Vertigo	2	3		1	2	2
Vital functions abnormal		1				1
Vitreous detachment		1				1
Vitreous floaters		1		1		
Vomiting	1	12	1	9		3
Vulval disorder		1				1
Vulvitis		1		1		
Weight decreased	1	2	1	2		
Weight increased		1		1		
Wheezing	2	4		2	2	2
White coat hypertension		1				1
	476	1,184	293	777	183	407

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Country Where Event Occurred

CHILE

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		2		1		1
Anaphylactic reaction		1				1
Angina pectoris		1				1
Arrhythmia		1				1
Arthralgia		2		2		
Asthenia	1	1	1	1		
Aversion		1		1		
Back pain		1		1		
Blood glucose increased		1				1
Bone pain		1		1		
Bronchitis	1	1	1	1		
Chest pain		1				1
Chills		1		1		
Choking		1				1
Cough	1	3	1	3		
Decreased appetite		1		1		
Dermatitis allergic		1				1
Diarrhoea		1		1		
Dizziness		1		1		
Dry skin		1		1		
Dysbiosis		1				1
Dyspnoea	1	2	1	1		1
Fall		1				1
Fatigue	1	3	1	3		
Fear	1	1	1	1		
Fear of disease	1	1	1	1		
General physical health deterioration	1	1	1	1		
Glossitis		1		1		
Headache	2	7	2	7		
Head injury		1				1
Hemiparaesthesia		1				1
Hypersensitivity	1	4	1	4		
Hyperventilation		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia		1				1
Hypotension		1				1
Injected limb mobility decreased	1	1	1	1		
Insomnia	1	1	1	1		
Loss of consciousness		1				1
Loss of personal independence in daily activities	1	1	1	1		
Lymph node pain		1		1		
Malaise	1	3	1	3		
Maternal exposure during pregnancy		1		1		
Muscle spasms	1	2	1	2		
Myalgia		2		2		
Myocardial infarction	1	1			1	1
Myocardial ischaemia	1	1			1	1
Nasal congestion		2		2		
Nausea		3		2		1
Off label use	1	1	1	1		
Pain	1	4	1	3		1
Pain in extremity	1	3	1	3		
Pallor		1				1
Pancreatitis		1				1
Panic reaction		1		1		
Paraesthesia		2		1		1
Product use issue	1	1	1	1		
Pruritus		1		1		
Pyrexia	1	4	1	4		
Rash		2		1		1
Rash pruritic		1				1
Seizure		1				1
Sensory loss		1		1		
Skin burning sensation		1		1		
Somnolence		1		1		
Swollen tongue		1		1		
Synovial cyst		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia		1				1
Therapeutic response unexpected	1	1	1	1		
Thirst	1	1	1	1		
Urine analysis abnormal		1				1
Urticaria		1				1
Vaccination site pain	2	4	2	4		
Vestibular disorder		1		1		
Wheezing	1	1	1	1		
Wound haemorrhage		1				1
Wrong product administered		1		1		
	28	112	26	81	2	31

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Country Where Event Occurred

COLOMBIA

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction		1				1
Aphthous ulcer	1	1	1	1		
Arthralgia	1	2	1	2		
Asphyxia	1	1			1	1
Asthenia	1	2	1	2		
Burning sensation	1	1	1	1		
Candida infection		1		1		
Chills	1	3	1	3		
Choking sensation	1	1			1	1
Cough		1		1		
Diarrhoea	1	2	1	2		
Dizziness	1	1	1	1		
Dyspnoea		1		1		
Erythema	1	2	1	2		
Exposure during pregnancy		1		1		
Feeling hot		1		1		
Gingivitis		1		1		
Headache	1	4	1	4		
Herpes zoster	1	1	1	1		
Hypersensitivity		1		1		
Hypertension		1		1		
Leukocytosis		1		1		
Malaise	1	3	1	3		
Myalgia	1	1	1	1		
Odynophagia	1	1	1	1		
Off label use		1		1		
Oral candidiasis		1		1		
Oropharyngeal pain		1		1		
Oxygen saturation decreased	1	1			1	1
Papule	1	1	1	1		
Product use issue		1		1		
Puncture site pain		1		1		
Pyrexia	2	4	2	4		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash		1		1		
Stomatitis		1		1		
Tinnitus	1	1	1	1		
Urticaria		1		1		
Vomiting	1	3	1	3		
	21	54	18	50	3	4

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Country Where Event Occurred

COSTA RICA

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Abdominal pain upper		2				2
Anaphylactic reaction		1				1
Anaphylactic shock		1				1
Arthralgia		2		2		
Asthenia		2				2
Back pain		1		1		
Burning sensation		1		1		
Chest discomfort		1				1
Chest pain		1				1
Chills		3		2		1
Condition aggravated		2		1		1
Constipation		1		1		
COVID-19		1				1
Death	1	2			1	2
Dermatitis allergic		2		1		1
Discomfort		1				1
Dizziness		2				2
Dry mouth		1				1
Dysgeusia		1				1
Dyspepsia		1				1
Dysphonia		1		1		
Dyspnoea		3		2		1
Energy increased		1		1		
Erythema		1		1		
Euphoric mood		1		1		
Extensive swelling of vaccinated limb		1		1		
Eye pruritus		2		2		
Faeces soft		1		1		
Fatigue	3	9	3	7		2
Feeling abnormal		1				1
Feeling cold		1		1		
Flatulence		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastritis		1				1
Gastrointestinal pain		1		1		
Gastrointestinal sounds abnormal		1		1		
Headache	2	9	2	6		3
Heart rate increased		1				1
Heart rate irregular		1		1		
Hyperhidrosis		1				1
Hypersensitivity		1		1		
Hypertension		1				1
Immunology test abnormal		1		1		
Infection		1		1		
Influenza like illness		1				1
Insomnia		1		1		
Intentional product use issue		1		1		
Limb discomfort		2		2		
Migraine	1	1	1	1		
Miosis		1				1
Mobility decreased		1		1		
Mouth swelling		1		1		
Muscle tightness	1	1	1	1		
Musculoskeletal chest pain		1		1		
Myalgia		3		2		1
Myocardial infarction		1				1
Nasopharyngitis		1		1		
Nausea		3		1		2
Ocular hyperaemia		2		2		
Oropharyngeal discomfort		1				1
Oxygen saturation decreased		1				1
Pain	1	2	1	2		
Pain in extremity		4		4		
Paraesthesia		1		1		
Poor quality product administered		1		1		
Pruritus		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia		4		3		1
Rash		1		1		
Red blood cell sedimentation rate increased		1		1		
Respiratory distress		1				1
Sensation of foreign body		1		1		
Skin lesion		1		1		
Sleep disorder		1		1		
Somnolence	1	2	1	2		
Swelling face		1		1		
Syncope		1				1
Tachycardia		2		2		
Tachypnoea		1		1		
Thirst		2				2
Throat tightness		1				1
Urticaria		1		1		
Vaccination failure		1				1
Vaccination site discomfort		1		1		
Vaccination site nodule		1		1		
Vaccination site pain	3	11	3	11		
Vaccination site urticaria		1		1		
Vasculitis		1		1		
Vomiting		2		1		1
	13	143	12	96	1	47

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Country Where Event Occurred

CROATIA

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	2		1	1	1
Altered state of consciousness		1				1
Anaemia		1				1
Anaphylactic reaction		2				2
Anaphylactic shock		1				1
Angina pectoris		1				1
Angioedema		1				1
Arrhythmia		4				4
Arthralgia	2	7	2	6		1
Arthritis	1	1			1	1
Asthenia	2	7	2	4		3
Asthma		1				1
Atrial f brillation		1				1
Axillary pain		1				1
Back pain		1				1
Blood creatine phosphokinase increased		1		1		
Blood creatinine increased	1	1			1	1
Blood glucose increased		3		2		1
Blood pressure increased		4		2		2
Body temperature increased	3	10	2	7	1	3
Bone pain	2	6	1	5	1	1
Breast pain		1		1		
Breath sounds abnormal		1				1
Bronchitis		1				1
Bronchospasm		2				2
Burning sensation	2	3	1	1	1	2
Cardiac arrest		1				1
Cardiac failure		1				1
Cardio-respiratory arrest		1				1
Cerebral artery thrombosis		1				1
Cerebral haemorrhage		1				1
Cerebral infarction		1				1
Cerebrovascular accident		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest discomfort		3		1		2
Chest pain	2	4			2	4
Chills	2	13	2	10		3
Coma		1				1
Confusional state	1	1	1	1		
Contusion	1	1			1	1
Cough		2		1		1
COVID-19	1	4		1	1	3
C-reactive protein increased	1	1	1	1		
Cyanosis		1				1
Deafness bilateral		1				1
Death		1				1
Deep vein thrombosis		2				2
Defaecation urgency		1		1		
Dermatitis allergic		1				1
Diabetes mellitus		1				1
Diarrhoea	1	2	1	1		1
Disturbance in attention	1	1	1	1		
Dizziness		1				1
Drug ineffective		1				1
Dysgeusia		2		1		1
Dysphonia		1				1
Dyspnoea	2	12		1	2	11
Erythema		4				4
Extensive swelling of vaccinated limb		6				6
Extensor plantar response		1		1		
Eyelid oedema		1		1		
Eyelid pain		1		1		
Eyelid ptosis		1				1
Facial nerve disorder		1		1		
Facial pain		1		1		
Facial paresis		2				2
Fall	1	2			1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fatigue	6	14	6	12		2
Fear		1				1
Feeling abnormal		1				1
Feeling hot		1		1		
Fibromyalgia		1				1
Gait disturbance	1	1			1	1
General physical health deterioration		1				1
Haemorrhage subcutaneous		1				1
Headache	6	27	5	19	1	8
Heart rate increased		1				1
Hemiparesis		1				1
Hepatic enzyme abnormal	1	1			1	1
Hyperaesthesia		1		1		
Hyperhidrosis		1				1
Hypertension		7		1		6
Hypertensive crisis		1				1
Hypoacusis		1				1
Hypoaesthesia		1				1
Hypoaesthesia oral		1				1
Hypotension		2		1		1
Lip disorder		1				1
Lip oedema		1				1
Livedo reticularis		1				1
Loss of consciousness	2	4			2	4
Lymphadenitis		1				1
Lymphadenopathy		3		2		1
Lymph node pain		1		1		
Malaise	2	7	2	5		2
Melaena		1				1
Motor dysfunction	1	1			1	1
Movement disorder	1	1			1	1
Multi-organ disorder		1				1
Muscular weakness	1	4		2	1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	3	12	3	11		1
Myocardial infarction	1	1			1	1
Nausea	1	5	1	4		1
Neck pain	1	1	1	1		
Neuritis		1		1		
Neurological symptom		1		1		
Neutrophil count increased		1		1		
Night sweats		1		1		
Oedema peripheral		1				1
Organic brain syndrome		1				1
Overdose	1	1	1	1		
Pain	1	3	1	3		
Pain in extremity	3	10	1	4	2	6
Pallor		2				2
Palpitations		7		2		5
Panic attack		1				1
Paraesthesia	1	3	1	2		1
Paraesthesia oral		2				2
Peripheral coldness		1				1
Peripheral swelling	1	1			1	1
Pharyngeal paraesthesia		1				1
Pharyngeal swelling		1		1		
Pneumonia		1				1
Presyncope		2		1		1
Product preparation error	1	1	1	1		
Pruritus		2				2
Pulmonary embolism	2	3			2	3
Pulmonary pain		1		1		
Pyrexia	3	21	3	17		4
Rales		1				1
Rash		2				2
Rash macular		1				1
Rash maculo-papular		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory distress		1				1
Respiratory failure		1				1
Respiratory rate decreased		1		1		
Respiratory tract oedema		1				1
Sensory disturbance	1	1			1	1
Sensory loss	1	1			1	1
Skin burning sensation		1				1
Skin hypertrophy		1				1
Skin oedema		1		1		
Skin reaction		1				1
Skin tightness		1				1
Somnolence		1				1
Speech disorder		1				1
Spinal pain	1	1			1	1
Stridor		2				2
Suffocation feeling		1				1
Swelling face		1				1
Swollen tongue		1				1
Syncope	1	2			1	2
Tachycardia		9		3		6
Tachypnoea		2				2
Throat tightness		1				1
Thrombocytopenia		1				1
Tinnitus		2		1		1
Tongue oedema		1				1
Transient ischaemic attack	1	1			1	1
Tremor		2		1		1
Type I hypersensitivity		4				4
Unresponsive to stimuli		1				1
Urinary tract infection		1				1
Urticaria	1	1	1	1		
Use of accessory respiratory muscles		1				1
Vaccination failure	1	2			1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site erythema		13		8		5
Vaccination site induration		3		2		1
Vaccination site lymphadenopathy		2		2		
Vaccination site movement impairment		1				1
Vaccination site oedema		4		2		2
Vaccination site pain	4	30	4	22		8
Vaccination site paraesthesia	1	1	1	1		
Vaccination site pruritus		1				1
Vaccination site swelling		7		6		1
Vertigo		2		1		1
Vomiting	1	3	1	1		2
Wheezing		2				2
White blood cell count increased		1		1		
	80	457	47	207	33	250

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Country Where Event Occurred

CYPRUS

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Acute kidney injury		1				1
Acute respiratory distress syndrome		1				1
Amenorrhoea	1	1	1	1		
Anaphylactic reaction		1				1
Aortic aneurysm		1				1
Bacterial sepsis		1				1
Cervix oedema		1		1		
Chills	1	4	1	4		
Cold sweat	1	1	1	1		
Condition aggravated		1		1		
COVID-19		2				2
Death		1				1
Dehydration		1				1
Diarrhoea		1		1		
Dizziness		2		2		
Drug ineffective		2				2
Dyspnoea		2		2		
Face oedema		1		1		
Facial paresis		2				2
Fatigue		2		2		
Gastrointestinal infection		1				1
Generalised tonic-clonic seizure		1				1
Headache		2		2		
Hypersensitivity		1		1		
Hypertension		1				1
Hypoacusis		1		1		
Hypotension		1				1
Inappropriate schedule of product administration		1		1		
Injection site pain		1		1		
Insomnia		1		1		
Lymphadenopathy		4		4		
Malaise		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Multiple organ dysfunction syndrome		1				1
Myalgia		5		5		
Myocardial infarction		1				1
Nasal congestion		1		1		
Nausea		2		2		
Off label use		2		2		
Overdose		1		1		
Product use issue		1		1		
Pulmonary oedema		1				1
Pyrexia		2		2		
Rash		1		1		
Respiratory distress		1				1
Shock		1				1
Syncope		1				1
Tachyarrhythmia		1				1
Tachycardia		2		1		1
Unresponsive to stimuli		1				1
Vaccination site oedema		2		2		
Vaccination site pain		1		1		
Vasculitis		2		1		1
Viral sepsis		1				1
Vomiting		1				1
	4	78	4	49		29

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Country Where Event Occurred

CZECH REPUBLIC

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	2			1	2
Abdominal pain	1	7	1	3		4
Abdominal pain lower	1	3	1	2		1
Abdominal pain upper	2	6	2	5		1
Abnormal dreams		2		2		
Acne	1	2		1	1	1
Acquired haemophilia	1	1			1	1
Acute kidney injury		1				1
Acute respiratory failure		1				1
Ageusia		2		1		1
Airway burns		2				2
Akinesia		1				1
Allergy to vaccine		2				2
Alopecia	1	2		1	1	1
Altered state of consciousness		2				2
Amnesia	1	1			1	1
Anaemia		3		1		2
Anaesthesia oral		1				1
Anaphylactic reaction		8				8
Aneurysm		1				1
Angina pectoris		2				2
Angioedema		2				2
Anosmia		4		2		2
Anuria		1				1
Anxiety	3	8	2	4	1	4
Aortic arteriosclerosis		1				1
Aortic stenosis		1				1
Apathy	3	7	1	2	2	5
Aphasia		2		1		1
Aphthous ulcer		2				2
Apnoea		1				1
Application site coldness		1				1
Arrhythmia	1	3			1	3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arteriosclerosis		2				2
Arthralgia	64	107	60	91	4	16
Asthenia	15	46	12	32	3	14
Asthma	2	3		1	2	2
Atrial fibrillation		4				4
Atrial flutter		1				1
Auditory disorder	1	1			1	1
Autoimmune haemolytic anaemia	1	1			1	1
Axillary pain	2	3	1	1	1	2
Back pain	7	14	6	11	1	3
Bacterial rhinitis		1				1
Bacterial test positive		1		1		
Balance disorder	3	3	1	1	2	2
Basal ganglia haemorrhage		1				1
Biliary colic	1	1	1	1		
Bladder pain	1	1			1	1
Blepharospasm	1	1			1	1
Blister		1				1
Blood chloride increased		1		1		
Blood glucose fluctuation	1	1	1	1		
Blood glucose increased		1		1		
Blood lactic acid increased		1		1		
Blood pressure decreased	1	1	1	1		
Blood pressure diastolic increased		1		1		
Blood pressure fluctuation	1	3	1	2		1
Blood pressure increased	4	10	2	3	2	7
Blood urine	1	1			1	1
Blood urine present		1		1		
Body temperature fluctuation	1	1	1	1		
Body temperature increased	1	1	1	1		
Bone pain	2	3	1	1	1	2
Bradycardia	1	3			1	3
Bradyphrenia	1	3	1	2		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Brain oedema		1				1
Breast pain		3		1		2
Bronchitis chronic		1		1		
Bundle branch block right		1				1
Burning sensation	2	2	2	2		
Cardiac arrest		3				3
Cardiac failure	1	4			1	4
Cardiac failure acute	1	1			1	1
Cardiac hypertrophy		1				1
Cardiomegaly	1	1	1	1		
Cardiomyopathy		1				1
Cardio-respiratory arrest		1				1
Cerebral atrophy		1				1
Cerebral ischaemia		1				1
Cerebral thrombosis		1				1
Cerebrovascular accident		6				6
Chest discomfort	3	11	2	3	1	8
Chest pain	5	10	1	3	4	7
Chills	49	95	47	84	2	11
Choking sensation		1				1
Circulatory collapse		3				3
Clumsiness	1	1	1	1		
Coagulopathy		1				1
Cognitive disorder	1	1			1	1
Coma		1				1
Communication disorder		1				1
Concussion	1	2	1	1		1
Condition aggravated	2	3		1	2	2
Confusional state	4	9	2	4	2	5
Constipation		2		1		1
Contusion	1	3	1	1		2
Coordination abnormal	1	1			1	1
Cor pulmonale		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	12	26	10	22	2	4
Cough decreased	1	1	1	1		
COVID-19	22	39	6	9	16	30
COVID-19 pneumonia		5				5
C-reactive protein increased	2	4	1	2	1	2
Cyanosis		1				1
Cystitis noninfective		1		1		
Deafness		1				1
Deafness neurosensory		2				2
Death	1	3			1	3
Decreased activity		1		1		
Decreased appetite	4	17	3	14	1	3
Deep vein thrombosis	7	8			7	8
Dehydration	1	3	1	2		1
Delirium		2				2
Dementia		1				1
Depression		1				1
Dermatitis		1				1
Diarrhoea	9	25	6	16	3	9
Diplopia		1				1
Discomfort	1	1			1	1
Disease recurrence		1				1
Disorganised speech		1				1
Disorientation	3	6	2	3	1	3
Disturbance in attention	1	4	1	2		2
Dizziness	11	21	8	17	3	4
Drug eruption	1	1			1	1
Drug hypersensitivity		1				1
Drug ineffective	10	17			10	17
Drug interaction		1				1
Dry mouth	1	4	1	3		1
Duodenal ulcer		1				1
Dysaesthesia		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysarthria		2		1		1
Dysgeusia	1	1	1	1		
Dyskinesia		1				1
Dyspepsia		2		1		1
Dysphagia	2	4	2	3		1
Dysphonia	1	1	1	1		
Dyspnoea	17	48	4	12	13	36
Dyspnoea at rest		1				1
Dyspnoea exertional		2		1		1
Dysstasia	1	1	1	1		
Dysuria	1	2	1	1		1
Ear discomfort		3		2		1
Ear pain	1	3	1	3		
Ear swelling		1				1
Eating disorder		2		1		1
Embolism	1	1			1	1
Epistaxis	3	8	2	4	1	4
Erysipelas		1				1
Erythema		15		9		6
Extensive swelling of vaccinated limb	1	1			1	1
Eye haemorrhage	1	4			1	4
Eye irritation	1	3			1	3
Eyelid oedema	2	2			2	2
Eye pain	3	4	3	4		
Eye pruritus		1		1		
Eye swelling		2		2		
Face oedema		2				2
Facial paralysis		4				4
Fall	2	5		1	2	4
Fatigue	122	196	119	174	3	22
Feeling abnormal	2	5		2	2	3
Feeling hot	3	8	1	5	2	3
Feeling of body temperature change	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Femur fracture	1	1			1	1
Flank pain		1		1		
Flatulence		2		1		1
Fluid intake reduced		1		1		
Flushing	1	3		1	1	2
Food intolerance		1				1
Formication	1	2	1	1		1
Gait disturbance	1	4		1	1	3
Gait inability		1		1		
Gastrointestinal disorder		1		1		
Gastrointestinal hypermotility		1				1
Gastrointestinal necrosis		1				1
Generalised onset non-motor seizure	1	1			1	1
General physical health deterioration		4		1		3
Genital pain	1	1			1	1
Gingival bleeding	1	1			1	1
Glaucoma		1				1
Glomerular filtration rate decreased		1		1		
Gout		1		1		
Groin pain		1		1		
Guillain-Barre syndrome		1				1
Haemarthrosis	1	1			1	1
Haematochezia		1				1
Haematoma	2	4		1	2	3
Haematuria	1	1	1	1		
Haemorrhage	1	2			1	2
Haemorrhage intracranial		1				1
Hallucination	1	2			1	2
Hallucinations, mixed		1				1
Hangover	1	1	1	1		
Headache	76	126	74	116	2	10
Head discomfort	1	2	1	1		1
Heart rate decreased		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate increased	2	5	1	2	1	3
Heart rate irregular		1		1		
Heavy menstrual bleeding	1	1	1	1		
Hemiparesis		1				1
Hemiplegia		2				2
Hepatic function abnormal		1				1
Hepatic infarction	1	2			1	2
Hepatitis		1				1
Herpes ophthalmic	1	1			1	1
Herpes simplex		2				2
Herpes zoster	3	10			3	10
Hot flush	2	6	1	1	1	5
Humerus fracture		1				1
Hyperaesthesia	1	1	1	1		
Hypercoagulation	1	1			1	1
Hyperglycaemia	1	4			1	4
Hyperhidrosis	3	9	3	8		1
Hyperphagia		1		1		
Hypersensitivity	7	24	4	10	3	14
Hypersomnia		2				2
Hypertension	5	16		2	5	14
Hyperventilation	2	3	1	2	1	1
Hypoacusis	1	2			1	2
Hypoaesthesia		3		1		2
Hypoaesthesia oral		1				1
Hypoglycaemia		2		1		1
Hypokalaemia		3				3
Hypokinesia		2		2		
Hypophagia		1		1		
Hypotension	1	12		2	1	10
Hypoxia		2				2
Illusion		1		1		
Immune system disorder		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Immune thrombocytopenia	1	1			1	1
Inappropriate schedule of product administration		3		3		
Incontinence	1	1	1	1		
Incorrect route of product administration		2		2		
Induration	1	1			1	1
Infection		1		1		
Inflammation	1	2			1	2
Influenza	2	2	2	2		
Influenza like illness	28	62	25	47	3	15
Insomnia	5	11	4	8	1	3
Intermittent claudication	1	1	1	1		
International normalised ratio increased		2		1		1
Intestinal haemorrhage	1	1			1	1
Intestinal infarction		1				1
Intraocular pressure increased	1	1	1	1		
Irritability	1	1	1	1		
Ischaemic stroke	1	3			1	3
Jaundice		1		1		
Joint effusion		1				1
Joint range of motion decreased	2	4	2	3		1
Joint stiffness		2		1		1
Joint swelling	2	4	1	2	1	2
Jugular vein distension		1		1		
Lacrimation increased		1		1		
Language disorder		1				1
Laryngospasm		1				1
Lethargy		1		1		
Leukopenia		2				2
Ligament sprain	1	1			1	1
Limb discomfort	1	2			1	2
Lip swelling	2	5			2	5
Livedo reticularis		1		1		
Localised oedema		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Loss of consciousness	1	4			1	4
Loss of personal independence in daily activities	1	2		1	1	1
Lymphadenitis	1	2			1	2
Lymphadenopathy	6	27	3	13	3	14
Lymph node pain	1	3	1	2		1
Malaise	10	21	10	18		3
Melaena		1				1
Memory impairment	2	3			2	3
Menstruation irregular	1	1	1	1		
Mental fatigue	1	1	1	1		
Mental impairment	1	1			1	1
Mesenteric arterial occlusion		1				1
Mesenteric vascular insufficiency		1				1
Micturition disorder	1	1	1	1		
Micturition urgency	1	1			1	1
Migraine	2	4	2	3		1
Migraine with aura		1		1		
Mineral metabolism disorder	1	1			1	1
Mobility decreased	2	4	1	3	1	1
Monoparesis		1				1
Motor dysfunction	1	1	1	1		
Movement disorder	2	3			2	3
Mucosal disorder		1				1
Mucosal dryness		1				1
Mucosal haemorrhage	1	1			1	1
Multiple organ dysfunction syndrome		2				2
Muscle spasms	1	3	1	3		
Muscular weakness	2	8	1	6	1	2
Musculoskeletal disorder	2	2	2	2		
Musculoskeletal pain		1		1		
Musculoskeletal stiffness	2	5	2	5		
Myalgia	50	76	47	68	3	8
Myocardial infarction		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myositis		1				1
Nasal congestion	1	2		1	1	1
Nasal dryness		1		1		
Nasopharyngitis	2	3	2	3		
Nausea	30	64	25	50	5	14
Neck pain	3	6	3	5		1
Nephrosclerosis		1				1
Nervousness	1	2		1	1	1
Neuropathy peripheral		2				2
Neutropenia		1				1
Night sweats	1	3	1	2		1
Nodule	1	1	1	1		
Nuchal rigidity	1	1			1	1
Nystagmus		1		1		
Ocular discomfort	1	2	1	1		1
Oedema peripheral	1	6		3	1	3
Off label use		6		6		
Oral pruritus	1	2	1	2		
Oropharyngeal discomfort		1				1
Oropharyngeal pain	4	6	4	6		
Overdose		3		3		
Oxygen saturation decreased		3		2		1
Pain	10	19	9	15	1	4
Pain in extremity	63	95	54	80	9	15
Palatal swelling	1	1			1	1
Palpitations	3	8	2	3	1	5
Pancreatic infarction		1				1
Panic attack	1	1			1	1
Panic reaction	1	1	1	1		
Paraesthesia	15	33	1	8	14	25
Paraesthesia oral	2	7			2	7
Paralysis		1				1
Paraparesis		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paresis		1				1
Patient uncooperative		1		1		
Peripheral coldness	1	5		3	1	2
Peripheral swelling	4	8	3	4	1	4
Peripheral venous disease		1				1
Petechiae		2				2
Pharyngeal oedema		1				1
Pharyngeal paraesthesia		1				1
Pharyngeal swelling		1				1
Photophobia		1		1		
Pneumoconiosis		1				1
Pneumonia	1	5			1	5
Pneumonitis		1				1
Polyarthrits		1				1
Polymenorrhoea	1	1			1	1
Poor quality product administered		1		1		
Posture abnormal		1		1		
Presyncope	3	5			3	5
Productive cough	1	4	1	1		3
Product preparation error		2		2		
Product use issue		5		5		
Prolonged expiration		1		1		
Prostate cancer		1				1
Pruritus	4	18	2	9	2	9
Psychomotor hyperactivity		1				1
Pulmonary embolism	5	7			5	7
Pulse abnormal		1		1		
Purpura		1				1
Pyrexia	88	163	77	121	11	42
Quadriparesis		1				1
Radiculitis brachial		1				1
Rash	6	18	3	6	3	12
Rash macular	2	3	1	1	1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash maculo-papular		3				3
Rash pruritic	3	8	2	3	1	5
Red blood cell sedimentation rate increased		1		1		
Renal colic	1	1			1	1
Renal cyst		1				1
Renal disorder		1		1		
Renal failure		2				2
Renal impairment		1				1
Renal infarct	1	1			1	1
Renal mass	1	1			1	1
Renal pain	1	3		2	1	1
Renal transplant failure		1				1
Respiration abnormal		1				1
Respiratory acidosis		1		1		
Respiratory depression		1				1
Respiratory disorder		1				1
Respiratory failure		4				4
Restlessness	2	5	2	5		
Retching	2	6	2	3		3
Retinal artery thrombosis	1	1			1	1
Rheumatoid arthritis	1	2			1	2
Rhinalgia		1		1		
Rhinitis	2	5	2	5		
Rhinorrhoea	4	10	4	9		1
Right ventricular dilatation		1				1
Salivary gland pain	1	1	1	1		
SARS-CoV-2 ant body test negative		1				1
SARS-CoV-2 test positive		1				1
Scab		2		2		
Seizure	1	3			1	3
Sensation of foreign body		2		1		1
Sepsis		2				2
Sinus bradycardia		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sinus pain		1		1		
Sinus tachycardia		1				1
Skin burning sensation	1	3	1	2		1
Skin disorder		1				1
Skin laceration		1				1
Skin mass		1		1		
Skin warm	1	1			1	1
Sleep talking		1		1		
Sneezing		1		1		
Somnolence	5	11	5	9		2
Speech disorder	1	2			1	2
Spinal disorder		1				1
Spinal pain	1	4	1	2		2
Splenic infarction		1				1
Splenic infection		1				1
Sputum purulent		1				1
Stridor		1		1		
Sudden death		3				3
Supraventricular extrasystoles		1		1		
Swelling		2		1		1
Swelling face	1	8	1	1		7
Swelling of eyelid		1				1
Swollen tongue		1				1
Syncope	1	8			1	8
Tachycardia	3	13	1	6	2	7
Tachypnoea		4				4
Tenderness		2		1		1
Tension headache		3		1		2
Tetany	1	1			1	1
Thirst		1		1		
Throat irritation		2				2
Throat tightness	3	7	1	3	2	4
Thrombocytopenia	2	3			2	3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thrombophlebitis	1	1			1	1
Thrombosis	2	2			2	2
Tinnitus		3				3
Tongue erythema	1	1	1	1		
Tongue oedema	1	4			1	4
Toothache	2	3	2	2		1
Tooth infection		1				1
Transient ischaemic attack		2				2
Tremor	3	8		3	3	5
Truncus coeliacus thrombosis		1				1
Underdose	1	1	1	1		
Urinary straining	1	1			1	1
Urinary tract disorder	1	1	1	1		
Urinary tract infection		3		1		2
Urinary tract infection enterococcal		1				1
Urogenital infection bacterial		1				1
Urosepsis	1	2			1	2
Urticaria	2	5			2	5
Vaccination complication		1				1
Vaccination failure	1	6			1	6
Vaccination site bruising	1	2	1	2		
Vaccination site discomfort	2	2	2	2		
Vaccination site erythema	14	29	11	19	3	10
Vaccination site hyperaesthesia	2	2	2	2		
Vaccination site hypersensitivity	2	3	1	1	1	2
Vaccination site induration	1	3	1	2		1
Vaccination site joint movement impairment		1		1		
Vaccination site joint pain		1		1		
Vaccination site mass		1				1
Vaccination site oedema	9	15	9	13		2
Vaccination site pain	119	145	118	141	1	4
Vaccination site paraesthesia		1		1		
Vaccination site pruritus	5	10	4	8	1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site rash		1		1		
Vaccination site reaction		2		1		1
Vaccination site swelling	10	15	10	14		1
Vaccination site urticaria		3		1		2
Vaccination site warmth	2	4	2	4		
Vascular pain		1				1
Vena cava thrombosis		1				1
Venous thrombosis	1	1			1	1
Ventricular tachycardia		2				2
Vertigo	4	16	1	10	3	6
Vision blurred	5	14		4	5	10
Visual acuity reduced	1	1			1	1
Visual impairment	1	2		1	1	1
Vomiting	8	30	7	22	1	8
Weight decreased		1		1		
Wheezing		2		1		1
White blood cell count decreased	1	1	1	1		
Yellow skin		1				1
	1,227	2,715	924	1673	303	1042

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Country Where Event Occurred

DENMARK

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal distension		1		1		
Abdominal pain	1	6		1	1	5
Abdominal pain upper	1	2			1	2
Abortion missed		1				1
Acute coronary syndrome	2	2			2	2
Acute kidney injury		3				3
Acute leukaemia		1				1
Acute myocardial infarction		1				1
Acute respiratory distress syndrome		1				1
Acute respiratory failure		1				1
Adrenal insufficiency		1				1
Adrenocortical insufficiency acute	1	1			1	1
Aggression		2				2
Alanine aminotransferase increased		1		1		
Allergy to vaccine	1	1			1	1
Altered state of consciousness		4				4
Amnesia		1				1
Anaemia		1				1
Anaphylactic reaction		8				8
Anaphylactic shock	2	4			2	4
Angioedema	1	5			1	5
Anti-glomerular basement membrane disease		1				1
Anxiety	1	1			1	1
Aphasia	1	4			1	4
Arthralgia	6	20	2	7	4	13
Arthritis		1		1		
Arthritis reactive		1				1
Aspiration		1				1
Asthenia	1	13	1	3		10
Asthma	1	5			1	5
Atrial fibrillation		5				5
Atrial flutter		2				2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Azotaemia		1				1
Back pain	1	4		2	1	2
Bacteraemia		1				1
Bacterial infection		1				1
Balance disorder	2	4			2	4
Basilar artery occlusion		1				1
Bell's palsy	1	1			1	1
Beta haemolytic streptococcal infection	1	1			1	1
Blindness	1	1			1	1
Blood albumin decreased		1		1		
Blood alkaline phosphatase increased		1		1		
Blood chloride increased		1		1		
Blood creatine phosphokinase increased		1				1
Blood creatinine abnormal	1	1			1	1
Blood creatinine increased		1				1
Blood glucose increased		1		1		
Blood iron decreased		1		1		
Blood lactic acid increased	1	2	1	2		
Blood potassium increased		1		1		
Blood pressure decreased		1		1		
Blood pressure increased	1	4			1	4
Blood pressure systolic increased		2		1		1
Blood prolactin increased	1	1	1	1		
Blood sodium decreased		1		1		
Blood test abnormal	1	1	1	1		
Blood uric acid abnormal		1		1		
Body temperature increased		3		3		
Bradycardia	1	3			1	3
Brain injury	1	1			1	1
Breath sounds abnormal		1				1
Bronchospasm		3				3
Burning sensation		1		1		
Bursitis		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Calcium ionised increased		1		1		
Carbon monoxide poisoning		1				1
Cardiac arrest	4	9			4	9
Cardiac failure	1	3			1	3
Cardiogenic shock		2				2
Cardiovascular disorder		1				1
Cerebellar embolism	1	1			1	1
Cerebral haemorrhage	1	1			1	1
Cerebral infarction	1	1			1	1
Cerebral ischaemia		1				1
Cerebral thrombosis		3				3
Cerebrovascular accident	1	11			1	11
Chest discomfort	1	4	1	1		3
Chest pain	8	15		2	8	13
Chills	9	22	3	10	6	12
Chorioretinitis		1				1
Chronic obstructive pulmonary disease	1	9			1	9
Circulatory collapse	2	3			2	3
Cognitive disorder		1				1
Cold sweat	1	1			1	1
Colitis		1				1
Coma		1				1
Condition aggravated		9				9
Confusional state	3	9		1	3	8
Conjunctival oedema	1	1			1	1
Constipation	2	2	1	1	1	1
Contusion		1				1
Coordination abnormal		2				2
Coronary artery thrombosis		1				1
Cough	4	13	1	3	3	10
COVID-19		8		2		6
C-reactive protein increased	1	7		1	1	6
Crying		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Death		10				10
Decreased appetite	2	9	1	2	1	7
Deep vein thrombosis	2	10			2	10
Dehydration	3	5			3	5
Delirium	1	9			1	9
Delusion		1				1
Dementia		1				1
Depressed level of consciousness		8				8
Dermatitis allergic		1				1
Diabetic complication		1				1
Diarrhoea	8	18		5	8	13
Diplopia		1				1
Discomfort	2	7	1	2	1	5
Disease progression	1	1			1	1
Disseminated intravascular coagulation		1				1
Disturbance in attention		1				1
Dizziness	12	39	2	11	10	28
Drug ineffective		3				3
Dry eye		1		1		
Dysaesthesia		1				1
Dysarthria		1				1
Dysgeusia		2		1		1
Dysphagia		2				2
Dysphonia	2	4	1	3	1	1
Dyspnoea	16	71	2	6	14	65
Dyspnoea at rest		1				1
Dyspnoea exertional		2				2
Dysstasia		1				1
Dysuria		1				1
Emphysema		1				1
Encephalitis	1	1			1	1
Endocarditis bacterial	1	1			1	1
Endophthalmitis	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Epilepsy	1	2			1	2
Epistaxis		2		1		1
Erysipelas	1	2			1	2
Erythema	2	10	1	4	1	6
Eyelid ptosis		2				2
Eye pain	1	4		3	1	1
Eye pruritus		2		2		
Eye swelling	1	1			1	1
Face oedema		1				1
Facial paralysis		2				2
Facial paresis	1	3	1	1		2
Fall	3	7	1	1	2	6
Fatigue	21	72	10	31	11	41
Feeling abnormal	1	2	1	2		
Feeling cold	2	4		1	2	3
Feeling hot	1	4	1	2		2
Femoral neck fracture	1	1			1	1
Fibrin D dimer increased		2				2
Flatulence		1		1		
Fluid intake reduced	1	4		1	1	3
Flushing		2				2
Foaming at mouth		2		1		1
Gait disturbance	1	5		1	1	4
Gastric ulcer		1				1
Gastrointestinal necrosis		1				1
Gastrooesophageal reflux disease		1				1
Generalised tonic-clonic seizure	1	3			1	3
General physical health deterioration	2	16	1	2	1	14
Glomerular filtration rate decreased		1				1
Guillain-Barre syndrome		1				1
Haematemesis		1				1
Haematochezia		1				1
Haematology test abnormal		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematuria		1				1
Haemodynamic instability		1				1
Haemoglobin abnormal	1	1			1	1
Haemoglobin decreased	1	2	1	1		1
Haemolysis		1				1
Haemoptysis	1	1			1	1
Haemorrhage		1				1
Haemorrhage intracranial		1				1
Haemorrhagic cerebral infarction	1	1			1	1
Haemorrhagic diathesis		1				1
Hallucination	1	1			1	1
Hallucination, visual	1	2			1	2
Headache	19	73	8	30	11	43
Head discomfort	1	3		1	1	2
Head injury	1	2	1	1		1
Heart rate increased	1	8		2	1	6
Hemiparesis	1	4			1	4
Hemiplegia		2				2
Hepatic enzyme increased	1	2	1	2		
Hepatic vein thrombosis	1	1			1	1
Herpes zoster	2	3	2	3		
Hot flush		1		1		
Hyperacusis		1				1
Hyperaesthesia	1	1			1	1
Hyperglycaemia		1				1
Hyperhidrosis		4		1		3
Hypermetabolism	1	1	1	1		
Hypersensitivity	2	8	1	3	1	5
Hypersomnia	1	3		1	1	2
Hypertension	2	7		1	2	6
Hypertonia		1				1
Hyperventilation	1	2			1	2
Hypoaesthesia	1	2			1	2

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			Nonserious		Serious	
			I	C	I	C
Hypoglycaemia		2		1		1
Hypokinesia	1	1	1	1		
Hypophagia	1	3		2	1	1
Hypotension		7		1		6
Hypothermia		2				2
Hypoxia		1				1
Idiopathic pulmonary fibrosis		1				1
IIIrd nerve paresis		1				1
Immune-mediated adverse reaction		1				1
Immune thrombocytopenia		1				1
Immunisation reaction	1	1	1	1		
Inappropriate schedule of product administration	1	5	1	5		
Incorrect route of product administration		1		1		
Infarction		1				1
Infection	3	4			3	4
Influenza	1	5	1	3		2
Influenza like illness	3	6	1	2	2	4
Insomnia		1		1		
Intestinal ischaemia		1				1
Intracardiac thrombus	1	2			1	2
Ischaemic stroke	1	1			1	1
Joint stiffness		2		1		1
Joint swelling	1	3			1	3
Ketoacidosis		1				1
Lethargy		1		1		
Limb discomfort		2		1		1
Lip pruritus		1				1
Lip swelling		2				2
Livedo reticularis		2				2
Liver function test increased		1		1		
Loss of consciousness	2	5			2	5
Loss of personal independence in daily activities	1	2			1	2
Low density lipoprotein increased		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lung disorder		2				2
Lung infiltration		1				1
Lymphadenopathy	1	6	1	4		2
Lymph node pain		1		1		
Lymphopenia		1				1
Malaise	11	52	1	15	10	37
Maternal exposure during pregnancy		1				1
Melaena		1				1
Meningitis	1	1			1	1
Mesenteric artery thrombosis		1				1
Metabolic acidosis		1				1
Metabolic alkalosis		1		1		
Micturition urgency		1				1
Migraine	1	2		1	1	1
Mobility decreased		2				2
Monoparesis		2				2
Monoplegia		1				1
Mouth swelling		1				1
Multimorbidity		1				1
Muscle spasms	1	2		1	1	1
Muscular weakness	3	9	1	3	2	6
Musculoskeletal chest pain	1	1	1	1		
Musculoskeletal pain	1	1			1	1
Musculoskeletal stiffness	1	1	1	1		
Myalgia	9	33	4	16	5	17
Myelitis		1				1
Myelosuppression		1				1
Myocardial infarction		1				1
Nasal congestion		1		1		
Nasal discomfort		1				1
Nasal pruritus		1				1
Nasopharyngitis		1		1		
Nausea	12	45	4	22	8	23

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neck pain	1	2		1	1	1
Nervous system disorder		1				1
Neuralgia		1				1
Neutrophil count increased		2		2		
Obliterative bronchiolitis		1				1
Obstructive airways disorder	1	4			1	4
Oedema	1	1			1	1
Oedema mucosal		1				1
Oedema peripheral	1	6		1	1	5
Off label use	1	9	1	9		
Oral discomfort		1				1
Oral mucosal eruption		1		1		
Oropharyngeal discomfort		1				1
Oropharyngeal pain	1	4		1	1	3
Orthostatic hypotension	1	1	1	1		
Oxygen saturation decreased		8		1		7
Pain	2	8	1	4	1	4
Painful respiration		1		1		
Pain in extremity	4	12	2	6	2	6
Pallor		4		1		3
Palpitations	1	8		2	1	6
Pancytopenia		1				1
Paraesthesia	3	9		3	3	6
Paraesthesia oral	1	5	1	2		3
Paresis		1				1
Parkinson's disease		1				1
Periarthritis		1		1		
Pericarditis	1	1			1	1
Periorbital swelling	2	4		1	2	3
Peripheral coldness	1	3			1	3
Peripheral swelling	1	5			1	5
Petechiae	1	1			1	1
Pharyngeal haemorrhage	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal paraesthesia		1		1		
Pharyngeal swelling	1	4		1	1	3
Phlebitis deep		1				1
Photophobia		2				2
Photopsia		2				2
Photosensitivity reaction		1		1		
Platelet count decreased	2	2	1	1	1	1
Pleural effusion		2				2
Pleuritic pain		1		1		
Pneumonia	3	19			3	19
Pneumonia aspiration		1				1
Pneumonia bacterial		1				1
Pneumonitis		1				1
Polycythaemia vera		1				1
Presyncope	1	3			1	3
Productive cough	1	2			1	2
Product use issue		6		6		
Prolonged expiration		1				1
Pruritus	2	8		4	2	4
Pulmonary arterial hypertension		1				1
Pulmonary arterial pressure increased		1		1		
Pulmonary congestion	1	1			1	1
Pulmonary embolism	8	25			8	25
Pulmonary fibrosis		2				2
Pulmonary oedema		6				6
Pulmonary pain		1		1		
Pulse abnormal		1				1
Pyrexia	17	66	5	20	12	46
Rales		1				1
Rash	4	13	2	8	2	5
Rash erythematous		3		2		1
Rash papular	1	1			1	1
Rash pruritic	2	4	2	2		2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal failure		4				4
Respiration abnormal		2				2
Respiratory acidosis		4				4
Respiratory alkalosis	1	1			1	1
Respiratory arrest		4				4
Respiratory disorder	1	1	1	1		
Respiratory distress	1	2			1	2
Respiratory failure	1	12			1	12
Respiratory rate increased	1	1	1	1		
Restlessness		3		2		1
Rhabdomyolysis	1	1			1	1
Rheumatoid arthritis	1	2			1	2
Rheumatoid factor increased		1				1
Rhinorrhoea		1				1
Salivary hypersecretion		1				1
SARS-CoV-2 test positive		1				1
Seizure	3	4			3	4
Sensation of foreign body		2				2
Sensory disturbance	1	3		1	1	2
Sepsis		2				2
Septic embolus	1	1			1	1
Sinus tachycardia		1		1		
Sneezing		1		1		
Somnolence	3	7	2	4	1	3
Speech disorder		2				2
Splenic infarction		1				1
Staphylococcal infection		1				1
Stress cardiomyopathy		1				1
Stridor		1				1
Subarachnoid haemorrhage	1	1			1	1
Sudden cardiac death		1				1
Sudden death		4				4
Swelling	1	4	1	3		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling face		4		1		3
Swelling of eyelid		1		1		
Swollen tongue		2				2
Syncope	3	7			3	7
Systemic immune activation		2				2
Systemic inflammatory response syndrome		1				1
Tachycardia	1	2			1	2
Tachypnoea		2				2
Tenderness	1	5	1	4		1
Therapeutic response unexpected	1	1	1	1		
Throat irritation	2	5		1	2	4
Throat tightness		1				1
Thrombocytopenia		4				4
Thrombosis	1	7			1	7
Tinnitus	1	1			1	1
Tongue discomfort	1	1			1	1
Tongue pruritus	1	1			1	1
Tooth infection	1	1			1	1
Toxicity to various agents		1				1
Tracheal stenosis		1				1
Transient ischaemic attack	1	3			1	3
Transplant failure		1				1
Tremor		5				5
Troponin I increased		1				1
Troponin increased		1				1
Type I hypersensitivity		1				1
Unresponsive to stimuli		1				1
Urinary tract infection		2				2
Urosepsis		1				1
Urticaria	4	14	1	5	3	9
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	3	10	3	9		1
Vaccination site haemorrhage	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site induration		1		1		
Vaccination site inflammation		1		1		
Vaccination site pain	10	43	9	36	1	7
Vaccination site pruritus		2		2		
Vaccination site rash		1		1		
Vaccination site swelling	2	9	2	8		1
Vaccination site warmth		4		4		
Vasculitis	1	2		1	1	1
Vasodilatation		1				1
Viral infection		1		1		
Vision blurred	1	2			1	2
Visual field defect	1	1			1	1
Visual impairment	1	1			1	1
Vomiting	7	26		5	7	21
Wheezing		1				1
White blood cell count increased	1	3	1	3		
Wound		1				1
Wound infection		1				1
	400	1,640	109	469	291	1171

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Country Where Event Occurred

ECUADOR

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Autoimmune myocarditis	1	1			1	1
Cough	1	1			1	1
COVID-19	2	2	1	1	1	1
Dizziness	1	1			1	1
Drug ineffective	1	1			1	1
Dysphagia	1	1			1	1
Dysphonia	1	1			1	1
Head discomfort	1	1			1	1
Hyperhidrosis	1	1			1	1
Insomnia	1	1			1	1
Malaise	1	1			1	1
Muscular weakness	1	1			1	1
Myalgia	1	2		1	1	1
Neck pain	1	1			1	1
Oropharyngeal pain	1	1			1	1
Pain	2	2			2	2
Paraesthesia	1	1			1	1
Pericarditis	2	2			2	2
Pyrexia		1		1		
Respiratory disorder	1	1			1	1
Rhinorrhoea	1	1			1	1
Sitting disability	1	1			1	1
Suffocation feeling	1	1			1	1
Supraventricular extrasystoles	1	1			1	1
Vaccination site urticaria	1	1	1	1		
Ventricular extrasystoles	1	1			1	1
	29	31	2	4	27	27

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Country Where Event Occurred

ESTONIA

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Abdominal pain upper		1				1
Acute myocardial infarction		1				1
Ageusia		2		2		
Angina pectoris	2	2			2	2
Arrhythmia	2	2			2	2
Arthralgia	2	5	2	5		
Asthenia		6		4		2
Atrial fibrillation	1	1			1	1
Balance disorder	1	1	1	1		
Blindness unilateral		1				1
Bone pain		1				1
Cardiac arrest	1	1			1	1
Cardiac failure congestive		1				1
Cerebral haemorrhage		1				1
Cerebral infarction		1				1
Cerebrovascular accident		1				1
Chest discomfort		1		1		
Chest pain		2		1		1
Chills		9		8		1
Chronic obstructive pulmonary disease		1				1
Cold sweat		1				1
Condition aggravated	1	1			1	1
Cough		2		2		
COVID-19	3	9			3	9
Cystitis	1	1			1	1
Death		2				2
Decreased appetite	2	4		2	2	2
Diarrhoea	1	2		1	1	1
Disease recurrence		2		1		1
Dizziness	3	7	2	5	1	2
Drug ineffective		2				2
Dysgeusia	1	3		1	1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysphagia	1	2		1	1	1
Dyspnoea	1	5		4	1	1
Dyspnoea exertional	1	1	1	1		
Ear disorder		1		1		
Facial paralysis		1				1
Fall	1	1			1	1
Fatigue	1	7	1	7		
Feeling hot		1		1		
Fine motor skill dysfunction	1	1	1	1		
Flushing		1		1		
General physical health deterioration	1	1			1	1
Haemorrhage in pregnancy		1				1
Headache	1	7	1	6		1
Hyperhidrosis	1	2	1	2		
Hypersensitivity		1				1
Hypertension		1		1		
Hypertensive heart disease		1				1
Hypoaesthesia		2		2		
Hypoaesthesia oral	1	3	1	3		
Hypoglycaemia		1				1
Hypotension	2	3	1	1	1	2
Hypothermia		2				2
Immunisation anxiety related reaction		1				1
Insomnia		2		2		
Intranasal paraesthesia		1		1		
Lymphadenopathy		1		1		
Malaise		5		3		2
Maternal exposure during pregnancy		1				1
Migraine with aura		1		1		
Muscular weakness		1		1		
Myalgia	2	5	2	4		1
Myocardial infarction	1	1			1	1
Nasal congestion		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	2	6	1	4	1	2
Off label use		1		1		
Oral herpes		1		1		
Oropharyngeal discomfort		1				1
Oropharyngeal pain		2		2		
Pain in extremity	1	2	1	2		
Pallor		1				1
Panic attack		1		1		
Paraesthesia		4		4		
Paraesthesia oral		2		2		
Peripheral sensory neuropathy		1				1
Peripheral swelling	1	1			1	1
Pharyngeal hypoaesthesia		1		1		
Pharyngeal paraesthesia		1		1		
Pharyngeal swelling		1		1		
Photopsia		1		1		
Presyncope		1				1
Product use issue		1		1		
Psoriasis		1				1
Pulmonary embolism	2	3			2	3
Pulmonary oedema		1				1
Pyrexia	3	12	2	10	1	2
Respiration abnormal		1				1
Respiratory failure		2				2
Retinal vascular thrombosis		1				1
Rhinitis		1		1		
Seizure		1				1
Somnolence	2	4	1	3	1	1
Speech disorder		1				1
Suspected COVID-19		1				1
Syncope	1	3			1	3
Throat tightness		1				1
Vaccination failure	3	8			3	8

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site erythema		2		2		
Vaccination site oedema		1		1		
Vaccination site pain	2	7	2	7		
Vaccine breakthrough infection		1				1
Visual impairment		1				1
Vomiting	3	4	1	2	2	2
	57	230	22	128	35	102

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Country Where Event Occurred

FINLAND

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal distension		2		2		
Abdominal pain	1	3			1	3
Abdominal pain lower	2	2			2	2
Abdominal pain upper	2	3			2	3
Abdominal symptom		1		1		
Acne	1	1			1	1
Acquired haemophilia		1				1
Acute hepatic failure	1	1			1	1
Acute myocardial infarction		2				2
Acute respiratory failure		1				1
Ageusia		1				1
Allergy to vaccine	1	2			1	2
Amnesia	1	1			1	1
Anaphylactic reaction	3	7			3	7
Anaphylactic shock		1				1
Ankylosing spondylitis		1				1
Anosmia	1	1			1	1
Anti factor VIII ant body positive		1				1
Anxiety	1	1			1	1
Aortitis		1				1
Apathy	1	1			1	1
Aphasia	1	2			1	2
Aphonia	1	2			1	2
Apnoea	1	4			1	4
Appendicitis perforated	1	1			1	1
Areflexia		1				1
Arrhythmia	4	7			4	7
Arteriosclerosis	1	1			1	1
Arthralgia	7	24		1	7	23
Arthritis		1				1
Arthritis reactive		1				1
Aspiration		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	10	28	3	4	7	24
Asthenopia		1				1
Asthma	1	2			1	2
Atelectasis	1	1			1	1
Atrial f brillation	2	5			2	5
Axillary pain	1	4	1	2		2
Back pain	1	4			1	4
Bacterial test positive		1				1
Balance disorder	2	3	1	1	1	2
Bell's palsy	1	1			1	1
Biopsy muscle abnormal	1	1			1	1
Bladder dysfunction	1	1			1	1
Blepharitis		1				1
Blister	1	1			1	1
Blood creatinine increased		1				1
Blood glucose increased	2	3			2	3
Blood lactic acid decreased		1		1		
Blood pressure decreased	1	4			1	4
Blood pressure diastolic decreased		1				1
Blood pressure fluctuation	2	3			2	3
Blood pressure increased	5	11			5	11
Blood uric acid increased		1				1
Body temperature decreased		1				1
Breath sounds abnormal	2	2			2	2
Bronchiolitis		1				1
Burning sensation		3		1		2
Cardiac death	1	1			1	1
Cardiac disorder	1	1			1	1
Cardiac failure	2	6			2	6
Cardiac hypertrophy		1				1
Carotid artery thrombosis	1	1			1	1
Cerebral haematoma	1	1			1	1
Cerebral haemorrhage	1	2			1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral infarction	4	10			4	10
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident		1				1
Cerebrovascular disorder	1	2			1	2
Chest discomfort	2	7			2	7
Chest pain	2	6		1	2	5
Chest X-ray abnormal		1				1
Chills	6	17	3	4	3	13
Chromatopsia	1	1			1	1
Circulatory collapse		1				1
Clumsiness	1	1			1	1
Cognitive disorder		1				1
Cold sweat	1	2			1	2
Coma scale abnormal		2				2
Condition aggravated	2	4			2	4
Confusional state	5	8	1	2	4	6
Congestive cardiomyopathy		1				1
Contusion	1	1			1	1
Coordination abnormal	1	1			1	1
Coronary artery thrombosis		1				1
Cough	7	17		2	7	15
COVID-19		1				1
C-reactive protein abnormal	1	1			1	1
C-reactive protein increased	4	12	1	2	3	10
CREST syndrome		1				1
Crohn's disease		1				1
Cyanosis		1				1
Cystitis		1				1
Deafness	1	1			1	1
Deafness unilateral		2				2
Death	4	14			4	14
Deep vein thrombosis	4	7			4	7
Dehydration	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dementia Alzheimer's type		4				4
Depressed level of consciousness		4				4
Depressed mood	1	1			1	1
Derealisation		1		1		
Diarrhoea	6	12		3	6	9
Disease recurrence	2	4	1	1	1	3
Disseminated varicella zoster virus infection	2	2			2	2
Disturbance in attention	1	1			1	1
Diverticulitis		1				1
Dizziness	11	32	2	4	9	28
Drug ineffective		1				1
Drug interaction	1	1			1	1
Dysarthria		8				8
Dysgeusia	1	2			1	2
Dysmetria		1				1
Dysphagia		5		1		4
Dysphonia	6	6	1	1	5	5
Dyspnoea	16	49	1	1	15	48
Dyspnoea exertional		2				2
Dysstasia		1				1
Ear discomfort	1	3		2	1	1
Ear pain		2		1		1
Eating disorder		1		1		
Eczema		1				1
Electric shock sensation		1		1		
Embolc cerebellar infarction	1	1			1	1
Embolc cerebral infarction	1	1			1	1
Epilepsy		1				1
Epistaxis		2				2
Erysipelas	1	2			1	2
Erythema	2	12		2	2	10
Erythema multiforme		1				1
Escherichia infection	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Extensive swelling of vaccinated limb		1		1		
Extrasystoles	1	2			1	2
Eye disorder		1				1
Eyelid ptosis		1				1
Eye oedema	1	1			1	1
Eye pain		1				1
Eye swelling	1	1			1	1
Face oedema	1	3			1	3
Facial pain		1		1		
Facial paralysis	2	8			2	8
Facial paresis	1	2	1	1		1
Fall	3	11		1	3	10
Fatigue	17	60	1	5	16	55
Feeling abnormal	6	12			6	12
Feeling cold	4	9	1	2	3	7
Feeling drunk		1				1
Feeling hot	1	6		2	1	4
Fibrin D dimer increased		2		2		
Fine motor skill dysfunction	1	1			1	1
Flank pain		1				1
Flatulence		1		1		
Fluid intake reduced		1				1
Fluid retention	1	1			1	1
Flushing		3				3
Foaming at mouth		1				1
Fracture	1	1			1	1
Gait deviation	1	1			1	1
Gait disturbance	2	6			2	6
Gait inability	1	1			1	1
Gastric disorder		1		1		
Gaze palsy		2				2
General physical health deterioration	9	27		1	9	26
Giant cell arteritis	1	2			1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gingival swelling		1		1		
Glomerular filtration rate decreased	1	1	1	1		
Glossodynia	1	1	1	1		
Haematoma		2		1		1
Haemodynamic instability		1				1
Haemoglobin decreased		2				2
Hallucination	1	1			1	1
Headache	20	53	3	8	17	45
Head discomfort	2	6		1	2	5
Heart rate abnormal	1	1			1	1
Heart rate decreased		2		1		1
Heart rate increased	2	7			2	7
Heart rate irregular	2	4			2	4
Heavy menstrual bleeding	1	1	1	1		
Hemianaesthesia	1	4			1	4
Hemiparaesthesia		2				2
Hemiparesis	2	6			2	6
Hemiplegia		2				2
Hepatic steatosis	1	1	1	1		
Herpes zoster	2	4			2	4
Herpes zoster cutaneous disseminated	1	1			1	1
Human herpesvirus 6 infection	1	1			1	1
Hyperacusis	1	1			1	1
Hyperhidrosis	3	6			3	6
Hypernatraemia		1				1
Hypersensitivity	6	10	1	1	5	9
Hypertension	2	6		1	2	5
Hyperventilation		1				1
Hypoacusis	1	3	1	3		
Hypoaesthesia	6	18	3	5	3	13
Hypoaesthesia oral	2	5	1	1	1	4
Hypokalaemia	1	5			1	5
Hyponatraemia		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypophagia		1				1
Hyporeflexia		1				1
Hypotonia	1	2			1	2
Illusion	1	1			1	1
Immune thrombocytopenia		1				1
Impaired reasoning		1				1
Impaired work ability	1	6			1	6
Inappropriate schedule of product administration	4	4	4	4		
Incorrect route of product administration		2		2		
Increased tendency to bruise		1				1
Increased upper airway secretion	1	4			1	4
Infection		2				2
Inflammation	1	1	1	1		
Inflammatory marker increased		1				1
Influenza		1		1		
Influenza like illness		1				1
Initial insomnia		1				1
Insomnia	1	2			1	2
International normalised ratio decreased		3		1		2
Intervertebral disc disorder		1		1		
Intestinal ischaemia	1	1			1	1
Iritis		1				1
Irritability	1	2			1	2
Joint effusion		1				1
Joint injury		1				1
Joint stiffness	1	1			1	1
Joint swelling	1	2		1	1	1
Ketoacidosis	1	1			1	1
Klebsiella infection	1	1			1	1
Laboratory test abnormal	1	1			1	1
Lethargy	1	1			1	1
Limb discomfort	1	1	1	1		
Limb injury		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lip pain		2		2		
Lip swelling	1	3		1	1	2
Loss of consciousness	4	7			4	7
Loss of control of legs		2				2
Loss of personal independence in daily activities	2	3			2	3
Lung disorder		2				2
Lymphadenitis	1	1			1	1
Lymphadenopathy	2	5	1	1	1	4
Lymph node pain		1				1
Macular oedema	1	1			1	1
Malaise	5	23		2	5	21
Mechanical ventilation		1				1
Memory impairment	1	2			1	2
Mental impairment		1				1
Mesenteric vein thrombosis	2	2			2	2
Middle insomnia		2		1		1
Migraine	1	6			1	6
Migraine with aura		1				1
Mobility decreased	2	4			2	4
Mouth haemorrhage		1				1
Movement disorder	1	1			1	1
Multiple sclerosis relapse	2	2			2	2
Muscle disorder		1				1
Muscle fatigue		1				1
Muscle rigidity	1	1			1	1
Muscle spasms	3	4	1	1	2	3
Muscle spasticity		2				2
Muscle strain		1				1
Muscle tightness		1				1
Muscle twitching	3	7	2	3	1	4
Muscular weakness	3	9	1	1	2	8
Musculoskeletal discomfort		1				1
Musculoskeletal disorder		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal pain		1				1
Musculoskeletal stiffness	1	6		1	1	5
Myalgia	12	34	3	5	9	29
Myelitis transverse	1	1			1	1
Myokymia	1	1			1	1
Narcolepsy		1				1
Nasal congestion		1				1
Nasopharyngitis		2				2
Nausea	13	35	2	4	11	31
Neck pain	1	4			1	4
Neuralgia	1	4		1	1	3
Neurological symptom		2				2
Nightmare	1	1			1	1
Obstruction		1				1
Oedema		1		1		
Oedema peripheral	1	6		3	1	3
Off label use	3	4	3	4		
Ophthalmic vein thrombosis		1				1
Opisthotonus		1				1
Oral discomfort		2		2		
Oral disorder		1				1
Oral pruritus	1	1			1	1
Oropharyngeal discomfort		2				2
Oropharyngeal oedema		1				1
Oropharyngeal pain	2	4			2	4
Osteoarthritis		1		1		
Oxygen saturation decreased		3				3
Pain		8				8
Painful respiration		1				1
Pain in extremity	12	30	3	6	9	24
Pain in jaw	1	1			1	1
Pain of skin	2	3	1	2	1	1
Pallor		2				2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Palpitations	5	10	2	2	3	8
Papule	1	2		1	1	1
Paraesthesia	4	16	1	3	3	13
Paraesthesia oral	4	11		3	4	8
Paresis		1				1
Peak expiratory flow rate decreased		2				2
Pelvic venous thrombosis		1				1
Peripheral embolism		1				1
Peripheral swelling	3	5	1	2	2	3
Peritonitis	1	1			1	1
Petit mal epilepsy		1				1
Pharyngeal oedema	1	3			1	3
Pharyngeal paraesthesia		1				1
Pharyngeal swelling	4	8	1	1	3	7
Photophobia	1	1			1	1
Photopsia		2				2
Photosensitivity reaction	1	2			1	2
Pigmentary glaucoma		1				1
Platelet count decreased	1	1			1	1
Pleural effusion	1	1			1	1
Pneumonia	2	9			2	9
Pneumonia aspiration		1				1
Polycythaemia	1	1	1	1		
Polymyalgia rheumatica	1	2			1	2
Porphyria		1				1
Post herpetic neuralgia	1	1	1	1		
Presyncope		3		1		2
Productive cough		2				2
Product use issue		1		1		
Pruritus	6	12	2	5	4	7
Pseudomonal sepsis		1				1
Pulmonary embolism	2	9			2	9
Pulmonary haemorrhage		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary oedema		1				1
Pulmonary pain		2				2
Pyelonephritis	1	2			1	2
Pyrexia	21	64	5	8	16	56
Rales		1				1
Rash	2	5	1	1	1	4
Rash erythematous		3		1		2
Rash macular		2				2
Rash papular	1	1			1	1
Rash vesicular	1	1			1	1
Rectal haemorrhage		1				1
Reduced facial expression		1		1		
Renal disorder		1		1		
Renal failure	1	1			1	1
Respiratory arrest		2				2
Respiratory rate increased	1	1			1	1
Respiratory tract infection		1				1
Retinal tear		1				1
Retinal vascular occlusion	1	2			1	2
Retinal vein occlusion	1	1			1	1
Rheumatoid arthritis		1				1
Rhinitis		1				1
Rhinorrhoea	1	2			1	2
Rhonchi		1				1
Right ventricular failure		1				1
SARS-CoV-2 test negative	1	2			1	2
Secretion discharge		1		1		
Seizure	1	3			1	3
Sensation of foreign body	1	4			1	4
Sinus tachycardia		2				2
Skin burning sensation	1	1			1	1
Skin sensitisation		1				1
Skin striae		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin warm		2		1		1
Skull fractured base		1				1
Sleep disorder	1	1	1	1		
Slow speech		1				1
Small intestinal resection	1	1			1	1
Snoring		1				1
Somnolence	4	6	1	1	3	5
Speech disorder	3	5			3	5
Spinal pain	1	1			1	1
Stertor	1	1			1	1
Stiff tongue		1				1
Strabismus		1				1
Stridor		1				1
Stupor		1				1
Subcutaneous abscess		1				1
Sudden death		3				3
Suicidal ideation	1	1			1	1
Swelling		2		1		1
Swelling face	1	2			1	2
Swollen tongue	2	3			2	3
Syncope	1	7			1	7
Synovial fluid white blood cells positive		1				1
Tachycardia	2	3			2	3
Tension headache	1	1			1	1
Thirst	2	2	1	1	1	1
Throat irritation	3	4			3	4
Throat tightness	2	4			2	4
Thrombocytopenia	1	1			1	1
Thrombophlebitis superficial	2	3			2	3
Thrombosis		4				4
Tinnitus	4	4	1	1	3	3
Tongue discolouration		1				1
Tongue discomfort		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue disorder		1				1
Tongue erythema		1				1
Tongue oedema		1				1
Tongue pruritus	1	1			1	1
Toothache		1		1		
Transient aphasia		1				1
Transient ischaemic attack		2				2
Traumatic intracranial haemorrhage	1	1			1	1
Tremor	1	8			1	8
Ulcerative keratitis		1				1
Unresponsive to stimuli	1	3			1	3
Urinary tract infection	2	5		1	2	4
Urine porphobilinogen increased		1				1
Urticaria	2	9	1	3	1	6
Vaccination site bruising	1	2	1	1		1
Vaccination site erythema		7		4		3
Vaccination site haematoma		1		1		
Vaccination site hyperaesthesia	1	1			1	1
Vaccination site hypersensitivity	1	1			1	1
Vaccination site hypoaesthesia	1	2			1	2
Vaccination site joint movement impairment		1		1		
Vaccination site mass		1				1
Vaccination site movement impairment	1	3			1	3
Vaccination site oedema	1	5		3	1	2
Vaccination site pain	7	20	2	4	5	16
Vaccination site pruritus		3		3		
Vaccination site reaction		3		2		1
Vaccination site swelling		1				1
Vaccination site warmth		5		2		3
Venous thrombosis		1				1
Venous thrombosis limb	2	2			2	2
Vertigo	2	3			2	3
Vertigo positional		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Viral infection		2				2
Visual acuity reduced	1	1			1	1
Visual impairment	2	5			2	5
Vomiting	4	16	1	2	3	14
Weight decreased		1		1		
Wheezing	2	4			2	4
White blood cell count decreased	1	1	1	1		
White blood cell count increased		2				2
	542	1,564	80	213	462	1351

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Country Where Event Occurred

FRANCE

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		2		2		
Abdominal distension	1	6		3	1	3
Abdominal mass	1	2	1	2		
Abdominal pain	13	49	7	24	6	25
Abdominal pain lower		2		1		1
Abdominal pain upper	9	27	3	7	6	20
Abdominal wall haematoma	1	1			1	1
Abnormal behaviour		2		1		1
Abnormal faeces		1		1		
Abnormal sensation in eye		1		1		
Abortion spontaneous	1	4			1	4
Acidosis hyperchloraemic		1				1
Acquired haemophilia		1				1
Activated partial thromboplastin time abnormal		1				1
Activated partial thromboplastin time prolonged	1	1			1	1
Activated partial thromboplastin time shortened		1				1
Acute abdomen		1				1
Acute coronary syndrome	3	16			3	16
Acute febrile neutrophilic dermatosis		1				1
Acute generalised exanthematous pustulosis	1	1			1	1
Acute kidney injury	12	32			12	32
Acute myeloid leukaemia		2				2
Acute myocardial infarction		4				4
Acute pulmonary oedema	4	22			4	22
Acute respiratory distress syndrome	5	20			5	20
Acute respiratory failure	2	17			2	17
Acute sinusitis		1		1		
Acute vestibular syndrome	1	1			1	1
Adrenal mass		1		1		
Adrenocortical insufficiency acute	1	2			1	2
Adult failure to thrive		1				1
Aerococcus urinae infection		1				1
Affective disorder	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	3	5	2	4	1	1
Aggression	1	6		1	1	5
Agitation	2	19		6	2	13
Agranulocytosis		2				2
Air embolism		1				1
Alanine aminotransferase increased	2	6		3	2	3
A buminuria		1				1
Allodynia	1	1	1	1		
Altered state of consciousness	2	11			2	11
Amaurosis	1	2			1	2
Amaurosis fugax		1				1
Amenorrhoea		1				1
Amnesia	3	6			3	6
Anaemia	7	17	1	2	6	15
Anaemia macrocytic		1				1
Anal incontinence	1	1	1	1		
Anaphylactic reaction	5	18			5	18
Anaphylactic shock	3	9			3	9
Anaphylactoid reaction	1	2			1	2
Anaphylactoid shock	1	1			1	1
Aneurysm	1	1			1	1
Aneurysm ruptured	1	1			1	1
Angina pectoris	1	7			1	7
Angina unstable		1				1
Angioedema	8	28			8	28
Ankylosing spondylitis	3	8			3	8
Anosmia	2	2			2	2
Anterograde amnesia	1	1			1	1
Anticoagulation drug level below therapeutic		2		1		1
Anti-neutrophil cytoplasmic antibody positive vasculitis		1				1
Antinuclear ant body positive		1				1
Antisynthetase syndrome		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anuria	1	3			1	3
Anxiety	4	17	1	5	3	12
Anxiety disorder		1		1		
Aortic arteriosclerosis	1	2	1	1		1
Aortic stenosis	1	2			1	2
Aortic valve calcification		1				1
Aortic valve incompetence		3				3
Apathy		4		2		2
Aphasia	7	21		4	7	17
Aphonia		1				1
Aphthous ulcer		2		1		1
Aplasia		1				1
Aplastic anaemia		1				1
Appendicitis	1	3			1	3
Arrhythmia	11	37			11	37
Arrhythmia supraventricular		3				3
Arterial disorder	1	2			1	2
Arterial thrombosis	2	2			2	2
Arteriosclerosis	1	3			1	3
Arteriosclerosis coronary artery	1	1	1	1		
Arteriovenous fistula thrombosis		1				1
Arteriovenous malformation	1	1			1	1
Artery dissection	1	1			1	1
Arthralgia	21	85	12	35	9	50
Arthritis		5		2		3
Arthritis reactive		4				4
Aspartate aminotransferase increased	1	5		3	1	2
Aspiration	1	4			1	4
Asthenia	76	317	46	119	30	198
Asthma	4	15	1	2	3	13
Asthmatic crisis	7	14			7	14
Asymptomatic COVID-19	1	9		1	1	8
Ataxia	3	7	2	4	1	3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Atrial fibrillation	30	86			30	86
Atrial flutter		4		1		3
Atrial thrombosis	1	2			1	2
Atrioventricular block	2	7		1	2	6
Atrioventricular block complete	1	4			1	4
Atrioventricular block first degree	1	1			1	1
Atrioventricular block second degree	1	1			1	1
Autoimmune haemolytic anaemia		1				1
Autoimmune hepatitis		1				1
Autoimmune thyroiditis	2	3			2	3
Axillary pain	1	5	1	2		3
Back pain	7	20	3	8	4	12
Bacteraemia	1	1			1	1
Bacterial infection		1				1
Bacterial pyelonephritis		1				1
Bacterial sepsis		1				1
Bacteriuria	1	1			1	1
Balance disorder	5	16	4	7	1	9
Bedridden	1	2		1	1	1
Behaviour disorder	2	10		1	2	9
Bell's palsy	1	1			1	1
Benign breast neoplasm		1		1		
Benign prostatic hyperplasia	2	3	2	3		
Bicytopenia	1	1			1	1
Biliary colic	1	1	1	1		
Bilirubin conjugated increased		1		1		
Bipolar disorder		1				1
Bladder dilatation		1				1
Bladder dysfunction	1	1	1	1		
Blastocystis infection		1				1
Blindness	2	2			2	2
Blindness transient		1				1
Blindness unilateral	1	3			1	3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blister	1	2			1	2
Blood albumin decreased		1		1		
Blood alkaline phosphatase increased	1	4		3	1	1
Blood bicarbonate decreased		1				1
Blood bilirubin abnormal		1		1		
Blood bilirubin increased		1		1		
Blood bilirubin unconjugated increased		1		1		
Blood blister	1	1			1	1
Blood calcium decreased		1		1		
Blood chloride increased	1	1			1	1
Blood cholesterol increased	1	1			1	1
Blood creatine phosphokinase increased		1				1
Blood creatinine abnormal		1				1
Blood creatinine decreased		1				1
Blood creatinine increased	3	5	1	3	2	2
Blood culture positive		1				1
Blood fibrinogen increased	2	2	2	2		
Blood folate decreased		1				1
Blood glucose fluctuation		1		1		
Blood glucose increased	1	8		5	1	3
Blood lactate dehydrogenase increased	2	3	1	2	1	1
Blood lactic acid increased	1	1			1	1
Blood loss anaemia		1				1
Blood parathyroid hormone increased		1		1		
Blood potassium increased		1		1		
Blood pressure abnormal		2		1		1
Blood pressure decreased	2	7	2	4		3
Blood pressure diastolic decreased	1	4		2	1	2
Blood pressure fluctuation	2	3		1	2	2
Blood pressure increased	11	22	4	7	7	15
Blood pressure systolic decreased		1		1		
Blood pressure systolic increased		5		1		4
Blood sodium decreased		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood sodium increased		3		1		2
Blood thyroid stimulating hormone decreased		1		1		
Blood thyroid stimulating hormone increased		3		2		1
Blood urea increased	2	2	1	1	1	1
Blood uric acid increased		1		1		
Blood urine present	1	1	1	1		
Body temperature decreased		3		1		2
Body temperature increased	4	7	4	5		2
Bone abscess		1				1
Bone pain		2				2
Bone swelling	1	1			1	1
Bradyarrhythmia	1	1	1	1		
Bradycardia	4	23			4	23
Bradyphrenia		1				1
Brain contusion		1				1
Brain hypoxia		1				1
Brain natriuretic peptide increased		4		2		2
Brain oedema	2	2			2	2
Brain stem haemorrhage		1				1
Brain stem stroke	1	1			1	1
Breast abscess		1				1
Breast pain		3		1		2
Breast swelling		1		1		
Breath sounds abnormal	2	3	2	2		1
Bronchial obstruction		1				1
Bronchiectasis	1	1			1	1
Bronchiolitis		1				1
Bronchitis	7	13	2	3	5	10
Bronchopneumopathy		4		1		3
Bronchospasm	3	9	1	1	2	8
Bundle branch block		1				1
Bundle branch block left	1	4			1	4
Bundle branch block right	1	8		3	1	5

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burning sensation	4	7	2	3	2	4
Burn oesophageal	1	1			1	1
Bursal fluid accumulation		1		1		
Bursal haematoma	1	1			1	1
Capillary fragility	1	1			1	1
Capillary leak syndrome	1	1			1	1
Carcinoembryonic antigen increased		1				1
Cardiac arrest	6	18			6	18
Cardiac discomfort		2		1		1
Cardiac failure	17	89			17	89
Cardiac failure acute	1	6			1	6
Cardiac failure congestive		1				1
Cardiac fibrillation		1				1
Cardiac flutter		2				2
Cardiac tamponade		1				1
Cardiogenic shock	3	8			3	8
Cardiomegaly	2	3			2	3
Cardiomyopathy		1				1
Cardiopulmonary failure	2	5			2	5
Cardio-respiratory arrest	6	33			6	33
Cardio-respiratory distress		2				2
Cardiovascular disorder	1	4	1	1		3
Carotid arteriosclerosis	1	1			1	1
Carotid artery occlusion		2				2
Carotid artery thrombosis		2				2
Cataract		1				1
Cell death		2				2
Central nervous system lesion		1				1
Cerebellar haematoma		1				1
Cerebellar infarction		1				1
Cerebellar stroke	2	3			2	3
Cerebellar syndrome	2	4			2	4
Cerebral amyloid angiopathy		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral arteriosclerosis		1				1
Cerebral artery stenosis		1				1
Cerebral atrophy		2				2
Cerebral disorder	1	2	1	1		1
Cerebral haematoma	1	8			1	8
Cerebral haemorrhage	1	8			1	8
Cerebral infarction	1	7			1	7
Cerebral ischaemia		1				1
Cerebral thrombosis		1				1
Cerebral venous thrombosis	1	2			1	2
Cerebrovascular accident	22	49			22	49
Cervicobrachial syndrome	2	5	1	2	1	3
Chest discomfort	7	30	2	9	5	21
Chest injury	2	3			2	3
Chest pain	30	92	6	14	24	78
Chest X-ray abnormal		1				1
Chillblains	4	4	4	4		
Chills	25	113	18	50	7	63
Choking	1	4			1	4
Cholecystitis acute	1	1			1	1
Cholelithiasis	2	2	1	1	1	1
Cholestasis	4	8			4	8
Cholestatic liver injury	2	2			2	2
Chromaturia		2		1		1
Chronic kidney disease	4	5			4	5
Chronic obstructive pulmonary disease	1	15		2	1	13
Circadian rhythm sleep disorder		1		1		
Circulatory collapse	1	6			1	6
Citrobacter infection		1				1
Clonic convulsion	1	1			1	1
Clumsiness	2	3	2	2		1
Cognitive disorder	4	7	2	3	2	4
Cold sweat	1	4		2	1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Colitis		1				1
Colitis ulcerative	1	1			1	1
Coma	2	11			2	11
Coma scale abnormal		1				1
Communication disorder	1	1			1	1
Condition aggravated	20	60	4	12	16	48
Conduction disorder		1				1
Confusional state	10	45	1	4	9	41
Conjunctival haemorrhage	2	6			2	6
Conjunctival hyperaemia		1		1		
Conjunctivitis	1	2	1	1		1
Conjunctivitis bacterial		1				1
Constipation	4	9	3	8	1	1
Contusion		1		1		
Coordination abnormal	1	2	1	1		1
Coronary artery disease		1				1
Coronary artery occlusion	1	1			1	1
Coronary artery stenosis	1	4			1	4
Coronavirus infection		1				1
Cough	16	58	11	26	5	32
COVID-19	108	266	1	19	107	247
COVID-19 pneumonia	16	34			16	34
Cranial nerve paralysis	1	1			1	1
C-reactive protein increased	9	45	2	18	7	27
Creatinine renal clearance decreased	1	2	1	1		1
Crepitations		3		2		1
Culture urine positive		1		1		
Cutaneous lupus erythematosus		1				1
Cutaneous vasculitis		1				1
Cyanosis	2	11	1	3	1	8
Cystic lymphangioma		1				1
Cystitis		1				1
Cystitis klebsiella		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Daydreaming		2				2
Deafness	2	4			2	4
Deafness unilateral	1	5			1	5
Death	11	91			11	91
Decreased appetite	19	50	10	25	9	25
Decubitus ulcer		3		1		2
Deep vein thrombosis	68	91			68	91
Defect conduction intraventricular		1				1
Deformity		1		1		
Degenerative mitral valve disease	1	1			1	1
Dehydration	8	32		7	8	25
Delirium	1	6			1	6
Delusion		3		1		2
Dementia	1	4			1	4
Dependent rubor		1				1
Depressed level of consciousness	2	15			2	15
Depression		1		1		
Dermabrasion		1		1		
Dermal cyst		1		1		
Dermatitis bullous	1	1			1	1
Dermatitis exfoliative generalised		1				1
Dermatomyositis		2				2
Dermatosis	1	1	1	1		
Dermo-hypodermatitis		2				2
Diabetes insipidus	1	1			1	1
Diabetes mellitus	4	12			4	12
Diabetes mellitus inadequate control	3	14			3	14
Diabetic coma		1				1
Diabetic hyperosmolar coma	1	2			1	2
Diabetic ketoacidosis	1	4			1	4
Diabetic ketosis	1	2			1	2
Diabetic metabolic decompensation	1	2			1	2
Diarrhoea	30	114	12	37	18	77

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea haemorrhagic		4				4
Diarrhoea infectious		1				1
Dilatation ventricular	1	1	1	1		
Diplopia	5	11		1	5	10
Discomfort	6	33	1	7	5	26
Disease progression	1	2			1	2
Disease recurrence	21	68	1	3	20	65
Disorientation	4	19	1	4	3	15
Disseminated intravascular coagulation		1				1
Disseminated varicella zoster virus infection	1	1			1	1
Disturbance in attention	2	8	1	3	1	5
Diverticulitis		1				1
Dizziness	33	82	16	32	17	50
Dizziness postural	1	2	1	1		1
Drop attacks	1	2			1	2
Drug eruption	1	2		1	1	1
Drug hypersensitivity		2				2
Drug ineffective	33	79	1	1	32	78
Drug interaction		1		1		
Drug reaction with eosinophilia and systemic symptoms		1				1
Dry eye		1				1
Dry mouth	3	5	2	3	1	2
Dry skin	1	1			1	1
Dysaesthesia	1	5		1	1	4
Dysarthria	6	17	4	5	2	12
Dysgeusia	7	17	5	7	2	10
Dysgraphia		1				1
Dyshidrotic eczema		1		1		
Dyskinesia	2	5		2	2	3
Dyslipidaemia		1		1		
Dysmetria	1	2			1	2
Dyspepsia	1	3	1	2		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysphagia	5	17	1	3	4	14
Dysphemia		1				1
Dysphonia	2	7	1	2	1	5
Dyspnoea	62	171	20	35	42	136
Dyspnoea at rest	1	5			1	5
Dyspnoea exertional	7	17	2	5	5	12
Dysstasia	1	4			1	4
Dysuria		1		1		
Ear haemorrhage	1	2		1	1	1
Ear pain	1	6		1	1	5
Ear swelling		1				1
Eating disorder		1				1
Ecchymosis	2	2	1	1	1	1
Eczema	1	2			1	2
Eczema nummular		1				1
Ejection fraction abnormal	1	1			1	1
Ejection fraction decreased	1	2	1	1		1
Electric shock sensation		1				1
Electrocardiogram abnormal	1	1			1	1
Electrocardiogram PR prolongation		1				1
Electrocardiogram QRS complex prolonged	1	2			1	2
Electrocardiogram QRS complex shortened		1				1
Electrocardiogram QT interval abnormal		1				1
Electrocardiogram repolarisation abnormality	1	3			1	3
Electrocardiogram ST segment elevation	1	1			1	1
Electrocardiogram T wave inversion		1				1
Embolic stroke	1	5			1	5
Embolism		1				1
Embolism venous		1				1
Emotional distress		1		1		
Encephalitis	1	3			1	3
Encephalopathy	1	1			1	1
Enlarged uvula		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Enteritis	1	1			1	1
Enterococcal infection		1				1
Enterocolitis haemorrhagic	1	1			1	1
Enthesopathy	1	1			1	1
Enuresis		1				1
Eosinophil count increased		1		1		
Eosinophilia	1	3			1	3
Epilepsy	8	26			8	26
Epistaxis	8	16	1	4	7	12
Epstein-Barr virus infection reactivation	1	1			1	1
Epstein-Barr virus test positive		1		1		
Eructation		2				2
Erysipelas	3	9			3	9
Erythema	13	48	8	20	5	28
Erythema multiforme	1	3			1	3
Erythema nodosum		1				1
Erythema of eyelid		1				1
Erythrosis	1	1	1	1		
Escherichia bacteraemia		1				1
Escherichia pyelonephritis	1	1			1	1
Escherichia test positive		1		1		
Escherichia urinary tract infection	2	5			2	5
Euphoric mood		1		1		
Exposure during pregnancy	1	1	1	1		
Exposure to SARS-CoV-2		1				1
Extensive swelling of vaccinated limb		3		3		
Extensor plantar response		1				1
Extradural haematoma		1				1
Extrapyramidal disorder		3		1		2
Extrasystoles	1	10	1	2		8
Extremity necrosis	1	2		1	1	1
Eye discharge		1				1
Eye disorder		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye haemorrhage	1	2			1	2
Eye inflammation	1	1			1	1
Eye irritation		1		1		
Eyelid disorder		1				1
Eyelid haematoma		1		1		
Eyelid oedema		3				3
Eyelid ptosis		2				2
Eye movement disorder	3	4	1	2	2	2
Eye oedema		1		1		
Eye pain	2	4	1	2	1	2
Eye swelling	1	3			1	3
Face injury	1	3			1	3
Face oedema	2	20		1	2	19
Facial asymmetry		2				2
Facial bones fracture		2				2
Facial paralysis	30	77			30	77
Facial paresis		3		1		2
Faecaloma	1	2			1	2
Faecal vomiting		2				2
Faeces discoloured		1		1		
Faeces soft		1		1		
Failure to thrive		1				1
Fall	22	80	6	18	16	62
Fatigue	32	151	18	72	14	79
Fat tissue increased		1		1		
Fear		2		1		1
Febrile bone marrow aplasia	1	1			1	1
Feeding disorder	1	1			1	1
Feeling abnormal	3	14	2	7	1	7
Feeling cold	1	12		6	1	6
Feeling drunk	1	3	1	1		2
Feeling hot	5	17	4	7	1	10
Feeling of body temperature change	1	2	1	1		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Femur fracture		2				2
Fibrin D dimer increased	6	9			6	9
Flank pain		2		1		1
Flatulence		2		1		1
Fluid overload	1	1			1	1
Fluid retention		1				1
Flushing	2	11	2	5		6
Foaming at mouth		1				1
Focal dyscognitive seizures		2				2
Folate deficiency	2	2	1	1	1	1
Food aversion		1				1
Food craving		1				1
Food refusal	1	1	1	1		
Foot deformity		1		1		
Formication		1				1
Fracture		1				1
Frostbite		1		1		
Functional gastrointestinal disorder		2				2
Gait disturbance	8	21	6	13	2	8
Gait inability	3	6	2	2	1	4
Gamma-glutamyltransferase increased	2	7		4	2	3
Gastric ulcer	1	1			1	1
Gastric ulcer haemorrhage	1	1			1	1
Gastric volvulus		1				1
Gastritis erosive		1				1
Gastroenteritis	3	4	1	1	2	3
Gastrointestinal disorder	5	7	5	6		1
Gastrointestinal haemorrhage	1	4			1	4
Gastrointestinal motility disorder		1		1		
Gastrointestinal pain	1	2			1	2
Gastrointestinal sounds abnormal		1		1		
Gastrooesophageal reflux disease		2		1		1
Gaze palsy		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Generalised anxiety disorder		1				1
Generalised oedema		1				1
Generalised tonic-clonic seizure	4	13			4	13
General physical health deterioration	15	52	3	9	12	43
Genital haemorrhage		1				1
Genital herpes		1				1
Giant cell arteritis	2	6			2	6
Gingival pain	1	1	1	1		
Glomerular filtration rate decreased	3	6	1	2	2	4
Glossitis		1				1
Glossodynia		1		1		
Glycosylated haemoglobin increased	2	3	1	2	1	1
Goitre		1		1		
Gout	1	4	1	2		2
Gross motor delay		1				1
Guillain-Barre syndrome	2	5			2	5
Haemarthrosis	1	3			1	3
Haematemesis		4				4
Haematochezia		2				2
Haematoma	3	12		1	3	11
Haematoma muscle		1				1
Haematuria	2	6	1	1	1	5
Haemodynamic instability	1	3		2	1	1
Haemoglobin decreased		6		3		3
Haemoglobinuria		1				1
Haemolysis	1	1			1	1
Haemolytic anaemia		2				2
Haemophagocytic lymphohistiocytosis		3				3
Haemoptysis		3				3
Haemorrhage		1				1
Haemorrhagic disorder		1				1
Haemorrhagic stroke	1	10			1	10
Haemorrhagic transformation stroke	2	3			2	3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hallucination	1	9			1	9
Hallucination, auditory		1				1
Hallucination, olfactory		1				1
Hallucinations, mixed	1	2			1	2
Hallucination, visual		7				7
Headache	88	295	54	122	34	173
Head discomfort	1	3	1	2		1
Head injury	4	13		1	4	12
Heart rate decreased	3	7	1	3	2	4
Heart rate increased	2	8	2	6		2
Heart rate irregular		2				2
Heart sounds abnormal	1	5	1	2		3
Heart valve incompetence	1	1	1	1		
Hemianaesthesia		1				1
Hemianopia homonymous		2				2
Hemiapraxia		1				1
Hemiataxia	1	1			1	1
Hemiparaesthesia	1	2			1	2
Hemiparesis	4	10			4	10
Hemiplegia	4	18			4	18
Hepatic cyst		1				1
Hepatic cyst infection		1				1
Hepatic cytolysis	3	9			3	9
Hepatic enzyme abnormal	1	1			1	1
Hepatic enzyme increased		3		1		2
Hepatic failure	1	1			1	1
Hepatic function abnormal		1		1		
Hepatic haematoma		1				1
Hepatic infarction	1	2			1	2
Hepatic steatosis	1	2	1	2		
Hepatitis	1	2			1	2
Hepatitis acute	1	1			1	1
Hepatitis B		1				1

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			Nonserious		Serious	
			I	C	I	C
Hepatitis E	1	1			1	1
Hepatocellular injury	2	4			2	4
Hepatomegaly	2	4			2	4
Herpes simplex		1		1		
Herpes virus infection	1	1	1	1		
Herpes zoster	48	86	23	33	25	53
Herpes zoster cutaneous disseminated		1				1
Herpes zoster meningoradiculitis	1	1			1	1
Herpes zoster reactivation	1	1	1	1		
High density lipoprotein decreased	1	1	1	1		
High-pitched crying		1		1		
Hippocampal atrophy		1				1
Hoffmann's sign		1		1		
Horner's syndrome		1				1
Hostility		1				1
Hot flush		15		5		10
Humerus fracture		1				1
Hyperacusis		1		1		
Hyperaesthesia	1	3		1	1	2
Hyperbilirubinaemia	1	4			1	4
Hypercalcaemia		1		1		
Hypercalcaemia of malignancy		1		1		
Hypercapnia		2				2
Hyperchloraemia		1				1
Hypergammaglobulinaemia	1	1	1	1		
Hyperglycaemia	3	15	1	6	2	9
Hyperglycinaemia		1				1
Hyperhidrosis	6	29	1	3	5	26
Hyperkalaemia	3	10			3	10
Hyperlactacidaemia	1	2			1	2
Hyperleukocytosis	3	17			3	17
Hypermetabolism	1	1			1	1
Hypernatraemia	1	8		3	1	5

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			Nonserious		Serious	
			I	C	I	C
Hypersensitivity	7	40	2	9	5	31
Hypersensitivity vasculitis		1				1
Hypersomnia		4		2		2
Hypertension	69	251	6	28	63	223
Hypertensive crisis	15	64			15	64
Hyperthermia	13	51	1	12	12	39
Hyperthyroidism		3				3
Hypertonia		1				1
Hypertriglyceridaemia	1	1	1	1		
Hypertrophic cardiomyopathy		1				1
Hyperuricaemia		1		1		
Hyperventilation	1	2		1	1	1
Hypoacusis		3				3
Hypoaesthesia	10	25	4	12	6	13
Hypoaesthesia eye	1	1	1	1		
Hypoaesthesia oral		3				3
Hypoalbuminaemia	2	2	1	1	1	1
Hypocalcaemia	1	2			1	2
Hypocapnia	1	1	1	1		
Hypogammaglobulinaemia	1	2			1	2
Hypoglycaemia	2	10	1	1	1	9
Hypokalaemia	2	7			2	7
Hypokinesia		1				1
Hyponatraemia	3	3	1	1	2	2
Hypotension	14	91	1	16	13	75
Hypothermia	1	7			1	7
Hypothyroidism	2	2			2	2
Hypotonia	2	9	1	3	1	6
Hypoventilation	1	1			1	1
Hypovolaemic shock		2				2
Hypoxia	4	25			4	25
Hypoxic-ischaemic encephalopathy	1	1			1	1
Idiopathic pulmonary fibrosis	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Illrd nerve paralysis	1	3			1	3
Ill-defined disorder		1				1
Illness	1	2	1	1		1
Illusion		1				1
Immune reconstitution inflammatory syndrome	1	1			1	1
Immune thrombocytopenia	10	17			10	17
Immunodeficiency		1				1
Immunoglobulin G4 related disease	1	1			1	1
Impaired driving ability	1	2			1	2
Impaired work ability	1	4		1	1	3
Impetigo	1	1			1	1
Inappropriate schedule of product administration	5	10	5	9		1
Incoherent	1	5		2	1	3
Incontinence	1	1			1	1
Incorrect dose administered	2	2	1	1	1	1
Incorrect route of product administration	3	9	3	9		
Increased bronchial secretion		3				3
Induration		1				1
Infarction	1	5			1	5
Infection	2	6	1	3	1	3
Inflammation	13	33	5	14	8	19
Inflammatory marker increased	1	1			1	1
Inflammatory pain		2				2
Influenza	5	20	3	6	2	14
Influenza like illness	46	167	21	48	25	119
Inhibitory drug interaction		1		1		
Initial insomnia		1				1
Injected limb mobility decreased		6		1		5
Injection site erythema		4		4		
Injection site hyperaesthesia		1		1		
Injection site oedema		1		1		
Injection site pain		1		1		
Injection site pruritus		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site rash		1				1
Injection site swelling		1		1		
Insomnia	8	26	5	16	3	10
Insulin-requiring type 2 diabetes mellitus		1				1
International normalised ratio abnormal		1				1
International normalised ratio increased	3	9		1	3	8
Interstitial lung disease	5	10			5	10
Intervertebral disc compression		1				1
Intervertebral disc protrusion		1		1		
Intestinal ischaemia	2	6			2	6
Intestinal obstruction		1				1
Intracardiac thrombus		2				2
Intracranial aneurysm	1	1			1	1
Intracranial haematoma		1				1
Intracranial pressure increased		1				1
Iridocyclitis	1	2			1	2
Iron binding capacity total abnormal	1	1			1	1
Iron deficiency anaemia		1				1
Irritability		1				1
Ischaemic limb pain		1				1
Ischaemic stroke	44	94			44	94
IVth nerve paralysis	1	1			1	1
Jaundice		4				4
Joint dislocation		1				1
Joint effusion		2				2
Joint injury		1				1
Joint stiffness		2				2
Joint swelling		4		2		2
Jugular vein distension		1				1
Jugular vein thrombosis	1	2			1	2
Ketoacidosis	1	1			1	1
Ketonuria	1	1			1	1
Klebsiella infection		2				2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Labile blood pressure		1				1
Laboratory test abnormal		1				1
Lacrimation increased		3		1		2
Lactic acidosis	1	2			1	2
Lactobacillus infection		1				1
Lacunar infarction		1				1
Lacunar stroke		1				1
Language disorder	1	3			1	3
Large intestine infection		1				1
Laryngeal discomfort	3	5		1	3	4
Laryngeal dyspnoea		2				2
Laryngeal oedema	1	6			1	6
Laryngeal stenosis	1	1			1	1
Laryngitis		2				2
Laryngitis allergic		1				1
Left atrial dilatation	1	2			1	2
Left ventricular dilatation		1		1		
Left ventricular end-diastolic pressure increased		1				1
Left ventricular failure	1	3			1	3
Left ventricular hypertrophy	1	2	1	1		1
Lethargy	1	1	1	1		
Leukocyte alkaline phosphatase increased	1	1			1	1
Leukocytosis	1	4		2	1	2
Leukocyturia	4	8	1	4	3	4
Leukoencephalopathy		4				4
Leukopenia		2				2
Lichenoid keratosis	1	1			1	1
Lichen planus		1				1
Limb discomfort	5	8	3	3	2	5
Lipase increased		1		1		
Lip blister	1	1	1	1		
Lip oedema	2	12		2	2	10
Lip pain		2				2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lip pruritus		1				1
Lip swelling	3	5	1	1	2	4
Listless		1				1
Lithiasis		1		1		
Livedo reticularis	3	12	3	6		6
Liver function test abnormal	2	2	1	1	1	1
Liver function test increased	1	2			1	2
Liver injury	2	2			2	2
Lividity		1				1
Localised oedema	1	7		2	1	5
Loss of consciousness	20	65			20	65
Loss of personal independence in daily activities	1	5		2	1	3
Low density lipoprotein increased	1	1			1	1
Lower respiratory tract congestion	1	6			1	6
Lower respiratory tract infection		1				1
Lung abscess		1				1
Lung disorder	7	32	1	7	6	25
Lung opacity		1				1
Lyme disease		1				1
Lymphadenitis		5		2		3
Lymphadenopathy	7	34	4	15	3	19
Lymph node pain		1				1
Lymphocyte count decreased		2		1		1
Lymphoedema	1	3	1	2		1
Lymphopenia	6	20	2	7	4	13
Macular oedema		1				1
Macule		1		1		
Madarosis		1				1
Major depression		1				1
Malaise	39	168	14	46	25	122
Malignant peritoneal neoplasm	1	1			1	1
Malnutrition	3	7		2	3	5
Mass		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Maternal exposure during pregnancy	2	4	1	2	1	2
Mean cell volume decreased		1				1
Melaena	3	4			3	4
Memory impairment		4		1		3
Meningioma	1	1			1	1
Meningitis		1				1
Meningitis aseptic	2	3			2	3
Meningoencephalitis herpetic	1	3			1	3
Meningoradiculitis		1				1
Meningorrhagia		1				1
Mental disorder	1	1			1	1
Mental impairment		1				1
Mesenteric artery thrombosis	1	1			1	1
Mesenteric vein thrombosis	2	2			2	2
Metabolic acidosis	3	3			3	3
Metamorphopsia		1				1
Metastases to peritoneum		1				1
Microcytic anaemia	1	1	1	1		
Middle insomnia	2	4			2	4
Migraine	2	11	2	5		6
Migraine with aura		1		1		
Miosis		1				1
Mitral valve calcification		2				2
Mitral valve disease		1				1
Mitral valve incompetence		3				3
Mitral valve stenosis		1				1
Mixed liver injury	1	1			1	1
Moaning		1				1
Mobility decreased	1	8		2	1	6
Monocytosis	2	4	1	2	1	2
Mononeuropathy multiplex	1	2			1	2
Monoparesis	2	5	2	2		3
Mood altered	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Moraxella infection		1				1
Morning sickness		1		1		
Motor dysfunction	9	19	5	6	4	13
Movement disorder	1	3	1	2		1
Mucosal discolouration		1				1
Multiple organ dysfunction syndrome	3	9			3	9
Multiple sclerosis	2	2			2	2
Multiple sclerosis relapse	1	1			1	1
Muscle contracture		3		1		2
Muscle discomfort	1	1			1	1
Muscle disorder		1		1		
Muscle fatigue	1	4	1	2		2
Muscle hypertrophy	1	1			1	1
Muscle rigidity		1		1		
Muscle spasms	5	11	2	4	3	7
Muscle spasticity	1	1			1	1
Muscle strength abnormal		1				1
Muscle tightness	1	2	1	2		
Muscle twitching	2	2			2	2
Muscular weakness	2	17		4	2	13
Musculoskeletal chest pain	1	4	1	2		2
Musculoskeletal pain		2		2		
Musculoskeletal stiffness	6	34	3	9	3	25
Mutism		2		1		1
Myalgia	35	121	24	57	11	64
Myasthenia gravis	3	5			3	5
Myasthenia gravis crisis		2				2
Mydriasis		5		2		3
Myelitis	1	1			1	1
Myelocytosis		1				1
Myelodysplastic syndrome		1				1
Myelofibrosis		1				1
Myocardial infarction	10	30			10	30

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myocardial ischaemia		2				2
Myocardial necrosis marker increased		1				1
Myocarditis	2	4			2	4
Myoclonus	2	5			2	5
Myositis		2				2
Nasal congestion	2	3			2	3
Nasal discomfort	1	1			1	1
Nasopharyngitis	1	3	1	3		
Nausea	50	156	28	58	22	98
Near death experience		1				1
Neck pain	4	12	2	5	2	7
Necrosis	1	1			1	1
Necrotising colitis		1				1
Neoplasm		1				1
Nephropathy		1				1
Nephrotic syndrome	2	2			2	2
Nerve compression		1		1		
Nerve conduction studies abnormal		1		1		
Nervousness		1				1
Nervous system disorder	2	5		1	2	4
Neuralgia	5	19	4	9	1	10
Neuralgic amyotrophy	1	1			1	1
Neuritis		1		1		
Neuroleptic malignant syndrome	1	1			1	1
Neurological decompensation	1	3		1	1	2
Neurological symptom	1	1	1	1		
Neuromuscular pain		1		1		
Neuromyelitis optica spectrum disorder	1	1			1	1
Neuropathy peripheral	2	5			2	5
Neutropenia	4	8			4	8
Neutrophil count abnormal		1				1
Neutrophil count decreased		2				2
Neutrophil count increased	1	6		4	1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neutrophilia	1	1	1	1		
Nightmare		1				1
Night sweats	1	3		1	1	2
Nitrite urine present		1		1		
Nocturia		1		1		
Nocturnal dyspnoea	1	1	1	1		
Noninfective gingivitis		2		1		1
Normochromic anaemia		1				1
Normocytic anaemia		1				1
N-terminal prohormone brain natriuretic peptide increased	3	5	2	2	1	3
Nystagmus	1	1	1	1		
Obstructive airways disorder		1		1		
Occipital neuralgia	2	2			2	2
Ocular discomfort	1	2		1	1	1
Ocular hyperaemia	1	4	1	1		3
Ocular myasthenia		1				1
Odynophagia	1	3		2	1	1
Oedema	2	6	1	1	1	5
Oedema mouth		1				1
Oedema peripheral	17	41	7	12	10	29
Oedematous pancreatitis	1	1			1	1
Oesophageal discomfort	1	1			1	1
Oesophageal spasm		1				1
Off label use	5	17	5	17		
Oliguria	1	1			1	1
Ophthalmic herpes zoster	11	20	1	1	10	19
Oppositional defiant disorder	1	1			1	1
Optic ischaemic neuropathy		1				1
Optic neuritis		1				1
Oral blood blister		1				1
Oral pain	1	2	1	2		
Oral pruritus	1	3	1	1		2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Orbital haematoma		1				1
Organising pneumonia	1	1			1	1
Oropharyngeal discomfort	2	5	2	4		1
Oropharyngeal pain	3	7	3	6		1
Orthopnoea	1	3	1	1		2
Orthostatic hypotension		2				2
Osteoarthritis		3		2		1
Otitis externa	1	2	1	1		1
Otolithiasis		1				1
Ovarian neoplasm	1	1			1	1
Overdose	4	4	4	4		
Oxygen saturation abnormal		1				1
Oxygen saturation decreased	29	111	8	15	21	96
Oxygen saturation increased		1				1
Pain	17	80	9	33	8	47
Painful respiration	1	1			1	1
Pain in extremity	29	75	14	34	15	41
Pain in jaw	1	5			1	5
Palatal oedema	1	3	1	1		2
Pallor	4	17	2	4	2	13
Palpitations	9	28	3	9	6	19
Pancreatitis		1				1
Pancreatitis acute	4	7			4	7
Pancytopenia	1	4			1	4
Papilloedema	1	1			1	1
Papule		1		1		
Paraesthesia	19	64	11	23	8	41
Paraesthesia oral	2	10	1	4	1	6
Paralysis	1	5			1	5
Paraplegia	1	1			1	1
Paresis		1				1
Parkinsonism		1				1
Parkinson's disease	1	2			1	2

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			Nonserious		Serious	
			I	C	I	C
Parotitis	2	2			2	2
Partial seizures		2				2
Pathological fracture	1	1			1	1
PCO2 increased	1	1			1	1
Peau d'orange		1		1		
Pelvic fracture	2	3			2	3
Pelvic pain		1				1
Pelvic venous thrombosis	1	1			1	1
Pemphigoid	1	5			1	5
Peptic ulcer		1				1
Pericardial effusion	5	9			5	9
Pericardial haemorrhage		1				1
Pericarditis	6	22			6	22
Periorbital haematoma	1	1	1	1		
Periorbital oedema	1	1			1	1
Periorbital pain		1				1
Peripheral arterial occlusive disease	1	1			1	1
Peripheral artery occlusion	1	1			1	1
Peripheral artery thrombosis	5	6			5	6
Peripheral coldness	2	9	2	6		3
Peripheral ischaemia	4	8	2	2	2	6
Peripheral swelling	8	15	4	8	4	7
Peripheral venous disease	1	2	1	2		
Peritonitis	3	3			3	3
Pernio-like erythema		1		1		
Persecutory delusion		2		1		1
Petechiae	1	4		1	1	3
Petit mal epilepsy		2				2
Pharyngeal disorder		1				1
Pharyngeal paraesthesia	3	6	3	4		2
Pharyngitis	1	1	1	1		
Phlebitis	5	9		1	5	8
Phlebitis superficial	2	2	1	1	1	1

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			Nonserious		Serious	
			I	C	I	C
Phonophobia		1				1
Photophobia		3		1		2
Physical examination abnormal	1	1	1	1		
Platelet count decreased		3		1		2
Platelet count increased	1	2	1	1		1
Pleural effusion	7	11	1	3	6	8
Pleurisy	1	1	1	1		
Pleuropericarditis	2	2			2	2
Pneumococcal sepsis		1				1
Pneumonia	4	30			4	30
Pneumonia aspiration	4	25			4	25
Pneumonia bacterial		3				3
Pneumonia respiratory syncytial viral	1	1			1	1
Pneumonia viral	1	1			1	1
Pneumonitis	1	4			1	4
Pneumoperitoneum		1				1
Pneumothorax		2				2
Pollakiuria	1	2	1	2		
Polyarthritits	3	5			3	5
Polydipsia		2		1		1
Polymyalgia rheumatica	4	6			4	6
Polyneuropathy	1	2			1	2
Polyp		1		1		
Portal hypertension	1	1			1	1
Portal vein phlebitis	1	1			1	1
Portal vein thrombosis	3	4			3	4
Posterior revers ble encephalopathy syndrome		1				1
Post lumbar puncture syndrome	1	1	1	1		
Prerenal failure		3				3
Presyncope	6	17	4	8	2	9
Procalcitonin increased	1	2		1	1	1
Proctitis	1	2	1	2		
Proctitis haemorrhagic	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product administered at inappropriate site	2	2	2	2		
Product administration error		1				1
Productive cough	3	7	2	2	1	5
Product preparation error		1		1		
Product use issue	1	10	1	10		
Progressive supranuclear palsy		1				1
Prohormone brain natriuretic peptide increased	1	1			1	1
Prostatitis		2		2		
Proteinuria	2	4	1	2	1	2
Prothrombin level abnormal		1				1
Prothrombin time prolonged	1	1			1	1
Prothrombin time shortened		2		1		1
Pruritus	13	38	8	14	5	24
Pseudomonal bacteraemia	1	1			1	1
Pseudomonal sepsis	1	1			1	1
Psoriasis		3		1		2
Psoriatic arthropathy		1				1
Psychomotor retardation		1				1
Psychomotor skills impaired	1	2			1	2
Pulmonary arterial hypertension	3	4			3	4
Pulmonary arterial pressure increased		1				1
Pulmonary artery dilatation		1				1
Pulmonary congestion	1	3			1	3
Pulmonary embolism	79	145			79	145
Pulmonary infarction	2	4			2	4
Pulmonary oedema	2	11			2	11
Pulmonary sepsis		1				1
Pulpitis dental		1				1
Pulse abnormal		1		1		
Pulse absent	1	4		2	1	2
Pupils unequal		1		1		
Purpura	2	7		1	2	6
Pyelonephritis	3	6			3	6

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia	82	318	44	109	38	209
Quadripareisis	1	2			1	2
Quadriplegia		2				2
Radial nerve palsy		1				1
Rales	4	13	4	5		8
Rash	6	18	2	7	4	11
Rash erythematous	1	4			1	4
Rash macular		2		1		1
Rash maculo-papular	3	11		2	3	9
Rash papular		1				1
Rash pruritic	1	6		2	1	4
Rash vesicular		1				1
Raynaud's phenomenon	1	2	1	1		1
Rebound effect		1				1
Recalled product administered		1		1		
Rectal haemorrhage	2	8			2	8
Red blood cell count decreased	1	1	1	1		
Red blood cell sedimentation rate increased		2		2		
Red blood cells urine positive		1				1
Renal colic	2	3	1	1	1	2
Renal failure	6	22			6	22
Renal impairment		3				3
Renal infarct		1				1
Renal pain		1				1
Renal tubular necrosis	1	1			1	1
Respiration abnormal		1				1
Respiratory acidosis		1				1
Respiratory alkalosis	1	3			1	3
Respiratory arrest	1	3			1	3
Respiratory depression		2				2
Respiratory disorder	3	13		1	3	12
Respiratory distress	6	37			6	37
Respiratory failure	3	14			3	14

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory rate decreased	1	2			1	2
Respiratory rate increased		2		1		1
Respiratory tract congestion		1				1
Respiratory tract infection	2	4			2	4
Respiratory tract infection bacterial		1				1
Respiratory tract oedema		1				1
Restlessness	1	12		5	1	7
Retinal artery occlusion	1	3			1	3
Retinal artery thrombosis	1	1			1	1
Retinal detachment	2	2			2	2
Retinal haemorrhage	1	1			1	1
Retinal infarction	1	1			1	1
Retinal vein occlusion		2				2
Retrograde amnesia		1				1
Rhabdomyolysis	1	5			1	5
Rheumatic disorder		2		1		1
Rheumatoid arthritis	8	20			8	20
Rheumatoid factor increased		1				1
Rhinitis	1	5	1	2		3
Rhinorrhoea	3	10	2	4	1	6
Rhonchi		2		1		1
Rib fracture	1	1			1	1
Right ventricular dilatation		1				1
Right ventricular failure	1	1			1	1
Road traffic accident		1				1
Salivary hypersecretion	2	2	1	1	1	1
SARS-CoV-2 ant body test negative		3		3		
SARS-CoV-2 ant body test positive	1	2	1	2		
SARS-CoV-2 test false positive		1		1		
SARS-CoV-2 test positive	4	18		1	4	17
Scan abdomen abnormal	1	1			1	1
Scan abnormal	1	1			1	1
Sciatica	1	2	1	2		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Scleritis	1	2			1	2
Secretion discharge	1	1	1	1		
Sedation		1		1		
Seizure	4	19			4	19
Sense of oppression	1	2			1	2
Sensorimotor disorder		1		1		
Sensory disturbance	1	2		1	1	1
Sensory loss		5		2		3
Sepsis	4	12			4	12
Septic shock	3	9			3	9
Serum sickness		1				1
Shock	4	8			4	8
Shock haemorrhagic	1	3			1	3
Sinus arrhythmia	1	1	1	1		
Sinus bradycardia	1	3			1	3
Sinusitis	1	1	1	1		
Sinus tachycardia		8		2		6
Sjogren's syndrome		2				2
Skin discolouration	1	4		2	1	2
Skin disorder		1		1		
Skin exfoliation	1	1	1	1		
Skin fissures		1				1
Skin lesion	2	4		1	2	3
Skin mass		1				1
Skin necrosis	1	1			1	1
Skin plaque	1	2	1	2		
Skin reaction	1	3	1	3		
Skin warm	1	2	1	2		
SLE arthritis		1				1
Sleep apnoea syndrome		1				1
Sleep disorder	2	5	1	2	1	3
Sleep talking		1		1		
Sluggishness		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Snoring	1	1	1	1		
Somnolence	8	37	4	15	4	22
Speech disorder	5	10	3	4	2	6
Spinal compression fracture		2				2
Spinal cord infarction		2				2
Spinal cord ischaemia		1				1
Spinal osteoarthritis		1		1		
Spinal pain		1				1
Splenic artery aneurysm	1	1			1	1
Splenic infarction		1				1
Splenic vein thrombosis	1	1			1	1
Spondylitis		1				1
Spondyloarthropathy		1		1		
Sputum abnormal		1				1
Staphylococcal bacteraemia		3				3
Staphylococcal sepsis		1				1
Staring		1				1
Status epilepticus		4				4
Status migrainosus		1				1
Stertor		1				1
Stress	1	3		2	1	1
Stress cardiomyopathy		2				2
Stridor	1	1			1	1
Subarachnoid haemorrhage	1	3			1	3
Subclavian vein thrombosis	1	1			1	1
Subcutaneous haematoma	1	1	1	1		
Subdural haematoma	1	3			1	3
Subileus	1	3			1	3
Subretinal haematoma	1	1			1	1
Sudden death	8	50			8	50
Sudden hearing loss		2				2
Sudden onset of sleep		1				1
Suffocation feeling	1	3			1	3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Suicidal ideation	1	2			1	2
Superinfection	1	2	1	1		1
Superinfection bacterial		1				1
Superinfection viral		1				1
Superior vena cava syndrome		1				1
Supraventricular extrasystoles	1	1	1	1		
Supraventricular tachyarrhythmia		1				1
Supraventricular tachycardia	3	7			3	7
Suspected COVID-19	4	7		1	4	6
Swelling	1	3	1	2		1
Swelling face	5	5	2	2	3	3
Swollen tongue	2	6		1	2	5
Symmetrical drug-related intertriginous and flexural exanthema	1	1			1	1
Syncope	10	25			10	25
Systemic inflammatory response syndrome	1	2	1	1		1
Systemic lupus erythematosus		1				1
Systolic hypertension	2	3			2	3
Tachyarrhythmia	4	7	1	2	3	5
Tachycardia	30	139	6	30	24	109
Tachypnoea	2	11	2	3		8
Tenderness		1		1		
Tendon disorder	2	2	1	1	1	1
Tendonitis	1	2	1	1		1
Tension	1	4	1	3		1
Testicular pain		1		1		
Tetany		1				1
Therapeutic response unexpected		2		2		
Thermal burns of eye		1				1
Thirst		3		2		1
Throat irritation	1	3	1	1		2
Throat tightness		3				3
Thrombocytopenia	14	36			14	36

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thrombocytopenic purpura	1	2			1	2
Thrombocytosis	1	1			1	1
Thrombophlebitis	7	12	2	2	5	10
Thrombophlebitis superficial	15	22	1	3	14	19
Thrombosed varicose vein		1				1
Thrombosis	6	12			6	12
Thrombosis mesenteric vessel		1				1
Thrombotic stroke	1	1			1	1
Thymoma	1	1			1	1
Thyroid disorder		1		1		
Thyroiditis subacute	1	1			1	1
Thyroid mass		1		1		
Thyroxine free decreased		1		1		
Tinnitus	10	22	5	8	5	14
Tongue biting	1	3			1	3
Tongue coated		1				1
Tongue discolouration	1	2			1	2
Tongue discomfort		1				1
Tongue disorder		1				1
Tongue dry		1				1
Tongue movement disturbance		1				1
Tongue oedema	3	8		2	3	6
Tonic clonic movements		6				6
Tonic convulsion		2				2
Tooth abscess		2		1		1
Toothache	1	2	1	2		
Torticollis		3		1		2
Toxicity to various agents		2				2
Toxic skin eruption		1				1
Toxocariasis		1				1
Toxoplasmosis		1		1		
Transaminases increased		1				1
Transient aphasia	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Transient ischaemic attack	14	34			14	34
Transplant rejection	1	1			1	1
Tremor	12	38	8	14	4	24
Trigeminal neuralgia	1	2			1	2
Tri-iodothyronine free decreased		1		1		
Troponin increased	3	13	1	3	2	10
Tumour perforation		1				1
Type I hypersensitivity		3				3
Type II hypersensitivity		1				1
Type III immune complex mediated reaction	1	1			1	1
Ulcer	1	1			1	1
Ulnar nerve palsy		1				1
Underdose		1		1		
Unresponsive to stimuli		2				2
Upper respiratory tract congestion	1	1	1	1		
Urinary incontinence	2	8	1	2	1	6
Urinary retention	1	4			1	4
Urinary tract candidiasis		1				1
Urinary tract discomfort		1		1		
Urinary tract infection	4	12	2	3	2	9
Urinary tract infection bacterial		3				3
Urine odour abnormal		2		2		
Urosepsis		1				1
Urticaria	10	37	5	12	5	25
Urticaria chronic		1				1
Uveitis	1	1			1	1
Uvulitis		1				1
Vaccination complication		1				1
Vaccination failure	93	168			93	168
Vaccination site abscess		1				1
Vaccination site bruising	1	1	1	1		
Vaccination site cellulitis		1				1
Vaccination site dysaesthesia		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site eczema		1				1
Vaccination site erythema	9	26	7	17	2	9
Vaccination site exfoliation		1				1
Vaccination site haematoma		6		2		4
Vaccination site hypersensitivity		3		3		
Vaccination site hypoaesthesia		1				1
Vaccination site induration	1	7	1	3		4
Vaccination site infection		1				1
Vaccination site inflammation	4	11	1	3	3	8
Vaccination site joint movement impairment		1				1
Vaccination site joint pain	1	2	1	1		1
Vaccination site movement impairment	1	8		2	1	6
Vaccination site oedema	1	10	1	4		6
Vaccination site pain	32	141	26	74	6	67
Vaccination site paraesthesia		2		1		1
Vaccination site plaque		1				1
Vaccination site pruritus	3	7	3	3		4
Vaccination site rash		1				1
Vaccination site reaction	2	8	1	4	1	4
Vaccination site swelling	3	14	3	11		3
Vaccination site urticaria	1	2	1	2		
Vaccination site warmth		5		1		4
Varicella virus test positive		1				1
Varicose vein		1		1		
Vascular encephalopathy		1				1
Vascular graft thrombosis	1	1			1	1
Vascular occlusion	1	1			1	1
Vascular pain	1	2	1	2		
Vascular purpura	8	12	1	2	7	10
Vascular rupture	1	1			1	1
Vascular stenosis		1				1
Vascular stent stenosis	1	1			1	1
Vasculitis	2	2	1	1	1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vasoplegia syndrome		1				1
Vein rupture		1				1
Vena cava thrombosis		1				1
Venous oxygen saturation decreased		1				1
Venous thrombosis	3	3			3	3
Venous thrombosis limb	4	6	1	1	3	5
Ventricular arrhythmia		1				1
Ventricular extrasystoles	2	5		2	2	3
Ventricular failure		1				1
Ventricular f brillation		2				2
Ventricular hypokinesia	1	3			1	3
Ventricular tachycardia	2	7			2	7
Vertigo	23	59	11	26	12	33
Vertigo positional	1	6			1	6
Vestibular disorder	2	3	1	2	1	1
Vestibular neuronitis	2	3			2	3
Viral pharyngitis	1	1			1	1
Vision blurred	6	12	3	4	3	8
Visual acuity reduced	1	2			1	2
Visual brightness		1				1
Visual field defect	1	1			1	1
Visual impairment	9	16	6	7	3	9
Vitamin D deficiency		2		1		1
Vlth nerve paralysis	1	2			1	2
Vitreous floaters		1				1
Volvulus of small bowel	1	1			1	1
Vomiting	37	130	24	52	13	78
Vulval haemorrhage	1	1			1	1
Wa king disability		1				1
Weight decreased	2	8	1	1	1	7
Weight increased	5	8	3	4	2	4
Wheezing		4		1		3
White blood cell count decreased	1	4	1	2		2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
White blood cell count increased	1	3		1	1	2
White matter lesion		1				1
Wound	1	2	1	1		1
Wrong patient received product		1		1		
	3,308	10,663	952	2553	2356	8110

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Country Where Event Occurred

FRENCH GUIANA

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Cerebral venous sinus thrombosis	1	1	1	1
Ischaemic stroke	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

FRENCH POLYNESIA

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute respiratory distress syndrome		1		1
Apraxia	1	1	1	1
Asthenia	1	2	1	2
Cardiopulmonary failure		1		1
Dermatitis bullous		1		1
Dermatosis		1		1
Dyspnoea	1	2	1	2
Dysstasia	1	1	1	1
Facial paralysis	1	1	1	1
Haemoptysis		1		1
Pulmonary embolism		1		1
Staphylococcal sepsis		1		1
Toxic epidermal necrolysis		1		1
	5	15	5	15

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Country Where Event Occurred

GEORGIA

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Sepsis		1		1
		1		1

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Country Where Event Occurred

GERMANY

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort		1				1		
Abdominal distension	1	1			1	1		
Abdominal pain	4	11			4	6		5
Abdominal pain lower	1	3			1	3		
Abdominal pain upper	2	7			1	5	1	2
Abnormal faeces	4	9			4	9		
Abortion missed		1						1
Abortion spontaneous		1						1
Abscess limb		1						1
Abscess neck		1						1
Abscess rupture	1	1					1	1
Accidental overdose		1				1		
Acute abdomen		3						3
Acute coronary syndrome		1						1
Acute kidney injury	5	15					5	15
Acute myeloid leukaemia		1						1
Acute myocardial infarction	1	10					1	10
Acute respiratory distress syndrome		1						1
Acute respiratory failure	1	3					1	3
Acute right ventricular failure		1						1
Ageusia	1	3			1	3		
Aggression		2						2
Agitation		2						2
Alanine aminotransferase increased		1						1
Allergy to vaccine	2	4					2	4
Allodynia		1				1		
Altered state of consciousness		2						2
Amnesia		4						4
Anaemia	1	1					1	1
Anaphylactic reaction	4	16					4	16
Anaphylactic shock	2	8					2	8
Angina pectoris	3	9					3	9
Angioedema	2	9					2	9

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Anosmia	1	2
Antibody test negative	1	1
Anxiety	1	3
Aortic aneurysm		1
Aortic valve stenosis		1
Apathy		5
Aphasia		4
Aphthous ulcer		1
Arrhythmia	8	22
Arterial occlusive disease		1
Arterial thrombosis		1
Arteriosclerosis		1
Arthralgia	12	31
Ascites	1	2
Aspartate aminotransferase increased		1
Aspiration		3
Asthenia	22	65
Asthma	3	10
Asymptomatic COVID-19	1	1
Ataxia		2
Atrial fibrillation		8
Atrioventricular block complete		2
Atrioventricular block first degree		1
Autoimmune disorder	1	1
Autoimmune thyroiditis		1
Axillary pain		1
Back pain	3	8
Balance disorder	3	3
Basedow's disease	1	1
Bedridden		2
Beta haemolytic streptococcal infection	1	1
Bladder discomfort	1	1
Bladder irritation	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
				1	1
		1	2		1
					1
					1
			3		2
			1		3
					1
				8	22
					1
					1
					1
		12	28		3
				1	2
			1		
					3
		18	50	4	15
		3	7		3
				1	1
					2
					8
					2
			1		
				1	1
					1
					1
		3	8		
		3	3		
				1	1
			1		1
				1	1
		1	1		
		1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Bladder pain	1	1			1	1		
Blindness	1	1					1	1
Blindness unilateral		1						1
Blister		2				2		
Blood calcium decreased		2				2		
Blood count abnormal		1						1
Blood creatine phosphokinase increased	1	2			1	2		
Blood creatine phosphokinase MB increased		1				1		
Blood glucose decreased	1	3				1	1	2
Blood glucose fluctuation		3				2		1
Blood glucose increased		2				2		
Blood methaemoglobin present		1				1		
Blood potassium decreased		3				1		2
Blood pressure abnormal		1				1		
Blood pressure decreased	1	7				3	1	4
Blood pressure fluctuation		1				1		
Blood pressure immeasurable	1	3					1	3
Blood pressure increased	3	13			2	4	1	9
Blood pressure systolic increased		1						1
Blood sodium decreased		1				1		
Blood thyroid stimulating hormone increased		1				1		
Blood uric acid increased	1	1			1	1		
Blood urine present		2						2
Bloody discharge		1				1		
Body temperature increased	5	16	1	1	5	11		5
Bone pain	2	9			2	8		1
Booster dose missed	1	1			1	1		
Bowel movement irregularity		1				1		
Bradyarrhythmia		1						1
Bradycardia		1						1
Brain injury		1						1
Brain oedema		1						1
Brain stem infarction	1	1					1	1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Brain stem ischaemia	1	1
Breast cancer recurrent	1	1
Breast inflammation	1	1
Breast pain	1	1
Breast swelling	1	1
Bronchial obstruction		1
Bronchitis	1	3
Bronchospasm		2
Burning sensation		2
Bursitis		1
Capillary nail refill test abnormal		2
Cardiac aneurysm		1
Cardiac arrest	1	12
Cardiac discomfort		2
Cardiac failure	1	19
Cardiac failure congestive	1	2
Cardiac fibrillation		1
Cardiac ventricular thrombosis	1	1
Cardiogenic shock	1	3
Cardiopulmonary failure		1
Cardio-respiratory arrest		1
Cardiovascular disorder	3	9
Carotid artery occlusion		1
Cerebellar syndrome		1
Cerebral haemorrhage	3	6
Cerebral infarction	1	4
Cerebral ischaemia		3
Cerebral venous sinus thrombosis	8	9
Cerebrovascular accident	5	16
Cerebrovascular disorder	2	2
Chest discomfort	4	9
Chest pain	4	12
Chest X-ray abnormal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
				1	1
		1	1		
				1	1
					1
		1	2		1
			1		1
			2		
					1
			1		1
				1	12
			1		1
				1	19
				1	2
					1
				1	1
				1	3
					1
					1
		2	3	1	6
					1
					1
				3	6
				1	4
					3
				8	9
				5	16
				2	2
		3	5	1	4
		4	11		1
					1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Chills	25	65
Chronic inflammatory demyelinating polyradiculoneuropathy		1
Chronic kidney disease		2
Chronic obstructive pulmonary disease		4
Circulatory collapse	2	21
Coagulopathy	2	2
Cognitive disorder		2
Colitis ulcerative	2	6
Coma		2
Condition aggravated	6	15
Confusional state	1	6
Conjunctival hyperaemia		1
Conjunctivitis		2
Constipation	1	1
Contusion	2	5
Coronary artery disease	1	2
Coronavirus test positive	1	2
Cor pulmonale	1	1
Cough	4	25
COVID-19	9	54
COVID-19 pneumonia	1	12
Cranial nerve disorder		1
C-reactive protein increased	2	6
Crepitations		1
CSF cell count increased	1	1
CSF protein increased	1	1
Cutaneous vasculitis		2
Cyanosis	2	5
Cystitis	1	1
Dark circles under eyes		1
Death	14	86
Decreased appetite	2	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1	24	57	1	8
					1
					2
					4
				2	21
		1	1	1	1
					2
				2	6
					2
		2	7	4	8
		1	1		5
					1
					2
		1	1		
				2	5
				1	2
				1	2
				1	1
		2	13	2	12
			6	9	48
				1	12
			1		
		2	4		2
					1
				1	1
				1	1
					2
		1	1	1	4
		1	1		
			1		
				14	86
		2	7		6

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Deep vein thrombosis	5	11
Dehydration		4
Delirium		1
Delusion		1
Dementia	1	6
Dementia of the Alzheimer's type, with delirium		1
Depressed level of consciousness		4
Depressed mood		1
Depression		2
Dermatitis allergic		2
Diabetes mellitus		1
Diabetes mellitus inadequate control		1
Diaphragmalgia		1
Diarrhoea	7	35
Diet refusal		4
Diplopia	1	2
Disease recurrence	2	6
Disorientation		3
Disturbance in attention	3	18
Diverticulitis	1	2
Dizziness	23	78
Dizziness postural		1
Drug eruption	1	2
Drug ineffective	11	38
Drug interaction	1	4
Dry mouth	1	3
Dry skin	1	2
Dysaesthesia		3
Dysarthria	1	3
Dysgeusia		5
Dyskinesia		1
Dysmenorrhoea	1	1
Dyspepsia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				5	11
					4
					1
					1
				1	6
					1
					4
					1
			2		
			2		
					1
					1
			1		
		6	23	1	12
					4
				1	2
		1	2	1	4
			2		1
		3	11		7
				1	2
		21	56	2	22
					1
		1	2		
				11	38
			1	1	3
		1	2		1
		1	2		
			1		2
				1	3
			4		1
					1
		1	1		
			1		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dysphagia	2	5
Dysphemia	1	1
Dysphonia		8
Dyspnoea	16	70
Dyspnoea at rest		1
Dyspnoea exertional	1	6
Ear congestion	1	1
Ear discomfort	1	2
Ear pain	1	2
Ear swelling	1	1
Eczema	3	4
Eczema asteatotic	1	1
Effusion		1
Electrocardiogram ST segment depression		1
Embolic cerebral infarction		1
Embolism		1
Emphysema		1
Enteritis	1	3
Eosinophilia		1
Epilepsy	3	12
Epistaxis	1	2
Erysipelas	1	1
Erythema	6	19
Essential tremor		1
Euphoric mood	1	1
Evans syndrome		1
Exposure via breast milk	1	1
Eye haemorrhage		2
Eye infection	1	1
Eye irritation	1	3
Eyelid function disorder	1	1
Eyelid irritation	1	1
Eyelid oedema		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	2	3
		1	1		
			5		3
		9	32	7	38
					1
		1	3		3
		1	1		
		1	1		1
		1	2		
		1	1		
		2	2	1	2
		1	1		
					1
					1
					1
					1
		1	1		2
					1
				3	12
			1	1	1
				1	1
		5	15	1	4
					1
		1	1		
					1
		1	1		
		1	2		1
				1	1
		1	1		
			1		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Eye oedema	1	1
Eye pain	1	2
Eye pruritus		5
Eye swelling	1	3
Facial paralysis	4	7
Facial paresis	2	7
Faeces discoloured		1
Fall	2	10
Fatigue	39	106
Fear	1	2
Feeling abnormal	4	8
Feeling cold	3	10
Feeling hot	1	9
Feeling of body temperature change	1	3
Femoral neck fracture		1
Femur fracture		1
Fibrin D dimer increased	1	1
Fibromyalgia	2	2
Fine motor skill dysfunction	1	1
Flatulence		2
Flushing	5	9
Food refusal		2
Fracture		1
Freezing phenomenon	1	1
Frequent bowel movements	1	1
Functional gastrointestinal disorder		1
Gait disturbance	6	8
Gait inability	1	2
Gamma-glutamyltransferase increased		1
Gastric dilatation	1	1
Gastritis	1	1
Gastrointestinal disorder	1	1
Gastrointestinal haemorrhage	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	2		
			1		4
		1	2		1
				4	7
			3	2	4
			1		
			1	2	9
1	1	38	94	1	12
		1	1		1
		3	7	1	1
		3	7		3
		1	5		4
		1	3		
					1
					1
		1	1		
		2	2		
		1	1		
			2		
		5	7		2
					2
					1
				1	1
		1	1		
			1		
		5	6	1	2
		1	2		
					1
		1	1		
		1	1		
		1	1		
				2	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Gastrointestinal motility disorder		1				1		
Gastrointestinal necrosis		1						1
Gastrointestinal pain	2	3			2	2		1
Generalised tonic-clonic seizure		1						1
General physical condition abnormal		5						5
General physical health deterioration	1	32				6	1	26
Gingival bleeding		1				1		
Gingival swelling		1						1
Glomerular filtration rate decreased		1				1		
Glomerulonephritis minimal lesion		1						1
Gout		1				1		
Granulocyte count increased		1				1		
Guillain-Barre syndrome	1	1					1	1
Guttate psoriasis	1	1			1	1		
Haematemesis		2						2
Haematochezia	1	1					1	1
Haematocrit decreased		2				2		
Haematoma	2	7			1	3	1	4
Haemoglobin decreased	1	3			1	3		
Haemolytic uraemic syndrome	1	1					1	1
Haemoptysis	1	1			1	1		
Haemorrhage		2						2
Hallucination	1	2					1	2
Hallucination, visual	1	1					1	1
Hand dermatitis	1	1			1	1		
Headache	49	118	1	1	47	102	2	16
Head discomfort	3	4			1	2	2	2
Heart rate decreased		2						2
Heart rate increased	5	12			3	8	2	4
Heavy menstrual bleeding	1	1			1	1		
Hemiparaesthesia		1						1
Hemiparesis	2	9					2	9
Hemiplegia		2						2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Hepatic cirrhosis		1						1
Hepatic failure		2						2
Hepatitis cholestatic		2						2
Herpes simplex		1						1
Herpes simplex encephalitis		1						1
Herpes zoster	13	19			11	17	2	2
Herpes zoster meningitis		1						1
Herpes zoster meningoencephalitis	1	1					1	1
Hot flush	3	6			3	6		
Hypercalcaemia		1						1
Hyperglycaemia		2						2
Hyperhidrosis	4	7			2	5	2	2
Hypernatraemia	1	1					1	1
Hypersensitivity	1	18			1	7		11
Hypersomnia	1	3			1	1		2
Hypertension	7	22			3	5	4	17
Hypertensive crisis	1	9					1	9
Hyperthyroidism		1						1
Hypoacusis	1	2			1	1		1
Hypoaesthesia	5	9			5	7		2
Hypoaesthesia oral	1	4			1	3		1
Hyponatraemia		1						1
Hypophagia		1						1
Hyporesponsive to stimuli		1						1
Hypotension	4	11			3	4	1	7
Hypotonia	1	6				2	1	4
Hypoxia		1						1
Ileectomy		1						1
Immature granulocyte count increased		1				1		
Immune thrombocytopenia		5						5
Immunisation reaction			1	1				
Impaired driving ability	1	1			1	1		
Inappropriate schedule of product administration	4	9			4	9		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Incomplete course of vaccination	1	1
Incontinence	2	3
Incorrect route of product administration	5	34
Increased appetite	1	1
Induration	1	1
Infarction		2
Infection		2
Infection susceptibility increased	1	1
Infective exacerbation of chronic obstructive airways disease		1
Inflammation	1	1
Influenza	3	6
Influenza like illness	13	32
Injection site pain		2
Insomnia		3
Intentional product misuse		2
Internal haemorrhage		1
International normalised ratio decreased		1
International normalised ratio increased		1
Intestinal ischaemia		2
Intracardiac thrombus	1	1
Intracranial aneurysm		1
Irregular breathing		1
Ischaemia		1
Ischaemic cerebral infarction		2
Ischaemic stroke		2
Jaundice		2
Jaw clicking		1
Joint range of motion decreased		3
Joint stiffness	2	2
Joint swelling	1	1
Keratoconus		1
Koebner phenomenon	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1	1	2
		4	33	1	1
		1	1		
		1	1		
					2
			1		1
				1	1
					1
		1	1		
		3	4		2
		12	28	1	4
			2		
			3		
			2		
					1
			1		
			1		
					2
				1	1
					1
					1
					2
					2
			1		1
					1
			2		1
		2	2		
		1	1		
					1
		1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Lacrimation increased		4				2		2
Language disorder		1						1
Laryngeal oedema	1	5					1	5
Leukaemia		1						1
Leukocytosis		1						1
Lhermitte's sign		1				1		
Limb discomfort	9	12			8	10	1	2
Lipase increased		1						1
Lipids increased	1	1			1	1		
Lip oedema		1						1
Lip swelling	2	5			2	2		3
Listless		1						1
Livedo reticularis		1				1		
Liver disorder		1						1
Liver function test increased		1						1
Local reaction	1	5			1	5		
Loss of consciousness	1	11					1	11
Loss of control of legs	1	1					1	1
Lower respiratory tract congestion		1				1		
Lung disorder	1	2			1	2		
Lymphadenopathy	10	24			10	23		1
Lymphangitis	1	1					1	1
Lymph node pain	4	8			4	8		
Lymphocytic infiltration		1						1
Lymphoedema	1	1					1	1
Lymphopenia		1						1
Macular degeneration			1	1				
Macular hole			1	1				
Malaise	9	30			8	20	1	10
Malignant pleural effusion		1						1
Marasmus		1						1
Maternal exposure during pregnancy	2	3			1	1	1	2
Medical induction of coma	1	1					1	1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Memory impairment		3
Meningism		1
Menstrual cycle management	2	2
Mental disorder		2
Mental impairment		1
Mesenteric vein thrombosis	1	4
Metabolic acidosis		1
Metabolic disorder		1
Microscopic polyangiitis		1
Micturition disorder		1
Micturition urgency		1
Migraine	3	7
Mobility decreased	1	5
Monocyte count increased		1
Monoparesis		2
Mouth haemorrhage		1
Movement disorder	4	5
Multiple organ dysfunction syndrome		6
Multiple sclerosis	2	3
Multiple sclerosis relapse	1	4
Muscle discomfort		1
Muscle spasms	3	10
Muscle spasticity		1
Muscle swelling		1
Muscle tightness	1	2
Muscle twitching		2
Muscular weakness	3	6
Musculoskeletal chest pain	1	1
Musculoskeletal pain	1	1
Myalgia	12	40
Myasthenia gravis		1
Myelitis		1
Myocardial infarction	5	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		1
			1		
		2	2		
					2
					1
				1	4
					1
					1
					1
			1		
			1		
		2	6	1	1
		1	3		2
			1		
			1		1
			1		
		4	4		1
					6
1	1			2	3
1	1			1	4
			1		
		3	6		4
					1
			1		
			1	1	1
			2		
		2	3	1	3
		1	1		
		1	1		
		12	36		4
					1
					1
				5	7

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous	
			Serious		Nonserious	Serious
			I	C	I	C
Myocarditis	4	7				4
Myocarditis infectious		1				1
Myocarditis septic		1				1
Nasal congestion		1			1	
Nasopharyngitis	2	8			2	8
Nausea	19	57			17	42
Neck pain	2	6			2	5
Nephrotic syndrome		1				1
Nervous system disorder	1	2				1
Neuralgia	4	8			4	8
Neuritis		1				1
Night sweats	2	2			2	2
Occipital neuralgia		1				1
Ocular discomfort	1	1			1	1
Ocular hyperaemia		3				1
Ocular myasthenia	1	1				2
Oedema		1				1
Oedema peripheral	1	4			1	2
Off label use	4	13			4	13
Oliguria		1				1
Ophthalmic herpes zoster	1	2				1
Ophthalmic vein thrombosis	1	1				2
Optic ischaemic neuropathy		1				1
Optic nerve disorder			1	1		
Optic neuritis		1				1
Oral fungal infection		1				1
Organ failure		1				1
Oropharyngeal pain	7	12			7	10
Orthopnoea		1				2
Osteoporosis		1				1
Otitis media		1				1
Overdose		1				1
Oxygen saturation decreased	2	10			2	3

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pain	4	16
Painful respiration	2	3
Pain in extremity	31	65
Pain in jaw	1	1
Pallor		1
Palpitations	6	17
Pancreatitis acute		1
Panic attack	1	1
Panic reaction	1	1
Paraesthesia	8	24
Paraesthesia oral	3	7
Paralysis	1	1
Paresis		2
Parkinson's disease		1
Parosmia	1	1
Partial seizures		1
Pathogen resistance		1
Pelvic fracture		1
Pelvic pain		1
Pelvic venous thrombosis	1	1
Performance status decreased	1	1
Pericardial effusion	1	1
Perioral dermatitis		1
Peripheral circulatory failure	1	3
Peripheral coldness	1	1
Peripheral swelling	2	5
Peripheral vascular disorder	3	10
Peroneal nerve injury		1
Personality change		6
Petechiae	3	7
Pharyngeal hypoaesthesia		1
Pharyngeal inflammation	1	2
Pharyngeal swelling	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	9	1	7
		2	3		
		28	57	3	8
		1	1		
					1
		5	12	1	5
					1
				1	1
		1	1		
		5	13	3	11
		2	4	1	3
				1	1
					2
					1
		1	1		
					1
					1
			1		
				1	1
		1	1		
				1	1
			1		
		1	2		1
		1	1		
		1	3	1	2
		3	5		5
					1
					6
		1	3	2	4
			1		
		1	2		
				1	5

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Platelet count decreased	3	4
Platelet count increased	1	1
Pleocytosis		1
Pleural effusion		2
Pleurisy		1
Pneumonia	3	21
Pneumonia bacterial		2
Pneumonia viral		1
Pneumonitis	1	1
PO2 decreased		1
Pollakiuria	1	1
Polycythaemia	1	1
Polydipsia		1
Polymyalgia rheumatica		1
Polymyositis	1	1
Polyneuropathy		1
Polyuria		1
Poor quality product administered	2	8
Poor quality sleep		1
Postictal state		1
Postoperative wound infection	1	1
Presbycusis		1
Presyncope	2	5
Product administration error	1	1
Product dose omission issue		1
Productive cough	2	2
Product preparation issue		2
Product storage error	1	2
Product supply issue		1
Product temperature excursion issue	1	6
Product use issue	2	8
Prostatic specific antigen increased	1	1
Proteinuria		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2	2	2
				1	1
					1
					2
					1
				3	21
					2
					1
				1	1
					1
		1	1		
				1	1
					1
				1	1
1	1				
					1
		2	7		1
					1
					1
				1	1
					1
		2	3		2
		1	1		
			1		
		2	2		
			2		
		1	2		
			1		
		1	5		1
		1	7	1	1
		1	1		
					1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pruritus	10	27
Pruritus allergic		1
Pseudoallergic reaction		1
Psoriasis	1	2
Pulmonary artery thrombosis	1	2
Pulmonary embolism	15	35
Pulmonary fibrosis		1
Pulmonary haemorrhage		1
Pulmonary infarction	1	2
Pulmonary oedema		2
Pulmonary pain	1	1
Pulmonary sepsis		1
Pulmonary vasculitis		1
Pulse absent		1
Pulse waveform abnormal		1
Purpura		1
Pustule	1	2
Pyrexia	30	109
Quadripareisis		2
Rash	3	15
Rash macular	1	4
Rash maculo-papular	1	3
Rash pruritic	2	3
Rash vesicular	1	1
Raynaud's phenomenon		1
Red blood cell count decreased		2
Red blood cell sedimentation rate increased		1
Renal disorder	1	1
Renal failure	2	9
Renal pain	2	3
Respiration abnormal	2	3
Respiratory arrest		1
Respiratory distress	1	32

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		9	19	1	8
					1
					1
		1	2		
				1	2
				15	35
					1
					1
				1	2
					2
		1	1		
					1
					1
					1
			1		
					1
		1	2		
		25	66	5	43
					2
		2	6	1	9
			3	1	1
		1	3		
		2	2		1
		1	1		
			1		
			2		
			1		
		1	1		
				2	9
		2	2		1
		2	3		
					1
				1	32

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Respiratory failure	3	16					3	16
Respiratory fume inhalation disorder		1						1
Respiratory tract infection		2						2
Respiratory tract infection viral		1				1		
Respiratory tract inflammation		1						1
Restlessness	2	6			1	3	1	3
Resuscitation		1						1
Retching		2				2		
Retinal tear		1						1
Retinal vein thrombosis	1	1					1	1
Retrograde amnesia		1						1
Rheumatic disorder	1	2			1	2		
Rheumatoid arthritis	3	5					3	5
Rhinalgia		1				1		
Rhinitis allergic		1						1
Rhinorrhoea	2	7			2	5		2
Rhonchi		1						1
Right ventricular failure		1						1
Rosacea		1						1
Salivary gland enlargement		1				1		
Salivary hypersecretion	2	2			2	2		
SARS-CoV-2 ant body test negative	2	8			2	7		1
SARS-CoV-2 ant body test positive		4				4		
SARS-CoV-2 sepsis		1						1
SARS-CoV-2 test positive		4				3		1
Seizure	3	15					3	15
Sensation of foreign body		2						2
Sensory disturbance	3	7			2	4	1	3
Sensory level abnormal		1				1		
Sepsis	1	1					1	1
Septic arthritis staphylococcal		1						1
Septic shock		2						2
Shock		1						1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Shock haemorrhagic		1						1
Sinusitis		1				1		
Sinus tachycardia		1						1
Skin burning sensation	1	1			1	1		
Skin exfoliation		1				1		
Skin haemorrhage	1	1			1	1		
Skin necrosis	1	1					1	1
Skin reaction	2	2			2	2		
Skin warm		1				1		
Sleep apnoea syndrome	1	1			1	1		
Sleep disorder	2	4			2	4		
Slow speech	1	1			1	1		
Sneezing		2				1		1
Somnolence	4	15			3	8	1	7
Sopor		1						1
Speech disorder	1	1			1	1		
Spinal disorder	1	1			1	1		
Spinal pain	1	2			1	1		1
Spontaneous haematoma	1	1					1	1
Staphylococcal sepsis		1						1
Status epilepticus		3						3
Stress		1						1
Stridor		2						2
Stupor		1						1
Subcutaneous abscess		1						1
Subileus		1				1		
Sudden cardiac death	2	3					2	3
Sudden death	6	24					6	24
Superinfection bacterial		1						1
Supraventricular extrasystoles		1						1
Supraventricular tachycardia	1	1			1	1		
Suspected COVID-19	2	2			1	1	1	1
Swelling	2	4			2	4		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Swelling face	4	10
Swelling of eyelid	2	3
Swollen tongue	2	6
Syncope	8	23
Systemic inflammatory response syndrome		1
Systemic lupus erythematosus		1
Tachyarrhythmia	1	3
Tachycardia	2	27
Tachycardia induced cardiomyopathy		1
Tachypnoea	1	3
Taste disorder		2
Tendonitis	1	2
Tendon pain	1	1
Tendon rupture		1
Tension	1	1
Therapeutic response unexpected	3	8
Thermal burn	1	1
Thinking abnormal	1	1
Throat clearing	1	1
Throat irritation	1	8
Throat tightness	2	9
Thrombectomy		1
Thrombocytopenia	6	10
Thrombosis		3
Thrombotic microangiopathy	1	1
Thyroiditis acute		1
Tinnitus	2	2
Tongue discomfort	1	1
Toothache		1
Toxicity to various agents		1
Transaminases increased		1
Transient aphasia		1
Transient ischaemic attack		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	8		2
		2	3		
		1	2	1	4
				8	23
					1
					1
				1	3
		2	14		13
					1
			1	1	2
			1		1
		1	1		1
		1	1		
					1
		1	1		
		3	8		
		1	1		
		1	1		
		1	7		1
		2	4		5
					1
				6	10
					3
				1	1
					1
		1	1	1	1
				1	1
			1		
					1
			1		
					1
					3

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Tremor	4	12
Trichoglossia	1	1
Trismus	2	2
Tryptase increased		1
Tumour marker increased	1	1
Type 1 diabetes mellitus		2
Unresponsive to stimuli	1	8
Upper gastrointestinal haemorrhage		2
Upper respiratory tract infection		2
Urinary incontinence	1	1
Urinary tract infection		1
Urine odour abnormal		1
Urticaria	3	14
Urticaria physical	1	1
Vaccination complication		1
Vaccination failure	2	8
Vaccination site abscess	1	1
Vaccination site dermatitis		1
Vaccination site discomfort	2	2
Vaccination site erythema	6	14
Vaccination site haematoma		3
Vaccination site haemorrhage		1
Vaccination site induration	2	4
Vaccination site lymphadenopathy		1
Vaccination site movement impairment	1	1
Vaccination site pain	25	75
Vaccination site paraesthesia		2
Vaccination site pruritus	2	4
Vaccination site rash	1	3
Vaccination site reaction	3	7
Vaccination site swelling	2	16
Vaccination site urticaria		1
Vaccination site warmth	4	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3	4	9
				1	1
		1	1	1	1
					1
				1	1
					2
				1	8
					2
					2
				1	1
					1
			1		
		3	8		6
		1	1		
					1
				2	8
				1	1
			1		
		2	2		
		6	12		2
			2		1
			1		
		2	4		
			1		
		1	1		
		24	71	1	4
			2		
		2	3		1
		1	2		1
		3	6		1
		2	12		4
					1
		4	9		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vasculitis		1						1
Venous thrombosis	1	2					1	2
Venous thrombosis limb	1	2					1	2
Ventricular extrasystoles	1	2					1	2
Ventricular f brillation	1	3					1	3
Ventricular tachycardia		1						1
Vertigo	1	3				1	1	2
Vision blurred		1						1
Visual field defect	2	2			1	1	1	1
Visual impairment	5	14			5	7		7
Vitreous disorder		1						1
Vomiting	9	39			5	18	4	21
Vulvovaginal mycotic infection	1	1			1	1		
Weight bearing difficulty	1	1			1	1		
Weight decreased	3	5			1	1	2	4
Weight increased	1	1			1	1		
Wheezing		1				1		
White blood cell count decreased	2	3			1	2	1	1
White blood cell count increased		2						2
	1,082	3,570	11	11	714	1777	368	1793

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Country Where Event Occurred

GREECE

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	1			1	1
Abdominal pain	3	3	2	2	1	1
Abdominal pain upper	1	3		2	1	1
Accident	1	1			1	1
Acne	1	1	1	1		
Acute myocardial infarction	1	3			1	3
Acute respiratory distress syndrome		1				1
Acute respiratory failure		1				1
Aggression		1				1
Agitation		1				1
Alanine aminotransferase increased		1		1		
Allergy to vaccine		1				1
Anaemia		1				1
Anaphylactic reaction		1				1
Anaphylactic shock		2				2
Angina pectoris		1				1
Angioedema		2				2
Ankylosing spondylitis		1				1
Aphasia		1				1
Arrhythmia	1	2			1	2
Arteriosclerosis		1				1
Arteriovenous graft thrombosis		1				1
Arthralgia	3	12	2	9	1	3
Arthritis enteropathic		1				1
Aspiration		1				1
Asthenia	2	7	2	5		2
Asthmatic crisis		1				1
Asymptomatic COVID-19		1				1
Atrial fibrillation	2	6			2	6
Auscultation		1		1		
Autonomic nervous system imbalance		1				1
Back pain		2		1		1
Blindness	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood calcium decreased		1		1		
Blood gases abnormal		1				1
Blood glucose abnormal		3		2		1
Blood glucose increased		1		1		
Blood iron decreased		1		1		
Blood parathyroid hormone increased	1	1	1	1		
Blood potassium decreased		1		1		
Blood pressure fluctuation		1		1		
Blood pressure inadequately controlled		1		1		
Blood pressure increased	1	9		4	1	5
Blood pressure systolic increased		1				1
Blood triglycerides increased		1				1
Blood urea increased		1		1		
Bone pain	1	4	1	4		
Brain death		1				1
Bronchospasm		2				2
Burning sensation	2	3	1	1	1	2
Cardiac arrest	2	5			2	5
Cardiac valve disease		1				1
Catarrh		1		1		
Cerebral haemorrhage		1				1
Cerebrovascular accident		2				2
Chest discomfort		1				1
Chest pain	1	4		2	1	2
Chills	2	11	1	6	1	5
Cholecystitis	1	1			1	1
Cholestasis	1	1			1	1
Cholinergic syndrome		1				1
Coma		1				1
Communication disorder		1		1		
Complex regional pain syndrome		2				2
Condition aggravated		4				4
Confusional state	1	3	1	2		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Contusion	1	2	1	2		
Coronary artery stenosis		1				1
Cough		2		1		1
COVID-19		2				2
Deafness unilateral		1				1
Death	2	5			2	5
Decreased appetite		1		1		
Deep vein thrombosis	3	6			3	6
Dehydration		1				1
Dermatitis allergic		1				1
Dermatomyositis		1				1
Diabetes mellitus inadequate control		4				4
Diarrhoea	2	5	1	3	1	2
Diastolic hypertension		1				1
Diplegia		2				2
Diplopia		1				1
Discomfort		1				1
Disease recurrence	2	4			2	4
Disorientation		2		1		1
Dizziness	2	15	2	8		7
Drug ineffective		1				1
Drug interaction		1				1
Dry eye		2		2		
Dry mouth		2		2		
Dry throat		1		1		
Dysarthria		1				1
Dysmenorrhoea	1	1	1	1		
Dyspepsia		1				1
Dysphagia		8		3		5
Dysphonia		2				2
Dyspnoea	4	15	3	8	1	7
Dysstasia		2		1		1
Ear pain	1	2		1	1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eating disorder symptom		1		1		
Electrocardiogram repolarisation abnormality		1				1
Epilepsy		1				1
Epistaxis		1		1		
Erythema	2	7	1	5	1	2
Eye haemorrhage		1				1
Eye irritation	1	1	1	1		
Eye pruritus		1		1		
Facial paralysis		3				3
Facial paresis	1	6			1	6
Fall	2	6	1	2	1	4
Fatigue	5	22	3	16	2	6
Feeding disorder		1		1		
Feeling cold		2		2		
Feeling hot	1	2		1	1	1
Femur fracture	1	2			1	2
Flushing		2				2
Gait disturbance	1	6		3	1	3
Gait inability	1	2	1	1		1
Gastric pH decreased	1	1			1	1
Gastrointestinal disorder		2		1		1
Gastrointestinal pain	1	1	1	1		
Glycosylated haemoglobin decreased		1		1		
Goitre		1				1
Guillain-Barre syndrome		3				3
Haematoma		1				1
Haematuria	1	2			1	2
Haemodynamic instability	1	1			1	1
Haemoglobin decreased		1		1		
Haemolysis	1	1			1	1
Haemoptysis		1				1
Headache	6	24	3	17	3	7
Head discomfort	1	3	1	3		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate decreased		1				1
Heart rate increased		1				1
Heavy menstrual bleeding	1	1			1	1
Hemianaesthesia	1	1			1	1
Hemiparesis	1	3			1	3
Hepatic function abnormal	1	1	1	1		
Hepatic pain	1	1	1	1		
Hepatorenal syndrome	1	1			1	1
Herpes zoster	1	2			1	2
Hiccups	1	1	1	1		
Hyperbilirubinaemia	1	1			1	1
Hyperhidrosis	1	3	1	2		1
Hyperpyrexia	1	1			1	1
Hypersensitivity	1	4		1	1	3
Hypertension	1	10		4	1	6
Hypertrophic cardiomyopathy		1				1
Hypoaesthesia	2	16	1	8	1	8
Hypoaesthesia oral	2	2			2	2
Hypoalbuminaemia		1		1		
Hypoglycaemia	1	5		3	1	2
Hypokalaemia		2				2
Hyponatraemia		3		1		2
Hyporeflexia		1				1
Illness		1				1
Immunoglobulins increased		1				1
Impaired gastric emptying		1				1
Incorrect route of product administration	2	3	2	3		
Infection	1	1	1	1		
Inner ear disorder	1	1	1	1		
Insomnia		1		1		
Insulin resistance		1				1
Iridocyclitis		1				1
Ischaemic cerebral infarction	1	2			1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ischaemic stroke		1				1
Jaundice	2	2			2	2
Laryngospasm		1				1
Left ventricular hypertrophy		1				1
Lethargy	2	4	2	3		1
Leukocytosis		1				1
Limb discomfort		1		1		
Lip oedema		1				1
Lip swelling		1		1		
Localised oedema	1	1			1	1
Loss of consciousness		4				4
Loss of personal independence in daily activities		1		1		
Lower limb fracture	1	1			1	1
Lower respiratory tract infection		1				1
Lymphadenitis		3		1		2
Lymphadenopathy	1	3	1	1		2
Lymph node pain	2	3	2	3		
Lymph node palpable	1	1	1	1		
Lymphoedema		1				1
Malaise	1	8		5	1	3
Memory impairment		2				2
Menstruation irregular	1	1	1	1		
Migraine	1	4		2	1	2
Mobility decreased	2	2	1	1	1	1
Monoparesis		1				1
Mouth ulceration		2		2		
Movement disorder		1		1		
Muscle spasms		1				1
Muscle strain		1		1		
Muscular weakness		4		1		3
Musculoskeletal discomfort	1	1	1	1		
Musculoskeletal stiffness		1		1		
Myalgia	3	18	3	12		6

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myocardial infarction	1	2			1	2
Myocarditis	1	1			1	1
Nasal pruritus		1		1		
Nausea		3		2		1
Neck mass	1	1	1	1		
Neck pain		1				1
Neoplasm progression	1	1	1	1		
Neuropathy peripheral		1				1
Neutrophil count decreased	1	1			1	1
Ocular hyperaemia		1				1
Oedema peripheral		2		1		1
Off label use		3		3		
Ophthalmic artery thrombosis	1	2			1	2
Oral disorder	1	1			1	1
Oral herpes		1				1
Oral mucosal erythema		1		1		
Oropharyngeal pain	1	2			1	2
Oxygen saturation decreased		3				3
Pain	1	6		4	1	2
Pain in extremity	2	5	1	1	1	4
Palpitations	2	3	2	2		1
Pancreatic carcinoma	1	1			1	1
Panic attack	1	1	1	1		
Paraesthesia		1				1
Paralysis		1				1
Paraparesis		1				1
Paratracheal lymphadenopathy		1				1
Paresis		2				2
Parotid gland enlargement		1				1
Pericarditis	1	1			1	1
Peripheral coldness		3		2		1
Peripheral venous disease		1		1		
Petit mal epilepsy		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Photophobia		1				1
Platelet count increased		1		1		
Pneumonia	1	2			1	2
Polydipsia		1		1		
Polyuria		1		1		
Portal vein thrombosis	1	1			1	1
Post herpetic neuralgia		1				1
Presyncope		2		1		1
Product use issue		3		3		
Protein total decreased		1		1		
Prothrombin time prolonged		1		1		
Pruritus	2	6	1	3	1	3
Pulmonary embolism	2	3			2	3
Pulmonary fibrosis		1				1
Pulmonary mass		1				1
Pulmonary oedema		1				1
Pulse absent		1				1
Purpura	1	1			1	1
Pyrexia	11	25	8	16	3	9
Rash	2	6	2	4		2
Rash erythematous		1		1		
Rash maculo-papular		1				1
Rash papular	1	1			1	1
Rash pruritic	1	1	1	1		
Raynaud's phenomenon		1				1
Reflexes abnormal		1				1
Renal failure		1				1
Renal impairment		1				1
Respiratory tract infection		2				2
Retinal vein thrombosis	1	1			1	1
Rheumatoid arthritis		1				1
Salivary gland enlargement		1				1
Sarcoidosis		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Scleritis		1				1
Seizure		1				1
Sjogren's syndrome		1				1
Skin burning sensation	1	1	1	1		
Soft tissue swelling		1		1		
Somnolence	1	3	1	3		
Speech disorder		4		2		2
Spinal pain		1				1
Sputum increased		1				1
Stomatitis	1	1			1	1
Sudden death		2				2
Supraventricular tachycardia	1	1			1	1
Suspected COVID-19		1		1		
Swelling	1	2			1	2
Swollen tongue		1		1		
Syncope	2	6			2	6
Tachycardia	1	9	1	4		5
Tension		1		1		
Therapeutic response unexpected	1	3	1	3		
Thirst		1		1		
Throat irritation		3		3		
Thrombosis	3	3			3	3
Transaminases increased	1	1	1	1		
Transient ischaemic attack	1	1			1	1
Tremor		2		1		1
Trigeminal neuralgia		1				1
Urinary incontinence		2		1		1
Urinary tract infection		2				2
Urticaria	2	2	1	1	1	1
Uveitis		1				1
Vaccination failure		1				1
Vaccination site discomfort		1		1		
Vaccination site hypoaesthesia		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site movement impairment		1		1		
Vaccination site oedema		1		1		
Vaccination site pain	5	9	4	8	1	1
Vasculitis		1				1
Venous thrombosis	1	1			1	1
Ventricular fibrillation	1	1			1	1
Vertigo	1	3	1	3		
Vision blurred	1	1			1	1
Visual impairment	1	1			1	1
Vitiligo	1	1	1	1		
Vomiting	2	7		2	2	5
Walking disability		1				1
White blood cell count decreased	1	2		1	1	1
	186	725	83	314	103	411

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Country Where Event Occurred

GUINEA

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Headache		1		1
Hypertension		1		1
		2		2

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Country Where Event Occurred

HONG KONG

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia		1		1		
Blood pressure increased		1		1		
Cardiac arrest	1	1			1	1
Chest discomfort		1		1		
Coronary artery disease		1				1
Dizziness		1				1
Dyspnoea		1		1		
Fatigue		1		1		
Lower respiratory tract infection	1	1			1	1
Malaise		1		1		
Myocardial ischaemia		1				1
Neuralgia		1		1		
Pneumonia	1	1			1	1
Syncope		1				1
	3	14		7	3	7

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Country Where Event Occurred

HUNGARY

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		3		3		
Abdominal pain	2	5	1	4	1	1
Acute kidney injury	1	1			1	1
Acute respiratory distress syndrome	1	1			1	1
Acute respiratory failure		1				1
Ageusia		2		2		
Aggression		1				1
Anaemia	1	2			1	2
Anal incontinence		1				1
Anaphylactic reaction	1	3			1	3
Angina pectoris	1	3			1	3
Angioedema		1				1
Anosmia		1		1		
Antibody test normal		1		1		
Anuria	1	2			1	2
Aphthous ulcer		1		1		
Arteriosclerosis	1	2			1	2
Arthralgia	3	9	3	7		2
Arthropathy		1		1		
Asphyxia		1				1
Asthenia	5	28	4	16	1	12
Asthenopia		1		1		
Atrial fibrillation		3				3
Atrioventricular block complete	1	1			1	1
Axillary mass		1		1		
Axillary pain		2		2		
Back pain	2	4	2	4		
Bell's palsy	1	1			1	1
Bezold-Jarisch reflex		1		1		
Blepharospasm		1		1		
Blindness		1				1
Blood glucose decreased		1		1		
Blood glucose increased		4		3		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased		1		1		
Blood pressure fluctuation	3	6	2	4	1	2
Blood pressure increased	2	6	2	4		2
Blood pressure systolic increased		1				1
Blood test abnormal	1	1	1	1		
Bone pain		1		1		
Bradycardia	2	3			2	3
Bradyphrenia		1		1		
Breast discomfort		2		2		
Bronchial neoplasm	1	1			1	1
Bronchitis		2		1		1
Burning sensation		3		3		
Cachexia	2	2			2	2
Cardiac arrest	4	4			4	4
Cardiac disorder	1	2			1	2
Cardiac failure	6	12			6	12
Cardiac failure congestive	1	1			1	1
Cardiogenic shock	1	1			1	1
Cardiomegaly		2		1		1
Cardiopulmonary failure	4	5			4	5
Cardiovascular disorder	1	2			1	2
Cardiovascular insufficiency	1	1			1	1
Chest discomfort		4		4		
Chest pain	1	6	1	4		2
Chills	4	16	3	15	1	1
Choking		1				1
Cholinergic syndrome	1	1			1	1
Chronic obstructive pulmonary disease		1		1		
Circulatory collapse	4	5			4	5
Clostridium difficile infection	1	1			1	1
Cold sweat		2		2		
Condition aggravated	2	5	1	2	1	3
Confusional state		3		1		2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	3	8	1	6	2	2
COVID-19	17	26	1	1	16	25
COVID-19 pneumonia	9	9			9	9
Craniofacial fracture		1				1
Cystitis	1	1	1	1		
Dark circles under eyes		1		1		
Death	5	8			5	8
Decreased appetite	1	4	1	3		1
Decubitus ulcer		1				1
Deep vein thrombosis	3	4			3	4
Defaecation urgency		1		1		
Dehydration	1	1			1	1
Dementia	1	1			1	1
Depressed mood		1		1		
Diarrhoea	4	13	3	11	1	2
Disease recurrence	1	1			1	1
Disturbance in attention		1				1
Dizziness	6	20	4	15	2	5
Drug hypersensitivity		1		1		
Drug ineffective	15	24			15	24
Dry eye		2		2		
Dry mouth	1	3	1	2		1
Dysgeusia		2		1		1
Dysphagia		4		1		3
Dysphemia		1				1
Dysphonia		2		1		1
Dyspnoea	11	20	3	6	8	14
Dyspnoea exertional		2		1		1
Ear pain		2		2		
Emphysema		1				1
Erythema	2	4	2	4		
Exposure during pregnancy		1		1		
Exposure to SARS-CoV-2	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Extrasystoles		1				1
Eye haemorrhage		1				1
Eye inflammation		2		1		1
Eye irritation		1		1		
Eye pain		1		1		
Facial pain		1		1		
Facial paralysis		2				2
Facial paresis		1		1		
Fall		3				3
Fatigue	3	15	3	14		1
Fear of death		1		1		
Feeding disorder		2				2
Feeling abnormal	1	2	1	1		1
Feeling hot		2		1		1
Feeling of body temperature change	1	2	1	2		
Femoral neck fracture		1				1
Fibrin D dimer increased	1	2			1	2
Flushing	1	3	1	2		1
Foaming at mouth		1				1
Functional gastrointestinal disorder		1		1		
Gastritis erosive		1				1
Gastrointestinal disorder	1	1	1	1		
Gastrointestinal haemorrhage		1				1
Gastrooesophageal reflux disease		1		1		
General physical health deterioration	1	2		1	1	1
Glomerular filtration rate decreased		1		1		
Glossitis	1	1	1	1		
Glossodynia		1		1		
Haematemesis	1	1			1	1
Haematoma		2				2
Haemoptysis		1				1
Haemorrhage		1				1
Headache	5	25	5	23		2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Head injury	1	1			1	1
Heart rate decreased		1		1		
Heart rate increased	2	5	1	4	1	1
Heart rate irregular		1		1		
Herpes zoster		1		1		
Hyperaesthesia		1		1		
Hyperhidrosis	2	5	1	3	1	2
Hypersensitivity		1		1		
Hypertension		1				1
Hypertensive encephalopathy	1	1			1	1
Hyperthyroidism	1	1			1	1
Hypoaesthesia	3	8	2	6	1	2
Hypoaesthesia oral	1	3		1	1	2
Hyporeflexia		2		2		
Hypotension		4		1		3
Hypovolaemic shock	1	1			1	1
Ileus	1	1			1	1
Ileus paralytic	1	1			1	1
Inappropriate schedule of product administration		1		1		
Incontinence	1	1	1	1		
Incorrect route of product administration		1		1		
Increased appetite	1	1	1	1		
Inflammation	1	3	1	3		
Influenza like illness		2		2		
Initial insomnia	1	1	1	1		
Injected limb mobility decreased	1	1	1	1		
Insomnia		3		3		
Ischaemic cardiomyopathy	1	1			1	1
Ischaemic stroke	2	3			2	3
Joint range of motion decreased		1		1		
Joint swelling	1	1	1	1		
Lacrimation increased		1		1		
Left ventricular failure		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lethargy		2		2		
Listless		1				1
Localised oedema		1		1		
Loss of consciousness	3	5			3	5
Lung disorder	1	1	1	1		
Lung neoplasm	1	1			1	1
Lymphadenitis	1	1	1	1		
Lymphadenopathy	1	8		7	1	1
Lymph node pain		3		3		
Macular oedema		1				1
Malaise	2	12	2	12		
Megacolon		1				1
Melaena		1				1
Memory impairment		1				1
Micturition urgency		1		1		
Migraine	1	2	1	2		
Monoplegia		1				1
Mucosal inflammation		1				1
Multiple organ dysfunction syndrome	2	2			2	2
Muscle spasms		1		1		
Muscle strain		1		1		
Muscular weakness		2		2		
Musculoskeletal chest pain		1		1		
Musculoskeletal stiffness	2	4	1	2	1	2
Myalgia	1	11	1	11		
Myocardial infarction	1	1			1	1
Nasal congestion		1		1		
Nasopharyngitis		1		1		
Nausea	3	11	3	10		1
Neck pain	1	2	1	2		
Neoplasm	1	1			1	1
Neoplasm malignant	1	1			1	1
Neoplasm progression	1	2			1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuralgia		1				1
Odynophagia		1		1		
Oedema peripheral		1		1		
Oesophageal haemorrhage	1	1			1	1
Oesophageal varices haemorrhage	1	1			1	1
Off label use	1	8	1	8		
Oral herpes	1	1	1	1		
Oropharyngeal pain		7		6		1
Oxygen consumption increased		1		1		
Oxygen saturation decreased	1	3	1	2		1
Pain	2	4	2	4		
Pain in extremity	8	18	6	15	2	3
Pain of skin		1		1		
Pallor		4		3		1
Palpitations	2	4	2	3		1
Pancreatitis acute	1	1			1	1
Paraesthesia		1				1
Paralysis		1				1
Pericarditis		1				1
Peripheral coldness		1		1		
Peripheral swelling	3	6	3	5		1
Pharyngeal swelling		1		1		
Photopsia		1		1		
Pneumonia	3	4			3	4
Pneumonitis	1	1			1	1
Polyarthrits		1				1
Poor quality product administered		1		1		
Poor quality sleep		1		1		
Post-acute COVID-19 syndrome		1		1		
Potentiating drug interaction		1		1		
Product administered at inappropriate site		1		1		
Product complaint		1		1		
Productive cough		2		2		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product use issue	1	7	1	7		
Progressive multifocal leukoencephalopathy	1	1			1	1
Pruritus	1	3	1	3		
Psychiatric symptom		1				1
Pulmonary arterial pressure increased		1				1
Pulmonary embolism	3	4			3	4
Pulmonary oedema	2	2			2	2
Pulpitis dental		1		1		
Pyrexia	12	37	6	26	6	11
Radiculopathy		1		1		
Rash		3		2		1
Rash erythematous		2		2		
Rash macular		1		1		
Rash pruritic		2		2		
Renal cyst		1		1		
Renal impairment		1				1
Respiratory arrest	1	1			1	1
Respiratory disorder		1		1		
Respiratory distress		2				2
Respiratory failure	3	3			3	3
Restlessness		1		1		
Retinal artery thrombosis	1	1			1	1
Retinal vein thrombosis	1	1			1	1
Rheumatoid arthritis	1	1			1	1
Rhinorrhoea		1		1		
SARS-CoV-2 test positive	2	4			2	4
Sciatica		1				1
Sensation of foreign body		1				1
Sensitive skin		1		1		
Sensory loss		1		1		
Sepsis	1	1			1	1
Shock	1	1			1	1
Sinus tachycardia	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin burning sensation	1	2	1	2		
Skin discolouration		1		1		
Skin disorder	1	1	1	1		
Skin swelling	1	1	1	1		
Skin ulcer	1	2	1	1		1
Skin warm		1		1		
Sleep disorder	1	3	1	3		
Somnolence	1	5	1	4		1
Spinal osteoarthritis		1		1		
Sudden death	3	3			3	3
Suspected COVID-19	1	1			1	1
Swelling face	1	1			1	1
Swelling of eyelid		1		1		
Syncope	3	8			3	8
Tachycardia	1	5		2	1	3
Tension		1		1		
Therapeutic response unexpected		1		1		
Thirst		2		1		1
Throat tightness		1				1
Thrombophlebitis	1	2		1	1	1
Thrombotic stroke		1				1
Toothache		1		1		
Tooth disorder		1				1
Total lung capacity decreased	1	1	1	1		
Tremor	1	5	1	4		1
Tricuspid valve incompetence		1				1
Type 1 diabetes mellitus	1	1			1	1
Urinary incontinence		1		1		
Urinary tract inflammation	1	1	1	1		
Urosepsis	1	1			1	1
Urticaria	2	3	1	2	1	1
Uveitis		1				1
Vaccination complication	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination failure	2	2			2	2
Vaccination site erythema	1	4	1	4		
Vaccination site haematoma		1		1		
Vaccination site haemorrhage		1		1		
Vaccination site induration		1		1		
Vaccination site joint movement impairment	1	1			1	1
Vaccination site movement impairment	1	3	1	3		
Vaccination site nodule		3		3		
Vaccination site pain	3	15	3	15		
Vaccination site paraesthesia		1		1		
Vaccination site swelling	1	5	1	5		
Vaccination site vesicles		1		1		
Vaccination site warmth		3		3		
Varicose vein		2		2		
Vascular dementia	1	1			1	1
Vasoconstriction		1				1
Vision blurred		1		1		
Visual impairment		1		1		
Vomiting		2		1		1
Weight decreased	1	2			1	2
Wound		1		1		
	300	887	113	508	187	379

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Country Where Event Occurred

ICELAND

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction		1				1
Anal incontinence		1		1		
Aortic aneurysm		1				1
Aphasia		2		1		1
Arthralgia		1		1		
Arthritis	1	1	1	1		
Asthenia		3		3		
Asthma		1				1
Back pain		2		2		
Balance disorder		1				1
Blood pressure decreased		1				1
Cardiac failure		2				2
Chest discomfort	1	1	1	1		
Chills	1	2	1	2		
Chronic obstructive pulmonary disease		1				1
Confusional state		1				1
Cough		3		2		1
Death		3				3
Decreased appetite		1		1		
Depressed level of consciousness		1				1
Disease progression		1				1
Dizziness		1		1		
Dyspnoea		1				1
Fatigue		2		1		1
Feeling abnormal		1		1		
Headache	3	6	3	6		
Hyperhidrosis		1				1
Hypertension		1		1		
Hypoaesthesia	1	1	1	1		
Hypoxia		1				1
Joint stiffness		1		1		
Malaise	1	5	1	3		2
Migraine		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Motor dysfunction		1				1
Myalgia	2	2	2	2		
Myocardial infarction		1				1
Nasopharyngitis	1	4	1	4		
Nausea		1		1		
Off label use		1		1		
Oropharyngeal pain		1		1		
Oxygen saturation decreased		2				2
Peripheral artery thrombosis		1				1
Pneumonia		3				3
Pneumonia aspiration		1				1
Productive cough		1		1		
Product use in unapproved indication		1		1		
Pulmonary embolism	1	1			1	1
Pyrexia	3	12	3	9		3
Respiratory failure		1				1
Rhinorrhoea		1		1		
Sepsis		1				1
Sudden death		1				1
Syncope		1				1
Throat tightness	1	1	1	1		
Transient ischaemic attack		1				1
Urinary incontinence		1		1		
Vaccination site erythema		1		1		
Vaccination site pain	1	2	1	2		
Ventricular tachycardia		1				1
	17	98	16	57	1	41

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Country Where Event Occurred

INDIA

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19	1	1	1	1
COVID-19 pneumonia	1	1	1	1
Drug ineffective	1	1	1	1
Myocardial infarction	1	1	1	1
	4	4	4	4

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Country Where Event Occurred

IRAQ

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Cerebrovascular accident	2	2			2	2
Chest pain	1	1			1	1
Cough		1		1		
Gait disturbance	1	1	1	1		
Headache		1		1		
Hyperhidrosis	1	1			1	1
Lacunar infarction	1	1			1	1
Myalgia		1		1		
Nausea		1		1		
Pyrexia		1		1		
Vaccination site pain	1	2	1	2		
	8	14	3	9	5	5

* I=Interval, C=Cumulative
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Country Where Event Occurred

IRELAND

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal distension	1	1			1	1
Abdominal pain	2	5		1	2	4
Abdominal pain upper		1				1
Abnormal loss of weight	1	1			1	1
Acute cardiac event		1				1
Acute myocardial infarction	1	1			1	1
Acute respiratory distress syndrome	1	1			1	1
Agitation		1				1
Alanine aminotransferase increased		1				1
Allergy to vaccine		1				1
Amnesia	1	1			1	1
Anal incontinence	1	1			1	1
Anaphylactic reaction	1	7			1	7
Anaphylactoid reaction	1	1			1	1
Angina pectoris	1	1			1	1
Angioedema	1	2			1	2
Angiopathy	1	1			1	1
Ankylosing spondylitis	1	1			1	1
Anosmia		1				1
Anxiety	1	2	1	1		1
Aortic aneurysm		1				1
Aphasia		1				1
Arthralgia	14	21	8	11	6	10
Arthritis	1	1			1	1
Aspiration		1				1
Asthenia	7	17	1	4	6	13
Asthma		2				2
Atrial fibrillation		1				1
Axillary mass		1		1		
Axillary pain		1		1		
Back pain	3	7	1	1	2	6
Bedridden	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bell's palsy	2	2			2	2
Blood bilirubin increased		1				1
Blood glucose fluctuation		1				1
Blood pH decreased		1				1
Blood pressure increased		4				4
Blood sodium decreased		1				1
Body temperature decreased		1				1
Body temperature increased		1		1		
Bone pain		3				3
Brain injury	1	1			1	1
Breast swelling		1				1
Burning sensation	1	1			1	1
Carbon dioxide increased		1				1
Cardiac arrest	1	4			1	4
Cardiac failure		1				1
Cardio-respiratory arrest	1	1			1	1
Cerebral disorder		1				1
Cerebral infarction	1	1			1	1
Cerebrovascular accident	4	5			4	5
Chest discomfort		5		1		4
Chest pain	4	8	2	2	2	6
Chills	11	26	4	5	7	21
Chromaturia		1				1
Cold sweat		2				2
Colitis ulcerative	1	1			1	1
Coma		1				1
Condition aggravated	3	4	2	2	1	2
Confusional state	3	5	1	1	2	4
Cough	2	5	1	1	1	4
COVID-19		4				4
C-reactive protein increased	1	2	1	1		1
Cyanosis	2	5		1	2	4
Deafness		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Death	2	11			2	11
Decreased activity		1				1
Decreased appetite	3	7			3	7
Decubitus ulcer	1	1			1	1
Deep vein thrombosis		4				4
Dental paraesthesia	1	1	1	1		
Depressed level of consciousness		2				2
Depressed mood		1				1
Diabetes mellitus inadequate control	1	1			1	1
Diarrhoea	3	8	2	2	1	6
Discomfort	1	3			1	3
Disease recurrence		4				4
Disorientation		1				1
Disseminated varicella zoster virus infection	1	1			1	1
Disturbance in attention	1	3		1	1	2
Dizziness	7	23	1	4	6	19
Drug ineffective	1	1			1	1
Dry throat		1				1
Dysarthria	1	1			1	1
Dysgeusia		1		1		
Dysphonia	1	2			1	2
Dyspnoea	2	12			2	12
Dyspnoea at rest		1				1
Dysstasia		1				1
Ear discomfort		1				1
Ear pain		1		1		
Emotional distress		1				1
Encephalopathy		1				1
Epilepsy		1				1
Erythema	1	3	1	2		1
Exfoliative rash	1	1			1	1
Exposure during pregnancy		1		1		
Extra dose administered	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid ptosis		1				1
Eye pain	1	3			1	3
Facial neuralgia	1	1			1	1
Facial pain	1	2	1	2		
Facial paralysis	1	1			1	1
Faeces discoloured		1				1
Faeces pale		1				1
Fall	3	4			3	4
Fatigue	18	48	6	15	12	33
Feeling abnormal	1	2			1	2
Feeling cold		2				2
Feeling hot	3	7	1	1	2	6
Feeling of body temperature change		2				2
Fluid intake reduced	1	1			1	1
Flushing		1				1
Gait disturbance	1	2			1	2
Gait inability		1				1
General physical health deterioration	1	5			1	5
Groin pain	1	1			1	1
Haematemesis		1				1
Haemoglobin decreased		1				1
Headache	13	47	5	12	8	35
Head injury	1	1			1	1
Heart rate increased		3				3
Heart rate irregular		1				1
Hemiparesis	1	2			1	2
Herpes zoster		1				1
Hot flush	1	1			1	1
Hyperaesthesia teeth	1	1	1	1		
Hyperhidrosis	4	11	1	1	3	10
Hypersensitivity		3		1		2
Hypersomnia	1	2			1	2
Hypertension	1	6			1	6

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia	2	8	1	5	1	3
Hypoaesthesia oral	1	4			1	4
Hypoglycaemia		1				1
Hypopnoea		1				1
Hypotension		3				3
Hypotonia		1				1
Hypoxia		1				1
Impaired work ability	6	10	1	2	5	8
Inappropriate schedule of product administration	1	2	1	2		
Inflammation	1	1			1	1
Influenza like illness		2		1		1
Injection site pain		1				1
Injury		1				1
Insomnia	1	5	1	1		4
Intervertebral disc disorder	1	1	1	1		
Irritability		1				1
Jaundice		1				1
Joint stiffness		1				1
Kidney infection	1	1			1	1
Lethargy	3	7		1	3	6
Limb discomfort		1				1
Lip swelling	1	8			1	8
Liver function test increased		1				1
Localised infection	1	1	1	1		
Loss of consciousness		5				5
Loss of personal independence in daily activities	2	2			2	2
Lower respiratory tract infection		1				1
Lymphadenopathy	3	8	1	1	2	7
Lymph node pain		3				3
Malaise	9	25	4	5	5	20
Maternal exposure during pregnancy	1	1	1	1		
Melaena		1				1
Memory impairment		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Metabolic acidosis		1				1
Migraine	2	4		1	2	3
Mobility decreased	1	3			1	3
Mood swings		1				1
Musculoskeletal chest pain	1	2			1	2
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	1	4		2	1	2
Myalgia	10	17	3	4	7	13
Myelitis transverse		1				1
Myocardial infarction		2				2
Myocardial ischaemia		1				1
Myocarditis		1				1
Nasal congestion		1				1
Nausea	11	34	2	6	9	28
Neck pain	3	5	2	3	1	2
Negative thoughts		1				1
Nervous system disorder		1				1
Neuralgia	1	1			1	1
Neuropathy peripheral		1				1
Neutropenia	1	1			1	1
Night sweats	1	2	1	2		
Normal pressure hydrocephalus		1				1
Off label use	1	2	1	2		
Oral herpes		2		1		1
Oral hyperaesthesia	1	1			1	1
Oral pruritus		1		1		
Oropharyngeal pain	1	6		1	1	5
Orthostatic hypotension		1				1
Oxygen saturation decreased	1	7			1	7
Pain	7	23	4	7	3	16
Pain in extremity	4	15	3	8	1	7
Pain in jaw		1		1		
Pallor		4		1		3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Palpitations		5		1		4
Pancreatitis relapsing		1				1
Panic attack		1				1
Paraesthesia	5	10	3	3	2	7
Paraesthesia oral	2	5		1	2	4
Pericarditis	2	2			2	2
Periorbital oedema		1		1		
Peripheral swelling		3				3
Pharyngeal paraesthesia		1				1
Pharyngeal swelling		2				2
Photophobia		1				1
Photosensitivity reaction	1	1			1	1
Platelet count decreased		2				2
Pneumonia	3	5			3	5
Pneumonitis		1				1
Poor quality sleep		1		1		
Presyncope		4		1		3
Productive cough	1	1			1	1
Pruritus	2	8	1	3	1	5
Psoriasis	2	2	2	2		
Pulmonary embolism	1	1			1	1
Pulmonary sepsis		1				1
Pulse abnormal		1				1
Pulseless electrical activity	1	1			1	1
Pyrexia	15	37	5	8	10	29
Rales		1				1
Rash	4	11	1	2	3	9
Rash erythematous	1	4			1	4
Rash macular		1				1
Rash pruritic		1				1
Rash vesicular	1	1	1	1		
Rectal haemorrhage	1	1			1	1
Red blood cell sedimentation rate increased	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory arrest	3	3			3	3
Respiratory distress		1				1
Respiratory failure		1				1
Respiratory rate decreased		3				3
Respiratory rate increased	1	3			1	3
Respiratory tract infection		3				3
Restlessness	1	1			1	1
Retching		1				1
Rheumatoid arthritis	1	1			1	1
Rhinitis		1				1
Seizure		2				2
Seizure like phenomena	1	1			1	1
Sensory disturbance	1	1			1	1
Sensory loss		1				1
Sinus headache	1	1			1	1
Sinusitis		1				1
Skin burning sensation		1				1
Skin discolouration		1		1		
Skin disorder	1	1			1	1
Sleep disorder	1	1			1	1
Somnolence	2	4	1	1	1	3
Spinal pain	1	1			1	1
Stridor		3				3
Sudden death		2				2
Supraventricular tachycardia		1				1
Suspected COVID-19	1	1			1	1
Swelling		2		1		1
Swelling face		3		1		2
Swollen tongue		5				5
Syncope	4	6			4	6
Syringe issue	1	1	1	1		
Tachycardia	1	9		1	1	8
Tenderness		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Throat tightness		1				1
Thrombosis		1				1
Tidal volume decreased		1				1
Tinnitus		2		1		1
Tonic clonic movements		1				1
Transient ischaemic attack		1				1
Tremor	1	4	1	1		3
Troponin increased		1				1
Unresponsive to stimuli	2	3			2	3
Upper gastrointestinal haemorrhage		1				1
Urinary incontinence	1	2			1	2
Urinary tract infection	1	1			1	1
Urine odour abnormal		1		1		
Urine output decreased	1	1			1	1
Urticaria	1	5			1	5
Uveitis	1	1			1	1
Vaccination site erythema	1	1			1	1
Vaccination site induration	1	1			1	1
Vaccination site inflammation	1	1			1	1
Vaccination site mass	1	1	1	1		
Vaccination site pain	4	11	2	6	2	5
Vaccination site paraesthesia		1				1
Vaccination site pruritus		1				1
Vaccination site swelling	2	2			2	2
Vaccination site urticaria		1		1		
Varicella zoster virus infection	1	1			1	1
Vertigo		3		2		1
Vision blurred	1	2			1	2
Vomiting	5	16	1	2	4	14
Weight bearing difficulty	1	1			1	1
Weight increased	1	1			1	1
Wheezing		6				6
	337	984	93	190	244	794

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Country Where Event Occurred

ISRAEL

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		3		2		1
Abdominal pain upper		1		1		
Activated partial thromboplastin time shortened		1				1
Acute myocardial infarction		1				1
Allergy to vaccine		2				2
Anaemia		1				1
Anaphylactic reaction		1				1
Angina pectoris		2				2
Anorectal discomfort		1		1		
Anxiety		1				1
Arthralgia		4		3		1
Arthritis		1		1		
Aspiration		1				1
Asthenia	8	31	8	27		4
Asthma		2		1		1
Atelectasis		1				1
Atrial fibrillation		5				5
Back pain		2		2		
Balance disorder		1		1		
Bell's palsy		1				1
Blindness transient		1				1
Blood chloride increased		2		1		1
Blood creatine phosphokinase increased	1	1			1	1
Blood glucose increased		2		1		1
Blood pressure decreased		1				1
Blood pressure increased		3		2		1
Bone pain	1	1	1	1		
Brain death		1				1
Brain injury		1				1
Brain oedema		1				1
Breast inflammation		1		1		
Burning sensation		1				1
Cardiac arrest		8				8

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac death		1				1
Cardiac dysfunction	1	1			1	1
Cardiac failure	1	6			1	6
Cardiac failure chronic		1				1
Cardiac flutter		1				1
Cardiac tamponade		1				1
Cardiomegaly	1	1			1	1
Cerebrovascular accident		3				3
Chest discomfort	1	2	1	2		
Chest pain	5	11	5	8		3
Chills	3	9	3	9		
Choking		1				1
Cholelithiasis		1		1		
Chronic inflammatory demyelinating polyradiculoneuropathy		1				1
Chronic lymphocytic leukaemia		1				1
Chronic obstructive pulmonary disease		2				2
Circulatory collapse		1				1
Condition aggravated		1				1
Confusional state		1				1
Contusion		1				1
Coronavirus infection	2	4			2	4
Cough	3	7	3	6		1
COVID-19		17		2		15
C-reactive protein increased		2		1		1
Crying		1		1		
Deafness		1				1
Deafness neurosensory		1				1
Deafness unilateral		1				1
Death	1	20			1	20
Deep vein thrombosis	1	3			1	3
Diabetic ketoacidosis		1				1
Diarrhoea	1	4	1	3		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Discomfort	1	1	1	1		
Disease recurrence		3		2		1
Disturbance in attention	1	1	1	1		
Dizziness	1	12	1	10		2
Drug hypersensitivity		2		1		1
Drug ineffective	2	16			2	16
Dry throat	1	1	1	1		
Dysgeusia		1		1		
Dysphagia		3		1		2
Dysphonia	1	1	1	1		
Dyspnoea	1	24		6	1	18
Dyspnoea exertional		1		1		
Dysstasia		1		1		
Ear discomfort		1		1		
Ear pain		1		1		
Eosinophilic oesophagitis		1		1		
Epilepsy	1	1			1	1
Erythema	1	7	1	7		
Erythromelalgia	1	1			1	1
Eye irritation		2		1		1
Face injury		1				1
Facial paralysis		6				6
Fall		2				2
Fatigue	3	11	3	11		
Feeling abnormal		4		1		3
Feeling cold		1		1		
Feeling hot		3		3		
Gait disturbance		2				2
Gastric haemorrhage		1				1
Gastrointestinal necrosis		1				1
General physical health deterioration		3				3
Glomerular filtration rate decreased		1				1
Guillain-Barre syndrome		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematemesis		1				1
Haemolytic anaemia		1				1
Haemorrhage		1				1
Headache	4	24	4	23		1
Heart rate increased	1	3	1	3		
Herpes virus infection		1		1		
Herpes zoster		11		11		
Hormone level abnormal		1		1		
Hot flush	1	1	1	1		
Hyperhidrosis		2		2		
Hypersensitivity		3		1		2
Hypertension	1	1			1	1
Hypoaesthesia		4		3		1
Hypoaesthesia oral		3		1		2
Hyponatraemia		1				1
Hypotension		4		2		2
Hypothermia		1				1
Hypoventilation		1				1
Illrd nerve paralysis		1				1
Illness		1		1		
Inappropriate schedule of product administration	1	1	1	1		
Incorrect dose administered		1		1		
Inflammation of wound		1		1		
Inflammatory marker increased		1				1
Influenza like illness		2		2		
Insomnia		2		2		
Intentional dose omission		1		1		
International normalised ratio decreased		1				1
Jaundice		1		1		
Lacrimation increased		2		1		1
Laryngeal inflammation		1		1		
Laryngitis bacterial		1				1
Leukocytosis		6				6

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Limb discomfort	1	1	1	1		
Lip swelling		1		1		
Loss of consciousness		6				6
Loss of libido		1		1		
Lung disorder		1				1
Lung infiltration		1				1
Lymphocyte count increased		1		1		
Lymphocytosis		1		1		
Lymphopenia		1				1
Malaise	1	4	1	3		1
Maternal exposure during pregnancy		1		1		
Mean cell haemoglobin concentration decreased		1		1		
Mean cell haemoglobin decreased		2		1		1
Mean cell volume decreased		1		1		
Menstruation irregular	1	1	1	1		
Mobility decreased		1		1		
Multiple sclerosis		1				1
Multiple sclerosis relapse		4				4
Muscular weakness		3		2		1
Musculoskeletal chest pain		1		1		
Myalgia	4	11	4	11		
Myasthenia gravis		2				2
Myocardial infarction		4				4
Myocarditis	2	12			2	12
Nasopharyngitis		1		1		
Nausea	1	7	1	6		1
Nephrolithiasis		1				1
Nervous system disorder		1		1		
Neutrophil count increased		1				1
Oedema mouth		1				1
Oedema peripheral		1				1
Off label use	1	3	1	3		
Ophthalmic herpes zoster		2				2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oropharyngeal discomfort		1		1		
Oropharyngeal pain		2		2		
Oxygen saturation decreased		1				1
Pain	1	10	1	9		1
Pain in extremity	2	8	2	7		1
Pallor		1		1		
Palpitations		4		3		1
Paraesthesia		7		4		3
Paraesthesia oral		3		3		
Pericardial effusion	3	4			3	4
Pericarditis	2	6			2	6
Peripheral artery occlusion		1				1
Peripheral ischaemia		1				1
Personality change		1		1		
Pharyngeal swelling		1		1		
Pleural effusion	2	4	1	1	1	3
Pleuritic pain		1				1
Pneumonia		2				2
Pneumonia aspiration		2				2
Premenstrual syndrome		1		1		
Presyncope		1		1		
Productive cough	1	1			1	1
Product use issue	1	4	1	4		
Pruritus		4		1		3
Psoriatic arthropathy		1				1
Pulmonary congestion	1	1			1	1
Pulmonary embolism	1	4			1	4
Pulmonary oedema		2				2
Pulse abnormal		1				1
Pyrexia	4	22	4	16		6
Rash	1	4	1	2		2
Rash maculo-papular		1		1		
Recall phenomenon		2		2		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Red blood cell count increased		1		1		
Respiratory arrest		1				1
Respiratory disorder		4		1		3
Respiratory distress		1				1
SARS-CoV-2 ant body test negative		2		2		
Seizure		6				6
Sepsis		1				1
Septic shock		1				1
Sinus tachycardia	1	1	1	1		
Skin burning sensation		1		1		
Skin exfoliation		1		1		
Skin reaction		1		1		
Sleep attacks	1	1	1	1		
Slow speech		1				1
Speech disorder		1				1
Streptococcal infection		1				1
Sudden death		1				1
Sudden hearing loss		2				2
Suffocation feeling		1				1
Swollen tongue		2				2
Syncope	1	4			1	4
Systemic inflammatory response syndrome		2				2
Tachycardia		2		1		1
Therapeutic response unexpected	6	7	6	7		
Throat tightness	1	2			1	2
Thrombocytopenia		1				1
Tic	1	1	1	1		
Tinnitus		4		2		2
Tongue oedema		1				1
Tonic convulsion		1				1
Transient ischaemic attack		5				5
Tremor		1		1		
Unresponsive to stimuli		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria		2				2
Uveitis		1				1
Vaccination failure		3				3
Vaccination site movement impairment		1		1		
Vaccination site pain	4	15	4	15		
Vaccination site swelling		1		1		
Vaginal haemorrhage	2	3	2	3		
Ventricular f brillation		2				2
Vertigo		4		2		2
Vision blurred		1		1		
Vlth nerve paralysis		1				1
Vomiting	1	5		3	1	2
Wheezing	1	3	1	2		1
	101	696	73	342	28	354

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Country Where Event Occurred

ITALY

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	1	2			1	2		
Abdominal distension		3				1		2
Abdominal pain	4	40	1	1		27	4	13
Abdominal pain lower	2	3			1	1	1	2
Abdominal pain upper	13	30	2	2	6	19	7	11
Abnormal behaviour		1				1		
Abortion spontaneous	1	1					1	1
Abscess limb		1				1		
Acarodermatitis	1	1					1	1
Acidosis	1	1					1	1
Activated partial thromboplastin time shortened	1	1			1	1		
Acute abdomen		1						1
Acute coronary syndrome	1	6					1	6
Acute kidney injury	1	4		1			1	4
Acute motor axonal neuropathy		1						1
Acute myocardial infarction	3	7					3	7
Acute polyneuropathy		1						1
Acute pulmonary oedema	1	2					1	2
Acute respiratory distress syndrome		2						2
Acute respiratory failure	3	9					3	9
Administration site pain		3				3		
Adnexa uteri pain	1	1			1	1		
Adrenomegaly		1				1		
Age-related macular degeneration		1						1
Ageusia		4				3		1
Agitation	4	10			1	6	3	4
Akinesia		1						1
Alanine aminotransferase increased	1	1			1	1		
Abumin CSF increased	1	1					1	1
Allergic respiratory symptom		1						1
Allergy to vaccine	1	5				1	1	4
Alopecia	1	2					1	2
Alpha globulin increased		1				1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Altered pitch perception		1				1		
Altered state of consciousness		3						3
Amaurosis fugax		1						1
Amnesia	4	6			1	3	3	3
Anaemia	4	5			1	1	3	4
Anaemia macrocytic		1						1
Anaesthesia		1				1		
Anaesthesia oral		1				1		
Anal incontinence		1						1
Anamnestic reaction	1	1			1	1		
Anaphylactic reaction	7	18		2			7	18
Anaphylactic shock	1	2		1			1	2
Angina pectoris		1						1
Angioedema	3	9					3	9
Ankylosing spondylitis	1	1					1	1
Anosmia		3				1		2
Antibody test abnormal		1				1		
Anti-thyroid antibody positive		1				1		
Anuria	1	2	1	1			1	2
Anxiety	2	7				3	2	4
Aortic arteriosclerosis	1	1					1	1
Aortic valve calcification	1	1					1	1
Aphasia	8	13	2	2			8	13
Aphonia	1	2					1	2
Aphthous ulcer		2				2		
Apical granuloma	1	1			1	1		
Aptyalism	1	1					1	1
Arrhythmia	1	6					1	6
Arterial thrombosis	1	1					1	1
Arteriosclerosis	2	3					2	3
Arteriosclerotic retinopathy		1						1
Arthralgia	34	160		1	21	121	13	39
Arthritis	3	4			1	2	2	2

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Aspartate aminotransferase increased	1	1
Asphyxia	1	2
Aspiration	1	1
Asthenia	49	157
Asthenopia		1
Asthma	1	16
Asthmatic crisis	1	4
Asymptomatic COVID-19	5	10
Atelectasis	1	2
Atrial fibrillation	6	13
Atrial flutter		2
Atrioventricular block		1
Atrioventricular block complete		1
Atrioventricular block first degree		1
Auditory disorder		2
Aura	1	1
Autoimmune arthritis	1	1
Autoimmune disorder	1	1
Autoimmune thyroiditis		2
Axillary pain		5
Azotaemia	1	2
Back pain	12	27
Balance disorder	3	7
Basedow's disease		1
Basilar artery occlusion	1	1
Bell's palsy	5	9
Bladder spasm	1	1
Blepharitis	1	1
Blepharospasm		1
Blindness	1	3
Blister	1	5
Blood creatinine increased	2	2
Blood fibrinogen increased	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				1	2
				1	1
1	3	14	87	35	70
			1		
			6	1	10
				1	4
				5	10
				1	2
1	1			6	13
					2
1	1				1
			1		
			1		1
		1	1		
				1	1
					2
			5		
				1	2
	1	6	14	6	13
1	2	1	2	2	5
					1
				1	1
				5	9
				1	1
		1	1		
					1
				1	3
			3	1	2
		1	1	1	1
		1	2		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Blood glucose abnormal	1	2					1	2
Blood glucose increased	2	3			1	2	1	1
Blood pressure abnormal	1	1					1	1
Blood pressure decreased	3	4			2	3	1	1
Blood pressure increased	16	29	2	2	5	12	11	17
Blood pressure systolic increased		2				2		
Blood thyroid stimulating hormone increased	1	3				2	1	1
Blood urea increased	1	1			1	1		
Bloody discharge		1						1
Body temperature abnormal		1				1		
Body temperature decreased		1						1
Body temperature increased	2	5	1	1	2	5		
Bone marrow disorder	1	1					1	1
Bone pain	3	18			2	12	1	6
Bradycardia		4	1	1				4
Bradykinesia		1	1	1				1
Bradyphrenia		1	1	1		1		
Brain compression		1						1
Brain stem haemorrhage		1						1
Breath sounds abnormal	2	3					2	3
Bronchitis		1						1
Bronchitis chronic	1	1			1	1		
Bronchospasm	2	16				5	2	11
Brow ptosis		1				1		
Bullous haemorrhagic dermatosis	1	1					1	1
Burning sensation	4	11			2	4	2	7
Capillary fragility	1	2					1	2
Cardiac arrest	8	20					8	20
Cardiac disorder	1	1					1	1
Cardiac failure	7	12	1	1			7	12
Cardiac failure congestive		2						2
Cardiac fibrillation		1						1
Cardiac murmur	1	1					1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Cardiac valve disease	1	1					1	1
Cardiomyopathy	1	1					1	1
Cardiopulmonary failure	2	3					2	3
Cardio-respiratory arrest	1	5					1	5
Cardioversion	1	1			1	1		
Carotid artery occlusion	1	1					1	1
Catarrh	1	3			1	1		2
Central nervous system lesion	1	1			1	1		
Central nervous system vasculitis	2	2					2	2
Cerebellar haemorrhage		1						1
Cerebral artery embolism	1	1					1	1
Cerebral artery occlusion	1	1					1	1
Cerebral haematoma	1	2					1	2
Cerebral haemorrhage	8	13					8	13
Cerebral infarction	1	1					1	1
Cerebral ischaemia	3	6					3	6
Cerebral thrombosis	1	1	1	1			1	1
Cerebral venous sinus thrombosis	2	3	1	1			2	3
Cerebral venous thrombosis	1	1					1	1
Cerebral ventricle collapse		1						1
Cerebrovascular accident	3	9	1	1			3	9
Cerebrovascular disorder			1	1				
Cervicobrachial syndrome	1	1					1	1
Chest discomfort	3	14	1	2		4	3	10
Chest injury			1	1				
Chest pain	13	31	2	3	2	11	11	20
Chillblains	1	1					1	1
Chills	31	142		1	21	107	10	35
Choking		1						1
Choking sensation		1						1
Cholangitis		1						1
Chronic kidney disease	1	1					1	1
Chronic obstructive pulmonary disease		1						1

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			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Circulatory collapse	1	2					1	2
Circumoral oedema		3				3		
Circumoral swelling		2						2
Clonic convulsion	3	3					3	3
Clostridial infection	1	1					1	1
Coagulopathy		1						1
Cognitive disorder	1	2			1	2		
Cold sweat	2	3					2	3
Coma	2	4					2	4
Coma scale abnormal		1						1
Complicated appendicitis	1	1					1	1
Condition aggravated	3	17	1	1		3	3	14
Confusional state	14	26	3	5	8	12	6	14
Conjunctival haemorrhage	2	3					2	3
Conjunctivitis	1	7				4	1	3
Constipation	2	2					2	2
Contusion		1				1		
Coronary artery disease	1	2					1	2
Coronary artery dissection		1						1
Coronary artery stenosis		1						1
Cough	10	48	1	1	2	19	8	29
COVID-19	20	48	1	2		5	20	43
COVID-19 pneumonia	4	5		1			4	5
Cranial nerve paralysis	4	4					4	4
Craniocerebral injury	1	1					1	1
C-reactive protein increased	2	6			1	3	1	3
Cyanosis	1	5				1	1	4
Cystitis		2				1		1
Deafness	1	2					1	2
Deafness neurosensory		2						2
Death	1	7					1	7
Decreased appetite	6	18	1	1	1	9	5	9
Deep vein thrombosis	17	26		1			17	26

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dehydration	1	3
Delirium	1	1
Delusion		1
Depressed level of consciousness	2	2
Depressed mood		1
Depression	2	2
Dermal cyst		1
Dermatitis	2	2
Dermatitis allergic		2
Dermatitis atopic		1
Dermatitis bullous		2
Dermatitis exfoliative generalised		1
Dermatitis herpetiformis		1
Dermatitis psoriasiform		1
Diaphragmatic disorder	1	1
Diarrhoea	11	57
Diplopia	8	10
Discomfort	2	6
Disease progression	2	2
Disease recurrence	6	19
Disorientation	3	9
Disturbance in attention	2	7
Diverticulitis		1
Diverticulum	1	1
Dizziness	14	64
Drooling		1
Drug abuse		1
Drug hypersensitivity		2
Drug ineffective	2	14
Drug interaction		
Dry mouth	3	13
Dry skin		1
Dry throat		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
				1	1
					1
	1			2	2
			1		
				2	2
			1		
		1	1	1	1
			1		1
			1		
					2
					1
					1
			1		
2	3	4	32	7	25
		1	2	7	8
		1	5	1	1
				2	2
		1	3	5	16
	2			3	9
		1	5	1	2
					1
				1	1
	1	5	37	9	27
			1		
					1
					2
				2	14
1	1				
		2	10	1	3
			1		
			1		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dysaesthesia	1	3
Dysaesthesia pharynx		1
Dysarthria	7	13
Dyschezia		1
Dysentery	1	19
Dysgeusia	3	12
Dyskinesia	2	2
Dysmetria		2
Dyspepsia		2
Dysphagia	4	18
Dysphonia	3	11
Dyspnoea	40	108
Dyspnoea at rest		1
Dyspnoea exertional	2	5
Dyspraxia	1	1
Dysstasia	1	1
Dysuria	1	4
Ear discomfort	1	3
Ear haemorrhage		1
Ear infection		1
Ear pain	3	6
Ear swelling	1	1
Eating disorder	1	1
Ecchymosis	3	6
Eczema	3	3
Electric shock sensation		1
Electrocardiogram T wave inversion		
Embolism		1
Embolism venous		1
Emotional disorder		1
Emphysema		1
Encephalitis	1	1
Enterococcal infection		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	2
			1		
3	3			7	13
					1
				1	19
		3	7		5
		1	1	1	1
					2
			2		
1	1		4	4	14
			1	3	10
7	10	7	19	33	89
					1
				2	5
				1	1
1	1			1	1
			1	1	3
		1	2		1
			1		
			1		
		1	4	2	2
				1	1
				1	1
		1	2	2	4
		2	2	1	1
			1		
	1				
1	1				1
					1
			1		
					1
				1	1
					1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Enthesopathy	1	2					1	2
Eosinophil count increased		1						1
Epilepsy	3	5					3	5
Epistaxis	1	6				3	1	3
Erectile dysfunction	1	1					1	1
Erysipelas		1	1	1				1
Erythema	15	60	2	4	7	30	8	30
Erythema multiforme	1	1					1	1
Erythema nodosum		2						2
Escherichia sepsis	1	1					1	1
Essential hypertension			1	1				
Euphoric mood		1				1		
Exposure during pregnancy	1	1			1	1		
Extensive swelling of vaccinated limb		1						1
Extrasystoles			1	1				
Extremity contracture		1				1		
Eye allergy		1				1		
Eye disorder		1						1
Eye haemorrhage		1						1
Eye irritation	4	9			4	7		2
Eyelid oedema	1	2			1	1		1
Eyelid ptosis		3				2		1
Eye movement disorder	1	1					1	1
Eye oedema	1	2			1	1		1
Eye pain	2	11			1	6	1	5
Eye pruritus	2	5			1	1	1	4
Eye swelling		2				1		1
Face oedema	3	9	1	1	1	2	2	7
Facial asymmetry		2						2
Facial nerve disorder		1						1
Facial neuralgia		1				1		
Facial pain	1	2				1	1	1
Facial paralysis	6	13					6	13

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Facial paresis	3	5				1	3	4
Facial spasm		1						1
Fall	6	9	1	1	3	3	3	6
Fatigue	47	143	1	1	31	107	16	36
Feeling abnormal		2				1		1
Feeling cold		10				8		2
Feeling hot	8	23			4	10	4	13
Feeling jittery		1						1
Feeling of body temperature change		2						2
Female sexual dysfunction		1				1		
Fibrin D dimer increased	4	8	1	1	2	4	2	4
Fibromyalgia	1	1			1	1		
Flatulence	1	1					1	1
Fluid retention		2						2
Flushing	1	11	1	1		7	1	4
Focal dyscognitive seizures		1						1
Gait disturbance	4	9			2	3	2	6
Gait inability		4						4
Gallbladder disorder	1	1					1	1
Gastritis	1	1					1	1
Gastrointestinal disorder	1	2			1	2		
Gastrointestinal pain	2	2			1	1	1	1
Gastrooesophageal reflux disease	1	1			1	1		
Gaze palsy	1	1					1	1
Generalised tonic-clonic seizure	2	3					2	3
General physical health deterioration	2	4				1	2	3
Gingival bleeding	3	5				1	3	4
Gingival pain		1				1		
Glaucoma	1	1					1	1
Glomerulonephritis		1						1
Glossitis		1						1
Glossodynia		1				1		
Gravitational oedema	1	1			1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Groin pain	1	1					1	1
Guillain-Barre syndrome	1	2					1	2
Guttate psoriasis		1						1
Haematochezia	1	2					1	2
Haematoma	3	9				2	3	7
Haematoma muscle	1	1			1	1		
Haematuria		1				1		
Haemodynamic instability	1	1					1	1
Haemoglobin decreased	1	2					1	2
Haemorrhage subcutaneous		1						1
Haemorrhagic cerebral infarction		1						1
Haemorrhagic diathesis	2	2					2	2
Haemorrhagic stroke	1	2					1	2
Hallucination	2	6	1	1			2	6
Hallucination, auditory		1	1	1				1
Hallucination, olfactory		1						1
Hallucinations, mixed		1						1
Hallucination, visual		1						1
Hand dermatitis		1				1		
Headache	82	297	6	9	51	212	31	85
Head discomfort	1	1			1	1		
Head injury			1	1				
Heart rate decreased	1	1					1	1
Heart rate increased	1	4				1	1	3
Heart rate irregular		1						1
Heavy menstrual bleeding		1				1		
Hemianaesthesia		1						1
Hemidysaesthesia	1	1					1	1
Hemiparaesthesia	1	4					1	4
Hemiparesis	7	14					7	14
Hemiplegia	3	6					3	6
Hepatic encephalopathy			1	1				
Hepatic enzyme increased	1	1		1			1	1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hepatic steatosis	1	1
Hepatitis acute	1	2
Herpes ophthalmic		2
Herpes virus infection	1	1
Herpes zoster	10	14
Herpes zoster oticus	1	1
Hot flush	7	12
Hydrocephalus		1
Hyperaemia	1	2
Hyperaesthesia	1	2
Hypercapnia	1	2
Hypercreatininaemia		1
Hyperglycaemia	3	7
Hyperhidrosis	3	18
Hyperpyrexia	9	23
Hypersensitivity	3	16
Hypersomnia		1
Hypertension	4	21
Hypertensive crisis	8	19
Hypertensive heart disease		2
Hyperthermia		3
Hyperthyroidism	1	1
Hypertonia	1	2
Hypertransaminasaemia		1
Hyperventilation		1
Hypoacusis		3
Hypoaesthesia	1	12
Hypoaesthesia oral	3	7
Hypoglycaemia	1	1
Hypokalaemia		1
Hypokinesia	1	2
Hyponatraemia	1	1
Hyporeflexia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	2
					2
				1	1
		8	10	2	4
				1	1
		3	6	4	6
					1
				1	2
		1	2		
				1	2
					1
			1	3	6
		2	10	1	8
	1			9	23
1	1		3	3	13
			1		
		1	4	3	17
				8	19
					2
			1		2
				1	1
1	1		1	1	1
1	1				1
					1
1	1		1		2
		1	7		5
		1	2	2	5
				1	1
					1
			1	1	1
1	1			1	1
					1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hyporesponsive to stimuli		1
Hyposmia	1	1
Hypotension	14	31
Hypotensive crisis		3
Hypothermia	1	3
Hypothyroidism	1	1
Hypotonia		1
Hypovolaemia		1
Hypoxia	4	9
Illrd nerve disorder		1
Illrd nerve paralysis		1
Illness	2	2
Immobilisation prolonged	1	1
Immune-mediated adverse reaction	1	1
Immune thrombocytopenia		1
Impaired fasting glucose	1	1
Impaired quality of life	3	4
Impaired work ability		1
Inappropriate schedule of product administration	2	6
Incontinence	1	1
Incorrect dose administered	1	1
Incorrect route of product administration		3
Increased viscosity of bronchial secretion		1
Infected cyst		1
Infection		1
Inflammation		1
Influenza	2	3
Influenza like illness	2	16
Injected limb mobility decreased		3
Injection site erythema		6
Injection site haematoma	1	1
Injection site joint pain		1
Injection site oedema		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
	1	3	7	11	24
					3
				1	3
				1	1
					1
					1
				4	9
					1
					1
		2	2		
				1	1
				1	1
	1				1
				1	1
			1	3	3
					1
		2	5		1
		1	1		
		1	1		
			3		
					1
					1
			1		
					1
		2	3		
		2	14		2
			2		1
			6		
		1	1		
			1		
			3		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Injection site pain		52				52		
Injection site pruritus		1				1		
Injection site reaction		5				5		
Injection site swelling		3				3		
Injection site urticaria		2				2		
Insomnia	6	25			2	18	4	7
Intentional product use issue	1	1			1	1		
Intermenstrual bleeding		1				1		
Intermittent claudication	1	1					1	1
International normalised ratio increased	1	2				1	1	1
Interstitial lung disease	4	7					4	7
Intervertebral disc degeneration	1	1					1	1
Intestinal ischaemia		1						1
Intestinal obstruction		1						1
Intra-abdominal haemorrhage	1	1					1	1
Intracranial pressure increased	1	1					1	1
Intranasal paraesthesia		1				1		
Intraventricular haemorrhage		1						1
Ischaemia	4	5					4	5
Ischaemic stroke	7	11	1	1			7	11
IVth nerve paralysis	1	1					1	1
Jaundice		2						2
Jaundice cholestatic		1						1
Joint effusion		1				1		
Joint lock	1	1					1	1
Joint range of motion decreased		2				1		1
Joint swelling		2				1		1
Klebsiella infection	1	1					1	1
Labyrinthitis	1	4				1	1	3
Lacrimation increased	1	6				2	1	4
Lactic acidosis	1	1					1	1
Lagophthalmos		1						1
Laryngeal oedema	4	22					4	22

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Laryngospasm	1	4					1	4
Lateropulsion		1						1
Lens disorder	1	1			1	1		
Lethargy	1	2				1	1	1
Leukaemia		1						1
Leukocytosis	2	3		1		1	2	2
Leukopenia		1						1
Lichen sclerosus	1	1					1	1
Limb discomfort	3	7			3	7		
Limb injury	1	1					1	1
Lipase increased		1				1		
Lip oedema	3	10				3	3	7
Lip pruritus	1	3				1	1	2
Lip swelling	2	5		1		1	2	4
Livedo reticularis		1		1		1		
Liver abscess	1	1					1	1
Localised oedema	2	4		1	1	2	1	2
Logorrhoea		1						1
Loss of consciousness	9	20					9	20
Loss of control of legs		1						1
Loss of personal independence in daily activities	1	1					1	1
Lung disorder		1						1
Lung neoplasm malignant		1						1
Lymphadenitis		2				2		
Lymphadenopathy	18	82			14	65	4	17
Lymphadenopathy mediastinal	1	1					1	1
Lymph node pain	1	7			1	5		2
Lymphocyte count decreased		1				1		
Lymphocyte count increased	1	1			1	1		
Lymphocytosis		1				1		
Macule	1	1					1	1
Maculopathy		1						1
Malaise	22	88	3	4	14	57	8	31

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Maternal exposure during pregnancy		4				4		
Mean cell volume increased		1				1		
Mechanical urticaria		2				1		1
Mechanical ventilation	1	1					1	1
Memory impairment	1	1					1	1
Menstruation irregular	4	4			4	4		
Metabolic acidosis		1						1
Micturition urgency	1	1			1	1		
Middle insomnia		1				1		
Migraine	3	15	1	1	3	13		2
Mobility decreased		1						1
Monocyte count increased		1				1		
Monoparesis	1	1			1	1		
Monoplegia		1						1
Mood altered		1				1		
Mood swings		1				1		
Motor dysfunction	2	7	1	1		1	2	6
Movement disorder		3				1		2
Mucous stools		1				1		
Multi-organ disorder	1	1					1	1
Multiple organ dysfunction syndrome		3		1				3
Multiple sclerosis	1	1					1	1
Multiple sclerosis relapse	2	2					2	2
Muscle contractions involuntary		1						1
Muscle contracture		2				1		1
Muscle discomfort	1	1			1	1		
Muscle rigidity	2	7			1	5	1	2
Muscle spasms	1	10				7	1	3
Muscle swelling		1						1
Muscle tightness		1				1		
Muscle twitching		3				3		
Muscular weakness	8	19			1	7	7	12
Musculoskeletal pain	7	36			4	29	3	7

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Musculoskeletal stiffness	3	9
Myalgia	33	160
Myasthenia gravis crisis	1	3
Myelitis	1	1
Myeloid leukaemia	1	1
Myocardial infarction	2	5
Myocardial ischaemia	2	4
Myringitis		1
Nasal congestion	1	2
Nasal discomfort	1	1
Nasopharyngitis	1	8
Nausea	35	138
Neck pain	3	17
Necrotising fasciitis	1	1
Nervousness	1	1
Nervous system disorder	3	5
Neuralgia		7
Neurological symptom	1	1
Neuropathy peripheral	1	4
Neutropenia		1
Neutrophilia		1
Nightmare	2	3
Night sweats		2
Nocturnal dyspnoea	1	1
Non-cardiac chest pain		1
Non-Hodgkin's lymphoma	1	1
Normal pressure hydrocephalus	1	1
Nuchal rigidity		4
Nystagmus		1
Obstructive airways disorder	1	2
Occipital neuralgia		1
Occult blood positive	1	1
Ocular discomfort		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3	2	6
	2	25	123	8	37
				1	3
				1	1
				1	1
				2	5
				2	4
					1
			1	1	1
				1	1
		1	7		1
3	4	18	88	17	50
		1	13	2	4
				1	1
		1	1		
				3	5
			4		3
1	2			1	1
				1	4
					1
					1
		1	2	1	1
			2		
		1	1		
					1
				1	1
				1	1
			3		1
					1
			1	1	1
					1
				1	1
			2		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Ocular hyperaemia	1	6
Oedema mouth		2
Oedema peripheral	7	16
Oesophageal spasm		1
Off label use	6	19
Oliguria		2
Ophthalmic herpes zoster	1	1
Optic neuritis		3
Oral discomfort	3	4
Oral dysaesthesia	1	1
Oral herpes	3	6
Oral pain	1	4
Oral pruritus		2
Oropharyngeal discomfort		2
Oropharyngeal pain	4	16
Oropharyngeal spasm		1
Oropharyngeal swelling	1	2
Orthopnoea		1
Orthostatic hypotension		1
Osteitis	1	1
Osteoarthritis	1	1
Otitis media acute	1	1
Overdose	4	10
Oxygen saturation abnormal		
Oxygen saturation decreased	11	31
Pain	19	63
Pain in extremity	40	122
Pain in jaw		1
Pain of skin		1
Palatal oedema		4
Palatal swelling		1
Pallor	2	5
Palpable purpura		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		3
					2
3	5	1	7	6	9
					1
		6	17		2
					2
				1	1
					3
		2	3	1	1
		1	1		
		2	4	1	2
		1	3		1
					2
			1		1
	1	3	9	1	7
					1
		1	2		
					1
					1
		1	1		
		1	1		
		1	1		
		4	9		1
	1				
1	2	1	5	10	26
		13	41	6	22
1	1	28	86	12	36
			1		
					1
			2		2
			1		
		1	2	1	3
			1		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Palpitations	2	5
Pancreatitis acute		1
Panic attack	1	1
Panniculitis		1
Papilloedema		1
Paraesthesia	21	78
Paraesthesia oral	6	41
Paraparesis		1
Paresis		1
Parosmia	1	3
Partial seizures	1	2
Pelvic fracture	1	1
Pemphigoid	1	2
Performance status decreased	1	1
Pericardial effusion	2	4
Pericarditis	2	2
Perioral dermatitis		1
Periorbital swelling	1	3
Peripheral coldness	2	5
Peripheral nerve palsy	1	1
Peripheral sensorimotor neuropathy		1
Peripheral swelling	6	20
Persecutory delusion	1	1
Petechiae	5	6
Petit mal epilepsy	1	1
Pharyngeal disorder		1
Pharyngeal erythema		2
Pharyngeal oedema		3
Pharyngeal paraesthesia		4
Pharyngeal swelling		1
Pharyngitis		2
Phlebitis	1	3
Phlebitis superficial		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3	1	2
					1
				1	1
					1
					1
1	1	13	46	8	32
		3	24	3	17
					1
			1		
			2	1	1
				1	2
				1	1
				1	2
		1	1		
				2	4
				2	2
			1		
			2	1	1
			1	2	4
		1	1		
					1
		4	10	2	10
				1	1
			1	5	5
				1	1
			1		
	1				2
			1		3
					3
					1
					2
		1	2		1
					1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Photophobia		6
Photopsia	1	2
Photosensitivity reaction		1
Pityriasis rosea		1
Platelet count decreased		1
Platelet disorder	1	1
Pleural effusion	2	3
Pleurisy	1	1
Pneumonia	4	8
Pneumonia aspiration	1	1
Pneumonia bacterial		2
Pneumonitis	3	4
Polyuria	3	4
Portal vein thrombosis	2	2
Post thrombotic syndrome	1	1
Presyncope	9	21
Procalcitonin increased	1	2
Product dose omission issue		1
Productive cough		4
Product use issue	4	14
Proteinuria	1	2
Pruritus	15	64
Psoriasis	1	3
Psoriatic arthropathy		2
Psychomotor hyperactivity	2	4
Pulmonary embolism	22	34
Pulmonary hypertension	1	2
Pulmonary hypoperfusion		1
Pulmonary microemboli		1
Pulmonary oedema	1	3
Pulse volume decreased		1
Purpura	2	3
Pustular psoriasis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		3
		1	1		1
					1
					1
			1		
				1	1
		1	1	1	2
		1	1		
				4	8
				1	1
					2
				3	4
		2	2	1	2
				2	2
				1	1
1	1	2	7	7	14
		1	2		
			1		
					4
		4	13		1
		1	2		
		6	34	9	30
			2	1	1
					2
			1	2	3
4	6		1	22	33
				1	2
					1
					1
				1	3
					1
1	1			2	3
					1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pyrexia	104	369
Q fever		2
Quadriparesis	1	1
Quality of life decreased		1
Rales	1	3
Rash	7	47
Rash erythematous		1
Rash macular	1	3
Rash maculo-papular		2
Rash papular		1
Rash pruritic		6
Rectal haemorrhage	1	2
Red blood cell count decreased		1
Red blood cell sedimentation rate increased		2
Red cell distribution width increased		1
Reduced facial expression		1
Regurgitation		1
Renal colic	1	1
Renal failure	5	8
Renal impairment	2	3
Renal pain	2	3
Respiratory acidosis	1	1
Respiratory arrest		2
Respiratory disorder		4
Respiratory distress	2	8
Respiratory failure	9	21
Respiratory fatigue		1
Respiratory tract oedema	1	2
Restless legs syndrome		1
Restlessness		3
Retching	1	4
Retinal artery embolism	1	1
Retinal artery occlusion	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
6	12	59	231	45	138
					2
				1	1
					1
				1	3
		3	22	4	25
					1
			2	1	1
			2		
			1		
			5		1
				1	2
					1
			1		1
			1		
					1
					1
				1	1
				5	8
				2	3
		1	2	1	1
				1	1
					2
			2		2
	1			2	8
1	1			9	21
					1
				1	2
					1
			1		2
				1	4
				1	1
				1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Retinal degeneration		1						1
Retinal detachment		1						1
Retinal disorder		1						1
Retinal drusen		1						1
Retinal ischaemia	1	1					1	1
Retinal oedema		1						1
Retinal vein occlusion	1	2					1	2
Rhabdomyolysis	1	1					1	1
Rheumatoid arthritis		3						3
Rhinalgia	1	1			1	1		
Rhinitis		2				2		
Rhinorrhoea	4	7			2	2	2	5
Right ventricular dysfunction	1	1					1	1
Salivary gland pain		1				1		
Salivary hypersecretion		1				1		
Sarcoidosis	1	2					1	2
SARS-CoV-2 test		1						1
SARS-CoV-2 test negative	1	1					1	1
SARS-CoV-2 test positive	2	5	1	1			2	5
Sciatica	1	3				2	1	1
Scleral discolouration	2	3			2	2		1
Secretion discharge		1						1
Seizure	2	7					2	7
Senile dementia	1	1					1	1
Sensation of foreign body		3				1		2
Sense of oppression		2				1		1
Sensitive skin	1	1					1	1
Sensorimotor disorder		1						1
Sensory disturbance	2	2			1	1	1	1
Sensory loss	1	3					1	3
Sepsis	2	4					2	4
Septic shock	2	5					2	5
Serratia test positive		1						1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Severe acute respiratory syndrome		1						1
Shock	1	3					1	3
Sinus headache		1				1		
Sinusitis		1				1		
Sinus tachycardia		2		1		1		1
Skin burning sensation		1				1		
Skin discolouration	2	2			1	1	1	1
Skin discomfort	1	1			1	1		
Skin exfoliation		1						1
Skin laceration		1						1
Skin lesion		3				1		2
Skin reaction	3	4			2	3	1	1
Skin tightness		1						1
Sleep disorder		1				1		
Sneezing	1	2			1	2		
Soliloquy		1				1		
Somnolence	9	23		2	6	13	3	10
Sopor	1	6	1	3			1	6
Speech disorder	4	7					4	7
Spinal pain	1	5			1	5		
Status epilepticus	1	1					1	1
Stenotrophomonas test positive		1						1
Stertor		1						1
Strabismus	1	1					1	1
Strangury			1	1				
Stridor	1	1					1	1
Stupor		4				1		3
Subarachnoid haemorrhage	1	3					1	3
Subdural haematoma	1	2					1	2
Sudden death	3	14					3	14
Sudden hearing loss	1	1					1	1
Suffocation feeling	1	3				1	1	2
Suicidal ideation	1	1					1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Superinfection bacterial		2						2
Suspected COVID-19	1	1					1	1
Swelling	2	6			1	4	1	2
Swelling face	7	14			1	6	6	8
Swollen tongue	3	10				3	3	7
Syncope	15	25	4	5			15	25
Systemic lupus erythematosus		2						2
Systolic hypertension		1						1
Tachyarrhythmia	1	2	1	1	1	2		
Tachycardia	15	61	2	3	7	30	8	31
Tachypnoea	5	11			1	4	4	7
Takayasu's arteritis	1	1					1	1
Taste disorder	2	6				4	2	2
Telangiectasia	1	1			1	1		
Tenderness	1	1			1	1		
Tendon disorder	1	1			1	1		
Tenosynovitis		1						1
Tension headache	1	2			1	2		
Testicular pain	1	1					1	1
Tetany		1						1
Therapeutic response unexpected	1	1			1	1		
Thirst	1	1			1	1		
Throat irritation	2	14			1	9	1	5
Throat tightness	4	19			1	5	3	14
Thromboangiitis obliterans		1						1
Thrombocytopenia	11	20	1	1			11	20
Thrombophlebitis	4	6			4	6		
Thrombophlebitis superficial	3	4			1	1	2	3
Thrombosis	3	6					3	6
Thrombotic stroke	1	1					1	1
Thrombotic thrombocytopenic purpura	1	1					1	1
Thyroid disorder	1	2			1	2		
Tinnitus	1	8			1	5		3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tongue biting	1	1					1	1
Tongue coated		1				1		
Tongue discomfort		3				2		1
Tongue dry		1				1		
Tongue oedema	1	7				1	1	6
Tongue pruritus		1				1		
Tongue ulceration		1				1		
Tonsillar inflammation	1	1			1	1		
Transaminases increased		1						1
Transient ischaemic attack	3	5					3	5
Tremor	9	23			1	7	8	16
Trigeminal nerve disorder		2				2		
Trigeminal neuralgia		1				1		
Trismus	1	1			1	1		
Troponin I increased		1						1
Troponin increased	1	2					1	2
Underdose	1	2			1	2		
Unresponsive to stimuli		2						2
Urinary incontinence	1	3					1	3
Urinary retention		2						2
Urinary tract infection	3	3					3	3
Urine flow decreased		1				1		
Urine output decreased	1	2					1	2
Urosepsis		1						1
Urticaria	2	41				28	2	13
Use of accessory respiratory muscles		3				1		2
Uterine leiomyoma	1	1					1	1
Vaccination complication	2	11			2	8		3
Vaccination failure	22	38	1	2		1	22	37
Vaccination site anaesthesia		1						1
Vaccination site bruising		1						1
Vaccination site discomfort	1	1			1	1		
Vaccination site eczema		1				1		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination site erythema	7	15
Vaccination site induration	1	3
Vaccination site inflammation	1	4
Vaccination site joint pain	1	2
Vaccination site lymphadenopathy		2
Vaccination site movement impairment	1	5
Vaccination site oedema	2	13
Vaccination site pain	47	135
Vaccination site pallor		1
Vaccination site paraesthesia		5
Vaccination site pruritus	2	3
Vaccination site reaction		2
Vaccination site swelling	1	10
Vaccination site warmth		5
Vaginal haemorrhage	1	1
Vascular purpura		1
Vasculitis	2	4
Vasoconstriction		1
Vasodilatation		1
Vena cava thrombosis	1	1
Venous arterialisation	1	1
Venous occlusion	1	1
Venous thrombosis	2	3
Venous thrombosis limb	1	1
Ventricular arrhythmia	1	1
Ventricular extrasystoles	2	3
Ventricular fibrillation		1
Vertebral artery occlusion	1	1
Vertigo	8	37
Vertigo positional		1
Vestibular neuritis	1	1
Vision blurred	4	10
Visual acuity reduced	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	11	2	4
		1	3		
		1	4		
		1	2		
			2		
		1	4		1
	1	2	12		1
	2	41	113	6	22
			1		
			3		2
		1	1	1	2
			1		1
	1	1	7		3
	1		5		
				1	1
					1
			1	2	3
					1
					1
				1	1
				1	1
				2	3
				1	1
				1	1
				2	3
					1
				1	1
3	4	4	24	4	13
	1				1
				1	1
1	1	1	2	3	8
	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Visual impairment	5	12			2	3	3	9
Vitreous detachment		1						1
Vitreous floaters	1	2					1	2
Vitreous haemorrhage		1						1
Vomiting	23	61	3	4	7	27	16	34
Weight decreased		1						1
Wheezing	4	9			1	4	3	5
White blood cell count increased	1	2					1	2
Withdrawal hypertension	1	1			1	1		
Wound	1	1					1	1
Xerosis		1						1
	1,907	6,031	121	198	697	2914	1210	3117

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Country Where Event Occurred

JAPAN

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	7		1	1	6
Abdominal distension	2	2	1	1	1	1
Abdominal pain	10	20	5	10	5	10
Abdominal pain lower	2	3	1	1	1	2
Abdominal pain upper		4				4
Abnormal sensation in eye	2	3	1	1	1	2
Acidosis	1	1			1	1
Acute abdomen	1	1			1	1
Acute disseminated encephalomyelitis	1	1			1	1
Acute lymphocytic leukaemia		1				1
Acute myocardial infarction	2	3			2	3
Acute respiratory distress syndrome		2				2
Affective disorder		1		1		
Alanine aminotransferase increased		1				1
Allergic reaction to excipient		2				2
Allergy to vaccine	2	2			2	2
Altered state of consciousness	8	13			8	13
Amnesia	2	3			2	3
Anaemia	1	2			1	2
Anaphylactic reaction	109	316	1	3	108	313
Anaphylactic shock	5	12			5	12
Anaphylactoid reaction		5				5
Aneurysm	1	1			1	1
Angina pectoris	1	2			1	2
Angioedema		2		1		1
Angiopathy	1	1			1	1
Anxiety	1	4	1	3		1
Anxiety disorder	1	1			1	1
Aortic dissection	2	2			2	2
Aphasia	1	2			1	2
Aphonia	1	2		1	1	1
Apnoea	2	2			2	2
Apraxia		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arrhythmia	3	5			3	5
Arterial occlusive disease	1	1	1	1		
Arthralgia	16	26	10	16	6	10
Arthritis	3	4	1	1	2	3
Arthritis reactive		1				1
Arthropathy	1	1			1	1
Ascites		1				1
Asphyxia	1	1			1	1
Asthenia	5	16	3	7	2	9
Asthenopia		1				1
Asthma	60	107	18	30	42	77
Asthmatic crisis	1	1			1	1
Autonomic neuropathy		1				1
Axillary pain	1	3	1	2		1
Back pain	5	7	2	3	3	4
Blister	1	1	1	1		
Blood alkaline phosphatase decreased		1		1		
Blood disorder	1	1	1	1		
Blood glucose decreased		1				1
Blood pressure abnormal		2				2
Blood pressure ambulatory abnormal	1	1			1	1
Blood pressure decreased	12	18	1	3	11	15
Blood pressure diastolic decreased	1	1			1	1
Blood pressure diastolic increased		1				1
Blood pressure immeasurable	2	2	1	1	1	1
Blood pressure increased	49	81	12	28	37	53
Blood pressure systolic decreased	1	1	1	1		
Blood pressure systolic increased	3	8	2	3	1	5
Body temperature increased	4	7	2	5	2	2
Bowel movement irregularity	1	1	1	1		
Bradycardia	1	3			1	3
Brain stem haemorrhage	1	2			1	2
Breath sounds abnormal	2	3			2	3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchial obstruction		1				1
Bronchitis	1	1	1	1		
Bronchospasm	2	4			2	4
Bronchostenosis	1	2			1	2
Burning sensation		1				1
Calculus urinary	1	1	1	1		
Cardiac arrest	5	5			5	5
Cardiac death		1				1
Cardiac failure	5	10			5	10
Cardiac failure acute	3	3			3	3
Cardiac failure chronic		1				1
Cardiac failure congestive	1	1			1	1
Cardiac hypertrophy	1	1	1	1		
Cardio-respiratory arrest	10	12			10	12
Carotid artery stenosis	1	1			1	1
Cellulitis		2				2
Cerebral haemorrhage		1				1
Cerebral infarction	5	5			5	5
Cerebral mass effect	1	1			1	1
Cerebral ventricular rupture	1	1			1	1
Cerebrovascular disorder	1	1			1	1
Chest discomfort	6	12	2	5	4	7
Chest pain	3	4		1	3	3
Chills	25	47	16	27	9	20
Choking	1	1			1	1
Cholinergic syndrome		1				1
Chromaturia	3	3	1	1	2	2
Chronic obstructive pulmonary disease	1	1	1	1		
Chronic respiratory disease	1	1	1	1		
Circulatory collapse		1				1
Clonic convulsion	1	1			1	1
Cold sweat	5	15	2	5	3	10
Colitis		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Colitis ulcerative		1				1
Completed suicide	1	1			1	1
Condition aggravated	1	4	1	2		2
Conjunctival hyperaemia	1	5	1	2		3
Coronary artery occlusion	1	1			1	1
Coronary artery stenosis	1	1			1	1
Cough	64	157	18	40	46	117
C-reactive protein increased	1	1	1	1		
CSF cell count increased	1	1			1	1
Cutaneous symptom		1				1
Cyanosis	3	4			3	4
Deafness	2	2			2	2
Deafness neurosensory	1	1			1	1
Death	2	2			2	2
Decreased appetite	6	9	3	4	3	5
Dehydration	3	4			3	4
Depressed level of consciousness	10	15	1	1	9	14
Dermatitis		1		1		
Dermatitis allergic	2	5	1	2	1	3
Dermatitis atopic	1	4	1	3		1
Diarrhoea	17	26	9	14	8	12
Diastolic hypotension		1				1
Diplopia		1		1		
Discomfort	2	4		2	2	2
Disease recurrence	6	7	1	1	5	6
Disseminated intravascular coagulation	1	1			1	1
Diverticulitis		2				2
Diverticulum		1				1
Diverticulum intestinal haemorrhagic	1	1			1	1
Dizziness	17	47	11	25	6	22
Dizziness postural	1	5	1	3		2
Drowning		1				1
Drug hypersensitivity		2				2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry mouth		1				1
Dysaesthesia		1				1
Dysgeusia	3	5	2	3	1	2
Dyskinesia	3	3	1	1	2	2
Dysphagia	3	5	1	1	2	4
Dysphonia	9	23	4	9	5	14
Dysphoria	4	5	2	2	2	3
Dyspnoea	54	113	19	36	35	77
Dysstasia	3	3			3	3
Ear discomfort	3	6	2	3	1	3
Ear swelling	1	1	1	1		
Eczema	2	3	1	2	1	1
Embolism venous	1	1			1	1
Enterocolitis	1	2			1	2
Epigastric discomfort		1				1
Epilepsy	3	3			3	3
Epistaxis	1	1	1	1		
Erythema	43	96	14	35	29	61
Erythema of eyelid	1	2			1	2
Eustachian tube dysfunction	1	1	1	1		
Excessive eye blinking		1				1
Exposure during pregnancy	1	1			1	1
Eye disorder		3		1		2
Eyelid function disorder		1				1
Eyelid irritation		1				1
Eyelid oedema	2	8	2	5		3
Eyelid ptosis		1				1
Eyelid rash	2	2			2	2
Eyelids pruritus	1	1			1	1
Eye movement disorder	1	1	1	1		
Eye oedema	1	2	1	1		1
Eye pain	1	1	1	1		
Eye pruritus	1	2			1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Face oedema	5	8	1	3	4	5
Facial pain		1				1
Facial paralysis	1	5			1	5
Fall	2	3	1	1	1	2
Fatigue	4	8	2	4	2	4
Feeling abnormal	49	76	26	32	23	44
Feeling cold	7	12	1	1	6	11
Feeling drunk	1	1	1	1		
Feeling hot	15	27	5	11	10	16
Feeling jittery		1				1
Flushing	8	18	4	7	4	11
Foaming at mouth	1	1	1	1		
Foreign body in throat		1				1
Gait disturbance	1	4	1	1		3
Gastrointestinal disorder	1	1			1	1
Gastrointestinal haemorrhage	1	2			1	2
Gastrointestinal hypermotility		1				1
Gastrointestinal hypomotility	1	1			1	1
Gastrointestinal motility disorder		1		1		
Gastrointestinal oedema	1	1			1	1
Gaze palsy		1				1
General physical health deterioration		1				1
Glomerulonephritis	1	1			1	1
Grip strength decreased		1				1
Guillain-Barre syndrome		2				2
Haematochezia		2				2
Haematoma	1	1			1	1
Haematuria	3	3			3	3
Haemorrhage	2	3			2	3
Haemorrhage subcutaneous	1	3			1	3
Headache	46	107	25	55	21	52
Head discomfort	4	11	1	6	3	5
Heart rate decreased	2	4	1	2	1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate increased	18	26	7	12	11	14
Heavy menstrual bleeding	1	1			1	1
Hemiplegia	2	3			2	3
Henoch-Schonlein purpura	3	3	1	1	2	2
Hepatic function abnormal	2	4			2	4
Hepatitis acute	1	1			1	1
Herpes simplex	1	1	1	1		
Herpes zoster	1	1	1	1		
Hot flush	10	21	6	11	4	10
Hyperaemia		1				1
Hyperhidrosis	8	17	3	6	5	11
Hyperreflexia		1				1
Hypersensitivity	18	31	5	11	13	20
Hypertension	5	9	2	2	3	7
Hypertensive emergency		2				2
Hyperthermia	1	2		1	1	1
Hyperventilation	4	10	1	4	3	6
Hypoacusis	2	3	1	1	1	2
Hypoaesthesia	17	38	7	14	10	24
Hypoaesthesia oral	6	12	3	5	3	7
Hypokalaemia		1				1
Hypophagia	2	4	1	2	1	2
Hypopnoea	1	1	1	1		
Hypothyroidism		1				1
Hypotonia		1				1
Hypoventilation		1				1
Ileus paralytic	1	1			1	1
Imaging procedure abnormal	1	1			1	1
Immunisation reaction	1	1	1	1		
Impaired work ability	1	1	1	1		
Inappropriate schedule of product administration	1	1	1	1		
Injected limb mobility decreased		1		1		
Injection site erythema		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site hypoaesthesia	1	1	1	1		
Injection site pain		1		1		
Injection site pruritus		1		1		
Injection site rash		1		1		
Internal haemorrhage	1	2			1	2
Intestinal ulcer	1	1			1	1
Intracranial aneurysm	1	2			1	2
Irregular breathing	1	1			1	1
Joint range of motion decreased	1	1	1	1		
Joint swelling		1		1		
Laryngeal discomfort	2	3	1	1	1	2
Laryngeal obstruction	1	2			1	2
Laryngeal oedema	3	4	1	1	2	3
Larynx irritation	1	3			1	3
Lethargy		1				1
Leukopenia		1				1
Limb discomfort		5		4		1
Lip erythema		1				1
Lip pruritus	2	4	1	1	1	3
Lip swelling	2	8		1	2	7
Loss of consciousness	7	12			7	12
Lymphadenitis		1		1		
Lymphadenopathy	2	4	2	3		1
Lymph node pain		2		1		1
Lymphoedema		1				1
Malaise	46	81	31	54	15	27
Marasmus	1	1			1	1
Melaena	1	2			1	2
Memory impairment	1	1			1	1
Meningitis	1	1			1	1
Meningitis aseptic		1				1
Mesenteric artery thrombosis	1	1			1	1
Middle insomnia		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Migraine	1	1			1	1
Mobility decreased	1	3	1	2		1
Monoparesis	1	1			1	1
Mouth swelling		3		2		1
Movement disorder		2				2
Mucosal disorder		1		1		
Multi-organ disorder		2		1		1
Muscle spasms	4	10	2	7	2	3
Muscle tightness	4	4	2	2	2	2
Muscular weakness	4	16	1	5	3	11
Musculoskeletal discomfort	2	2	1	1	1	1
Musculoskeletal stiffness	1	2		1	1	1
Myalgia	12	18	9	13	3	5
Myocardial infarction	3	4			3	4
Myocardial ischaemia	2	2			2	2
Myocardial rupture	1	1			1	1
Nasal congestion	5	6	4	4	1	2
Nasal obstruction	1	1			1	1
Nasal oedema	1	1	1	1		
Nasopharyngitis	1	1	1	1		
Nausea	58	114	23	42	35	72
Neck pain	2	5		1	2	4
Nephrotic syndrome		1				1
Neuropathy peripheral	3	7			3	7
Nystagmus	1	1			1	1
Obstructive airways disorder	1	2			1	2
Ocular hyperaemia	1	4		3	1	1
Oculomucocutaneous syndrome	1	2			1	2
Odynophagia		1				1
Oedema	2	4			2	4
Oedema peripheral	3	4	1	1	2	3
Off label use	1	1	1	1		
Oliguria	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral allergy syndrome	1	1	1	1		
Oral discomfort	1	6	1	3		3
Oral mucosa erosion		1		1		
Oral mucosal blistering		1		1		
Oral pain		1		1		
Oral pruritus	1	4	1	2		2
Oropharyngeal discomfort	47	101	18	40	29	61
Oropharyngeal pain	5	14	3	8	2	6
Orthopnoea	1	1			1	1
Oxygen saturation decreased	16	29	1	4	15	25
Pain	13	16	6	7	7	9
Pain in extremity	3	11	3	8		3
Pallor	5	9	2	2	3	7
Palmar erythema	1	1			1	1
Palpitations	30	55	19	31	11	24
Paraesthesia	5	12	4	9	1	3
Paraesthesia oral	2	6		3	2	3
Parasympathetic nerve injury	1	1			1	1
Paresis	1	1			1	1
Parotitis		1		1		
Paroxysmal sympathetic hyperactivity	1	1			1	1
Pemphigoid	1	1			1	1
Pericardial effusion	1	1			1	1
Peripheral coldness	1	7		4	1	3
Peripheral swelling	6	7	3	4	3	3
Petit mal epilepsy		1				1
Pharyngeal inflammation	1	1	1	1		
Pharyngeal oedema	3	3	1	1	2	2
Pharyngeal paraesthesia	1	1			1	1
Pharyngeal stenosis	1	1			1	1
Pharyngeal swelling	2	3	1	2	1	1
Photopsia	1	2		1	1	1
Physical deconditioning	1	5	1	3		2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pleural effusion		1				1
Pneumonia	2	3			2	3
Pneumonia aspiration	4	4			4	4
Postural tremor		1				1
Presyncope	11	17	5	8	6	9
Product administered at inappropriate site	1	1	1	1		
Productive cough	3	7	3	6		1
Proteinuria	1	1			1	1
Protein urine present	1	2		1	1	1
Pruritus	69	130	25	49	44	81
Pulmonary artery thrombosis	1	1			1	1
Pulmonary embolism	1	2			1	2
Pulse abnormal	1	1	1	1		
Purpura	1	1	1	1		
Putamen haemorrhage	1	1			1	1
Pyrexia	74	120	41	70	33	50
Radial pulse abnormal	2	3	1	1	1	2
Radiation pneumonitis	1	1	1	1		
Rash	37	55	15	25	22	30
Rash erythematous	2	2	2	2		
Reaction to excipient		1				1
Red blood cells urine positive	1	1			1	1
Respiration abnormal	3	3			3	3
Respiratory alkalosis	1	1			1	1
Respiratory arrest	1	1			1	1
Respiratory disorder		4				4
Respiratory distress	1	3			1	3
Respiratory failure	2	2			2	2
Respiratory rate increased	3	3	1	1	2	2
Respiratory symptom		4		1		3
Restlessness	1	1			1	1
Retinal haemorrhage	1	1			1	1
Retinal vein occlusion	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rheumatoid arthritis	1	1			1	1
Rhinalgia	1	1	1	1		
Rhinorrhoea	8	12	2	4	6	8
Ruptured cerebral aneurysm	1	1			1	1
Salivary hypersecretion	3	4	1	1	2	3
Scar pain	1	1	1	1		
Scratch	1	1	1	1		
Seizure	7	10			7	10
Sensation of foreign body	3	6	1	3	2	3
Sensory disturbance	2	5	1	3	1	2
Septic shock	1	1			1	1
Serum ferritin increased	1	1	1	1		
Shock	1	3			1	3
Shock haemorrhagic	1	1			1	1
Sinus tachycardia	3	3			3	3
Sitting disability		1		1		
Skin erosion	1	1	1	1		
Sneezing	3	7		2	3	5
Somnolence	4	8	2	3	2	5
Speech disorder	1	2			1	2
Sputum discoloured		1		1		
Sputum increased	2	2			2	2
Status asthmaticus	1	1			1	1
Stenosis	1	1			1	1
Stridor	1	6	1	3		3
Subarachnoid haemorrhage	2	3			2	3
Sudden hearing loss		1				1
Sunburn		1		1		
Swelling	4	8	3	4	1	4
Swelling face	3	8	3	5		3
Swelling of eyelid	2	7	2	3		4
Syncope	4	7			4	7
Tachycardia	15	30	4	8	11	22

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachypnoea	4	5	2	3	2	2
Tension	1	1	1	1		
Tetany	1	1			1	1
Thalamus haemorrhage	1	1			1	1
Thirst	2	4	1	2	1	2
Throat irritation	12	27	8	17	4	10
Throat tightness	11	22	1	4	10	18
Thrombocytopenic purpura	1	1			1	1
Tinnitus	3	4	1	1	2	3
Tongue discomfort	1	1			1	1
Tongue oedema	1	1	1	1		
Tongue pruritus	1	1	1	1		
Tracheal obstruction		1				1
Tracheal stenosis	1	1			1	1
Tremor	6	15	2	5	4	10
Trigeminal nerve disorder		2				2
Type I hypersensitivity		3				3
Upper airway obstruction		1				1
Upper respiratory tract inflammation	1	1	1	1		
Urinary occult blood positive	2	2			2	2
Urinary retention		1				1
Urinary tract infection bacterial	1	1	1	1		
Urticaria	38	76	11	26	27	50
Use of accessory respiratory muscles	1	1			1	1
Vaccination site coldness	1	1			1	1
Vaccination site erythema	4	11	3	7	1	4
Vaccination site haemorrhage	1	2	1	1		1
Vaccination site hypoaesthesia	2	2			2	2
Vaccination site movement impairment	1	1	1	1		
Vaccination site pain	29	44	19	30	10	14
Vaccination site papule	1	1	1	1		
Vaccination site paraesthesia	1	2		1	1	1
Vaccination site pruritus	4	9	2	5	2	4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site rash	1	1	1	1		
Vaccination site swelling	6	9	5	8	1	1
Vaccination site urticaria	2	4	1	2	1	2
Vaccination site warmth	2	2	2	2		
Vascular occlusion	1	1			1	1
Vasculitis	2	2	2	2		
Ventricular extrasystoles	1	1	1	1		
Ventricular f brillation	2	2			2	2
Ventricular hypokinesia		1				1
Ventricular tachycardia	1	1			1	1
Vertigo	2	8	2	3		5
Vision blurred	1	1			1	1
Visual impairment	5	7	1	1	4	6
Vocal cord disorder		1				1
Vomiting	25	49	5	12	20	37
Wheezing	20	41	4	4	16	37
White blood cell count increased		1		1		
White blood cells urine positive	1	1			1	1
Yawning		2				2
	1,840	3,611	665	1242	1175	2369

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Country Where Event Occurred

JORDAN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Acne	1	1	1	1		
Asthenia	1	1	1	1		
Condition aggravated		1				1
COVID-19	1	2			1	2
COVID-19 pneumonia		1				1
Drug ineffective	1	1			1	1
Feeling cold	1	1	1	1		
Hypoxia		1				1
Increased bronchial secretion		1				1
Increased viscosity of upper respiratory secretion		1				1
Lung disorder		1				1
Pruritus	1	1	1	1		
Respiratory failure		1				1
Sputum retention		1				1
Swelling face		1		1		
Tachypnoea		1				1
Vaccination failure		1				1
	6	19	4	5	2	14

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Country Where Event Occurred
KOREA, REPUBLIC OF (SOUTH KOREA)

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Brain oedema	1	1	1	1
Cerebral infarction	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

LATVIA

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		2				2
Anaphylactic reaction		1				1
Anxiety		1				1
Arthralgia	1	5	1	4		1
Asthenia		3		3		
Asthma		2		1		1
Body temperature increased		2		2		
Bradycardia		1				1
Chest pain		1		1		
Chills		1		1		
Condition aggravated		1		1		
Cough		1		1		
COVID-19	1	1			1	1
Death	1	1			1	1
Decreased appetite		1		1		
Depressed mood		1		1		
Diplopia		1				1
Disturbance in attention		3		3		
Dizziness		5		2		3
Drug ineffective	1	1			1	1
Dysphonia		1		1		
Dyspnoea		1		1		
Ear discomfort		1				1
Erythema		1		1		
Extrasystoles		1				1
Eye pain		1		1		
Facial paresis		1				1
Fatigue	1	8		5	1	3
Generalised tonic-clonic seizure		1				1
Headache	1	6	1	4		2
Heart rate increased		1				1
Hot flush		2		1		1
Hyperaesthesia		2				2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertension		1				1
Initial insomnia		1		1		
Insomnia	1	2			1	2
Lacrimation increased		1				1
Loss of proprioception		1				1
Muscle spasms		1				1
Muscular weakness		1				1
Myalgia	1	2	1	2		
Nausea		2		2		
Neuralgia		1				1
Off label use		1		1		
Pain in extremity		2		1		1
Palpitations		1				1
Paraesthesia		3				3
Photophobia		1		1		
Product use issue		1		1		
Pulse volume decreased		1		1		
Pyrexia	1	7	1	4		3
Respiratory distress		1				1
Skin burning sensation		1				1
Somatic dysfunction		1				1
Somnolence		2				2
Tachycardia		4		1		3
Thirst		1				1
Throat irritation		1		1		
Thrombosis	1	1			1	1
Urticaria	1	1			1	1
Urticaria papular	1	1			1	1
Vaccination site erythema		4		3		1
Vaccination site mass		1				1
Vaccination site oedema		1		1		
Vaccination site pain	1	9	1	8		1
Vaccination site rash		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site warmth		1		1		
	13	123	5	64	8	59

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Country Where Event Occurred

LEBANON

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Back pain		1		1		
Confusional state	1	1	1	1		
COVID-19	1	1			1	1
Death		1				1
Dysarthria	1	1	1	1		
Embolism venous	1	1			1	1
Eyelid ptosis	1	1			1	1
Fatigue	1	1			1	1
Headache	1	2		1	1	1
Influenza		1		1		
Limb discomfort		1		1		
Muscle twitching		1		1		
Muscular weakness	1	1	1	1		
Myalgia		1		1		
Oropharyngeal pain		1		1		
Pain in extremity		1		1		
Paraesthesia		2		2		
Paralysis	1	1			1	1
Thrombocytopenia	1	1			1	1
Vaccination failure	1	1			1	1
Vomiting	1	1			1	1
	12	23	3	13	9	10

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Country Where Event Occurred

LITHUANIA

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Anaphylactic reaction		1				1
Arthralgia		2		2		
Asthenia	1	2		1	1	1
Blood pressure increased	1	1			1	1
Body temperature increased	1	1			1	1
Cardiogenic shock		1				1
Chest pain		1		1		
Condition aggravated	1	2	1	1		1
Cough		1		1		
COVID-19 pneumonia		1				1
Death		2				2
Depressed level of consciousness	1	1			1	1
Dizziness	1	1	1	1		
Dry eye		1		1		
Dry mouth	1	1			1	1
Dysgeusia		1		1		
Dysphagia	1	1			1	1
Dyspnoea	1	2	1	1		1
Ear pain		1		1		
Eye pain		1		1		
Feeling abnormal	1	1			1	1
Feeling hot	1	1			1	1
Feeling of body temperature change		1		1		
Gait disturbance	1	1			1	1
Groin pain	1	1	1	1		
Headache		1		1		
Heart rate increased	1	2		1	1	1
Hyperhidrosis	1	1			1	1
Hypoaesthesia	1	1			1	1
Induration	1	1			1	1
Irritability		1				1
Joint swelling	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lacrimation increased		1		1		
Loss of consciousness	1	2			1	2
Lymphadenopathy		1		1		
Malaise		2				2
Mucosal disorder		1		1		
Myalgia		1		1		
Nausea	1	1	1	1		
Off label use		1		1		
Pain		1				1
Pain in extremity	3	3	2	2	1	1
Paraesthesia	1	1			1	1
Peripheral coldness	1	1			1	1
Peripheral swelling	1	1			1	1
Peritonsillar abscess		1				1
Phlebitis	1	1			1	1
Product use issue		1		1		
Pulse abnormal	1	1			1	1
Pyrexia		1		1		
Skin discolouration	1	1			1	1
Slow response to stimuli		1		1		
Speech disorder	1	1			1	1
Swelling	1	1			1	1
Swelling face	1	1			1	1
Throat tightness	1	1			1	1
Thrombophlebitis	1	1			1	1
Thrombosis	1	1			1	1
Tongue dry	1	1			1	1
Tongue movement disturbance	1	1			1	1
Tonsillar hypertrophy		1		1		
Tremor	1	1			1	1
Vaccination failure		1				1
Vaccination site pain	1	2		1	1	1
Vomiting	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	41	77	8	30	33	47

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Country Where Event Occurred

LUXEMBOURG

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension		1				1
Abdominal pain upper		1				1
Acute coronary syndrome		1				1
Acute kidney injury		1				1
Altered state of consciousness		1				1
Apathy	1	1			1	1
Arthralgia	3	4	1	2	2	2
Asthenia	1	1			1	1
Asthmatic crisis		1				1
Atrial fibrillation		1				1
Cardiac arrest	1	1			1	1
Carotid arteriosclerosis	1	1	1	1		
Cervical radiculopathy	1	1			1	1
Chest discomfort	2	4			2	4
Chest pain	1	2			1	2
Chills	1	4	1	2		2
Claudication of jaw muscles	1	1			1	1
Confusional state	1	1			1	1
COVID-19 pneumonia		1				1
C-reactive protein increased	2	2	1	1	1	1
Decreased appetite	1	2			1	2
Deep vein thrombosis	1	1			1	1
Diarrhoea		1		1		
Dizziness		1				1
Dry mouth		1				1
Dry skin		1				1
Dysgeusia		1				1
Dyspnoea	3	6			3	6
Dyspnoea exertional	2	2			2	2
Facial pain	1	1	1	1		
Facial paralysis	1	1			1	1
Fatigue	4	9	2	3	2	6
Feeling cold	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gait disturbance	1	1			1	1
Generalised tonic-clonic seizure	1	1			1	1
Haematoma		1		1		
Headache	4	7	2	3	2	4
Herpes zoster		1		1		
Hypernatraemia		1				1
Hypersensitivity		1				1
Hypertension	1	4		1	1	3
Hypertensive crisis	1	1			1	1
Hyperthermia		2		1		1
Hypoaesthesia		1				1
Hypotension	1	1	1	1		
Hypotonia	1	1	1	1		
Hypoxia		1				1
Inflammation	1	1			1	1
Limb discomfort	1	1			1	1
Lip pain	1	1	1	1		
Lung disorder		1				1
Lymphadenopathy	3	3			3	3
Lymph node pain	1	1			1	1
Lymphoedema	1	1			1	1
Malaise		4		1		3
Muscular weakness	1	1			1	1
Musculoskeletal stiffness		1				1
Myalgia	2	4			2	4
Nausea		2				2
Neck pain	3	3			3	3
Oral herpes		1		1		
Oxygen saturation decreased		1				1
Pain in extremity		2		1		1
Paraesthesia		1				1
Paresis		1				1
Peripheral coldness		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral swelling		1		1		
Phlebitis	1	1			1	1
Pneumonia	1	1			1	1
Pneumonia aspiration	1	1			1	1
Presyncope	1	1	1	1		
Pruritus		1				1
Psoriasis	1	1	1	1		
Pulmonary embolism	1	1			1	1
Pulmonary pain		1				1
Pyrexia	2	3	1	1	1	2
Rash		1				1
Sepsis		1				1
Skin haemorrhage		1				1
Somnolence		1				1
Speech disorder	1	1			1	1
Swelling face		1		1		
Tetany		1		1		
Therapeutic response unexpected		1		1		
Tremor		2		1		1
Urinary tract infection		1		1		
Uveitis	1	1			1	1
Vaccination complication	1	2			1	2
Vaccination site pain	1	2	1	1		1
Vlth nerve paralysis		1				1
Wheezing		2				2
	66	145	16	34	50	111

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Country Where Event Occurred

MALAYSIA

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1			1	1
Abdominal pain upper	1	1			1	1
Abdominal sepsis	1	1			1	1
Blood uric acid increased	1	1			1	1
Cardiac disorder	1	1			1	1
Death	1	1			1	1
Gastrointestinal necrosis	1	1			1	1
Hepatic function abnormal	1	1			1	1
Intestinal ischaemia	1	1			1	1
Labile blood pressure	1	1			1	1
Loss of consciousness	1	1			1	1
Malaise	1	1			1	1
Nausea	1	1			1	1
Perforation	1	1			1	1
Rash	1	1	1	1		
Renal impairment	1	1			1	1
Septic shock	1	1			1	1
Speech disorder	1	1			1	1
Thrombosis	1	1			1	1
Vomiting	1	1			1	1
	20	20	1	1	19	19

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Country Where Event Occurred

MALTA

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Activated partial thromboplastin time prolonged		2		2		
Activated partial thromboplastin time ratio increased		1		1		
Acute kidney injury	2	4			2	4
Alanine aminotransferase increased		1		1		
Altered state of consciousness	2	3			2	3
Anaphylactic reaction		5				5
Angioedema		1				1
Arrhythmia	1	1			1	1
Arthralgia		2		2		
Asthenia		2		1		1
Asthma		2				2
Atrial fibrillation	1	2			1	2
Basophil count increased		1		1		
Bell's palsy		1				1
Blood alkaline phosphatase increased		2		2		
Blood calcium decreased		1		1		
Blood creatinine increased		1		1		
Blood glucose increased		1		1		
Blood magnesium decreased		1		1		
Blood osmolality increased		1		1		
Blood phosphorus decreased		1		1		
Blood urea increased		2		2		
Bronchospasm		2				2
Cardiac arrest		2				2
Cardiac failure	1	1			1	1
Cardiac failure congestive	2	2			2	2
Cerebellar atrophy		1				1
Cerebral atrophy		2				2
Cerebral thrombosis	1	1			1	1
Cerebrovascular accident	1	2			1	2
Chest discomfort		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest pain		1		1		
Chills	1	2	1	2		
Cough		1				1
COVID-19	2	8			2	8
COVID-19 pneumonia		2				2
C-reactive protein increased		3		3		
Deep vein thrombosis	1	1			1	1
Dehydration		1		1		
Diarrhoea		2		1		1
Discomfort	1	1	1	1		
Drug ineffective	1	4			1	4
Dysgeusia		1		1		
Dysphagia		1				1
Dysphonia		2				2
Dyspnoea	1	6			1	6
Eosinophil count decreased		1		1		
Erythema		4		2		2
Eye swelling		1				1
Facial paralysis		1				1
Fatigue		3		3		
Flushing		1				1
Fungal skin infection		1		1		
Goitre		1		1		
Haematemesis		1				1
Haematocrit decreased		3		3		
Haemoglobin decreased		3		3		
Hemiplegia	1	1			1	1
Hypersensitivity		1				1
Hypertension		1				1
Hypoaesthesia	1	3	1	3		
Hypothermia		1				1
Hypoxia	1	4			1	4
Immature granulocyte count increased		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection		1		1		
International normalised ratio increased		1		1		
Lethargy	3	4	1	2	2	2
Limb discomfort	1	1	1	1		
Lip swelling		1				1
Loss of consciousness		1				1
Lymphadenopathy	1	1	1	1		
Lymphocyte count decreased		3		3		
Malaise		2		2		
Mean cell haemoglobin concentration decreased		1		1		
Mean cell haemoglobin concentration increased		1		1		
Mean cell volume increased		1		1		
Mean platelet volume decreased		1		1		
Monocyte count decreased		1		1		
Monocyte count increased		1		1		
Musculoskeletal stiffness		1		1		
Myalgia		1		1		
Nausea		3		1		2
Neck pain		2		2		
Neoplasm progression		1				1
Neutrophil count increased		3		3		
Normochromic normocytic anaemia		1		1		
Nucleated red cells		1		1		
Off label use		2		2		
Overdose		1		1		
Oxygen saturation decreased		1		1		
Pain		1		1		
Pain in extremity		1		1		
Palpitations		1				1
Panic reaction		1		1		
Paraesthesia		3		3		
Paraesthesia oral		2		2		
Peripheral coldness		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Platelet count decreased		1		1		
Platelet count increased		2		2		
Poor peripheral circulation		1		1		
Product use issue		1		1		
Prothrombin time prolonged		1		1		
Pruritus		2				2
Pulmonary artery thrombosis	1	1			1	1
Pulmonary embolism		1				1
Pyrexia	1	3	1	3		
Rash	1	3	1	1		2
Rash pruritic		2				2
Red blood cell count decreased		3		3		
Red cell distribution width increased		2		2		
Renal failure	1	1			1	1
Respiratory arrest		2				2
Respiratory depression		1				1
Respiratory distress		2				2
Respiratory failure	1	2			1	2
Reticulocyte count increased		1		1		
Sepsis	1	3			1	3
Septic shock		1				1
Somnolence		1		1		
Speech disorder	1	1	1	1		
Swelling		1				1
Swelling face		2		1		1
Swollen tongue		1				1
Syncope		1				1
Tachycardia		2				2
Tachypnoea	1	4			1	4
Throat tightness		1				1
Thrombocytopenia	2	3			2	3
Urinary retention	1	1			1	1
Urinary tract infection	1	2		1	1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urosepsis		1				1
Urticaria		1				1
Use of accessory respiratory muscles		1				1
Vaccination failure	1	4			1	4
Vaccination site discomfort		1		1		
Vaccination site erythema		1		1		
Vaccination site induration		1		1		
Vaccination site pain	1	4	1	4		
Vaccination site pruritus		1		1		
Vaccination site rash		1		1		
Vaccination site urticaria		1				1
Vision blurred		1				1
Vomiting		1				1
Wheezing		2				2
White blood cell count increased		1		1		
	40	247	10	117	30	130

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Country Where Event Occurred

MEXICO

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal distension	1	2	1	2		
Abdominal pain	3	10	3	9		1
Abdominal pain lower		1		1		
Abdominal pain upper		1		1		
Abnormal sensation in eye	1	1	1	1		
Abscess		1		1		
Acute myocardial infarction		1				1
Ageusia		1		1		
Analgesic therapy	1	1	1	1		
Anaphylactic reaction		2				2
Anaphylactic shock		4				4
Angioedema		3				3
Anxiety		5		3		2
Aphasia		1		1		
Arrhythmia		1				1
Arthralgia	17	32	12	26	5	6
Asthenia	24	51	17	42	7	9
Asthma		1		1		
Asthmatic crisis		1				1
Auricular swelling	1	1	1	1		
Back pain	2	3		1	2	2
Balance disorder		1		1		
Bell's palsy		1				1
Blister	1	1	1	1		
Blood glucose increased	1	2		1	1	1
Blood pressure abnormal	2	2	2	2		
Blood pressure decreased		1				1
Blood pressure increased	6	8	3	3	3	5
Blood pressure systolic increased	1	1			1	1
Body temperature increased	6	11	6	11		
Bradycardia	1	1			1	1
Breast pain	1	1			1	1
Bronchospasm	2	11	2	7		4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cellulitis		2				2
Cerebral haematoma		1				1
Cerebrovascular accident		1				1
Cheilitis		1		1		
Chest pain	3	6	3	5		1
Chills	15	31	14	28	1	3
Colitis		1		1		
Condition aggravated		3		1		2
Confusional state	1	1	1	1		
Conjunctivitis	1	1	1	1		
Contusion		1		1		
Cough	14	20	11	16	3	4
COVID-19	2	4			2	4
COVID-19 pneumonia		1				1
Crying	2	2	1	1	1	1
Cyanosis		1		1		
Death		1				1
Decreased appetite	3	8	3	7		1
Dehydration		2		2		
Demyelinating polyneuropathy		1				1
Depressed level of consciousness		1				1
Diarrhoea	7	15	6	14	1	1
Diplopia		1		1		
Discomfort	2	3	2	3		
Disease recurrence		1				1
Disseminated Bacillus Calmette-Guerin infection		1				1
Dizziness	18	41	12	32	6	9
Drug ineffective		2				2
Dry mouth	2	2	2	2		
Dysaesthesia		1		1		
Dysarthria		1		1		
Dysgeusia	1	1	1	1		
Dyslalia	1	2	1	1		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspepsia		1		1		
Dysphagia	2	3	1	2	1	1
Dysphonia	2	3	1	2	1	1
Dyspnoea	9	29	6	20	3	9
Dyspnoea exertional	1	1			1	1
Dysstasia		1		1		
Ear discomfort		1		1		
Ear pain		1				1
Ecchymosis	1	1	1	1		
Embolism		1				1
Encephalitis post immunisation		1				1
Epistaxis		1		1		
Erythema	8	15	8	15		
Eye discharge		1		1		
Eye injury	1	2	1	2		
Eye irritation	1	3	1	3		
Eyelid oedema	1	1	1	1		
Eyelid ptosis		1		1		
Eye pruritus	1	2	1	2		
Eye swelling		1		1		
Face oedema		1		1		
Facial paralysis		1				1
Fall	1	2		1	1	1
Fatigue	24	52	16	41	8	11
Feeling abnormal		1		1		
Feeling cold		2		1		1
Feeling hot	1	1	1	1		
Flank pain		1		1		
Flushing		2		2		
Gastroenteritis		1		1		
Gastrointestinal hypermotility		1		1		
Gastrointestinal motility disorder		1		1		
Gingival hypertrophy	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Guillain-Barre syndrome		1				1
Haematochezia		1				1
Haemorrhage		1				1
Haemorrhagic disorder		1				1
Hallucination	1	1			1	1
Hallucination, visual		1				1
Headache	44	75	30	58	14	17
Head discomfort	1	1			1	1
Heart rate abnormal	1	1	1	1		
Heart rate increased	1	1			1	1
Herpes zoster	1	1	1	1		
Hyperglycaemia		3		2		1
Hyperhidrosis	4	7	3	6	1	1
Hypersensitivity		3		2		1
Hypersomnia		1		1		
Hypertension	6	10	3	5	3	5
Hypertensive crisis	1	2			1	2
Hypertensive emergency		1				1
Hyperthermia	1	3	1	3		
Hypoaesthesia	1	4	1	2		2
Hypoaesthesia oral		1				1
Hypoglycaemia	2	2	1	1	1	1
Hypotension	3	5		2	3	3
Hypoxia	1	1			1	1
Inappropriate schedule of product administration		1		1		
Incorrect route of product administration	1	1	1	1		
Induration	2	7	2	7		
Inflammation	4	11	4	11		
Influenza	1	1	1	1		
Insomnia		1				1
Intussusception		1				1
Irritability	6	9	6	8		1
Jaw disorder	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint swelling		1		1		
Lacrimation increased	1	1	1	1		
Laryngeal oedema		1				1
Leukopenia		1				1
Local reaction		2		2		
Loss of consciousness		3				3
Lymphadenopathy	2	6	2	6		
Malaise	3	8	3	8		
Masticatory pain		1		1		
Maternal exposure during pregnancy		3		3		
Measles		1				1
Mobility decreased	1	3	1	3		
Movement disorder	1	1	1	1		
Muscle atrophy		1		1		
Muscle spasms	1	3	1	2		1
Muscle tightness		1		1		
Muscular weakness	1	2	1	2		
Myalgia	18	36	15	32	3	4
Myalgia intercostal		1		1		
Myelitis transverse		1				1
Myocardial infarction		2				2
Nasal congestion		2		2		
Nausea	19	39	17	33	2	6
Neck pain		2		2		
Nervousness		1		1		
Neuritis		1		1		
Neuropathy peripheral		2				2
Neutrophil count increased		2		2		
Nodule	2	8	2	8		
Ocular hyperaemia		2		2		
Odynophagia	2	3	1	2	1	1
Oedema	5	15	3	12	2	3
Oedema peripheral	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Off label use	3	4	3	4		
Oropharyngeal discomfort		2		2		
Oropharyngeal pain	10	17	7	14	3	3
Oxygen saturation decreased	3	4	1	1	2	3
Pain	26	41	22	37	4	4
Pain in extremity	5	9	4	8	1	1
Pallor		1		1		
Palpitations		1		1		
Panic attack	1	1	1	1		
Paraesthesia	5	10	4	8	1	2
Paraesthesia oral		2		1		1
Paralysis		1				1
Parotid gland enlargement		1		1		
Parotitis		1		1		
Periorbital oedema		1		1		
Peripheral swelling	1	2	1	2		
Peripheral vascular disorder		1				1
Petit mal epilepsy		1				1
Pharyngeal erythema	2	3	2	3		
Pharyngeal paraesthesia		1				1
Pharyngeal swelling	2	2			2	2
Photophobia		1		1		
Photopsia	1	1	1	1		
Platelet count increased		2		2		
Productive cough	1	1	1	1		
Product use issue	3	3	3	3		
Prurigo		1		1		
Pruritus	10	21	7	17	3	4
Pulmonary embolism	1	1			1	1
Pulmonary pain	1	1	1	1		
Pyrexia	15	29	9	23	6	6
Rales	1	1	1	1		
Rash	5	16	2	11	3	5

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash macular		1		1		
Respiratory distress	8	29			8	29
Respiratory failure		2				2
Rhinalgia		1		1		
Rhinorrhoea	9	17	6	14	3	3
Seizure	2	5			2	5
Sensitive skin	25	36	23	34	2	2
Skin burning sensation		1		1		
Skin discolouration		1		1		
Skin mass	1	1	1	1		
Sneezing		1		1		
Somnolence		2		2		
Speech disorder		1		1		
Spinal pain	1	1	1	1		
Swelling face	1	1	1	1		
Swollen tongue		1		1		
Syncope		1				1
Tachycardia	8	24	6	19	2	5
Tachypnoea		2				2
Therapeutic response unexpected	3	3	3	3		
Throat irritation	2	4	1	3	1	1
Throat tightness	2	2			2	2
Thrombosis		2				2
Tinnitus	1	2	1	2		
Tongue oedema		1				1
Transaminases increased		1				1
Tremor		1		1		
Urticaria	1	2	1	2		
Vaccination site cellulitis		1		1		
Vaccination site dermatitis	1	1			1	1
Vaccination site discomfort		2		2		
Vaccination site erythema	1	4	1	4		
Vaccination site haematoma		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site haemorrhage		1		1		
Vaccination site hyperaesthesia		1		1		
Vaccination site hypersensitivity	1	3		2	1	1
Vaccination site induration		3		3		
Vaccination site inflammation	1	2	1	2		
Vaccination site nodule		2		2		
Vaccination site oedema	1	3	1	3		
Vaccination site pain	12	24	8	20	4	4
Vaccination site pruritus		1		1		
Vaccination site swelling		1		1		
Vaccination site warmth		1		1		
Vascular test abnormal		1		1		
Vision blurred	1	2	1	1		1
Vomiting	3	15	3	11		4
Wheezing		3		1		2
Wrong technique in product usage process		1		1		
	518	1,184	381	891	137	293

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Country Where Event Occurred

NETHERLANDS

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	1	6			1	5		1
Abdominal distension		1				1		
Abdominal pain		3				2		1
Abdominal pain upper	3	4			3	4		
Abnormal behaviour		1						1
Abnormal faeces		1						1
Acute abdomen		1						1
Acute cardiac event		1						1
Acute coronary syndrome		1						1
Acute kidney injury	1	1					1	1
Acute myocardial infarction	2	7					2	7
Acute respiratory failure		1						1
Ageusia		2				2		
Alanine aminotransferase increased	2	2			1	1	1	1
Altered state of consciousness		1						1
Amnesia		1						1
Amylase increased		1				1		
Anaphylactic reaction		4						4
Anaphylactic shock		2						2
Aneurysm		1						1
Angina pectoris		2						2
Angina unstable		1						1
Angioedema	1	5					1	5
Ankylosing spondylitis	1	1					1	1
Anosmia		1				1		
Anxiety	1	2			1	2		
Aortic aneurysm	1	1					1	1
Aortic arteriosclerosis	1	1			1	1		
Aortic dissection		1						1
Aortic valve stenosis		3						3
Apallic syndrome		2						2
Apathy		1						1
Aphasia	1	3					1	3

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Aphonia	1	2
Arrhythmia	2	9
Arterial thrombosis		1
Arthralgia	9	39
Aspartate aminotransferase increased	2	3
Aspiration		1
Asthenia	1	7
Asthma	2	5
Atrial fibrillation	3	10
Atrial flutter		1
Atrioventricular block complete		1
Axillary pain	1	1
Azotaemia		2
Back pain	2	5
Balance disorder		2
Basilar artery thrombosis		1
Basophil count decreased		1
Bedridden		1
Bell's palsy	1	2
Blepharospasm	1	1
Blindness	1	4
Blood alcohol decreased		1
Blood alkaline phosphatase increased		1
Blood bicarbonate decreased		1
Blood bilirubin increased		2
Blood calcium decreased		1
Blood cholesterol increased	2	3
Blood creatinine decreased	1	1
Blood creatinine increased	2	7
Blood glucose decreased		1
Blood glucose fluctuation	1	4
Blood glucose increased	4	11
Blood lactate dehydrogenase increased	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		1
				2	9
					1
		9	34		5
			1	2	2
					1
		1	4		3
		2	2		3
				3	10
					1
					1
		1	1		
					2
		1	4	1	1
			2		
					1
			1		
			1		
				1	2
		1	1		
				1	4
			1		
			1		
			2		
			1		
		2	3		
		1	1		
		1	6	1	1
			1		
		1	4		
		3	9	1	2
			1	1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Blood lactic acid increased	1	1					1	1
Blood loss anaemia		1						1
Blood potassium decreased		1				1		
Blood pressure decreased		3						3
Blood pressure increased	1	6				2	1	4
Blood pressure systolic increased	1	1			1	1		
Blood sodium decreased		1				1		
Blood sodium increased	1	1					1	1
Blood urea increased	3	7			2	6	1	1
Blood uric acid increased		1				1		
Body temperature decreased		2						2
Body temperature increased		5				4		1
Bradycardia		1						1
Bradykinesia		1				1		
Bradyphrenia		3				2		1
Brain natriuretic peptide increased		1				1		
Bronchiectasis	1	1					1	1
Bronchitis		1						1
Burning sensation	1	2			1	2		
Cachexia		3						3
Calcium ionised decreased	1	1			1	1		
Candida infection		1						1
Cardiac arrest	1	13					1	13
Cardiac asthma		4						4
Cardiac death	2	5					2	5
Cardiac disorder		3						3
Cardiac failure	3	26					3	26
Cardiac failure acute	1	3					1	3
Cardiac failure congestive		1						1
Cardiac flutter	1	1					1	1
Cardiogenic shock		3						3
Cardiovascular disorder		2						2
Carotid artery thrombosis	1	2					1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebral amyloid angiopathy		1
Cerebral atrophy		1
Cerebral haemorrhage	2	8
Cerebral infarction	15	21
Cerebral ischaemia	1	3
Cerebral thrombosis		1
Cerebrovascular accident	6	21
Cerebrovascular disorder		2
Chest discomfort	1	3
Chest injury		1
Chest pain	3	12
Chills	8	62
Choking		1
Choking sensation		1
Chorea		1
Chronic obstructive pulmonary disease		4
Circulatory collapse	1	4
Coagulopathy		1
Cognitive disorder		1
Cold sweat		2
Coma hepatic		1
Condition aggravated	5	15
Confusional state	2	11
Consciousness fluctuating		1
Constipation		1
Coordination abnormal		2
Coronary artery disease	1	2
Cough	1	6
COVID-19		11
COVID-19 pneumonia		1
C-reactive protein increased	1	6
Cutaneous vasculitis	1	3
Cyanosis		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				2	8
				15	21
				1	3
					1
				6	21
			1		1
			1	1	2
					1
		2	6	1	6
		7	48	1	14
					1
					1
					1
			1		3
				1	4
			1		
					1
					2
					1
		1	4	4	11
			4	2	7
					1
					1
			1		1
				1	2
		1	5		1
			1		10
					1
			4	1	2
				1	3
			1		2

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Cystitis	1	6
Cystitis noninfective		1
Deafness unilateral		1
Death	3	25
Decreased appetite		11
Deep vein thrombosis	5	16
Dehydration	1	6
Delirium	2	15
Delusion		1
Dementia		3
Dementia Alzheimer's type		1
Depressed level of consciousness		8
Depressed mood		2
Diabetes mellitus inadequate control		1
Diarrhoea	3	14
Diarrhoea haemorrhagic	1	1
Diplegia	1	1
Diplopia	1	4
Discomfort	1	2
Disease recurrence	1	6
Disorientation		1
Dissociation		1
Disturbance in attention		2
Dizziness	5	21
Drug ineffective		3
Dry eye		1
Dry mouth	1	4
Dysarthria		3
Dysphagia	4	16
Dysphonia		1
Dyspnoea	10	53
Dyspnoea at rest	1	1
Dyspnoea exertional		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4		2
					1
					1
				3	25
			8		3
				5	16
			2	1	4
				2	15
			1		
					3
					1
					8
			2		
					1
		3	12		2
				1	1
				1	1
			3	1	1
			1	1	1
				1	6
					1
			1		
			2		
		4	18	1	3
					3
			1		
			3	1	1
			2		1
		1	5	3	11
					1
1	1	6	19	4	34
				1	1
					2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Dysstasia	1	3				1	1	2
Ear pain		1				1		
Ecchymosis		2						2
Electrolyte imbalance		1						1
Embolism		1						1
Encephalitis enteroviral		1						1
Endocarditis		1						1
Endocrine ophthalmopathy		1						1
Eosinophil count decreased		1				1		
Epilepsy	1	12					1	12
Epistaxis	1	6	1	1	1	2		4
Erythema	1	3			1	3		
Extensive swelling of vaccinated limb		12				12		
Eye disorder		1				1		
Eyelid ptosis		1				1		
Eye symptom		1				1		
Facial bones fracture		1						1
Facial paralysis	2	7					2	7
Fall	3	17				5	3	12
Fatigue	18	127			17	94	1	33
Febrile convulsion		1				1		
Feeding disorder	1	4				2	1	2
Feeling abnormal	1	4			1	4		
Feeling cold		2				2		
Feeling hot		4				3		1
Feeling jittery		1				1		
Fibrin D dimer increased	1	4				2	1	2
Flank pain	1	1					1	1
Fluid intake reduced		3				1		2
Fluid retention	1	2			1	2		
Flushing		2				2		
Fracture		1						1
Gait disturbance		2				1		1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Gait inability	1	2
Gamma-glutamyltransferase increased	1	3
Gastrointestinal haemorrhage		3
Gastrointestinal obstruction		1
Gaze palsy		1
Generalised tonic-clonic seizure		2
General physical health deterioration	1	13
Glomerular filtration rate decreased		3
Glomerulonephritis minimal lesion		1
Glossodynia		1
Glucose tolerance impaired		1
Haematemesis		1
Haematocrit decreased		3
Haematocrit increased	1	1
Haematoma		2
Haemodynamic instability	2	2
Haemoglobin decreased	2	7
Haemophagocytic lymphohistiocytosis		1
Haemophilia		1
Haemorrhoids		1
Hallucination		1
Hand deformity		1
Hand fracture		1
Headache	12	67
Head discomfort	1	2
Heart rate decreased		1
Heart rate increased	1	6
Hemianaesthesia		1
Hemiparesis	2	8
Hemiplegia		1
Henoch-Schonlein purpura	1	1
Hepatitis	1	1
Hepatitis C		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
		1	3		
					3
					1
					1
					2
		1	4		9
			3		
					1
			1		
			1		
					1
			3		
				1	1
			1		1
		1	1	1	1
		1	4	1	3
					1
					1
			1		
					1
					1
					1
		12	63		4
			1	1	1
			1		
		1	2		4
					1
				2	8
					1
				1	1
				1	1
					1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hernia pain		1
Herpes zoster	2	3
Herpes zoster reactivation	1	2
Hiatus hernia	1	1
High density lipoprotein increased	1	1
Hip fracture		2
Human epidermal growth factor receptor decreased		1
Hydrocephalus		1
Hyperaesthesia teeth		1
Hyperglycaemia		1
Hyperhidrosis		7
Hyperkalaemia	1	1
Hypernatraemia		2
Hyperpyrexia		5
Hypersensitivity	4	6
Hypersomnia		2
Hypertension	2	11
Hypertensive urgency		1
Hypertriglyceridaemia		1
Hyperventilation		1
Hypoaesthesia	1	1
Hypoglycaemia		3
Hypokalaemia		1
Hypokinesia	1	2
Hyponatraemia	1	1
Hypophagia	1	6
Hypopnoea		1
Hyporesponsive to stimuli		1
Hypotension	2	10
Hypothermia		1
Hypoxia	2	10
Illness		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		2	3		
				1	2
		1	1		
		1	1		
					2
					1
					1
			1		
					1
			5		2
				1	1
					2
					5
		1	3	3	3
			2		
		1	4	1	7
					1
					1
		1	1		
			1		2
					1
		1	2		
		1	1		
			1	1	5
			1		
			1		
			2	2	8
					1
				2	10
					1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Immune thrombocytopenia		1						1
Inappropriate schedule of product administration	2	2			2	2		
Incontinence		2						2
Increased tendency to bruise		1				1		
Infarction		1						1
Infection		4						4
Inflammation		1						1
Inflammatory marker increased	1	2			1	1		1
Influenza	1	1			1	1		
Influenza like illness		2				1		1
Injection site pruritus		1				1		
Insomnia		1				1		
International normalised ratio increased	1	2			1	1		1
Interstitial lung disease		1						1
Intestinal haemorrhage		1						1
Intestinal ischaemia		1						1
Intestinal obstruction		1						1
Ischaemic cerebral infarction	1	11					1	11
Ischaemic stroke		1						1
IVth nerve paralysis		1				1		
Jaundice		1						1
Kidney infection		1						1
Lacrimation increased		1				1		
Lacunar infarction		1						1
Left ventricular dysfunction		1						1
Left ventricular failure		1						1
Left ventricular hypertrophy		1						1
Leukaemia	1	1					1	1
Limb discomfort	2	3			2	3		
Lip swelling	2	2					2	2
Listless	1	4			1	4		
Livedo reticularis		1						1
Loss of consciousness	1	8					1	8

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Loss of control of legs	1	1					1	1
Loss of personal independence in daily activities	1	4			1	3		1
Lung disorder		3				1		2
Lymphadenopathy		3				3		
Lymphangitis	1	1					1	1
Lymph node pain		1				1		
Lymphocyte count decreased		2				1		1
Macroglossia	1	1					1	1
Malaise	17	136			12	78	5	58
Melaena		1						1
Memory impairment		1				1		
Meningitis		1						1
Menstruation irregular	1	1			1	1		
Mental impairment		3						3
Mesenteric artery thrombosis		1						1
Metastases to lung	1	1					1	1
Migraine		1				1		
Mobility decreased	1	4				2	1	2
Monocyte count increased		1				1		
Monoparesis	2	2					2	2
Monoplegia		1						1
Movement disorder		1						1
Multiple organ dysfunction syndrome		1						1
Multiple sclerosis		1						1
Muscle contractions involuntary		1				1		
Muscle spasms	3	6			1	3	2	3
Muscle strain	1	1			1	1		
Muscle twitching		1						1
Muscular weakness	4	9			1	5	3	4
Musculoskeletal chest pain	1	2			1	1		1
Musculoskeletal discomfort		1				1		
Musculoskeletal disorder		1						1
Musculoskeletal stiffness		2				2		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myalgia	18	86
Myelitis transverse	1	1
Myelodysplastic syndrome	1	2
Myelopathy		1
Myocardial calcification	1	1
Myocardial infarction	4	16
Nasal congestion	2	4
Nasopharyngitis	1	4
Nausea	9	68
Neck pain		1
Nephrotic syndrome		1
Neuralgia	1	1
Neuritis		1
Neurologic neglect syndrome	1	2
Neuropathy peripheral	1	5
Neutrophil count decreased		1
Neutrophil count increased	1	3
Nocturnal dyspnoea	1	1
Normocytic anaemia	1	1
Nystagmus		1
Ocular discomfort		1
Ocular vascular disorder	1	1
Oedema		1
Oedema peripheral		4
Off label use	1	1
Oliguria		1
Optic neuritis		1
Oral discomfort	1	1
Oral disorder		1
Oropharyngeal pain		3
Oxygen saturation abnormal		2
Oxygen saturation decreased	1	16
Pain	1	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		17	76	1	10
				1	1
				1	2
					1
		1	1		
				4	16
		2	3		1
		1	3		1
		7	49	2	19
			1		
					1
		1	1		
					1
				1	2
				1	5
					1
		1	3		
		1	1		
		1	1		
			1		
			1		
				1	1
			1		
			1		3
		1	1		
			1		
					1
		1	1		
			1		
			3		
					2
			1	1	15
		1	3		3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Pain in extremity	4	8			3	6	1	2
Pallor		5				3		2
Palpitations		4				4		
Pancytopenia		1						1
Paraesthesia	2	4				2	2	2
Paraesthesia oral		4				4		
Paralysis		2						2
Paresis		1				1		
Parkinson's disease		2						2
Pemphigoid		1						1
Peripheral coldness		3				2		1
Peripheral swelling		1				1		
Peroneal nerve palsy		2				1		1
Petechiae		2				2		
Pharyngeal oedema		1						1
Pharyngeal swelling		2				1		1
Platelet count decreased		5				4		1
Platelet count increased		1				1		
Pleural effusion	1	3			1	1		2
Pneumonia	6	24	1	1			6	24
Pneumonia aspiration		6						6
Pneumonia bacterial		1						1
PO2 increased	1	1					1	1
Polyneuropathy chronic	1	1			1	1		
Polyuria		1				1		
Presyncope		2						2
Product administered at inappropriate site	1	1			1	1		
Productive cough		2				1		1
Prolapse		1				1		
Prothrombin time prolonged		1				1		
Prothrombin time ratio increased		1				1		
Pruritus	2	2			1	1	1	1
Psoriasis	2	2			2	2		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Pulmonary embolism	10	25					10	25
Pulmonary haemorrhage		1						1
Pulmonary hypertension		1	1	1				1
Pulmonary infarction	1	1					1	1
Pulmonary oedema	1	2					1	2
Pulmonary sepsis	1	1					1	1
Pupillary disorder		1				1		
Purpura		1				1		
Pyelonephritis		1						1
Pyrexia	11	81	1	1	10	44	1	37
Quadriplegia		1						1
Rash	1	2			1	2		
Rash erythematous		1				1		
Rash pruritic		1				1		
Raynaud's phenomenon		1				1		
Rectal prolapse		1						1
Red blood cell count decreased		2				2		
Renal disorder		2				2		
Renal failure	2	4					2	4
Renal impairment	2	4					2	4
Respiration abnormal		1						1
Respiratory disorder		1						1
Respiratory failure	2	9					2	9
Respiratory rate increased	1	4				1	1	3
Respiratory tract infection		1						1
Restlessness		4				3		1
Retching		1						1
Retinal vein occlusion	1	1					1	1
Rheumatic disorder		1				1		
Rheumatoid arthritis	1	2					1	2
Rhinitis		1				1		
SARS-CoV-2 test positive		1						1
Secondary hypertension		1						1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Seizure		3						3
Sensation of foreign body		1				1		
Sepsis		1						1
Serum ferritin abnormal		1						1
Shock		2						2
Sinus bradycardia		1						1
Sinus tachycardia		2				2		
Skin burning sensation		1				1		
Skin discolouration	1	2			1	1		1
Sleep disorder		1				1		
Slow speech		1				1		
Small intestinal obstruction		1						1
Soft tissue infection		1						1
Somnolence		10				4		6
Speech disorder	2	5				1	2	4
Spinal cord compression		1						1
Spinal cord injury	1	1					1	1
Spinal epidural haemorrhage		1						1
Spinal meningeal cyst		1						1
Sputum discoloured	1	1			1	1		
Sputum increased		1				1		
Starvation	1	1					1	1
Status epilepticus		1						1
Stridor		2				1		1
Subdural haematoma		1						1
Sudden cardiac death	1	4					1	4
Sudden death	1	12					1	12
Sudden hearing loss		1						1
Supraventricular tachycardia	1	1			1	1		
Suspected COVID-19		2				1		1
Suspiciousness		1				1		
Swelling face	1	3				2	1	1
Swelling of eyelid		1				1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Swollen tongue	2	4				1	2	3
Syncope	2	14					2	14
Tachycardia		3				1		2
Tachypnoea		1				1		
Thirst decreased		1						1
Throat tightness		1				1		
Thrombocytopenia	6	7			2	2	4	5
Thrombophlebitis		2				1		1
Thrombophlebitis superficial		1						1
Thrombosis	1	10					1	10
Thrombosis mesenteric vessel		1						1
Thunderclap headache		1						1
Tinnitus	1	2				1	1	1
Tongue oedema		1						1
Torticollis		1				1		
Total cholesterol/HDL ratio decreased	1	1			1	1		
Transient aphasia		1						1
Transient global amnesia		1				1		
Transient ischaemic attack	3	14					3	14
Transverse sinus thrombosis	1	1					1	1
Tremor		3				2		1
Troponin I increased	1	1					1	1
Troponin increased		1						1
Type 1 diabetes mellitus		1						1
Unresponsive to stimuli		3						3
Upper limb fracture		1						1
Urinary incontinence	1	3				1	1	2
Urinary retention		2						2
Urinary tract infection		4				1		3
Urine output decreased		1				1		
Urosepsis		4						4
Urticaria	2	5				3	2	2
Vaccination site bruising		7				7		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site erythema		18				18		
Vaccination site haematoma		10				10		
Vaccination site induration		1				1		
Vaccination site inflammation	1	22			1	22		
Vaccination site pain	3	52			3	50		2
Vaccination site papule		1				1		
Vaccination site pruritus	1	8			1	8		
Vaccination site rash		1				1		
Vaccination site swelling		29				29		
Vaccination site warmth	1	23			1	23		
Vascular parkinsonism	1	1					1	1
Vasculitis		1				1		
Ventricular f brillation		1						1
Vertigo	1	3				2	1	1
Viral infection		2						2
Vision blurred		3				3		
Vitamin B12 deficiency	1	1			1	1		
Vomiting	4	25			3	9	1	16
Weight decreased		4				2		2
Weight increased		1				1		
White blood cell count decreased		1				1		
White blood cell count increased	3	4			2	3	1	1
Wound		1				1		
Wrist fracture		1						1
	435	2,366	5	5	208	1168	227	1198

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Country Where Event Occurred

NEW ZEALAND

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypoglycaemia		3		3
Nausea		1		1
		4		4

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Country Where Event Occurred

NORWAY

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal infection		1				1
Abdominal pain	1	5		1	1	4
Abdominal pain upper	1	5			1	5
Abnormal behaviour		1				1
Acute kidney injury	2	5			2	5
Acute myocardial infarction	2	6			2	6
Acute respiratory failure	1	1			1	1
Adenoma benign		1				1
Aggression		2		1		1
Agitation		1				1
Allergy to vaccine		2				2
Altered state of consciousness	1	7			1	7
Amnesia		1				1
Anal incontinence		1				1
Anaphylactic reaction	4	7			4	7
Anaphylactic shock	1	1			1	1
Angioedema		1				1
Anxiety	2	4		1	2	3
Aortic arteriosclerosis		1		1		
Aortic stenosis		1				1
Apathy		2				2
Aphasia		3				3
Apnoea		2				2
Apnoeic attack		1				1
Arrhythmia	1	2			1	2
Arterial haemorrhage		1				1
Arteriosclerosis coronary artery		1				1
Arthralgia	4	13	3	10	1	3
Arthritis		1		1		
Asthenia		9		4		5
Asthma	2	3	1	2	1	1
Asymptomatic COVID-19	1	1			1	1
Atelectasis		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Atrial f brillation	2	2			2	2
Atrial flutter		1				1
Atrioventricular block first degree		1				1
Axillary mass		1				1
Axillary pain		1				1
Back pain		8		4		4
Bacterial sepsis		1				1
Balance disorder	1	3	1	1		2
Bedridden		4				4
Blindness		1				1
Blindness transient	1	1			1	1
Blood calcium decreased		1		1		
Blood creatinine increased	1	1			1	1
Blood glucose decreased		1		1		
Blood glucose fluctuation		3		3		
Blood glucose increased	2	3	1	2	1	1
Blood phosphorus decreased		1		1		
Blood potassium decreased	1	2		1	1	1
Blood pressure decreased	1	6	1	2		4
Blood pressure diastolic decreased		1		1		
Blood pressure increased	2	2			2	2
Blood pressure systolic increased	1	1			1	1
Body temperature decreased		1		1		
Bone pain	1	3		1	1	2
Brachiocephalic vein thrombosis	1	1			1	1
Bradycardia	1	4			1	4
Brain injury	1	1			1	1
Breast enlargement		1		1		
Breast pain		1		1		
Breath sounds abnormal		1				1
Bronchitis		1		1		
Bronchospasm	1	1			1	1
Burning sensation		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac arrest	2	4			2	4
Cardiac failure		4				4
Cardiomegaly		1				1
Cardio-respiratory arrest		1				1
Cardiovascular disorder		1				1
Carotid arteriosclerosis		1		1		
CD4 lymphocytes decreased	1	1			1	1
Cerebellar haemorrhage	1	1			1	1
Cerebral artery embolism		1				1
Cerebral haemorrhage	2	7			2	7
Cerebral infarction	1	7			1	7
Cerebral thrombosis		1				1
Cerebral venous thrombosis	1	1			1	1
Cerebrovascular accident	1	13			1	13
Cerebrovascular disorder		1				1
Chest discomfort		1		1		
Chest pain	1	11		3	1	8
Chills	1	12		8	1	4
Cholecystitis		1				1
Chronic kidney disease		1				1
Chronic obstructive pulmonary disease		6				6
Circulatory collapse		3				3
Coating in mouth	1	1			1	1
Cognitive disorder		2		1		1
Cold sweat	2	6			2	6
Coma		1				1
Communication disorder		1		1		
Concomitant disease aggravated		1				1
Concussion		1				1
Condition aggravated	1	5		1	1	4
Confusional state	1	22		5	1	17
Conjunctivitis		1		1		
Constipation		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Contusion	1	3	1	2		1
Coordination abnormal		1				1
Coronary artery occlusion		1				1
Cough	2	10	1	4	1	6
COVID-19	4	5			4	5
COVID-19 pneumonia	2	2			2	2
C-reactive protein increased	2	16		3	2	13
Cutaneous vasculitis	1	1			1	1
Cyanosis		2				2
Cystic lung disease		1		1		
Death	1	24			1	24
Decreased appetite	2	10	1	3	1	7
Decubitus ulcer		1		1		
Deep vein thrombosis	4	6			4	6
Defaecation disorder		1				1
Dehydration	1	2	1	2		
Delirium		4				4
Delusion		1				1
Dementia		2				2
Dementia Alzheimer's type		1				1
Demyelinating polyneuropathy		1				1
Depressed level of consciousness	2	7			2	7
Depressed mood		1		1		
Diabetes mellitus inadequate control		1				1
Diarrhoea	1	10		2	1	8
Disease recurrence		3				3
Disseminated varicella zoster virus infection	1	1			1	1
Diverticulitis		1				1
Dizziness	3	16	2	9	1	7
Drooling		1		1		
Drug ineffective	2	2			2	2
Drug interaction		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug reaction with eosinophilia and systemic symptoms		1				1
Dry mouth		1				1
Dry skin		1		1		
Dysarthria		4		1		3
Dysgeusia		1		1		
Dysphagia		5		1		4
Dysphonia	2	4		2	2	2
Dyspnoea	13	48	5	14	8	34
Dyspnoea at rest	1	2			1	2
Ear discomfort		1		1		
Ear pain		1		1		
Ear swelling		1		1		
Ecchymosis		1				1
Eczema		1				1
Emphysema		1		1		
Encephalitis brain stem	1	1			1	1
Epilepsy		3				3
Epistaxis		1				1
Erysipelas	2	3			2	3
Erythema	1	4		2	1	2
Extrasystoles		1				1
Eye pain		1		1		
Facial paralysis		1				1
Facial paresis	1	3	1	1		2
Faeces discoloured	1	2			1	2
Fall		11		3		8
Fatigue	14	49	9	28	5	21
Febrile neutropenia	1	1			1	1
Feeling abnormal		2		1		1
Feeling cold	1	2	1	2		
Feeling hot	1	3		1	1	2
Femur fracture		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fibrin D dimer increased	1	1			1	1
Flatulence		1		1		
Foaming at mouth		1		1		
Food refusal		1				1
Forced expiratory flow	1	1			1	1
Fracture		1				1
Fungal infection	1	1			1	1
Gait disturbance	1	3		1	1	2
Gastric haemorrhage		1				1
Gastrointestinal haemorrhage		2				2
General physical health deterioration	3	48		11	3	37
General symptom		1				1
Giant cell arteritis		1				1
Glomerulonephritis chronic		1				1
Glomerulonephritis minimal lesion		1				1
Guillain-Barre syndrome		1				1
Haematemesis		2				2
Haematoma		2				2
Haemoglobin decreased		3				3
Haemorrhage		2				2
Haemothorax		1				1
Hallucination	1	5			1	5
Hallucination, visual	2	2			2	2
Headache	6	22	3	14	3	8
Heart rate decreased	1	1			1	1
Heart rate increased	1	10	1	5		5
Heart rate irregular		2		1		1
Hemianopia		1				1
Hemiparesis	2	4			2	4
Hemiplegia	2	4			2	4
Herpes zoster	2	2	2	2		
Hyperaesthesia		1				1
Hypercapnia		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperglycaemia		2		1		1
Hyperhidrosis	1	4	1	4		
Hyperkalaemia		1				1
Hypersensitivity	1	1			1	1
Hypersomnia	1	1	1	1		
Hypertension		3		3		
Hyperventilation	2	5		3	2	2
Hypoaesthesia	2	2	1	1	1	1
Hypogeusia	1	1	1	1		
Hypokinesia		2		1		1
Hypophagia		1				1
Hypotension	1	12	1	2		10
Hypothermia		1				1
Hypoxia		3				3
Illness	1	2	1	2		
Immune-mediated adverse reaction	1	2			1	2
Immune system disorder	1	1			1	1
Immune thrombocytopenia	2	3			2	3
Impaired driving ability	1	1			1	1
Inappropriate schedule of product administration		2		2		
Incomplete course of vaccination	1	1			1	1
Incorrect route of product administration		1		1		
Increased bronchial secretion		1				1
Infection	3	10		1	3	9
Infective exacerbation of chronic obstructive airways disease		1				1
Inflammation		1				1
Influenza like illness		3		1		2
International normalised ratio increased		1				1
Interstitial lung disease		1				1
Intracardiac thrombus		1				1
Irritability postvaccinal		1				1
Ischaemic stroke		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint swelling		1		1		
Jugular vein thrombosis	1	1			1	1
Kidney fibrosis		1				1
Left ventricular failure		1				1
Lethargy	1	2		1	1	1
Leukocytosis		2		1		1
Local reaction		1				1
Loss of consciousness	1	8			1	8
Lung consolidation		1				1
Lung infiltration	1	1	1	1		
Lung opacity		1				1
Lymphadenitis		1		1		
Lymphadenopathy		1		1		
Lymphocyte count decreased	1	1			1	1
Lymphocytosis		1		1		
Malaise	3	14	1	6	2	8
Malignant hypertension		1				1
Mania		1				1
Marasmus		1				1
Mediastinal haemorrhage		1				1
Melaena		1				1
Memory impairment		1		1		
Menstrual discomfort	1	1			1	1
Metastases to peritoneum		1				1
Middle insomnia		1		1		
Moaning		1				1
Mobility decreased		1		1		
Monocytosis	1	1	1	1		
Monoparesis		1				1
Motor dysfunction		1		1		
Mouth ulceration		1				1
Multiple fractures		1				1
Multiple sclerosis	2	2			2	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle contractions involuntary	1	1	1	1		
Muscle spasms	1	4		1	1	3
Muscular weakness		3		2		1
Musculoskeletal stiffness		5		3		2
Myalgia	6	16	3	9	3	7
Myocardial infarction	1	3			1	3
Myopia		1				1
Nasal pruritus		1				1
Nasopharyngitis		1				1
Nausea	10	34	3	15	7	19
Neck pain	1	5	1	4		1
Neuropathy peripheral		1				1
Neutropenia	2	3			2	3
Neutrophilia	1	1	1	1		
N-terminal prohormone brain natriuretic peptide increased		2				2
Obstructive airways disorder	1	2			1	2
Odynophagia	1	1			1	1
Oedema peripheral		3		2		1
Off label use		1		1		
Ophthalmic herpes zoster		1				1
Oral mucosa haematoma		1				1
Oral pruritus		1				1
Oropharyngeal pain	1	3		1	1	2
Orthostatic hypotension	1	2			1	2
Oxygen saturation decreased	1	13		1	1	12
Pain	3	11		6	3	5
Painful respiration	1	2		1	1	1
Pain in extremity	1	4		3	1	1
Pallor		3				3
Palpitations	3	4	1	2	2	2
Paraesthesia	3	4	2	3	1	1
Paralysis		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paranoia		1				1
Paresis		1		1		
Pelvic venous thrombosis	1	1			1	1
Pericardial effusion	1	3			1	3
Pericardial haemorrhage		1				1
Pericarditis	1	3			1	3
Peripheral coldness	1	2	1	1		1
Peripheral swelling	1	7		4	1	3
Personality change		1				1
Petechiae	1	3			1	3
Pharyngeal paraesthesia	1	1			1	1
Pharyngeal swelling	1	1			1	1
Photophobia		1				1
Platelet count increased	1	1			1	1
Pleural effusion	1	3			1	3
Pleurisy		1				1
Pneumonia	2	19			2	19
Pneumonia aspiration		1				1
Pneumonia bacterial		1				1
Pneumonitis		1				1
Presyncope	1	6	1	1		5
Productive cough		4				4
Pruritus	1	6		1	1	5
Psoriasis	1	1			1	1
Psychological trauma	1	1			1	1
Psychomotor hyperactivity		1				1
Pulmonary congestion		1				1
Pulmonary embolism	10	14			10	14
Pulmonary infarction	1	1			1	1
Pulmonary oedema		1				1
Pupil fixed		2				2
Purpura	1	1			1	1
Pyelonephritis		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia	12	52	7	20	5	32
Radiculopathy	1	1			1	1
Rales		3		1		2
Rash	3	9		4	3	5
Rash erythematous	1	3		2	1	1
Rash macular	1	1	1	1		
Rash pruritic		1		1		
Red blood cell sedimentation rate increased		2		1		1
Renal cyst		1				1
Renal impairment		1				1
Respiratory acidosis		1				1
Respiratory arrest		4				4
Respiratory disorder		1				1
Respiratory distress	1	1			1	1
Respiratory failure	3	12			3	12
Respiratory rate increased	1	8		4	1	4
Respiratory tract congestion		1				1
Respiratory tract infection		1				1
Restlessness		7		3		4
Retching		2		1		1
Rhinorrhoea		2		2		
Right ventricular failure	1	1			1	1
Road traffic accident	1	1			1	1
Secretion discharge		2				2
Seizure	1	1			1	1
Sepsis		2				2
Serum sickness	1	1			1	1
Shock		1				1
Sinoatrial block	1	1			1	1
Skin discolouration	1	1			1	1
Skin haemorrhage		1		1		
Sleep disorder		1				1
Snoring		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Soft tissue infection	1	1			1	1
Somnolence		9		3		6
Speech disorder		4		2		2
Spinal vascular disorder	1	1			1	1
Splenic infarction	1	1			1	1
Sputum increased		1		1		
Stenosis		1				1
Stridor		1				1
Sudden death	2	9			2	9
Swelling	1	1			1	1
Swelling face		1				1
Swollen tongue	1	1			1	1
Syncope	2	14			2	14
Systemic inflammatory response syndrome	1	1			1	1
Tachycardia	3	7	1	2	2	5
Tachypnoea		1				1
Tendon pain		1		1		
Terminal state		1				1
Thirst		1				1
Throat irritation		1		1		
Throat tightness	3	4			3	4
Thrombocytopenia	1	4			1	4
Thrombophlebitis		2		1		1
Thrombotic stroke		1				1
Transfusion reaction		1		1		
Transient ischaemic attack		3				3
Tremor	1	5	1	2		3
Troponin increased		1				1
Tubulointerstitial nephritis		1				1
Unresponsive to stimuli		2				2
Urinary incontinence		2		1		1
Urinary retention		2				2
Urinary tract infection		3		3		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urosepsis		1				1
Urticaria	1	4			1	4
Vaccination failure	5	6			5	6
Vaccination site erythema	2	5	2	4		1
Vaccination site oedema		1		1		
Vaccination site pain	2	9	2	7		2
Vaccination site pruritus		1				1
Vaccination site reaction	1	3		1	1	2
Vaccination site swelling	2	4	1	1	1	3
Vaccination site warmth		1				1
Vaccine breakthrough infection		1				1
Vaginal haemorrhage	1	1			1	1
Vena cava thrombosis	1	1			1	1
Ventricular extrasystoles		2		1		1
Ventricular tachycardia		1				1
Vertigo		1				1
Vision blurred	1	3	1	1		2
Visual impairment		1				1
Vomiting	3	25	1	8	2	17
Weight decreased		1		1		
Wheezing	1	3			1	3
White blood cell count decreased	1	1			1	1
	314	1,363	75	385	239	978

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Country Where Event Occurred

OMAN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Therapeutic response unexpected		1		1
		1		1

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Country Where Event Occurred

PANAMA

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Allergy to vaccine	2	2	2	2		
Anosmia	1	1	1	1		
Arthralgia	4	4	4	4		
Asthenia	5	5	3	3	2	2
Asthmatic crisis	1	1			1	1
Back pain	1	1	1	1		
Bronchospasm	2	2			2	2
Burning sensation	1	1	1	1		
Chest discomfort	1	1	1	1		
Chest pain	2	2	2	2		
Chills	2	2	2	2		
Cough	2	2	1	1	1	1
COVID-19	1	1			1	1
Diarrhoea	1	1	1	1		
Discomfort	1	1	1	1		
Dizziness	6	6	5	5	1	1
Drug ineffective	1	1			1	1
Dysphonia	1	1	1	1		
Dyspnoea	2	2	1	1	1	1
Ear pain	1	1	1	1		
Fatigue	1	1	1	1		
Feeling hot	1	1	1	1		
Haematoma	1	1	1	1		
Headache	13	13	12	12	1	1
Hyperhidrosis	1	1	1	1		
Hypersensitivity	1	1	1	1		
Hypoaesthesia	1	1	1	1		
Hypotension	1	1	1	1		
Incorrect route of product administration	2	2	2	2		
Irritability postvaccinal	1	1	1	1		
Lip oedema	1	1	1	1		
Local reaction	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Malaise	2	2	1	1	1	1
Monoparesis	1	1	1	1		
Myalgia	3	3	3	3		
Nausea	3	3	3	3		
Neck pain	1	1	1	1		
Oropharyngeal pain	2	2	2	2		
Pain	2	2	2	2		
Pain in extremity	1	1	1	1		
Papule	1	1	1	1		
Paraesthesia	2	2	2	2		
Periorbital oedema	1	1	1	1		
Pruritus	4	4	3	3	1	1
Pyrexia	7	7	7	7		
Rash	3	3	2	2	1	1
Rash erythematous		1				1
Rash pruritic		1				1
Rhinorrhoea	1	1	1	1		
Seizure	2	2			2	2
Somnolence	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination site pain	2	2	2	2		
Vaccination site papule	1	1	1	1		
Vaccination site reaction	4	4	4	4		
Vertigo	1	1	1	1		
	110	112	94	94	16	18

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Country Where Event Occurred

PERU

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		1		1		
Bronchial disorder	1	1			1	1
COVID-19		1				1
Drug ineffective		1				1
General physical health deterioration	1	1			1	1
Oxygen saturation decreased	1	1			1	1
Pain		1		1		
Vaccination site pain	1	1	1	1		
	4	8	1	3	3	5

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Country Where Event Occurred

PHILIPPINES

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dizziness	1	1	1	1
Headache	2	2	2	2
Pyrexia	1	1	1	1
Sinusitis	1	1	1	1
Somnolence	1	1	1	1
Vaccination site discomfort	1	1	1	1
Vaccination site movement impairment	1	1	1	1
Vaccination site pain	2	2	2	2
Vaccination site swelling	1	1	1	1
	11	11	11	11

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Country Where Event Occurred

POLAND

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal distension		1				1
Abdominal pain		2				2
Abdominal pain upper	1	3	1	3		
Acute kidney injury		1				1
Acute myocardial infarction	1	2			1	2
Ageusia	1	2	1	2		
Allergic reaction to excipient		2		2		
Allergy to vaccine	1	1	1	1		
Altered state of consciousness	2	2	1	1	1	1
Amnesia	1	1	1	1		
Anaphylactic reaction		1				1
Angioedema	1	2			1	2
Angiopathy		1				1
Anosmia		1		1		
Anuria		2				2
Anxiety		1		1		
Apnoea		1				1
Arteriosclerosis		1		1		
Arthralgia	5	12	4	9	1	3
Asthenia	5	16	5	11		5
Atrial fibrillation		2				2
Atrial flutter		2				2
Back pain	2	3	2	3		
Balance disorder	2	3	2	3		
Basophil count decreased		1		1		
Bladder cancer		1				1
Bladder disorder	1	1	1	1		
Blood creatine phosphokinase increased		1		1		
Blood pressure decreased		2				2
Blood pressure fluctuation	1	1	1	1		
Blood pressure increased		2				2
Blood smear test abnormal		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Body temperature decreased		1		1		
Body temperature increased	1	4		2	1	2
Bone density decreased		1		1		
Bone pain		1				1
Brain oedema		1				1
Burning sensation		2		2		
Bursitis		1		1		
Cardiac arrest	2	7			2	7
Cardiac fibrillation	1	1			1	1
Cardiogenic shock		1				1
Cerebral haemorrhage		1				1
Cerebrovascular accident		2				2
Chest discomfort	1	3	1	3		
Chest pain	3	4	3	3		1
Chills	1	4	1	3		1
Choking sensation		1				1
Coma		1				1
Contusion	1	3	1	2		1
Cough	3	6	3	3		3
COVID-19	5	16	1	2	4	14
C-reactive protein increased		1		1		
Death	1	8			1	8
Decreased activity		1		1		
Decreased appetite	2	3	2	2		1
Decreased immune responsiveness	1	1	1	1		
Depressed level of consciousness		1				1
Depressed mood	1	1	1	1		
Derealisation	1	1	1	1		
Diarrhoea	1	4	1	3		1
Disease recurrence		1				1
Disturbance in attention	1	1	1	1		
Dizziness	4	7	4	7		
Drug hypersensitivity		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug ineffective	3	8			3	8
Dysarthria		1				1
Dysphonia	1	1			1	1
Dyspnoea	2	6	2	3		3
Ear discomfort	1	1	1	1		
Emphysema		1		1		
Eosinophil count decreased		1		1		
Eructation	1	1	1	1		
Erythema	2	5	1	1	1	4
Exposure during pregnancy		1		1		
Faeces soft		1				1
Fall		3				3
Fatigue		1		1		
Feeling hot		1		1		
Flatulence		1				1
Gait disturbance	1	2			1	2
Gait inability	1	1			1	1
General physical health deterioration		1				1
Glomerulonephritis chronic	1	1			1	1
Haematuria		1		1		
Haemoptysis		1		1		
Haemorrhagic diathesis		1				1
Haemorrhagic stroke	1	1			1	1
Headache	6	11	6	9		2
Head discomfort	1	2	1	2		
Head injury		1				1
Heart rate increased	1	2	1	1		1
Hiccups	1	1	1	1		
Hot flush	1	1	1	1		
Hyperhidrosis	1	5	1	4		1
Hyperpyrexia		2				2
Hypersensitivity	1	1			1	1
Hypoaesthesia	2	3	2	3		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia oral	2	2	1	1	1	1
Hypotension	1	1	1	1		
Hypotonia		1				1
Hypotonic-hyporesponsive episode		1				1
Immune system disorder	1	1	1	1		
Inappropriate schedule of product administration	1	2	1	2		
Incorrect route of product administration		1		1		
Infection	1	1	1	1		
Inflammation		3		2		1
Influenza like illness	1	4	1	3		1
Insomnia	1	1	1	1		
Iritis		1		1		
Ischaemic stroke		1				1
Joint effusion		1		1		
Joint injury		1				1
Joint range of motion decreased		1		1		
Joint stiffness		1		1		
Joint swelling	1	3		1	1	2
Laryngeal pain	1	1	1	1		
Lethargy		1				1
Lividity		1				1
Loss of consciousness		4				4
Lung disorder		1		1		
Lung opacity		1		1		
Lymphadenopathy		2		2		
Lymphocyte count decreased		1		1		
Malaise	3	7	2	4	1	3
Monocyte count decreased		1		1		
Muscular weakness		1				1
Musculoskeletal pain		1				1
Musculoskeletal stiffness		1		1		
Myalgia	5	11	4	8	1	3
Nausea	2	5	2	3		2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neck pain		1		1		
Neuralgia	1	1	1	1		
Neutrophil count increased		1		1		
Off label use		2		2		
Oliguria		1		1		
Oxygen saturation decreased		1				1
Pain	2	5	1	4	1	1
Pain in extremity	6	15	6	15		
Paraesthesia oral	1	1	1	1		
Paraparesis		1				1
Parosmia		2		2		
Peripheral swelling	1	3	1	2		1
Petechiae	1	1			1	1
Phlebitis		1		1		
Photophobia	1	1	1	1		
Pleural effusion		1		1		
Pneumonia	1	3			1	3
Pneumonia viral		1				1
Poor quality product administered		1		1		
Presyncope	1	2	1	1		1
Product use issue		1		1		
Protein urine present	1	2	1	2		
Pruritus	1	2	1	1		1
Pulmonary calcification		1		1		
Pulmonary congestion		1				1
Pulmonary mass		1		1		
Pulmonary oedema	1	1			1	1
Pyrexia	4	13	4	11		2
Rash		1		1		
Rash erythematous	1	3	1	2		1
Rash macular	1	2	1	2		
Rash papular		1		1		
Rash pruritic	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Reaction to excipient		1		1		
Renal failure	1	1			1	1
Renal pain		1		1		
Respiratory failure	1	2			1	2
Rheumatoid arthritis	1	1			1	1
Rhinorrhoea	1	3	1	3		
Seizure	1	1			1	1
Skin lesion	1	1	1	1		
Somnolence	2	2	2	2		
Speech disorder	1	2	1	2		
Sudden cardiac death		1				1
Swelling	1	1			1	1
Syncope		3				3
Synovial disorder		1		1		
Systemic lupus erythematosus		1				1
Tachycardia	2	4	1	1	1	3
Tachypnoea		1				1
Taste disorder		1		1		
Therapeutic response unexpected		2		2		
Thrombophlebitis		1		1		
Thrombosis		1				1
Tinnitus	2	3	2	2		1
Transaminases increased		1				1
Tremor		1		1		
Trigeminal neuralgia	1	1			1	1
Type 2 diabetes mellitus	1	1			1	1
Urticaria		2		1		1
Vaccination complication		1		1		
Vaccination failure		2				2
Vaccination site erythema	2	2	1	1	1	1
Vaccination site extravasation		1		1		
Vaccination site haemorrhage	1	1	1	1		
Vaccination site hypersensitivity	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site oedema		1		1		
Vaccination site pain	3	10	3	9		1
Vaccination site pruritus		1		1		
Vaccination site reaction		1				1
Vaccination site swelling	1	1			1	1
Vaccination site warmth		1		1		
Venous thrombosis		1				1
Vision blurred		1		1		
Visual impairment	1	1	1	1		
Vomiting	1	4	1	2		2
Yellow skin	1	1	1	1		
	155	452	113	261	42	191

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Country Where Event Occurred

PORTUGAL

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	3	6	1	1	2	5
Abdominal pain upper		2		1		1
Aborted pregnancy		1				1
Acidosis		1				1
Acute myocardial infarction		2				2
Altered state of consciousness		1				1
Anaphylactic reaction	2	6			2	6
Anaphylactoid reaction		1				1
Angioedema		1				1
Anti-neutrophil cytoplasmic antibody positive vasculitis	1	1			1	1
Anxiety	1	2	1	2		
Apathy		1				1
Arrhythmia	2	5			2	5
Arteriosclerosis		1		1		
Arthralgia	3	20	2	2	1	18
Asthenia	3	9	1	1	2	8
Asymptomatic COVID-19		2				2
Atrial fibrillation		1				1
Atrioventricular block complete		2				2
Atrioventricular block second degree	1	1			1	1
Autonomic nervous system imbalance		1				1
Axillary pain	2	4	1	1	1	3
Back pain		1				1
Bacterial infection		1				1
Balance disorder	1	2			1	2
Bedridden		1				1
Bell's palsy	1	1			1	1
Blindness unilateral	1	1			1	1
Blood glucose fluctuation		1		1		
Blood pressure decreased		1				1
Blood pressure diastolic decreased		1		1		
Blood pressure increased		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure systolic increased		1		1		
Blood thyroid stimulating hormone increased		1				1
Body temperature increased		2		1		1
Bradycardia	1	4			1	4
Bradyphrenia		1				1
Bradypnoea		1				1
Breast pain		1				1
Breast swelling		1				1
Bronchial hyperreactivity	1	1			1	1
Bronchospasm		5				5
Cardiac failure		1				1
Cardio-respiratory arrest	1	4			1	4
Cerebrovascular accident	3	5			3	5
Chapped lips	1	1	1	1		
Chest discomfort		5		1		4
Chest pain	3	5	2	2	1	3
Chills	1	21	1	3		18
Choking sensation		1				1
Cholinergic syndrome		1				1
Circumoral oedema		1				1
Computerised tomogram thorax abnormal		1		1		
Condition aggravated	2	6	1	1	1	5
Confusional state	1	1	1	1		
Cough	1	10		1	1	9
COVID-19		7		3		4
COVID-19 pneumonia	1	2			1	2
Crohn's disease		1				1
Cutaneous vasculitis		1				1
Cyanosis		1				1
Deafness		1				1
Deafness neurosensory		1				1
Deafness unilateral		2				2
Death		4				4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite		8				8
Deep vein thrombosis	2	3			2	3
Diarrhoea	5	20	3	5	2	15
Diplopia		1		1		
Discomfort	2	3	2	2		1
Disease recurrence		1				1
Disorientation		2				2
Dizziness	3	19	1	3	2	16
Drug-induced liver injury		1				1
Drug ineffective		1				1
Drug interaction		1				1
Dry mouth	1	3	1	1		2
Dry skin		1				1
Dysarthria	1	1			1	1
Dysgeusia		2		1		1
Dysphagia		1				1
Dysphonia		1				1
Dyspnoea	7	20	4	5	3	15
Dyspnoea at rest		1				1
Dyspnoea exertional	1	2			1	2
Ear congestion	1	1			1	1
Ear pain	1	1	1	1		
Ecchymosis	1	2			1	2
Electric shock sensation	1	1			1	1
Emotional distress	1	1			1	1
Epistaxis		1				1
Erythema		5		1		4
Exposure during pregnancy	1	2	1	2		
Extrasystoles		1		1		
Eye haemorrhage	1	1			1	1
Eye irritation		1		1		
Eye pain	1	1	1	1		
Face oedema		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fall	1	2		1	1	1
Fatigue	8	33	6	6	2	27
Feeling abnormal		1				1
Feeling cold	1	3	1	2		1
Feeling hot	1	4	1	2		2
Fibrin D dimer increased		2		2		
Flushing		1		1		
Gait inability		1				1
Gastric disorder		1				1
Generalised tonic-clonic seizure		1				1
Glossodynia		1		1		
Haematoma	1	2			1	2
Haemorrhagic stroke	1	1			1	1
Haemorrhagic transformation stroke		1				1
Headache	9	63	7	12	2	51
Head discomfort	1	2			1	2
Heart rate decreased	1	2			1	2
Heart rate increased	2	2	2	2		
Hemiparesis		1				1
Herpes zoster	2	2	1	1	1	1
Hydrocephalus		1				1
Hyperglycaemia		3				3
Hyperhidrosis	2	5	1	1	1	4
Hyperlactacidaemia		1				1
Hypersensitivity	1	2			1	2
Hypertension	2	7			2	7
Hypertensive crisis		1				1
Hyperthermia		1				1
Hypoacusis	1	3			1	3
Hypoaesthesia	4	5	1	1	3	4
Hypoaesthesia oral	1	2		1	1	1
Hypoglycaemia	1	2			1	2
Hypopnoea		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypotension	2	6	2	2		4
Hypothyroidism		1				1
Impetigo		1				1
Inappropriate schedule of product administration	1	2	1	2		
Incorrect route of product administration	1	3	1	3		
Influenza like illness		1		1		
Insomnia	1	1	1	1		
Intermenstrual bleeding	1	1	1	1		
International normalised ratio increased		1				1
Ischaemic stroke	4	5			4	5
Jaundice	1	1			1	1
Lacunar stroke		1				1
Laryngeal oedema		1				1
Leukaemoid reaction		1				1
Limb discomfort	1	1			1	1
Limb mass		1		1		
Lip oedema		3		1		2
Liver function test abnormal	1	1			1	1
Liver injury	1	1			1	1
Localised oedema	1	3			1	3
Loss of personal independence in daily activities		1				1
Lung infiltration		1				1
Lymphadenitis		1		1		
Lymphadenopathy	7	28	5	8	2	20
Lymphoedema		1				1
Lymphoproliferative disorder		1				1
Malaise	2	13	1	1	1	12
Meningioma		1				1
Migraine		2		1		1
Miliaria	1	1	1	1		
Moaning	1	1			1	1
Mobility decreased		1				1
Monocyte count increased		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Movement disorder	1	2		1	1	1
Muscle fatigue		2		1		1
Muscle rigidity		1				1
Muscular weakness	2	6			2	6
Musculoskeletal disorder		1				1
Musculoskeletal stiffness	1	3	1	1		2
Myalgia	11	61	8	12	3	49
Myalgia intercostal		1				1
Myocarditis		1				1
Myoclonus		1				1
Nasal congestion		1				1
Nasal discomfort		1		1		
Nasal dryness		1		1		
Nasal obstruction		1				1
Nasopharyngitis	1	1	1	1		
Nausea	8	33	1	4	7	29
Neck pain	1	1	1	1		
Night sweats		2				2
Occupational exposure to SARS-CoV-2		1		1		
Odynophagia		2				2
Oedema peripheral	1	3			1	3
Off label use	1	5	1	5		
Ophthalmic artery thrombosis	1	1			1	1
Oropharyngeal discomfort		3				3
Oropharyngeal pain	3	3	2	2	1	1
Overdose	1	2	1	2		
Oxygen saturation decreased		4				4
Pain	5	13	4	6	1	7
Pain in extremity	4	12	3	5	1	7
Pain in jaw		1				1
Pallor		1				1
Palmar-plantar erythrodysesthesia syndrome		1				1
Palpitations		3		1		2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia	4	9	3	4	1	5
Paraesthesia oral		2				2
Paralysis		1				1
Parkinson's disease	1	1			1	1
Pericarditis	1	1			1	1
Perineal pain		1				1
Peripheral artery occlusion		1				1
Peripheral artery stenosis		1				1
Peripheral coldness	1	2			1	2
Peripheral swelling	1	2		1	1	1
Phlebitis	1	2			1	2
Platelet count increased		1		1		
Pneumonia	1	1			1	1
PO2 decreased		1				1
Postural orthostatic tachycardia syndrome		1				1
Presyncope	2	7	1	1	1	6
Product administered at inappropriate site	2	2	2	2		
Product use issue		4		4		
Pruritus	2	11	2	5		6
Pulmonary embolism	3	6			3	6
Purpura		2				2
Pyrexia	7	48	7	11		37
Rash	3	15	1	2	2	13
Rash erythematous	2	3	1	1	1	2
Rash macular	1	7	1	1		6
Rash maculo-papular		1				1
Rash papular		1				1
Rash pruritic	1	1	1	1		
Renal pain	1	1			1	1
Respiratory disorder		1				1
Respiratory distress		1				1
Respiratory failure		1				1
Respiratory tract infection		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rhinorrhoea	1	2	1	1		1
SARS-CoV-2 test positive		1				1
Sciatica		1				1
Seizure	1	3			1	3
Sensory loss		2				2
Shock		1				1
Sinus tachycardia		1				1
Skin burning sensation		1				1
Skin exfoliation		1				1
Skin lesion		1				1
Skin reaction		1				1
Skin warm		1		1		
Sleep disorder		1				1
Sneezing		1				1
Soft tissue haemorrhage		1		1		
Somnolence	2	11	2	5		6
Stroke in evolution		1				1
Sudden cardiac death		1				1
Sudden hearing loss		1				1
Suffocation feeling	1	1			1	1
Swelling		2		1		1
Swollen tongue	1	1			1	1
Syncope	1	3			1	3
Synovial cyst	1	2	1	1		1
Tachyarrhythmia		1				1
Tachycardia	3	10	2	2	1	8
Tachypnoea		2				2
Taste disorder	1	4	1	1		3
Tenosynovitis		1		1		
Throat tightness		1				1
Thrombocytopenia		1				1
Thrombocytopenic purpura	1	1			1	1
Thrombophlebitis		2				2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thyroid function test abnormal		1		1		
Tinnitus	1	3			1	3
Tongue discomfort		1				1
Tongue dry		1				1
Tongue oedema		2		1		1
Transient ischaemic attack	1	1			1	1
Tremor	1	3		1	1	2
Upper gastrointestinal haemorrhage		1				1
Urinary tract infection		1				1
Urticaria		3				3
Urticaria papular		1				1
Vaccination failure	1	5			1	5
Vaccination site erythema	2	11	1	4	1	7
Vaccination site haematoma		1		1		
Vaccination site hypoaesthesia		1				1
Vaccination site induration		1				1
Vaccination site inflammation		2		1		1
Vaccination site movement impairment	2	2			2	2
Vaccination site oedema	3	10	2	4	1	6
Vaccination site pain	8	50	4	17	4	33
Vaccination site paraesthesia		1				1
Vaccination site pruritus		5		3		2
Vaccination site rash		1				1
Vaccination site swelling	2	5	2	2		3
Vaccination site warmth	2	5	1	1	1	4
Vaginal haemorrhage		1				1
Vasculitis	1	2			1	2
Venous occlusion	1	1			1	1
Ventricular extrasystoles		1				1
Vertigo	1	2			1	2
Vision blurred		1				1
Visual acuity reduced	1	1			1	1
Visual impairment		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vomiting	2	12	1	3	1	9
Vulvovaginal burning sensation		1				1
Vulvovaginal swelling		1				1
Wheezing		4				4
	250	1,069	119	242	131	827

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Country Where Event Occurred

PUERTO RICO

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain	1	2	1	2		
Arthralgia	1	3	1	3		
Asthenia		1		1		
Balance disorder		1		1		
Blood pressure increased		1		1		
Burning sensation		1		1		
Chest pain		1		1		
Chills	1	2	1	2		
Death		1				1
Deep vein thrombosis		1				1
Diarrhoea	1	2	1	2		
Discomfort		1		1		
Dizziness		3		2		1
Dizziness postural		1		1		
Dysgeusia		1		1		
Dyskinesia		1				1
Dyspnoea		1				1
Erythema		1		1		
Eyelid oedema	1	1	1	1		
Face oedema	1	1	1	1		
Facial paralysis		2				2
Fatigue	1	4	1	4		
Feeling cold		1				1
Flushing		1		1		
Gait disturbance		1		1		
Headache	2	7	1	6	1	1
Heart rate decreased		1				1
Heart rate increased		1		1		
Hyperhidrosis		1				1
Hypertension		2		2		
Hypoaesthesia	1	4		2	1	2
Illness		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Insomnia		1		1		
Joint range of motion decreased		1		1		
Joint swelling		1		1		
Limb discomfort		1		1		
Lymphadenopathy	1	4	1	4		
Migraine		1				1
Muscle spasms	1	1			1	1
Musculoskeletal stiffness		1		1		
Myalgia	1	4	1	4		
Nausea	1	3	1	3		
Neuralgia		1		1		
Night sweats		1				1
Oedema	1	1	1	1		
Oral discomfort		1		1		
Oropharyngeal pain	1	1	1	1		
Pain		1		1		
Pain in extremity	1	4	1	4		
Palpitations		1		1		
Paraesthesia	2	2	1	1	1	1
Peripheral swelling		1		1		
Photophobia		1		1		
Pneumonia		1				1
Productive cough		1		1		
Pruritus		1		1		
Pyrexia	1	5	1	5		
Rash		4		4		
Rhinorrhoea		1		1		
Sinus arrhythmia		1				1
Somnolence		1		1		
Swelling face		1		1		
Tachycardia		1		1		
Thrombosis		1				1
Urinary tract infection		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site induration	1	2	1	2		
Vaccination site pain		2		2		
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	1	4	1	4		
Vaccination site warmth	1	1	1	1		
Vaginal haemorrhage	1	1	1	1		
	25	117	21	95	4	22

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Country Where Event Occurred

QATAR

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic shock		1				1
Asthenia		2		1		1
Blood pressure decreased		1		1		
Disturbance in attention		1		1		
Dizziness		1				1
Dyspnoea	1	2			1	2
Erythema		1		1		
Feeling hot		1				1
Heart rate increased		1		1		
Hyperhidrosis		1				1
Muscle spasticity		1				1
Pulse abnormal	1	1			1	1
Pyrexia	1	2		1	1	1
Tachycardia	1	1			1	1
	4	17		6	4	11

* I=Interval, C=Cumulative
* AE=Adverse Event

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Country Where Event Occurred

ROMANIA

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1				1
Abdominal pain		2		1		1
Abdominal pain upper	2	2	1	1	1	1
Acute coronary syndrome		1				1
Acute myocardial infarction	1	1			1	1
Acute pulmonary oedema		2				2
Administration site pain		1		1		
Administration site swelling		1		1		
Anaphylactic reaction		1				1
Anaphylactic shock	1	1			1	1
Angina pectoris		1				1
Anosmia	1	1			1	1
Anxiety	1	2			1	2
Arrhythmia		2				2
Arthralgia	6	12	2	5	4	7
Asphyxia		2				2
Asthenia	2	7	2	5		2
Asthma		1				1
Asthmatic crisis		1				1
Autoimmune disorder		1				1
Back disorder		1		1		
Back pain	1	6	1	2		4
Blood glucose decreased		1				1
Blood pressure abnormal	1	1	1	1		
Blood pressure fluctuation		2				2
Blood pressure increased	1	4		1	1	3
Blood pressure systolic increased		1				1
Breast inflammation		2				2
Breast pain		1				1
Bronchospasm		5		2		3
Burning sensation	1	1			1	1
Cardiac arrest		1				1
Cardio-respiratory arrest	1	3			1	3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cataract		1				1
Cerebrovascular accident	2	3			2	3
Chest discomfort		1		1		
Chest pain	1	5			1	5
Chills	3	22	1	9	2	13
Coma		1				1
Coma hepatic		1				1
Condition aggravated		3		1		2
Confusional state	1	1	1	1		
Cough	2	6		2	2	4
COVID-19	1	4	1	1		3
C-reactive protein increased	1	1	1	1		
Cyanosis		2		1		1
Death	1	1			1	1
Decreased appetite	1	2		1	1	1
Deep vein thrombosis		1				1
Dehydration	1	1			1	1
Dementia		1				1
Depressed level of consciousness		1				1
Diarrhoea	1	2			1	2
Discomfort		1		1		
Disease recurrence	1	1	1	1		
Dizziness	5	16	2	6	3	10
Drug eruption		1				1
Drug ineffective		1				1
Dysmenorrhoea	1	1	1	1		
Dysphagia	1	2			1	2
Dyspnoea	2	7		1	2	6
Dyspnoea exertional		1				1
Dysstasia		1				1
Encephalopathy	1	1			1	1
Erythema		2		1		1
Eye haemorrhage		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid oedema	1	1			1	1
Eye pain		1				1
Eye pruritus		1		1		
Facial paralysis		1				1
Facial paresis	1	1			1	1
Faeces soft	1	1	1	1		
Fall	1	1	1	1		
Fatigue	7	23	5	16	2	7
Feeding disorder	1	1	1	1		
Feeling cold		1		1		
Feeling hot		2				2
Flatulence		1				1
Flushing		1		1		
Gait disturbance	1	2			1	2
General physical condition abnormal		1		1		
General physical health deterioration		2		2		
Goitre		1				1
Guillain-Barre syndrome	1	1			1	1
Headache	7	31	4	13	3	18
Heart rate increased	3	7	2	2	1	5
Heavy menstrual bleeding	1	1	1	1		
Herpes simplex	1	1	1	1		
Hyperglycaemia	2	4			2	4
Hyperhidrosis		5				5
Hyperkalaemia		2				2
Hypersensitivity	2	2			2	2
Hypersomnia	1	1	1	1		
Hypertension	5	13			5	13
Hypertensive crisis		1				1
Hypoaesthesia	2	9	1	4	1	5
Hypokinesia		1		1		
Hypotension	1	4		1	1	3
Hypothyroidism		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoxic-ischaemic encephalopathy		1				1
Inappropriate schedule of product administration	1	1	1	1		
Incomplete course of vaccination		1		1		
Influenza like illness		2		2		
Insomnia	1	2			1	2
Ischaemic stroke		1				1
Laboratory test abnormal		1		1		
Lethargy	1	1			1	1
Lip dry		1				1
Lip oedema		2				2
Loss of consciousness		3				3
Loss of personal independence in daily activities		1		1		
Lung disorder		1		1		
Lymphadenitis		2		1		1
Lymphadenopathy	4	10	1	1	3	9
Lymph node palpable		1		1		
Malaise	4	12	1	3	3	9
Maternal exposure during pregnancy		1		1		
Mean cell haemoglobin increased		1		1		
Menometrorrhagia	1	1			1	1
Menstruation irregular	1	1	1	1		
Metabolic acidosis	1	2			1	2
Migraine	1	2			1	2
Mobility decreased		1		1		
Muscle rigidity		1				1
Muscle spasms	1	1			1	1
Muscular weakness	1	1			1	1
Myalgia	7	29	3	12	4	17
Myocardial infarction		1				1
Myocardial ischaemia		1				1
Nasal congestion	1	1			1	1
Nausea	3	15		6	3	9
Neuronal neuropathy		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuropathy peripheral	1	1			1	1
Night sweats	1	1			1	1
Obstructive airways disorder		1				1
Ocular discomfort		1				1
Ocular hyperaemia		1		1		
Oedema		1				1
Oedema peripheral	1	1			1	1
Oesophageal oedema	1	1			1	1
Off label use		1		1		
Organic brain syndrome		1				1
Oxygen saturation abnormal		1				1
Oxygen saturation decreased		3				3
Pain	3	6	2	3	1	3
Pain in extremity	2	5	1	3	1	2
Pain of skin		1				1
Pallor		2				2
Palpitations		2				2
Paraesthesia	1	6	1	2		4
Parkinson's disease		1				1
Pelvic pain		1				1
Polyuria		1				1
Presyncope		1				1
Productive cough		1				1
Product use issue		1		1		
Pulse volume decreased		1		1		
Pyrexia	10	27	5	11	5	16
Rales		1				1
Rash	1	4	1	2		2
Rash erythematous		1				1
Rash pruritic	1	2		1	1	1
Raynaud's phenomenon		1				1
Renal pain		1				1
Respiration abnormal		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory disorder		2		1		1
Respiratory distress		2				2
Respiratory failure		1				1
Rheumatic disorder		1		1		
Rheumatoid factor increased	1	1	1	1		
Rhinalgia		1				1
Rhinitis	1	1			1	1
Rhinorrhoea	1	1	1	1		
SARS-CoV-2 ant body test negative		1		1		
Sensory disturbance	1	1			1	1
Sensory loss		1		1		
Shock		1				1
Sialoadenitis		1				1
Sluggishness	1	1			1	1
Somnolence	3	10	2	6	1	4
Speech disorder	1	1			1	1
Stomatitis		1				1
Stress	1	1	1	1		
Stridor		1		1		
Suffocation feeling	1	1			1	1
Supraventricular tachycardia		1				1
Swelling	1	1			1	1
Swelling face	2	2	1	1	1	1
Swollen tongue	1	1			1	1
Syncope	1	6			1	6
Systolic hypertension		1				1
Tachycardia	1	7		2	1	5
Tachypnoea		1				1
Tendon pain		1				1
Thirst	2	2			2	2
Throat tightness		1		1		
Thrombosis		1				1
Tinnitus		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tremor	1	2			1	2
Type 2 diabetes mellitus		1				1
Urinary incontinence		1				1
Urticaria	2	4	1	2	1	2
Use of accessory respiratory muscles		1		1		
Vaccination failure		2				2
Vaccination site erythema		2		1		1
Vaccination site inflammation	1	1			1	1
Vaccination site movement impairment		1				1
Vaccination site pain	3	17	1	8	2	9
Vaccination site urticaria		1		1		
Ventricular arrhythmia	1	1			1	1
Vertigo	1	5	1	3		2
Visual acuity reduced		1				1
Visual impairment		1				1
Vomiting	3	10	1	2	2	8
Weight increased		1				1
Wheezing		2		1		1
White blood cell count decreased	1	1	1	1		
	166	590	61	198	105	392

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Country Where Event Occurred

SAUDI ARABIA

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acquired haemophilia		1				1
Cardiac arrest		1				1
Carotid artery stenosis		1				1
Cerebrovascular accident	1	1			1	1
Fatigue		2		2		
Gait disturbance		1		1		
Gait inability		1				1
Headache		1		1		
Heart rate decreased		1				1
Heavy menstrual bleeding	1	1	1	1		
Hyperhidrosis		1				1
Movement disorder		1		1		
Musculoskeletal stiffness		1		1		
Nasopharyngitis		1		1		
Pain		1		1		
Pyrexia		1				1
Rhinorrhoea		1		1		
Sitting disability		1				1
Somnolence		1		1		
Stomatitis	1	1			1	1
Syncope		1				1
Vaccination site pain		1		1		
Vomiting		1				1
	3	24	1	12	2	12

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Country Where Event Occurred

SERBIA

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Abscess		1				1
Arthralgia		1		1		
Axillary pain		1				1
Blood bilirubin increased	1	1	1	1		
Blood calcium decreased	1	1	1	1		
Blood creatinine increased	1	1	1	1		
Blood iron decreased	1	1	1	1		
Body temperature increased		2		2		
Chills		1				1
Circulatory collapse	1	1			1	1
COVID-19		1		1		
C-reactive protein increased		1		1		
Diarrhoea	1	1	1	1		
Facial paralysis		1				1
Fatigue	2	3	2	3		
Fibrin D dimer increased		1		1		
Gamma-glutamyltransferase increased	1	1	1	1		
Guillain-Barre syndrome	1	1			1	1
Headache	1	3	1	3		
Influenza like illness		1		1		
Lung disorder	1	1	1	1		
Lymphadenitis		1				1
Lymphadenopathy		1				1
Malaise		1		1		
Myalgia	1	1	1	1		
Nausea	1	1	1	1		
Pain		2		1		1
Pain in extremity	1	2	1	2		
Pallor	1	1			1	1
Paraesthesia oral	1	1			1	1
Phlebitis		1				1
Pulmonary pain		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia	3	6	3	5		1
Red blood cell count increased		1		1		
Seizure	1	1			1	1
Swelling		1				1
Tumour pseudoprogession	1	1			1	1
Vaccination site pain		2		2		
Vomiting	1	1	1	1		
Wrong product administered		1		1		
	23	54	17	38	6	16

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Country Where Event Occurred

SINGAPORE

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1				1
Acute kidney injury		1				1
Acute psychosis		1				1
Anaphylactic reaction		9				9
Anaphylactic shock		1				1
Angioedema		2				2
Arthritis		1				1
Asthma		2				2
Bicytopenia		1				1
Blood pressure increased		1				1
Blood pressure systolic increased		2				2
Breath sounds abnormal		1				1
Chest discomfort		4		1		3
Chills		1		1		
Complement factor C3 increased		1				1
Confusional state		1				1
Diarrhoea		2		1		1
Diplopia	1	1			1	1
Disease recurrence		1				1
Dizziness		6				6
Dry eye		1				1
Dyskinesia		1				1
Dysphagia		1				1
Dysphonia		2		1		1
Dyspnoea		8		1		7
Eye movement disorder		1				1
Eye pruritus		1		1		
Eye swelling		1				1
Fatigue		1		1		
Feeding disorder		1				1
Flushing		1				1
Generalised tonic-clonic seizure		1				1
Haematuria		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache		2		1		1
Head discomfort		1		1		
Hypoaesthesia		2				2
Hypotension		1				1
Influenza like illness		1		1		
IVth nerve paralysis	1	1			1	1
Lacrimation increased		1				1
Mental status changes		1				1
Muscular weakness		1				1
Musculoskeletal stiffness		1				1
Myalgia		1		1		
Nausea		3		1		2
Nerve injury		1				1
Odynophagia		1				1
Oedema peripheral		1		1		
Optic neuritis		1				1
Oxygen saturation decreased		1				1
Palatal oedema		1				1
Palpitations		2				2
Parosmia		1		1		
Periorbital swelling		3		1		2
Pharyngeal mass		1		1		
Pharyngeal swelling		1				1
Pituitary tumour	1	1			1	1
Pneumonia aspiration		1				1
Proteinuria		1				1
Pruritus		1				1
Pyrexia		3		1		2
Radiculopathy		1				1
Rash		3				3
Rash erythematous		1		1		
Rash macular		1				1
Rash maculo-papular		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal impairment		1				1
Rheumatoid arthritis		1				1
Secretion discharge		1		1		
Seizure		1				1
Sensation of foreign body		1				1
Status epilepticus		1				1
Swelling face		1				1
Swollen tongue		1				1
Syncope		1				1
Tachycardia		2				2
Tenosynovitis		1				1
Throat irritation		3		2		1
Throat tightness		2		1		1
Troponin increased		1				1
Unresponsive to stimuli		1				1
Urticaria		2				2
Vaccination site erythema	1	2	1	2		
Vaccination site hypoaesthesia		1				1
Vaccination site pain		2				2
Vaccination site paraesthesia		1				1
Vaccination site pruritus	1	2	1	2		
Vaccination site rash	1	2	1	1		1
Vaccination site urticaria	1	1	1	1		
Vision blurred		1				1
Vomiting		4		1		3
Wheezing		3		1		2
	7	145	4	30	3	115

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Country Where Event Occurred

SLOVAKIA

090177e19749cf15\Approved\Approved On: 14-Jun-2021 14:01 (GMT)

* I=Interval, C=Cumulative

* AE=Adverse Event

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper		1		1		
Acute myocardial infarction		1				1
Altered state of consciousness		1				1
Amnesia		1				1
Anaphylactic reaction		1				1
Angioedema		1				1
Arthralgia		2		2		
Asphyxia		1				1
Asthenia	1	4	1	3		1
Asymptomatic COVID-19		1				1
Axillary pain		1		1		
Blood glucose increased		2		2		
Blood pressure increased		3		1		2
Body temperature decreased	1	1			1	1
Body temperature increased	1	2	1	1		1
Bone pain		1		1		
Cardiac failure		1				1
Cardiac failure chronic	1	1			1	1
Chest discomfort		1				1
Chills	3	6	2	5	1	1
Coronary artery disease	1	1			1	1
Cough	1	1	1	1		
COVID-19		2				2
COVID-19 pneumonia	1	1			1	1
Deafness		1				1
Dehydration		1		1		
Diarrhoea	1	3	1	2		1
Dizziness		4		3		1
Drug ineffective	1	3			1	3
Dyspnoea	2	3	1	1	1	2
Erysipelas		1				1
Extra dose administered		1		1		
Facial paresis	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fall		1		1		
Fatigue	1	3	1	3		
Feeling hot		1		1		
Feeling of body temperature change		1		1		
Flatulence		1		1		
Headache		1		1		
Head discomfort		1		1		
Hyperhidrosis		1		1		
Hypoaesthesia		1		1		
Influenza like illness	1	1	1	1		
Insulin resistance		1				1
Left ventricular hypertrophy	1	1			1	1
Limb discomfort		1		1		
Lip oedema		1		1		
Loss of consciousness		1				1
Lymphadenopathy		2		2		
Malaise		4		3		1
Migraine	1	1	1	1		
Movement disorder		1		1		
Myalgia	1	3	1	3		
Myocardial ischaemia		1				1
Nausea	1	3	1	3		
Oxygen saturation decreased	1	1			1	1
Pain in extremity		3		3		
Paraesthesia	1	2	1	2		
Pneumonia	1	1			1	1
Product administered at inappropriate site		1		1		
Prostatitis	1	1			1	1
Pruritus		1		1		
Pyelonephritis	1	1			1	1
Pyrexia	1	5	1	4		1
Rash		2		2		
Rash pruritic		2		2		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rectal haemorrhage	1	1			1	1
Retching		1		1		
Somnolence		1		1		
Speech disorder		1				1
Sudden hearing loss		1				1
Syncope		2				2
Thirst		1		1		
Tinnitus		1		1		
Tissue infiltration		1		1		
Urinary tract infection	1	1			1	1
Urosepsis	1	1			1	1
Urticaria		1				1
Vaccination failure		1				1
Vaccination site erythema		1		1		
Vaccination site oedema		1		1		
Vaccination site pain	2	8	2	8		
Vaccination site pruritus		1		1		
Vaccination site swelling		1		1		
Vaccination site urticaria		1		1		
Venous thrombosis limb		1				1
Vertigo		1		1		
Vomiting	1	3	1	2		1
Wheezing		1				1
	33	141	18	90	15	51

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Country Where Event Occurred

SLOVENIA

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Acute myocardial infarction		1				1
Acute respiratory failure		1				1
Anaemia	1	1			1	1
Anaphylactic reaction		1				1
Angioedema		1				1
Aphasia		1				1
Arthralgia	1	1			1	1
Asthenia	1	3		2	1	1
Asymptomatic bacteriuria		1				1
Atrial fibrillation		1				1
Back pain	1	1	1	1		
Basilar artery thrombosis		1				1
Blood creatine phosphokinase increased		1				1
Blood pressure increased		1		1		
Body temperature increased		1				1
Bradycardia		1				1
Brain injury		1				1
Cardiac arrest	1	2			1	2
Cardiac failure		1				1
Cardiac failure congestive		1				1
Cardiomegaly		1				1
Cardiopulmonary failure		1				1
Cerebral haemorrhage		1				1
Cerebrovascular accident		1				1
Chest discomfort		2		1		1
Chest pain	1	3	1	2		1
Chills		1		1		
Confusional state		1				1
Contusion		1		1		
Cough		1				1
COVID-19		3				3
COVID-19 pneumonia		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased insulin requirement	1	1	1	1		
Dementia		1				1
Diarrhoea		1		1		
Disease recurrence		1				1
Dysarthria		1				1
Dyspnoea		4		1		3
Epilepsy		1				1
Epistaxis	1	1			1	1
Erythema		1		1		
Eyelid oedema		1		1		
Eye pruritus		1		1		
Factor VIII deficiency	1	1			1	1
Fall		2				2
Fatigue	1	4	1	4		
Feeling hot		3		1		2
General physical health deterioration		1				1
Haematoma	1	1			1	1
Haemorrhage	1	1			1	1
Headache	1	3	1	3		
Herpes zoster	1	1			1	1
Hot flush		1				1
Hypertension		1				1
Hypochromasia		1		1		
Hypoglycaemia	1	1			1	1
Hypotension		1				1
Immobile		2				2
Infection	1	2	1	1		1
Ischaemic cerebral infarction		1				1
Ischaemic stroke		1				1
Joint injury	1	1	1	1		
Joint swelling	1	1			1	1
Lip oedema		1				1
Lip swelling		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Loss of consciousness		2				2
Lower respiratory tract infection		1				1
Lymphadenitis	1	1	1	1		
Malaise	2	6	2	3		3
Metabolic acidosis		1				1
Migraine		1		1		
Miosis		1				1
Monoparesis		1				1
Myalgia		2		1		1
Myocardial fibrosis		1				1
Myocardial infarction	2	3			2	3
Myoglobin blood increased		1				1
Nausea	1	3	1	2		1
Oropharyngeal pain		1		1		
Osteopenia		1		1		
Oxygen saturation decreased		3				3
Pain		1		1		
Pain in extremity	1	3	1	2		1
Paraesthesia		1		1		
Paraesthesia oral		1				1
Pharyngeal erythema		1		1		
Pneumonia		1				1
Pneumonia bacterial		1				1
Pneumothorax spontaneous		1				1
Pulmonary embolism		1				1
Pulmonary oedema		1				1
Pyrexia		2				2
Quadripareisis		1				1
Rash		1				1
Rash pruritic		1		1		
Respiratory acidosis		1				1
Restlessness		1		1		
Rhabdomyolysis		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensation of foreign body		1				1
Skin abrasion		1		1		
Skin disorder		1				1
Somnolence		2		1		1
Speech disorder	1	1			1	1
Subarachnoid haemorrhage		1				1
Sudden cardiac death		1				1
Sudden death		2				2
Superficial vein prominence		1				1
Swollen tongue		2		2		
Syncope		2				2
Tachycardia		2		2		
Tongue movement disturbance		1		1		
Tongue pruritus		2		2		
Total lung capacity decreased		1				1
Transient ischaemic attack	1	1			1	1
Unresponsive to stimuli		3				3
Urinary incontinence		1				1
Vaccination failure		1				1
Vaccination site pain		2		2		
Vaccination site warmth		1				1
Vascular stent thrombosis		1				1
Ventricular extrasystoles		1		1		
Vertebral artery thrombosis		1				1
Vertigo		3		2		1
Vomiting		1				1
White blood cell count increased		1		1		
	27	174	12	60	15	114

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Country Where Event Occurred

SOUTH AFRICA

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Death	1	1			1	1
Dizziness	1	1	1	1		
	2	2	1	1	1	1

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Country Where Event Occurred

SPAIN

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	5	1	3	1	2
Abdominal distension	1	1	1	1		
Abdominal pain	5	14	3	6	2	8
Abdominal pain lower	1	2	1	2		
Abdominal pain upper	3	7	1	3	2	4
Abdominal wall haematoma	1	1			1	1
Abnormal faeces		1		1		
Abortion spontaneous		1				1
Activated partial thromboplastin time shortened		1		1		
Acute coronary syndrome	1	2			1	2
Acute hepatic failure		1				1
Acute kidney injury	3	6			3	6
Acute leukaemia		1				1
Acute myocardial infarction	9	10			9	10
Acute respiratory distress syndrome		1				1
Acute respiratory failure	2	13			2	13
Adrenal mass		1		1		
Ageusia		1				1
Agitation	2	5	1	1	1	4
Alanine aminotransferase increased	1	1	1	1		
Allergy to vaccine	1	5		1	1	4
Amaurosis fugax		1				1
Amino acid level increased	1	1	1	1		
Amnesia		2		1		1
Amyloidosis senile	1	1			1	1
Anaemia	3	5	1	1	2	4
Anal incontinence	1	2		1	1	1
Anal sphincter atony		1				1
Anamnestic reaction	1	1			1	1
Anaphylactic reaction	3	19			3	19
Anaphylactic shock		2				2
Angina pectoris		1				1
Angioedema	1	6			1	6

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angiopathy	1	1	1	1		
Angular cheilitis		1		1		
Anisocytosis	1	1	1	1		
Anosmia		1				1
Antibody test abnormal		1		1		
Antipsychotic drug level increased		1				1
Anuria	1	1			1	1
Anxiety	4	7	1	3	3	4
Aortic arteriosclerosis	1	1			1	1
Aortic stenosis	1	1			1	1
Aortic valve incompetence	1	1			1	1
Apallic syndrome	1	1			1	1
Apathy		1				1
Aphasia	3	7	1	2	2	5
Aphonia	2	2	1	1	1	1
Aphthous ulcer		1				1
Apnoea		1				1
Appendicitis		1				1
Arrhythmia	1	3			1	3
Arterial thrombosis	1	1			1	1
Arteriosclerosis	2	2			2	2
Arteriosclerosis coronary artery	1	1			1	1
Arthralgia	11	29	6	14	5	15
Arthritis	1	1			1	1
Arthritis reactive		1				1
Asphyxia		2				2
Aspiration	5	6			5	6
AST/ALT ratio abnormal	2	2	2	2		
Asthenia	14	46	7	13	7	33
Asthenopia		1				1
Asthma		4		1		3
Asthmatic crisis		2				2
Asymptomatic bacteriuria	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19	3	10		1	3	9
Ataxia		1				1
Atelectasis		2				2
Atrial fibrillation	11	17			11	17
Atrioventricular block first degree		1		1		
Atypical haemolytic uraemic syndrome		1				1
Autoantibody negative		1				1
Autoimmune demyelinating disease		1				1
Autoimmune haemolytic anaemia		1				1
Autoimmune hepatitis		2				2
Axillary pain		1				1
Axillary vein thrombosis	1	1			1	1
Back pain	3	8	2	6	1	2
Bacteraemia	1	2			1	2
Bacterial test		1				1
Bacteriuria	2	2	2	2		
Balance disorder	1	5		2	1	3
Basal cell carcinoma	1	1			1	1
Basal ganglia haematoma	1	1			1	1
Basal ganglia stroke	1	1			1	1
Base excess decreased		1		1		
Basilar artery thrombosis		1				1
Bedridden		1				1
Bell's palsy	3	5			3	5
Bile duct stone	1	1			1	1
Biliary colic	1	1			1	1
Biliary cyst		1		1		
Biliary sepsis	1	1			1	1
Blepharitis		1		1		
Blindness unilateral		1				1
Blister	1	2	1	1		1
Blood bicarbonate decreased		1				1
Blood bicarbonate increased		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood calcium decreased		1		1		
Blood chloride decreased		1		1		
Blood cholesterol decreased	1	1	1	1		
Blood creatine phosphokinase increased	1	1			1	1
Blood creatinine decreased	2	2	2	2		
Blood creatinine increased	1	2	1	2		
Blood fibrinogen decreased		1		1		
Blood fibrinogen increased	5	6	4	5	1	1
Blood gases abnormal		1				1
Blood glucose decreased		1				1
Blood glucose increased	4	5	3	4	1	1
Blood iron decreased	1	1			1	1
Blood lactate dehydrogenase increased	1	3	1	2		1
Blood lactic acid increased	2	2	2	2		
Blood parathyroid hormone increased	1	1	1	1		
Blood phosphorus increased	1	1			1	1
Blood potassium decreased	1	1	1	1		
Blood pressure decreased	1	3		1	1	2
Blood pressure diastolic decreased	2	3	2	2		1
Blood pressure diastolic increased		1				1
Blood pressure increased	6	11	3	7	3	4
Blood pressure systolic increased	1	1	1	1		
Blood sodium decreased		1		1		
Blood sodium increased	1	1	1	1		
Blood urea increased	4	5	4	4		1
Body temperature decreased	2	4	2	3		1
Body temperature increased	1	1			1	1
Bradycardia	1	2			1	2
Bradykinesia		2		1		1
Bradyphrenia		4		2		2
Breast mass		1		1		
Breath sounds abnormal		1				1
Bronchial hyperreactivity		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchospasm	1	13			1	13
Bulbar palsy	1	1			1	1
Bundle branch block left		1				1
Capillary fragility	1	1	1	1		
Cardiac amyloidosis	1	1			1	1
Cardiac arrest	1	5			1	5
Cardiac death	1	1			1	1
Cardiac disorder		2		1		1
Cardiac failure	5	19			5	19
Cardiac failure acute	2	7			2	7
Cardiac failure congestive	3	6			3	6
Cardiac murmur	1	1	1	1		
Cardiac tamponade	1	2			1	2
Cardiogenic shock	1	1			1	1
Cardiomegaly	1	3	1	1		2
Cardio-respiratory arrest	8	19			8	19
Cardio-respiratory distress		1				1
Carotid bruit		1				1
Cell death		1				1
Cellulitis		1				1
Cellulitis staphylococcal		1				1
Cephalhaematoma		1				1
Cerebellar infarction		1				1
Cerebral arteriosclerosis	1	1			1	1
Cerebral disorder		1				1
Cerebral haematoma	1	3			1	3
Cerebral haemorrhage	1	5			1	5
Cerebral infarction		2				2
Cerebral ischaemia	1	1			1	1
Cerebral thrombosis	1	1			1	1
Cerebral venous sinus thrombosis	2	3			2	3
Cerebral venous thrombosis		1				1
Cerebrovascular accident	1	2			1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebrovascular disorder		1				1
Chest discomfort	2	5	1	2	1	3
Chest injury		1				1
Chest pain	9	16	5	5	4	11
Chest X-ray abnormal	1	1	1	1		
Chills	10	37	8	24	2	13
Choking		1				1
Choking sensation	1	4		1	1	3
Cholangitis	1	1			1	1
Cholecystitis	1	1			1	1
Cholestasis		1				1
Chronic kidney disease		2				2
Chronic obstructive pulmonary disease	2	3	1	1	1	2
Chronic respiratory failure		2				2
Chronic sinusitis	1	1	1	1		
Circadian rhythm sleep disorder		1				1
Citrobacter infection		1				1
Clostridium test positive	1	1			1	1
Cognitive disorder	1	3			1	3
Cold sweat	1	3		1	1	2
Colitis ischaemic	2	2			2	2
Colitis ulcerative		1				1
Colon neoplasm		1				1
Coma scale abnormal	1	1			1	1
Complications of transplanted kidney	1	1			1	1
Concomitant disease aggravated		3				3
Condition aggravated	11	21	2	2	9	19
Confusional state	5	8	3	3	2	5
Conjunctival haemorrhage		1				1
Conjunctival hyperaemia		1				1
Conjunctival laceration		1		1		
Constipation	1	6	1	4		2
Contraindication to vaccination	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Contusion	1	5		2	1	3
Coombs positive haemolytic anaemia		1				1
Coordination abnormal		1				1
Coronary artery stenosis	1	1			1	1
Costochondritis		1				1
Cough	5	14	3	6	2	8
COVID-19	4	24	2	4	2	20
COVID-19 pneumonia	4	12			4	12
Craniocerebral injury	1	5			1	5
C-reactive protein increased	3	6	1	4	2	2
Cutaneous vasculitis		1				1
Cyanosis		4		1		3
Death	3	9			3	9
Decreased appetite	3	10	1	3	2	7
Decreased nasolabial fold		1				1
Deep vein thrombosis	19	28			19	28
Dehydration	1	2		1	1	1
Delirium		3				3
Delusion		1				1
Demyelination		2				2
Depressed level of consciousness	2	12			2	12
Depressed mood		1		1		
Dermatitis	2	2			2	2
Dermatitis allergic	1	3			1	3
Diabetes mellitus	2	4			2	4
Diabetes mellitus inadequate control	1	2			1	2
Diabetic ketoacidosis		1				1
Diabetic metabolic decompensation		1				1
Diarrhoea	14	45	8	24	6	21
Diarrhoea haemorrhagic	1	2			1	2
Diplopia	1	5			1	5
Discomfort	1	6	1	3		3
Disease recurrence	5	8			5	8

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disorganised speech		1				1
Disorientation	3	12	1	4	2	8
Disturbance in attention		1				1
Diverticulitis intestinal haemorrhagic	1	1			1	1
Dizziness	11	47	4	15	7	32
Dizziness postural		1				1
Drowning	1	2			1	2
Drug effective for unapproved indication	1	1	1	1		
Drug hypersensitivity	1	1	1	1		
Drug ineffective	2	12			2	12
Drug interaction		2		1		1
Dry eye	1	2	1	2		
Dry mouth	2	2	2	2		
Dysaesthesia	2	2	1	1	1	1
Dysarthria	4	10	3	5	1	5
Dysgeusia		5		2		3
Dyskinesia		1				1
Dyspepsia	1	2			1	2
Dysphagia	3	9		1	3	8
Dysphonia		3		1		2
Dyspnoea	29	81	6	13	23	68
Dyspnoea at rest	1	2			1	2
Dyspnoea exertional		7		3		4
Dyspnoea paroxysmal nocturnal	1	1			1	1
Dysstasia	1	1	1	1		
Dystonia		1				1
Dysuria	1	4	1	3		1
Ear pain	2	2	1	1	1	1
Eating disorder		1		1		
Ecchymosis		1				1
Eczema	1	3	1	2		1
Effusion	1	1			1	1
Electrocardiogram abnormal	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Electrocardiogram normal		1				1
Electrocardiogram QRS complex prolonged		1				1
Electrocardiogram repolarisation abnormality		1				1
Electrocardiogram ST-T change		1				1
Embolic stroke	4	5			4	5
Emotional disorder	1	1			1	1
Encephalitis	1	4			1	4
Encephalopathy		1				1
Enterococcal infection		1				1
Eosinophil count increased	1	1	1	1		
Epididymitis	1	1			1	1
Epigastric discomfort		1				1
Epilepsy	2	5			2	5
Episcleritis		1				1
Epistaxis	3	6		1	3	5
Erythema	3	14	2	7	1	7
Escherichia infection		2				2
Escherichia urinary tract infection	1	1			1	1
Essential tremor		1				1
Extensor plantar response		1		1		
Extrapyramidal disorder		1				1
Eye irritation	1	1	1	1		
Eyelid disorder	1	1	1	1		
Eyelid oedema	1	3			1	3
Eyelid ptosis	1	1	1	1		
Eye pain	2	6	1	1	1	5
Eye swelling		1				1
Face injury		1				1
Face oedema	4	9	1	1	3	8
Facial paralysis	4	17			4	17
Facial paresis	1	1	1	1		
Faecal vomiting	1	1			1	1
Faeces soft		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fall	1	9		3	1	6
Fatigue	16	32	10	16	6	16
Fear	1	1	1	1		
Febrile convulsion		2				2
Feeling abnormal	2	3	2	3		
Feeling cold		1				1
Feeling hot	1	6		4	1	2
Fibrin D dimer increased	3	8	1	2	2	6
Fibrinolysis abnormal	1	1			1	1
Fluid overload		1				1
Flushing	2	2	1	1	1	1
Foreign body in throat	1	1			1	1
Formication		1		1		
Gait disturbance	6	12	3	3	3	9
Gait inability		4		1		3
Gallbladder enlargement		1				1
Gamma-glutamyltransferase increased		1		1		
Gastritis		1				1
Gastroenteritis	1	1			1	1
Gastrointestinal disorder	1	2	1	2		
Gastrointestinal haemorrhage	1	4			1	4
Gastrooesophageal reflux disease		1		1		
Generalised oedema	1	2			1	2
Generalised tonic-clonic seizure	3	7			3	7
General physical health deterioration	4	9	2	4	2	5
Giant cell arteritis		1				1
Gingival bleeding	1	1			1	1
Gingival swelling	1	1	1	1		
Glomerular filtration rate decreased	2	3	1	2	1	1
Glossitis		1				1
Glossodynia		1				1
Glycosylated haemoglobin increased	1	1	1	1		
Goitre	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Granulomatous liver disease		1				1
Guillain-Barre syndrome	3	5			3	5
Haematemesis	2	2			2	2
Haematocrit decreased	4	5	4	5		
Haematoma	1	6	1	5		1
Haematoma muscle	1	4			1	4
Haematuria		3		1		2
Haemodynamic instability	1	1			1	1
Haemoglobin decreased	2	5	1	4	1	1
Haemoglobin increased		1		1		
Haemophagocytic lymphohistiocytosis		1				1
Haemoptysis		2				2
Haemorrhage		1				1
Haemorrhage intracranial	1	2			1	2
Haemorrhagic diathesis		1				1
Haemorrhagic stroke	1	2			1	2
Hallucination	2	4			2	4
Hallucination, auditory		1				1
Hallucinations, mixed		1				1
Hallucination, visual	1	2			1	2
Headache	37	94	24	43	13	51
Head injury		3		1		2
Heart rate abnormal	1	1			1	1
Heart rate increased	1	3	1	2		1
Heavy menstrual bleeding	1	1	1	1		
Hemianaesthesia	1	1			1	1
Hemidysaesthesia		1				1
Hemiparaesthesia		4				4
Hemiparesis	1	4			1	4
Hemiplegia	1	3			1	3
Hepatic cyst	1	3	1	3		
Hepatic failure		1				1
Hepatic steatosis		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hepatitis acute		3				3
Hepatitis B virus test positive		1		1		
Herpes ophthalmic	1	2			1	2
Herpes simplex	1	1			1	1
Herpes virus infection	1	1	1	1		
Herpes zoster	10	22	2	3	8	19
Herpes zoster cutaneous disseminated		1				1
Herpes zoster oticus	1	1			1	1
Hiatus hernia	1	3	1	1		2
Humerus fracture	1	1			1	1
Hydrocephalus	1	1			1	1
Hyperaesthesia	1	1	1	1		
Hypercapnic coma	1	1			1	1
Hypercholesterolaemia		1		1		
Hyperglycaemia	4	12			4	12
Hyperhidrosis	3	7	1	3	2	4
Hyperkalaemia	1	2			1	2
Hypernatraemia		2				2
Hypersensitivity	4	11	2	3	2	8
Hypertension	6	20		2	6	18
Hypertensive crisis	3	13			3	13
Hypertensive encephalopathy		1				1
Hypertensive urgency		2				2
Hyperthermia	1	1	1	1		
Hyperthyroidism		1				1
Hypertrophic cardiomyopathy	1	1			1	1
Hyperuricaemia	1	1	1	1		
Hyperventilation	1	1			1	1
Hypoacusis	1	2	1	1		1
Hypoaesthesia	2	8	1	1	1	7
Hypoaesthesia eye		1				1
Hypoaesthesia oral		2		1		1
Hypocalcaemia	2	3	2	2		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypochromasia	1	1	1	1		
Hypochromic anaemia	1	1			1	1
Hypoglycaemia	2	5	1	1	1	4
Hypokalaemia	1	2			1	2
Hypomagnesaemia	1	1			1	1
Hyponatraemia	1	3			1	3
Hypophagia	1	1	1	1		
Hypoproteinaemia	1	1	1	1		
Hyporeflexia	1	1	1	1		
Hypotension	3	14		3	3	11
Hypothermia	1	1			1	1
Hypotonia		1		1		
Hypoxia	3	14			3	14
Ileus paralytic	1	2			1	2
Ill-defined disorder		1				1
Immobilisation syndrome		1		1		
Immune system disorder		1				1
Immune thrombocytopenia	3	7			3	7
Immunodeficiency	1	1			1	1
Inappropriate schedule of product administration		5		5		
Incoherent		2				2
Incorrect dose administered	3	5	3	5		
Incorrect route of product administration		2		2		
Increased bronchial secretion		1				1
Induration	1	1	1	1		
Infection		1		1		
Infective exacerbation of bronchiectasis		1				1
Inflammation		1				1
Inflammatory bowel disease		2				2
Influenza like illness		1		1		
Injury	1	2		1	1	1
Insomnia	3	4	2	2	1	2
Insulin resistance		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
International normalised ratio increased	4	4	2	2	2	2
Interstitial lung disease	1	3			1	3
Intervertebral disc disorder	1	1	1	1		
Intestinal angina	1	1			1	1
Intestinal ischaemia	1	2			1	2
Intestinal obstruction	1	2			1	2
Intraventricular haemorrhage	1	1			1	1
Iridocyclitis		1				1
Iron deficiency	1	1	1	1		
Iron deficiency anaemia	1	1			1	1
Ischaemia	1	1	1	1		
Ischaemic cerebral infarction		1				1
Ischaemic stroke	10	21			10	21
Jaundice	1	1	1	1		
Joint injury		1				1
Jugular vein thrombosis	2	2			2	2
Kaposi's sarcoma AIDS related		1				1
Keratitis		1				1
Labyrinthitis		1				1
Lacunar infarction	1	1			1	1
Lacunar stroke		1				1
Large intestine infection		1				1
Laryngeal disorder		1				1
Laryngeal oedema	1	4			1	4
Larynx irritation		1				1
Left ventricular failure	1	1			1	1
Leukocytosis	2	2			2	2
Leukoencephalopathy	1	2			1	2
Limb discomfort		2		1		1
Lipase decreased		1		1		
Lip oedema	1	8	1	1		7
Lip swelling	2	2			2	2
Liver function test abnormal		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Localised infection		1				1
Localised oedema		1				1
Local reaction	1	3	1	1		2
Loss of consciousness	4	13			4	13
Lower respiratory tract infection		1				1
Lung consolidation	1	1			1	1
Lung disorder		2				2
Lung infiltration	2	5	1	3	1	2
Lymphadenitis	1	1	1	1		
Lymphadenopathy	10	29	5	11	5	18
Lymphadenopathy mediastinal	1	1			1	1
Lymph node pain	1	1			1	1
Lymphocyte count decreased	3	4	3	4		
Lymphocyte count increased	1	2	1	2		
Lymphocyte percentage decreased		1		1		
Lymphopenia	2	2	2	2		
Macular oedema		1				1
Malaise	21	68	12	25	9	43
Maternal exposure during pregnancy		2		2		
Maternal exposure timing unspecified		1		1		
Mean cell haemoglobin concentration decreased	2	3	2	3		
Mean cell volume decreased	1	1	1	1		
Medication error		1		1		
Melaena		1				1
Memory impairment	2	2	2	2		
Meningitis aseptic	1	1			1	1
Meningitis herpes		1				1
Menstrual disorder	1	1	1	1		
Menstruation irregular	1	1	1	1		
Mental disorder		1				1
Mesenteric artery thrombosis	1	1			1	1
Mesenteric vein thrombosis	1	1			1	1
Microangiopathy	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Microcytosis	1	1	1	1		
Micturition urgency		1				1
Migraine		2				2
Migraine with aura		1				1
Mitral valve calcification	1	1			1	1
Mitral valve incompetence	1	1			1	1
Mitral valve stenosis	1	1			1	1
Mobility decreased	1	5	1	3		2
Monoparesis	1	2			1	2
Monoplegia		1				1
Morganella infection		1				1
Motor dysfunction	1	1			1	1
Mouth swelling		1				1
Mouth ulceration		1				1
Movement disorder	1	3	1	1		2
Mucosal disorder	1	1	1	1		
Multiple organ dysfunction syndrome	1	5			1	5
Multiple sclerosis		1				1
Muscle rigidity		1				1
Muscle spasms	2	3	2	2		1
Muscle strain	1	1			1	1
Muscle tightness		1				1
Muscular weakness	3	6	2	3	1	3
Musculoskeletal chest pain	1	2		1	1	1
Musculoskeletal discomfort	1	2	1	1		1
Musculoskeletal pain	2	10	1	3	1	7
Musculoskeletal stiffness	3	4	3	3		1
Mutism	1	1			1	1
Myalgia	16	54	13	28	3	26
Myocardial infarction		1				1
Myocardial ischaemia	1	1			1	1
Myocarditis		1				1
Myoclonic dystonia		1				1

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			Nonserious		Serious	
			I	C	I	C
Myositis		1				1
Nasal congestion	1	2			1	2
Nasal disorder		1		1		
Nasal herpes		1				1
Nasopharyngitis		1		1		
Nausea	11	44	7	22	4	22
Neck mass		1		1		
Neck pain	4	7	2	2	2	5
Neoplasm		2		1		1
Neoplasm progression	1	1	1	1		
Nephrotic syndrome	1	1			1	1
Nervousness	2	2	2	2		
Nervous system disorder	1	2	1	1		1
Neuralgia		3		1		2
Neutrophil count decreased	1	1			1	1
Neutrophil count increased	5	9	5	9		
Neutrophilia	1	2			1	2
Neutrophilic dermatosis		1				1
Neutrophil percentage increased		1		1		
Nodule		1		1		
N-terminal prohormone brain natriuretic peptide increased	1	2	1	1		1
Ocular discomfort	1	1	1	1		
Ocular icterus	1	1	1	1		
Odynophagia	5	8	2	2	3	6
Oedema	1	2		1	1	1
Oedema peripheral	6	12	4	6	2	6
Off label use	1	10	1	10		
Ophthalmic herpes zoster	2	3			2	3
Oral disorder		1				1
Oral herpes	1	1	1	1		
Oral pruritus		2				2
Oropharyngeal discomfort	1	2			1	2

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			Nonserious		Serious	
			I	C	I	C
Oropharyngeal pain	2	3	1	2	1	1
Orthopnoea	3	3	2	2	1	1
Ovarian cyst		1				1
Overdose		1		1		
Oxygen saturation decreased	8	21	2	4	6	17
Pain	6	9	3	4	3	5
Pain in extremity	5	13	2	6	3	7
Palatal oedema	2	5			2	5
Pallor	1	6		2	1	4
Palpitations	3	9	1	3	2	6
Pancreatitis chronic		1				1
Pancytopenia	1	2			1	2
Panic attack	1	1	1	1		
Paraesthesia	9	26	2	7	7	19
Paraesthesia oral	1	4			1	4
Paraparesis	1	3	1	1		2
Parosmia		1				1
Paroxysmal atrioventricular block	1	1			1	1
Partial seizures		2				2
PCO2 decreased		1		1		
PCO2 increased	2	2	2	2		
Periarthritis	1	1			1	1
Pericarditis	1	6			1	6
Periorbital haematoma		1				1
Peripheral coldness		2		2		
Peripheral ischaemia	1	2			1	2
Peripheral swelling		2		2		
Peripheral venous disease	1	2	1	1		1
Persistent depressive disorder		1				1
Persistent generalised lymphadenopathy		1				1
Petechiae	1	8		2	1	6
Petit mal epilepsy	1	4			1	4
Pharyngeal inflammation		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal lesion	1	1	1	1		
Pharyngotonsillitis		1				1
Phlebitis		1				1
Photophobia	1	3	1	2		1
Platelet count decreased	6	7	5	5	1	2
Platelet count increased	1	2	1	2		
Pleural effusion	3	7		1	3	6
Pleuritic pain		1				1
Pleuropericarditis	2	3			2	3
Pneumonia	2	11			2	11
Pneumonia aspiration	2	5			2	5
Pneumonitis		1				1
PO2 decreased	1	4	1	4		
Pollakiuria		1				1
Poor quality sleep		1				1
Portal vein thrombosis		1				1
Portosplenomesenteric venous thrombosis	1	1			1	1
Positron emission tomogram		1				1
Post thrombotic syndrome		1				1
Post-traumatic stress disorder	1	1			1	1
Prerenal failure		1				1
Presyncope	2	6			2	6
Procalcitonin increased	1	1			1	1
Proctalgia		1		1		
Product administered at inappropriate site	1	1	1	1		
Product administration interrupted	1	1	1	1		
Productive cough	1	2	1	2		
Product use issue		4		4		
Prothrombin level decreased		1				1
Prothrombin level increased	1	1			1	1
Prothrombin time prolonged		3		2		1
Prothrombin time shortened	1	1	1	1		
Pruritus	5	17	4	8	1	9

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pruritus allergic	1	1	1	1		
Psoriatic arthropathy		1				1
Psychomotor hyperactivity	1	3			1	3
Pulmonary embolism	24	52			24	52
Pulmonary haemorrhage		1				1
Pulmonary hypertension		1				1
Pulmonary infarction		2				2
Pulmonary oedema	2	2			2	2
Pulmonary sepsis		1				1
Pulmonary thrombosis		3				3
Pulse abnormal		1				1
Pulseless electrical activity	1	1			1	1
Pupils unequal	1	1	1	1		
Purpura		1				1
Pyrexia	47	163	33	76	14	87
Rash	4	13	1	4	3	9
Rash erythematous		2				2
Rash macular	3	3	2	2	1	1
Rash maculo-papular		2		1		1
Rash papular		1				1
Rash pruritic		5		1		4
Raynaud's phenomenon		1				1
Reaction to preservatives	1	1	1	1		
Rectal haemorrhage	1	4			1	4
Rectal tenesmus		1				1
Red cell distribution width increased	1	1	1	1		
Renal cyst		2		2		
Renal failure	1	5			1	5
Renal impairment	2	4			2	4
Respiratory acidosis	1	3			1	3
Respiratory alkalosis	2	2			2	2
Respiratory arrest		1				1
Respiratory distress	4	11			4	11

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory failure	3	10			3	10
Respiratory fatigue	1	1			1	1
Respiratory tract infection	2	7			2	7
Restlessness		3		2		1
Restrictive cardiomyopathy	1	1			1	1
Retinal artery occlusion		1				1
Retinal vein occlusion		1				1
Retinal vein thrombosis	2	3			2	3
Rheumatoid arthritis	1	1			1	1
Rhinitis	1	1	1	1		
Rhinorrhoea	1	2	1	2		
Rhonchi	2	2	1	1	1	1
Right ventricular hypertrophy	1	1			1	1
SARS-CoV-2 ant body test positive		1		1		
SARS-CoV-2 test positive	1	2		1	1	1
Scleritis		1				1
Scoliosis		1				1
Seizure	2	9			2	9
Sensation of foreign body	1	3	1	1		2
Sense of oppression		1				1
Sensory disturbance		2				2
Sensory loss	1	1			1	1
Sepsis	2	4			2	4
Septic shock		2				2
Serum ferritin abnormal	1	1			1	1
Serum ferritin increased	1	1	1	1		
Shock		1				1
Silent thyroiditis		1				1
Sinus bradycardia		1		1		
Sinus tachycardia		3		1		2
Skin exfoliation		1				1
Skin lesion	2	4	2	2		2
Skin ulcer	1	5		3	1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
SLE arthritis		1				1
Slow response to stimuli	1	1	1	1		
Slow speech		2		1		1
Sneezing	1	2		1	1	1
Somnolence	2	6	1	3	1	3
Spasmodic dysphonia		1		1		
Speech disorder	2	5	1	2	1	3
Spinal cord injury		1				1
Spinal osteoarthritis		1				1
Staphylococcal infection		1				1
Status epilepticus	1	2			1	2
Stomatitis		1		1		
Stridor	1	2			1	2
Subarachnoid haemorrhage	1	2			1	2
Subclavian vein thrombosis	2	2			2	2
Subcutaneous haematoma		1				1
Subdural haematoma	1	1			1	1
Sudden death	6	19			6	19
Suicide attempt		1				1
Swelling		1		1		
Swollen tongue	2	4			2	4
Syncope	6	30			6	30
Systemic inflammatory response syndrome	1	1			1	1
Systemic lupus erythematosus	1	2			1	2
Systolic dysfunction	1	1			1	1
Tachyarrhythmia		1				1
Tachycardia	3	19	2	5	1	14
Tachypnoea	4	10	2	4	2	6
Temperature regulation disorder	2	6	1	5	1	1
Tension headache		2				2
Thalamic infarction		1				1
Thalamus haemorrhage	1	1			1	1
Therapeutic response unexpected	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Throat irritation		5				5
Throat tightness	1	1	1	1		
Thrombocytopenia	8	11			8	11
Thrombophlebitis	2	3			2	3
Thrombophlebitis septic	1	1			1	1
Thrombophlebitis superficial		4		1		3
Thrombosis	1	2			1	2
Thrombosis mesenteric vessel	1	1			1	1
Tinnitus	1	2			1	2
Tongue oedema		3				3
Tongue pruritus		2				2
Tonic clonic movements		1				1
Toxicity to various agents		1				1
Tracheitis	1	1			1	1
Tracheobronchitis bacterial	1	1			1	1
Transaminases increased		1				1
Transferrin abnormal	1	1			1	1
Transient global amnesia		1				1
Transient ischaemic attack	2	6			2	6
Transverse sinus thrombosis	1	1			1	1
Tremor	4	9	3	5	1	4
Troponin I increased	1	2			1	2
Troponin T increased	1	2	1	1		1
Upper gastrointestinal haemorrhage		1				1
Upper limb fracture		1		1		
Urinary incontinence	1	2	1	2		
Urinary retention		1				1
Urinary sediment present		1		1		
Urinary tract infection	2	9		1	2	8
Urinary tract infection bacterial		1				1
Urinary tract infection pseudomonal		1				1
Urosepsis		1				1
Urticaria	3	12	1	4	2	8

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Uterine leiomyoma	1	1	1	1		
Uvulitis		1				1
Vaccination complication		1				1
Vaccination failure	4	18			4	18
Vaccination site cellulitis	1	1			1	1
Vaccination site erythema	1	3	1	3		
Vaccination site haematoma	1	3			1	3
Vaccination site induration	1	3	1	2		1
Vaccination site inflammation	1	3		1	1	2
Vaccination site joint erythema		2		2		
Vaccination site joint movement impairment	1	1	1	1		
Vaccination site joint pain	1	1	1	1		
Vaccination site joint swelling		1		1		
Vaccination site macule	1	1	1	1		
Vaccination site movement impairment		2		1		1
Vaccination site oedema	1	1			1	1
Vaccination site pain	19	42	15	30	4	12
Vaccination site paraesthesia		1				1
Vaccination site phlebitis	1	1			1	1
Vaccination site pruritus		3		1		2
Vaccination site rash		2				2
Vaccination site reaction	1	1	1	1		
Vaccination site swelling	1	2	1	2		
Vaccination site warmth	1	4	1	4		
Vaginal discharge		1		1		
Vaginal haemorrhage		1				1
Vascular graft thrombosis	1	1			1	1
Vasculitis		1				1
Vasoplegia syndrome	1	2			1	2
Venous thrombosis limb	2	7			2	7
Ventricular dysfunction		1				1
Ventricular enlargement		1				1
Ventricular extrasystoles		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ventricular f brillation		1				1
Ventricular hypokinesia	1	1			1	1
Vertigo	1	5	1	2		3
Viral keratouveitis		1				1
Vision blurred	3	9		1	3	8
Visual impairment		1				1
Vitamin B12 decreased	1	1	1	1		
Vitamin D decreased	1	1	1	1		
Vomiting	18	52	10	23	8	29
Vulvovaginal candidiasis	1	1	1	1		
Weight bearing difficulty	1	1			1	1
Wheezing		4		1		3
White blood cell count decreased	1	1			1	1
White blood cell count increased	5	7	5	7		
White matter lesion	1	1			1	1
Wound	1	1			1	1
Yersinia bacteraemia	1	1			1	1
Yersinia infection	1	1			1	1
	1,175	3,225	461	976	714	2249

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Country Where Event Occurred

SWEDEN

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	2	2	2		
Abdominal distension	2	2			2	2
Abdominal pain	6	12	2	3	4	9
Abdominal pain lower		1				1
Abdominal pain upper	3	6	2	3	1	3
Abdominal symptom		1				1
Abdominal tenderness	1	1	1	1		
Abnormal behaviour	1	4		1	1	3
Abnormal dreams	1	1			1	1
Abnormal uterine bleeding	1	1	1	1		
Abscess limb	1	1			1	1
Acetonaemia	1	1			1	1
Acute kidney injury	1	6			1	6
Acute left ventricular failure		1				1
Acute myocardial infarction	2	6			2	6
Acute respiratory distress syndrome	1	1			1	1
Acute respiratory failure	1	1			1	1
Adrenocortical insufficiency acute		1				1
Ageusia	1	3		1	1	2
Aggression		1				1
Agitation		2		1		1
Akathisia	1	1			1	1
Allergy to vaccine		1				1
Altered state of consciousness	1	1			1	1
Amnesia	1	1			1	1
Anaemia	2	3			2	3
Anaphylactic reaction	2	11			2	11
Anaphylactic shock	1	4			1	4
Angina pectoris	1	3			1	3
Angioedema		3				3
Anosmia	1	4		1	1	3
Anxiety	1	8	1	3		5
Aortic aneurysm	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic arteriosclerosis		2		1		1
Aortic rupture	1	1			1	1
Apathy	1	1			1	1
Aphasia		2				2
Apnoea		2				2
Arrhythmia	1	4			1	4
Arterial thrombosis		1				1
Arteriosclerosis	2	4			2	4
Arteriosclerosis coronary artery		1				1
Arthralgia	12	19	5	10	7	9
Arthritis		3				3
Ascites		1				1
Aspiration		1				1
Asthenia	5	16	4	6	1	10
Asthenopia		2				2
Asthma		1				1
Asymptomatic COVID-19		1				1
Atelectasis		1				1
Atrial f brillation	5	11			5	11
Atrial flutter	1	2			1	2
Atrial septal defect		1				1
Atrial thrombosis		1				1
Atrioventricular block complete		2				2
Atypical pneumonia	1	1			1	1
Autonomic nervous system imbalance		1				1
Axillary pain		1				1
Back pain	1	5	1	2		3
Balance disorder	3	8			3	8
Ballismus	1	1			1	1
Basedow's disease	1	2			1	2
Basilar artery thrombosis		1				1
Bedridden	1	1	1	1		
Bell's palsy		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Biliary colic	1	2			1	2
Biliary dilatation		1				1
Biliary tract disorder		1				1
Bladder dysfunction	1	1			1	1
Blepharospasm	1	1			1	1
Blindness	1	1			1	1
Blindness unilateral	1	1			1	1
Blister	1	2	1	1		1
Blood albumin increased	1	1			1	1
Blood alkaline phosphatase increased		1				1
Blood bilirubin increased		1				1
Blood creatine increased	1	1	1	1		
Blood creatinine increased		3		3		
Blood fibrinogen decreased		1				1
Blood glucose abnormal		1		1		
Blood glucose decreased		2		1		1
Blood glucose increased	2	5	1	2	1	3
Blood lactate dehydrogenase increased		1				1
Blood phosphorus decreased		1		1		
Blood potassium increased		2		1		1
Blood pressure abnormal		1				1
Blood pressure decreased	2	10	1	3	1	7
Blood pressure diastolic decreased		1		1		
Blood pressure fluctuation	1	1			1	1
Blood pressure increased	1	2	1	2		
Blood pressure measurement	1	1			1	1
Blood pressure systolic increased		1				1
Body temperature decreased		2				2
Body temperature increased	1	4	1	2		2
Bone disorder		1		1		
Bradycardia		1				1
Brain herniation		1				1
Brain injury	1	2			1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Brain scan abnormal		1				1
Breath sounds abnormal		1				1
Bronchial haemorrhage		1				1
Bronchitis		1				1
Bundle branch block left		2		1		1
Bundle branch block right		1				1
Cachexia		1				1
Cardiac arrest	2	20			2	20
Cardiac death		1				1
Cardiac disorder	1	4			1	4
Cardiac failure	1	17			1	17
Cardiac failure acute	1	3			1	3
Cardiac failure chronic		1				1
Cardiac fibrillation		1				1
Cardiac murmur		1				1
Cardiogenic shock		2				2
Cardiopulmonary failure		1				1
Cardiovascular disorder		1				1
Catheter site haemorrhage		1		1		
Cerebellar haemorrhage		1				1
Cerebellar infarction	1	1			1	1
Cerebral artery embolism	1	2			1	2
Cerebral atrophy		1				1
Cerebral disorder	1	1			1	1
Cerebral haemorrhage	4	9			4	9
Cerebral infarction	4	7			4	7
Cerebral ischaemia	1	1			1	1
Cerebral small vessel ischaemic disease	1	1			1	1
Cerebrovascular accident	9	21			9	21
Cerebrovascular disorder	2	3			2	3
Chest discomfort	2	8	1	4	1	4
Chest pain	4	20	1	6	3	14
Chills	13	37	6	17	7	20

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chronic gastritis		1				1
Chronic obstructive pulmonary disease	2	7			2	7
Chronic respiratory failure		1				1
Circulatory collapse	1	7			1	7
Circumoral swelling	1	1			1	1
Coagulopathy		1				1
Coeliac artery stenosis		1				1
Cognitive disorder	3	4			3	4
Cold sweat	1	3		1	1	2
Colitis	1	1			1	1
Colitis ulcerative	1	1			1	1
Coma	1	1			1	1
Condition aggravated	3	15		1	3	14
Confusional state	3	16		2	3	14
Constipation		1		1		
Contusion	2	3			2	3
Coronary artery disease	1	1			1	1
Coronary artery stenosis		1				1
Coronary artery thrombosis	1	1			1	1
Cor pulmonale acute		1				1
Cough	6	22	3	12	3	10
COVID-19	7	20	3	3	4	17
COVID-19 pneumonia		1				1
Cranial nerve disorder		1				1
C-reactive protein decreased	1	1	1	1		
C-reactive protein increased	2	15	1	7	1	8
Crepitations		2		1		1
Crying		1		1		
Cutaneous vasculitis	1	1			1	1
Cyanosis		4		2		2
Death	3	37			3	37
Decreased appetite	3	15	2	7	1	8
Decubitus ulcer		1		1		

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			Nonserious		Serious	
			I	C	I	C
Deep vein thrombosis	7	21			7	21
Dehydration		7		1		6
Delirium		1				1
Delusional disorder, unspecified type		1				1
Dementia		1				1
Dementia Alzheimer's type		1				1
Depressed level of consciousness		13				13
Depression	1	2	1	2		
Depressive symptom	1	1			1	1
Dermatitis		2		1		1
Device related infection		1				1
Diarrhoea	8	30	2	11	6	19
Dilatation ventricular		1		1		
Discomfort	1	2		1	1	1
Disease recurrence	2	10		1	2	9
Disorganised speech		1				1
Disorientation		2		1		1
Dissociation		1				1
Disturbance in attention		1		1		
Diverticulitis		1				1
Diverticulum		1		1		
Dizziness	29	55	10	17	19	38
Drug eruption		1				1
Drug ineffective	2	9			2	9
Drug intolerance	1	1			1	1
Dry eye	1	1			1	1
Dry mouth	1	2	1	1		1
Dry skin		1		1		
Dysarthria	1	4		1	1	3
Dysgeusia		3				3
Dysphagia		9		4		5
Dysphonia	1	2			1	2
Dyspnoea	19	79	2	9	17	70

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea exertional		1				1
Dysstasia	1	3	1	1		2
Dystonia		1				1
Ear swelling		1				1
Eating disorder		1				1
Ecchymosis	1	1			1	1
Eczema		1				1
Electrocardiogram ST segment elevation		1				1
Electrocardiogram T wave inversion		1				1
Electrolyte imbalance		1		1		
Embolic cerebral infarction		1				1
Embolism	1	3			1	3
Embolism arterial		1				1
Encephalitis		1				1
Epilepsy		1				1
Epistaxis		4		2		2
Erysipelas	1	4			1	4
Erythema	2	17		8	2	9
Escherichia infection		1				1
Escherichia sepsis		1				1
Extrasystoles		2				2
Eye disorder		1				1
Eye inflammation	1	1			1	1
Eye irritation		1				1
Eye pain		5				5
Face injury		1				1
Facial neuralgia		1				1
Facial paralysis		4				4
Facial paresis	2	9			2	9
Fall	3	14	1	4	2	10
Fatigue	34	110	15	47	19	63
Fear	1	1			1	1
Feeling abnormal	2	7	1	3	1	4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feeling cold		3		2		1
Feeling hot	2	7		2	2	5
Feeling of body temperature change		1				1
Femoral neck fracture		1				1
Fluid intake reduced		1				1
Food refusal		1				1
Gait disturbance	6	7		1	6	6
Gamma-glutamyltransferase increased		1				1
Gastric disorder		1		1		
Gastric haemorrhage		1				1
Gastroenteritis		1				1
Gastrointestinal haemorrhage		1				1
Generalised oedema		2				2
Generalised tonic-clonic seizure		1				1
General physical health deterioration	6	46	1	9	5	37
Gingival bleeding	1	1			1	1
Gingival erythema	1	1			1	1
Gingival swelling	1	1			1	1
Glomerular filtration rate decreased		2		1		1
Glossodynia		1		1		
Glucose tolerance impaired	1	1			1	1
Goitre		1				1
Gout		1				1
Graft versus host disease		1				1
Grip strength decreased	1	1			1	1
Haematemesi		4				4
Haematochezia		1				1
Haematoma		5				5
Haematuria		1				1
Haemoglobin decreased		2				2
Haemolytic anaemia		2				2
Haemoptysis		1				1
Haemorrhage		4				4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemorrhage intracranial		1				1
Haemorrhage subcutaneous	2	2			2	2
Hallucination	1	3			1	3
Hallucination, visual		2				2
Headache	32	81	16	37	16	44
Head discomfort	1	1	1	1		
Head injury	1	4		2	1	2
Heart rate decreased	1	3	1	2		1
Heart rate increased	6	12		1	6	11
Heart rate irregular		2		2		
Hemiparesis	1	6			1	6
Hepatic enzyme increased	1	1			1	1
Hepatic pain	1	1			1	1
Herpes zoster	2	6	2	3		3
Hiccups		1				1
Hip fracture		1				1
Hot flush		1				1
Hydrothorax		1				1
Hyperacusis		1				1
Hypercalcaemia		1				1
Hyperglycaemia	1	2			1	2
Hyperhidrosis	1	12		5	1	7
Hypernatraemia		1				1
Hyperparathyroidism primary		1		1		
Hypersensitivity	4	15		1	4	14
Hypersomnia	1	1			1	1
Hypertension	1	6			1	6
Hypertonic bladder	1	1			1	1
Hyperventilation	1	3	1	1		2
Hypoacusis		1				1
Hypoaesthesia	4	14		3	4	11
Hypoaesthesia oral	1	5			1	5
Hypoalbuminaemia		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoglycaemia	1	4			1	4
Hypokalaemia		1				1
Hypokinesia	1	2			1	2
Hypoperfusion		1				1
Hypophagia		2				2
Hypopnoea		1				1
Hypotension		18		2		16
Hypothermia		3				3
Hypovolaemic shock	1	1			1	1
Hypoxia		1				1
Idiopathic pulmonary fibrosis		1				1
Illness		1				1
Immune thrombocytopenia	1	2			1	2
Immunisation reaction		1				1
Inappropriate schedule of product administration	1	3	1	3		
Incontinence	1	2		1	1	1
Incorrect route of product administration		4		4		
Increased insulin requirement	1	1	1	1		
Increased tendency to bruise	1	1			1	1
Increased upper airway secretion		2		2		
Infection	1	11		1	1	10
Inflammation	2	2			2	2
Inflammatory marker increased	2	2			2	2
Influenza like illness		5		3		2
Infrequent bowel movements		1		1		
Insomnia		3		1		2
Interstitial lung disease	1	1			1	1
Intestinal haemorrhage		3				3
Intestinal ischaemia		2				2
Intracardiac thrombus	1	1			1	1
Intraventricular haemorrhage	1	1			1	1
Irregular breathing		1		1		
Ischaemic stroke	3	8			3	8

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Jaundice		1				1
Jaw disorder		1				1
Lacrimation increased		1				1
Lactic acidosis		1				1
Lacunar infarction	1	1			1	1
Laryngeal oedema		1				1
Left ventricular hypertrophy		1				1
Lethargy		1				1
Leukocytosis	1	2	1	1		1
Leukopenia		2				2
Ligament sprain	1	1			1	1
Lip swelling		1				1
Livedo reticularis		1		1		
Liver disorder		1				1
Loss of consciousness	1	14			1	14
Loss of personal independence in daily activities	1	1			1	1
Low density lipoprotein increased	1	1			1	1
Lung disorder		2				2
Lung infiltration	2	3			2	3
Lung opacity	1	1			1	1
Lung transplant rejection		1				1
Lymphadenitis		1				1
Lymphadenopathy		4		2		2
Lymphoedema		1				1
Malaise	11	30	3	12	8	18
Memory impairment	2	4		2	2	2
Meningism		1				1
Meningitis		1				1
Menstruation irregular	1	1			1	1
Mesenteric artery embolism		1				1
Metabolic disorder		1		1		
Metastasis		1				1
Migraine	1	5		1	1	4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Miosis		1		1		
Motor dysfunction		1				1
Mouth swelling	1	1			1	1
Movement disorder	1	1			1	1
Multiple sclerosis		2				2
Muscle spasms		6		3		3
Muscle tone disorder		1				1
Muscular weakness	2	6			2	6
Musculoskeletal discomfort	1	1			1	1
Musculoskeletal stiffness	4	8	3	3	1	5
Myalgia	14	33	5	13	9	20
Myelitis		1				1
Myelosuppression		1				1
Myocardial fibrosis		1				1
Myocardial infarction	5	15			5	15
Myocardial ischaemia		3				3
Myocardial rupture		1				1
Myocarditis	1	2			1	2
Nail discolouration		1				1
Nasal congestion		4		1		3
Nasal dryness	1	1	1	1		
Nasal oedema	1	2		1	1	1
Nasopharyngitis	2	7	1	2	1	5
Nausea	22	58	9	22	13	36
Neck pain	4	6	1	2	3	4
Necrotising fasciitis	1	1			1	1
Neoplasm progression	1	2			1	2
Neuralgic amyotrophy		1				1
Neuritis		1				1
Neurological symptom	1	1			1	1
Neuropathy peripheral		1				1
Neuropsychiatric symptoms	1	1			1	1
Nightmare		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
N-terminal prohormone brain natriuretic peptide increased		1		1		
Obstructive airways disorder		2				2
Ocular discomfort	1	1	1	1		
Ocular hyperaemia	1	1			1	1
Oedema peripheral	1	2		1	1	1
Off label use	2	5	2	5		
Ophthalmic migraine	1	1			1	1
Oral herpes		2		2		
Oral pain		1		1		
Oral pruritus		2		2		
Oropharyngeal pain	3	13	2	8	1	5
Oropharyngeal spasm		1				1
Oropharyngeal swelling	1	1			1	1
Orthostatic hypotension	1	2			1	2
Osteoarthritis	1	1			1	1
Oxygen saturation abnormal		1		1		
Oxygen saturation decreased		24		3		21
Pain	9	32	5	14	4	18
Pain in extremity	22	42	8	18	14	24
Pain in jaw	1	2			1	2
Pain of skin	1	2	1	2		
Pallor		7		4		3
Palpable purpura	1	1			1	1
Palpitations	5	14		4	5	10
Pancytopenia		1				1
Paraesthesia	4	14		3	4	11
Paranasal sinus haemorrhage		1		1		
Paraparesis	1	1			1	1
Parkinson's disease		1				1
Parosmia	1	2			1	2
PCO2 increased		1		1		
Pemphigoid		2				2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pericardial effusion		1				1
Pericardial haemorrhage		1				1
Pericarditis		1				1
Periorbital oedema		2				2
Peripheral coldness		1				1
Peripheral embolism		1				1
Peripheral motor neuropathy		1				1
Peripheral sensory neuropathy		1				1
Peripheral swelling	10	19	1	3	9	16
Personality change	1	1			1	1
Petechiae		4		1		3
Petit mal epilepsy		2				2
Pharyngeal disorder		1				1
Pharyngeal hypoaesthesia		1				1
Pharyngeal swelling	4	7	1	1	3	6
Pharyngitis		1		1		
Phlebitis		1				1
Photophobia		1				1
Physical disability	1	1			1	1
Platelet count decreased		2		1		1
Pleural effusion		1				1
Pneumonia	2	12			2	12
Pneumonia aspiration		3				3
Pneumonia bacterial		1				1
Pneumonia pneumococcal		1				1
Pneumonia streptococcal		1				1
Polyarthrits		1				1
Polyneuropathy	1	2			1	2
Postoperative wound complication		1				1
Post stroke epilepsy		1				1
Presyncope		2		1		1
Procalcitonin decreased	1	1	1	1		
Procalcitonin increased		2				2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Productive cough		5				5
Product use issue	1	2	1	2		
Pruritus	7	15	3	5	4	10
Psoriasis		1		1		
Psychotic disorder		1				1
Pulmonary artery thrombosis		1				1
Pulmonary embolism	19	50			19	50
Pulmonary fibrosis	1	1			1	1
Pulmonary hypertension		1				1
Pulmonary infarction		1				1
Pulmonary oedema	3	10			3	10
Pulmonary pain	1	1	1	1		
Pulmonary thrombosis		2				2
Pulse abnormal		2		2		
Pyrexia	23	118	15	47	8	71
Rash	3	10	1	5	2	5
Rash erythematous		2				2
Rash macular	1	1			1	1
Rash pruritic		1				1
Red blood cell sedimentation rate increased		1				1
Renal failure	1	2			1	2
Renal haemorrhage		1				1
Renal impairment		2				2
Renal infarct		1				1
Renal pain	1	1	1	1		
Respiration abnormal		1				1
Respiratory arrest		5				5
Respiratory disorder	1	2		1	1	1
Respiratory distress		8				8
Respiratory failure	2	5			2	5
Respiratory rate increased		6		1		5
Respiratory symptom	1	1			1	1
Restless legs syndrome		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Retinal tear	1	1			1	1
Retinal vein occlusion	1	2			1	2
Rhinitis		1		1		
Rhinorrhoea	1	3	1	3		
Rib fracture		1				1
Scapula fracture		1				1
Sciatica		1		1		
Seizure		7				7
Seizure like phenomena		2				2
Sensation of foreign body		1				1
Sensory disturbance	1	1			1	1
Sepsis	3	9			3	9
Septic shock		2				2
Sinus tachycardia	1	1			1	1
Skin discolouration	1	3			1	3
Skin turgor decreased		1				1
Slow speech		1				1
Solar dermatitis		1				1
Somnolence	2	7	1	2	1	5
Speech disorder	1	4		1	1	3
Spinal pain		1		1		
Spinal subdural haemorrhage	1	1			1	1
Spleen disorder		1				1
Status epilepticus		1				1
Stevens-Johnson syndrome		1				1
Streptococcal bacteraemia		1				1
Stress		1		1		
Stress cardiomyopathy	1	1			1	1
Stroke in evolution	1	1			1	1
Subarachnoid haemorrhage		2				2
Subcutaneous haematoma	1	1			1	1
Subdural haematoma	1	3			1	3
Sudden death		4				4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sudden visual loss		1				1
Swelling	1	5	1	2		3
Swelling face	3	7		1	3	6
Swollen tongue		1				1
Syncope	1	7			1	7
Systemic inflammatory response syndrome		1				1
Systemic lupus erythematosus		1				1
Tachycardia		4		1		3
Tachypnoea		3		2		1
Taste disorder	1	3		1	1	2
Temperature regulation disorder		1		1		
Tenderness	1	2	1	1		1
Tenosynovitis		1				1
Throat irritation		1		1		
Throat tightness		3				3
Thrombocytopenia	2	11			2	11
Thrombocytopenic purpura		1				1
Thrombophlebitis		1				1
Thrombophlebitis superficial		1				1
Thrombosis	3	8			3	8
Tinnitus	2	7			2	7
Tongue erythema		1		1		
Toxic epidermal necrolysis		1				1
Tracheal haemorrhage		1				1
Transaminases increased		1				1
Transient global amnesia	1	1			1	1
Transient ischaemic attack	4	8			4	8
Tremor	4	8	1	2	3	6
Troponin abnormal	1	1			1	1
Troponin increased		1		1		
Troponin T increased	1	1			1	1
Unresponsive to stimuli		2				2
Upper gastrointestinal haemorrhage		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Upper respiratory tract infection		1				1
Urinary incontinence		1				1
Urinary retention		1				1
Urinary tract infection	2	12		5	2	7
Urine output decreased		2				2
Urosepsis		3				3
Urticaria	3	10	1	3	2	7
Vaccination failure	1	5			1	5
Vaccination site bruising		1				1
Vaccination site discolouration	1	1			1	1
Vaccination site erythema	3	15	1	10	2	5
Vaccination site haematoma	1	3			1	3
Vaccination site haemorrhage	2	2			2	2
Vaccination site induration		3		2		1
Vaccination site lymphadenopathy		1				1
Vaccination site pain	13	35	9	24	4	11
Vaccination site pruritus	3	4		1	3	3
Vaccination site reaction	2	4		1	2	3
Vaccination site swelling	4	16	1	10	3	6
Vaccination site warmth	1	6	1	6		
Vascular dementia		1				1
Vasculitis		1				1
Vasodilatation		1		1		
Ventricular fibrillation		2				2
Ventricular tachycardia		1				1
Vertigo	1	2	1	2		
Vestibular neuritis	1	1			1	1
Viral infection		1		1		
Vision blurred	1	2			1	2
Visual field defect	2	2			2	2
Visual impairment	1	1			1	1
Vitreous detachment	1	1			1	1
Vomiting	9	46	2	8	7	38

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Weight decreased	1	1			1	1
Wheezing		9		2		7
White blood cell count decreased		1		1		
White blood cell count increased		2		2		
White blood cells urine positive		1		1		
Wound		2		1		1
	732	2,641	191	664	541	1977

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Country Where Event Occurred

SWITZERLAND

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort		1		1		
Abdominal pain	2	6	1	2	1	4
Acute kidney injury	1	3			1	3
Acute myocardial infarction		2				2
Acute pulmonary oedema		2				2
Acute stress disorder	1	1			1	1
Alanine aminotransferase increased		1		1		
Altered state of consciousness		1				1
Anaemia		1				1
Anal haemorrhage		1		1		
Anaphylactic reaction	1	6			1	6
Anaphylactic shock		1				1
Angioedema	1	4			1	4
Aphasia		1				1
Aphthous ulcer		1				1
Apnoea		1				1
Arrhythmia	1	1			1	1
Arteriosclerosis		1				1
Arteriosclerosis coronary artery		1				1
Arthralgia	3	6	3	3		3
Ascites		1				1
Asthenia	4	10	3	5	1	5
Asthma	1	3			1	3
Atrial fibrillation	1	2			1	2
Atrioventricular block second degree	1	1			1	1
Atrophy		1				1
Atypical pneumonia	1	1			1	1
Autonomic nervous system imbalance	1	1	1	1		
Back pain		3		2		1
Balance disorder	3	3	2	2	1	1
Blood alkaline phosphatase increased		1		1		
Blood pressure decreased		1				1
Blood pressure increased		2				2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Body temperature increased	1	1	1	1		
Brain hypoxia		1				1
Bronchial wall thickening	1	1	1	1		
Cardiac arrest		2				2
Cardiac disorder	1	1			1	1
Cardiac failure		4				4
Cardiac failure acute		1				1
Cardiac failure chronic		1				1
Cardiac fibrillation		1				1
Cardiac valve disease		1				1
Cardiogenic shock	1	1			1	1
Cardio-respiratory arrest		1				1
Cerebral infarction		1				1
Cerebrovascular accident		2				2
Chest injury	1	1			1	1
Chills	3	9	2	3	1	6
Cholecystitis acute		1				1
Cholestasis		2				2
Chronic obstructive pulmonary disease		2				2
Circulatory collapse	2	3			2	3
Colitis ulcerative	1	1			1	1
Coma		2				2
Condition aggravated	3	5	1	1	2	4
Confusional state	1	3	1	1		2
Cough	1	3	1	2		1
COVID-19	2	12		1	2	11
COVID-19 pneumonia	2	3			2	3
Craniocerebral injury	1	1			1	1
C-reactive protein increased	2	6	1	2	1	4
Crohn's disease	1	1			1	1
CSF test abnormal		1				1
Cystitis		1				1
Death	2	8			2	8

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite		2				2
Deep vein thrombosis	2	3			2	3
Dehydration		2				2
Delirium		4				4
Dermatitis bullous	1	1			1	1
Diabetic ketoacidosis		1				1
Diabetic metabolic decompensation		1				1
Diarrhoea	5	11	4	5	1	6
Diarrhoea haemorrhagic	1	1			1	1
Disease recurrence	2	3			2	3
Disorientation		1				1
Disturbance in attention		1				1
Dizziness	4	11	3	5	1	6
Drug ineffective	1	2			1	2
Drug interaction	1	1	1	1		
Duodenal ulcer haemorrhage	1	1			1	1
Dyskinesia	1	1	1	1		
Dysphonia		1		1		
Dyspnoea	6	14	1	3	5	11
Ear discomfort	1	1	1	1		
Embolism		1				1
Encephalitis	2	2			2	2
Encephalopathy	1	1			1	1
Enthesopathy	1	1	1	1		
Enuresis		1				1
Eosinophilia		1		1		
Epilepsy		3				3
Epistaxis		1		1		
Erythema	1	2			1	2
Erythema annulare		1				1
Extrasystoles	1	1			1	1
Extremity necrosis	1	1			1	1
Eyelid oedema		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facet joint syndrome	1	1	1	1		
Facial bones fracture	1	1			1	1
Facial paralysis	1	2			1	2
Facial paresis		1				1
Fall	3	5	1	1	2	4
Fatigue	8	14	5	6	3	8
Feeding disorder		2		1		1
Feeling cold		1		1		
Feeling hot	1	2			1	2
Fluid overload		1				1
Gastric disorder		1				1
Gastritis		1				1
Gastrointestinal disorder		1				1
Gastroesophageal reflux disease		1				1
Generalised tonic-clonic seizure	1	2			1	2
General physical health deterioration		4		2		2
Haematemesis		1				1
Haemophagocytic lymphohistiocytosis		1				1
Haemoptysis	1	1			1	1
Headache	7	16	3	6	4	10
Head injury	1	1			1	1
Heart rate decreased		1				1
Heavy menstrual bleeding	1	1	1	1		
Hemiplegia		1				1
Hepatic cirrhosis		1				1
Hepatocellular injury		1				1
Herpes zoster	4	9			4	9
Hot flush	1	1			1	1
Hyperglycaemia		1				1
Hypersensitivity	1	5			1	5
Hypertension	3	9		2	3	7
Hypertensive crisis	2	2			2	2
Hypertensive emergency		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperthermia	1	2		1	1	1
Hyperventilation	1	1			1	1
Hypoglycaemic coma		1				1
Hypotension	1	5	1	2		3
Immune thrombocytopenia		1				1
Immunisation anxiety related reaction		1				1
Inappropriate schedule of product administration	1	1	1	1		
Incorrect route of product administration	2	8	2	8		
Infection		1		1		
Inflammation		2				2
Influenza like illness		2				2
Ischaemic cerebral infarction		1				1
Joint swelling	2	3	1	1	1	2
Left ventricular failure		1				1
Lethargy		1		1		
Leukopenia	1	1			1	1
Lip swelling	1	1	1	1		
Liver disorder		1				1
Liver injury		1				1
Loss of consciousness		2				2
Lung consolidation	1	1	1	1		
Lung disorder		1				1
Lung infiltration	1	1			1	1
Lymphadenopathy	3	4	2	2	1	2
Lymphangiectasia		1				1
Lymphopenia		1				1
Malaise	5	14	2	5	3	9
Meniere's disease		1				1
Meningioma		1				1
Mobility decreased		1		1		
Monocytosis		1		1		
Multiple sclerosis relapse	1	1			1	1
Muscular weakness		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal stiffness	1	1	1	1		
Myalgia	4	9	2	4	2	5
Myelitis		1				1
Myocarditis	1	1			1	1
Nausea	5	15	4	6	1	9
Neck pain	1	1	1	1		
Nervous system disorder		1				1
Neuralgia	1	1	1	1		
Neutrophilia		1				1
Odynophagia		1				1
Oesophageal perforation		1				1
Off label use	2	2	2	2		
Oropharyngeal pain		1		1		
Overdose	1	1	1	1		
Oxygen saturation decreased		3				3
Pain	3	5	2	2	1	3
Pain in extremity	2	2			2	2
Pallor	1	1	1	1		
Palpitations		1				1
Pancreatitis		1				1
Paraesthesia	1	2	1	1		1
Paraesthesia ear	1	1	1	1		
Paranoia		1				1
Paresis	1	1	1	1		
Pemphigoid	1	1			1	1
Performance status decreased		1				1
Peripheral swelling	1	2			1	2
Peripheral vascular disorder		1				1
Peripheral venous disease	1	1	1	1		
Petechiae	1	1			1	1
Pleural effusion		1		1		
Pneumonia		4				4
Pneumonia aspiration	1	2			1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonia bacterial		1				1
Pneumonia pneumococcal		1				1
Polyneuropathy		1				1
Presyncope	2	3			2	3
Pruritus		2				2
Pulmonary congestion	1	1			1	1
Pulmonary embolism	3	6			3	6
Pulmonary fibrosis		1				1
Purpura		1				1
Pyrexia	7	27	2	5	5	22
Rash	2	5	2	4		1
Rash erythematous		1				1
Rash maculo-papular	1	2			1	2
Renal failure		2				2
Renal impairment		1				1
Respiratory depression		1				1
Respiratory distress	1	2			1	2
Respiratory failure		3				3
Respiratory paralysis		1				1
Restless legs syndrome	1	1			1	1
Rheumatoid arthritis		2				2
Rhinitis		1		1		
Sedation		1				1
Sensory disturbance		1				1
Sepsis		2				2
Septic shock	1	2			1	2
Sinus disorder	1	1	1	1		
Skin lesion		1				1
Skin reaction	1	2	1	1		1
Somnolence		2				2
Spinal disorder	1	1	1	1		
Subclavian vein thrombosis	1	1			1	1
Sudden death		3				3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Superinfection bacterial	1	1			1	1
Swelling face	1	1			1	1
Swelling of eyelid	1	1	1	1		
Syncope	1	2			1	2
Synovitis	1	1	1	1		
Tachycardia	2	5			2	5
Tachypnoea		1				1
Tendon rupture	1	1	1	1		
Thrombocytopenia		2				2
Transient ischaemic attack		1				1
Tremor	1	2	1	1		1
Underdose	1	1	1	1		
Upper gastrointestinal haemorrhage	1	1			1	1
Urinary retention	1	1			1	1
Urinary tract infection		1				1
Urinary tract infection bacterial		1				1
Urticaria		2				2
Vaccination failure	3	6			3	6
Vaccination site erythema	1	3	1	2		1
Vaccination site haematoma		1				1
Vaccination site oedema		1		1		
Vaccination site pain	1	5	1	4		1
Vaccination site pruritus	1	2	1	2		
Vaccination site reaction		1				1
Vaccination site swelling		2				2
Vaccination site urticaria	1	2	1	1		1
Vaccination site warmth		1		1		
Vascular encephalopathy		1				1
Ventricular fibrillation		1				1
Vertigo		1				1
Visual impairment		2				2
Vomiting	4	20	3	6	1	14
Weight decreased		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
White matter lesion		1		1		
	215	623	90	160	125	463

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Country Where Event Occurred

THAILAND

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breast haematoma	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

TUNISIA

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills		1		1
Cough		1		1
Face oedema	1	1	1	1
Fatigue		1		1
Headache	1	1	1	1
Hypertension	1	1	1	1
Pyrexia		1		1
Skin swelling	1	1	1	1
Vaccination site pain		1		1
Vasculitis	1	1	1	1
	5	10	5	10

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Country Where Event Occurred

TURKEY

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	2	2	1	1	1	1
Asthenia	1	1	1	1		
Back pain	3	3	2	2	1	1
Blister	1	1	1	1		
Bone pain	1	1	1	1		
Chills	2	2	1	1	1	1
COVID-19		1				1
Dizziness	1	3	1	3		
Drug ineffective		1				1
Dry mouth	1	1	1	1		
Dyspnoea		1		1		
Erythema	1	2	1	2		
Headache	4	6	2	4	2	2
Herpes zoster	1	2	1	2		
Hypersensitivity	1	1			1	1
Hypoaesthesia	1	1	1	1		
Hypokinesia	1	1			1	1
Incorrect route of product administration	1	1	1	1		
Invasive ductal breast carcinoma		1				1
Lymphadenopathy		1		1		
Malaise	1	1	1	1		
Mouth ulceration	1	1	1	1		
Muscle contracture	1	1	1	1		
Myalgia	2	2	2	2		
Nausea	1	1	1	1		
Pain	1	1	1	1		
Pain in extremity	5	5	4	4	1	1
Pelvic pain	1	1			1	1
Pruritus	3	3	2	2	1	1
Pyrexia	4	4	3	3	1	1
Rash erythematous	1	1	1	1		
Sensitive skin	1	1	1	1		
Somnolence	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling	1	1	1	1		
Tinnitus	2	2	2	2		
Tremor	1	1	1	1		
Vaccination site pain	1	3	1	3		
Vaccination site swelling	1	1	1	1		
Vein disorder	1	1	1	1		
	52	65	41	51	11	14

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Country Where Event Occurred
TURKS AND CAICOS ISLANDS

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fatigue		1		1		
Generalised tonic-clonic seizure		1				1
Myalgia		1		1		
Neck mass		1		1		
Seizure		1				1
		5		3		2

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* AE=Adverse Event
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Country Where Event Occurred

UKRAINE

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypoaesthesia		1		1
		1		1

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Country Where Event Occurred

UNITED ARAB EMIRATES

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		1		1		
Back pain		1		1		
Chest pain		1				1
Chills		1		1		
Cough		1		1		
COVID-19		1				1
Decreased appetite		1		1		
Drug ineffective		1				1
Dyspnoea		2		1		1
Erythropeia		1				1
Fatigue		3		3		
Feeling abnormal		1		1		
Fibromyalgia		1		1		
Headache		1		1		
Head injury		1				1
Hypoxia		1				1
Injection site pain		1		1		
Loss of consciousness		1				1
Nausea		1		1		
Off label use		1		1		
Product use issue		1		1		
Pyrexia		3		3		
Sleep deficit		1		1		
Somnolence		1		1		
Suspected COVID-19		1				1
Tachypnoea		1		1		
Thrombosis		1				1
		32		22		10

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Country Where Event Occurred

UNITED KINGDOM

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	22	81		1	10	24	12	57
Abdominal distension	9	53			3	17	6	36
Abdominal infection		1						1
Abdominal migraine		1						1
Abdominal pain	22	153			10	40	12	113
Abdominal pain lower	5	16			1	3	4	13
Abdominal pain upper	45	233		1	17	60	28	173
Abdominal rigidity		1						1
Abdominal tenderness		1						1
Abnormal behaviour	2	5			2	2		3
Abnormal clotting factor	1	1					1	1
Abnormal dreams	4	16			1	6	3	10
Abnormal loss of weight	1	1					1	1
Abnormal sensation in eye		3				1		2
Abnormal weight gain		1						1
Abortion spontaneous	1	12					1	12
Abscess	1	3				1	1	2
Abscess oral		2						2
Accident		1				1		
Acidosis		3				1		2
Acne	1	7					1	7
Acne pustular		1						1
Acquired haemophilia		1						1
Activated partial thromboplastin time prolonged	2	4					2	4
Acute abdomen		1						1
Acute aortic syndrome	1	1					1	1
Acute cardiac event		1						1
Acute coronary syndrome	1	3					1	3
Acute disseminated encephalomyelitis		1						1
Acute febrile neutrophilic dermatosis		1						1
Acute hepatic failure	1	1					1	1
Acute kidney injury	2	26					2	26
Acute leukaemia		1						1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acute myocardial infarction		7
Acute respiratory distress syndrome		1
Acute respiratory failure		1
Addison's disease		1
Adiposis dolorosa	1	1
Administration site joint movement impairment		1
Adrenocortical insufficiency acute	1	9
Adverse drug reaction	2	11
Adverse reaction		
Affective disorder		1
Affect lability		3
African trypanosomiasis		1
Ageusia	8	44
Aggression		5
Agitation		15
Airway burns		1
Alanine aminotransferase increased	1	5
A buminuria		1
Alcohol interaction	1	2
Alexia		1
Alexithymia		1
Allergic oedema		2
Allergic reaction to excipient		1
Allergic sinusitis		1
Allergy to chemicals	2	2
Allergy to vaccine	1	13
Allodynia	1	4
Alopecia	8	14
Alopecia areata		2
Alopecia totalis		1
Altered state of consciousness	2	6
Amblyopia		1
Amenorrhoea	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					7
					1
					1
					1
				1	1
					1
				1	9
		2	9		2
	1				
					1
					3
					1
		5	16	3	28
			1		4
			5		10
					1
		1	1		4
					1
				1	2
			1		
			1		
					2
					1
					1
				2	2
			4	1	9
		1	1		3
		2	2	6	12
					2
					1
				2	6
					1
		1	1		1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Ammonia abnormal		1
Amnesia	3	18
Anaemia	2	13
Anaemia vitamin B12 deficiency		1
Anaesthesia oral	1	1
Anal fissure		1
Anal haemorrhage		2
Anal incontinence	1	8
Anal pruritus		2
Anaphylactic reaction	8	83
Anaphylactic shock	1	5
Anaphylactoid reaction		3
Anaphylactoid shock	1	2
Androgenetic alopecia		1
Aneurysm		1
Anger		3
Angina bullosa haemorrhagica		1
Angina pectoris	4	14
Angina unstable		1
Angioedema	3	40
Angle closure glaucoma	1	1
Ankyloglossia congenital	1	1
Ankylosing spondylitis		6
Anorectal discomfort		2
Anosmia	3	18
Anticoagulation drug level below therapeutic		1
Antinuclear ant body increased	1	1
Antiphospholipid syndrome	1	3
Anuria		2
Anxiety	6	71
Aortic arteriosclerosis		1
Aortic dissection		1
Aortic embolus		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			3	3	15
			2	2	11
					1
		1	1		
					1
					2
	1		1	1	7
			1		1
				8	83
				1	5
					3
				1	2
					1
					1
			2		1
					1
				4	14
					1
				3	40
				1	1
				1	1
					6
			1		1
		2	6	1	12
					1
		1	1		
				1	3
					2
		2	18	4	53
					1
					1
					1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Aortic stenosis		1						1
Apathy		2				1		1
Aphasia	3	13			2	3	1	10
Aphonia	2	11				1	2	10
Aphthous ulcer		4				1		3
Aplasia pure red cell	1	1					1	1
Apnoea		1						1
Apnoeic attack	1	1					1	1
Apparent death		1						1
Appetite disorder		2						2
Apraxia		1				1		
Arrhythmia	1	11					1	11
Arrhythmia supraventricular		1						1
Arterial stenosis	2	3					2	3
Arterial thrombosis	1	2			1	1		1
Arteriosclerosis coronary artery		2						2
Arthralgia	207	1,113	4	20	55	262	152	851
Arthritis	16	70			2	10	14	60
Arthritis reactive		3						3
Arthritis viral		1						1
Arthropathy		7				2		5
Ascites		2						2
Aspartate aminotransferase increased		1						1
Aspiration		4						4
Asthenia	65	323	3	4	13	79	52	244
Asthenopia	7	18			2	4	5	14
Asthma	22	135			5	22	17	113
Asthma late onset		1						1
Asthma prophylaxis		1						1
Asymptomatic COVID-19		3						3
Ataxia		2						2
Atonic seizures		1						1
Atopy		1						1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Atrial fibrillation	5	35
Atrial flutter		2
Auditory disorder	1	4
Aura		3
Auricular swelling		2
Autoimmune anaemia	1	1
Autoimmune disorder	4	13
Autoimmune haemolytic anaemia	4	4
Autoimmune hepatitis	1	1
Autoimmune neutropenia		1
Autoimmune thyroid disorder	1	1
Autonomic nervous system imbalance	1	2
Autoscopy		3
Axillary mass	10	30
Axillary pain	50	181
Axonal neuropathy		1
Bacille Calmette-Guerin scar reactivation		2
Back pain	48	260
Bacterial infection	2	3
Balance disorder	21	76
Basal cell carcinoma		1
Bedridden	2	6
Behaviour disorder		3
Behcet's syndrome		5
Bell's palsy	19	83
Benign lymph node neoplasm	1	1
Biliary colic		1
Bipolar disorder	1	1
Bladder disorder	1	2
Bladder pain	1	2
Blepharitis		1
Blepharospasm	3	6
Blindness	6	18

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	1			5	35
					2
				1	4
					3
					2
				1	1
				4	13
				4	4
				1	1
					1
				1	1
				1	2
					3
		2	9	8	21
		11	37	39	144
			1		1
	2	13	64	35	196
				2	3
1	2	4	14	17	62
					1
		1	2	1	4
					3
					5
				19	83
				1	1
					1
				1	1
				1	2
				1	2
					1
				3	6
				6	18

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Blindness transient		3						3
Blindness unilateral	1	4					1	4
Blister	18	46			7	11	11	35
Blood alkaline phosphatase increased		1						1
Blood blister	2	8			1	2	1	6
Blood creatine phosphokinase increased	1	3					1	3
Blood creatinine increased		2				1		1
Blood disorder	1	1					1	1
Blood fibrinogen decreased		1						1
Blood folate decreased	1	1					1	1
Blood glucose		2						2
Blood glucose abnormal	1	3				1	1	2
Blood glucose decreased	4	17			1	4	3	13
Blood glucose fluctuation		12				4		8
Blood glucose increased	5	57				17	5	40
Blood heavy metal increased		1				1		
Blood immunoglobulin E increased		1						1
Blood ketone body	1	1					1	1
Blood ketone body increased		1						1
Blood ketone body present		1						1
Blood lactic acid increased		4				2		2
Blood magnesium decreased		1				1		
Blood pH		1						1
Blood potassium abnormal		1						1
Blood potassium decreased		2				1		1
Blood potassium increased	1	1					1	1
Blood pressure abnormal	1	5				2	1	3
Blood pressure decreased	2	16			2	4		12
Blood pressure fluctuation	1	4					1	4
Blood pressure increased	9	50			2	11	7	39
Blood pressure systolic decreased		1						1
Blood pressure systolic increased	2	5			1	3	1	2
Blood sodium decreased	2	5			1	1	1	4

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Blood test abnormal	1	4
Blood urea increased		1
Blood urine present	2	3
Blue toe syndrome	1	1
Body temperature	2	4
Body temperature abnormal	2	20
Body temperature decreased	5	18
Body temperature fluctuation	1	10
Body temperature increased	14	90
Bone disorder	1	1
Bone neoplasm		2
Bone pain	12	72
Bone swelling	1	3
Bowel movement irregularity		1
Bradycardia	2	11
Bradykinesia		1
Bradyphrenia	1	5
Brain injury		1
Brain neoplasm		2
Brain oedema		1
Brain stem stroke		1
Breast cancer	5	13
Breast cancer stage I	1	1
Breast discomfort	1	3
Breast disorder		1
Breast enlargement		2
Breast inflammation	2	2
Breast mass		5
Breast pain	9	31
Breast swelling	6	14
Breast tenderness	3	9
Breath odour		3
Breath sounds abnormal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	4
					1
			1	2	2
				1	1
		2	3		1
			5	2	15
		2	4	3	14
			2	1	8
	2	7	35	7	55
		1	1		
			1		1
	2	4	15	8	57
			1	1	2
					1
				2	11
			1		
		1	2		3
					1
					2
					1
					1
				5	13
				1	1
			1	1	2
					1
					2
		1	1	1	1
					5
		3	5	6	26
		1	4	5	10
		3	4		5
			1		2
					1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Bronchial secretion retention		1				1		
Bronchiectasis	3	8					3	8
Bronchitis		1						1
Bronchopulmonary aspergillosis		1						1
Bronchospasm	2	9				1	2	8
Bruxism	1	1					1	1
Bulbar palsy		1						1
Bundle branch block right		1				1		
Burning feet syndrome		1						1
Burning sensation	23	73			10	22	13	51
Burn oesophageal		1						1
Burn oral cavity		1						1
Bursitis	1	4				1	1	3
Butterfly rash		2				1		1
Cachexia		1						1
Candida infection		2						2
Capsular contracture associated with breast implant	1	1					1	1
Cardiac amyloidosis	1	1					1	1
Cardiac arrest	2	28					2	28
Cardiac disorder	1	5				1	1	4
Cardiac failure	1	13					1	13
Cardiac failure acute		2						2
Cardiac failure chronic		1						1
Cardiac failure congestive		3						3
Cardiac flutter	4	17					4	17
Cardiac murmur	1	3					1	3
Cardiac valve disease		1						1
Cardiomegaly		1				1		
Cardiomyopathy	1	1					1	1
Cardiopulmonary failure		1						1
Cardio-respiratory arrest		1						1
Cardiospasm	1	1					1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Cardiovascular disorder		2						2
Carotid artery occlusion	1	2					1	2
Carpal tunnel syndrome	1	3					1	3
Cataplexy		2						2
Cataract	1	1					1	1
Catatonia		1						1
Cavernous sinus thrombosis		1						1
Cellulitis	3	27					3	27
Central nervous system lesion		1				1		
Central nervous system vasculitis		1						1
Central venous pressure abnormal		1				1		
Central vision loss		1						1
Cerebellar haemorrhage	1	1					1	1
Cerebellar stroke		1						1
Cerebral artery thrombosis		2						2
Cerebral disorder	1	3			1	2		1
Cerebral haemorrhage		12						12
Cerebral infarction	3	17					3	17
Cerebral thrombosis		4						4
Cerebral venous sinus thrombosis	4	11					4	11
Cerebrospinal fluid leakage		1						1
Cerebrovascular accident	17	84					17	84
Change of bowel habit	1	3			1	2		1
Chapped lips		3						3
Charles Bonnet syndrome		1						1
Cheilitis	1	5				1	1	4
Chest discomfort	34	192			16	50	18	142
Chest injury		1						1
Chest pain	57	288		2	15	40	42	248
Chest X-ray abnormal		1				1		
Chillblains	1	9			1	6		3
Chills	162	1,043	1	8	70	310	92	733
Chloropsia	1	1					1	1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Choking		4
Choking sensation		1
Cholangitis		1
Cholecystitis infective		1
Cholelithiasis		2
Cholestasis	1	1
Chorea		2
Choroidal neovascularisation		1
Chromaturia	3	10
Chronic fatigue syndrome	5	19
Chronic gastritis		1
Chronic kidney disease		5
Chronic lymphocytic leukaemia	2	3
Chronic lymphocytic leukaemia recurrent	1	1
Chronic obstructive pulmonary disease	3	15
Chronic spontaneous urticaria		1
Circulatory collapse		21
Circumstance or information capable of leading to medication error		1
Clinically isolated syndrome	1	1
Clonus	1	1
Clostridium test positive		1
Clot retraction		1
Clumsiness	1	3
Cluster headache	6	22
Coagulation time prolonged	1	1
Coagulopathy	1	3
Coeliac disease		3
Cognitive disorder	2	22
Cold-stimulus headache		1
Cold sweat	13	85
Colitis	4	14
Colitis ischaemic		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					4
					1
					1
					1
					2
				1	1
					2
					1
			1	3	9
		2	4	3	15
					1
					5
				2	3
				1	1
		1	1	2	14
					1
					21
			1		
				1	1
		1	1		
					1
					1
		1	1		2
		1	2	5	20
				1	1
				1	3
					3
		1	3	1	19
					1
		1	17	12	68
		1	1	3	13
					1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Colitis microscopic		1						1
Colitis ulcerative	6	26		1			6	26
Colon cancer		1						1
Coma		4						4
Coma scale abnormal		2						2
Communication disorder		3						3
Concussion		1						1
Condition aggravated	32	169		2	4	25	28	144
Confusional arousal		1						1
Confusional state	30	153		1	6	28	24	125
Congenital cystic lung		1						1
Conjunctival haemorrhage		5						5
Conjunctival hyperaemia		1						1
Conjunctival oedema		1						1
Conjunctivitis	1	9					1	9
Constipation	3	25			1	4	2	21
Contrast media reaction		1						1
Contusion	28	80			7	17	21	63
Coordination abnormal	1	13				2	1	11
Corneal graft rejection	2	2					2	2
Corneal reflex decreased		1				1		
Coronary artery disease		2						2
Coronary artery stenosis		1						1
Coronary artery thrombosis	1	1					1	1
Coronavirus infection		1						1
Cortisol decreased		1						1
Costochondritis	1	7			1	2		5
Cough	40	290		1	12	84	28	206
Cough decreased		1				1		
Cough variant asthma	1	1					1	1
COVID-19	12	139	1	2	3	26	9	113
COVID-19 immunisation		1						1
COVID-19 pneumonia	1	18					1	18

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Cranial nerve disorder		1						1
C-reactive protein abnormal		1						1
C-reactive protein increased	3	13			1	2	2	11
Creatinine renal clearance decreased		1						1
Crepitations		1				1		
Crohn's disease	3	18					3	18
Crying	3	12			2	5	1	7
Cyanosis	1	13				4	1	9
Cyanosis central		1						1
Cyst	1	2				1	1	1
Cystitis	1	7				1	1	6
Cystitis interstitial		1						1
Dark circles under eyes		1						1
Deafness	4	28					4	28
Deafness bilateral	1	1					1	1
Deafness neurosensory		5						5
Deafness unilateral	1	4					1	4
Death	4	42					4	42
Decreased activity	1	2				1	1	1
Decreased appetite	37	248	1	3	10	57	27	191
Decreased immune responsiveness		2						2
Decreased insulin requirement		1						1
Decreased interest		2						2
Decubitus ulcer		1						1
Deep vein thrombosis	18	47		1			18	47
Defaecation urgency		5						5
Dehydration	7	30			1	7	6	23
Delirium	2	29					2	29
Delusion		3				1		2
Dementia	1	9					1	9
Dementia Alzheimer's type		1						1
Dementia with Lewy bodies		1						1
Demyelination	1	3					1	3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Dental caries		1						1
Dental discomfort		1						1
Depressed level of consciousness		6						6
Depressed mood	12	35			4	7	8	28
Depression	3	27				1	3	26
Derealisation	1	1					1	1
Dermatitis	4	14			1	4	3	10
Dermatitis allergic		17				5		12
Dermatitis atopic	1	4					1	4
Dermatitis bullous		1						1
Dermatitis contact		1						1
Dermatitis diaper		1				1		
Dermatitis exfoliative		1						1
Dermatomyositis	1	4					1	4
Device infusion issue		1						1
Diabetes mellitus	4	20					4	20
Diabetes mellitus inadequate control	1	8					1	8
Diabetic coma		1						1
Diabetic complication		2						2
Diabetic eye disease		1				1		
Diabetic ketoacidosis		5						5
Diabetic ketosis	1	1					1	1
Diaphragmalgia	1	2			1	1		1
Diaphragmatic disorder		1						1
Diarrhoea	89	569		4	42	141	47	428
Diarrhoea haemorrhagic		2						2
Diplegia	1	5					1	5
Diplopia	4	25				4	4	21
Discharge		1						1
Discoloured vomit		1						1
Discomfort	18	57		1	7	21	11	36
Disease progression	1	1					1	1
Disease recurrence	30	116	1	1	6	11	24	105

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Disorganised speech		1						1
Disorientation	12	36				5	12	31
Disseminated intravascular coagulation		1						1
Disseminated varicella zoster virus infection		1						1
Dissociation		6				3		3
Disturbance in attention	10	69		1	1	16	9	53
Diverticulitis		3						3
Dizziness	195	915	1	7	70	232	125	683
Dizziness exertional		6				1		5
Dizziness postural	18	100		1	7	27	11	73
Dreamy state		1				1		
Drooling		3				1		2
Drooping shoulder syndrome		1				1		
Drug eruption		3						3
Drug hypersensitivity		6						6
Drug-induced liver injury		1						1
Drug ineffective	14	142	1	2			14	142
Drug interaction	2	3					2	3
Drug level decreased		1						1
Drug level fluctuating		1						1
Drug withdrawal syndrome		1						1
Dry eye	8	25			4	9	4	16
Dry lung syndrome	1	1					1	1
Dry mouth	13	70		1	5	19	8	51
Dry skin	7	26			3	8	4	18
Dry throat	4	22		1	2	10	2	12
Duodenal ulcer perforation		1						1
Duodenogastric reflux		1						1
Dysarthria	2	28				2	2	26
Dyschromatopsia	1	1					1	1
Dysgeusia	30	117			21	58	9	59
Dysgraphia		1						1
Dyshidrotic eczema	2	3					2	3

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dyskinesia	4	16
Dysmenorrhoea	19	26
Dysmorphism		1
Dyspepsia	8	29
Dysphagia	11	60
Dysphemia	1	3
Dysphonia	4	26
Dyspnoea	106	581
Dyspnoea at rest		4
Dyspnoea exertional	9	26
Dysstasia	2	21
Dystonia		2
Dysuria	1	10
Ear congestion		2
Ear discomfort	3	13
Ear disorder		4
Ear haemorrhage		1
Ear infection	1	12
Ear infection bacterial		1
Ear pain	35	107
Ear pruritus		2
Ear swelling	1	4
Eating disorder	1	12
Eczema	6	21
Eczema asteatotic	1	1
Eczema eyelids		1
Eczema herpeticum		2
Eczema weeping		1
Effusion	1	1
Electric shock		2
Electric shock sensation	1	4
Electrocardiogram abnormal	1	3
Electrocardiogram ST segment elevation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3	3	13
		8	11	11	15
					1
		2	7	6	22
		5	14	6	46
		1	2		1
			6	4	20
		22	96	84	485
					4
			5	9	21
			6	2	15
					2
			2	1	8
					2
		1	4	2	9
			1		3
					1
			3	1	9
					1
		8	25	27	82
			1		1
		1	3		1
			2	1	10
		1	4	5	17
				1	1
			1		
					2
			1		
				1	1
					2
			1	1	3
		1	1		2
					1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Embolic cerebral infarction		1
Embolic stroke		1
Embolism	12	29
Embolism venous	1	1
Emotional disorder	2	9
Emotional distress	2	6
Emphysema		1
Encephalitis	1	5
Encephalitis viral		1
Encephalopathy		2
Endometriosis	2	3
Energy increased		2
Enlarged uvula		2
Enteritis	1	3
Enthesopathy		1
Enuresis		2
Eosinophil count increased		1
Eosinophilia	2	2
Epicondylitis		2
Epigastric discomfort		2
Epiglottic oedema		1
Epiglottitis		2
Epilepsy	8	23
Epileptic aura		1
Epileptic encephalopathy		1
Epiphyses premature fusion		1
Episcleritis		1
Epistaxis	15	61
Epstein-Barr virus infection		1
Erectile dysfunction		2
Eructation		5
Erythema	47	229
Erythema annulare		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
				12	29
				1	1
			2	2	7
		1	2	1	4
					1
				1	5
					1
					2
		1	1	1	2
					2
			1		1
				1	3
					1
					2
					2
					2
					1
				2	2
					2
					2
					1
					2
				8	23
					1
					1
					1
					1
		4	12	11	49
					1
					2
			1		4
	1	24	102	23	127
					1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Erythema induratum	1	1					1	1
Erythema multiforme		7						7
Erythema nodosum	2	5				1	2	4
Erythema of eyelid		1						1
Erythroptosis		1						1
Essential hypertension		1						1
Euphoric mood	2	6				2	2	4
Excessive cerumen production		1						1
Exercise tolerance decreased		2				1		1
Exertional headache		1				1		
Exfoliative rash	1	1					1	1
Exposure during pregnancy	2	8			1	5	1	3
Exposure to extreme temperature		1						1
Exposure to SARS-CoV-2		1						1
Exposure via breast milk		1				1		
Extensive swelling of vaccinated limb	2	5				3	2	2
External ear cellulitis		1						1
External ear disorder	1	1					1	1
External ear pain		1				1		
Extraocular muscle paresis		1						1
Extrasystoles	7	12				2	7	10
Extremity necrosis		1						1
Eye allergy		1						1
Eye colour change		1						1
Eye contusion	2	5			1	3	1	2
Eye discharge	3	7			2	2	1	5
Eye disorder	3	10				1	3	9
Eye haematoma	1	1					1	1
Eye haemorrhage	3	9					3	9
Eye infection	1	3					1	3
Eye inflammation	2	4				1	2	3
Eye injury	1	1			1	1		
Eye irritation	3	14				1	3	13

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Eyelid cyst		1						1
Eyelid disorder		1						1
Eyelid infection	1	1					1	1
Eyelid oedema		1						1
Eyelid pain	1	4				1	1	3
Eyelid ptosis	1	8				3	1	5
Eye movement disorder	1	5					1	5
Eye oedema		1				1		
Eye pain	35	138			15	33	20	105
Eye pruritus	6	26		1	3	10	3	16
Eye swelling	18	73		1	5	15	13	58
Eye symptom		1						1
Face oedema	1	5			1	3		2
Facial asymmetry		1				1		
Facial discomfort	2	3					2	3
Facial neuralgia		3				1		2
Facial pain	5	41			1	11	4	30
Facial paralysis	7	59		1			7	59
Facial paresis	3	18			2	5	1	13
Facial spasm	1	4				2	1	2
Faecal calprotectin		1						1
Faecal calprotectin increased	1	1			1	1		
Faecaloma		2						2
Faeces discoloured		11				5		6
Faeces pale	1	1			1	1		
Failed in vitro fertilisation		1						1
Fall	10	61			1	12	9	49
Familial periodic paralysis		1						1
Fatigue	468	2,495	8	40	184	680	284	1815
Fear	1	6				1	1	5
Febrile convulsion		3				3		
Feeding disorder	2	13				1	2	12
Feeling abnormal	58	251		1	18	70	40	181

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Feeling cold	31	218		2	9	64	22	154
Feeling drunk	2	12				3	2	9
Feeling hot	56	199	1	1	20	72	36	127
Feeling jittery		4				1		3
Feeling of body temperature change	12	69			4	22	8	47
Feeling of despair		2						2
Femoral artery embolism	1	1					1	1
Fever neonatal	1	1					1	1
Fibrin D dimer increased	1	6				1	1	5
Fibromyalgia	4	11		1	1	2	3	9
Fine motor skill dysfunction		1						1
Flank pain	2	4				1	2	3
Flashback		1						1
Flatulence	5	17			4	7	1	10
Fluid intake reduced		1						1
Fluid retention	4	9				1	4	8
Flushing	16	62			8	24	8	38
Foetal death		1						1
Follicular lymphoma	1	2					1	2
Food allergy	1	1					1	1
Food aversion		3						3
Food craving	1	2					1	2
Food refusal	1	3					1	3
Forced expiratory volume increased		1						1
Foreign body in gastrointestinal tract		1						1
Foreign body in mouth		1						1
Foreign body sensation in eyes	1	4			1	3		1
Formication	1	8			1	2		6
Foveal reflex abnormal		1						1
Fracture		1						1
Fractured skull depressed		1						1
Freezing phenomenon		3						3
Frequent bowel movements	3	12			1	4	2	8

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Frustration tolerance decreased	1	1					1	1
Full blood count increased		1						1
Functional gastrointestinal disorder		1						1
Furuncle	1	5			1	1		4
Gait disturbance	19	100		1	3	15	16	85
Gait inability	8	39			1	4	7	35
Galactorrhoea		2						2
Gastric antral vascular ectasia	1	3					1	3
Gastric cancer		1						1
Gastric dilatation		1						1
Gastric disorder		4				1		3
Gastric haemorrhage		1						1
Gastric varices haemorrhage		1						1
Gastritis		6				1		5
Gastroenteritis	1	9				1	1	8
Gastroenteritis norovirus		1						1
Gastroenteritis viral		1						1
Gastrointestinal carcinoma		1						1
Gastrointestinal disorder	1	7				3	1	4
Gastrointestinal haemorrhage		1						1
Gastrointestinal pain	3	16				1	3	15
Gastrointestinal sounds abnormal		4				1		3
Gastrointestinal stoma complication		1						1
Gastrooesophageal reflux disease	4	16			1	1	3	15
Gastroschisis		1						1
Generalised oedema		1						1
Generalised tonic-clonic seizure	2	10					2	10
General physical health deterioration	1	6			1	2		4
Genital herpes	3	3					3	3
Genital pain		1						1
Genital tract inflammation		1				1		
Giant cell arteritis		3						3
Gingival bleeding	1	4				2	1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Gingival blister		1				1		
Gingival discomfort		1						1
Gingival disorder		2				1		1
Gingival pain	1	12				2	1	10
Gingival swelling		2						2
Gingivitis	1	2			1	2		
Glaucoma	1	3					1	3
Glios		1						1
Glomerulonephritis minimal lesion		2						2
Glossitis	1	4				1	1	3
Glossodynia	4	28			1	8	3	20
Glucose urine present		1						1
Goitre		2				1		1
Gout	1	10					1	10
Graft versus host disease		1						1
Grief reaction		1						1
Grip strength decreased	3	11				2	3	9
Groin pain	4	16			1	4	3	12
Guillain-Barre syndrome	4	12					4	12
Guttate psoriasis		1						1
Habit cough	1	2				1	1	1
Haemarthrosis	1	2					1	2
Haematemes		8						8
Haematochezia	1	12					1	12
Haematocrit increased		1						1
Haematoma	1	6			1	3		3
Haematospermia		1						1
Haematuria	3	9			1	1	2	8
Haemodynamic instability		1						1
Haemoglobin decreased	2	8				3	2	5
Haemoglobin increased		1						1
Haemolysis	3	3					3	3
Haemolytic anaemia	2	2					2	2

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Haemophilia		1
Haemoptysis	3	14
Haemorrhage	16	39
Haemorrhage intracranial		4
Haemorrhage urinary tract		2
Haemorrhagic infarction		1
Haemorrhagic stroke	1	3
Haemorrhoids	1	3
Hair disorder		1
Hair texture abnormal	1	3
Hallucination	3	25
Hallucination, auditory		2
Hallucination, olfactory		1
Hallucination, visual	1	3
Halo vision	1	1
Hand-arm vibration syndrome		1
Hand deformity		2
Hangover	1	5
Headache	489	2,667
Head banging	1	2
Head discomfort	11	54
Head injury		9
Head titubation	1	1
Heart injury	2	5
Heart rate	1	5
Heart rate abnormal	1	10
Heart rate decreased	1	9
Heart rate increased	31	127
Heart rate irregular	5	17
Heart sounds abnormal		1
Heat exhaustion	1	1
Heat illness		1
Heat oedema	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		2		3	12
				16	39
					4
					2
					1
				1	3
				1	3
		1			
				1	3
				3	25
					2
					1
				1	3
		1	1		
					1
					2
		1	2		3
4	26	199	762	290	1905
			1	1	1
		3	12	8	42
			2		7
		1	1		
				2	5
				1	5
	1	1	2		8
				1	9
		9	36	22	91
		1	1	4	16
					1
		1	1		
					1
				1	1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Heat stroke		1
Heavy menstrual bleeding	37	49
Hemiparesis		12
Hemiplegia	1	4
Hemiplegic migraine		1
Hepatic artery embolism		1
Hepatic cirrhosis	1	1
Hepatic enzyme increased		2
Hepatic pain		2
Hepatic vein thrombosis	1	1
Hepatitis	1	3
Hepatitis viral		1
Hepatocellular carcinoma	1	1
Hernia	1	1
Herpes simplex	2	7
Herpes virus infection	1	2
Herpes zoster	114	202
Herpes zoster meningoencephalitis		1
Herpes zoster oticus	3	3
Herpes zoster reactivation	1	2
Hiatus hernia	2	2
Hiccups		1
Hilar lymphadenopathy	1	1
Hip fracture		1
HIV infection	1	1
Hodgkin's disease	1	1
Hordeolum		1
Hormone level abnormal	1	1
Hot flush	22	103
Hyperacusis	3	13
Hyperaesthesia	2	16
Hyperaesthesia teeth	2	3
Hypercapnia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		13	15	24	34
					12
				1	4
					1
					1
				1	1
			1		1
					2
				1	1
				1	3
					1
				1	1
				1	1
			2	2	5
				1	2
		38	61	76	141
					1
				3	3
		1	1		1
				2	2
					1
				1	1
				1	1
					1
				1	1
		10	32	12	71
			1	3	12
		1	7	1	9
				2	3
					1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hyperchlorhydria	1	5
Hypergeusia		1
Hyperglycaemia	3	28
Hyperhidrosis	41	227
Hyperintensity in brain deep nuclei	1	1
Hyperkalaemia		2
Hyperoxia		1
Hyperpyrexia		1
Hypersensitivity	24	81
Hypersensitivity pneumonitis		1
Hypersomnia	12	60
Hypertension	14	80
Hypertensive crisis		1
Hypertensive heart disease		4
Hyperthermia		1
Hyperthyroidism	1	6
Hypertonia		2
Hypertonic bladder		1
Hypertrophic cardiomyopathy		1
Hyperventilation	2	3
Hypervigilance	1	1
Hypervolaemia		1
Hyphaema		1
Hypnopompic hallucination	1	1
Hypoacusis	4	12
Hypoaesthesia	68	250
Hypoaesthesia eye		2
Hypoaesthesia oral	14	59
Hypocalcaemia		2
Hypoglycaemia	9	41
Hypoglycaemic coma		1
Hypokalaemic syndrome		2
Hypokinesia	6	22

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	4
					1
			3	3	25
	1	14	46	27	181
				1	1
					2
					1
					1
		7	17	17	64
					1
		2	17	10	43
	1	2	18	12	62
					1
					4
					1
				1	6
					2
			1		
					1
		1	1	1	2
				1	1
					1
				1	1
			1	4	11
	4	31	76	37	174
					2
		11	28	3	31
					2
		2	7	7	34
					1
					2
		1	3	5	19

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Hypomenorrhoea	4	5			2	2	2	3
Hyponatraemia		2						2
Hyponatraemic syndrome		1						1
Hypophagia	2	11					2	11
Hypopnoea	5	16					5	16
Hyporeflexia		3				1		2
Hyporesponsive to stimuli		1						1
Hyposmia		2						2
Hyposomnia		1						1
Hypotension	10	52			5	12	5	40
Hypothermia		9						9
Hypothyroidism	1	8					1	8
Hypotonia		3						3
Hypoventilation		1						1
Hypovitaminosis		1						1
Hypovolaemic shock		1						1
Hypoxia		9						9
Idiopathic intracranial hypertension	1	2					1	2
IgA nephropathy	1	2					1	2
IIIrd nerve disorder		2						2
IIIrd nerve paralysis		2						2
Ileal perforation	1	1					1	1
Illness	39	203			11	44	28	159
Immobile	1	6					1	6
Immune system disorder	2	12				1	2	11
Immune thrombocytopenia	8	26					8	26
Immunisation anxiety related reaction		1						1
Immunodeficiency		3						3
Immunodeficiency common variable		1						1
Immunology test	1	1					1	1
Impaired driving ability		3				2		1
Impaired gastric emptying	1	2					1	2
Impaired quality of life	1	2					1	2

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Impaired work ability	2	5
Implant site pain		1
Implant site swelling	1	1
Inadequate analgesia		1
Inappropriate affect		1
Inappropriate schedule of product administration	153	281
Incoherent	1	6
Incontinence	1	7
Incorrect dose administered		1
Incorrect route of product administration		10
Increased insulin requirement		1
Increased tendency to bruise	1	1
Increased upper airway secretion		2
Increased viscosity of upper respiratory secretion	1	4
Infarction		2
Infection	7	30
Infectious mononucleosis		2
Infectious pleural effusion		1
Infective exacerbation of chronic obstructive airways disease		1
Infective pericardial effusion	1	1
Inflammation	14	42
Inflammatory bowel disease		1
Inflammatory marker increased		2
Inflammatory pain		3
Influenza	35	175
Influenza like illness	54	361
Infusion related reaction	1	1
Infusion site infection		1
Inhibitory drug interaction		1
Initial insomnia	1	2
Injected limb mobility decreased	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	4
					1
		1	1		
					1
					1
1	1	148	274	5	7
			2	1	4
			3	1	4
			1		
			10		
					1
				1	1
			1		1
				1	4
					2
		1	5	6	25
					2
					1
					1
				1	1
		6	13	8	29
					1
			1		1
			2		1
2	3	13	43	22	132
1	3	17	112	37	249
				1	1
					1
					1
			1	1	1
		1	2		1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Injection related reaction	1	9
Injection site bruising	1	1
Injection site coldness		1
Injection site erythema	6	10
Injection site hypoaesthesia	1	1
Injection site indentation	1	1
Injection site mass	3	3
Injection site muscle weakness		1
Injection site pain	9	19
Injection site paraesthesia		1
Injection site pruritus	1	2
Injection site pustule		1
Injection site rash	1	1
Injection site reaction		1
Injection site swelling	1	2
Injection site warmth	1	1
Injury	1	1
Injury corneal		1
Inner ear disorder		1
Inner ear inflammation	1	2
Insomnia	50	218
Insulin resistance	2	5
Insulin resistant diabetes	1	1
Intentional self-injury		1
Intermenstrual bleeding	7	9
Internal haemorrhage	1	1
International normalised ratio abnormal		1
International normalised ratio decreased	1	5
International normalised ratio increased		9
Interstitial lung disease		1
Intervertebral disc compression		1
Intestinal haemorrhage		1
Intestinal infarction		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	9
		1	1		
			1		
		4	8	2	2
		1	1		
				1	1
		1	1	2	2
					1
		6	12	3	7
			1		
		1	2		
					1
				1	1
					1
			1	1	1
				1	1
				1	1
					1
					1
				1	2
		22	70	28	148
			1	2	4
				1	1
					1
		3	4	4	5
				1	1
			1		
				1	5
			2		7
					1
					1
					1
					1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Intestinal ischaemia		2						2
Intestinal obstruction		3						3
Intestinal perforation	1	2					1	2
Intracranial aneurysm		1						1
Intranasal paraesthesia	1	1			1	1		
Intrusive thoughts		1						1
Invasive ductal breast carcinoma	1	1					1	1
Iodine uptake increased		1						1
Iridocyclitis		5						5
Iritis		2				1		1
Iron deficiency		3						3
Iron deficiency anaemia	1	1					1	1
Irregular breathing		2						2
Irritability	4	13			2	5	2	8
Irritable bowel syndrome	3	16			2	4	1	12
Ischaemic stroke	1	9					1	9
Itching scar		1				1		
Jaundice	3	6					3	6
Joint effusion		7				1		6
Joint range of motion decreased	12	42			2	11	10	31
Joint stiffness	8	56				7	8	49
Joint swelling	20	90			2	18	18	72
Joint warmth		1						1
Jugular vein thrombosis		2				1		1
Keratitis		2				1		1
Kidney infection		3						3
Kidney small		1						1
Kidney transplant rejection		1						1
Klebsiella infection		1						1
Labile blood pressure		2						2
Labyrinthitis	5	13			2	3	3	10
Lacrimation increased	2	27			1	5	1	22
Lactation disorder	1	1					1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lagophthalmos	1	1
Language disorder		2
Laryngeal pain		1
Laryngitis		2
Latent autoimmune diabetes in adults		1
Left ventricular dysfunction		3
Left ventricular failure		2
Lethargy	46	258
Leukaemia		1
Leukopenia		1
Lichenoid keratosis		2
Lichen planus	1	1
Lichen sclerosus	1	1
Ligament disorder		1
Ligamentitis		1
Limbal swelling		1
Limb crushing injury	1	1
Limb discomfort	43	182
Limbic encephalitis	1	1
Limb immobilisation		3
Limb injury	1	5
Limb mass	2	8
Lip blister	2	4
Lip discolouration	1	1
Lip disorder		4
Lip dry	3	11
Lip oedema		2
Lip pain	1	7
Lip swelling	22	101
Listless	1	3
Livedo reticularis		2
Liver function test abnormal	1	5
Liver function test increased		5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					2
					1
					2
					1
					3
					2
		9	70	37	188
					1
					1
					2
				1	1
				1	1
					1
					1
				1	1
	3	24	70	19	112
				1	1
			2		1
				1	5
			2	2	6
				2	4
				1	1
			2		2
			2	3	9
					2
			2	1	5
	1	10	27	12	74
				1	3
					2
			1	1	4
			1		4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Liver injury		1						1
Liver tenderness	1	2					1	2
Localised infection		6				1		5
Localised oedema		3				1		2
Local reaction	1	7			1	4		3
Logorrhoea		1						1
Long thoracic nerve palsy		1				1		
Loss of consciousness	10	77					10	77
Loss of control of legs	2	3					2	3
Loss of libido	1	2					1	2
Loss of personal independence in daily activities	12	54			2	17	10	37
Lower respiratory tract infection	7	59					7	59
Lung consolidation		2						2
Lung disorder	1	7				1	1	6
Lung neoplasm malignant		1						1
Lupus nephritis	1	1					1	1
Lymphadenitis	4	19			4	7		12
Lymphadenopathy	175	673	1	1	50	193	125	480
Lymphangitis	1	1					1	1
Lymph gland infection		2				1		1
Lymph node pain	43	145			10	33	33	112
Lymph node palpable	2	2			2	2		
Lymphocyte count increased		1						1
Lymphocytosis	1	1			1	1		
Lymphoedema	4	21			2	6	2	15
Lymphoma		3						3
Lymphopenia		1				1		
Macular degeneration		1						1
Macular rupture		1						1
Macule		2				1		1
MAGIC syndrome		1						1
Malaise	155	933	3	8	56	260	99	673
Mania		1						1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Mass	2	7
Mast cell activation syndrome	1	3
Mastication disorder		3
Mastitis		5
Mastocytosis		1
Maternal exposure before pregnancy		1
Maternal exposure during breast feeding	1	6
Maternal exposure during pregnancy	2	22
Mechanic's hand	1	1
Medial tibial stress syndrome		1
Medication overuse headache	1	1
Melaena		2
Memory impairment	4	30
Meniere's disease		4
Meningitis		2
Meningitis aseptic		1
Meningitis viral		1
Menopausal symptoms		1
Menopause	1	1
Menstrual disorder	7	13
Menstruation delayed	9	13
Menstruation irregular	17	21
Mental disorder		2
Mental fatigue	3	24
Mental impairment		5
Mental status changes		1
Mesenteric vein thrombosis	2	3
Metamorphopsia		3
Metastatic neoplasm		1
Microvascular coronary artery disease		1
Micturition disorder		4
Micturition urgency		1
Middle ear inflammation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	2	6
				1	3
					3
					5
					1
					1
			2	1	4
1	2	1	11	1	11
				1	1
					1
		1	1		
					2
		1	5	3	25
					4
					2
					1
					1
			1		
				1	1
		5	6	2	7
		6	7	3	6
		8	11	9	10
			1		1
			2	3	22
					5
					1
				2	3
			1		2
					1
					1
			2		2
					1
					1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Middle insomnia		11
Migraine	56	268
Migraine with aura	7	26
Migraine without aura	1	1
Miliaria	2	10
Mini mental status examination abnormal		1
Miosis	1	3
Mitral valve incompetence	1	2
Moaning		1
Mobility decreased	13	80
Moebius II syndrome	1	1
Monoparesis	4	11
Monoplegia	2	10
Mood altered		2
Mood swings	2	5
Morning sickness		1
Morose		2
Motion sickness	1	3
Mouth breathing		2
Mouth haemorrhage	1	4
Mouth swelling	2	18
Mouth ulceration	7	47
Movement disorder	2	26
Mucosal disorder	1	1
Mucosal dryness	1	1
Mucosal haemorrhage	1	2
Mucous stools		2
Multiple allergies	1	1
Multiple injuries		1
Multiple organ dysfunction syndrome		3
Multiple sclerosis	2	17
Multiple sclerosis relapse	1	16
Multiple sclerosis relapse prophylaxis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		9
	1	9	42	47	226
		1	3	6	23
				1	1
		2	4		6
					1
		1	1		2
				1	2
					1
		5	18	8	62
				1	1
1	1	2	2	2	9
				2	10
			1		1
			1	2	4
					1
			2		
			1	1	2
					2
			1	1	3
		1	2	1	16
		3	16	4	31
		2	4		22
		1	1		
				1	1
				1	2
					2
				1	1
					1
					3
				2	17
				1	16
					1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Mumps		1						1
Muscle atrophy		1						1
Muscle contractions involuntary	2	4				1	2	3
Muscle disorder	1	3					1	3
Muscle fatigue	8	52	1	1	3	9	5	43
Muscle injury		1						1
Muscle mass	1	1					1	1
Muscle rigidity		3						3
Muscle rupture		3						3
Muscle spasms	24	105	2	2	4	20	20	85
Muscle spasticity	1	2					1	2
Muscle strain	1	6			1	1		5
Muscle swelling		3				1		2
Muscle tightness	2	14				4	2	10
Muscle tone disorder		1						1
Muscle twitching	8	27			4	9	4	18
Muscular weakness	37	167	1	1	8	30	29	137
Musculoskeletal chest pain	3	25				3	3	22
Musculoskeletal discomfort	5	21			1	7	4	14
Musculoskeletal disorder		5				1		4
Musculoskeletal pain	2	11					2	11
Musculoskeletal stiffness	33	173	1	2	6	37	27	136
Mutism		1				1		
Myalgia	190	1,142	2	11	83	336	107	806
Myasthenia gravis	1	6					1	6
Myasthenia gravis crisis		1						1
Mydriasis	1	3			1	1		2
Myelitis transverse	1	6					1	6
Myelodysplastic syndrome		1						1
Myocardial haemorrhage		1						1
Myocardial infarction	2	26					2	26
Myocardial ischaemia		8						8
Myocardial oedema	1	1					1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Myocarditis	3	7					3	7
Myoclonus	1	3					1	3
Myopathy	1	1					1	1
Myositis	1	5					1	5
Nail avulsion		1				1		
Nail discolouration		3				1		2
Nail pigmentation		1						1
Nail ridging		1						1
Narcolepsy		1						1
Nasal congestion	10	36			5	10	5	26
Nasal crusting	1	1			1	1		
Nasal discharge discolouration		1				1		
Nasal discomfort	1	8			1	1		7
Nasal disorder		1				1		
Nasal dryness	1	3			1	1		2
Nasal herpes	1	1					1	1
Nasal obstruction		1						1
Nasal odour	1	2					1	2
Nasal oedema	1	1					1	1
Nasopharyngitis	20	108			6	29	14	79
Nausea	236	1,411	1	9	91	382	145	1029
Neck mass		2						2
Neck pain	39	262		1	10	64	29	198
Necrosis	1	1					1	1
Necrotising fasciitis		2						2
Negative thoughts		1						1
Neoplasm	1	3					1	3
Neoplasm progression	2	2			1	1	1	1
Neoplasm recurrence	1	1					1	1
Nephrolithiasis		1						1
Nephrotic syndrome	2	9					2	9
Nerve compression	1	4				2	1	2
Nerve injury		6				2		4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Nervousness	4	34			1	8	3	26
Nervous system disorder		2				1		1
Neuralgia	22	57			4	12	18	45
Neuritis	1	1					1	1
Neurogenic shock		1						1
Neurological symptom	3	8					3	8
Neurologic neglect syndrome		1						1
Neuromuscular pain		1						1
Neuropathy peripheral	5	27					5	27
Neuropsychiatric symptoms		1				1		
Neutropenia	2	14					2	14
Neutropenic sepsis		1						1
Neutrophil count decreased	1	3			1	3		
Neutrophilia		1						1
Nightmare	8	22			3	5	5	17
Night sweats	16	62		1	8	20	8	42
Nipple pain	1	6				1	1	5
Nipple swelling		1				1		
Nodule	1	6			1	3		3
Non-cardiac chest pain		2				1		1
Noninfective gingivitis		1						1
Noninfective sialoadenitis		1						1
Numb chin syndrome		1						1
Obsessive-compulsive symptom		1						1
Obstructive airways disorder		1						1
Obstructive pancreatitis		1						1
Occipital neuralgia		2						2
Occupational exposure to SARS-CoV-2		1				1		
Ocular discomfort	2	8			1	4	1	4
Ocular hyperaemia	10	35			4	11	6	24
Ocular myasthenia		1						1
Ocular sarcoidosis		1						1
Ocular vascular disorder	2	2			2	2		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Odynophagia	1	9
Oedema	3	10
Oedema mouth		1
Oedema peripheral	3	15
Oesophageal pain		2
Oesophageal varices haemorrhage		1
Oesophagitis		1
Off label use	137	565
Oligodendroglioma		1
Oliguria		2
Onychoclasia		2
Ophthalmic herpes simplex	1	1
Ophthalmic herpes zoster	2	2
Ophthalmic migraine	1	3
Ophthalmic vein thrombosis	1	1
Ophthalmological examination abnormal		1
Ophthalmoplegia		1
Optic nerve disorder	1	1
Optic neuritis	1	5
Oral allergy syndrome		1
Oral blood blister	1	3
Oral candidiasis		3
Oral discomfort	3	16
Oral disorder	2	6
Oral dysaesthesia		1
Oral herpes	9	30
Oral lichen planus		2
Oral mucosal blistering	1	6
Oral mucosal erythema		4
Oral mucosal exfoliation		1
Oral mucosal roughening		1
Oral pain	4	20
Oral pruritus		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			4	1	5
			2	3	8
					1
			3	3	12
					2
					1
			1		
1	1	135	547	2	18
					1
					2
			1		1
				1	1
				2	2
				1	3
				1	1
			1		
					1
				1	1
				1	5
					1
		1	2		1
			1		2
		2	4	1	12
		1	3	1	3
					1
		5	11	4	19
					2
		1	5		1
			1		3
			1		
					1
		2	7	2	13
			1		2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Orchitis		1						1
Oropharyngeal blistering		5						5
Oropharyngeal discomfort	3	13			2	5	1	8
Oropharyngeal oedema		1						1
Oropharyngeal pain	45	286		2	18	89	27	197
Oropharyngeal spasm		1						1
Orthopnoea	1	3				1	1	2
Orthostatic hypotension		2						2
Osmophobia		1						1
Osteoarthritis	3	9			1	1	2	8
Osteopenia	1	1					1	1
Osteoporosis	1	1					1	1
Otitis externa		1						1
Otorrhoea		1				1		
Overdose		2				2		
Overflow diarrhoea		1				1		
Oversensing	1	2					1	2
Oxygen saturation		1						1
Oxygen saturation decreased	4	34				4	4	30
Pain	186	929	1	6	73	297	113	632
Painful respiration		9						9
Pain in extremity	295	1,369	4	25	122	441	173	928
Pain in jaw	13	42			1	6	12	36
Pain of skin	11	39			7	11	4	28
Palatal swelling		1						1
Palate injury	1	1					1	1
Palindromic rheumatism		1						1
Pallor	9	37			3	12	6	25
Palmoplantar pustulosis	1	1					1	1
Palpitations	49	223		1	17	52	32	171
Pancreatic carcinoma		2						2
Pancreatic disorder		1						1
Pancreatitis	1	1					1	1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pancreatitis acute		2
Pancytopenia		1
Panic attack	2	7
Panic disorder		2
Panic reaction	2	6
Papule	2	9
Paraesthesia	86	346
Paraesthesia oral	18	134
Parainfluenzae viral laryngotracheobronchitis		1
Paralysis	4	22
Paramnesia		2
Paranasal sinus discomfort		1
Paranoia	1	5
Paresis		2
Parkinsonism		4
Parkinson's disease	1	7
Paronychia	1	1
Parophthalmia		1
Parosmia	4	24
Parotid gland enlargement		1
Parotitis		1
Partial seizures	1	4
Patellofemoral pain syndrome		1
Patient-device incompatibility	1	1
Patient elopement		1
Peak expiratory flow rate		1
Peak expiratory flow rate abnormal		1
Peak expiratory flow rate decreased		1
Pelvic discomfort		1
Pelvic pain	2	11
Pelvic venous thrombosis	1	1
Pemphigoid	1	6
Pemphigus		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
			1	2	6
					2
		1	1	1	5
			2	2	7
	2	37	101	49	245
	1	13	52	5	82
					1
	1			4	22
					2
					1
			1	1	4
					2
			1		3
				1	7
		1	1		
					1
		2	6	2	18
					1
			1		
				1	4
					1
		1	1		
					1
					1
					1
					1
			2	2	9
				1	1
				1	6
					2

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Penile oedema	1	1
Penis disorder	1	1
Periarthritis	6	13
Pericardial effusion		1
Pericardial haemorrhage		1
Pericarditis	6	16
Perinatal depression	1	1
Periorbital cellulitis		1
Periorbital discomfort	1	1
Periorbital haematoma		1
Periorbital infection	1	1
Periorbital oedema		3
Periorbital swelling	6	19
Peripheral circulatory failure		1
Peripheral coldness	18	59
Peripheral embolism		1
Peripheral ischaemia	3	5
Peripheral sensory neuropathy	1	2
Peripheral swelling	76	329
Peripheral vascular disorder		1
Peripheral vein stenosis		1
Peritonitis		1
Peroneal nerve palsy		3
Persistent postural-perceptual dizziness		2
Personality change		2
Petechiae	4	11
Petit mal epilepsy		4
Phantom limb syndrome		1
Pharyngeal disorder	1	1
Pharyngeal erythema		1
Pharyngeal hypoaesthesia	1	5
Pharyngeal inflammation		3
Pharyngeal oedema		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1		
		2	3	4	10
					1
					1
				6	16
				1	1
					1
		1	1		
				1	1
					3
		3	6	3	13
					1
		7	17	11	42
					1
			1	3	4
		1	1		1
	1	28	96	48	233
			1		
					1
					1
			1		2
			1		1
					2
			1	4	10
					4
					1
				1	1
					1
		1	2		3
					3
					1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pharyngeal paraesthesia	1	7
Pharyngeal swelling	10	51
Pharyngeal ulceration		2
Pharyngitis		2
Pharyngitis streptococcal	1	3
Phlebitis	2	6
Photophobia	17	61
Photopsia	3	11
Photosensitivity reaction	2	9
pH urine increased		1
Physical disability		1
Pigmentation disorder		1
Piloerection	1	6
Pineal gland cyst		1
Pityriasis	1	2
Pityriasis lichenoides et varioliformis acuta	1	2
Pityriasis rosea	1	1
Plantar fasciitis		2
Platelet count abnormal		1
Platelet count decreased	10	30
Platelet count increased		1
Pleural effusion		5
Pleurisy		6
Pleuritic pain	2	8
Plicated tongue		1
Pneumonia	5	29
Pneumonia aspiration		4
Pneumonitis	2	10
Pneumothorax	1	2
Pollakiuria	3	10
Polyarthrits	1	4
Polychondritis		1
Polychromasia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		4
		1	8	9	43
					2
					2
		1	1		2
			1	2	5
		3	8	14	53
		1	4	2	7
			3	2	6
					1
					1
			1		
		1	1		5
					1
		1	2		
		1	2		
		1	1		
			1		1
			1		
		2	6	8	24
					1
					5
					6
		1	2	1	6
					1
				5	29
					4
				2	10
				1	2
		1	3	2	7
				1	4
					1
					1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Polycystic ovaries	2	2
Polydipsia		1
Polymenorrhoea	3	7
Polymyalgia rheumatica	4	17
Polymyositis	1	2
Polyuria		2
Poor peripheral circulation	2	2
Poor quality sleep	13	37
Portal vein thrombosis	1	2
Post herpetic neuralgia	4	4
Postmenopausal haemorrhage	3	4
Postprandial hypoglycaemia		1
Post procedural complication		1
Post procedural infection	1	1
Post-traumatic stress disorder	1	3
Postural orthostatic tachycardia syndrome		2
Posture abnormal		1
Post viral fatigue syndrome	5	22
Pre-existing condition improved		2
Premenstrual dysphoric disorder	1	1
Premenstrual syndrome	1	2
Pressure of speech		1
Presyncope	11	47
Primary biliary cholangitis		1
Primary cough headache	1	1
Primary gastrointestinal follicular lymphoma		1
Prion disease		1
Procedural dizziness		1
Procedural nausea		1
Proctalgia	2	6
Proctitis ulcerative		1
Product administered at inappropriate site		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	1
					1
	1	2	4	1	3
				4	17
				1	2
			1		1
				2	2
	1	6	12	7	25
				1	2
		1	1	3	3
				3	4
					1
					1
		1	1		
				1	3
					2
					1
		1	2	4	20
			2		
				1	1
		1	1		1
					1
		3	11	8	36
					1
		1	1		
					1
					1
			2	2	4
					1
			3		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Product administered to patient of inappropriate age	1	3				2	1	1
Productive cough	6	32			1	6	5	26
Product use issue	3	322			3	307		15
Prophylaxis of nausea and vomiting	1	1			1	1		
Prostate cancer	1	1					1	1
Prostatic abscess		1						1
Prostatic specific antigen increased		1				1		
Prostatomegaly		1				1		
Proteinuria		1						1
Pruritus	99	401	1	2	45	155	54	246
Psoriasis	7	32			2	9	5	23
Psoriatic arthropathy	2	14					2	14
Psychiatric symptom		1						1
Psychogenic seizure		2						2
Psychomotor hyperactivity	1	5					1	5
Psychotic behaviour		1						1
Psychotic disorder		4						4
Pulmonary artery dilatation		1						1
Pulmonary artery thrombosis		1						1
Pulmonary congestion	1	2					1	2
Pulmonary embolism	24	76					24	76
Pulmonary fibrosis	1	2					1	2
Pulmonary function test		1						1
Pulmonary haemorrhage		1						1
Pulmonary hypertension		1						1
Pulmonary mass	1	1					1	1
Pulmonary oedema	2	8					2	8
Pulmonary pain	1	17				4	1	13
Pulmonary sarcoidosis		2				1		1
Pulmonary thrombosis	2	5					2	5
Pulse abnormal		2						2
Pulseless electrical activity		2						2

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pulse pressure increased	1	1
Pupillary disorder		1
Purging		1
Purple glove syndrome		1
Purpura	2	11
Purpura non-thrombocytopenic	1	1
Pustular psoriasis		1
Pustule		1
Pyelonephritis		1
Pyrexia	197	1,379
Q fever	1	5
Radiculitis brachial		3
Radioisotope uptake increased		1
Rales	1	2
Rash	110	382
Rash erythematous	40	125
Rash macular	18	60
Rash maculo-papular	1	7
Rash morbilliform	2	2
Rash papular	9	36
Rash pruritic	36	117
Rash pustular		1
Rash vesicular	3	10
Raynaud's phenomenon	5	13
Reaction to excipient		1
Reaction to preservatives		1
Reading disorder		1
Rectal abscess		1
Rectal discharge	4	4
Rectal haemorrhage	6	18
Red blood cell sedimentation rate increased		2
Reduced facial expression		2
Reflux gastritis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
					1
					1
			4	2	7
				1	1
					1
					1
					1
1	10	82	409	115	970
				1	5
			1		2
					1
				1	2
	1	53	131	57	251
	2	20	50	20	75
		10	29	8	31
		1	3		4
		1	1	1	1
		7	17	2	19
		19	45	17	72
					1
		2	4	1	6
		1	4	4	9
					1
					1
					1
					1
		1	1	3	3
				6	18
					2
			2		
					1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Renal cancer		2						2
Renal cyst		2						2
Renal disorder		1						1
Renal failure		7						7
Renal haemorrhage		1						1
Renal impairment	3	12					3	12
Renal injury	1	1					1	1
Renal pain	10	33			5	10	5	23
Respiration abnormal		10				3		7
Respiratory acidosis		1						1
Respiratory arrest		6						6
Respiratory depression		1						1
Respiratory disorder	3	9					3	9
Respiratory distress	1	5					1	5
Respiratory failure	1	7					1	7
Respiratory muscle weakness		1						1
Respiratory rate increased	4	18			1	1	3	17
Respiratory symptom				1				
Respiratory tract congestion	1	1					1	1
Respiratory tract infection	1	2					1	2
Respiratory tract irritation	1	2					1	2
Respiratory tract oedema		2						2
Restless legs syndrome	2	10			1	3	1	7
Restlessness	4	24			1	5	3	19
Retching		17				6		11
Reticulocyte count decreased		1						1
Retinal aneurysm		1						1
Retinal detachment		1						1
Retinal disorder		1				1		
Retinal exudates		1						1
Retinal fovea disorder		1						1
Retinal haemorrhage		1						1
Retinal injury	1	1					1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Retinal migraine		4						4
Retinal toxicity		1						1
Retinal vasculitis		1						1
Retinal vein occlusion	1	1					1	1
Retinopathy		1						1
Retroperitoneal haemorrhage		1						1
Retroperitoneal lymphadenopathy	1	1					1	1
Rhabdomyolysis		2						2
Rheumatic disorder		1						1
Rheumatoid arthritis	9	61		1			9	61
Rheumatoid factor increased	1	1					1	1
Rhinalgia	1	2			1	1		1
Rhinitis		9				3		6
Rhinitis allergic		1						1
Rhinorrhoea	9	89		4	2	18	7	71
Rib fracture		1						1
Right ventricular enlargement		1				1		
Road traffic accident	3	4			2	2	1	2
Rosacea	3	3					3	3
Rotator cuff syndrome	1	3					1	3
Rubber sensitivity		1						1
Sacroiliitis		3				1		2
Salivary gland disorder		1						1
Salivary gland enlargement	1	3					1	3
Salivary gland pain		3						3
Salivary hypersecretion	3	9			2	5	1	4
Salt craving		1						1
Sarcoidosis	1	7					1	7
Sarcoma		1						1
SARS-CoV-2 ant body test negative		4				1		3
SARS-CoV-2 ant body test positive		1				1		
SARS-CoV-2 test		1						1
SARS-CoV-2 test negative		1						1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
SARS-CoV-2 test positive	1	11
Scab	1	3
Sciatica	2	9
Sciatic nerve neuropathy		1
Scintillating scotoma	1	1
Scleral discolouration		3
Scleritis	1	2
Scleroderma associated digital ulcer		1
Scratch		4
Screaming		2
Seasonal allergy	3	6
Seborrhoeic dermatitis	1	1
Secondary hypertension	1	1
Secretion discharge		4
Seizure	7	62
Senile dementia		1
Sensation of blood flow		1
Sensation of foreign body		8
Sense of a foreshortened future		2
Sensitisation		1
Sensitive skin	2	19
Sensitivity to weather change		1
Sensory disturbance	7	22
Sensory loss	5	11
Sensory overload	1	1
Sepsis	1	14
Sepsis syndrome		1
Septic shock		3
Serositis		1
Serotonin syndrome		1
Serum ferritin decreased		1
Serum sickness		1
Shock	1	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3	1	8
		1	2		1
			1	2	8
					1
		1	1		
			1		2
				1	2
					1
			1		3
			1		1
			1	3	5
				1	1
				1	1
			1		3
				7	62
					1
					1
			1		7
			2		
					1
			6	2	13
					1
		4	11	3	11
			1	5	10
				1	1
				1	14
					1
					3
					1
					1
					1
				1	5

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Shock symptom		1						1
Sight disability		1						1
Sinonasal obstruction	1	5				2	1	3
Sinus congestion	2	7			1	1	1	6
Sinus disorder	2	4			1	1	1	3
Sinus headache	6	45	1	2	2	17	4	28
Sinusitis	2	10			2	4		6
Sinus pain	2	16			1	4	1	12
Sinus tachycardia		2						2
Sjogren's syndrome	1	4					1	4
Skin abrasion		2				1		1
Skin burning sensation	9	24		2	6	10	3	14
Skin cancer		1						1
Skin depigmentation		1						1
Skin discolouration	1	18				5	1	13
Skin disorder		8				3		5
Skin erosion		6				2		4
Skin exfoliation	4	19			1	6	3	13
Skin haemorrhage	1	2					1	2
Skin hypertrophy		1				1		
Skin indentation	1	1			1	1		
Skin induration		3				2		1
Skin infection		3				1		2
Skin irritation	2	11			2	6		5
Skin laceration		3				2		1
Skin lesion	4	11	1	1	2	6	2	5
Skin mass	1	2			1	1		1
Skin odour abnormal	2	3				1	2	2
Skin reaction	2	8			1	4	1	4
Skin sensitisation		2						2
Skin swelling	2	7			1	4	1	3
Skin temperature		2				1		1
Skin test positive	1	1			1	1		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Skin tightness		7
Skin ulcer	1	2
Skin warm	1	25
Skin weeping		2
Skin wrinkling		1
Skull fracture		1
Sleep apnoea syndrome	1	2
Sleep attacks		1
Sleep deficit	1	4
Sleep disorder	9	61
Sleep disorder due to a general medical condition		5
Sleep disorder due to general medical condition, insomnia type		7
Sleep paralysis	1	1
Sleep terror	1	3
Slow speech		2
Sluggishness		4
Sneezing	4	35
Social avoidant behaviour		1
Soft tissue swelling	1	2
Solid organ transplant rejection	1	1
Somnolence	32	164
Speech disorder	4	24
Spinal column injury		1
Spinal cord infarction	1	1
Spinal disorder		2
Spinal fracture		1
Spinal pain	3	15
Spleen atrophy		1
Splenic rupture		1
Splenic vein thrombosis	1	1
Splenomegaly	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		4
				1	2
	1		6	1	19
					2
					1
					1
				1	2
					1
			1	1	3
		3	23	6	38
			1		4
			2		5
		1	1		
		1	1		2
					2
					4
	1	2	14	2	21
					1
		1	2		
				1	1
	1	11	42	21	122
			5	4	19
					1
				1	1
			1		1
					1
			2	3	13
					1
					1
				1	1
				1	3

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Spondylitis	1	2
Sputum abnormal		1
Sputum discoloured		3
Sputum increased	1	2
Staphylococcal infection		1
Staphylococcal sepsis		1
Status epilepticus	2	8
Steatorrhoea	1	2
Stevens-Johnson syndrome		2
Still birth	1	1
Stoma site discharge		1
Stoma site haemorrhage	1	1
Stomatitis	1	9
Stress	2	7
Stress cardiomyopathy		1
Stridor	1	4
Subarachnoid haemorrhage		4
Subcutaneous haematoma		1
Subdural haematoma		1
Subdural haemorrhage	1	1
Sudden death	1	14
Sudden hearing loss	2	4
Suffocation feeling		1
Suicidal ideation	3	10
Sunburn		2
Superior sagittal sinus thrombosis		1
Suprapubic pain		1
Supraventricular tachycardia		2
Suspected COVID-19	10	92
Sweating fever	1	10
Swelling	66	214
Swelling face	27	122
Swelling of eyelid	5	17

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
					1
			1		2
				1	2
					1
					1
				2	8
			1	1	1
					2
				1	1
					1
	1	1	3		6
				2	7
					1
				1	4
					4
			1		
					1
				1	1
				1	14
				2	4
			1		
				3	10
					2
					1
			1		
					2
		4	32	6	60
				1	10
		23	70	43	144
	1	9	29	18	93
		1	4	4	13

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Swollen tongue	13	68
Symptom recurrence		1
Syncope	24	126
Synovial cyst		2
Synovitis		3
Syphilis	1	1
Systemic immune activation		1
Systemic inflammatory response syndrome		1
Systemic lupus erythematosus	3	12
Systemic lupus erythematosus rash	1	5
Systolic hypertension		2
Tachycardia	10	106
Tachypnea		1
Tachypnoea	1	9
Taste disorder	9	36
Tearfulness	1	7
Telangiectasia		1
Temperature difference of extremities		1
Temperature intolerance		2
Temperature regulation disorder		3
Temporomandibular joint syndrome		1
Tenderness	17	43
Tendon disorder	1	1
Tendonitis	2	4
Tendon pain	1	2
Tendon rupture	1	1
Tenosynovitis stenosis		2
Tension		2
Tension headache	6	40
Terminal insomnia	2	2
Testicular pain		2
Testicular swelling		1
Therapeutic product ineffective		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	15	9	53
					1
				24	126
			1		1
					3
				1	1
					1
					1
	1			3	12
			1	1	4
					2
	1	4	29	6	77
					1
			2	1	7
		4	15	5	21
		1	2		5
					1
					1
					2
			1		2
			1		
1	2	8	27	9	16
				1	1
		1	1	1	3
				1	2
				1	1
					2
					2
	1	1	9	5	31
		1	1	1	1
			1		1
			1		
					1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Therapeutic response unexpected	7	25			7	19		6
Thermal burn		3						3
Thermal burns of eye		2						2
Thinking abnormal	1	7				2	1	5
Thirst	11	46			3	11	8	35
Throat clearing		1						1
Throat irritation	9	47			4	12	5	35
Throat tightness	4	54			1	5	3	49
Thrombocytopenia	28	59					28	59
Thrombocytopenic purpura	1	1					1	1
Thrombophlebitis	1	2					1	2
Thrombophlebitis superficial	1	2				1	1	1
Thrombosis	23	64	1	1			23	64
Thrombosis in device		1						1
Thrombotic stroke		1						1
Thrombotic thrombocytopenic purpura		2						2
Thyroid function test abnormal		1				1		
Thyroiditis	1	1					1	1
Thyroiditis subacute		1				1		
Thyroid pain		1						1
Tinnitus	36	127			7	22	29	105
Tongue blistering	1	4				1	1	3
Tongue coated	2	5			1	3	1	2
Tongue discolouration	1	5				1	1	4
Tongue discomfort		6				2		4
Tongue disorder	3	13			1	2	2	11
Tongue dry		1						1
Tongue eruption		2						2
Tongue erythema		1				1		
Tongue exfoliation	1	1					1	1
Tongue movement disturbance		1				1		
Tongue oedema		3						3
Tongue paralysis		1						1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tongue pruritus		1						1
Tongue spasm		1						1
Tongue ulceration		3				1		2
Tonic convulsion		1						1
Tonsillar hypertrophy		5						5
Tonsillar inflammation		1						1
Tonsillitis	2	6					2	6
Toothache	5	16				1	5	15
Tooth discolouration	1	1					1	1
Tooth disorder		1				1		
Toxic epidermal necrolysis		1		1				1
Toxicity to various agents		1		1				1
Transaminases increased		1						1
Transient global amnesia		1						1
Transient ischaemic attack	2	16					2	16
Traumatic haematoma	2	2					2	2
Traumatic haemorrhage		1						1
Tremor	38	219		1	6	42	32	177
Trichodynia		1						1
Tricuspid valve incompetence	1	1					1	1
Trigeminal neuralgia	3	4					3	4
Trigger finger		1						1
Tri-iodothyronine decreased		1						1
Trismus	2	6			1	1	1	5
Troponin increased	1	3					1	3
Tubulointerstitial nephritis		1						1
Tunnel vision		4						4
Tympanic membrane hyperaemia		1						1
Type 1 diabetes mellitus		3						3
Type III immune complex mediated reaction		1						1
Type IV hypersensitivity reaction		2						2
Typical aura without headache	1	3			1	1		2
Ulcer		4				1		3

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Ulcerative keratitis		3
Umbilical cord abnormality	1	1
Underdose		2
Unresponsive to stimuli	2	17
Upper-airway cough syndrome		1
Upper airway obstruction		1
Upper gastrointestinal haemorrhage		1
Upper respiratory tract congestion		1
Upper respiratory tract infection		2
Urinary incontinence	2	14
Urinary retention	1	11
Urinary tract disorder		1
Urinary tract infection	2	23
Urinary tract infection bacterial		1
Urine abnormality	1	3
Urine analysis abnormal		1
Urine flow decreased	1	3
Urine ketone body present		1
Urine odour abnormal		2
Urine output		1
Urine output decreased	1	3
Urosepsis		2
Urticaria	33	144
Urticaria contact	1	1
Uterine haemorrhage		1
Uterine polyp	1	1
Uveitis	2	11
Vaccination complication		5
Vaccination failure		2
Vaccination site bruising	7	35
Vaccination site cellulitis	1	5
Vaccination site discolouration		4
Vaccination site discomfort	4	23

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					3
				1	1
			2		
				2	17
			1		
					1
					1
					2
			2	2	12
				1	11
					1
		1	5	1	18
					1
			1	1	2
					1
				1	3
					1
					2
					1
		1	1		2
					2
		17	46	16	98
				1	1
					1
				1	1
				2	11
			1		4
					2
		5	16	2	19
			2	1	3
			1		3
		2	12	2	11

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination site dryness		1
Vaccination site erythema	27	159
Vaccination site haemorrhage	2	10
Vaccination site hyperaesthesia		2
Vaccination site hypoaesthesia	1	5
Vaccination site induration	2	21
Vaccination site infection	1	6
Vaccination site inflammation	5	18
Vaccination site irritation	2	5
Vaccination site joint erythema	1	2
Vaccination site joint movement impairment	2	6
Vaccination site joint pain	2	6
Vaccination site joint swelling		1
Vaccination site joint warmth		1
Vaccination site lymphadenopathy		9
Vaccination site mass	18	77
Vaccination site movement impairment	7	25
Vaccination site oedema	2	5
Vaccination site pain	124	796
Vaccination site paraesthesia	2	9
Vaccination site photosensitivity reaction	1	1
Vaccination site pruritus	14	69
Vaccination site rash	6	34
Vaccination site reaction		14
Vaccination site swelling	33	198
Vaccination site ulcer		1
Vaccination site urticaria	2	6
Vaccination site vesicles	1	2
Vaccination site warmth	20	98
Vaccine breakthrough infection		1
Vaginal cyst		1
Vaginal disorder		1
Vaginal haemorrhage	10	18

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		17	77	10	82
		1	3	1	7
			1		1
			1	1	4
		1	11	1	10
		1	2		4
		4	13	1	5
		1	2	1	3
		1	2		
			2	2	4
		1	3	1	3
			1		
			1		
			3		6
		10	30	8	47
		1	8	6	17
		2	3		2
1	6	70	341	54	455
			3	2	6
		1	1		
		9	32	5	37
		3	14	3	20
			6		8
		17	77	16	121
					1
			2	2	4
		1	1		1
		12	40	8	58
					1
					1
					1
		2	4	8	14

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Varicella	2	4
Varicose vein		3
Vascular dementia		4
Vascular headache	2	7
Vascular pain		2
Vascular stent thrombosis		1
Vasculitic rash		2
Vasculitis	3	19
Vasoconstriction		1
Vasodilatation		2
Vein disorder		1
Vein rupture		1
Venous injury		1
Venous thrombosis		1
Ventricular arrhythmia	2	2
Ventricular extrasystoles	2	8
Ventricular f brillation		2
Ventricular tachycardia		2
Vertebral artery stenosis		1
Vertigo	29	129
Vertigo labyrinthine	2	2
Vertigo positional	2	12
Vestibular disorder		1
Vestibular migraine		2
Vestibular neuritis		4
Viral infection	3	7
Viral labyrinthitis		3
Viral rash	1	3
Virologic failure		1
Visceral venous thrombosis		1
Vision blurred	34	119
Visual acuity reduced		2
Visual field defect	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	4
					3
					4
			1	2	6
			1		1
					1
			1		1
			5	3	14
					1
					2
					1
					1
					1
				2	2
				2	8
					2
					2
					1
		6	22	23	107
				2	2
				2	12
			1		
					2
					4
				3	7
			3		
			1	1	2
					1
					1
		14	30	20	89
					2
		1	1	1	4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Visual impairment	11	49			2	14	9	35
Visual snow syndrome		1						1
Visuospatial deficit	1	1					1	1
Vital capacity		1						1
Vitamin D deficiency		1						1
Vlth nerve paralysis	1	3					1	3
Vitiligo		1						1
Vitreous detachment	1	3					1	3
Vitreous disorder	1	1					1	1
Vitreous floaters	4	6				1	4	5
Vitreous haemorrhage	2	2					2	2
Vocal cord disorder		1						1
Vomiting	65	441	1	1	26	112	39	329
Vomiting projectile	2	9				4	2	5
Vomiting psychogenic		1						1
Vulval haemorrhage		1						1
Vulvovaginal candidiasis		5				2		3
Vulvovaginal dryness	1	1					1	1
Vulvovaginal pain		2				1		1
Vulvovaginal ulceration		1						1
Wa king aid user	1	1					1	1
Weight bearing difficulty		2				1		1
Weight decreased	5	19			1	7	4	12
Weight increased		2				1		1
Weight loss diet		1						1
Wheat-free diet		1						1
Wheezing	20	104			7	22	13	82
White blood cell count abnormal		1						1
White blood cell count decreased	2	4			1	1	1	3
White blood cell count increased	1	8				1	1	7
Withdrawal syndrome	1	3				2	1	1
Wound	1	4					1	4
Wound complication		1						1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Wound secretion		1						1
Wrist fracture		1						1
Wrong product administered	5	7			5	7		
Xanthopsia	1	1					1	1
Yawning		1						1
	6	8			6	8		
	8,989	44,539	59	301	3197	12263	5792	32276

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Country Where Event Occurred

UNITED STATES

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	22	111			20	105	2	6
Abdominal distension	4	21			3	17	1	4
Abdominal infection		1						1
Abdominal pain	19	118			15	94	4	24
Abdominal pain lower	1	13			1	10		3
Abdominal pain upper	30	149			28	133	2	16
Abdominal rigidity		2				1		1
Abdominal tenderness	1	1			1	1		
Abnormal behaviour	1	8			1	7		1
Abnormal dreams	1	7			1	6		1
Abnormal faeces	2	4			2	4		
Abnormal loss of weight	1	1			1	1		
Abnormal sensation in eye	1	7			1	7		
Abnormal sleep-related event	1	1			1	1		
Abortion spontaneous		5						5
Abortion threatened	1	1					1	1
Abscess		1						1
Accidental exposure to product	1	5			1	5		
Accidental overdose		2				2		
Accidental underdose		1				1		
Acetonaemia		1				1		
Acne	1	8			1	8		
Acute coronary syndrome		1						1
Acute febrile neutrophilic dermatosis		2						2
Acute hepatic failure		1						1
Acute kidney injury	1	8					1	8
Acute myeloid leukaemia		3						3
Acute myocardial infarction		4						4
Acute pulmonary oedema		1						1
Acute respiratory distress syndrome		1						1
Acute respiratory failure	1	2	1	1			1	2
Acute stress disorder	1	1			1	1		
Administration site bruise		1				1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Administration site joint erythema		1				1		
Adnexa uteri pain		1				1		
Adrenal disorder		2				1		1
Adrenal insufficiency		2						2
Adrenocortical insufficiency acute		2						2
Adverse drug reaction		1				1		
Adverse event	1	1			1	1		
Affective disorder		1				1		
Ageusia	14	76			11	68	3	8
Aggression	2	4			1	2	1	2
Agitation	3	13			3	12		1
Agnosia	1	1			1	1		
Agonal respiration	1	1					1	1
Alanine aminotransferase abnormal		1				1		
Alanine aminotransferase decreased		1						1
Alanine aminotransferase increased	1	8			1	7		1
Allergic cough	1	2			1	2		
Allergic reaction to excipient		2				1		1
Allergic sinusitis		1				1		
Allergy test positive		1				1		
Allergy to chemicals		1				1		
Allergy to vaccine	6	36			2	15	4	21
Alopecia	2	20			2	16		4
Alopecia areata		1				1		
Altered state of consciousness		5						5
Altered visual depth perception		1				1		
Amnesia	8	24			5	17	3	7
Amyloidosis		1						1
Anaemia	1	10			1	6		4
Anal abscess	2	2					2	2
Anal haemorrhage		2				1		1
Anal incontinence	2	6			1	5	1	1
Anal pruritus		1				1		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Anaphylactic reaction	23	155
Anaphylactic shock	4	15
Anaphylactoid reaction		2
Aneurysm	1	1
Anger	2	10
Angina pectoris	3	16
Angioedema	3	35
Angiokeratoma		1
Angiolymphoid hyperplasia with eosinophilia		1
Angiopathy		3
Angle closure glaucoma		1
Animal bite		1
Anion gap decreased		1
Anion gap increased		1
Ankylosing spondylitis	1	2
Anomalous pulmonary venous connection		1
Anorectal discomfort		1
Anosmia	5	48
Anterior chamber cell		1
Antibody test abnormal		3
Antibody test negative		1
Anti Kell antibody test positive		1
Anti-neutrophil cytoplasmic antibody positive vasculitis	1	1
Antinuclear ant body positive	1	1
Anti-thyroid antibody positive	1	1
Anxiety	21	121
Aortic arteriosclerosis		1
Apathy		2
Aphasia	3	22
Aphonia	5	20
Aphthous ulcer	2	5
Apnoea		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				23	155
				4	15
					2
				1	1
		2	8		2
				3	16
				3	35
			1		
			1		
			2		1
					1
			1		
			1		
					1
				1	2
					1
			1		
		4	40	1	8
					1
			3		
			1		
			1		
				1	1
		1	1		
		1	1		
		19	104	2	17
			1		
			1		1
		3	10		12
		4	12	1	8
			3	2	2
					2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Appendicectomy		1				1		
Appendicitis	2	17					2	17
Appendicitis perforated		2						2
Appendix disorder		2				1		1
Appetite disorder		3				3		
Application site haemorrhage		1						1
Apraxia	1	1			1	1		
Aptyalism		1				1		
Arachnoid cyst		1						1
Areflexia		2				1		1
Arrhythmia		30						30
Arterial occlusive disease		1						1
Arterial thrombosis		1						1
Arteriosclerosis		2						2
Arteriosclerosis coronary artery		1				1		
Arteriospasm coronary		1						1
Arthralgia	141	828		1	122	753	19	75
Arthritis	15	53			10	45	5	8
Arthropathy	4	21			3	20	1	1
Arthropod bite	1	2			1	2		
Arthropod sting		2				2		
Aspartate aminotransferase increased		6				5		1
Aspiration	1	2					1	2
Asthenia	107	582		1	89	486	18	96
Asthenopia		12				10		2
Asthma	14	75			12	55	2	20
Asthma prophylaxis		2				1		1
Asymptomatic COVID-19	2	7			1	2	1	5
Ataxia	1	4				1	1	3
Atelectasis	2	6			1	2	1	4
Atopy	1	1			1	1		
Atrial fibrillation	10	57	1	1			10	57
Atrial flutter		3				2		1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Atrioventricular block	1	1
Atrioventricular block complete		2
Atrioventricular block second degree		1
Attention deficit hyperactivity disorder	1	1
Atypical pneumonia	1	1
Aura	1	3
Autoimmune disorder	4	18
Autoimmune haemolytic anaemia		2
Autoimmune thyroid disorder		1
Autoimmune thyroiditis	1	3
Autonomic nervous system imbalance		3
Autonomic neuropathy		1
Autoscopy		1
Axillary mass	1	5
Axillary pain	7	51
Back disorder		4
Back injury	1	3
Back pain	57	273
Bacteraemia		1
Bacterial disease carrier		1
Bacterial infection	2	3
Bacterial test positive	1	1
Balance disorder	16	93
Band neutrophil count increased		1
Basal cell carcinoma		1
Basal ganglia haemorrhage		1
Basedow's disease		2
Basilar artery thrombosis	1	1
Basophil count abnormal		1
Bed rest		2
Bedridden	2	23
Behaviour disorder		1
Belligerence		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					2
					1
		1	1		
				1	1
		1	2		1
				4	18
					2
					1
				1	3
			1		2
					1
			1		
		1	5		
		7	51		
			4		
		1	3		
		46	224	11	49
					1
			1		
		2	3		
		1	1		
		13	77	3	16
					1
					1
					1
					2
				1	1
			1		
			2		
		2	20		3
					1
					1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bell's palsy	13	101
Biliary tract disorder		1
Biopsy		1
Bladder disorder		2
Bladder dysfunction		1
Blast cell count increased		1
Blast cell crisis		1
Blepharitis		2
Blepharospasm	1	5
Blindness	8	21
Blindness transient		1
Blindness unilateral		3
Blister	14	42
Blood albumin decreased		3
Blood alkaline phosphatase increased		1
Blood bilirubin decreased		2
Blood bilirubin increased	1	4
Blood blister	1	4
Blood calcium decreased		2
Blood calcium increased		3
Blood chloride decreased		2
Blood chloride increased		3
Blood cholesterol abnormal		2
Blood cholesterol increased	3	10
Blood copper increased		1
Blood count abnormal	1	1
Blood creatine increased		1
Blood creatine phosphokinase abnormal		1
Blood creatine phosphokinase increased		5
Blood creatinine abnormal		1
Blood creatinine decreased		2
Blood creatinine increased		6
Blood disorder		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	13	100
			1		
			1		
			2		
			1		
					1
					1
			2		
		1	5		
				8	21
					1
					3
		10	33	4	9
			3		
			1		
			2		
		1	3		1
		1	3		1
			1		1
			2		1
			1		1
			3		
			2		
		2	9	1	1
			1		
		1	1		
					1
			1		
			1		4
					1
			1		1
			5		1
			3		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood electrolytes decreased		1
Blood folate increased		1
Blood follicle stimulating hormone increased		1
Blood glucose	1	1
Blood glucose abnormal	2	7
Blood glucose decreased	8	33
Blood glucose fluctuation		2
Blood glucose increased	10	79
Blood immunoglobulin E increased		1
Blood immunoglobulin G decreased		1
Blood immunoglobulin G increased	1	2
Blood immunoglobulin M increased		1
Blood insulin increased		1
Blood iron decreased		4
Blood ketone body increased		1
Blood lactic acid increased		4
Blood magnesium decreased		2
Blood phosphorus decreased		1
Blood potassium decreased		15
Blood potassium increased		2
Blood pressure abnormal	3	14
Blood pressure decreased	4	32
Blood pressure diastolic decreased		3
Blood pressure diastolic increased		2
Blood pressure fluctuation	1	11
Blood pressure increased	15	174
Blood pressure systolic increased		6
Blood sodium decreased	2	8
Blood test abnormal	1	3
Blood thyroid stimulating hormone abnormal	1	1
Blood thyroid stimulating hormone decreased	2	2
Blood thyroid stimulating hormone increased	1	3
Blood triglycerides abnormal		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
					1
		1	1		
		1	4	1	3
		7	23	1	10
			2		
		6	55	4	24
					1
			1		
			1	1	1
			1		
			1		
			1		3
					1
			1		3
					2
					1
			8		7
					2
		2	10	1	4
		4	18		14
			2		1
			1		1
			7	1	4
		7	109	8	65
			2		4
		2	6		2
		1	3		
		1	1		
		1	1	1	1
			1	1	2
			1		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Blood triglycerides increased	1	3
Blood urea increased		3
Blood uric acid increased		1
Blood urine		2
Blood urine present	4	13
Blue toe syndrome		2
Body height decreased	2	17
Body mass index increased	1	1
Body temperature		2
Body temperature abnormal	6	14
Body temperature decreased	1	13
Body temperature fluctuation	3	5
Body temperature increased	9	59
Body tinea		1
Bone contusion	1	1
Bone density abnormal		1
Bone disorder		2
Bone marrow disorder	2	3
Bone pain	13	54
Bone swelling		1
Bowel movement irregularity	2	9
Brachial plexopathy		1
Bradycardia		4
Bradykinesia		3
Bradyphrenia		3
Brain cancer metastatic		1
Brain injury	1	4
Brain natriuretic peptide increased	1	1
Brain oedema	2	3
Brain stem haemorrhage		1
Brain stem infarction	1	2
Brain stem syndrome		1
Breast cancer		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		1
			1		2
			1		
			2		
		3	8	1	5
					2
		2	17		
		1	1		
			2		
		6	13		1
		1	11		2
		3	5		
		7	53	2	6
			1		
		1	1		
			1		
			1		1
		2	3		
		11	47	2	7
					1
		2	8		1
					1
			3		
			1		2
					1
				1	4
				1	1
				2	3
					1
				1	2
					1
					1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Breast cellulitis	1	1
Breast discharge		1
Breast discomfort		1
Breast disorder	1	3
Breast mass		2
Breast pain	9	38
Breast swelling	1	6
Breast tenderness	1	3
Bronchial disorder		1
Bronchitis	5	16
Bronchospasm		23
Brown-Sequard syndrome	1	1
Bruxism	1	1
Burning mouth syndrome		1
Burning sensation	30	124
Burn oral cavity		1
Bursa disorder		1
Bursitis	3	7
Butterfly rash		2
Calcinosis	1	1
Candida infection	1	3
Carbohydrate antigen 125 increased		1
Carcinoembryonic antigen increased	1	1
Cardiac arrest	3	24
Cardiac discomfort		1
Cardiac disorder	2	21
Cardiac failure		2
Cardiac failure congestive	2	8
Cardiac flutter	4	19
Cardiac neoplasm unspecified		1
Cardiac tamponade	1	1
Cardiac valve disease		2
Cardiac valve vegetation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		
					1
			2	1	1
			1		1
		9	35		3
		1	6		
		1	3		
			1		
		3	12	2	4
			10		13
				1	1
		1	1		
			1		
		19	89	11	35
					1
			1		
		3	6		1
			1		1
		1	1		
		1	3		
			1		
				1	1
				3	24
			1		
		1	13	1	8
					2
				2	8
				4	19
					1
				1	1
			2		
					1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Cardiogenic shock		1
Cardiomegaly	1	1
Cardiomyopathy		3
Cardio-respiratory arrest		3
Cardiospasm		1
Cardiovascular disorder	1	5
Carpal tunnel syndrome	2	3
Cataract	2	4
Cataract nuclear		1
Catatonia		2
Cellulitis	7	19
Central nervous system lesion		1
Cerebellar haemorrhage	1	1
Cerebellar stroke		2
Cerebral artery embolism		1
Cerebral artery stenosis	1	1
Cerebral atrophy	1	1
Cerebral disorder	2	7
Cerebral haematoma	1	1
Cerebral haemorrhage	1	5
Cerebral infarction		1
Cerebral thrombosis	3	4
Cerebral venous sinus thrombosis		3
Cerebrospinal fluid leakage		1
Cerebrovascular accident	23	82
Cerumen impaction		1
Cervical radiculopathy	1	1
Cervical spinal stenosis	1	1
Cervicogenic vertigo	1	1
Change in sustained attention		1
Cheilitis	1	4
Chest discomfort	26	207
Chest injury		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1		
					3
					3
			1		
		1	5		
		2	3		
				2	4
					1
			1		1
				7	19
					1
				1	1
					2
					1
				1	1
				1	1
		2	6		1
				1	1
				1	5
					1
				3	4
					3
					1
				23	82
			1		
		1	1		
				1	1
		1	1		
			1		
		1	3		1
		16	143	10	64
					2

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Chest pain	57	231
Chest X-ray abnormal		1
Chillblains	1	3
Chills	220	1,358
Chloropsia	1	1
Choking	1	10
Choking sensation		4
Cholelithiasis	1	2
Cholestasis		2
Chondritis		1
Chorea		1
Chromatopsia		1
Chromaturia		3
Chronic fatigue syndrome	1	1
Chronic inflammatory demyelinating polyradiculoneuropathy	1	3
Chronic kidney disease		2
Chronic myeloid leukaemia recurrent		1
Chronic obstructive pulmonary disease	2	7
Circadian rhythm sleep disorder		1
Circulatory collapse		3
Circumoral swelling	1	1
Circumstance or information capable of leading to device use error		1
Circumstance or information capable of leading to medication error	8	111
Claustrophobia		1
Clostridium difficile infection	1	1
Clumsiness	1	3
Coagulation time prolonged		1
Coagulopathy		4
Coccidioidomycosis	1	1
Coeliac disease	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		39	164	18	67
					1
		1	3		
		200	1243	20	115
				1	1
				1	10
			2		2
				1	2
					2
			1		
					1
			1		
		1	1		
				1	3
					2
					1
	1	1	2	1	5
					1
					3
		1	1		
			1		
		8	111		
			1		
				1	1
		1	3		
			1		
			2		2
				1	1
				1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Cognitive disorder	6	18			6	14		4
Cold-stimulus headache		1				1		
Cold sweat	8	52			7	44	1	8
Cold urticaria	1	1			1	1		
Colitis	1	6				3	1	3
Colitis ischaemic	1	1					1	1
Colitis ulcerative	2	6	1	1			2	6
Colon cancer		1						1
Coma	1	4					1	4
Communication disorder		3				2		1
Complex regional pain syndrome		1				1		
Complicated appendicitis		1						1
Complication associated with device		1						1
Computerised tomogram normal		1				1		
Concussion	3	6			1	2	2	4
Condition aggravated	51	215	1	1	32	139	19	76
Confusional state	12	74			9	51	3	23
Conjunctival haemorrhage		5						5
Conjunctival hyperaemia		1						1
Conjunctivitis		4				4		
Conjunctivitis allergic		1				1		
Consciousness fluctuating		1						1
Constipation	4	24			3	20	1	4
Contraindicated product administered		1				1		
Contraindication to medical treatment		1				1		
Contraindication to vaccination		4				4		
Contusion	11	58			10	50	1	8
Conversion disorder		1				1		
Coordination abnormal	2	10			1	5	1	5
Coprolalia	1	1			1	1		
Corneal disorder		1						1
Corneal graft rejection		1						1
Corneal infection		1						1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Corneal infiltrates		1						1
Coronary artery disease		1						1
Coronary artery occlusion		1						1
Coronary artery thrombosis	1	1					1	1
Coronavirus infection		1				1		
Cor pulmonale acute		1						1
Costochondritis	3	4			2	3	1	1
Cough	60	331			52	274	8	57
COVID-19	78	326	2	5	28	95	50	231
COVID-19 immunisation		2				2		
COVID-19 pneumonia	2	19	2	2			2	19
Cranial nerve injury	1	1					1	1
C-reactive protein increased		9				5		4
Crepitations	1	2			1	2		
Crohn's disease	3	5					3	5
Crying	3	15			2	11	1	4
Crystal urine		1				1		
CSF oligoclonal band present		1						1
CSF protein increased		2						2
Culture urine positive		1				1		
Cutaneous lupus erythematosus		1						1
Cutaneous vasculitis	1	6				1	1	5
Cyanosis		12				7		5
Cyst		1				1		
Cystitis	3	8			2	3	1	5
Cystitis escherichia		1						1
Cytogenetic analysis abnormal	1	1					1	1
Daydreaming		2				2		
Deafness	7	28				1	7	27
Deafness bilateral		1						1
Deafness neurosensory		6						6
Deafness unilateral	2	16					2	16
Death	3	45		1			3	45

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Decreased appetite	32	214
Decreased interest		2
Deep vein thrombosis	17	42
Defaecation disorder		1
Defaecation urgency		1
Degenerative bone disease	1	2
Dehydration	17	65
Delirium	4	22
Delirium febrile		1
Delusion	1	5
Delusional perception		3
Dementia		7
Demyelinating polyneuropathy		1
Demyelination	1	1
Dental caries	1	2
Depersonalisation/derealisation disorder		1
Depressed level of consciousness		6
Depressed mood	1	12
Depression	4	19
Dermatitis	3	7
Dermatitis acneiform		2
Dermatitis allergic		3
Dermatitis contact		2
Dermatitis diaper		1
Dermatomyositis		3
Device leakage		1
Diabetes mellitus	1	9
Diabetes mellitus inadequate control	1	4
Diabetic coma		1
Diabetic foot infection		1
Diabetic ketoacidosis		1
Diaphragmatic disorder		1
Diarrhoea	72	489

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		27	189	5	25
			1		1
				17	42
			1		
			1		
		1	2		
		4	30	13	35
				4	22
					1
		1	2		3
			2		1
					7
					1
				1	1
		1	2		
			1		
					6
		1	12		
		3	16	1	3
		3	7		
			2		
			3		
			2		
					1
					3
			1		
				1	9
				1	4
					1
			1		
					1
			1		
	1	64	436	8	53

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Diarrhoea haemorrhagic		8
Diet refusal		1
Diplegia	1	1
Diplopia	2	14
Disability		1
Discomfort	13	62
Discouragement		1
Disease progression	1	3
Disease recurrence	13	73
Disorganised speech		1
Disorientation	6	34
Disseminated intravascular coagulation	1	2
Disseminated varicella zoster vaccine virus infection	1	1
Disseminated varicella zoster virus infection		1
Dissociation		1
Distract bility	1	1
Disturbance in attention	7	33
Disturbance in social behaviour		1
Diverticulitis	1	8
Diverticulum intestinal		1
Dizziness	183	992
Dizziness postural	3	17
Drainage	1	2
Droping	1	2
Drug effective for unapproved indication		4
Drug eruption		1
Drug hypersensitivity	2	21
Drug ineffective	36	196
Drug interaction	2	17
Dry eye	4	19
Dry mouth	12	60
Dry skin	8	18

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					8
					1
				1	1
		1	7	1	7
			1		
		13	58		4
			1		
			1	1	2
		6	38	7	35
					1
		5	26	1	8
				1	2
				1	1
					1
			1		
		1	1		
		6	29	1	4
			1		
				1	8
					1
1	2	157	840	26	152
		3	14		3
		1	2		
		1	2		
			4		
			1		
			16	2	5
3	5			36	196
		2	13		4
		4	17		2
		11	51	1	9
		7	15	1	3

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Dry throat	1	8
Dumping syndrome		1
Duodenogastric reflux	1	2
Dupuytren's contracture		1
Dysaesthesia		3
Dysarthria	11	28
Dyschezia	2	2
Dysentery		1
Dysgeusia	10	90
Dysgraphia		2
Dyskinesia	3	19
Dyslexia		1
Dyslipidaemia		1
Dysmenorrhoea	2	7
Dyspepsia	4	30
Dysphagia	14	94
Dysphemia		3
Dysphonia	7	80
Dyspnoea	128	645
Dyspnoea at rest		2
Dyspnoea exertional	2	11
Dysstasia	8	54
Dystonia	1	6
Dysuria	4	16
Ear congestion	1	4
Ear discomfort	10	40
Ear disorder	1	11
Ear haemorrhage		2
Ear infection	2	8
Ear pain	16	69
Ear pruritus	1	6
Ear swelling	4	10
Eating disorder	11	39

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	8		
			1		
		1	2		
					1
			2		1
		8	17	3	11
		1	1	1	1
					1
		8	80	2	10
			1		1
		3	16		3
			1		
			1		
		2	7		
		4	29		1
	1	8	67	6	27
					3
		6	50	1	30
	2	78	386	50	259
					2
		2	8		3
		5	35	3	19
				1	6
		2	11	2	5
		1	3		1
		7	35	3	5
		1	6		5
			1		1
		2	6		2
		13	60	3	9
			3	1	3
		4	9		1
		9	29	2	10

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Eating disorder symptom		1
Eczema	1	4
Ejection fraction decreased	1	2
Electric shock	1	1
Electric shock sensation	1	6
Electrocardiogram abnormal	2	6
Electrocardiogram QT prolonged		2
Electrocardiogram ST segment elevation		1
Electrocardiogram T wave abnormal		1
Embolic stroke	1	3
Emotional disorder	3	10
Emotional distress	1	4
Emphysema	1	1
Encephalitis		2
Encephalomalacia		1
Encephalopathy		1
Endocarditis		2
Endocrine disorder	1	1
Endocrine ophthalmopathy		2
Endometrial cancer	1	2
Endometrial thickening		1
Endometriosis		1
Energy increased	2	8
Enlarged uvula	1	5
Enuresis	1	1
Eosinophil count increased		3
Eosinophilia		1
Epicondylitis		1
Epigastric discomfort		1
Epilepsy		2
Epistaxis	7	49
Epstein-Barr virus antibody positive		1
Epstein-Barr virus antigen positive		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	4		
				1	2
		1	1		
		1	6		
		1	4	1	2
					2
					1
			1		
				1	3
		3	9		1
		1	4		
		1	1		
					2
					1
					1
					2
		1	1		
					2
				1	2
			1		
					1
		2	8		
			2	1	3
		1	1		
			1		2
			1		
			1		
					2
		6	33	1	16
			1		
			1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Erectile dysfunction		2						2
Erection increased		1						1
Eructation		6				5		1
Erythema	55	312			44	255	11	57
Erythema marginatum		1				1		
Erythema multiforme	1	3					1	3
Erythema nodosum		1				1		
Erythema of eyelid		5				4		1
Erythrodermic psoriasis	1	1			1	1		
Erythrospia	1	1			1	1		
Escherichia infection	1	1					1	1
Escherichia urinary tract infection		1						1
Euphoric mood	1	5			1	5		
Eustachian tube dysfunction		1						1
Exaggerated startle response	1	1			1	1		
Excessive cerumen production		1				1		
Exercise tolerance decreased		2				2		
Exophthalmos		3						3
Expired product administered		1				1		
Exposure during pregnancy	3	8			3	8		
Exposure to SARS-CoV-2	3	11			3	11		
Exposure via skin contact	1	4			1	4		
Extensive swelling of vaccinated limb		1				1		
External ear disorder		1				1		
Extra dose administered	1	1			1	1		
Extraocular muscle disorder		1				1		
Extraocular muscle paresis		2						2
Extrasystoles		6				5		1
Extremity contracture		1				1		
Eye colour change		2						2
Eye contusion	1	4			1	4		
Eye discharge	2	5			2	5		
Eye disorder	5	24			4	20	1	4

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Eye haemorrhage	2	15					2	15
Eye infection		3				3		
Eye inflammation		5				3		2
Eye injury		2				1		1
Eye irritation	4	15			3	13	1	2
Eyelid disorder		3				3		
Eyelid function disorder		4				2		2
Eyelid haematoma		1				1		
Eyelid irritation		2				2		
Eyelid margin crusting		1				1		
Eyelid oedema		3				3		
Eyelid pain		2				2		
Eyelid ptosis		3				2		1
Eyelid rash	1	2			1	2		
Eyelid sensory disorder		1				1		
Eyelids pruritus	2	8			2	6		2
Eye movement disorder		5				4		1
Eye oedema		3				3		
Eye pain	6	53			6	45		8
Eye paraesthesia		2				1		1
Eye pruritus	7	39			5	28	2	11
Eye swelling	12	63			10	46	2	17
Eye ulcer		1				1		
Face injury		2				2		
Face oedema		3				1		2
Facial bones fracture		2						2
Facial discomfort		4				4		
Facial nerve disorder		3				2		1
Facial neuralgia		1				1		
Facial pain	3	28			2	22	1	6
Facial paralysis	3	30					3	30
Facial paresis	2	8			1	4	1	4
Facial spasm		1						1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Faeces discoloured	2	7
Faeces soft		4
Fall	26	111
False positive investigation result		1
Fatigue	335	1,875
Fear	2	21
Fear of falling	1	1
Fear of injection		1
Febrile convulsion		2
Feeding disorder	11	29
Feeling abnormal	114	536
Feeling cold	23	98
Feeling drunk	4	16
Feeling hot	36	218
Feeling jittery	3	13
Feeling of body temperature change	7	27
Female reproductive tract disorder	1	1
Femur fracture		1
Fibrin D dimer increased	2	8
Fibromyalgia	3	9
Finger deformity	1	1
Flank pain		5
Flatulence		16
Flea infestation	1	1
Fluid intake reduced		4
Fluid overload	1	2
Fluid retention	2	6
Flushing	16	141
Foaming at mouth	1	3
Foetal death	1	1
Folliculitis		1
Food allergy	2	3
Food aversion		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	5	1	2
			3		1
		15	60	11	51
			1		
	1	298	1728	37	147
		2	17		4
		1	1		
			1		
					2
		9	24	2	5
		102	486	12	50
		20	84	3	14
		4	14		2
		33	184	3	34
		3	9		4
		7	23		4
				1	1
					1
		2	7		1
		3	7		2
		1	1		
			3		2
			15		1
		1	1		
			2		2
		1	1		1
		1	4	1	2
		13	109	3	32
			2	1	1
				1	1
			1		
		2	3		
			2		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Food intolerance	1	1
Food poisoning		2
Foot deformity	1	2
Foot fracture		1
Foreign body aspiration		1
Foreign body in throat		1
Foreign body sensation in eyes	2	4
Formication	1	4
Freezing phenomenon	1	4
Frequent bowel movements		6
Frustration tolerance decreased	2	7
Full blood count abnormal		2
Functional gastrointestinal disorder		3
Fungal infection	1	1
Furuncle		1
Gait disturbance	35	183
Gait inability	13	50
Gallbladder disorder		3
Gallbladder polyp		1
Gastric disorder	3	13
Gastric infection		1
Gastritis	1	3
Gastroenteritis viral	1	7
Gastrointestinal disorder	6	28
Gastrointestinal haemorrhage		6
Gastrointestinal hypomotility		1
Gastrointestinal infection	1	1
Gastrointestinal inflammation		1
Gastrointestinal motility disorder		2
Gastrointestinal pain	1	7
Gastrointestinal sounds abnormal		1
Gastrointestinal stoma complication		1
Gastrointestinal viral infection		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
			2		
		1	2		
					1
					1
					1
		2	4		
		1	3		1
		1	4		
			5		1
		2	7		
			2		
			3		
		1	1		
			1		
		22	124	13	59
		8	30	5	20
			1		2
			1		
		3	12		1
					1
			2	1	1
		1	6		1
		5	24	1	4
					6
					1
				1	1
			1		
			2		
		1	7		
			1		
			1		
			1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Gastroesophageal reflux disease	5	23			5	21		2
Generalised anxiety disorder		1				1		
Generalised tonic-clonic seizure	3	9					3	9
General physical health deterioration	1	7			1	2		5
Genital herpes	1	2				1	1	1
Genital herpes simplex		1				1		
Gingival abscess	1	1			1	1		
Gingival bleeding		5				3		2
Gingival discomfort		2				1		1
Gingival disorder		1				1		
Gingival erythema		3				3		
Gingival pain	2	8			2	7		1
Gingival recession		1				1		
Gingival swelling		5				3		2
Glassy eyes		5				4		1
Glaucoma	1	1					1	1
Glomerular filtration rate abnormal		1				1		
Glomerular filtration rate decreased		4				3		1
Glossitis	1	4				3	1	1
Glossodynia	2	14			2	13		1
Glycosylated haemoglobin increased		3				1		2
Goitre	2	4			1	2	1	2
Gout	2	6				3	2	3
Granulocytes abnormal		1						1
Granuloma annulare		1				1		
Granuloma skin		1						1
Grip strength decreased		7				7		
Groin pain	6	14			5	11	1	3
Growing pains	1	1			1	1		
Grunting		6				5		1
Guillain-Barre syndrome		9						9
Haematemesis		2						2
Haematochezia	3	14	1	1			3	14

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Haematocrit decreased		3				2		1
Haematocrit increased		1				1		
Haematoma		3				3		
Haematuria		4				2		2
Haemoglobin abnormal		1						1
Haemoglobin decreased	2	15				5	2	10
Haemoglobin increased		1				1		
Haemolysis		1						1
Haemolytic anaemia		2						2
Haemophagocytic lymphohistiocytosis		1						1
Haemoptysis	1	9				3	1	6
Haemorrhage	6	20					6	20
Haemorrhage subcutaneous		1						1
Haemorrhage urinary tract	4	7					4	7
Haemorrhagic diathesis	1	1					1	1
Haemorrhagic stroke		3						3
Haemorrhagic urticaria		1						1
Haemorrhagic varicella syndrome		1						1
Haemorrhoids	1	5			1	3		2
Hair disorder		1				1		
Hair injury	1	2			1	2		
Hair texture abnormal	1	1			1	1		
Hallucination	2	21					2	21
Hallucination, auditory		4						4
Hallucination, visual		6						6
Hand fracture		4						4
Hangover	1	5			1	5		
Haptoglobin increased		1				1		
Headache	366	2,084			340	1904	26	180
Head discomfort	15	73			15	62		11
Head injury	3	14			2	9	1	5
Heart injury		2						2
Heart rate abnormal	2	17			2	16		1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Heart rate decreased	3	19
Heart rate increased	61	297
Heart rate irregular	3	23
Heart valve incompetence		1
Heat illness		1
Heavy menstrual bleeding	9	18
Hemiparesis	3	10
Hemiplegia		3
Hemiplegic migraine	1	1
Henoch-Schonlein purpura		2
Heparin-induced thrombocytopenia		1
Hepatic cyst		1
Hepatic enzyme abnormal		3
Hepatic enzyme increased		4
Hepatic failure	1	1
Hepatic pain	1	2
Hepatic steatosis		1
Hepatitis acute		1
Hepatitis A virus test positive		1
Hepatitis C	2	2
Hepatomegaly		1
Herpes ophthalmic	1	1
Herpes simplex		1
Herpes virus infection		2
Herpes zoster	64	112
Herpes zoster oticus	1	2
Herpes zoster reactivation	1	2
Hiatus hernia		1
Hiccups		1
Hip fracture	1	5
Histamine level increased		1
HIV infection		1
Hordeolum		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	13		6
		44	224	17	73
		2	18	1	5
			1		
			1		
		6	13	3	5
1	1			3	10
					3
		1	1		
					2
					1
					1
					3
			3		1
				1	1
		1	2		
			1		
					1
			1		
				2	2
			1		
				1	1
			1		
			1		1
		46	82	18	30
1	1			1	2
		1	2		
			1		
			1		
				1	5
			1		
			1		
			3		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Hospitalisation		1						1
Hostility		1						1
Hot flush	15	73			13	63	2	10
Hunger	1	5			1	5		
Hydronephrosis		1						1
Hyperactive pharyngeal reflex		1				1		
Hyperacusis	3	13			3	13		
Hyperaesthesia	3	16			1	13	2	3
Hyperaesthesia teeth	1	2			1	2		
Hyperbilirubinaemia		1						1
Hypercholesterolaemia	1	1			1	1		
Hyperexplexia	1	1			1	1		
Hyperglycaemia	2	8			1	3	1	5
Hyperhidrosis	39	238			36	207	3	31
Hypernatraemia		1						1
Hyperphagia	1	1			1	1		
Hyperpyrexia	1	5					1	5
Hypersensitivity	43	156			28	99	15	57
Hypersomnia	8	49			6	44	2	5
Hypersomnia-bulimia syndrome	1	1					1	1
Hypertension	26	147		1	12	81	14	66
Hypertensive crisis		1						1
Hypertensive emergency		4						4
Hypertensive heart disease		1						1
Hyperthermia		1				1		
Hyperthyroidism	1	3					1	3
Hypertonia		1						1
Hypertrichosis		1				1		
Hyperventilation	6	17			3	12	3	5
Hypervigilance		1				1		
Hypoacusis	6	26			4	20	2	6
Hypoaesthesia	67	366			48	272	19	94
Hypoaesthesia eye		4				4		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hypoaesthesia oral	17	104
Hypoaesthesia teeth		1
Hypobarism		1
Hypocalcaemia		1
Hypogammaglobulinaemia		1
Hypogeusia	1	4
Hypoglycaemia	1	8
Hypokalaemia		3
Hypokalaemic syndrome		1
Hypokinesia	3	18
Hypomagnesaemia		1
Hyponatraemia		1
Hyponatraemic syndrome		1
Hypophagia		3
Hypopnoea	3	9
Hyporeflexia		1
Hyporesponsive to stimuli		1
Hyposmia		1
Hypotension	5	45
Hypothermia	3	8
Hypothyroidism	2	6
Hypovolaemic shock		1
Hypoxia	1	5
Hypoxic-ischaemic encephalopathy		1
Idiopathic urticaria	1	1
Idiosyncratic drug reaction		1
IgA nephropathy	1	1
IIIrd nerve paralysis		2
Ileus		1
III-defined disorder		1
Illness	53	204
Immobile	1	5
Immune system disorder	5	23

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		13	76	4	28
			1		
					1
					1
					1
		1	3		1
		1	5		3
					3
			1		
		2	11	1	7
					1
			1		
			1		
			1		2
		3	8		1
					1
					1
			1		
		4	21	1	24
				3	8
				2	6
					1
				1	5
					1
				1	1
			1		
				1	1
					2
					1
			1		
	1	48	185	5	19
				1	5
		3	17	2	6

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Immune thrombocytopenia	2	9
Immunisation		1
Immunisation reaction		1
Immunodeficiency	2	3
Impaired driving ability	1	2
Impaired gastric emptying	1	1
Impaired healing		3
Impaired quality of life		1
Impaired self-care		1
Impaired work ability	3	7
Inappropriate schedule of product administration	34	160
Incision site haemorrhage		1
Incoherent		6
Incomplete course of vaccination		3
Incontinence	1	5
Incorrect dose administered	2	4
Incorrect product administration duration		1
Incorrect route of product administration	5	28
Increased tendency to bruise	1	2
Increased upper airway secretion		4
Increased viscosity of bronchial secretion		1
Increased viscosity of upper respiratory secretion		1
Induration	1	1
Infarction	2	2
Infection	1	12
Infection reactivation	1	1
Infectious mononucleosis		2
Infertility female		1
Inflammation	17	57
Inflammatory bowel disease		1
Inflammatory carcinoma of the breast	1	1
Inflammatory marker increased	3	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	9
			1		
					1
2	2			2	3
		1	1		1
				1	1
			2		1
					1
					1
		3	7		
		34	159		1
					1
			3		3
			3		
			2	1	3
		2	4		
			1		
		5	27		1
			1	1	1
			2		2
					1
					1
		1	1		
				2	2
		1	8		4
		1	1		
			2		
					1
		16	51	1	6
					1
				1	1
		2	4	1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Inflammatory pain		2				2		
Influenza	7	50			6	45	1	5
Influenza A virus test positive		1				1		
Influenza B virus test positive		1				1		
Influenza like illness	33	181			30	161	3	20
Initial insomnia		3				3		
Injected limb mobility decreased		3				3		
Injection site abscess		1				1		
Injection site bruising		1				1		
Injection site erythema	3	27			3	27		
Injection site haematoma		1						1
Injection site haemorrhage	1	1			1	1		
Injection site induration		1				1		
Injection site inflammation		1				1		
Injection site mass	1	5			1	5		
Injection site pain	8	81			7	79	1	2
Injection site papule		1				1		
Injection site paraesthesia		1				1		
Injection site pruritus		10				10		
Injection site rash		6				6		
Injection site reaction		4				4		
Injection site swelling	1	21			1	21		
Injection site urticaria		6				5		1
Injection site vesicles		1				1		
Injection site warmth		9				9		
Injury		3				2		1
Inner ear disorder		1						1
Inner ear inflammation		1				1		
Insomnia	45	191			37	162	8	29
Inspiratory capacity decreased	1	1			1	1		
Instillation site pain		1				1		
Instillation site warmth	1	1			1	1		
Insulin resistance		1						1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Intentional product misuse		1				1		
Intermenstrual bleeding	2	5			1	4	1	1
Internal haemorrhage		2						2
International normalised ratio decreased		3				2		1
International normalised ratio increased	1	5			1	3		2
Intervertebral disc degeneration		2				2		
Intervertebral disc protrusion	1	4				1	1	3
Intestinal haemorrhage			1	1				
Intestinal obstruction	1	2					1	2
Intestinal perforation		1						1
Intra-abdominal haematoma		1						1
Intracardiac thrombus		1						1
Intracranial aneurysm		1						1
Intracranial pressure increased	1	4					1	4
Intranasal hypoaesthesia		1				1		
Intranasal paraesthesia		2				2		
Intraocular pressure increased		1						1
Intraocular pressure test abnormal	1	1			1	1		
Intrusive thoughts		1				1		
Iridocyclitis		2						2
Iritis		1				1		
Iron deficiency	1	1			1	1		
Irregular breathing		1				1		
Irritability	3	11			3	10		1
Irritable bowel syndrome		4				3		1
Ischaemic stroke	1	7					1	7
IVth nerve paralysis		1						1
Jaundice		1						1
Jaw clicking		1				1		
Jaw disorder		3		1		3		
Job dissatisfaction		1				1		
Joint dislocation	2	6			1	2	1	4
Joint effusion	1	4			1	4		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Joint injury	2	11
Joint instability		4
Joint lock	1	4
Joint noise	1	1
Joint range of motion decreased	1	21
Joint stabilisation		1
Joint stiffness	7	32
Joint swelling	17	72
Joint warmth		1
Kawasaki's disease	1	1
Keratic precipitates		2
Keratitis		1
Keratosis pilaris	1	2
Kidney infection	2	5
Knee operation		1
Labile hypertension		1
Laboratory test abnormal	1	4
Laboratory test normal		1
Labyrinthitis		2
Lack of spontaneous speech		1
Lacrimal disorder	1	2
Lacrimation increased	6	27
Lactic acidosis		1
Lacunar infarction		1
Lacunar stroke		1
Laryngeal oedema		3
Laryngeal pain		1
Laryngitis	2	7
Laryngospasm		3
Latent autoimmune diabetes in adults		1
Laziness		1
Lethargy	20	99
Leukaemia		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	9	1	2
			1		3
			3	1	1
		1	1		
		1	16		5
					1
		6	29	1	3
		11	61	6	11
			1		
				1	1
					2
					1
		1	2		
				2	5
					1
			1		
		1	3		1
			1		
			1		1
					1
		1	2		
		6	23		4
					1
					1
					1
					3
			1		
		1	5	1	2
					3
					1
			1		
		19	87	1	12
					2

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			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Leukaemia recurrent		1						1
Leukocytosis		3				2		1
Lichen planus		1				1		
Lichen sclerosus		1				1		
Ligament injury	1	1			1	1		
Ligamentitis	1	1					1	1
Ligament pain	1	1					1	1
Ligament rupture	2	2			2	2		
Ligament sprain		5				5		
Limb discomfort	25	99			25	90		9
Limb injury	2	17			2	17		
Limb mass		1				1		
Lip blister	2	7				4	2	3
Lip discolouration		1				1		
Lip disorder	1	4				3	1	1
Lip dry	2	5			2	3		2
Lip erythema	1	5			1	5		
Lip haemorrhage		1						1
Lipids increased		1				1		
Lip injury	1	3			1	3		
Lip oedema		2				1		1
Lipoma		1						1
Lip pain	5	8			4	7	1	1
Lip pruritus		9				5		4
Lip swelling	21	98			9	53	12	45
Listless		3				3		
Livedo reticularis		4				2		2
Liver contusion		1						1
Liver disorder		1				1		
Liver function test abnormal		2				1		1
Liver function test increased	2	2			1	1	1	1
Liver injury		3				1		2
Liver tenderness		1				1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Localised infection	2	5			1	4	1	1
Localised oedema		2				1		1
Loose body in joint		1						1
Loss of consciousness	32	137					32	137
Loss of control of legs		2						2
Loss of personal independence in daily activities	10	58			7	45	3	13
Loss of proprioception		1						1
Low density lipoprotein increased	2	3			2	3		
Lower gastrointestinal haemorrhage		2						2
Lower respiratory tract congestion		1				1		
Lower respiratory tract infection		3						3
Lumbar puncture abnormal		1						1
Lumbar radiculopathy		1				1		
Lung carcinoma cell type unspecified recurrent	1	1					1	1
Lung disorder	4	14			1	9	3	5
Lung hyperinflation		1				1		
Lung infiltration		2				1		1
Lung neoplasm malignant		1						1
Lung opacity		2				1		1
Lupus-like syndrome	1	1					1	1
Lupus myositis		1						1
Lyme disease	1	1					1	1
Lymphadenitis	2	6				2	2	4
Lymphadenopathy	67	390		1	60	358	7	32
Lymph gland infection		1				1		
Lymph node pain	12	83			12	76		7
Lymphocyte count abnormal		2				2		
Lymphocyte count decreased	1	6				5	1	1
Lymphocyte count increased	1	4				2	1	2
Lymphocytosis		1				1		
Lymphoedema	2	8			2	8		
Lymphoma	1	2					1	2
Macular degeneration		2						2

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Macular oedema		1
Macule	1	3
Malaise	103	604
Malnutrition	1	1
Mammogram abnormal		1
Mania		1
Mass	7	22
Mastication disorder		5
Mastitis	1	1
Maternal exposure during pregnancy	6	15
May-Thurner syndrome		1
Mean cell haemoglobin increased	1	1
Mean cell volume increased	1	1
Measles	1	3
Mechanical urticaria	1	2
Mediastinal mass	1	1
Medication error		2
Melaena		1
Melanoma recurrent		2
Memory impairment	11	39
Meniere's disease		2
Meningitis		1
Meningitis aseptic		1
Meningitis noninfective		1
Meniscus injury		2
Menopause		1
Menstrual disorder	7	14
Menstruation delayed	1	2
Menstruation irregular	7	12
Mental disorder	2	10
Mental fatigue	1	1
Mental impairment	3	24
Mental status changes	1	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	3		
		90	546	13	58
				1	1
			1		
			1		
		5	19	2	3
			3		2
				1	1
		6	15		
					1
		1	1		
		1	1		
				1	3
		1	2		
		1	1		
			2		
					1
					2
		11	34		5
					2
					1
					1
					1
			1		1
			1		
		5	11	2	3
				1	2
		6	11	1	1
		2	7		3
		1	1		
				3	24
		1	5		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Meralgia paraesthetica		1
Metabolic encephalopathy		1
Metabolic function test abnormal		2
Metamorphopsia		1
Metamyelocyte count increased		1
Microangiopathic haemolytic anaemia		1
Microembolism		1
Micturition disorder	1	2
Micturition urgency	1	5
Middle ear effusion		1
Middle insomnia	2	9
Migraine	24	137
Migraine with aura	1	2
Miliaria	1	4
Miosis	1	2
Mitral valve disease		1
Mitral valve prolapse		1
Mixed connective tissue disease	1	1
Moaning		2
Mobility decreased	9	50
Monoclonal gammopathy		1
Monocyte count abnormal		1
Monocyte count increased		4
Monoplegia	5	7
Mood altered		2
Mood swings		1
Morning sickness		1
Motion sickness		4
Motor dysfunction	1	7
Mouth haemorrhage		3
Mouth swelling	3	20
Mouth ulceration	2	9
Movement disorder	16	59

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
			2		
					1
					1
					1
					1
		1	2		
		1	4		1
			1		
		2	8		1
		18	107	6	30
		1	2		
		1	4		
		1	2		
					1
					1
				1	1
			1		1
		5	37	4	13
			1		
			1		
			2		2
				5	7
			2		
					1
					1
			4		
		1	3		4
			3		
		3	15		5
		2	9		
		13	47	3	12

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Mucosal disorder	1	5			1	4		1
Mucous stools		2				2		
Multi-organ disorder		3				2		1
Multiple organ dysfunction syndrome		3						3
Multiple sclerosis	3	8					3	8
Multiple sclerosis relapse	3	8					3	8
Muscle atrophy	1	2				1	1	1
Muscle contractions involuntary	1	4			1	3		1
Muscle discomfort		7				7		
Muscle disorder	2	6			1	3	1	3
Muscle fatigue	3	5			3	5		
Muscle injury	1	3			1	3		
Muscle rigidity		3				1		2
Muscle rupture	2	3					2	3
Muscle spasms	24	143			18	114	6	29
Muscle spasticity	1	4			1	3		1
Muscle strain	3	6			3	6		
Muscle swelling	1	5			1	5		
Muscle tightness	8	48			7	36	1	12
Muscle twitching	3	25			3	17		8
Muscular weakness	22	131			10	86	12	45
Musculoskeletal chest pain	3	27			3	24		3
Musculoskeletal discomfort	5	36			4	33	1	3
Musculoskeletal disorder	2	6			2	5		1
Musculoskeletal pain	2	13			2	11		2
Musculoskeletal stiffness	39	142			32	124	7	18
Mutism		2				1		1
Myalgia	121	725		1	108	665	13	60
Myasthenia gravis		2						2
Mydriasis	1	3			1	3		
Myelitis	1	1					1	1
Myelitis transverse		4						4
Myelocyte count increased		1						1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Myelopathy		1						1
Myocardial infarction	8	42				1	8	41
Myocardial necrosis marker increased	1	3					1	3
Myocardial strain		1						1
Myocarditis	1	7					1	7
Myoclonus	1	3					1	3
Myokymia		1				1		
Myopathy	1	1					1	1
Myositis	2	4			1	1	1	3
Nail discolouration		1				1		
Narcolepsy		1						1
Nasal congestion	21	112			19	100	2	12
Nasal discomfort	4	14			3	11	1	3
Nasal disorder		2				1		1
Nasal dryness		2				2		
Nasal injury		1				1		
Nasal oedema	1	7				3	1	4
Nasal pruritus	1	2			1	1		1
Nasopharyngitis	12	84			12	80		4
Nausea	178	1,127		1	164	1001	14	126
Near death experience	2	10					2	10
Neck injury		1				1		
Neck mass	3	6			2	5	1	1
Neck pain	29	190			23	162	6	28
Neoplasm	1	4			1	4		
Neoplasm malignant	1	2					1	2
Neoplasm progression	1	3					1	3
Neoplasm recurrence	1	1			1	1		
Neoplasm skin	1	1			1	1		
Nephritis	1	1					1	1
Nephrolithiasis		5						5
Nephropathy		3				1		2
Nerve compression		8				7		1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Nerve injury	1	6
Nervousness	9	64
Nervous system disorder	6	16
Neuralgia	10	51
Neuralgic amyotrophy		1
Neuritis	2	5
Neurological examination normal		1
Neurological procedural complication	1	1
Neurological symptom	4	10
Neuromyelitis optica spectrum disorder		2
Neuropathy peripheral	11	56
Neutropenia	1	3
Neutrophil count abnormal		1
Neutrophil count decreased	1	4
Neutrophil count increased		4
Neutrophilia		1
Nightmare		10
Night sweats	11	42
Nipple pain		3
Nipple swelling		1
No adverse event		7
Nocturia		2
Nodule	1	7
Non-cardiac chest pain		1
Non-Hodgkin's lymphoma		1
Noninfective encephalitis	2	5
Non-pitting oedema		1
Norepinephrine increased		1
Normocytic anaemia		1
Nose deformity		2
Nuchal rigidity		2
Nucleated red cells	1	1
Nystagmus	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			5	1	1
		8	59	1	5
		6	13		3
		7	43	3	8
			1		
		1	4	1	1
			1		
		1	1		
		2	6	2	4
					2
		1	1	10	55
				1	3
					1
		1	3		1
			2		2
			1		
			9		1
		10	40	1	2
			3		
			1		
			7		
			2		
		1	7		
			1		
					1
				2	5
					1
			1		
			1		
			2		
			1		1
		1	1		
		1	3		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Obsessive-compulsive personality disorder	1	1
Obsessive thoughts		1
Obstructive airways disorder	1	2
Obstructive shock		1
Occipital neuralgia		1
Ocular discomfort	6	26
Ocular hyperaemia	7	39
Ocular ischaemic syndrome	1	1
Ocular vascular disorder	1	1
Odynophagia	2	11
Oedema	2	9
Oedema peripheral	2	11
Oesophageal disorder	1	2
Oesophageal pain	1	2
Off label use	33	183
Oligodipsia		1
Oligomenorrhoea	2	2
Ophthalmic herpes zoster	3	4
Ophthalmic migraine		4
Ophthalmic vein thrombosis	1	1
Ophthalmoplegia	1	1
Optic neuritis	1	3
Oral blood blister		1
Oral candidiasis		1
Oral discomfort	5	27
Oral disorder	2	7
Oral fungal infection		1
Oral herpes	5	24
Oral lichen planus		1
Oral mucosal blistering	4	8
Oral mucosal eruption	2	3
Oral mucosal erythema		2
Oral mucosal exfoliation		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
		1	1		1
					1
					1
		6	23		3
		6	32	1	7
				1	1
				1	1
		2	10		1
		2	7		2
		2	7		4
				1	2
			1	1	1
		33	181		2
					1
		2	2		
				3	4
			4		
				1	1
				1	1
				1	3
					1
			1		
		2	19	3	8
		2	6		1
			1		
		5	23		1
			1		
		4	7		1
				2	3
			2		
			1		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Oral pain	4	13
Oral pruritus	2	13
Oral viral infection		1
Organising pneumonia		1
Oromandibular dystonia		1
Oropharyngeal blistering	1	3
Oropharyngeal cobble stone mucosa		1
Oropharyngeal discomfort	4	37
Oropharyngeal pain	34	202
Oropharyngeal spasm	1	3
Oropharyngeal swelling		1
Orthopnoea		1
Orthostatic hypotension		3
Osteitis	1	1
Osteoarthritis	1	5
Osteochondritis		1
Osteogenesis imperfecta		1
Osteolysis	1	1
Osteomyelitis		1
Osteopenia	1	1
Otitis media	1	2
Ovarian cyst	1	1
Ovarian cyst ruptured	1	1
Ovarian disorder		1
Overdose	3	15
Oversensing		1
Overweight		2
Ovulation disorder	1	1
Oxygen consumption		1
Oxygen consumption decreased		1
Oxygen saturation		2
Oxygen saturation abnormal		4
Oxygen saturation decreased	9	45

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	13		
		1	7	1	6
			1		
			1		1
			1		
				1	3
			1		
		2	29	2	8
		31	185	3	17
				1	3
			1		
					1
			1		2
		1	1		
		1	5		
			1		
					1
		1	1		
					1
		1	1		
		1	2		
		1	1		
				1	1
					1
		3	14		1
			1		
			2		
		1	1		
			1		
			1		
			2		
			4		
		3	18	6	27

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pain	261	1,331
Painful respiration	1	9
Pain in extremity	251	1,274
Pain in jaw	7	40
Pain of skin	8	22
Palatal disorder		1
Palatal swelling	1	4
Pallor	5	31
Palmar erythema		2
Palpable purpura		1
Palpitations	47	218
Pancreatic carcinoma metastatic	1	1
Pancreatic disorder		2
Pancreatitis	2	6
Pancreatitis acute	2	5
Pancreatitis relapsing		1
Pancytopenia	1	2
Panic attack	5	16
Panic reaction	2	8
Panniculitis	1	1
Papule		1
Paraesthesia	63	361
Paraesthesia oral	11	103
Paralysis	6	15
Paranasal sinus discomfort	4	12
Paranoia	1	3
Paraplegia		1
Paresis		1
Parkinsonism	1	3
Parkinson's disease	1	3
Parosmia	5	21
Paroxysmal sympathetic hyperactivity		1
Patient elopement	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	2	229	1207	32	124
			5	1	4
	3	226	1180	25	94
	1	7	34		6
		8	20		2
			1		
			1	1	3
		5	24		7
			1		1
			1		
		35	167	12	51
				1	1
			2		
				2	6
				2	5
					1
				1	2
		5	14		2
		2	7		1
				1	1
			1		
		47	288	16	73
		8	72	3	31
				6	15
		3	11	1	1
		1	3		
					1
					1
			1	1	2
				1	3
		5	19		2
					1
		1	2		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
PCO2 decreased		1
Peau d'orange	1	1
Pelvic pain	2	5
Pemphigoid	2	3
Pemphigus	1	1
Penile haemorrhage		1
Periarthritis		1
Pericardial effusion	3	7
Pericarditis	7	14
Periorbital cellulitis		1
Periorbital discomfort		1
Periorbital pain		1
Periorbital swelling		14
Peripheral arterial occlusive disease		1
Peripheral artery thrombosis	2	3
Peripheral coldness	7	34
Peripheral nerve injury		1
Peripheral sensory neuropathy	1	2
Peripheral swelling	73	264
Peripheral venous disease		2
Perivascular dermatitis		1
Peroneal nerve palsy		5
Personality change	1	1
Pertussis	1	1
Petechiae	2	14
Pharyngeal disorder	1	4
Pharyngeal erythema		7
Pharyngeal hypoaesthesia		7
Pharyngeal inflammation	1	3
Pharyngeal mass		3
Pharyngeal oedema		1
Pharyngeal paraesthesia	1	15
Pharyngeal swelling	18	101

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1		
		1	4	1	1
				2	3
				1	1
					1
					1
				3	7
				7	14
					1
			1		
			1		
			13		1
					1
			1	2	2
		4	26	3	8
					1
				1	2
	1	53	218	20	46
			2		
			1		
			3		2
		1	1		
				1	1
			4	2	10
		1	3		1
			7		
			4		3
			2	1	1
			2		1
					1
		1	10		5
		14	54	4	47

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Pharyngitis		2				1		1
Pharyngitis streptococcal		1				1		
Phlebitis		2				2		
Photophobia	7	31			7	29		2
Photopsia	1	7			1	5		2
Photosensitivity reaction	3	8	1	1	2	5	1	3
Physical deconditioning		1				1		
Pigmentation disorder		3				2		1
Piloerection	3	6			3	6		
Pituitary tumour benign		1						1
Plantar fasciitis		1				1		
Plasma cell myeloma	1	2					1	2
Platelet count decreased	4	27	1	1	2	6	2	21
Platelet count increased	2	8			2	4		4
Platelet disorder		3				1		2
Pleural effusion	1	7				2	1	5
Pleurisy	3	7				2	3	5
Pleuritic pain		2				2		
Plicated tongue		1				1		
Pneumocystis jirovecii pneumonia		1						1
Pneumonia	11	45				1	11	44
Pneumonia aspiration	2	6					2	6
Pneumonia bacterial	1	2					1	2
Pneumonia staphylococcal		1						1
Pneumonia viral	1	2					1	2
Pneumonitis	1	3			1	1		2
Pneumothorax		3						3
PO2 decreased		1						1
POEMS syndrome	1	1					1	1
Pollakiuria	4	20			4	20		
Polychondritis		1						1
Polycythaemia		1				1		
Polydipsia		1				1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Polymenorrhoea	2	2			1	1	1	1
Polymyalgia rheumatica		7						7
Polymyositis		1						1
Polyneuropathy		1						1
Polyserositis		1						1
Polyuria		5				4		1
Poor peripheral circulation		2						2
Poor quality product administered	2	10			2	10		
Poor quality sleep	1	13			1	12		1
Poor venous access		1				1		
Portal vein thrombosis	1	2					1	2
Post concussion syndrome	1	1			1	1		
Post herpetic neuralgia	2	4			1	3	1	1
Postmenopausal haemorrhage	2	6					2	6
Postoperative wound infection		1						1
Post procedural infection		1						1
Post procedural oedema		1				1		
Post-traumatic neck syndrome	1	4			1	1		3
Postural orthostatic tachycardia syndrome	1	4		1	1	2		2
Posture abnormal	1	1			1	1		
Posturing		1						1
Potentiating drug interaction		6				6		
Pre-existing condition improved	2	6			2	6		
Premature delivery		1						1
Premature labour		1						1
Premature rupture of membranes	1	2					1	2
Premenstrual syndrome		1				1		
Pressure of speech		1				1		
Presyncope	10	70			8	42	2	28
Prinzmetal angina		2						2
Procedural pain		2				1		1
Procedural site reaction		1						1
Product administered at inappropriate site	4	23			4	21		2

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Product administration error		3
Product colour issue		1
Product confusion		1
Product dose omission issue	3	16
Productive cough	5	32
Product leakage	1	2
Product preparation error	1	8
Product preparation issue		2
Product prescribing error		1
Product storage error	2	6
Product substitution error		1
Product supply issue	1	3
Product temperature excursion issue		2
Product use in unapproved indication		1
Product use issue	7	116
Prostate cancer		2
Prostate examination abnormal	1	1
Prostate infection		1
Prostatic specific antigen increased		1
Prostatitis	1	1
Protein total decreased		3
Protein total increased		1
Protein urine present		1
Prothrombin time prolonged		2
Pruritus	114	520
Pruritus genital		1
Psoriasis	4	13
Psoriatic arthropathy		6
Psychomotor hyperactivity		3
Psychotic disorder		1
Pulmonary artery occlusion		1
Pulmonary artery thrombosis		1
Pulmonary congestion	1	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		1
			1		
			1		
		3	15		1
		4	28	1	4
		1	2		
		1	8		
			2		
			1		
		2	6		
			1		
		1	3		
			2		
			1		
		7	114		2
					2
		1	1		
					1
			1	1	1
			3		
					1
			1		
			1		1
		96	425	18	95
					1
		4	12		1
					6
			2		1
					1
					1
					1
				1	10

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pulmonary embolism	18	52
Pulmonary fibrosis		5
Pulmonary hypertension		1
Pulmonary infarction		1
Pulmonary mass		1
Pulmonary oedema	6	18
Pulmonary pain	5	16
Pulmonary thrombosis	6	14
Pulmonary venous thrombosis		1
Pulse abnormal	1	8
Pulse absent		1
Pulseless electrical activity		1
Pulse pressure decreased		1
Pulse pressure increased		1
Pupil fixed		1
Pupillary disorder		1
Purpura	2	4
Pustule	1	5
Pyrexia	237	1,357
Quality of life decreased		2
Radial nerve injury	1	1
Radial pulse abnormal	1	1
Radiation injury	1	1
Rash	100	505
Rash erythematous	8	69
Rash macular	17	61
Rash maculo-papular	3	8
Rash morbilliform		7
Rash papular	6	31
Rash pruritic	25	88
Rash pustular	1	1
Rash vesicular	2	6
Raynaud's phenomenon	3	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				18	52
					5
	1				1
					1
			1		
		1	1	5	17
		4	12	1	4
				6	14
					1
		1	4		4
					1
					1
					1
			1		
			1		1
		1	3	1	1
				1	5
		210	1215	27	142
			1		1
				1	1
				1	1
		1	1		
		82	417	18	88
		7	55	1	14
		15	49	2	12
		3	8		
			4		3
		6	27		4
		21	70	4	18
				1	1
		2	5		1
		2	5	1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Reaction to excipient		4				1		3
Reactogenicity event		1				1		
Rectal haemorrhage	1	5					1	5
Rectal tenesmus		1				1		
Red blood cell count abnormal		1				1		
Red blood cell count decreased	4	9			1	3	3	6
Red blood cell count increased	1	3			1	3		
Red blood cell sedimentation rate abnormal		1				1		
Red blood cell sedimentation rate increased	3	7			2	3	1	4
Red cell distribution width increased		1						1
Red ear syndrome		1				1		
Reduced facial expression	1	2				1	1	1
Regurgitation	1	2			1	2		
Renal atrophy		2						2
Renal cyst	1	1			1	1		
Renal disorder	2	10				5	2	5
Renal failure	5	10					5	10
Renal function test abnormal	1	1			1	1		
Renal impairment	2	7					2	7
Renal pain	6	12			4	9	2	3
Respiration abnormal		6				6		
Respiratory arrest	1	8					1	8
Respiratory disorder	3	27			3	15		12
Respiratory distress		28						28
Respiratory failure		5						5
Respiratory rate decreased		3				1		2
Respiratory rate increased		12				2		10
Respiratory symptom		3				2		1
Respiratory tract congestion		12				8		4
Respiratory tract infection	1	4					1	4
Respiratory tract irritation		1						1
Respiratory tract oedema	1	5					1	5
Restless legs syndrome		7				6		1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Restlessness	1	22
Restrictive pulmonary disease		1
Retching	3	25
Retinal aneurysm	1	1
Retinal artery occlusion		2
Retinal detachment		1
Retinal disorder		1
Retinal vein occlusion	2	4
Retinitis		1
Retinogram abnormal	1	1
Rhabdomyolysis	2	3
Rheumatoid arthritis	8	39
Rhinalgia		5
Rhinitis		3
Rhinitis allergic		1
Rhinorrhoea	22	139
Right ventricular dilatation		1
Road traffic accident	1	1
Rosacea	1	6
Salivary gland enlargement	1	2
Salivary gland mass	1	1
Salivary gland pain		1
Salivary hypersecretion	1	5
Sarcoidosis	1	1
SARS-CoV-2 ant body test		1
SARS-CoV-2 ant body test negative		15
SARS-CoV-2 ant body test positive	1	3
SARS-CoV-2 test false positive		1
SARS-CoV-2 test negative		1
SARS-CoV-2 test positive	3	34
Scab	4	10
Scar		4
Sciatica	3	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	17		5
					1
		1	21	2	4
				1	1
					2
					1
			1		
				2	4
					1
				1	1
				2	3
3	4			8	39
			4		1
			2		1
					1
		22	126		13
			1		
		1	1		
			5	1	1
			1	1	1
				1	1
			1		
		1	3		2
				1	1
			1		
			13		2
		1	3		
					1
			1		
			11	3	23
		4	9		1
			1		3
			7	3	6

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Scleral discolouration		1
Scleritis		2
Scleroderma		2
Scratch	1	9
Screaming		2
Scrotal pain		1
Seasonal allergy		3
Secretion discharge	1	6
Sedation		4
Seizure	14	60
Seizure like phenomena	1	3
Senile dementia	1	1
Sensation of foreign body	1	17
Sensitive skin	3	12
Sensitivity to weather change		2
Sensory disturbance	1	11
Sensory loss	1	5
Sepsis	3	12
Septic shock	1	1
Seronegative arthritis		2
Serratia infection	1	1
Serum ferritin decreased		2
Serum sickness		1
Shock		9
Shock hypoglycaemic	1	1
Shock symptom		1
Shoulder injury related to vaccine administration		1
Sialoadenitis		2
Sinus bradycardia		2
Sinus congestion	3	12
Sinus disorder	4	19
Sinus headache	1	6
Sinusitis	5	28

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					2
					2
		1	8		1
			1		1
			1		
			3		
			2	1	4
			3		1
				14	60
				1	3
				1	1
		1	15		2
		2	11	1	1
			2		
		1	10		1
		1	3		2
				3	12
				1	1
					2
				1	1
					2
					1
					9
				1	1
					1
			1		
					2
			1		1
		2	11	1	1
		4	17		2
		1	6		
		4	26	1	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Sinusitis bacterial		1						1
Sinus pain	3	8			3	8		
Sinus tachycardia	1	5			1	3		2
Sitting disability		3				2		1
Sjogren's syndrome	2	5					2	5
Skin abrasion	1	3			1	3		
Skin bacterial infection		1						1
Skin burning sensation	9	21			7	19	2	2
Skin cancer	1	1					1	1
Skin depigmentation		1				1		
Skin discolouration	7	34			7	29		5
Skin disorder	11	34			10	27	1	7
Skin exfoliation	3	10			2	9	1	1
Skin fissures		2				1		1
Skin haemorrhage		4				3		1
Skin hypertrophy		1				1		
Skin indentation		1				1		
Skin infection		2				1		1
Skin injury		2				2		
Skin irritation	3	9			2	8	1	1
Skin laceration	2	8			2	4		4
Skin laxity		1				1		
Skin lesion	1	8			1	8		
Skin mass	2	4			2	4		
Skin odour abnormal		1				1		
Skin reaction	3	4			3	4		
Skin sensitisation	1	1			1	1		
Skin swelling	1	4			1	3		1
Skin tightness	1	7			1	6		1
Skin turgor decreased		1						1
Skin ulcer		2				2		
Skin warm		4				4		
Skin weeping	1	1			1	1		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Skin wrinkling		1
Sleep apnoea syndrome		1
Sleep attacks		1
Sleep deficit		4
Sleep disorder	6	47
Sleep disorder due to a general medical condition	2	4
Sleep disorder due to general medical condition, insomnia type	1	2
Sleep paralysis		1
Sleep talking		1
Sleep terror		1
Slow speech		2
Sluggishness	2	14
Small fibre neuropathy		1
Small intestinal obstruction		2
Sneezing	12	51
Snoring		2
Soft tissue disorder		1
Soft tissue injury	1	2
Somnambulism	1	1
Somnolence	35	157
Speech disorder	12	56
Speech sound disorder		1
Spinal cord disorder	1	2
Spinal disorder		1
Spinal fracture	1	1
Spinal fusion surgery		1
Spinal osteoarthritis		1
Spinal pain	3	11
Spinal stenosis	1	1
Spleen disorder	1	1
Splenic rupture	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
					1
			1		
			4		
		6	46		1
		2	4		
		1	2		
			1		
			1		
			2		
		2	14		
					1
					2
		11	48	1	3
			2		
			1		
			1	1	1
		1	1		
		32	137	3	20
		7	26	5	30
			1		
				1	2
			1		
				1	1
					1
			1		
		2	8	1	3
				1	1
		1	1		
				1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Splenic vein thrombosis		1						1
Splenomegaly		2				1		1
Splinter		1				1		
Splinter haemorrhages		1				1		
Spondylitis	2	2			2	2		
Sputum discoloured		4				1		3
Staphylococcal infection	1	2					1	2
Staring	1	4				1	1	3
Starvation	1	1					1	1
Status asthmaticus		1						1
Stevens-Johnson syndrome	1	2					1	2
Stiff tongue		1						1
Still's disease		1	1	1				1
Stoma site haemorrhage	1	2					1	2
Stomatitis	9	24			9	22		2
Strabismus		1						1
Stress	6	22			6	22		
Stress urinary incontinence	1	2			1	2		
Stridor		6				3		3
Subarachnoid haemorrhage	1	3					1	3
Subdural haemorrhage		1						1
Sudden cardiac death		2						2
Sudden death		2						2
Sudden hearing loss		3						3
Sudden visual loss		1						1
Suicidal behaviour	1	1					1	1
Suicidal ideation	1	6					1	6
Suicide attempt		1						1
Sunburn	1	3				2	1	1
Superficial injury of eye		1				1		
Superior sagittal sinus thrombosis		1						1
Supraventricular extrasystoles		3				2		1
Supraventricular tachycardia	1	4				1	1	3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Surgery	1	1			1	1		
Suspected COVID-19	15	33			9	16	6	17
Suture related complication		1						1
Swelling	38	187			30	152	8	35
Swelling face	20	160			12	116	8	44
Swelling of eyelid	5	20			3	17	2	3
Swollen tongue	15	92		1	6	44	9	48
Symptom recurrence		1				1		
Syncope	18	99				1	18	98
Synovial cyst		1				1		
Systemic inflammatory response syndrome	1	2					1	2
Systemic lupus erythematosus		6						6
Systemic scleroderma		1						1
Tachycardia	11	130			5	75	6	55
Tachyphrenia		2				2		
Tachypnoea		25				15		10
Tardive dyskinesia		1						1
Taste disorder	6	45			6	39		6
Temperature intolerance		5				3		2
Temperature regulation disorder		1				1		
Temporomand bular joint syndrome		1				1		
Tenderness	7	25			7	25		
Tendonitis	4	4			1	1	3	3
Tendon pain	1	3				1	1	2
Tension	1	2			1	2		
Tension headache	2	6			2	5		1
Testicular disorder	1	1			1	1		
Testicular pain	2	2			2	2		
Testicular swelling	2	3			2	3		
Tetanus		1						1
Tetany		1						1
Thalamic infarction		1						1
Therapeutic product effect decreased	1	1			1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Therapeutic product effect incomplete		1						1
Therapeutic response decreased	1	1			1	1		
Therapeutic response unexpected	9	51			9	51		
Thinking abnormal	2	16			2	15		1
Thirst	6	35			5	32	1	3
Thoracic vertebral fracture		1						1
Throat clearing	1	6			1	2		4
Throat irritation	19	92			16	66	3	26
Throat tightness	25	133			15	65	10	68
Thrombocytopenia	4	13					4	13
Thrombophlebitis		2				2		
Thrombophlebitis superficial		3				2		1
Thrombosis	32	79	1	1			32	79
Thrombotic microangiopathy		1						1
Thrombotic stroke		1						1
Thyroid disorder	2	10				7	2	3
Thyroid function test abnormal		2				2		
Thyroid hormones increased		2				2		
Thyroiditis	1	1			1	1		
Thyroiditis subacute		1				1		
Thyroid mass	1	1			1	1		
Thyroid pain		2				2		
Thyrotoxic crisis		3						3
Thyroxine decreased		1				1		
Tic	1	3			1	2		1
Tinea infection	1	1			1	1		
Tinnitus	32	135			23	99	9	36
T-lymphocyte count increased		1				1		
Tobacco user	1	1			1	1		
Tongue biting		1						1
Tongue blistering	2	4			2	4		
Tongue coated		1						1
Tongue discolouration	1	4			1	3		1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Tongue discomfort	3	19
Tongue disorder	4	12
Tongue dry	1	2
Tongue eruption		4
Tongue erythema	1	5
Tongue movement disturbance		1
Tongue oedema	1	3
Tongue paralysis		1
Tongue pruritus	3	10
Tongue rough	1	1
Tongue ulceration		3
Tonic clonic movements		1
Tonsillar disorder		1
Tonsillar hypertrophy		1
Tooth abscess		1
Toothache	2	18
Tooth discolouration		1
Tooth disorder		4
Tooth fracture	1	1
Tooth injury		2
Torsade de pointes		1
Torticollis		1
Tourette's disorder		1
Tracheal obstruction		1
Tracheal stenosis	1	1
Tracheitis	1	1
Tracheomalacia		1
Transaminases decreased		1
Transaminases increased		2
Transient ischaemic attack	4	19
Transplant failure		1
Tremor	40	201
Trichorrhexis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	15	2	4
		4	9		3
		1	2		
			2		2
			4	1	1
			1		
			1	1	2
					1
		2	6	1	4
		1	1		
			3		
					1
			1		
			1		
			1		
		2	16		2
			1		
			3		1
		1	1		
			1		1
			1		1
					1
					1
					1
			1		1
		1	1		
					1
					1
			1		1
				1	1
					1
					1
			1		1
				4	19
					1
		31	155	9	46
		1	1		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Trigeminal nerve disorder		1
Trigeminal neuralgia	1	5
Trigger finger	2	7
Tri-iodothyronine decreased		1
Tri-iodothyronine increased	1	1
Trismus		3
Troponin I increased		1
Troponin increased	2	14
Tryptase increased		1
Tumour marker abnormal		1
Tumour marker increased	1	1
Tumour pain	1	1
Tunnel vision		7
Type 1 diabetes mellitus	1	2
Type III immune complex mediated reaction		1
Type IV hypersensitivity reaction	1	1
Type V hyperlipidaemia		1
Ulcer	2	4
Ulcerative keratitis	1	1
Ulcer haemorrhage		1
Underdose	5	14
Underweight	1	1
Undifferentiated connective tissue disease		1
Unevaluable event		1
Unresponsive to stimuli	1	21
Upper-airway cough syndrome		10
Upper airway obstruction		1
Upper respiratory tract congestion	3	14
Upper respiratory tract infection		4
Urethral disorder		1
Urge incontinence		1
Urinary assistance device user		1
Urinary incontinence	3	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2	1	3
		1	6	1	1
			1		
				1	1
			2		1
			1		
			4	2	10
			1		
					1
				1	1
				1	1
					7
				1	2
					1
		1	1		
					1
		2	4		
				1	1
					1
		4	13	1	1
		1	1		
					1
			1		
				1	21
			8		2
					1
		3	12		2
			4		
			1		
			1		
			1		
		2	8	1	5

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Urinary retention	5	6
Urinary tract infection	5	28
Urinary tract infection bacterial		2
Urine analysis abnormal		5
Urine odour abnormal	1	1
Urine output decreased		2
Urine output increased		2
Urosepsis		1
Urticaria	76	315
Urticaria chronic	2	2
Use of accessory respiratory muscles		5
Uterine haemorrhage	1	2
Uterine inflammation		1
Uveitis		5
Vaccination complication		2
Vaccination error		1
Vaccination failure	13	41
Vaccination site bruising	7	26
Vaccination site cellulitis	1	4
Vaccination site coldness		2
Vaccination site dermatitis		1
Vaccination site discolouration	3	11
Vaccination site discomfort	4	17
Vaccination site erythema	20	177
Vaccination site extravasation	1	2
Vaccination site haemorrhage	4	14
Vaccination site hypoaesthesia	1	5
Vaccination site induration	2	18
Vaccination site infection		2
Vaccination site inflammation		7
Vaccination site injury		1
Vaccination site irritation	1	2
Vaccination site joint movement impairment		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				5	6
		1	14	4	14
					2
			5		
		1	1		
			2		
			2		
					1
		62	237	14	78
		1	1	1	1
			3		2
				1	2
					1
					5
	1		1		1
			1		
	1		1	13	40
		7	26		
			2	1	2
			2		
					1
		3	11		
		3	15	1	2
		19	165	1	12
		1	2		
		3	13	1	1
		1	5		
		2	17		1
			2		
			7		
			1		
		1	2		
			4		

* I=Interval, C=Cumulative
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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination site joint pain	1	4
Vaccination site lymphadenopathy		3
Vaccination site macule		1
Vaccination site mass	9	37
Vaccination site movement impairment		15
Vaccination site nerve damage	1	1
Vaccination site nodule		2
Vaccination site oedema		4
Vaccination site pain	119	820
Vaccination site pallor		1
Vaccination site papule		3
Vaccination site paraesthesia	1	4
Vaccination site pruritus	11	95
Vaccination site rash	9	46
Vaccination site reaction	2	9
Vaccination site scab	1	2
Vaccination site streaking		1
Vaccination site swelling	28	181
Vaccination site urticaria	1	22
Vaccination site vesicles		3
Vaccination site warmth	7	71
Vaginal discharge		2
Vaginal haemorrhage	3	10
Vaginal lesion	1	1
Varicella		1
Varicella zoster virus infection		1
Varicocele		1
Varicose vein		1
Vascular dementia		1
Vascular injury	1	1
Vascular occlusion		1
Vascular pain		1
Vascular rupture	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4		
			3		
			1		
		8	32	1	5
			15		
		1	1		
			2		
			2		2
	2	113	779	6	41
			1		
			3		
		1	3		1
		10	85	1	10
		8	41	1	5
		1	6	1	3
		1	2		
			1		
		26	174	2	7
		1	19		3
			3		
		6	65	1	6
			2		
		2	8	1	2
				1	1
			1		
			1		
					1
					1
				1	1
					1
			1		
		1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vasculitic rash	1	2
Vasculitis	2	2
Vasodilatation	1	1
Vein discolouration	1	2
Vein disorder	3	6
Vein wall hypertrophy	1	1
Venous thrombosis limb	1	3
Ventricular arrhythmia		1
Ventricular extrasystoles		9
Ventricular f brillation		1
Vertigo	26	129
Vertigo positional		2
Vestibular disorder	1	2
Vestibular migraine		1
Vestibular neuronitis	1	1
V bratory sense increased		1
Viral infection	3	4
Viral myelitis	1	1
Viral myocarditis		1
Viral rash		1
Viral sepsis	1	1
Viral upper respiratory tract infection		2
Vision blurred	19	90
Visual acuity reduced	1	4
Visual field defect	1	7
Visual impairment	13	53
Vital functions abnormal	1	1
Vitamin B12 decreased		2
Vitamin B12 increased		1
Vitamin D decreased		2
Vitamin D deficiency		1
Vlth nerve paralysis		2
Vitreous degeneration		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2		
		2	2		
		1	1		
		1	2		
		3	6		
				1	1
				1	3
					1
			4		5
					1
		22	102	4	27
					2
		1	2		
			1		
				1	1
			1		
		3	4		
				1	1
					1
			1		
				1	1
			1		1
		15	65	4	25
			3	1	1
		1	6		1
		8	34	5	19
				1	1
					2
			1		
			1		1
			1		
					2
					1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vitreous detachment		1						1
Vitreous floaters	3	6			2	3	1	3
Vocal cord disorder	1	3					1	3
Vocal cord inflammation	1	1					1	1
Vocal cord paresis		1				1		
Vomiting	69	387		1	58	309	11	78
Vomiting projectile		7				7		
Vulvovaginal burning sensation	1	1					1	1
Vulvovaginal discomfort	1	1					1	1
Vulvovaginal dryness	1	1			1	1		
Vulvovaginal erythema	1	1			1	1		
Vulvovaginal mycotic infection		2				2		
Vulvovaginal pain	3	4			2	3	1	1
Vulvovaginal pruritus	1	2			1	1		1
Vulvovaginal rash	1	2			1	1		1
Vulvovaginal swelling	1	2					1	2
Wa king aid user	1	3			1	2		1
Wa king disability	3	7				4	3	3
Weight bearing difficulty	2	2			2	2		
Weight decreased	21	75			17	65	4	10
Weight fluctuation		2				2		
Weight increased	1	14			1	13		1
Wheezing	12	89			8	54	4	35
White blood cell count abnormal	1	1					1	1
White blood cell count decreased	2	13			1	10	1	3
White blood cell count increased	7	31			7	21		10
White blood cells urine	1	1			1	1		
White matter lesion		2						2
Winged scapula		1				1		
Wound		5				4		1
Wound haemorrhage		1				1		
Wound secretion		1						1
Wrong product administered	3	7			3	7		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Wrong schedule		2				2		
Wrong technique in device usage process		1				1		
Wrong technique in product usage process	2	7			2	7		
Yawning	1	1			1	1		
Yellow skin		3				1		2
		2				2		
	8,026	42,541	26	62	6076	32860	1950	9681

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Country Where Event Occurred

URUGUAY

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Paraesthesia	1	1	1	1
Pruritus	1	1	1	1
	2	2	2	2

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* AE=Adverse Event
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APPENDIX 2.6: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Sources Organized per MedDRA System Organ Class by High Level Term

Cumulative Reporting Period: Through 31-MAY-2021

Interval Reporting Period: 30-APR-2021 Through 31-MAY-2021

Total Number of Cases: 47,174 (Interval) / 167,956 (Cumulative)

Total Number of Adverse Events (PT): 174,177 (Interval) / 631,356 (Cumulative)

MedDRA Version: v.24.0J

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Anaemia deficiencies	5	13			2	6	3	7
Anaemias haemolytic immune	7	19					7	19
Anaemias haemolytic mechanical factor	2	5					2	5
Anaemias haemolytic NEC	5	21					5	21
Anaemias NEC	67	161	1	1	17	43	50	118
Bleeding tendencies	15	49	1	1	2	9	13	40
Coagulation factor deficiencies	2	8	1	1			2	8
Coagulopathies	46	112			8	16	38	96
Eosinophilic disorders	7	19			2	5	5	14
Haematological disorders	13	32			6	15	7	17
Haemolyses NEC	8	13					8	13
Leukocytoses NEC	25	107		1	10	36	15	71
Leukopenias NEC	26	98		1	8	24	18	74
Lymphatic system disorders NEC	2,312	9,991	7	33	1522	6235	790	3756
Marrow depression and hypoplastic anaemias	12	42					12	42
Neutropenias	23	79		1			23	79
Platelet disorders NEC	1	8				2	1	6
Polycythaemia (excl rubra vera)	2	3			1	2	1	1
Purpuras (excl thrombocytopenic)	1	1					1	1
Red blood cell abnormal findings NEC	5	13			5	7		6
Sickle cell trait and disorders	1	4					1	4
Spleen disorders	12	37			2	7	10	30
Thrombocytopenias	255	573	1	3	2	4	253	569

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Thrombocytoses	2	7				2	2	5
White blood cell abnormal findings NEC	1	3			1	1		2
	2,855	11,418	11	42	1588	6414	1267	5004

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Aortic valvular disorders	2	15					2	15
Cardiac conduction disorders	37	113	1	1	5	17	32	96
Cardiac disorders NEC	105	365			40	136	65	229
Cardiac hypertensive complications	1	11					1	11
Cardiac signs and symptoms NEC	732	2,698	1	6	411	1368	321	1330
Cardiac valve disorders NEC	3	12			1	4	2	8
Cardiomyopathies	16	43				1	16	42
Coronary artery disorders NEC	31	86			2	3	29	83
Heart failure signs and symptoms		8				1		7
Heart failures NEC	134	543	1	1			134	543
Ischaemic coronary artery disorders	352	1,058				2	352	1056
Left ventricular failures	4	19					4	19
Mitral valvular disorders	9	27					9	27
Myocardial disorders NEC	49	116			17	29	32	87
Noninfectious myocarditis	99	258			1	2	98	256
Noninfectious pericarditis	95	242					95	242
Pericardial disorders NEC	47	113				1	47	112
Rate and rhythm disorders NEC	1,454	4,809	9	25	767	2079	687	2730
Right ventricular failures	6	19					6	19
Supraventricular arrhythmias	280	1,071	2	5	25	100	255	971
Tricuspid valvular disorders	3	9					3	9
Ventricular arrhythmias and cardiac arrest	222	743			5	34	217	709

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System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
	3,681	12,378	14	38	1274	3777	2407	8601

System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Arterial disorders congenital		1						1
Autosomal chromosomal abnormalities	1	1					1	1
Cardiac disorders congenital NEC		2						2
Cardiac septal defects congenital	2	8					2	8
Cardiac valve disorders congenital	1	1					1	1
Central nervous system disorders congenital NEC	1	1					1	1
Cerebral disorders congenital	3	7					3	7
Coagulation disorders congenital	1	6				1	1	5
Congenital disorders NEC	2	5					2	5
Connective tissue disorders congenital	1	2					1	2
Corneal and scleral disorders congenital		1						1
Gastrointestinal tract disorders congenital NEC		1						1
Gene mutations and other alterations NEC		1						1
Great vessel disorders congenital	1	1					1	1
Haematological disorders congenital NEC		1						1
Immune system abnormalities congenital	1	2					1	2
Inborn errors of amino acid metabolism		2				1		1
Inborn errors of bilirubin metabolism	1	1			1	1		
Inborn errors of lipid metabolism		2						2
Inborn errors of porphyrin metabolism		2						2
Lymphatic system disorders congenital		1						1
Musculoskeletal and connective tissue disorders of limbs congenital	1	2					1	2

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Musculoskeletal and connective tissue disorders of skull congenital	1	1					1	1
Musculoskeletal and connective tissue disorders of spine congenital	2	2					2	2
Musculoskeletal disorders congenital NEC		1						1
Neurological disorders congenital NEC	4	14			2	3	2	11
Non-site specific bone disorders congenital		1						1
Ocular disorders congenital NEC		1				1		
Palate disorders congenital	1	1					1	1
Peripheral nervous system disorders congenital NEC		1						1
Pulmonary and bronchial disorders congenital		1						1
Retinal disorders congenital		2						2
Skin and subcutaneous tissue disorders congenital NEC		2				1		1
Thyroid disorders congenital		1						1
Tongue disorders congenital	4	12	1	1			4	12
Vascular anomalies congenital NEC	2	2					2	2
Venous disorders congenital		1						1
	30	94	1	1	3	8	27	86

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ear disorders NEC	408	1,433			253	868	155	565
Eustachian tube disorders	4	11			3	6	1	5
External ear disorders NEC	6	34			4	22	2	12
External ear infections and inflammations	1	3			1	2		1
Hearing disorders NEC	6	23			2	10	4	13
Hearing losses	274	895	3	3	49	163	225	732

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Hyperacusia	23	95			13	53	10	42
Inner ear disorders NEC	21	79			7	18	14	61
Inner ear infections and inflammations	4	7			1	3	3	4
Inner ear signs and symptoms	1,029	3,719	6	12	566	1976	463	1743
Mastoid disorders		2				1		1
Middle ear disorders NEC	2	5			1	3	1	2
Middle ear infections and inflammations		1						1
Tympanic membrane disorders (excl infections)	2	5				2	2	3
	1,780	6,312	9	15	900	3127	880	3185

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic thyroiditis	21	60	6	18	15	42
Adrenal cortical hyperfunctions	2	3		1	2	2
Adrenal cortical hypofunctions	3	22			3	22
Adrenal gland disorders NEC	3	11	1	7	2	4
Anterior pituitary hypofunction	2	2	2	2		
Ectopic endocrine disorders		1		1		
Endocrine abnormalities of puberty	1	2	1	2		
Endocrine disorders NEC	1	1	1	1		
Female gonadal function disorders	4	5	3	3	1	2
Hyperparathyroid disorders	1	3		2	1	1
Hypothalamic and pituitary disorders NEC		1				1
Posterior pituitary disorders	2	3			2	3
Thyroid disorders NEC	24	73	14	42	10	31
Thyroid hyperfunction disorders	19	56			19	56
Thyroid hypofunction disorders	10	34			10	34
Thyroid neoplasms		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	93	278	28	79	65	199

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Amblyopic vision impairment		2				1		1
Cataract conditions	12	22					12	22
Chambers (anterior and posterior) and lens infections and inflammations		1						1
Choroid and vitreous haemorrhages and vascular disorders	3	11					3	11
Choroid and vitreous structural change, deposit and degeneration	43	107		1	11	27	32	80
Colour blindness (incl acquired)	3	7				3	3	4
Conjunctival and corneal bleeding and vascular disorders	27	111	1	3			27	111
Conjunctival infections, irritations and inflammations	28	89			16	47	12	42
Conjunctival structural change, deposit and degeneration	1	2					1	2
Corneal disorders NEC		3						3
Corneal infections, oedemas and inflammations	3	19				5	3	14
Corneal structural change, deposit and degeneration	1	11					1	11
Eyelid movement disorders	55	194			29	94	26	100
Glaucomas (excl congenital)	7	26			1	2	6	24
Iris and ciliary body structural change, deposit and degeneration	2	8			2	4		4
Iris and uveal tract infections, irritations and inflammations	15	74	1	1	1	5	14	69
Lacrimation disorders	112	477			86	314	26	163

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* AE=Adverse Event

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lid bleeding and vascular disorders	2	6
Lid, lash and lacrimal infections, irritations and inflammations	144	501
Lid, lash and lacrimal structural disorders	5	16
Ocular bleeding and vascular disorders NEC	60	158
Ocular disorders NEC	596	2,254
Ocular infections, inflammations and associated manifestations	282	1,141
Ocular nerve and muscle disorders	38	124
Ocular sensation disorders	178	732
Optic disc abnormalities NEC	8	15
Optic nerve bleeding and vascular disorders	4	13
Orbital infections, inflammations and irritations	1	3
Orbital structural change, deposit and degeneration	3	8
Pupil disorders	36	98
Refractive and accommodative disorders	5	18
Retinal bleeding and vascular disorders (excl retinopathy)	74	144
Retinal, choroid and vitreous infections and inflammations	2	15
Retinal structural change, deposit and degeneration	15	55
Retinopathies NEC	1	9
Scleral infections, irritations and inflammations	5	27
Scleral structural change, deposit and degeneration	3	11
Structural change, deposit and degeneration of eye NEC	6	19
Visual colour distortions	7	17
Visual disorders NEC	492	1,644
Visual field disorders	28	76
Visual impairment and blindness (excl colour blindness)	302	968

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	4	1	2
	1	83	277	61	224
		1	6	4	10
		2	4	58	154
	3	375	1297	221	957
	3	192	750	90	391
		12	31	26	93
		126	412	52	320
		1	1	7	14
				4	13
				1	3
				3	8
		24	52	12	46
		3	12	2	6
	1	3	4	71	140
				2	15
2	2	2	2	13	53
				1	9
			6	5	21
		3	6		5
			1	6	18
		2	8	5	9
1	1	260	840	232	804
		10	31	18	45
	4	103	317	199	651

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Visual pathway disorders	3	8	1	1	1	1	2	7
	2,612	9,244	6	21	1350	4564	1262	4680

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal findings abnormal	10	38			7	24	3	14
Abdominal hernias NEC		1						1
Abdominal wall conditions NEC	2	6					2	6
Acute and chronic pancreatitis	38	100					38	100
Anal and rectal disorders NEC		10				2		8
Anal and rectal pains	4	13			2	8	2	5
Anal and rectal signs and symptoms	6	25			2	14	4	11
Anal and rectal ulcers and perforation		1						1
Benign neoplasms gastrointestinal (excl oral cavity)		3				2		1
Benign oral cavity neoplasms	1	6			1	4		2
Colitis (excl infective)	58	170	3	4	9	25	49	145
Cystic pancreatic disorders	1	2				1	1	1
Dental and periodontal infections and inflammations	2	6			2	5		1
Dental disorders NEC	5	35			4	28	1	7
Dental pain and sensation disorders	66	239			40	166	26	73
Dental surface disorders	1	2				1	1	1
Diaphragmatic hernias	8	15			3	7	5	8
Diarrhoea (excl infective)	1,793	6,901	4	23	1310	4384	483	2517
Diverticula	4	14				4	4	10
Duodenal and small intestinal stenosis and obstruction	1	7					1	7
Duodenal ulcers and perforation	3	7					3	7

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dyspeptic signs and symptoms	85	441
Faecal abnormalities NEC	53	202
Flatulence, bloating and distension	140	549
Gastric and oesophageal haemorrhages	4	18
Gastric and pyloric stenosis and obstruction		2
Gastric ulcers and perforation	8	19
Gastritis (excl infective)	22	69
Gastrointestinal and abdominal pains (excl oral and throat)	1,388	4,747
Gastrointestinal atonic and hypomotility disorders NEC	105	423
Gastrointestinal disorders NEC	87	333
Gastrointestinal dyskinetic disorders	20	68
Gastrointestinal fistulae	1	1
Gastrointestinal inflammatory disorders NEC	14	39
Gastrointestinal mucosal dystrophies and secretion disorders	4	16
Gastrointestinal necrosis and gangrene (excl gangrenous hernia)	3	11
Gastrointestinal signs and symptoms NEC	597	2,206
Gastrointestinal spastic and hypermotility disorders	35	155
Gastrointestinal stenosis and obstruction NEC	11	52
Gastrointestinal vascular malformations	3	6
Gastrointestinal vascular occlusion and infarction	38	92
Gingival disorders, signs and symptoms NEC	40	186
Gingival haemorrhages	20	59
Haemorrhoids and gastrointestinal varices (excl oesophageal)	10	35
Inguinal hernias	1	1
Intestinal haemorrhages	41	144
Intestinal ulcers and perforation NEC	5	9
Large intestinal stenosis and obstruction		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		62	283	23	158
		38	137	15	65
	1	79	326	61	223
				4	18
					2
				8	19
		13	38	9	31
5	13	912	2830	476	1917
		64	240	41	183
	1	66	238	21	95
		14	53	6	15
				1	1
1	1	4	11	10	28
		2	6	2	10
				3	11
3	13	381	1295	216	911
		27	81	8	74
			1	11	51
				3	6
				38	92
	1	25	105	15	81
		6	28	14	31
		6	15	4	20
				1	1
1	1	1	7	40	137
				5	9
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Malabsorption syndromes	5	14
Nausea and vomiting symptoms	6,743	25,739
Non-mechanical ileus	4	12
Non-site specific gastrointestinal haemorrhages	81	339
Oesophageal disorders NEC	2	7
Oesophageal stenosis and obstruction		2
Oesophageal ulcers and perforation		3
Oesophagitis (excl infective)	3	10
Oral dryness and saliva altered	212	868
Oral soft tissue disorders NEC	45	219
Oral soft tissue haemorrhages	12	51
Oral soft tissue infections	1	5
Oral soft tissue signs and symptoms	769	3,402
Oral soft tissue swelling and oedema	314	1,346
Pancreatic disorders NEC	1	7
Peptic ulcers and perforation	2	5
Peritoneal and retroperitoneal disorders	1	9
Peritoneal and retroperitoneal fibrosis and adhesions		2
Peritoneal and retroperitoneal haemorrhages		4
Rectal inflammations NEC	2	6
Salivary gland disorders NEC	11	28
Salivary gland enlargements	9	36
Salivary gland infections and inflammations		3
Salivary gland stenosis and obstruction		2
Stomatitis and ulceration	95	414
Tongue disorders	48	204
Tongue signs and symptoms	318	1,485
Tooth missing	2	3
	13,418	51,710

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	5	12
15	104	4745	16007	1998	9732
				4	12
2	2		1	81	338
			1	2	6
					2
					3
		2	7	1	3
	2	151	531	61	337
		29	129	16	90
		9	25	3	26
		1	4		1
1	6	510	2097	259	1305
	4	170	637	144	709
		1	3		4
				2	5
				1	9
					2
					4
		1	3	1	3
		8	18	3	10
		4	21	5	15
			1		2
					2
1	3	64	235	31	179
		30	122	18	82
	3	161	692	157	793
		1	1	1	2
36	182	8967	30906	4451	20804

System Organ Class

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Administration site reactions NEC	12	188
Adverse effect absent	25	98
Application and instillation site reactions	25	45
Asthenic conditions	13,468	51,776
Body temperature altered	126	451
Breast complications associated with device	1	1
Complications associated with device NEC	1	7
Death and sudden death	286	1,382
Eye complications associated with device		1
Febrile disorders	7,364	29,767
Feelings and sensations NEC	7,363	29,269
Fibrosis NEC	1	2
Gait disturbances	392	1,457
General signs and symptoms NEC	4,240	15,272
Healing abnormal NEC	3	12
Hernias NEC	4	5
Implant and catheter site reactions	2	7
Inflammations	420	923
Infusion site reactions		9
Injection site reactions	330	4,102
Interactions	40	144
Mass conditions NEC	346	664
Mucosal findings abnormal	20	70
Necrosis NEC	4	9
Oedema NEC	667	1,615
Pain and discomfort NEC	6,551	22,129
Therapeutic and nontherapeutic responses	1,643	6,018
Trophic disorders	1	3
Ulcers NEC	9	22
Vaccination site reactions	8,809	35,149
Vascular complications associated with device	2	6
Withdrawal and rebound effects	5	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		11	178	1	10
		25	98		
		23	38	2	7
47	273	10215	35385	3253	16391
		66	164	60	287
			4	1	3
	2			286	1382
					1
21	113	5815	20448	1549	9319
14	75	5657	20581	1706	8688
			1	1	1
1	3	196	699	196	758
11	34	2624	8332	1616	6940
		2	7	1	5
		2	2	2	3
		2	6		1
		337	659	83	264
			9		
	1	302	3980	28	122
1	1	25	98	15	46
		321	581	25	83
		11	36	9	34
				4	9
6	9	475	977	192	638
12	45	4710	14603	1841	7526
15	26	96	304	1547	5714
		1	2		1
		5	12	4	10
7	98	7596	28136	1213	7013
				2	6
		1	3	4	7

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
	52,160	200,613	135	680	38518	135343	13642	65270

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Bile duct infections and inflammations	8	19			4	5	4	14
Cholecystitis and cholelithiasis	12	37			1	6	11	31
Cholestasis and jaundice	31	108			5	20	26	88
Gallbladder disorders NEC	4	20			1	7	3	13
Hepatic and hepatobiliary disorders NEC	10	34			2	12	8	22
Hepatic enzymes and function abnormalities	12	33	1	1	4	10	8	23
Hepatic failure and associated disorders	5	20					5	20
Hepatic fibrosis and cirrhosis	1	6					1	6
Hepatic vascular disorders	30	46					30	46
Hepatobiliary signs and symptoms	18	48			6	19	12	29
Hepatocellular damage and hepatitis NEC	43	132			3	9	40	123
Obstructive bile duct disorders (excl neoplasms)	2	3					2	3
Structural and other bile duct disorders	1	7				2	1	5
	177	513	1	1	26	90	151	423

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute and chronic sarcoidosis	5	18					5	18
Allergic conditions NEC	582	2,155	3	10	258	935	324	1220

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System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Allergies to foods, food additives, drugs and other chemicals	111	515	1	2	52	261	59	254
Amyloidoses	3	4					3	4
Anaphylactic and anaphylactoid responses	759	3,041	1	6	1	5	758	3036
Atopic disorders	26	58			14	37	12	21
Autoimmune disorders NEC	25	71					25	71
Immune and associated conditions NEC	52	156	1	1	25	70	27	86
Immunodeficiency disorders NEC	9	23	2	2			9	23
Primary immunodeficiency syndromes	1	2					1	2
Transplant rejections	5	9					5	9
Vasculitides	2	3					2	3
	1,580	6,055	8	21	350	1308	1230	4747

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal and gastrointestinal infections	77	452	2	9	5	27	72	425
Adenoviral infections		1				1		
Aspergillus infections		1						1
Babesia infections		1						1
Bacterial infections NEC	109	515			22	63	87	452
Blastocystis infections		1						1
Bone and joint infections	4	15					4	15
Bordetella infections	1	4					1	4
Borrelial infections	8	18			1	1	7	17
Breast infections	17	55				2	17	53
Caliciviral infections	1	2			1	1		1
Campylobacter infections	2	2					2	2
Candida infections	15	77			9	40	6	37

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiac infections	3	11
Central nervous system and spinal infections	40	129
Clostridia infections	7	15
Coccidioides infections	1	3
Coronavirus infections	2,248	8,420
Coxiella infections	2	18
Coxsackie viral infections		1
Cytomegaloviral infections	3	6
Dental and oral soft tissue infections	35	127
Ear infections	45	186
Ectoparasitic infestations	3	7
Enterococcal infections	2	7
Enteroviral infections NEC	1	2
Epstein-Barr viral infections	11	34
Escherichia infections	12	32
Eye and eyelid infections	54	199
Female reproductive tract infections	7	19
Filovirus viral infections		1
Flaviviral infections	1	1
Fungal infections NEC	6	36
Hanta viral infections	1	1
Helicobacter infections		2
Hepatitis virus infections	5	9
Hepatobiliary and spleen infections	3	8
Herpes viral infections	1,553	3,079
Infections NEC	115	529
Infectious disorders carrier		2
Infectious transmissions		1
Inflammatory disorders following infection		1
Influenza viral infections	249	1,062
Klebsiella infections	3	9
Legionella infections		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	11
		1	1	39	128
				7	15
				1	3
16	29	561	2010	1687	6410
				2	18
			1		
				3	6
		20	73	15	54
		25	86	20	100
		1	2	2	5
				2	7
		1	1		1
		3	10	8	24
				12	32
		34	119	20	80
		2	7	5	12
					1
				1	1
		5	27	1	9
				1	1
					2
				5	9
				3	8
1	4	982	1713	571	1366
	1	43	189	72	340
			1		1
					1
			1		
3	7	157	504	92	558
				3	9
					1

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Listeria infections	1	2
Lower respiratory tract and lung infections	228	889
Male reproductive tract infections	5	16
Moraxella infections		2
Mumps viral infections	4	8
Muscle and soft tissue infections	6	14
Mycoplasma infections	1	2
Neisseria infections		2
Nematode infections		2
Parainfluenzae viral infections	1	2
Parvoviral infections		1
Pneumocystis infections		1
Polyomavirus infections	1	1
Prion-associated disorders		5
Pseudomonal infections	4	8
Respiratory syncytial viral infections	1	1
Retroviral infections	1	4
Rhinoviral infections		4
Rotaviral infections	1	2
Rubella viral infections		1
Rubeola viral infections	3	8
Sepsis, bacteraemia, viraemia and fungaemia NEC	57	229
Serratia infections	2	2
Skin structures and soft tissue infections	23	114
Staphylococcal infections	7	56
Streptobacillus infections	1	2
Streptococcal infections	45	116
Tinea infections	2	5
Toxoplasma infections		1
Treponema infections	1	4
Trypanosomal infections		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
2	2	18	54	210	835
			1	5	15
					2
		2	3	2	5
				6	14
			1	1	1
					2
					2
				1	2
			1		
					1
				1	1
					5
				4	8
				1	1
			1	1	3
			3		1
		1	1		1
			1		
				3	8
				57	229
				2	2
	1	13	55	10	59
		4	13	3	43
				1	2
1	2	8	20	37	96
		2	5		
			1		
				1	4
					2

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tuberculous infections	2	18
Upper respiratory tract infections	451	1,680
Urinary tract infections	138	510
Vascular infections	6	36
Viral infections NEC	86	375
Yersinia infections	2	2
	5,724	19,229

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	18
1	4	330	1173	121	507
	1	51	201	87	309
				6	36
	1	23	96	63	279
				2	2
26	61	2325	6510	3399	12719

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Abdominal and gastrointestinal injuries NEC	19	61
Accidental exposures to product	12	69
Anaesthetic and allied procedural complications	1	4
Atmospheric pressure injuries	1	3
Bone and joint injuries NEC	15	58
Cardiac and vascular procedural complications	8	15
Cardiovascular injuries	7	28
Cerebral injuries NEC	35	90
Chemical injuries		1
Chest and respiratory tract injuries NEC	9	40
Conditions caused by cold	28	84
Cranial nerve injuries	1	2
Ear injuries NEC		1
Exposures associated with pregnancy, delivery and lactation	407	1,322
Exposures to agents or circumstances NEC	16	121
Eye and ear procedural complications	1	1
Eye injuries NEC	37	102

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		12	34	7	27
		12	68		1
			1	1	3
		1	2		1
		9	37	6	21
				8	15
		2	3	5	25
		2	10	33	80
					1
1	1		2	9	38
		21	63	7	21
				1	2
			1		
5	10	330	1127	77	195
	1	15	105	1	16
				1	1
	1	26	65	11	37

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* AE=Adverse Event

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Fractures and dislocations NEC	7	30
Gastrointestinal and hepatobiliary procedural complications	1	9
Heat injuries (excl thermal burns)	5	19
Intentional product misuses	1	16
Intentional product use issues	3	18
Limb fractures and dislocations	23	114
Medication errors, product use errors and issues NEC	416	2,793
Muscle, tendon and ligament injuries	72	184
Musculoskeletal procedural complications		1
Nerve injuries NEC	20	64
Neurological and psychiatric procedural complications	3	11
Non-occupational environmental exposures		2
Non-site specific injuries NEC	331	1,209
Non-site specific procedural complications	5	48
Occupational exposures	5	32
Off label uses	862	2,914
Overdoses NEC	614	1,033
Pathways and sources of exposure	8	50
Pelvic fractures and dislocations	4	10
Peripheral nerve injuries	3	15
Poisoning and toxicity	2	23
Product administration errors and issues	1,883	5,822
Product confusion errors and issues		9
Product dispensing errors and issues		1
Product preparation errors and issues	493	1,098
Product prescribing errors and issues	4	15
Product storage errors and issues in the product use system	112	185
Product transcribing errors and communication issues		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	4	5	26
		1	4		5
		3	10	2	9
		1	16		
		3	18		
		1	5	22	109
		402	2733	14	60
	1	42	98	30	86
					1
		8	30	12	34
		2	4	1	7
			1		1
4	5	121	457	210	752
	1		8	5	40
		5	31		1
2	2	840	2836	22	78
		608	1016	6	17
		8	50		
				4	10
		1	1	2	14
	1			2	23
2	2	1831	5697	52	125
			9		
			1		
		492	1090	1	8
		3	14	1	1
		112	185		
			2		

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Radiation injuries	9	22
Renal and urinary tract injuries NEC	1	1
Reproductive system and breast injuries	1	2
Reproductive tract and breast procedural complications		2
Respiratory tract and thoracic cavity procedural complications		1
Site specific injuries NEC	85	329
Skin injuries NEC	268	852
Skin procedural complications		2
Skull fractures, facial bone fractures and dislocations	8	28
Spinal cord injuries NEC	4	7
Spinal fractures and dislocations	6	12
Stoma complications	2	10
Thermal burns	18	58
Thoracic cage fractures and dislocations	9	25
Transfusion related complications		1
Transplantation complications	1	3
Underdoses NEC	90	431
Vaccination related complications	67	266
	6,043	19,781

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		7	16	2	6
				1	1
			1	1	1
					2
					1
3	3	33	145	52	184
	2	148	490	120	362
			2		
				8	28
				4	7
				6	12
			3	2	7
		6	17	12	41
			1	9	24
			1		
				1	3
		88	427	2	4
1	4	50	192	17	74
18	34	5248	17133	795	2648

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Adrenal cortex tests		2
Adrenal medulla tests	1	5
Auditory and vestibular diagnostic procedures	1	4
Autoimmunity analyses	10	26

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		1	4		1
			3	1	1
		6	11	4	15

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bacteria identification and serology (excl mycobacteria)	5	25
Blood counts NEC	4	23
Blood gas and acid base analyses	234	929
Blood grouping and cross-matching analyses		1
Bone marrow and immune tissue imaging procedures		3
Carbohydrate tolerance analyses (incl diabetes)	108	471
Cardiac auscultatory investigations	9	22
Cardiac function diagnostic procedures	5	15
Cardiac imaging procedures		1
Cell marker analyses	6	19
Central nervous system imaging procedures	1	6
Cerebrospinal fluid tests (excl microbiology)	7	15
Chemistry analyses NEC	18	38
Cholesterol analyses	24	59
Chromosome analyses	1	1
Coagulation and bleeding analyses	130	368
Digestive enzymes	6	31
ECG investigations	36	115
Endocrine analyses and imaging NEC	9	15
Faecal analyses NEC	8	11
Foetal and neonatal diagnostic procedures	2	6
Gastrointestinal and abdominal imaging procedures	1	2
Gastrointestinal function diagnostic procedures	1	6
Gastrointestinal, pancreatic and APUD hormone analyses		1
Haematological analyses NEC	11	54
Haem metabolism analyses		5
Heart rate and pulse investigations	674	2,573
Histopathology procedures NEC		2
Imaging procedures NEC	4	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	11	2	14
		4	14		9
2	4	62	236	172	693
			1		
			1		2
		54	264	54	207
		6	8	3	14
		1	3	4	12
					1
		1	8	5	11
			1	1	5
				7	15
		8	15	10	23
		17	47	7	12
				1	1
1	1	56	145	74	223
		3	20	3	11
	1	6	24	30	91
		6	8	3	7
		6	6	2	5
		1	1	1	5
				1	2
			5	1	1
			1		
		9	30	2	24
			2		3
1	2	353	1427	321	1146
			2		
		1	2	3	7

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Immune response protein analyses NEC	3	8
Immunoglobulin analyses	10	35
Immunology analyses NEC	5	54
Immunology skin tests NEC	1	1
Investigations NEC	29	80
Lipoprotein and lipid tests NEC	2	6
Liver function analyses	99	350
Metabolism tests NEC	16	50
Microbiology and serology tests NEC	1	11
Mineral and electrolyte analyses	48	196
Musculoskeletal and soft tissue histopathology procedures	2	3
Musculoskeletal and soft tissue imaging procedures		2
Musculoskeletal and soft tissue tests NEC	1	4
Mycobacteria identification and serology		1
Neurologic diagnostic procedures	5	30
Ophthalmic function diagnostic procedures	6	25
Ophthalmic histopathology and imaging procedures	1	1
Parasite identification and serology		1
Parathyroid analyses	3	4
Physical examination procedures and organ system status	829	2,716
Pituitary analyses anterior	8	34
Platelet analyses	83	241
Protein analyses NEC	112	402
Psychiatric investigations		1
Red blood cell analyses	60	229
Renal function analyses	52	146
Reproductive hormone analyses	1	5
Reproductive organ and breast imaging procedures	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	5		3
		7	27	3	8
		2	50	3	4
		1	1		
		16	42	13	38
		1	5	1	1
	1	39	171	60	179
		9	24	7	26
			7	1	4
		22	113	26	83
		1	1	1	2
			2		
				1	4
			1		
		1	9	4	21
		3	12	3	13
				1	1
			1		
		3	4		
3	6	646	1920	183	796
		4	22	4	12
1	1	39	106	44	135
		57	200	55	202
					1
		39	149	21	80
		34	98	18	48
			3	1	2
			1	2	2

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* AE=Adverse Event

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Respiratory and pulmonary function diagnostic procedures	5	26			4	8	1	18
Respiratory tract and thoracic histopathology procedures		3						3
Respiratory tract and thoracic imaging procedures	3	10			2	4	1	6
Skeletal and cardiac muscle analyses	57	187			9	42	48	145
Therapeutic drug monitoring analyses		11				2		9
Thyroid analyses	4	33			3	23	1	10
Tissue enzyme analyses NEC	15	52			7	28	8	24
Toxicology laboratory analyses	5	10			2	5	3	5
Triglyceride analyses	2	10			1	6	1	4
Urinalysis NEC	50	152			26	89	24	63
Urinary tract function analyses NEC	9	36			4	20	5	16
Vascular auscultatory investigations	3	6			1	2	2	4
Vascular tests NEC (incl blood pressure)	1,055	2,894	4	8	447	1311	608	1583
Virus identification and serology	133	918	4	4	55	437	78	481
Vitamin analyses	6	26			5	17	1	9
Water and electrolyte analyses NEC	2	6			1	4	1	2
White blood cell analyses	135	438	1	1	93	290	42	148
	4,179	14,320	17	29	2191	7562	1988	6758

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Amino acid metabolism disorders NEC	1	1			1	1		
Appetite disorders	653	2,519	2	7	447	1486	206	1033
Calcium metabolism disorders	12	34			5	9	7	25
Cell metabolism disorders NEC		5						5
Chloride imbalance		1						1

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* AE=Adverse Event

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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Diabetes mellitus (incl subtypes)	39	162
Diabetic complications NEC	5	33
Diabetic complications neurological		1
Disorders of purine metabolism	33	99
Electrolyte imbalance NEC	2	16
Elevated cholesterol	2	5
Elevated triglycerides	2	3
Fat soluble vitamin deficiencies and disorders	2	15
Fluid intake decreased	3	21
Fluid intake increased	6	25
Food malabsorption and intolerance syndromes (excl sugar intolerance)	7	19
General nutritional disorders NEC	94	289
Hyperglycaemic conditions NEC	38	153
Hyperlipidaemias NEC		2
Hypervitaminoses NEC		1
Hypoglycaemic conditions NEC	45	156
Iron deficiencies	5	10
Iron excess	3	5
Lipid metabolism and deposit disorders NEC	1	7
Magnesium metabolism disorders	1	3
Metabolic acidoses (excl diabetic acidoses)	15	48
Metabolic alkaloses		1
Metabolic disorders NEC	2	6
Mineral related disorders NEC	1	1
Mixed acid-base disorders	2	9
Phosphorus metabolism disorders	1	2
Potassium imbalance	21	84
Protein metabolism disorders NEC	4	7
Sodium imbalance	18	68
Sugar intolerance (excl glucose intolerance)	2	3
Total fluid volume decreased	105	404

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3	37	159
				5	33
					1
		12	44	21	55
		1	5	1	11
		1	3	1	2
		1	1	1	2
		2	9		6
			7	3	14
		3	13	3	12
		3	7	4	12
		48	153	46	136
		9	34	29	119
			1		1
					1
		14	49	31	107
		4	6	1	4
		1	2	2	3
		1	7		
			1	1	2
			4	15	44
			1		
		1	2	1	4
				1	1
			1	2	8
		1	2		
			2	21	82
		2	4	2	3
1	1	5	19	13	49
		2	3		
		40	167	65	237

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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Total fluid volume increased	18	62
Vitamin deficiencies NEC	1	4
Water soluble vitamin deficiencies	7	9
	1,151	4,293

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		9	28	9	34
		1	2		2
		6	7	1	2
3	8	622	2083	529	2210

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arthropathies NEC	148	481
Bone disorders NEC	26	66
Bone related signs and symptoms	335	1,427
Bursal disorders	18	67
Cartilage disorders	11	43
Connective tissue disorders NEC	30	94
Crystal arthropathic disorders	1	4
Epiphyseal disorders		1
Extremity deformities	8	24
Fractures NEC	1	1
Intervertebral disc disorders NEC	8	29
Joint related disorders NEC	54	162
Joint related signs and symptoms	4,600	17,382
Ligament disorders	3	10
Lupus erythematosus (incl subtypes)	10	42
Metabolic bone disorders	5	11
Muscle infections and inflammations	23	60
Muscle pains	5,554	21,317
Muscle related signs and symptoms NEC	562	2,150
Muscle tone abnormalities	42	166
Muscle weakness conditions	404	1,573

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		64	222	84	259
	1	19	42	7	24
	4	229	911	106	516
	1	8	27	10	40
		6	13	5	30
				30	94
				1	4
					1
		6	16	2	8
				1	1
		2	15	6	14
	1	20	63	34	99
8	65	3448	11874	1152	5508
			3	3	7
1	2			10	42
		3	8	2	3
	1	12	21	11	39
5	82	4618	15299	936	6018
3	6	349	1276	213	874
	1	29	97	13	69
2	2	194	741	210	832

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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Musculoskeletal and connective tissue conditions NEC	638	2,415	1	4	407	1360	231	1055
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity	5	22			2	8	3	14
Musculoskeletal and connective tissue infections and inflammations NEC	1	18				6	1	12
Musculoskeletal and connective tissue pain and discomfort	6,165	23,749	17	82	4428	16116	1737	7633
Myopathies	17	44			1	2	16	42
Osteoarthropathies	24	66			13	37	11	29
Psoriatic arthropathies	2	28	1	1			2	28
Rheumatoid arthropathies	51	191	6	8			51	191
Soft tissue disorders NEC	105	373		2	62	206	43	167
Spine and neck deformities	5	12			2	5	3	7
Spondyloarthropathies	20	70		1	2	3	18	67
Synovial disorders	16	47			11	20	5	27
Tendon disorders	44	148			19	75	25	73
Trunk deformities		1				1		
	18,936	72,294	44	264	13954	48467	4982	23827

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aural neoplasms malignant and unspecified		1		1		
B-cell lymphomas NEC	1	4			1	4
Bile duct neoplasms malignant	1	1			1	1
Bladder neoplasms malignant		1				1
Bone neoplasms unspecified malignancy	1	5		2	1	3
Breast and nipple neoplasms benign		1		1		
Breast and nipple neoplasms malignant	13	30			13	30

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiovascular neoplasms benign	1	3	1	2		1
Cardiovascular neoplasms malignant and unspecified		1				1
Central nervous system neoplasms malignant NEC		1				1
Colorectal and anal neoplasms malignancy unspecified		1				1
Colorectal neoplasms malignant		2				2
Diffuse large B-cell lymphomas		1				1
Endocrine neoplasms benign NEC	3	4	1	1	2	3
Endocrine neoplasms malignant and unspecified NEC	2	2			2	2
Endometrial neoplasms malignant	1	2			1	2
Female reproductive neoplasms unspecified malignancy	1	1			1	1
Follicular lymphomas		1				1
Gastric neoplasms malignant		1				1
Gastrointestinal neoplasms malignant NEC	2	3			2	3
Germ cell neoplasms site unspecified NEC	1	1			1	1
Haematologic neoplasms NEC	1	1			1	1
Hepatic neoplasms malignant	2	2			2	2
Hepatobiliary neoplasms benign	1	1	1	1		
Histiocytoses	2	2			2	2
Hodgkin's disease NEC	1	1			1	1
Islet cell neoplasms and APUDoma NEC		1				1
Kaposi's sarcomas		1				1
Leukaemias acute lymphocytic		3				3
Leukaemias acute myeloid		8		1		7
Leukaemias acute NEC		4				4
Leukaemias chronic lymphocytic	5	10			5	10
Leukaemias chronic myeloid		1				1
Leukaemias myeloid NEC	1	1			1	1
Leukaemias NEC	2	12			2	12

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lip and oral cavity neoplasms malignancy unspecified	1	1			1	1
Lymphomas unspecified NEC	4	22			4	22
Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)	1	2			1	2
Mediastinal neoplasms malignancy unspecified NEC	1	2			1	2
Metastases to specified sites	2	12			2	12
Metastases to unknown and unspecified sites		2				2
Mycoses fungoides	1	1			1	1
Myelodysplastic syndromes	1	4			1	4
Myeloproliferative disorders (excl leukaemias)		3				3
Neoplasms benign site unspecified NEC		4		3		1
Neoplasms malignant site unspecified NEC	10	28			10	28
Neoplasms unspecified malignancy and site unspecified NEC	16	39	8	19	8	20
Nervous system neoplasms benign NEC	1	1			1	1
Nervous system neoplasms unspecified malignancy NEC	2	10			2	10
Neuromas		4				4
Non-Hodgkin's lymphomas NEC	1	5			1	5
Oncologic complications and emergencies	5	7	1	1	4	6
Ovarian neoplasms malignant (excl germ cell)	1	2			1	2
Pancreatic neoplasms malignant (excl islet cell and carcinoid)	2	5			2	5
Plasma cell myelomas	3	5			3	5
Plasma cell neoplasms NEC	2	6		1	2	5
Prostatic neoplasms malignant	1	7			1	7
Renal neoplasms malignant		2				2
Reproductive neoplasms female benign NEC	1	1			1	1
Reproductive neoplasms male unspecified malignancy		1				1
Respiratory tract and pleural neoplasms malignancy unspecified NEC	2	2			2	2

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC	3	11			3	11
Salivary gland neoplasms unspecified malignancy	1	1			1	1
Skin melanomas (excl ocular)	1	4			1	4
Skin neoplasms benign	3	6	2	2	1	4
Skin neoplasms malignant and unspecified (excl melanoma)	5	13	1	4	4	9
Soft tissue neoplasms benign NEC	1	9	1	4		5
Soft tissue sarcomas histology unspecified		1				1
Thyroid neoplasms malignant	1	2			1	2
Urinary tract neoplasms unspecified malignancy NEC		2				2
Uterine neoplasms benign	7	7	1	1	6	6
	122	349	17	44	105	305

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal reflexes	14	50			3	15	11	35
Abnormal sleep-related events	2	10			2	8		2
Absence seizures	6	48					6	48
Acute polyneuropathies	65	178			1	1	64	177
Alzheimer's disease (incl subtypes)	2	14					2	14
Auditory nerve disorders		4				1		3
Autonomic nervous system disorders	12	50			2	9	10	41
Central nervous system aneurysms and dissections	7	22					7	22
Central nervous system haemorrhages and cerebrovascular accidents	885	2,386	5	7	1	1	884	2385

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* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		2
1	1	3	5	31	63
1	1			48	101
		6	21	6	20
			1	1	5
		1	2	3	14
				29	78
3	7	180	552	178	703
2	3	28	93	83	258
			6	11	25
				11	71
				13	40
13	32	666	2355	1433	5923
		2	9		2
3	3	187	566	127	468
			2	3	27
				7	17
				10	39
1	1				1
			2	16	65
2	6	31	147	505	1985
				38	144
					1
25	149	9413	28645	2373	12424
				4	9
				5	15
		1	2	20	54
				1	1
		16	55	15	48
		84	254	82	284
					1

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System Organ Class

Nervous system disorders

High Level Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	4	113	355	117	498
2	10	270	1088	242	1178
				1	2
		10	51	19	63
				1	2
3	3		4	34	125
1	1	12	57	15	64
				11	45
		49	245	34	168
				1	4
		34	83	36	127
9	72	3263	9605	1460	6301
		1	1	9	54
		13	60	17	90
				6	29
2	4	162	579	49	230
				15	47
7	26	1881	6432	1043	4260
2	3	37	57	247	870
		6	22	12	50
			2	1	8
				1	1
1	2	11	47	121	402
1	1	10	50	373	1430
2	10	662	2434	302	1277
		3	12	2	14
5	8	100	326	141	530
			11	12	42
			5	15	46
	1			144	414
3	9	312	1185	213	1141

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Trigeminal disorders	37	136			15	57	22	79
Vagus nerve disorders	1	8				1	1	7
Vertigos NEC	2	2			1	1	1	1
	28,347	100,737	94	364	17592	55523	10755	45214

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abortion related conditions and complications	1	3					1	3
Abortions not specified as induced or spontaneous	9	25					9	25
Abortions spontaneous	52	184	2	2			52	184
Amniotic fluid and cavity disorders of pregnancy NEC		1						1
Failed labour	1	1					1	1
Foetal complications NEC	1	3					1	3
Foetal growth complications	5	10					5	10
Foetal position and presentation abnormalities		1				1		
Gestational age and weight conditions	5	14			1	1	4	13
Haemorrhagic complications of pregnancy	3	5					3	5
High risk pregnancies	1	1			1	1		
Hypertension associated disorders of pregnancy	1	1					1	1
Labour onset and length abnormalities	2	9				1	2	8
Maternal complications of labour NEC	1	3				1	1	2
Maternal complications of pregnancy NEC	5	20			1	3	4	17
Multiple pregnancies		1				1		
Neonatal disorders due to birth trauma (excl intracranial haemorrhages)		1						1
Normal pregnancy, labour and delivery	1	7				4	1	3
Postpartum complications NEC	1	3				2	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Pregnancy complicated by maternal disorders	2	4			1	1	1	3
Still birth and foetal death	8	20					8	20
Umbilical cord complications	2	2					2	2
Unintended pregnancies	3	5					3	5
	104	324	2	2	4	16	100	308

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Counterfeit, falsified and substandard products	2	11	2	11		
Device incompatibility issues	1	1	1	1		
Device issues NEC	2	6	1	4	1	2
Device malfunction events NEC	5	20	2	6	3	14
Device physical property and chemical issues	10	45	10	42		3
Product contamination and sterility issues	3	6	3	6		
Product distribution and storage issues	309	793	309	791		2
Product label issues	2	3	2	3		
Product packaging issues	4	28	4	28		
Product physical issues	27	126	27	126		
Product quality issues NEC	11	74	11	71		3
Product supply and availability issues	12	54	12	54		
	388	1,167	384	1143	4	24

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Abnormal behaviour NEC	18	70
Abnormal food elimination		1
Adjustment disorders		2
Affect alterations NEC	8	29
Amnesic symptoms		2
Anxiety disorders NEC	3	11
Anxiety symptoms	439	1,804
Attention deficit and disruptive behaviour disorders	3	6
Behaviour and socialisation disturbances	26	116
Bipolar disorders	4	9
Cognitive and attention disorders and disturbances NEC	24	110
Communications disorders	12	48
Confusion and disorientation	367	1,595
Decreased physical activity levels	1	6
Deliria	34	208
Delusional disorders	1	2
Delusional symptoms	7	34
Dementia NEC		1
Depressive disorders	57	208
Dissociative states	4	42
Disturbances in initiating and maintaining sleep	601	2,459
Dyssomnias	58	238
Eating disorders NEC	32	129
Emotional and mood disturbances NEC	291	699
Factitious disorders		1
Fear symptoms and phobic disorders (incl social phobia)	34	128
Fluctuating mood symptoms	12	28
Hallucinations (excl sleep-related)	103	399
Impulse control disorders		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		8	24	10	46
					1
					2
		5	16	3	13
					2
			6	3	5
	1	310	1149	129	655
		2	3	1	3
1	1	14	47	12	69
				4	9
		11	33	13	77
		2	21	10	27
6	15	147	617	220	978
			2	1	4
			1	34	207
				1	2
		2	14	5	20
					1
		24	80	33	128
		3	27	1	15
	1	396	1593	205	866
	1	38	147	20	91
		23	79	9	50
		205	471	86	228
					1
		23	86	11	42
		3	9	9	19
3	3	1	1	102	398
			2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Increased physical activity levels	61	288
Learning disorders	4	7
Mental disorders due to a general medical condition NEC	1	5
Mental disorders NEC	19	69
Mood alterations with depressive symptoms	99	316
Mood alterations with manic symptoms	3	13
Mood disorders NEC	34	136
Narcolepsy and associated conditions	3	9
Obsessive-compulsive disorders and symptoms		4
Orgasmic disorders and disturbances	1	2
Panic attacks and disorders	57	220
Parasomnias	83	315
Perception disturbances NEC	30	103
Personality disorders NEC	1	2
Personality disorders with anxious behaviour (Cluster C)	1	1
Personality disorders with eccentric behaviour (Cluster A)		1
Pervasive developmental disorders NEC	2	3
Psychiatric elimination disorders	7	16
Psychiatric symptoms NEC	8	23
Psychotic disorder NEC	3	32
Schizophrenia NEC		3
Sexual desire disorders	4	14
Sleep disorders NEC	145	644
Somatic symptom disorders	8	29
Speech and language usage disturbances	4	20
Speech articulation and rhythm disturbances	15	47
Stereotypies and automatisms	14	29
Stress disorders	5	13
Substance related and addictive disorders		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		36	163	25	125
		2	2	2	5
			1	1	4
		12	44	7	25
	1	57	153	42	163
		3	5		8
		17	69	17	67
		2	4	1	5
					4
		1	1		1
		36	131	21	89
		49	199	34	116
		9	30	21	73
			1	1	1
		1	1		
			1		
				2	3
		1	4	6	12
		5	13	3	10
		2	6	1	26
					3
		3	8	1	6
1	3	93	402	52	242
		3	14	5	15
		1	5	3	15
		9	18	6	29
		8	12	6	17
		2	4	3	9
					3

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Suicidal and self-injurious behaviour	27	72
Thinking disturbances	36	158
Tic disorders	8	18
	2,822	11,002

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2	26	70
1	1	27	100	9	58
		6	9	2	9
12	27	1603	5830	1219	5172

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bladder and urethral symptoms	169	626
Bladder disorders NEC	9	26
Bladder infections and inflammations	1	11
Genital and urinary tract disorders NEC	2	8
Genitourinary tract infections and inflammations NEC	1	6
Glomerulonephritis and nephrotic syndrome	18	49
Myoneurogenic bladder disorders	5	18
Nephritis NEC	5	8
Nephropathies and tubular disorders NEC	5	14
Renal disorders NEC	16	57
Renal failure and impairment	130	447
Renal failure complications	1	6
Renal lithiasis	12	43
Renal neoplasms	2	13
Renal obstructive disorders		2
Renal structural abnormalities and trauma		3
Renal vascular and ischaemic conditions	8	17
Structural and obstructive urethral disorders (excl congenital)		1
Ureteric disorders NEC		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1	78	263	91	363
		4	10	5	16
			1	1	10
		2	4		4
		1	2		4
				18	49
		1	5	4	13
				5	8
		3	4	2	10
		2	20	14	37
1	2		6	130	441
				1	6
				12	43
		2	6		7
					2
					3
				8	17
					1
					2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Urethral disorders NEC		2				1		1
Urethral infections and inflammations	1	1			1	1		
Urinary abnormalities	75	236			33	114	42	122
Urinary tract lithiasis (excl renal)	2	3			2	3		
Urinary tract signs and symptoms NEC	92	310			42	142	50	168
	554	1,909	2	3	171	582	383	1327

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Benign and malignant breast neoplasms	2	7			1	4	1	3
Breast disorders NEC	13	69			6	36	7	33
Breast infections and inflammations	5	11			3	5	2	6
Breast signs and symptoms	178	614		1	97	325	81	289
Cervix disorders NEC		4				1		3
Erection and ejaculation conditions and disorders	12	51					12	51
Lactation disorders	4	22			2	10	2	12
Menopausal effects NEC	1	7			1	4		3
Menopausal effects on the genitourinary tract	34	52					34	52
Menstruation and uterine bleeding NEC	613	862		2	450	611	163	251
Menstruation with decreased bleeding	231	324	1	1	181	219	50	105
Menstruation with increased bleeding	391	530		2	252	324	139	206
Ovarian and fallopian tube cysts and neoplasms	9	12			6	7	3	5
Ovarian and fallopian tube disorders NEC	10	13			3	4	7	9
Pelvic prolapse conditions	1	1					1	1
Pelvis and broad ligament disorders NEC	5	24			3	13	2	11
Penile and scrotal infections and inflammations		1				1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Penile disorders NEC (excl erection and ejaculation)	7	16			6	10	1	6
Prostate and seminal vesicles infections and inflammations	3	11			1	3	2	8
Prostatic neoplasms and hypertrophy	3	5			2	3	1	2
Prostatic signs, symptoms and disorders NEC	2	9			2	6		3
Reproductive tract disorders NEC (excl neoplasms)	9	22			3	9	6	13
Reproductive tract infections and inflammations NEC		2				2		
Reproductive tract signs and symptoms NEC	31	100			12	50	19	50
Scrotal disorders NEC	1	17			1	9		8
Sexual function and fertility disorders NEC	1	5			1	3		2
Spermatogenesis and semen disorders	2	5			1	2	1	3
Testicular and epididymal disorders NEC	18	47			11	28	7	19
Testicular and epididymal infections and inflammations		1				1		
Uterine disorders NEC	23	42			6	9	17	33
Uterine infections and inflammations (excl cervix)		2				1		1
Uterine neoplasms	1	1					1	1
Uterine tone disorders	1	4				2	1	2
Vaginal and vulval infections and inflammations		1						1
Vulvovaginal cysts and neoplasms		2						2
Vulvovaginal disorders NEC	108	239			45	97	63	142
Vulvovaginal signs and symptoms	23	61			11	34	12	27
	1,742	3,196	1	6	1107	1833	635	1363

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Breathing abnormalities	2,322	9,536
Bronchial conditions NEC	10	29
Bronchospasm and obstruction	454	1,698
Conditions associated with abnormal gas exchange	65	233
Coughing and associated symptoms	1,508	4,818
Diaphragmatic disorders	1	8
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	5	32
Laryngeal spasm, oedema and obstruction	57	334
Lower respiratory tract inflammatory and immunologic conditions	38	166
Lower respiratory tract signs and symptoms	81	306
Mediastinal disorders	2	3
Nasal congestion and inflammations	228	819
Nasal disorders NEC	229	808
Neonatal hypoxic conditions	1	2
Newborn respiratory disorders NEC	2	3
Paranasal sinus disorders (excl infections and neoplasms)	36	186
Parenchymal lung disorders NEC	50	145
Pharyngeal disorders (excl infections and neoplasms)	262	1,156
Pleural infections and inflammations	11	37
Pneumothorax and pleural effusions NEC	48	138
Pulmonary hypertensions	7	23
Pulmonary oedemas	67	269
Pulmonary thrombotic and embolic conditions	638	1,418
Respiratory failures (excl neonatal)	78	299
Respiratory signs and symptoms NEC	65	225
Respiratory tract disorders NEC	108	524
Thoracic musculoskeletal disorders	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
11	27	936	3460	1386	6076
		2	8	8	21
1	6	186	595	268	1103
		4	6	61	227
5	11	1048	2962	460	1856
			3	1	5
		1	5	4	27
		8	32	49	302
		3	9	35	157
		43	128	38	178
		2	2		1
	1	175	635	53	184
1	2	141	444	88	364
				1	2
				2	3
		28	144	8	42
1	1	11	26	39	119
	2	125	518	137	638
		4	7	7	30
		6	16	42	122
1	2			7	23
		1	3	66	266
4	7		1	638	1417
2	2			78	299
	1	30	96	35	129
		38	182	70	342
				1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tracheal disorders (excl infections and neoplasms)	4	14			1	4	3	10
Upper respiratory tract neoplasms		1				1		
Upper respiratory tract signs and symptoms	3,058	9,758	4	23	2251	6458	807	3300
Vascular pulmonary disorders NEC	1	5					1	5
	9,437	32,995	30	85	5044	15745	4393	17250

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acnes	35	89			27	69	8	20
Alopecias	41	137			19	68	22	69
Angioedemas	121	640			6	19	115	621
Apocrine and eccrine gland disorders	1,029	4,376	1	7	666	2576	363	1800
Bullous conditions	199	611		2	83	234	116	377
Connective tissue disorders	2	14				1	2	13
Dermal and epidermal conditions NEC	2,343	4,468	2	5	2057	3441	286	1027
Dermatitis and eczema	198	683		1	119	378	79	305
Dermatitis ascribed to specific agent	26	84			6	28	20	56
Erythemas	1,332	4,373	5	11	892	2871	440	1502
Exfoliative conditions	42	151			18	71	24	80
Granulomatous and deep cutaneous inflammatory conditions		6				3		3
Hyperkeratoses	3	9			1	4	2	5
Hyperpigmentation disorders	3	9			2	5	1	4
Hypertrichoses	1	3				2	1	1
Hypopigmentation disorders	3	9			2	5	1	4
Lipodystrophies		1						1
Nail and nail bed conditions (excl infections and infestations)	5	33			2	21	3	12

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Panniculitides	10	38
Papulosquamous conditions	17	58
Photosensitivity and photodermatitis conditions	31	91
Pigmentation changes NEC	7	19
Pilar disorders NEC	19	59
Pruritus NEC	1,945	6,124
Psoriatic conditions	31	102
Purpura and related conditions	157	397
Pustular conditions	1	4
Rashes, eruptions and exanthems NEC	2,647	8,960
Rosaceas	6	18
Scaly conditions	2	9
Sebaceous gland disorders	1	3
Skin and subcutaneous conditions NEC	16	53
Skin and subcutaneous tissue ulcerations	14	48
Skin cysts and polyps	3	8
Skin dystrophies	1	6
Skin haemorrhages	21	64
Skin hyperplasias and hypertrophies	4	11
Skin hypoplasias and atrophies	2	5
Skin injuries and mechanical dermatoses	2	10
Skin preneoplastic conditions NEC		1
Skin vascular conditions NEC	1	5
Skin vasculitides	20	63
Skin vasomotor conditions	15	71
Telangiectasia and related conditions	2	4
Urticarias	1,025	3,339
	11,383	35,266

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	10	9	28
		8	31	9	27
1	1	21	50	10	41
		6	15	1	4
		16	35	3	24
4	10	1297	3961	648	2163
		17	52	14	50
1	3	64	175	93	222
				1	4
	13	1784	5597	863	3363
			8	6	10
		1	6	1	3
		1	2		1
		11	32	5	21
		7	20	7	28
		3	6		2
		1	4		2
		3	17	18	47
		3	8	1	3
		1	3	1	2
		1	4	1	6
			1		
			4	1	1
		1	12	19	51
	1	8	30	7	41
		1	2	1	2
1	4	651	2055	374	1284
15	58	7807	21936	3576	13330

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Age related issues	6	9	3	5	3	4
Dietary and nutritional issues		1		1		
Disability issues	275	920	122	452	153	468
Drug and chemical abuse	1	1			1	1
Educational issues		1				1
Employment issues		2		2		
Family and partner issues		1		1		
Non-occupational and unspecified environmental problems		3		1		2
Pregnancy related circumstances		1				1
Social issues NEC	13	40	5	27	8	13
Tobacco use	1	2	1	2		
	296	981	131	491	165	490

System Organ Class

SOC Not Yet Coded

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
	22	51	22	51
	22	51	22	51

System Organ Class

Surgical and medical procedures

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal therapeutic procedures NEC		1		1		
Anaesthesia and allied procedures	1	2		1	1	1
Analgesia supportive care	1	1	1	1		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Surgical and medical procedures

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arterial therapeutic procedures (excl aortic)	1	2			1	2
Breast therapeutic procedures NEC		3				3
Bronchial and pulmonary therapeutic procedures		1				1
Cardiac therapeutic procedures NEC	1	1	1	1		
Contraceptive methods female		1		1		
Cranial nerve therapeutic procedures		1				1
Dental and gingival therapeutic procedures	1	6	1	5		1
Dietary and nutritional therapies		3				3
Gastrointestinal therapeutic procedures NEC	1	3	1	1		2
Gynaecological therapeutic procedures NEC	3	4	3	4		
Hernia repairs		1				1
Immunisations	1	15	1	10		5
Induced abortions		1				1
Joint therapeutic procedures	1	3	1	1		2
Large intestine therapeutic procedures		1		1		
Limb therapeutic procedures	7	16	5	11	2	5
Nervous system therapeutic procedures NEC	1	4			1	4
Paranasal therapeutic procedures		1		1		
Prophylactic procedures NEC		1				1
Renal therapeutic procedures		1		1		
Respiratory tract therapeutic procedures NEC	2	6		1	2	5
Skin and subcutaneous tissue therapeutic procedures NEC		2		2		
Skin lesion excisions		1		1		
Small intestine therapeutic procedures	1	2			1	2
Spine and spinal cord therapeutic procedures		1				1
Therapeutic procedures NEC	9	28	7	20	2	8
Uterine therapeutic procedures		1				1
Vascular therapeutic procedures NEC	2	4			2	4
Venous therapeutic procedures	1	1			1	1
	34	119	21	64	13	55

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Accelerated and malignant hypertension	121	554
Aneurysms and dissections non-site specific	12	24
Aortic aneurysms and dissections	13	34
Aortic embolism and thrombosis	2	4
Aortic infections and inflammations		2
Aortic necrosis and vascular insufficiency	10	23
Arterial infections and inflammations	9	30
Blood pressure disorders NEC	60	150
Bruising, ecchymosis and purpura		1
Circulatory collapse and shock	91	434
Haemorrhages NEC	195	540
Lymphangiopathies		2
Lymphoedemas	36	121
Non-site specific embolism and thrombosis	408	932
Non-site specific necrosis and vascular insufficiency NEC	62	135
Non-site specific vascular disorders NEC	75	185
Peripheral embolism and thrombosis	648	1,257
Peripheral vascular disorders NEC	587	2,522
Peripheral vasoconstriction, necrosis and vascular insufficiency	207	742
Phlebitis NEC	38	95
Site specific embolism and thrombosis NEC	1	1
Site specific necrosis and vascular insufficiency NEC		2
Site specific vascular disorders NEC	177	615
Varicose veins NEC	11	31
Vascular hypertensive disorders NEC	899	2,913
Vascular hypotensive disorders	308	1,276
Vascular malformations and acquired anomalies		1
Vasculitides NEC	33	108
Vena caval embolism and thrombosis	2	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	2		1	121	553
		1	1	11	23
		1	1	12	33
				2	4
					2
		5	8	5	15
				9	30
		29	79	31	71
			1		
1	2	3	8	88	426
	2	18	80	177	460
					2
1	2	21	62	15	59
6	8	4	5	404	927
		11	23	51	112
		44	106	31	79
	5	35	90	613	1167
2	4	368	1526	219	996
1	3	102	392	105	350
		8	38	30	57
				1	1
					2
2	3	98	289	79	326
		7	19	4	12
2	8	340	1006	559	1907
2	6	147	462	161	814
					1
		16	42	17	66
				2	7

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
	4,005	12,741	17	45	1258	4239	2747	8502

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

APPENDIX 2.6.1: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per MedDRA System Organ Class by High Level Term per Country

Cumulative Reporting Period: Through 31-MAY-2021

Interval Reporting Period: 30-APR-2021 Through 31-MAY-2021

Total Number of Cases: 47,174 (Interval) / 167,956 (Cumulative)

Total Number of Adverse Events (PT): 174,177 (Interval) / 631,356 (Cumulative)

MedDRA Version: v.24.0J

Country Where Event Occurred

AFGHANISTAN

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Feelings and sensations NEC		2		2
General signs and symptoms NEC		1		1
		3		3

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle related signs and symptoms NEC		1		1
		1		1

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial cranial nerve disorders		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesias and dysaesthesias		1		1		
		2		1		1

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Erythemas		1		1
Pruritus NEC		1		1
Rashes, eruptions and exanthems NEC		1		1
		3		3

* I=Interval, C=Cumulative
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Country Where Event Occurred

ALBANIA

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Coronavirus infections		2		2
		2		2

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Medication errors, product use errors and issues NEC		1		1
Off label uses		1		1
		2		2

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Country Where Event Occurred

AMERICAN SAMOA

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Feelings and sensations NEC	1	2	1	2
Pain and discomfort NEC		1		1
	1	3	1	3

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Country Where Event Occurred

ANDORRA

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product administration errors and issues		1		1
		1		1

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Country Where Event Occurred

ANGOLA

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Nausea and vomiting symptoms		1		1
Tongue signs and symptoms		1		1
		2		2

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Febrile disorders		1		1
		1		1

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Upper respiratory tract infections		1		1
		1		1

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product administration errors and issues		1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
		1		1

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Country Where Event Occurred

ARGENTINA

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Inner ear signs and symptoms	1	1	1	1
	1	1	1	1

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Thyroid disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Nausea and vomiting symptoms	1	1	1	1
	1	1	1	1

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	1	1	1	1		
Febrile disorders	2	2	1	1	1	1

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* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gait disturbances	2	2	2	2		
Injection site reactions	1	1	1	1		
Pain and discomfort NEC	1	1	1	1		
Therapeutic and nontherapeutic responses	2	2			2	2
	9	9	6	6	3	3

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Allergic conditions NEC		1		1
		1		1

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	4	4	2	2	2	2
Influenza viral infections	1	1	1	1		
	5	5	3	3	2	2

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Intentional product misuses		1		1

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Medication errors, product use errors and issues NEC		1		1
		2		2

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Immunoglobulin analyses		2		2		
Vascular tests NEC (incl blood pressure)	1	1			1	1
Virus identification and serology		1		1		
	1	4		3	1	1

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Diabetes mellitus (incl subtypes)	1	2	1	2
	1	2	1	2

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Intervertebral disc disorders NEC	1	1			1	1
Musculoskeletal and connective tissue conditions NEC	1	1	1	1		

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* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal and connective tissue pain and discomfort		1		1		
	2	3	1	2	1	1

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Dyskinesias and movement disorders NEC	1	1	1	1
Headaches NEC	2	2	2	2
Memory loss (excl dementia)	1	1	1	1
Mental impairment (excl dementia and memory loss)	1	1	1	1
Neurological signs and symptoms NEC	1	1	1	1
	6	6	6	6

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	1	1	1	1		
Confusion and disorientation	1	1			1	1
	2	2	1	1	1	1

System Organ Class

Respiratory, thoracic and mediastinal disorders

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary thrombotic and embolic conditions	1	1			1	1
Respiratory tract disorders NEC	1	1	1	1		
	2	2	1	1	1	1

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	1	1			1	1
Pruritus NEC	1	1	1	1		
Rashes, eruptions and exanthems NEC	1	1	1	1		
	3	3	2	2	1	1

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral vascular disorders NEC	1	1			1	1
Vascular hypertensive disorders NEC	1	1	1	1		
	2	2	1	1	1	1

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Country Where Event Occurred

AUSTRALIA

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias NEC	1	1	1	1		
Coagulopathies	1	1			1	1
Haematological disorders		1		1		
Lymphatic system disorders NEC	13	33	13	32		1
Marrow depression and hypoplastic anaemias	1	1			1	1
Neutropenias	1	1			1	1
Spleen disorders	1	1	1	1		
Thrombocytopenias	7	7			7	7
	25	46	15	35	10	11

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders	1	1			1	1
Cardiac signs and symptoms NEC	5	16	5	16		
Heart failures NEC	2	2			2	2
Ischaemic coronary artery disorders	3	5			3	5
Noninfectious pericarditis	1	1			1	1
Rate and rhythm disorders NEC	28	50	20	33	8	17
Supraventricular arrhythmias		1		1		
Ventricular arrhythmias and cardiac arrest	2	7			2	7
	42	83	25	50	17	33

System Organ Class

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System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	3	5	3	5		
Hearing losses	4	9			4	9
Inner ear signs and symptoms	1	9	1	8		1
	8	23	4	13	4	10

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Adrenal cortical hyperfunctions	1	1	1	1
Adrenal cortical hypofunctions		1		1
Thyroid hyperfunction disorders	2	4	2	4
	3	6	3	6

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival and corneal bleeding and vascular disorders	3	5			3	5
Iris and uveal tract infections, irritations and inflammations		1				1
Lacrimation disorders	1	1	1	1		
Lid, lash and lacrimal infections, irritations and inflammations	1	1	1	1		
Ocular disorders NEC	1	6	1	6		
Ocular infections, inflammations and associated manifestations	2	9	2	9		
Ocular sensation disorders	1	4	1	4		

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* AE=Adverse Event

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pupil disorders		6				6
Retinal bleeding and vascular disorders (excl retinopathy)		1				1
Retinopathies NEC	1	1			1	1
Visual disorders NEC	7	9	6	8	1	1
Visual impairment and blindness (excl colour blindness)	2	5	1	4	1	1
	19	49	13	33	6	16

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis		1				1
Diarrhoea (excl infective)	17	30	17	30		
Gastrointestinal and abdominal pains (excl oral and throat)	16	35	16	34		1
Gastrointestinal disorders NEC	1	1	1	1		
Gastrointestinal signs and symptoms NEC	3	9	2	6	1	3
Gastrointestinal stenosis and obstruction NEC	1	1			1	1
Intestinal haemorrhages	2	6		1	2	5
Nausea and vomiting symptoms	63	173	61	159	2	14
Non-site specific gastrointestinal haemorrhages		2				2
Oral dryness and saliva altered	1	2	1	2		
Oral soft tissue signs and symptoms	12	24	12	22		2
Oral soft tissue swelling and oedema	8	11	8	11		
Stomatitis and ulceration	2	2	2	2		
Tongue signs and symptoms	7	11	7	10		1
	133	308	127	278	6	30

System Organ Class

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	77	172	76	164	1	8
Death and sudden death	13	19			13	19
Febrile disorders	81	153	78	145	3	8
Feelings and sensations NEC	45	108	45	105		3
Gait disturbances	3	6	3	6		
General signs and symptoms NEC	36	61	22	36	14	25
Inflammations		2		2		
Injection site reactions	2	7	2	7		
Oedema NEC	3	6	2	4	1	2
Pain and discomfort NEC	40	74	37	70	3	4
Therapeutic and nontherapeutic responses	1	2			1	2
Vaccination site reactions	87	190	87	186		4
	388	800	352	725	36	75

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hepatocellular damage and hepatitis NEC		1		1
		1		1

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	4	8	4	8		
Anaphylactic and anaphylactoid responses	26	80			26	80
	30	88	4	8	26	80

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections		1				1
Bacterial infections NEC	3	6		1	3	5
Coronavirus infections	1	3		1	1	2
Herpes viral infections	2	5	2	5		
Infections NEC		1				1
Lower respiratory tract and lung infections	17	28	1	1	16	27
Rhinoviral infections		1		1		
Sepsis, bacteraemia, viraemia and fungaemia NEC	6	13			6	13
Upper respiratory tract infections	7	11	6	10	1	1
Urinary tract infections	1	1			1	1
Viral infections NEC	1	2			1	2
	38	72	9	19	29	53

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal injuries NEC	1	1	1	1		
Cerebral injuries NEC	1	1			1	1
Exposures associated with pregnancy, delivery and lactation	1	2	1	2		
Medication errors, product use errors and issues NEC	1	6	1	6		
Muscle, tendon and ligament injuries	2	2	2	2		
Nerve injuries NEC		1		1		
Non-site specific injuries NEC	7	12	3	5	4	7
Off label uses		2		2		
Pelvic fractures and dislocations		1				1
Product administration errors and issues		3		3		

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* AE=Adverse Event

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product preparation errors and issues		2		2		
Skin injuries NEC	4	12	3	10	1	2
Vaccination related complications	3	5			3	5
	20	50	11	34	9	16

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	5	10	4	5	1	5
Coagulation and bleeding analyses	3	3	3	3		
Heart rate and pulse investigations	3	8	3	6		2
Liver function analyses	1	2	1	2		
Neurologic diagnostic procedures	2	3			2	3
Physical examination procedures and organ system status	3	8	1	3	2	5
Pituitary analyses anterior	1	1	1	1		
Platelet analyses	1	1	1	1		
Skeletal and cardiac muscle analyses		1				1
Vascular tests NEC (incl blood pressure)	6	14	5	11	1	3
White blood cell analyses	1	3	1	3		
	26	54	20	35	6	19

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	3	12	1	7	2	5

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* AE=Adverse Event

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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diabetes mellitus (incl subtypes)		1				1
Diabetic complications NEC	1	2			1	2
Diabetic complications neurological		1				1
Hyperglycaemic conditions NEC		1				1
Hypoglycaemic conditions NEC		1		1		
Potassium imbalance	1	1			1	1
	5	19	1	8	4	11

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	1	1	1	1		
Bone related signs and symptoms	1	2	1	2		
Joint related disorders NEC	1	1	1	1		
Joint related signs and symptoms	49	100	49	100		
Lupus erythematosus (incl subtypes)	1	1			1	1
Muscle pains	93	169	93	168		1
Muscle related signs and symptoms NEC	1	6	1	6		
Muscle weakness conditions	1	2	1	2		
Musculoskeletal and connective tissue conditions NEC	1	4	1	4		
Musculoskeletal and connective tissue pain and discomfort	16	34	16	34		
	165	320	164	318	1	2

System Organ Class

Nervous system disorders

Interval Total #	Cumulative Total #	Spontaneous			
		Nonserious		Serious	

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal reflexes		1				1
Absence seizures	1	1			1	1
Central nervous system haemorrhages and cerebrovascular accidents	11	21			11	21
Cerebrovascular venous and sinus thrombosis	2	2			2	2
Coordination and balance disturbances	2	4	2	3		1
Cortical dysfunction NEC	1	2	1	1		1
Demyelinating disorders NEC	1	2			1	2
Disturbances in consciousness NEC	138	246	80	129	58	117
Dyskinesias and movement disorders NEC	1	2		1	1	1
Facial cranial nerve disorders	10	24	2	3	8	21
Generalised tonic-clonic seizures	3	3			3	3
Headaches NEC	119	247	119	245		2
Mental impairment (excl dementia and memory loss)		1				1
Migraine headaches	3	8	3	8		
Multiple sclerosis acute and progressive	1	4			1	4
Neurological signs and symptoms NEC	40	123	36	100	4	23
Olfactory nerve disorders	1	1	1	1		
Paraesthesias and dysaesthesias	11	45	11	45		
Paralysis and paresis (excl cranial nerve)	3	6			3	6
Peripheral neuropathies NEC		1				1
Seizures and seizure disorders NEC	11	21			11	21
Sensory abnormalities NEC	8	14	8	14		
Speech and language abnormalities	3	7	1	2	2	5
Transient cerebrovascular events	1	3			1	3
Tremor (excl congenital)	2	13	2	13		
Trigeminal disorders		1		1		
	373	803	266	566	107	237

System Organ Class

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System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous	2	2	2	2
	2	2	2	2

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	1	12		5	1	7
Confusion and disorientation	2	9	2	8		1
Deliria		2				2
Disturbances in initiating and maintaining sleep	2	6	2	6		
Hallucinations (excl sleep-related)	2	5			2	5
Increased physical activity levels	1	1	1	1		
Mood alterations with depressive symptoms	1	2	1	2		
Panic attacks and disorders		1		1		
Somatic symptom disorders		1				1
	9	39	6	23	3	16

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	1	3	1	2		1
Renal failure and impairment	3	5			3	5
Renal lithiasis	1	1			1	1
	5	9	1	2	4	7

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Menstruation and uterine bleeding NEC	2	2	1	1	1	1
Reproductive tract signs and symptoms NEC	1	1	1	1		
Uterine disorders NEC	1	1			1	1
Vulvovaginal disorders NEC	1	1	1	1		
	5	5	3	3	2	2

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	76	114	68	90	8	24
Bronchospasm and obstruction	19	28	18	26	1	2
Conditions associated with abnormal gas exchange	1	4			1	4
Coughing and associated symptoms	54	89	54	87		2
Laryngeal spasm, oedema and obstruction	2	2	2	2		
Lower respiratory tract inflammatory and immunologic conditions	3	6			3	6
Lower respiratory tract signs and symptoms	1	4	1	3		1
Nasal congestion and inflammations	7	10	7	10		
Nasal disorders NEC	3	4	3	4		
Paranasal sinus disorders (excl infections and neoplasms)	2	2	2	2		
Pharyngeal disorders (excl infections and neoplasms)	3	5	3	3		2
Pneumothorax and pleural effusions NEC	1	1			1	1
Pulmonary oedemas	2	5			2	5
Pulmonary thrombotic and embolic conditions	4	9			4	9
Respiratory failures (excl neonatal)	1	4			1	4
Respiratory signs and symptoms NEC	1	1	1	1		
Respiratory tract disorders NEC		1				1

* I=Interval, C=Cumulative

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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Upper respiratory tract signs and symptoms	56	105	56	103		2
	236	394	215	331	21	63

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	11	14			11	14
Apocrine and eccrine gland disorders	6	32	6	28		4
Bullous conditions	3	3	2	2	1	1
Dermal and epidermal conditions NEC		2		2		
Dermatitis and eczema		1		1		
Erythemas	6	15	6	15		
Photosensitivity and photodermatosis conditions		1		1		
Pruritus NEC	18	36	17	35	1	1
Purpura and related conditions	1	1	1	1		
Rashes, eruptions and exanthems NEC	68	101	68	98		3
Urticarias	24	40	24	40		
	137	246	124	223	13	23

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circulatory collapse and shock		2				2
Haemorrhages NEC	3	3			3	3
Lymphoedemas	1	1	1	1		
Non-site specific embolism and thrombosis	8	9		1	8	8

* I=Interval, C=Cumulative

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System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral embolism and thrombosis	23	28		2	23	26
Peripheral vascular disorders NEC	16	35	15	33	1	2
Peripheral vasoconstriction, necrosis and vascular insufficiency		2		2		
Site specific vascular disorders NEC	2	4	1	2	1	2
Vascular hypertensive disorders NEC	10	38	10	37		1
Vascular hypotensive disorders	6	19	3	13	3	6
Vasculitides NEC	1	1	1	1		
	70	142	31	92	39	50

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Country Where Event Occurred

AUSTRIA

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias haemolytic immune		1				1
Anaemias haemolytic NEC	1	1			1	1
Anaemias NEC	3	6			3	6
Bleeding tendencies		1				1
Coagulopathies		2				2
Eosinophilic disorders	1	1			1	1
Haematological disorders		1				1
Leukocytoses NEC		3				3
Leukopenias NEC	2	7		1	2	6
Lymphatic system disorders NEC	25	66	22	44	3	22
Marrow depression and hypoplastic anaemias	1	3			1	3
Neutropenias		2				2
Spleen disorders		2		1		1
Thrombocytopenias	3	8			3	8
	36	104	22	46	14	58

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders		2				2
Cardiac disorders NEC	7	19	7	17		2
Cardiac signs and symptoms NEC	5	27	4	12	1	15
Cardiomyopathies	1	2			1	2
Coronary artery disorders NEC	1	4			1	4
Heart failures NEC	4	16			4	16

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* AE=Adverse Event

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System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ischaemic coronary artery disorders	8	20			8	20
Left ventricular failures		3				3
Mitral valvular disorders	1	1			1	1
Myocardial disorders NEC	1	3		1	1	2
Noninfectious myocarditis	3	7			3	7
Noninfectious pericarditis		1				1
Pericardial disorders NEC		2				2
Rate and rhythm disorders NEC	15	46	3	6	12	40
Supraventricular arrhythmias	1	13			1	13
Ventricular arrhythmias and cardiac arrest		8				8
	47	174	14	36	33	138

System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Gene mutations and other alterations NEC		1		1
		1		1

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	2	6	2	6		
External ear disorders NEC		1				1
Hearing disorders NEC	1	1	1	1		
Hearing losses	4	7	2	2	2	5
Inner ear signs and symptoms	13	41	8	22	5	19

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* AE=Adverse Event

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System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	20	56	13	31	7	25

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute and chronic thyroiditis		1		1
		1		1

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Choroid and vitreous haemorrhages and vascular disorders		2				2
Choroid and vitreous structural change, deposit and degeneration	1	1			1	1
Colour blindness (incl acquired)	1	1			1	1
Conjunctival and corneal bleeding and vascular disorders		2				2
Conjunctival infections, irritations and inflammations	1	1	1	1		
Eyelid movement disorders	3	5	2	2	1	3
Lacrimation disorders		1		1		
Lid, lash and lacrimal infections, irritations and inflammations	1	3	1	1		2
Ocular bleeding and vascular disorders NEC		1				1
Ocular disorders NEC	3	8	2	5	1	3
Ocular infections, inflammations and associated manifestations		5		4		1

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular nerve and muscle disorders	3	5		1	3	4
Ocular sensation disorders	1	5		4	1	1
Pupil disorders		2				2
Refractive and accommodative disorders	2	3	2	3		
Retinal bleeding and vascular disorders (excl retinopathy)	2	3			2	3
Retinal structural change, deposit and degeneration		1				1
Retinopathies NEC		1				1
Structural change, deposit and degeneration of eye NEC		1				1
Visual disorders NEC	4	12	2	7	2	5
Visual field disorders	1	4		1	1	3
Visual impairment and blindness (excl colour blindness)	7	16	1	2	6	14
	30	83	11	32	19	51

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis	1	1			1	1
Colitis (excl infective)	1	2			1	2
Dental pain and sensation disorders		1				1
Diarrhoea (excl infective)	18	48	16	36	2	12
Faecal abnormalities NEC	1	1			1	1
Flatulence, bloating and distension		2		2		
Gastrointestinal and abdominal pains (excl oral and throat)	4	15	2	5	2	10
Gastrointestinal disorders NEC		2		2		
Gastrointestinal dyskinetic disorders		1		1		

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal signs and symptoms NEC		10		3		7
Gastrointestinal spastic and hypermotility disorders		2		2		
Gastrointestinal stenosis and obstruction NEC	1	1			1	1
Gastrointestinal vascular occlusion and infarction	1	2			1	2
Nausea and vomiting symptoms	67	178	58	129	9	49
Non-site specific gastrointestinal haemorrhages		2				2
Oral dryness and saliva altered	1	11		7	1	4
Oral soft tissue disorders NEC		2		1		1
Oral soft tissue haemorrhages		1				1
Oral soft tissue signs and symptoms	5	26	4	9	1	17
Oral soft tissue swelling and oedema	1	10	1	1		9
Stomatitis and ulceration	1	3		2	1	1
Tongue disorders		1		1		
Tongue signs and symptoms	2	17	1	4	1	13
	104	339	82	205	22	134

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site reactions NEC		1		1		
Application and instillation site reactions		1		1		
Asthenic conditions	151	326	133	263	18	63
Body temperature altered	3	3			3	3
Complications associated with device NEC		1		1		
Death and sudden death	3	21			3	21
Febrile disorders	145	288	131	218	14	70
Feelings and sensations NEC	69	195	64	139	5	56
Gait disturbances	5	13	4	9	1	4

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
General signs and symptoms NEC	29	96	12	38	17	58
Healing abnormal NEC	1	1	1	1		
Inflammations	1	3			1	3
Injection site reactions		5		4		1
Mass conditions NEC	1	1	1	1		
Mucosal findings abnormal		1		1		
Necrosis NEC	1	1			1	1
Oedema NEC	1	10		2	1	8
Pain and discomfort NEC	20	66	8	29	12	37
Therapeutic and nontherapeutic responses	84	132	2	2	82	130
Vaccination site reactions	156	337	148	276	8	61
	670	1,502	504	986	166	516

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bile duct infections and inflammations		1				1
Cholestasis and jaundice	1	2			1	2
Hepatic vascular disorders		1				1
Hepatobiliary signs and symptoms		2		1		1
Hepatocellular damage and hepatitis NEC		1		1		
	1	7		2	1	5

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

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* AE=Adverse Event
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System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	4	21	1	2	3	19
Allergies to foods, food additives, drugs and other chemicals	2	2	1	1	1	1
Anaphylactic and anaphylactoid responses	3	19			3	19
Autoimmune disorders NEC		1				1
	9	43	2	3	7	40

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections		1		1		
Bacterial infections NEC	1	6			1	6
Bone and joint infections	1	1			1	1
Central nervous system and spinal infections		1				1
Coronavirus infections	88	151	6	11	82	140
Dental and oral soft tissue infections	1	3		2	1	1
Ear infections		1				1
Epstein-Barr viral infections	1	1			1	1
Escherichia infections	2	3			2	3
Eye and eyelid infections		1				1
Female reproductive tract infections	1	1			1	1
Helicobacter infections		1				1
Herpes viral infections	17	29	11	16	6	13
Infections NEC	2	5			2	5
Influenza viral infections		1		1		
Lower respiratory tract and lung infections	2	13			2	13
Sepsis, bacteraemia, viraemia and fungaemia NEC	1	4			1	4
Skin structures and soft tissue infections		5		3		2

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Streptococcal infections		1				1
Upper respiratory tract infections	3	6	2	5	1	1
Urinary tract infections	1	2			1	2
Viral infections NEC		4		1		3
	121	241	19	40	102	201

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral injuries NEC		3				3
Chest and respiratory tract injuries NEC		1				1
Conditions caused by cold	1	1			1	1
Exposures associated with pregnancy, delivery and lactation		2		2		
Eye injuries NEC		2				2
Medication errors, product use errors and issues NEC	1	10	1	10		
Non-site specific injuries NEC	2	13	1	2	1	11
Off label uses	4	12	4	12		
Overdoses NEC		1				1
Poisoning and toxicity		1				1
Product administration errors and issues	5	19	5	19		
Product preparation errors and issues		1		1		
Site specific injuries NEC		1				1
Skin injuries NEC		2				2
Skull fractures, facial bone fractures and dislocations		1				1
Thoracic cage fractures and dislocations		1				1
Underdoses NEC	1	2	1	2		
Vaccination related complications		1				1

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* AE=Adverse Event

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	14	74	12	48	2	26

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmunity analyses		1				1
Blood gas and acid base analyses	3	12	1	3	2	9
Carbohydrate tolerance analyses (incl diabetes)	5	8	1	2	4	6
Chemistry analyses NEC	3	3			3	3
Cholesterol analyses	1	1			1	1
Coagulation and bleeding analyses	7	10	4	5	3	5
ECG investigations		4		1		3
Faecal analyses NEC		1				1
Haematological analyses NEC		1		1		
Heart rate and pulse investigations	1	7	1	3		4
Immune response protein analyses NEC		1				1
Immunology analyses NEC		2		2		
Liver function analyses	3	7		3	3	4
Metabolism tests NEC	1	3	1	2		1
Mineral and electrolyte analyses	1	5		4	1	1
Neurologic diagnostic procedures		3				3
Ophthalmic function diagnostic procedures		1				1
Physical examination procedures and organ system status	8	27	7	22	1	5
Platelet analyses	1	4		3	1	1
Protein analyses NEC	3	9	2	6	1	3
Renal function analyses	1	3	1	3		
Respiratory and pulmonary function diagnostic procedures		1		1		

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* AE=Adverse Event

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skeletal and cardiac muscle analyses		11		3		8
Therapeutic drug monitoring analyses		1				1
Tissue enzyme analyses NEC	1	2		1	1	1
Toxicology laboratory analyses		1				1
Urinalysis NEC		1				1
Vascular tests NEC (incl blood pressure)	4	23	3	9	1	14
Virus identification and serology	21	29	1	1	20	28
White blood cell analyses		5		3		2
	64	187	22	78	42	109

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	5	12	4	9	1	3
Food malabsorption and intolerance syndromes (excl sugar intolerance)		1				1
General nutritional disorders NEC	1	4			1	4
Hyperglycaemic conditions NEC		2				2
Hypoglycaemic conditions NEC	2	3			2	3
Potassium imbalance	2	3			2	3
Sodium imbalance	3	4			3	4
Total fluid volume decreased		2		1		1
Total fluid volume increased	1	1	1	1		
	14	32	5	11	9	21

System Organ Class

Musculoskeletal and connective tissue disorders

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	2	2	2	2		
Bone related signs and symptoms	4	9	4	7		2
Bursal disorders		2		1		1
Intervertebral disc disorders NEC	1	2			1	2
Joint related signs and symptoms	81	145	77	111	4	34
Muscle pains	70	123	69	103	1	20
Muscle related signs and symptoms NEC	4	16	1	8	3	8
Muscle tone abnormalities	2	4	1	2	1	2
Muscle weakness conditions	1	12		3	1	9
Musculoskeletal and connective tissue conditions NEC	4	7	1	2	3	5
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		1				1
Musculoskeletal and connective tissue pain and discomfort	41	132	36	95	5	37
Myopathies		1				1
Rheumatoid arthropathies		1				1
Soft tissue disorders NEC		1		1		
Tendon disorders		1		1		
	210	459	191	336	19	123

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Neoplasms malignant site unspecified NEC		1		1
		1		1

System Organ Class

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* AE=Adverse Event
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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal reflexes		1				1
Absence seizures		1				1
Acute polyneuropathies	2	2			2	2
Central nervous system haemorrhages and cerebrovascular accidents	7	31			7	31
Central nervous system vascular disorders NEC		1				1
Cerebrovascular venous and sinus thrombosis	2	3			2	3
Coma states	1	1			1	1
Coordination and balance disturbances	3	8	2	4	1	4
Cortical dysfunction NEC	2	7	1	3	1	4
Demyelinating disorders NEC	1	4			1	4
Disturbances in consciousness NEC	22	80	7	25	15	55
Dyskinesias and movement disorders NEC		7		4		3
Encephalopathies NEC		1				1
Facial cranial nerve disorders	10	29			10	29
Generalised tonic-clonic seizures		3				3
Glossopharyngeal nerve disorders		1				1
Headaches NEC	147	312	137	251	10	61
Hypoglossal nerve disorders		1				1
Lumbar spinal cord and nerve root disorders	2	2			2	2
Memory loss (excl dementia)	2	8	1	4	1	4
Mental impairment (excl dementia and memory loss)	4	11	3	6	1	5
Migraine headaches	2	9	1	5	1	4
Mononeuropathies		2				2
Multiple sclerosis acute and progressive	1	3			1	3
Muscle tone abnormal		5		3		2
Narcolepsy and hypersomnia	1	4	1	3		1
Nervous system disorders NEC		1				1
Neurological signs and symptoms NEC	45	148	36	89	9	59
Neurologic visual problems NEC	1	3	1	1		2
Neuromuscular disorders NEC		4		1		3

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* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuromuscular junction dysfunction	1	1			1	1
Olfactory nerve disorders	2	6	1	4	1	2
Optic nerve disorders NEC	1	1			1	1
Paraesthesias and dysaesthesias	20	103	7	37	13	66
Paralysis and paresis (excl cranial nerve)	9	19			9	19
Parkinson's disease and parkinsonism		1		1		
Peripheral neuropathies NEC		3				3
Seizures and seizure disorders NEC	6	17		1	6	16
Sensory abnormalities NEC	9	32	7	19	2	13
Speech and language abnormalities	2	10	1	3	1	7
Spinal cord and nerve root disorders NEC		1				1
Transient cerebrovascular events	1	2			1	2
Tremor (excl congenital)	3	7	1	3	2	4
Trigeminal disorders		2				2
	309	898	207	467	102	431

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Device physical property and chemical issues		1		1
		1		1

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	3	11	2	8	1	3

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Behaviour and socialisation disturbances		1				1
Cognitive and attention disorders and disturbances NEC		1				1
Confusion and disorientation	3	13	3	6		7
Deliria		1				1
Depressive disorders	1	1			1	1
Disturbances in initiating and maintaining sleep	1	7		4	1	3
Fear symptoms and phobic disorders (incl social phobia)	1	1			1	1
Hallucinations (excl sleep-related)		1				1
Increased physical activity levels	1	6		4	1	2
Mood alterations with manic symptoms		1				1
Mood disorders NEC	1	3		2	1	1
Narcolepsy and associated conditions		1		1		
Panic attacks and disorders		2		1		1
Psychiatric symptoms NEC	1	1	1	1		
Psychotic disorder NEC		1				1
Sleep disorders NEC	2	5	1	2	1	3
Somatic symptom disorders		1				1
Speech and language usage disturbances		1		1		
Speech articulation and rhythm disturbances		1				1
Stereotypies and automatisms		1				1
Thinking disturbances		2		1		1
	14	63	7	31	7	32

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	1	5		2	1	3

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System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal disorders NEC		1		1		
Renal failure and impairment	1	5			1	5
Urinary abnormalities	2	4	1	1	1	3
Urinary tract signs and symptoms NEC		3				3
	4	18	1	4	3	14

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast signs and symptoms		1		1		
Menstruation and uterine bleeding NEC	3	5	2	2	1	3
Menstruation with decreased bleeding		1				1
Menstruation with increased bleeding	2	3	1	1	1	2
Prostatic neoplasms and hypertrophy	1	1			1	1
Reproductive tract signs and symptoms NEC	2	2	1	1	1	1
Testicular and epididymal disorders NEC	1	1			1	1
Vulvovaginal disorders NEC		2				2
Vulvovaginal signs and symptoms		1		1		
	9	17	4	6	5	11

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	33	98	5	17	28	81
Bronchospasm and obstruction	1	7	1	2		5

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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conditions associated with abnormal gas exchange	1	2			1	2
Coughing and associated symptoms	8	21	5	15	3	6
Laryngeal spasm, oedema and obstruction		2				2
Lower respiratory tract inflammatory and immunologic conditions	1	5			1	5
Lower respiratory tract signs and symptoms	1	3		1	1	2
Nasal congestion and inflammations	1	2	1	1		1
Nasal disorders NEC	1	5	1	4		1
Paranasal sinus disorders (excl infections and neoplasms)		1		1		
Parenchymal lung disorders NEC	2	6	1	2	1	4
Pharyngeal disorders (excl infections and neoplasms)	2	9	2	4		5
Pleural infections and inflammations		1				1
Pneumothorax and pleural effusions NEC	3	7			3	7
Pulmonary hypertensions		1				1
Pulmonary oedemas	1	5			1	5
Pulmonary thrombotic and embolic conditions	16	41			16	41
Respiratory failures (excl neonatal)	4	6			4	6
Respiratory signs and symptoms NEC	2	4	1	3	1	1
Respiratory tract disorders NEC	3	6		2	3	4
Upper respiratory tract signs and symptoms	10	35	6	18	4	17
	90	267	23	70	67	197

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecias	1	3	1	3		
Angioedemas		3				3

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* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	5	13	3	8	2	5
Bullous conditions	1	4	1	1		3
Dermal and epidermal conditions NEC	1	10		4	1	6
Dermatitis and eczema	3	10	2	4	1	6
Dermatitis ascribed to specific agent		2				2
Erythemas	1	17	1	10		7
Exfoliative conditions		2		1		1
Hypertrichoses		1		1		
Nail and nail bed conditions (excl infections and infestations)		1		1		
Pruritus NEC	7	40	2	9	5	31
Psoriatic conditions		1				1
Purpura and related conditions	2	6		1	2	5
Rashes, eruptions and exanthems NEC	11	56	6	16	5	40
Skin haemorrhages	1	1			1	1
Skin hypoplasias and atrophies		1		1		
Skin vasculitides	1	1			1	1
Skin vasomotor conditions		1		1		
Urticarias	7	25		2	7	23
	41	198	16	63	25	135

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	7	23	1	7	6	16
Social issues NEC		1				1
	7	24	1	7	6	17

System Organ Class

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System Organ Class

Surgical and medical procedures

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Respiratory tract therapeutic procedures NEC	1	1	1	1
Therapeutic procedures NEC	1	1	1	1
	2	2	2	2

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	5	16			5	16
Aneurysms and dissections non-site specific		1				1
Blood pressure disorders NEC	1	1			1	1
Circulatory collapse and shock	11	36			11	36
Haemorrhages NEC		3				3
Lymphoedemas	2	2			2	2
Non-site specific embolism and thrombosis	2	6			2	6
Non-site specific necrosis and vascular insufficiency NEC	1	3			1	3
Peripheral embolism and thrombosis	16	30		1	16	29
Peripheral vascular disorders NEC	2	18		3	2	15
Peripheral vasoconstriction, necrosis and vascular insufficiency		4		3		1
Phlebitis NEC	1	1			1	1
Site specific vascular disorders NEC		7		2		5
Varicose veins NEC	1	2			1	2
Vascular hypertensive disorders NEC	4	16	1	2	3	14
Vascular hypotensive disorders	3	15	3	6		9
Vasculitides NEC		1				1
	49	162	4	17	45	145

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Country Where Event Occurred

BAHRAIN

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC		1		1
		1		1

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cardiac conduction disorders	1	1	1	1
Ischaemic coronary artery disorders	1	1	1	1
	2	2	2	2

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Ocular sensation disorders	1	1	1	1
	1	1	1	1

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea and vomiting symptoms	2	3		1	2	2

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* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	2	3		1	2	2

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	2	2	2	2		
Febrile disorders	2	5	2	4		1
Feelings and sensations NEC		3		2		1
General signs and symptoms NEC	1	2	1	1		1
Pain and discomfort NEC	1	4		1	1	3
Therapeutic and nontherapeutic responses	1	1			1	1
Vaccination site reactions		1		1		
	7	18	5	11	2	7

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic and anaphylactoid responses	2	2	2	2
	2	2	2	2

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C

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* AE=Adverse Event
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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coronavirus infections	1	1	1	1
	1	1	1	1

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Heart rate and pulse investigations		1		1
Skeletal and cardiac muscle analyses	1	1	1	1
	1	2	1	2

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle pains		2		2		
Muscle related signs and symptoms NEC		1				1
Muscle weakness conditions	2	2	2	2		
Musculoskeletal and connective tissue pain and discomfort	1	2	1	2		
	3	7	3	6		1

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute polyneuropathies	1	1			1	1

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	3	3			3	3
Disturbances in consciousness NEC	1	1			1	1
Headaches NEC	5	6	3	4	2	2
Neurological signs and symptoms NEC	1	1	1	1		
Olfactory nerve disorders	1	1	1	1		
Paraesthesias and dysaesthesias	3	4	1	1	2	3
Sensory abnormalities NEC	2	2	2	2		
Speech and language abnormalities	1	1			1	1
	18	20	8	9	10	11

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	1	2	1	1		1
Coughing and associated symptoms	1	1	1	1		
Nasal congestion and inflammations	1	1	1	1		
Upper respiratory tract signs and symptoms	1	1	1	1		
	4	5	4	4		1

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	1	2			1	2
Pruritus NEC		1		1		
	1	3		1	1	2

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System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Peripheral vascular disorders NEC		1		1
		1		1

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Country Where Event Occurred

BELGIUM

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias haemolytic mechanical factor	1	1			1	1
Coagulopathies	23	40	4	7	19	33
Leukocytoses NEC	1	3			1	3
Lymphatic system disorders NEC	29	73	22	28	7	45
Neutropenias		1				1
Thrombocytopenias	7	9			7	9
	61	127	26	35	35	92

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders		3				3
Cardiac disorders NEC	7	66	2	10	5	56
Cardiac signs and symptoms NEC	8	22	1	6	7	16
Cardiomyopathies		1		1		
Coronary artery disorders NEC		1				1
Heart failures NEC		6				6
Ischaemic coronary artery disorders	3	7			3	7
Myocardial disorders NEC	1	2			1	2
Noninfectious myocarditis	2	2			2	2
Noninfectious pericarditis	3	4			3	4
Pericardial disorders NEC	1	2			1	2
Rate and rhythm disorders NEC	7	51	3	5	4	46
Supraventricular arrhythmias		5				5
Ventricular arrhythmias and cardiac arrest	1	15			1	15

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System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	33	187	6	22	27	165

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	3	11	1	4	2	7
Hearing disorders NEC	1	2	1	1		1
Hearing losses		5				5
Hyperacusia		2				2
Inner ear disorders NEC	2	4			2	4
Inner ear signs and symptoms	11	46	9	16	2	30
	17	70	11	21	6	49

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival infections, irritations and inflammations	1	1			1	1
Eyelid movement disorders	1	1			1	1
Glaucomas (excl congenital)		2				2
Iris and uveal tract infections, irritations and inflammations	1	1			1	1
Lacrimation disorders	1	3		1	1	2
Lid, lash and lacrimal infections, irritations and inflammations	1	2			1	2
Ocular disorders NEC	4	15	3	8	1	7

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular infections, inflammations and associated manifestations	1	3	1	2		1
Ocular nerve and muscle disorders		1				1
Ocular sensation disorders	2	7		2	2	5
Pupil disorders		1		1		
Retinal bleeding and vascular disorders (excl retinopathy)	2	2	1	1	1	1
Retinal structural change, deposit and degeneration	1	1			1	1
Retinopathies NEC		1				1
Scleral structural change, deposit and degeneration		1				1
Structural change, deposit and degeneration of eye NEC		1				1
Visual disorders NEC	5	17	3	8	2	9
Visual field disorders	1	3			1	3
Visual impairment and blindness (excl colour blindness)	6	15	1	3	5	12
	27	78	9	26	18	52

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis	2	2			2	2
Dental disorders NEC	1	1	1	1		
Dental pain and sensation disorders		1				1
Diarrhoea (excl infective)	18	47	6	11	12	36
Dyspeptic signs and symptoms	2	3	2	2		1
Faecal abnormalities NEC	1	2			1	2
Flatulence, bloating and distension	2	6	1	4	1	2
Gastritis (excl infective)	1	1			1	1

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* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal and abdominal pains (excl oral and throat)	24	45	9	12	15	33
Gastrointestinal atonic and hypomotility disorders NEC	2	7	1	2	1	5
Gastrointestinal disorders NEC	3	6	2	2	1	4
Gastrointestinal signs and symptoms NEC	4	18	2	9	2	9
Gastrointestinal stenosis and obstruction NEC		1				1
Gastrointestinal vascular occlusion and infarction		2				2
Gingival disorders, signs and symptoms NEC	1	3	1	1		2
Intestinal haemorrhages	1	1			1	1
Nausea and vomiting symptoms	165	520	76	109	89	411
Oral dryness and saliva altered	2	7	1	2	1	5
Oral soft tissue signs and symptoms	2	10	1	3	1	7
Oral soft tissue swelling and oedema	1	6	1	2		4
Salivary gland disorders NEC	1	1			1	1
Salivary gland enlargements	1	1			1	1
Stomatitis and ulceration	1	5	1	1		4
Tongue signs and symptoms	1	10		1	1	9
	236	706	105	162	131	544

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	385	1,197	165	275	220	922
Body temperature altered		6		2		4
Death and sudden death	13	33			13	33
Febrile disorders	218	619	134	201	84	418
Feelings and sensations NEC	217	646	100	152	117	494
Gait disturbances	2	5			2	5

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
General signs and symptoms NEC	85	240	63	89	22	151
Inflammmations	2	5		1	2	4
Injection site reactions	4	20	4	12		8
Oedema NEC	1	5		2	1	3
Pain and discomfort NEC	59	128	34	50	25	78
Therapeutic and nontherapeutic responses	29	117		1	29	116
Vaccination site reactions	245	653	123	237	122	416
	1,260	3,674	623	1022	637	2652

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bile duct infections and inflammations		1				1
Cholecystitis and cholelithiasis	1	1			1	1
Hepatic and hepatobiliary disorders NEC	4	8		2	4	6
Hepatic failure and associated disorders		1				1
Hepatobiliary signs and symptoms	1	1	1	1		
Hepatocellular damage and hepatitis NEC	2	4			2	4
	8	16	1	3	7	13

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	5	26		3	5	23
Allergies to foods, food additives, drugs and other chemicals		4		1		3

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* AE=Adverse Event

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System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic and anaphylactoid responses	2	41			2	41
Autoimmune disorders NEC	2	8			2	8
Immune and associated conditions NEC	1	1			1	1
	10	80		4	10	76

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections	2	4			2	4
Bacterial infections NEC		1				1
Coronavirus infections	41	162	5	22	36	140
Ear infections	1	1	1	1		
Female reproductive tract infections	2	2			2	2
Herpes viral infections	15	30	11	16	4	14
Infections NEC		7		2		5
Influenza viral infections	12	16	9	11	3	5
Lower respiratory tract and lung infections	2	6			2	6
Mumps viral infections	1	1	1	1		
Sepsis, bacteraemia, viraemia and fungaemia NEC		5				5
Skin structures and soft tissue infections	1	2	1	1		1
Streptococcal infections	1	3			1	3
Upper respiratory tract infections	13	21	6	7	7	14
Urinary tract infections		3		1		2
Viral infections NEC	1	2			1	2
	92	266	34	62	58	204

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral injuries NEC	2	3			2	3
Chest and respiratory tract injuries NEC	1	1			1	1
Conditions caused by cold		1				1
Exposures associated with pregnancy, delivery and lactation	5	9	4	8	1	1
Medication errors, product use errors and issues NEC	80	119	80	119		
Muscle, tendon and ligament injuries	10	21	5	7	5	14
Nerve injuries NEC	2	2	1	1	1	1
Non-site specific injuries NEC	3	15		2	3	13
Non-site specific procedural complications		1				1
Occupational exposures		1		1		
Off label uses	3	7	3	7		
Pathways and sources of exposure		1		1		
Product administration errors and issues	79	136	79	134		2
Product preparation errors and issues		1		1		
Skin injuries NEC	3	6	2	3	1	3
Skull fractures, facial bone fractures and dislocations		1				1
Underdoses NEC		1		1		
	188	326	174	285	14	41

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	2	30		1	2	29
Carbohydrate tolerance analyses (incl diabetes)		2		2		
Coagulation and bleeding analyses	4	7	1	1	3	6
Digestive enzymes	1	1	1	1		
Haematological analyses NEC		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate and pulse investigations	4	19	3	8	1	11
Investigations NEC	1	2	1	1		1
Liver function analyses		7		4		3
Metabolism tests NEC		2				2
Mineral and electrolyte analyses		1		1		
Physical examination procedures and organ system status	8	24	6	11	2	13
Platelet analyses	1	1			1	1
Protein analyses NEC	4	8	1	3	3	5
Skeletal and cardiac muscle analyses	1	5			1	5
Tissue enzyme analyses NEC	1	1			1	1
Urinalysis NEC		1				1
Vascular tests NEC (incl blood pressure)	8	30	4	8	4	22
Virus identification and serology	1	3		1	1	2
White blood cell analyses	1	2		1	1	1
	37	147	17	44	20	103

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	9	23	3	7	6	16
Calcium metabolism disorders		1				1
Diabetic complications NEC		1				1
Fat soluble vitamin deficiencies and disorders		1				1
General nutritional disorders NEC	1	1			1	1
Hyperglycaemic conditions NEC	2	2			2	2
Hypoglycaemic conditions NEC	2	7	1	1	1	6
Iron excess	1	1			1	1
Metabolic acidoses (excl diabetic acidoses)		6				6

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Potassium imbalance		1				1
Sodium imbalance		1				1
Total fluid volume decreased		1				1
Total fluid volume increased	1	1	1	1		
Water soluble vitamin deficiencies	2	2	2	2		
	18	49	7	11	11	38

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	1	5	1	2		3
Bone disorders NEC		1		1		
Bone related signs and symptoms	7	15	5	7	2	8
Joint related signs and symptoms	104	286	39	56	65	230
Muscle pains	225	613	118	167	107	446
Muscle related signs and symptoms NEC	5	11	2	3	3	8
Muscle weakness conditions	5	10	5	6		4
Musculoskeletal and connective tissue conditions NEC	44	100	37	66	7	34
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		1				1
Musculoskeletal and connective tissue infections and inflammations NEC	1	2			1	2
Musculoskeletal and connective tissue pain and discomfort	116	202	75	109	41	93
Soft tissue disorders NEC		1				1
Synovial disorders	1	1	1	1		
Tendon disorders	1	1			1	1
	510	1,249	283	418	227	831

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Oncologic complications and emergencies	1	1	1	1
	1	1	1	1

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal reflexes		1				1
Autonomic nervous system disorders		1				1
Central nervous system haemorrhages and cerebrovascular accidents	16	33			16	33
Coma states		1				1
Coordination and balance disturbances	4	14	2	2	2	12
Cortical dysfunction NEC	4	7			4	7
Disturbances in consciousness NEC	17	86	2	4	15	82
Disturbances in sleep phase rhythm	1	1	1	1		
Dyskinesias and movement disorders NEC	4	4	1	1	3	3
Dystonias		1				1
Encephalitis NEC	1	1			1	1
Facial cranial nerve disorders	12	33		2	12	31
Generalised tonic-clonic seizures	1	4			1	4
Headaches NEC	306	818	174	249	132	569
Memory loss (excl dementia)		3		1		2
Mental impairment (excl dementia and memory loss)	2	4		1	2	3
Migraine headaches	12	29	6	6	6	23
Mononeuropathies	2	2			2	2
Narcolepsy and hypersomnia	2	4	2	2		2
Nervous system disorders NEC	14	52	3	9	11	43
Neurological signs and symptoms NEC	28	102	20	33	8	69

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuromuscular disorders NEC		1				1
Olfactory nerve disorders	2	5	2	3		2
Paraesthesias and dysaesthesias	32	69	20	32	12	37
Paralysis and paresis (excl cranial nerve)	9	16			9	16
Parkinson's disease and parkinsonism		2				2
Peripheral neuropathies NEC		5				5
Seizures and seizure disorders NEC	6	28			6	28
Sensory abnormalities NEC	10	33	5	14	5	19
Sleep disturbances NEC		1				1
Speech and language abnormalities	3	6		3	3	3
Structural brain disorders NEC		1				1
Transient cerebrovascular events	1	2			1	2
Tremor (excl congenital)	6	18	5	6	1	12
Trigeminal disorders	2	2			2	2
	497	1,390	243	369	254	1021

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Device physical property and chemical issues		1		1
		1		1

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour NEC		1				1

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	2	17	1	4	1	13
Behaviour and socialisation disturbances	2	2	1	1	1	1
Confusion and disorientation	2	9		2	2	7
Deliria	1	2			1	2
Delusional symptoms	1	1			1	1
Disturbances in initiating and maintaining sleep	16	37	9	15	7	22
Dyssomnias	3	7	3	5		2
Emotional and mood disturbances NEC		1				1
Hallucinations (excl sleep-related)	1	6			1	6
Increased physical activity levels		3		1		2
Mood alterations with depressive symptoms	1	1	1	1		
Mood disorders NEC		3		1		2
Parasomnias	1	3			1	3
Perception disturbances NEC		1				1
Psychotic disorder NEC		1				1
Sleep disorders NEC	2	9		3	2	6
Thinking disturbances		1				1
	32	105	15	33	17	72

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms		1				1
Renal disorders NEC	2	7			2	7
Renal failure and impairment	3	9			3	9
Urinary abnormalities	3	4	1	2	2	2
Urinary tract signs and symptoms NEC	3	6	1	1	2	5
	11	27	2	3	9	24

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast signs and symptoms		3		1		2
Lactation disorders		1				1
Reproductive tract signs and symptoms NEC	1	1	1	1		
Vulvovaginal disorders NEC	1	2	1	1		1
	2	7	2	3		4

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	29	103	11	16	18	87
Bronchial conditions NEC		1				1
Bronchospasm and obstruction	2	11	1	1	1	10
Conditions associated with abnormal gas exchange		2				2
Coughing and associated symptoms	10	28	1	5	9	23
Laryngeal spasm, oedema and obstruction		2				2
Lower respiratory tract inflammatory and immunologic conditions	1	5			1	5
Lower respiratory tract signs and symptoms	1	4	1	1		3
Nasal congestion and inflammations	4	5	2	3	2	2
Nasal disorders NEC	1	3	1	1		2
Parenchymal lung disorders NEC		1				1
Pharyngeal disorders (excl infections and neoplasms)	2	10	1	1	1	9
Pneumothorax and pleural effusions NEC		2				2
Pulmonary hypertensions		1				1
Pulmonary oedemas		4				4
Pulmonary thrombotic and embolic conditions	12	22			12	22
Respiratory failures (excl neonatal)	1	6			1	6
Respiratory signs and symptoms NEC	2	7	2	2		5

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory tract disorders NEC	7	65	1	5	6	60
Upper respiratory tract signs and symptoms	19	52	11	23	8	29
	91	334	32	58	59	276

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	1	5			1	5
Apocrine and eccrine gland disorders	26	42	20	22	6	20
Bullous conditions	1	1			1	1
Dermal and epidermal conditions NEC	29	79	15	22	14	57
Dermatitis and eczema	4	5	3	4	1	1
Erythemas	14	34	10	15	4	19
Pruritus NEC	8	33	4	12	4	21
Psoriatic conditions		1		1		
Purpura and related conditions	2	3	1	2	1	1
Rashes, eruptions and exanthems NEC	12	31	10	18	2	13
Skin and subcutaneous conditions NEC		1				1
Skin haemorrhages	1	1	1	1		
Skin vasculitides	1	2			1	2
Skin vasomotor conditions		1				1
Urticarias	5	11	3	3	2	8
	104	250	67	100	37	150

System Organ Class

Social circumstances

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	3	6		2	3	4
	3	6		2	3	4

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension		1				1
Circulatory collapse and shock		3				3
Haemorrhages NEC	3	6	2	3	1	3
Lymphoedemas		1				1
Non-site specific embolism and thrombosis	5	8			5	8
Non-site specific necrosis and vascular insufficiency NEC	1	1			1	1
Non-site specific vascular disorders NEC	3	3	2	2	1	1
Peripheral embolism and thrombosis	11	17	1	1	10	16
Peripheral vascular disorders NEC	5	21	1	4	4	17
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	2			1	2
Phlebitis NEC	4	5	1	1	3	4
Site specific vascular disorders NEC		3				3
Vascular hypertensive disorders NEC	6	42	2	5	4	37
Vascular hypotensive disorders	6	23	5	6	1	17
Vasculitides NEC		2		1		1
	45	138	14	23	31	115

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

BERMUDA

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear disorders NEC		2		2
		2		2

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Visual impairment and blindness (excl colour blindness)		1		1
		1		1

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea (excl infective)		1		1

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* AE=Adverse Event
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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
		1		1

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Febrile disorders		1		1		
Feelings and sensations NEC		2		2		
General signs and symptoms NEC	1	2	1	1		1
Pain and discomfort NEC		1				1
	1	6	1	4		2

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposures associated with pregnancy, delivery and lactation	1	1	1	1
	1	1	1	1

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms	1	1	1	1
Musculoskeletal and connective tissue pain and discomfort	1	1	1	1

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* AE=Adverse Event
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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
	2	2	2	2

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Coordination and balance disturbances		1		1
Neurological signs and symptoms NEC		1		1
Paraesthesias and dysaesthesias		1		1
		3		3

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breathing abnormalities		1		1
		1		1

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders		1		1		
Erythemas		1				1
Rashes, eruptions and exanthems NEC		1		1		
		3		2		1

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

BOLIVIA

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Rate and rhythm disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute and chronic pancreatitis	1	1	1	1
	1	1	1	1

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Feelings and sensations NEC	1	1	1	1
	1	1	1	1

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Heart rate and pulse investigations	1	1	1	1
Vascular tests NEC (incl blood pressure)	1	1	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
	2	2	2	2

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Neurological signs and symptoms NEC	1	1	1	1
	1	1	1	1

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Coughing and associated symptoms	1	1	1	1
Upper respiratory tract signs and symptoms	1	1	1	1
	2	2	2	2

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Vascular hypertensive disorders NEC	1	1	1	1
	1	1	1	1

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* AE=Adverse Event
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Country Where Event Occurred

BOSNIA AND HERZEGOVINA

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Oedema NEC	1	1	1	1
Pain and discomfort NEC	1	1	1	1
	2	2	2	2

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Coronavirus infections		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

BRAZIL

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Leukopenias NEC	1	1	1	1
Lymphatic system disorders NEC	4	4	4	4
	5	5	5	5

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rate and rhythm disorders NEC	2	2	2	2		
Ventricular arrhythmias and cardiac arrest	1	1			1	1
	3	3	2	2	1	1

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lid, lash and lacrimal infections, irritations and inflammations	1	1	1	1
Ocular disorders NEC	3	3	3	3
Ocular sensation disorders	1	1	1	1
Visual impairment and blindness (excl colour blindness)	1	1	1	1
	6	6	6	6

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea (excl infective)	5	5	5	5
Gastrointestinal and abdominal pains (excl oral and throat)	3	3	3	3
Gastrointestinal signs and symptoms NEC	1	1	1	1
Nausea and vomiting symptoms	10	10	10	10
Oral dryness and saliva altered	3	3	3	3
Oral soft tissue signs and symptoms	1	1	1	1
	23	23	23	23

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	28	28	27	27	1	1
Febrile disorders	21	21	20	20	1	1
Feelings and sensations NEC	21	21	21	21		
Gait disturbances	1	1	1	1		
General signs and symptoms NEC	6	6	6	6		
Pain and discomfort NEC	14	15	14	15		
Therapeutic and nontherapeutic responses	3	3	1	1	2	2
Vaccination site reactions	38	38	33	33	5	5
	132	133	123	124	9	9

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	5	5	4	4	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	5	5	4	4	1	1

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	4	4	2	2	2	2
Upper respiratory tract infections	1	1	1	1		
	5	5	3	3	2	2

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation	7	7	4	4	3	3
Medication errors, product use errors and issues NEC	2	2	2	2		
Off label uses	1	1	1	1		
Overdoses NEC	4	4	4	4		
Product administration errors and issues	3	3	3	3		
Product preparation errors and issues	1	1	1	1		
Skin injuries NEC	1	1	1	1		
	19	19	16	16	3	3

System Organ Class

Investigations

Spontaneous

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Carbohydrate tolerance analyses (incl diabetes)	1	1	1	1		
Heart rate and pulse investigations	1	1	1	1		
Physical examination procedures and organ system status	1	1	1	1		
Virus identification and serology	2	2	1	1	1	1
White blood cell analyses	3	3	3	3		
	8	8	7	7	1	1

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders	3	3	3	3
	3	3	3	3

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Bone related signs and symptoms	2	2	2	2
Joint related signs and symptoms	4	4	4	4
Muscle pains	11	11	11	11
Musculoskeletal and connective tissue conditions NEC	1	1	1	1
Musculoskeletal and connective tissue pain and discomfort	23	23	23	23
	41	41	41	41

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in consciousness NEC	3	3	3	3		
Dyskinesias and movement disorders NEC	2	2	2	2		
Headaches NEC	26	26	26	26		
Neurological signs and symptoms NEC	5	5	5	5		
Paraesthesias and dysaesthesias	2	2	2	2		
Seizures and seizure disorders NEC	1	1			1	1
Sensory abnormalities NEC	1	1	1	1		
Speech and language abnormalities	1	1	1	1		
Tremor (excl congenital)	2	2	2	2		
	43	43	42	42	1	1

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Gestational age and weight conditions	1	1	1	1
Labour onset and length abnormalities	1	1	1	1
Still birth and foetal death	1	1	1	1
	3	3	3	3

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anxiety symptoms	2	2	2	2
Disturbances in initiating and maintaining sleep	1	1	1	1
Sleep disorders NEC	1	1	1	1
	4	4	4	4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Bladder and urethral symptoms	1	1	1	1
	1	1	1	1

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Menstruation and uterine bleeding NEC	1	1	1	1
Menstruation with increased bleeding	1	1	1	1
	2	2	2	2

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	2	2	1	1	1	1
Coughing and associated symptoms	6	6	6	6		
Nasal congestion and inflammations	2	2	2	2		
Nasal disorders NEC	1	1	1	1		
Pneumothorax and pleural effusions NEC	1	1			1	1
Respiratory signs and symptoms NEC	1	1	1	1		
Upper respiratory tract signs and symptoms	6	6	6	6		
	19	19	17	17	2	2

System Organ Class

Skin and subcutaneous tissue disorders

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	2	2	2	2		
Dermal and epidermal conditions NEC	1	1			1	1
Erythemas	3	3	3	3		
Pruritus NEC	4	4	3	3	1	1
Rashes, eruptions and exanthems NEC	2	2	1	1	1	1
Urticarias	2	2	1	1	1	1
	14	14	10	10	4	4

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemorrhages NEC	1	1			1	1
Non-site specific embolism and thrombosis	1	1			1	1
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	1	1	1		
Vascular hypotensive disorders	1	1	1	1		
	4	4	2	2	2	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

BULGARIA

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia deficiencies	1	1	1	1		
Leukopenias NEC		1				1
Lymphatic system disorders NEC	5	25	4	23	1	2
	6	27	5	24	1	3

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC	1	5	1	4		1
Ischaemic coronary artery disorders		1				1
Rate and rhythm disorders NEC	1	8	1	5		3
Ventricular arrhythmias and cardiac arrest		1				1
	2	15	2	9		6

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hearing losses		1				1
Inner ear signs and symptoms	2	16	2	12		4
	2	17	2	12		5

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Conjunctival infections, irritations and inflammations		1		1
Lacrimation disorders	1	3	1	3
Ocular disorders NEC	3	5	3	5
Ocular infections, inflammations and associated manifestations	1	1	1	1
Ocular sensation disorders	1	2	1	2
Visual disorders NEC	1	1	1	1
	7	13	7	13

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dental pain and sensation disorders		1		1		
Diarrhoea (excl infective)	1	3	1	3		
Dyspeptic signs and symptoms		1		1		
Gastrointestinal and abdominal pains (excl oral and throat)	1	4	1	2		2
Gastrointestinal disorders NEC		1		1		
Gastrointestinal signs and symptoms NEC	1	2	1	2		
Nausea and vomiting symptoms	9	27	9	25		2
Oral dryness and saliva altered		2		2		
Oral soft tissue signs and symptoms		1		1		
Oral soft tissue swelling and oedema	2	3	1	1	1	2
Tongue signs and symptoms		1				1
	14	46	13	39	1	7

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Application and instillation site reactions	2	2	2	2		
Asthenic conditions	22	77	22	75		2
Body temperature altered		1				1
Febrile disorders	18	49	18	47		2
Feelings and sensations NEC	10	40	9	36	1	4
Gait disturbances	1	4	1	3		1
General signs and symptoms NEC	7	16	6	15	1	1
Injection site reactions	1	8	1	8		
Interactions	1	1			1	1
Oedema NEC	1	3	1	3		
Pain and discomfort NEC	4	13	4	13		
Therapeutic and nontherapeutic responses	2	13			2	13
Vaccination site reactions	37	140	36	131	1	9
	106	367	100	333	6	34

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	4	4	1	1	3	3
Allergies to foods, food additives, drugs and other chemicals		1		1		
Anaphylactic and anaphylactoid responses		1				1
	4	6	1	2	3	4

System Organ Class

Infections and infestations

Interval Total #	Cumulative Total #	Spontaneous			
		Nonserious		Serious	

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	4	20	2	5	2	15
Herpes viral infections	1	2	1	2		
Infections NEC		1				1
Lower respiratory tract and lung infections	1	3		1	1	2
Upper respiratory tract infections		5		5		
Urinary tract infections	1	1			1	1
Viral infections NEC		1				1
	7	33	3	13	4	20

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone and joint injuries NEC		1				1
Off label uses		1		1		
Overdoses NEC		2		2		
Product administration errors and issues		1		1		
Skull fractures, facial bone fractures and dislocations		1				1
		6		4		2

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmunity analyses		2		1		1
Carbohydrate tolerance analyses (incl diabetes)	1	3		1	1	2
Coagulation and bleeding analyses	1	1			1	1

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* AE=Adverse Event

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate and pulse investigations	1	3	1	3		
Immunology analyses NEC		1		1		
Physical examination procedures and organ system status	21	47	20	44	1	3
Protein analyses NEC		1				1
Thyroid analyses		1				1
Vascular tests NEC (incl blood pressure)	2	12	2	8		4
Virus identification and serology		2		1		1
White blood cell analyses		1		1		
	26	74	23	60	3	14

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	3	5	3	4		1
Hyperglycaemic conditions NEC	1	1			1	1
	4	6	3	4	1	2

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC		1		1		
Bone related signs and symptoms	1	3		2	1	1
Joint related signs and symptoms	10	38	8	36	2	2
Muscle pains	12	46	12	46		
Muscle related signs and symptoms NEC	2	2	2	2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle tone abnormalities		1		1		
Muscle weakness conditions	1	1	1	1		
Musculoskeletal and connective tissue conditions NEC	3	7	2	5	1	2
Musculoskeletal and connective tissue pain and discomfort	15	36	12	33	3	3
Rheumatoid arthropathies		1				1
	44	136	37	127	7	9

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Demyelinating disorders NEC		1				1
Disturbances in consciousness NEC	2	5	2	3		2
Dyskinesias and movement disorders NEC		2		1		1
Facial cranial nerve disorders		3				3
Headaches NEC	21	63	20	58	1	5
Mental impairment (excl dementia and memory loss)	1	2	1	2		
Myelitis (incl infective)		1				1
Neurological signs and symptoms NEC	5	24	5	22		2
Olfactory nerve disorders		2		2		
Paraesthesias and dysaesthesias	5	14	4	12	1	2
Peripheral neuropathies NEC		1		1		
Seizures and seizure disorders NEC		1				1
Sensory abnormalities NEC	1	3	1	3		
Tremor (excl congenital)		5		4		1
	35	127	33	108	2	19

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anxiety symptoms		2		2
Communications disorders	1	1	1	1
Confusion and disorientation	1	1	1	1
Disturbances in initiating and maintaining sleep	1	2	1	2
Fear symptoms and phobic disorders (incl social phobia)	1	1	1	1
Panic attacks and disorders		2		2
	4	9	4	9

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Urinary tract signs and symptoms NEC	1	2	1	2
	1	2	1	2

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast signs and symptoms	1	2	1	2		
Erection and ejaculation conditions and disorders		1				1
Menstruation with increased bleeding	1	1	1	1		
	2	4	2	3		1

System Organ Class

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* AE=Adverse Event
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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	3	9	3	7		2
Coughing and associated symptoms	3	8	3	8		
Nasal disorders NEC	1	2	1	2		
Parenchymal lung disorders NEC		1				1
Respiratory signs and symptoms NEC		1		1		
Upper respiratory tract signs and symptoms	4	13	4	13		
	11	34	11	31		3

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	1	7	1	5		2
Dermal and epidermal conditions NEC	1	1	1	1		
Dermatitis ascribed to specific agent		1		1		
Erythemas	3	8	3	8		
Pruritus NEC	2	5	1	3	1	2
Rashes, eruptions and exanthems NEC	6	13	3	9	3	4
Urticarias	3	6	1	3	2	3
	16	41	10	30	6	11

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure disorders NEC		2		2		
Circulatory collapse and shock		1				1
Haemorrhages NEC		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Non-site specific necrosis and vascular insufficiency NEC		1				1
Non-site specific vascular disorders NEC		1		1		
Peripheral vascular disorders NEC		1		1		
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	2	1	2		
Site specific vascular disorders NEC		2		1		1
Vascular hypertensive disorders NEC	3	6	2	4	1	2
	4	17	3	11	1	6

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* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

CANADA

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC	10	40	9	34	1	6
Neutropenias	1	1			1	1
Spleen disorders		1				1
Thrombocytopenias		2				2
	11	44	9	34	2	10

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC		2		1		1
Cardiac signs and symptoms NEC	7	13	3	8	4	5
Heart failures NEC		1				1
Ischaemic coronary artery disorders	3	5			3	5
Noninfectious myocarditis	1	3			1	3
Noninfectious pericarditis	4	5			4	5
Pericardial disorders NEC	1	2			1	2
Rate and rhythm disorders NEC	16	37	2	10	14	27
Supraventricular arrhythmias	1	5			1	5
Ventricular arrhythmias and cardiac arrest	1	2			1	2
	34	75	5	19	29	56

System Organ Class

Ear and labyrinth disorders

Interval Total #	Cumulative Total #	Spontaneous			
		Nonserious		Serious	

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	6	13	5	12	1	1
External ear disorders NEC		2		2		
Hearing losses	9	15	1	4	8	11
Hyperacusia	1	1	1	1		
Inner ear signs and symptoms	19	36	10	22	9	14
	35	67	17	41	18	26

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Acute and chronic thyroiditis	1	1	1	1
Thyroid disorders NEC		1		1
	1	2	1	2

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Choroid and vitreous structural change, deposit and degeneration	1	3		1	1	2
Conjunctival and corneal bleeding and vascular disorders	1	1			1	1
Eyelid movement disorders		2				2
Iris and uveal tract infections, irritations and inflammations		1				1
Lacrimation disorders		4		4		
Lid, lash and lacrimal infections, irritations and inflammations	2	5	2	4		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lid, lash and lacrimal structural disorders		1		1		
Ocular bleeding and vascular disorders NEC	1	1			1	1
Ocular disorders NEC	12	22	7	15	5	7
Ocular infections, inflammations and associated manifestations	3	6	2	4	1	2
Ocular nerve and muscle disorders	2	2			2	2
Ocular sensation disorders	4	6	3	5	1	1
Pupil disorders	1	1	1	1		
Retinal bleeding and vascular disorders (excl retinopathy)	1	1			1	1
Scleral structural change, deposit and degeneration	1	1	1	1		
Visual disorders NEC	7	15	3	8	4	7
Visual impairment and blindness (excl colour blindness)	3	5	1	2	2	3
Visual pathway disorders	1	1	1	1		
	40	78	21	47	19	31

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Benign neoplasms gastrointestinal (excl oral cavity)		1				1
Colitis (excl infective)	1	2			1	2
Dental pain and sensation disorders	3	4	1	2	2	2
Diaphragmatic hernias		1		1		
Diarrhoea (excl infective)	15	42	11	35	4	7
Dyspeptic signs and symptoms		1		1		
Faecal abnormalities NEC		2		2		
Flatulence, bloating and distension		3		3		

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastric ulcers and perforation		2				2
Gastrointestinal and abdominal pains (excl oral and throat)	13	28	11	24	2	4
Gastrointestinal atonic and hypomotility disorders NEC	1	2	1	2		
Gastrointestinal disorders NEC	1	3	1	3		
Gastrointestinal dyskinetic disorders		1		1		
Gastrointestinal signs and symptoms NEC	5	19	3	15	2	4
Gastrointestinal spastic and hypermotility disorders	2	3	2	3		
Intestinal haemorrhages		1				1
Malabsorption syndromes		1				1
Nausea and vomiting symptoms	51	134	41	108	10	26
Non-site specific gastrointestinal haemorrhages		3				3
Oesophageal disorders NEC		1				1
Oesophagitis (excl infective)		1				1
Oral dryness and saliva altered	1	5	1	4		1
Oral soft tissue disorders NEC		3		3		
Oral soft tissue haemorrhages		1		1		
Oral soft tissue signs and symptoms	9	37	5	23	4	14
Oral soft tissue swelling and oedema	9	17	6	11	3	6
Stomatitis and ulceration	1	4	1	4		
Tongue disorders		5		4		1
Tongue signs and symptoms	4	14	2	10	2	4
	116	341	86	260	30	81

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse effect absent	2	4	2	4		

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	99	259	84	224	15	35
Death and sudden death	2	3			2	3
Febrile disorders	31	92	27	82	4	10
Feelings and sensations NEC	59	144	52	132	7	12
Gait disturbances	10	13	10	11		2
General signs and symptoms NEC	43	103	25	63	18	40
Inflammations	2	3	2	3		
Infusion site reactions		1		1		
Injection site reactions	4	14	4	14		
Interactions	2	4	1	1	1	3
Mass conditions NEC		1		1		
Mucosal findings abnormal		2		2		
Necrosis NEC		1				1
Oedema NEC	1	4		1	1	3
Pain and discomfort NEC	48	122	39	101	9	21
Therapeutic and nontherapeutic responses	12	64	4	10	8	54
Vaccination site reactions	56	156	44	139	12	17
	371	990	294	789	77	201

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hepatic vascular disorders	1	1	1	1
	1	1	1	1

System Organ Class

Immune system disorders

Spontaneous

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System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	9	30	7	14	2	16
Allergies to foods, food additives, drugs and other chemicals		2		2		
Amyloidoses	1	1			1	1
Anaphylactic and anaphylactoid responses	6	49			6	49
Atopic disorders	1	1	1	1		
Autoimmune disorders NEC	2	3			2	3
Immune and associated conditions NEC	1	1	1	1		
	20	87	9	18	11	69

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections	1	2		1	1	1
Bacterial infections NEC	1	2	1	1		1
Breast infections	1	1			1	1
Candida infections	1	2	1	2		
Central nervous system and spinal infections		1				1
Coronavirus infections	10	61	3	6	7	55
Ear infections	1	2			1	2
Eye and eyelid infections	1	2	1	2		
Female reproductive tract infections		1		1		
Fungal infections NEC		1		1		
Herpes viral infections	31	46	23	32	8	14
Infections NEC		1		1		
Inflammatory disorders following infection		1		1		
Lower respiratory tract and lung infections	1	4		1	1	3
Parvoviral infections		1		1		

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sepsis, bacteraemia, viraemia and fungaemia NEC		2				2
Skin structures and soft tissue infections		2		2		
Streptococcal infections		1				1
Upper respiratory tract infections	1	4	1	4		
Urinary tract infections	1	3		2	1	1
Viral infections NEC		2		2		
	50	142	30	60	20	82

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental exposures to product		1		1		
Conditions caused by cold	1	1	1	1		
Exposures associated with pregnancy, delivery and lactation	19	75	19	72		3
Intentional product misuses		1		1		
Limb fractures and dislocations		1				1
Medication errors, product use errors and issues NEC	16	51	16	50		1
Muscle, tendon and ligament injuries		2		2		
Non-site specific injuries NEC	1	8	1	2		6
Off label uses	20	88	20	87		1
Overdoses NEC		12		12		
Poisoning and toxicity		1				1
Product administration errors and issues	9	70	9	70		
Product preparation errors and issues	1	18	1	18		
Skin injuries NEC	6	14	3	9	3	5
Thoracic cage fractures and dislocations		1				1
Underdoses NEC		13		13		

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	73	357	70	338	3	19

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses		1				1
Carbohydrate tolerance analyses (incl diabetes)	2	5	1	2	1	3
Cholesterol analyses		1		1		
Coagulation and bleeding analyses	2	2	1	1	1	1
Heart rate and pulse investigations	9	23	5	12	4	11
Immunoglobulin analyses		1		1		
Liver function analyses		8		3		5
Mineral and electrolyte analyses	1	1	1	1		
Ophthalmic function diagnostic procedures	1	1			1	1
Physical examination procedures and organ system status	7	13	5	10	2	3
Platelet analyses	2	3	1	2	1	1
Protein analyses NEC	1	3	1	2		1
Red blood cell analyses	1	9		8	1	1
Renal function analyses		1		1		
Skeletal and cardiac muscle analyses		3		2		1
Therapeutic drug monitoring analyses		2		1		1
Urinalysis NEC		3		3		
Vascular auscultatory investigations	1	1	1	1		
Vascular tests NEC (incl blood pressure)	5	13	3	7	2	6
Virus identification and serology	1	2			1	2
Vitamin analyses	1	2	1	1		1
White blood cell analyses	2	10	2	10		
	36	108	22	69	14	39

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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	3	11	1	8	2	3
Diabetes mellitus (incl subtypes)		1				1
Disorders of purine metabolism	4	5	3	4	1	1
Fluid intake increased		1		1		
Total fluid volume decreased	2	3	2	3		
Total fluid volume increased	1	4	1	4		
	10	25	7	20	3	5

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	8	10	3	5	5	5
Bone related signs and symptoms	3	6	2	4	1	2
Bursal disorders		1		1		
Cartilage disorders	1	1	1	1		
Connective tissue disorders NEC		1				1
Extremity deformities	1	1	1	1		
Joint related disorders NEC		1		1		
Joint related signs and symptoms	38	81	26	63	12	18
Lupus erythematosus (incl subtypes)		1				1
Muscle infections and inflammations	1	1	1	1		
Muscle pains	17	68	15	62	2	6
Muscle related signs and symptoms NEC	8	14	6	11	2	3
Muscle tone abnormalities	1	1	1	1		
Muscle weakness conditions	7	14	4	10	3	4
Musculoskeletal and connective tissue conditions NEC	6	19	4	17	2	2
Musculoskeletal and connective tissue pain and discomfort	75	146	65	127	10	19

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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Osteoarthropathies	1	1	1	1		
Rheumatoid arthropathies	1	5			1	5
Soft tissue disorders NEC	2	3	2	3		
Spondyloarthropathies	1	1			1	1
Synovial disorders	2	2			2	2
Tendon disorders	1	4		3	1	1
	174	382	132	312	42	70

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal reflexes		1				1
Central nervous system aneurysms and dissections		2				2
Central nervous system haemorrhages and cerebrovascular accidents	12	18	1	1	11	17
Cerebrovascular venous and sinus thrombosis		1				1
Coma states	2	2			2	2
Coordination and balance disturbances	4	10	3	7	1	3
Cortical dysfunction NEC		2		2		
Disturbances in consciousness NEC	24	63	8	18	16	45
Dyskinesias and movement disorders NEC	5	8	4	7	1	1
Encephalitis NEC	1	1			1	1
Eye movement disorders		1				1
Facial cranial nerve disorders	3	18			3	18
Generalised tonic-clonic seizures		1				1
Headaches NEC	64	177	52	156	12	21
Memory loss (excl dementia)		1		1		
Mental impairment (excl dementia and memory loss)	5	14	3	10	2	4

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Migraine headaches	6	16	6	14		2
Multiple sclerosis acute and progressive	1	3			1	3
Narcolepsy and hypersomnia		4		4		
Nervous system disorders NEC		1				1
Neurological signs and symptoms NEC	55	117	41	88	14	29
Olfactory nerve disorders	2	3	2	3		
Paraesthesias and dysaesthesias	61	122	43	78	18	44
Paralysis and paresis (excl cranial nerve)		4				4
Peripheral neuropathies NEC	4	4	1	1	3	3
Seizures and seizure disorders NEC	1	5			1	5
Sensory abnormalities NEC	10	35	7	27	3	8
Speech and language abnormalities	6	9	6	8		1
Transient cerebrovascular events		2				2
Tremor (excl congenital)	3	10	2	8	1	2
Trigeminal disorders	1	1			1	1
	270	656	179	433	91	223

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortions spontaneous		3				3
Foetal growth complications		3				3
Labour onset and length abnormalities		1		1		
Maternal complications of pregnancy NEC		1				1
Postpartum complications NEC		1		1		
Pregnancy complicated by maternal disorders		1				1
		10		2		8

System Organ Class

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System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Device malfunction events NEC	1	1	1	1
Device physical property and chemical issues		1		1
Product packaging issues		1		1
Product quality issues NEC		5		5
Product supply and availability issues	1	3	1	3
	2	11	2	11

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Affect alterations NEC	1	2	1	2		
Anxiety symptoms	8	20	5	15	3	5
Cognitive and attention disorders and disturbances NEC		1		1		
Communications disorders	1	1			1	1
Confusion and disorientation	4	6	3	5	1	1
Deliria		1				1
Depressive disorders		2		2		
Disturbances in initiating and maintaining sleep	8	13	6	11	2	2
Dyssomnias	1	1			1	1
Eating disorders NEC	1	1	1	1		
Emotional and mood disturbances NEC	3	4	2	3	1	1
Fear symptoms and phobic disorders (incl social phobia)	1	2	1	2		
Hallucinations (excl sleep-related)	1	1			1	1
Mental disorders NEC	1	1	1	1		
Mood alterations with depressive symptoms	1	1			1	1
Panic attacks and disorders	1	1	1	1		
Parasomnias	1	2		1	1	1

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Psychotic disorder NEC		1				1
Sleep disorders NEC	4	7	3	6	1	1
Somatic symptom disorders	1	1			1	1
Speech articulation and rhythm disturbances		1		1		
Suicidal and self-injurious behaviour		1				1
Thinking disturbances	1	1	1	1		
	39	72	25	53	14	19

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	3	9	1	4	2	5
Renal failure and impairment	1	2			1	2
Urinary abnormalities		1		1		
Urinary tract signs and symptoms NEC		5		1		4
	4	17	1	6	3	11

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast signs and symptoms	2	6	2	5		1
Lactation disorders	1	1	1	1		
Menopausal effects on the genitourinary tract	1	1			1	1
Menstruation and uterine bleeding NEC	33	38	30	35	3	3
Menstruation with decreased bleeding	3	4	3	4		
Menstruation with increased bleeding	20	24	16	19	4	5

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System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Penile disorders NEC (excl erection and ejaculation)		1				1
Reproductive tract signs and symptoms NEC	1	1			1	1
Testicular and epididymal disorders NEC		2		1		1
Vulvovaginal disorders NEC	6	10	1	4	5	6
Vulvovaginal signs and symptoms		1		1		
	67	89	53	70	14	19

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	13	51	9	35	4	16
Bronchospasm and obstruction	3	10		4	3	6
Conditions associated with abnormal gas exchange		1				1
Coughing and associated symptoms	5	20	5	16		4
Laryngeal spasm, oedema and obstruction	1	2			1	2
Lower respiratory tract inflammatory and immunologic conditions		1				1
Lower respiratory tract signs and symptoms	1	2			1	2
Nasal congestion and inflammations		2		1		1
Nasal disorders NEC		1		1		
Paranasal sinus disorders (excl infections and neoplasms)	1	1	1	1		
Pharyngeal disorders (excl infections and neoplasms)	4	13	3	8	1	5
Pneumothorax and pleural effusions NEC	1	2			1	2
Pulmonary oedemas	1	2			1	2
Pulmonary thrombotic and embolic conditions	5	9			5	9
Respiratory failures (excl neonatal)		2				2

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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory tract disorders NEC	1	5		1	1	4
Upper respiratory tract signs and symptoms	14	52	8	39	6	13
	50	176	26	106	24	70

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes	1	2	1	2		
Angioedemas	4	6			4	6
Apocrine and eccrine gland disorders	13	23	11	17	2	6
Bullous conditions	2	4			2	4
Dermal and epidermal conditions NEC	8	18	8	18		
Dermatitis and eczema	1	3	1	2		1
Erythemas	11	27	8	20	3	7
Exfoliative conditions	1	2		1	1	1
Photosensitivity and photodermatosis conditions	3	3	2	2	1	1
Pruritus NEC	13	41	6	27	7	14
Purpura and related conditions		4		4		
Rashes, eruptions and exanthems NEC	23	72	14	56	9	16
Skin preneoplastic conditions NEC		1		1		
Skin vasomotor conditions	2	2	2	2		
Urticarias	17	47	13	36	4	11
	99	255	66	188	33	67

System Organ Class

Social circumstances

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

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System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	4	10	3	8	1	2
Social issues NEC	1	2	1	2		
	5	12	4	10	1	2

System Organ Class

Surgical and medical procedures

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Vascular therapeutic procedures NEC	1	1	1	1
	1	1	1	1

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension		1				1
Aneurysms and dissections non-site specific	1	2			1	2
Blood pressure disorders NEC	1	2		1	1	1
Circulatory collapse and shock	3	3			3	3
Haemorrhages NEC	1	1			1	1
Lymphoedemas	3	3	3	3		
Non-site specific embolism and thrombosis	13	20	1	1	12	19
Non-site specific vascular disorders NEC		1		1		
Peripheral embolism and thrombosis	4	5			4	5
Peripheral vascular disorders NEC	8	16	7	13	1	3
Peripheral vasoconstriction, necrosis and vascular insufficiency	3	9	2	5	1	4
Phlebitis NEC	1	1			1	1

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System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Site specific vascular disorders NEC	3	6	3	5		1
Vascular hypertensive disorders NEC	7	25	2	9	5	16
Vascular hypotensive disorders	6	14	4	9	2	5
	54	109	22	47	32	62

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Country Where Event Occurred

CAYMAN ISLANDS

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cardiac signs and symptoms NEC		1		1
		1		1

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dyspeptic signs and symptoms		1		1
		1		1

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenic conditions		1		1
		1		1

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle related signs and symptoms NEC		2		2
Musculoskeletal and connective tissue pain and discomfort	12	12	12	12
	12	14	12	14

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headaches NEC		1		1
		1		1

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Emotional and mood disturbances NEC		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

CHILE

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC	5	15	5	14		1
Spleen disorders		1				1
	5	16	5	14		2

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ischaemic coronary artery disorders	2	3			2	3
Rate and rhythm disorders NEC	1	6	1	3		3
	3	9	1	3	2	6

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear disorders NEC		1		1
Inner ear disorders NEC		1		1
Inner ear signs and symptoms		1		1
		3		3

System Organ Class

Eye disorders

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lid, lash and lacrimal infections, irritations and inflammations	1	1			1	1
Ocular disorders NEC	3	6		2	3	4
Ocular infections, inflammations and associated manifestations	1	5		2	1	3
Ocular nerve and muscle disorders		1				1
Ocular sensation disorders		1				1
	5	14		4	5	10

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis		1				1
Anal and rectal pains	1	1	1	1		
Colitis (excl infective)		1		1		
Dental pain and sensation disorders		1		1		
Diarrhoea (excl infective)		9		9		
Dyspeptic signs and symptoms	2	2	2	2		
Faecal abnormalities NEC		1		1		
Flatulence, bloating and distension	1	1	1	1		
Gastrointestinal and abdominal pains (excl oral and throat)	2	10	2	9		1
Gastrointestinal disorders NEC		1				1
Gastrointestinal signs and symptoms NEC		1		1		
Haemorrhoids and gastrointestinal varices (excl oesophageal)	1	1	1	1		
Nausea and vomiting symptoms	5	23	5	20		3
Oral dryness and saliva altered		1				1
Tongue disorders		1		1		
Tongue signs and symptoms		2		1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	12	57	12	49		8

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	14	52	14	51		1
Febrile disorders	9	39	9	37		2
Feelings and sensations NEC	8	25	8	24		1
Gait disturbances		5		3		2
General signs and symptoms NEC	3	11	1	6	2	5
Inflammations		1		1		
Injection site reactions	1	1	1	1		
Mass conditions NEC		2		2		
Oedema NEC	1	5		1	1	4
Pain and discomfort NEC	8	31	8	28		3
Therapeutic and nontherapeutic responses	2	4	2	3		1
Vaccination site reactions	8	41	8	38		3
	54	217	51	195	3	22

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hepatocellular damage and hepatitis NEC		2		1		1
		2		1		1

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	2	10	2	10		
Allergies to foods, food additives, drugs and other chemicals	1	1	1	1		
Anaphylactic and anaphylactoid responses		3				3
	3	14	3	11		3

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	1	4	1	2		2
Herpes viral infections	1	1	1	1		
Lower respiratory tract and lung infections	1	1	1	1		
	3	6	3	4		2

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal injuries NEC		1				1
Exposures associated with pregnancy, delivery and lactation	1	4	1	4		
Medication errors, product use errors and issues NEC	2	4	2	4		
Non-site specific injuries NEC		2				2
Off label uses	1	4	1	4		
Overdoses NEC		1		1		
Product administration errors and issues	1	15	1	15		
Product preparation errors and issues		1		1		

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* AE=Adverse Event

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Site specific injuries NEC		1				1
Skin injuries NEC	1	3	1	3		
	6	36	6	32		4

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses		1		1		
Carbohydrate tolerance analyses (incl diabetes)		2		1		1
Immune response protein analyses NEC		1		1		
Investigations NEC	1	2	1	2		
Liver function analyses		2		1		1
Protein analyses NEC		1		1		
Urinalysis NEC		1				1
Vascular tests NEC (incl blood pressure)	1	2	1	2		
Virus identification and serology		1		1		
White blood cell analyses		1		1		
	2	14	2	11		3

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders	1	3	1	3
Diabetes mellitus (incl subtypes)		1		1
Fluid intake increased		1		1
	1	5	1	5

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* AE=Adverse Event
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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	1	2			1	2
Bone related signs and symptoms		2		2		
Cartilage disorders	1	1	1	1		
Joint related signs and symptoms	2	12	2	10		2
Muscle pains	2	31	2	29		2
Muscle related signs and symptoms NEC	1	5	1	5		
Muscle weakness conditions		1		1		
Musculoskeletal and connective tissue conditions NEC	1	1	1	1		
Musculoskeletal and connective tissue pain and discomfort	11	30	11	30		
Myopathies		1				1
Soft tissue disorders NEC		1		1		
Synovial disorders		1		1		
	19	88	18	81	1	7

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute polyneuropathies		2				2
Cortical dysfunction NEC		1				1
Disturbances in consciousness NEC		6		3		3
Facial cranial nerve disorders		1				1
Headaches NEC	13	55	13	53		2
Muscle tone abnormal		1		1		
Neurological signs and symptoms NEC	3	9	3	9		
Paraesthesias and dysaesthesias	2	18	2	14		4
Paralysis and paresis (excl cranial nerve)		2				2
Seizures and seizure disorders NEC		2				2

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensory abnormalities NEC		3		1		2
	18	100	18	81		19

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product supply and availability issues	1	2	1	2
	1	2	1	2

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anxiety symptoms		2		2
Behaviour and socialisation disturbances		1		1
Disturbances in initiating and maintaining sleep	2	5	2	5
Emotional and mood disturbances NEC		2		2
Fear symptoms and phobic disorders (incl social phobia)	2	3	2	3
Mental disorders NEC		1		1
Mood alterations with depressive symptoms	3	4	3	4
Panic attacks and disorders	1	3	1	3
	8	21	8	21

System Organ Class

Reproductive system and breast disorders

Spontaneous	
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* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breast signs and symptoms	3	5	3	5
Lactation disorders		1		1
	3	6	3	6

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	2	10	2	5		5
Bronchospasm and obstruction	1	1	1	1		
Coughing and associated symptoms	1	4	1	3		1
Nasal congestion and inflammations		2		2		
Pharyngeal disorders (excl infections and neoplasms)	1	1			1	1
Respiratory tract disorders NEC	1	2	1	1		1
Upper respiratory tract signs and symptoms		9		7		2
	6	29	5	19	1	10

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes	1	1	1	1		
Angioedemas		2				2
Apocrine and eccrine gland disorders		2		2		
Dermal and epidermal conditions NEC	2	5	2	5		
Dermatitis and eczema		5		4		1
Erythemas	2	5	1	4	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Panniculitides		1				1
Pruritus NEC	2	4	1	3	1	1
Rashes, eruptions and exanthems NEC	2	5		1	2	4
Urticarias	1	3		1	1	2
	10	33	5	21	5	12

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Disability issues	2	4	2	4
	2	4	2	4

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure disorders NEC		1		1		
Haemorrhages NEC		1				1
Non-site specific embolism and thrombosis		1				1
Non-site specific vascular disorders NEC	1	1	1	1		
Peripheral vascular disorders NEC	1	2	1	2		
Site specific vascular disorders NEC		1				1
Vascular hypertensive disorders NEC		2		2		
Vascular hypotensive disorders		1				1
Vasculitides NEC		1				1
	2	11	2	6		5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

COLOMBIA

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Leukocytoses NEC		1		1
Lymphatic system disorders NEC	2	4	2	4
	2	5	2	5

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC	1	1			1	1
Ischaemic coronary artery disorders	1	1			1	1
Rate and rhythm disorders NEC	1	2	1	2		
	3	4	1	2	2	2

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inner ear signs and symptoms	4	5	4	4		1
	4	5	4	4		1

System Organ Class

Eye disorders

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular disorders NEC	2	3	2	3		
Ocular infections, inflammations and associated manifestations	1	2	1	2		
Ocular sensation disorders	1	1	1	1		
Visual disorders NEC	2	2			2	2
	6	8	4	6	2	2

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anal and rectal signs and symptoms	1	1	1	1		
Diarrhoea (excl infective)	2	4	2	3		1
Gastrointestinal and abdominal pains (excl oral and throat)	1	2	1	2		
Gastrointestinal dyskinetic disorders	1	1			1	1
Gastrointestinal signs and symptoms NEC	3	3	3	3		
Nausea and vomiting symptoms	6	11	5	9	1	2
Oral dryness and saliva altered	2	2	1	1	1	1
Stomatitis and ulceration	1	2	1	2		
	17	26	14	21	3	5

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site reactions NEC		1		1		
Asthenic conditions	13	28	13	25		3
Death and sudden death		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Febrile disorders	5	11	5	10		1
Feelings and sensations NEC	6	16	6	15		1
Gait disturbances	1	2	1	2		
General signs and symptoms NEC	3	5	3	5		
Inflammations	1	1	1	1		
Oedema NEC		1		1		
Pain and discomfort NEC	9	13	7	10	2	3
Therapeutic and nontherapeutic responses	9	10			9	10
Vaccination site reactions	4	12	4	12		
	51	101	40	82	11	19

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	3	7	1	5	2	2
Allergies to foods, food additives, drugs and other chemicals		1		1		
Anaphylactic and anaphylactoid responses	1	5			1	5
	4	13	1	6	3	7

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Candida infections		2		2		
Coronavirus infections	19	24	9	11	10	13
Dental and oral soft tissue infections		1		1		

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes viral infections	4	4	4	4		
Influenza viral infections		2		2		
Lower respiratory tract and lung infections	1	1			1	1
Upper respiratory tract infections	1	1	1	1		
	25	35	14	21	11	14

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposures associated with pregnancy, delivery and lactation		1		1
Medication errors, product use errors and issues NEC	1	2	1	2
Off label uses		1		1
Product administration errors and issues	1	2	1	2
Underdoses NEC		1		1
	2	7	2	7

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	3	5		2	3	3
Physical examination procedures and organ system status	3	3	3	3		
Vascular tests NEC (incl blood pressure)		1		1		
	6	9	3	6	3	3

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders		1		1
		1		1

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	1	1	1	1		
Bone related signs and symptoms	2	3	2	3		
Joint related signs and symptoms	5	11	5	11		
Muscle pains	5	9	5	9		
Muscle related signs and symptoms NEC	1	2	1	2		
Musculoskeletal and connective tissue conditions NEC	1	1			1	1
Musculoskeletal and connective tissue pain and discomfort	7	8	7	8		
Soft tissue disorders NEC	1	1			1	1
	23	36	21	34	2	2

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in consciousness NEC	1	2			1	2
Dyskinesias and movement disorders NEC	1	1	1	1		
Facial cranial nerve disorders	1	1			1	1
Headaches NEC	12	26	12	24		2
Neurological signs and symptoms NEC	6	9	5	8	1	1
Paraesthesias and dysaesthesias	3	8	3	8		

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* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Seizures and seizure disorders NEC		1				1
Sensory abnormalities NEC	3	3	2	2	1	1
Tremor (excl congenital)	1	1			1	1
	28	52	23	43	5	9

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms		1				1
Disturbances in initiating and maintaining sleep	1	1	1	1		
	1	2	1	1		1

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Renal disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	2	7	1	4	1	3
Conditions associated with abnormal gas exchange	1	2			1	2

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* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coughing and associated symptoms	2	8	2	7		1
Nasal congestion and inflammations	2	2	2	2		
Pharyngeal disorders (excl infections and neoplasms)	2	3	1	2	1	1
Respiratory signs and symptoms NEC		1		1		
Respiratory tract disorders NEC	1	1			1	1
Upper respiratory tract signs and symptoms	5	10	4	9	1	1
	15	34	10	25	5	9

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders		1		1		
Bullous conditions	1	2	1	2		
Dermal and epidermal conditions NEC	1	3	1	3		
Erythemas	2	6	2	6		
Pruritus NEC	2	3	2	3		
Rashes, eruptions and exanthems NEC	5	10	3	6	2	4
Urticarias		4		4		
	11	29	9	25	2	4

System Organ Class

SOC Not Yet Coded

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral embolism and thrombosis	1	1	1	1		
Peripheral vascular disorders NEC		1		1		
Varicose veins NEC	1	1	1	1		
Vascular hypertensive disorders NEC		2		1		1
	2	5	2	4		1

* I=Interval, C=Cumulative
* AE=Adverse Event
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Country Where Event Occurred

COSTA RICA

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC	1	6	1	6		
Spleen disorders		1				1
Thrombocytopenias		1				1
	1	8	1	6		2

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ischaemic coronary artery disorders		2				2
Rate and rhythm disorders NEC	1	4	1	4		
Ventricular arrhythmias and cardiac arrest	1	1			1	1
	2	7	1	4	1	3

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	1	2	1	2		
Hearing losses		1				1
Inner ear signs and symptoms	2	4	2	4		
	3	7	3	6		1

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lacrimation disorders	1	2	1	2		
Lid, lash and lacrimal infections, irritations and inflammations		2		2		
Ocular disorders NEC	2	3	2	3		
Ocular infections, inflammations and associated manifestations		7		7		
Pupil disorders		1				1
Visual disorders NEC	1	3	1	3		
	4	18	4	17		1

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal findings abnormal		1		1		
Colitis (excl infective)	1	1	1	1		
Dental disorders NEC		1		1		
Dental pain and sensation disorders	1	1	1	1		
Diarrhoea (excl infective)	5	14	5	12		2
Dyspeptic signs and symptoms		2				2
Faecal abnormalities NEC		1		1		
Flatulence, bloating and distension		2		1		1
Gastritis (excl infective)		2		1		1
Gastrointestinal and abdominal pains (excl oral and throat)	2	9	2	6		3
Gastrointestinal atonic and hypomotility disorders NEC		2		2		
Gastrointestinal disorders NEC		1		1		
Gastrointestinal dyskinetic disorders	1	1	1	1		
Gastrointestinal signs and symptoms NEC	1	2	1	2		
Gingival disorders, signs and symptoms NEC		2		2		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gingival haemorrhages		1		1		
Nausea and vomiting symptoms	2	17	2	13		4
Oral dryness and saliva altered		1				1
Oral soft tissue swelling and oedema		1		1		
Stomatitis and ulceration		1		1		
	13	63	13	49		14

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Application and instillation site reactions	2	4	2	4		
Asthenic conditions	24	73	24	68		5
Body temperature altered		2		1		1
Death and sudden death	1	3			1	3
Febrile disorders	8	33	8	31		2
Feelings and sensations NEC	9	33	9	28		5
General signs and symptoms NEC	4	12	3	9	1	3
Oedema NEC	1	1	1	1		
Pain and discomfort NEC	19	42	19	39		3
Therapeutic and nontherapeutic responses	8	15			8	15
Vaccination site reactions	18	73	18	73		
	94	291	84	254	10	37

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC		1		1		
Anaphylactic and anaphylactoid responses		3				3
		4		1		3

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	8	20		3	8	17
Dental and oral soft tissue infections		1		1		
Infections NEC		2		2		
Influenza viral infections	2	3	2	3		
Upper respiratory tract infections		1		1		
Vascular infections		1				1
	10	28	2	10	8	18

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation	1	1	1	1		
Intentional product use issues		1		1		
Non-site specific injuries NEC		1				1
Product administration errors and issues		3		3		
Skin injuries NEC		2		1		1
Vaccination related complications		1		1		
	1	9	1	7		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacteria identification and serology (excl mycobacteria)	1	1	1	1		
Blood gas and acid base analyses		5		1		4
Cholesterol analyses	3	3	3	3		
Coagulation and bleeding analyses		1		1		
Haematological analyses NEC		1		1		
Heart rate and pulse investigations	1	3		1	1	2
Immunology analyses NEC		1		1		
Liver function analyses		1				1
Platelet analyses		2				2
Vascular tests NEC (incl blood pressure)		1		1		
Virus identification and serology		1		1		
	5	20	4	11	1	9

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms		1		1		
Joint related signs and symptoms	3	13	3	12		1
Muscle pains	7	30	7	28		2
Muscle related signs and symptoms NEC	1	4	1	4		
Musculoskeletal and connective tissue conditions NEC	1	4	1	3		1
Musculoskeletal and connective tissue pain and discomfort	9	49	9	49		
	21	101	21	97		4

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents		3				3
Coordination and balance disturbances	1	1	1	1		
Disturbances in consciousness NEC	3	10	3	9		1
Encephalopathies NEC		1				1
Headaches NEC	22	58	22	55		3
Migraine headaches	3	7	3	6		1
Narcolepsy and hypersomnia		1		1		
Nervous system disorders NEC		1		1		
Neurological signs and symptoms NEC	4	13	4	10		3
Olfactory nerve disorders		1		1		
Paraesthesias and dysaesthesias	3	8	3	8		
Seizures and seizure disorders NEC		1				1
Sensory abnormalities NEC		3		2		1
Speech and language abnormalities		1		1		
Tremor (excl congenital)		1		1		
	36	110	36	96		14

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous		1		1
		1		1

System Organ Class

Psychiatric disorders

Interval Total #	Cumulative Total #	Spontaneous
		Nonserious

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* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Communications disorders		1		1
Depressive disorders		1		1
Disturbances in initiating and maintaining sleep		1		1
Emotional and mood disturbances NEC		1		1
Sleep disorders NEC		2		2
		6		6

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal disorders NEC	1	2		1	1	1
	1	2		1	1	1

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breast signs and symptoms		1		1
Pelvis and broad ligament disorders NEC		2		2
		3		3

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	1	12	1	9		3
Bronchospasm and obstruction		1		1		
Coughing and associated symptoms	1	5	1	5		
Lower respiratory tract inflammatory and immunologic conditions		1				1
Lower respiratory tract signs and symptoms		1		1		
Nasal congestion and inflammations		1		1		
Nasal disorders NEC		2		1		1
Pneumothorax and pleural effusions NEC		1				1
Respiratory signs and symptoms NEC	1	1	1	1		
Respiratory tract disorders NEC		4		2		2
Upper respiratory tract signs and symptoms	2	15	2	13		2
	5	44	5	34		10

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	4	7	4	6		1
Dermal and epidermal conditions NEC	1	4	1	4		
Dermatitis and eczema		2		1		1
Dermatitis ascribed to specific agent	2	2			2	2
Erythemas	1	2	1	2		
Pruritus NEC	1	8	1	8		
Purpura and related conditions		3		2		1
Rashes, eruptions and exanthems NEC	4	10	4	10		
Urticarias		2		2		
	13	40	11	35	2	5

System Organ Class

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* AE=Adverse Event
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System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	1	4		3	1	1
	1	4		3	1	1

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension		1				1
Haemorrhages NEC		1				1
Non-site specific embolism and thrombosis	1	2			1	2
Non-site specific necrosis and vascular insufficiency NEC	1	2		1	1	1
Peripheral embolism and thrombosis	1	1	1	1		
Peripheral vasoconstriction, necrosis and vascular insufficiency		1		1		
Vascular hypertensive disorders NEC		1				1
Vasculitides NEC		1		1		
	3	10	1	4	2	6

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

CROATIA

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias NEC		1				1
Leukopenias NEC		1		1		
Lymphatic system disorders NEC	6	20	6	16		4
Thrombocytopenias		1				1
	6	23	6	17		6

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC		1				1
Cardiac signs and symptoms NEC		12		5		7
Cardiomyopathies		2				2
Heart failures NEC	1	6			1	6
Ischaemic coronary artery disorders	1	2			1	2
Rate and rhythm disorders NEC	1	21	1	7		14
Supraventricular arrhythmias		2				2
Ventricular arrhythmias and cardiac arrest		2				2
	3	48	1	12	2	36

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC		5		1		4

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hearing losses		4		1		3
Inner ear signs and symptoms	4	15	2	8	2	7
	4	24	2	10	2	14

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Choroid and vitreous structural change, deposit and degeneration		1				1
Conjunctival and corneal bleeding and vascular disorders		3				3
Conjunctival infections, irritations and inflammations		1				1
Eyelid movement disorders		3				3
Lacrimation disorders		3		2		1
Lid, lash and lacrimal infections, irritations and inflammations		2		1		1
Ocular bleeding and vascular disorders NEC		2				2
Ocular disorders NEC		6		6		
Ocular infections, inflammations and associated manifestations		1		1		
Ocular sensation disorders	1	1	1	1		
Structural change, deposit and degeneration of eye NEC		1		1		
Visual disorders NEC		1				1
Visual impairment and blindness (excl colour blindness)	1	2	1	1		1
	2	27	2	13		14

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	3	8	3	6		2
Dyspeptic signs and symptoms		2		2		
Gastritis (excl infective)		1		1		
Gastrointestinal and abdominal pains (excl oral and throat)	1	6		4	1	2
Gastrointestinal signs and symptoms NEC		3				3
Gastrointestinal spastic and hypermotility disorders		2		2		
Gingival haemorrhages		1		1		
Intestinal haemorrhages		1				1
Nausea and vomiting symptoms	9	54	9	42		12
Non-site specific gastrointestinal haemorrhages		1				1
Oral dryness and saliva altered		5		1		4
Oral soft tissue disorders NEC		1				1
Oral soft tissue signs and symptoms	1	11		5	1	6
Oral soft tissue swelling and oedema	1	5			1	5
Stomatitis and ulceration		1		1		
Tongue disorders		1				1
Tongue signs and symptoms	1	7			1	7
	16	110	12	65	4	45

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Application and instillation site reactions		1		1		
Asthenic conditions	36	119	29	94	7	25
Death and sudden death		3				3
Febrile disorders	23	111	21	84	2	27
Feelings and sensations NEC	17	82	15	68	2	14

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gait disturbances	3	5	1	1	2	4
General signs and symptoms NEC	4	15	1	4	3	11
Oedema NEC	2	6		2	2	4
Pain and discomfort NEC	12	33	6	18	6	15
Therapeutic and nontherapeutic responses	62	78			62	78
Vaccination site reactions	35	248	33	185	2	63
	194	701	106	457	88	244

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC		25				25
Allergies to foods, food additives, drugs and other chemicals		1		1		
Anaphylactic and anaphylactoid responses		4				4
Immune and associated conditions NEC		1		1		
		31		2		29

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	61	80		3	61	77
Ear infections		1				1
Escherichia infections		1				1
Herpes viral infections	2	2	2	2		
Klebsiella infections		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lower respiratory tract and lung infections		4				4
Sepsis, bacteraemia, viraemia and fungaemia NEC	1	1			1	1
Staphylococcal infections		1				1
Upper respiratory tract infections	3	5		2	3	3
Urinary tract infections		1				1
Viral infections NEC		1		1		
	67	98	2	8	65	90

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation		1		1		
Medication errors, product use errors and issues NEC		3		3		
Non-site specific injuries NEC	1	4			1	4
Off label uses		1		1		
Overdoses NEC	1	2	1	2		
Product administration errors and issues		2		1		1
Product preparation errors and issues	1	2	1	2		
Skin injuries NEC	1	1			1	1
Underdoses NEC		1				1
	4	17	2	10	2	7

System Organ Class

Investigations

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmunity analyses		1		1		
Blood gas and acid base analyses	1	2			1	2
Carbohydrate tolerance analyses (incl diabetes)		3		2		1
Heart rate and pulse investigations	2	6	1	3	1	3
Liver function analyses	1	1			1	1
Ophthalmic function diagnostic procedures		1		1		
Physical examination procedures and organ system status	7	24	6	20	1	4
Protein analyses NEC	1	1	1	1		
Renal function analyses	1	1			1	1
Skeletal and cardiac muscle analyses		2		2		
Vascular tests NEC (incl blood pressure)		19		7		12
White blood cell analyses		2		2		
	13	63	8	39	5	24

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	1	7	1	6		1
Diabetes mellitus (incl subtypes)		1				1
General nutritional disorders NEC		1		1		
	1	9	1	7		2

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	1	1			1	1
Bone related signs and symptoms	4	12	2	10	2	2
Joint related signs and symptoms	4	24	4	20		4
Muscle pains	20	68	19	59	1	9
Muscle related signs and symptoms NEC		5		3		2
Muscle tone abnormalities	1	1	1	1		
Muscle weakness conditions	1	6		3	1	3
Musculoskeletal and connective tissue conditions NEC		2		1		1
Musculoskeletal and connective tissue pain and discomfort	13	45	11	34	2	11
Soft tissue disorders NEC	1	1	1	1		
Spondyloarthropathies		1				1
Synovial disorders		1				1
	45	167	38	132	7	35

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal reflexes		1		1		
Abnormal sleep-related events		1		1		
Central nervous system haemorrhages and cerebrovascular accidents		7				7
Central nervous system vascular disorders NEC		1				1
Coma states		1				1
Coordination and balance disturbances	1	4	1	1		3
Disturbances in consciousness NEC	5	19	1	3	4	16
Dyskinesias and movement disorders NEC	2	5			2	5
Encephalitis NEC		1				1
Facial cranial nerve disorders	1	12		2	1	10

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headaches NEC	28	109	24	84	4	25
Memory loss (excl dementia)		1		1		
Mental impairment (excl dementia and memory loss)	1	2	1	2		
Migraine headaches		1		1		
Neurological signs and symptoms NEC	4	23	2	13	2	10
Neuromuscular disorders NEC		2		1		1
Olfactory nerve disorders	3	4			3	4
Paraesthesias and dysaesthesias	6	28	4	15	2	13
Paralysis and paresis (excl cranial nerve)	1	6	1	1		5
Peripheral neuropathies NEC		1		1		
Seizures and seizure disorders NEC		1				1
Sensory abnormalities NEC	4	9		2	4	7
Speech and language abnormalities		3		1		2
Transient cerebrovascular events	1	2			1	2
Tremor (excl congenital)	3	15	2	11	1	4
	60	259	36	141	24	118

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous		1		1
		1		1

System Organ Class

Psychiatric disorders

Interval Total #

Cumulative Total #

Spontaneous	
Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	1	2	1	2		
Communications disorders		1				1
Confusion and disorientation	4	7	3	4	1	3
Disturbances in initiating and maintaining sleep	1	7	1	7		
Fear symptoms and phobic disorders (incl social phobia)		1				1
Increased physical activity levels		1				1
Mental disorders due to a general medical condition NEC		1				1
Panic attacks and disorders		2				2
Parasomnias		1		1		
	6	23	5	14	1	9

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms		1				1
Urinary abnormalities		1		1		
Urinary tract signs and symptoms NEC		1		1		
		3		2		1

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breast signs and symptoms		1		1
Menstruation and uterine bleeding NEC		1		1
Menstruation with increased bleeding	2	3	2	3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
	2	5	2	5

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	6	30	1	6	5	24
Bronchospasm and obstruction		9				9
Conditions associated with abnormal gas exchange		1				1
Coughing and associated symptoms	3	11	1	5	2	6
Diaphragmatic disorders		1				1
Laryngeal spasm, oedema and obstruction		2				2
Lower respiratory tract signs and symptoms		2		1		1
Nasal congestion and inflammations	2	3		1	2	2
Pharyngeal disorders (excl infections and neoplasms)		2		1		1
Pneumothorax and pleural effusions NEC		1				1
Pulmonary thrombotic and embolic conditions	3	5			3	5
Respiratory failures (excl neonatal)		1				1
Respiratory signs and symptoms NEC	1	4			1	4
Respiratory tract disorders NEC		1				1
Upper respiratory tract signs and symptoms	2	20		9	2	11
	17	93	2	23	15	70

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas		2				2
Apocrine and eccrine gland disorders		12		8		4
Bullous conditions		1				1
Dermal and epidermal conditions NEC		9		2		7
Dermatitis and eczema	1	3		1	1	2
Dermatitis ascribed to specific agent	1	1			1	1
Erythemas	5	25	3	6	2	19
Pruritus NEC	5	16	4	6	1	10
Psoriatic conditions		1		1		
Rashes, eruptions and exanthems NEC	8	30	5	8	3	22
Skin haemorrhages		1				1
Skin hyperplasias and hypertrophies		1				1
Skin vascular conditions NEC		1		1		
Skin vasomotor conditions		1				1
Urticarias	4	9	4	4		5
	24	113	16	37	8	76

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Disability issues		2		2
		2		2

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension		1				1
Haemorrhages NEC		1		1		
Non-site specific embolism and thrombosis		1				1
Non-site specific vascular disorders NEC		1		1		
Peripheral embolism and thrombosis	1	4			1	4
Peripheral vascular disorders NEC	1	7	1	2		5
Peripheral vasoconstriction, necrosis and vascular insufficiency		4		1		3
Site specific vascular disorders NEC		3				3
Vascular hypertensive disorders NEC	2	13	1	2	1	11
Vascular hypotensive disorders		4		1		3
	4	39	2	8	2	31

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Country Where Event Occurred

CYPRUS

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC	1	7	1	6		1
	1	7	1	6		1

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ischaemic coronary artery disorders		3				3
Rate and rhythm disorders NEC	3	7	3	4		3
	3	10	3	4		6

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear disorders NEC		2		2
Hearing losses		1		1
Inner ear signs and symptoms		1		1
		4		4

System Organ Class

Eye disorders

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid movement disorders		1		1		
Ocular disorders NEC		2		2		
Ocular sensation disorders		1				1
Visual disorders NEC	1	1	1	1		
	1	5	1	4		1

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)		2		2		
Gastric and oesophageal haemorrhages		1				1
Gastrointestinal and abdominal pains (excl oral and throat)	1	2	1	2		
Gastrointestinal signs and symptoms NEC		1		1		
Nausea and vomiting symptoms	1	18	1	17		1
Oral dryness and saliva altered	1	1	1	1		
Oral soft tissue signs and symptoms		3		1		2
Tongue signs and symptoms	1	3	1	3		
	4	31	4	27		4

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	11	46	11	46		
Death and sudden death		1				1
Febrile disorders	6	24	6	24		

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* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feelings and sensations NEC	10	27	10	27		
Gait disturbances		3		3		
General signs and symptoms NEC	3	9	3	8		1
Inflammations		1		1		
Injection site reactions		1		1		
Interactions		1		1		
Oedema NEC	1	3	1	2		1
Pain and discomfort NEC	1	8	1	8		
Therapeutic and nontherapeutic responses	4	12	1	2	3	10
Vaccination site reactions	5	26	5	26		
	41	162	38	149	3	13

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC		1		1		
Anaphylactic and anaphylactoid responses		2				2
		3		1		2

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections		1				1
Bacterial infections NEC		1				1
Central nervous system and spinal infections		1				1
Coronavirus infections	4	17		1	4	16

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dental and oral soft tissue infections		1				1
Herpes viral infections	3	3	3	3		
Influenza viral infections		1		1		
Upper respiratory tract infections	1	2	1	2		
Viral infections NEC		1				1
	8	28	4	7	4	21

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Medication errors, product use errors and issues NEC		1		1
Off label uses		2		2
Overdoses NEC		1		1
Product administration errors and issues		2		2
Skin injuries NEC		2		2
		8		8

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses		3		1		2
Coagulation and bleeding analyses		1		1		
Physical examination procedures and organ system status	1	2	1	2		
Protein analyses NEC		1		1		
Vascular tests NEC (incl blood pressure)		1				1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Virus identification and serology		1				1
	1	9	1	5		4

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sodium imbalance		2		2		
Total fluid volume decreased		1				1
		3		2		1

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone disorders NEC	1	1	1	1		
Bone related signs and symptoms		1		1		
Joint related signs and symptoms	4	21	4	21		
Muscle pains	10	41	10	41		
Muscle related signs and symptoms NEC	1	1	1	1		
Muscle weakness conditions		2		1		1
Musculoskeletal and connective tissue conditions NEC	1	3	1	3		
Musculoskeletal and connective tissue pain and discomfort	1	5	1	5		
	18	75	18	74		1

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute polyneuropathies		1				1
Central nervous system haemorrhages and cerebrovascular accidents		1				1
Coordination and balance disturbances		1		1		
Disturbances in consciousness NEC	2	5	2	2		3
Facial cranial nerve disorders	1	9	1	1		8
Generalised tonic-clonic seizures		1				1
Headaches NEC	7	25	7	25		
Migraine headaches		2		2		
Neurological signs and symptoms NEC	3	11	3	10		1
Paraesthesias and dysaesthesias	2	9	2	7		2
Sensory abnormalities NEC		2		2		
Tremor (excl congenital)		2		2		
	15	69	15	52		17

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Confusion and disorientation		2		2
Disturbances in initiating and maintaining sleep	1	4	1	4
	1	6	1	6

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bladder and urethral symptoms		1		1

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* AE=Adverse Event
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System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Renal failure and impairment		1		1
		2		2

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cervix disorders NEC		1		1
Menstruation with decreased bleeding	1	1	1	1
	1	2	1	2

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	5	13	3	8	2	5
Coughing and associated symptoms	2	2	2	2		
Nasal congestion and inflammations		1		1		
Nasal disorders NEC		1				1
Paranasal sinus disorders (excl infections and neoplasms)	1	1	1	1		
Pharyngeal disorders (excl infections and neoplasms)		1		1		
Pulmonary oedemas		2				2
Pulmonary thrombotic and embolic conditions		6				6
Respiratory tract disorders NEC		1				1
Upper respiratory tract signs and symptoms	3	3	3	3		
	11	31	9	16	2	15

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Apocrine and eccrine gland disorders	3	6	3	6
Dermatitis and eczema		2		2
Erythemas		1		1
Rashes, eruptions and exanthems NEC		3		3
	3	12	3	12

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysms and dissections		1				1
Circulatory collapse and shock		1				1
Site specific vascular disorders NEC		1		1		
Vascular hypertensive disorders NEC		2		1		1
Vascular hypotensive disorders		3				3
Vasculitides NEC		2		1		1
		10		3		7

* I=Interval, C=Cumulative
* AE=Adverse Event
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Country Where Event Occurred

CZECH REPUBLIC

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias haemolytic immune	1	1			1	1
Anaemias NEC		3		1		2
Coagulation factor deficiencies	1	1			1	1
Coagulopathies	1	2			1	2
Leukocytoses NEC	1	3	1	3		
Leukopenias NEC		2				2
Lymphatic system disorders NEC	47	146	34	82	13	64
Neutropenias		1				1
Spleen disorders		1				1
Thrombocytopenias	3	4			3	4
	54	164	35	86	19	78

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders	2	3			2	3
Cardiac disorders NEC		1				1
Cardiac signs and symptoms NEC	9	30	6	13	3	17
Cardiomyopathies		1				1
Heart failures NEC	2	7			2	7
Ischaemic coronary artery disorders	4	13			4	13
Myocardial disorders NEC	1	3	1	1		2
Noninfectious myocarditis		1				1
Rate and rhythm disorders NEC	8	54	1	19	7	35
Right ventricular failures		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Supraventricular arrhythmias	2	12	1	3	1	9
Ventricular arrhythmias and cardiac arrest		7				7
	28	133	9	36	19	97

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	8	23	5	13	3	10
Hearing disorders NEC	1	1			1	1
Hearing losses	4	14		2	4	12
Hyperacusia		1				1
Inner ear disorders NEC	1	2			1	2
Inner ear signs and symptoms	20	77	10	43	10	34
	34	118	15	58	19	60

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Endocrine abnormalities of puberty	1	1	1	1
	1	1	1	1

System Organ Class

Eye disorders

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival infections, irritations and inflammations		1		1		
Eyelid movement disorders	1	2			1	2
Glaucomas (excl congenital)		1				1
Lacrimation disorders	2	6	2	4		2
Lid, lash and lacrimal infections, irritations and inflammations	6	12			6	12
Lid, lash and lacrimal structural disorders		1		1		
Ocular bleeding and vascular disorders NEC	1	4			1	4
Ocular disorders NEC	8	25	7	18	1	7
Ocular infections, inflammations and associated manifestations	4	13	3	7	1	6
Ocular nerve and muscle disorders		2		1		1
Ocular sensation disorders		5		4		1
Orbital structural change, deposit and degeneration		1				1
Pupil disorders		1				1
Retinal bleeding and vascular disorders (excl retinopathy)	1	1			1	1
Visual disorders NEC	14	36	6	14	8	22
Visual field disorders		2				2
Visual impairment and blindness (excl colour blindness)	3	8		1	3	7
	40	121	18	51	22	70

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dental pain and sensation disorders	3	8	2	6	1	2
Diarrhoea (excl infective)	16	59	13	43	3	16
Duodenal ulcers and perforation		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspeptic signs and symptoms		9		5		4
Flatulence, bloating and distension	1	5	1	4		1
Gastric ulcers and perforation		2				2
Gastrointestinal and abdominal pains (excl oral and throat)	9	35	9	24		11
Gastrointestinal atonic and hypomotility disorders NEC		4		2		2
Gastrointestinal disorders NEC		3		3		
Gastrointestinal necrosis and gangrene (excl gangrenous hernia)	1	2			1	2
Gastrointestinal signs and symptoms NEC	4	19	2	6	2	13
Gastrointestinal spastic and hypermotility disorders		2		1		1
Gastrointestinal stenosis and obstruction NEC	1	1			1	1
Gastrointestinal vascular occlusion and infarction		4				4
Gingival disorders, signs and symptoms NEC		1		1		
Gingival haemorrhages	2	2	1	1	1	1
Intestinal haemorrhages	1	1			1	1
Nausea and vomiting symptoms	84	254	76	203	8	51
Non-site specific gastrointestinal haemorrhages		3				3
Oesophagitis (excl infective)		1		1		
Oral dryness and saliva altered	4	12	3	7	1	5
Oral soft tissue signs and symptoms	7	45	1	8	6	37
Oral soft tissue swelling and oedema	4	15		1	4	14
Pancreatic disorders NEC		1				1
Salivary gland disorders NEC	1	1	1	1		
Stomatitis and ulceration		4				4
Tongue signs and symptoms	2	19	1	2	1	17
	140	513	110	319	30	194

System Organ Class

General disorders and administration site conditions

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site reactions NEC	1	2	1	2		
Application and instillation site reactions		3		1		2
Asthenic conditions	270	618	262	532	8	86
Death and sudden death	1	7			1	7
Febrile disorders	200	478	170	343	30	135
Feelings and sensations NEC	152	371	143	324	9	47
Gait disturbances	4	17		4	4	13
General signs and symptoms NEC	92	253	68	156	24	97
Inflammations	1	3		1	1	2
Injection site reactions		3		2		1
Interactions	1	2	1	1		1
Mass conditions NEC	1	4	1	2		2
Mucosal findings abnormal	1	4		1	1	3
Oedema NEC	9	33	4	14	5	19
Pain and discomfort NEC	47	125	28	77	19	48
Therapeutic and nontherapeutic responses	16	45			16	45
Vaccination site reactions	302	700	281	532	21	168
	1,098	2,668	959	1992	139	676

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bile duct infections and inflammations	1	1	1	1		
Cholestasis and jaundice		1		1		
Gallbladder disorders NEC		1		1		
Hepatic enzymes and function abnormalities		1				1
Hepatic vascular disorders	1	2			1	2
Hepatobiliary signs and symptoms	1	1			1	1
Hepatocellular damage and hepatitis NEC		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	3	8	1	3	2	5

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	12	59	5	19	7	40
Allergies to foods, food additives, drugs and other chemicals		9		2		7
Anaphylactic and anaphylactoid responses		19				19
Immune and associated conditions NEC		1				1
Transplant rejections		1				1
	12	89	5	21	7	68

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections		2		1		1
Bacterial infections NEC	1	4			1	4
Borrelial infections		1				1
Central nervous system and spinal infections		1				1
Clostridia infections	1	1			1	1
Coronavirus infections	37	91	10	21	27	70
Dental and oral soft tissue infections		3				3
Ear infections	1	1			1	1
Enterococcal infections		2				2
Escherichia infections		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye and eyelid infections	1	2	1	1		1
Hepatobiliary and spleen infections		1				1
Herpes viral infections	16	36		2	16	34
Infections NEC		1		1		
Influenza viral infections	3	4	3	4		
Klebsiella infections	1	2			1	2
Lower respiratory tract and lung infections	1	9			1	9
Sepsis, bacteraemia, viraemia and fungaemia NEC	1	4			1	4
Skin structures and soft tissue infections		2		2		
Streptococcal infections		2				2
Upper respiratory tract infections	5	14	5	13		1
Urinary tract infections		4		1		3
Viral infections NEC		3		1		2
	68	191	19	47	49	144

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral injuries NEC	1	2	1	1		1
Chest and respiratory tract injuries NEC		1				1
Exposures associated with pregnancy, delivery and lactation		2		2		
Limb fractures and dislocations	1	2			1	2
Medication errors, product use errors and issues NEC		6		6		
Muscle, tendon and ligament injuries	2	3	1	1	1	2
Non-site specific injuries NEC	3	13	1	4	2	9
Off label uses	1	11	1	11		
Overdoses NEC	2	6	2	6		

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* AE=Adverse Event

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product administration errors and issues	2	99	2	99		
Product preparation errors and issues		84		84		
Skin injuries NEC	2	6	1	1	1	5
Thermal burns		2				2
Underdoses NEC	1	1	1	1		
Vaccination related complications		4		3		1
	15	242	10	219	5	23

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacteria identification and serology (excl mycobacteria)		1		1		
Blood gas and acid base analyses		7		3		4
Carbohydrate tolerance analyses (incl diabetes)	1	3	1	3		
Chemistry analyses NEC	2	2	1	1	1	1
Coagulation and bleeding analyses	1	3	1	2		1
ECG investigations		2		1		1
Haematological analyses NEC		1		1		
Heart rate and pulse investigations	4	13	3	8	1	5
Immunoglobulin analyses		1		1		
Immunology analyses NEC		1		1		
Investigations NEC		1		1		
Liver function analyses	2	2	2	2		
Mineral and electrolyte analyses		1		1		
Ophthalmic function diagnostic procedures	1	1	1	1		
Physical examination procedures and organ system status	9	19	8	15	1	4
Platelet analyses	1	1			1	1

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* AE=Adverse Event

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Protein analyses NEC	5	10	4	6	1	4
Red blood cell analyses	3	3	3	3		
Renal function analyses		2		2		
Skeletal and cardiac muscle analyses		1				1
Urinalysis NEC	1	3		2	1	1
Vascular tests NEC (incl blood pressure)	12	35	7	17	5	18
Virus identification and serology		7		3		4
White blood cell analyses	4	4	3	3	1	1
	46	124	34	78	12	46

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	7	43	5	32	2	11
Calcium metabolism disorders	1	1			1	1
Disorders of purine metabolism		1		1		
Fluid intake decreased		1		1		
Food malabsorption and intolerance syndromes (excl sugar intolerance)		1				1
General nutritional disorders NEC	1	1			1	1
Hyperglycaemic conditions NEC	1	6		1	1	5
Hyperlipidaemias NEC		1		1		
Hypoglycaemic conditions NEC		2		1		1
Magnesium metabolism disorders		1		1		
Mineral related disorders NEC	1	1			1	1
Potassium imbalance		6				6
Total fluid volume decreased	1	3	1	2		1
	12	68	6	40	6	28

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	3	6			3	6
Bone disorders NEC	1	2	1	1		1
Bone related signs and symptoms	10	20	8	13	2	7
Bursal disorders	1	1			1	1
Joint related disorders NEC		1				1
Joint related signs and symptoms	137	313	123	252	14	61
Ligament disorders		1		1		
Muscle infections and inflammations		1				1
Muscle pains	99	214	93	179	6	35
Muscle related signs and symptoms NEC	7	19	5	10	2	9
Muscle tone abnormalities	1	2		1	1	1
Muscle weakness conditions	7	22	4	14	3	8
Musculoskeletal and connective tissue conditions NEC	13	31	9	23	4	8
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		1				1
Musculoskeletal and connective tissue pain and discomfort	141	273	119	224	22	49
Rheumatoid arthropathies	1	3			1	3
Soft tissue disorders NEC	1	3		2	1	1
Tendon disorders		1				1
	422	914	362	720	60	194

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Prostatic neoplasms malignant		1		1
		1		1

System Organ Class

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* AE=Adverse Event
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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Absence seizures	1	1			1	1
Acute polyneuropathies		1				1
Central nervous system haemorrhages and cerebrovascular accidents	4	26			4	26
Cerebrovascular venous and sinus thrombosis		2				2
Coma states	1	2			1	2
Coordination and balance disturbances	7	12	4	6	3	6
Cortical dysfunction NEC		5		2		3
Cranial nerve disorders NEC		2				2
Dementia (excl Alzheimer's type)		1				1
Disturbances in consciousness NEC	25	96	10	29	15	67
Dyskinesias and movement disorders NEC	7	15	3	7	4	8
Facial cranial nerve disorders	3	17			3	17
Headaches NEC	152	357	146	319	6	38
Increased intracranial pressure disorders		3				3
Lumbar spinal cord and nerve root disorders	1	1			1	1
Memory loss (excl dementia)	5	8			5	8
Mental impairment (excl dementia and memory loss)	7	14	3	5	4	9
Migraine headaches	3	16	3	10		6
Mononeuropathies		1				1
Multiple sclerosis acute and progressive		2				2
Muscle tone abnormal		1		1		
Narcolepsy and hypersomnia	1	7	1	1		6
Neurological signs and symptoms NEC	35	87	20	51	15	36
Neuromuscular disorders NEC		2		1		1
Olfactory nerve disorders	1	12		7	1	5
Paraesthesias and dysaesthesias	59	145	24	58	35	87
Paralysis and paresis (excl cranial nerve)	2	18	1	1	1	17
Parkinson's disease and parkinsonism	2	2	1	1	1	1
Peripheral neuropathies NEC	1	5			1	5
Seizures and seizure disorders NEC	3	13			3	13

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* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensory abnormalities NEC	5	16	2	7	3	9
Sleep disturbances NEC		1				1
Speech and language abnormalities	1	9		3	1	6
Spinal cord and nerve root disorders NEC		2				2
Structural brain disorders NEC		1				1
Transient cerebrovascular events		2				2
Tremor (excl congenital)	6	22	3	11	3	11
	332	927	221	520	111	407

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous		1		1
Still birth and foetal death		1		1
		2		2

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	5	17	3	11	2	6
Attention deficit and disruptive behaviour disorders		1		1		
Cognitive and attention disorders and disturbances NEC	1	1	1	1		
Communications disorders	1	2			1	2
Confusion and disorientation	9	25	4	9	5	16
Deliria		3				3

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* AE=Adverse Event

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Depressive disorders		3		1		2
Disturbances in initiating and maintaining sleep	12	31	11	24	1	7
Dyssomnias	2	2	2	2		
Eating disorders NEC		2		1		1
Emotional and mood disturbances NEC	1	2	1	2		
Fear symptoms and phobic disorders (incl social phobia)		2		2		
Fluctuating mood symptoms	1	1			1	1
Hallucinations (excl sleep-related)	1	4			1	4
Increased physical activity levels	2	7	2	6		1
Mental disorders NEC		1		1		
Mood alterations with depressive symptoms		1		1		
Mood disorders NEC	4	11	2	4	2	7
Panic attacks and disorders	2	2	1	1	1	1
Parasomnias	1	4	1	4		
Perception disturbances NEC		1		1		
Sleep disorders NEC	1	5	1	3		2
Speech and language usage disturbances		2		1		1
Speech articulation and rhythm disturbances		1				1
Suicidal and self-injurious behaviour	1	1			1	1
Thinking disturbances	1	3	1	2		1
	45	135	30	78	15	57

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	7	10	4	4	3	6
Bladder infections and inflammations		1		1		
Genital and urinary tract disorders NEC	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Genitourinary tract infections and inflammations NEC		3		1		2
Nephropathies and tubular disorders NEC		1				1
Renal disorders NEC	1	2		1	1	1
Renal failure and impairment	1	8			1	8
Renal neoplasms		1				1
Renal vascular and ischaemic conditions	1	1			1	1
Urinary abnormalities	1	1	1	1		
Urinary tract signs and symptoms NEC	2	4		2	2	2
	14	33	6	11	8	22

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast signs and symptoms	4	10	2	5	2	5
Menstruation and uterine bleeding NEC	15	17	8	10	7	7
Menstruation with decreased bleeding	2	3		1	2	2
Menstruation with increased bleeding	4	4	2	2	2	2
Reproductive tract signs and symptoms NEC	1	1			1	1
	26	35	12	18	14	17

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	32	126	9	32	23	94
Bronchospasm and obstruction	2	10		5	2	5

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conditions associated with abnormal gas exchange		3		1		2
Coughing and associated symptoms	20	60	17	44	3	16
Laryngeal spasm, oedema and obstruction		4		2		2
Lower respiratory tract inflammatory and immunologic conditions		3		1		2
Lower respiratory tract signs and symptoms	1	3	1	2		1
Nasal congestion and inflammations	4	9		5	4	4
Nasal disorders NEC	4	13	2	7	2	6
Pharyngeal disorders (excl infections and neoplasms)	1	10			1	10
Pleural infections and inflammations	1	1			1	1
Pulmonary oedemas		1				1
Pulmonary thrombotic and embolic conditions	6	10			6	10
Respiratory failures (excl neonatal)	1	8			1	8
Respiratory tract disorders NEC	2	6			2	6
Tracheal disorders (excl infections and neoplasms)	1	1	1	1		
Upper respiratory tract signs and symptoms	20	73	16	50	4	23
Vascular pulmonary disorders NEC	1	1			1	1
	96	342	46	150	50	192

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes	1	2		1	1	1
Alopecias	1	3		1	1	2
Angioedemas	1	3			1	3
Apocrine and eccrine gland disorders	11	42	11	36		6
Bullous conditions	1	3			1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermal and epidermal conditions NEC	4	22	1	10	3	12
Dermatitis and eczema	7	19	2	4	5	15
Dermatitis ascribed to specific agent	1	5			1	5
Erythemas	3	37	2	21	1	16
Exfoliative conditions		2		1		1
Panniculitides		1				1
Photosensitivity and photodermatosis conditions	1	2	1	2		
Pigmentation changes NEC	1	1	1	1		
Pruritus NEC	9	52	3	18	6	34
Purpura and related conditions		5				5
Rashes, eruptions and exanthems NEC	30	113	12	35	18	78
Skin and subcutaneous conditions NEC		1		1		
Skin vasomotor conditions		1		1		
Urticarias	7	18		2	7	16
	78	332	33	134	45	198

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	1	5		2	1	3
Social issues NEC		1		1		
	1	6		3	1	3

System Organ Class

Surgical and medical procedures

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Surgical and medical procedures

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Limb therapeutic procedures		1		1
		1		1

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	1	1			1	1
Aneurysms and dissections non-site specific		1				1
Aortic necrosis and vascular insufficiency		2				2
Blood pressure disorders NEC	2	4	1	2	1	2
Circulatory collapse and shock		13				13
Haemorrhages NEC	4	9		1	4	8
Lymphoedemas		1		1		
Non-site specific embolism and thrombosis	7	8			7	8
Non-site specific necrosis and vascular insufficiency NEC	1	4			1	4
Non-site specific vascular disorders NEC	1	3	1	2		1
Peripheral embolism and thrombosis	13	17			13	17
Peripheral vascular disorders NEC	6	28	3	15	3	13
Peripheral vasoconstriction, necrosis and vascular insufficiency	5	15	2	10	3	5
Site specific vascular disorders NEC		10		6		4
Vascular hypertensive disorders NEC	11	48		10	11	38
Vascular hypotensive disorders	7	30	2	7	5	23
Vena caval embolism and thrombosis		1				1
	58	195	9	54	49	141

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

DENMARK

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias NEC		2		1		1
Bleeding tendencies		1				1
Coagulopathies		1				1
Haematological disorders	1	1	1	1		
Haemolyses NEC		1				1
Leukocytoses NEC		1		1		
Leukopenias NEC	1	5		1	1	4
Lymphatic system disorders NEC	6	41	6	31		10
Marrow depression and hypoplastic anaemias		2				2
Spleen disorders		2				2
Thrombocytopenias	2	7			2	7
Thrombocytoses		1				1
	10	65	7	35	3	30

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC	2	7			2	7
Cardiac signs and symptoms NEC	8	35	3	18	5	17
Cardiomyopathies		1				1
Coronary artery disorders NEC		2				2
Heart failures NEC	1	6			1	6
Ischaemic coronary artery disorders	5	12			5	12
Noninfectious myocarditis		1				1
Noninfectious pericarditis	1	3			1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rate and rhythm disorders NEC	3	14	1	2	2	12
Supraventricular arrhythmias	2	15		2	2	13
Ventricular arrhythmias and cardiac arrest	6	15			6	15
	28	111	4	22	24	89

System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cerebral disorders congenital	1	1	1	1
Musculoskeletal and connective tissue disorders of skull congenital	1	1	1	1
Palate disorders congenital	1	1	1	1
	3	3	3	3

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	1	3	1	2		1
External ear disorders NEC		1		1		
Hearing losses		4		2		2
Hyperacusia	1	3		1	1	2
Inner ear disorders NEC	1	2	1	1		1
Inner ear signs and symptoms	2	10	1	5	1	5
	5	23	3	12	2	11

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Adrenal cortical hypofunctions	1	2	1	2
Thyroid hyperfunction disorders	1	1	1	1
	2	3	2	3

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival and corneal bleeding and vascular disorders		1				1
Conjunctival infections, irritations and inflammations	1	2		1	1	1
Eyelid movement disorders		2				2
Lacrimation disorders		4		4		
Lid, lash and lacrimal infections, irritations and inflammations		3		2		1
Ocular disorders NEC	5	16	1	10	4	6
Ocular infections, inflammations and associated manifestations		7		6		1
Ocular nerve and muscle disorders	1	1			1	1
Ocular sensation disorders		5		1		4
Pupil disorders		1		1		
Retinal bleeding and vascular disorders (excl retinopathy)		1				1
Visual disorders NEC	5	15		2	5	13
Visual field disorders	1	1			1	1
Visual impairment and blindness (excl colour blindness)	5	7	1	2	4	5
	18	66	2	29	16	37

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal findings abnormal	1	1			1	1
Acute and chronic pancreatitis	1	2			1	2
Colitis (excl infective)		2		1		1
Diarrhoea (excl infective)	17	54	6	28	11	26
Dyspeptic signs and symptoms		1		1		
Faecal abnormalities NEC		1		1		
Flatulence, bloating and distension	2	4		2	2	2
Gastric ulcers and perforation		1				1
Gastrointestinal and abdominal pains (excl oral and throat)	9	38	6	19	3	19
Gastrointestinal atonic and hypomotility disorders NEC	2	5	1	3	1	2
Gastrointestinal disorders NEC	1	2		1	1	1
Gastrointestinal mucosal dystrophies and secretion disorders		1		1		
Gastrointestinal necrosis and gangrene (excl gangrenous hernia)		1				1
Gastrointestinal signs and symptoms NEC	1	14		6	1	8
Gastrointestinal spastic and hypermotility disorders		1		1		
Gastrointestinal vascular occlusion and infarction		2				2
Nausea and vomiting symptoms	69	266	37	155	32	111
Non-mechanical ileus		1				1
Non-site specific gastrointestinal haemorrhages		3				3
Oral dryness and saliva altered		6		4		2
Oral soft tissue signs and symptoms	4	28	3	15	1	13
Oral soft tissue swelling and oedema	1	7	1	1		6
Salivary gland disorders NEC		1		1		
Salivary gland enlargements		1		1		
Stomatitis and ulceration		1		1		
Tongue signs and symptoms	2	17		4	2	13
	110	461	54	246	56	215

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse effect absent	1	1	1	1		
Asthenic conditions	99	442	63	264	36	178
Body temperature altered		2				2
Death and sudden death		21				21
Febrile disorders	68	291	49	194	19	97
Feelings and sensations NEC	32	150	19	91	13	59
Gait disturbances	2	7		1	2	6
General signs and symptoms NEC	28	126	20	60	8	66
Inflammations		1				1
Injection site reactions		2		2		
Interactions		1				1
Mucosal findings abnormal		1				1
Oedema NEC	3	14		3	3	11
Pain and discomfort NEC	40	142	24	73	16	69
Therapeutic and nontherapeutic responses	1	10	1	1		9
Vaccination site reactions	110	453	101	409	9	44
	384	1,664	278	1099	106	565

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hepatic and hepatobiliary disorders NEC		1		1		
Hepatic vascular disorders	1	1			1	1
Hepatocellular damage and hepatitis NEC		1				1
	1	3		1	1	2

System Organ Class

Immune system disorders

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	6	31	3	9	3	22
Allergies to foods, food additives, drugs and other chemicals	2	5			2	5
Anaphylactic and anaphylactoid responses	2	31			2	31
Atopic disorders		1		1		
Immune and associated conditions NEC	1	4	1	1		3
	11	72	4	11	7	61

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections		4				4
Bacterial infections NEC	1	5			1	5
Central nervous system and spinal infections	2	3			2	3
Coronavirus infections		23		4		19
Dental and oral soft tissue infections	1	1			1	1
Eye and eyelid infections	1	2			1	2
Fungal infections NEC		1		1		
Herpes viral infections	6	8	5	6	1	2
Infections NEC	5	10	1	3	4	7
Influenza viral infections	2	13	2	8		5
Lower respiratory tract and lung infections	9	30			9	30
Sepsis, bacteraemia, viraemia and fungaemia NEC	1	6			1	6
Staphylococcal infections		1				1
Streptococcal infections	3	4			3	4
Upper respiratory tract infections	2	8	2	7		1
Urinary tract infections		4		1		3
Vascular infections		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Viral infections NEC		1		1		
	33	125	10	31	23	94

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental exposures to product		1		1		
Exposures associated with pregnancy, delivery and lactation	4	6	2	3	2	3
Limb fractures and dislocations	1	2			1	2
Medication errors, product use errors and issues NEC		8		8		
Non-site specific injuries NEC	4	16	1	2	3	14
Off label uses	2	12	2	12		
Pathways and sources of exposure		1		1		
Poisoning and toxicity		2				2
Product administration errors and issues	4	14	4	13		1
Product preparation errors and issues		1		1		
Site specific injuries NEC	1	3	1	1		2
Skin injuries NEC	1	5		1	1	4
Transplantation complications		1				1
Underdoses NEC		2		2		
Vaccination related complications		2		1		1
	17	76	10	46	7	30

System Organ Class

Investigations

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmunity analyses		1				1
Blood counts NEC		1		1		
Blood gas and acid base analyses	2	11	1	3	1	8
Carbohydrate tolerance analyses (incl diabetes)		2		2		
Cholesterol analyses		1		1		
Coagulation and bleeding analyses		3		1		2
ECG investigations		2				2
Haematological analyses NEC		1				1
Heart rate and pulse investigations	5	25	2	15	3	10
Investigations NEC	1	1	1	1		
Liver function analyses	1	5	1	5		
Metabolism tests NEC		1		1		
Mineral and electrolyte analyses		6		6		
Physical examination procedures and organ system status	1	11	1	8		3
Pituitary analyses anterior	1	1	1	1		
Platelet analyses	3	4	2	2	1	2
Protein analyses NEC	3	22	2	8	1	14
Red blood cell analyses	2	5	1	1	1	4
Renal function analyses	1	4			1	4
Skeletal and cardiac muscle analyses		5		1		4
Tissue enzyme analyses NEC		2		2		
Urinalysis NEC	1	1			1	1
Vascular tests NEC (incl blood pressure)	6	23	2	8	4	15
Virus identification and serology		1				1
White blood cell analyses	2	6	2	6		
	29	145	16	73	13	72

System Organ Class

Metabolism and nutrition disorders

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	5	15	2	6	3	9
Diabetic complications NEC		1				1
Fluid intake decreased	1	4		1	1	3
Hyperglycaemic conditions NEC		1				1
Hypoglycaemic conditions NEC		2		1		1
Metabolic acidoses (excl diabetic acidoses)		2				2
Metabolic alkaloses		1		1		
Metabolic disorders NEC	1	1	1	1		
Potassium imbalance	1	3			1	3
Sodium imbalance	1	1			1	1
Total fluid volume decreased	4	6			4	6
	13	37	3	10	10	27

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC		1		1		
Bursal disorders		1				1
Joint related disorders NEC		3		2		1
Joint related signs and symptoms	37	100	25	63	12	37
Muscle pains	43	166	32	122	11	44
Muscle related signs and symptoms NEC	8	22	3	11	5	11
Muscle weakness conditions	6	19	1	6	5	13
Musculoskeletal and connective tissue conditions NEC	2	10	2	5		5
Musculoskeletal and connective tissue pain and discomfort	24	101	14	72	10	29
Myopathies	1	2			1	2
Rheumatoid arthropathies	1	2			1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Soft tissue disorders NEC		2		2		
Spondyloarthropathies	1	2			1	2
	123	431	77	284	46	147

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Leukaemias acute NEC		1		1
Myeloproliferative disorders (excl leukaemias)		1		1
		2		2

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Absence seizures	1	1			1	1
Acute polyneuropathies		1				1
Autonomic nervous system disorders	1	1			1	1
Central nervous system haemorrhages and cerebrovascular accidents	28	53			28	53
Cerebrovascular venous and sinus thrombosis	1	1			1	1
Coma states		1				1
Coordination and balance disturbances	4	10			4	10
Cortical dysfunction NEC	3	6			3	6
Dementia (excl Alzheimer's type)		1				1
Disturbances in consciousness NEC	19	77	4	15	15	62
Dyskinesias and movement disorders NEC	3	4	3	3		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye movement disorders		2				2
Facial cranial nerve disorders	5	13	1	2	4	11
Generalised tonic-clonic seizures	1	5			1	5
Headaches NEC	91	384	68	277	23	107
Increased intracranial pressure disorders		1				1
Memory loss (excl dementia)	1	7			1	7
Mental impairment (excl dementia and memory loss)	1	8	1	3		5
Migraine headaches	4	11	2	6	2	5
Muscle tone abnormal		2		1		1
Myelitis (incl infective)	1	1			1	1
Narcolepsy and hypersomnia	1	5		1	1	4
Nervous system disorders NEC		1				1
Neurological signs and symptoms NEC	51	225	20	107	31	118
Neurologic visual problems NEC		2				2
Olfactory nerve disorders	1	3	1	3		
Paraesthesias and dysaesthesias	20	74	4	35	16	39
Paralysis and paresis (excl cranial nerve)	4	18			4	18
Parkinson's disease and parkinsonism		1				1
Peripheral neuropathies NEC	2	2			2	2
Seizures and seizure disorders NEC	6	14			6	14
Sensory abnormalities NEC	13	35	6	20	7	15
Speech and language abnormalities	3	10		1	3	9
Spinal cord and nerve root disorders NEC	1	1			1	1
Structural brain disorders NEC	1	2		1	1	1
Transient cerebrovascular events	4	6			4	6
Tremor (excl congenital)	3	22	3	9		13
	274	1,011	113	484	161	527

System Organ Class

Pregnancy, puerperium and perinatal conditions

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions not specified as induced or spontaneous	1	3	1	3
Abortions spontaneous	1	1	1	1
	2	4	2	4

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	1	6		2	1	4
Behaviour and socialisation disturbances		2				2
Confusion and disorientation	5	18		1	5	17
Deliria	1	9			1	9
Delusional symptoms		1				1
Disturbances in initiating and maintaining sleep	2	9	1	8	1	1
Dyssomnias		1		1		
Eating disorders NEC		1		1		
Hallucinations (excl sleep-related)	3	4			3	4
Increased physical activity levels	2	11	2	8		3
Mood alterations with depressive symptoms	2	2	2	2		
Panic attacks and disorders		1				1
Parasomnias	1	1			1	1
Perception disturbances NEC		5		4		1
Sleep disorders NEC	1	4	1	4		
Thinking disturbances		1				1
	18	76	6	31	12	45

System Organ Class

Renal and urinary disorders

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	1	5			1	5
Glomerulonephritis and nephrotic syndrome		1				1
Renal failure and impairment	1	9			1	9
Renal failure complications		1				1
Urinary abnormalities		3		1		2
Urinary tract signs and symptoms NEC		2		1		1
	2	21		2	2	19

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast signs and symptoms		1		1		
Menopausal effects on the genitourinary tract		1				1
Menstruation with decreased bleeding	1	1	1	1		
Menstruation with increased bleeding	2	2	2	2		
Vulvovaginal disorders NEC		2		1		1
Vulvovaginal signs and symptoms		3		3		
	3	10	3	8		2

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	33	155	5	31	28	124
Bronchospasm and obstruction	3	24		1	3	23
Conditions associated with abnormal gas exchange	1	6			1	6

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coughing and associated symptoms	10	39	2	16	8	23
Laryngeal spasm, oedema and obstruction		1				1
Lower respiratory tract inflammatory and immunologic conditions		2				2
Lower respiratory tract signs and symptoms		3		2		1
Nasal congestion and inflammations		5		5		
Nasal disorders NEC	1	8		2	1	6
Parenchymal lung disorders NEC	2	7			2	7
Pharyngeal disorders (excl infections and neoplasms)	3	18	1	5	2	13
Pleural infections and inflammations	1	1			1	1
Pneumothorax and pleural effusions NEC		2				2
Pulmonary hypertensions		1				1
Pulmonary oedemas	1	8			1	8
Pulmonary thrombotic and embolic conditions	10	33			10	33
Respiratory failures (excl neonatal)	1	16			1	16
Respiratory signs and symptoms NEC		3		2		1
Respiratory tract disorders NEC	1	4	1	1		3
Tracheal disorders (excl infections and neoplasms)		1				1
Upper respiratory tract signs and symptoms	8	73	4	50	4	23
	75	410	13	115	62	295

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	1	8			1	8
Apocrine and eccrine gland disorders	7	29	4	17	3	12
Dermal and epidermal conditions NEC	4	12	3	7	1	5
Dermatitis and eczema	1	5	1	3		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythemas	8	44	4	25	4	19
Exfoliative conditions	1	1	1	1		
Papulosquamous conditions	1	1	1	1		
Photosensitivity and photodermatitis conditions		1		1		
Pruritus NEC	10	50	7	34	3	16
Purpura and related conditions	3	3			3	3
Rashes, eruptions and exanthems NEC	19	90	16	63	3	27
Skin haemorrhages		1				1
Skin vasculitides	1	1			1	1
Skin vasomotor conditions		2				2
Urticarias	18	52	8	27	10	25
	74	300	45	179	29	121

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	2	3	1	1	1	2
	2	3	1	1	1	2

System Organ Class

SOC Not Yet Coded

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
	1	1	1	1
	1	1	1	1

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysms and dissections		1				1
Blood pressure disorders NEC		1		1		
Circulatory collapse and shock	2	3			2	3
Haemorrhages NEC		2		1		1
Non-site specific embolism and thrombosis	2	12			2	12
Non-site specific necrosis and vascular insufficiency NEC		1				1
Non-site specific vascular disorders NEC	2	4	2	2		2
Peripheral embolism and thrombosis	8	19			8	19
Peripheral vascular disorders NEC	1	18		11	1	7
Peripheral vasoconstriction, necrosis and vascular insufficiency	2	5	1	1	1	4
Phlebitis NEC		1				1
Site specific vascular disorders NEC		12		3		9
Vascular hypertensive disorders NEC	2	21		7	2	14
Vascular hypotensive disorders	2	13	1	2	1	11
Vasculitides NEC	1	2		1	1	1
	22	115	4	29	18	86

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

ECUADOR

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC		1		1
		1		1

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ischaemic coronary artery disorders		1				1
Noninfectious myocarditis	1	1			1	1
Noninfectious pericarditis	2	2			2	2
Rate and rhythm disorders NEC	1	1	1	1		
Supraventricular arrhythmias	1	1			1	1
Ventricular arrhythmias and cardiac arrest	1	1			1	1
	6	7	1	1	5	6

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular disorders NEC		1		1
		1		1

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)		4		4		
Gastrointestinal and abdominal pains (excl oral and throat)	1	1			1	1
Gastrointestinal signs and symptoms NEC	1	1			1	1
Nausea and vomiting symptoms		1		1		
Oral soft tissue swelling and oedema		1		1		
	2	8		6	2	2

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	3	5	2	4	1	1
Febrile disorders	2	8	2	8		
Feelings and sensations NEC	1	2	1	2		
Oedema NEC		1		1		
Pain and discomfort NEC	4	9	2	7	2	2
Therapeutic and nontherapeutic responses	25	29			25	29
Vaccination site reactions	5	11	5	11		
	40	65	12	33	28	32

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	26	34	1	3	25	31
Influenza viral infections	1	1	1	1		
Upper respiratory tract infections	1	4	1	4		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	28	39	3	8	25	31

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vascular tests NEC (incl blood pressure)		2		2
Virus identification and serology		1		1
		3		3

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint related signs and symptoms	1	2	1	2		
Muscle pains	3	4	2	3	1	1
Muscle weakness conditions	1	1			1	1
Musculoskeletal and connective tissue conditions NEC		1		1		
Musculoskeletal and connective tissue pain and discomfort	1	2		1	1	1
	6	10	3	7	3	3

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents		1				1
Headaches NEC	1	2	1	2		
Neurological signs and symptoms NEC	3	5	1	3	2	2
Paraesthesias and dysaesthesias	1	1			1	1
Transient cerebrovascular events	1	1			1	1
	6	10	2	5	4	5

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	2	2	2	2		
Disturbances in initiating and maintaining sleep	1	1			1	1
Mood alterations with depressive symptoms		1		1		
	3	4	2	3	1	1

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coughing and associated symptoms	1	2		1	1	1
Parenchymal lung disorders NEC		1		1		
Respiratory signs and symptoms NEC	1	1			1	1
Respiratory tract disorders NEC	1	1			1	1
Upper respiratory tract signs and symptoms	4	5	1	2	3	3
	7	10	1	4	6	6

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	1	1			1	1
Erythemas	1	1	1	1		
Purpura and related conditions	1	1	1	1		
	3	3	2	2	1	1

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Disability issues	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

EGYPT

System Organ Class

General disorders and administration site conditions

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Therapeutic and nontherapeutic responses		1		1
		1		1

System Organ Class

Infections and infestations

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Coronavirus infections		1		1
		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
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Country Where Event Occurred

EL SALVADOR

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Lower respiratory tract and lung infections	2	2	2	2
	2	2	2	2

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Musculoskeletal and connective tissue pain and discomfort	1	1	1	1
	1	1	1	1

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Central nervous system haemorrhages and cerebrovascular accidents	1	1	1	1
	1	1	1	1

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Disturbances in initiating and maintaining sleep	1	1	1	1
	1	1	1	1

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchospasm and obstruction	1	1	1	1		
Pneumothorax and pleural effusions NEC	2	2			2	2
Pulmonary oedemas	1	1			1	1
	4	4	1	1	3	3

* I=Interval, C=Cumulative
* AE=Adverse Event
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Country Where Event Occurred

ESTONIA

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	2	8	2	8
	2	8	2	8

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac hypertensive complications		1				1
Cardiac signs and symptoms NEC		3		3		
Heart failures NEC		1				1
Ischaemic coronary artery disorders	3	4			3	4
Rate and rhythm disorders NEC	2	6		3	2	3
Supraventricular arrhythmias	1	2			1	2
Ventricular arrhythmias and cardiac arrest	1	2			1	2
	7	19		6	7	13

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	1	3	1	3		
Inner ear signs and symptoms		2		1		1
	1	5	1	4		1

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* AE=Adverse Event
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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lacrimation disorders	1	1	1	1		
Ocular disorders NEC		1		1		
Retinal bleeding and vascular disorders (excl retinopathy)		1				1
Visual disorders NEC	1	4	1	4		
Visual impairment and blindness (excl colour blindness)		2				2
	2	9	2	6		3

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	1	4		3	1	1
Dyspeptic signs and symptoms		1		1		
Gastrointestinal and abdominal pains (excl oral and throat)	1	4		2	1	2
Gastrointestinal signs and symptoms NEC	1	3		1	1	2
Nausea and vomiting symptoms	7	26	3	17	4	9
Oral dryness and saliva altered	1	1			1	1
Oral soft tissue signs and symptoms	1	6	1	6		
Oral soft tissue swelling and oedema		2				2
Tongue signs and symptoms	1	1	1	1		
	13	48	5	31	8	17

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	21	68	18	55	3	13
Body temperature altered		5				5
Death and sudden death		2				2
Febrile disorders	12	50	11	47	1	3
Feelings and sensations NEC	6	31	6	30		1
General signs and symptoms NEC	5	10		4	5	6
Pain and discomfort NEC		10		7		3
Therapeutic and nontherapeutic responses	36	63			36	63
Vaccination site reactions	15	73	15	73		
	95	312	50	216	45	96

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC		6		1		5
Allergies to foods, food additives, drugs and other chemicals		1				1
Anaphylactic and anaphylactoid responses	1	1			1	1
Immune and associated conditions NEC		1				1
	1	9		1	1	8

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacterial infections NEC	1	1			1	1
Coronavirus infections	36	66		1	36	65

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes viral infections	1	3	1	3		
Infections NEC		1				1
Lower respiratory tract and lung infections	1	2	1	1		1
Upper respiratory tract infections	1	2	1	2		
Urinary tract infections	1	1			1	1
	41	76	3	7	38	69

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral injuries NEC	1	1			1	1
Exposures associated with pregnancy, delivery and lactation	4	12	4	11		1
Exposures to agents or circumstances NEC	1	1	1	1		
Fractures and dislocations NEC		1				1
Medication errors, product use errors and issues NEC		1		1		
Non-site specific injuries NEC	2	7		3	2	4
Off label uses		1		1		
Skin injuries NEC		1				1
Skull fractures, facial bone fractures and dislocations	1	1			1	1
Spinal cord injuries NEC		1				1
Underdoses NEC		1		1		
	9	28	5	18	4	10

System Organ Class

Investigations

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
ECG investigations	1	1			1	1
Heart rate and pulse investigations	1	2			1	2
Physical examination procedures and organ system status		1		1		
Protein analyses NEC		1		1		
Skeletal and cardiac muscle analyses		1		1		
Vascular tests NEC (incl blood pressure)	1	2	1	1		1
	3	8	1	4	2	4

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	2	5		3	2	2
Hypoglycaemic conditions NEC		1				1
	2	6		3	2	3

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms		2		1		1
Joint related signs and symptoms	4	21	4	21		
Muscle pains	9	25	9	24		1
Muscle related signs and symptoms NEC		1		1		
Muscle weakness conditions		3		3		
Musculoskeletal and connective tissue conditions NEC	1	2	1	1		1

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal and connective tissue pain and discomfort	5	19	5	15		4
Tendon disorders		1		1		
	19	74	19	67		7

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	2	5			2	5
Coordination and balance disturbances	2	4	2	4		
Demyelinating disorders NEC		2				2
Disturbances in consciousness NEC	11	32	5	13	6	19
Dyskinesias and movement disorders NEC	1	1	1	1		
Eye movement disorders		1				1
Facial cranial nerve disorders	1	3		1	1	2
Headaches NEC	14	53	14	49		4
Mental impairment (excl dementia and memory loss)		1		1		
Migraine headaches		1		1		
Myelitis (incl infective)		1				1
Neurological signs and symptoms NEC	6	20	5	14	1	6
Paraesthesias and dysaesthesias	2	24	1	20	1	4
Peripheral neuropathies NEC		1				1
Seizures and seizure disorders NEC		1				1
Sensory abnormalities NEC	2	10	1	7	1	3
Speech and language abnormalities	1	2			1	2
Tremor (excl congenital)		2		2		
Trigeminal disorders		1				1
	42	165	29	113	13	52

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Haemorrhagic complications of pregnancy		1		1
		1		1

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Device physical property and chemical issues		1		1
		1		1

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms		12		9		3
Disturbances in initiating and maintaining sleep	1	6	1	6		
Increased physical activity levels		3		3		
Panic attacks and disorders		1		1		
	1	22	1	19		3

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bladder and urethral symptoms		2		2
		2		2

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* AE=Adverse Event
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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	3	17	2	12	1	5
Bronchospasm and obstruction		1				1
Coughing and associated symptoms	3	7	3	7		
Laryngeal spasm, oedema and obstruction	1	3			1	3
Nasal congestion and inflammations		1		1		
Nasal disorders NEC	1	2		1	1	1
Pharyngeal disorders (excl infections and neoplasms)		3		3		
Pulmonary oedemas		1				1
Pulmonary thrombotic and embolic conditions	2	4			2	4
Respiratory failures (excl neonatal)		3				3
Respiratory signs and symptoms NEC		1		1		
Upper respiratory tract signs and symptoms	9	18	9	15		3
	19	61	14	40	5	21

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	3	7	2	5	1	2
Erythemas	1	1	1	1		
Pruritus NEC	2	3	2	3		
Psoriatic conditions		1				1
Skin and subcutaneous tissue ulcerations	1	1			1	1
Urticarias	1	1	1	1		
	8	14	6	10	2	4

System Organ Class

Vascular disorders

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemorrhages NEC		1		1		
Peripheral embolism and thrombosis	2	4		1	2	3
Peripheral vascular disorders NEC	1	2	1	2		
Site specific vascular disorders NEC		1				1
Vascular hypertensive disorders NEC	2	6	1	4	1	2
Vascular hypotensive disorders	3	5	1	1	2	4
	8	19	3	9	5	10

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

FINLAND

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bleeding tendencies		1				1
Coagulation factor deficiencies		2				2
Lymphatic system disorders NEC	17	76	11	36	6	40
Neutropenias		1				1
Platelet disorders NEC		1				1
Polycythaemia (excl rubra vera)	1	1	1	1		
Spleen disorders	1	1			1	1
Thrombocytopenias	2	3			2	3
Thrombocytoses		1				1
	21	87	12	37	9	50

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC	4	4			4	4
Cardiac signs and symptoms NEC	12	32	5	11	7	21
Cardiomyopathies		1				1
Coronary artery disorders NEC		1				1
Heart failures NEC	2	9			2	9
Ischaemic coronary artery disorders	2	6			2	6
Myocardial disorders NEC		1				1
Noninfectious myocarditis		1				1
Rate and rhythm disorders NEC	14	51		4	14	47
Right ventricular failures		2				2
Supraventricular arrhythmias	5	14			5	14

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ventricular arrhythmias and cardiac arrest		2				2
	39	124	5	15	34	109

System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Inborn errors of porphyrin metabolism		1		1
		1		1

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	1	14		11	1	3
Hearing losses	5	13	2	5	3	8
Hyperacusia	1	2			1	2
Inner ear disorders NEC	1	2			1	2
Inner ear signs and symptoms	10	22	2	7	8	15
Tympanic membrane disorders (excl infections)		1		1		
	18	54	4	24	14	30

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Choroid and vitreous structural change, deposit and degeneration	1	1			1	1
Conjunctival infections, irritations and inflammations		1				1
Corneal infections, oedemas and inflammations		2				2
Eyelid movement disorders		1				1
Glaucomas (excl congenital)		1				1
Iris and uveal tract infections, irritations and inflammations		1				1
Lacrimation disorders		1				1
Lid, lash and lacrimal infections, irritations and inflammations	3	14	1	2	2	12
Ocular bleeding and vascular disorders NEC	1	3			1	3
Ocular disorders NEC	5	16	3	7	2	9
Ocular infections, inflammations and associated manifestations		3		1		2
Ocular nerve and muscle disorders		4		1		3
Ocular sensation disorders	2	7	1	2	1	5
Pupil disorders		1		1		
Refractive and accommodative disorders		1		1		
Retinal bleeding and vascular disorders (excl retinopathy)	4	9			4	9
Retinal, choroid and vitreous infections and inflammations	1	2			1	2
Retinal structural change, deposit and degeneration		1				1
Visual colour distortions	1	1			1	1
Visual disorders NEC	5	13	2	5	3	8
Visual impairment and blindness (excl colour blindness)	12	20	1	2	11	18
	35	103	8	22	27	81

System Organ Class

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* AE=Adverse Event
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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anal and rectal ulcers and perforation		1				1
Colitis (excl infective)		1				1
Dental pain and sensation disorders		2		2		
Diarrhoea (excl infective)	17	36	7	15	10	21
Dyspeptic signs and symptoms		1				1
Flatulence, bloating and distension		4		3		1
Gastrointestinal and abdominal pains (excl oral and throat)	16	37	6	11	10	26
Gastrointestinal disorders NEC		1		1		
Gastrointestinal necrosis and gangrene (excl gangrenous hernia)		1				1
Gastrointestinal signs and symptoms NEC	5	19	3	6	2	13
Gastrointestinal vascular occlusion and infarction	5	7			5	7
Gingival disorders, signs and symptoms NEC		1		1		
Intestinal haemorrhages		1				1
Nausea and vomiting symptoms	53	168	27	63	26	105
Non-site specific gastrointestinal haemorrhages		1				1
Oral dryness and saliva altered		4				4
Oral soft tissue disorders NEC		2		1		1
Oral soft tissue haemorrhages		1				1
Oral soft tissue signs and symptoms	16	58	5	25	11	33
Oral soft tissue swelling and oedema	5	14		4	5	10
Salivary gland enlargements		1				1
Salivary gland infections and inflammations		1				1
Stomatitis and ulceration	1	1			1	1
Tongue disorders		1				1
Tongue signs and symptoms	10	23	2	3	8	20
	128	387	50	135	78	252

System Organ Class

General disorders and administration site conditions

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	114	353	52	119	62	234
Body temperature altered		4				4
Death and sudden death	5	21			5	21
Febrile disorders	75	230	45	89	30	141
Feelings and sensations NEC	73	181	39	71	34	110
Gait disturbances	5	17		2	5	15
General signs and symptoms NEC	25	88	3	13	22	75
Inflammations	1	2	1	1		1
Interactions	2	2			2	2
Mass conditions NEC		3		2		1
Oedema NEC	9	36	5	13	4	23
Pain and discomfort NEC	18	97	6	25	12	72
Therapeutic and nontherapeutic responses	1	4			1	4
Vaccination site reactions	55	246	37	147	18	99
	383	1,284	188	482	195	802

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholecystitis and cholelithiasis		1				1
Cholestasis and jaundice		1				1
Hepatic failure and associated disorders	1	1			1	1
Hepatic vascular disorders	1	1			1	1
Hepatocellular damage and hepatitis NEC	1	1	1	1		
	3	5	1	1	2	4

System Organ Class

Immune system disorders

Spontaneous

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* AE=Adverse Event
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System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	9	27	2	4	7	23
Allergies to foods, food additives, drugs and other chemicals	1	5			1	5
Anaphylactic and anaphylactoid responses	12	31			12	31
Immune and associated conditions NEC	1	1			1	1
	23	64	2	4	21	60

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections	2	5			2	5
Bacterial infections NEC	2	3	1	2	1	1
Borrelial infections		1				1
Central nervous system and spinal infections		2				2
Coronavirus infections	1	4			1	4
Dental and oral soft tissue infections		1				1
Epstein-Barr viral infections	1	1			1	1
Escherichia infections	1	1			1	1
Eye and eyelid infections		2				2
Female reproductive tract infections		1				1
Hanta viral infections	1	1			1	1
Herpes viral infections	13	30	4	12	9	18
Infections NEC		4				4
Influenza viral infections		3		1		2
Klebsiella infections	1	1			1	1
Lower respiratory tract and lung infections	4	17			4	17
Mumps viral infections	1	1			1	1
Pseudomonal infections		1				1

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sepsis, bacteraemia, viraemia and fungaemia NEC	1	1			1	1
Skin structures and soft tissue infections		1				1
Streptococcal infections	3	5			3	5
Upper respiratory tract infections	2	13		1	2	12
Urinary tract infections	6	16		1	6	15
Viral infections NEC		5				5
	39	120	5	17	34	103

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone and joint injuries NEC	1	2			1	2
Cerebral injuries NEC	2	2			2	2
Exposures associated with pregnancy, delivery and lactation		1		1		
Fractures and dislocations NEC	1	1			1	1
Limb fractures and dislocations		1				1
Medication errors, product use errors and issues NEC		2		2		
Muscle, tendon and ligament injuries		1				1
Non-site specific injuries NEC	7	19		1	7	18
Non-site specific procedural complications		1				1
Off label uses	5	8	5	8		
Product administration errors and issues	7	31	7	31		
Product preparation errors and issues		12		12		
Site specific injuries NEC	5	9		1	5	8
Skin injuries NEC	2	4	1	2	1	2
Skull fractures, facial bone fractures and dislocations		1				1

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* AE=Adverse Event

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	30	95	13	58	17	37

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Auditory and vestibular diagnostic procedures		2		2		
Bacteria identification and serology (excl mycobacteria)		3				3
Blood gas and acid base analyses		4		1		3
Bone marrow and immune tissue imaging procedures		1				1
Carbohydrate tolerance analyses (incl diabetes)	3	5			3	5
Cerebrospinal fluid tests (excl microbiology)		2				2
Chemistry analyses NEC	1	2			1	2
Cholesterol analyses	1	1			1	1
Coagulation and bleeding analyses		7		3		4
ECG investigations		2				2
Haematological analyses NEC		1				1
Haem metabolism analyses		1				1
Heart rate and pulse investigations	18	47	3	7	15	40
Investigations NEC	1	1			1	1
Liver function analyses		2				2
Metabolism tests NEC		1				1
Mineral and electrolyte analyses	1	1			1	1
Musculoskeletal and soft tissue histopathology procedures	1	2			1	2
Neurologic diagnostic procedures		2				2
Physical examination procedures and organ system status	7	18	1	4	6	14
Platelet analyses	1	1			1	1

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* AE=Adverse Event

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Protein analyses NEC	8	22	3	6	5	16
Red blood cell analyses		2				2
Renal function analyses	1	3	1	1		2
Respiratory and pulmonary function diagnostic procedures		3				3
Respiratory tract and thoracic imaging procedures		1				1
Skeletal and cardiac muscle analyses		1				1
Tissue enzyme analyses NEC		1				1
Urinalysis NEC		4				4
Vascular tests NEC (incl blood pressure)	26	63	10	14	16	49
Virus identification and serology	4	8	2	3	2	5
White blood cell analyses	1	5	1	1		4
	74	219	21	42	53	177

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	1	11	1	1		10
Disorders of purine metabolism	2	2			2	2
Fluid intake decreased		1				1
General nutritional disorders NEC		2				2
Metabolic acidoses (excl diabetic acidoses)	1	2			1	2
Potassium imbalance	1	6			1	6
Sodium imbalance		2				2
Total fluid volume decreased	1	2	1	1		1
Total fluid volume increased	1	1			1	1
	7	29	2	2	5	27

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* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC		3				3
Bone disorders NEC	1	1			1	1
Bone related signs and symptoms	2	7		2	2	5
Connective tissue disorders NEC	2	4			2	4
Intervertebral disc disorders NEC		1		1		
Joint related signs and symptoms	29	103	13	41	16	62
Muscle pains	43	146	28	56	15	90
Muscle related signs and symptoms NEC	13	33	4	9	9	24
Muscle tone abnormalities	2	5		3	2	2
Muscle weakness conditions	4	31	1	4	3	27
Musculoskeletal and connective tissue conditions NEC	6	27	1	11	5	16
Musculoskeletal and connective tissue pain and discomfort	53	188	24	75	29	113
Osteoarthropathies		1		1		
Rheumatoid arthropathies		1				1
Soft tissue disorders NEC		1				1
Spine and neck deformities		1				1
Spondyloarthropathies		3				3
Tendon disorders		2				2
	155	558	71	203	84	355

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Lymphomas unspecified NEC		1		1
		1		1

System Organ Class

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal reflexes		2				2
Absence seizures	1	2			1	2
Alzheimer's disease (incl subtypes)		4				4
Central nervous system haemorrhages and cerebrovascular accidents	18	35			18	35
Central nervous system inflammatory disorders NEC		1				1
Central nervous system vascular disorders NEC	1	2			1	2
Coordination and balance disturbances	4	10	1	2	3	8
Cortical dysfunction NEC	2	4			2	4
Demyelinating disorders NEC		1				1
Disturbances in consciousness NEC	26	63	2	3	24	60
Dyskinesias and movement disorders NEC	4	8		3	4	5
Dystonias		1				1
Eye movement disorders	1	1			1	1
Facial cranial nerve disorders	9	25	1	1	8	24
Headaches NEC	79	215	40	82	39	133
Memory loss (excl dementia)	4	7		1	4	6
Mental impairment (excl dementia and memory loss)	1	7		1	1	6
Migraine headaches	2	15	1	2	1	13
Multiple sclerosis acute and progressive	2	2			2	2
Muscle tone abnormal	1	4			1	4
Myelitis (incl infective)	1	1			1	1
Narcolepsy and hypersomnia		3		1		2
Neurological signs and symptoms NEC	43	125	15	35	28	90
Neuromuscular disorders NEC		2				2
Olfactory nerve disorders	3	4	1	2	2	2
Paraesthesias and dysaesthesias	42	153	16	44	26	109
Paralysis and paresis (excl cranial nerve)	4	15			4	15
Parkinson's disease and parkinsonism		1		1		
Peripheral neuropathies NEC		1				1

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* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Seizures and seizure disorders NEC	4	12			4	12
Sensory abnormalities NEC	12	33	6	13	6	20
Speech and language abnormalities	3	18		1	3	17
Spinal cord and nerve root disorders NEC	1	1			1	1
Transient cerebrovascular events	3	8			3	8
Tremor (excl congenital)	5	20	1	3	4	17
Trigeminal disorders		1				1
	276	807	84	195	192	612

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous		1		1
		1		1

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product distribution and storage issues	1	1	1	1
Product quality issues NEC		1		1
	1	2	1	2

System Organ Class

Psychiatric disorders

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

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* AE=Adverse Event
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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Affect alterations NEC	1	1			1	1
Anxiety symptoms	2	4			2	4
Confusion and disorientation	6	12	1	3	5	9
Deliria		1				1
Delusional symptoms		2		2		
Disturbances in initiating and maintaining sleep	7	26	2	8	5	18
Dyssomnias		1				1
Eating disorders NEC		1		1		
Emotional and mood disturbances NEC	1	3			1	3
Fear symptoms and phobic disorders (incl social phobia)		1		1		
Hallucinations (excl sleep-related)	3	6			3	6
Mood alterations with depressive symptoms	1	1			1	1
Mood disorders NEC	1	1			1	1
Parasomnias	2	2			2	2
Perception disturbances NEC	2	3		1	2	2
Psychiatric symptoms NEC		1		1		
Sleep disorders NEC	1	1	1	1		
Speech and language usage disturbances	1	1			1	1
Suicidal and self-injurious behaviour	1	2			1	2
Thinking disturbances		1				1
	29	71	4	18	25	53

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	1	4		1	1	3
Genital and urinary tract disorders NEC		1				1
Myoneurogenic bladder disorders	1	1			1	1

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* AE=Adverse Event

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System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nephritis NEC	1	1			1	1
Renal disorders NEC		1		1		
Renal failure and impairment	1	4			1	4
Renal lithiasis	1	1			1	1
Urinary abnormalities		1				1
	5	14		2	5	12

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Benign and malignant breast neoplasms	1	2	1	1		1
Breast signs and symptoms		3				3
Menstruation and uterine bleeding NEC		1				1
Menstruation with increased bleeding	2	2	2	2		
Reproductive tract disorders NEC (excl neoplasms)		1				1
Vaginal and vulval infections and inflammations		1				1
	3	10	3	3		7

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	28	120	6	15	22	105
Bronchospasm and obstruction	3	11		1	3	10
Coughing and associated symptoms	12	37		3	12	34
Laryngeal spasm, oedema and obstruction		2				2

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lower respiratory tract inflammatory and immunologic conditions		1				1
Lower respiratory tract signs and symptoms	3	12		1	3	11
Nasal congestion and inflammations	2	7	1	3	1	4
Nasal disorders NEC		7		2		5
Paranasal sinus disorders (excl infections and neoplasms)		1				1
Parenchymal lung disorders NEC	2	2			2	2
Pharyngeal disorders (excl infections and neoplasms)	10	32	1	5	9	27
Pneumothorax and pleural effusions NEC	1	1			1	1
Pulmonary oedemas		1				1
Pulmonary thrombotic and embolic conditions	4	15			4	15
Respiratory failures (excl neonatal)		1				1
Respiratory signs and symptoms NEC		3				3
Respiratory tract disorders NEC	1	5			1	5
Upper respiratory tract signs and symptoms	36	95	10	29	26	66
	102	353	18	59	84	294

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes	1	1			1	1
Apocrine and eccrine gland disorders	9	24	4	9	5	15
Bullous conditions	1	5		2	1	3
Dermal and epidermal conditions NEC	9	20	4	8	5	12
Dermatitis and eczema		2				2
Dermatitis ascribed to specific agent		2		2		
Erythemas	10	48	3	15	7	33
Photosensitivity and photodermatosis conditions	1	2			1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pruritus NEC	17	32	8	17	9	15
Rashes, eruptions and exanthems NEC	15	40	7	16	8	24
Skin and subcutaneous conditions NEC	1	1			1	1
Skin and subcutaneous tissue ulcerations	1	1			1	1
Skin hypoplasias and atrophies		1				1
Urticarias	14	40	8	15	6	25
	79	219	34	84	45	135

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	7	26	1	2	6	24
	7	26	1	2	6	24

System Organ Class

Surgical and medical procedures

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Arterial therapeutic procedures (excl aortic)	1	1	1	1
Respiratory tract therapeutic procedures NEC		1		1
Small intestine therapeutic procedures	1	1	1	1
Therapeutic procedures NEC		1		1
Vascular therapeutic procedures NEC	1	1	1	1
	3	5	3	5

System Organ Class

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* AE=Adverse Event
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System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic infections and inflammations		1				1
Arterial infections and inflammations	1	2			1	2
Blood pressure disorders NEC	4	5	1	1	3	4
Circulatory collapse and shock		2				2
Haemorrhages NEC	2	7		3	2	4
Non-site specific embolism and thrombosis	1	7			1	7
Non-site specific necrosis and vascular insufficiency NEC	1	1			1	1
Non-site specific vascular disorders NEC		1				1
Peripheral embolism and thrombosis	19	26	2	2	17	24
Peripheral vascular disorders NEC	1	12		2	1	10
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	2			1	2
Site specific vascular disorders NEC	1	7	1	2		5
Vascular hypertensive disorders NEC	4	12	1	2	3	10
Vascular hypotensive disorders		3				3
	35	88	5	12	30	76

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Country Where Event Occurred

FRANCE

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia deficiencies		1				1
Anaemias haemolytic immune		1				1
Anaemias haemolytic NEC		2				2
Anaemias NEC	12	29	3	6	9	23
Bleeding tendencies		2				2
Coagulation factor deficiencies		2				2
Coagulopathies		1				1
Eosinophilic disorders	1	6			1	6
Haematological disorders	1	1	1	1		
Haemolyses NEC	2	2			2	2
Leukocytoses NEC	8	34	2	7	6	27
Leukopenias NEC	9	31	3	9	6	22
Lymphatic system disorders NEC	44	184	29	95	15	89
Marrow depression and hypoplastic anaemias	5	10			5	10
Neutropenias	4	15			4	15
Sickle cell trait and disorders	1	1			1	1
Spleen disorders	1	2			1	2
Thrombocytopenias	37	77			37	77
Thrombocytoses	1	2		1	1	1
	126	403	38	119	88	284

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic valvular disorders		5				5

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System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders	10	36		5	10	31
Cardiac disorders NEC	4	14	1	2	3	12
Cardiac signs and symptoms NEC	28	97	10	37	18	60
Cardiac valve disorders NEC	1	1	1	1		
Cardiomyopathies	1	7			1	7
Coronary artery disorders NEC	7	16	2	2	5	14
Heart failure signs and symptoms		1		1		
Heart failures NEC	30	136			30	136
Ischaemic coronary artery disorders	33	114			33	114
Left ventricular failures	2	5			2	5
Mitral valvular disorders	2	10			2	10
Myocardial disorders NEC	11	22	5	7	6	15
Noninfectious myocarditis	7	15			7	15
Noninfectious pericarditis	21	46			21	46
Pericardial disorders NEC	8	18			8	18
Rate and rhythm disorders NEC	135	527	22	91	113	436
Right ventricular failures	1	1			1	1
Supraventricular arrhythmias	69	224	5	10	64	214
Tricuspid valvular disorders	1	2			1	2
Ventricular arrhythmias and cardiac arrest	35	124		4	35	120
	406	1,421	46	160	360	1261

System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autosomal chromosomal abnormalities	1	1			1	1
Cardiac septal defects congenital		2				2
Coagulation disorders congenital		1		1		
Congenital disorders NEC		1				1

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System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Immune system abnormalities congenital	1	2			1	2
Inborn errors of amino acid metabolism		1				1
Lymphatic system disorders congenital		1				1
Musculoskeletal and connective tissue disorders of spine congenital	2	2			2	2
Tongue disorders congenital		3				3
Vascular anomalies congenital NEC	1	1			1	1
	5	15		1	5	14

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	5	35	1	14	4	21
Hearing disorders NEC		1				1
Hearing losses	13	50		3	13	47
Hyperacusia		1		1		
Inner ear disorders NEC	4	19	1	4	3	15
Inner ear signs and symptoms	90	271	40	92	50	179
	112	377	42	114	70	263

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic thyroiditis	4	8			4	8
Adrenal cortical hypofunctions	1	3			1	3
Adrenal gland disorders NEC		1		1		

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System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ectopic endocrine disorders		1		1		
Posterior pituitary disorders	1	2			1	2
Thyroid disorders NEC	2	5	1	4	1	1
Thyroid hyperfunction disorders		6				6
Thyroid hypofunction disorders	2	3			2	3
	10	29	1	6	9	23

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cataract conditions		1				1
Choroid and vitreous haemorrhages and vascular disorders	1	1			1	1
Choroid and vitreous structural change, deposit and degeneration	2	3			2	3
Colour blindness (incl acquired)	1	1			1	1
Conjunctival and corneal bleeding and vascular disorders	4	19			4	19
Conjunctival infections, irritations and inflammations		3		3		
Corneal infections, oedemas and inflammations	1	1			1	1
Eyelid movement disorders		5		1		4
Glaucomas (excl congenital)	1	2			1	2
Iris and uveal tract infections, irritations and inflammations	2	4			2	4
Lacrimation disorders	1	12	1	8		4
Lid bleeding and vascular disorders		1		1		
Lid, lash and lacrimal infections, irritations and inflammations	4	26	3	11	1	15
Ocular bleeding and vascular disorders NEC	2	10			2	10
Ocular disorders NEC	14	43	8	21	6	22

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular infections, inflammations and associated manifestations	6	16	2	4	4	12
Ocular nerve and muscle disorders	4	8	1	2	3	6
Ocular sensation disorders	3	16	3	6		10
Optic disc abnormalities NEC	1	1			1	1
Optic nerve bleeding and vascular disorders		2				2
Orbital infections, inflammations and irritations		1				1
Pupil disorders		7		3		4
Refractive and accommodative disorders	1	2			1	2
Retinal bleeding and vascular disorders (excl retinopathy)	12	24	1	1	11	23
Retinal, choroid and vitreous infections and inflammations		2				2
Retinal structural change, deposit and degeneration	4	5			4	5
Scleral infections, irritations and inflammations	2	3			2	3
Scleral structural change, deposit and degeneration		1				1
Structural change, deposit and degeneration of eye NEC		2				2
Visual disorders NEC	25	69	7	17	18	52
Visual field disorders	3	6			3	6
Visual impairment and blindness (excl colour blindness)	22	58	8	11	14	47
Visual pathway disorders	1	1			1	1
	117	356	34	89	83	267

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal findings abnormal	1	3	1	3		

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Abdominal wall conditions NEC	1	1
Acute and chronic pancreatitis	14	24
Colitis (excl infective)	2	9
Cystic pancreatic disorders	1	1
Dental pain and sensation disorders	1	3
Diarrhoea (excl infective)	60	258
Diverticula	1	3
Duodenal and small intestinal stenosis and obstruction	1	1
Dyspeptic signs and symptoms	5	16
Faecal abnormalities NEC	3	10
Flatulence, bloating and distension	4	15
Gastric and pyloric stenosis and obstruction		2
Gastric ulcers and perforation	3	4
Gastritis (excl infective)	1	2
Gastrointestinal and abdominal pains (excl oral and throat)	57	200
Gastrointestinal atonic and hypomotility disorders NEC	12	25
Gastrointestinal disorders NEC	12	28
Gastrointestinal dyskinetic disorders		3
Gastrointestinal inflammatory disorders NEC	1	2
Gastrointestinal mucosal dystrophies and secretion disorders	1	1
Gastrointestinal signs and symptoms NEC	20	53
Gastrointestinal spastic and hypermotility disorders		2
Gastrointestinal stenosis and obstruction NEC	2	6
Gastrointestinal vascular malformations	1	1
Gastrointestinal vascular occlusion and infarction	6	13
Gingival disorders, signs and symptoms NEC	1	5
Gingival haemorrhages	2	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		14	24
	1	2	8
		1	1
1	2		1
29	95	31	163
	1	1	2
		1	1
2	3	3	13
1	6	2	4
3	9	1	6
			2
		3	4
		1	2
28	83	29	117
11	21	1	4
11	15	1	13
	2		1
		1	2
1	1		
8	21	12	32
	1		1
		2	6
		1	1
		6	13
1	3		2
2	2		1

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemorrhoids and gastrointestinal varices (excl oesophageal)	1	3			1	3
Intestinal haemorrhages	4	12			4	12
Nausea and vomiting symptoms	204	794	126	313	78	481
Non-site specific gastrointestinal haemorrhages	5	21			5	21
Oral dryness and saliva altered	10	20	8	12	2	8
Oral soft tissue disorders NEC	2	5	2	3		2
Oral soft tissue haemorrhages	2	7	2	3		4
Oral soft tissue signs and symptoms	19	59	14	28	5	31
Oral soft tissue swelling and oedema	11	43	6	12	5	31
Pancreatic disorders NEC	1	1	1	1		
Peptic ulcers and perforation		1				1
Peritoneal and retroperitoneal disorders		1				1
Rectal inflammations NEC	2	3	1	2	1	1
Salivary gland disorders NEC		1		1		
Stomatitis and ulceration	2	14	1	8	1	6
Tongue disorders		5		3		2
Tongue signs and symptoms	11	33	3	10	8	23
Tooth missing	1	1			1	1
	488	1,718	263	665	225	1053

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse effect absent		2		2		
Application and instillation site reactions		1		1		
Asthenic conditions	411	1,784	246	741	165	1043
Body temperature altered	30	109	7	26	23	83
Death and sudden death	29	192			29	192

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Febrile disorders	215	822	136	344	79	478
Feelings and sensations NEC	112	480	78	219	34	261
Gait disturbances	18	54	12	25	6	29
General signs and symptoms NEC	271	1,007	104	245	167	762
Inflamations	19	55	9	23	10	32
Injection site reactions	13	61	8	31	5	30
Interactions	1	4	1	3		1
Mass conditions NEC		1				1
Mucosal findings abnormal	1	4	1	3		1
Necrosis NEC	1	2			1	2
Oedema NEC	37	142	17	38	20	104
Pain and discomfort NEC	167	616	71	225	96	391
Therapeutic and nontherapeutic responses	233	574	2	5	231	569
Ulcers NEC	1	1			1	1
Vaccination site reactions	190	884	147	514	43	370
Vascular complications associated with device	1	2			1	2
Withdrawal and rebound effects		1				1
	1,750	6,798	839	2445	911	4353

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bile duct infections and inflammations	1	1	1	1		
Cholecystitis and cholelithiasis	3	6	1	1	2	5
Cholestasis and jaundice	8	24			8	24
Hepatic and hepatobiliary disorders NEC	1	3		1	1	2
Hepatic enzymes and function abnormalities	1	3		2	1	1
Hepatic failure and associated disorders	1	1			1	1
Hepatic vascular disorders	8	11			8	11

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System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hepatobiliary signs and symptoms	4	7	1	2	3	5
Hepatocellular damage and hepatitis NEC	20	45	2	3	18	42
	47	101	5	10	42	91

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	22	102	3	29	19	73
Allergies to foods, food additives, drugs and other chemicals		8		3		5
Anaphylactic and anaphylactoid responses	18	72			18	72
Immune and associated conditions NEC	1	5			1	5
Immunodeficiency disorders NEC	2	4			2	4
Transplant rejections	1	1			1	1
Vasculitides		1				1
	44	193	3	32	41	161

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections	11	23	1	2	10	21
Bacterial infections NEC	2	22			2	22
Blastocystis infections		1				1
Bone and joint infections		1				1
Borrelial infections		2				2
Breast infections	1	2			1	2

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Candida infections		2				2
Central nervous system and spinal infections	8	15			8	15
Coronavirus infections	232	716	7	81	225	635
Coxsackie viral infections		1		1		
Cytomegaloviral infections		2				2
Dental and oral soft tissue infections	3	10		2	3	8
Ear infections	2	7	2	4		3
Enterococcal infections		1				1
Epstein-Barr viral infections	2	6			2	6
Escherichia infections	4	9			4	9
Eye and eyelid infections	4	11	2	5	2	6
Fungal infections NEC		1		1		
Hepatitis virus infections	2	3			2	3
Hepatobiliary and spleen infections	1	2			1	2
Herpes viral infections	176	329	97	140	79	189
Infections NEC	9	27	2	7	7	20
Influenza viral infections	23	77	12	25	11	52
Klebsiella infections		3				3
Lower respiratory tract and lung infections	16	64	3	6	13	58
Moraxella infections		2				2
Mycoplasma infections	1	1			1	1
Nematode infections		1				1
Pseudomonal infections	2	2			2	2
Respiratory syncytial viral infections	1	1			1	1
Sepsis, bacteraemia, viraemia and fungaemia NEC	9	27			9	27
Skin structures and soft tissue infections	1	8			1	8
Staphylococcal infections		4				4
Streptococcal infections	6	18			6	18
Toxoplasma infections		1		1		
Upper respiratory tract infections	17	44	11	26	6	18
Urinary tract infections	13	27	2	3	11	24

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular infections	1	3			1	3
Viral infections NEC	10	27		3	10	24
	557	1,503	139	307	418	1196

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal injuries NEC	1	2		1	1	1
Accidental exposures to product	1	1	1	1		
Bone and joint injuries NEC		1				1
Cardiac and vascular procedural complications	5	8			5	8
Cerebral injuries NEC	3	8			3	8
Chest and respiratory tract injuries NEC	2	3			2	3
Conditions caused by cold	10	14	10	13		1
Exposures associated with pregnancy, delivery and lactation	19	29	9	16	10	13
Exposures to agents or circumstances NEC		1				1
Eye injuries NEC	3	7	2	3	1	4
Fractures and dislocations NEC		2				2
Limb fractures and dislocations	5	11			5	11
Medication errors, product use errors and issues NEC	3	25	2	24	1	1
Muscle, tendon and ligament injuries	3	5	1	1	2	4
Nerve injuries NEC	1	2			1	2
Neurological and psychiatric procedural complications	2	2	1	1	1	1
Non-site specific injuries NEC	45	144	14	32	31	112
Occupational exposures		2		2		
Off label uses	10	37	9	35	1	2
Overdoses NEC	12	22	12	22		

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pathways and sources of exposure		1		1		
Pelvic fractures and dislocations	2	3			2	3
Poisoning and toxicity		2				2
Product administration errors and issues	214	446	213	439	1	7
Product confusion errors and issues		1		1		
Product preparation errors and issues	39	64	39	64		
Product storage errors and issues in the product use system	6	7	6	7		
Product transcribing errors and communication issues		1		1		
Radiation injuries		1				1
Site specific injuries NEC	10	32		1	10	31
Skin injuries NEC	7	9	5	7	2	2
Skull fractures, facial bone fractures and dislocations	2	4			2	4
Spinal fractures and dislocations		2				2
Thermal burns	2	5	1	1	1	4
Thoracic cage fractures and dislocations	2	6			2	6
Underdoses NEC	8	29	8	29		
Vaccination related complications	3	9		3	3	6
	420	948	333	705	87	243

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmunity analyses	2	4	2	2		2
Bacteria identification and serology (excl mycobacteria)		4		3		1
Blood gas and acid base analyses	42	160	11	23	31	137
Carbohydrate tolerance analyses (incl diabetes)	5	15	1	9	4	6

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac auscultatory investigations	2	6	2	3		3
Cardiac function diagnostic procedures	3	5	1	1	2	4
Cell marker analyses	1	2			1	2
Central nervous system imaging procedures		1				1
Chemistry analyses NEC	1	1			1	1
Cholesterol analyses	3	4	1	1	2	3
Coagulation and bleeding analyses	21	45	5	8	16	37
Digestive enzymes		2		2		
ECG investigations	6	19		1	6	18
Endocrine analyses and imaging NEC		1				1
Gastrointestinal and abdominal imaging procedures	1	1			1	1
Gastrointestinal function diagnostic procedures		1		1		
Haematological analyses NEC		2		2		
Heart rate and pulse investigations	14	48	6	22	8	26
Imaging procedures NEC	2	2			2	2
Immunoglobulin analyses	5	7	5	6		1
Investigations NEC	1	2	1	1		1
Liver function analyses	13	42	3	24	10	18
Metabolism tests NEC	6	16	3	7	3	9
Microbiology and serology tests NEC		3		2		1
Mineral and electrolyte analyses	4	11		5	4	6
Neurologic diagnostic procedures	1	5		2	1	3
Parathyroid analyses		1		1		
Physical examination procedures and organ system status	18	57	13	21	5	36
Pituitary analyses anterior		6		4		2
Platelet analyses	3	8	2	4	1	4
Protein analyses NEC	18	72	6	33	12	39
Red blood cell analyses	1	11	1	6		5
Renal function analyses	10	20	5	8	5	12

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory tract and thoracic histopathology procedures		1				1
Respiratory tract and thoracic imaging procedures	1	3			1	3
Skeletal and cardiac muscle analyses	7	24	2	6	5	18
Therapeutic drug monitoring analyses		2		1		1
Thyroid analyses		2		2		
Tissue enzyme analyses NEC	5	11	2	8	3	3
Urinalysis NEC	2	5	2	4		1
Vascular auscultatory investigations		1		1		
Vascular tests NEC (incl blood pressure)	39	109	20	38	19	71
Virus identification and serology	9	63	1	32	8	31
Vitamin analyses		1				1
Water and electrolyte analyses NEC	1	1	1	1		
White blood cell analyses	6	27	4	15	2	12
	253	834	100	310	153	524

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amino acid metabolism disorders NEC	1	1	1	1		
Appetite disorders	34	104	19	49	15	55
Calcium metabolism disorders	3	6		1	3	5
Cell metabolism disorders NEC		4				4
Chloride imbalance		1				1
Diabetes mellitus (incl subtypes)	8	33			8	33
Diabetic complications NEC	3	10			3	10
Disorders of purine metabolism	3	8	1	4	2	4
Elevated cholesterol		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Elevated triglycerides	2	2	1	1	1	1
Fat soluble vitamin deficiencies and disorders		2		1		1
Fluid intake increased		2		1		1
General nutritional disorders NEC	13	21	1	4	12	17
Hyperglycaemic conditions NEC	4	16	2	7	2	9
Hypervitaminoses NEC		1				1
Hypoglycaemic conditions NEC	4	16	1	3	3	13
Iron excess	2	3	1	1	1	2
Lipid metabolism and deposit disorders NEC	1	3	1	3		
Metabolic acidoses (excl diabetic acidoses)	8	12			8	12
Metabolic disorders NEC	1	1			1	1
Phosphorus metabolism disorders	1	1	1	1		
Potassium imbalance	6	20			6	20
Protein metabolism disorders NEC	3	4	1	1	2	3
Sodium imbalance	8	16	3	7	5	9
Total fluid volume decreased	10	37		8	10	29
Total fluid volume increased	2	3	1	1	1	2
Vitamin deficiencies NEC	1	1	1	1		
Water soluble vitamin deficiencies	3	3	2	2	1	1
	121	332	37	98	84	234

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	9	28		5	9	23
Bone related signs and symptoms	7	30	4	10	3	20
Bursal disorders	2	8		2	2	6
Cartilage disorders		1				1
Connective tissue disorders NEC	7	12			7	12

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Crystal arthropathic disorders	1	2			1	2
Extremity deformities		1		1		
Fractures NEC	1	1			1	1
Intervertebral disc disorders NEC		3		2		1
Joint related disorders NEC	3	11	2	4	1	7
Joint related signs and symptoms	80	308	47	135	33	173
Lupus erythematosus (incl subtypes)		1				1
Muscle infections and inflammations		4		1		3
Muscle pains	114	454	87	217	27	237
Muscle related signs and symptoms NEC	25	53	13	26	12	27
Muscle tone abnormalities	2	8	2	6		2
Muscle weakness conditions	11	46	4	15	7	31
Musculoskeletal and connective tissue conditions NEC	31	151	18	51	13	100
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity	1	3			1	3
Musculoskeletal and connective tissue pain and discomfort	129	373	71	175	58	198
Myopathies	1	7			1	7
Osteoarthropathies	3	9		4	3	5
Psoriatic arthropathies		1				1
Rheumatoid arthropathies	9	21			9	21
Soft tissue disorders NEC	2	3	2	3		
Spondyloarthropathies	3	14		1	3	13
Synovial disorders	5	7	3	3	2	4
Tendon disorders	11	24	4	9	7	15
	457	1,584	257	670	200	914

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Interval Total #

Cumulative Total #

Spontaneous	
Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
B-cell lymphomas NEC		1				1
Breast and nipple neoplasms benign		1		1		
Endocrine neoplasms benign NEC	1	1	1	1		
Female reproductive neoplasms unspecified malignancy	1	1			1	1
Gastrointestinal neoplasms malignant NEC	2	2			2	2
Islet cell neoplasms and APUDoma NEC		1				1
Leukaemias acute myeloid		2				2
Mediastinal neoplasms malignancy unspecified NEC	1	1			1	1
Metastases to specified sites		1				1
Myelodysplastic syndromes		1				1
Myeloproliferative disorders (excl leukaemias)		1				1
Neoplasms benign site unspecified NEC		1		1		
Neoplasms unspecified malignancy and site unspecified NEC		1				1
Nervous system neoplasms unspecified malignancy NEC	1	1			1	1
Oncologic complications and emergencies		1				1
Ovarian neoplasms malignant (excl germ cell)	1	1			1	1
Plasma cell neoplasms NEC		2				2
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC	1	1			1	1
Soft tissue neoplasms benign NEC		2				2
	8	23	1	3	7	20

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal reflexes	1	3		1	1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Absence seizures		9				9
Acute polyneuropathies	5	10			5	10
Autonomic nervous system disorders		1				1
Central nervous system aneurysms and dissections	2	2			2	2
Central nervous system haemorrhages and cerebrovascular accidents	141	345			141	345
Central nervous system vascular disorders NEC	5	11	1	1	4	10
Cerebrovascular venous and sinus thrombosis	2	4			2	4
Cervical spinal cord and nerve root disorders	5	11	2	4	3	7
Coma states	5	22			5	22
Coordination and balance disturbances	27	83	12	29	15	54
Cortical dysfunction NEC	15	45	3	9	12	36
Cranial nerve disorders NEC	1	1			1	1
Dementia (excl Alzheimer's type)	1	5			1	5
Demyelinating disorders NEC	1	2			1	2
Disturbances in consciousness NEC	90	304	9	28	81	276
Disturbances in sleep phase rhythm		1		1		
Dyskinesias and movement disorders NEC	26	67	15	24	11	43
Encephalopathies NEC	4	11			4	11
Eye movement disorders	5	9			5	9
Facial cranial nerve disorders	61	180		3	61	177
Generalised tonic-clonic seizures	5	16			5	16
Headaches NEC	291	984	183	437	108	547
Hydrocephalic conditions		1				1
Hypoglossal nerve disorders		1				1
Increased intracranial pressure disorders	3	4			3	4
Lumbar spinal cord and nerve root disorders	3	6	3	4		2
Memory loss (excl dementia)	11	33	2	5	9	28
Mental impairment (excl dementia and memory loss)	14	32	7	12	7	20
Migraine headaches	8	46	7	23	1	23

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mononeuropathies	1	5		1	1	4
Multiple sclerosis acute and progressive	3	3			3	3
Muscle tone abnormal	4	15	1	3	3	12
Narcolepsy and hypersomnia	1	7	1	4		3
Nervous system disorders NEC	9	22	5	8	4	14
Neurological signs and symptoms NEC	115	372	58	142	57	230
Neurologic visual problems NEC	1	7			1	7
Neuromuscular disorders NEC	1	13		3	1	10
Neuromuscular junction dysfunction	3	7			3	7
Olfactory nerve disorders	5	16	2	9	3	7
Optic nerve disorders NEC	1	2			1	2
Paraesthesias and dysaesthesias	114	360	54	140	60	220
Paralysis and paresis (excl cranial nerve)	30	87	4	5	26	82
Parkinson's disease and parkinsonism	1	4			1	4
Partial complex seizures		3				3
Peripheral neuropathies NEC	11	25		2	11	23
Seizures and seizure disorders NEC	28	106			28	106
Sensory abnormalities NEC	48	153	32	72	16	81
Sleep disturbances NEC		2				2
Speech and language abnormalities	25	74	12	20	13	54
Spinal cord and nerve root disorders NEC	1	3			1	3
Structural brain disorders NEC	1	6		1	1	5
Transient cerebrovascular events	36	72			36	72
Tremor (excl congenital)	25	84	15	31	10	53
Trigeminal disorders	3	5	1	1	2	4
Vagus nerve disorders	1	2			1	2
	1,200	3,704	429	1023	771	2681

System Organ Class

Pregnancy, puerperium and perinatal conditions

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortions spontaneous	6	15			6	15
Failed labour	1	1			1	1
Foetal growth complications	1	1			1	1
Gestational age and weight conditions	2	3	1	1	1	2
Maternal complications of labour NEC	1	1			1	1
Maternal complications of pregnancy NEC		1		1		
Normal pregnancy, labour and delivery	1	1			1	1
Umbilical cord complications	1	1			1	1
	13	24	1	2	12	22

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Device physical property and chemical issues	1	4	1	4
Product contamination and sterility issues	2	3	2	3
Product distribution and storage issues	143	305	143	305
Product physical issues	10	11	10	11
Product quality issues NEC	1	17	1	17
	157	340	157	340

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour NEC	2	16		3	2	13
Anxiety disorders NEC		2		1		1
Anxiety symptoms	20	73	9	31	11	42

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Attention deficit and disruptive behaviour disorders	1	1			1	1
Behaviour and socialisation disturbances	1	9		1	1	8
Bipolar disorders		1				1
Cognitive and attention disorders and disturbances NEC		3				3
Communications disorders	2	4		1	2	3
Confusion and disorientation	25	97	2	17	23	80
Decreased physical activity levels	1	1			1	1
Deliria	1	9			1	9
Delusional symptoms		6		3		3
Dementia NEC		1				1
Depressive disorders	2	6		1	2	5
Disturbances in initiating and maintaining sleep	18	87	8	37	10	50
Eating disorders NEC		2		1		1
Emotional and mood disturbances NEC	2	6	1	4	1	2
Fear symptoms and phobic disorders (incl social phobia)		5		2		3
Hallucinations (excl sleep-related)	5	37			5	37
Impulse control disorders		1		1		
Increased physical activity levels	2	13	1	6	1	7
Mental disorders NEC	1	1			1	1
Mood alterations with depressive symptoms	1	3	1	1		2
Mood disorders NEC	3	12	1	6	2	6
Panic attacks and disorders		2		1		1
Parasomnias	1	4	1	3		1
Perception disturbances NEC		4				4
Psychiatric elimination disorders		1				1
Sexual desire disorders		1		1		
Sleep disorders NEC	7	22	5	11	2	11
Speech and language usage disturbances		1				1
Speech articulation and rhythm disturbances		3				3

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stereotypies and automatisms	1	3	1	1		2
Suicidal and self-injurious behaviour	1	2			1	2
Thinking disturbances		2				2
	97	441	30	133	67	308

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	9	29	5	10	4	19
Bladder disorders NEC	2	3	2	2		1
Glomerulonephritis and nephrotic syndrome	3	5			3	5
Myoneurogenic bladder disorders	1	1	1	1		
Nephropathies and tubular disorders NEC		1				1
Renal disorders NEC	1	1			1	1
Renal failure and impairment	27	79		1	27	78
Renal neoplasms		2				2
Renal vascular and ischaemic conditions	3	5			3	5
Urinary abnormalities	11	30	3	10	8	20
Urinary tract lithiasis (excl renal)	1	1	1	1		
Urinary tract signs and symptoms NEC	3	10	1	3	2	7
	61	167	13	28	48	139

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast disorders NEC	1	2	1	1		1

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* AE=Adverse Event
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System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast signs and symptoms	2	8		2	2	6
Erection and ejaculation conditions and disorders		4				4
Menstruation and uterine bleeding NEC	2	4	1	1	1	3
Menstruation with decreased bleeding	4	6	4	4		2
Menstruation with increased bleeding	3	4	3	3		1
Pelvis and broad ligament disorders NEC	1	1	1	1		
Prostate and seminal vesicles infections and inflammations		4		2		2
Prostatic neoplasms and hypertrophy	2	4	2	3		1
Reproductive tract disorders NEC (excl neoplasms)		1				1
Reproductive tract signs and symptoms NEC		5				5
Testicular and epididymal disorders NEC		1		1		
Uterine tone disorders	1	1			1	1
Vulvovaginal disorders NEC	1	2			1	2
	17	47	12	18	5	29

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	130	432	41	85	89	347
Bronchial conditions NEC	1	3		1	1	2
Bronchospasm and obstruction	18	72	3	8	15	64
Conditions associated with abnormal gas exchange	12	42	2	2	10	40
Coughing and associated symptoms	26	130	19	54	7	76
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)		4				4
Laryngeal spasm, oedema and obstruction	8	20			8	20

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lower respiratory tract inflammatory and immunologic conditions	6	38		1	6	37
Lower respiratory tract signs and symptoms	7	35	4	7	3	28
Nasal congestion and inflammations	5	9	2	5	3	4
Nasal disorders NEC	23	49	6	15	17	34
Newborn respiratory disorders NEC	1	1			1	1
Paranasal sinus disorders (excl infections and neoplasms)		1				1
Parenchymal lung disorders NEC	8	16			8	16
Pharyngeal disorders (excl infections and neoplasms)	6	18	5	9	1	9
Pleural infections and inflammations	1	2	1	1		1
Pneumothorax and pleural effusions NEC	10	21	1	3	9	18
Pulmonary hypertensions	3	6			3	6
Pulmonary oedemas	19	74			19	74
Pulmonary thrombotic and embolic conditions	140	256			140	256
Respiratory failures (excl neonatal)	5	34			5	34
Respiratory signs and symptoms NEC	5	12	2	3	3	9
Respiratory tract disorders NEC	16	75	2	10	14	65
Tracheal disorders (excl infections and neoplasms)	1	1			1	1
Upper respiratory tract signs and symptoms	38	122	26	63	12	59
Vascular pulmonary disorders NEC		1				1
	489	1,474	114	267	375	1207

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes		2		2		
Alopecias		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	18	76	1	1	17	75
Apocrine and eccrine gland disorders	25	112	11	39	14	73
Bullous conditions	8	22		1	8	21
Connective tissue disorders		3				3
Dermal and epidermal conditions NEC	14	56	8	31	6	25
Dermatitis and eczema	2	10		4	2	6
Dermatitis ascribed to specific agent	5	9		1	5	8
Erythemas	31	123	21	59	10	64
Exfoliative conditions	1	4	1	1		3
Hyperkeratoses	1	1			1	1
Hyperpigmentation disorders		1				1
Panniculitides		3		1		2
Papulosquamous conditions		1				1
Photosensitivity and photodermatitis conditions		1		1		
Pilar disorders NEC		2		1		1
Pruritus NEC	34	112	19	49	15	63
Psoriatic conditions		4		2		2
Purpura and related conditions	34	60	11	21	23	39
Pustular conditions	1	1			1	1
Rashes, eruptions and exanthems NEC	43	168	17	67	26	101
Skin and subcutaneous conditions NEC		2		1		1
Skin and subcutaneous tissue ulcerations		2		1		1
Skin cysts and polyps		2		1		1
Skin injuries and mechanical dermatoses		3		1		2
Skin vasculitides	2	5			2	5
Skin vasomotor conditions	5	16	4	7	1	9
Urticarias	35	102	19	41	16	61
	259	904	112	333	147	571

System Organ Class

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System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	17	51	3	9	14	42
	17	51	3	9	14	42

System Organ Class

Surgical and medical procedures

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin and subcutaneous tissue therapeutic procedures NEC		1		1		
Therapeutic procedures NEC		1				1
Vascular therapeutic procedures NEC		1				1
		3		1		2

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	35	188		1	35	187
Aneurysms and dissections non-site specific	4	5			4	5
Aortic aneurysms and dissections	2	4	1	1	1	3
Aortic necrosis and vascular insufficiency	3	5	1	1	2	4
Arterial infections and inflammations	4	12			4	12
Blood pressure disorders NEC	6	14		3	6	11
Circulatory collapse and shock	6	23		1	6	22
Haemorrhages NEC	8	26	1	4	7	22
Lymphoedemas	2	6	1	4	1	2
Non-site specific embolism and thrombosis	23	44			23	44
Non-site specific necrosis and vascular insufficiency NEC	6	16	2	3	4	13

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* AE=Adverse Event

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System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Non-site specific vascular disorders NEC	6	13	1	5	5	8
Peripheral embolism and thrombosis	157	241	4	13	153	228
Peripheral vascular disorders NEC	20	96	11	42	9	54
Peripheral vasoconstriction, necrosis and vascular insufficiency	18	46	9	20	9	26
Phlebitis NEC	15	32	3	11	12	21
Site specific necrosis and vascular insufficiency NEC		1				1
Site specific vascular disorders NEC	8	34	3	5	5	29
Varicose veins NEC		2		1		1
Vascular hypertensive disorders NEC	212	698	26	94	186	604
Vascular hypotensive disorders	35	180	6	36	29	144
Vasculitides NEC	5	7	3	4	2	3
Vena caval embolism and thrombosis		2				2
	575	1,695	72	249	503	1446

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Country Where Event Occurred

FRENCH GUIANA

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Central nervous system haemorrhages and cerebrovascular accidents	1	1	1	1
Cerebrovascular venous and sinus thrombosis	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

FRENCH POLYNESIA

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Heart failures NEC		1		1
		1		1

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Asthenic conditions	1	3	1	3
Body temperature altered		1		1
	1	4	1	4

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Staphylococcal infections		1		1
		1		1

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Blood gas and acid base analyses		1		1

* I=Interval, C=Cumulative

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
		1		1

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Joint related signs and symptoms		1		1
		1		1

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coordination and balance disturbances	1	2	1	2
Cortical dysfunction NEC	1	1	1	1
Dyskinesias and movement disorders NEC		1		1
Facial cranial nerve disorders	1	1	1	1
Memory loss (excl dementia)		1		1
Paraesthesias and dysaesthesias		1		1
	3	7	3	7

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Confusion and disorientation		1		1

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
		1		1

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breathing abnormalities	1	2	1	2
Coughing and associated symptoms		1		1
Pulmonary oedemas		1		1
Pulmonary thrombotic and embolic conditions		1		1
	1	5	1	5

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bullous conditions		2		2
Dermal and epidermal conditions NEC		1		1
		3		3

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Country Where Event Occurred
FRENCH SOUTHERN TERRITORIES

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Death and sudden death		1		1
		1		1

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Country Where Event Occurred

GAMBIA

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Oedema NEC		1		1
		1		1

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Renal function analyses		1		1
		1		1

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vascular hypertensive disorders NEC		1		1
		1		1

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* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

GEORGIA

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Lower respiratory tract and lung infections		1		1
Sepsis, bacteraemia, viraemia and fungaemia		1		1
NEC				
		2		2

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product administration errors and issues	1	1	1	1
	1	1	1	1

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product physical issues	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

GERMANY

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Anaemias haemolytic immune		1						1
Anaemias haemolytic mechanical factor	1	2					1	2
Anaemias NEC	4	9			2	3	2	6
Bleeding tendencies	3	3					3	3
Coagulopathies	3	7			1	1	2	6
Eosinophilic disorders		1						1
Haematological disorders		1						1
Leukocytoses NEC		3						3
Leukopenias NEC	5	10				1	5	9
Lymphatic system disorders NEC	105	207		1	103	199	2	8
Marrow depression and hypoplastic anaemias	1	3					1	3
Neutropenias		3						3
Polycythaemia (excl rubra vera)	1	1					1	1
Spleen disorders	1	1					1	1
Thrombocytopenias	15	32					15	32
	139	284		1	106	204	33	80

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Aortic valvular disorders		1						1
Cardiac conduction disorders		8				1		7
Cardiac disorders NEC	27	75			16	42	11	33
Cardiac hypertensive complications	1	1					1	1
Cardiac signs and symptoms NEC	24	87		4	22	62	2	25

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Cardiac valve disorders NEC	1	1					1	1
Cardiomyopathies	3	6					3	6
Coronary artery disorders NEC	4	8					4	8
Heart failures NEC	11	64					11	64
Ischaemic coronary artery disorders	36	89					36	89
Left ventricular failures		1						1
Myocardial disorders NEC	3	4			1	1	2	3
Noninfectious myocarditis	26	39					26	39
Noninfectious pericarditis	1	2					1	2
Pericardial disorders NEC	2	4					2	4
Rate and rhythm disorders NEC	50	205		7	22	72	28	133
Right ventricular failures	2	5					2	5
Supraventricular arrhythmias	7	43			2	7	5	36
Ventricular arrhythmias and cardiac arrest	11	41				1	11	40
	209	684		11	63	186	146	498

System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neurological disorders congenital NEC	1	4	1	1		3
Vascular anomalies congenital NEC	1	1			1	1
	2	5	1	1	1	4

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	13	24	11	20	2	4
Hearing losses	10	33	4	5	6	28
Hyperacusia		1		1		
Inner ear signs and symptoms	17	38	14	30	3	8
	40	96	29	56	11	40

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute and chronic thyroiditis		3		3
Thyroid hyperfunction disorders	1	4	1	4
Thyroid hypofunction disorders	1	2	1	2
	2	9	2	9

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Conjunctival and corneal bleeding and vascular disorders	1	3					1	3
Conjunctival infections, irritations and inflammations		1						1
Corneal structural change, deposit and degeneration		1						1
Eyelid movement disorders	2	2			1	1	1	1
Glaucomas (excl congenital)	1	1					1	1
Iris and uveal tract infections, irritations and inflammations		2						2

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* AE=Adverse Event

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lacrimation disorders	4	15
Lid bleeding and vascular disorders	1	1
Lid, lash and lacrimal infections, irritations and inflammations	5	13
Lid, lash and lacrimal structural disorders	1	1
Ocular bleeding and vascular disorders NEC	8	16
Ocular disorders NEC	17	36
Ocular infections, inflammations and associated manifestations	14	35
Ocular nerve and muscle disorders	1	2
Ocular sensation disorders	4	5
Optic disc abnormalities NEC	1	2
Optic nerve bleeding and vascular disorders		1
Pupil disorders		2
Retinal bleeding and vascular disorders (excl retinopathy)	3	5
Retinal structural change, deposit and degeneration	2	5
Retinopathies NEC		1
Scleral infections, irritations and inflammations		1
Structural change, deposit and degeneration of eye NEC	1	1
Visual disorders NEC	2	21
Visual field disorders	2	5
Visual impairment and blindness (excl colour blindness)	17	51
Visual pathway disorders		1
	87	230

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	12		3
		1	1		
		5	9		4
		1	1		
				8	16
		16	31	1	5
		14	26		9
				1	2
		4	5		
				1	2
					1
			1		1
				3	5
2	2			2	5
					1
			1		
				1	1
		1	12	1	9
		1	2	1	3
		12	21	5	30
1	1				1
3	3	60	123	27	107

System Organ Class

Gastrointestinal disorders

Interval Total # Cumulative Total #

Non Interventional Study		Spontaneous	
Serious		Nonserious	Serious

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* AE=Adverse Event
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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acute and chronic pancreatitis	3	5
Anal and rectal disorders NEC		1
Benign neoplasms gastrointestinal (excl oral cavity)		1
Colitis (excl infective)	2	6
Dental pain and sensation disorders		1
Diarrhoea (excl infective)	66	192
Dyspeptic signs and symptoms	1	5
Faecal abnormalities NEC	11	26
Flatulence, bloating and distension	2	9
Gastritis (excl infective)	1	2
Gastrointestinal and abdominal pains (excl oral and throat)	41	99
Gastrointestinal atonic and hypomotility disorders NEC	4	6
Gastrointestinal disorders NEC	2	5
Gastrointestinal dyskinetic disorders		2
Gastrointestinal inflammatory disorders NEC	2	4
Gastrointestinal necrosis and gangrene (excl gangrenous hernia)		3
Gastrointestinal signs and symptoms NEC	7	38
Gastrointestinal spastic and hypermotility disorders	1	2
Gastrointestinal stenosis and obstruction NEC		5
Gastrointestinal vascular occlusion and infarction	5	13
Gingival disorders, signs and symptoms NEC	2	4
Gingival haemorrhages		3
Intestinal haemorrhages	1	2
Intestinal ulcers and perforation NEC	1	1
Nausea and vomiting symptoms	182	490
Non-mechanical ileus	1	3
Non-site specific gastrointestinal haemorrhages	6	16
Oesophagitis (excl infective)		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	5
					1
			1		
				2	6
			1		
	11	56	158	10	34
		1	5		
		10	24	1	2
	1	2	8		1
		1	2		
	2	37	72	4	27
		4	6		
		2	4		1
			2		
		2	2		2
					3
	1	2	20	5	18
		1	2		
			1		4
				5	13
		2	3		1
			1		2
				1	2
				1	1
	43	163	390	19	100
				1	3
				6	16
					1

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* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral dryness and saliva altered	6	18
Oral soft tissue haemorrhages		1
Oral soft tissue signs and symptoms	23	62
Oral soft tissue swelling and oedema	6	22
Peritoneal and retroperitoneal disorders	1	2
Salivary gland enlargements		2
Stomatitis and ulceration	1	6
Tongue disorders	5	8
Tongue signs and symptoms	9	34
	392	1,100

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	13		5
			1		
		20	51	3	11
		6	8		14
				1	2
			2		
		1	2		4
		3	6	2	2
		7	19	2	15
	58	326	804	66	296

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Adverse effect absent	1	3
Application and instillation site reactions	3	4
Asthenic conditions	540	1,283
Body temperature altered		5
Death and sudden death	74	313
Febrile disorders	293	675
Feelings and sensations NEC	334	735
Gait disturbances	18	33
General signs and symptoms NEC	168	452
Healing abnormal NEC		1
Inflammations	5	10
Injection site reactions	8	14
Interactions	3	8
Mass conditions NEC		1
Mucosal findings abnormal	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3		
		3	3		1
1	106	520	1170	20	113
					5
				74	313
	26	281	572	12	103
1	28	322	658	12	77
		10	17	8	16
	4	148	321	20	131
					1
		4	5	1	5
		8	14		
		2	5	1	3
			1		
		1	1		1

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* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Necrosis NEC		1						1
Oedema NEC	4	16			4	10		6
Pain and discomfort NEC	95	221		3	86	176	9	45
Therapeutic and nontherapeutic responses	99	420			9	20	90	400
Vaccination site reactions	423	1,180		68	420	1144	3	36
	2,069	5,377	2	235	1819	4120	250	1257

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholecystitis and cholelithiasis		1		1		
Cholestasis and jaundice		6		3		3
Hepatic and hepatobiliary disorders NEC		1				1
Hepatic failure and associated disorders		4				4
Hepatic fibrosis and cirrhosis		1				1
Hepatobiliary signs and symptoms		1		1		
Hepatocellular damage and hepatitis NEC	2	2			2	2
	2	16		5	2	11

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Allergic conditions NEC	31	130		4	23	62	8	68
Allergies to foods, food additives, drugs and other chemicals	5	11			2	5	3	6
Anaphylactic and anaphylactoid responses	28	137		1			28	137

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System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Atopic disorders	2	3			2	3		
Autoimmune disorders NEC	3	4					3	4
Immune and associated conditions NEC			1	1				
	69	285	1	6	27	70	42	215

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal and gastrointestinal infections	3	6		1			3	6
Bacterial infections NEC	1	12					1	12
Borrelial infections	4	4			1	1	3	3
Breast infections	2	2					2	2
Candida infections		1						1
Cardiac infections		2						2
Central nervous system and spinal infections	2	9					2	9
Coronavirus infections	135	630		1	45	178	90	452
Dental and oral soft tissue infections	1	4			1	1		3
Ear infections		1				1		
Epstein-Barr viral infections		3						3
Escherichia infections		1						1
Eye and eyelid infections	3	9			3	6		3
Female reproductive tract infections		1						1
Fungal infections NEC	1	3			1	1		2
Herpes viral infections	122	195			103	151	19	44
Infections NEC	7	28		1	1	5	6	23
Influenza viral infections	16	24			16	22		2
Lower respiratory tract and lung infections	15	60			1	3	14	57
Muscle and soft tissue infections		2						2
Mycoplasma infections		1				1		

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* AE=Adverse Event

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Prion-associated disorders		2						2
Sepsis, bacteraemia, viraemia and fungaemia NEC	3	12					3	12
Skin structures and soft tissue infections	7	17		1	7	14		3
Staphylococcal infections		3						3
Streptococcal infections	7	11					7	11
Upper respiratory tract infections	30	75		1	30	65		10
Urinary tract infections	3	7			2	4	1	3
Vascular infections	1	3					1	3
Viral infections NEC	1	7				4	1	3
	364	1,135		5	211	457	153	678

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accidental exposures to product	1	2			1	2		
Cardiac and vascular procedural complications	1	1					1	1
Cerebral injuries NEC		2						2
Chemical injuries		1						1
Exposures associated with pregnancy, delivery and lactation	47	96			45	93	2	3
Fractures and dislocations NEC		1						1
Intentional product misuses		2				2		
Limb fractures and dislocations		3						3
Medication errors, product use errors and issues NEC	10	37			9	36	1	1
Muscle, tendon and ligament injuries	1	2		1	1	1		1
Nerve injuries NEC	1	1					1	1
Neurological and psychiatric procedural complications		1						1

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* AE=Adverse Event

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Non-site specific injuries NEC	11	33
Occupational exposures		1
Off label uses	16	53
Overdoses NEC	4	6
Pathways and sources of exposure	1	1
Pelvic fractures and dislocations		1
Peripheral nerve injuries	1	2
Poisoning and toxicity		2
Product administration errors and issues	85	259
Product preparation errors and issues	3	14
Product prescribing errors and issues	1	1
Product storage errors and issues in the product use system	10	12
Site specific injuries NEC	1	4
Skin injuries NEC	3	11
Spinal fractures and dislocations	1	1
Thermal burns	1	1
Thoracic cage fractures and dislocations	1	1
Underdoses NEC	3	24
Vaccination related complications	6	10
	209	586

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	6	8	27
			1		
		16	53		
		4	4		2
		1	1		
					1
		1	1		1
					2
		84	251	1	8
		3	14		
		1	1		
		10	12		
		1	1		3
			3	3	8
				1	1
		1	1		
				1	1
		3	24		
		4	4	2	6
	1	188	511	21	75

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood counts NEC	1	2
Blood gas and acid base analyses	4	21
Carbohydrate tolerance analyses (incl diabetes)	3	14
Cell marker analyses	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		1
		3	5	1	16
		1	9	2	5
		1	1	1	1

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebrospinal fluid tests (excl microbiology)	2	2
Chemistry analyses NEC	2	3
Cholesterol analyses		2
Coagulation and bleeding analyses	5	12
Digestive enzymes	1	3
ECG investigations	1	4
Haematological analyses NEC	2	4
Haem metabolism analyses		1
Heart rate and pulse investigations	12	30
Immune response protein analyses NEC		1
Immunoglobulin analyses		1
Immunology analyses NEC	1	5
Investigations NEC	3	4
Lipoprotein and lipid tests NEC	1	2
Liver function analyses	11	25
Metabolism tests NEC	2	2
Mineral and electrolyte analyses	1	11
Musculoskeletal and soft tissue tests NEC		1
Neurologic diagnostic procedures	1	5
Ophthalmic function diagnostic procedures	1	2
Physical examination procedures and organ system status	60	139
Pituitary analyses anterior		1
Platelet analyses	8	12
Protein analyses NEC	7	20
Red blood cell analyses	7	16
Renal function analyses	1	4
Respiratory tract and thoracic imaging procedures		1
Skeletal and cardiac muscle analyses	4	7
Tissue enzyme analyses NEC	2	4
Urinalysis NEC	1	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
		2	2		1
			2		
		4	10	1	2
		1	2		1
				1	4
		1	3	1	1
			1		
		8	17	4	13
			1		
			1		
			3	1	2
		3	4		
		1	2		
		8	13	3	12
		2	2		
			5	1	6
					1
		1	4		1
			1	1	1
1	1	58	116	2	23
			1		
		2	4	6	8
		5	14	2	6
		3	9	4	7
		1	3		1
					1
		2	4	2	3
		1	1	1	3
		1	2		2

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vascular tests NEC (incl blood pressure)	19	76		3	9	36	10	40
Virus identification and serology	13	118			9	95	4	23
White blood cell analyses	5	21			3	17	2	4
	183	582	1	4	131	391	52	191

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	15	50	14	33	1	17
Calcium metabolism disorders		3				3
Diabetes mellitus (incl subtypes)	2	7			2	7
Disorders of purine metabolism		1		1		
Electrolyte imbalance NEC		2		1		1
Fluid intake increased		1				1
General nutritional disorders NEC	3	4	3	3		1
Hyperglycaemic conditions NEC	1	3	1	1		2
Hypoglycaemic conditions NEC		2		2		
Iron deficiencies	1	1	1	1		
Lipid metabolism and deposit disorders NEC		1		1		
Metabolic acidoses (excl diabetic acidoses)		1				1
Metabolic disorders NEC		1				1
Mixed acid-base disorders		1				1
Potassium imbalance	1	2			1	2
Sodium imbalance	2	8		3	2	5
Total fluid volume decreased	3	9	3	4		5
Total fluid volume increased		1		1		
	28	98	22	51	6	47

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arthropathies NEC	2	6
Bone disorders NEC	1	3
Bone related signs and symptoms	17	45
Bursal disorders		2
Connective tissue disorders NEC		2
Extremity deformities	1	1
Joint related disorders NEC		1
Joint related signs and symptoms	85	209
Lupus erythematosus (incl subtypes)		1
Metabolic bone disorders		1
Muscle infections and inflammations	2	4
Muscle pains	134	352
Muscle related signs and symptoms NEC	18	50
Muscle tone abnormalities	3	5
Muscle weakness conditions	17	35
Musculoskeletal and connective tissue conditions NEC	12	35
Musculoskeletal and connective tissue pain and discomfort	395	831
Myopathies	2	5
Rheumatoid arthropathies	6	8
Soft tissue disorders NEC	1	3
Spondyloarthropathies		1
Tendon disorders	4	7
	700	1,607

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	5
		1	1		2
		17	41		4
	1		1		1
					2
		1	1		
			1		
	22	82	188	3	21
					1
			1		
		1	2	1	2
	35	131	333	3	19
	1	15	37	3	13
		2	3	1	2
		15	26	2	9
		10	27	2	8
		383	773	12	58
				2	5
				6	8
		1	2		1
					1
		4	5		2
	59	664	1443	36	164

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
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Spontaneous			
Nonserious		Serious	
I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast and nipple neoplasms malignant	3	3			3	3
Endocrine neoplasms benign NEC	1	1			1	1
Histiocytoses	1	1			1	1
Leukaemias acute myeloid		2		1		1
Leukaemias chronic lymphocytic	1	1			1	1
Leukaemias NEC		1				1
Neoplasms malignant site unspecified NEC	1	1			1	1
Neoplasms unspecified malignancy and site unspecified NEC		1				1
Oncologic complications and emergencies		1				1
Skin melanomas (excl ocular)		1				1
Skin neoplasms malignant and unspecified (excl melanoma)	1	1			1	1
	8	14		1	8	13

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Absence seizures		1						1
Acute polyneuropathies	6	8					6	8
Alzheimer's disease (incl subtypes)		1						1
Autonomic nervous system disorders		4				2		2
Central nervous system aneurysms and dissections		1						1
Central nervous system haemorrhages and cerebrovascular accidents	51	158					51	158
Central nervous system vascular disorders NEC	2	5					2	5
Cerebrovascular venous and sinus thrombosis	16	26					16	26
Cervical spinal cord and nerve root disorders	1	1			1	1		
Chronic polyneuropathies	1	2					1	2

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* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Coma states	1	3
Coordination and balance disturbances	10	26
Cortical dysfunction NEC	4	23
Cranial nerve disorders NEC	1	3
Dementia (excl Alzheimer's type)	1	9
Disturbances in consciousness NEC	60	202
Dyskinesias and movement disorders NEC	13	32
Encephalitis NEC	1	2
Eye movement disorders	1	5
Facial cranial nerve disorders	35	109
Generalised tonic-clonic seizures		3
Headaches NEC	458	1,072
Increased intracranial pressure disorders	1	6
Memory loss (excl dementia)	4	21
Mental impairment (excl dementia and memory loss)	18	62
Migraine headaches	17	27
Motor neurone diseases		1
Multiple sclerosis acute and progressive	3	9
Muscle tone abnormal	10	28
Narcolepsy and hypersomnia	3	8
Nervous system disorders NEC	4	9
Neurological signs and symptoms NEC	155	458
Neuromuscular disorders NEC	2	4
Neuromuscular junction dysfunction		1
Olfactory nerve disorders	8	18
Optic nerve disorders NEC	1	3
Paraesthesias and dysaesthesias	84	262
Paralysis and paresis (excl cranial nerve)	15	59
Parkinson's disease and parkinsonism	3	7
Peripheral neuropathies NEC	2	19
Seizures and seizure disorders NEC	13	88

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	3
		8	11	2	15
		3	9	1	14
			2	1	1
				1	9
	2	24	45	36	157
		10	18	3	14
				1	2
				1	5
		6	24	29	85
					3
1	57	440	976	18	96
				1	6
		1	6	3	15
		17	45	1	17
		16	24	1	3
					1
2	2			3	9
		8	19	2	9
		3	6		2
		2	3	2	6
	41	140	343	15	115
		2	2		2
					1
		6	14	2	4
				1	3
	5	72	183	12	79
		1	5	14	54
		1	2	2	5
1	1		4	2	15
				13	88

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Sensory abnormalities NEC	56	129			52	114	4	15
Sleep disturbances NEC		1						1
Speech and language abnormalities	6	22			3	7	3	15
Spinal cord and nerve root disorders NEC		3				1		2
Structural brain disorders NEC		2						2
Transient cerebrovascular events	2	8					2	8
Tremor (excl congenital)	9	46			3	20	6	26
Trigeminal disorders	3	5			2	4	1	1
	1,081	3,002	4	108	821	1890	260	1112

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions not specified as induced or spontaneous		1		1
Abortions spontaneous		4		4
Haemorrhagic complications of pregnancy	1	1	1	1
Unintended pregnancies		1		1
	1	7	1	7

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Counterfeit, falsified and substandard products		1		1		
Device issues NEC		1				1
Product distribution and storage issues	9	45	9	43		2

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* AE=Adverse Event

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System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product physical issues	3	4	3	4		
Product quality issues NEC	1	4	1	4		
Product supply and availability issues		2		2		
	13	57	13	54		3

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour NEC	1	1	1	1		
Anxiety symptoms	8	25	8	17		8
Behaviour and socialisation disturbances		12		1		11
Communications disorders		1		1		
Confusion and disorientation	7	31	3	11	4	20
Deliria	1	7			1	7
Delusional symptoms		2				2
Depressive disorders	2	8	2	7		1
Disturbances in initiating and maintaining sleep	16	32	15	30	1	2
Dyssomnias	2	9	2	7		2
Eating disorders NEC		2		2		
Emotional and mood disturbances NEC	3	4	3	3		1
Fear symptoms and phobic disorders (incl social phobia)	2	3	2	2		1
Hallucinations (excl sleep-related)	6	12			6	12
Increased physical activity levels	9	22	7	17	2	5
Mental disorders NEC	1	6	1	3		3
Mood alterations with depressive symptoms	4	7	4	5		2
Mood disorders NEC	4	16	4	10		6
Panic attacks and disorders	2	8	1	4	1	4
Psychiatric elimination disorders	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sleep disorders NEC	9	21	9	20		1
Somatic symptom disorders	1	2	1	1		1
Speech articulation and rhythm disturbances	2	2	2	2		
Stereotypies and automatisms		1				1
Stress disorders		2				2
Suicidal and self-injurious behaviour	1	1			1	1
Thinking disturbances	2	2	2	2		
	84	240	67	146	17	94

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	10	21	8	15	2	6
Bladder infections and inflammations		1				1
Genitourinary tract infections and inflammations NEC		1				1
Glomerulonephritis and nephrotic syndrome		2				2
Myoneurogenic bladder disorders		1				1
Nephropathies and tubular disorders NEC	1	1	1	1		
Renal disorders NEC	1	3	1	1		2
Renal failure and impairment	9	41			9	41
Renal lithiasis		1				1
Urinary abnormalities	2	5	2	4		1
Urinary tract signs and symptoms NEC	2	7	2	4		3
	25	84	14	25	11	59

System Organ Class

Reproductive system and breast disorders

Non Interventional Study	Spontaneous
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* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Breast infections and inflammations	1	1
Breast signs and symptoms	3	5
Cervix disorders NEC		1
Erection and ejaculation conditions and disorders	3	3
Menstruation and uterine bleeding NEC	10	17
Menstruation with decreased bleeding	1	1
Menstruation with increased bleeding	8	9
Prostate and seminal vesicles infections and inflammations	1	1
Reproductive tract disorders NEC (excl neoplasms)		1
Reproductive tract signs and symptoms NEC		2
Spermatogenesis and semen disorders	1	1
Uterine disorders NEC	1	1
Vulvovaginal disorders NEC	1	1
Vulvovaginal signs and symptoms		3
	30	47

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
	1	1	3	2	2
					1
				3	3
		9	16	1	1
				1	1
		7	8	1	1
		1	1		
					1
			2		
		1	1		
		1	1		
		1	1		
			1		2
	1	21	34	9	13

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Breathing abnormalities	86	387
Bronchial conditions NEC		1
Bronchospasm and obstruction	9	56
Conditions associated with abnormal gas exchange		3
Coughing and associated symptoms	29	90
Laryngeal spasm, oedema and obstruction	3	17

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	2	48	130	38	257
			1		
		7	25	2	31
					3
	1	27	70	2	20
				3	17

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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Lower respiratory tract inflammatory and immunologic conditions	2	7					2	7
Lower respiratory tract signs and symptoms	6	14			4	7	2	7
Nasal congestion and inflammations	3	10			3	8		2
Nasal disorders NEC	4	11		1	3	8	1	3
Paranasal sinus disorders (excl infections and neoplasms)	1	3			1	3		
Parenchymal lung disorders NEC	2	5					2	5
Pharyngeal disorders (excl infections and neoplasms)	4	23		1	3	11	1	12
Pleural infections and inflammations		1						1
Pneumothorax and pleural effusions NEC	2	5					2	5
Pulmonary hypertensions		1						1
Pulmonary oedemas	2	11					2	11
Pulmonary thrombotic and embolic conditions	57	124					57	124
Respiratory failures (excl neonatal)	4	29					4	29
Respiratory signs and symptoms NEC	5	9			4	8	1	1
Respiratory tract disorders NEC	4	12			4	6		6
Upper respiratory tract signs and symptoms	44	168		2	43	139	1	29
	267	987		7	147	416	120	571

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acnes	2	3			2	3		
Alopecias	1	5			1	3		2
Angioedemas	6	41				1	6	40
Apocrine and eccrine gland disorders	36	89		1	31	72	5	17
Bullous conditions	3	14			2	7	1	7
Dermal and epidermal conditions NEC	25	48			24	39	1	9

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* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dermatitis and eczema	15	44
Dermatitis ascribed to specific agent	2	4
Erythemas	30	101
Exfoliative conditions		3
Nail and nail bed conditions (excl infections and infestations)		1
Photosensitivity and photodermatitis conditions	1	2
Pilar disorders NEC	1	1
Pruritus NEC	40	115
Psoriatic conditions	2	4
Purpura and related conditions	6	19
Pustular conditions		1
Rashes, eruptions and exanthems NEC	77	199
Rosaceas		1
Skin and subcutaneous tissue ulcerations		1
Skin haemorrhages	2	3
Skin vasculitides		6
Skin vasomotor conditions		1
Urticarias	24	67
	273	773

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		13	37	2	7
		2	3		1
	2	28	78	2	23
			3		
			1		
		1	2		
		1	1		
	2	38	85	2	30
		2	3		1
		3	8	3	11
					1
	4	70	146	7	53
					1
			1		
		1	1	1	2
					6
			1		
	1	23	51	1	16
	10	242	546	31	227

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Disability issues	4	10
	4	10

Spontaneous			
Nonserious		Serious	
I	C	I	C
4	8		2
4	8		2

System Organ Class

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* AE=Adverse Event
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System Organ Class

Surgical and medical procedures

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cranial nerve therapeutic procedures		1				1
Gynaecological therapeutic procedures NEC	2	2	2	2		
Nervous system therapeutic procedures NEC	1	1			1	1
Small intestine therapeutic procedures		1				1
Therapeutic procedures NEC		1				1
Vascular therapeutic procedures NEC		1				1
	3	7	2	2	1	5

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accelerated and malignant hypertension	2	22					2	22
Aortic aneurysms and dissections		5						5
Aortic necrosis and vascular insufficiency	1	1			1	1		
Arterial infections and inflammations	1	2					1	2
Blood pressure disorders NEC	1	6				5	1	1
Circulatory collapse and shock	19	82		1	2	6	17	76
Haemorrhages NEC	12	32			6	12	6	20
Lymphoedemas	4	6			3	5	1	1
Non-site specific embolism and thrombosis	25	51					25	51
Non-site specific necrosis and vascular insufficiency NEC	4	14				1	4	13
Non-site specific vascular disorders NEC	2	2			1	1	1	1
Peripheral embolism and thrombosis	60	111			5	10	55	101
Peripheral vascular disorders NEC	43	140		1	39	85	4	55
Peripheral vasoconstriction, necrosis and vascular insufficiency	7	13			7	12		1
Phlebitis NEC		1				1		
Site specific vascular disorders NEC	1	9			1	3		6

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* AE=Adverse Event

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System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Varicose veins NEC	1	2				1	1	1
Vascular hypertensive disorders NEC	20	94		3	12	39	8	55
Vascular hypotensive disorders	13	59			9	31	4	28
Vasculitides NEC	1	7				1	1	6
	217	659		5	86	214	131	445

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* AE=Adverse Event
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Country Where Event Occurred

GREECE

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias NEC		1				1
Haemolyses NEC	1	1			1	1
Leukocytoses NEC		2		1		1
Leukopenias NEC		1		1		
Lymphatic system disorders NEC	20	88	18	49	2	39
Neutropenias	1	1			1	1
Thrombocytopenias	1	1			1	1
	23	95	18	51	5	44

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC	4	34	4	18		16
Cardiac valve disorders NEC		1				1
Coronary artery disorders NEC	1	3			1	3
Heart failures NEC		1				1
Ischaemic coronary artery disorders	9	17			9	17
Myocardial disorders NEC	1	2			1	2
Noninfectious myocarditis	3	4			3	4
Noninfectious pericarditis	1	1			1	1
Rate and rhythm disorders NEC	17	97	8	40	9	57
Supraventricular arrhythmias	8	15			8	15
Ventricular arrhythmias and cardiac arrest	5	14			5	14
	49	189	12	58	37	131

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cardiac septal defects congenital		1		1
		1		1

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	1	5		2	1	3
Hearing losses	1	5			1	5
Inner ear disorders NEC	1	1	1	1		
Inner ear signs and symptoms	5	26	3	17	2	9
	8	37	4	20	4	17

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic thyroiditis		3		1		2
Thyroid disorders NEC		1				1
Thyroid neoplasms		1				1
		5		1		4

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival infections, irritations and inflammations		2		2		
Eyelid movement disorders	1	4		1	1	3
Iris and uveal tract infections, irritations and inflammations		6				6
Lacrimation disorders	2	5	2	5		
Lid, lash and lacrimal infections, irritations and inflammations		7		5		2
Ocular bleeding and vascular disorders NEC	1	3			1	3
Ocular disorders NEC		8		4		4
Ocular infections, inflammations and associated manifestations	2	10	1	5	1	5
Ocular nerve and muscle disorders	1	1			1	1
Ocular sensation disorders		1				1
Optic disc abnormalities NEC		1				1
Pupil disorders	2	2			2	2
Retinal bleeding and vascular disorders (excl retinopathy)	2	2			2	2
Scleral infections, irritations and inflammations		2				2
Visual disorders NEC	4	9	1	3	3	6
Visual impairment and blindness (excl colour blindness)	2	4		1	2	3
	17	67	4	26	13	41

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis		2				2
Dental disorders NEC		1				1
Dental pain and sensation disorders	1	1	1	1		
Diarrhoea (excl infective)	10	37	8	25	2	12

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspeptic signs and symptoms		11		6		5
Flatulence, bloating and distension	1	4		1	1	3
Gastrointestinal and abdominal pains (excl oral and throat)	13	33	8	21	5	12
Gastrointestinal atonic and hypomotility disorders NEC		2		1		1
Gastrointestinal disorders NEC	1	11	1	10		1
Gastrointestinal signs and symptoms NEC	4	30	1	9	3	21
Gastrointestinal spastic and hypermotility disorders		2				2
Nausea and vomiting symptoms	14	85	7	50	7	35
Non-site specific gastrointestinal haemorrhages		2				2
Oral dryness and saliva altered		9		7		2
Oral soft tissue disorders NEC	2	5			2	5
Oral soft tissue signs and symptoms	9	41	7	21	2	20
Oral soft tissue swelling and oedema	8	21	5	11	3	10
Salivary gland disorders NEC		2		2		
Salivary gland enlargements		3		1		2
Stomatitis and ulceration	1	3		2	1	1
Tongue disorders		1		1		
Tongue signs and symptoms	3	12	1	2	2	10
	67	318	39	171	28	147

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse effect absent	1	4	1	4		
Asthenic conditions	75	253	63	166	12	87
Body temperature altered	2	4			2	4
Death and sudden death	5	16			5	16

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* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Febrile disorders	89	264	73	179	16	85
Feelings and sensations NEC	27	128	23	73	4	55
Fibrosis NEC	1	1			1	1
Gait disturbances	3	15	1	6	2	9
General signs and symptoms NEC	12	40	7	18	5	22
Inflammations		4		1		3
Injection site reactions	6	8	6	8		
Interactions		1				1
Mucosal findings abnormal		1				1
Oedema NEC	4	20	2	9	2	11
Pain and discomfort NEC	24	89	11	41	13	48
Therapeutic and nontherapeutic responses	12	42	1	5	11	37
Vaccination site reactions	97	233	94	209	3	24
	358	1,123	282	719	76	404

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholecystitis and cholelithiasis	1	2			1	2
Cholestasis and jaundice	4	4			4	4
Hepatic enzymes and function abnormalities	1	1	1	1		
Hepatic failure and associated disorders	1	1			1	1
Hepatic vascular disorders	1	1			1	1
Hepatobiliary signs and symptoms	1	1	1	1		
Hepatocellular damage and hepatitis NEC		1				1
	9	11	2	2	7	9

System Organ Class

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* AE=Adverse Event
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System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic sarcoidosis		1				1
Allergic conditions NEC	5	41	1	16	4	25
Allergies to foods, food additives, drugs and other chemicals		5		1		4
Anaphylactic and anaphylactoid responses	4	28			4	28
	9	75	1	17	8	58

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections		2				2
Central nervous system and spinal infections	1	3			1	3
Coronavirus infections	15	57	4	15	11	42
Dental and oral soft tissue infections		1		1		
Eye and eyelid infections		2		2		
Herpes viral infections	7	34	4	17	3	17
Infections NEC	2	6	2	3		3
Influenza viral infections	1	1	1	1		
Listeria infections	1	1			1	1
Lower respiratory tract and lung infections	2	5			2	5
Upper respiratory tract infections	1	5		4	1	1
Urinary tract infections		3		1		2
Viral infections NEC		2		2		
	30	122	11	46	19	76

System Organ Class

Injury, poisoning and procedural complications

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal injuries NEC	1	1	1	1		
Cardiac and vascular procedural complications		1				1
Exposures associated with pregnancy, delivery and lactation	1	6	1	6		
Limb fractures and dislocations	2	3			2	3
Medication errors, product use errors and issues NEC	1	8	1	8		
Muscle, tendon and ligament injuries		2		2		
Non-site specific injuries NEC	3	10	1	4	2	6
Occupational exposures		1		1		
Off label uses		4		4		
Overdoses NEC		1		1		
Product administration errors and issues	3	13	3	13		
Product preparation errors and issues		1		1		
Site specific injuries NEC		1		1		
Skin injuries NEC	2	3	2	3		
Underdoses NEC	1	1	1	1		
	14	56	10	46	4	10

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Auditory and vestibular diagnostic procedures		1		1		
Blood gas and acid base analyses		10		1		9
Carbohydrate tolerance analyses (incl diabetes)	2	7	2	6		1
Cell marker analyses		2		1		1
Cerebrospinal fluid tests (excl microbiology)		1				1
Coagulation and bleeding analyses	5	8	5	7		1
Digestive enzymes	1	1	1	1		

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
ECG investigations		1				1
Gastrointestinal function diagnostic procedures	1	1			1	1
Heart rate and pulse investigations	1	35		17	1	18
Immunoglobulin analyses		1				1
Liver function analyses	1	5	1	4		1
Mineral and electrolyte analyses	4	7	4	7		
Neurologic diagnostic procedures		1		1		
Parathyroid analyses	1	1	1	1		
Physical examination procedures and organ system status	3	5	3	5		
Platelet analyses	1	2	1	2		
Protein analyses NEC	4	7	4	7		
Red blood cell analyses	3	6	3	5		1
Renal function analyses	1	2	1	2		
Skeletal and cardiac muscle analyses	3	4	3	4		
Tissue enzyme analyses NEC	1	1	1	1		
Triglyceride analyses		1				1
Urinalysis NEC	1	1	1	1		
Vascular tests NEC (incl blood pressure)	16	89	12	44	4	45
Virus identification and serology	1	4		3	1	1
White blood cell analyses	5	6	3	4	2	2
	55	210	46	125	9	85

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	2	7	1	5	1	2
Diabetes mellitus (incl subtypes)		4				4
Fluid intake increased		1		1		

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* AE=Adverse Event

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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
General nutritional disorders NEC		5		1		4
Hyperglycaemic conditions NEC		1				1
Hypoglycaemic conditions NEC	1	5		3	1	2
Potassium imbalance		2				2
Protein metabolism disorders NEC		1		1		
Sodium imbalance		3		1		2
Total fluid volume decreased		1				1
	3	30	1	12	2	18

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC		3		1		2
Bone disorders NEC	1	1	1	1		
Bone related signs and symptoms	5	15	5	9		6
Bursal disorders		2		1		1
Connective tissue disorders NEC		1				1
Extremity deformities		1				1
Intervertebral disc disorders NEC	1	3		2	1	1
Joint related disorders NEC		2		2		
Joint related signs and symptoms	26	100	23	59	3	41
Muscle pains	52	169	48	120	4	49
Muscle related signs and symptoms NEC	5	14	2	5	3	9
Muscle tone abnormalities		1		1		
Muscle weakness conditions	2	14	1	5	1	9
Musculoskeletal and connective tissue conditions NEC	6	9	4	6	2	3
Musculoskeletal and connective tissue pain and discomfort	33	95	28	78	5	17

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* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Osteoarthropathies	1	1	1	1		
Psoriatic arthropathies		1				1
Rheumatoid arthropathies		2				2
Soft tissue disorders NEC	1	3	1	2		1
Spondyloarthropathies		1				1
Tendon disorders	1	1			1	1
	134	439	114	293	20	146

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Leukaemias NEC		1				1
Neoplasms unspecified malignancy and site unspecified NEC	1	1	1	1		
Pancreatic neoplasms malignant (excl islet cell and carcinoid)	1	1			1	1
Skin neoplasms benign	1	1			1	1
	3	4	1	1	2	3

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal reflexes		2				2
Absence seizures		1				1
Acute polyneuropathies	1	8			1	8
Autonomic nervous system disorders		5				5

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* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	12	21			12	21
Cerebrovascular venous and sinus thrombosis		1				1
Cervical spinal cord and nerve root disorders		1				1
Coma states	1	2			1	2
Coordination and balance disturbances	2	9		3	2	6
Cortical dysfunction NEC		1				1
Cranial nerve disorders NEC	1	2			1	2
Disturbances in consciousness NEC	14	61	8	25	6	36
Dyskinesias and movement disorders NEC	2	9	2	7		2
Facial cranial nerve disorders	7	25	2	4	5	21
Headaches NEC	63	198	52	138	11	60
Hydrocephalic conditions	1	1			1	1
Lumbar spinal cord and nerve root disorders		1				1
Memory loss (excl dementia)		2				2
Mental impairment (excl dementia and memory loss)	1	2			1	2
Migraine headaches	2	10	1	7	1	3
Mononeuropathies	1	1	1	1		
Muscle tone abnormal	2	8	1	4	1	4
Nervous system disorders NEC	1	1			1	1
Neurological signs and symptoms NEC	26	130	20	82	6	48
Olfactory nerve disorders	1	4	1	2		2
Paraesthesias and dysaesthesias	32	152	20	88	12	64
Paralysis and paresis (excl cranial nerve)	4	17			4	17
Peripheral neuropathies NEC		6				6
Seizures and seizure disorders NEC		2				2
Sensory abnormalities NEC	12	41	11	22	1	19
Speech and language abnormalities	1	9	1	3		6
Transient cerebrovascular events	2	3			2	3
Tremor (excl congenital)		18		12		6
Trigeminal disorders	2	3	1	1	1	2

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	191	757	121	399	70	358

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous		1		1
		1		1

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Device malfunction events NEC	1	1			1	1
Product physical issues		4		4		
Product quality issues NEC		1		1		
	1	6		5	1	1

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms		7		5		2
Behaviour and socialisation disturbances		1				1
Communications disorders		1		1		
Confusion and disorientation	3	15	2	5	1	10

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* AE=Adverse Event

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Depressive disorders	1	2		1	1	1
Disturbances in initiating and maintaining sleep		7		5		2
Dyssomnias		1		1		
Eating disorders NEC		1				1
Emotional and mood disturbances NEC		5		1		4
Increased physical activity levels		1		1		
Obsessive-compulsive disorders and symptoms		1				1
Panic attacks and disorders	1	2	1	1		1
Stereotypies and automatisms	1	1			1	1
	6	45	3	21	3	24

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms		3		2		1
Renal failure and impairment	1	3			1	3
Urinary abnormalities	1	2			1	2
Urinary tract signs and symptoms NEC		1		1		
	2	9		3	2	6

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast signs and symptoms	1	2	1	2		
Cervix disorders NEC		1				1

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* AE=Adverse Event
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System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erection and ejaculation conditions and disorders	1	1			1	1
Menstruation and uterine bleeding NEC	3	6	3	5		1
Menstruation with decreased bleeding	1	2	1	2		
Menstruation with increased bleeding	3	4	2	2	1	2
	9	16	7	11	2	5

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	10	59	6	23	4	36
Bronchospasm and obstruction	2	15	1	2	1	13
Coughing and associated symptoms	5	38	2	16	3	22
Laryngeal spasm, oedema and obstruction		11				11
Lower respiratory tract signs and symptoms	2	2	1	1	1	1
Nasal congestion and inflammations		3		3		
Nasal disorders NEC	2	5	2	5		
Parenchymal lung disorders NEC		1				1
Pharyngeal disorders (excl infections and neoplasms)	2	4		1	2	3
Pneumothorax and pleural effusions NEC	1	1			1	1
Pulmonary oedemas	1	3			1	3
Pulmonary thrombotic and embolic conditions	3	7			3	7
Respiratory failures (excl neonatal)	1	3			1	3
Respiratory signs and symptoms NEC	1	1	1	1		
Respiratory tract disorders NEC		2				2
Upper respiratory tract signs and symptoms	9	71	6	33	3	38
	39	226	19	85	20	141

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes	2	3	2	3		
Alopecias		1		1		
Angioedemas		16				16
Apocrine and eccrine gland disorders	6	33	2	15	4	18
Bullous conditions	1	5	1	5		
Connective tissue disorders		1				1
Dermal and epidermal conditions NEC	3	8	3	5		3
Dermatitis and eczema	3	8	1	3	2	5
Erythemas	11	76	8	51	3	25
Granulomatous and deep cutaneous inflammatory conditions		1		1		
Hyperkeratoses		1		1		
Hypopigmentation disorders	1	1	1	1		
Nail and nail bed conditions (excl infections and infestations)		3		3		
Pruritus NEC	16	81	11	46	5	35
Psoriatic conditions		1		1		
Purpura and related conditions	1	4		1	1	3
Rashes, eruptions and exanthems NEC	18	112	14	58	4	54
Skin vasculitides		1				1
Skin vasomotor conditions		1		1		
Urticarias	9	16	7	12	2	4
	71	373	50	208	21	165

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues		3		1		2
Non-occupational and unspecified environmental problems		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
		4		1		3

System Organ Class

Surgical and medical procedures

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Nervous system therapeutic procedures NEC		1		1
		1		1

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension		16				16
Blood pressure disorders NEC		2		2		
Circulatory collapse and shock		1				1
Haemorrhages NEC	1	2	1	1		1
Lymphoedemas		1				1
Non-site specific embolism and thrombosis	9	12			9	12
Non-site specific necrosis and vascular insufficiency NEC		2		1		1
Non-site specific vascular disorders NEC	1	2		1	1	1
Peripheral embolism and thrombosis	3	8			3	8
Peripheral vascular disorders NEC	3	39	2	17	1	22
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	12	1	3		9
Site specific vascular disorders NEC		3		2		1
Vascular hypertensive disorders NEC	8	46	5	22	3	24
Vascular hypotensive disorders	2	24		7	2	17

* I=Interval, C=Cumulative

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System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vasculitides NEC		1				1
	28	171	9	56	19	115

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Country Where Event Occurred

GUINEA

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Headaches NEC		1		1
		1		1

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Vascular hypertensive disorders NEC		1		1
		1		1

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Country Where Event Occurred

HAITI

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inner ear signs and symptoms		1		1
		1		1

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenic conditions		1		1
		1		1

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dyskinesias and movement disorders NEC		1		1
Neurological signs and symptoms NEC		1		1
		2		2

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Country Where Event Occurred
HOLY SEE (VATICAN CITY STATE)

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular disorders NEC		1		1
		1		1

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenic conditions		1		1
Injection site reactions		1		1
Oedema NEC		2		2
Vaccination site reactions		2		2
		6		6

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Musculoskeletal and connective tissue pain and discomfort		1		1
		1		1

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Country Where Event Occurred

HONDURAS

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
General signs and symptoms NEC	2	2	2	2
	2	2	2	2

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Coronavirus infections	2	2	2	2
	2	2	2	2

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Country Where Event Occurred

HONG KONG

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC		2		2
		2		2

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC	17	33	5	10	12	23
Coronary artery disorders NEC	2	4			2	4
Ischaemic coronary artery disorders	1	2			1	2
Rate and rhythm disorders NEC	2	2			2	2
Ventricular arrhythmias and cardiac arrest	2	2			2	2
	24	43	5	10	19	33

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival and corneal bleeding and vascular disorders	1	1			1	1
Lid, lash and lacrimal infections, irritations and inflammations	2	2	2	2		
	3	3	2	2	1	1

System Organ Class

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* AE=Adverse Event
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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal and abdominal pains (excl oral and throat)		2				2
Gastrointestinal signs and symptoms NEC	1	1	1	1		
Nausea and vomiting symptoms	2	7	2	4		3
Oral soft tissue swelling and oedema	1	1	1	1		
	4	11	4	6		5

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	1	8		6	1	2
Death and sudden death	1	1			1	1
Febrile disorders	3	5	2	3	1	2
Feelings and sensations NEC	1	1	1	1		
General signs and symptoms NEC	2	2	1	1	1	1
Injection site reactions		1		1		
Pain and discomfort NEC	17	34	8	14	9	20
Vaccination site reactions	2	8	1	6	1	2
	27	60	13	32	14	28

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	1	5		2	1	3
Allergies to foods, food additives, drugs and other chemicals	1	4	1	2		2
Anaphylactic and anaphylactoid responses	1	3			1	3

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* AE=Adverse Event

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System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	3	12	1	4	2	8

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Enteroviral infections NEC	1	1	1	1		
Lower respiratory tract and lung infections	2	2			2	2
	3	3	1	1	2	2

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abdominal and gastrointestinal injuries NEC		1		1
Non-site specific injuries NEC		3		3
Skin injuries NEC		1		1
		5		5

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular tests NEC (incl blood pressure)	4	11	2	7	2	4
	4	11	2	7	2	4

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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders		1		1
		1		1

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint related signs and symptoms	1	3		2	1	1
Muscle pains	1	2	1	2		
Muscle related signs and symptoms NEC		1		1		
Muscle weakness conditions		1				1
Musculoskeletal and connective tissue conditions NEC	1	2	1	2		
Musculoskeletal and connective tissue pain and discomfort	2	3	1	1	1	2
	5	12	3	8	2	4

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	1	3			1	3
Coma states	2	2			2	2
Cortical dysfunction NEC		1		1		
Disturbances in consciousness NEC	22	41			22	41
Dyskinesias and movement disorders NEC		1		1		
Facial cranial nerve disorders	13	16			13	16
Headaches NEC	4	9	1	4	3	5

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Migraine headaches		1		1		
Neurological signs and symptoms NEC	25	54	8	21	17	33
Paraesthesias and dysaesthesias	7	22		7	7	15
Paralysis and paresis (excl cranial nerve)		2				2
Seizures and seizure disorders NEC	12	18			12	18
Sensory abnormalities NEC		1		1		
Transient cerebrovascular events	1	1			1	1
Tremor (excl congenital)		1		1		
	87	173	9	37	78	136

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous		1		1
		1		1

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	6	13	2	4	4	9
Lower respiratory tract signs and symptoms	1	1			1	1
Pharyngeal disorders (excl infections and neoplasms)		1		1		
	7	15	2	5	5	10

System Organ Class

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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders		2		2		
Dermatitis and eczema	1	1	1	1		
Erythemas	1	1			1	1
Pruritus NEC	2	3		1	2	2
Rashes, eruptions and exanthems NEC	13	30	4	15	9	15
Urticarias	1	2	1	1		1
	18	39	6	20	12	19

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	1	1			1	1
Aortic aneurysms and dissections	1	1			1	1
Vascular hypertensive disorders NEC	11	26	4	7	7	19
	13	28	4	7	9	21

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Country Where Event Occurred

HUNGARY

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias NEC	1	2			1	2
Eosinophilic disorders	1	1	1	1		
Leukocytoses NEC		1				1
Lymphatic system disorders NEC	20	72	17	61	3	11
Thrombocytopenias	1	1			1	1
	23	77	18	62	5	15

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders	1	1			1	1
Cardiac disorders NEC	3	6			3	6
Cardiac signs and symptoms NEC	6	14	6	12		2
Cardiomyopathies	1	1			1	1
Heart failures NEC	13	21			13	21
Ischaemic coronary artery disorders	5	11			5	11
Left ventricular failures	1	2			1	2
Myocardial disorders NEC		2		1		1
Noninfectious pericarditis		1				1
Rate and rhythm disorders NEC	10	23	2	8	8	15
Supraventricular arrhythmias	3	7			3	7
Tricuspid valvular disorders		1				1
Ventricular arrhythmias and cardiac arrest	4	5			4	5
	47	95	8	21	39	74

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* AE=Adverse Event

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System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	1	11	1	9		2
Inner ear signs and symptoms	1	6	1	6		
	2	17	2	15		2

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic thyroiditis		2		1		1
Thyroid hyperfunction disorders	2	2			2	2
	2	4		1	2	3

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid movement disorders		1		1		
Iris and uveal tract infections, irritations and inflammations		1				1
Lacrimation disorders		7		7		
Lid, lash and lacrimal infections, irritations and inflammations		4		4		
Ocular bleeding and vascular disorders NEC	2	4			2	4
Ocular disorders NEC	2	8	2	6		2
Ocular infections, inflammations and associated manifestations	2	7		4	2	3
Ocular nerve and muscle disorders	1	1	1	1		
Ocular sensation disorders	1	2	1	2		

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Retinal bleeding and vascular disorders (excl retinopathy)	3	3			3	3
Retinal, choroid and vitreous infections and inflammations		1				1
Visual disorders NEC	1	4	1	4		
Visual impairment and blindness (excl colour blindness)		3		1		2
	12	46	5	30	7	16

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis	1	1			1	1
Dental disorders NEC		1				1
Dental pain and sensation disorders		1		1		
Diarrhoea (excl infective)	10	35	7	29	3	6
Dyspeptic signs and symptoms		2		2		
Flatulence, bloating and distension		3		3		
Gastric and oesophageal haemorrhages	2	2			2	2
Gastric ulcers and perforation		1				1
Gastrointestinal and abdominal pains (excl oral and throat)	5	15	3	13	2	2
Gastrointestinal atonic and hypomotility disorders NEC		2		2		
Gastrointestinal disorders NEC	2	3	2	3		
Gastrointestinal inflammatory disorders NEC		1				1
Gastrointestinal signs and symptoms NEC	2	17	1	6	1	11
Gastrointestinal spastic and hypermotility disorders	1	2	1	2		
Gastrointestinal stenosis and obstruction NEC	1	1			1	1
Gingival disorders, signs and symptoms NEC		2		2		

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea and vomiting symptoms	33	96	31	87	2	9
Non-mechanical ileus	1	2			1	2
Non-site specific gastrointestinal haemorrhages	2	5			2	5
Oral dryness and saliva altered	2	4	2	3		1
Oral soft tissue disorders NEC	1	1			1	1
Oral soft tissue signs and symptoms	2	10	1	7	1	3
Oral soft tissue swelling and oedema		6		2		4
Salivary gland enlargements		1		1		
Stomatitis and ulceration		1		1		
Tongue disorders	1	2	1	2		
Tongue signs and symptoms	2	4		2	2	2
	68	221	49	168	19	53

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	69	236	66	213	3	23
Death and sudden death	17	23			17	23
Febrile disorders	53	162	45	145	8	17
Feelings and sensations NEC	29	125	28	113	1	12
Gait disturbances	2	6		4	2	2
General signs and symptoms NEC	21	55	13	38	8	17
Inflammations	2	5	2	5		
Injection site reactions	3	4	3	4		
Interactions	1	3	1	3		
Mucosal findings abnormal		1				1
Oedema NEC		7		3		4
Pain and discomfort NEC	16	50	14	45	2	5
Therapeutic and nontherapeutic responses	29	64		2	29	62

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site reactions	57	203	56	201	1	2
	299	944	228	776	71	168

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholecystitis and cholelithiasis		1				1
Hepatic enzymes and function abnormalities	1	1	1	1		
Hepatic vascular disorders	1	1			1	1
Structural and other bile duct disorders		1				1
	2	4	1	1	1	3

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic sarcoidosis	1	1			1	1
Allergic conditions NEC	2	14		8	2	6
Allergies to foods, food additives, drugs and other chemicals		3		2		1
Anaphylactic and anaphylactoid responses	3	7			3	7
Immune and associated conditions NEC	1	1	1	1		
	7	26	1	11	6	15

System Organ Class

Infections and infestations

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacterial infections NEC		1				1
Clostridia infections	1	1			1	1
Coronavirus infections	53	95	4	10	49	85
Dental and oral soft tissue infections		1		1		
Female reproductive tract infections	2	2	1	1	1	1
Herpes viral infections	6	19	6	18		1
Influenza viral infections		1		1		
Lower respiratory tract and lung infections	4	10		1	4	9
Polyomavirus infections	1	1			1	1
Sepsis, bacteraemia, viraemia and fungaemia NEC	2	2			2	2
Streptococcal infections		1				1
Upper respiratory tract infections	5	11	5	11		
Urinary tract infections	2	2	2	2		
	76	147	18	45	58	102

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone and joint injuries NEC		1				1
Exposures associated with pregnancy, delivery and lactation	48	92	47	90	1	2
Exposures to agents or circumstances NEC	1	1	1	1		
Heat injuries (excl thermal burns)	1	1	1	1		
Limb fractures and dislocations		2				2
Medication errors, product use errors and issues NEC	49	92	49	92		
Muscle, tendon and ligament injuries		2		2		
Non-site specific injuries NEC		9		4		5
Off label uses	49	92	49	92		

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* AE=Adverse Event

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Overdoses NEC		1		1		
Product administration errors and issues	2	8	1	7	1	1
Site specific injuries NEC	1	1			1	1
Skull fractures, facial bone fractures and dislocations		1				1
Vaccination related complications	1	2	1	2		
	152	305	149	292	3	13

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood counts NEC		1				1
Blood gas and acid base analyses	1	4	1	3		1
Carbohydrate tolerance analyses (incl diabetes)		5		4		1
Coagulation and bleeding analyses	1	2			1	2
Haematological analyses NEC		1		1		
Heart rate and pulse investigations	10	23	6	17	4	6
Immunology analyses NEC		2		2		
Investigations NEC	1	1	1	1		
Liver function analyses	4	8	1	5	3	3
Mineral and electrolyte analyses		1		1		
Physical examination procedures and organ system status	3	6	1	3	2	3
Pituitary analyses anterior		1		1		
Renal function analyses		1		1		
Respiratory and pulmonary function diagnostic procedures	1	1	1	1		
Thyroid analyses		3		3		
Urinary tract function analyses NEC	1	1	1	1		
Vascular tests NEC (incl blood pressure)	12	43	7	25	5	18

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* AE=Adverse Event

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Virus identification and serology	4	16		8	4	8
White blood cell analyses	1	3	1	3		
	39	123	20	80	19	43

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	8	17	8	16		1
Diabetes mellitus (incl subtypes)	1	1			1	1
General nutritional disorders NEC	3	6	1	2	2	4
Hypoglycaemic conditions NEC		1		1		
Metabolic acidoses (excl diabetic acidoses)		1				1
Total fluid volume decreased	1	2			1	2
	13	28	9	19	4	9

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC		3		1		2
Bone related signs and symptoms	2	4	2	4		
Bursal disorders		1		1		
Connective tissue disorders NEC		1				1
Intervertebral disc disorders NEC		1		1		
Joint related disorders NEC		1		1		
Joint related signs and symptoms	24	45	24	41		4
Muscle pains	23	71	23	70		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle related signs and symptoms NEC	3	8	2	6	1	2
Muscle weakness conditions	5	13	5	13		
Musculoskeletal and connective tissue conditions NEC	4	10	3	8	1	2
Musculoskeletal and connective tissue pain and discomfort	39	115	35	109	4	6
Osteoarthropathies		1		1		
Rheumatoid arthropathies	1	1			1	1
Soft tissue disorders NEC		1		1		
Spondyloarthropathies		1				1
Tendon disorders	1	1	1	1		
	102	278	95	258	7	20

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Leukaemias acute lymphocytic		1		1
Neoplasms malignant site unspecified NEC	1	1	1	1
Neoplasms unspecified malignancy and site unspecified NEC	2	3	2	3
Respiratory tract and pleural neoplasms malignancy unspecified NEC	2	2	2	2
	5	7	5	7

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal reflexes		2		2		
Acute polyneuropathies		1				1
Autonomic nervous system disorders	1	1			1	1
Central nervous system haemorrhages and cerebrovascular accidents	4	10			4	10
Cervical spinal cord and nerve root disorders		1		1		
Coordination and balance disturbances	4	6	2	4	2	2
Dementia (excl Alzheimer's type)	2	3			2	3
Disturbances in consciousness NEC	14	44	4	18	10	26
Dyskinesias and movement disorders NEC	4	5	1	1	3	4
Encephalopathies NEC	1	1			1	1
Facial cranial nerve disorders	4	10	3	5	1	5
Headaches NEC	42	135	41	127	1	8
Lumbar spinal cord and nerve root disorders		1				1
Memory loss (excl dementia)		2		1		1
Mental impairment (excl dementia and memory loss)		2		1		1
Migraine headaches	2	8	2	7		1
Muscle tone abnormal		1				1
Nervous system disorders NEC	2	2	1	1	1	1
Neurological signs and symptoms NEC	27	72	23	62	4	10
Olfactory nerve disorders		4		4		
Paraesthesias and dysaesthesias	16	56	12	46	4	10
Paralysis and paresis (excl cranial nerve)	1	6			1	6
Peripheral neuropathies NEC		1				1
Seizures and seizure disorders NEC	1	1			1	1
Sensory abnormalities NEC	4	19	4	17		2
Sleep disturbances NEC	1	1	1	1		
Speech and language abnormalities	3	4	1	2	2	2
Spinal cord and nerve root disorders NEC		2		1		1
Structural brain disorders NEC	1	2		1	1	1
Transient cerebrovascular events	1	2			1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tremor (excl congenital)	6	17	5	13	1	4
Trigeminal disorders	1	1	1	1		
	142	423	101	316	41	107

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions not specified as induced or spontaneous		3		3
Still birth and foetal death	1	1	1	1
	1	4	1	4

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Counterfeit, falsified and substandard products		1		1
Product physical issues		1		1
Product quality issues NEC		1		1
		3		3

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour NEC		1		1		

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* AE=Adverse Event

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	1	6	1	6		
Behaviour and socialisation disturbances		1				1
Confusion and disorientation	1	5		2	1	3
Depressive disorders		2		2		
Disturbances in initiating and maintaining sleep	3	12	3	12		
Dyssomnias	2	3	1	2	1	1
Emotional and mood disturbances NEC	1	4	1	4		
Fear symptoms and phobic disorders (incl social phobia)	2	4	2	4		
Increased physical activity levels	1	3		2	1	1
Mood alterations with depressive symptoms	1	3	1	3		
Mood disorders NEC		1				1
Panic attacks and disorders		1		1		
Psychiatric symptoms NEC		2				2
Sleep disorders NEC	2	6	2	6		
Speech articulation and rhythm disturbances	1	2	1	1		1
Stereotypies and automatisms	1	1	1	1		
Thinking disturbances		1		1		
	16	58	13	48	3	10

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	3	6	3	5		1
Genitourinary tract infections and inflammations NEC	1	1	1	1		
Renal failure and impairment	3	5			3	5
Renal neoplasms		1		1		
Urinary abnormalities		3		2		1

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* AE=Adverse Event

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System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urinary tract signs and symptoms NEC		3		3		
	7	19	4	12	3	7

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast disorders NEC		1				1
Breast signs and symptoms		3		3		
Lactation disorders		1		1		
Menstruation and uterine bleeding NEC	2	3	2	3		
Menstruation with decreased bleeding	1	2	1	2		
Menstruation with increased bleeding	2	2	2	2		
Pelvis and broad ligament disorders NEC		1		1		
Prostatic signs, symptoms and disorders NEC	1	1	1	1		
Vulvovaginal signs and symptoms		1		1		
	6	15	6	14		1

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	23	47	7	17	16	30
Bronchospasm and obstruction	1	3		1	1	2
Conditions associated with abnormal gas exchange	2	6			2	6
Coughing and associated symptoms	8	24	3	16	5	8
Laryngeal spasm, oedema and obstruction		2				2

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* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lower respiratory tract inflammatory and immunologic conditions	1	1			1	1
Nasal congestion and inflammations	2	4	2	4		
Nasal disorders NEC		1		1		
Parenchymal lung disorders NEC		1				1
Pharyngeal disorders (excl infections and neoplasms)	2	7	1	5	1	2
Pulmonary oedemas	4	4			4	4
Pulmonary thrombotic and embolic conditions	6	7			6	7
Respiratory failures (excl neonatal)	4	7			4	7
Respiratory signs and symptoms NEC	2	3	1	2	1	1
Respiratory tract disorders NEC	1	2	1	2		
Thoracic musculoskeletal disorders	1	1			1	1
Upper respiratory tract signs and symptoms	16	53	12	40	4	13
	73	173	27	88	46	85

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecias		1		1		
Angioedemas	1	3			1	3
Apocrine and eccrine gland disorders	5	17	4	15	1	2
Bullous conditions		5		3		2
Dermal and epidermal conditions NEC	8	28	7	26	1	2
Dermatitis and eczema	1	3	1	3		
Erythemas	4	21	3	19	1	2
Papulosquamous conditions		1		1		
Pruritus NEC	6	18	5	16	1	2
Purpura and related conditions	1	2		1	1	1

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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rashes, eruptions and exanthems NEC	6	38	4	30	2	8
Skin and subcutaneous conditions NEC		1				1
Skin and subcutaneous tissue ulcerations	1	2	1	1		1
Skin cysts and polyps	1	1	1	1		
Skin haemorrhages	1	1	1	1		
Skin hyperplasias and hypertrophies		1		1		
Skin injuries and mechanical dermatoses		1				1
Skin vasculitides		1		1		
Urticarias	9	18	7	14	2	4
	44	163	34	134	10	29

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	1	2			1	2
Blood pressure disorders NEC	5	9	4	6	1	3
Circulatory collapse and shock	6	9			6	9
Haemorrhages NEC	1	7		1	1	6
Lymphoedemas		1		1		
Non-site specific embolism and thrombosis	1	1			1	1
Non-site specific necrosis and vascular insufficiency NEC	1	3			1	3
Non-site specific vascular disorders NEC	2	4	1	3	1	1
Peripheral embolism and thrombosis	5	11		1	5	10
Peripheral vascular disorders NEC	3	13	2	9	1	4
Peripheral vasoconstriction, necrosis and vascular insufficiency		5		4		1
Site specific vascular disorders NEC		5		4		1
Varicose veins NEC		2		2		

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System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular hypertensive disorders NEC	2	6	1	4	1	2
Vascular hypotensive disorders	1	8		2	1	6
Vasculitides NEC		1		1		
	28	87	8	38	20	49

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Country Where Event Occurred

ICELAND

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	1	6	1	6
	1	6	1	6

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC	1	1	1	1		
Heart failures NEC		2				2
Ischaemic coronary artery disorders		3				3
Rate and rhythm disorders NEC	3	6	1	2	2	4
Supraventricular arrhythmias		1				1
Ventricular arrhythmias and cardiac arrest		1				1
	4	14	2	3	2	11

System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cerebral disorders congenital		1		1
		1		1

System Organ Class

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* AE=Adverse Event
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System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear disorders NEC		1		1
		1		1

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular disorders NEC		2		2
Visual impairment and blindness (excl colour blindness)		1		1
		3		3

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Gastrointestinal and abdominal pains (excl oral and throat)		1		1
Gastrointestinal signs and symptoms NEC		1		1
Nausea and vomiting symptoms	8	21	8	21
Oral dryness and saliva altered		1		1
Salivary gland enlargements		1		1
Salivary gland infections and inflammations		1		1
	8	26	8	26

System Organ Class

General disorders and administration site conditions

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	9	59	9	53		6
Death and sudden death	1	9			1	9
Febrile disorders	15	57	14	52	1	5
Feelings and sensations NEC	7	27	7	27		
General signs and symptoms NEC	1	6	1	4		2
Injection site reactions	1	3	1	3		
Oedema NEC		1		1		
Pain and discomfort NEC	4	16	2	13	2	3
Vaccination site reactions	11	47	11	47		
	49	225	45	200	4	25

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic and anaphylactoid responses	1	1	1	1
	1	1	1	1

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lower respiratory tract and lung infections		4				4
Sepsis, bacteraemia, viraemia and fungaemia NEC		1				1
Upper respiratory tract infections	1	6	1	6		
	1	11	1	6		5

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* AE=Adverse Event

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation	1	3		2	1	1
Medication errors, product use errors and issues NEC	1	6	1	6		
Non-site specific injuries NEC		1		1		
Off label uses	1	5	1	5		
Skin injuries NEC		1				1
	3	16	2	14	1	2

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses		2				2
Coagulation and bleeding analyses		1				1
ECG investigations	1	1			1	1
Heart rate and pulse investigations	3	5	3	5		
Liver function analyses		2		1		1
Physical examination procedures and organ system status		1				1
Vascular tests NEC (incl blood pressure)	1	3	1	2		1
	5	15	4	8	1	7

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders		4		4		
Total fluid volume increased		1				1

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* AE=Adverse Event

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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
		5		4		1

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	1	2	1	2		
Bone related signs and symptoms	1	3	1	3		
Joint related signs and symptoms	2	10	2	10		
Muscle pains	13	38	13	38		
Muscle related signs and symptoms NEC		2		2		
Muscle weakness conditions	1	2	1	2		
Musculoskeletal and connective tissue pain and discomfort	6	18	5	15	1	3
	24	75	23	72	1	3

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents		1				1
Coordination and balance disturbances		1				1
Cortical dysfunction NEC	2	4		1	2	3
Disturbances in consciousness NEC	1	7			1	7
Dyskinesias and movement disorders NEC		1				1
Facial cranial nerve disorders	1	1			1	1
Headaches NEC	15	52	15	52		
Memory loss (excl dementia)		1		1		

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* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Migraine headaches		1		1		
Narcolepsy and hypersomnia		1		1		
Neurological signs and symptoms NEC	7	18	7	18		
Paraesthesias and dysaesthesias	3	8	2	7	1	1
Sensory abnormalities NEC	1	3	1	3		
Speech and language abnormalities	1	1			1	1
Transient cerebrovascular events		2				2
Tremor (excl congenital)	1	2	1	2		
	32	104	26	86	6	18

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Behaviour and socialisation disturbances		1				1
Confusion and disorientation	1	2			1	2
Deliria		3				3
Disturbances in initiating and maintaining sleep		2		2		
Dyssomnias		1		1		
Emotional and mood disturbances NEC	1	1			1	1
Sleep disorders NEC	1	2	1	1		1
	3	12	1	4	2	8

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms		2		1		1

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System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
		2		1		1

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breast infections and inflammations		1		1
		1		1

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	1	9	1	5		4
Bronchospasm and obstruction		2				2
Conditions associated with abnormal gas exchange		3				3
Coughing and associated symptoms		6		5		1
Lower respiratory tract inflammatory and immunologic conditions		1				1
Lower respiratory tract signs and symptoms	1	2	1	2		
Parenchymal lung disorders NEC		1				1
Pharyngeal disorders (excl infections and neoplasms)		1		1		
Pulmonary oedemas		1				1
Pulmonary thrombotic and embolic conditions	1	1			1	1
Respiratory failures (excl neonatal)		1				1
Respiratory signs and symptoms NEC		1		1		
Upper respiratory tract signs and symptoms	1	11	1	11		

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* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	4	40	3	25	1	15

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	1	5	1	4		1
Dermal and epidermal conditions NEC		4		4		
Erythemas		5		5		
Pruritus NEC	1	6	1	6		
Rashes, eruptions and exanthems NEC	1	4	1	4		
Urticarias	1	1	1	1		
	4	25	4	24		1

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysms and dissections		1				1
Circulatory collapse and shock		1				1
Peripheral embolism and thrombosis		3				3
Peripheral vascular disorders NEC		1		1		
Site specific vascular disorders NEC		2		2		
Vascular hypertensive disorders NEC		1		1		
Vascular hypotensive disorders	1	1	1	1		
	1	10	1	5		5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

INDIA

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Ischaemic coronary artery disorders	1	1	1	1
	1	1	1	1

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Nausea and vomiting symptoms		1		1
		1		1

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Asthenic conditions		2		2
Pain and discomfort NEC		1		1
Therapeutic and nontherapeutic responses	3	4	3	4
Vaccination site reactions		1		1
	3	8	3	8

System Organ Class

Infections and infestations

Interval Total #	Cumulative Total #	Spontaneous	
		Serious	

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coronavirus infections	4	5	4	5
	4	5	4	5

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Off label uses		1		1
Product administration errors and issues		1		1
		2		2

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Blood gas and acid base analyses		1		1
		1		1

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Disturbances in consciousness NEC		1		1
Headaches NEC		1		1
Neurological signs and symptoms NEC		1		1
		3		3

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Counterfeit, falsified and substandard products		1		1
		1		1

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Country Where Event Occurred

IRAQ

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Ischaemic coronary artery disorders	1	1	1	1
	1	1	1	1

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Nausea and vomiting symptoms		1		1
		1		1

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	1	2	1	2		
Febrile disorders	2	4	2	4		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gait disturbances	1	1	1	1		
Pain and discomfort NEC	1	1			1	1
Therapeutic and nontherapeutic responses	1	1			1	1
Vaccination site reactions	1	3	1	3		
	7	12	5	10	2	2

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast infections	1	1			1	1
Coronavirus infections	5	5	4	4	1	1
	6	6	4	4	2	2

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Blood gas and acid base analyses	1	1	1	1
	1	1	1	1

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders		1		1

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* AE=Adverse Event
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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
		1		1

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle pains		1		1
Musculoskeletal and connective tissue pain and discomfort	2	2	2	2
	2	3	2	3

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	3	3			3	3
Headaches NEC		1		1		
Paraesthesias and dysaesthesias	1	1	1	1		
Tremor (excl congenital)	1	1	1	1		
	5	6	2	3	3	3

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Disturbances in initiating and maintaining sleep		1		1

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
		1		1

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Coughing and associated symptoms		1		1
		1		1

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Apocrine and eccrine gland disorders	1	1	1	1
	1	1	1	1

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Peripheral embolism and thrombosis	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

IRELAND

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias NEC		1				1
Lymphatic system disorders NEC	14	46	3	7	11	39
Neutropenias	1	2			1	2
	15	49	3	7	12	42

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC		1				1
Cardiac signs and symptoms NEC	6	23	1	3	5	20
Coronary artery disorders NEC		2				2
Heart failures NEC		2				2
Ischaemic coronary artery disorders	3	6			3	6
Noninfectious myocarditis	2	3			2	3
Noninfectious pericarditis	2	2			2	2
Pericardial disorders NEC	1	1			1	1
Rate and rhythm disorders NEC	8	30		1	8	29
Supraventricular arrhythmias	2	6			2	6
Ventricular arrhythmias and cardiac arrest	4	7			4	7
	28	83	1	4	27	79

System Organ Class

Ear and labyrinth disorders

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	4	8	1	2	3	6
Hearing losses	1	3			1	3
Inner ear signs and symptoms	6	14	2	6	4	8
Tympanic membrane disorders (excl infections)	1	1			1	1
	12	26	3	8	9	18

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute and chronic thyroiditis	1	1	1	1
	1	1	1	1

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Choroid and vitreous structural change, deposit and degeneration	1	4	1	1		3
Eyelid movement disorders		3				3
Iris and uveal tract infections, irritations and inflammations	1	1			1	1
Lacrimation disorders	1	5			1	5
Lid, lash and lacrimal infections, irritations and inflammations	3	6		1	3	5
Ocular disorders NEC	2	14		3	2	11
Ocular infections, inflammations and associated manifestations	3	8		2	3	6
Ocular nerve and muscle disorders		3				3

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular sensation disorders	1	3			1	3
Pupil disorders		2		2		
Visual disorders NEC	3	10	1	3	2	7
Visual field disorders	1	1	1	1		
Visual impairment and blindness (excl colour blindness)		6		1		5
	16	66	3	14	13	52

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal findings abnormal	1	1	1	1		
Acute and chronic pancreatitis		1				1
Colitis (excl infective)	1	1			1	1
Dental pain and sensation disorders	4	4	3	3	1	1
Diarrhoea (excl infective)	14	34	7	10	7	24
Dyspeptic signs and symptoms	2	2	2	2		
Faecal abnormalities NEC		2				2
Flatulence, bloating and distension	1	6		2	1	4
Gastrointestinal and abdominal pains (excl oral and throat)	9	21	3	6	6	15
Gastrointestinal atonic and hypomotility disorders NEC	1	3	1	1		2
Gastrointestinal disorders NEC		1				1
Gastrointestinal signs and symptoms NEC	6	14	2	5	4	9
Gastrointestinal spastic and hypermotility disorders	1	2	1	1		1
Intestinal haemorrhages	1	1			1	1
Nausea and vomiting symptoms	69	214	28	60	41	154
Non-site specific gastrointestinal haemorrhages		4				4

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* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral dryness and saliva altered		4		2		2
Oral soft tissue disorders NEC		1				1
Oral soft tissue signs and symptoms	10	33	4	10	6	23
Oral soft tissue swelling and oedema	2	13	1	1	1	12
Tongue disorders		1				1
Tongue signs and symptoms	2	10		1	2	9
	124	373	53	105	71	268

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse effect absent		1		1		
Asthenic conditions	118	325	56	115	62	210
Complications associated with device NEC		2		2		
Death and sudden death	2	14			2	14
Febrile disorders	65	168	29	53	36	115
Feelings and sensations NEC	73	178	35	52	38	126
Gait disturbances	2	11		1	2	10
General signs and symptoms NEC	26	77	14	25	12	52
Inflamations	1	3			1	3
Injection site reactions	3	9	1	3	2	6
Mass conditions NEC		2				2
Pain and discomfort NEC	58	186	22	46	36	140
Therapeutic and nontherapeutic responses	7	13			7	13
Vaccination site reactions	49	124	22	53	27	71
	404	1,113	179	351	225	762

System Organ Class

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System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cholestasis and jaundice		1		1
Hepatobiliary signs and symptoms	1	1	1	1
	1	2	1	2

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	1	10	1	2		8
Allergies to foods, food additives, drugs and other chemicals		2				2
Anaphylactic and anaphylactoid responses	3	13			3	13
	4	25	1	2	3	23

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections		2				2
Bacterial infections NEC	2	6			2	6
Breast infections		2				2
Central nervous system and spinal infections		1				1
Coronavirus infections	9	22	2	3	7	19
Ear infections	1	2			1	2
Eye and eyelid infections	2	4		1	2	3
Herpes viral infections	5	12	1	3	4	9
Infections NEC	1	5	1	2		3
Influenza viral infections	1	3	1	2		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lower respiratory tract and lung infections	4	7			4	7
Sepsis, bacteraemia, viraemia and fungaemia NEC		1				1
Staphylococcal infections		1				1
Upper respiratory tract infections	3	7	2	3	1	4
Urinary tract infections	2	3		1	2	2
Viral infections NEC	1	1	1	1		
	31	79	8	16	23	63

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental exposures to product		3		3		
Conditions caused by cold	1	2			1	2
Exposures associated with pregnancy, delivery and lactation	5	23	3	19	2	4
Medication errors, product use errors and issues NEC	1	19	1	19		
Muscle, tendon and ligament injuries	1	1			1	1
Nerve injuries NEC	1	2			1	2
Non-site specific injuries NEC	7	11		1	7	10
Off label uses	3	13	3	13		
Overdoses NEC	1	1	1	1		
Pathways and sources of exposure		2		2		
Product administration errors and issues	11	33	10	32	1	1
Product preparation errors and issues	6	14	5	13	1	1
Site specific injuries NEC	2	3			2	3
Skin injuries NEC	1	3	1	3		
Underdoses NEC	1	11	1	11		
	41	141	25	117	16	24

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	2	14			2	14
Carbohydrate tolerance analyses (incl diabetes)		1				1
ECG investigations	1	1			1	1
Haematological analyses NEC	1	1	1	1		
Heart rate and pulse investigations	6	23	2	3	4	20
Investigations NEC		1				1
Liver function analyses		3				3
Mineral and electrolyte analyses		1				1
Musculoskeletal and soft tissue histopathology procedures	1	1	1	1		
Ophthalmic function diagnostic procedures		1				1
Physical examination procedures and organ system status	2	11		1	2	10
Platelet analyses		2				2
Protein analyses NEC	1	3	1	1		2
Red blood cell analyses		1				1
Respiratory and pulmonary function diagnostic procedures		1				1
Skeletal and cardiac muscle analyses	1	2			1	2
Tissue enzyme analyses NEC		1				1
Urinalysis NEC		1				1
Urinary tract function analyses NEC	1	1			1	1
Vascular tests NEC (incl blood pressure)	2	14		1	2	13
Virus identification and serology		1				1
White blood cell analyses	1	3		1	1	2
	19	88	5	9	14	79

System Organ Class

Metabolism and nutrition disorders

Interval Total #

Cumulative Total #

Spontaneous	
Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	12	24	3	5	9	19
Calcium metabolism disorders	1	1	1	1		
Diabetes mellitus (incl subtypes)	1	1			1	1
Fluid intake decreased	1	1			1	1
General nutritional disorders NEC	3	4			3	4
Hypoglycaemic conditions NEC		2				2
Metabolic acidoses (excl diabetic acidoses)		1				1
Total fluid volume decreased		2		1		1
	18	36	4	7	14	29

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	2	2			2	2
Bone disorders NEC	1	1	1	1		
Bone related signs and symptoms	7	14	3	5	4	9
Intervertebral disc disorders NEC	1	1	1	1		
Joint related disorders NEC		1				1
Joint related signs and symptoms	44	99	18	35	26	64
Muscle pains	42	99	24	36	18	63
Muscle related signs and symptoms NEC	4	20	2	6	2	14
Muscle weakness conditions	3	9			3	9
Musculoskeletal and connective tissue conditions NEC	10	25	3	9	7	16
Musculoskeletal and connective tissue pain and discomfort	54	153	33	61	21	92
Rheumatoid arthropathies	1	1			1	1
Soft tissue disorders NEC	1	4		1	1	3
Spondyloarthropathies	1	1			1	1

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* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	171	430	85	155	86	275

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Skin neoplasms benign		1		1
		1		1

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	7	11			7	11
Central nervous system vascular disorders NEC		1				1
Coma states		1				1
Coordination and balance disturbances	2	6	2	3		3
Cortical dysfunction NEC	2	4			2	4
Cranial nerve disorders NEC		1				1
Disturbances in consciousness NEC	36	86	4	6	32	80
Dyskinesias and movement disorders NEC	1	4		1	1	3
Encephalopathies NEC		1				1
Eye movement disorders		1				1
Facial cranial nerve disorders	12	31		1	12	30
Generalised tonic-clonic seizures	1	1			1	1
Headaches NEC	93	244	44	75	49	169
Hydrocephalic conditions		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lumbar spinal cord and nerve root disorders	2	2	1	1	1	1
Memory loss (excl dementia)	2	4			2	4
Mental impairment (excl dementia and memory loss)	1	5		2	1	3
Migraine headaches	8	16	5	7	3	9
Mononeuropathies		1				1
Muscle tone abnormal		2				2
Myelitis (incl infective)		1				1
Narcolepsy and hypersomnia	4	5	1	1	3	4
Nervous system disorders NEC		2				2
Neurological signs and symptoms NEC	47	126	15	33	32	93
Olfactory nerve disorders	1	3		1	1	2
Paraesthesias and dysaesthesias	39	117	18	38	21	79
Paralysis and paresis (excl cranial nerve)	1	4			1	4
Peripheral neuropathies NEC		1				1
Seizures and seizure disorders NEC	3	8			3	8
Sensory abnormalities NEC	14	34	7	12	7	22
Sleep disturbances NEC		1				1
Speech and language abnormalities	3	9	2	3	1	6
Structural brain disorders NEC	1	1			1	1
Transient cerebrovascular events	2	5			2	5
Tremor (excl congenital)	3	13	1	2	2	11
Trigeminal disorders	2	5			2	5
	287	758	100	186	187	572

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous	2	5	2	5

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Haemorrhagic complications of pregnancy	1	1	1	1
	3	6	3	6

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Device physical property and chemical issues	2	2	2	2
Product distribution and storage issues	1	2	1	2
Product packaging issues		1		1
Product physical issues	1	1	1	1
Product quality issues NEC		5		5
	4	11	4	11

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	6	15	4	6	2	9
Confusion and disorientation	5	16	1	1	4	15
Deliria	1	1			1	1
Depressive disorders	2	2	1	1	1	1
Disturbances in initiating and maintaining sleep	16	32	6	7	10	25
Dyssomnias		1		1		
Eating disorders NEC	1	1	1	1		
Emotional and mood disturbances NEC	2	5			2	5
Fluctuating mood symptoms		1				1
Hallucinations (excl sleep-related)		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Increased physical activity levels	1	1			1	1
Mood alterations with depressive symptoms		2				2
Panic attacks and disorders		3				3
Sleep disorders NEC	2	3			2	3
Thinking disturbances	1	1	1	1		
	37	85	14	18	23	67

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	1	6		1	1	5
Urinary abnormalities		4		2		2
	1	10		3	1	7

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast disorders NEC		1				1
Breast signs and symptoms		9		1		8
Menstruation and uterine bleeding NEC	2	7		1	2	6
Menstruation with decreased bleeding		2		1		1
Menstruation with increased bleeding	3	4	3	4		
Vulvovaginal disorders NEC		3				3
	5	26	3	7	2	19

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	17	49		1	17	48
Bronchospasm and obstruction		9				9
Conditions associated with abnormal gas exchange		1				1
Coughing and associated symptoms	7	18	4	5	3	13
Laryngeal spasm, oedema and obstruction		3				3
Lower respiratory tract inflammatory and immunologic conditions		1				1
Lower respiratory tract signs and symptoms	1	2			1	2
Nasal congestion and inflammations	1	4	1	2		2
Nasal disorders NEC		3		1		2
Paranasal sinus disorders (excl infections and neoplasms)		1				1
Pharyngeal disorders (excl infections and neoplasms)	2	11	1	5	1	6
Pulmonary oedemas	1	1			1	1
Pulmonary thrombotic and embolic conditions	1	3			1	3
Respiratory failures (excl neonatal)		1				1
Respiratory tract disorders NEC		1				1
Upper respiratory tract signs and symptoms	8	35	5	13	3	22
	38	143	11	27	27	116

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	1	5			1	5
Apocrine and eccrine gland disorders	12	42	5	10	7	32
Bullous conditions		1				1
Dermal and epidermal conditions NEC	3	10	2	3	1	7
Dermatitis and eczema	2	6	1	2	1	4

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythemas	3	10	1	4	2	6
Exfoliative conditions	1	2			1	2
Panniculitides	1	1			1	1
Photosensitivity and photodermatosis conditions	1	1			1	1
Pruritus NEC	14	34	7	13	7	21
Psoriatic conditions	2	2	2	2		
Purpura and related conditions	1	1			1	1
Rashes, eruptions and exanthems NEC	34	75	11	21	23	54
Skin dystrophies		1				1
Skin injuries and mechanical dermatoses	1	1			1	1
Urticarias	8	27	4	9	4	18
	84	219	33	64	51	155

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	33	62	6	10	27	52
	33	62	6	10	27	52

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aneurysms and dissections non-site specific	1	1	1	1		
Aortic aneurysms and dissections		1				1
Haemorrhages NEC		1				1
Non-site specific embolism and thrombosis		2				2

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Non-site specific vascular disorders NEC	1	1			1	1
Peripheral embolism and thrombosis	1	7			1	7
Peripheral vascular disorders NEC	7	16	3	4	4	12
Peripheral vasoconstriction, necrosis and vascular insufficiency	3	3	2	2	1	1
Site specific vascular disorders NEC	1	12	1	4		8
Vascular hypertensive disorders NEC	8	25	2	3	6	22
Vascular hypotensive disorders	1	12		3	1	9
	23	81	9	17	14	64

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* AE=Adverse Event
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Country Where Event Occurred

ISRAEL

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias haemolytic immune		1				1
Anaemias haemolytic NEC		1				1
Anaemias NEC	1	3		1	1	2
Coagulopathies		1				1
Leukocytoses NEC		8		1		7
Leukopenias NEC		2				2
Lymphatic system disorders NEC	3	23	3	19		4
Marrow depression and hypoplastic anaemias		1				1
Neutropenias		1				1
Thrombocytopenias		3				3
	4	44	3	21	1	23

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders	2	2	1	1	1	1
Cardiac disorders NEC	1	3			1	3
Cardiac signs and symptoms NEC	2	14	2	12		2
Heart failures NEC	1	10			1	10
Ischaemic coronary artery disorders		15				15
Myocardial disorders NEC	1	2		1	1	1
Noninfectious myocarditis	14	84			14	84
Noninfectious pericarditis	3	46			3	46
Pericardial disorders NEC	5	8			5	8
Rate and rhythm disorders NEC	3	16		5	3	11

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Supraventricular arrhythmias	3	13	1	2	2	11
Ventricular arrhythmias and cardiac arrest		15				15
	35	228	4	21	31	207

System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Musculoskeletal and connective tissue disorders of limbs congenital		1		1
		1		1

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	4	15	4	13		2
Hearing losses	1	17	1	2		15
Hyperacusia	1	1	1	1		
Inner ear signs and symptoms	3	22	3	11		11
	9	55	9	27		28

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Female gonadal function disorders	1	1	1	1		

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* AE=Adverse Event

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System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thyroid hyperfunction disorders		1				1
	1	2	1	1		1

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Colour blindness (incl acquired)		1		1		
Conjunctival structural change, deposit and degeneration		1				1
Eyelid movement disorders		1		1		
Iris and uveal tract infections, irritations and inflammations		2				2
Lacrimation disorders		2		1		1
Lid, lash and lacrimal infections, irritations and inflammations		1		1		
Ocular bleeding and vascular disorders NEC		1				1
Ocular disorders NEC	7	19	6	12	1	7
Ocular infections, inflammations and associated manifestations	1	4	1	3		1
Ocular sensation disorders		1		1		
Pupil disorders		1				1
Visual disorders NEC	1	8	1	8		
Visual impairment and blindness (excl colour blindness)		1				1
	9	43	8	28	1	15

System Organ Class

Gastrointestinal disorders

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis	2	3			2	3
Anal and rectal signs and symptoms		1		1		
Dental pain and sensation disorders	1	4	1	4		
Diarrhoea (excl infective)	4	26	4	24		2
Dyspeptic signs and symptoms	1	7	1	7		
Faecal abnormalities NEC	3	3	3	3		
Gastric and oesophageal haemorrhages		1				1
Gastrointestinal and abdominal pains (excl oral and throat)	2	14	2	13		1
Gastrointestinal atonic and hypomotility disorders NEC	2	2	1	1	1	1
Gastrointestinal necrosis and gangrene (excl gangrenous hernia)		1				1
Gastrointestinal signs and symptoms NEC	1	11	1	8		3
Gingival disorders, signs and symptoms NEC		1		1		
Gingival haemorrhages		1				1
Intestinal haemorrhages		2		2		
Nausea and vomiting symptoms	30	101	24	85	6	16
Non-site specific gastrointestinal haemorrhages	1	3			1	3
Oesophagitis (excl infective)		1		1		
Oral dryness and saliva altered		1		1		
Oral soft tissue disorders NEC		2		2		
Oral soft tissue signs and symptoms	1	36	1	32		4
Oral soft tissue swelling and oedema	1	5	1	3		2
Stomatitis and ulceration		1		1		
Tongue signs and symptoms		6		1		5
Tooth missing	1	1	1	1		
	50	234	40	191	10	43

System Organ Class

General disorders and administration site conditions

Non Interventional Study	Spontaneous
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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Asthenic conditions	91	334
Body temperature altered		1
Death and sudden death	2	37
Febrile disorders	59	173
Feelings and sensations NEC	59	181
Gait disturbances		7
General signs and symptoms NEC	9	51
Inflammations	1	15
Injection site reactions	1	1
Oedema NEC	1	4
Pain and discomfort NEC	44	133
Therapeutic and nontherapeutic responses	21	88
Vaccination site reactions	59	208
	347	1,233

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		85	303	6	31
					1
				2	37
		56	149	3	24
		57	166	2	15
			2		5
		9	39		12
			2	1	13
		1	1		
			1	1	3
		38	103	6	30
	1	9	16	12	72
		56	202	3	6
	1	311	984	36	249

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cholecystitis and cholelithiasis		1
Cholestasis and jaundice		2
Hepatic enzymes and function abnormalities		2
Hepatic failure and associated disorders		1
Hepatobiliary signs and symptoms	1	1
Hepatocellular damage and hepatitis NEC		4
	1	11

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	1		1
			2
			1
		1	1
			4
	2	1	9

System Organ Class

Immune system disorders

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	3	18	2	7	1	11
Allergies to foods, food additives, drugs and other chemicals		7		3		4
Anaphylactic and anaphylactoid responses	1	9			1	9
	4	34	2	10	2	24

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal and gastrointestinal infections		1						1
Bacterial infections NEC		3				1		2
Bone and joint infections	1	2					1	2
Cardiac infections		1						1
Central nervous system and spinal infections		1						1
Coronavirus infections	12	84		1		10	12	74
Dental and oral soft tissue infections		2				2		
Ear infections		2				2		
Eye and eyelid infections	1	4			1	3		1
Herpes viral infections	6	41			5	32	1	9
Infections NEC		2				1		1
Influenza viral infections	1	4			1	4		
Lower respiratory tract and lung infections	1	6					1	6
Muscle and soft tissue infections	1	1					1	1
Pseudomonal infections	1	2					1	2
Sepsis, bacteraemia, viraemia and fungaemia NEC		3						3
Streptococcal infections		1						1
Upper respiratory tract infections	1	7			1	6		1
Urinary tract infections	1	2				1	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Viral infections NEC		2				1		1
	26	171		1	8	63	18	108

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal and gastrointestinal injuries NEC		1				1		
Bone and joint injuries NEC		1						1
Exposures associated with pregnancy, delivery and lactation	14	31			13	27	1	4
Exposures to agents or circumstances NEC				1				
Intentional product use issues		1				1		
Limb fractures and dislocations		1						1
Medication errors, product use errors and issues NEC	3	11			3	11		
Muscle, tendon and ligament injuries	1	1			1	1		
Non-occupational environmental exposures		1				1		
Non-site specific injuries NEC		8				4		4
Off label uses	2	9			2	9		
Overdoses NEC		5				5		
Pelvic fractures and dislocations		1						1
Product administration errors and issues	13	60			13	60		
Product preparation errors and issues		6				6		
Site specific injuries NEC		3				1		2
Skin injuries NEC	1	3			1	2		1
Skin procedural complications		2				2		
Thoracic cage fractures and dislocations		1						1
Underdoses NEC		3				3		
	34	149		1	33	134	1	15

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmunity analyses		2		1		1
Blood gas and acid base analyses		2		1		1
Carbohydrate tolerance analyses (incl diabetes)		3		1		2
Chemistry analyses NEC		1				1
Coagulation and bleeding analyses	1	5		1	1	4
Digestive enzymes	1	1			1	1
ECG investigations		3		1		2
Endocrine analyses and imaging NEC	1	2	1	2		
Foetal and neonatal diagnostic procedures		1				1
Heart rate and pulse investigations	7	17	6	14	1	3
Immunoglobulin analyses		1		1		
Liver function analyses	4	6	3	4	1	2
Mineral and electrolyte analyses	4	7		1	4	6
Physical examination procedures and organ system status	4	11	4	8		3
Platelet analyses		1		1		
Protein analyses NEC	3	7	1	3	2	4
Red blood cell analyses		6		5		1
Renal function analyses		2		1		1
Reproductive organ and breast imaging procedures	1	1			1	1
Skeletal and cardiac muscle analyses	3	6			3	6
Tissue enzyme analyses NEC		1				1
Triglyceride analyses	1	1			1	1
Vascular tests NEC (incl blood pressure)	8	25	6	15	2	10
Virus identification and serology		5		2		3
Vitamin analyses		1				1
White blood cell analyses	1	4		2	1	2
	39	122	21	64	18	58

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	3	16	3	14		2
Diabetic complications NEC		1				1
Food malabsorption and intolerance syndromes (excl sugar intolerance)		1		1		
Sodium imbalance		1				1
	3	19	3	15		4

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	1	3	1	3		
Bone related signs and symptoms	8	16	8	16		
Extremity deformities	1	1			1	1
Joint related signs and symptoms	21	64	16	50	5	14
Muscle infections and inflammations	1	1			1	1
Muscle pains	50	124	46	114	4	10
Muscle related signs and symptoms NEC	3	8	3	8		
Muscle tone abnormalities		1		1		
Muscle weakness conditions	4	12	3	7	1	5
Musculoskeletal and connective tissue conditions NEC	4	11	2	7	2	4
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		1		1		
Musculoskeletal and connective tissue pain and discomfort	41	134	34	119	7	15
Myopathies		1				1
Psoriatic arthropathies		1				1
Spondyloarthropathies		1				1
	134	379	113	326	21	53

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Leukaemias chronic lymphocytic		1		1
Non-Hodgkin's lymphomas NEC		1		1
		2		2

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute polyneuropathies	1	5			1	5
Central nervous system haemorrhages and cerebrovascular accidents	1	18			1	18
Cerebrovascular venous and sinus thrombosis		1				1
Chronic polyneuropathies		1				1
Coordination and balance disturbances	1	6	1	4		2
Cortical dysfunction NEC		2		1		1
Disturbances in consciousness NEC	2	29	1	4	1	25
Dyskinesias and movement disorders NEC	1	15	1	10		5
Encephalitis NEC	1	1			1	1
Eye movement disorders		2				2
Facial cranial nerve disorders	3	47		1	3	46
Generalised tonic-clonic seizures	1	1			1	1
Headaches NEC	58	180	58	170		10
Increased intracranial pressure disorders		1				1
Mental impairment (excl dementia and memory loss)	2	2	2	2		
Migraine headaches	3	5	3	5		
Multiple sclerosis acute and progressive		7				7
Narcolepsy and hypersomnia		1		1		
Nervous system disorders NEC	1	2	1	2		
Neurological signs and symptoms NEC	26	81	25	68	1	13

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuromuscular disorders NEC		4		4		
Neuromuscular junction dysfunction		2				2
Olfactory nerve disorders	1	7	1	7		
Paraesthesias and dysaesthesias	29	124	28	108	1	16
Paralysis and paresis (excl cranial nerve)	1	8			1	8
Parkinson's disease and parkinsonism		1		1		
Peripheral neuropathies NEC		5		3		2
Seizures and seizure disorders NEC	1	20			1	20
Sensory abnormalities NEC	6	32	6	27		5
Speech and language abnormalities		10		4		6
Structural brain disorders NEC		1				1
Transient cerebrovascular events	1	7			1	7
Tremor (excl congenital)	2	12	2	11		1
Trigeminal disorders	1	1	1	1		
	143	641	130	434	13	207

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortions not specified as induced or spontaneous	1	1			1	1
Abortions spontaneous		2				2
High risk pregnancies	1	1	1	1		
Labour onset and length abnormalities		1				1
Maternal complications of labour NEC		1		1		
Multiple pregnancies		1		1		
Still birth and foetal death		4				4
	2	11	1	3	1	8

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product distribution and storage issues	1	1	1	1
Product packaging issues		12		12
Product physical issues	4	20	4	20
Product quality issues NEC	2	3	2	3
	7	36	7	36

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	1	12	1	10		2
Behaviour and socialisation disturbances		1		1		
Confusion and disorientation	3	7	3	5		2
Depressive disorders		2		1		1
Disturbances in initiating and maintaining sleep	5	13	4	12	1	1
Dyssomnias	1	3	1	3		
Emotional and mood disturbances NEC	2	4	2	4		
Fear symptoms and phobic disorders (incl social phobia)	1	1	1	1		
Fluctuating mood symptoms	1	1	1	1		
Hallucinations (excl sleep-related)		2				2
Increased physical activity levels		2		1		1
Mental disorders NEC	1	2	1	2		
Mood alterations with depressive symptoms		5		4		1
Narcolepsy and associated conditions	1	1	1	1		
Parasomnias	1	1	1	1		
Schizophrenia NEC		1				1
Sexual desire disorders		1		1		
Sleep disorders NEC		3		2		1
Speech articulation and rhythm disturbances		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stereotypies and automatisms	1	1			1	1
Suicidal and self-injurious behaviour		1				1
Thinking disturbances		1		1		
Tic disorders	2	2	2	2		
	20	68	18	53	2	15

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Glomerulonephritis and nephrotic syndrome	4	4	4	4
Renal failure and impairment	2	4	2	4
Renal lithiasis		1		1
	6	9	6	9

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast infections and inflammations		1		1		
Breast signs and symptoms		3		3		
Menstruation and uterine bleeding NEC	34	41	33	40	1	1
Menstruation with decreased bleeding	7	9	7	9		
Menstruation with increased bleeding	17	20	17	20		
Pelvis and broad ligament disorders NEC		1		1		
Reproductive tract signs and symptoms NEC		1		1		
Testicular and epididymal disorders NEC		1		1		
Uterine disorders NEC	1	3	1	2		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vulvovaginal disorders NEC	10	20	10	15		5
	69	100	68	93	1	7

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	10	69	7	29	3	40
Bronchospasm and obstruction	1	8	1	3		5
Coughing and associated symptoms	7	21	5	16	2	5
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)		1		1		
Lower respiratory tract inflammatory and immunologic conditions		3				3
Lower respiratory tract signs and symptoms		2		1		1
Nasal congestion and inflammations	1	1	1	1		
Nasal disorders NEC	1	3			1	3
Parenchymal lung disorders NEC		2				2
Pharyngeal disorders (excl infections and neoplasms)		5		3		2
Pleural infections and inflammations	1	1			1	1
Pneumothorax and pleural effusions NEC	2	4	1	1	1	3
Pulmonary oedemas	1	4			1	4
Pulmonary thrombotic and embolic conditions	1	7			1	7
Respiratory failures (excl neonatal)		1				1
Respiratory signs and symptoms NEC		3				3
Respiratory tract disorders NEC		7		2		5
Tracheal disorders (excl infections and neoplasms)		1				1
Upper respiratory tract signs and symptoms	11	43	9	31	2	12
	36	186	24	88	12	98

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* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecias	1	2	1	2		
Angioedemas		4				4
Apocrine and eccrine gland disorders	4	19	4	19		
Bullous conditions	1	2	1	1		1
Dermal and epidermal conditions NEC	2	10	2	10		
Dermatitis and eczema	1	1	1	1		
Erythemas	4	21	4	18		3
Exfoliative conditions		1		1		
Panniculitides	1	1			1	1
Pruritus NEC	4	18	4	14		4
Purpura and related conditions		2		1		1
Rashes, eruptions and exanthems NEC	13	37	12	29	1	8
Urticarias	1	10	1	6		4
	32	128	30	102	2	26

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Disability issues	3	5	3	5
Social issues NEC		1		1
	3	6	3	6

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aneurysms and dissections non-site specific	1	1			1	1

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* AE=Adverse Event
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System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure disorders NEC	1	2			1	2
Circulatory collapse and shock		2				2
Haemorrhages NEC		2				2
Non-site specific embolism and thrombosis	1	5			1	5
Non-site specific vascular disorders NEC		1		1		
Peripheral embolism and thrombosis	1	4			1	4
Peripheral vascular disorders NEC	7	7	6	6	1	1
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	8	1	6		2
Site specific vascular disorders NEC		2		2		
Vascular hypertensive disorders NEC	1	8		3	1	5
Vascular hypotensive disorders	1	6	1	3		3
	14	48	8	21	6	27

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Country Where Event Occurred

ITALY

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Anaemias NEC	8	13	1	1	1	3	7	10
Bleeding tendencies	3	3	1	1	1	1	2	2
Coagulation factor deficiencies			1	1				
Coagulopathies		1						1
Haematological disorders	2	3					2	3
Haemolyses NEC	1	1					1	1
Leukocytoses NEC	3	9		1	1	5	2	4
Leukopenias NEC		8		1				8
Lymphatic system disorders NEC	246	1,885	2	21	222	1651	24	234
Neutropenias	1	2		1			1	2
Platelet disorders NEC	1	1					1	1
Spleen disorders		1						1
Thrombocytopenias	23	45	1	3			23	45
Thrombocytoses	1	1					1	1
	289	1,973	6	30	225	1660	64	313

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Aortic valvular disorders	1	2					1	2
Cardiac conduction disorders	2	6	1	1	1	2	1	4
Cardiac disorders NEC	3	6				1	3	5
Cardiac hypertensive complications		3						3
Cardiac signs and symptoms NEC	12	58			8	36	4	22
Cardiac valve disorders NEC	1	1					1	1

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* AE=Adverse Event

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System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Cardiomyopathies	1	1					1	1
Coronary artery disorders NEC	1	6					1	6
Heart failures NEC	10	27	1	1			10	27
Ischaemic coronary artery disorders	26	56					26	56
Left ventricular failures		1						1
Mitral valvular disorders		5						5
Myocardial disorders NEC	3	7			1	3	2	4
Noninfectious myocarditis	3	9					3	9
Noninfectious pericarditis	8	20					8	20
Pericardial disorders NEC	5	17					5	17
Rate and rhythm disorders NEC	109	611	8	15	58	343	51	268
Supraventricular arrhythmias	17	71	1	2	1	16	16	55
Tricuspid valvular disorders		2						2
Ventricular arrhythmias and cardiac arrest	23	66				7	23	59
	225	975	11	19	69	408	156	567

System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Cardiac septal defects congenital		1						1
Corneal and scleral disorders congenital		1						1
Inborn errors of bilirubin metabolism	1	1			1	1		
Thyroid disorders congenital		1						1
Tongue disorders congenital	2	4	1	1			2	4
	3	8	1	1	1	1	2	7

System Organ Class

Ear and labyrinth disorders

Non Interventional Study	Spontaneous
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* AE=Adverse Event
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System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ear disorders NEC	16	94			7	65	9	29
Hearing disorders NEC	1	4				2	1	2
Hearing losses	12	35	2	2	1	5	11	30
Hyperacusia	1	5			1	4		1
Inner ear disorders NEC	1	2					1	2
Inner ear signs and symptoms	76	545	5	9	58	428	18	117
	107	685	7	11	67	504	40	181

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic thyroiditis	2	10		3	2	7
Adrenal gland disorders NEC	1	3	1	3		
Anterior pituitary hypofunction	1	1	1	1		
Thyroid disorders NEC	4	10	4	7		3
Thyroid hyperfunction disorders	2	5			2	5
Thyroid hypofunction disorders	1	1			1	1
	11	30	6	14	5	16

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Choroid and vitreous haemorrhages and vascular disorders		1						1
Choroid and vitreous structural change, deposit and degeneration	3	10		1			3	10

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* AE=Adverse Event
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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Conjunctival and corneal bleeding and vascular disorders	5	15
Conjunctival infections, irritations and inflammations	3	13
Corneal structural change, deposit and degeneration	1	4
Eyelid movement disorders	7	24
Glaucomas (excl congenital)	1	1
Iris and ciliary body structural change, deposit and degeneration		1
Iris and uveal tract infections, irritations and inflammations		8
Lacrimation disorders	9	44
Lid bleeding and vascular disorders	1	1
Lid, lash and lacrimal infections, irritations and inflammations	5	45
Lid, lash and lacrimal structural disorders		4
Ocular bleeding and vascular disorders NEC	4	8
Ocular disorders NEC	31	155
Ocular infections, inflammations and associated manifestations	24	157
Ocular nerve and muscle disorders	6	12
Ocular sensation disorders	8	70
Optic disc abnormalities NEC	1	3
Optic nerve bleeding and vascular disorders	1	2
Orbital structural change, deposit and degeneration		1
Pupil disorders	3	5
Refractive and accommodative disorders	1	3
Retinal bleeding and vascular disorders (excl retinopathy)	7	13
Retinal, choroid and vitreous infections and inflammations		2
Retinal structural change, deposit and degeneration	1	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	2			5	15
		1	6	2	7
				1	4
		2	10	5	14
				1	1
					1
					8
		6	32	3	12
				1	1
	1	4	28	1	17
			1		3
	1	25	117	6	38
	1	20	123	4	34
			1	6	11
		7	58	1	12
				1	3
				1	2
					1
		2	3	1	2
			1	1	2
	1			7	13
					2
				1	10

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* AE=Adverse Event

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Retinopathies NEC		1						1
Scleral infections, irritations and inflammations		2				1		1
Scleral structural change, deposit and degeneration	2	3			2	2		1
Structural change, deposit and degeneration of eye NEC	3	3					3	3
Visual colour distortions		1						1
Visual disorders NEC	41	138	1	1	21	88	20	50
Visual field disorders	2	7			1	5	1	2
Visual impairment and blindness (excl colour blindness)	21	63		3	9	28	12	35
Visual pathway disorders		1						1
	191	831	1	11	100	504	91	327

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal findings abnormal	2	4			2	4		
Acute and chronic pancreatitis		6						6
Anal and rectal disorders NEC		1						1
Anal and rectal signs and symptoms		1						1
Colitis (excl infective)	4	6			2	3	2	3
Dental and periodontal infections and inflammations	1	1			1	1		
Dental pain and sensation disorders	3	7			1	5	2	2
Diaphragmatic hernias	1	1					1	1
Diarrhoea (excl infective)	152	794	3	6	126	658	26	136
Diverticula	1	1					1	1
Duodenal ulcers and perforation	1	1					1	1
Dyspeptic signs and symptoms	5	37			4	32	1	5

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* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Faecal abnormalities NEC	1	5
Flatulence, bloating and distension	10	40
Gastritis (excl infective)	5	6
Gastrointestinal and abdominal pains (excl oral and throat)	115	632
Gastrointestinal atonic and hypomotility disorders NEC	7	22
Gastrointestinal disorders NEC	12	57
Gastrointestinal dyskinetic disorders	3	5
Gastrointestinal inflammatory disorders NEC	1	4
Gastrointestinal signs and symptoms NEC	31	164
Gastrointestinal spastic and hypermotility disorders	1	9
Gastrointestinal stenosis and obstruction NEC	1	3
Gastrointestinal vascular occlusion and infarction	4	8
Gingival disorders, signs and symptoms NEC	2	11
Gingival haemorrhages	4	7
Haemorrhoids and gastrointestinal varices (excl oesophageal)	3	3
Intestinal haemorrhages	6	8
Nausea and vomiting symptoms	451	2,796
Non-site specific gastrointestinal haemorrhages	6	12
Oesophageal disorders NEC		1
Oral dryness and saliva altered	20	125
Oral soft tissue disorders NEC	1	5
Oral soft tissue haemorrhages		2
Oral soft tissue infections		1
Oral soft tissue signs and symptoms	68	463
Oral soft tissue swelling and oedema	26	180
Peritoneal and retroperitoneal haemorrhages		1
Salivary gland disorders NEC		1
Salivary gland enlargements		3
Stomatitis and ulceration	6	29

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3	1	2
		7	30	3	10
		4	5	1	1
5	7	91	521	24	111
		5	17	2	5
	1	12	51		6
		2	2	1	3
1	1	1	3		1
2	6	17	93	14	71
		1	6		3
				1	3
				4	8
	1	2	7		4
			1	4	6
		1	1	2	2
				6	8
9	27	357	2268	94	528
1	1			6	12
					1
	1	15	92	5	33
		1	3		2
			1		1
			1		
1	5	44	314	24	149
	3	16	110	10	70
					1
			1		
			2		1
	1	4	23	2	6

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* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tongue disorders	4	21			4	14		7
Tongue signs and symptoms	25	153		1	17	86	8	67
	983	5,637	22	61	737	4358	246	1279

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Administration site reactions NEC	5	140			5	138		2
Adverse effect absent	1	3			1	3		
Application and instillation site reactions		5				5		
Asthenic conditions	1,016	6,826	14	33	860	6042	156	784
Body temperature altered	13	70			8	35	5	35
Death and sudden death	13	41		1			13	41
Febrile disorders	1,049	6,289	12	55	884	5068	165	1221
Feelings and sensations NEC	487	3,135	1	9	416	2672	71	463
Gait disturbances	17	63	1	1	8	29	9	34
General signs and symptoms NEC	140	619	3	7	99	451	41	168
Implant and catheter site reactions		2				2		
Inflamations	1	14			1	10		4
Infusion site reactions		7				7		
Injection site reactions	75	2,831		1	73	2825	2	6
Interactions		1	1	1				1
Mass conditions NEC		2				2		
Mucosal findings abnormal	1	11				4	1	7
Oedema NEC	43	195	6	9	26	128	17	67
Pain and discomfort NEC	250	1,315	8	18	189	1044	61	271
Therapeutic and nontherapeutic responses	181	383	7	10	4	11	177	372
Vaccination site reactions	1,061	5,189		11	998	4724	63	465
	4,353	27,141	53	156	3572	23200	781	3941

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* AE=Adverse Event

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System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Bile duct infections and inflammations		2						2
Cholecystitis and cholelithiasis		3				1		2
Cholestasis and jaundice	4	9				1	4	8
Gallbladder disorders NEC	1	1					1	1
Hepatic and hepatobiliary disorders NEC	1	1					1	1
Hepatic enzymes and function abnormalities		2	1	1				2
Hepatic vascular disorders	3	3					3	3
Hepatobiliary signs and symptoms		3				3		
Hepatocellular damage and hepatitis NEC	3	5					3	5
	12	29	1	1		5	12	24

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute and chronic sarcoidosis	1	2					1	2
Allergic conditions NEC	22	101	3	6	7	35	15	66
Allergies to foods, food additives, drugs and other chemicals	4	24	1	1	1	5	3	19
Anaphylactic and anaphylactoid responses	15	109	1	5			15	109
Atopic disorders		1						1
Autoimmune disorders NEC	3	3					3	3
Immune and associated conditions NEC	2	4			1	3	1	1
Primary immunodeficiency syndromes	1	1					1	1
	48	245	5	12	9	43	39	202

System Organ Class

Infections and infestations

Non Interventional Study	Spontaneous
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* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Abdominal and gastrointestinal infections	18	204
Adenoviral infections		1
Bacterial infections NEC	1	8
Bone and joint infections		2
Breast infections	1	8
Candida infections	2	4
Central nervous system and spinal infections	3	5
Clostridia infections	2	2
Coronavirus infections	225	483
Coxiella infections		9
Dental and oral soft tissue infections		6
Ear infections	2	25
Ectoparasitic infestations	1	1
Enterococcal infections		1
Escherichia infections	1	1
Eye and eyelid infections	10	38
Female reproductive tract infections		2
Fungal infections NEC		1
Hepatobiliary and spleen infections	1	1
Herpes viral infections	82	221
Infections NEC	7	26
Influenza viral infections	13	46
Klebsiella infections	1	1
Legionella infections		1
Listeria infections		1
Lower respiratory tract and lung infections	9	29
Male reproductive tract infections	1	2
Muscle and soft tissue infections	1	3
Parainfluenzae viral infections	1	1
Retroviral infections		1
Sepsis, bacteraemia, viraemia and fungaemia NEC	5	13

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
2	8	1	8	17	196
			1		
			1	1	7
					2
				1	8
		1	3	1	1
				3	5
				2	2
7	11	31	72	194	411
					9
			6		
		1	16	1	9
				1	1
					1
				1	1
		5	24	5	14
			2		
			1		
				1	1
	1	63	143	19	78
		5	19	2	7
		13	43		3
				1	1
					1
					1
		2	3	7	26
				1	2
				1	3
				1	1
					1
				5	13

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Skin structures and soft tissue infections	1	7			1	4		3
Staphylococcal infections		1				1		
Streptococcal infections	3	5	1	2	1	1	2	4
Upper respiratory tract infections	47	153	1	2	36	113	11	40
Urinary tract infections	6	13			3	9	3	4
Vascular infections	1	11					1	11
Viral infections NEC	3	9				2	3	7
	448	1,346	11	24	163	472	285	874

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Atmospheric pressure injuries		1				1		
Cerebral injuries NEC	3	4					3	4
Chest and respiratory tract injuries NEC		1	1	1				1
Conditions caused by cold	1	7				5	1	2
Exposures associated with pregnancy, delivery and lactation	22	49			22	44		5
Exposures to agents or circumstances NEC		2				2		
Fractures and dislocations NEC		2						2
Heat injuries (excl thermal burns)		4				3		1
Intentional product misuses		1				1		
Intentional product use issues	1	1			1	1		
Limb fractures and dislocations	1	2					1	2
Medication errors, product use errors and issues NEC	14	36			14	34		2
Muscle, tendon and ligament injuries	2	5			1	4	1	1
Nerve injuries NEC		1				1		
Neurological and psychiatric procedural complications		1						1

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Non-site specific injuries NEC	16	39
Non-site specific procedural complications		1
Occupational exposures	1	2
Off label uses	24	53
Overdoses NEC	25	73
Pelvic fractures and dislocations	1	1
Product administration errors and issues	39	103
Product confusion errors and issues		1
Product preparation errors and issues	9	14
Site specific injuries NEC	3	7
Skin injuries NEC	6	18
Skull fractures, facial bone fractures and dislocations	2	4
Spinal cord injuries NEC		1
Spinal fractures and dislocations	1	1
Stoma complications		1
Thermal burns		4
Thoracic cage fractures and dislocations	1	1
Underdoses NEC	3	15
Vaccination related complications	39	159
	214	615

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
3	3	3	9	13	30
			1		
		1	2		
		23	50	1	3
		23	68	2	5
				1	1
		37	99	2	4
			1		
		9	14		
1	1			3	7
		3	11	3	7
				2	4
					1
				1	1
					1
			2		2
				1	1
		3	15		
	2	39	144		15
5	7	179	512	35	103

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Autoimmunity analyses		1
Bacteria identification and serology (excl mycobacteria)		2
Blood counts NEC	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					2
		1	2		

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood gas and acid base analyses	20	82
Carbohydrate tolerance analyses (incl diabetes)	3	8
Cardiac auscultatory investigations	1	1
Central nervous system imaging procedures	1	1
Cerebrospinal fluid tests (excl microbiology)	1	1
Coagulation and bleeding analyses	14	28
Digestive enzymes	2	11
ECG investigations	1	6
Endocrine analyses and imaging NEC	1	1
Faecal analyses NEC	2	2
Haematological analyses NEC	1	5
Haem metabolism analyses		1
Heart rate and pulse investigations	7	45
Immune response protein analyses NEC		1
Immunology analyses NEC		2
Investigations NEC	6	14
Liver function analyses	4	11
Microbiology and serology tests NEC	1	5
Mineral and electrolyte analyses		2
Neurologic diagnostic procedures		1
Ophthalmic function diagnostic procedures	1	1
Physical examination procedures and organ system status	14	80
Pituitary analyses anterior	1	3
Platelet analyses	3	5
Protein analyses NEC	5	17
Red blood cell analyses	4	15
Renal function analyses	3	4
Respiratory and pulmonary function diagnostic procedures		1
Skeletal and cardiac muscle analyses	2	9
Thyroid analyses		4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
2	4	2	13	18	69
		1	4	2	4
				1	1
				1	1
				1	1
1	1	7	14	7	14
			5	2	6
	1		1	1	5
				1	1
		1	1	1	1
		1	2		3
					1
		4	21	3	24
					1
			2		
		2	5	4	9
	1	2	5	2	6
			3	1	2
			2		
					1
		1	1		
1	2	10	62	4	18
			2	1	1
		1	2	2	3
		4	11	1	6
		2	10	2	5
		2	3	1	1
			1		
				2	9
			2		2

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tissue enzyme analyses NEC		2
Toxicology laboratory analyses	1	1
Urinary tract function analyses NEC	1	3
Vascular tests NEC (incl blood pressure)	51	194
Virus identification and serology	15	61
Vitamin analyses	1	1
White blood cell analyses	4	18
	172	652

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
				1	1
				1	3
4	5	25	110	26	84
4	4	6	26	9	35
		1	1		
		3	9	1	9
12	18	76	320	96	332

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Appetite disorders	32	136
Calcium metabolism disorders		2
Diabetes mellitus (incl subtypes)	1	2
Electrolyte imbalance NEC		1
Elevated cholesterol		1
Fat soluble vitamin deficiencies and disorders		1
Fluid intake increased	1	4
Food malabsorption and intolerance syndromes (excl sugar intolerance)		1
General nutritional disorders NEC		2
Hyperglycaemic conditions NEC	5	13
Hypoglycaemic conditions NEC	1	6
Iron excess		1
Metabolic acidoses (excl diabetic acidoses)	2	3
Metabolic disorders NEC		1
Mixed acid-base disorders	1	1
Potassium imbalance		3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	2	21	103	11	33
			1		1
				1	2
					1
					1
			1		
		1	4		
			1		
			1		1
			3	5	10
			4	1	2
			1		
				2	3
					1
				1	1
					3

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* AE=Adverse Event

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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Sodium imbalance	1	2	1	1			1	2
Sugar intolerance (excl glucose intolerance)	1	1			1	1		
Total fluid volume decreased	3	9					3	9
Total fluid volume increased		4				2		2
Water soluble vitamin deficiencies	1	1			1	1		
	49	195	2	3	24	123	25	72

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Arthropathies NEC	7	17			2	7	5	10
Bone disorders NEC	1	1			1	1		
Bone related signs and symptoms	47	275			41	227	6	48
Bursal disorders	1	1					1	1
Connective tissue disorders NEC	2	5					2	5
Extremity deformities		1				1		
Intervertebral disc disorders NEC	1	1					1	1
Joint related disorders NEC	3	13			2	10	1	3
Joint related signs and symptoms	465	3,429	1	11	401	3044	64	385
Lupus erythematosus (incl subtypes)		2						2
Muscle infections and inflammations	3	7		1	2	3	1	4
Muscle pains	574	4,063		13	521	3692	53	371
Muscle related signs and symptoms NEC	16	109		1	12	82	4	27
Muscle tone abnormalities	13	62			10	46	3	16
Muscle weakness conditions	25	116			11	78	14	38
Musculoskeletal and connective tissue conditions NEC	17	84		1	12	55	5	29
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity	2	4					2	4

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* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Musculoskeletal and connective tissue infections and inflammations NEC		4				3		1
Musculoskeletal and connective tissue pain and discomfort	432	2,525	4	12	361	2172	71	353
Myopathies	1	2					1	2
Osteoarthropathies	1	2			1	2		
Psoriatic arthropathies		3						3
Rheumatoid arthropathies		5						5
Soft tissue disorders NEC	3	9		2	1	7	2	2
Spondyloarthropathies	1	1		1			1	1
Tendon disorders	4	14			1	7	3	7
	1,619	10,755	5	42	1379	9437	240	1318

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Germ cell neoplasms site unspecified NEC	1	1			1	1
Histiocytoses	1	1			1	1
Leukaemias myeloid NEC	1	1			1	1
Leukaemias NEC		1				1
Neoplasms malignant site unspecified NEC	1	1			1	1
Neoplasms unspecified malignancy and site unspecified NEC	1	1	1	1		
Nervous system neoplasms unspecified malignancy NEC		1				1
Non-Hodgkin's lymphomas NEC	1	1			1	1
Oncologic complications and emergencies	1	1	1	1		
Plasma cell neoplasms NEC	2	2			2	2
Reproductive neoplasms female benign NEC	1	1			1	1

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* AE=Adverse Event

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Reproductive neoplasms male unspecified malignancy		1				1
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC	1	2			1	2
Soft tissue neoplasms benign NEC	1	2	1	1		1
Uterine neoplasms benign	1	1			1	1
	13	18	3	3	10	15

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal reflexes	4	7			1	1	3	6
Absence seizures	1	3					1	3
Acute polyneuropathies	6	12					6	12
Alzheimer's disease (incl subtypes)		1						1
Central nervous system aneurysms and dissections		2						2
Central nervous system haemorrhages and cerebrovascular accidents	72	143	4	5			72	143
Central nervous system inflammatory disorders NEC		1				1		
Central nervous system vascular disorders NEC	6	6	1	1			6	6
Cerebrovascular venous and sinus thrombosis	3	5	1	1			3	5
Cervical spinal cord and nerve root disorders	3	14			1	9	2	5
Chronic polyneuropathies	1	3					1	3
Coma states	4	8					4	8
Coordination and balance disturbances	21	65	2	5	7	27	14	38
Cortical dysfunction NEC	21	48	2	3	1	5	20	43
Cranial nerve disorders NEC	7	13				3	7	10
Dementia (excl Alzheimer's type)	1	1					1	1

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* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Demyelinating disorders NEC		1
Disturbances in consciousness NEC	157	722
Disturbances in sleep phase rhythm		1
Dyskinesias and movement disorders NEC	16	89
Dystonias		1
Encephalopathies NEC		2
Encephalopathies toxic and metabolic		
Eye movement disorders	2	9
Facial cranial nerve disorders	50	165
Generalised tonic-clonic seizures	2	6
Headaches NEC	1,138	5,818
Hydrocephalic conditions	1	2
Hypoglossal nerve disorders		2
Increased intracranial pressure disorders	1	3
Lumbar spinal cord and nerve root disorders	5	12
Memory loss (excl dementia)	14	33
Mental impairment (excl dementia and memory loss)	7	44
Migraine headaches	33	250
Mononeuropathies	5	7
Multiple sclerosis acute and progressive	4	12
Muscle tone abnormal	1	15
Narcolepsy and hypersomnia	1	9
Nervous system disorders NEC	6	14
Neurological signs and symptoms NEC	154	782
Neurologic visual problems NEC	2	5
Neuromuscular disorders NEC	5	19
Neuromuscular junction dysfunction	1	6
Olfactory nerve disorders	21	65
Optic nerve disorders NEC	1	7
Paraesthesias and dysaesthesias	212	1,278
Paralysis and paresis (excl cranial nerve)	35	102

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
6	13	47	283	110	439
			1		
3	3	5	48	11	41
					1
					2
1	1				
			1	2	8
2	4	4	26	46	139
				2	6
10	31	1029	5153	109	665
				1	2
					2
				1	3
		3	9	2	3
		4	13	10	20
	2	3	25	4	19
2	4	29	208	4	42
		3	4	2	3
1	1		4	4	8
1	1		10	1	5
		1	6		3
		1	2	5	12
3	8	96	517	58	265
				2	5
		2	12	3	7
				1	6
2	4	14	44	7	21
				1	7
6	12	148	916	64	362
		11	15	24	87

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Parkinson's disease and parkinsonism		1						1
Partial complex seizures		1						1
Peripheral neuropathies NEC	5	34		1	1	10	4	24
Seizures and seizure disorders NEC	20	66	1	1		7	20	59
Sensory abnormalities NEC	72	329	2	8	51	248	21	81
Sleep disturbances NEC		2						2
Speech and language abnormalities	26	60	5	7	2	11	24	49
Spinal cord and nerve root disorders NEC	1	8				6	1	2
Transient cerebrovascular events	7	12					7	12
Tremor (excl congenital)	37	192	2	4	23	113	14	79
Trigeminal disorders	2	23				12	2	11
Vagus nerve disorders		2						2
Vertigos NEC	1	1					1	1
	2,195	10,544	57	120	1487	7750	708	2794

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortions not specified as induced or spontaneous	1	3			1	3
Abortions spontaneous	2	7			2	7
Foetal growth complications		1				1
Maternal complications of pregnancy NEC		2		1		1
Still birth and foetal death	1	1			1	1
	4	14		1	4	13

System Organ Class

Product issues

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Device issues NEC		1		1		
Device malfunction events NEC		1				1
Product physical issues	1	1	1	1		
	1	3	1	2		1

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal behaviour NEC	1	2				1	1	1
Affect alterations NEC		4				3		1
Anxiety disorders NEC		1				1		
Anxiety symptoms	20	96		1	10	63	10	33
Behaviour and socialisation disturbances		1	1	1		1		
Cognitive and attention disorders and disturbances NEC	1	1			1	1		
Confusion and disorientation	39	202	6	14	17	117	22	85
Deliria	3	4					3	4
Delusional symptoms	3	5				1	3	4
Depressive disorders	3	5			1	3	2	2
Dissociative states		3				3		
Disturbances in initiating and maintaining sleep	54	362			40	317	14	45
Dyssomnias	1	2				1	1	1
Eating disorders NEC	1	1					1	1
Emotional and mood disturbances NEC	10	26			8	20	2	6
Fear symptoms and phobic disorders (incl social phobia)	1	1			1	1		
Fluctuating mood symptoms	1	2				1	1	1
Hallucinations (excl sleep-related)	6	27	3	3			6	27
Increased physical activity levels	5	16			5	12		4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Mental disorders due to a general medical condition NEC		1						1
Mental disorders NEC		2				1		1
Mood alterations with depressive symptoms	2	3			2	3		
Mood disorders NEC	1	4			1	2		2
Obsessive-compulsive disorders and symptoms		1						1
Panic attacks and disorders	3	12			2	8	1	4
Parasomnias	4	5			3	4	1	1
Psychiatric elimination disorders	1	1					1	1
Psychiatric symptoms NEC	1	1			1	1		
Psychotic disorder NEC		1						1
Sexual desire disorders		1				1		
Sleep disorders NEC	3	32	1	3	1	21	2	11
Somatic symptom disorders	1	1			1	1		
Speech and language usage disturbances	1	2					1	2
Speech articulation and rhythm disturbances		1						1
Substance related and addictive disorders		1						1
Suicidal and self-injurious behaviour	1	1					1	1
Thinking disturbances		4	1	1		2		2
	167	835	12	23	94	590	73	245

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Bladder and urethral symptoms	9	41	1	1	4	15	5	26
Bladder disorders NEC		1						1
Bladder infections and inflammations	1	6					1	6
Glomerulonephritis and nephrotic syndrome		1						1
Myoneurogenic bladder disorders		2						2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Nephropathies and tubular disorders NEC	1	1					1	1
Renal failure and impairment	13	29	1	2			13	29
Renal failure complications	1	3					1	3
Renal vascular and ischaemic conditions	1	1					1	1
Urinary abnormalities	4	17			2	10	2	7
Urinary tract signs and symptoms NEC	11	29			5	20	6	9
	41	131	2	3	11	45	30	86

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Benign and malignant breast neoplasms		1		1		
Breast disorders NEC	2	4	1	3	1	1
Breast infections and inflammations	1	1	1	1		
Breast signs and symptoms	6	36	5	25	1	11
Erection and ejaculation conditions and disorders	5	9			5	9
Menstruation and uterine bleeding NEC	26	37	25	33	1	4
Menstruation with decreased bleeding	12	14	9	11	3	3
Menstruation with increased bleeding	19	24	16	17	3	7
Ovarian and fallopian tube cysts and neoplasms	1	1	1	1		
Ovarian and fallopian tube disorders NEC	1	1			1	1
Pelvis and broad ligament disorders NEC	1	2	1	2		
Penile disorders NEC (excl erection and ejaculation)		1		1		
Reproductive tract signs and symptoms NEC	3	9	3	8		1
Scrotal disorders NEC		1				1
Sexual function and fertility disorders NEC		1		1		
Spermatogenesis and semen disorders	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Testicular and epididymal disorders NEC	2	2			2	2
Uterine disorders NEC		1				1
Vulvovaginal disorders NEC	2	5		2	2	3
Vulvovaginal signs and symptoms		2		2		
	82	153	62	108	20	45

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Breathing abnormalities	139	611	10	19	52	233	87	378
Bronchial conditions NEC	1	3			1	1		2
Bronchospasm and obstruction	25	122	1	5	7	40	18	82
Conditions associated with abnormal gas exchange	11	21					11	21
Coughing and associated symptoms	69	291	3	4	38	161	31	130
Diaphragmatic disorders	1	3				1	1	2
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)		7				1		6
Laryngeal spasm, oedema and obstruction	18	120			1	7	17	113
Lower respiratory tract inflammatory and immunologic conditions	4	8					4	8
Lower respiratory tract signs and symptoms	3	13			1	6	2	7
Mediastinal disorders	1	1			1	1		
Nasal congestion and inflammations	19	40			11	28	8	12
Nasal disorders NEC	15	42			8	29	7	13
Parenchymal lung disorders NEC	7	16			1	1	6	15
Pharyngeal disorders (excl infections and neoplasms)	16	96		1	11	45	5	51
Pleural infections and inflammations	1	2			1	1		1
Pneumothorax and pleural effusions NEC	2	12			1	2	1	10

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pulmonary hypertensions	1	2
Pulmonary oedemas	3	11
Pulmonary thrombotic and embolic conditions	50	75
Respiratory failures (excl neonatal)	21	51
Respiratory signs and symptoms NEC	3	21
Respiratory tract disorders NEC	5	29
Tracheal disorders (excl infections and neoplasms)		2
Upper respiratory tract signs and symptoms	108	565
Vascular pulmonary disorders NEC		1
	523	2,165

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
				3	11
4	6		1	50	74
1	1			21	51
		1	9	2	12
		2	7	3	22
			1		1
1	5	73	347	35	218
					1
20	41	210	922	313	1243

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acnes	3	3
Alopecias	2	7
Angioedemas	16	80
Apocrine and eccrine gland disorders	47	333
Bullous conditions	13	45
Connective tissue disorders		1
Dermal and epidermal conditions NEC	22	121
Dermatitis and eczema	14	44
Dermatitis ascribed to specific agent		3
Erythemas	75	486
Exfoliative conditions	1	8
Lipodystrophies		1
Panniculitides	1	8
Papulosquamous conditions	1	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	3		
		1	2	1	5
		1	6	15	74
	1	34	250	13	83
	1	3	12	10	33
			1		
		14	79	8	42
		11	35	3	9
			1		2
5	7	55	348	20	138
			3	1	5
					1
			4	1	4
			6	1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Photosensitivity and photodermatosis conditions	3	6			3	4		2
Pilar disorders NEC		1						1
Pruritus NEC	75	530	2	4	56	413	19	117
Psoriatic conditions	1	7				3	1	4
Purpura and related conditions	19	36	1	3	4	13	15	23
Rashes, eruptions and exanthems NEC	90	524		4	76	372	14	152
Rosaceas		2				1		1
Skin and subcutaneous conditions NEC	1	3			1	3		
Skin and subcutaneous tissue ulcerations		1				1		
Skin cysts and polyps	1	3			1	3		
Skin haemorrhages		2						2
Skin hyperplasias and hypertrophies	2	3			1	2	1	1
Skin hypoplasias and atrophies		1				1		
Skin vascular conditions NEC	1	3				2	1	1
Skin vasculitides		5				2		3
Skin vasomotor conditions	1	2		1		1	1	1
Telangiectasia and related conditions	1	1			1	1		
Urticarias	59	423	1	3	46	304	13	119
	449	2,701	9	24	311	1876	138	825

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	3	12		6	3	6
Family and partner issues		1		1		
Social issues NEC	7	11	2	5	5	6
	10	24	2	12	8	12

System Organ Class

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System Organ Class

Surgical and medical procedures

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac therapeutic procedures NEC	1	1	1	1		
Gynaecological therapeutic procedures NEC		1		1		
Immunisations	1	2	1	2		
Joint therapeutic procedures	1	1	1	1		
Limb therapeutic procedures	1	2		1	1	1
Respiratory tract therapeutic procedures NEC	1	1			1	1
Therapeutic procedures NEC		1		1		
Venous therapeutic procedures	1	1			1	1
	6	10	3	7	3	3

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accelerated and malignant hypertension	29	116		2			29	116
Aneurysms and dissections non-site specific		1						1
Aortic aneurysms and dissections		1						1
Aortic necrosis and vascular insufficiency	1	1					1	1
Arterial infections and inflammations	1	1					1	1
Blood pressure disorders NEC	1	8				4	1	4
Circulatory collapse and shock	5	13	1	1	1	1	4	12
Haemorrhages NEC	11	29			1	11	10	18
Lymphoedemas		9				7		2
Non-site specific embolism and thrombosis	28	45	3	3	2	2	26	43
Non-site specific necrosis and vascular insufficiency NEC	15	24			2	3	13	21
Non-site specific vascular disorders NEC	8	23			4	11	4	12
Peripheral embolism and thrombosis	63	98		4	12	17	51	81
Peripheral vascular disorders NEC	50	296	2	2	36	232	14	64

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System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Peripheral vasoconstriction, necrosis and vascular insufficiency	12	46	1	2	2	24	10	22
Phlebitis NEC	3	12			2	8	1	4
Site specific vascular disorders NEC	6	32	2	3	5	22	1	10
Varicose veins NEC		1				1		
Vascular hypertensive disorders NEC	40	183	2	3	17	87	23	96
Vascular hypotensive disorders	33	197	2	5	14	100	19	97
Vascular malformations and acquired anomalies		1						1
Vasculitides NEC	6	19			3	10	3	9
Vena caval embolism and thrombosis	1	1					1	1
	313	1,157	13	25	101	540	212	617

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Country Where Event Occurred

JAPAN

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias haemolytic NEC	1	1			1	1
Anaemias NEC	4	10		4	4	6
Bleeding tendencies	1	1			1	1
Coagulopathies	1	2			1	2
Haematological disorders	1	1	1	1		
Leukopenias NEC		1				1
Lymphatic system disorders NEC	31	46	25	37	6	9
Thrombocytopenias	3	4			3	4
	42	66	26	42	16	24

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders	3	4	1	2	2	2
Cardiac disorders NEC	2	5	1	4	1	1
Cardiac signs and symptoms NEC	178	323	88	166	90	157
Cardiomyopathies	3	3			3	3
Coronary artery disorders NEC	3	3			3	3
Heart failures NEC	12	19			12	19
Ischaemic coronary artery disorders	20	27			20	27
Myocardial disorders NEC	2	3	1	1	1	2
Noninfectious myocarditis	2	6			2	6
Noninfectious pericarditis	1	3			1	3
Pericardial disorders NEC	4	5			4	5
Rate and rhythm disorders NEC	108	175	37	58	71	117

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* AE=Adverse Event

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System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Supraventricular arrhythmias	21	28	4	7	17	21
Ventricular arrhythmias and cardiac arrest	37	48	1	3	36	45
	396	652	133	241	263	411

System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac septal defects congenital	1	1			1	1
Cerebral disorders congenital	1	1			1	1
Ocular disorders congenital NEC		1		1		
	2	3		1	2	2

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	14	24	10	14	4	10
Eustachian tube disorders	1	1	1	1		
Hearing disorders NEC		1		1		
Hearing losses	14	28	1	2	13	26
Inner ear disorders NEC	2	2			2	2
Inner ear signs and symptoms	25	45	11	18	14	27
	56	101	23	36	33	65

System Organ Class

Endocrine disorders

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic thyroiditis	2	2	1	1	1	1
Adrenal cortical hyperfunctions	1	2		1	1	1
Posterior pituitary disorders	1	1			1	1
Thyroid hyperfunction disorders	1	1			1	1
Thyroid hypofunction disorders		1				1
	5	7	1	2	4	5

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Choroid and vitreous structural change, deposit and degeneration		1		1		
Conjunctival and corneal bleeding and vascular disorders	2	4			2	4
Conjunctival infections, irritations and inflammations	15	33	7	16	8	17
Eyelid movement disorders	8	15	5	5	3	10
Iris and uveal tract infections, irritations and inflammations	1	1			1	1
Lacrimation disorders	8	13	2	5	6	8
Lid, lash and lacrimal infections, irritations and inflammations	28	65	16	34	12	31
Ocular bleeding and vascular disorders NEC	2	3			2	3
Ocular disorders NEC	15	34	9	15	6	19
Ocular infections, inflammations and associated manifestations	26	59	14	36	12	23
Ocular nerve and muscle disorders	6	12	3	3	3	9
Ocular sensation disorders	10	16	6	9	4	7
Optic disc abnormalities NEC		1				1
Orbital structural change, deposit and degeneration	1	1			1	1

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* AE=Adverse Event

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pupil disorders		2		2		
Retinal bleeding and vascular disorders (excl retinopathy)	5	7			5	7
Scleral infections, irritations and inflammations		1				1
Visual colour distortions	1	2	1	1		1
Visual disorders NEC	16	27	8	16	8	11
Visual field disorders	1	2	1	2		
Visual impairment and blindness (excl colour blindness)	21	28	11	15	10	13
	166	327	83	160	83	167

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis	1	1			1	1
Anal and rectal signs and symptoms		1				1
Colitis (excl infective)	3	6			3	6
Dental pain and sensation disorders	1	2	1	2		
Diarrhoea (excl infective)	108	173	64	100	44	73
Diverticula	1	2			1	2
Duodenal ulcers and perforation	1	1			1	1
Dyspeptic signs and symptoms	1	8		4	1	4
Faecal abnormalities NEC	5	10	3	7	2	3
Flatulence, bloating and distension	6	7	1	2	5	5
Gastric ulcers and perforation	4	4			4	4
Gastrointestinal and abdominal pains (excl oral and throat)	82	145	47	77	35	68
Gastrointestinal atonic and hypomotility disorders NEC	2	2			2	2
Gastrointestinal disorders NEC	9	13	3	3	6	10

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* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal dyskinetic disorders	3	4	1	2	2	2
Gastrointestinal inflammatory disorders NEC	4	9			4	9
Gastrointestinal mucosal dystrophies and secretion disorders		1				1
Gastrointestinal necrosis and gangrene (excl gangrenous hernia)	1	1			1	1
Gastrointestinal signs and symptoms NEC	30	65	9	24	21	41
Gastrointestinal spastic and hypermotility disorders		4		1		3
Gastrointestinal vascular occlusion and infarction	4	4			4	4
Gingival haemorrhages	1	1			1	1
Intestinal ulcers and perforation NEC	1	1			1	1
Nausea and vomiting symptoms	561	921	241	411	320	510
Non-mechanical ileus	1	2			1	2
Non-site specific gastrointestinal haemorrhages	10	19			10	19
Oral dryness and saliva altered	3	7	1	2	2	5
Oral soft tissue disorders NEC	1	2	1	2		
Oral soft tissue haemorrhages	1	2	1	2		
Oral soft tissue signs and symptoms	68	121	34	67	34	54
Oral soft tissue swelling and oedema	16	38	4	17	12	21
Peritoneal and retroperitoneal disorders		1				1
Salivary gland disorders NEC	3	3	3	3		
Salivary gland enlargements	1	2	1	2		
Stomatitis and ulceration	3	6	2	5	1	1
Tongue disorders		1				1
Tongue signs and symptoms	8	10	6	8	2	2
	944	1,600	423	741	521	859

System Organ Class

General disorders and administration site conditions

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site reactions NEC	1	3		2	1	1
Adverse effect absent	1	1	1	1		
Asthenic conditions	471	772	316	517	155	255
Body temperature altered	8	14	3	5	5	9
Complications associated with device NEC	1	1			1	1
Death and sudden death	9	12			9	12
Febrile disorders	476	824	323	579	153	245
Feelings and sensations NEC	566	944	304	513	262	431
Gait disturbances	14	26	6	8	8	18
General signs and symptoms NEC	96	166	52	91	44	75
Inflammations	2	3	1	2	1	1
Injection site reactions	5	22	4	19	1	3
Mass conditions NEC	1	1	1	1		
Mucosal findings abnormal	5	8	1	3	4	5
Oedema NEC	28	47	10	16	18	31
Pain and discomfort NEC	163	272	93	159	70	113
Therapeutic and nontherapeutic responses	17	25			17	25
Vaccination site reactions	469	779	368	619	101	160
	2,333	3,920	1483	2535	850	1385

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholecystitis and cholelithiasis	1	1			1	1
Gallbladder disorders NEC	1	1			1	1
Hepatic and hepatobiliary disorders NEC		1				1
Hepatic enzymes and function abnormalities	7	14	2	4	5	10
Hepatic vascular disorders	2	2			2	2
Hepatocellular damage and hepatitis NEC	5	5			5	5

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* AE=Adverse Event

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System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Obstructive bile duct disorders (excl neoplasms)	1	1			1	1
Structural and other bile duct disorders	1	1			1	1
	18	26	2	4	16	22

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	88	151	25	53	63	98
Allergies to foods, food additives, drugs and other chemicals	16	38	6	16	10	22
Anaphylactic and anaphylactoid responses	466	1,218	1	4	465	1214
Immune and associated conditions NEC	4	4	1	1	3	3
	574	1,411	33	74	541	1337

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections	1	6		1	1	5
Bacterial infections NEC	6	13	1	1	5	12
Caliciviral infections	1	1	1	1		
Cardiac infections		1				1
Central nervous system and spinal infections	5	16			5	16
Coronavirus infections	37	48	13	15	24	33
Dental and oral soft tissue infections	2	5	2	4		1
Eye and eyelid infections	1	1			1	1
Herpes viral infections	17	24	13	14	4	10

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* AE=Adverse Event

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Infections NEC		1		1		
Lower respiratory tract and lung infections	9	14	2	2	7	12
Muscle and soft tissue infections	1	1			1	1
Sepsis, bacteraemia, viraemia and fungaemia NEC	3	3			3	3
Streptococcal infections		1				1
Upper respiratory tract infections	10	12	8	10	2	2
Urinary tract infections	10	10	1	1	9	9
Viral infections NEC	1	5	1	1		4
	104	162	42	51	62	111

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiovascular injuries		1		1		
Cerebral injuries NEC	4	4			4	4
Chest and respiratory tract injuries NEC	1	5			1	5
Conditions caused by cold	3	3	2	2	1	1
Exposures associated with pregnancy, delivery and lactation	3	5	1	3	2	2
Fractures and dislocations NEC		1		1		
Medication errors, product use errors and issues NEC		1				1
Muscle, tendon and ligament injuries		1		1		
Nerve injuries NEC	1	1			1	1
Non-site specific injuries NEC	23	34	7	13	16	21
Occupational exposures	1	1	1	1		
Off label uses	4	5	4	5		
Overdoses NEC		1		1		
Product administration errors and issues	14	24	14	24		

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product preparation errors and issues	1	3	1	3		
Radiation injuries	1	2	1	2		
Site specific injuries NEC	1	2		1	1	1
Skin injuries NEC	4	5	3	3	1	2
Spinal cord injuries NEC	2	2			2	2
Underdoses NEC	1	6	1	6		
Vaccination related complications		2		1		1
	64	109	35	68	29	41

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmunity analyses		1				1
Blood gas and acid base analyses	44	65	8	13	36	52
Carbohydrate tolerance analyses (incl diabetes)	1	2	1	1		1
Cerebrospinal fluid tests (excl microbiology)	1	2			1	2
Chemistry analyses NEC	1	1	1	1		
Coagulation and bleeding analyses	1	2	1	1		1
ECG investigations	6	6	1	1	5	5
Heart rate and pulse investigations	87	139	32	58	55	81
Imaging procedures NEC	1	1			1	1
Liver function analyses	3	4	1	1	2	3
Mineral and electrolyte analyses	1	1	1	1		
Neurologic diagnostic procedures		1				1
Physical examination procedures and organ system status	30	55	15	31	15	24
Platelet analyses	3	6	2	2	1	4
Protein analyses NEC	4	6	2	3	2	3
Renal function analyses	2	3		1	2	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skeletal and cardiac muscle analyses	4	5		1	4	4
Thyroid analyses	1	1	1	1		
Tissue enzyme analyses NEC	1	2		1	1	1
Urinalysis NEC	9	10	1	2	8	8
Urinary tract function analyses NEC	1	1			1	1
Vascular tests NEC (incl blood pressure)	405	607	100	196	305	411
Virus identification and serology		2		2		
White blood cell analyses	8	13	4	7	4	6
	614	936	171	324	443	612

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	41	60	20	28	21	32
Calcium metabolism disorders	2	3	1	1	1	2
Diabetes mellitus (incl subtypes)	2	2			2	2
Electrolyte imbalance NEC	1	1	1	1		
Fluid intake decreased	1	1			1	1
Fluid intake increased	1	1	1	1		
General nutritional disorders NEC	11	16	5	6	6	10
Hyperglycaemic conditions NEC		1		1		
Hypoglycaemic conditions NEC	2	2			2	2
Mixed acid-base disorders	1	2			1	2
Potassium imbalance	2	5			2	5
Sodium imbalance	1	1	1	1		
Total fluid volume decreased	9	13	1	2	8	11
	74	108	30	41	44	67

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	8	12	4	5	4	7
Bone related signs and symptoms	2	2	1	1	1	1
Connective tissue disorders NEC	1	1			1	1
Joint related disorders NEC	1	1			1	1
Joint related signs and symptoms	167	245	127	180	40	65
Lupus erythematosus (incl subtypes)	1	1			1	1
Muscle infections and inflammations	2	4	1	2	1	2
Muscle pains	153	254	133	218	20	36
Muscle related signs and symptoms NEC	30	49	15	25	15	24
Muscle weakness conditions	41	75	17	28	24	47
Musculoskeletal and connective tissue conditions NEC	21	33	12	20	9	13
Musculoskeletal and connective tissue pain and discomfort	128	219	89	156	39	63
Myopathies	1	1	1	1		
Rheumatoid arthropathies	2	2			2	2
Soft tissue disorders NEC	1	3			1	3
Spondyloarthropathies	1	2			1	2
	560	904	400	636	160	268

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bile duct neoplasms malignant	1	1	1	1
Breast and nipple neoplasms malignant		1		1
Leukaemias acute lymphocytic		1		1
Lymphomas unspecified NEC	1	2	1	2
Neoplasms unspecified malignancy and site unspecified NEC	1	1	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Nervous system neoplasms unspecified malignancy NEC		1		1
Neuromas		1		1
	3	8	3	8

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal reflexes	4	5	1	1	3	4
Absence seizures		2				2
Acute polyneuropathies	6	12	1	1	5	11
Alzheimer's disease (incl subtypes)	1	1			1	1
Autonomic nervous system disorders	2	8	1	2	1	6
Central nervous system aneurysms and dissections	4	7			4	7
Central nervous system haemorrhages and cerebrovascular accidents	74	94			74	94
Central nervous system vascular disorders NEC	4	5			4	5
Cerebrovascular venous and sinus thrombosis	2	3			2	3
Coma states	2	2			2	2
Coordination and balance disturbances	24	27	7	7	17	20
Cortical dysfunction NEC	5	7	1	1	4	6
Dementia (excl Alzheimer's type)	1	1			1	1
Demyelinating disorders NEC	4	4			4	4
Disturbances in consciousness NEC	152	251	20	30	132	221
Dyskinesias and movement disorders NEC	19	27	12	15	7	12
Dystonias		1				1
Eye movement disorders		2				2
Facial cranial nerve disorders	16	31			16	31
Headaches NEC	442	724	283	464	159	260

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoglossal nerve disorders	1	1			1	1
Increased intracranial pressure disorders		2		1		1
Lumbar spinal cord and nerve root disorders	1	1	1	1		
Memory loss (excl dementia)	10	14	5	6	5	8
Mental impairment (excl dementia and memory loss)	1	2	1	1		1
Migraine headaches	3	5			3	5
Mononeuropathies	2	2			2	2
Multiple sclerosis acute and progressive		1				1
Muscle tone abnormal	1	3		1	1	2
Nervous system disorders NEC	1	1	1	1		
Neurological signs and symptoms NEC	323	550	152	293	171	257
Olfactory nerve disorders	4	5	1	2	3	3
Optic nerve disorders NEC	1	1			1	1
Paraesthesias and dysaesthesias	205	341	119	198	86	143
Paralysis and paresis (excl cranial nerve)	23	29	2	2	21	27
Parkinson's disease and parkinsonism		1				1
Peripheral neuropathies NEC	38	66		1	38	65
Seizures and seizure disorders NEC	30	51		1	30	50
Sensory abnormalities NEC	45	59	25	32	20	27
Speech and language abnormalities	8	11	3	5	5	6
Structural brain disorders NEC	3	3			3	3
Transient cerebrovascular events	2	2			2	2
Tremor (excl congenital)	52	80	23	30	29	50
Trigeminal disorders	2	6	1	2	1	4
Vagus nerve disorders		1				1
	1,518	2,452	660	1098	858	1354

System Organ Class

Product issues

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Device physical property and chemical issues	1	3	1	3
Product packaging issues	1	1	1	1
Product physical issues		2		2
	2	6	2	6

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour NEC	1	1	1	1		
Anxiety disorders NEC	3	3			3	3
Anxiety symptoms	20	37	10	18	10	19
Cognitive and attention disorders and disturbances NEC		1				1
Communications disorders	2	4		1	2	3
Confusion and disorientation	3	4	2	3	1	1
Deliria	1	2			1	2
Dissociative states	2	3	2	3		
Disturbances in initiating and maintaining sleep	10	13	7	9	3	4
Dyssomnias	2	3	2	3		
Eating disorders NEC	1	3	1	1		2
Emotional and mood disturbances NEC	43	51	18	21	25	30
Fear symptoms and phobic disorders (incl social phobia)	1	1			1	1
Hallucinations (excl sleep-related)	3	4			3	4
Increased physical activity levels	3	3			3	3
Mental disorders NEC	2	2	1	1	1	1
Mood alterations with depressive symptoms	3	3	1	1	2	2
Mood disorders NEC	1	5		4	1	1
Panic attacks and disorders	6	7	1	1	5	6

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Parasomnias	1	1	1	1		
Perception disturbances NEC	6	7	5	5	1	2
Psychiatric symptoms NEC		1		1		
Sleep disorders NEC	1	3			1	3
Somatic symptom disorders	2	4	1	3	1	1
Stereotypies and automatisms	1	1	1	1		
Stress disorders	1	1	1	1		
Suicidal and self-injurious behaviour	2	2			2	2
Thinking disturbances		1				1
Tic disorders	1	1			1	1
	122	172	55	79	67	93

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	8	13			8	13
Glomerulonephritis and nephrotic syndrome	2	3			2	3
Nephropathies and tubular disorders NEC	1	1	1	1		
Renal disorders NEC	1	1			1	1
Renal failure and impairment	3	3			3	3
Urinary abnormalities	10	12	2	2	8	10
Urinary tract lithiasis (excl renal)	1	2	1	2		
Urinary tract signs and symptoms NEC	2	2	1	1	1	1
	28	37	5	6	23	31

System Organ Class

Reproductive system and breast disorders

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Menopausal effects on the genitourinary tract	1	1			1	1
Menstruation and uterine bleeding NEC	6	6	5	5	1	1
Menstruation with increased bleeding	3	3	2	2	1	1
Ovarian and fallopian tube disorders NEC	1	1			1	1
Prostate and seminal vesicles infections and inflammations		1				1
Prostatic signs, symptoms and disorders NEC		1				1
Reproductive tract disorders NEC (excl neoplasms)	4	4	1	1	3	3
Uterine disorders NEC	1	1			1	1
Vulvovaginal disorders NEC	3	3			3	3
Vulvovaginal signs and symptoms	1	1	1	1		
	20	22	9	9	11	13

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	306	552	83	168	223	384
Bronchial conditions NEC	1	1			1	1
Bronchospasm and obstruction	135	234	36	59	99	175
Conditions associated with abnormal gas exchange	8	12	1	2	7	10
Coughing and associated symptoms	206	431	74	146	132	285
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	3	7	1	2	2	5
Laryngeal spasm, oedema and obstruction	10	25	3	7	7	18
Lower respiratory tract inflammatory and immunologic conditions	4	4			4	4
Lower respiratory tract signs and symptoms	1	1			1	1
Nasal congestion and inflammations	14	18	10	10	4	8

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nasal disorders NEC	6	10	5	5	1	5
Parenchymal lung disorders NEC	3	5			3	5
Pharyngeal disorders (excl infections and neoplasms)	29	47	10	19	19	28
Pneumothorax and pleural effusions NEC		3				3
Pulmonary oedemas	1	4			1	4
Pulmonary thrombotic and embolic conditions	7	10			7	10
Respiratory failures (excl neonatal)	5	5			5	5
Respiratory signs and symptoms NEC	3	11		2	3	9
Respiratory tract disorders NEC	11	19	4	6	7	13
Tracheal disorders (excl infections and neoplasms)	1	3			1	3
Upper respiratory tract signs and symptoms	402	769	174	350	228	419
	1,156	2,171	401	776	755	1395

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecias	1	1	1	1		
Angioedemas	7	16		2	7	14
Apocrine and eccrine gland disorders	93	180	42	84	51	96
Bullous conditions	14	25	2	2	12	23
Dermal and epidermal conditions NEC	8	16	4	10	4	6
Dermatitis and eczema	25	46	12	28	13	18
Dermatitis ascribed to specific agent	10	23	3	9	7	14
Erythemas	309	570	118	269	191	301
Exfoliative conditions	2	2	1	1	1	1
Nail and nail bed conditions (excl infections and infestations)	1	1			1	1
Pigmentation changes NEC		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pilar disorders NEC	1	3	1	1		2
Pruritus NEC	372	680	144	324	228	356
Purpura and related conditions	13	16	11	14	2	2
Rashes, eruptions and exanthems NEC	277	480	122	242	155	238
Skin and subcutaneous conditions NEC	2	7		3	2	4
Skin and subcutaneous tissue ulcerations	1	1	1	1		
Skin haemorrhages	10	18			10	18
Skin vasculitides		1		1		
Skin vasomotor conditions		1		1		
Urticarias	224	450	86	230	138	220
	1,370	2,538	548	1224	822	1314

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	5	6	3	4	2	2
	5	6	3	4	2	2

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	2	5			2	5
Aneurysms and dissections non-site specific	3	4			3	4
Aortic aneurysms and dissections	3	5			3	5
Blood pressure disorders NEC	1	3	1	2		1
Circulatory collapse and shock	10	22			10	22

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* AE=Adverse Event

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System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemorrhages NEC	21	36	1	1	20	35
Lymphoedemas		1				1
Non-site specific embolism and thrombosis	2	6			2	6
Non-site specific necrosis and vascular insufficiency NEC	3	4	1	1	2	3
Non-site specific vascular disorders NEC	3	7	1	3	2	4
Peripheral embolism and thrombosis	2	5		1	2	4
Peripheral vascular disorders NEC	109	197	47	96	62	101
Peripheral vasoconstriction, necrosis and vascular insufficiency	32	62	16	36	16	26
Phlebitis NEC		1		1		
Site specific vascular disorders NEC	59	81	19	27	40	54
Vascular hypertensive disorders NEC	34	57	7	12	27	45
Vascular hypotensive disorders	4	6	1	1	3	5
Vasculitides NEC	4	5	4	5		
	292	507	98	186	194	321

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Country Where Event Occurred

JORDAN

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal and abdominal pains (excl oral and throat)		1				1
Gastrointestinal vascular occlusion and infarction		1				1
Non-site specific gastrointestinal haemorrhages		1				1
Tongue disorders		1		1		
		4		1		3

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	2	7	2	6		1
Febrile disorders	1	2	1	2		
Feelings and sensations NEC	1	2	1	2		
General signs and symptoms NEC		5		3		2
Injection site reactions		1		1		
Pain and discomfort NEC		2		2		
Therapeutic and nontherapeutic responses	1	2			1	2
Vaccination site reactions	1	3	1	3		
	6	24	5	19	1	5

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacterial infections NEC		1				1
Coronavirus infections	2	6		1	2	5
Influenza viral infections		1		1		
Lower respiratory tract and lung infections		1				1
	2	9		2	2	7

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Non-site specific injuries NEC		1		1
Product administration errors and issues	1	1	1	1
Skin injuries NEC	1	1	1	1
	2	3	2	3

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chemistry analyses NEC	1	1	1	1		
Physical examination procedures and organ system status		1		1		
Vascular tests NEC (incl blood pressure)		1				1
	1	3	1	2		1

System Organ Class

Musculoskeletal and connective tissue disorders

Spontaneous

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* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms		1		1
Muscle pains	1	4	1	4
Muscle related signs and symptoms NEC		1		1
Musculoskeletal and connective tissue pain and discomfort		3		3
	1	9	1	9

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents		2				2
Disturbances in consciousness NEC		3				3
Headaches NEC	1	3	1	3		
Neurological signs and symptoms NEC		1		1		
Olfactory nerve disorders		1		1		
Paraesthesias and dysaesthesias	1	1	1	1		
Sensory abnormalities NEC		1		1		
	2	12	2	7		5

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Confusion and disorientation		1		1
		1		1

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Testicular and epididymal disorders NEC		1		1
		1		1

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities		2				2
Bronchospasm and obstruction		2		1		1
Conditions associated with abnormal gas exchange		1				1
Coughing and associated symptoms		2		1		1
Lower respiratory tract signs and symptoms		1				1
Respiratory failures (excl neonatal)		1				1
Respiratory tract disorders NEC		1				1
Upper respiratory tract signs and symptoms		1				1
		11		2		9

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes	1	1	1	1		
Erythemas		1				1
Pruritus NEC	2	2	2	2		
	3	4	3	3		1

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Country Where Event Occurred
KOREA, REPUBLIC OF (SOUTH KOREA)

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
General signs and symptoms NEC	1	1	1	1
	1	1	1	1

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms		1		1
		1		1

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Central nervous system haemorrhages and cerebrovascular accidents	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Increased intracranial pressure disorders	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

KUWAIT

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC	1	2		1	1	1
Spleen disorders		1		1		
	1	3		2	1	1

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Ear disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions		2		2		
Febrile disorders		2		2		
General signs and symptoms NEC		2		2		
Mucosal findings abnormal		1		1		
Pain and discomfort NEC	1	4		3	1	1
Vaccination site reactions		2		2		
	1	13		12	1	1

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Coronavirus infections		2		2
		2		2

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposures associated with pregnancy, delivery and lactation	1	1	1	1
	1	1	1	1

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Red blood cell analyses		1		1
White blood cell analyses		1		1
		2		2

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint related signs and symptoms	1	1			1	1
Muscle pains		1		1		
Muscle related signs and symptoms NEC	1	1			1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal and connective tissue conditions NEC		1		1		
Musculoskeletal and connective tissue pain and discomfort	2	4		2	2	2
	4	8		4	4	4

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headaches NEC		2		2		
Paraesthesias and dysaesthesias	2	2			2	2
	2	4		2	2	2

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breast signs and symptoms	1	1	1	1
	1	1	1	1

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Bronchospasm and obstruction		1		1
		1		1

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System Organ Class

Skin and subcutaneous tissue disorders

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Apocrine and eccrine gland disorders	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

LATVIA

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC	3	33	3	25		8
	3	33	3	25		8

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders		1				1
Cardiac signs and symptoms NEC		3				3
Ischaemic coronary artery disorders		1				1
Rate and rhythm disorders NEC		11		1		10
Supraventricular arrhythmias		1				1
		17		1		16

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC		3		1		2
Hearing losses		2		1		1
Hyperacusia	1	1	1	1		
Inner ear signs and symptoms		4		4		
	1	10	1	7		3

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* AE=Adverse Event

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System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Thyroid hypofunction disorders		1		1
		1		1

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival and corneal bleeding and vascular disorders		1				1
Lacrimation disorders		2		1		1
Lid, lash and lacrimal infections, irritations and inflammations		1		1		
Ocular disorders NEC	2	14	1	13	1	1
Ocular sensation disorders	2	6	2	5		1
Visual disorders NEC		2				2
	4	26	3	20	1	6

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dental pain and sensation disorders		1		1		
Diarrhoea (excl infective)	1	7	1	7		
Gastrointestinal and abdominal pains (excl oral and throat)	1	9	1	7		2
Nausea and vomiting symptoms	5	37	5	35		2
Oral dryness and saliva altered		2		1		1
Oral soft tissue signs and symptoms	2	5	2	3		2
Oral soft tissue swelling and oedema		1		1		

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* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stomatitis and ulceration		1				1
Tongue signs and symptoms	1	2	1	1		1
	10	65	10	56		9

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	15	113	13	99	2	14
Death and sudden death	1	1			1	1
Febrile disorders	16	97	16	82		15
Feelings and sensations NEC	7	65	7	64		1
Gait disturbances		2		2		
General signs and symptoms NEC	2	10	1	6	1	4
Mucosal findings abnormal		1				1
Oedema NEC		3				3
Pain and discomfort NEC	3	10	3	8		2
Therapeutic and nontherapeutic responses	3	9			3	9
Vaccination site reactions	16	130	16	114		16
	63	441	56	375	7	66

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	1	1	1	1		
Anaphylactic and anaphylactoid responses		1				1
Immune and associated conditions NEC		1		1		

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* AE=Adverse Event

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System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	1	3	1	2		1

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	3	12		3	3	9
Herpes viral infections	1	2	1	1		1
Upper respiratory tract infections		1		1		
	4	15	1	5	3	10

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation		2		1		1
Medication errors, product use errors and issues NEC		1		1		
Off label uses		2		2		
Product administration errors and issues	1	2	1	2		
Site specific injuries NEC	1	1			1	1
	2	8	1	6	1	2

System Organ Class

Investigations

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate and pulse investigations		3		2		1
Physical examination procedures and organ system status	11	61	11	60		1
Protein analyses NEC		3		3		
Renal function analyses		1		1		
Skeletal and cardiac muscle analyses		1		1		
Vascular tests NEC (incl blood pressure)		4		2		2
Virus identification and serology		1				1
White blood cell analyses		1		1		
	11	75	11	70		5

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders	1	9	1	9
	1	9	1	9

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms		2		2		
Joint related signs and symptoms	8	62	7	56	1	6
Muscle pains	12	70	11	65	1	5
Muscle related signs and symptoms NEC	1	3	1	2		1
Muscle weakness conditions	1	6	1	3		3
Musculoskeletal and connective tissue conditions NEC	2	5	2	3		2

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* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal and connective tissue pain and discomfort	4	19	4	16		3
Myopathies		1				1
	28	168	26	147	2	21

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents		1				1
Coordination and balance disturbances		1		1		
Disturbances in consciousness NEC	2	13	1	8	1	5
Facial cranial nerve disorders		3				3
Generalised tonic-clonic seizures		1				1
Headaches NEC	14	93	12	82	2	11
Mental impairment (excl dementia and memory loss)		9		5		4
Migraine headaches	1	3		1	1	2
Neurological signs and symptoms NEC	1	24		18	1	6
Neurologic visual problems NEC		1				1
Olfactory nerve disorders		1				1
Paraesthesias and dysaesthesias	2	21	1	7	1	14
Peripheral neuropathies NEC		1				1
Sensory abnormalities NEC		9		3		6
Transient cerebrovascular events		1				1
	20	182	14	125	6	57

System Organ Class

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System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions not specified as induced or spontaneous		1		1
		1		1

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms		2				2
Confusion and disorientation		1		1		
Depressive disorders		1		1		
Disturbances in initiating and maintaining sleep	1	6		4	1	2
Mood alterations with depressive symptoms		1		1		
Sleep disorders NEC		3		3		
Thinking disturbances		1		1		
	1	15		11	1	4

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Urinary tract signs and symptoms NEC		1		1
		1		1

System Organ Class

Reproductive system and breast disorders

Interval Total #	Cumulative Total #	Spontaneous
		Nonserious

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Menstruation and uterine bleeding NEC	1	1	1	1
Menstruation with increased bleeding	1	2	1	2
	2	3	2	3

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	1	10	1	6		4
Bronchospasm and obstruction		2		1		1
Coughing and associated symptoms	1	9	1	9		
Nasal congestion and inflammations	2	4	2	4		
Nasal disorders NEC		2		1		1
Pharyngeal disorders (excl infections and neoplasms)	1	2	1	2		
Upper respiratory tract signs and symptoms	1	16	1	14		2
	6	45	6	37		8

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	4	14	4	13		1
Dermal and epidermal conditions NEC	1	4	1	2		2
Dermatitis and eczema	1	1	1	1		
Erythemas	1	3	1	2		1
Pruritus NEC	1	4	1	2		2
Purpura and related conditions		2				2

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* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rashes, eruptions and exanthems NEC	1	9	1	8		1
Skin vasculitides		1		1		
Urticarias	2	3		1	2	2
	11	41	9	30	2	11

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension		2				2
Non-site specific embolism and thrombosis	1	1			1	1
Peripheral vascular disorders NEC	2	5	2	4		1
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	3	1	2		1
Vascular hypertensive disorders NEC		3		2		1
Vascular hypotensive disorders		1		1		
	4	15	3	9	1	6

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

LEBANON

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Thrombocytopenias	1	1	1	1
	1	1	1	1

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rate and rhythm disorders NEC		3		2		1
		3		2		1

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid movement disorders	1	1			1	1
Visual disorders NEC		1		1		
	1	2		1	1	1

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal and abdominal pains (excl oral and throat)		1		1		
Gastrointestinal spastic and hypermotility disorders		1		1		
Nausea and vomiting symptoms	1	1			1	1
	1	4		3	1	1

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	1	4		3	1	1
Death and sudden death		11				11
Febrile disorders		6		5		1
Feelings and sensations NEC		7		6		1
General signs and symptoms NEC	1	1	1	1		
Inflammations	1	1	1	1		
Pain and discomfort NEC	1	3	1	3		
Therapeutic and nontherapeutic responses	5	13	1	1	4	12
Vaccination site reactions		1		1		
	9	47	4	21	5	26

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC		1				1
Allergies to foods, food additives, drugs and other chemicals		1		1		

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* AE=Adverse Event
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System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic and anaphylactoid responses		1				1
		3		1		2

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	4	18		4	4	14
Influenza viral infections		1		1		
Urinary tract infections		1				1
	4	20		5	4	15

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product administration errors and issues		2		2
		2		2

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders		1		1
Total fluid volume decreased		1		1
		2		2

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* AE=Adverse Event
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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms		1		1
Muscle pains	1	3	1	3
Muscle related signs and symptoms NEC		1		1
Muscle weakness conditions	1	1	1	1
Musculoskeletal and connective tissue pain and discomfort		5		5
	2	11	2	11

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents		1				1
Cortical dysfunction NEC	1	1			1	1
Disturbances in consciousness NEC		1				1
Facial cranial nerve disorders		2				2
Headaches NEC	1	5		4	1	1
Lumbar spinal cord and nerve root disorders		1		1		
Neurological signs and symptoms NEC	2	3		1	2	2
Paraesthesias and dysaesthesias	2	7	2	7		
Paralysis and paresis (excl cranial nerve)	1	1			1	1
Speech and language abnormalities	1	2	1	2		
	8	24	3	15	5	9

System Organ Class

Product issues

Interval Total #	Cumulative Total #	Spontaneous
		Nonserious

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product packaging issues	1	1	1	1
	1	1	1	1

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Confusion and disorientation	1	1	1	1		
Disturbances in initiating and maintaining sleep		1		1		
Emotional and mood disturbances NEC		1		1		
Panic attacks and disorders		1		1		
Speech articulation and rhythm disturbances	1	1			1	1
	2	5	1	4	1	1

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Menstruation with decreased bleeding	4	4	4	4
	4	4	4	4

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities		2		2		

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory tract disorders NEC		2				2
Upper respiratory tract signs and symptoms		8		6		2
		12		8		4

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders		1		1		
Dermatitis and eczema		1		1		
Erythemas		1				1
Pruritus NEC		1				1
Rashes, eruptions and exanthems NEC		2				2
Urticarias		1		1		
		7		3		4

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Non-site specific embolism and thrombosis	1	1			1	1
Peripheral vascular disorders NEC		1		1		
Vascular hypertensive disorders NEC	1	6	1	4		2
Vascular hypotensive disorders		1		1		
	2	9	1	6	1	3

* I=Interval, C=Cumulative

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Country Where Event Occurred

LIECHTENSTEIN

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Herpes viral infections	1	1	1	1
	1	1	1	1

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product administration errors and issues	1	2	1	2
	1	2	1	2

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Sensory abnormalities NEC	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
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Country Where Event Occurred

LITHUANIA

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias haemolytic NEC		1				1
Leukopenias NEC	1	1	1	1		
Lymphatic system disorders NEC	1	9	1	7		2
	2	11	2	8		3

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC	2	2			2	2
Heart failures NEC		1				1
Ischaemic coronary artery disorders	1	5			1	5
Rate and rhythm disorders NEC	8	11	3	4	5	7
Supraventricular arrhythmias	1	1			1	1
Ventricular arrhythmias and cardiac arrest	1	1			1	1
	13	21	3	4	10	17

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	3	5	2	4	1	1
Hearing losses		1		1		
Inner ear signs and symptoms		2		1		1
	3	8	2	6	1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid movement disorders		1				1
Lacrimation disorders		4		3		1
Ocular disorders NEC	2	8	2	8		
Ocular infections, inflammations and associated manifestations	1	2	1	2		
Ocular sensation disorders	1	1	1	1		
Visual impairment and blindness (excl colour blindness)		1		1		
	4	17	4	15		2

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	1	7	1	5		2
Diverticula		1		1		
Dyspeptic signs and symptoms		1		1		
Flatulence, bloating and distension		1		1		
Gastritis (excl infective)		1		1		
Gastrointestinal and abdominal pains (excl oral and throat)	1	5		3	1	2
Gastrointestinal signs and symptoms NEC	1	2			1	2
Nausea and vomiting symptoms	9	29	9	21		8
Oral dryness and saliva altered	2	2	1	1	1	1
Oral soft tissue signs and symptoms	1	2	1	1		1
Oral soft tissue swelling and oedema		1		1		
Tongue signs and symptoms	3	3	1	1	2	2
	18	55	13	37	5	18

System Organ Class

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	16	54	10	39	6	15
Death and sudden death	1	4			1	4
Febrile disorders	10	41	10	40		1
Feelings and sensations NEC	6	31	4	25	2	6
Gait disturbances	1	2			1	2
General signs and symptoms NEC	8	16	4	8	4	8
Injection site reactions		2		2		
Mucosal findings abnormal		1		1		
Pain and discomfort NEC	3	13	3	10		3
Therapeutic and nontherapeutic responses		1				1
Vaccination site reactions	12	63	11	58	1	5
	57	228	42	183	15	45

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Allergic conditions NEC	1	2	1	2
Anaphylactic and anaphylactoid responses		3		3
	1	5	1	5

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections		1				1
Coronavirus infections		2		1		1
Herpes viral infections		1		1		

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* AE=Adverse Event
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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Infections NEC	6	15			6	15
Lower respiratory tract and lung infections	1	2			1	2
Upper respiratory tract infections	3	8	3	7		1
	10	29	3	9	7	20

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation		1		1		
Medication errors, product use errors and issues NEC		1		1		
Off label uses		1		1		
Overdoses NEC		1		1		
Product administration errors and issues		1				1
Product preparation errors and issues		1				1
Thermal burns	1	1			1	1
Underdoses NEC		1		1		
Vaccination related complications		1		1		
	1	9		6	1	3

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate and pulse investigations	2	11		6	2	5
Physical examination procedures and organ system status	3	8	1	4	2	4

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* AE=Adverse Event

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular tests NEC (incl blood pressure)	3	14		4	3	10
	8	33	1	14	7	19

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders	1	3	1	3
	1	3	1	3

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms	2	8	2	8		
Joint related signs and symptoms	6	21	5	19	1	2
Muscle infections and inflammations		2		1		1
Muscle pains	3	24	3	22		2
Muscle related signs and symptoms NEC		2		2		
Muscle weakness conditions	1	3	1	3		
Musculoskeletal and connective tissue conditions NEC		2		2		
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		1				1
Musculoskeletal and connective tissue pain and discomfort	8	31	7	29	1	2
Soft tissue disorders NEC	1	1	1	1		
Tendon disorders		1		1		
	21	96	19	88	2	8

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	1	1			1	1
Coordination and balance disturbances		2		1		1
Cortical dysfunction NEC	1	1	1	1		
Disturbances in consciousness NEC	7	23	1	6	6	17
Facial cranial nerve disorders		6		1		5
Headaches NEC	9	42	9	35		7
Memory loss (excl dementia)	1	2	1	2		
Mental impairment (excl dementia and memory loss)	1	2			1	2
Neurological signs and symptoms NEC	7	22	6	17	1	5
Paraesthesias and dysaesthesias	3	16	1	12	2	4
Paralysis and paresis (excl cranial nerve)	1	2			1	2
Seizures and seizure disorders NEC		7				7
Sensory abnormalities NEC		3		1		2
Speech and language abnormalities	1	1			1	1
Tremor (excl congenital)	3	8		4	3	4
	35	138	19	80	16	58

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	1	3	1	2		1
Confusion and disorientation		3		1		2
Disturbances in initiating and maintaining sleep	2	4	2	4		
Emotional and mood disturbances NEC		1				1
Mood disorders NEC		1		1		
Panic attacks and disorders	1	1			1	1
	4	13	3	8	1	5

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* AE=Adverse Event

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System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Bladder and urethral symptoms		1		1
		1		1

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Menstruation and uterine bleeding NEC	1	1	1	1
Menstruation with decreased bleeding	1	1	1	1
Menstruation with increased bleeding	1	1	1	1
	3	3	3	3

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	6	11	4	7	2	4
Coughing and associated symptoms	1	5	1	5		
Nasal congestion and inflammations	1	3		2	1	1
Nasal disorders NEC	1	1	1	1		
Pharyngeal disorders (excl infections and neoplasms)	1	2		1	1	1
Pulmonary oedemas		1				1
Pulmonary thrombotic and embolic conditions	1	1			1	1
Upper respiratory tract signs and symptoms	3	6	2	5	1	1
	14	30	8	21	6	9

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	5	8	2	5	3	3
Bullous conditions	1	1			1	1
Dermal and epidermal conditions NEC	1	3		2	1	1
Erythemas		3		2		1
Pruritus NEC	3	6	2	5	1	1
Rashes, eruptions and exanthems NEC	5	8	2	4	3	4
Skin and subcutaneous conditions NEC		1				1
Urticarias	2	2	1	1	1	1
	17	32	7	19	10	13

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension		1				1
Blood pressure disorders NEC	1	3	1	2		1
Non-site specific embolism and thrombosis	1	2			1	2
Peripheral embolism and thrombosis	1	2			1	2
Peripheral vascular disorders NEC		1		1		
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	2		1	1	1
Phlebitis NEC	1	1			1	1
Site specific vascular disorders NEC	2	3			2	3
Vascular hypertensive disorders NEC	1	3		1	1	2
Vascular hypotensive disorders	1	2			1	2
	9	20	1	5	8	15

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

LUXEMBOURG

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC	6	11	2	6	4	5
	6	11	2	6	4	5

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cardiac signs and symptoms NEC		3		3
Ischaemic coronary artery disorders		1		1
Rate and rhythm disorders NEC	1	7	1	7
Supraventricular arrhythmias		1		1
Ventricular arrhythmias and cardiac arrest	1	1	1	1
	2	13	2	13

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hearing losses	1	1			1	1
Inner ear signs and symptoms	1	3	1	2		1
	2	4	1	2	1	2

System Organ Class

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* AE=Adverse Event
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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Iris and uveal tract infections, irritations and inflammations	1	1			1	1
Lid, lash and lacrimal infections, irritations and inflammations		2		1		1
Ocular disorders NEC	1	2			1	2
Ocular nerve and muscle disorders		1				1
Visual disorders NEC		1				1
	2	7		1	2	6

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)		7		1		6
Flatulence, bloating and distension		1				1
Gastrointestinal and abdominal pains (excl oral and throat)		2				2
Intestinal haemorrhages		1				1
Nausea and vomiting symptoms	4	19	4	5		14
Oral dryness and saliva altered		2				2
Oral soft tissue signs and symptoms	1	2	1	2		
Tongue disorders		1				1
	5	35	5	8		27

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	21	61	13	17	8	44

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Body temperature altered		2		1		1
Febrile disorders	13	31	8	10	5	21
Feelings and sensations NEC	6	24	3	6	3	18
Gait disturbances	1	1			1	1
General signs and symptoms NEC	3	10	2	5	1	5
Inflammations	1	1			1	1
Injection site reactions		2		1		1
Oedema NEC		2				2
Pain and discomfort NEC	7	13	2	3	5	10
Therapeutic and nontherapeutic responses		2		1		1
Vaccination site reactions	15	41	13	29	2	12
	67	190	41	73	26	117

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC		4		1		3
Anaphylactic and anaphylactoid responses	1	1			1	1
	1	5		1	1	4

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacterial infections NEC	1	1			1	1
Coronavirus infections		2				2
Eye and eyelid infections		1				1

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* AE=Adverse Event
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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes viral infections		2		2		
Influenza viral infections		6		2		4
Lower respiratory tract and lung infections	1	2			1	2
Sepsis, bacteraemia, viraemia and fungaemia NEC		1				1
Upper respiratory tract infections		1		1		
Urinary tract infections		1		1		
	2	17		6	2	11

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral injuries NEC	1	1			1	1
Conditions caused by cold		1		1		
Non-site specific injuries NEC		2				2
Vaccination related complications	1	6		1	1	5
	2	10		2	2	8

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses		1				1
Heart rate and pulse investigations		2				2
Physical examination procedures and organ system status	1	1			1	1
Protein analyses NEC	3	3	2	2	1	1
Red blood cell analyses		1				1

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* AE=Adverse Event

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular tests NEC (incl blood pressure)		1				1
Virus identification and serology		1				1
	4	10	2	2	2	8

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	1	2			1	2
Calcium metabolism disorders		1		1		
General nutritional disorders NEC		1				1
Sodium imbalance		1				1
Water soluble vitamin deficiencies		1				1
	1	6		1	1	5

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms	1	1			1	1
Joint related signs and symptoms	8	24	3	7	5	17
Muscle pains	10	36	5	11	5	25
Muscle weakness conditions	1	2			1	2
Musculoskeletal and connective tissue conditions NEC		2				2
Musculoskeletal and connective tissue pain and discomfort	8	17	4	8	4	9
	28	82	12	26	16	56

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* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	1	2			1	2
Central nervous system vascular disorders NEC	1	1	1	1		
Cervical spinal cord and nerve root disorders	1	1			1	1
Coma states	1	1			1	1
Disturbances in consciousness NEC	1	5			1	5
Eye movement disorders		1				1
Facial cranial nerve disorders	1	1			1	1
Generalised tonic-clonic seizures	1	1			1	1
Headaches NEC	16	52	10	16	6	36
Migraine headaches		1				1
Muscle tone abnormal	1	1	1	1		
Narcolepsy and hypersomnia	1	2		1	1	1
Neurological signs and symptoms NEC	3	10	3	3		7
Paraesthesias and dysaesthesias	1	8			1	8
Paralysis and paresis (excl cranial nerve)	1	2			1	2
Seizures and seizure disorders NEC		3				3
Sensory abnormalities NEC		1				1
Speech and language abnormalities	1	1			1	1
Tremor (excl congenital)		3		1		2
	31	97	15	23	16	74

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms		3		2		1
Confusion and disorientation	2	2			2	2
Disturbances in initiating and maintaining sleep	2	3	1	1	1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fear symptoms and phobic disorders (incl social phobia)		1		1		
Mood disorders NEC	1	1			1	1
Panic attacks and disorders	1	2	1	2		
Thinking disturbances		1				1
	6	13	2	6	4	7

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bladder and urethral symptoms		1		1
Renal failure and impairment		1		1
		2		2

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	5	11			5	11
Bronchospasm and obstruction		3				3
Conditions associated with abnormal gas exchange		1				1
Coughing and associated symptoms		2				2
Lower respiratory tract inflammatory and immunologic conditions	1	1			1	1
Lower respiratory tract signs and symptoms		1				1
Nasal disorders NEC	1	2	1	1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal disorders (excl infections and neoplasms)	1	1			1	1
Pulmonary thrombotic and embolic conditions	1	4			1	4
Respiratory failures (excl neonatal)		1				1
Respiratory tract disorders NEC		1				1
Upper respiratory tract signs and symptoms	1	6			1	6
	10	34	1	1	9	33

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders		2				2
Bullous conditions		1				1
Dermal and epidermal conditions NEC	1	2	1	1		1
Dermatitis and eczema		1				1
Erythemas	2	2			2	2
Panniculitides		1				1
Pruritus NEC	2	8	1	2	1	6
Psoriatic conditions	1	1	1	1		
Rashes, eruptions and exanthems NEC	1	4			1	4
Skin haemorrhages		1				1
Urticarias	1	2	1	2		
	8	25	4	6	4	19

System Organ Class

Vascular disorders

Interval Total #

Cumulative Total #

Spontaneous	
Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	1	1			1	1
Blood pressure disorders NEC	1	1	1	1		
Haemorrhages NEC	1	2		1	1	1
Lymphoedemas	1	1			1	1
Peripheral embolism and thrombosis	3	4			3	4
Peripheral vascular disorders NEC		1				1
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	2			1	2
Phlebitis NEC	1	1			1	1
Site specific vascular disorders NEC		1				1
Vascular hypertensive disorders NEC	2	9		1	2	8
Vascular hypotensive disorders	3	7	2	2	1	5
	14	30	3	5	11	25

* I=Interval, C=Cumulative
* AE=Adverse Event

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Country Where Event Occurred

MACAO

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Ischaemic coronary artery disorders		1		1
		1		1

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Facial cranial nerve disorders	4	4	4	4
	4	4	4	4

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Country Where Event Occurred

MACEDONIA, THE FORMER YUGOSLAV REPUBLIC OF

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Oral soft tissue swelling and oedema	1	1	1	1
	1	1	1	1

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenic conditions	2	5	2	5
Febrile disorders	3	4	3	4
Vaccination site reactions	1	2	1	2
	6	11	6	11

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Allergic conditions NEC	1	1	1	1
	1	1	1	1

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	1	1			1	1
Lower respiratory tract and lung infections	1	1			1	1
Upper respiratory tract infections		1		1		
	2	3		1	2	2

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product administration errors and issues		1		1
		1		1

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Physical examination procedures and organ system status	1	3	1	3
	1	3	1	3

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* AE=Adverse Event
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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms		1		1
Muscle pains	2	3	2	3
	2	4	2	4

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in consciousness NEC		1				1
Headaches NEC	1	4	1	4		
	1	5	1	4		1

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Upper respiratory tract signs and symptoms		1		1
		1		1

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Rashes, eruptions and exanthems NEC		1		1
		1		1

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Country Where Event Occurred

MALAYSIA

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coagulopathies	1	1	1	1
	1	1	1	1

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cardiac disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal and abdominal pains (excl oral and throat)	1	1			1	1
Gastrointestinal atonic and hypomotility disorders NEC		1		1		
Gastrointestinal necrosis and gangrene (excl gangrenous hernia)	1	1			1	1
Gastrointestinal signs and symptoms NEC	1	1			1	1
Gastrointestinal vascular occlusion and infarction	1	1			1	1
Nausea and vomiting symptoms	2	2			2	2
Oral dryness and saliva altered	1	1	1	1		
	7	8	1	2	6	6

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* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse effect absent	4	5	4	5		
Asthenic conditions	1	4		3	1	1
Death and sudden death	1	2			1	2
Febrile disorders		1		1		
General signs and symptoms NEC	1	1			1	1
Vaccination site reactions	2	6	2	6		
	9	19	6	15	3	4

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hepatic enzymes and function abnormalities	1	1	1	1
	1	1	1	1

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic and anaphylactoid responses	1	1	1	1
	1	1	1	1

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacterial infections NEC		1				1
Coronavirus infections		1		1		
Sepsis, bacteraemia, viraemia and fungaemia NEC	2	2			2	2
	2	4		1	2	3

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposures associated with pregnancy, delivery and lactation	2	3	2	3
Skin injuries NEC	1	1	1	1
	3	4	3	4

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Metabolism tests NEC	1	1			1	1
Platelet analyses	1	1	1	1		
	2	2	1	1	1	1

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Musculoskeletal and connective tissue conditions NEC		1		1
		1		1

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	3	3			3	3
Disturbances in consciousness NEC	1	1			1	1
Headaches NEC		2		2		
Memory loss (excl dementia)	2	2	2	2		
Neurological signs and symptoms NEC		1		1		
Paraesthesias and dysaesthesias		1		1		
Peripheral neuropathies NEC		2				2
Seizures and seizure disorders NEC		1				1
Speech and language abnormalities	1	1			1	1
	7	14	2	6	5	8

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product quality issues NEC	1	1	1	1
	1	1	1	1

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Renal failure and impairment	1	1	1	1
	1	1	1	1

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Menstruation with increased bleeding	1	1	1	1
	1	1	1	1

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bronchospasm and obstruction	1	1	1	1
	1	1	1	1

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermal and epidermal conditions NEC	1	2	1	1		1
Papulosquamous conditions		1		1		
Pilar disorders NEC		1		1		
Rashes, eruptions and exanthems NEC	1	3	1	3		
Urticarias	1	1	1	1		

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* AE=Adverse Event
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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	3	8	3	7		1

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Blood pressure disorders NEC	1	1	1	1
Non-site specific embolism and thrombosis	1	1	1	1
	2	2	2	2

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* AE=Adverse Event
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Country Where Event Occurred

MALTA

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias NEC		1		1		
Lymphatic system disorders NEC	3	5	3	5		
Red blood cell abnormal findings NEC		1		1		
Thrombocytopenias	2	3			2	3
	5	10	3	7	2	3

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC		5		1		4
Heart failures NEC	3	3			3	3
Pericardial disorders NEC	1	1			1	1
Rate and rhythm disorders NEC	1	5			1	5
Supraventricular arrhythmias	1	3			1	3
Ventricular arrhythmias and cardiac arrest		2				2
	6	19		1	6	18

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC		2		2		
Hearing losses	1	1			1	1
Inner ear signs and symptoms	3	3	1	1	2	2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	4	6	1	3	3	3

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Thyroid disorders NEC		1		1
		1		1

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular disorders NEC	1	3		1	1	2
Ocular infections, inflammations and associated manifestations		1		1		
Retinal bleeding and vascular disorders (excl retinopathy)		1				1
Visual disorders NEC		2				2
	1	7		2	1	5

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dental pain and sensation disorders		1		1		
Diarrhoea (excl infective)	1	4	1	3		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal and abdominal pains (excl oral and throat)		2		2		
Gastrointestinal signs and symptoms NEC		2		1		1
Gastrointestinal spastic and hypermotility disorders		1		1		
Nausea and vomiting symptoms	3	12	3	8		4
Non-site specific gastrointestinal haemorrhages		1				1
Oral soft tissue signs and symptoms		3		3		
Oral soft tissue swelling and oedema	1	2	1	1		1
Stomatitis and ulceration		1		1		
Tongue disorders		1		1		
Tongue signs and symptoms		1				1
	5	31	5	22		9

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	5	30	5	27		3
Body temperature altered		1				1
Febrile disorders	6	27	6	25		2
Feelings and sensations NEC	5	15	5	14		1
Gait disturbances		2		2		
General signs and symptoms NEC	1	11	1	5		6
Healing abnormal NEC	1	1			1	1
Pain and discomfort NEC	4	15	4	12		3
Therapeutic and nontherapeutic responses	2	10			2	10
Ulcers NEC		1		1		
Vaccination site reactions	4	25	4	24		1
	28	138	25	110	3	28

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	2	10	2	6		4
Anaphylactic and anaphylactoid responses		8				8
	2	18	2	6		12

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone and joint infections		1				1
Coronavirus infections	2	13		1	2	12
Fungal infections NEC		1		1		
Sepsis, bacteraemia, viraemia and fungaemia NEC	1	5			1	5
Urinary tract infections	1	2		1	1	1
	4	22		3	4	19

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Medication errors, product use errors and issues NEC		1		1		
Non-site specific injuries NEC	1	1			1	1
Off label uses		2		2		
Overdoses NEC		1		1		
Product administration errors and issues	1	2	1	2		
	2	7	1	6	1	1

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* AE=Adverse Event

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses		1		1		
Carbohydrate tolerance analyses (incl diabetes)		1		1		
Coagulation and bleeding analyses		5		5		
Heart rate and pulse investigations		2		1		1
Liver function analyses		1		1		
Mineral and electrolyte analyses		3		3		
Physical examination procedures and organ system status	1	1	1	1		
Platelet analyses		4		4		
Protein analyses NEC		3		3		
Red blood cell analyses		15		15		
Renal function analyses		3		3		
Tissue enzyme analyses NEC		2		2		
Water and electrolyte analyses NEC		1		1		
White blood cell analyses		12		12		
	1	54	1	53		1

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders		1		1
Total fluid volume decreased		1		1
		2		2

System Organ Class

Musculoskeletal and connective tissue disorders

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms		2		2		
Joint related signs and symptoms	3	7	3	7		
Muscle pains	2	11	2	11		
Muscle related signs and symptoms NEC		2		2		
Musculoskeletal and connective tissue conditions NEC	1	4	1	4		
Musculoskeletal and connective tissue pain and discomfort	6	20	6	17		3
Soft tissue disorders NEC	1	1	1	1		
Spondyloarthropathies	1	1			1	1
	14	48	13	44	1	4

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Neoplasms unspecified malignancy and site unspecified NEC		1		1
		1		1

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	2	3			2	3
Disturbances in consciousness NEC	5	26	1	15	4	11
Dyskinesias and movement disorders NEC	1	1	1	1		
Facial cranial nerve disorders		5				5

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* AE=Adverse Event
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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Generalised tonic-clonic seizures		1				1
Headaches NEC	3	9	3	9		
Migraine headaches		1		1		
Neurological signs and symptoms NEC		4		4		
Olfactory nerve disorders		1		1		
Paraesthesias and dysaesthesias	4	15	4	13		2
Paralysis and paresis (excl cranial nerve)	1	1			1	1
Sensory abnormalities NEC		3		2		1
Speech and language abnormalities	1	1	1	1		
Structural brain disorders NEC		3				3
Tremor (excl congenital)		1				1
	17	75	10	47	7	28

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Disturbances in initiating and maintaining sleep	2	3	2	3
Fear symptoms and phobic disorders (incl social phobia)		1		1
Increased physical activity levels	1	1	1	1
Panic attacks and disorders		1		1
	3	6	3	6

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bladder and urethral symptoms	1	1	1	1
Renal failure and impairment	3	5	3	5
	4	6	4	6

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	2	17			2	17
Bronchospasm and obstruction		7				7
Conditions associated with abnormal gas exchange	1	4			1	4
Coughing and associated symptoms		3		2		1
Pulmonary thrombotic and embolic conditions	2	3			2	3
Respiratory failures (excl neonatal)	1	2			1	2
Respiratory signs and symptoms NEC		2				2
Upper respiratory tract signs and symptoms		5		1		4
	6	43		3	6	40

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas		2				2
Apocrine and eccrine gland disorders	1	4	1	4		
Erythemas	1	9	1	6		3
Pigmentation changes NEC	1	1	1	1		
Pruritus NEC	1	9	1	5		4

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rashes, eruptions and exanthems NEC	2	14	2	6		8
Urticarias	1	3	1	2		1
	7	42	7	24		18

System Organ Class

Surgical and medical procedures

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Therapeutic procedures NEC		1		1
		1		1

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Non-site specific embolism and thrombosis		1				1
Peripheral embolism and thrombosis	3	4			3	4
Peripheral vascular disorders NEC		6		4		2
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	3	1	3		
Vascular hypertensive disorders NEC		3		1		2
	4	17	1	8	3	9

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* AE=Adverse Event
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Country Where Event Occurred

MEXICO

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias haemolytic NEC		1				1
Bleeding tendencies	2	12			2	12
Leukocytoses NEC	1	1	1	1		
Leukopenias NEC	1	6	1	2		4
Lymphatic system disorders NEC	91	185	84	169	7	16
Spleen disorders		1		1		
Thrombocytopenias	2	7		2	2	5
	97	213	86	175	11	38

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC		1		1		
Cardiac signs and symptoms NEC	19	44	15	36	4	8
Heart failures NEC	1	1			1	1
Ischaemic coronary artery disorders	1	6			1	6
Pericardial disorders NEC		1		1		
Rate and rhythm disorders NEC	557	1,041	481	836	76	205
Supraventricular arrhythmias	1	7		2	1	5
Ventricular arrhythmias and cardiac arrest	1	3			1	3
	580	1,104	496	876	84	228

System Organ Class

Ear and labyrinth disorders

Spontaneous

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	18	33	15	29	3	4
External ear disorders NEC	1	2	1	2		
External ear infections and inflammations		1		1		
Hearing losses	2	8	1	4	1	4
Hyperacusia	1	1	1	1		
Inner ear infections and inflammations	1	1	1	1		
Inner ear signs and symptoms	64	112	53	92	11	20
Tympanic membrane disorders (excl infections)	1	2		1	1	1
	88	160	72	131	16	29

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival and corneal bleeding and vascular disorders	1	6			1	6
Conjunctival infections, irritations and inflammations	5	9	5	8		1
Conjunctival structural change, deposit and degeneration	1	1			1	1
Corneal structural change, deposit and degeneration		1				1
Eyelid movement disorders	2	8	2	8		
Lacrimation disorders	8	21	8	21		
Lid, lash and lacrimal infections, irritations and inflammations	24	34	19	27	5	7
Ocular bleeding and vascular disorders NEC	2	2			2	2
Ocular disorders NEC	55	87	49	79	6	8
Ocular infections, inflammations and associated manifestations	21	52	19	49	2	3
Ocular nerve and muscle disorders		1				1
Ocular sensation disorders	22	29	20	27	2	2

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* AE=Adverse Event

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pupil disorders	1	1	1	1		
Visual disorders NEC	62	102	51	84	11	18
Visual field disorders	1	1	1	1		
Visual impairment and blindness (excl colour blindness)	5	8	1	2	4	6
	210	363	176	307	34	56

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Colitis (excl infective)	2	4	2	4		
Dental pain and sensation disorders		2		2		
Diarrhoea (excl infective)	356	587	313	505	43	82
Diverticula		1				1
Dyspeptic signs and symptoms	2	5	2	5		
Faecal abnormalities NEC	6	13	6	11		2
Flatulence, bloating and distension	6	8	6	8		
Gastritis (excl infective)	2	6	2	6		
Gastrointestinal and abdominal pains (excl oral and throat)	278	462	253	413	25	49
Gastrointestinal atonic and hypomotility disorders NEC	3	5	2	4	1	1
Gastrointestinal disorders NEC	3	4	3	3		1
Gastrointestinal dyskinetic disorders	1	5	1	5		
Gastrointestinal signs and symptoms NEC	116	200	101	169	15	31
Gastrointestinal spastic and hypermotility disorders	2	4	2	4		
Gastrointestinal stenosis and obstruction NEC		13				13
Gingival disorders, signs and symptoms NEC	1	4	1	4		
Gingival haemorrhages	1	2		1	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea and vomiting symptoms	1,423	2,222	1251	1910	172	312
Non-site specific gastrointestinal haemorrhages	1	22			1	22
Oral dryness and saliva altered	40	64	38	54	2	10
Oral soft tissue disorders NEC	4	9	3	7	1	2
Oral soft tissue haemorrhages		1				1
Oral soft tissue signs and symptoms	78	129	61	98	17	31
Oral soft tissue swelling and oedema	13	21	9	16	4	5
Salivary gland enlargements		1		1		
Stomatitis and ulceration		3		3		
Tongue disorders	2	2			2	2
Tongue signs and symptoms	5	11	5	10		1
	2,345	3,810	2061	3243	284	567

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site reactions NEC		1		1		
Application and instillation site reactions	12	12	12	12		
Asthenic conditions	2,801	4,389	2532	3929	269	460
Body temperature altered	38	72	34	50	4	22
Death and sudden death	1	5			1	5
Febrile disorders	879	1,421	805	1286	74	135
Feelings and sensations NEC	1,136	1,750	1059	1575	77	175
Fibrosis NEC		1		1		
Gait disturbances	14	20	7	13	7	7
General signs and symptoms NEC	522	824	503	775	19	49
Inflammations	286	436	261	396	25	40
Injection site reactions	18	20	18	20		
Mass conditions NEC	295	480	283	451	12	29

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mucosal findings abnormal		2		2		
Oedema NEC	399	649	351	563	48	86
Pain and discomfort NEC	1,949	2,858	1830	2619	119	239
Therapeutic and nontherapeutic responses	14	44	4	4	10	40
Trophic disorders		1		1		
Vaccination site reactions	1,023	1,605	961	1508	62	97
	9,387	14,590	8660	13206	727	1384

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholestasis and jaundice	1	5	1	1		4
Hepatic enzymes and function abnormalities		1		1		
Hepatobiliary signs and symptoms		1		1		
	1	7	1	3		4

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	15	57	10	42	5	15
Allergies to foods, food additives, drugs and other chemicals		10		6		4
Anaphylactic and anaphylactoid responses	3	76			3	76
Immune and associated conditions NEC		2		2		
	18	145	10	50	8	95

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections		2		1		1
Bacterial infections NEC	14	82	2	16	12	66
Candida infections	1	3		2	1	1
Central nervous system and spinal infections	1	4			1	4
Coronavirus infections	48	124	30	66	18	58
Dental and oral soft tissue infections	1	3	1	3		
Ear infections	1	7	1	7		
Enterococcal infections	1	1			1	1
Eye and eyelid infections	12	24	12	24		
Herpes viral infections	6	9	6	9		
Infections NEC	8	19	7	17	1	2
Influenza viral infections	5	10	4	9	1	1
Lower respiratory tract and lung infections	9	34	1	1	8	33
Mumps viral infections	1	1	1	1		
Rubeola viral infections		1				1
Sepsis, bacteraemia, viraemia and fungaemia NEC		2				2
Skin structures and soft tissue infections	1	1	1	1		
Staphylococcal infections	1	1	1	1		
Tuberculous infections	1	13			1	13
Upper respiratory tract infections	12	24	9	17	3	7
Urinary tract infections	1	5	1	4		1
Vascular infections		1				1
Viral infections NEC		3		1		2
	124	374	77	180	47	194

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal injuries NEC		1		1		
Bone and joint injuries NEC	1	2		1	1	1
Cardiovascular injuries	1	1	1	1		
Chest and respiratory tract injuries NEC		3		2		1
Exposures associated with pregnancy, delivery and lactation	3	21	3	21		
Exposures to agents or circumstances NEC		1		1		
Eye injuries NEC	21	40	18	32	3	8
Limb fractures and dislocations		1				1
Medication errors, product use errors and issues NEC	21	35	19	33	2	2
Non-site specific injuries NEC	2	9	1	5	1	4
Off label uses	15	27	15	27		
Overdoses NEC	2	3	2	3		
Peripheral nerve injuries		1				1
Poisoning and toxicity		1				1
Product administration errors and issues	19	41	18	40	1	1
Skin injuries NEC	2	6	2	6		
Thermal burns		4				4
Vaccination related complications	2	4	2	3		1
	89	201	81	176	8	25

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Auditory and vestibular diagnostic procedures	1	1			1	1
Blood gas and acid base analyses	33	83	13	43	20	40
Carbohydrate tolerance analyses (incl diabetes)	6	10	3	6	3	4
Coagulation and bleeding analyses		1				1

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* AE=Adverse Event

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Faecal analyses NEC	1	1	1	1		
Heart rate and pulse investigations	13	31	6	22	7	9
Immunology analyses NEC		6		6		
Liver function analyses		4		1		3
Physical examination procedures and organ system status	266	434	241	389	25	45
Platelet analyses		5		4		1
Protein analyses NEC	1	2	1	2		
Red blood cell analyses		3		3		
Respiratory and pulmonary function diagnostic procedures	1	1	1	1		
Respiratory tract and thoracic imaging procedures	1	1	1	1		
Vascular tests NEC (incl blood pressure)	172	229	107	142	65	87
Virus identification and serology	4	10	4	8		2
White blood cell analyses		4		3		1
	499	826	378	632	121	194

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	121	214	115	198	6	16
Diabetes mellitus (incl subtypes)		1				1
Diabetic complications NEC		1				1
Electrolyte imbalance NEC		1				1
Fluid intake increased	1	1			1	1
Food malabsorption and intolerance syndromes (excl sugar intolerance)	1	1	1	1		
Hyperglycaemic conditions NEC	1	5	1	3		2
Hypoglycaemic conditions NEC	6	7	2	2	4	5

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lipid metabolism and deposit disorders NEC		1		1		
Sodium imbalance		1				1
Total fluid volume decreased	3	8	3	6		2
	133	241	122	211	11	30

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	3	5	2	3	1	2
Bone disorders NEC	2	2	2	2		
Bone related signs and symptoms	7	11	5	7	2	4
Joint related signs and symptoms	1,139	1,757	1058	1607	81	150
Lupus erythematosus (incl subtypes)		1				1
Muscle pains	1,362	2,082	1268	1908	94	174
Muscle related signs and symptoms NEC	13	30	13	29		1
Muscle tone abnormalities	3	4	2	3	1	1
Muscle weakness conditions	30	56	20	35	10	21
Musculoskeletal and connective tissue conditions NEC	28	48	25	45	3	3
Musculoskeletal and connective tissue pain and discomfort	235	383	221	360	14	23
Myopathies		1		1		
Osteoarthropathies	5	5	5	5		
Soft tissue disorders NEC	1	3	1	3		
Synovial disorders	1	3	1	3		
	2,829	4,391	2623	4011	206	380

System Organ Class

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Diffuse large B-cell lymphomas		1		1
		1		1

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal reflexes	2	5		3	2	2
Absence seizures		1				1
Acute polyneuropathies	7	16			7	16
Central nervous system aneurysms and dissections		1				1
Central nervous system haemorrhages and cerebrovascular accidents	2	14			2	14
Central nervous system vascular disorders NEC	1	1			1	1
Choreiform movements	1	1			1	1
Chronic polyneuropathies		1				1
Coordination and balance disturbances	10	20	8	14	2	6
Cortical dysfunction NEC		2		2		
Demyelinating disorders NEC		3				3
Disturbances in consciousness NEC	56	188	36	58	20	130
Disturbances in sleep phase rhythm	1	1	1	1		
Dyskinesias and movement disorders NEC	27	46	21	36	6	10
Dystonias		2				2
Encephalitis NEC		1				1
Facial cranial nerve disorders	5	40		6	5	34
Generalised tonic-clonic seizures	1	9			1	9
Headaches NEC	2,792	3,986	2563	3597	229	389
Hypoglossal nerve disorders	2	3			2	3
Increased intracranial pressure disorders		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lumbar spinal cord and nerve root disorders		1				1
Memory loss (excl dementia)	3	4	3	3		1
Mental impairment (excl dementia and memory loss)		2		2		
Migraine headaches	5	6	5	6		
Mononeuropathies		3				3
Muscle tone abnormal	2	5	1	4	1	1
Myelitis (incl infective)		1				1
Narcolepsy and hypersomnia	1	4	1	3		1
Nervous system disorders NEC		3				3
Neurological signs and symptoms NEC	1,244	1,967	1115	1706	129	261
Neuromuscular disorders NEC	3	9	2	5	1	4
Olfactory nerve disorders	37	67	37	64		3
Optic nerve disorders NEC	1	1			1	1
Paraesthesias and dysaesthesias	275	475	236	378	39	97
Paralysis and paresis (excl cranial nerve)	19	67	7	10	12	57
Parkinson's disease and parkinsonism	1	1	1	1		
Peripheral neuropathies NEC	2	11		2	2	9
Seizures and seizure disorders NEC	29	133	9	31	20	102
Sensory abnormalities NEC	47	93	44	82	3	11
Sleep disturbances NEC	1	1	1	1		
Speech and language abnormalities	10	17	4	10	6	7
Spinal cord and nerve root disorders NEC		3				3
Tremor (excl congenital)	22	47	20	42	2	5
	4,609	7,263	4115	6067	494	1196

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C

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* AE=Adverse Event
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System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Counterfeit, falsified and substandard products	2	6	2	6
Product physical issues		1		1
Product quality issues NEC		1		1
Product supply and availability issues		1		1
	2	9	2	9

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Affect alterations NEC		1		1		
Anxiety symptoms	57	108	47	84	10	24
Behaviour and socialisation disturbances		2		2		
Communications disorders	1	1			1	1
Confusion and disorientation	6	18	6	15		3
Deliria		1				1
Depressive disorders	1	2	1	2		
Disturbances in initiating and maintaining sleep	12	17	11	15	1	2
Eating disorders NEC		1		1		
Emotional and mood disturbances NEC	123	235	109	200	14	35
Fear symptoms and phobic disorders (incl social phobia)	2	2	2	2		
Hallucinations (excl sleep-related)	1	4			1	4
Increased physical activity levels		1		1		
Mood alterations with depressive symptoms	3	6	3	6		
Mood disorders NEC	1	2	1	2		
Panic attacks and disorders	1	2	1	2		
Parasomnias		1				1
Perception disturbances NEC		1				1
Sleep disorders NEC	1	2			1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Somatic symptom disorders		2		2		
Stereotypies and automatisms	1	1			1	1
Tic disorders	1	1	1	1		
	211	411	182	336	29	75

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	3	5	2	4	1	1
Renal failure and impairment		1				1
Urinary abnormalities	2	4	2	2		2
	5	10	4	6	1	4

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast signs and symptoms	4	5	3	4	1	1
Menstruation and uterine bleeding NEC	2	5	2	5		
Reproductive tract disorders NEC (excl neoplasms)		1		1		
Reproductive tract infections and inflammations NEC		1		1		
Reproductive tract signs and symptoms NEC	1	4	1	3		1
Vulvovaginal disorders NEC	3	4		1	3	3
	10	20	6	15	4	5

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	221	1,467	87	564	134	903
Bronchial conditions NEC		2		2		
Bronchospasm and obstruction	46	130	31	73	15	57
Conditions associated with abnormal gas exchange	11	12	1	1	10	11
Coughing and associated symptoms	471	792	421	692	50	100
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)		2				2
Laryngeal spasm, oedema and obstruction	3	19	2	4	1	15
Lower respiratory tract inflammatory and immunologic conditions		1		1		
Lower respiratory tract signs and symptoms	3	5	2	4	1	1
Nasal congestion and inflammations	22	39	22	39		
Nasal disorders NEC	11	23	11	20		3
Pharyngeal disorders (excl infections and neoplasms)	18	36	12	19	6	17
Pneumothorax and pleural effusions NEC		1		1		
Pulmonary oedemas		1				1
Pulmonary thrombotic and embolic conditions	1	1			1	1
Respiratory failures (excl neonatal)		3				3
Respiratory signs and symptoms NEC	4	9	4	8		1
Respiratory tract disorders NEC	1	5	1	4		1
Upper respiratory tract signs and symptoms	1,081	1,746	1001	1596	80	150
	1,893	4,294	1595	3028	298	1266

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes	1	3	1	3		
Angioedemas	3	13	1	1	2	12

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	77	127	67	101	10	26
Bullous conditions	5	16	5	7		9
Dermal and epidermal conditions NEC	1,755	2,351	1664	2188	91	163
Dermatitis and eczema	3	8	3	8		
Erythemas	295	488	268	434	27	54
Exfoliative conditions	1	2		1	1	1
Nail and nail bed conditions (excl infections and infestations)		1		1		
Photosensitivity and photodermatosis conditions	3	4	3	4		
Pigmentation changes NEC		1		1		
Pilar disorders NEC	1	1	1	1		
Pruritus NEC	369	555	310	459	59	96
Purpura and related conditions	16	27	14	20	2	7
Rashes, eruptions and exanthems NEC	258	442	204	343	54	99
Skin and subcutaneous conditions NEC	1	2	1	2		
Skin haemorrhages		1		1		
Skin vasomotor conditions	2	5		3	2	2
Urticarias	16	31	10	23	6	8
	2,806	4,078	2552	3601	254	477

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dietary and nutritional issues		1		1		
Disability issues	6	8	4	5	2	3
Social issues NEC	1	1	1	1		
	7	10	5	7	2	3

System Organ Class

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System Organ Class

Surgical and medical procedures

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Analgesia supportive care	1	1	1	1
	1	1	1	1

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	14	85			14	85
Blood pressure disorders NEC	6	6	6	6		
Circulatory collapse and shock	1	36			1	36
Haemorrhages NEC	1	29		2	1	27
Lymphoedemas	1	1	1	1		
Non-site specific embolism and thrombosis	4	9			4	9
Non-site specific necrosis and vascular insufficiency NEC	2	2	1	1	1	1
Non-site specific vascular disorders NEC	10	17	9	15	1	2
Peripheral embolism and thrombosis	2	2			2	2
Peripheral vascular disorders NEC	29	49	26	42	3	7
Peripheral vasoconstriction, necrosis and vascular insufficiency	3	13	3	12		1
Site specific vascular disorders NEC	5	14	3	10	2	4
Varicose veins NEC	2	2	1	1	1	1
Vascular hypertensive disorders NEC	239	343	149	209	90	134
Vascular hypotensive disorders	37	63	19	33	18	30
Vasculitides NEC	1	1	1	1		
	357	672	219	333	138	339

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Country Where Event Occurred

MONACO

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Therapeutic and nontherapeutic responses		1		1
		1		1

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coronavirus infections		1		1
		1		1

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Speech and language abnormalities		1		1
		1		1

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Country Where Event Occurred

NETHERLANDS

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias haemolytic NEC		1				1
Anaemias NEC	2	4	2	3		1
Bleeding tendencies		1		1		
Coagulopathies	1	2		1	1	1
Leukocytoses NEC	1	1	1	1		
Leukopenias NEC	1	2			1	2
Lymphatic system disorders NEC	37	172	37	171		1
Marrow depression and hypoplastic anaemias		1				1
Spleen disorders		1				1
Thrombocytopenias	16	21	2	2	14	19
	58	206	42	179	16	27

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Aortic valvular disorders		4						4
Cardiac conduction disorders	2	4				1	2	3
Cardiac disorders NEC	1	11				1	1	10
Cardiac signs and symptoms NEC	12	62			8	50	4	12
Cardiomyopathies	1	1					1	1
Coronary artery disorders NEC	1	3					1	3
Heart failure signs and symptoms		7						7
Heart failures NEC	11	50					11	50
Ischaemic coronary artery disorders	23	61					23	61
Left ventricular failures		1						1

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* AE=Adverse Event

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System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Myocardial disorders NEC	1	5			1	2		3
Noninfectious pericarditis		3						3
Pericardial disorders NEC	1	1					1	1
Rate and rhythm disorders NEC	30	71	1	1	5	19	25	52
Right ventricular failures		2						2
Supraventricular arrhythmias	15	50		1	2	7	13	43
Ventricular arrhythmias and cardiac arrest	11	32					11	32
	109	368	1	2	16	80	93	288

System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coagulation disorders congenital		1		1
Tongue disorders congenital	1	1	1	1
	1	2	1	2

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ear disorders NEC	5	13			5	13		
External ear disorders NEC		1				1		
Hearing losses	5	18				1	5	17
Hyperacusia		1				1		
Inner ear disorders NEC		5						5
Inner ear signs and symptoms	8	36	1	2	6	31	2	5
	18	74	1	2	11	47	7	27

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* AE=Adverse Event

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System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Adrenal cortical hypofunctions		1		1
Adrenal gland disorders NEC		1		1
Hypothalamic and pituitary disorders NEC		1		1
Thyroid disorders NEC	1	1	1	1
Thyroid hyperfunction disorders	2	2	2	2
Thyroid hypofunction disorders	1	1	1	1
	4	7	4	7

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Conjunctival and corneal bleeding and vascular disorders	2	4	1	1			2	4
Conjunctival infections, irritations and inflammations		1						1
Eyelid movement disorders	1	3			1	3		
Iris and uveal tract infections, irritations and inflammations	1	2					1	2
Lacrimation disorders	1	8			1	8		
Lid, lash and lacrimal infections, irritations and inflammations	2	9			2	8		1
Ocular bleeding and vascular disorders NEC	2	5					2	5
Ocular disorders NEC	6	25			5	22	1	3
Ocular infections, inflammations and associated manifestations	9	19			8	16	1	3
Ocular nerve and muscle disorders		3				1		2
Ocular sensation disorders	1	3			1	3		
Optic disc abnormalities NEC	1	1					1	1
Optic nerve bleeding and vascular disorders		1						1
Pupil disorders	1	2				1	1	1

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* AE=Adverse Event

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Refractive and accommodative disorders		2
Retinal bleeding and vascular disorders (excl retinopathy)	5	8
Retinal structural change, deposit and degeneration		2
Scleral infections, irritations and inflammations		1
Structural change, deposit and degeneration of eye NEC		1
Visual disorders NEC	3	32
Visual field disorders	2	2
Visual impairment and blindness (excl colour blindness)	7	34
	44	168

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
				5	8
					2
			1		
					1
		2	29	1	3
				2	2
	1	2	10	5	24
1	2	22	104	22	64

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anal and rectal disorders NEC		2
Colitis (excl infective)	1	2
Dental pain and sensation disorders	3	5
Diaphragmatic hernias	2	3
Diarrhoea (excl infective)	23	83
Duodenal and small intestinal stenosis and obstruction		1
Dyspeptic signs and symptoms	2	7
Faecal abnormalities NEC	1	4
Flatulence, bloating and distension		2
Gastric and oesophageal haemorrhages		1
Gastrointestinal and abdominal pains (excl oral and throat)	17	48

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		1
		1	2
2	4	1	1
1	1	1	2
20	77	3	6
			1
2	7		
1	3		1
	2		
			1
15	44	2	4

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal atonic and hypomotility disorders NEC	1	5	1	4		1
Gastrointestinal disorders NEC	2	3	1	2	1	1
Gastrointestinal inflammatory disorders NEC		1				1
Gastrointestinal mucosal dystrophies and secretion disorders		1		1		
Gastrointestinal signs and symptoms NEC	16	54	11	31	5	23
Gastrointestinal spastic and hypermotility disorders	3	4	3	4		
Gastrointestinal stenosis and obstruction NEC	1	3			1	3
Gastrointestinal vascular occlusion and infarction	3	7			3	7
Gingival disorders, signs and symptoms NEC		1		1		
Gingival haemorrhages	1	1	1	1		
Haemorrhoids and gastrointestinal varices (excl oesophageal)		1		1		
Intestinal haemorrhages	1	6			1	6
Nausea and vomiting symptoms	194	980	182	907	12	73
Non-site specific gastrointestinal haemorrhages	3	12			3	12
Oral dryness and saliva altered	2	8	1	6	1	2
Oral soft tissue disorders NEC	1	4	1	4		
Oral soft tissue signs and symptoms	10	52	9	45	1	7
Oral soft tissue swelling and oedema	6	14	2	6	4	8
Salivary gland disorders NEC		1		1		
Stomatitis and ulceration	1	4	1	4		
Tongue disorders	2	6	1	3	1	3
Tongue signs and symptoms	13	32	4	16	9	16
	309	1,358	259	1176	50	182

System Organ Class

General disorders and administration site conditions

Interval Total #

Cumulative Total #

Non Interventional Study	Spontaneous	
Serious	Nonserious	Serious

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Administration site reactions NEC		1
Asthenic conditions	736	3,466
Body temperature altered	2	6
Death and sudden death	15	70
Febrile disorders	193	1,003
Feelings and sensations NEC	241	1,260
Gait disturbances	7	25
General signs and symptoms NEC	31	132
Hernias NEC	1	1
Inflammations		5
Injection site reactions	10	59
Interactions	1	1
Mass conditions NEC		1
Mucosal findings abnormal		1
Oedema NEC	8	19
Pain and discomfort NEC	42	191
Therapeutic and nontherapeutic responses	20	36
Vaccination site reactions	861	4,282
Vascular complications associated with device		1
	2,168	10,560

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		705	3276	31	190
				2	6
				15	70
1	1	165	833	28	170
		231	1219	10	41
		2	14	5	11
		21	78	10	54
		1	1		
			3		2
		10	59		
				1	1
			1		
			1		
		3	8	5	11
		35	159	7	32
				20	36
		858	4271	3	11
					1
1	1	2031	9924	137	636

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cholecystitis and cholelithiasis	1	2
Cholestasis and jaundice		5
Hepatic failure and associated disorders		2
Hepatic vascular disorders	1	1
Hepatobiliary signs and symptoms		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	2
	1		4
			2
		1	1
	1		

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* AE=Adverse Event
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System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hepatocellular damage and hepatitis NEC	2	4			2	4
	4	15		2	4	13

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Allergic conditions NEC	14	38			7	21	7	17
Allergies to foods, food additives, drugs and other chemicals	2	6		1		2	2	4
Amyloidoses	1	1					1	1
Anaphylactic and anaphylactoid responses	3	22					3	22
Immune and associated conditions NEC	1	5			1	1		4
	21	72		1	8	24	13	48

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal and gastrointestinal infections	2	4					2	4
Bacterial infections NEC		3						3
Bone and joint infections	1	2					1	2
Borrelial infections	1	1					1	1
Breast infections	1	1					1	1
Candida infections		1						1
Cardiac infections		1						1
Central nervous system and spinal infections		1						1
Coronavirus infections	31	64			10	17	21	47

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* AE=Adverse Event

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Dental and oral soft tissue infections		2						2
Enteroviral infections NEC		1						1
Escherichia infections		1						1
Eye and eyelid infections	1	2					1	2
Female reproductive tract infections		1						1
Hepatitis virus infections		1						1
Herpes viral infections	74	91			73	82	1	9
Infections NEC	1	11			1	1		10
Influenza viral infections	1	1			1	1		
Lower respiratory tract and lung infections	17	47	1	1			17	47
Muscle and soft tissue infections		1						1
Sepsis, bacteraemia, viraemia and fungaemia NEC	2	8					2	8
Staphylococcal infections	1	1					1	1
Streptococcal infections	6	10					6	10
Tinea infections	1	1			1	1		
Upper respiratory tract infections	10	36			10	35		1
Urinary tract infections	6	26			5	14	1	12
Vascular infections	1	3					1	3
Viral infections NEC		5				1		4
	157	327	1	1	101	152	56	175

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Cerebral injuries NEC	1	4					1	4
Chest and respiratory tract injuries NEC		2						2
Conditions caused by cold		3				3		

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* AE=Adverse Event

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Exposures associated with pregnancy, delivery and lactation	1	10				7	1	3
Exposures to agents or circumstances NEC	1	2			1	2		
Eye injuries NEC	1	2			1	2		
Fractures and dislocations NEC		1						1
Intentional product use issues		1				1		
Limb fractures and dislocations		5						5
Medication errors, product use errors and issues NEC		1				1		
Muscle, tendon and ligament injuries	3	10			3	9		1
Non-site specific injuries NEC	8	40		1	4	18	4	22
Occupational exposures		1				1		
Off label uses	5	13			5	13		
Pelvic fractures and dislocations		1						1
Product administration errors and issues	9	19			9	19		
Product confusion errors and issues		1				1		
Product preparation errors and issues	1	4			1	4		
Product storage errors and issues in the product use system		1				1		
Reproductive system and breast injuries		1				1		
Site specific injuries NEC		4				1		3
Skin injuries NEC	5	10			4	7	1	3
Skull fractures, facial bone fractures and dislocations	1	2					1	2
Spinal cord injuries NEC	1	1					1	1
	37	139		1	28	91	9	48

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacteria identification and serology (excl mycobacteria)		1				1
Blood gas and acid base analyses	6	34	1	8	5	26
Bone marrow and immune tissue imaging procedures		1		1		
Carbohydrate tolerance analyses (incl diabetes)	7	21	5	18	2	3
Cell marker analyses		1				1
Chemistry analyses NEC	1	2	1	1		1
Cholesterol analyses	5	9	5	9		
Coagulation and bleeding analyses	7	17	2	8	5	9
Digestive enzymes		1		1		
ECG investigations	1	2			1	2
Gastrointestinal function diagnostic procedures		1		1		
Haematological analyses NEC	1	1	1	1		
Heart rate and pulse investigations	13	37	11	27	2	10
Immune response protein analyses NEC	3	3	3	3		
Liver function analyses	5	16	2	13	3	3
Metabolism tests NEC	1	3	1	3		
Mineral and electrolyte analyses	2	8	1	6	1	2
Physical examination procedures and organ system status	24	166	23	153	1	13
Platelet analyses	1	8		6	1	2
Protein analyses NEC	2	14	1	10	1	4
Red blood cell analyses	8	29	6	24	2	5
Renal function analyses	8	23	6	21	2	2
Skeletal and cardiac muscle analyses	1	4		2	1	2
Tissue enzyme analyses NEC	1	4		3	1	1
Toxicology laboratory analyses		1		1		
Urinary tract function analyses NEC		2		2		
Vascular tests NEC (incl blood pressure)	4	27	3	14	1	13
Virus identification and serology	1	5	1	2		3
White blood cell analyses	5	18	4	15	1	3

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	107	459	77	353	30	106

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	9	37	7	23	2	14
Calcium metabolism disorders	2	2			2	2
Diabetes mellitus (incl subtypes)		3				3
Electrolyte imbalance NEC		1				1
Elevated triglycerides		1				1
Fluid intake decreased		3		1		2
General nutritional disorders NEC	2	10		4	2	6
Hyperglycaemic conditions NEC	2	4	2	3		1
Hypoglycaemic conditions NEC	2	6	1	3	1	3
Iron deficiencies	1	1			1	1
Metabolic acidoses (excl diabetic acidoses)		1		1		
Potassium imbalance	2	4			2	4
Sodium imbalance	1	4	1	2		2
Total fluid volume decreased	2	8		2	2	6
Total fluid volume increased	2	5	2	3		2
Water soluble vitamin deficiencies	1	1	1	1		
	26	91	14	43	12	48

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC		4		1		3
Bone related signs and symptoms	2	10	1	8	1	2
Bursal disorders		1		1		
Connective tissue disorders NEC	1	1			1	1
Extremity deformities		1				1
Joint related signs and symptoms	138	773	135	757	3	16
Lupus erythematosus (incl subtypes)	1	1			1	1
Muscle pains	398	1,768	397	1745	1	23
Muscle related signs and symptoms NEC	9	24	5	18	4	6
Muscle tone abnormalities	2	4	1	3	1	1
Muscle weakness conditions	11	25	6	15	5	10
Musculoskeletal and connective tissue conditions NEC	5	21	4	18	1	3
Musculoskeletal and connective tissue pain and discomfort	57	205	53	190	4	15
Osteoarthropathies		1		1		
Rheumatoid arthropathies	3	5			3	5
Soft tissue disorders NEC		1				1
Spondyloarthropathies	1	1			1	1
Tendon disorders	1	2	1	2		
	629	2,848	603	2759	26	89

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Leukaemias NEC	1	1	1	1
Metastases to specified sites	1	1	1	1
Myelodysplastic syndromes	1	2	1	2
Plasma cell myelomas	1	1	1	1

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Urinary tract neoplasms unspecified malignancy NEC		1		1
	4	6	4	6

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute polyneuropathies	2	3					2	3
Alzheimer's disease (incl subtypes)		1						1
Autonomic nervous system disorders	1	3					1	3
Central nervous system aneurysms and dissections	1	1					1	1
Central nervous system haemorrhages and cerebrovascular accidents	75	179	1	2			75	179
Central nervous system vascular disorders NEC		4				1		3
Cerebrovascular venous and sinus thrombosis	2	3					2	3
Cervical spinal cord and nerve root disorders		1				1		
Choreiform movements		1						1
Chronic polyneuropathies	1	1			1	1		
Coma states	2	3					2	3
Coordination and balance disturbances	2	21			1	12	1	9
Cortical dysfunction NEC	8	26			2	6	6	20
Dementia (excl Alzheimer's type)		3						3
Disturbances in consciousness NEC	43	201	3	4	3	14	40	187
Dyskinesias and movement disorders NEC	2	9			2	7		2
Encephalitis NEC		1						1
Encephalopathies NEC	1	2					1	2
Eye movement disorders		1				1		
Facial cranial nerve disorders	8	27				2	8	25
Generalised tonic-clonic seizures		6						6

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Headaches NEC	400	1,788			395	1757	5	31
Hydrocephalic conditions		1						1
Increased intracranial pressure disorders	1	2					1	2
Lumbar spinal cord and nerve root disorders		1						1
Memory loss (excl dementia)	3	9			3	7		2
Mental impairment (excl dementia and memory loss)	5	16			5	11		5
Migraine headaches	4	9			4	8		1
Mononeuropathies		2				1		1
Multiple sclerosis acute and progressive		2						2
Myelitis (incl infective)	1	1					1	1
Narcolepsy and hypersomnia	1	4			1	4		
Nervous system cysts and polyps		1						1
Neurological signs and symptoms NEC	53	246			48	215	5	31
Neurologic visual problems NEC	2	2					2	2
Neuromuscular disorders NEC		2				2		
Olfactory nerve disorders	2	11			2	11		
Optic nerve disorders NEC		1						1
Paraesthesias and dysaesthesias	37	99			28	85	9	14
Paralysis and paresis (excl cranial nerve)	11	36				1	11	35
Parkinson's disease and parkinsonism	1	4					1	4
Peripheral neuropathies NEC	4	10					4	10
Seizures and seizure disorders NEC	7	56				2	7	54
Sensory abnormalities NEC	8	54			8	54		
Speech and language abnormalities	4	25			2	10	2	15
Spinal cord and nerve root disorders NEC		2						2
Structural brain disorders NEC	1	2					1	2
Transient cerebrovascular events	31	81		1			31	81
Tremor (excl congenital)	3	21			2	17	1	4
Trigeminal disorders	2	4			2	4		
	729	2,989	4	7	509	2234	220	755

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* AE=Adverse Event

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System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion related conditions and complications		2		2
Abortions not specified as induced or spontaneous		2		2
Abortions spontaneous	2	13	2	13
	2	17	2	17

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product packaging issues	1	1	1	1
	1	1	1	1

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour NEC	1	2			1	2
Affect alterations NEC	1	3	1	3		
Anxiety symptoms	6	18	5	16	1	2
Behaviour and socialisation disturbances		1		1		
Communications disorders		2				2
Confusion and disorientation	9	35	5	17	4	18
Decreased physical activity levels		2		1		1
Deliria	6	30			6	30
Delusional symptoms		1		1		
Depressive disorders	1	7		4	1	3
Dissociative states		1		1		

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* AE=Adverse Event

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in initiating and maintaining sleep	2	8	2	8		
Dyssomnias	1	2	1	2		
Emotional and mood disturbances NEC		5		3		2
Fear symptoms and phobic disorders (incl social phobia)		2		1		1
Hallucinations (excl sleep-related)	7	12			7	12
Increased physical activity levels	3	10	3	9		1
Mental disorders NEC	2	2	1	1	1	1
Mood alterations with depressive symptoms	1	5	1	5		
Mood disorders NEC	4	11	4	10		1
Panic attacks and disorders		1		1		
Parasomnias		6		6		
Perception disturbances NEC		3		2		1
Personality disorders NEC		1		1		
Psychotic disorder NEC		2				2
Sleep disorders NEC		1		1		
Somatic symptom disorders		1				1
Speech and language usage disturbances		1		1		
Suicidal and self-injurious behaviour		1				1
Thinking disturbances	1	5	1	4		1
	45	181	24	99	21	82

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	3	17	1	6	2	11
Bladder infections and inflammations		1				1
Glomerulonephritis and nephrotic syndrome	2	5			2	5
Renal disorders NEC		2		2		

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System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal failure and impairment	8	16		1	8	15
Renal failure complications		2				2
Renal lithiasis		3				3
Renal vascular and ischaemic conditions	2	3			2	3
Urinary tract signs and symptoms NEC		1		1		
	15	50	1	10	14	40

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast disorders NEC		1		1		
Breast signs and symptoms		1		1		
Erection and ejaculation conditions and disorders	1	2			1	2
Menopausal effects on the genitourinary tract		2				2
Menstruation and uterine bleeding NEC	12	13	12	13		
Menstruation with decreased bleeding	2	2	2	2		
Menstruation with increased bleeding	2	2	2	2		
Reproductive tract disorders NEC (excl neoplasms)		1		1		
Reproductive tract signs and symptoms NEC	1	3	1	3		
Vulvovaginal disorders NEC	1	2	1	2		
Vulvovaginal signs and symptoms		1		1		
	19	30	18	26	1	4

System Organ Class

Respiratory, thoracic and mediastinal disorders

Interval Total #	Cumulative Total #	Non Interventional Study	Spontaneous	
		Serious	Nonserious	Serious

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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Breathing abnormalities	47	204
Bronchial conditions NEC	1	1
Bronchospasm and obstruction	6	16
Conditions associated with abnormal gas exchange	2	17
Coughing and associated symptoms	13	43
Laryngeal spasm, oedema and obstruction	3	7
Lower respiratory tract inflammatory and immunologic conditions	1	12
Lower respiratory tract signs and symptoms	1	5
Nasal congestion and inflammations	6	10
Nasal disorders NEC	4	21
Parenchymal lung disorders NEC	1	2
Pharyngeal disorders (excl infections and neoplasms)	7	26
Pneumothorax and pleural effusions NEC	1	4
Pulmonary hypertensions		1
Pulmonary oedemas	1	3
Pulmonary thrombotic and embolic conditions	36	73
Respiratory failures (excl neonatal)	3	13
Respiratory signs and symptoms NEC	3	6
Respiratory tract disorders NEC	1	15
Upper respiratory tract signs and symptoms	26	91
	163	570

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	2	29	111	18	93
				1	1
		2	5	4	11
				2	17
		11	36	2	7
			1	3	6
				1	12
		1	4		1
		6	9		1
1	1	4	14		7
		1	1		1
		2	8	5	18
		1	1		3
1	1				1
				1	3
				36	73
				3	13
		2	5	1	1
			6	1	9
		19	69	7	22
3	4	78	270	85	300

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acnes		1
Angioedemas	6	20

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				6	20

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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Apocrine and eccrine gland disorders	12	55			12	48		7
Bullous conditions	4	10			2	4	2	6
Dermal and epidermal conditions NEC	3	25			3	23		2
Dermatitis and eczema	6	12			6	12		
Dermatitis ascribed to specific agent	1	2					1	2
Erythemas	15	56			14	48	1	8
Exfoliative conditions	1	1			1	1		
Nail and nail bed conditions (excl infections and infestations)		1				1		
Panniculitides		2						2
Papulosquamous conditions		1				1		
Pilar disorders NEC	1	2			1	2		
Pruritus NEC	18	48		1	16	43	2	5
Psoriatic conditions	2	2			2	2		
Purpura and related conditions	1	9				6	1	3
Rashes, eruptions and exanthems NEC	26	77		1	26	71		6
Scaly conditions		1				1		
Skin vasculitides	2	4					2	4
Skin vasomotor conditions		1						1
Urticarias	8	28			6	21	2	7
	106	358		2	89	285	17	73

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	2	7	2	5		2
	2	7	2	5		2

System Organ Class

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System Organ Class

SOC Not Yet Coded

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
		1		1
		1		1

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accelerated and malignant hypertension		2						2
Aneurysms and dissections non-site specific		1						1
Aortic aneurysms and dissections	1	2					1	2
Aortic embolism and thrombosis	1	1					1	1
Aortic necrosis and vascular insufficiency	1	2			1	1		1
Arterial infections and inflammations		2						2
Blood pressure disorders NEC	3	3			2	2	1	1
Circulatory collapse and shock	4	12					4	12
Haemorrhages NEC	2	8				3	2	5
Lymphoedemas	1	1			1	1		
Non-site specific embolism and thrombosis	5	28					5	28
Non-site specific necrosis and vascular insufficiency NEC		2						2
Non-site specific vascular disorders NEC	3	4			1	1	2	3
Peripheral embolism and thrombosis	25	59			2	6	23	53
Peripheral vascular disorders NEC	2	14			2	11		3
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	10			1	8		2
Site specific vascular disorders NEC	3	18			3	11		7
Varicose veins NEC	2	2			1	1	1	1
Vascular hypertensive disorders NEC	16	54			7	26	9	28
Vascular hypotensive disorders	11	31		1	6	14	5	17
Vasculitides NEC		3				3		

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* AE=Adverse Event

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System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
	81	259		1	27	88	54	171

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Country Where Event Occurred

NEW ZEALAND

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Nausea and vomiting symptoms	1	2	1	2
	1	2	1	2

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	1	1	1	1		
General signs and symptoms NEC	1	2			1	2
Pain and discomfort NEC	1	1			1	1
Therapeutic and nontherapeutic responses		2				2
	3	6	1	1	2	5

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Allergic conditions NEC	20	25	20	25
	20	25	20	25

System Organ Class

Infections and infestations

Interval Total #	Cumulative Total #	Spontaneous
		Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coronavirus infections		1		1
		1		1

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures to agents or circumstances NEC		1				1
Product administration errors and issues	1	1	1	1		
	1	2	1	1		1

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate and pulse investigations	2	2	1	1	1	1
	2	2	1	1	1	1

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypoglycaemic conditions NEC		3		3
		3		3

System Organ Class

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* AE=Adverse Event
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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint related signs and symptoms	1	1	1	1		
Muscle pains	1	1			1	1
Musculoskeletal and connective tissue conditions NEC	1	1			1	1
	3	3	1	1	2	2

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Central nervous system haemorrhages and cerebrovascular accidents	1	1	1	1
Headaches NEC	1	1	1	1
Seizures and seizure disorders NEC	1	1	1	1
	3	3	3	3

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Non-site specific embolism and thrombosis	1	1	1	1
	1	1	1	1

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Country Where Event Occurred
NORTHERN MARIANA ISLANDS

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenic conditions		1		1
Feelings and sensations NEC		1		1
Pain and discomfort NEC		1		1
		3		3

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product administration errors and issues		2		2
		2		2

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms		1		1
Musculoskeletal and connective tissue pain and discomfort		1		1
		2		2

System Organ Class

Nervous system disorders

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headaches NEC		1		1
Neurological signs and symptoms NEC		1		1
		2		2

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Confusion and disorientation		1		1
Dyssomnias		1		1
		2		2

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Country Where Event Occurred

NORWAY

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia deficiencies	1	1			1	1
Bleeding tendencies		1				1
Eosinophilic disorders		1				1
Leukocytoses NEC	3	6	2	4	1	2
Lymphatic system disorders NEC	2	8	2	6		2
Marrow depression and hypoplastic anaemias		1				1
Neutropenias	3	4			3	4
Spleen disorders	1	1			1	1
Thrombocytopenias	4	11			4	11
	14	34	4	10	10	24

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders	2	4			2	4
Cardiac disorders NEC	1	4			1	4
Cardiac signs and symptoms NEC	9	16	3	7	6	9
Coronary artery disorders NEC	1	3			1	3
Heart failures NEC	1	5			1	5
Ischaemic coronary artery disorders	9	19			9	19
Left ventricular failures		1				1
Myocardial disorders NEC		1				1
Noninfectious pericarditis	5	11			5	11
Pericardial disorders NEC	1	4			1	4
Rate and rhythm disorders NEC	14	33	1	7	13	26

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Right ventricular failures	2	2			2	2
Supraventricular arrhythmias	5	12			5	12
Ventricular arrhythmias and cardiac arrest	4	11		1	4	10
	54	126	4	15	50	111

System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Neurological disorders congenital NEC	1	1	1	1
	1	1	1	1

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC		6		6		
Hearing disorders NEC		1		1		
Hearing losses	1	1			1	1
Inner ear signs and symptoms	1	5		1	1	4
	2	13		8	2	5

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Thyroid hyperfunction disorders		2		2
Thyroid hypofunction disorders	1	1	1	1
	1	3	1	3

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid movement disorders		1		1		
Iris and uveal tract infections, irritations and inflammations		2				2
Lacrimation disorders	1	1	1	1		
Lid, lash and lacrimal infections, irritations and inflammations	1	3	1	2		1
Ocular bleeding and vascular disorders NEC	1	3			1	3
Ocular disorders NEC	2	4	2	4		
Ocular infections, inflammations and associated manifestations	2	4	2	3		1
Ocular sensation disorders	1	4	1	3		1
Orbital structural change, deposit and degeneration		1				1
Pupil disorders		2				2
Refractive and accommodative disorders		1				1
Retinal bleeding and vascular disorders (excl retinopathy)	2	2			2	2
Visual disorders NEC	1	7	1	2		5
Visual field disorders	1	1			1	1
Visual impairment and blindness (excl colour blindness)	5	10	1	3	4	7
	17	46	9	19	8	27

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal wall conditions NEC		1				1
Acute and chronic pancreatitis	1	1			1	1
Colitis (excl infective)	1	1			1	1
Diarrhoea (excl infective)	8	38	3	20	5	18
Faecal abnormalities NEC	1	3		1	1	2
Flatulence, bloating and distension		1		1		
Gastric and oesophageal haemorrhages		1				1
Gastritis (excl infective)		1		1		
Gastrointestinal and abdominal pains (excl oral and throat)	12	41	6	19	6	22
Gastrointestinal atonic and hypomotility disorders NEC		2		1		1
Gastrointestinal disorders NEC		1				1
Gastrointestinal dyskinetic disorders		1				1
Gastrointestinal inflammatory disorders NEC		1				1
Gastrointestinal necrosis and gangrene (excl gangrenous hernia)		1				1
Gastrointestinal signs and symptoms NEC	2	12		4	2	8
Gastrointestinal spastic and hypermotility disorders	1	1	1	1		
Gastrointestinal vascular occlusion and infarction		2				2
Intestinal haemorrhages		2				2
Nausea and vomiting symptoms	53	182	23	93	30	89
Non-site specific gastrointestinal haemorrhages	4	9			4	9
Oral dryness and saliva altered		6		5		1
Oral soft tissue haemorrhages		2				2
Oral soft tissue signs and symptoms	12	22	6	10	6	12
Oral soft tissue swelling and oedema	5	6	2	2	3	4
Stomatitis and ulceration		1				1
Tongue disorders	1	1			1	1
Tongue signs and symptoms	9	9	2	2	7	7
	110	349	43	160	67	189

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* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	69	251	46	177	23	74
Body temperature altered		2				2
Death and sudden death	5	41			5	41
Febrile disorders	43	156	32	98	11	58
Feelings and sensations NEC	27	84	19	58	8	26
Gait disturbances	1	3		1	1	2
General signs and symptoms NEC	27	145	12	48	15	97
Inflammations	3	4	1	1	2	3
Injection site reactions	1	5	1	5		
Interactions	1	5		3	1	2
Oedema NEC		6		2		4
Pain and discomfort NEC	25	82	4	38	21	44
Therapeutic and nontherapeutic responses	16	21		1	16	20
Ulcers NEC	1	1	1	1		
Vaccination site reactions	34	105	32	88	2	17
	253	911	148	521	105	390

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cholecystitis and cholelithiasis		1		1
Hepatic and hepatobiliary disorders NEC		1		1
Hepatocellular damage and hepatitis NEC	1	1	1	1
	1	3	1	3

System Organ Class

Immune system disorders

Spontaneous

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* AE=Adverse Event
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System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	8	16	1	3	7	13
Allergies to foods, food additives, drugs and other chemicals		2				2
Anaphylactic and anaphylactoid responses	20	32			20	32
Immune and associated conditions NEC	2	3			2	3
	30	53	1	3	29	50

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections		5				5
Bacterial infections NEC	1	4			1	4
Borrelial infections		1				1
Breast infections	1	1			1	1
Central nervous system and spinal infections	1	1			1	1
Coronavirus infections	18	23	1	2	17	21
Eye and eyelid infections		1		1		
Fungal infections NEC	1	1			1	1
Herpes viral infections	16	19	13	14	3	5
Infections NEC	10	20	1	2	9	18
Influenza viral infections		2		2		
Lower respiratory tract and lung infections	4	32		1	4	31
Muscle and soft tissue infections	1	1			1	1
Sepsis, bacteraemia, viraemia and fungaemia NEC		6				6
Staphylococcal infections		1				1
Streptococcal infections	2	5			2	5
Upper respiratory tract infections		2		1		1
Urinary tract infections		7		5		2

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* AE=Adverse Event

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular infections		1				1
Viral infections NEC	1	1			1	1
	56	134	15	28	41	106

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal injuries NEC		1				1
Cardiac and vascular procedural complications		2				2
Cerebral injuries NEC	1	5			1	5
Conditions caused by cold	3	4	2	2	1	2
Exposures associated with pregnancy, delivery and lactation	1	3	1	3		
Exposures to agents or circumstances NEC	1	1	1	1		
Fractures and dislocations NEC		2				2
Limb fractures and dislocations		3				3
Medication errors, product use errors and issues NEC		2		2		
Non-site specific injuries NEC	6	29	1	6	5	23
Off label uses	6	10	6	10		
Product administration errors and issues	9	30	7	28	2	2
Product preparation errors and issues		11		11		
Site specific injuries NEC	1	3			1	3
Skin injuries NEC	1	5	1	2		3
Thoracic cage fractures and dislocations	1	1			1	1
Transfusion related complications		1		1		
Underdoses NEC		1		1		
	30	114	19	67	11	47

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmunity analyses		1		1		
Bacteria identification and serology (excl mycobacteria)		2		1		1
Blood gas and acid base analyses	3	22		2	3	20
Carbohydrate tolerance analyses (incl diabetes)	2	8	1	7	1	1
Cardiac auscultatory investigations	1	1	1	1		
Chemistry analyses NEC		1				1
Cholesterol analyses		1		1		
Coagulation and bleeding analyses	3	5			3	5
Haematological analyses NEC		2		1		1
Heart rate and pulse investigations	10	32	5	15	5	17
Liver function analyses		2		2		
Metabolism tests NEC		2				2
Mineral and electrolyte analyses	1	5		4	1	1
Physical examination procedures and organ system status	2	22	1	10	1	12
Platelet analyses	1	1			1	1
Protein analyses NEC	10	40	3	11	7	29
Red blood cell analyses		3				3
Renal function analyses	1	1			1	1
Respiratory and pulmonary function diagnostic procedures	1	1			1	1
Skeletal and cardiac muscle analyses		2		1		1
Thyroid analyses		1		1		
Vascular tests NEC (incl blood pressure)	15	35	5	11	10	24
Vitamin analyses		1		1		
White blood cell analyses	3	6		2	3	4
	53	197	16	72	37	125

System Organ Class

Metabolism and nutrition disorders

Spontaneous

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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	3	23	1	8	2	15
Diabetes mellitus (incl subtypes)		1				1
Electrolyte imbalance NEC		1				1
General nutritional disorders NEC	1	2	1	1		1
Hyperglycaemic conditions NEC		2		1		1
Potassium imbalance		1				1
Sodium imbalance		3				3
Total fluid volume decreased	2	5	2	3		2
	6	38	4	13	2	25

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	1	3		1	1	2
Bone related signs and symptoms	2	4		1	2	3
Bursal disorders	1	1			1	1
Connective tissue disorders NEC	1	1			1	1
Joint related signs and symptoms	22	53	14	40	8	13
Muscle pains	26	70	18	51	8	19
Muscle related signs and symptoms NEC	3	10	1	3	2	7
Muscle tone abnormalities		1				1
Muscle weakness conditions	2	9	1	3	1	6
Musculoskeletal and connective tissue conditions NEC	2	11	2	8		3
Musculoskeletal and connective tissue pain and discomfort	19	64	14	47	5	17
Soft tissue disorders NEC		1				1
Spondyloarthropathies		1				1
Tendon disorders	1	2		1	1	1

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* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	80	231	50	155	30	76

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Metastases to specified sites		1		1
Neoplasms benign site unspecified NEC		1		1
		2		2

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal sleep-related events	1	1	1	1		
Acute polyneuropathies		1				1
Alzheimer's disease (incl subtypes)		1				1
Autonomic nervous system disorders		1				1
Central nervous system haemorrhages and cerebrovascular accidents	20	73			20	73
Central nervous system vascular disorders NEC	2	4		1	2	3
Cerebrovascular venous and sinus thrombosis	1	1			1	1
Chronic polyneuropathies		1				1
Coma states		1				1
Coordination and balance disturbances	2	13	1	4	1	9
Cortical dysfunction NEC		5				5
Dementia (excl Alzheimer's type)		2				2
Disturbances in consciousness NEC	26	112	5	18	21	94

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* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyskinesias and movement disorders NEC	1	7	1	4		3
Eye movement disorders		1				1
Facial cranial nerve disorders	7	20	2	5	5	15
Generalised tonic-clonic seizures	1	2			1	2
Headaches NEC	52	152	37	113	15	39
Increased intracranial pressure disorders	1	1			1	1
Memory loss (excl dementia)	1	8	1	6		2
Mental impairment (excl dementia and memory loss)	3	9	2	5	1	4
Migraine headaches		6		2		4
Multiple sclerosis acute and progressive	2	2			2	2
Narcolepsy and hypersomnia	1	2	1	2		
Neurological signs and symptoms NEC	28	103	11	47	17	56
Neurologic visual problems NEC		1				1
Neuromuscular disorders NEC	1	3	1	2		1
Olfactory nerve disorders	1	3	1	3		
Paraesthesias and dysaesthesias	15	38	11	25	4	13
Paralysis and paresis (excl cranial nerve)	6	19		1	6	18
Peripheral neuropathies NEC		2				2
Seizures and seizure disorders NEC	2	9			2	9
Sensory abnormalities NEC	7	12	5	9	2	3
Speech and language abnormalities	1	15		4	1	11
Spinal cord and nerve root disorders NEC	1	1			1	1
Structural brain disorders NEC	1	1			1	1
Transient cerebrovascular events	2	7			2	7
Tremor (excl congenital)	5	13	2	5	3	8
	191	653	82	257	109	396

System Organ Class

Pregnancy, puerperium and perinatal conditions

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous	1	2	1	2
	1	2	1	2

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product distribution and storage issues	5	12	5	12
	5	12	5	12

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour NEC		1				1
Anxiety symptoms	3	7		1	3	6
Behaviour and socialisation disturbances		4		1		3
Communications disorders		1		1		
Confusion and disorientation	8	40	2	12	6	28
Deliria	1	7			1	7
Delusional symptoms	1	2			1	2
Disturbances in initiating and maintaining sleep	1	3	1	3		
Fear symptoms and phobic disorders (incl social phobia)	1	2		1	1	1
Hallucinations (excl sleep-related)	8	18			8	18
Increased physical activity levels	4	17		5	4	12
Mood alterations with depressive symptoms		1		1		
Mood alterations with manic symptoms		1				1

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* AE=Adverse Event

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mood disorders NEC	1	4	1	2		2
Panic attacks and disorders		1		1		
Parasomnias	1	3	1	3		
Perception disturbances NEC		1		1		
Psychiatric symptoms NEC	2	2	1	1	1	1
Sleep disorders NEC	2	5	1	2	1	3
	33	120	7	35	26	85

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	1	6		1	1	5
Glomerulonephritis and nephrotic syndrome		2				2
Nephritis NEC		1				1
Renal disorders NEC		1				1
Renal failure and impairment	3	10			3	10
Renal lithiasis		1				1
Renal neoplasms		1				1
Urinary tract signs and symptoms NEC	1	1	1	1		
	5	23	1	2	4	21

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast disorders NEC		1		1		
Breast signs and symptoms	1	2	1	2		

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System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Menstruation and uterine bleeding NEC	2	2	1	1	1	1
Menstruation with increased bleeding	1	1	1	1		
Vulvovaginal disorders NEC	1	1			1	1
	5	7	3	5	2	2

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	52	147	9	40	43	107
Bronchospasm and obstruction	10	23	3	4	7	19
Conditions associated with abnormal gas exchange	1	8			1	8
Coughing and associated symptoms	13	40	5	18	8	22
Laryngeal spasm, oedema and obstruction	1	3			1	3
Lower respiratory tract inflammatory and immunologic conditions		5				5
Lower respiratory tract signs and symptoms	1	11		3	1	8
Mediastinal disorders		1				1
Nasal congestion and inflammations	4	9	2	7	2	2
Nasal disorders NEC	2	8	2	6		2
Parenchymal lung disorders NEC	1	7	1	3		4
Pharyngeal disorders (excl infections and neoplasms)	5	10		1	5	9
Pleural infections and inflammations		1				1
Pneumothorax and pleural effusions NEC	1	4			1	4
Pulmonary oedemas		2				2
Pulmonary thrombotic and embolic conditions	33	47			33	47
Respiratory failures (excl neonatal)	5	15			5	15
Respiratory signs and symptoms NEC	4	5		1	4	4
Respiratory tract disorders NEC		3				3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Upper respiratory tract signs and symptoms	27	61	6	30	21	31
	160	410	28	113	132	297

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	4	7			4	7
Apocrine and eccrine gland disorders	11	33	3	16	8	17
Bullous conditions	2	2			2	2
Dermal and epidermal conditions NEC	3	6	2	4	1	2
Dermatitis and eczema		2				2
Dermatitis ascribed to specific agent		1				1
Erythemas	8	22	3	13	5	9
Exfoliative conditions		1				1
Pruritus NEC	11	28	5	11	6	17
Psoriatic conditions	1	2		1	1	1
Purpura and related conditions	4	10	1	2	3	8
Rashes, eruptions and exanthems NEC	23	45	8	22	15	23
Skin haemorrhages		4		2		2
Skin injuries and mechanical dermatoses		1		1		
Skin vasculitides	2	2			2	2
Skin vasomotor conditions		1		1		
Urticarias	19	30	11	14	8	16
	88	197	33	87	55	110

System Organ Class

Social circumstances

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	2	12	1	3	1	9
	2	12	1	3	1	9

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension		2				2
Aortic aneurysms and dissections	1	1			1	1
Aortic necrosis and vascular insufficiency		2		1		1
Arterial infections and inflammations		1				1
Circulatory collapse and shock	1	6			1	6
Haemorrhages NEC		6				6
Non-site specific embolism and thrombosis	1	2			1	2
Peripheral embolism and thrombosis	16	28	1	4	15	24
Peripheral vascular disorders NEC	3	10	2	6	1	4
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	4	1	3		1
Site specific embolism and thrombosis NEC	1	1			1	1
Site specific necrosis and vascular insufficiency NEC		1				1
Site specific vascular disorders NEC	2	14	1	5	1	9
Vascular hypertensive disorders NEC	5	11	2	6	3	5
Vascular hypotensive disorders	3	22	1	3	2	19
Vena caval embolism and thrombosis	1	1			1	1
	35	112	8	28	27	84

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

OMAN

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea (excl infective)		1		1
Gastritis (excl infective)		1		1
		2		2

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions		1		1		
Febrile disorders		1		1		
Pain and discomfort NEC		1		1		
Therapeutic and nontherapeutic responses	1	2		1	1	1
	1	5		4	1	1

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coronavirus infections	1	1	1	1
	1	1	1	1

System Organ Class

Injury, poisoning and procedural complications

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product administration errors and issues		1		1
		1		1

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headaches NEC		1		1
		1		1

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product supply and availability issues		1		1
		1		1

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Non-site specific embolism and thrombosis	1	1	1	1
	1	1	1	1

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* AE=Adverse Event
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Country Where Event Occurred
PALESTINIAN TERRITORY, OCCUPIED

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Feelings and sensations NEC	1	1	1	1
	1	1	1	1

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breathing abnormalities	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

PANAMA

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	4	5	4	5
	4	5	4	5

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC	4	5	4	5		
Rate and rhythm disorders NEC	7	7	5	5	2	2
	11	12	9	10	2	2

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear disorders NEC	1	1	1	1
Inner ear signs and symptoms	3	3	3	3
	4	4	4	4

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular disorders NEC	2	2	2	2
Visual disorders NEC	2	2	2	2
	4	4	4	4

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	9	9	8	8	1	1
Flatulence, bloating and distension		1		1		
Gastrointestinal and abdominal pains (excl oral and throat)	1	1	1	1		
Gastrointestinal signs and symptoms NEC	1	2	1	2		
Nausea and vomiting symptoms	15	15	13	13	2	2
Non-site specific gastrointestinal haemorrhages	1	1			1	1
Oral dryness and saliva altered	1	2	1	2		
Oral soft tissue signs and symptoms	2	3	2	2		1
Oral soft tissue swelling and oedema	3	3	3	3		
	33	37	29	32	4	5

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	31	38	27	34	4	4
Febrile disorders	33	35	31	32	2	3
Feelings and sensations NEC	28	29	27	28	1	1
Gait disturbances		1				1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
General signs and symptoms NEC	11	14	7	10	4	4
Oedema NEC	3	3	3	3		
Pain and discomfort NEC	23	23	22	22	1	1
Therapeutic and nontherapeutic responses	2	2			2	2
Vaccination site reactions	31	36	31	35		1
	162	181	148	164	14	17

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	7	9	6	8	1	1
Allergies to foods, food additives, drugs and other chemicals	11	13	10	12	1	1
Anaphylactic and anaphylactoid responses	2	3			2	3
	20	25	16	20	4	5

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacterial infections NEC	1	1	1	1		
Coronavirus infections	6	6	4	4	2	2
Herpes viral infections	1	1	1	1		
	8	8	6	6	2	2

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Medication errors, product use errors and issues NEC	1	1	1	1
Off label uses	1	1	1	1
Overdoses NEC		1		1
Product administration errors and issues	9	10	9	10
	11	13	11	13

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vascular tests NEC (incl blood pressure)	1	1	1	1
	1	1	1	1

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperglycaemic conditions NEC	2	2	1	1	1	1
	2	2	1	1	1	1

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone disorders NEC	1	1	1	1		
Bone related signs and symptoms	1	1	1	1		

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint related signs and symptoms	8	9	8	9		
Muscle pains	11	11	10	10	1	1
Muscle weakness conditions	1	1			1	1
Musculoskeletal and connective tissue conditions NEC	1	1	1	1		
Musculoskeletal and connective tissue pain and discomfort	12	12	11	11	1	1
	35	36	32	33	3	3

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute polyneuropathies	1	1			1	1
Coordination and balance disturbances	1	1	1	1		
Disturbances in consciousness NEC	1	4	1	1		3
Dyskinesias and movement disorders NEC		1		1		
Headaches NEC	47	48	45	46	2	2
Lumbar spinal cord and nerve root disorders	1	1	1	1		
Migraine headaches		1		1		
Muscle tone abnormal	1	2		1	1	1
Neurological signs and symptoms NEC	26	26	23	23	3	3
Neuromuscular disorders NEC	3	5	1	2	2	3
Olfactory nerve disorders	2	2	2	2		
Paraesthesias and dysaesthesias	13	14	12	12	1	2
Paralysis and paresis (excl cranial nerve)	1	2	1	1		1
Seizures and seizure disorders NEC	4	4			4	4
Sensory abnormalities NEC	4	4	4	4		
	105	116	91	96	14	20

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	3	3	3	3		
Confusion and disorientation		1		1		
Emotional and mood disturbances NEC	1	2		1	1	1
Mood alterations with depressive symptoms	1	1			1	1
	5	7	3	5	2	2

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bladder and urethral symptoms	1	1	1	1
	1	1	1	1

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	7	8	4	4	3	4
Bronchospasm and obstruction	3	3			3	3
Coughing and associated symptoms	9	9	7	7	2	2
Lower respiratory tract signs and symptoms		1				1
Nasal congestion and inflammations	2	2	2	2		
Nasal disorders NEC	1	1	1	1		
Pulmonary thrombotic and embolic conditions	1	1			1	1
Upper respiratory tract signs and symptoms	9	10	9	10		
	32	35	23	24	9	11

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	1	1			1	1
Apocrine and eccrine gland disorders	6	6	6	6		
Dermal and epidermal conditions NEC	2	2	2	2		
Erythemas	3	4	3	4		
Photosensitivity and photodermatosis conditions		1		1		
Pigmentation changes NEC	1	1	1	1		
Pruritus NEC	15	15	7	7	8	8
Rashes, eruptions and exanthems NEC	18	26	11	11	7	15
Urticarias	1	1	1	1		
	47	57	31	33	16	24

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	4	4			4	4
Haemorrhages NEC	1	1	1	1		
Peripheral vascular disorders NEC	2	2	2	2		
Site specific vascular disorders NEC	2	3	1	2	1	1
Vascular hypertensive disorders NEC	8	9	5	6	3	3
Vascular hypotensive disorders	3	3	3	3		
	20	22	12	14	8	8

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

PERU

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea (excl infective)	1	1	1	1
Gastrointestinal and abdominal pains (excl oral and throat)	2	2	2	2
Nausea and vomiting symptoms	2	2	2	2
Tongue signs and symptoms	1	1	1	1
	6	6	6	6

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Application and instillation site reactions	1	1	1	1		
Asthenic conditions	2	3	2	3		
Febrile disorders	1	7	1	7		
Feelings and sensations NEC	3	3	3	3		
General signs and symptoms NEC	1	1			1	1
Pain and discomfort NEC	2	6	2	6		
Therapeutic and nontherapeutic responses	3	4			3	4
Vaccination site reactions	5	7	5	7		
	18	32	14	27	4	5

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	3	5		1	3	4
Ear infections	1	1	1	1		
Streptococcal infections	1	1	1	1		
	5	7	2	3	3	4

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposures associated with pregnancy, delivery and lactation		2		2
Medication errors, product use errors and issues NEC		2		2
Off label uses		2		2
		6		6

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	1	1			1	1
Heart rate and pulse investigations	1	2	1	2		
	2	3	1	2	1	1

System Organ Class

Metabolism and nutrition disorders

Interval Total #	Cumulative Total #
------------------	--------------------

Spontaneous
Nonserious

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Food malabsorption and intolerance syndromes (excl sugar intolerance)	1	1	1	1
	1	1	1	1

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms	1	2	1	2
Musculoskeletal and connective tissue pain and discomfort	4	7	4	7
	5	9	5	9

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headaches NEC	5	10	5	10
Paraesthesias and dysaesthesias	1	1	1	1
Tremor (excl congenital)	1	1	1	1
	7	12	7	12

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchial conditions NEC	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nasal disorders NEC		2		1		1
Pharyngeal disorders (excl infections and neoplasms)	1	1	1	1		
Respiratory failures (excl neonatal)	1	1			1	1
Upper respiratory tract signs and symptoms	2	3	2	3		
	5	8	3	5	2	3

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Apocrine and eccrine gland disorders		1		1
		1		1

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular hypertensive disorders NEC	2	2	1	1	1	1
Vascular hypotensive disorders	1	1	1	1		
	3	3	2	2	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

PHILIPPINES

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea (excl infective)	1	1	1	1
	1	1	1	1

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	1	1	1	1		
Febrile disorders	5	5	5	5		
Feelings and sensations NEC	3	3	3	3		
Gait disturbances	1	1	1	1		
Pain and discomfort NEC	4	4	4	4		
Therapeutic and nontherapeutic responses	2	2	1	1	1	1
Vaccination site reactions	14	14	14	14		
	30	30	29	29	1	1

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	1	1			1	1
Upper respiratory tract infections	1	1	1	1		
	2	2	1	1	1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Physical examination procedures and organ system status	1	1	1	1
Vascular tests NEC (incl blood pressure)	7	7	7	7
	8	8	8	8

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms	2	2	2	2
Musculoskeletal and connective tissue pain and discomfort	1	1	1	1
	3	3	3	3

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Disturbances in consciousness NEC	1	1	1	1
Headaches NEC	2	2	2	2
Neurological signs and symptoms NEC	1	1	1	1
	4	4	4	4

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	2	2	1	1	1	1
Coughing and associated symptoms	1	1	1	1		
Upper respiratory tract signs and symptoms	1	1	1	1		
	4	4	3	3	1	1

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Country Where Event Occurred

POLAND

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias NEC	1	2			1	2
Bleeding tendencies		1				1
Coagulopathies	1	3		1	1	2
Lymphatic system disorders NEC	9	112	9	46		66
Thrombocytopenias	1	2			1	2
	12	120	9	47	3	73

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC	1	4	1	2		2
Cardiac signs and symptoms NEC	5	13	3	5	2	8
Coronary artery disorders NEC		1				1
Heart failures NEC		2				2
Ischaemic coronary artery disorders	3	8			3	8
Myocardial disorders NEC		2				2
Noninfectious myocarditis		1				1
Rate and rhythm disorders NEC	12	55	4	8	8	47
Supraventricular arrhythmias	3	9			3	9
Ventricular arrhythmias and cardiac arrest	9	21			9	21
	33	116	8	15	25	101

System Organ Class

Ear and labyrinth disorders

Spontaneous

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	1	3	1	2		1
Hearing losses	2	6	1	1	1	5
Hyperacusia		1		1		
Inner ear disorders NEC	1	1			1	1
Inner ear signs and symptoms	5	17	4	10	1	7
	9	28	6	14	3	14

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute and chronic thyroiditis		1		1
Thyroid disorders NEC		2		2
		3		3

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cataract conditions	1	1			1	1
Conjunctival and corneal bleeding and vascular disorders		1				1
Conjunctival infections, irritations and inflammations		3		1		2
Iris and uveal tract infections, irritations and inflammations	1	2		1	1	1
Lacrimation disorders	1	8	1	1		7
Lid, lash and lacrimal infections, irritations and inflammations		1				1

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* AE=Adverse Event

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lid, lash and lacrimal structural disorders		1		1		
Ocular disorders NEC	5	18	4	7	1	11
Ocular infections, inflammations and associated manifestations	2	4	1	1	1	3
Ocular sensation disorders	6	10	5	6	1	4
Scleral infections, irritations and inflammations	1	1			1	1
Visual disorders NEC	2	3	1	2	1	1
Visual field disorders		2		2		
Visual impairment and blindness (excl colour blindness)	10	16	6	8	4	8
	29	71	18	30	11	41

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis		2				2
Dental pain and sensation disorders		3		2		1
Diarrhoea (excl infective)	10	45	9	29	1	16
Dyspeptic signs and symptoms	1	2	1	1		1
Faecal abnormalities NEC		1				1
Flatulence, bloating and distension	1	4	1	2		2
Gastritis (excl infective)	1	1			1	1
Gastrointestinal and abdominal pains (excl oral and throat)	4	29	3	16	1	13
Gastrointestinal atonic and hypomotility disorders NEC	1	1	1	1		
Gastrointestinal disorders NEC	2	4	1	2	1	2
Gastrointestinal signs and symptoms NEC	1	8	1	2		6
Gastrointestinal spastic and hypermotility disorders	2	2	2	2		

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gingival disorders, signs and symptoms NEC		1		1		
Nausea and vomiting symptoms	36	134	32	85	4	49
Non-site specific gastrointestinal haemorrhages		4				4
Oral dryness and saliva altered		3		2		1
Oral soft tissue disorders NEC		1				1
Oral soft tissue signs and symptoms	9	20	8	11	1	9
Oral soft tissue swelling and oedema	1	3	1	1		2
Stomatitis and ulceration		1		1		
Tongue signs and symptoms	1	5	1	1		4
	70	274	61	159	9	115

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	101	345	86	242	15	103
Body temperature altered		1				1
Death and sudden death	3	24			3	24
Febrile disorders	72	300	61	176	11	124
Feelings and sensations NEC	55	195	53	142	2	53
Gait disturbances	4	9	2	5	2	4
General signs and symptoms NEC	25	59	20	39	5	20
Inflammations		4		3		1
Injection site reactions		4		4		
Oedema NEC	4	15	3	5	1	10
Pain and discomfort NEC	21	57	18	42	3	15
Therapeutic and nontherapeutic responses	27	99		5	27	94
Vaccination site reactions	80	332	69	243	11	89
	392	1,444	312	906	80	538

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System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	3	28	1	4	2	24
Allergies to foods, food additives, drugs and other chemicals	2	9	2	5		4
Anaphylactic and anaphylactoid responses	2	27			2	27
Immune and associated conditions NEC	2	2	2	2		
	9	66	5	11	4	55

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Candida infections		1		1		
Coronavirus infections	43	133	8	18	35	115
Dental and oral soft tissue infections		2		2		
Ear infections		2				2
Herpes viral infections	5	10	5	10		
Infections NEC	2	7	2	5		2
Influenza viral infections	1	2	1	2		
Lower respiratory tract and lung infections	5	13			5	13
Rotaviral infections	1	1	1	1		
Sepsis, bacteraemia, viraemia and fungaemia NEC		1				1
Streptococcal infections		1				1
Upper respiratory tract infections	5	12	5	9		3
Urinary tract infections		1		1		
Viral infections NEC		4		2		2
	62	190	22	51	40	139

System Organ Class

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental exposures to product	1	1	1	1		
Bone and joint injuries NEC		1				1
Exposures associated with pregnancy, delivery and lactation	2	17	2	17		
Medication errors, product use errors and issues NEC	2	13	2	12		1
Muscle, tendon and ligament injuries		1				1
Nerve injuries NEC	1	1	1	1		
Non-site specific injuries NEC	1	6	1	1		5
Off label uses	2	16	2	15		1
Pathways and sources of exposure	1	1	1	1		
Peripheral nerve injuries		1				1
Product administration errors and issues	13	30	13	30		
Product confusion errors and issues		2		2		
Product preparation errors and issues		1		1		
Site specific injuries NEC		1				1
Skin injuries NEC	3	10	3	4		6
Underdoses NEC	2	2	2	2		
Vaccination related complications		2		2		
	28	106	28	89		17

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	2	17	1	4	1	13
Carbohydrate tolerance analyses (incl diabetes)	1	3	1	1		2
Cell marker analyses		1				1
Coagulation and bleeding analyses		2		1		1
Heart rate and pulse investigations	12	25	7	13	5	12

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Histopathology procedures NEC		1		1		
Immunology analyses NEC		10		10		
Liver function analyses		5				5
Musculoskeletal and soft tissue imaging procedures		1		1		
Physical examination procedures and organ system status	13	28	9	18	4	10
Pituitary analyses anterior		1				1
Protein analyses NEC		4		2		2
Skeletal and cardiac muscle analyses		3		1		2
Urinalysis NEC	1	3	1	3		
Vascular tests NEC (incl blood pressure)	13	65	5	14	8	51
Virus identification and serology	2	5	1	3	1	2
White blood cell analyses	1	7	1	6		1
	45	181	26	78	19	103

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	7	20	7	13		7
Diabetes mellitus (incl subtypes)	1	2			1	2
Electrolyte imbalance NEC		1		1		
Metabolic acidoses (excl diabetic acidoses)		1				1
	8	24	7	14	1	10

System Organ Class

Musculoskeletal and connective tissue disorders

Interval Total #	Cumulative Total #	Spontaneous			
		Nonserious		Serious	

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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	5	8	5	8		
Bone related signs and symptoms	7	31	6	21	1	10
Bursal disorders		1		1		
Intervertebral disc disorders NEC		1				1
Joint related signs and symptoms	24	114	21	76	3	38
Lupus erythematosus (incl subtypes)		1				1
Muscle pains	34	159	31	107	3	52
Muscle related signs and symptoms NEC	2	6	2	6		
Muscle weakness conditions	5	11	3	5	2	6
Musculoskeletal and connective tissue conditions NEC	4	11	4	10		1
Musculoskeletal and connective tissue pain and discomfort	54	159	50	129	4	30
Myopathies		1				1
Psoriatic arthropathies		1				1
Rheumatoid arthropathies	1	1			1	1
Soft tissue disorders NEC		1		1		
Spine and neck deformities		1				1
Synovial disorders		1		1		
	136	508	122	365	14	143

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bladder neoplasms malignant		1		1
		1		1

System Organ Class

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute polyneuropathies		1				1
Central nervous system haemorrhages and cerebrovascular accidents	3	13			3	13
Choreiform movements		1		1		
Coma states		1				1
Coordination and balance disturbances	5	9	5	8		1
Cortical dysfunction NEC		3		1		2
Cranial nerve disorders NEC		1				1
Disturbances in consciousness NEC	25	101	8	17	17	84
Dyskinesias and movement disorders NEC	3	6	3	5		1
Encephalopathies NEC		2				2
Facial cranial nerve disorders	3	15			3	15
Generalised tonic-clonic seizures		1				1
Headaches NEC	53	191	49	137	4	54
Increased intracranial pressure disorders		1				1
Lumbar spinal cord and nerve root disorders		2		1		1
Memory loss (excl dementia)	4	7	4	6		1
Mental impairment (excl dementia and memory loss)	4	11	3	8	1	3
Migraine headaches	2	4	2	4		
Mononeuropathies		1		1		
Multiple sclerosis acute and progressive		1				1
Muscle tone abnormal		3				3
Nervous system disorders NEC	1	2			1	2
Neurological signs and symptoms NEC	32	88	31	57	1	31
Neuromuscular disorders NEC	1	26		4	1	22
Olfactory nerve disorders	2	17	2	13		4
Optic nerve disorders NEC		1				1
Paraesthesias and dysaesthesias	24	82	17	44	7	38
Paralysis and paresis (excl cranial nerve)	2	11		1	2	10
Parkinson's disease and parkinsonism	1	1			1	1
Peripheral neuropathies NEC		1				1

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Seizures and seizure disorders NEC	6	38			6	38
Sensory abnormalities NEC	13	37	11	24	2	13
Speech and language abnormalities	5	16	4	7	1	9
Spinal cord and nerve root disorders NEC		3		2		1
Transient cerebrovascular events		1				1
Tremor (excl congenital)	3	10	2	6	1	4
Trigeminal disorders	2	6		2	2	4
	194	715	141	349	53	366

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Device physical property and chemical issues	1	2	1	2
Product contamination and sterility issues		1		1
Product distribution and storage issues		1		1
Product physical issues	1	1	1	1
Product supply and availability issues	2	2	2	2
	4	7	4	7

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	2	12	2	7		5
Cognitive and attention disorders and disturbances NEC		1		1		
Communications disorders		1		1		

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Confusion and disorientation	5	13	4	6	1	7
Deliria	1	3			1	3
Disturbances in initiating and maintaining sleep	9	20	8	19	1	1
Dyssomnias		1		1		
Eating disorders NEC		1		1		
Emotional and mood disturbances NEC	1	2	1	2		
Fear symptoms and phobic disorders (incl social phobia)	1	1			1	1
Hallucinations (excl sleep-related)		1				1
Increased physical activity levels		1				1
Mental disorders NEC	1	2	1	2		
Mood alterations with depressive symptoms	2	2	1	1	1	1
Parasomnias		1		1		
Perception disturbances NEC	1	1	1	1		
Psychiatric symptoms NEC		2		1		1
Sleep disorders NEC	1	2	1	1		1
	24	67	19	45	5	22

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	3	6	3	3		3
Bladder disorders NEC	1	1	1	1		
Genitourinary tract infections and inflammations NEC		1				1
Glomerulonephritis and nephrotic syndrome	1	1			1	1
Renal disorders NEC	1	1			1	1
Renal failure and impairment	1	11		1	1	10
Renal obstructive disorders		1				1

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* AE=Adverse Event

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System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urinary abnormalities	1	5	1	2		3
Urinary tract signs and symptoms NEC		1		1		
	8	28	5	8	3	20

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast disorders NEC	1	2	1	2		
Breast signs and symptoms		2		1		1
Lactation disorders		2		1		1
Menstruation and uterine bleeding NEC	5	5	5	5		
Pelvis and broad ligament disorders NEC		1		1		
Prostate and seminal vesicles infections and inflammations		1				1
	6	13	6	10		3

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	16	72	6	18	10	54
Bronchospasm and obstruction	1	11	1	1		10
Conditions associated with abnormal gas exchange		2				2
Coughing and associated symptoms	9	29	7	15	2	14
Laryngeal spasm, oedema and obstruction		9				9
Lower respiratory tract signs and symptoms	1	3	1	2		1
Nasal congestion and inflammations		2		1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nasal disorders NEC	1	3	1	3		
Parenchymal lung disorders NEC		2		2		
Pharyngeal disorders (excl infections and neoplasms)	1	6	1	3		3
Pneumothorax and pleural effusions NEC		1		1		
Pulmonary oedemas	2	6			2	6
Pulmonary thrombotic and embolic conditions	1	1			1	1
Respiratory failures (excl neonatal)	3	8			3	8
Respiratory signs and symptoms NEC	1	4	1	2		2
Respiratory tract disorders NEC	1	7	1	4		3
Tracheal disorders (excl infections and neoplasms)		1				1
Upper respiratory tract signs and symptoms	7	32	5	23	2	9
	44	199	24	75	20	124

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecias	1	1	1	1		
Angioedemas	1	13			1	13
Apocrine and eccrine gland disorders	10	34	8	22	2	12
Bullous conditions	1	5			1	5
Dermal and epidermal conditions NEC	6	11	5	6	1	5
Dermatitis and eczema	1	2			1	2
Erythemas	7	20	5	9	2	11
Exfoliative conditions		1				1
Pruritus NEC	5	13	5	8		5
Purpura and related conditions	5	10	1	2	4	8
Rashes, eruptions and exanthems NEC	11	41	5	15	6	26

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin and subcutaneous conditions NEC		1		1		
Skin haemorrhages		1				1
Skin hyperplasias and hypertrophies		1		1		
Skin vasomotor conditions	2	6			2	6
Urticarias	2	14	1	4	1	10
	52	174	31	69	21	105

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	1	3	1	2		1
Educational issues		1				1
	1	4	1	2		2

System Organ Class

SOC Not Yet Coded

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
		1		1
		1		1

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

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System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysms and dissections		1				1
Blood pressure disorders NEC	2	4	1	1	1	3
Circulatory collapse and shock	1	4			1	4
Haemorrhages NEC		1		1		
Lymphoedemas	1	1	1	1		
Non-site specific embolism and thrombosis	7	16			7	16
Non-site specific necrosis and vascular insufficiency NEC		2		1		1
Non-site specific vascular disorders NEC	1	3	1	2		1
Peripheral embolism and thrombosis	4	6	2	3	2	3
Peripheral vascular disorders NEC	1	12	1	6		6
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	3	1	2		1
Phlebitis NEC		1		1		
Site specific vascular disorders NEC	2	12	1	2	1	10
Varicose veins NEC		1				1
Vascular hypertensive disorders NEC	3	11		1	3	10
Vascular hypotensive disorders	1	6	1	2		4
	24	84	9	23	15	61

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

PORTUGAL

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias NEC		1		1		
Coagulopathies		1				1
Leukocytoses NEC		3				3
Lymphatic system disorders NEC	54	306	39	82	15	224
Marrow depression and hypoplastic anaemias		2				2
Thrombocytopenias	1	2			1	2
	55	315	39	83	16	232

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders	1	3			1	3
Cardiac disorders NEC		1				1
Cardiac signs and symptoms NEC	7	27	3	7	4	20
Heart failures NEC		1				1
Ischaemic coronary artery disorders		6				6
Noninfectious myocarditis		2				2
Noninfectious pericarditis	1	2			1	2
Pericardial disorders NEC		1				1
Rate and rhythm disorders NEC	24	109	11	25	13	84
Supraventricular arrhythmias	2	6			2	6
Ventricular arrhythmias and cardiac arrest	2	8	1	1	1	7
	37	166	15	33	22	133

System Organ Class

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	4	9	1	2	3	7
Hearing disorders NEC		1				1
Hearing losses	3	13			3	13
Inner ear signs and symptoms	15	41	6	10	9	31
	22	64	7	12	15	52

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute and chronic thyroiditis		1		1
Thyroid disorders NEC		1		1
Thyroid hypofunction disorders		1		1
		3		3

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Choroid and vitreous structural change, deposit and degeneration		1				1
Conjunctival and corneal bleeding and vascular disorders		1				1
Conjunctival infections, irritations and inflammations		1				1
Corneal structural change, deposit and degeneration		2				2
Eyelid movement disorders	1	2	1	1		1
Lacrimation disorders		2		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lid, lash and lacrimal infections, irritations and inflammations	3	7	1	1	2	6
Ocular bleeding and vascular disorders NEC	3	3			3	3
Ocular disorders NEC	6	14	2	8	4	6
Ocular infections, inflammations and associated manifestations	2	10	2	6		4
Ocular nerve and muscle disorders		1				1
Ocular sensation disorders		9		3		6
Retinal bleeding and vascular disorders (excl retinopathy)	1	2			1	2
Retinal, choroid and vitreous infections and inflammations		1				1
Scleral infections, irritations and inflammations		1				1
Structural change, deposit and degeneration of eye NEC		1				1
Visual disorders NEC	9	18	3	8	6	10
Visual impairment and blindness (excl colour blindness)	6	14	1	2	5	12
	31	90	10	30	21	60

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis		1				1
Colitis (excl infective)		2				2
Diarrhoea (excl infective)	25	120	16	38	9	82
Dyspeptic signs and symptoms		7		3		4
Faecal abnormalities NEC		2				2
Flatulence, bloating and distension		4		1		3
Gastrointestinal and abdominal pains (excl oral and throat)	13	60	7	17	6	43

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal atonic and hypomotility disorders NEC		1				1
Gastrointestinal disorders NEC	4	8	2	2	2	6
Gastrointestinal signs and symptoms NEC	7	45	5	13	2	32
Gastrointestinal stenosis and obstruction NEC	1	1			1	1
Nausea and vomiting symptoms	103	438	62	126	41	312
Non-site specific gastrointestinal haemorrhages		1				1
Oesophageal disorders NEC		1				1
Oral dryness and saliva altered	2	12	2	6		6
Oral soft tissue disorders NEC	1	4	1	2		2
Oral soft tissue signs and symptoms	9	50	6	18	3	32
Oral soft tissue swelling and oedema	2	21		1	2	20
Stomatitis and ulceration		7		3		4
Tongue disorders		3		2		1
Tongue signs and symptoms	2	32		7	2	25
	169	820	101	239	68	581

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site reactions NEC		5		4		1
Application and instillation site reactions	1	1	1	1		
Asthenic conditions	100	591	78	167	22	424
Body temperature altered	2	18	1	4	1	14
Death and sudden death	2	11			2	11
Febrile disorders	121	619	102	185	19	434
Feelings and sensations NEC	66	333	51	100	15	233
Gait disturbances	1	7	1	3		4
General signs and symptoms NEC	11	49	4	15	7	34

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inflamations	1	6			1	6
Injection site reactions	2	10	2	9		1
Interactions		2				2
Mass conditions NEC	1	2	1	2		
Mucosal findings abnormal		1				1
Oedema NEC	17	73	6	17	11	56
Pain and discomfort NEC	58	214	42	78	16	136
Therapeutic and nontherapeutic responses	11	137			11	137
Vaccination site reactions	254	1,076	226	534	28	542
	648	3,155	515	1119	133	2036

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bile duct infections and inflammations		1				1
Cholestasis and jaundice	1	3			1	3
Hepatic and hepatobiliary disorders NEC	1	1	1	1		
Hepatocellular damage and hepatitis NEC	1	3			1	3
	3	8	1	1	2	7

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	3	16		4	3	12
Allergies to foods, food additives, drugs and other chemicals		4				4

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic and anaphylactoid responses	6	32			6	32
Immune and associated conditions NEC		1		1		
Vasculitides	1	1			1	1
	10	54		5	10	49

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacterial infections NEC	1	4	1	1		3
Breast infections	1	3			1	3
Candida infections		2				2
Central nervous system and spinal infections		1				1
Coronavirus infections	46	228	38	73	8	155
Dental and oral soft tissue infections		1		1		
Escherichia infections		1				1
Herpes viral infections	9	15	4	5	5	10
Infections NEC		2		1		1
Influenza viral infections		7		1		6
Lower respiratory tract and lung infections	2	4			2	4
Neisseria infections		1				1
Sepsis, bacteraemia, viraemia and fungaemia NEC		1				1
Skin structures and soft tissue infections		1				1
Treponema infections		2				2
Upper respiratory tract infections	2	9	2	5		4
Urinary tract infections	1	8	1	1		7
Viral infections NEC	1	2	1	1		1
	63	292	47	89	16	203

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* AE=Adverse Event

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conditions caused by cold		1		1		
Exposures associated with pregnancy, delivery and lactation	7	31	7	30		1
Exposures to agents or circumstances NEC		1				1
Gastrointestinal and hepatobiliary procedural complications		1				1
Limb fractures and dislocations		1				1
Medication errors, product use errors and issues NEC	4	17	4	17		
Non-site specific injuries NEC	2	7	1	4	1	3
Non-site specific procedural complications		1				1
Occupational exposures		1		1		
Off label uses	6	21	6	21		
Overdoses NEC	19	42	18	40	1	2
Product administration errors and issues	13	43	13	42		1
Product preparation errors and issues	1	1	1	1		
Site specific injuries NEC		1				1
Skin injuries NEC	2	4		1	2	3
Underdoses NEC	1	1	1	1		
Vaccination related complications	1	5	1	2		3
	56	179	52	161	4	18

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	2	15			2	15
Carbohydrate tolerance analyses (incl diabetes)		2		1		1
Central nervous system imaging procedures		1		1		
Coagulation and bleeding analyses		4		3		1
Digestive enzymes		2				2

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
ECG investigations	1	1	1	1		
Heart rate and pulse investigations	7	13	5	6	2	7
Liver function analyses	1	2			1	2
Mineral and electrolyte analyses	1	1			1	1
Physical examination procedures and organ system status	2	14	1	5	1	9
Pituitary analyses anterior		1				1
Platelet analyses		1		1		
Red blood cell analyses	1	1	1	1		
Renal function analyses	1	1	1	1		
Respiratory and pulmonary function diagnostic procedures		2				2
Respiratory tract and thoracic imaging procedures		1		1		
Thyroid analyses		1		1		
Vascular tests NEC (incl blood pressure)	6	20	2	5	4	15
Virus identification and serology	8	17	6	6	2	11
White blood cell analyses	1	2	1	2		
	31	102	18	35	13	67

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	6	42	2	7	4	35
Fluid intake increased		5				5
Hyperglycaemic conditions NEC		5		1		4
Hypoglycaemic conditions NEC	3	6	1	1	2	5
Metabolic acidoses (excl diabetic acidoses)		1				1
Mixed acid-base disorders		1				1
Potassium imbalance		3				3

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	9	63	3	9	6	54

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	1	2			1	2
Bone related signs and symptoms	1	5	1	2		3
Bursal disorders		1				1
Joint related signs and symptoms	56	257	44	63	12	194
Muscle pains	191	885	165	289	26	596
Muscle related signs and symptoms NEC		10		3		7
Muscle tone abnormalities		2				2
Muscle weakness conditions	7	22	4	5	3	17
Musculoskeletal and connective tissue conditions NEC	7	23	3	7	4	16
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		1				1
Musculoskeletal and connective tissue pain and discomfort	39	150	26	57	13	93
Myopathies	1	2			1	2
Soft tissue disorders NEC	1	5		2	1	3
Spondyloarthropathies		1				1
Synovial disorders	3	12	3	3		9
Tendon disorders		1		1		
	307	1,379	246	432	61	947

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Spontaneous

* I=Interval, C=Cumulative
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* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)		1		1
Nervous system neoplasms unspecified malignancy NEC		1		1
		2		2

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autonomic nervous system disorders	1	3			1	3
Central nervous system haemorrhages and cerebrovascular accidents	26	43			26	43
Cerebrovascular venous and sinus thrombosis		2				2
Coordination and balance disturbances	7	17	3	3	4	14
Cortical dysfunction NEC	1	3			1	3
Disturbances in consciousness NEC	20	130	11	45	9	85
Dyskinesias and movement disorders NEC	4	14	3	5	1	9
Dystonias	1	1			1	1
Facial cranial nerve disorders	4	19		1	4	18
Generalised tonic-clonic seizures	1	4			1	4
Headaches NEC	169	772	140	264	29	508
Hydrocephalic conditions		1				1
Hypoglossal nerve disorders	1	1			1	1
Lumbar spinal cord and nerve root disorders		1				1
Memory loss (excl dementia)		1		1		
Mental impairment (excl dementia and memory loss)	1	2	1	1		1
Migraine headaches		9		3		6
Mononeuropathies	1	1	1	1		
Neurological signs and symptoms NEC	54	244	33	76	21	168

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuromuscular disorders NEC	1	5		1	1	4
Olfactory nerve disorders	4	8	3	3	1	5
Paraesthesias and dysaesthesias	39	160	22	58	17	102
Paralysis and paresis (excl cranial nerve)	2	6			2	6
Parkinson's disease and parkinsonism	1	1			1	1
Peripheral neuropathies NEC		2				2
Seizures and seizure disorders NEC	1	12			1	12
Sensory abnormalities NEC	9	56	7	26	2	30
Speech and language abnormalities	1	10		2	1	8
Spinal cord and nerve root disorders NEC		1				1
Transient cerebrovascular events	1	2			1	2
Tremor (excl congenital)	8	52	5	12	3	40
Trigeminal disorders		2		1		1
	358	1,585	229	503	129	1082

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions not specified as induced or spontaneous	1	1	1	1
Abortions spontaneous	1	3	1	3
	2	4	2	4

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour NEC	1	1			1	1
Anxiety symptoms	4	19	3	9	1	10
Cognitive and attention disorders and disturbances NEC		1				1
Confusion and disorientation	3	8	2	3	1	5
Disturbances in initiating and maintaining sleep	9	34	7	14	2	20
Dyssomnias		2				2
Emotional and mood disturbances NEC	1	3		1	1	2
Fear symptoms and phobic disorders (incl social phobia)	1	2			1	2
Hallucinations (excl sleep-related)		1				1
Increased physical activity levels		1		1		
Mood alterations with depressive symptoms		1				1
Mood disorders NEC		1				1
Sexual desire disorders		1		1		
Sleep disorders NEC	1	6	1	1		5
Thinking disturbances	1	3			1	3
	21	84	13	30	8	54

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms		1				1
Bladder disorders NEC		1				1
Renal failure and impairment		5		1		4
Renal vascular and ischaemic conditions		1				1
Urinary abnormalities		3		2		1
Urinary tract signs and symptoms NEC	1	2			1	2
	1	13		3	1	10

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast disorders NEC		2		1		1
Breast signs and symptoms		9		4		5
Lactation disorders		1		1		
Menstruation and uterine bleeding NEC	1	3	1	2		1
Menstruation with decreased bleeding		1		1		
Reproductive tract signs and symptoms NEC		1				1
Vulvovaginal disorders NEC		2				2
Vulvovaginal signs and symptoms		3		1		2
	1	22	1	10		12

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	14	77	7	13	7	64
Bronchospasm and obstruction	1	13		1	1	12
Conditions associated with abnormal gas exchange	1	1			1	1
Coughing and associated symptoms	14	72	9	19	5	53
Laryngeal spasm, oedema and obstruction	2	15			2	15
Lower respiratory tract inflammatory and immunologic conditions		2				2
Lower respiratory tract signs and symptoms		2				2
Nasal congestion and inflammations	3	9	1	2	2	7
Nasal disorders NEC	1	11		6	1	5
Parenchymal lung disorders NEC		2		1		1
Pharyngeal disorders (excl infections and neoplasms)	2	21		4	2	17
Pulmonary oedemas		1				1
Pulmonary thrombotic and embolic conditions	7	11			7	11

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory failures (excl neonatal)		1				1
Respiratory signs and symptoms NEC	1	2			1	2
Respiratory tract disorders NEC		2				2
Upper respiratory tract signs and symptoms	28	126	23	54	5	72
	74	368	40	100	34	268

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes		1				1
Alopecias	1	1	1	1		
Angioedemas	1	13			1	13
Apocrine and eccrine gland disorders	12	49	6	12	6	37
Bullous conditions	2	2	1	1	1	1
Dermal and epidermal conditions NEC	7	24	4	6	3	18
Dermatitis and eczema	3	6			3	6
Dermatitis ascribed to specific agent	1	2			1	2
Erythemas	12	45	7	16	5	29
Exfoliative conditions	2	6			2	6
Nail and nail bed conditions (excl infections and infestations)	1	1			1	1
Panniculitides		1				1
Papulosquamous conditions		2				2
Pigmentation changes NEC	1	1	1	1		
Pilar disorders NEC		4				4
Pruritus NEC	17	64	12	21	5	43
Purpura and related conditions	9	17	4	5	5	12
Rashes, eruptions and exanthems NEC	19	134	10	42	9	92
Skin vasculitides	1	2			1	2

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Telangiectasia and related conditions	1	1			1	1
Urticarias	11	32	6	11	5	21
	101	408	52	116	49	292

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues		9		1		8
Pregnancy related circumstances		1				1
		10		1		9

System Organ Class

Surgical and medical procedures

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breast therapeutic procedures NEC		1		1
		1		1

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	4	9			4	9
Arterial infections and inflammations		1				1
Blood pressure disorders NEC		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circulatory collapse and shock		2				2
Haemorrhages NEC	6	10	1	2	5	8
Lymphoedemas		1				1
Non-site specific embolism and thrombosis	5	10			5	10
Non-site specific necrosis and vascular insufficiency NEC	1	2		1	1	1
Non-site specific vascular disorders NEC		1				1
Peripheral embolism and thrombosis	9	15	1	1	8	14
Peripheral vascular disorders NEC	3	27	2	7	1	20
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	8			1	8
Phlebitis NEC	2	3			2	3
Site specific vascular disorders NEC	4	17	1	3	3	14
Vascular hypertensive disorders NEC	7	47	1	5	6	42
Vascular hypotensive disorders	7	33	3	4	4	29
Vasculitides NEC	2	4			2	4
	51	191	9	23	42	168

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

PUERTO RICO

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	1	9	1	9
	1	9	1	9

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC		1		1		
Rate and rhythm disorders NEC		3		3		
Supraventricular arrhythmias		1				1
		5		4		1

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Eyelid movement disorders		1		1
Lid, lash and lacrimal infections, irritations and inflammations	1	1	1	1
Ocular sensation disorders		2		2
	1	4	1	4

System Organ Class

Gastrointestinal disorders

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea (excl infective)	1	4	1	4
Dyspeptic signs and symptoms		1		1
Flatulence, bloating and distension		1		1
Gastrointestinal and abdominal pains (excl oral and throat)	1	3	1	3
Gastrointestinal signs and symptoms NEC		4		4
Gingival haemorrhages		1		1
Nausea and vomiting symptoms	1	8	1	8
Oral dryness and saliva altered		1		1
Oral soft tissue signs and symptoms		1		1
	3	24	3	24

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	1	20	1	20		
Death and sudden death		1				1
Febrile disorders	1	19	1	19		
Feelings and sensations NEC	2	11	2	10		1
Gait disturbances		1		1		
General signs and symptoms NEC		9		8		1
Inflammations		1		1		
Mass conditions NEC		1		1		
Oedema NEC	2	2	2	2		
Pain and discomfort NEC	2	14		12	2	2
Vaccination site reactions	4	20	4	20		
	12	99	10	94	2	5

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections		1		1		
Herpes viral infections		2		2		
Lower respiratory tract and lung infections		1				1
Urinary tract infections		1				1
		5		3		2

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposures associated with pregnancy, delivery and lactation		1		1
Off label uses		1		1
Product administration errors and issues	2	16	2	16
	2	18	2	18

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmunity analyses		1		1		
Haematological analyses NEC		1		1		
Heart rate and pulse investigations		2		1		1
Immunology analyses NEC		1		1		
Investigations NEC		1		1		
Vascular tests NEC (incl blood pressure)		1		1		
		7		6		1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders		1		1
Total fluid volume decreased		1		1
		2		2

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone disorders NEC		1		1		
Bone related signs and symptoms		1		1		
Joint related signs and symptoms	1	12	1	12		
Muscle pains	1	11	1	11		
Muscle related signs and symptoms NEC	2	4		2	2	2
Muscle weakness conditions	1	1			1	1
Musculoskeletal and connective tissue conditions NEC		1		1		
Musculoskeletal and connective tissue pain and discomfort	2	16	2	16		
	7	47	4	44	3	3

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents		1				1
Coordination and balance disturbances		1		1		
Disturbances in consciousness NEC	1	4		3	1	1
Dyskinesias and movement disorders NEC		2		1		1

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial cranial nerve disorders	1	4			1	4
Headaches NEC	3	25	2	24	1	1
Migraine headaches		1				1
Neurological signs and symptoms NEC		7		6		1
Paraesthesias and dysaesthesias	4	17	1	13	3	4
Sensory abnormalities NEC		5		5		
Speech and language abnormalities		1		1		
	9	68	3	54	6	14

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anxiety symptoms		1		1
Depressive disorders		1		1
Disturbances in initiating and maintaining sleep		1		1
Sleep disorders NEC		1		1
		4		4

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vulvovaginal disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	1	3	1	2		1
Coughing and associated symptoms		1		1		
Pharyngeal disorders (excl infections and neoplasms)	1	1			1	1
Upper respiratory tract signs and symptoms	1	3	1	3		
	3	8	2	6	1	2

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders		2				2
Dermatitis and eczema		1		1		
Erythemas		3		3		
Pruritus NEC		2		2		
Rashes, eruptions and exanthems NEC		5		5		
Urticarias		1		1		
		14		12		2

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Disability issues		2		2
		2		2

System Organ Class

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* AE=Adverse Event
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System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemorrhages NEC		1		1		
Non-site specific embolism and thrombosis		1				1
Peripheral embolism and thrombosis		1				1
Peripheral vascular disorders NEC	1	3		2	1	1
Vascular hypertensive disorders NEC	1	4	1	3		1
Vascular hypotensive disorders	1	1			1	1
	3	11	1	6	2	5

* I=Interval, C=Cumulative
 * AE=Adverse Event
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Country Where Event Occurred

QATAR

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rate and rhythm disorders NEC	1	3		1	1	2
	1	3		1	1	2

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Inner ear signs and symptoms		1		1
		1		1

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Ocular infections, inflammations and associated manifestations		1		1
		1		1

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspeptic signs and symptoms		2		2		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea and vomiting symptoms		1				1
		3		2		1

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions		2		1		1
Febrile disorders	1	3		1	1	2
Feelings and sensations NEC		2		1		1
Gait disturbances		1		1		
Therapeutic and nontherapeutic responses		2				2
	1	10		4	1	6

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic and anaphylactoid responses		1		1
		1		1

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections		3		1		2

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes viral infections		2		2		
Rhinoviral infections		1				1
		6		3		3

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposures associated with pregnancy, delivery and lactation		1		1
Medication errors, product use errors and issues NEC		1		1
Overdoses NEC		1		1
Product preparation errors and issues		1		1
		4		4

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chemistry analyses NEC		1				1
Haematological analyses NEC		1				1
Heart rate and pulse investigations	1	3		2	1	1
Platelet analyses		1				1
Protein analyses NEC		1				1
Vascular tests NEC (incl blood pressure)		1		1		
White blood cell analyses		2				2
	1	10		3	1	7

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
General nutritional disorders NEC		1		1
		1		1

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle pains		1		1		
Musculoskeletal and connective tissue pain and discomfort		3				3
		4		1		3

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in consciousness NEC		1				1
Facial cranial nerve disorders		1				1
Headaches NEC		2		2		
Mental impairment (excl dementia and memory loss)		1		1		
Neurological signs and symptoms NEC		3				3
Neuromuscular disorders NEC		1				1
Sensory abnormalities NEC		2		2		
		11		5		6

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Confusion and disorientation		1		1
Disturbances in initiating and maintaining sleep		1		1
Emotional and mood disturbances NEC		1		1
Mood alterations with depressive symptoms		1		1
Sleep disorders NEC		1		1
		5		5

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Sexual function and fertility disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breathing abnormalities	1	2	1	2
Coughing and associated symptoms		1		1
	1	3	1	3

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders		1				1
Erythemas		2		1		1
Rashes, eruptions and exanthems NEC		1				1
		4		1		3

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Peripheral vasoconstriction, necrosis and vascular insufficiency		1		1
Vascular hypertensive disorders NEC		1		1
Vascular hypotensive disorders		1		1
		3		3

* I=Interval, C=Cumulative
* AE=Adverse Event
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Country Where Event Occurred

ROMANIA

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coagulopathies	2	2			2	2
Leukopenias NEC		1				1
Lymphatic system disorders NEC	30	74	16	39	14	35
	32	77	16	39	16	38

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders		1				1
Cardiac disorders NEC	2	2			2	2
Cardiac signs and symptoms NEC	4	14	1	2	3	12
Cardiomyopathies	1	1			1	1
Ischaemic coronary artery disorders	4	10			4	10
Noninfectious pericarditis	1	2			1	2
Rate and rhythm disorders NEC	23	56	1	10	22	46
Supraventricular arrhythmias		5				5
Ventricular arrhythmias and cardiac arrest	3	7		1	3	6
	38	98	2	13	36	85

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	3	7	1	4	2	3

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hearing losses	2	6			2	6
Inner ear disorders NEC	1	2		1	1	1
Inner ear signs and symptoms	6	35	2	8	4	27
	12	50	3	13	9	37

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic thyroiditis	1	2		1	1	1
Thyroid disorders NEC		1				1
Thyroid hypofunction disorders		1				1
	1	4		1	1	3

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cataract conditions		1				1
Eyelid movement disorders		2		1		1
Glaucomas (excl congenital)		1				1
Lid, lash and lacrimal infections, irritations and inflammations	1	4		1	1	3
Ocular bleeding and vascular disorders NEC	1	3			1	3
Ocular disorders NEC	1	6		2	1	4
Ocular infections, inflammations and associated manifestations	1	3		2	1	1
Ocular sensation disorders	1	3	1	1		2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Orbital structural change, deposit and degeneration	1	1			1	1
Pupil disorders	16	16	10	10	6	6
Visual disorders NEC	3	9		1	3	8
Visual field disorders	1	2	1	1		1
Visual impairment and blindness (excl colour blindness)	5	11		1	5	10
	31	62	12	20	19	42

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis		1				1
Dental disorders NEC		1				1
Diarrhoea (excl infective)	5	21	3	9	2	12
Dyspeptic signs and symptoms		1				1
Faecal abnormalities NEC	1	2	1	1		1
Flatulence, bloating and distension		1				1
Gastrointestinal and abdominal pains (excl oral and throat)	8	19	3	7	5	12
Gastrointestinal signs and symptoms NEC	5	11	3	5	2	6
Gastrointestinal spastic and hypermotility disorders	1	1			1	1
Intestinal haemorrhages		1				1
Nausea and vomiting symptoms	35	126	16	52	19	74
Oesophageal disorders NEC	1	1			1	1
Oral dryness and saliva altered	2	6			2	6
Oral soft tissue signs and symptoms	5	12	2	5	3	7
Oral soft tissue swelling and oedema	2	11		3	2	8
Stomatitis and ulceration		2				2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue signs and symptoms	2	5	1	1	1	4
	67	222	29	83	38	139

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site reactions NEC		9		8		1
Adverse effect absent		1		1		
Asthenic conditions	84	231	51	147	33	84
Death and sudden death	2	11			2	11
Febrile disorders	90	232	51	128	39	104
Feelings and sensations NEC	68	201	35	98	33	103
Gait disturbances	1	3			1	3
General signs and symptoms NEC	11	36	6	22	5	14
Inflamations	3	6	1	3	2	3
Injection site reactions	1	5	1	5		
Mass conditions NEC	2	2	1	1	1	1
Mucosal findings abnormal		1				1
Oedema NEC	5	14	1	3	4	11
Pain and discomfort NEC	29	70	16	39	13	31
Therapeutic and nontherapeutic responses	9	114			9	114
Vaccination site reactions	85	329	70	268	15	61
	390	1,265	233	723	157	542

System Organ Class

Hepatobiliary disorders

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholestasis and jaundice	2	2	1	1	1	1
Hepatocellular damage and hepatitis NEC		1				1
	2	3	1	1	1	2

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	5	30		21	5	9
Allergies to foods, food additives, drugs and other chemicals		1		1		
Anaphylactic and anaphylactoid responses	11	27			11	27
Autoimmune disorders NEC		1				1
	16	59		22	16	37

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	15	205	6	17	9	188
Dental and oral soft tissue infections		1				1
Herpes viral infections	7	9	4	5	3	4
Lower respiratory tract and lung infections	1	3			1	3
Nematode infections		1				1
Upper respiratory tract infections	2	4	1	2	1	2
Viral infections NEC		2				2
	25	225	11	24	14	201

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental exposures to product	1	1	1	1		
Cerebral injuries NEC	1	1			1	1
Exposures associated with pregnancy, delivery and lactation	4	9	4	9		
Exposures to agents or circumstances NEC		1		1		
Fractures and dislocations NEC	1	1			1	1
Medication errors, product use errors and issues NEC	7	34	6	33	1	1
Non-site specific injuries NEC	3	3	1	1	2	2
Off label uses	6	11	6	11		
Overdoses NEC		1		1		
Product administration errors and issues	20	33	5	15	15	18
Product preparation errors and issues	1	22	1	22		
Site specific injuries NEC		1				1
Skin injuries NEC	4	5		1	4	4
Thermal burns		1				1
Underdoses NEC		3		3		
Vaccination related complications	1	1			1	1
	49	128	24	98	25	30

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmunity analyses	1	1	1	1		
Bacteria identification and serology (excl mycobacteria)		1		1		
Blood gas and acid base analyses		6		1		5
Carbohydrate tolerance analyses (incl diabetes)		2				2
Cholesterol analyses		1		1		
Coagulation and bleeding analyses		1		1		

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Digestive enzymes		1		1		
Gastrointestinal function diagnostic procedures		1		1		
Heart rate and pulse investigations	14	42	4	11	10	31
Investigations NEC		2		2		
Liver function analyses	2	3		1	2	2
Metabolism tests NEC		2		2		
Parasite identification and serology		1		1		
Physical examination procedures and organ system status	2	11	2	8		3
Protein analyses NEC	1	1	1	1		
Red blood cell analyses		1		1		
Urinalysis NEC		4		4		
Vascular tests NEC (incl blood pressure)	7	24	2	8	5	16
Virus identification and serology	1	25	1	19		6
White blood cell analyses	1	1	1	1		
	29	131	12	66	17	65

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	4	14	3	7	1	7
Calcium metabolism disorders	1	2	1	1		1
Diabetes mellitus (incl subtypes)		2				2
General nutritional disorders NEC	1	1	1	1		
Hyperglycaemic conditions NEC	2	5		1	2	4
Hypoglycaemic conditions NEC	2	2			2	2
Metabolic acidoses (excl diabetic acidoses)	1	2			1	2
Potassium imbalance		2				2
Total fluid volume decreased	2	3			2	3

* I=Interval, C=Cumulative

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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	13	33	5	10	8	23

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone disorders NEC		1				1
Bone related signs and symptoms	4	16	1	5	3	11
Intervertebral disc disorders NEC	1	1			1	1
Joint related disorders NEC	1	2			1	2
Joint related signs and symptoms	24	81	10	43	14	38
Metabolic bone disorders	1	1	1	1		
Muscle infections and inflammations	1	1			1	1
Muscle pains	71	198	45	111	26	87
Muscle related signs and symptoms NEC	4	6	1	2	3	4
Muscle tone abnormalities		1				1
Muscle weakness conditions	2	8	1	6	1	2
Musculoskeletal and connective tissue conditions NEC	3	9	2	5	1	4
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity	1	1	1	1		
Musculoskeletal and connective tissue pain and discomfort	30	91	16	60	14	31
Osteoarthropathies	1	1	1	1		
Synovial disorders	1	1			1	1
Tendon disorders		1				1
	145	420	79	235	66	185

System Organ Class

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Neuromas		1		1
		1		1

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute polyneuropathies	1	2			1	2
Autonomic nervous system disorders		1				1
Central nervous system haemorrhages and cerebrovascular accidents	4	10			4	10
Central nervous system vascular disorders NEC		1				1
Cervical spinal cord and nerve root disorders	1	1	1	1		
Coma states		3				3
Coordination and balance disturbances	4	10		2	4	8
Cortical dysfunction NEC	1	1			1	1
Dementia (excl Alzheimer's type)		1				1
Disturbances in consciousness NEC	63	140	14	32	49	108
Dyskinesias and movement disorders NEC		2		1		1
Encephalopathies NEC	1	2			1	2
Facial cranial nerve disorders	8	23	2	4	6	19
Headaches NEC	74	235	51	140	23	95
Increased intracranial pressure disorders	1	2			1	2
Lumbar spinal cord and nerve root disorders	1	1	1	1		
Memory loss (excl dementia)		1				1
Mental impairment (excl dementia and memory loss)	2	6	1	2	1	4
Migraine headaches	3	6		1	3	5
Muscle tone abnormal		1				1
Narcolepsy and hypersomnia	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nervous system disorders NEC		3		3		
Neurological signs and symptoms NEC	37	109	18	47	19	62
Neuromuscular disorders NEC	1	3	1	2		1
Olfactory nerve disorders	2	9	1	4	1	5
Optic nerve disorders NEC	1	2			1	2
Paraesthesias and dysaesthesias	35	97	15	37	20	60
Paralysis and paresis (excl cranial nerve)	6	11			6	11
Parkinson's disease and parkinsonism		1				1
Peripheral neuropathies NEC	3	6			3	6
Seizures and seizure disorders NEC	3	6			3	6
Sensory abnormalities NEC	1	13		6	1	7
Speech and language abnormalities	2	3	1	1	1	2
Tremor (excl congenital)	6	12		2	6	10
Trigeminal disorders		1				1
	262	726	107	287	155	439

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous	1	2	1	2
	1	2	1	2

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Device physical property and chemical issues		1		1

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System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product physical issues	1	1	1	1
Product quality issues NEC		1		1
	1	3	1	3

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	3	17	2	6	1	11
Behaviour and socialisation disturbances	1	1			1	1
Confusion and disorientation	5	7	3	4	2	3
Deliria	1	1			1	1
Disturbances in initiating and maintaining sleep	6	13	5	7	1	6
Emotional and mood disturbances NEC	3	4	2	3	1	1
Fear symptoms and phobic disorders (incl social phobia)		1		1		
Hallucinations (excl sleep-related)	1	1			1	1
Mental disorders due to a general medical condition NEC		1				1
Mental disorders NEC	1	2			1	2
Panic attacks and disorders	2	5		3	2	2
Parasomnias	1	1	1	1		
Sleep disorders NEC		1				1
Stereotypies and automatisms	1	1	1	1		
	25	56	14	26	11	30

System Organ Class

Renal and urinary disorders

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

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System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	2	4	2	2		2
Nephropathies and tubular disorders NEC	1	2			1	2
Urinary abnormalities	1	1	1	1		
Urinary tract signs and symptoms NEC	3	9			3	9
	7	16	3	3	4	13

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast infections and inflammations	1	3	1	1		2
Breast signs and symptoms	4	8	2	3	2	5
Lactation disorders		1		1		
Menstruation and uterine bleeding NEC	6	9	6	7		2
Menstruation with decreased bleeding		1		1		
Menstruation with increased bleeding	2	2	1	1	1	1
Pelvis and broad ligament disorders NEC		1				1
Reproductive tract signs and symptoms NEC		1				1
	13	26	10	14	3	12

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	11	38		3	11	35
Bronchospasm and obstruction		11		3		8
Conditions associated with abnormal gas exchange	1	3			1	3

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* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coughing and associated symptoms	5	18	1	7	4	11
Laryngeal spasm, oedema and obstruction		5		1		4
Lower respiratory tract signs and symptoms		1				1
Nasal congestion and inflammations	2	3	1	1	1	2
Nasal disorders NEC	1	6		2	1	4
Pleural infections and inflammations		1				1
Pulmonary oedemas		2				2
Pulmonary thrombotic and embolic conditions	2	2			2	2
Respiratory failures (excl neonatal)	1	2			1	2
Respiratory signs and symptoms NEC	5	10		2	5	8
Respiratory tract disorders NEC		3		2		1
Upper respiratory tract signs and symptoms	11	27	4	14	7	13
	39	132	6	35	33	97

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas		6				6
Apocrine and eccrine gland disorders	21	46	18	27	3	19
Bullous conditions		1				1
Dermal and epidermal conditions NEC	3	10	1	4	2	6
Dermatitis and eczema	4	11	2	3	2	8
Dermatitis ascribed to specific agent		2				2
Erythemas	7	28	3	15	4	13
Exfoliative conditions	1	1			1	1
Panniculitides		2		1		1
Photosensitivity and photodermatosis conditions		1				1
Pruritus NEC	1	13		6	1	7
Purpura and related conditions		1				1

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* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rashes, eruptions and exanthems NEC	6	31	3	16	3	15
Skin hyperplasias and hypertrophies		1				1
Skin vasomotor conditions		1				1
Urticarias	7	24	5	12	2	12
	50	179	32	84	18	95

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	2	7	1	3	1	4
	2	7	1	3	1	4

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension		2				2
Blood pressure disorders NEC	2	5			2	5
Circulatory collapse and shock	1	2			1	2
Haemorrhages NEC	2	2			2	2
Non-site specific embolism and thrombosis	3	4			3	4
Non-site specific necrosis and vascular insufficiency NEC	1	2			1	2
Non-site specific vascular disorders NEC		1				1
Peripheral embolism and thrombosis	2	6		1	2	5
Peripheral vascular disorders NEC		5		3		2
Peripheral vasoconstriction, necrosis and vascular insufficiency		4		1		3

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* AE=Adverse Event

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System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Site specific vascular disorders NEC	16	20	15	16	1	4
Vascular hypertensive disorders NEC	24	73	4	12	20	61
Vascular hypotensive disorders	23	30	16	17	7	13
	74	156	35	50	39	106

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Country Where Event Occurred

SAUDI ARABIA

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coagulation factor deficiencies		1				1
Lymphatic system disorders NEC	1	4	1	4		
	1	5	1	4		1

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Ventricular arrhythmias and cardiac arrest		1		1
		1		1

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal and abdominal pains (excl oral and throat)	1	3		1	1	2
Nausea and vomiting symptoms	1	5	1	2		3
Stomatitis and ulceration	1	2		1	1	1
	3	10	1	4	2	6

System Organ Class

General disorders and administration site conditions

Spontaneous

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* AE=Adverse Event
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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	1	12	1	11		1
Death and sudden death	2	2			2	2
Febrile disorders		7		6		1
Feelings and sensations NEC		4		4		
Gait disturbances		3		1		2
Pain and discomfort NEC		7		6		1
Therapeutic and nontherapeutic responses	2	2			2	2
Vaccination site reactions	1	10	1	10		
	6	47	2	38	4	9

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic and anaphylactoid responses		1		1
		1		1

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	3	6	1	4	2	2
Female reproductive tract infections	1	2	1	2		
Herpes viral infections		1		1		
Infections NEC		1		1		
Upper respiratory tract infections		1		1		
	4	11	2	9	2	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposures associated with pregnancy, delivery and lactation	2	2	2	2
Medication errors, product use errors and issues NEC	2	2	2	2
Off label uses	2	2	2	2
Overdoses NEC	1	1	1	1
Product administration errors and issues	2	4	2	4
Product preparation errors and issues		1		1
	9	12	9	12

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematological analyses NEC		1		1		
Heart rate and pulse investigations		1				1
Physical examination procedures and organ system status	1	1	1	1		
Protein analyses NEC		1		1		
Vascular tests NEC (incl blood pressure)	1	1	1	1		
	2	5	2	4		1

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders	1	1	1	1
General nutritional disorders NEC	2	2	2	2
	3	3	3	3

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* AE=Adverse Event
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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms		1		1		
Joint related signs and symptoms	1	4	1	4		
Muscle pains		7		6		1
Musculoskeletal and connective tissue conditions NEC		6		5		1
Musculoskeletal and connective tissue pain and discomfort	1	5	1	3		2
	2	23	2	19		4

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Lymphomas unspecified NEC		1		1
		1		1

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	2	2			2	2
Central nervous system vascular disorders NEC		1				1
Coordination and balance disturbances		1				1
Disturbances in consciousness NEC		4		1		3
Dyskinesias and movement disorders NEC		1		1		
Headaches NEC	3	9	3	9		
Lumbar spinal cord and nerve root disorders		2		2		

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mental impairment (excl dementia and memory loss)	1	1	1	1		
Neurological signs and symptoms NEC	2	4	2	3		1
Paraesthesias and dysaesthesias	1	1	1	1		
Seizures and seizure disorders NEC		2				2
Tremor (excl congenital)		1		1		
	9	29	7	19	2	10

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions not specified as induced or spontaneous	1	1	1	1
	1	1	1	1

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Sleep disorders NEC		1		1
		1		1

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C

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System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Bladder and urethral symptoms		1		1
		1		1

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Menstruation and uterine bleeding NEC	1	2	1	2		
Menstruation with increased bleeding	1	1	1	1		
Vulvovaginal disorders NEC	1	1			1	1
	3	4	2	3	1	1

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	1	1	1	1		
Nasal disorders NEC	1	1	1	1		
Pulmonary thrombotic and embolic conditions		1				1
Upper respiratory tract signs and symptoms		2		2		
	2	5	2	4		1

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders		5		4		1
Dermal and epidermal conditions NEC		1		1		
		6		5		1

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Disability issues		1		1
		1		1

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral vascular disorders NEC		1		1		
Peripheral vasoconstriction, necrosis and vascular insufficiency		2		2		
Vascular hypertensive disorders NEC	1	1	1	1		
Vascular hypotensive disorders		1				1
	1	5	1	4		1

* I=Interval, C=Cumulative
* AE=Adverse Event
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Country Where Event Occurred

SERBIA

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Leukopenias NEC	1	1			1	1
Lymphatic system disorders NEC	5	9	5	7		2
	6	10	5	7	1	3

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC		2		2		
Ischaemic coronary artery disorders		1				1
Noninfectious myocarditis		1				1
Rate and rhythm disorders NEC	1	4		1	1	3
	1	8		3	1	5

System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Neurological disorders congenital NEC		1		1
		1		1

System Organ Class

Ear and labyrinth disorders

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hearing losses		2				2
Inner ear signs and symptoms		2		2		
		4		2		2

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid movement disorders		2				2
Lacrimation disorders		1		1		
Lid, lash and lacrimal infections, irritations and inflammations	1	3	1	3		
Ocular disorders NEC		1		1		
Ocular sensation disorders		1		1		
Visual disorders NEC		2		1		1
	1	10	1	7		3

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis		1				1
Diarrhoea (excl infective)	2	4	2	4		
Gastrointestinal and abdominal pains (excl oral and throat)		1		1		
Nausea and vomiting symptoms	7	29	6	24	1	5
Non-site specific gastrointestinal haemorrhages		1				1
Oral dryness and saliva altered		1		1		
Oral soft tissue disorders NEC		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral soft tissue signs and symptoms	2	6		3	2	3
Oral soft tissue swelling and oedema		2		2		
Tongue signs and symptoms		2		1		1
	11	48	8	37	3	11

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse effect absent		1		1		
Asthenic conditions	19	61	19	56		5
Death and sudden death		1				1
Febrile disorders	23	60	23	54		6
Feelings and sensations NEC	6	21	5	17	1	4
General signs and symptoms NEC		6		4		2
Mucosal findings abnormal		1				1
Oedema NEC	1	5	1	4		1
Pain and discomfort NEC	1	11	1	7		4
Therapeutic and nontherapeutic responses	2	6			2	6
Vaccination site reactions	13	40	13	39		1
	65	213	62	182	3	31

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	1	3	1	2		1
Anaphylactic and anaphylactoid responses		1				1

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	1	4	1	2		2

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	6	18	4	11	2	7
Eye and eyelid infections		1		1		
Herpes viral infections	1	2	1	2		
Infections NEC	1	2	1	1		1
Lower respiratory tract and lung infections		1				1
Upper respiratory tract infections		1		1		
Vascular infections	1	1			1	1
	9	26	6	16	3	10

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation		3		3		
Non-site specific injuries NEC		2		1		1
Off label uses		1		1		
Overdoses NEC		1				1
Product administration errors and issues	1	3	1	3		
Vaccination related complications	2	7	1	6	1	1
	3	17	2	14	1	3

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses		1				1
Chemistry analyses NEC		1		1		
Coagulation and bleeding analyses		1		1		
Haematological analyses NEC		1				1
Heart rate and pulse investigations		1		1		
Liver function analyses	2	2	2	2		
Mineral and electrolyte analyses	2	2	2	2		
Ophthalmic function diagnostic procedures		1				1
Physical examination procedures and organ system status	9	23	8	21	1	2
Protein analyses NEC	1	3	1	2		1
Red blood cell analyses		1		1		
Renal function analyses	1	1	1	1		
Tissue enzyme analyses NEC		1				1
Vascular tests NEC (incl blood pressure)		2		1		1
Virus identification and serology		4		2		2
White blood cell analyses		1		1		
	15	46	14	36	1	10

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders	1	2	1	2
	1	2	1	2

System Organ Class

Musculoskeletal and connective tissue disorders

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms		3		3		
Joint related signs and symptoms	8	20	7	17	1	3
Muscle infections and inflammations		1				1
Muscle pains	12	27	11	25	1	2
Muscle weakness conditions	1	3		2	1	1
Musculoskeletal and connective tissue conditions NEC		1		1		
Musculoskeletal and connective tissue pain and discomfort	9	25	8	22	1	3
	30	80	26	70	4	10

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Oncologic complications and emergencies	1	1	1	1
	1	1	1	1

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute polyneuropathies	2	2			2	2
Central nervous system haemorrhages and cerebrovascular accidents		1				1
Coordination and balance disturbances		1				1
Disturbances in consciousness NEC	3	11	1	3	2	8
Dyskinesias and movement disorders NEC		1		1		
Facial cranial nerve disorders		2				2

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headaches NEC	17	40	16	36	1	4
Neurological signs and symptoms NEC	3	9	3	8		1
Olfactory nerve disorders	1	4	1	4		
Optic nerve disorders NEC		1				1
Paraesthesias and dysaesthesias	2	9		7	2	2
Seizures and seizure disorders NEC	1	1			1	1
Sensory abnormalities NEC	1	6	1	4		2
Tremor (excl congenital)		2		2		
	30	90	22	65	8	25

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product supply and availability issues	1	1	1	1
	1	1	1	1

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms		3		2		1
Confusion and disorientation	1	2	1	2		
Disturbances in initiating and maintaining sleep		2		1		1
Emotional and mood disturbances NEC		1		1		
Fear symptoms and phobic disorders (incl social phobia)		2		1		1
Sleep disorders NEC	1	2	1	2		

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* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	2	12	2	9		3

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Menstruation with increased bleeding	2	2	2	2
	2	2	2	2

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities		5		1		4
Bronchospasm and obstruction		3		1		2
Conditions associated with abnormal gas exchange		2				2
Coughing and associated symptoms	4	7	3	4	1	3
Lower respiratory tract signs and symptoms		2		1		1
Nasal congestion and inflammations	2	4	1	2	1	2
Respiratory tract disorders NEC	1	1	1	1		
Upper respiratory tract signs and symptoms	2	6	1	3	1	3
	9	30	6	13	3	17

System Organ Class

Skin and subcutaneous tissue disorders

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders		4		3		1
Dermal and epidermal conditions NEC		3		1		2
Erythemas	1	9	1	8		1
Pruritus NEC	1	2	1	2		
Rashes, eruptions and exanthems NEC	4	9	4	6		3
Urticarias	3	6	2	5	1	1
	9	33	8	25	1	8

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circulatory collapse and shock	2	2			2	2
Haemorrhages NEC		1		1		
Non-site specific embolism and thrombosis	1	2			1	2
Non-site specific vascular disorders NEC		1		1		
Peripheral embolism and thrombosis		1				1
Phlebitis NEC		1				1
Site specific vascular disorders NEC	1	3		2	1	1
Vascular hypertensive disorders NEC		8		2		6
	4	19		6	4	13

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

SINGAPORE

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eosinophilic disorders		1				1
Lymphatic system disorders NEC		1		1		
Marrow depression and hypoplastic anaemias		1				1
		3		1		2

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC		10		1		9
Ischaemic coronary artery disorders		1				1
Rate and rhythm disorders NEC	1	7			1	7
Supraventricular arrhythmias		1				1
	1	19		1	1	18

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hearing disorders NEC		1		1		
Hearing losses		1				1
Inner ear signs and symptoms		1		1		
		3		2		1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Thyroid hyperfunction disorders		1		1
		1		1

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid movement disorders		1		1		
Iris and ciliary body structural change, deposit and degeneration		1		1		
Lacrimation disorders		2				2
Lid, lash and lacrimal infections, irritations and inflammations		1				1
Ocular disorders NEC		9		2		7
Ocular infections, inflammations and associated manifestations		2		1		1
Ocular nerve and muscle disorders		4				4
Visual disorders NEC	1	6		2	1	4
Visual impairment and blindness (excl colour blindness)		2		1		1
	1	28		8	1	20

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)		5		1		4
Gastrointestinal and abdominal pains (excl oral and throat)		6				6

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal atonic and hypomotility disorders NEC		1				1
Gastrointestinal signs and symptoms NEC		3				3
Nausea and vomiting symptoms		20		7		13
Oral dryness and saliva altered		1		1		
Oral soft tissue disorders NEC		4				4
Oral soft tissue swelling and oedema		6		1		5
Tongue signs and symptoms		1				1
		47		10		37

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	5	14	5	10		4
Febrile disorders	3	14	3	8		6
Feelings and sensations NEC	1	14	1	4		10
Gait disturbances		1				1
General signs and symptoms NEC	1	7	1	4		3
Injection site reactions		1		1		
Oedema NEC	1	2	1	2		
Pain and discomfort NEC	1	19	1	5		14
Therapeutic and nontherapeutic responses	1	1			1	1
Vaccination site reactions	8	23	8	17		6
	21	96	20	51	1	45

System Organ Class

Hepatobiliary disorders

Interval Total #	Cumulative Total #

Spontaneous
Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hepatocellular damage and hepatitis NEC		1		1
		1		1

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC		3		1		2
Allergies to foods, food additives, drugs and other chemicals		1				1
Anaphylactic and anaphylactoid responses		22				22
		26		1		25

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacterial infections NEC		1				1
Coronavirus infections	1	1			1	1
Herpes viral infections	1	1	1	1		
Infections NEC		1				1
Viral infections NEC		2		1		1
	2	6	1	2	1	4

System Organ Class

Injury, poisoning and procedural complications

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation		1		1		
Limb fractures and dislocations		1				1
Medication errors, product use errors and issues NEC	1	1	1	1		
Nerve injuries NEC		1				1
Non-site specific injuries NEC		2				2
Product administration errors and issues		3		3		
Product preparation errors and issues	1	1	1	1		
Skin injuries NEC		1				1
Vaccination related complications		1				1
	2	12	2	6		6

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmunity analyses	1	1	1	1		
Blood gas and acid base analyses		3				3
Heart rate and pulse investigations		3				3
Immune response protein analyses NEC		1				1
Liver function analyses		5				5
Ophthalmic function diagnostic procedures		1				1
Physical examination procedures and organ system status		4				4
Red blood cell analyses		2				2
Skeletal and cardiac muscle analyses		1				1
Tissue enzyme analyses NEC		1				1
Vascular tests NEC (incl blood pressure)		10		2		8
	1	32	1	3		29

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Appetite disorders		1		1
General nutritional disorders NEC		1		1
Total fluid volume decreased		1		1
		3		3

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC		1				1
Joint related signs and symptoms		2				2
Muscle pains	1	5	1	4		1
Muscle weakness conditions		2				2
Musculoskeletal and connective tissue conditions NEC		1				1
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		1				1
Musculoskeletal and connective tissue pain and discomfort	3	8	3	6		2
Rheumatoid arthropathies		1				1
Tendon disorders		1				1
	4	22	4	10		12

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Endocrine neoplasms malignant and unspecified NEC	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neoplasms benign site unspecified NEC		1		1		
	1	2		1	1	1

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Absence seizures		1				1
Coordination and balance disturbances		1				1
Cranial nerve disorders NEC	1	1			1	1
Disturbances in consciousness NEC		9		2		7
Dyskinesias and movement disorders NEC		4				4
Eye movement disorders	2	3			2	3
Facial cranial nerve disorders		3				3
Generalised tonic-clonic seizures		2				2
Headaches NEC		8		6		2
Migraine headaches		1				1
Neurological signs and symptoms NEC		28		8		20
Olfactory nerve disorders		2		2		
Optic nerve disorders NEC		1				1
Paraesthesias and dysaesthesias		6		1		5
Peripheral neuropathies NEC		1				1
Seizures and seizure disorders NEC		7				7
Sensory abnormalities NEC	1	4	1	3		1
Spinal cord and nerve root disorders NEC		1				1
Tremor (excl congenital)		1		1		
	4	84	1	23	3	61

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Maternal complications of pregnancy NEC	1	1	1	1
	1	1	1	1

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product quality issues NEC	1	1	1	1
	1	1	1	1

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Confusion and disorientation		2				2
Disturbances in initiating and maintaining sleep	1	1	1	1		
Mental disorders NEC		1				1
Psychotic disorder NEC		1				1
Sleep disorders NEC		1		1		
Tic disorders		1				1
	1	7	1	2		5

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Renal failure and impairment		2		2
Urinary abnormalities		2		2
		4		4

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities		24		2		22
Bronchospasm and obstruction		6		1		5
Coughing and associated symptoms		4				4
Laryngeal spasm, oedema and obstruction		1				1
Lower respiratory tract inflammatory and immunologic conditions		1				1
Pharyngeal disorders (excl infections and neoplasms)		3		1		2
Pulmonary thrombotic and embolic conditions		1				1
Upper respiratory tract signs and symptoms		26		5		21
		66		9		57

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes		1		1		
Angioedemas		7				7
Apocrine and eccrine gland disorders		3		1		2
Bullous conditions		2				2
Dermal and epidermal conditions NEC		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermatitis and eczema		1		1		
Dermatitis ascribed to specific agent		1				1
Erythemas		2				2
Pruritus NEC		5				5
Pustular conditions		1				1
Rashes, eruptions and exanthems NEC	1	27	1	10		17
Urticarias	1	14	1	3		11
	2	65	2	17		48

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral embolism and thrombosis		1				1
Peripheral vascular disorders NEC		3				3
Peripheral vasoconstriction, necrosis and vascular insufficiency		1		1		
Site specific vascular disorders NEC		1				1
Vascular hypertensive disorders NEC	1	6			1	6
Vascular hypotensive disorders		5				5
	1	17		1	1	16

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

SLOVAKIA

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	7	21	7	21
	7	21	7	21

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC		8		8		
Coronary artery disorders NEC	1	1			1	1
Heart failures NEC	1	2			1	2
Ischaemic coronary artery disorders		2				2
Myocardial disorders NEC	1	1			1	1
Rate and rhythm disorders NEC	1	14		7	1	7
Supraventricular arrhythmias		3				3
	4	31		15	4	16

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hearing losses		3				3
Inner ear signs and symptoms	1	21	1	20		1
	1	24	1	20		4

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* AE=Adverse Event
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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lacrimation disorders		1		1		
Lid, lash and lacrimal infections, irritations and inflammations	1	2	1	2		
Ocular disorders NEC		6		4		2
Ocular infections, inflammations and associated manifestations	1	8	1	8		
Ocular sensation disorders		2		2		
Pupil disorders		1		1		
Visual disorders NEC	1	5	1	5		
Visual impairment and blindness (excl colour blindness)		1				1
	3	26	3	23		3

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis		1				1
Diarrhoea (excl infective)	2	10	2	8		2
Flatulence, bloating and distension		1		1		
Gastrointestinal and abdominal pains (excl oral and throat)		4		3		1
Gastrointestinal signs and symptoms NEC	1	5	1	4		1
Intestinal haemorrhages	1	1			1	1
Nausea and vomiting symptoms	8	50	8	44		6
Oral dryness and saliva altered		3		2		1
Oral soft tissue disorders NEC		1		1		
Oral soft tissue infections	1	1	1	1		
Oral soft tissue signs and symptoms		4		3		1
Oral soft tissue swelling and oedema		1		1		
Tongue signs and symptoms		2		1		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	13	84	12	69	1	15

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	23	123	21	114	2	9
Febrile disorders	9	72	9	69		3
Feelings and sensations NEC	14	107	13	100	1	7
Gait disturbances		1		1		
General signs and symptoms NEC	2	8	2	8		
Inflammations		1		1		
Oedema NEC	1	6	1	5		1
Pain and discomfort NEC	3	23	3	22		1
Therapeutic and nontherapeutic responses	5	14			5	14
Vaccination site reactions	30	139	30	137		2
	87	494	79	457	8	37

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC		2		1		1
Anaphylactic and anaphylactoid responses		2				2
		4		1		3

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	5	19		3	5	16
Eye and eyelid infections		2		1		1
Herpes viral infections	1	1			1	1
Lower respiratory tract and lung infections	1	1			1	1
Sepsis, bacteraemia, viraemia and fungaemia NEC	1	1			1	1
Skin structures and soft tissue infections		1		1		
Streptococcal infections		1				1
Upper respiratory tract infections	2	4	2	4		
Urinary tract infections	2	2			2	2
Vascular infections		1				1
Viral infections NEC		1				1
	12	34	2	9	10	25

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral injuries NEC		1				1
Exposures associated with pregnancy, delivery and lactation		4		4		
Medication errors, product use errors and issues NEC		1		1		
Non-site specific injuries NEC		2		1		1
Off label uses		2		2		
Peripheral nerve injuries		1				1
Product administration errors and issues		4		3		1
		15		11		4

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	1	1			1	1
Carbohydrate tolerance analyses (incl diabetes)	1	3	1	3		
Heart rate and pulse investigations		5		5		
Immunology analyses NEC		1		1		
Physical examination procedures and organ system status	7	40	6	35	1	5
Vascular tests NEC (incl blood pressure)	3	31	2	11	1	20
Virus identification and serology		3		1		2
	12	84	9	56	3	28

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	1	6	1	6		
Hyperglycaemic conditions NEC		1				1
Total fluid volume decreased		2		1		1
	1	9	1	7		2

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms		2		2		
Joint related signs and symptoms	5	38	5	37		1
Muscle pains	9	54	9	54		
Muscle weakness conditions	1	3	1	2		1
Musculoskeletal and connective tissue conditions NEC		1		1		

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal and connective tissue pain and discomfort	15	73	15	73		
Synovial disorders		1		1		
Tendon disorders		1		1		
	30	173	30	171		2

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents		1				1
Cervical spinal cord and nerve root disorders		1				1
Coordination and balance disturbances		1		1		
Cortical dysfunction NEC		2		1		1
Disturbances in consciousness NEC		21		4		17
Dyskinesias and movement disorders NEC		3		3		
Facial cranial nerve disorders	1	2	1	1		1
Headaches NEC	12	82	12	81		1
Memory loss (excl dementia)		1				1
Migraine headaches	2	3	2	3		
Nervous system disorders NEC	1	1			1	1
Neurological signs and symptoms NEC	3	33	3	26		7
Olfactory nerve disorders	1	1	1	1		
Paraesthesias and dysaesthesias	5	29	5	24		5
Seizures and seizure disorders NEC		2				2
Speech and language abnormalities		2		1		1
Tremor (excl congenital)		1				1
	25	186	24	146	1	40

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Confusion and disorientation	1	2		1	1	1
Disturbances in initiating and maintaining sleep	1	4	1	4		
Increased physical activity levels		2				2
Parasomnias		1		1		
Sexual desire disorders	1	1	1	1		
	3	10	2	7	1	3

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bladder and urethral symptoms		1		1
Urinary tract signs and symptoms NEC	1	1	1	1
	1	2	1	2

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Prostate and seminal vesicles infections and inflammations	1	1	1	1
	1	1	1	1

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	3	13	2	8	1	5
Bronchospasm and obstruction		1				1
Conditions associated with abnormal gas exchange		1				1
Coughing and associated symptoms	2	10	2	10		
Respiratory signs and symptoms NEC	1	1	1	1		
Upper respiratory tract signs and symptoms	1	8	1	8		
	7	34	6	27	1	7

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas		2				2
Apocrine and eccrine gland disorders	2	12	2	9		3
Dermal and epidermal conditions NEC		1		1		
Dermatitis and eczema		1		1		
Erythemas	1	7	1	6		1
Pruritus NEC	1	5	1	4		1
Purpura and related conditions		1		1		
Rashes, eruptions and exanthems NEC		9		9		
Skin vasculitides		1		1		
Urticarias	3	4	3	3		1
	7	43	7	35		8

System Organ Class

Vascular disorders

Interval Total #

Cumulative Total #

Spontaneous	
Nonserious	Serious

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension		1				1
Non-site specific embolism and thrombosis		2				2
Non-site specific vascular disorders NEC	1	1	1	1		
Peripheral embolism and thrombosis		4				4
Peripheral vascular disorders NEC	1	10	1	7		3
Peripheral vasoconstriction, necrosis and vascular insufficiency		4		3		1
Site specific vascular disorders NEC		3		2		1
Vascular hypertensive disorders NEC		4		3		1
	2	29	2	16		13

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

SLOVENIA

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias NEC	1	2			1	2
Lymphatic system disorders NEC	1	7	1	7		
Neutropenias		1				1
Red blood cell abnormal findings NEC		1		1		
Thrombocytopenias		2				2
	2	13	1	8	1	5

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart failures NEC		5				5
Ischaemic coronary artery disorders	2	7			2	7
Mitral valvular disorders	1	1			1	1
Myocardial disorders NEC		3				3
Pericardial disorders NEC		1				1
Rate and rhythm disorders NEC		10		3		7
Supraventricular arrhythmias		5				5
Tricuspid valvular disorders	1	1			1	1
Ventricular arrhythmias and cardiac arrest	2	5		1	2	4
	6	38		4	6	34

System Organ Class

Congenital, familial and genetic disorders

Interval Total # Cumulative Total #

Spontaneous
Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coagulation disorders congenital	1	1	1	1
	1	1	1	1

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC		1				1
Inner ear signs and symptoms		11		5		6
		12		5		7

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute and chronic thyroiditis		1		1
		1		1

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lid, lash and lacrimal infections, irritations and inflammations		1		1		
Ocular disorders NEC		1		1		
Ocular infections, inflammations and associated manifestations		1		1		

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* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pupil disorders		1				1
Visual impairment and blindness (excl colour blindness)		1				1
		5		3		2

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	3	10	3	9		1
Diverticula		1				1
Gastrointestinal and abdominal pains (excl oral and throat)		5		5		
Gastrointestinal signs and symptoms NEC		2		2		
Nausea and vomiting symptoms	3	15	2	9	1	6
Oral dryness and saliva altered		1		1		
Oral soft tissue signs and symptoms		3		1		2
Oral soft tissue swelling and oedema		2		1		1
Tongue signs and symptoms		5		5		
	6	44	5	33	1	11

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site reactions NEC	1	1	1	1		
Asthenic conditions	8	57	7	43	1	14
Death and sudden death		4				4
Febrile disorders	2	13	2	11		2

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Feelings and sensations NEC	2	15	1	11	1	4
Gait disturbances		2				2
General signs and symptoms NEC	1	3			1	3
Oedema NEC	1	3			1	3
Pain and discomfort NEC	2	16	1	7	1	9
Therapeutic and nontherapeutic responses		3				3
Vaccination site reactions	10	81	10	75		6
Vascular complications associated with device		1				1
	27	199	22	148	5	51

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	1	2		1	1	1
Anaphylactic and anaphylactoid responses		1				1
	1	3		1	1	2

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacterial infections NEC		2				2
Coronavirus infections		6				6
Herpes viral infections	1	2			1	2
Infections NEC	1	2	1	1		1
Lower respiratory tract and lung infections		3				3
Upper respiratory tract infections		3		3		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	2	18	1	4	1	14

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone and joint injuries NEC	1	1	1	1		
Exposures associated with pregnancy, delivery and lactation		1		1		
Non-site specific injuries NEC		4		1		3
Off label uses		3		3		
Product administration errors and issues		3		3		
Site specific injuries NEC		1		1		
Skin injuries NEC		2		2		
	1	15	1	12		3

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses		3				3
Musculoskeletal and soft tissue tests NEC		1				1
Physical examination procedures and organ system status	5	16	3	12	2	4
Protein analyses NEC		1		1		
Respiratory and pulmonary function diagnostic procedures		1				1
Skeletal and cardiac muscle analyses		1				1
Vascular tests NEC (incl blood pressure)		1		1		

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
White blood cell analyses		1		1		
	5	25	3	15	2	10

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	1	1	1	1		
Diabetes mellitus (incl subtypes)	1	2	1	1		1
Hypoglycaemic conditions NEC	1	1			1	1
Metabolic acidoses (excl diabetic acidoses)		1				1
Potassium imbalance		2		1		1
Total fluid volume decreased	1	1	1	1		
	4	8	3	4	1	4

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Connective tissue disorders NEC	1	1			1	1
Joint related signs and symptoms	3	8		5	3	3
Metabolic bone disorders		1		1		
Muscle pains	4	16	3	13	1	3
Muscle weakness conditions		1		1		
Musculoskeletal and connective tissue pain and discomfort	5	8	5	7		1
Myopathies		1				1
	13	36	8	27	5	9

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
B-cell lymphomas NEC		1		1
Leukaemias acute lymphocytic		1		1
		2		2

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute polyneuropathies		2				2
Central nervous system haemorrhages and cerebrovascular accidents	4	12			4	12
Coordination and balance disturbances		1				1
Cortical dysfunction NEC		2				2
Dementia (excl Alzheimer's type)		1				1
Disturbances in consciousness NEC	5	30	2	7	3	23
Facial cranial nerve disorders		1				1
Headaches NEC	8	31	6	25	2	6
Memory loss (excl dementia)	1	1			1	1
Migraine headaches		3		1		2
Neurological signs and symptoms NEC		12		5		7
Olfactory nerve disorders		2		2		
Paraesthesias and dysaesthesias	2	11		5	2	6
Paralysis and paresis (excl cranial nerve)	1	4			1	4
Seizures and seizure disorders NEC	1	5			1	5
Sensory abnormalities NEC		5		4		1
Speech and language abnormalities	2	5		1	2	4
Structural brain disorders NEC		1				1
Transient cerebrovascular events	2	3			2	3
Tremor (excl congenital)	1	1	1	1		
	27	133	9	51	18	82

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Behaviour and socialisation disturbances		1		1		
Confusion and disorientation	1	4		1	1	3
Disturbances in initiating and maintaining sleep		3		3		
Emotional and mood disturbances NEC		2				2
Increased physical activity levels		1		1		
Parasomnias		1		1		
Thinking disturbances		1		1		
	1	13		8	1	5

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bladder and urethral symptoms		1		1
Renal failure and impairment		1		1
		2		2

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Uterine tone disorders		1		1
		1		1

System Organ Class

Respiratory, thoracic and mediastinal disorders

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	1	9	1	2		7
Bronchial conditions NEC		1				1
Bronchospasm and obstruction		1				1
Conditions associated with abnormal gas exchange		1				1
Coughing and associated symptoms	1	2			1	2
Nasal disorders NEC	1	1			1	1
Pharyngeal disorders (excl infections and neoplasms)		1		1		
Pneumothorax and pleural effusions NEC		1				1
Pulmonary hypertensions	1	1			1	1
Pulmonary oedemas		1				1
Pulmonary thrombotic and embolic conditions		3				3
Respiratory failures (excl neonatal)		1				1
Respiratory signs and symptoms NEC		1				1
Upper respiratory tract signs and symptoms		2		2		
	4	26	1	5	3	21

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas		1				1
Apocrine and eccrine gland disorders		1				1
Dermal and epidermal conditions NEC	1	3	1	2		1
Erythemas	1	3		1	1	2
Papulosquamous conditions		1		1		
Rashes, eruptions and exanthems NEC		4		3		1
Urticarias		1				1
	2	14	1	7	1	7

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Disability issues		4		4
		4		4

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circulatory collapse and shock		3				3
Haemorrhages NEC	2	2			2	2
Non-site specific vascular disorders NEC		1				1
Peripheral embolism and thrombosis	3	6			3	6
Peripheral vascular disorders NEC		1				1
Peripheral vasoconstriction, necrosis and vascular insufficiency		1		1		
Vascular hypertensive disorders NEC		5				5
Vascular hypotensive disorders		1				1
	5	20		1	5	19

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Country Where Event Occurred

SOUTH AFRICA

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cardiac signs and symptoms NEC	2	2	2	2
	2	2	2	2

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inner ear signs and symptoms	1	1	1	1
	1	1	1	1

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Conjunctival infections, irritations and inflammations	1	1	1	1
Visual disorders NEC	1	1	1	1
	2	2	2	2

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C

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* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea (excl infective)	1	1	1	1
Gastrointestinal and abdominal pains (excl oral and throat)	1	1	1	1
Nausea and vomiting symptoms	1	1	1	1
Oral soft tissue swelling and oedema	1	1	1	1
	4	4	4	4

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	5	5	5	5		
Death and sudden death	2	2			2	2
Febrile disorders	1	1	1	1		
Feelings and sensations NEC	1	1	1	1		
General signs and symptoms NEC	2	2	1	1	1	1
Pain and discomfort NEC	4	4	4	4		
Vaccination site reactions	2	2	2	2		
	17	17	14	14	3	3

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Heart rate and pulse investigations	1	1	1	1
	1	1	1	1

System Organ Class

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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders	1	1	1	1
General nutritional disorders NEC	1	1	1	1
Total fluid volume decreased	1	1	1	1
	3	3	3	3

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Bone related signs and symptoms	1	1	1	1
Joint related signs and symptoms	1	1	1	1
Musculoskeletal and connective tissue pain and discomfort	1	1	1	1
Soft tissue disorders NEC	1	1	1	1
	4	4	4	4

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	1	1			1	1
Cerebrovascular venous and sinus thrombosis	1	1			1	1
Cortical dysfunction NEC	1	1			1	1
Headaches NEC	6	6	6	6		
Neurological signs and symptoms NEC	2	2	2	2		
	11	11	8	8	3	3

System Organ Class

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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Erythemas	1	1	1	1
Pruritus NEC	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

SPAIN

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemia deficiencies	2	2	1	1	1	1
Anaemias haemolytic immune		2				2
Anaemias haemolytic mechanical factor		1				1
Anaemias NEC	6	9	3	4	3	5
Bleeding tendencies		2				2
Coagulopathies	2	4			2	4
Leukocytoses NEC	4	9		3	4	6
Leukopenias NEC	2	5	2	4		1
Lymphatic system disorders NEC	89	244	69	123	20	121
Marrow depression and hypoplastic anaemias	2	4			2	4
Neutropenias	2	3			2	3
Red blood cell abnormal findings NEC	3	3	3	3		
Spleen disorders	1	1			1	1
Thrombocytopenias	20	35			20	35
	133	324	78	138	55	186

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic valvular disorders	1	2			1	2
Cardiac conduction disorders	3	6	1	2	2	4
Cardiac disorders NEC	2	4	1	2	1	2
Cardiac signs and symptoms NEC	10	35	5	10	5	25
Cardiomyopathies	1	1			1	1
Coronary artery disorders NEC	2	2			2	2

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* AE=Adverse Event

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System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart failures NEC	15	42			15	42
Ischaemic coronary artery disorders	17	31			17	31
Left ventricular failures	1	1			1	1
Mitral valvular disorders	3	3			3	3
Myocardial disorders NEC	12	20	3	3	9	17
Noninfectious myocarditis		4				4
Noninfectious pericarditis	6	16			6	16
Pericardial disorders NEC	2	4			2	4
Rate and rhythm disorders NEC	27	117	11	27	16	90
Right ventricular failures	1	1			1	1
Supraventricular arrhythmias	20	47	1	3	19	44
Tricuspid valvular disorders		1				1
Ventricular arrhythmias and cardiac arrest	18	37			18	37
	141	374	22	47	119	327

System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cardiac septal defects congenital	1	1	1	1
Neurological disorders congenital NEC		2		2
Tongue disorders congenital		1		1
	1	4	1	4

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
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System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	7	15	5	6	2	9
Hearing losses	3	14	1	1	2	13
Hyperacusia		1				1
Inner ear disorders NEC		1				1
Inner ear signs and symptoms	12	47	6	15	6	32
	22	78	12	22	10	56

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic thyroiditis	3	4			3	4
Adrenal gland disorders NEC		1		1		
Thyroid disorders NEC	3	4	1	2	2	2
Thyroid hyperfunction disorders	2	3			2	3
Thyroid hypofunction disorders	1	3			1	3
	9	15	1	3	8	12

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Choroid and vitreous structural change, deposit and degeneration		4				4
Colour blindness (incl acquired)		1				1
Conjunctival and corneal bleeding and vascular disorders	3	11			3	11
Conjunctival infections, irritations and inflammations	1	4	1	1		3

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Corneal infections, oedemas and inflammations		2				2
Eyelid movement disorders	3	5	3	4		1
Iris and uveal tract infections, irritations and inflammations	2	3			2	3
Lacrimation disorders	1	8	1	3		5
Lid, lash and lacrimal infections, irritations and inflammations	2	10	1	4	1	6
Lid, lash and lacrimal structural disorders		1				1
Ocular bleeding and vascular disorders NEC	1	2			1	2
Ocular disorders NEC	11	23	6	10	5	13
Ocular infections, inflammations and associated manifestations	4	12	3	5	1	7
Ocular nerve and muscle disorders		2		1		1
Ocular sensation disorders	4	18	3	8	1	10
Optic disc abnormalities NEC	1	1	1	1		
Orbital infections, inflammations and irritations	1	1			1	1
Pupil disorders	1	2	1	1		1
Refractive and accommodative disorders	1	2	1	2		
Retinal bleeding and vascular disorders (excl retinopathy)	4	8	1	1	3	7
Retinal, choroid and vitreous infections and inflammations		1				1
Retinal structural change, deposit and degeneration	1	1	1	1		
Scleral infections, irritations and inflammations		2				2
Visual disorders NEC	12	39	6	14	6	25
Visual field disorders	3	3	2	2	1	1
Visual impairment and blindness (excl colour blindness)	3	12			3	12
	59	178	31	58	28	120

System Organ Class

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal findings abnormal		1		1		
Abdominal wall conditions NEC	1	1			1	1
Acute and chronic pancreatitis		1				1
Anal and rectal disorders NEC		3				3
Anal and rectal pains		1		1		
Anal and rectal signs and symptoms		2				2
Colitis (excl infective)	3	7	1	2	2	5
Dental and periodontal infections and inflammations		1		1		
Diaphragmatic hernias	1	4	1	2		2
Diarrhoea (excl infective)	66	206	53	130	13	76
Duodenal ulcers and perforation		1				1
Dyspeptic signs and symptoms	4	8	2	3	2	5
Faecal abnormalities NEC		4		3		1
Flatulence, bloating and distension	3	10	2	8	1	2
Gastritis (excl infective)		2		1		1
Gastrointestinal and abdominal pains (excl oral and throat)	28	77	20	49	8	28
Gastrointestinal atonic and hypomotility disorders NEC	1	11	1	7		4
Gastrointestinal disorders NEC	2	6	2	5		1
Gastrointestinal dyskinetic disorders	1	1	1	1		
Gastrointestinal inflammatory disorders NEC	1	1			1	1
Gastrointestinal signs and symptoms NEC	30	77	17	34	13	43
Gastrointestinal stenosis and obstruction NEC	1	5			1	5
Gastrointestinal vascular occlusion and infarction	7	9			7	9
Gingival disorders, signs and symptoms NEC	3	5	2	2	1	3
Gingival haemorrhages	2	5		1	2	4
Inguinal hernias	1	1			1	1
Intestinal haemorrhages	2	8			2	8
Nausea and vomiting symptoms	169	472	143	311	26	161
Non-mechanical ileus	1	3			1	3

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Non-site specific gastrointestinal haemorrhages	5	13			5	13
Oral dryness and saliva altered	2	11	2	3		8
Oral soft tissue disorders NEC	1	9		1	1	8
Oral soft tissue haemorrhages	2	2			2	2
Oral soft tissue infections		1		1		
Oral soft tissue signs and symptoms	17	61	12	26	5	35
Oral soft tissue swelling and oedema	11	52	1	6	10	46
Rectal inflammations NEC		1				1
Salivary gland enlargements		2		2		
Stomatitis and ulceration	6	17	4	10	2	7
Tongue disorders	3	11	2	5	1	6
Tongue signs and symptoms	10	43	1	8	9	35
	384	1,156	267	624	117	532

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site reactions NEC	1	3	1	3		
Adverse effect absent		1		1		
Asthenic conditions	305	785	257	517	48	268
Body temperature altered	16	54	11	26	5	28
Death and sudden death	16	43			16	43
Febrile disorders	341	926	305	644	36	282
Feelings and sensations NEC	102	271	90	182	12	89
Gait disturbances	11	31	8	11	3	20
General signs and symptoms NEC	66	143	32	53	34	90
Inflammations	7	20	4	11	3	9
Injection site reactions	3	6	3	6		
Interactions	1	3		1	1	2

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* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mass conditions NEC		3		1		2
Mucosal findings abnormal	1	2	1	1		1
Necrosis NEC	1	2			1	2
Oedema NEC	28	68	11	17	17	51
Pain and discomfort NEC	65	202	49	106	16	96
Therapeutic and nontherapeutic responses	32	109	3	3	29	106
Ulcers NEC	1	1	1	1		
Vaccination site reactions	188	594	167	429	21	165
Vascular complications associated with device	1	1			1	1
	1,186	3,268	943	2013	243	1255

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bile duct infections and inflammations	2	4			2	4
Cholecystitis and cholelithiasis	2	2			2	2
Cholestasis and jaundice	2	4	2	2		2
Gallbladder disorders NEC		1				1
Hepatic and hepatobiliary disorders NEC	2	4	1	3	1	1
Hepatic enzymes and function abnormalities	1	5		1	1	4
Hepatic failure and associated disorders		2				2
Hepatic vascular disorders	2	3			2	3
Hepatobiliary signs and symptoms		1				1
Hepatocellular damage and hepatitis NEC	2	13			2	13
Obstructive bile duct disorders (excl neoplasms)	1	1			1	1
Structural and other bile duct disorders		1		1		
	14	41	3	7	11	34

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	10	42	5	9	5	33
Allergies to foods, food additives, drugs and other chemicals	7	21	3	4	4	17
Amyloidoses	1	1			1	1
Anaphylactic and anaphylactoid responses	8	63			8	63
Immune and associated conditions NEC	1	5		2	1	3
Immunodeficiency disorders NEC	1	1			1	1
	28	133	8	15	20	118

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal and gastrointestinal infections	3	13			1	5	2	8
Bacterial infections NEC	9	25			2	2	7	23
Bordetella infections		2						2
Breast infections	1	1					1	1
Candida infections	2	7			2	5		2
Cardiac infections	1	1					1	1
Central nervous system and spinal infections	3	9					3	9
Clostridia infections		1						1
Coronavirus infections	40	177			5	37	35	140
Dental and oral soft tissue infections	3	8			1	3	2	5
Ear infections		2						2
Enterococcal infections	1	2					1	2
Epstein-Barr viral infections		2						2
Escherichia infections	2	4					2	4
Eye and eyelid infections		1						1
Flaviviral infections	1	1					1	1
Fungal infections NEC		1						1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hepatobiliary and spleen infections	1	1
Herpes viral infections	60	148
Infections NEC	3	13
Infectious disorders carrier		1
Influenza viral infections	4	11
Lower respiratory tract and lung infections	5	22
Male reproductive tract infections	2	2
Pseudomonal infections	1	2
Retroviral infections		1
Sepsis, bacteraemia, viraemia and fungaemia NEC	4	11
Serratia infections	1	1
Skin structures and soft tissue infections		2
Staphylococcal infections		3
Tuberculous infections		1
Upper respiratory tract infections	8	27
Urinary tract infections	5	20
Vascular infections		3
Viral infections NEC	2	6
Yersinia infections	2	2
	164	534

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
	1	20	38	40	110
		1	2	2	11
					1
		3	6	1	5
		1	1	4	21
				2	2
				1	2
					1
				4	11
				1	1
					2
					3
					1
		6	16	2	11
		2	5	3	15
					3
		1	1	1	5
				2	2
	1	45	121	119	413

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Abdominal and gastrointestinal injuries NEC	3	4
Bone and joint injuries NEC	1	3
Cardiac and vascular procedural complications	2	3
Cerebral injuries NEC	4	10

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	2	1	2
		1	3
		2	3
		4	10

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest and respiratory tract injuries NEC	1	3			1	3
Exposures associated with pregnancy, delivery and lactation	10	28	10	24		4
Eye injuries NEC	1	3	1	2		1
Fractures and dislocations NEC	1	2	1	1		1
Limb fractures and dislocations	1	5		1	1	4
Medication errors, product use errors and issues NEC	5	16	5	16		
Muscle, tendon and ligament injuries	2	3	1	2	1	1
Non-site specific injuries NEC	11	33	3	11	8	22
Off label uses	11	25	11	25		
Overdoses NEC	2	11	2	11		
Peripheral nerve injuries		1				1
Poisoning and toxicity		2				2
Product administration errors and issues	24	51	24	51		
Product preparation errors and issues	1	10	1	10		
Site specific injuries NEC		5		1		4
Skin injuries NEC	1	7		2	1	5
Skull fractures, facial bone fractures and dislocations		3				3
Spinal cord injuries NEC		1				1
Thoracic cage fractures and dislocations	2	3			2	3
Transplantation complications	1	1			1	1
Underdoses NEC	4	5	4	5		
Vaccination related complications	1	5		1	1	4
	89	243	65	165	24	78

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmunity analyses		1				1
Bacteria identification and serology (excl mycobacteria)	1	2			1	2
Blood gas and acid base analyses	14	39	7	15	7	24
Carbohydrate tolerance analyses (incl diabetes)	10	13	8	9	2	4
Cardiac auscultatory investigations	2	2	2	2		
Cardiac imaging procedures		1				1
Cerebrospinal fluid tests (excl microbiology)	1	1			1	1
Cholesterol analyses	1	1	1	1		
Coagulation and bleeding analyses	26	43	15	22	11	21
Digestive enzymes		1		1		
ECG investigations	1	9			1	9
Endocrine analyses and imaging NEC	1	1	1	1		
Foetal and neonatal diagnostic procedures		1				1
Haematological analyses NEC		2		2		
Heart rate and pulse investigations	3	13	2	5	1	8
Imaging procedures NEC		2				2
Immunology analyses NEC		1		1		
Liver function analyses	4	8	3	4	1	4
Metabolism tests NEC	1	2	1	1		1
Microbiology and serology tests NEC		1		1		
Mineral and electrolyte analyses	8	11	4	7	4	4
Neurologic diagnostic procedures	1	1			1	1
Ophthalmic function diagnostic procedures		1				1
Parathyroid analyses	1	1	1	1		
Physical examination procedures and organ system status	4	10	3	6	1	4
Pituitary analyses anterior		1		1		
Platelet analyses	9	11	8	9	1	2
Protein analyses NEC	8	12	4	8	4	4
Red blood cell analyses	11	18	9	15	2	3
Renal function analyses	13	16	12	14	1	2

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory tract and thoracic imaging procedures	1	1	1	1		
Skeletal and cardiac muscle analyses	4	7	1	1	3	6
Therapeutic drug monitoring analyses		1				1
Thyroid analyses		1		1		
Tissue enzyme analyses NEC	1	3	1	2		1
Urinalysis NEC		2		2		
Urinary tract function analyses NEC		1		1		
Vascular auscultatory investigations		2				2
Vascular tests NEC (incl blood pressure)	22	46	13	27	9	19
Virus identification and serology	2	18	1	13	1	5
Vitamin analyses	2	2	2	2		
White blood cell analyses	26	37	24	34	2	3
	178	347	124	210	54	137

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	6	21	4	9	2	12
Calcium metabolism disorders	2	4	2	3		1
Cell metabolism disorders NEC		1				1
Diabetes mellitus (incl subtypes)	3	7			3	7
Diabetic complications NEC		3				3
Disorders of purine metabolism	1	1	1	1		
Electrolyte imbalance NEC		1				1
Elevated cholesterol		1		1		
Fat soluble vitamin deficiencies and disorders	2	3	2	3		
Fluid intake increased	1	1			1	1
General nutritional disorders NEC	1	3	1	2		1

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* AE=Adverse Event

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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperglycaemic conditions NEC	6	16	1	1	5	15
Hypoglycaemic conditions NEC	5	10	3	3	2	7
Iron deficiencies	1	2	1	2		
Magnesium metabolism disorders	1	1			1	1
Metabolic acidoses (excl diabetic acidoses)	2	2			2	2
Phosphorus metabolism disorders		1		1		
Potassium imbalance	3	5			3	5
Protein metabolism disorders NEC	1	1	1	1		
Sodium imbalance	1	7		1	1	6
Total fluid volume decreased	2	5	1	3	1	2
Total fluid volume increased		1				1
Water soluble vitamin deficiencies		1		1		
	38	98	17	32	21	66

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	4	9			4	9
Bone disorders NEC	1	2	1	2		
Bone related signs and symptoms		3		1		2
Bursal disorders		2				2
Cartilage disorders		1				1
Intervertebral disc disorders NEC	1	1	1	1		
Joint related disorders NEC	4	10	2	4	2	6
Joint related signs and symptoms	75	210	65	145	10	65
Lupus erythematosus (incl subtypes)	1	2			1	2
Muscle infections and inflammations		4				4
Muscle pains	144	413	131	295	13	118
Muscle related signs and symptoms NEC	6	21	3	9	3	12

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* AE=Adverse Event

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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle tone abnormalities	3	9	2	2	1	7
Muscle weakness conditions	9	24	8	15	1	9
Musculoskeletal and connective tissue conditions NEC	7	32	5	14	2	18
Musculoskeletal and connective tissue pain and discomfort	92	240	75	145	17	95
Osteoarthropathies		2		1		1
Psoriatic arthropathies		1				1
Rheumatoid arthropathies	1	1			1	1
Soft tissue disorders NEC	2	4	2	3		1
Spine and neck deformities		1				1
Spondyloarthropathies		2				2
Tendon disorders	2	6	1	2	1	4
	352	1,000	296	639	56	361

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiovascular neoplasms benign	1	1	1	1		
Colorectal and anal neoplasms malignancy unspecified		1				1
Hepatobiliary neoplasms benign	1	1	1	1		
Kaposi's sarcomas		1				1
Leukaemias acute NEC		1				1
Leukaemias chronic lymphocytic		1				1
Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)	1	1			1	1
Neoplasms unspecified malignancy and site unspecified NEC	1	3	1	2		1
Skin neoplasms malignant and unspecified (excl melanoma)	1	1			1	1

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* AE=Adverse Event

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Soft tissue neoplasms benign NEC		1		1		
Uterine neoplasms benign	1	1	1	1		
	6	13	4	6	2	7

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal reflexes	1	3	1	2		1
Absence seizures	1	7			1	7
Acute polyneuropathies	3	9			3	9
Auditory nerve disorders		1				1
Central nervous system haemorrhages and cerebrovascular accidents	43	96			43	96
Central nervous system vascular disorders NEC	4	5	1	1	3	4
Cerebrovascular venous and sinus thrombosis	4	8			4	8
Cervical spinal cord and nerve root disorders		2		1		1
Coma states	2	2			2	2
Coordination and balance disturbances	7	28	3	11	4	17
Cortical dysfunction NEC	4	13	1	2	3	11
Demyelinating disorders NEC		3				3
Disturbances in consciousness NEC	42	190	8	21	34	169
Disturbances in sleep phase rhythm		1				1
Dyskinesias and movement disorders NEC	6	21	3	8	3	13
Dystonias		2		1		1
Encephalopathies NEC	1	5			1	5
Facial cranial nerve disorders	27	80	1	2	26	78
Generalised tonic-clonic seizures	5	12			5	12
Headaches NEC	262	710	229	475	33	235
Hydrocephalic conditions	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Increased intracranial pressure disorders	1	2	1	1		1
Memory loss (excl dementia)	6	16	2	6	4	10
Mental impairment (excl dementia and memory loss)	8	25	4	6	4	19
Migraine headaches	3	17	1	4	2	13
Mixed cranial nerve disorders	1	1			1	1
Mononeuropathies	2	3			2	3
Multiple sclerosis acute and progressive		1				1
Muscle tone abnormal	1	2		1	1	1
Narcolepsy and hypersomnia	2	3	2	2		1
Nervous system disorders NEC	2	5	1	1	1	4
Neurological signs and symptoms NEC	101	310	76	166	25	144
Neurologic visual problems NEC		1				1
Neuromuscular disorders NEC	1	6		3	1	3
Olfactory nerve disorders	4	15	2	6	2	9
Optic nerve disorders NEC	2	3			2	3
Paraesthesias and dysaesthesias	67	241	37	80	30	161
Paralysis and paresis (excl cranial nerve)	8	25	2	3	6	22
Partial complex seizures	1	1			1	1
Peripheral neuropathies NEC	3	13	1	2	2	11
Seizures and seizure disorders NEC	12	40			12	40
Sensory abnormalities NEC	24	65	15	31	9	34
Speech and language abnormalities	12	28	7	12	5	16
Structural brain disorders NEC	1	3		1	1	2
Transient cerebrovascular events	3	11			3	11
Tremor (excl congenital)	12	27	9	12	3	15
Trigeminal disorders	1	4	1	2		2
	691	2,067	408	863	283	1204

System Organ Class

Pregnancy, puerperium and perinatal conditions

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortion related conditions and complications	1	1	1	1
Abortions not specified as induced or spontaneous	1	3	1	3
Abortions spontaneous		3		3
Neonatal disorders due to birth trauma (excl intracranial haemorrhages)		1		1
	2	8	2	8

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour NEC	1	1			1	1
Anxiety symptoms	16	38	11	23	5	15
Communications disorders	1	1			1	1
Confusion and disorientation	14	43	7	17	7	26
Deliria		4				4
Delusional symptoms		1				1
Depressive disorders	2	3	1	1	1	2
Disturbances in initiating and maintaining sleep	5	14	4	9	1	5
Dyssomnias	1	2	1	1		1
Eating disorders NEC		1		1		
Emotional and mood disturbances NEC	1	5		1	1	4
Fear symptoms and phobic disorders (incl social phobia)	2	3	2	2		1
Hallucinations (excl sleep-related)	4	12			4	12
Increased physical activity levels	3	8	3	5		3
Mental disorders NEC		1				1
Mood alterations with depressive symptoms		5		5		
Mood disorders NEC		1				1
Narcolepsy and associated conditions	1	1	1	1		

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Panic attacks and disorders	1	2	1	1		1
Psychotic disorder NEC		2		1		1
Sexual desire disorders		1				1
Somatic symptom disorders		1		1		
Speech and language usage disturbances		1				1
Stereotypies and automatisms	1	2	1	2		
Stress disorders	1	1			1	1
Suicidal and self-injurious behaviour		1				1
Thinking disturbances	1	8	1	4		4
Tic disorders	1	4	1	1		3
	56	167	34	76	22	91

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	2	16	2	6		10
Glomerulonephritis and nephrotic syndrome	1	1			1	1
Myoneurogenic bladder disorders		2				2
Renal failure and impairment	11	29			11	29
Renal neoplasms	1	3	1	3		
Urinary abnormalities	2	6	1	3	1	3
Urinary tract signs and symptoms NEC	3	4	2	2	1	2
	20	61	6	14	14	47

System Organ Class

Reproductive system and breast disorders

Interval Total #	Cumulative Total #	Nonserious	Serious
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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast disorders NEC		1		1		
Breast signs and symptoms	3	5			3	5
Lactation disorders	1	2			1	2
Menopausal effects on the genitourinary tract	3	3			3	3
Menstruation and uterine bleeding NEC	17	27	16	18	1	9
Menstruation with decreased bleeding	3	6	1	1	2	5
Menstruation with increased bleeding	5	8	4	5	1	3
Ovarian and fallopian tube cysts and neoplasms		1				1
Pelvis and broad ligament disorders NEC		1		1		
Penile disorders NEC (excl erection and ejaculation)		1		1		
Reproductive tract disorders NEC (excl neoplasms)		2		1		1
Reproductive tract signs and symptoms NEC		1		1		
Testicular and epididymal disorders NEC		1		1		
Uterine disorders NEC		2				2
Vulvovaginal disorders NEC	1	6		2	1	4
Vulvovaginal signs and symptoms		1		1		
	33	68	21	33	12	35

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	78	244	26	46	52	198
Bronchial conditions NEC		1				1
Bronchospasm and obstruction	4	41	2	6	2	35
Conditions associated with abnormal gas exchange	7	25			7	25
Coughing and associated symptoms	23	76	15	36	8	40

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)		3				3
Laryngeal spasm, oedema and obstruction	3	20		1	3	19
Lower respiratory tract inflammatory and immunologic conditions	2	7			2	7
Lower respiratory tract signs and symptoms	4	10	2	3	2	7
Nasal congestion and inflammations	6	21	4	14	2	7
Nasal disorders NEC	5	12	1	4	4	8
Parenchymal lung disorders NEC	6	14	3	6	3	8
Pharyngeal disorders (excl infections and neoplasms)	3	21	1	3	2	18
Pneumothorax and pleural effusions NEC	4	10	1	2	3	8
Pulmonary hypertensions	2	4			2	4
Pulmonary oedemas	3	5			3	5
Pulmonary thrombotic and embolic conditions	50	97			50	97
Respiratory failures (excl neonatal)	11	37			11	37
Respiratory signs and symptoms NEC		3				3
Respiratory tract disorders NEC	6	13		1	6	12
Upper respiratory tract signs and symptoms	43	134	26	62	17	72
	260	798	81	184	179	614

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes	2	2	2	2		
Alopecias		2				2
Angioedemas	5	42		1	5	41
Apocrine and eccrine gland disorders	9	35	5	14	4	21
Bullous conditions	3	10	2	3	1	7
Dermal and epidermal conditions NEC	13	30	13	17		13

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermatitis and eczema	7	19	4	6	3	13
Dermatitis ascribed to specific agent	2	5		1	2	4
Erythemas	23	81	13	37	10	44
Exfoliative conditions		2				2
Panniculitides	1	3			1	3
Papulosquamous conditions	1	6			1	6
Pigmentation changes NEC		1		1		
Pruritus NEC	37	121	25	49	12	72
Psoriatic conditions		1				1
Purpura and related conditions	6	16	2	5	4	11
Pustular conditions		1				1
Rashes, eruptions and exanthems NEC	35	132	19	45	16	87
Skin and subcutaneous tissue ulcerations	1	5		3	1	2
Skin injuries and mechanical dermatoses	1	1	1	1		
Skin vasculitides	1	3			1	3
Skin vasomotor conditions		1				1
Urticarias	24	88	9	34	15	54
	171	607	95	219	76	388

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	2	6	1	2	1	4
Social issues NEC	1	1	1	1		
	3	7	2	3	1	4

System Organ Class

Surgical and medical procedures

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Surgical and medical procedures

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Induced abortions		1				1
Limb therapeutic procedures	3	4	3	3		1
	3	5	3	3		2

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	15	46			15	46
Aortic aneurysms and dissections	2	3			2	3
Aortic necrosis and vascular insufficiency	4	4	2	2	2	2
Arterial infections and inflammations		1				1
Blood pressure disorders NEC	1	1			1	1
Circulatory collapse and shock	2	6			2	6
Haemorrhages NEC	8	20	3	8	5	12
Non-site specific embolism and thrombosis	5	8			5	8
Non-site specific necrosis and vascular insufficiency NEC	7	9	2	2	5	7
Non-site specific vascular disorders NEC	7	8	4	5	3	3
Peripheral embolism and thrombosis	59	93		2	59	91
Peripheral vascular disorders NEC	8	21	5	10	3	11
Peripheral vasoconstriction, necrosis and vascular insufficiency	6	21	3	8	3	13
Phlebitis NEC	1	5		2	1	3
Site specific vascular disorders NEC	5	12	3	5	2	7
Varicose veins NEC	1	1	1	1		
Vascular hypertensive disorders NEC	25	81	7	21	18	60
Vascular hypotensive disorders	16	50	6	14	10	36
Vasculitides NEC		3				3
	172	393	36	80	136	313

* I=Interval, C=Cumulative
* AE=Adverse Event

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Country Where Event Occurred

SWEDEN

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias haemolytic NEC		2				2
Anaemias NEC	2	3			2	3
Bleeding tendencies	1	3			1	3
Coagulopathies		1				1
Leukocytoses NEC	1	2	1	1		1
Leukopenias NEC	1	3			1	3
Lymphatic system disorders NEC	23	56	22	42	1	14
Marrow depression and hypoplastic anaemias		3				3
Neutropenias	1	1			1	1
Spleen disorders	1	2			1	2
Thrombocytopenias	10	27			10	27
	40	103	23	43	17	60

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders		5		1		4
Cardiac disorders NEC	2	8			2	8
Cardiac signs and symptoms NEC	12	48	2	10	10	38
Cardiomyopathies	1	1			1	1
Coronary artery disorders NEC	2	5			2	5
Heart failures NEC	4	27			4	27
Ischaemic coronary artery disorders	20	49			20	49
Left ventricular failures		1				1
Myocardial disorders NEC		5		1		4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Noninfectious myocarditis	1	4			1	4
Noninfectious pericarditis		1				1
Pericardial disorders NEC		4				4
Rate and rhythm disorders NEC	12	40	4	9	8	31
Right ventricular failures		1				1
Supraventricular arrhythmias	10	25			10	25
Ventricular arrhythmias and cardiac arrest	3	26			3	26
	67	250	6	21	61	229

System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cardiac septal defects congenital		1		1
		1		1

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	4	11	2	2	2	9
Hearing losses	5	15			5	15
Hyperacusia		1				1
Inner ear disorders NEC	1	1	1	1		
Inner ear signs and symptoms	10	31	3	5	7	26
	20	59	6	8	14	51

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adrenal cortical hypofunctions		1				1
Adrenal gland disorders NEC	1	1			1	1
Hyperparathyroid disorders		1		1		
Thyroid disorders NEC		2				2
Thyroid hyperfunction disorders	1	2			1	2
	2	7		1	2	6

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Choroid and vitreous structural change, deposit and degeneration	2	2			2	2
Eyelid movement disorders	1	2			1	2
Lacrimation disorders	1	2			1	2
Ocular bleeding and vascular disorders NEC		2				2
Ocular disorders NEC	5	29	4	7	1	22
Ocular infections, inflammations and associated manifestations	6	12	2	2	4	10
Ocular nerve and muscle disorders	1	1			1	1
Ocular sensation disorders		9				9
Optic nerve bleeding and vascular disorders	1	1			1	1
Pupil disorders		1		1		
Refractive and accommodative disorders		1				1
Retinal bleeding and vascular disorders (excl retinopathy)	2	5			2	5
Retinal structural change, deposit and degeneration	1	1			1	1
Visual disorders NEC	7	16	2	4	5	12
Visual field disorders	2	6			2	6

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Visual impairment and blindness (excl colour blindness)	9	23		1	9	22
	38	113	8	15	30	98

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal wall conditions NEC		1				1
Colitis (excl infective)	2	2			2	2
Dental disorders NEC		1				1
Dental pain and sensation disorders	1	1	1	1		
Diarrhoea (excl infective)	21	67	11	36	10	31
Diverticula		1		1		
Dyspeptic signs and symptoms		1		1		
Flatulence, bloating and distension	3	7		2	3	5
Gastric and oesophageal haemorrhages		1				1
Gastritis (excl infective)		2		1		1
Gastrointestinal and abdominal pains (excl oral and throat)	24	56	16	29	8	27
Gastrointestinal atonic and hypomotility disorders NEC	2	5	2	5		
Gastrointestinal disorders NEC	1	3		1	1	2
Gastrointestinal signs and symptoms NEC	5	25	3	8	2	17
Gastrointestinal vascular occlusion and infarction		5				5
Gingival disorders, signs and symptoms NEC	3	3	1	1	2	2
Gingival haemorrhages	1	1			1	1
Intestinal haemorrhages		4				4
Nausea and vomiting symptoms	92	263	52	113	40	150
Non-site specific gastrointestinal haemorrhages		7				7
Oesophageal ulcers and perforation		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral dryness and saliva altered	4	6	3	3	1	3
Oral soft tissue signs and symptoms	12	54	4	19	8	35
Oral soft tissue swelling and oedema	2	12		2	2	10
Peritoneal and retroperitoneal disorders		1				1
Peritoneal and retroperitoneal haemorrhages		1				1
Stomatitis and ulceration	2	5	2	4		1
Tongue signs and symptoms	2	23		4	2	19
	177	559	95	231	82	328

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	174	483	109	261	65	222
Body temperature altered		4		1		3
Death and sudden death	4	53			4	53
Febrile disorders	160	423	130	253	30	170
Feelings and sensations NEC	88	254	61	141	27	113
Gait disturbances	9	15	1	3	8	12
General signs and symptoms NEC	57	208	19	60	38	148
Implant and catheter site reactions		1		1		
Inflammations	2	6			2	6
Injection site reactions	3	4	3	4		
Mass conditions NEC	1	3	1	2		1
Oedema NEC	1	5		1	1	4
Pain and discomfort NEC	88	249	55	120	33	129
Therapeutic and nontherapeutic responses	9	26			9	26
Vaccination site reactions	186	442	131	318	55	124
	782	2,176	510	1165	272	1011

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* AE=Adverse Event

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System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bile duct infections and inflammations	1	2	1	2
Cholecystitis and cholelithiasis		1		1
Cholestasis and jaundice		1		1
Gallbladder disorders NEC	1	3	1	3
Hepatic and hepatobiliary disorders NEC		2		2
Hepatobiliary signs and symptoms	1	1	1	1
Hepatocellular damage and hepatitis NEC		1		1
Structural and other bile duct disorders		2		2
	3	13	3	13

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	7	46		5	7	41
Allergies to foods, food additives, drugs and other chemicals		3		1		2
Anaphylactic and anaphylactoid responses	6	36			6	36
Immune and associated conditions NEC		2				2
Transplant rejections		1				1
	13	88		6	13	82

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections	2	5			2	5
Bacterial infections NEC		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system and spinal infections		5				5
Clostridia infections		1				1
Coronavirus infections	17	67	8	33	9	34
Escherichia infections		3				3
Herpes viral infections	8	29	2	7	6	22
Infections NEC	3	18		2	3	16
Lower respiratory tract and lung infections	4	20			4	20
Muscle and soft tissue infections	1	1			1	1
Sepsis, bacteraemia, viraemia and fungaemia NEC	3	15			3	15
Staphylococcal infections		1				1
Streptococcal infections	1	10			1	10
Upper respiratory tract infections	10	27	7	13	3	14
Urinary tract infections	3	14		6	3	8
Viral infections NEC	2	5		2	2	3
	54	222	17	63	37	159

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral injuries NEC	2	6		1	2	5
Exposures associated with pregnancy, delivery and lactation	4	4	3	3	1	1
Heat injuries (excl thermal burns)		1				1
Limb fractures and dislocations	1	4			1	4
Medication errors, product use errors and issues NEC	1	31	1	31		
Muscle, tendon and ligament injuries	1	1			1	1
Non-site specific injuries NEC	10	29	4	8	6	21
Non-site specific procedural complications		1				1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Off label uses	3	7	3	7		
Overdoses NEC		2		2		
Product administration errors and issues	10	61	9	60	1	1
Product preparation errors and issues	1	5	1	5		
Respiratory tract and thoracic cavity procedural complications		1				1
Site specific injuries NEC	2	8		2	2	6
Skin injuries NEC	5	8	1	1	4	7
Skull fractures, facial bone fractures and dislocations	1	1			1	1
Thoracic cage fractures and dislocations	1	2			1	2
Underdoses NEC	2	7	2	7		
Vaccination related complications	1	1			1	1
	45	180	24	127	21	53

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	3	30		6	3	24
Carbohydrate tolerance analyses (incl diabetes)	3	9	2	5	1	4
Cardiac auscultatory investigations		1				1
Central nervous system imaging procedures		1				1
Chemistry analyses NEC	2	2			2	2
Cholesterol analyses	1	1			1	1
Coagulation and bleeding analyses	1	3			1	3
ECG investigations	4	7	1	1	3	6
Haematological analyses NEC		1				1
Heart rate and pulse investigations	15	49	2	15	13	34
Lipoprotein and lipid tests NEC	1	1			1	1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Liver function analyses	2	6			2	6
Metabolism tests NEC		1		1		
Mineral and electrolyte analyses		3		2		1
Physical examination procedures and organ system status	4	24	2	7	2	17
Platelet analyses	1	3		1	1	2
Protein analyses NEC	6	23	3	10	3	13
Red blood cell analyses		2				2
Renal function analyses	1	8	1	5		3
Skeletal and cardiac muscle analyses	4	5		1	4	4
Tissue enzyme analyses NEC		2				2
Urinalysis NEC		1		1		
Urinary tract function analyses NEC		2				2
Vascular tests NEC (incl blood pressure)	10	37	3	11	7	26
White blood cell analyses	2	5	1	4	1	1
	60	227	15	70	45	157

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	4	25	2	10	2	15
Calcium metabolism disorders		1				1
Diabetes mellitus (incl subtypes)	1	1	1	1		
Disorders of purine metabolism	1	2			1	2
Electrolyte imbalance NEC		1		1		
Fluid intake decreased		1				1
General nutritional disorders NEC		3		1		2
Hyperglycaemic conditions NEC	2	3			2	3
Hypoglycaemic conditions NEC	1	5			1	5

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Metabolic acidoses (excl diabetic acidoses)	1	3			1	3
Metabolic disorders NEC		2		1		1
Potassium imbalance		2				2
Protein metabolism disorders NEC		1		1		
Sodium imbalance		1				1
Total fluid volume decreased		8		2		6
Total fluid volume increased		2				2
	10	61	3	17	7	44

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	3	8	3	3		5
Bone disorders NEC		2		1		1
Bone related signs and symptoms	3	7	2	4	1	3
Bursal disorders		1				1
Connective tissue disorders NEC		1				1
Joint related disorders NEC	2	4			2	4
Joint related signs and symptoms	56	114	36	64	20	50
Lupus erythematosus (incl subtypes)		1				1
Muscle pains	69	167	47	93	22	74
Muscle related signs and symptoms NEC	6	29	3	8	3	21
Muscle tone abnormalities		1				1
Muscle weakness conditions	8	35	2	6	6	29
Musculoskeletal and connective tissue conditions NEC	14	42	11	21	3	21
Musculoskeletal and connective tissue pain and discomfort	110	269	71	163	39	106
Osteoarthropathies	3	3	1	1	2	2

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rheumatoid arthropathies	1	1			1	1
Tendon disorders		1				1
	275	686	176	364	99	322

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Metastases to unknown and unspecified sites		1		1
Neoplasms unspecified malignancy and site unspecified NEC	1	2	1	2
	1	3	1	3

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal reflexes		1				1
Abnormal sleep-related events		2		1		1
Absence seizures		2				2
Acute polyneuropathies		1				1
Alzheimer's disease (incl subtypes)		1				1
Autonomic nervous system disorders		2				2
Central nervous system haemorrhages and cerebrovascular accidents	51	106			51	106
Central nervous system vascular disorders NEC	3	5			3	5
Coma states	1	1			1	1
Coordination and balance disturbances	9	28	4	5	5	23
Cortical dysfunction NEC	1	4			1	4

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cranial nerve disorders NEC		1				1
Dementia (excl Alzheimer's type)		2				2
Disturbances in consciousness NEC	16	94	4	9	12	85
Dyskinesias and movement disorders NEC	6	10			6	10
Dystonias		1				1
Encephalopathies NEC		1				1
Facial cranial nerve disorders	8	41			8	41
Generalised tonic-clonic seizures		1				1
Headaches NEC	168	380	123	237	45	143
Lumbar spinal cord and nerve root disorders		2		1		1
Memory loss (excl dementia)	6	18	1	3	5	15
Mental impairment (excl dementia and memory loss)	6	14	1	3	5	11
Migraine headaches	8	19	5	9	3	10
Mononeuropathies	1	1			1	1
Multiple sclerosis acute and progressive		3				3
Muscle tone abnormal		1				1
Narcolepsy and hypersomnia	1	4		1	1	3
Nervous system disorders NEC	2	3	1	1	1	2
Neurological signs and symptoms NEC	70	202	29	66	41	136
Neuromuscular disorders NEC		1				1
Olfactory nerve disorders	7	17	2	5	5	12
Paraesthesias and dysaesthesias	31	158	10	46	21	112
Paralysis and paresis (excl cranial nerve)	4	17			4	17
Parkinson's disease and parkinsonism		2				2
Peripheral neuropathies NEC	3	11			3	11
Seizures and seizure disorders NEC	5	25			5	25
Sensory abnormalities NEC	8	36	3	14	5	22
Speech and language abnormalities	3	15		3	3	12
Structural brain disorders NEC	1	3			1	3
Transient cerebrovascular events	8	17			8	17
Tremor (excl congenital)	4	19	1	3	3	16

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* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Trigeminal disorders		2				2
	431	1,274	184	407	247	867

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous	1	2	1	2
	1	2	1	2

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product distribution and storage issues	5	6	5	6
Product physical issues		36		36
	5	42	5	42

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour NEC	1	4		1	1	3
Anxiety symptoms	5	27	4	14	1	13
Behaviour and socialisation disturbances	3	4			3	4
Cognitive and attention disorders and disturbances NEC	2	10	2	3		7

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Confusion and disorientation	7	28	3	6	4	22
Deliria		1				1
Delusional disorders		1				1
Depressive disorders	1	3	1	2		1
Dissociative states		1				1
Disturbances in initiating and maintaining sleep	2	12	2	6		6
Dyssomnias		2		1		1
Eating disorders NEC		1				1
Fear symptoms and phobic disorders (incl social phobia)	1	2			1	2
Hallucinations (excl sleep-related)	2	10			2	10
Learning disorders		1				1
Mental disorders due to a general medical condition NEC	1	1			1	1
Mood alterations with depressive symptoms	1	6		1	1	5
Mood alterations with manic symptoms	1	1	1	1		
Mood disorders NEC	2	4	1	1	1	3
Panic attacks and disorders		4				4
Parasomnias	1	7		2	1	5
Perception disturbances NEC		1				1
Psychiatric symptoms NEC		1				1
Psychotic disorder NEC		3				3
Sleep disorders NEC	2	8	2	2		6
Speech and language usage disturbances		1				1
	32	144	16	40	16	104

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	1	4		1	1	3
Myoneurogenic bladder disorders	2	2			2	2
Renal disorders NEC		1				1
Renal failure and impairment	3	13			3	13
Renal lithiasis		1				1
Renal vascular and ischaemic conditions		2				2
Urinary abnormalities		1				1
Urinary tract signs and symptoms NEC	3	5	3	4		1
	9	29	3	5	6	24

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Benign and malignant breast neoplasms	1	1			1	1
Breast signs and symptoms	1	2	1	1		1
Menstruation and uterine bleeding NEC	5	6	3	3	2	3
Menstruation with decreased bleeding		1		1		
Pelvis and broad ligament disorders NEC	1	1	1	1		
Penile disorders NEC (excl erection and ejaculation)		1				1
Reproductive tract signs and symptoms NEC	1	1			1	1
Uterine infections and inflammations (excl cervix)		1		1		
Vulvovaginal disorders NEC		1				1
	9	15	5	7	4	8

System Organ Class

Respiratory, thoracic and mediastinal disorders

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	44	189	10	29	34	160
Bronchial conditions NEC		1				1
Bronchospasm and obstruction	5	25	1	4	4	21
Conditions associated with abnormal gas exchange		2				2
Coughing and associated symptoms	14	55	4	20	10	35
Laryngeal spasm, oedema and obstruction		1				1
Lower respiratory tract inflammatory and immunologic conditions		3				3
Lower respiratory tract signs and symptoms	5	8	2	2	3	6
Nasal congestion and inflammations	1	13		5	1	8
Nasal disorders NEC	8	16	3	7	5	9
Paranasal sinus disorders (excl infections and neoplasms)		3		3		
Parenchymal lung disorders NEC	5	8			5	8
Pharyngeal disorders (excl infections and neoplasms)	11	37	3	7	8	30
Pleural infections and inflammations		1				1
Pneumothorax and pleural effusions NEC	1	7		1	1	6
Pulmonary hypertensions		1				1
Pulmonary oedemas	4	13			4	13
Pulmonary thrombotic and embolic conditions	36	89			36	89
Respiratory failures (excl neonatal)	3	7			3	7
Respiratory signs and symptoms NEC	3	5	1	3	2	2
Respiratory tract disorders NEC	4	9	1	2	3	7
Upper respiratory tract signs and symptoms	26	105	16	64	10	41
	170	598	41	147	129	451

System Organ Class

Skin and subcutaneous tissue disorders

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes	1	2	1	2		
Angioedemas	1	7			1	7
Apocrine and eccrine gland disorders	6	35		12	6	23
Bullous conditions	2	8	1	2	1	6
Dermal and epidermal conditions NEC	7	21	3	9	4	12
Dermatitis and eczema	1	5		2	1	3
Dermatitis ascribed to specific agent		3		2		1
Erythemas	8	44	2	21	6	23
Exfoliative conditions	1	1			1	1
Nail and nail bed conditions (excl infections and infestations)		1				1
Photosensitivity and photodermatosis conditions	1	2	1	1		1
Pruritus NEC	16	48	9	19	7	29
Psoriatic conditions	1	2		1	1	1
Purpura and related conditions	3	9		1	3	8
Rashes, eruptions and exanthems NEC	11	44	3	15	8	29
Skin and subcutaneous tissue ulcerations		4				4
Skin haemorrhages	2	3			2	3
Skin injuries and mechanical dermatoses		1		1		
Skin vasculitides	2	2			2	2
Skin vasomotor conditions		1		1		
Urticarias	13	52	10	24	3	28
	76	295	30	113	46	182

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	4	7	1	2	3	5
	4	7	1	2	3	5

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System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysms and dissections	1	2			1	2
Aortic necrosis and vascular insufficiency		2		1		1
Blood pressure disorders NEC	1	2			1	2
Circulatory collapse and shock	2	9			2	9
Haemorrhages NEC	1	12			1	12
Lymphoedemas		1				1
Non-site specific embolism and thrombosis	11	29			11	29
Non-site specific necrosis and vascular insufficiency NEC	2	4			2	4
Non-site specific vascular disorders NEC	1	2	1	2		
Peripheral embolism and thrombosis	22	52	1	2	21	50
Peripheral vascular disorders NEC	3	13	2	5	1	8
Peripheral vasoconstriction, necrosis and vascular insufficiency	2	6		1	2	5
Phlebitis NEC		1				1
Site specific vascular disorders NEC	1	9		4	1	5
Varicose veins NEC	1	1	1	1		
Vascular hypertensive disorders NEC	6	23		3	6	20
Vascular hypotensive disorders	2	26	1	5	1	21
Vasculitides NEC	1	2			1	2
	57	196	6	24	51	172

* I=Interval, C=Cumulative

* AE=Adverse Event

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Country Where Event Occurred

SWITZERLAND

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias NEC		1				1
Eosinophilic disorders		1		1		
Leukocytoses NEC	1	3		1	1	2
Leukopenias NEC	1	2			1	2
Lymphatic system disorders NEC	11	16	10	11	1	5
Sickle cell trait and disorders		1				1
Thrombocytopenias		3				3
	13	27	10	13	3	14

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders	2	2			2	2
Cardiac disorders NEC	1	3			1	3
Cardiac signs and symptoms NEC	1	5			1	5
Cardiac valve disorders NEC		1				1
Cardiomyopathies		1				1
Coronary artery disorders NEC		1				1
Heart failures NEC	1	10			1	10
Ischaemic coronary artery disorders		4				4
Left ventricular failures		1				1
Noninfectious myocarditis	1	1			1	1
Pericardial disorders NEC		1				1
Rate and rhythm disorders NEC	10	30	1	3	9	27
Supraventricular arrhythmias	4	9			4	9

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* AE=Adverse Event

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System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ventricular arrhythmias and cardiac arrest		4				4
	20	73	1	3	19	70

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	2	4	2	2		2
Hearing losses	1	3			1	3
Inner ear disorders NEC		1				1
Inner ear signs and symptoms	7	13	3	4	4	9
	10	21	5	6	5	15

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Corneal infections, oedemas and inflammations	1	1			1	1
Lid, lash and lacrimal infections, irritations and inflammations	1	4	1	1		3
Ocular bleeding and vascular disorders NEC	1	2			1	2
Ocular disorders NEC	4	5	2	3	2	2
Ocular infections, inflammations and associated manifestations	2	2			2	2
Ocular nerve and muscle disorders	1	1			1	1
Ocular sensation disorders	1	2	1	1		1
Visual disorders NEC		1				1
Visual field disorders	1	1			1	1

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* AE=Adverse Event

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Visual impairment and blindness (excl colour blindness)		4				4
	12	23	4	5	8	18

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis		1				1
Colitis (excl infective)	3	3			3	3
Diarrhoea (excl infective)	9	21	6	9	3	12
Duodenal ulcers and perforation	1	1			1	1
Dyspeptic signs and symptoms	1	1	1	1		
Flatulence, bloating and distension	1	1	1	1		
Gastritis (excl infective)		1				1
Gastrointestinal and abdominal pains (excl oral and throat)	3	10	2	3	1	7
Gastrointestinal atonic and hypomotility disorders NEC		2				2
Gastrointestinal disorders NEC		4		2		2
Gastrointestinal signs and symptoms NEC	5	8	3	4	2	4
Intestinal haemorrhages		1		1		
Nausea and vomiting symptoms	22	65	15	24	7	41
Non-site specific gastrointestinal haemorrhages	1	2			1	2
Oesophageal ulcers and perforation		1				1
Oral dryness and saliva altered		1				1
Oral soft tissue disorders NEC	1	1	1	1		
Oral soft tissue signs and symptoms	1	6		2	1	4
Oral soft tissue swelling and oedema	2	4	1	1	1	3
Peritoneal and retroperitoneal disorders		1				1
Stomatitis and ulceration	1	2	1	1		1

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* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue signs and symptoms	1	3			1	3
	52	140	31	50	21	90

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	51	113	31	50	20	63
Body temperature altered	1	2		1	1	1
Death and sudden death	2	12			2	12
Febrile disorders	34	81	25	35	9	46
Feelings and sensations NEC	20	50	14	23	6	27
Gait disturbances	1	5	1	2		3
General signs and symptoms NEC	18	39	10	17	8	22
Inflammations		3				3
Injection site reactions	1	1	1	1		
Interactions	1	2	1	2		
Oedema NEC	1	4		1	1	3
Pain and discomfort NEC	8	27	4	8	4	19
Therapeutic and nontherapeutic responses	5	18		2	5	16
Trophic disorders		1				1
Vaccination site reactions	35	69	33	48	2	21
	178	427	120	190	58	237

System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C

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System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cholecystitis and cholelithiasis		1		1
Cholestasis and jaundice		2		2
Hepatic and hepatobiliary disorders NEC		1		1
Hepatic fibrosis and cirrhosis		1		1
Hepatocellular damage and hepatitis NEC		2		2
		7		7

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	6	30	1	5	5	25
Allergies to foods, food additives, drugs and other chemicals	1	1			1	1
Anaphylactic and anaphylactoid responses	4	19			4	19
Immune and associated conditions NEC		2		1		1
	11	52	1	6	10	46

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections		2				2
Bacterial infections NEC	2	5	1	1	1	4
Central nervous system and spinal infections	2	4			2	4
Coronavirus infections	5	27		2	5	25
Dental and oral soft tissue infections	1	2			1	2
Ear infections	1	1			1	1

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* AE=Adverse Event

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Herpes viral infections	12	35	3	3	9	32
Infections NEC		2		1		1
Influenza viral infections	2	3	2	2		1
Lower respiratory tract and lung infections	2	6			2	6
Sepsis, bacteraemia, viraemia and fungaemia NEC	1	4			1	4
Skin structures and soft tissue infections	1	3	1	1		2
Streptococcal infections		3				3
Upper respiratory tract infections		2		1		1
Urinary tract infections	2	5			2	5
Viral infections NEC		1		1		
	31	105	7	12	24	93

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebral injuries NEC	1	4		1	1	3
Chest and respiratory tract injuries NEC	1	1			1	1
Fractures and dislocations NEC		1				1
Medication errors, product use errors and issues NEC		1		1		
Muscle, tendon and ligament injuries	1	2	1	1		1
Non-site specific injuries NEC	6	14	1	3	5	11
Off label uses	2	3	2	3		
Overdoses NEC	1	1	1	1		
Product administration errors and issues	5	15	5	14		1
Site specific injuries NEC	2	2			2	2
Skin injuries NEC	1	4	1	4		
Skull fractures, facial bone fractures and dislocations	1	2			1	2

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* AE=Adverse Event

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Thoracic cage fractures and dislocations		1		1		
Underdoses NEC	1	3	1	3		
	22	54	12	32	10	22

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmunity analyses		1				1
Blood gas and acid base analyses		3				3
Carbohydrate tolerance analyses (incl diabetes)		1		1		
Cardiac auscultatory investigations	1	1			1	1
Cell marker analyses		2		2		
Cerebrospinal fluid tests (excl microbiology)		1				1
ECG investigations	1	1			1	1
Heart rate and pulse investigations	1	3	1	1		2
Liver function analyses		1		1		
Neurologic diagnostic procedures		1				1
Physical examination procedures and organ system status	1	3	1	3		
Platelet analyses		1		1		
Protein analyses NEC	3	7	1	2	2	5
Respiratory and pulmonary function diagnostic procedures		1				1
Skeletal and cardiac muscle analyses	1	1			1	1
Tissue enzyme analyses NEC		1		1		
Vascular auscultatory investigations	2	2			2	2
Vascular tests NEC (incl blood pressure)	3	10	1	3	2	7
Virus identification and serology		1		1		
	13	42	4	16	9	26

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* AE=Adverse Event

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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders		3		1		2
Diabetic complications NEC		2				2
Disorders of purine metabolism		1				1
Elevated cholesterol	1	1			1	1
General nutritional disorders NEC		2		1		1
Hyperglycaemic conditions NEC		2				2
Potassium imbalance	1	1			1	1
Total fluid volume decreased		2				2
Total fluid volume increased		1				1
	2	15		2	2	13

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone disorders NEC	1	2	1	2		
Bone related signs and symptoms	1	2		1	1	1
Joint related disorders NEC	2	2	1	1	1	1
Joint related signs and symptoms	20	33	17	20	3	13
Muscle pains	26	46	19	26	7	20
Muscle related signs and symptoms NEC	1	5			1	5
Muscle weakness conditions	2	4			2	4
Musculoskeletal and connective tissue conditions NEC	2	4	2	3		1
Musculoskeletal and connective tissue pain and discomfort	20	36	14	22	6	14
Rheumatoid arthropathies		2				2
Synovial disorders	1	1	1	1		
Tendon disorders	1	2	1	2		
	77	139	56	78	21	61

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* AE=Adverse Event

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Nervous system neoplasms unspecified malignancy NEC		1		1
		1		1

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autonomic nervous system disorders	1	1	1	1		
Central nervous system haemorrhages and cerebrovascular accidents	2	12			2	12
Central nervous system vascular disorders NEC		2				2
Coma states		3				3
Coordination and balance disturbances	3	3	2	2	1	1
Cortical dysfunction NEC		4				4
Dementia (excl Alzheimer's type)		1				1
Disturbances in consciousness NEC	6	24		1	6	23
Dyskinesias and movement disorders NEC	1	1	1	1		
Encephalopathies NEC	1	2			1	2
Facial cranial nerve disorders	7	13			7	13
Generalised tonic-clonic seizures	2	4			2	4
Headaches NEC	41	75	31	44	10	31
Memory loss (excl dementia)	1	3		2	1	1
Mental impairment (excl dementia and memory loss)	1	5	1	2		3
Migraine headaches	1	2	1	2		
Multiple sclerosis acute and progressive	1	1			1	1
Muscle tone abnormal	1	1			1	1
Nervous system disorders NEC		2				2
Neurological signs and symptoms NEC	20	51	13	18	7	33

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesias and dysaesthesias	13	22	5	7	8	15
Paralysis and paresis (excl cranial nerve)	2	4	1	1	1	3
Peripheral neuropathies NEC	1	4			1	4
Seizures and seizure disorders NEC	1	8			1	8
Sensory abnormalities NEC	9	17	3	5	6	12
Speech and language abnormalities	1	4			1	4
Spinal cord and nerve root disorders NEC		1				1
Structural brain disorders NEC		1		1		
Transient cerebrovascular events	1	3			1	3
Tremor (excl congenital)	2	5	2	2		3
Trigeminal disorders		1				1
	119	280	61	89	58	191

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	1	4			1	4
Behaviour and socialisation disturbances		1				1
Confusion and disorientation	2	7	1	1	1	6
Deliria		5				5
Dissociative states		1				1
Disturbances in initiating and maintaining sleep	3	6	3	6		
Hallucinations (excl sleep-related)		1				1
Mood alterations with depressive symptoms		1		1		
Perception disturbances NEC		1		1		
Psychiatric elimination disorders		1				1
Psychiatric symptoms NEC	1	1			1	1
Sleep disorders NEC		1		1		
Stress disorders	1	3			1	3

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	8	33	4	10	4	23

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bladder and urethral symptoms	1	2	1	2
Genital and urinary tract disorders NEC		1		1
Glomerulonephritis and nephrotic syndrome		1		1
Renal failure and impairment	1	7	1	7
	2	11	2	11

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast signs and symptoms		2				2
Menstruation with increased bleeding	1	1	1	1		
	1	3	1	1		2

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	13	42	2	6	11	36
Bronchial conditions NEC	1	1	1	1		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchospasm and obstruction	2	8			2	8
Coughing and associated symptoms	6	13	5	7	1	6
Lower respiratory tract inflammatory and immunologic conditions	1	2			1	2
Nasal congestion and inflammations	1	1	1	1		
Nasal disorders NEC	1	2	1	2		
Paranasal sinus disorders (excl infections and neoplasms)	1	1	1	1		
Parenchymal lung disorders NEC	2	3	1	1	1	2
Pharyngeal disorders (excl infections and neoplasms)		2				2
Pneumothorax and pleural effusions NEC		2		1		1
Pulmonary oedemas	1	4			1	4
Pulmonary thrombotic and embolic conditions	6	11			6	11
Respiratory failures (excl neonatal)		4				4
Respiratory tract disorders NEC		1				1
Upper respiratory tract signs and symptoms	8	14	6	8	2	6
	43	111	18	28	25	83

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecias		1				1
Angioedemas	4	13			4	13
Apocrine and eccrine gland disorders	2	7	2	2		5
Bullous conditions	3	4		1	3	3
Dermal and epidermal conditions NEC	4	7	4	4		3
Dermatitis and eczema	2	3	1	2	1	1
Dermatitis ascribed to specific agent		1				1
Erythemas	3	11		2	3	9

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Papulosquamous conditions	1	2	1	1		1
Pilar disorders NEC		1		1		
Pruritus NEC	9	23	5	8	4	15
Psoriatic conditions	1	1	1	1		
Purpura and related conditions	1	2			1	2
Rashes, eruptions and exanthems NEC	12	29	8	14	4	15
Skin vasomotor conditions	1	1	1	1		
Urticarias	4	10	2	3	2	7
	47	116	25	40	22	76

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Disability issues	3	4	3	4
	3	4	3	4

System Organ Class

Surgical and medical procedures

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breast therapeutic procedures NEC		1		1
		1		1

System Organ Class

Vascular disorders

Interval Total #	Cumulative Total #	Spontaneous	
		Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	3	6			3	6
Circulatory collapse and shock	2	5			2	5
Lymphangiopathies		1				1
Non-site specific embolism and thrombosis	1	2			1	2
Non-site specific necrosis and vascular insufficiency NEC	1	2	1	1		1
Peripheral embolism and thrombosis	5	8			5	8
Peripheral vascular disorders NEC	3	6			3	6
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	3			1	3
Site specific vascular disorders NEC	2	4	2	2		2
Vascular hypertensive disorders NEC	7	25	3	5	4	20
Vascular hypotensive disorders	2	9	1	2	1	7
	27	71	7	10	20	61

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Country Where Event Occurred

THAILAND

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breast signs and symptoms	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

TUNISIA

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inner ear signs and symptoms		1		1
		1		1

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea (excl infective)	1	1	1	1
	1	1	1	1

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenic conditions		4		4
Febrile disorders		1		1
Feelings and sensations NEC		1		1
General signs and symptoms NEC		1		1
Injection site reactions		1		1
Oedema NEC	1	1	1	1
Vaccination site reactions	1	3	1	3
	2	12	2	12

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Coronavirus infections		1		1
Herpes viral infections	4	4	4	4
Influenza viral infections	1	1	1	1
	5	6	5	6

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms		1		1
Muscle pains		2		2
Musculoskeletal and connective tissue conditions NEC		1		1
Musculoskeletal and connective tissue pain and discomfort	1	1	1	1
	1	5	1	5

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headaches NEC	1	2	1	2
Neurological signs and symptoms NEC		2		2
Paraesthesias and dysaesthesias		1		1
Sensory abnormalities NEC		1		1
	1	6	1	6

System Organ Class

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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Coughing and associated symptoms		1		1
		1		1

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dermal and epidermal conditions NEC	1	1	1	1
	1	1	1	1

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vascular hypertensive disorders NEC	1	2	1	2
Vasculitides NEC	1	1	1	1
	2	3	2	3

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Country Where Event Occurred

TURKEY

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	1	2	1	2
	1	2	1	2

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hearing losses	1	1			1	1
Hyperacusia	1	1	1	1		
Inner ear signs and symptoms	3	3	3	3		
	5	5	4	4	1	1

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dental pain and sensation disorders		2		2
Gastrointestinal signs and symptoms NEC	1	1	1	1
Nausea and vomiting symptoms	3	5	3	5
Oral dryness and saliva altered	1	1	1	1
Stomatitis and ulceration	1	1	1	1
	6	10	6	10

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	15	21	15	21		
Febrile disorders	10	13	9	12	1	1
Feelings and sensations NEC	9	10	7	8	2	2
General signs and symptoms NEC	3	4	3	4		
Pain and discomfort NEC	6	6	5	5	1	1
Therapeutic and nontherapeutic responses	2	3	1	1	1	2
Vaccination site reactions	14	18	14	18		
	59	75	54	69	5	6

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	3	3	2	2	1	1
Anaphylactic and anaphylactoid responses		1				1
	3	4	2	2	1	2

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* AE=Adverse Event

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacterial infections NEC	1	1			1	1
Central nervous system and spinal infections		1				1
Coronavirus infections	1	5		3	1	2
Cytomegaloviral infections	1	1			1	1
Ear infections	1	1	1	1		
Herpes viral infections	1	2	1	2		
Influenza viral infections	1	1	1	1		
Upper respiratory tract infections	1	1	1	1		
	7	13	4	8	3	5

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposures associated with pregnancy, delivery and lactation	2	3	2	3
Medication errors, product use errors and issues NEC	2	2	2	2
Off label uses	1	1	1	1
Overdoses NEC		1		1
Product administration errors and issues	2	4	2	4
Product preparation errors and issues		2		2
Skin injuries NEC	1	1	1	1
	8	14	8	14

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
ECG investigations	1	1			1	1
Heart rate and pulse investigations	2	2	1	1	1	1
Physical examination procedures and organ system status	1	1	1	1		
Vascular tests NEC (incl blood pressure)	2	2	1	1	1	1
	6	6	3	3	3	3

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms	1	1	1	1		
Extremity deformities	1	1	1	1		
Joint related signs and symptoms	7	9	6	8	1	1
Muscle pains	7	7	7	7		
Muscle related signs and symptoms NEC	1	1	1	1		
Musculoskeletal and connective tissue conditions NEC	2	2	2	2		
Musculoskeletal and connective tissue pain and discomfort	22	24	19	21	3	3
	41	45	37	41	4	4

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breast and nipple neoplasms malignant		1		1
		1		1

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute polyneuropathies	1	1			1	1
Cortical dysfunction NEC	1	1			1	1
Demyelinating disorders NEC	1	1			1	1
Disturbances in consciousness NEC	4	4	2	2	2	2
Dyskinesias and movement disorders NEC	2	2	1	1	1	1
Headaches NEC	19	24	17	22	2	2
Neurological signs and symptoms NEC	9	11	8	10	1	1
Paraesthesias and dysaesthesias	9	9	9	9		
Partial simple seizures NEC	1	1			1	1
Seizures and seizure disorders NEC	1	1			1	1
Sensory abnormalities NEC	1	1	1	1		
Tremor (excl congenital)	1	1	1	1		
	50	57	39	46	11	11

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Parasomnias	1	1	1	1
Sleep disorders NEC	1	1	1	1
	2	2	2	2

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Urinary abnormalities	1	1	1	1
Urinary tract signs and symptoms NEC	1	1	1	1

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* AE=Adverse Event

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System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
	2	2	2	2

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Reproductive tract signs and symptoms NEC	1	1	1	1
	1	1	1	1

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	3	4	1	2	2	2
Coughing and associated symptoms		1		1		
Pharyngeal disorders (excl infections and neoplasms)		1		1		
Upper respiratory tract signs and symptoms	3	4	3	4		
	6	10	4	8	2	2

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	1	1	1	1		
Bullous conditions	3	3	3	3		
Dermal and epidermal conditions NEC	2	3	2	3		

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* AE=Adverse Event

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System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythemas	4	6	4	6		
Pruritus NEC	6	7	5	6	1	1
Rashes, eruptions and exanthems NEC	6	6	6	6		
Urticarias		1		1		
	22	27	21	26	1	1

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Non-site specific embolism and thrombosis	1	1			1	1
Non-site specific vascular disorders NEC	1	1	1	1		
Vascular hypertensive disorders NEC	2	2	1	1	1	1
Vascular hypotensive disorders	1	1	1	1		
	5	5	3	3	2	2

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Country Where Event Occurred
TURKS AND CAICOS ISLANDS

System Organ Class

General disorders and administration site conditions

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Asthenic conditions		1		1
		1		1

System Organ Class

Musculoskeletal and connective tissue disorders

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Muscle pains		1		1
Soft tissue disorders NEC		1		1
		2		2

System Organ Class

Nervous system disorders

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Central nervous system haemorrhages and cerebrovascular accidents		1		1
Generalised tonic-clonic seizures		1		1
Seizures and seizure disorders NEC		1		1
		3		3

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Country Where Event Occurred

UKRAINE

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Paraesthesias and dysaesthesias		1		1
		1		1

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Country Where Event Occurred

UNITED ARAB EMIRATES

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC	2	5	2	5		
Red blood cell abnormal findings NEC		1				1
	2	6	2	5		1

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hearing losses		1		1
		1		1

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular bleeding and vascular disorders NEC		1				1
Visual disorders NEC		2		2		
Visual impairment and blindness (excl colour blindness)		1				1
		4		2		2

System Organ Class

Gastrointestinal disorders

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal and abdominal pains (excl oral and throat)		4		4		
Intestinal haemorrhages		1				1
Nausea and vomiting symptoms	1	9	1	8		1
	1	14	1	12		2

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions		8		8		
Death and sudden death		2				2
Febrile disorders	1	12	1	12		
Feelings and sensations NEC		5		5		
Gait disturbances		1		1		
General signs and symptoms NEC	1	2	1	1		1
Injection site reactions		2		2		
Pain and discomfort NEC	2	8	2	6		2
Therapeutic and nontherapeutic responses	2	10			2	10
Vaccination site reactions	1	8	1	8		
	7	58	5	43	2	15

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic and anaphylactoid responses	1	1	1	1
	1	1	1	1

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Babesia infections		1				1
Borrelial infections		1				1
Coronavirus infections	3	14	1	3	2	11
Herpes viral infections		1				1
Lower respiratory tract and lung infections		1				1
Upper respiratory tract infections		1		1		
	3	19	1	4	2	15

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation		1		1		
Medication errors, product use errors and issues NEC		1		1		
Off label uses		1		1		
Product administration errors and issues	1	2	1	2		
Site specific injuries NEC		1				1
	1	6	1	5		1

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate and pulse investigations	1	1	1	1		
Vascular tests NEC (incl blood pressure)		1				1
Virus identification and serology		3		3		

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	1	5	1	4		1

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders		1		1
		1		1

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Bone related signs and symptoms		1		1
Joint related signs and symptoms		2		2
Muscle pains		3		3
Muscle related signs and symptoms NEC		1		1
Musculoskeletal and connective tissue pain and discomfort		4		4
		11		11

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in consciousness NEC	2	5	1	2	1	3
Facial cranial nerve disorders		2				2

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 * AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headaches NEC	3	10	3	9		1
Lumbar spinal cord and nerve root disorders		2		2		
Nervous system disorders NEC		1				1
Neurological signs and symptoms NEC	2	6	2	5		1
Paraesthesias and dysaesthesias		2		1		1
Sensory abnormalities NEC		3		3		
Sleep disturbances NEC		1		1		
Tremor (excl congenital)		1		1		
	7	33	6	24	1	9

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Mood alterations with depressive symptoms		1		1
		1		1

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Erection and ejaculation conditions and disorders		1		1
		1		1

System Organ Class

Respiratory, thoracic and mediastinal disorders

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	1	4	1	3		1
Conditions associated with abnormal gas exchange		1				1
Coughing and associated symptoms	1	2	1	2		
Respiratory tract disorders NEC		1		1		
	2	8	2	6		2

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders		1		1		
Dermatitis and eczema		1		1		
Pruritus NEC		1		1		
Rashes, eruptions and exanthems NEC		3		2		1
Urticarias		1				1
		7		5		2

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Non-site specific embolism and thrombosis		2				2
Vascular hypertensive disorders NEC		2		1		1
		4		1		3

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* AE=Adverse Event

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Country Where Event Occurred

UNITED KINGDOM

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Anaemia deficiencies	1	7				3	1	4
Anaemias haemolytic immune	5	9					5	9
Anaemias haemolytic NEC	2	3					2	3
Anaemias NEC	16	40			1	3	15	37
Bleeding tendencies	2	12				4	2	8
Coagulation factor deficiencies	1	2					1	2
Coagulopathies	6	20			2	3	4	17
Eosinophilic disorders	4	5			1	2	3	3
Haematological disorders	3	8					3	8
Haemolyses NEC	4	7					4	7
Leukocytoses NEC	1	6			1	2		4
Leukopenias NEC		6				2		4
Lymphatic system disorders NEC	961	3,823	5	10	358	1314	603	2509
Marrow depression and hypoplastic anaemias	1	5					1	5
Neutropenias	5	30					5	30
Platelet disorders NEC		2						2
Purpuras (excl thrombocytopenic)	1	1					1	1
Red blood cell abnormal findings NEC	1	5			1	1		4
Spleen disorders	3	7					3	7
Thrombocytopenias	75	183					75	183
Thrombocytoses		2				1		1
White blood cell abnormal findings NEC		2						2
	1,092	4,185	5	10	364	1335	728	2850

System Organ Class

Cardiac disorders

Interval Total #	Cumulative Total #	Non Interventional Study		Spontaneous	
		Serious		Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiac conduction disorders	2	11
Cardiac disorders NEC	13	29
Cardiac hypertensive complications		5
Cardiac signs and symptoms NEC	178	880
Cardiac valve disorders NEC		1
Cardiomyopathies	1	5
Coronary artery disorders NEC	2	13
Heart failures NEC	4	34
Ischaemic coronary artery disorders	38	203
Left ventricular failures		2
Mitral valvular disorders	1	3
Myocardial disorders NEC	5	18
Noninfectious myocarditis	7	22
Noninfectious pericarditis	9	24
Pericardial disorders NEC	2	10
Rate and rhythm disorders NEC	109	606
Right ventricular failures		2
Supraventricular arrhythmias	34	207
Tricuspid valvular disorders	1	1
Ventricular arrhythmias and cardiac arrest	18	106
	424	2,182

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	2	10
		2	4	11	25
					5
	1	78	262	100	618
					1
				1	5
				2	13
				4	34
				38	203
					2
				1	3
			2	5	16
				7	22
				9	24
				2	10
	1	29	140	80	466
					2
	1	3	20	31	187
				1	1
		1	2	17	104
	3	113	431	311	1751

System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiac disorders congenital NEC		2
Cardiac septal defects congenital		1
Central nervous system disorders congenital NEC	1	1

Spontaneous	
Serious	
I	C
	2
	1
1	1

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System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cerebral disorders congenital	1	1	1	1
Coagulation disorders congenital		1		1
Congenital disorders NEC		1		1
Connective tissue disorders congenital	1	2	1	2
Gastrointestinal tract disorders congenital NEC		1		1
Great vessel disorders congenital	1	1	1	1
Haematological disorders congenital NEC		1		1
Musculoskeletal disorders congenital NEC		1		1
Neurological disorders congenital NEC	1	3	1	3
Peripheral nervous system disorders congenital NEC		1		1
Pulmonary and bronchial disorders congenital		1		1
Retinal disorders congenital		1		1
Tongue disorders congenital	1	1	1	1
	6	20	6	20

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ear disorders NEC	144	521			55	166	89	355
Eustachian tube disorders	1	4					1	4
External ear disorders NEC	3	13			1	4	2	9
External ear infections and inflammations	1	2			1	1		1
Hearing disorders NEC	1	7				1	1	6
Hearing losses	68	223			9	26	59	197
Hyperacusia	9	39			1	10	8	29
Inner ear disorders NEC		16				2		14
Inner ear infections and inflammations	2	3					2	3
Inner ear signs and symptoms	313	1,104		1	80	228	233	876

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* AE=Adverse Event

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System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Middle ear disorders NEC	2	3			1	1	1	2
Middle ear infections and inflammations		1						1
Tympanic membrane disorders (excl infections)		1						1
	544	1,937		1	148	439	396	1498

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic thyroiditis	3	4	1	2	2	2
Adrenal cortical hypofunctions	1	10			1	10
Adrenal gland disorders NEC	1	1			1	1
Endocrine abnormalities of puberty		1		1		
Female gonadal function disorders	3	4	2	2	1	2
Hyperparathyroid disorders	1	1			1	1
Thyroid disorders NEC	2	9		2	2	7
Thyroid hyperfunction disorders	2	11			2	11
Thyroid hypofunction disorders	1	11			1	11
	14	52	3	7	11	45

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Amblyopic vision impairment		2				1		1
Cataract conditions	3	4					3	4
Choroid and vitreous haemorrhages and vascular disorders	2	7					2	7

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Choroid and vitreous structural change, deposit and degeneration	22	49
Colour blindness (incl acquired)	1	2
Conjunctival and corneal bleeding and vascular disorders	4	22
Conjunctival infections, irritations and inflammations		4
Corneal disorders NEC		1
Corneal infections, oedemas and inflammations		8
Corneal structural change, deposit and degeneration		1
Eyelid movement disorders	17	53
Glaucomas (excl congenital)	2	7
Iris and ciliary body structural change, deposit and degeneration	1	2
Iris and uveal tract infections, irritations and inflammations	4	24
Lacrimation disorders	30	142
Lid bleeding and vascular disorders		1
Lid, lash and lacrimal infections, irritations and inflammations	25	106
Lid, lash and lacrimal structural disorders	4	7
Ocular bleeding and vascular disorders NEC	12	25
Ocular disorders NEC	233	901
Ocular infections, inflammations and associated manifestations	79	322
Ocular nerve and muscle disorders	6	25
Ocular sensation disorders	66	323
Optic disc abnormalities NEC	3	5
Optic nerve bleeding and vascular disorders	2	3
Orbital infections, inflammations and irritations		1
Orbital structural change, deposit and degeneration	1	2
Pupil disorders	5	18

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	11	17	38
			1	1	1
				4	22
					4
					1
			3		5
					1
		7	20	10	33
				2	7
		1	1		1
			1	4	23
		16	48	14	94
					1
		5	33	20	73
			1	4	6
		2	2	10	23
	2	92	275	141	626
	2	38	117	41	205
		3	5	3	20
		32	102	34	221
				3	5
				2	3
					1
				1	2
		3	5	2	13

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* AE=Adverse Event

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Retinal bleeding and vascular disorders (excl retinopathy)	13	28					13	28
Retinal, choroid and vitreous infections and inflammations	1	4					1	4
Retinal structural change, deposit and degeneration	2	12					2	12
Retinopathies NEC		3						3
Scleral infections, irritations and inflammations	1	7				1	1	6
Scleral structural change, deposit and degeneration		4				2		2
Structural change, deposit and degeneration of eye NEC		1						1
Visual colour distortions	2	6				2	2	4
Visual disorders NEC	152	591			49	170	103	421
Visual field disorders	4	13			1	3	3	10
Visual impairment and blindness (excl colour blindness)	63	272			15	61	48	211
Visual pathway disorders	1	3					1	3
	761	3,011		4	269	865	492	2146

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal findings abnormal	2	16			1	4	1	12
Abdominal hernias NEC		1						1
Acute and chronic pancreatitis	4	14					4	14
Anal and rectal disorders NEC		2						2
Anal and rectal pains	2	8				3	2	5
Anal and rectal signs and symptoms	5	12			1	5	4	7
Benign oral cavity neoplasms		4				2		2
Colitis (excl infective)	17	69		1	1	2	16	67

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* AE=Adverse Event

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dental and periodontal infections and inflammations		1
Dental disorders NEC	2	6
Dental pain and sensation disorders	24	73
Dental surface disorders	1	1
Diaphragmatic hernias	3	3
Diarrhoea (excl infective)	398	2,120
Diverticula	1	3
Duodenal and small intestinal stenosis and obstruction		2
Duodenal ulcers and perforation		2
Dyspeptic signs and symptoms	30	155
Faecal abnormalities NEC	9	51
Flatulence, bloating and distension	62	241
Gastric and oesophageal haemorrhages	2	8
Gastric ulcers and perforation	1	3
Gastritis (excl infective)	7	27
Gastrointestinal and abdominal pains (excl oral and throat)	365	1,552
Gastrointestinal atonic and hypomotility disorders NEC	38	164
Gastrointestinal disorders NEC	7	41
Gastrointestinal dyskinetic disorders	3	12
Gastrointestinal inflammatory disorders NEC	3	8
Gastrointestinal mucosal dystrophies and secretion disorders	3	9
Gastrointestinal signs and symptoms NEC	130	538
Gastrointestinal spastic and hypermotility disorders	13	74
Gastrointestinal stenosis and obstruction NEC		6
Gastrointestinal vascular malformations	2	4
Gastrointestinal vascular occlusion and infarction	2	10
Gingival disorders, signs and symptoms NEC	15	79

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	4	1	2
		5	19	19	54
				1	1
		1	1	2	2
1	5	201	679	197	1441
			1	1	2
					2
					2
		15	49	15	106
		5	22	4	29
		25	82	37	159
				2	8
				1	3
		3	7	4	20
	4	126	448	239	1104
		12	32	26	132
		2	13	5	28
		2	7	1	5
			1	3	7
		1	2	2	7
1	5	60	184	70	354
		6	16	7	58
					6
				2	4
				2	10
		3	19	12	60

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gingival haemorrhages	5	17
Haemorrhoids and gastrointestinal varices (excl oesophageal)	3	14
Intestinal haemorrhages	16	56
Intestinal ulcers and perforation NEC	3	5
Malabsorption syndromes	3	10
Nausea and vomiting symptoms	1,443	7,961
Non-mechanical ileus		1
Non-site specific gastrointestinal haemorrhages	12	67
Oesophageal stenosis and obstruction		1
Oesophagitis (excl infective)		1
Oral dryness and saliva altered	64	294
Oral soft tissue disorders NEC	13	66
Oral soft tissue haemorrhages	3	17
Oral soft tissue infections		1
Oral soft tissue signs and symptoms	209	1,049
Oral soft tissue swelling and oedema	86	407
Pancreatic disorders NEC		1
Peptic ulcers and perforation	2	4
Peritoneal and retroperitoneal disorders		3
Peritoneal and retroperitoneal f brosis and adhesions		2
Peritoneal and retroperitoneal haemorrhages		2
Rectal inflammations NEC		2
Salivary gland disorders NEC	3	10
Salivary gland enlargements	3	12
Salivary gland infections and inflammations		1
Salivary gland stenosis and obstruction		1
Stomatitis and ulceration	36	196
Tongue disorders	15	65
Tongue signs and symptoms	97	501
	3,167	16,086

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	6	4	11
		2	2	1	12
				16	56
				3	5
			1	3	9
4	29	655	2748	788	5213
					1
			1	12	66
					1
			1		
	1	27	112	37	182
		7	26	6	40
		2	8	1	9
					1
	1	129	519	80	530
	1	42	140	44	267
					1
				2	4
					3
					2
					2
			1		1
		2	3	1	7
		1	4	2	8
					1
					1
1	2	20	73	16	123
		7	25	8	40
	1	38	173	59	328
7	50	1404	5445	1763	10641

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* AE=Adverse Event

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Administration site reactions NEC	2	9			2	4		5
Adverse effect absent	3	8			3	8		
Application and instillation site reactions	2	3					2	3
Asthenic conditions	2,852	14,565	32	130	1242	5009	1610	9556
Body temperature altered	5	42				4	5	38
Breast complications associated with device	1	1					1	1
Complications associated with device NEC		1				1		
Death and sudden death	16	141					16	141
Eye complications associated with device		1						1
Febrile disorders	1,034	6,578	7	30	497	2464	537	4114
Feelings and sensations NEC	1,504	7,978	11	37	702	3032	802	4946
Gait disturbances	86	419		2	23	83	63	336
General signs and symptoms NEC	1,391	5,864	7	20	550	1923	841	3941
Healing abnormal NEC		2						2
Hernias NEC	1	1					1	1
Implant and catheter site reactions	1	2			1	1		1
Inflamations	35	147			13	50	22	97
Injection site reactions	98	213			81	153	17	60
Interactions	9	22			4	7	5	15
Mass conditions NEC	15	48			6	16	9	32
Mucosal findings abnormal	4	7			2	2	2	5
Necrosis NEC	1	1					1	1
Oedema NEC	30	103			7	31	23	72
Pain and discomfort NEC	1,662	7,128	3	22	656	2543	1006	4585
Therapeutic and nontherapeutic responses	93	746	1	3	17	56	76	690
Ulcers NEC	1	6				1	1	5
Vaccination site reactions	1,341	7,352	6	16	819	3796	522	3556
Vascular complications associated with device		1						1
Withdrawal and rebound effects	5	9			1	3	4	6
	10,192	51,398	67	260	4626	19187	5566	32211

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* AE=Adverse Event

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System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bile duct infections and inflammations	1	3			1	3
Cholecystitis and cholelithiasis		3				3
Cholestasis and jaundice	6	14		1	6	13
Gallbladder disorders NEC		1				1
Hepatic and hepatobiliary disorders NEC	1	2			1	2
Hepatic enzymes and function abnormalities		1				1
Hepatic failure and associated disorders	1	2			1	2
Hepatic fibrosis and cirrhosis	1	3			1	3
Hepatic vascular disorders	5	8			5	8
Hepatobiliary signs and symptoms	4	15	1	2	3	13
Hepatocellular damage and hepatitis NEC	4	18			4	18
Obstructive bile duct disorders (excl neoplasms)		1				1
	23	71	1	3	22	68

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic sarcoidosis	2	11			2	11
Allergic conditions NEC	90	393	31	107	59	286
Allergies to foods, food additives, drugs and other chemicals	14	102	2	31	12	71
Anaphylactic and anaphylactoid responses	49	353			49	353
Atopic disorders	15	28	3	8	12	20
Autoimmune disorders NEC	7	22			7	22
Immune and associated conditions NEC	14	46	3	8	11	38
Immunodeficiency disorders NEC	2	5			2	5
Primary immunodeficiency syndromes		1				1
Transplant rejections	4	5			4	5
	197	966	39	154	158	812

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal and gastrointestinal infections	5	39			1	3	4	36
Aspergillus infections		1						1
Bacterial infections NEC	23	170			5	14	18	156
Bone and joint infections		1						1
Borrelial infections		1						1
Breast infections	5	23					5	23
Caliciviral infections		1						1
Campylobacter infections	1	1					1	1
Candida infections	6	37			2	10	4	27
Cardiac infections	2	2					2	2
Central nervous system and spinal infections	5	23					5	23
Clostridia infections		2						2
Coronavirus infections	141	1,179	1	3	49	318	92	861
Coxiella infections	2	9					2	9
Cytomegaloviral infections		1						1
Dental and oral soft tissue infections	8	25			2	7	6	18
Ear infections	20	87			6	19	14	68
Ectoparasitic infestations		1						1
Epstein-Barr viral infections	2	7					2	7
Escherichia infections	1	1					1	1
Eye and eyelid infections	13	50			6	13	7	37
Female reproductive tract infections	1	2					1	2
Fungal infections NEC		3						3
Hepatitis virus infections	1	2					1	2
Hepatobiliary and spleen infections		2						2
Herpes viral infections	477	945		1	203	340	274	605
Infections NEC	33	193			10	47	23	146
Infectious transmissions		1						1
Influenza viral infections	123	653	3	7	50	193	73	460
Klebsiella infections		1						1
Lower respiratory tract and lung infections	28	181				1	28	180

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Male reproductive tract infections		6						6
Mumps viral infections	1	4					1	4
Muscle and soft tissue infections	1	4					1	4
Neisseria infections		1						1
Parainfluenzae viral infections		1						1
Prion-associated disorders		3						3
Retroviral infections	1	1					1	1
Rotaviral infections		1						1
Rubeola viral infections		2						2
Sepsis, bacteraemia, viraemia and fungaemia NEC	5	43					5	43
Skin structures and soft tissue infections	6	35			1	11	5	24
Staphylococcal infections	3	21			2	5	1	16
Streptococcal infections	3	9			1	1	2	8
Treponema infections	1	1					1	1
Trypanosomal infections		2						2
Tuberculous infections	1	2					1	2
Upper respiratory tract infections	115	498		1	47	178	68	320
Urinary tract infections	27	134		1	7	22	20	112
Vascular infections	1	6					1	6
Viral infections NEC	41	195		1	6	23	35	172
	1,103	4,613	4	14	398	1205	705	3408

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal and gastrointestinal injuries NEC	3	12			1	1	2	11
Accidental exposures to product	3	9			3	8		1
Anaesthetic and allied procedural complications	1	4				1	1	3

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Atmospheric pressure injuries	1	1
Bone and joint injuries NEC	2	11
Cardiovascular injuries	3	16
Cerebral injuries NEC	2	8
Chest and respiratory tract injuries NEC	2	8
Conditions caused by cold	6	35
Cranial nerve injuries		1
Exposures associated with pregnancy, delivery and lactation	89	331
Exposures to agents or circumstances NEC		3
Eye and ear procedural complications	1	1
Eye injuries NEC	8	27
Fractures and dislocations NEC	1	3
Gastrointestinal and hepatobiliary procedural complications		5
Heat injuries (excl thermal burns)	4	11
Intentional product misuses		1
Intentional product use issues	1	2
Limb fractures and dislocations	3	23
Medication errors, product use errors and issues NEC	50	537
Muscle, tendon and ligament injuries	19	54
Musculoskeletal procedural complications		1
Nerve injuries NEC	1	20
Neurological and psychiatric procedural complications		5
Non-occupational environmental exposures		1
Non-site specific injuries NEC	52	236
Non-site specific procedural complications	5	34
Occupational exposures	1	4
Off label uses	500	1,447
Overdoses NEC	5	28
Pathways and sources of exposure	3	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	6	1	5
				3	16
			1	2	7
				2	8
		4	25	2	10
					1
5	10	51	224	38	107
			1		2
				1	1
	1	2	7	6	20
				1	3
			1		4
		2	4	2	7
			1		
		1	2		
		1	1	2	22
		45	498	5	39
		6	10	13	44
					1
			6	1	14
			1		4
					1
		13	63	39	173
			5	5	29
		1	4		
2	2	483	1384	17	63
		4	26	1	2
		3	3		

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Peripheral nerve injuries	1	6
Poisoning and toxicity	1	7
Product administration errors and issues	588	1,314
Product confusion errors and issues		1
Product preparation errors and issues	4	17
Product prescribing errors and issues	1	2
Product storage errors and issues in the product use system	7	9
Radiation injuries	2	5
Renal and urinary tract injuries NEC	1	1
Reproductive system and breast injuries	1	1
Reproductive tract and breast procedural complications		2
Site specific injuries NEC	18	83
Skin injuries NEC	110	369
Skull fractures, facial bone fractures and dislocations		2
Spinal fractures and dislocations	3	5
Stoma complications	1	5
Thermal burns	6	26
Thoracic cage fractures and dislocations	1	2
Underdoses NEC	4	16
Vaccination related complications	5	30
	1,520	4,785

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	6
	1			1	7
2	2	569	1265	19	49
			1		
		4	16		1
			1	1	1
		7	9		
		1	2	1	3
				1	1
				1	1
					2
		5	22	13	61
	2	35	132	75	237
					2
				3	5
			1	1	4
		1	6	5	20
				1	2
		3	15	1	1
		1	10	4	20
9	18	1248	3764	272	1021

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Adrenal cortex tests		2
Adrenal medulla tests	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
		1	2		1

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Autoimmunity analyses	3	4
Bacteria identification and serology (excl mycobacteria)		1
Blood counts NEC	1	6
Blood gas and acid base analyses	18	91
Bone marrow and immune tissue imaging procedures		1
Carbohydrate tolerance analyses (incl diabetes)	17	125
Cardiac auscultatory investigations	2	9
Cardiac function diagnostic procedures	1	2
Cell marker analyses	1	2
Central nervous system imaging procedures		2
Chemistry analyses NEC		8
Cholesterol analyses	1	5
Coagulation and bleeding analyses	19	98
Digestive enzymes		1
ECG investigations	2	13
Endocrine analyses and imaging NEC	4	6
Faecal analyses NEC	3	5
Foetal and neonatal diagnostic procedures	2	2
Gastrointestinal and abdominal imaging procedures		1
Haematological analyses NEC		9
Haem metabolism analyses		1
Heart rate and pulse investigations	149	649
Imaging procedures NEC		2
Immunoglobulin analyses	2	6
Immunology analyses NEC	1	3
Immunology skin tests NEC	1	1
Investigations NEC	11	26
Liver function analyses	14	59
Metabolism tests NEC	3	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	2	3
					1
		1	1		5
		1	13	17	78
					1
		1	32	16	93
		1	2	1	7
			1	1	1
			1	1	1
					2
			2		6
				1	5
		1	14	18	84
			1		
		1	3	1	10
		2	2	2	4
		2	2	1	3
		1	1	1	1
					1
			1		8
					1
1	2	45	184	104	465
					2
			2	2	4
			2	1	1
		1	1		
		3	6	8	20
		1	12	13	47
		1	1	2	5

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Microbiology and serology tests NEC		1
Mineral and electrolyte analyses	7	31
Musculoskeletal and soft tissue tests NEC		1
Neurologic diagnostic procedures		4
Ophthalmic function diagnostic procedures	1	5
Physical examination procedures and organ system status	143	687
Pituitary analyses anterior	1	7
Platelet analyses	21	65
Protein analyses NEC	7	37
Psychiatric investigations		1
Red blood cell analyses	4	19
Renal function analyses	2	7
Reproductive hormone analyses		3
Reproductive organ and breast imaging procedures	1	1
Respiratory and pulmonary function diagnostic procedures		9
Respiratory tract and thoracic histopathology procedures		2
Respiratory tract and thoracic imaging procedures		1
Skeletal and cardiac muscle analyses	4	17
Therapeutic drug monitoring analyses		5
Thyroid analyses		8
Tissue enzyme analyses NEC		5
Toxicology laboratory analyses	1	2
Urinalysis NEC	14	40
Urinary tract function analyses NEC	3	14
Vascular tests NEC (incl blood pressure)	61	327
Virus identification and serology	9	77
Vitamin analyses	2	5
Water and electrolyte analyses NEC		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	10	6	21
					1
					4
			1	1	4
1	3	65	272	78	415
			5	1	2
		7	15	14	50
		1	7	6	30
					1
			4	4	15
			2	2	5
			2		1
				1	1
					9
					2
			1		
			1	4	16
					5
			2		6
			1		4
			1	1	1
		3	9	11	31
		1	5	2	9
		17	115	44	212
		2	26	7	51
		1	2	1	3
			1		

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
White blood cell analyses	12	49			8	18	4	31
	549	2,580	2	5	170	787	379	1793

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Appetite disorders	169	909	1	5	70	284	99	625
Calcium metabolism disorders		4						4
Diabetes mellitus (incl subtypes)	10	54					10	54
Diabetic complications NEC	1	11					1	11
Disorders of purine metabolism	14	42			3	3	11	39
Electrolyte imbalance NEC		2				1		1
Fat soluble vitamin deficiencies and disorders		3						3
Fluid intake decreased		2						2
Fluid intake increased	2	5			1	2	1	3
Food malabsorption and intolerance syndromes (excl sugar intolerance)	4	11				1	4	10
General nutritional disorders NEC	19	89			10	35	9	54
Hyperglycaemic conditions NEC	7	52				7	7	45
Hypoglycaemic conditions NEC	10	49			3	10	7	39
Iron deficiencies		3						3
Lipid metabolism and deposit disorders NEC		1				1		
Metabolic acidoses (excl diabetic acidoses)		5						5
Mixed acid-base disorders		3				1		2
Potassium imbalance		5						5
Sodium imbalance		7						7
Sugar intolerance (excl glucose intolerance)		1				1		
Total fluid volume decreased	21	98			6	29	15	69
Total fluid volume increased	7	19			1	3	6	16

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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vitamin deficiencies NEC		3				1		2
	264	1,378	1	5	94	379	170	999

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Arthropathies NEC	43	166			8	25	35	141
Bone disorders NEC	8	17			2	3	6	14
Bone related signs and symptoms	95	461		3	33	141	62	320
Bursal disorders	7	22			2	3	5	19
Cartilage disorders	5	27			2	4	3	23
Connective tissue disorders NEC	10	41					10	41
Crystal arthropathic disorders		2						2
Epiphyseal disorders		1						1
Extremity deformities	2	6			1	2	1	4
Intervertebral disc disorders NEC		3				1		2
Joint related disorders NEC	28	75		1	5	12	23	63
Joint related signs and symptoms	993	4,976	7	31	367	1533	626	3443
Ligament disorders	1	4					1	4
Lupus erythematosus (incl subtypes)	3	15		1			3	15
Metabolic bone disorders	2	3					2	3
Muscle infections and inflammations	6	17			1	4	5	13
Muscle pains	912	5,248	5	33	487	2030	425	3218
Muscle related signs and symptoms NEC	176	742	3	4	69	227	107	515
Muscle tone abnormalities	4	27		1	2	4	2	23
Muscle weakness conditions	99	527	2	2	24	138	75	389
Musculoskeletal and connective tissue conditions NEC	214	957	1	3	84	311	130	646

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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		1				1		
Musculoskeletal and connective tissue infections and inflammations NEC		7				1		6
Musculoskeletal and connective tissue pain and discomfort	2,107	8,980	13	67	965	3471	1142	5509
Myopathies	4	9					4	9
Osteoarthropathies	8	26			2	5	6	21
Psoriatic arthropathies	2	14					2	14
Rheumatoid arthropathies	13	74		1			13	74
Soft tissue disorders NEC	58	215			25	78	33	137
Spine and neck deformities	1	2					1	2
Spondyloarthropathies	6	27					6	27
Synovial disorders	1	12			1	2		10
Tendon disorders	6	34			2	7	4	27
Trunk deformities		1				1		
	4,814	22,739	31	147	2082	8004	2732	14735

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
B-cell lymphomas NEC	1	2			1	2
Bone neoplasms unspecified malignancy	1	3		1	1	2
Breast and nipple neoplasms malignant	8	20			8	20
Cardiovascular neoplasms benign		1		1		
Colorectal neoplasms malignant		1				1
Endocrine neoplasms benign NEC	1	1			1	1
Endocrine neoplasms malignant and unspecified NEC	1	1			1	1
Follicular lymphomas		1				1

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastric neoplasms malignant		1				1
Gastrointestinal neoplasms malignant NEC		1				1
Haematologic neoplasms NEC	1	1			1	1
Hepatic neoplasms malignant	2	2			2	2
Hodgkin's disease NEC	1	1			1	1
Leukaemias acute NEC		1				1
Leukaemias chronic lymphocytic	3	4			3	4
Leukaemias NEC		1				1
Lip and oral cavity neoplasms malignancy unspecified	1	1			1	1
Lymphomas unspecified NEC	2	13			2	13
Metastases to specified sites	1	8			1	8
Metastases to unknown and unspecified sites		1				1
Myelodysplastic syndromes		1				1
Myeloproliferative disorders (excl leukaemias)		1				1
Neoplasms malignant site unspecified NEC	2	8			2	8
Neoplasms unspecified malignancy and site unspecified NEC	6	10	3	4	3	6
Nervous system neoplasms benign NEC	1	1			1	1
Nervous system neoplasms unspecified malignancy NEC		3				3
Neuromas		2				2
Non-Hodgkin's lymphomas NEC		1				1
Pancreatic neoplasms malignant (excl islet cell and carcinoid)		3				3
Plasma cell myelomas		1				1
Plasma cell neoplasms NEC		1				1
Prostatic neoplasms malignant	1	1			1	1
Renal neoplasms malignant		2				2
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC		3				3
Skin neoplasms benign	1	3	1	1		2

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Skin neoplasms malignant and unspecified (excl melanoma)		4				4
Soft tissue neoplasms benign NEC		2		1		1
Soft tissue sarcomas histology unspecified		1				1
Urinary tract neoplasms unspecified malignancy NEC		1				1
Uterine neoplasms benign	4	4			4	4
	38	118	4	8	34	110

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal reflexes	1	10				2	1	8
Abnormal sleep-related events	1	4			1	3		1
Absence seizures		15						15
Acute polyneuropathies	9	37					9	37
Alzheimer's disease (incl subtypes)		1						1
Autonomic nervous system disorders	2	7					2	7
Central nervous system aneurysms and dissections		2						2
Central nervous system haemorrhages and cerebrovascular accidents	75	406					75	406
Central nervous system inflammatory disorders NEC		1						1
Central nervous system vascular disorders NEC	3	8					3	8
Cerebrovascular venous and sinus thrombosis	9	29					9	29
Cervical spinal cord and nerve root disorders		3						3
Choreiform movements		2						2
Coma states	1	7					1	7
Coordination and balance disturbances	97	412	1	2	29	92	68	320

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* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cortical dysfunction NEC	13	51
Cranial nerve disorders NEC		3
Dementia (excl Alzheimer's type)	1	17
Demyelinating disorders NEC	4	11
Disturbances in consciousness NEC	506	2,660
Disturbances in sleep phase rhythm		1
Dyskinesias and movement disorders NEC	66	265
Dystonias		9
Encephalitis NEC	1	2
Encephalopathies NEC		3
Eye movement disorders	2	14
Facial cranial nerve disorders	85	518
Generalised tonic-clonic seizures	5	38
Headaches NEC	2,356	12,103
Hydrocephalic conditions	1	1
Hypoglossal nerve disorders	1	2
Increased intracranial pressure disorders	2	7
Lumbar spinal cord and nerve root disorders	8	29
Memory loss (excl dementia)	30	141
Mental impairment (excl dementia and memory loss)	79	319
Migraine headaches	270	1,205
Mixed cranial nerve disorders		1
Mononeuropathies	7	36
Motor neurone diseases	1	1
Multiple sclerosis acute and progressive	4	44
Muscle tone abnormal	2	12
Myelitis (incl infective)	3	21
Narcolepsy and hypersomnia	34	181
Nervous system cysts and polyps	1	2
Nervous system disorders NEC	3	20
Neurological signs and symptoms NEC	1,008	4,837

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	12	10	39
					3
				1	17
				4	11
2	11	145	607	361	2053
			1		
		25	69	41	196
					9
				1	2
					3
				2	14
	2	4	27	81	491
				5	38
14	61	1164	4565	1192	7538
				1	1
				1	2
				2	7
		3	8	5	21
		10	35	20	106
	2	20	71	59	248
	6	85	286	185	919
					1
		1	9	6	27
				1	1
				4	44
			1	2	11
				3	21
		10	62	24	119
				1	2
		1	8	2	12
4	20	415	1621	593	3216

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neurologic visual problems NEC	1	12
Neuromuscular disorders NEC	7	21
Neuromuscular junction dysfunction	1	8
Olfactory nerve disorders	41	188
Optic nerve disorders NEC	5	15
Paraesthesias and dysaesthesias	681	2,776
Paralysis and paresis (excl cranial nerve)	34	174
Parkinson's disease and parkinsonism	3	21
Partial complex seizures		4
Peripheral neuropathies NEC	17	69
Seizures and seizure disorders NEC	84	413
Sensory abnormalities NEC	307	1,228
Sleep disturbances NEC	2	8
Speech and language abnormalities	33	179
Spinal cord and nerve root disorders NEC	2	8
Structural brain disorders NEC	2	5
Transient cerebrovascular events	19	97
Tremor (excl congenital)	156	865
Trigeminal disorders	10	35
	6,096	29,624

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	12
		1	4	6	17
				1	8
		32	85	9	103
				5	15
	8	324	1079	357	1697
1	2	6	8	28	166
		2	6	1	15
			1		3
		1	4	16	65
		1	8	83	405
	2	163	557	144	671
			2	2	6
	1	8	37	25	142
			1	2	7
				2	5
				19	97
	3	65	253	91	612
		3	10	7	25
22	120	2522	9534	3574	20090

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Abortions not specified as induced or spontaneous	3	4
Abortions spontaneous	13	64
Amniotic fluid and cavity disorders of pregnancy NEC		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	4
2	2			13	64
					1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Foetal complications NEC	1	1
Foetal growth complications	1	1
Foetal position and presentation abnormalities		1
Gestational age and weight conditions		2
Haemorrhagic complications of pregnancy	1	2
Labour onset and length abnormalities		1
Maternal complications of labour NEC		1
Maternal complications of pregnancy NEC	2	12
Normal pregnancy, labour and delivery		4
Postpartum complications NEC	1	1
Pregnancy complicated by maternal disorders	2	3
Still birth and foetal death	2	5
Umbilical cord complications	1	1
Unintended pregnancies	3	4
	30	108

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
			1		
					2
				1	2
					1
					1
		1	1	1	11
			3		1
				1	1
		1	1	1	2
				2	5
				1	1
				3	4
2	2	2	6	28	102

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Device incompatibility issues	1	1
Device issues NEC	1	1
Device malfunction events NEC	3	15
Device physical property and chemical issues	2	4
Product contamination and sterility issues	1	2
Product distribution and storage issues	1	72
Product packaging issues		4
Product physical issues	1	5
Product quality issues NEC	1	4
Product supply and availability issues		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
1	1		
1	3	2	12
2	3		1
1	2		
1	72		
	4		
1	5		
1	2		2
	1		

* I=Interval, C=Cumulative
* AE=Adverse Event

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System Organ Class

Product issues

High Level Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
9	94	2	15

11

109

9

94

2

15

System Organ Class

Psychiatric disorders

High Level Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	4	1	12
					1
					2
2			3	2	9
					2
82		31	161	51	345
					2
7		3	8	4	25
3				3	6
17		4	16	13	64
1			5	1	8
117	1	25	108	92	471
					1
9				9	70
1		1	3		3
23		3	7	20	95
2		1	13	1	12
202	1	81	307	121	567
30	1	13	49	17	78
4			4	4	25
44		13	54	31	111
					1

Abnormal behaviour NEC

3

16

Abnormal food elimination

1

Adjustment disorders

2

Affect alterations NEC

2

12

Amnesic symptoms

2

Anxiety symptoms

82

506

Attention deficit and disruptive behaviour disorders

2

Behaviour and socialisation disturbances

7

33

Bipolar disorders

3

6

Cognitive and attention disorders and disturbances NEC

17

80

Communications disorders

1

13

Confusion and disorientation

117

579

Decreased physical activity levels

1

Deliria

9

70

Delusional symptoms

1

6

Depressive disorders

23

102

Dissociative states

2

25

Disturbances in initiating and maintaining sleep

202

874

Dyssomnias

30

127

Eating disorders NEC

4

29

Emotional and mood disturbances NEC

44

165

Factitious disorders

1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

High Level Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	10	4	20
		2	5	7	14
				26	135
		8	26	11	67
				2	4
			1		
			5	1	7
		20	47	34	139
					5
			5	8	30
				1	5
					1
		1	1		1
		5	19	7	44
		21	77	27	94
			3	2	16
				1	1
				2	2
			2	4	8
		1	2	1	4
			1	1	12
					1
		1	2	1	5
		22	129	36	172
			1	3	9
			1	1	6
		1	3	2	9
		1	3	3	9
				1	3
					1

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Suicidal and self-injurious behaviour	6	30					6	30
Thinking disturbances	13	46			7	15	6	31
Tic disorders		2						2
	837	3,897		3	269	1100	568	2797

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	59	231	19	51	40	180
Bladder disorders NEC	3	10	1	1	2	9
Bladder infections and inflammations		2				2
Genital and urinary tract disorders NEC	1	3	1	1		2
Glomerulonephritis and nephrotic syndrome	4	20			4	20
Myoneurogenic bladder disorders	1	8		3	1	5
Nephritis NEC	2	4			2	4
Renal disorders NEC	2	8			2	8
Renal failure and impairment	14	81			14	81
Renal lithiasis	1	2			1	2
Renal neoplasms		2				2
Renal structural abnormalities and trauma		1				1
Renal vascular and ischaemic conditions	1	2			1	2
Structural and obstructive urethral disorders (excl congenital)		1				1
Ureteric disorders NEC		1				1
Urinary abnormalities	19	74	4	26	15	48
Urinary tract signs and symptoms NEC	33	136	13	42	20	94
	140	586	38	124	102	462

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Benign and malignant breast neoplasms		2
Breast disorders NEC	6	31
Breast infections and inflammations	2	4
Breast signs and symptoms	96	307
Cervix disorders NEC		1
Erection and ejaculation conditions and disorders		17
Lactation disorders	1	9
Menopausal effects NEC	1	6
Menopausal effects on the genitourinary tract	16	23
Menstruation and uterine bleeding NEC	307	398
Menstruation with decreased bleeding	167	235
Menstruation with increased bleeding	224	302
Ovarian and fallopian tube cysts and neoplasms	5	6
Ovarian and fallopian tube disorders NEC	6	7
Pelvic prolapse conditions	1	1
Pelvis and broad ligament disorders NEC	2	10
Penile disorders NEC (excl erection and ejaculation)	2	5
Prostate and seminal vesicles infections and inflammations		2
Prostatic signs, symptoms and disorders NEC		5
Reproductive tract disorders NEC (excl neoplasms)	4	7
Reproductive tract infections and inflammations NEC		1
Reproductive tract signs and symptoms NEC	14	42
Scrotal disorders NEC	1	10
Sexual function and fertility disorders NEC		1
Spermatogenesis and semen disorders		2
Testicular and epididymal disorders NEC	6	22
Uterine disorders NEC	10	19
Uterine neoplasms	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		1
		1	6	5	25
		1	1	1	3
		33	87	63	220
					1
					17
			1	1	8
		1	3		3
				16	23
	2	179	212	128	186
1	1	128	149	39	86
	2	115	140	109	162
		3	4	2	2
		2	2	4	5
				1	1
				2	10
		2	3		2
					2
			3		2
		2	3	2	4
			1		
		1	9	13	33
		1	3		7
					1
					2
		2	9	4	13
		1	2	9	17
				1	1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Uterine tone disorders		1				1		
Vulvovaginal cysts and neoplasms		2						2
Vulvovaginal disorders NEC	56	117			16	29	40	88
Vulvovaginal signs and symptoms	8	20			1	7	7	13
	936	1,616	1	5	489	676	447	940

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Breathing abnormalities	405	1,970		2	113	430	292	1540
Bronchial conditions NEC	4	11				1	4	10
Bronchospasm and obstruction	89	423			23	90	66	333
Conditions associated with abnormal gas exchange	2	25					2	25
Coughing and associated symptoms	188	1,079	2	5	79	363	109	716
Diaphragmatic disorders		1						1
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)		2						2
Laryngeal spasm, oedema and obstruction	2	17				1	2	16
Lower respiratory tract inflammatory and immunologic conditions	4	28				2	4	26
Lower respiratory tract signs and symptoms	14	77			1	13	13	64
Nasal congestion and inflammations	27	125		1	11	44	16	81
Nasal disorders NEC	75	309			35	111	40	198
Neonatal hypoxic conditions	1	2					1	2
Paranasal sinus disorders (excl infections and neoplasms)	11	43			5	12	6	31
Parenchymal lung disorders NEC	4	15			1	2	3	13
Pharyngeal disorders (excl infections and neoplasms)	54	281			19	85	35	196

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pleural infections and inflammations	2	15
Pneumothorax and pleural effusions NEC	4	17
Pulmonary hypertensions		2
Pulmonary oedemas	4	26
Pulmonary thrombotic and embolic conditions	69	239
Respiratory failures (excl neonatal)	1	10
Respiratory signs and symptoms NEC	11	51
Respiratory tract disorders NEC	13	60
Thoracic musculoskeletal disorders		1
Tracheal disorders (excl infections and neoplasms)		2
Upper respiratory tract neoplasms		1
Upper respiratory tract signs and symptoms	465	2,235
Vascular pulmonary disorders NEC		1
	1,449	7,068

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	14
				4	17
					2
				4	26
	1			69	239
				1	10
	1	4	11	7	40
		3	13	10	47
					1
			2		
			1		
3	15	226	818	239	1417
					1
5	25	521	2000	928	5068

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acnes	8	22
Alopecias	22	55
Angioedemas	16	124
Apocrine and eccrine gland disorders	293	1,641
Bullous conditions	74	237
Connective tissue disorders	2	5
Dermal and epidermal conditions NEC	219	874
Dermatitis and eczema	56	261
Dermatitis ascribed to specific agent	1	10
Erythemas	229	983

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	8	4	14
		2	6	20	49
			1	16	123
1	5	110	547	183	1094
	1	27	64	47	173
				2	5
2	5	102	346	117	528
	1	24	84	32	177
		1	4		6
	2	131	501	98	482

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Exfoliative conditions	17	62
Granulomatous and deep cutaneous inflammatory conditions		3
Hyperkeratoses	1	3
Hyperpigmentation disorders	2	4
Hypertrichoses	1	1
Hypopigmentation disorders	1	4
Nail and nail bed conditions (excl infections and infestations)	2	12
Panniculitides	3	9
Papulosquamous conditions	11	26
Photosensitivity and photodermatitis conditions	9	37
Pigmentation changes NEC	3	7
Pilar disorders NEC	6	21
Pruritus NEC	422	1,639
Psoriatic conditions	14	48
Purpura and related conditions	17	71
Rashes, eruptions and exanthems NEC	863	3,098
Rosaceas	5	8
Scaly conditions	2	7
Sebaceous gland disorders	1	2
Skin and subcutaneous conditions NEC	3	15
Skin and subcutaneous tissue ulcerations	7	22
Skin cysts and polyps	1	2
Skin dystrophies		2
Skin haemorrhages	2	12
Skin hyperplasias and hypertrophies		1
Skin hypoplasias and atrophies	1	1
Skin injuries and mechanical dermatoses		2
Skin vasculitides	4	13
Skin vasomotor conditions	1	17
Telangiectasia and related conditions		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	16	12	46
			1		2
				1	3
		1	2	1	2
				1	1
				1	4
		1	4	1	8
			1	3	8
		4	11	7	15
		3	9	6	28
		2	4	1	3
		3	6	3	15
2	3	254	779	168	860
		3	12	11	36
		5	28	12	43
	4	506	1452	357	1646
			1	5	7
		1	4	1	3
		1	1		1
		2	5	1	10
		3	5	4	17
		1	1		1
			1		1
			2	2	10
			1		
				1	1
					2
			2	4	11
		1	5		12
					1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Urticarias	132	606			76	270	56	336
	2,451	9,968	5	21	1273	4184	1178	5784

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Age related issues	6	7	3	3	3	4
Disability issues	67	265	19	76	48	189
Non-occupational and unspecified environmental problems		1				1
Social issues NEC	3	6		1	3	5
Tobacco use		1		1		
	76	280	22	81	54	199

System Organ Class

SOC Not Yet Coded

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
	20	42	20	42
	20	42	20	42

System Organ Class

Surgical and medical procedures

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaesthesia and allied procedures	1	1			1	1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Surgical and medical procedures

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arterial therapeutic procedures (excl aortic)		1				1
Breast therapeutic procedures NEC		1				1
Bronchial and pulmonary therapeutic procedures		1				1
Dental and gingival therapeutic procedures		1				1
Dietary and nutritional therapies		3				3
Gastrointestinal therapeutic procedures NEC	1	3	1	1		2
Gynaecological therapeutic procedures NEC	1	1	1	1		
Immunisations		6		1		5
Limb therapeutic procedures	2	8	1	5	1	3
Nervous system therapeutic procedures NEC		2				2
Prophylactic procedures NEC		1				1
Respiratory tract therapeutic procedures NEC		1				1
Skin and subcutaneous tissue therapeutic procedures NEC		1		1		
Therapeutic procedures NEC	1	5		2	1	3
	6	36	3	11	3	25

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accelerated and malignant hypertension	4	12					4	12
Aneurysms and dissections non-site specific		1						1
Aortic aneurysms and dissections	2	5					2	5
Aortic embolism and thrombosis	1	3					1	3
Aortic necrosis and vascular insufficiency		3						3
Arterial infections and inflammations	1	7					1	7
Blood pressure disorders NEC	8	20			3	5	5	15
Bruising, ecchymosis and purpura		1				1		
Circulatory collapse and shock	9	96					9	96

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Haemorrhages NEC	65	152		2	1	5	64	147
Lymphangiopathies		1						1
Lymphoedemas	17	65	1	2	7	19	10	46
Non-site specific embolism and thrombosis	90	252	2	3	1	1	89	251
Non-site specific necrosis and vascular insufficiency NEC	6	17				1	6	16
Non-site specific vascular disorders NEC	10	38			1	9	9	29
Peripheral embolism and thrombosis	56	185		1	1	10	55	175
Peripheral vascular disorders NEC	153	722		1	72	297	81	425
Peripheral vasoconstriction, necrosis and vascular insufficiency	74	267		1	28	90	46	177
Phlebitis NEC	8	21			1	6	7	15
Site specific vascular disorders NEC	34	154			19	64	15	90
Varicose veins NEC		6				2		4
Vascular hypertensive disorders NEC	71	385		1	17	99	54	286
Vascular hypotensive disorders	37	221			15	60	22	161
Vasculitides NEC	7	39			1	7	6	32
Vena caval embolism and thrombosis		2						2
	653	2,675	3	11	167	676	486	1999

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

UNITED STATES

System Organ Class

Blood and lymphatic system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Anaemia deficiencies		1				1		
Anaemias haemolytic immune	1	3					1	3
Anaemias haemolytic mechanical factor		1						1
Anaemias haemolytic NEC	1	8					1	8
Anaemias NEC	5	17			4	11	1	6
Bleeding tendencies	3	5			1	3	2	2
Coagulopathies	4	20			1	3	3	17
Eosinophilic disorders		2				1		1
Haematological disorders	5	15			3	11	2	4
Haemolyses NEC		1						1
Leukocytoses NEC		8				4		4
Leukopenias NEC		1						1
Lymphatic system disorders NEC	308	1,743		1	278	1627	30	116
Marrow depression and hypoplastic anaemias	1	5					1	5
Neutropenias	3	9					3	9
Platelet disorders NEC		4				2		2
Polycythaemia (excl rubra vera)		1				1		
Red blood cell abnormal findings NEC	1	2			1	1		1
Sickle cell trait and disorders		2						2
Spleen disorders	2	9			1	3	1	6
Thrombocytopenias	19	71					19	71
White blood cell abnormal findings NEC	1	1			1	1		
	354	1,929		1	290	1669	64	260

System Organ Class

Cardiac disorders

Interval Total #	Cumulative Total #	Non Interventional Study		Spontaneous			
		Serious		Nonserious		Serious	

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Aortic valvular disorders		1
Cardiac conduction disorders	3	9
Cardiac disorders NEC	20	86
Cardiac hypertensive complications		1
Cardiac signs and symptoms NEC	134	633
Cardiac valve disorders NEC		6
Cardiomyopathies	1	7
Coronary artery disorders NEC	3	7
Heart failures NEC	4	23
Ischaemic coronary artery disorders	63	214
Mitral valvular disorders	1	4
Myocardial disorders NEC	6	10
Noninfectious myocarditis	26	47
Noninfectious pericarditis	25	46
Pericardial disorders NEC	13	26
Rate and rhythm disorders NEC	65	513
Right ventricular failures		2
Supraventricular arrhythmias	41	200
Tricuspid valvular disorders		1
Ventricular arrhythmias and cardiac arrest	14	91
	419	1,927

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		1	1	2	8
		9	49	11	37
					1
1	1	112	505	22	128
			3		3
				1	7
			1	3	6
				4	23
			2	63	212
				1	4
		4	5	2	5
		1	2	25	45
				25	46
				13	26
	1	19	237	46	276
					2
1	1	5	20	36	180
					1
		2	13	12	78
2	3	153	838	266	1089

System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arterial disorders congenital		1
Cardiac valve disorders congenital	1	1
Cerebral disorders congenital		3
Coagulation disorders congenital		2

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
		1	1
			3
			2

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Congenital, familial and genetic disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Congenital disorders NEC	2	3			2	3
Inborn errors of amino acid metabolism		1		1		
Inborn errors of lipid metabolism		2				2
Inborn errors of porphyrin metabolism		1				1
Musculoskeletal and connective tissue disorders of limbs congenital	1	1			1	1
Neurological disorders congenital NEC	1	3	1	2		1
Non-site specific bone disorders congenital		1				1
Retinal disorders congenital		1				1
Skin and subcutaneous tissue disorders congenital NEC		2		1		1
Tongue disorders congenital		2				2
Venous disorders congenital		1				1
	5	25	1	4	4	21

System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ear disorders NEC	131	491			109	424	22	67
Eustachian tube disorders	2	6			2	5		1
External ear disorders NEC	2	14			2	12		2
Hearing disorders NEC	1	3				2	1	1
Hearing losses	101	330	1	1	25	94	76	236
Hyperacusia	6	32			6	29		3
Inner ear disorders NEC	5	17			3	7	2	10
Inner ear infections and inflammations	1	3				2	1	1
Inner ear signs and symptoms	264	968			210	765	54	203
Mastoid disorders		2				1		1
Middle ear disorders NEC		2				2		

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System Organ Class

Ear and labyrinth disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
	513	1,868	1	1	357	1343	156	525

System Organ Class

Endocrine disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic thyroiditis	4	16	3	8	1	8
Adrenal cortical hypofunctions		4				4
Adrenal gland disorders NEC		3		2		1
Anterior pituitary hypofunction	1	1	1	1		
Endocrine disorders NEC	1	1	1	1		
Hyperparathyroid disorders		1		1		
Thyroid disorders NEC	11	34	7	24	4	10
Thyroid hyperfunction disorders	3	11			3	11
Thyroid hypofunction disorders	2	8			2	8
	22	79	12	37	10	42

System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Cataract conditions	8	15					8	15
Chambers (anterior and posterior) and lens infections and inflammations		1						1
Choroid and vitreous structural change, deposit and degeneration	10	27			5	13	5	14
Colour blindness (incl acquired)		1				1		
Conjunctival and corneal bleeding and vascular disorders		11						11

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Conjunctival infections, irritations and inflammations		6
Corneal disorders NEC		2
Corneal infections, oedemas and inflammations	1	5
Corneal structural change, deposit and degeneration		2
Eyelid movement disorders	6	40
Glaucomas (excl congenital)	2	10
Iris and ciliary body structural change, deposit and degeneration	1	4
Iris and uveal tract infections, irritations and inflammations	1	11
Lacrimation disorders	37	143
Lid bleeding and vascular disorders		2
Lid, lash and lacrimal infections, irritations and inflammations	19	97
Ocular bleeding and vascular disorders NEC	15	54
Ocular disorders NEC	119	636
Ocular infections, inflammations and associated manifestations	61	328
Ocular nerve and muscle disorders	5	30
Ocular sensation disorders	31	149
Optic nerve bleeding and vascular disorders		3
Orbital structural change, deposit and degeneration		1
Pupil disorders	6	19
Refractive and accommodative disorders		3
Retinal bleeding and vascular disorders (excl retinopathy)	5	17
Retinal, choroid and vitreous infections and inflammations		2
Retinal structural change, deposit and degeneration	3	16
Retinopathies NEC		1
Scleral infections, irritations and inflammations	1	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			5		1
					2
			2	1	3
					2
		5	31	1	9
		1	2	1	8
		1	2		2
1	1	1	3		8
		37	132		11
			2		
		14	82	5	15
			2	15	52
		102	539	17	97
		53	287	8	41
		4	14	1	16
		29	139	2	10
					3
					1
		6	17		2
			3		
			1	5	16
					2
		1	1	2	15
					1
			2	1	4

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* AE=Adverse Event

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Scleral structural change, deposit and degeneration		1				1		
Structural change, deposit and degeneration of eye NEC	2	7					2	7
Visual colour distortions	3	7			1	5	2	2
Visual disorders NEC	90	387			74	300	16	87
Visual field disorders	1	14			1	11		3
Visual impairment and blindness (excl colour blindness)	66	261			29	130	37	131
Visual pathway disorders		1						1
	493	2,320	1	1	364	1727	129	593

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal findings abnormal	3	11			2	10	1	1
Abdominal wall conditions NEC		2						2
Acute and chronic pancreatitis	7	26					7	26
Anal and rectal disorders NEC		1				1		
Anal and rectal pains	1	3			1	3		
Anal and rectal signs and symptoms		7				7		
Benign neoplasms gastrointestinal (excl oral cavity)		1				1		
Benign oral cavity neoplasms	1	2			1	2		
Colitis (excl infective)	14	43	3	3	2	10	12	33
Cystic pancreatic disorders		1				1		
Dental and periodontal infections and inflammations	1	3			1	3		
Dental disorders NEC	2	23			2	22		1
Dental pain and sensation disorders	20	109			20	102		7

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dental surface disorders		1
Diaphragmatic hernias	1	3
Diarrhoea (excl infective)	289	1,600
Diverticula		1
Duodenal and small intestinal stenosis and obstruction		3
Dyspeptic signs and symptoms	26	138
Faecal abnormalities NEC	10	58
Flatulence, bloating and distension	34	154
Gastric and oesophageal haemorrhages		3
Gastric ulcers and perforation		2
Gastritis (excl infective)	4	13
Gastrointestinal and abdominal pains (excl oral and throat)	199	905
Gastrointestinal atonic and hypomotility disorders NEC	26	141
Gastrointestinal disorders NEC	22	120
Gastrointestinal dyskinetic disorders	7	31
Gastrointestinal fistulae	1	1
Gastrointestinal inflammatory disorders NEC	2	8
Gastrointestinal mucosal dystrophies and secretion disorders		3
Gastrointestinal signs and symptoms NEC	143	687
Gastrointestinal spastic and hypermotility disorders	7	34
Gastrointestinal stenosis and obstruction NEC	1	5
Gastrointestinal vascular malformations		1
Gastrointestinal vascular occlusion and infarction		2
Gingival disorders, signs and symptoms NEC	12	63
Gingival haemorrhages	1	13
Haemorrhoids and gastrointestinal varices (excl oesophageal)	2	13
Intestinal haemorrhages	5	27

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			2	1	1
	1	259	1450	30	150
					1
					3
		25	132	1	6
		8	48	2	10
		28	140	6	14
					3
					2
		3	11	1	2
		167	784	32	121
		20	125	6	16
		20	107	2	13
		6	29	1	2
				1	1
		1	5	1	3
			1		2
	1	114	577	29	110
		7	30		4
				1	5
					1
					2
		12	56		7
		1	11		2
		2	10		3
1	1	1	3	4	24

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System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Intestinal ulcers and perforation NEC		2
Large intestinal stenosis and obstruction		1
Malabsorption syndromes	2	3
Nausea and vomiting symptoms	948	5,222
Non-site specific gastrointestinal haemorrhages	24	101
Oesophageal disorders NEC	1	3
Oesophageal stenosis and obstruction		1
Oesophageal ulcers and perforation		1
Oesophagitis (excl infective)	3	5
Oral dryness and saliva altered	34	188
Oral soft tissue disorders NEC	17	90
Oral soft tissue haemorrhages	4	14
Oral soft tissue infections		1
Oral soft tissue signs and symptoms	141	843
Oral soft tissue swelling and oedema	75	354
Pancreatic disorders NEC		4
Salivary gland disorders NEC	3	7
Salivary gland enlargements	4	6
Salivary gland stenosis and obstruction		1
Stomatitis and ulceration	27	87
Tongue disorders	15	65
Tongue signs and symptoms	80	416
Tooth missing		1
	2,219	11,678

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					2
					1
			1	2	2
2	5	847	4673	101	549
1	1			24	101
			1	1	2
					1
					1
		2	4	1	1
		31	161	3	27
		12	71	5	19
		4	9		5
			1		
		109	676	32	167
		48	247	27	107
			2		2
		2	5	1	2
		2	4	2	2
					1
		22	77	5	10
		12	53	3	12
	1	57	292	23	124
					1
7	13	1851	9961	368	1717

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Administration site reactions NEC	1	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	12		

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System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Adverse effect absent	11	63
Application and instillation site reactions	2	7
Asthenic conditions	1,846	10,147
Body temperature altered	6	20
Complications associated with device NEC		2
Death and sudden death	22	147
Febrile disorders	1,012	5,604
Feelings and sensations NEC	1,529	8,505
Gait disturbances	140	585
General signs and symptoms NEC	918	4,124
Healing abnormal NEC	1	7
Hernias NEC	2	3
Implant and catheter site reactions	1	2
Inflammations	42	150
Infusion site reactions		1
Injection site reactions	65	749
Interactions	16	81
Mass conditions NEC	29	106
Mucosal findings abnormal	6	17
Necrosis NEC		1
Oedema NEC	13	68
Pain and discomfort NEC	1,348	6,975
Therapeutic and nontherapeutic responses	473	2,358
Trophic disorders	1	1
Ulcers NEC	5	12
Vaccination site reactions	942	6,029
	8,431	45,776

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		11	63		
		2	6		1
	4	1707	9453	139	694
		2	8	4	12
					2
	1			22	147
1	1	929	5201	83	403
1	1	1438	7928	91	577
		89	413	51	172
1	3	734	3480	184	644
		1	6		1
		1	1	1	2
		1	2		
		35	129	7	21
			1		
		64	744	1	5
		14	71	2	10
		26	94	3	12
		5	13	1	4
					1
		10	52	3	16
1	2	1169	6260	179	715
7	12	33	149	440	2209
		1	1		
		3	8	2	4
1	3	896	5775	46	254
12	27	7172	39870	1259	5906

System Organ Class

Hepatobiliary disorders

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Hepatobiliary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bile duct infections and inflammations	2	3	2	3		
Cholecystitis and cholelithiasis	3	10		2	3	8
Cholestasis and jaundice	2	22	1	8	1	14
Gallbladder disorders NEC	1	12	1	6		6
Hepatic and hepatobiliary disorders NEC		8		4		4
Hepatic enzymes and function abnormalities		1				1
Hepatic failure and associated disorders	1	5			1	5
Hepatic fibrosis and cirrhosis		1				1
Hepatic vascular disorders	3	10			3	10
Hepatobiliary signs and symptoms	4	11	2	6	2	5
Hepatocellular damage and hepatitis NEC		15		3		12
Structural and other bile duct disorders		2		1		1
	16	100	6	33	10	67

System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acute and chronic sarcoidosis	1	3					1	3
Allergic conditions NEC	146	559			97	393	49	166
Allergies to foods, food additives, drugs and other chemicals	42	207			23	151	19	56
Amyloidoses		1						1
Anaphylactic and anaphylactoid responses	47	418				1	47	417
Atopic disorders	8	24			8	24		
Autoimmune disorders NEC	8	29					8	29
Immune and associated conditions NEC	20	63			14	44	6	19
Immunodeficiency disorders NEC	4	13	2	2			4	13
Transplant rejections		1						1
Vasculitides	1	1					1	1

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System Organ Class

Immune system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
	277	1,319	2	2	142	613	135	706

System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal and gastrointestinal infections	27	117			1	4	26	113
Bacterial infections NEC	34	119			7	21	27	98
Bone and joint infections	1	5					1	5
Bordetella infections	1	2					1	2
Borrelial infections	3	6					3	6
Breast infections	2	10				2	2	8
Campylobacter infections	1	1					1	1
Candida infections	3	15			3	15		
Cardiac infections		3						3
Central nervous system and spinal infections	7	21			1	1	6	20
Clostridia infections	3	7					3	7
Coccidioides infections	1	3					1	3
Coronavirus infections	727	3,127	8	13	243	891	484	2236
Cytomegaloviral infections	2	2					2	2
Dental and oral soft tissue infections	14	43			13	36	1	7
Ear infections	13	42			12	34	1	8
Ectoparasitic infestations	2	5			1	2	1	3
Epstein-Barr viral infections	5	14			3	10	2	4
Escherichia infections	1	5					1	5
Eye and eyelid infections	4	39			3	35	1	4
Female reproductive tract infections		4				1		3
Filovirus viral infections		1						1
Fungal infections NEC	4	23			4	21		2
Helicobacter infections		1						1

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* AE=Adverse Event

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hepatitis virus infections	2	3
Hepatobiliary and spleen infections		1
Herpes viral infections	334	670
Infections NEC	14	95
Infectious disorders carrier		1
Influenza viral infections	35	162
Lower respiratory tract and lung infections	43	192
Male reproductive tract infections	2	6
Mumps viral infections		1
Pneumocystis infections		1
Pseudomonal infections		1
Retroviral infections		1
Rhinoviral infections		2
Rubella viral infections		1
Rubeola viral infections	3	5
Sepsis, bacteraemia, viraemia and fungaemia NEC	5	30
Serratia infections	1	1
Skin structures and soft tissue infections	5	27
Staphylococcal infections	2	16
Streptobacillus infections	1	2
Streptococcal infections	9	23
Tinea infections	1	4
Treponema infections		1
Tuberculous infections		2
Upper respiratory tract infections	124	597
Urinary tract infections	42	180
Vascular infections		1
Viral infections NEC	21	73
	1,499	5,714

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	3
					1
1	1	280	559	54	111
		7	61	7	34
			1		
		32	151	3	11
1	1	5	30	38	162
			1	2	5
			1		
					1
					1
			1		
			2		
			1		
				3	5
				5	30
				1	1
		1	15	4	12
		1	6	1	10
				1	2
		5	17	4	6
		1	4		
					1
					2
		115	565	9	32
		25	113	17	67
					1
		13	43	8	30
10	15	776	2644	723	3070

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Abdominal and gastrointestinal injuries NEC	10	36
Accidental exposures to product	5	50
Atmospheric pressure injuries		1
Bone and joint injuries NEC	9	34
Cardiovascular injuries	3	10
Cerebral injuries NEC	5	20
Chest and respiratory tract injuries NEC	1	11
Conditions caused by cold	2	11
Cranial nerve injuries	1	1
Ear injuries NEC		1
Exposures associated with pregnancy, delivery and lactation	74	382
Exposures to agents or circumstances NEC	12	106
Eye injuries NEC	3	21
Fractures and dislocations NEC	3	12
Gastrointestinal and hepatobiliary procedural complications	1	3
Heat injuries (excl thermal burns)		2
Intentional product misuses	1	10
Intentional product use issues	1	12
Limb fractures and dislocations	8	43
Medication errors, product use errors and issues NEC	135	1,640
Muscle, tendon and ligament injuries	24	65
Nerve injuries NEC	12	32
Neurological and psychiatric procedural complications	1	2
Non-site specific injuries NEC	94	387
Non-site specific procedural complications		9
Occupational exposures	2	18
Off label uses	156	891
Overdoses NEC	535	799
Pathways and sources of exposure	3	40

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		7	26	3	10
		5	50		
					1
		7	29	2	5
		1	1	2	9
		1	6	4	14
				1	11
		2	10		1
				1	1
			1		
		62	349	12	33
		11	95	1	11
		2	19	1	2
		1	2	2	10
		1	3		
			2		
		1	10		
		1	12		
			3	8	40
		131	1629	4	11
		19	52	5	13
		6	20	6	12
		1	2		
1	1	56	238	38	149
	1		2		7
		2	17		1
		153	883	3	8
		533	795	2	4
		3	40		

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pelvic fractures and dislocations	1	2
Peripheral nerve injuries	1	3
Poisoning and toxicity	1	5
Product administration errors and issues	658	2,770
Product confusion errors and issues		3
Product dispensing errors and issues		1
Product preparation errors and issues	422	782
Product prescribing errors and issues	2	12
Product storage errors and issues in the product use system	89	156
Product transcribing errors and communication issues		1
Radiation injuries	6	14
Site specific injuries NEC	37	151
Skin injuries NEC	86	305
Skull fractures, facial bone fractures and dislocations		4
Spinal cord injuries NEC	1	1
Spinal fractures and dislocations	1	3
Stoma complications	1	4
Thermal burns	8	14
Thoracic cage fractures and dislocations		5
Transplantation complications		1
Underdoses NEC	57	281
Vaccination related complications	1	8
	2,473	9,175

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
				1	3
				1	5
		650	2745	8	25
			3		
			1		
		422	777		5
		2	12		
		89	156		
			1		
		5	12	1	2
2	2	26	111	11	40
		71	260	15	45
					4
				1	1
				1	3
			2	1	2
		3	7	5	7
					5
					1
		56	279	1	2
1	2	1	7		1
4	6	2331	8669	142	506

System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
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Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Adrenal medulla tests		2
Autoimmunity analyses	3	3
Bacteria identification and serology (excl mycobacteria)	3	7
Blood counts NEC	1	11
Blood gas and acid base analyses	21	124
Blood grouping and cross-matching analyses		1
Carbohydrate tolerance analyses (incl diabetes)	34	184
Cardiac auscultatory investigations		1
Cardiac function diagnostic procedures	1	8
Cell marker analyses	2	7
Cerebrospinal fluid tests (excl microbiology)	2	5
Chemistry analyses NEC	4	9
Cholesterol analyses	8	28
Chromosome analyses	1	1
Coagulation and bleeding analyses	8	47
Digestive enzymes		6
ECG investigations	8	29
Endocrine analyses and imaging NEC	2	4
Faecal analyses NEC	2	2
Foetal and neonatal diagnostic procedures		2
Gastrointestinal function diagnostic procedures		2
Gastrointestinal, pancreatic and APUD hormone analyses		1
Haematological analyses NEC	6	16
Haem metabolism analyses		1
Heart rate and pulse investigations	229	1,114
Histopathology procedures NEC		1
Imaging procedures NEC	1	2
Immunoglobulin analyses	3	15
Immunology analyses NEC	3	18
Investigations NEC	3	22

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		1	1	2	2
		2	4	1	3
		1	9		2
		7	62	14	62
			1		
		22	130	12	54
					1
			1	1	7
			3	2	4
				2	5
		2	6	2	3
		7	27	1	1
				1	1
		6	31	2	16
			5		1
		2	13	6	16
		2	3		1
		2	2		
					2
			2		
			1		
		5	10	1	6
			1		
		169	862	60	252
			1		
		1	2		
		2	13	1	2
		2	17	1	1
		3	17		5

* I=Interval, C=Cumulative

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lipoprotein and lipid tests NEC		3
Liver function analyses	21	93
Metabolism tests NEC	1	8
Microbiology and serology tests NEC		1
Mineral and electrolyte analyses	10	76
Musculoskeletal and soft tissue imaging procedures		1
Musculoskeletal and soft tissue tests NEC	1	1
Mycobacteria identification and serology		1
Neurologic diagnostic procedures		3
Ophthalmic function diagnostic procedures	1	9
Ophthalmic histopathology and imaging procedures	1	1
Parathyroid analyses	1	1
Physical examination procedures and organ system status	117	593
Pituitary analyses anterior	4	11
Platelet analyses	21	87
Protein analyses NEC	3	36
Red blood cell analyses	15	59
Renal function analyses	4	34
Reproductive hormone analyses	1	2
Reproductive organ and breast imaging procedures		1
Respiratory and pulmonary function diagnostic procedures	2	4
Respiratory tract and thoracic imaging procedures		1
Skeletal and cardiac muscle analyses	17	57
Thyroid analyses	3	11
Tissue enzyme analyses NEC	2	5
Toxicology laboratory analyses	3	5
Triglyceride analyses	1	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			3		
		8	57	13	36
			4	1	4
			1		
		8	44	2	32
			1		
				1	1
			1		
			2		1
		1	7		2
				1	1
		1	1		
		100	518	17	75
		2	6	2	5
1	1	11	41	10	46
		2	28	1	8
		10	37	5	22
		2	23	2	11
			1	1	1
			1		
		2	4		
					1
		1	10	16	47
		2	10	1	1
		2	5		
		2	3	1	2
		1	6		2

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Urinalysis NEC	20	67			17	56	3	11
Urinary tract function analyses NEC	2	11			2	11		
Vascular tests NEC (incl blood pressure)	95	582			56	357	39	225
Virus identification and serology	35	419			19	171	16	248
Vitamin analyses		13				10		3
Water and electrolyte analyses NEC	1	3				1	1	2
White blood cell analyses	39	154	1	1	23	97	16	57
	766	4,034	2	2	508	2743	258	1291

System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	126	609	115	549	11	60
Calcium metabolism disorders		3				3
Diabetes mellitus (incl subtypes)	7	33			7	33
Diabetic complications NEC		1				1
Disorders of purine metabolism	8	36	4	30	4	6
Electrolyte imbalance NEC	1	4			1	4
Elevated cholesterol	1	1	1	1		
Fat soluble vitamin deficiencies and disorders		5		4		1
Fluid intake decreased		7		4		3
Fluid intake increased		2		2		
Food malabsorption and intolerance syndromes (excl sugar intolerance)	1	2	1	2		
General nutritional disorders NEC	31	106	22	87	9	19
Hyperglycaemic conditions NEC	2	9	1	3	1	6
Hyperlipidaemias NEC		1				1
Hypoglycaemic conditions NEC	3	17	2	10	1	7
Iron deficiencies	2	3	2	3		

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Metabolism and nutrition disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lipid metabolism and deposit disorders NEC		1		1		
Magnesium metabolism disorders		1				1
Metabolic acidoses (excl diabetic acidoses)		4		3		1
Mixed acid-base disorders		1				1
Potassium imbalance	1	7		1	1	6
Sodium imbalance		3		2		1
Sugar intolerance (excl glucose intolerance)	1	1	1	1		
Total fluid volume decreased	37	168	18	94	19	74
Total fluid volume increased	3	18	2	12	1	6
	224	1,043	169	809	55	234

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Arthropathies NEC	40	166			29	143	11	23
Bone disorders NEC	6	27		1	6	23		4
Bone related signs and symptoms	75	364		1	67	324	8	40
Bursal disorders	6	19			6	15		4
Cartilage disorders	4	12			2	7	2	5
Connective tissue disorders NEC	5	22					5	22
Extremity deformities	2	10			2	9		1
Intervertebral disc disorders NEC	1	10				6	1	4
Joint related disorders NEC	9	33			7	24	2	9
Joint related signs and symptoms	561	2,995		1	502	2763	59	232
Ligament disorders	2	5				2	2	3
Lupus erythematosus (incl subtypes)	3	14	1	1			3	14
Metabolic bone disorders	2	5			2	5		
Muscle infections and inflammations	7	13			6	7	1	6
Muscle pains	419	2,590		1	391	2437	28	153

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System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle related signs and symptoms NEC	181	792
Muscle tone abnormalities	5	26
Muscle weakness conditions	76	380
Musculoskeletal and connective tissue conditions NEC	153	646
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity	1	6
Musculoskeletal and connective tissue infections and inflammations NEC		5
Musculoskeletal and connective tissue pain and discomfort	1,471	7,104
Myopathies	6	9
Osteoarthropathies	1	13
Psoriatic arthropathies		6
Rheumatoid arthropathies	10	53
Soft tissue disorders NEC	26	99
Spine and neck deformities	4	7
Spondyloarthropathies	4	8
Synovial disorders	1	3
Tendon disorders	10	39
	3,091	15,481

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		158	682	23	110
		5	19		7
		45	271	31	109
		131	565	22	81
		1	5		1
			2		3
	3	1346	6604	125	500
				6	9
		1	13		
1	1				6
6	7			10	53
		23	89	3	10
		2	5	2	2
		2	2	2	6
		1	3		
		4	31	6	8
8	16	2739	14056	352	1425

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Aural neoplasms malignant and unspecified		1
Bone neoplasms unspecified malignancy		2
Breast and nipple neoplasms malignant	2	5
Cardiovascular neoplasms benign		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	1		1
		2	5
			1

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* AE=Adverse Event
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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiovascular neoplasms malignant and unspecified		1				1
Central nervous system neoplasms malignant NEC		1				1
Colorectal neoplasms malignant		1				1
Endocrine neoplasms benign NEC		1				1
Endometrial neoplasms malignant	1	2			1	2
Leukaemias acute myeloid		4				4
Leukaemias acute NEC		1				1
Leukaemias chronic lymphocytic	1	3			1	3
Leukaemias chronic myeloid		1				1
Leukaemias NEC	1	7			1	7
Lymphomas unspecified NEC	1	5			1	5
Mediastinal neoplasms malignancy unspecified NEC		1				1
Metastases to specified sites		1				1
Mycoses fungoides	1	1			1	1
Neoplasms benign site unspecified NEC		1		1		
Neoplasms malignant site unspecified NEC	5	16			5	16
Neoplasms unspecified malignancy and site unspecified NEC	3	15	2	11	1	4
Nervous system neoplasms unspecified malignancy NEC	1	2			1	2
Non-Hodgkin's lymphomas NEC		2				2
Oncologic complications and emergencies	2	2			2	2
Ovarian neoplasms malignant (excl germ cell)		1				1
Pancreatic neoplasms malignant (excl islet cell and carcinoid)	1	1			1	1
Plasma cell myelomas	2	3			2	3
Plasma cell neoplasms NEC		1		1		
Prostatic neoplasms malignant		5				5
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC	1	5			1	5

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* AE=Adverse Event

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Salivary gland neoplasms unspecified malignancy	1	1			1	1
Skin melanomas (excl ocular)	1	3			1	3
Skin neoplasms benign	1	1	1	1		
Skin neoplasms malignant and unspecified (excl melanoma)	3	7	1	4	2	3
Soft tissue neoplasms benign NEC		2		1		1
Thyroid neoplasms malignant	1	2			1	2
Uterine neoplasms benign	1	1			1	1
	30	110	4	21	26	89

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal reflexes	1	5				2	1	3
Abnormal sleep-related events		2				2		
Acute polyneuropathies	11	38					11	38
Alzheimer's disease (incl subtypes)	1	3					1	3
Auditory nerve disorders		3				1		2
Autonomic nervous system disorders	3	11				4	3	7
Central nervous system aneurysms and dissections		4						4
Central nervous system haemorrhages and cerebrovascular accidents	99	354					99	354
Central nervous system vascular disorders NEC	2	4					2	4
Cerebrovascular venous and sinus thrombosis	2	7					2	7
Cervical spinal cord and nerve root disorders	1	4			1	3		1
Choreiform movements		1						1
Chronic polyneuropathies	1	7				1	1	6
Coma states	3	8					3	8

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* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Coordination and balance disturbances	87	374
Cortical dysfunction NEC	17	61
Cranial nerve disorders NEC		3
Dementia (excl Alzheimer's type)	4	23
Demyelinating disorders NEC	1	5
Disturbances in consciousness NEC	416	1,729
Disturbances in sleep phase rhythm		5
Dyskinesias and movement disorders NEC	82	326
Dystonias	2	10
Encephalitis NEC	2	7
Encephalopathies NEC	1	5
Encephalopathies toxic and metabolic		1
Eye movement disorders	3	14
Facial cranial nerve disorders	108	495
Generalised tonic-clonic seizures	8	17
Headaches NEC	1,533	7,807
Hypoglossal nerve disorders		4
Increased intracranial pressure disorders	9	19
Intellectual disabilities	1	1
Lumbar spinal cord and nerve root disorders	7	34
Memory loss (excl dementia)	54	177
Meningitis NEC		1
Mental impairment (excl dementia and memory loss)	52	215
Migraine headaches	102	485
Mononeuropathies	7	46
Multiple sclerosis acute and progressive	12	29
Muscle tone abnormal		8
Myelitis (incl infective)	5	17
Narcolepsy and hypersomnia	27	153
Nervous system cysts and polyps		1
Nervous system disorders NEC	23	61

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		66	274	21	100
		11	33	6	28
			1		2
				4	23
				1	5
2	2	175	780	241	949
			4		1
		65	264	17	62
			1	2	9
				2	7
				1	5
					1
				3	14
		1	22	107	473
				8	17
		1452	7319	81	488
					4
				9	19
				1	1
		3	23	4	11
		44	141	10	36
					1
		32	118	20	97
		77	412	25	73
		4	33	3	13
				12	29
			6		2
				5	17
		23	137	4	16
					1
		17	43	6	18

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Neurological signs and symptoms NEC	771	3,843	2	3	654	3260	117	583
Neurologic visual problems NEC	3	21					3	21
Neuromuscular disorders NEC	4	17			3	11	1	6
Neuromuscular junction dysfunction		4						4
Olfactory nerve disorders	50	296			42	262	8	34
Optic nerve disorders NEC	1	8					1	8
Paraesthesias and dysaesthesias	638	2,820	1	1	516	2325	122	495
Paralysis and paresis (excl cranial nerve)	42	127	1	1		2	42	125
Parkinson's disease and parkinsonism	5	20			1	9	4	11
Partial complex seizures		1				1		
Peripheral neuropathies NEC	36	135			7	16	29	119
Seizures and seizure disorders NEC	79	227					79	227
Sensory abnormalities NEC	185	1,017			159	908	26	109
Sleep disturbances NEC	1	7			1	7		
Speech and language abnormalities	65	252			39	155	26	97
Spinal cord and nerve root disorders NEC	5	12					5	12
Structural brain disorders NEC	2	13					2	13
Transient cerebrovascular events	11	49					11	49
Tremor (excl congenital)	128	628	1	2	106	507	22	121
Trigeminal disorders	3	24			2	15	1	9
Vagus nerve disorders		3				1		2
Vertigos NEC	1	1			1	1		
	4,717	22,109	7	9	3502	17104	1215	5005

System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortions not specified as induced or spontaneous		2				2

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Pregnancy, puerperium and perinatal conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortions spontaneous	20	50			20	50
Foetal complications NEC		2				2
Foetal growth complications	3	4			3	4
Gestational age and weight conditions	2	8			2	8
Hypertension associated disorders of pregnancy	1	1			1	1
Labour onset and length abnormalities	1	5			1	5
Maternal complications of pregnancy NEC	2	3			2	3
Normal pregnancy, labour and delivery		2		1		1
Postpartum complications NEC		1		1		
Still birth and foetal death	3	7			3	7
	32	85		2	32	83

System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Counterfeit, falsified and substandard products		2		2		
Device issues NEC	1	3		2	1	1
Device malfunction events NEC		2		2		
Device physical property and chemical issues	3	25	3	23		2
Product distribution and storage issues	143	348	143	348		
Product label issues	2	3	2	3		
Product packaging issues	1	7	1	7		
Product physical issues	4	37	4	37		
Product quality issues NEC	4	29	4	28		1
Product supply and availability issues	7	41	7	41		
	165	497	164	493	1	4

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Abnormal behaviour NEC	6	23
Affect alterations NEC	3	6
Anxiety disorders NEC		5
Anxiety symptoms	152	651
Attention deficit and disruptive behaviour disorders	2	2
Behaviour and socialisation disturbances	12	37
Bipolar disorders	1	2
Cognitive and attention disorders and disturbances NEC	3	10
Communications disorders	2	13
Confusion and disorientation	61	313
Decreased physical activity levels		2
Deliria	7	41
Delusional disorders	1	1
Delusional symptoms	1	7
Depressive disorders	18	55
Dissociative states		8
Disturbances in initiating and maintaining sleep	161	710
Dyssomnias	12	66
Eating disorders NEC	24	81
Emotional and mood disturbances NEC	48	152
Fear symptoms and phobic disorders (incl social phobia)	8	53
Fluctuating mood symptoms		4
Hallucinations (excl sleep-related)	23	94
Impulse control disorders		1
Increased physical activity levels	4	60
Learning disorders	2	2
Mental disorders NEC	8	33
Mood alterations with depressive symptoms	17	60
Mood alterations with manic symptoms	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	12	2	11
		3	4		2
			4		1
		141	597	11	54
		2	2		
		10	28	2	9
				1	2
		3	10		
		1	8	1	5
		40	216	21	97
			1		1
			1	7	40
				1	1
		1	4		3
		14	42	4	13
			7		1
		142	639	19	71
		12	65		1
		20	63	4	18
		44	137	4	15
		7	47	1	6
			2		2
		1	1	22	93
			1		
		3	52	1	8
		2	2		
		6	26	2	7
	1	16	56	1	4
		2	4		1

* I=Interval, C=Cumulative

* AE=Adverse Event

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System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mood disorders NEC	2	20
Narcolepsy and associated conditions		1
Obsessive-compulsive disorders and symptoms		1
Panic attacks and disorders	23	87
Parasomnias	18	98
Perception disturbances NEC	19	55
Personality disorders with anxious behaviour (Cluster C)	1	1
Personality disorders with eccentric behaviour (Cluster A)		1
Pervasive developmental disorders NEC		1
Psychiatric elimination disorders	1	2
Psychiatric symptoms NEC	1	5
Psychotic disorder NEC	2	7
Schizophrenia NEC		1
Sexual desire disorders	1	1
Sleep disorders NEC	41	181
Somatic symptom disorders		5
Speech and language usage disturbances	1	3
Speech articulation and rhythm disturbances	8	22
Stereotypies and automatisms	2	4
Stress disorders	1	3
Substance related and addictive disorders		1
Suicidal and self-injurious behaviour	14	29
Thinking disturbances	15	72
Tic disorders	3	7
	731	3,105

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	19		1
			1		
					1
		20	74	3	13
		18	91		7
		3	11	16	44
		1	1		
			1		
					1
		1	2		
		1	5		
		2	4		3
					1
		1	1		
		38	172	3	9
			5		
		1	1		2
		5	11	3	11
		2	3		1
		1	3		
					1
		1	2	13	27
		13	64	2	8
		2	5	1	2
	1	586	2507	145	598

System Organ Class

Renal and urinary disorders

Interval Total # Cumulative Total #

Spontaneous	
Nonserious	Serious

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	37	164	22	124	15	40
Bladder disorders NEC	3	10		6	3	4
Genital and urinary tract disorders NEC		2		2		
Glomerulonephritis and nephrotic syndrome	1	3			1	3
Myoneurogenic bladder disorders		1		1		
Nephritis NEC	2	2			2	2
Nephropathies and tubular disorders NEC	1	7	1	2		5
Renal disorders NEC	5	25	1	13	4	12
Renal failure and impairment	16	57		2	16	55
Renal lithiasis	9	32			9	32
Renal neoplasms	1	3	1	2		1
Renal obstructive disorders		1				1
Renal structural abnormalities and trauma		2				2
Renal vascular and ischaemic conditions		2				2
Ureteric disorders NEC		1				1
Urethral disorders NEC		2		1		1
Urethral infections and inflammations	1	1	1	1		
Urinary abnormalities	15	51	11	40	4	11
Urinary tract signs and symptoms NEC	22	73	11	49	11	24
	113	439	48	243	65	196

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Benign and malignant breast neoplasms		1		1		
Breast disorders NEC	3	23	2	20	1	3
Breast signs and symptoms	45	170	42	161	3	9
Erection and ejaculation conditions and disorders	2	13			2	13

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lactation disorders	1	3	1	3		
Menopausal effects NEC		1		1		
Menopausal effects on the genitourinary tract	13	21			13	21
Menstruation and uterine bleeding NEC	114	204	102	187	12	17
Menstruation with decreased bleeding	21	27	18	23	3	4
Menstruation with increased bleeding	58	97	43	78	15	19
Ovarian and fallopian tube cysts and neoplasms	3	4	2	2	1	2
Ovarian and fallopian tube disorders NEC	2	4	1	2	1	2
Pelvis and broad ligament disorders NEC		3		3		
Penile and scrotal infections and inflammations		1		1		
Penile disorders NEC (excl erection and ejaculation)	5	7	4	5	1	2
Prostate and seminal vesicles infections and inflammations	1	1			1	1
Prostatic signs, symptoms and disorders NEC	1	2	1	2		
Reproductive tract disorders NEC (excl neoplasms)	1	4		2	1	2
Reproductive tract signs and symptoms NEC	4	23	3	20	1	3
Scrotal disorders NEC		6		6		
Sexual function and fertility disorders NEC		2		1		1
Spermatogenesis and semen disorders		1		1		
Testicular and epididymal disorders NEC	9	16	9	14		2
Testicular and epididymal infections and inflammations		1		1		
Uterine disorders NEC	9	14	3	4	6	10
Uterine infections and inflammations (excl cervix)		1				1
Uterine tone disorders		1		1		
Vulvovaginal disorders NEC	19	53	13	37	6	16
Vulvovaginal signs and symptoms	14	24	9	14	5	10
	325	728	253	590	72	138

System Organ Class

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Breathing abnormalities	388	1,857
Bronchial conditions NEC		1
Bronchospasm and obstruction	60	332
Conditions associated with abnormal gas exchange	2	18
Coughing and associated symptoms	232	1,141
Diaphragmatic disorders		3
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	2	6
Laryngeal spasm, oedema and obstruction		19
Lower respiratory tract inflammatory and immunologic conditions	7	17
Lower respiratory tract signs and symptoms	22	73
Mediastinal disorders	1	1
Nasal congestion and inflammations	79	432
Nasal disorders NEC	51	214
Newborn respiratory disorders NEC	1	2
Paranasal sinus disorders (excl infections and neoplasms)	19	128
Parenchymal lung disorders NEC	5	27
Pharyngeal disorders (excl infections and neoplasms)	67	384
Pleural infections and inflammations	4	10
Pneumothorax and pleural effusions NEC	11	25
Pulmonary hypertensions		2
Pulmonary oedemas	14	60
Pulmonary thrombotic and embolic conditions	63	187
Respiratory failures (excl neonatal)	1	14
Respiratory signs and symptoms NEC	4	37
Respiratory tract disorders NEC	25	150
Tracheal disorders (excl infections and neoplasms)	1	2
Upper respiratory tract signs and symptoms	475	2,656

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
	2	254	1174	134	683
			1		
	1	46	222	14	110
				2	18
	1	198	983	34	158
			2		1
			1	2	5
			6		13
		3	4	4	13
		20	60	2	13
		1	1		
		76	402	3	30
		46	173	5	41
				1	2
		17	120	2	8
1	1	2	6	3	21
		42	248	25	136
		1	4	3	6
		1	3	10	22
	1				2
		1	3	13	57
				63	187
1	1			1	14
		2	24	2	13
		14	102	11	48
				1	2
	1	407	2234	68	422

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Respiratory, thoracic and mediastinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vascular pulmonary disorders NEC		1
	1,534	7,799

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
2	8	1131	5773	403	2026

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acnes	11	39
Alopecias	10	53
Angioedemas	12	85
Apocrine and eccrine gland disorders	233	1,160
Bullous conditions	49	165
Connective tissue disorders		4
Dermal and epidermal conditions NEC	167	595
Dermatitis and eczema	33	127
Dermatitis ascribed to specific agent		5
Erythemas	171	849
Exfoliative conditions	12	47
Granulomatous and deep cutaneous inflammatory conditions		2
Hyperkeratoses	1	4
Hyperpigmentation disorders	1	4
Hypertrichoses		1
Hypopigmentation disorders	1	4
Nail and nail bed conditions (excl infections and infestations)	1	11
Panniculitides	3	5
Papulosquamous conditions	2	8
Photosensitivity and photodermatitis conditions	8	27
Pigmentation changes NEC		5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		9	36	2	3
		10	46		7
		3	6	9	79
		214	1043	19	117
		29	111	20	54
					4
		147	523	20	72
		28	115	5	12
			4		1
		147	730	24	119
		9	40	3	7
			1		1
		1	3		1
		1	3		1
			1		
		1	4		
		1	10		1
		1	3	2	2
		2	8		
1	1	7	22	1	5
			4		1

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pilar disorders NEC	9	22
Pruritus NEC	341	1,576
Psoriatic conditions	6	23
Purpura and related conditions	11	56
Rashes, eruptions and exanthems NEC	566	2,510
Rosaceas	1	7
Scaly conditions		1
Sebaceous gland disorders		1
Skin and subcutaneous conditions NEC	8	18
Skin and subcutaneous tissue ulcerations	2	8
Skin dystrophies	1	3
Skin haemorrhages	2	14
Skin hyperplasias and hypertrophies	2	3
Skin hypoplasias and atrophies	1	1
Skin vascular conditions NEC		1
Skin vasculitides	3	12
Skin vasomotor conditions	1	8
Telangiectasia and related conditions		1
Urticarias	300	1,007
	1,969	8,472

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		9	21		1
		286	1367	55	209
		6	21		2
		5	35	6	21
		483	2161	83	349
			6	1	1
			1		
			1		
		7	16	1	2
		2	7		1
		1	3		
			9	2	5
		2	3		
		1	1		
			1		
		1	4	2	8
			4	1	4
			1		
		246	807	54	200
1	1	1659	7182	310	1290

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Age related issues		2
Disability issues	93	352
Drug and chemical abuse	1	1
Employment issues		2

Spontaneous			
Nonserious		Serious	
I	C	I	C
	2		
62	275	31	77
		1	1
	2		

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Non-occupational and unspecified environmental problems		1		1		
Social issues NEC		16		15		1
Tobacco use	1	1	1	1		
	95	375	63	296	32	79

System Organ Class

SOC Not Yet Coded

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
	1	5	1	5
	1	5	1	5

System Organ Class

Surgical and medical procedures

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal therapeutic procedures NEC		1		1		
Anaesthesia and allied procedures		1		1		
Contraceptive methods female		1		1		
Dental and gingival therapeutic procedures	1	5	1	5		
Hernia repairs		1				1
Immunisations		7		7		
Joint therapeutic procedures		2				2
Large intestine therapeutic procedures		1		1		
Limb therapeutic procedures	1	1	1	1		
Paranasal therapeutic procedures		1		1		
Renal therapeutic procedures		1		1		

* I=Interval, C=Cumulative
* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Surgical and medical procedures

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory tract therapeutic procedures NEC		2		1		1
Skin lesion excisions		1		1		
Spine and spinal cord therapeutic procedures		1				1
Therapeutic procedures NEC	7	17	7	16		1
Uterine therapeutic procedures		1				1
	9	44	9	37		7

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Accelerated and malignant hypertension		10						10
Aneurysms and dissections non-site specific	2	6					2	6
Aortic infections and inflammations		1						1
Aortic necrosis and vascular insufficiency		1				1		
Arterial infections and inflammations	1	1					1	1
Blood pressure disorders NEC	11	43			8	32	3	11
Circulatory collapse and shock	4	34					4	34
Haemorrhages NEC	38	121				15	38	106
Lymphoedemas	3	18			3	18		
Non-site specific embolism and thrombosis	139	315	1	2			139	315
Non-site specific necrosis and vascular insufficiency NEC	8	17			2	6	6	11
Non-site specific vascular disorders NEC	11	39			11	34		5
Peripheral embolism and thrombosis	46	139			1	10	45	129
Peripheral vascular disorders NEC	91	641			76	535	15	106
Peripheral vasoconstriction, necrosis and vascular insufficiency	25	142			18	120	7	22
Phlebitis NEC	1	7			1	7		
Site specific vascular disorders NEC	17	90			15	68	2	22

* I=Interval, C=Cumulative

* AE=Adverse Event

* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Varicose veins NEC	2	8			2	7		1
Vascular hypertensive disorders NEC	87	408		1	44	229	43	179
Vascular hypotensive disorders	34	136			19	68	15	68
Vasculitides NEC	3	5			2	4	1	1
	523	2,182	1	3	202	1154	321	1028

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

UNITED STATES MINOR OUTLYING ISLANDS

System Organ Class

Gastrointestinal disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea (excl infective)		1		1
Gastrointestinal and abdominal pains (excl oral and throat)		1		1
		2		2

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vaccination site reactions		1		1
		1		1

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product administration errors and issues		1		1
		1		1

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Musculoskeletal and connective tissue pain and discomfort		1		1
		1		1

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Neurological signs and symptoms NEC		1		1
		1		1

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

URUGUAY

System Organ Class

General disorders and administration site conditions

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenic conditions	1	1	1	1
Febrile disorders	1	1	1	1
Inflammations		1		1
Pain and discomfort NEC	1	2	1	2
	3	5	3	5

System Organ Class

Injury, poisoning and procedural complications

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposures associated with pregnancy, delivery and lactation	2	2	2	2
	2	2	2	2

System Organ Class

Musculoskeletal and connective tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Synovial disorders		1		1
		1		1

System Organ Class

Nervous system disorders

Spontaneous

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Nervous system disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headaches NEC	1	1	1	1
Paraesthesias and dysaesthesias	1	1	1	1
	2	2	2	2

System Organ Class

Skin and subcutaneous tissue disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pruritus NEC	1	1	1	1
	1	1	1	1

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Appendix 3 (Referred to in Section 9.2 Overview of Signals)

Tabular Summary of Safety Topics and Signals Evaluated During the Reporting Period

Product name: PF-07302048 (BNT162b2)

Reporting interval: 30 April 2021 – 31 May 2021

Please note the following items that were included in SMSR # 5 (01 April – 29 April 2021) and are therefore not included in the table below:

- On 05 May 2021, Trigeminal Neuralgia was reviewed and determined not to be a validated signal.
- On 06 May 2021, Nephrotic syndrome was reviewed and determined not to be a validated signal.
- On 06 May 2021, the safety signal Seizure was reviewed and determined not to be a risk.

Table 1. Tabular Summary of Safety Topics and Signals Considered During the Reporting Period

Safety Topic or Signal	Date opened	Status	Date closed	Source	Reason	Data reviewed	Result or Action(s)
Signals Determined to be Risks							
None							
Signals Determined not to be Risks							
Appendicitis	18 Sep 20 Re-opened 06 May 2021	Closed	13 May 2021	18 Sep 2020: Clinical Trial Data 06 May 2021: Request from a health authority (Health Canada)	To determine if appendicitis is a risk	Clinical study, post-authorization safety data and O/E analyses	The available data do not support a causal association with the vaccine. The topic will continue to be monitored with routine surveillance.
Dizziness	Reopened 10 May 2021	Closed	09 Jun 2021	Request from a health authority (UK MHRA)	To determine if dizziness is a risk	Clinical study, post-authorization safety data	The available data do not support a causal association with the vaccine at this time.
Safety Topics Determined not to be Validated Signals							

Table 1. Tabular Summary of Safety Topics and Signals Considered During the Reporting Period

Safety Topic or Signal	Date opened	Status	Date closed	Source	Reason	Data reviewed	Result or Action(s)
Menstrual cycle abnormalities	10 May 2021	Closed	19 May 2021	Request from a health authority (Israel MOH)	Request from Israeli Ministry of Health for information that has accumulated about changes in the menstrual cycle associated with vaccination	Clinical study and post-authorization safety data	The available data do not support this topic as a validated signal
Acute Pancreatitis	21 May 2021	Closed	04 Jun 2021	Information in health authority PV report	France ANSM 14 th PV report on AEs reported with the Pfizer-BioNTech Comirnaty vaccine considered this a potential signal	Post-authorization safety database data	The available data do not support this topic as a validated signal
Acute disseminated encephalomyelitis (ADEM)	09 May 2021	Closed	26 May 2021	Epidemiology signal detection and health authority request (PRAC in SMSR #5)	Observed versus expected analysis performed for the April (5 th) 2021 SMSR had an upper level of the 95% CI exceed 1 for at least one of the risk windows in at least one of the risk periods. A request was received in the SMSR #5 Assessment Report to provide an evaluation of reports of ADEM	Post-authorization safety data and review of O/E Analysis (please refer to Appendix 5.1 for details)	The available data do not support this topic as a validated signal
Transverse myelitis	09 May 2021 Re-opened 01 Jun 2021	Closed	26 May 2021 and 07 Jun 2021	Epidemiology signal detection and health authority request (TGA in SMSR #5)	Observed versus expected analysis performed for the April (5 th) 2021 SMSR had an upper level of the 95% CI exceed 1 for at least one of the risk windows in at least one of the risk periods	Post-authorization safety data and review of O/E Analysis (please refer to Appendix 5.1 for details)	The available data do not support this topic as a validated signal

Table 1. Tabular Summary of Safety Topics and Signals Considered During the Reporting Period

Safety Topic or Signal	Date opened	Status	Date closed	Source	Reason	Data reviewed	Result or Action(s)
Guillain-Barre syndrome	26 Feb 2021 Re-opened 21 May 2021	Closed	26 May 2021	Information in health authority PV report and Epidemiology signal detection	France ANSM 14 th PV report on AEs reported with the Pfizer-BioNTech Comirnaty vaccine considered this a potential signal and Observed versus expected analysis performed for the April (5 th) 2021 SMSR had an upper level of the 95% CI exceed 1 for at least one of the risk windows in at least one of the risk periods	Post-authorization safety data and review of O/E Analysis (please refer to Appendix 5.1 for details)	The available data do not support this topic as a validated signal
Abnormal Behavior/ Mental Disorder	13 May 2021	Closed	28 May 2021	Request from a health authority (Japan PMDA)	Request from PMDA to provide literature review and opinion of case review.	Post-authorization safety data and literature review	The available data do not support this topic as a validated signal
Acquired Hemophilia	25 May 2021	Closed	04 Jun 2021	Information in health authority PV report	France ANSM 15 th PV report on AEs reported with the Pfizer-BioNTech Comirnaty vaccine considered this a potential signal	Post-authorization safety database review	The available data do not support this topic as a validated signal
Ongoing Safety Topics/Signals							
Myocarditis and Pericarditis	15 Feb 2021 Re-opened 19 April 2021 Re-opened 24 May 2021	Ongoing	N/A	Ongoing discussions with a health authority (Israel MoH) Request from health authorities	To determine if myocarditis or pericarditis is a risk	Clinical study and post-authorization safety data. Literature and O/E analyses	Data available to Pfizer/BNT does not support a causal association with vaccine, however this signal will remain open while other evaluations are ongoing

Appendix 3.1 (Referred to in Section 9.2 Overview of Signals)

Summary of Safety Topic and Signal Evaluations

Table 1 presents summaries of safety topics and signals for PF-07302048 (BNT162b2) during the current reporting period.

Please note the following items that were included in SMSR # 5 (01 April – 29 April 2021) and are therefore not included in the table below:

- On 05 May 2021, Trigeminal Neuralgia was reviewed and determined not to be a validated signal.
- On 06 May 2021, Nephrotic syndrome was reviewed and determined not to be a validated signal.
- On 06 May 2021, the safety signal Seizure was reviewed and determined not to be a risk.

Table 1. Summary of Safety Topics & Signals Considered During the Reporting Period

Signal/Topic	Summary of Evaluation
Signals determined to be risks	
None	
Signals determined not to be risks	
Appendicitis	A request was received from Health Canada for a cumulative assessment of reports of appendicitis following vaccination with Pfizer/BNT COVID-19 Vaccine and referenced data from the Uppsala Monitoring Center dated April 2021. The data was not provided and was not able to be found by Pfizer. Clinical study data, post-authorization AE reports and O/E analyses were reviewed and the available information did not support a causal association with the vaccine at this time (see Appendix 3.2). This topic will continue to be monitored with routine surveillance.
Dizziness	A request was received from UK (MHRA) to review dizziness and determine if it should be considered an ADR. An evaluation of dizziness reports in the post-authorization setting and clinical study (C4591001) was performed (see Appendix 3.7). Post-authorization reports of dizziness were highest within 24 hours following vaccination and decreased with time from vaccination. There were relatively few cases of dizziness where an inability to drive was reported. The available information supports dizziness associated with the vaccination process (i.e. stress-related response) but not a causal association with the vaccine itself at this time.
Safety topics determined not to be validated signals	
Menstrual cycle abnormalities	A request was received from the Israel Ministry of Health to review information about changes in menstrual cycles reported in association with the vaccine. A review of menstrual terms from the clinical study data and from the post-authorization AE reports was undertaken. The available data did not support a validated signal at this time. This topic will continue to be monitored with routine surveillance.
Acute Pancreatitis	The ANSM 14 th PV report of AEs reported co-incident with Pfizer/BNT COVID-19 vaccinations, noted 15 serious cases of acute pancreatitis as of 29 April 2021 as a potential signal. A review of post-authorization safety reports of acute pancreatitis was undertaken and this topic was determined not to be a validated signal.

Table 1. Summary of Safety Topics & Signals Considered During the Reporting Period

Signal/Topic	Summary of Evaluation
Acute disseminated encephalomyelitis (ADEM)	The epidemiology signal detection O/E analyses had an upper level of the 95% CI that exceeded 1 for at least one of the risk windows in at least one of the risk periods in the previous SMSR. Post-authorization safety data was reviewed as was the numerator and denominator used for the O/E analyses. A smaller denominator was used while the numerator was unchanged (see Appendix 5.1 for details). In the PRAC Assessment Report for SMSR #5, a request was made for an evaluation of ADEM to be provided in the SMSR #6. The post-authorization data review (see Appendix 3.3) and examination of O/E analyses was done and this topic was determined not to be a validated signal.
Transverse myelitis	A request was received from Australia TGA to provide a cumulative overview of TM cases in the next SMSR. In addition, the epidemiology signal detection O/E analyses had an upper level of the 95% CI that exceeded 1 for at least one of the risk windows in at least one of the risk periods in the previous SMSR. Post-authorization safety data was reviewed (see Appendix 3.6) as was the numerator and denominator used for the O/E analyses. A smaller denominator was used while the numerator was unchanged (see Appendix 5.1 for details). This topic was determined not to be a validated signal.
Guillain-Barre syndrome	The ANSM 14th PV report of AEs reported co-incident with Pfizer/BNT COVID-19 vaccinations, noted 2 new cases of Guillain Barré syndrome over the period, bringing the total to 7 cases since the start of vaccination and considered it to be a potential signal. A review of post-authorization safety reports of GBS cases was undertaken (see Appendix 3.8) and this topic was determined not to be a validated signal.
Abnormal behavior/Mental disorder	A request was received from Japan PMDA to provide a summary of literature and evaluation of the safety reports on abnormal behavior or mental disorders reported co-incident with vaccination. Following review of all information, this topic was determined not to be a validated signal.
Acquired Hemophilia	The ANSM 15 th PV report of AEs reported co-incident with Pfizer/BNT COVID-19 vaccinations, noted 3 cases of acquired hemophilia since the start of vaccination and considered is a potential signal. A review of the small number of post-authorization AE reports of acquired hemophilia was undertaken and this topic was determined not to be a validated signal
Ongoing evaluations of safety topics or signals	
Myocarditis and Pericarditis	Due to ongoing discussions with the Israel MoH regarding cases of myocarditis reported in Israel, a re-evaluation of accrued cases of myocarditis and pericarditis was undertaken. The review of clinical study data and post-authorization reports utilized the newly published draft Brighton Collaboration case definition of myocarditis (see Appendix 3.9). The available data did not support a causal association with the vaccine; however, this signal will remain open as additional investigations are ongoing.

APPENDIX 3.2 SAFETY EVALUATION OF APPENDICITIS

1. INTRODUCTION

Appendicitis is an inflammation of the vestigial vermiform appendix that may present with right lower quadrant abdominal pain, anorexia, nausea, vomiting, and low-grade fever.ⁱ Appendicitis is a known worldwide disease. The incidence of appendicitis is approximately 100 per 100,000 patients in North America and it ranged from 105 in Eastern Europe to 151 per 100,000 patients in Western Europe. The incidence of appendicitis is higher in newly industrialized countries in Asia (South Korea: 206), the Middle East (Turkey: 160), and Southern America (Chile: 202).ⁱⁱ Although appendicitis can strike at any age, it is rare in children younger than 2.ⁱⁱⁱ Appendicitis is more common in males as compared to females (male-to-female ratio of 1.4:1). The incidence is highest in the 10-to-19-year-old age group, and in adults it occurs most frequently in the second and third decades of life.^{iv} Appendicitis may have more than one underlying etiology.^v The primary cause of appendicitis is appendiceal obstruction and it can be caused by fecalith, calculi, benign or malignant tumors, foreign body, lymphoid hyperplasia, abdominal trauma, infections and or parasites.^{vi} Appendicitis is the most common abdominal surgical emergency, and most patients will require immediate appendectomy (laparoscopic or open).^{vii} Appendicitis is not a common feature of SARS-CoV-2 virus, but it has been reported in four case reports that suggested a possible association.^{viii}

No articles in the literature have been found that causally establish a link of vaccination to appendicitis. A single article by Gee et al 2011 on monitoring the safety of quadrivalent human papillomavirus vaccine mentioned that although the biologic plausibility of appendicitis following HPV4 is not substantiated, appendicitis was identified as one of the frequently reported serious adverse events following HPV4 during prelicensure trials when compared to the placebo group (0.03% HPV4 (5 cases) vs. 0.01% placebo (1 case)). This statistical signal indicating a potential increased risk of appendicitis following HPV4 vaccination among youth was shown after further investigation that it was not a true association, but rather the result was due to a modification of the electronic medical record system.^{ix}

2. METHODOLOGY

Pfizer's safety database contains cases of adverse events reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious adverse events that have been unblinded reported from clinical studies regardless of causality.

The Pfizer safety database was searched for all BNT162b2 vaccine spontaneous and literature reports and serious clinical trial reports received through 7 May 2021 using the following MedDRA version 24.0 search criteria: PTs: Appendicitis, Appendicitis perforated; Complicated appendicitis.

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an adverse event, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.
- Because many external factors influence whether or not an adverse event is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.
- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.
- An accumulation of adverse event reports does not necessarily indicate that a particular adverse event was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

3. RESULTS

Post-Authorisation Data

A total of 96 cases have been retrieved using the criteria mentioned above. There were 65 females, 28 males, and for 3 cases gender was not reported. Age was reported as ranging from 22 to 85 years (mean: 48.4; N: 89). A total of 70 cases were reported in adults (≥ 18 -<65), 19 cases were reported by elderly (≥ 65), and for 7 cases age was not reported. All cases were reported as serious.

Most cases were reported by US (63.5%), UK (9.4%) and France (6.3%). Medical history was provided in 49 cases. Relevant medical history was provided in 19 cases: 4 cases reported appendicitis in the medical history, 6 cases reported Covid-19 infection, 5 cases reported diabetes, 2 reported Mixed connective tissue disease / Sjogren's syndrome and Cutaneous lupus erythematosus / Sjogren's syndrome, 2 cases reported cancer, 1 case reported Diverticulitis, 1 case reported Hodgkin's disease / Sarcoidosis, 1 case reported diarrhea/gastrointestinal disorder, 2 cases reported general disease/familiar risk factors, and 1 case reported abdominal pain.

Latency from vaccination to appendicitis was provided in 88 reports and ranged from day 0 to day 225:

- Same day of vaccination (6)
- 1-7 day following vaccination (58)
- 8-14 days following vaccination (12)
- >14-28 days following vaccination (8)
- >28 days following vaccination (4)

Outcome was reported as recovered/recovering/recovered with sequel in 77 cases, not recovered at time of reporting in 10 cases, and unknown in 9 cases.

Clinical trial data

Cases of appendicitis (including PTs Appendicitis perforated and Complicated appendicitis) were also searched for in the placebo-controlled period of Study C4591001.

In the Phase 2/3 safety population of Study C4591001 in participants ≥ 16 years of age, from the time of dose 1 to the unblinding date, the number of cases was similar in the two arms. There were 14 cases of appendicitis and 1 case of perforated appendicitis in the BNT162b2 group (15 cases total, N=21,926), and 9 cases of appendicitis, 2 cases of complicated appendicitis, and 1 case of perforated appendicitis in the placebo group (12 cases total, N=21,921). The data-lock date was 13 March 2021.

4. EPIDEMIOLOGY ANALYSIS

The MAH conducted unadjusted observed to expected ratio (O/E) analyses for the 96 reported appendicitis cases. The O/E ratio was below 1 for both the 21-day risk window and no risk window, indicating there was not an increased risk of appendicitis among recipients of the BNT162b2 vaccine.

Table 5. Observed versus Expected (O/E) Analysis of 96 Spontaneously Reported Appendicitis Cases through 07 May 2021

	21-Day Risk Window (11,312,184 PY ^a)	No Risk Window (30,415,757 PY)
O/E ratio (95% CI)	0.009 (0.007, 0.011)	0.003 (0.003, 0.004)
Expected cases ^b	10,916.26	29,351.21

a. PY through 30 April 2021

b. Derived from 96.5 per 100,000 PY background rate

Observed case counts were identified using the PT codes appendicitis, perforated appendicitis, and appendicitis complicated. Expected case counts were derived using a background incidence rate of 96.5 per 100,000 person years.^X Person years of exposure estimates were derived from publicly available information reported by countries where the BNT162b2 vaccine is authorized.^{XI} For periods when more than one vaccine brand was

authorized for use in each country, the doses administered were assumed to be divided equally by the number of brands of vaccines authorized. The estimate of administered doses does not reflect exposure in persons vaccinated in countries that did not publicly report.

O/E ratios were calculated using a 21-day risk window and no risk window. However, the 21-day risk window was not applied to the observed case count; all 96 cases were included in the numerator regardless of the duration between vaccination and event onset date.

Several limitations of the observed to expected comparison must be noted. With respect to observed cases, case ascertainment through the spontaneous reports likely reflect an underreporting due to incomplete reporting or a lag in reporting. Additionally, spontaneous surveillance systems are prone to reporting bias whereby events that have been previously identified as potentially related to the vaccine are more likely to be reported despite not meeting the clinical definition. Conversely, events that have not been previously associated with a vaccine are likely to be underreported.

With respect to the expected case counts, estimates concerning both exposure to vaccine and the background rate have limitations. Our exposure estimate assumes that the number of reported administrations is complete and accurate when in fact not all countries administering vaccine have reported counts of vaccine administration to the data source. Thus, the exposure is underestimated.

The expected count also assumes that the expected incidence rate in the vaccinated population is the same as that in the population used to calculate the background rate. However, it is possible that the delivery of health care, population demographics, and underlying health status of the population used for the background rate estimate differ from those expected in the vaccinated population. To date, the majority of exposure derives from the US.

A final limitation concerns the risk window, the period during which one is expected to be at risk of a given event if there is a causal association between the event and the vaccine. Two periods, 21 days and no risk window, were selected to provide an estimate assuming a more acute onset (21-day window) and a more latent onset (no risk window). The 21-day risk window is particularly conservative as all observed cases are included in the numerator of the O/E ratio regardless of the days since vaccination dose, which will lead to an overestimation of the ratio if observed cases occurred outside of the risk window.

5. CONCLUSION

Appendicitis has been spontaneously reported following vaccination with Pfizer/BNT B162b2 vaccine in the post-authorization setting. However, the totality of the reviewed information does not support a causal association between the vaccine and appendicitis. There is not a clear mechanism to explain why vaccinated individuals may have an increased risk for appendicitis and there is a distinct lack of literature establishing a causal association of any vaccination to the occurrence of appendicitis. There are a relatively low number of reports of appendicitis in the context of the hundreds of millions of doses of vaccine administered in the post-authorization setting, statistical signal detection activities have not

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identified a disproportionate occurrence of reports of appendicitis, and the observed to expected analyses have not identified a higher than expected number of cases of appendicitis.

Additionally, the placebo-controlled clinical trial data did not show a concerning imbalance in number of cases of appendicitis in BNT162b2 recipients compared to placebo-recipients.

This topic will continue to be followed by the MAH. The benefit risk of the vaccine remains favorable.

ⁱ Martin, R. F. (2021, January 19). Acute appendicitis in adults: Clinical manifestations and differential diagnosis. UpToDate. <https://www.uptodate.com/contents/acute-appendicitis-in-adults-clinical-manifestations-and-differential-diagnosis/print#>!

ⁱⁱ Ferris M, Quan S, Kaplan BS, Molodecky N, Ball CG, Chernoff GW, Bhala N, Ghosh S, Dixon E, Ng S, Kaplan GG. The Global Incidence of Appendicitis: A Systematic Review of Population-based Studies. *Ann Surg.* 2017 Aug;266(2):237-241. doi: 10.1097/SLA.0000000000002188. PMID: 28288060.

ⁱⁱⁱ Khatri, minesha. (2019, September 28). Appendicitis: Early Symptoms, Causes, Pain Location, Surgery, Recovery. WebMD. <https://www.webmd.com/digestive-disorders/digestive-diseases-appendicitis>.

^{iv} Martin, R. F. (2021, January 19). Acute appendicitis in adults: Clinical manifestations and differential diagnosis. UpToDate. <https://www.uptodate.com/contents/acute-appendicitis-in-adults-clinical-manifestations-and-differential-diagnosis/print#>!

^v U.S. Department of Health and Human Services. (n.d.). Symptoms & Causes of Appendicitis. National Institute of Diabetes and Digestive and Kidney Diseases. <https://www.niddk.nih.gov/health-information/digestive-diseases/appendicitis/symptoms-causes>.

^{vi} Martin, R. F. (2021, January 19). Acute appendicitis in adults: Clinical manifestations and differential diagnosis. UpToDate. <https://www.uptodate.com/contents/acute-appendicitis-in-adults-clinical-manifestations-and-differential-diagnosis/print#!>

^{vii} smink, douglas. (2021, February 15). UpToDate.
https://www.uptodate.com/contents/management-of-acute-appendicitis-in-adults?search=appendicitis+management&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1.

^{viii} Meyer, J. S., Robinson, G., Moonah, S., Levin, D., McGahren, E., Herring, K., Shirley, D.-A. (2021). Acute appendicitis in four children with SARS-CoV-2 infection. *Journal of Pediatric Surgery Case Reports*, 64, 101734. <https://doi.org/10.1016/j.epsc.2020.101734>

^{ix}Julianne Gee , Allison Naleway, Irene Shui, James Baggs, Ruihua Yin, Rong Li , Martin Kulldorff, Edwin Lewis, Bruce Fireman, Matthew F. Daley, Nicola P. Klein, Eric S. Weintraub Monitoring the safety of quadrivalent human papillomavirus vaccine: Findings from the Vaccine Safety Datalink. *Vaccine* 29 (2011) 8279– 8284

^x Coward S, Kareemi H, Clement F, et al. Incidence of Appendicitis over Time: A Comparative Analysis of an Administrative Healthcare Database and a Pathology-Proven Appendicitis Registry. *PLoS One*. 2016 Nov 7;11(11):e0165161

^{xi} Our World in Data. Coronavirus (COVID-19) Vaccinations. Available from: <https://ourworldindata.org/covid-vaccinations#daily-vaccination-rates>. Accessed May 2021

APPENDIX 3.3 SAFETY EVALUATION OF ACUTE DISSEMINATED ENCEPHALOMYELITIS

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LIST OF ABBREVIATIONS

Abbreviation	Definition
ADEM	acute disseminated encephalomyelitis
CNS	central nervous system
CSF	cerebrospinal fluid
COVID-19	Coronavirus Disease 2019
MedDRA	Medical Dictionary for Regulatory Activities
MMR	measles, mumps, and rubella
MRI	magnetic resonance imaging
SARS	Severe Acute Respiratory Syndrome
SARS-CoV-2	Coronavirus-2; virus causing the disease COVID-19
SMQ	standardized MedDRA query

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1. INTRODUCTION

The topic of encephalomyelitis was reviewed because an observed versus expected analysis performed for the April 2021 Summary Monthly Safety Report had an observed to expected ratio greater than 1 for the cumulative 21-day risk window and for the interval evaluations. The review is to include data from spontaneous reports as well as an observed/expected analysis.

1.1 ACUTE DISSEMINATED ENCEPHALOMYELITIS (ADEM)

Acute disseminated encephalomyelitis (ADEM) is considered a monophasic demyelinating disease of the central nervous system (CNS). ADEM presents most commonly with multifocal neurological deficits along with encephalopathy. Symptoms most commonly include: altered consciousness (lethargy, stupor, coma) and/or altered behavior (irritability or confusion), weakness of the lower and/or upper extremities, ataxia, cranial nerve palsies, seizures, fever, headache and/or vomiting, and meningeal signs. The most common MRI finding is the presence of multiple bilateral T2-enhancing supratentorial white matter lesions. Analysis of the CSF is initially necessary to exclude acute CNS infection, because of the acute therapeutic implications of identifying an infection. CSF usually shows inflammation with pleocytosis and/or elevated protein; however, CSF findings are reported at variable time points within the clinical course of ADEM.¹⁻³

Young and adolescent children are most commonly affected. The estimated incidence in the general population is 0.8 per 100,000 population per year,³ nevertheless, the estimated incidence of ADEM varies according to age. The current reported incidence of ADEM is 0.4/ 100 000/ year (< 20 years of age) or 0.64/ 100,000/ year (< 15 years), and is even greater when considering data for younger ages (0.8/ 100,000/ year [5– 9 years]).² In about 50% to 75% of all cases, the clinical onset of disease is preceded by viral or bacterial infections, mostly non-specific upper respiratory tract infections.³

1.2 ENCEPHALOMYELITIS AND VACCINATION

Acute disseminated encephalomyelitis following a vaccination has also been described. It has been previously reported that approximately 5% of cases of ADEM are preceded by vaccination within 1 month prior to symptom onset, however no causal link has been established between ADEM and vaccination.

Vaccination-associated ADEM has been most frequently observed after measles, mumps and rubella vaccinations.⁴ The incidence of a measles vaccination-associated ADEM is about 10 to 20 per 100 000 vaccinated individuals and thus considerably lower than the incidence of ADEM after a wild-type measles encephalitis (100 per 100 000 infected individuals).³

Typically, there is a latency of 7 to 14 days between a febrile illness and the onset of neurological symptoms. In the case of vaccination-associated ADEM, this latency period has been described to be longer. The Collaborating Center for Reference and Research on Viral Hepatitis of the World Health Organization (Geneva, Switzerland), for instance, has deemed a maximal period of 3 months to diagnose a vaccination-associated ADEM.³ Numerous report of ADEM have been described both after H1N1 infection and H1N1 vaccination.⁵⁻⁷

1.2 ENCEPHALOMYELITIS AND COVID-19

Although the respiratory system complications of Coronavirus Disease 2019 (COVID-19) have been the most frequent and life threatening, there are increasing reports of central and peripheral nervous system involvement. These neurological complications have included encephalopathy, meningo-encephalitis, ischaemic stroke, acute necrotizing encephalopathy, and Guillain-Barré Syndrome. The postulated mechanisms of the various neurological syndromes include, either individually or in combination, direct viral neuronal injury, a secondary hyperinflammation syndrome⁸ para- and post-infectious inflammatory or immune-mediated disorders, or the effects of a severe systemic disorder with the neurological consequences of sepsis, hyperpyrexia, hypoxia, hypercoagulability and critical illness.⁹

A well written review by Garg et al¹⁰ describes the hypoxic/metabolic changes that are produced by intense inflammatory response against the virus which in turn triggers cytokine storm and subsequently acute respiratory distress syndrome. In some cases, in presence of comorbidities, the hypoxic/metabolic changes predispose to development of encephalopathy and multiple organ failure. The presence of anosmia and ageusia can help in differentiation from other encephalopathies. Detection of SARS-CoV-2 has been detected in some cases in the nasopharyngeal swab but in other cases was detected only in the cerebrospinal fluid.¹¹

Encephalopathy is common in older patients, the majority are more than 50 years of age and mostly in subjects that are severely or critically ill. Instead, ADEM is more common in children and adolescent. Most of the time encephalitis secondary to SARS-CoV-2 is preceded by commoner clinical features like, fever, cough, dyspnoea, and headache. In majority, patients are already in the intensive care unit, when encephalopathy develops.^{10,12} Nevertheless, few case reports describing headache and neurological symptoms before hypoxic symptoms have also been described.¹¹ Other cases reported association of diffuse leukoencephalopathy and microhemorrhages.^{13,14}

2. METHODOLOGY

Pfizer's safety database contains cases of adverse events reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious adverse events reported from clinical studies regardless of causality.

The Pfizer safety database was searched for all BNT162b2 vaccine cases received through 18 May 2021 using the MedDRA version 24.0 search criteria: SMQ: Non-infectious encephalitis, narrow.

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an adverse

event, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.

- Because many external factors influence whether or not an adverse event is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.
- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.
- An accumulation of adverse event reports does not necessarily indicate that a particular adverse event was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

Brighton Collaboration Criteria

Cases were adjudicated according to Brighton Collaboration case definition and level of diagnostic certainty for encephalitis as described below.¹⁵

Level 1 of diagnostic certainty: Encephalitis

- a. Demonstration of acute inflammation of central nervous system parenchyma (\pm meninges) by histopathology.

Level 2 of diagnostic certainty: Encephalitis

- a. Encephalopathy (e.g. depressed or altered level of consciousness, lethargy, or personality change lasting >24 h),

AND INCLUDING

- b. ONE OR MORE of the following:

1. Decreased or absent response to environment, as defined by response to loud noise or painful stimuli,
2. Decreased or absent eye contact,
3. Inconsistent or absent response to external stimuli,
4. Decreased arousability,
5. Seizure associated with loss of consciousness

OR

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- c. Focal or multifocal findings referable to the central nervous system, including one or more of the following:
1. Focal cortical signs (including but not limited to: aphasia, alexia, agraphia, cortical blindness),
 2. Cranial nerve abnormality/abnormalities,
 3. Visual field defect/defect(s),
 4. Presence of primitive reflexes (Babinski's sign, glabellar reflex, snout/sucking reflex),
 5. Motor weakness (either diffuse or focal; more often focal)
 6. Sensory abnormalities (either positive or negative; sensory level),
 7. Altered deep tendon reflexes (hypo- or hyperreflexia, reflex asymmetry),
 8. Cerebellar dysfunction, including ataxia, dysmetria, cerebellar nystagmus.

AND (for both possibilities to reach Level 2)

- d. TWO OR MORE of the following indicators of inflammation of the CNS:
1. Fever (temperature $\geq 38^{\circ}\text{C}$),
 2. CSF pleocytosis (>5 WBC/mm³ in children >2 months of age; >15 WBC/mm³ in children <2 months of age),
 3. EEG findings consistent with encephalitis, or
 4. Neuroimaging consistent with encephalitis.

Level 3 of diagnostic certainty: Encephalitis

- a. Encephalopathy (eg, depressed or altered level of consciousness, lethargy, or personality change lasting >24 h),

AND INCLUDING

- b. ONE OR MORE of the following:
1. Decreased or absent response to environment, as defined by response to loud noise or painful stimuli,
 2. Decreased or absent eye contact,
 3. Inconsistent or absent response to external stimuli,

4. Decreased arousability, or
5. Seizure associated with loss of consciousness

OR

- c. Focal or multifocal findings referable to the central nervous system, including one or more of the following:
 1. Focal cortical signs (including but not limited to: aphasia, alexia, agraphia, cortical blindness),
 2. Cranial nerve abnormality/abnormalities,
 3. Visual field defect/defect(s),
 4. Presence of primitive reflexes (Babinski's sign, glabellar reflex, snout/sucking reflex),
 5. Motor weakness (either diffuse or focal; more often focal)
 6. Sensory abnormalities (either positive or negative; sensory level),
 7. Altered deep tendon reflexes (hypo- or hyperreflexia, reflex asymmetry), or
 8. Cerebellar dysfunction, including ataxia, dysmetria, cerebellar nystagmus.

AND (for both possibilities to reach Level 3)

- d. ONE of the following indicators of inflammation of CNS:
 1. Fever (temperature $\geq 38^{\circ}\text{C}$),
 2. CSF pleocytosis ($>5\text{WBC}/\text{mm}^3$ in children >2 months of age; $>15\text{WBC}/\text{mm}^3$ in children <2 months of age),
 3. EEG findings consistent with encephalitis, or
 4. Neuroimaging consistent with encephalitis.

Level 3A of diagnostic certainty

- a. Insufficient information is available to distinguish case between acute encephalitis or ADEM; case unable to be definitively classified.

Additional category for analysis

Level 4

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Reported encephalitis/ADEM with insufficient evidence to meet the case definition.

Level 5

Not a case of encephalitis/ADEM (investigation reveals a negative finding of a necessary criterion or if an exclusion criterion is met such as presence of a clear alternative acute infection or other diagnosis of illness).

3. RESULTS

A total of 78 cases were identified from the database using the search criteria mentioned above through 18 May 2021. Almost all cases (77) were spontaneous reports, only one was from a Pfizer-sponsored interventional study. The majority of the cases, 64 (82.1%), were medically confirmed, and the remaining 14 (17.9%) were non-medically confirmed. The reported age ranged from 18 years to 91 years (mean 54.2 N=74, median 51.5 N=74), with the case distribution by age as shown in Table 1.

Table 1. Case Distribution by Age

	Number of cases	Percentage (%)
18 - 30 years	12	15.4 %
31 - 50 years	24	30.8 %
51 - 64 years	9	11.5 %
65 - 74 years	8	10.3 %
Greater than or equal to 75 years	21	26.9 %
Unknown	4	5.1 %

Of the 78 reports, 48 (61.5%) were reported as females, 29 (37.2%) as males, and in 1 (1.3%) case sex was not reported.

Most of the cases were reported from United States (18, 23.1%), followed by United Kingdom (14, 17.9%) and France and Spain (6 each, 7.7%). The top ten reporting countries are in Table 2.

Table 2. Top 10 Reporting Countries

	Number of cases	Percentage (%)
UNITED STATES	18	23.1 %
UNITED KINGDOM	14	17.9 %
FRANCE	6	7.7 %
SPAIN	6	7.7 %
GERMANY	5	6.4 %
JAPAN	5	6.4 %
SWITZERLAND	4	5.1 %
AUSTRIA	3	3.8 %

FINLAND	2	2.6 %
ISRAEL	2	2.6 %
ITALY	2	2.6 %
MEXICO	2	2.6 %
SWEDEN	2	2.6 %

Case outcome was reported as recovered/recovering/recovered with sequelae in 33 cases (42.3%), not recovered at time of reporting in 28 cases (35.9 %), and outcome was unknown in 11 cases (14.1%) There were also 6 fatal cases (7.7%) (see separate discussion below).

Time to onset was reported in 58 cases and in 12 cases (15.4%) it was reported as the same vaccination day or the day after, in 43 cases (55.1%), time to onset ranged between 2 to 21 days post vaccination, in 3 cases (3.8%) time to onset was reported as 22, 28 and 38 days post vaccination respectively and in 20 cases (25.6%) it was not reported.

In 27 cases (34.6%), the events were reported after the first dose of the vaccination, in 14 cases (17.9%) after the second dose and in 37 cases (47.4%) it was unspecified.

Among the 27 cases reporting the event after the first dose of the vaccination, time to onset was reported as detailed in Table 3.

Table 3. Time to Onset After 1st Vaccination

Days after 1 st vaccination	Number of cases
Same vaccination day	4
1-4 days	8
5-12 days	7
13-21 days	2
>21 days	2
Unspecified	4
Total	27

Among the 14 cases reporting the event after the second dose of the vaccination, time to onset was reported as detailed in Table 4.

Table 4. Time to Onset After 2nd Vaccination

Days after 2 nd vaccination	Number of cases
Same vaccination day	2
1-4 days	6
5-12 days	3
13-21 days	2
38 days	1
Total	14

All cases were assessed according to BC criteria. Two cases were removed. One was a duplicate and the other one did not mention any relevant PT for this analysis in the case narrative. Of note, none of the cases met BC level 1. The remaining 75 cases were assessed as follows:

- 7 cases (9.2%) met level 2;
- 11 cases (14.5%) met level 3;
- 41 cases (55.3%) met level 4 (reported encephalitis/ADEM with insufficient evidence to meet the case definition);
- 16 cases (21%) met level 5 (not a case of encephalitis/ADEM).

Among the 59 cases that met BC level 2, 3 and 4, alternative explanations including previous recent infections/COVID-19 infection, previous auto-immune disease/neurologic co-morbidities, underlying disease and confounding therapy, alternative medical conditions/background medical history that may have predisposed to the occurrence of encephalopathy or encephalomyelitis were reported.

A detailed analysis of alternative explanations is reported below:

- 5 cases reported recent previous viral or bacterial infections (including COVID-19 infection, underlying urinary tract infection)
- 3 cases reported a relevant medical history of previous multiple sclerosis, leukoencephalopathy, meningitis or immune-mediated encephalopathy.
- 3 cases reported a medical history of breast cancer or ovarian cancer.
- 6 cases reported encephalitis or meningoencephalitis due to other causes (meningoencephalitis due to Listeria infection, encephalitis diagnosed as a secondary problem to shingles, encephalopathy secondary to systemic lupus erythematosus, HZ encephalitis and meningoencephalitis with cerebritis and sepsis due to Listeria monocytogenes infection, viral encephalitis).
- 6 cases were reported as encephalitis/ADEM but included information suggestive of alternative diagnosis (cerebritis, cerebral edema as a consequence of an earlier migraine attack, multiple sclerosis, cerebellitis).
- 2 cases reported encephalitis in the context of COVID-19 infection and anaphylaxis with a time to onset reported as the same day of the vaccination.

Of the remaining 34 cases, in 22 case reports, there was insufficient information on event details, which precludes a full assessment (event details, time to onset, medical history, concomitant medication, treatment details, no MRI, EEG or CSF data reported).

For the remaining 12 cases that did not report medical history or recent history of confounding factors, there were:

- 8 cases that were assessed as BC level 3:

- In 5 cases (AER# (b) (6) ; AER# (b) (6) ; AER# (b) (6) ; AER# (b) (6) ; AER# (b) (6)), MRI showed evidence of inflammation in the brain with time to onset that ranged between 2 days up to 38 days in a single case;
 - In 1 case (AER# (b) (6)), symptoms were possibly pre-existing pre vaccination (more than 10 kg loss within 2 months) and worsened after vaccination suggesting a possible alternative explanation. MRI was normal, pleocytosis in cerebrospinal fluid.
 - In 2 cases (AER# (b) (6) ; AER# (b) (6)), MRI was normal but there was CSF pleocytosis and elevated protein.
- 4 cases that were categorized as BC level 2:
- **AER# (b) (6)** : 34-year old female patient with no relevant medical history and no concomitant medications reported. One day after the second dose, the patient experienced headache, malaise and neck to shoulder pain. About 4 days after the vaccination, memory loss, loss of voice, ataxia, involuntary movements of the limbs were reported. Treatment with steroid was started and the patient started to recover from the events. About 12 days after the vaccination, acute disseminated encephalomyelitis was suspected. Magnetic resonance showed diffuse or multiple white matter lesions observed on T2-weighted / diffusion-weighted images or FLAIR images (with or without gadolinium enhancement on T1-weighted images) and diffuse, unclear borders, large (> 1-2 cm) lesions predominantly cerebral white matter. Cerebrospinal fluid test showed no pleocytosis and a normal protein level. The patient was recovering from all events at the time of the reporting.
 - **AER# (b) (6)** : 72-year-old male patient with no medical history and concomitant medications reported. About 11 days after the first dose of the vaccine, he developed symptoms of meningoencephalitis with somnolence, aphasia, agitation, lymphocytic pleocytosis in the cerebrospinal fluid and MRI image consistent with mild encephalopathy with reversible lesion in the splenium (MERS) (corpus callosum with lesions on MRI). Myelin oligodendrocyte glycoprotein (MOG) antibody was also detected. The patient recovered from all events at the time of the reporting.
 - **AER# (b) (6)** : 55-year-old female patient with no medical history reported and no concomitant medications who, about 30 minutes after the second vaccination, developed rotational dizziness, difficulty reading texts, and difficulty finding words. Upon arrival at the emergency room shortly after the onset of symptoms, she became confused. At the clinical examination, only slightly increased patellar reflex left was observed, otherwise neurological status was without remarks. An extensive investigation with CT brain, CT angiography cerebral and carotid arteries, MRI brain, and lumbar puncture showed encephalitis changes on an unspecified date. Other examinations turned out to be normal. The outcome of all events was unknown.

- **AER# (b) (6)**: 50-year-old male patient with no medical history and concomitant medications reported that 5 days after the second dose of the vaccination experienced fever, confusion, limb pain, diarrhea and blister appeared on forehead. The day after he experienced decreased level of consciousness, convulsions and clumsiness of the right hand. Encephalitis was detected based on clinical picture and cerebrospinal fluid sample. The encephalitis was initially reported by the consumer (patient's brother) to have been caused by the herpes virus; however, the physician later reported that the causative agent of encephalitis was not evident in the cerebrospinal fluid sample. The clinical outcome of all the events was recovering at the time of the reporting.

Cases reporting a fatal outcome:

Six cases had a fatal outcome.

Two cases were assessed as BC level 4 and four cases were BC level 5 (patient with multiple sclerosis, patient with a post-stroke epilepsy, two patients with cerebral hemorrhage).

Most cases were reported in elderly frail subjects. In one case (AER# **(b) (6)**, BC level 4) with a fatal outcome, the patient had previously compromised renal function, was taking multiple concomitant medications and reportedly experienced meningoencephalitis with no clear evidence (CSF negative, MRI not performed and EEG not supportive of encephalitis) other than age-related brain deterioration.

In another case (AER# **(b) (6)**, BC level 4) time to onset was not reported and the patient experience meningoencephalitis and listeria infection with no other details reported.

In one case (AER# **(b) (6)**, BC level 5), the patient experienced meningitis and encephalitis as a consequence of cerebral hemorrhage and after 2 months of treatment for seizures. The patient died due consequences related to cerebral hemorrhage.

In the last case (AER# **(b) (6)**, BC level 5), lumbar puncture was negative and brain CT results did not support the diagnosis of meningoencephalitis; rather the case was considered a post stroke epilepsy.

The other two cases referred to adult (non-elderly) subjects. AER# **(b) (6)** (BC level 5) referred to a 35-year-old female patient who experienced a very rare aggressive form of multiple sclerosis and died of it shortly after the diagnosis. AER# **(b) (6)** (BC level 5) referred to a 54-year-old female patient with a medical history of Pilzeus Merzbacher Syndrome who was diagnosed with a sinus vein thrombosis with intracranial stasis hemorrhage and thrombocytopenia a few days after vaccination.

4. OBSERVED VERSUS EXPECTED ANALYSIS OF SPONTANEOUSLY REPORTED EVENTS

The MAH conducted unadjusted observed to expected ratio (O/E) analyses for the 78 reported ADEM cases. The O/E ratio was below 1 for both the 21-day risk window and no

risk window, indicating there was not an increased risk of ADEM among recipients of the BNT162b2 vaccine.

Table 5. Observed versus Expected (O/E) Analysis of 78 Spontaneously Reported Acute Disseminated Encephalomyelitis Cases through 10 May 2021

	21-Day Risk Window (12,398,436 PY ^a)	No Risk Window (34,796,539 PY)
O/E ratio (95% CI)	0.119 (0.094, 0.148)	0.042 (0.033, 0.053)
Expected cases ^b	657	1,844

a. PY through 09 May 2021

b. Derived from 5.3 per 100,000 PY background rate (Willame, 2021)

In this analysis, expected case counts were derived using a background incidence rate of 5.3 per 100,000 person years from the ADVANCE project, which includes ADEM, encephalitis, encephalomyelitis, and encephalopathy, previously used in earlier SMSRs ¹⁶.

In the April 2021 SMSR report, the MAH used a background rate of 0.1 from the ACCESS initiative ¹⁷. The ACCESS background rate is derived from medical records coded as ADEM only. The use of the 5.3 per 100,000 person years background rate is justified to better align with the spontaneously reported case definition, which includes PT codes for acute disseminated encephalomyelitis, encephalitis, encephalopathy, and encephalomyelitis. Person years of exposure estimates were derived from publicly available information reported by countries where the BNT162b2 vaccine is authorized ¹⁸. For periods when more than one vaccine brand was authorized for use in each country, the doses administered were assumed to be divided equally by the number of brands of vaccines authorized. The estimate of administered doses does not reflect exposure in persons vaccinated in countries that did not publicly report.

O/E ratios were calculated using a 21-day risk window and no risk window. However, the 21-day risk window was not applied to the observed case count; all 78 cases were included in the numerator regardless of the duration between vaccination and event onset date.

Several limitations of the observed to expected comparison must be noted. With respect to observed cases, case ascertainment through the spontaneous reports likely reflect an underreporting due to incomplete reporting or a lag in reporting. Additionally, spontaneous surveillance systems are prone to reporting bias whereby events that have been previously identified as potentially related to the vaccine are more likely to be reported despite not meeting the clinical definition. Conversely, events that have not been previously associated with a vaccine are likely to be underreported.

With respect to the expected case counts, estimates concerning both exposure to vaccine and the background rate have limitations. Our exposure estimate assumes that the number of reported administrations is complete and accurate when in fact not all countries administering vaccine have reported counts of vaccine administration to the data source. Thus, the exposure is underestimated.

The expected count also assumes that the expected incidence rate in the vaccinated population is the same as that in the population used to calculate the background rate. However, it is possible that the delivery of health care, population demographics, and underlying health status of the population used for the background rate estimate differ from those expected in the vaccinated population. To date, the United States contributes the most exposure data.

A final limitation concerns the risk window, the period during which one is expected to be at risk of a given event if there is a causal association between the event and the vaccine. Two periods, 21 days and no risk window, were selected to provide an estimate assuming a more acute onset (21-day window) and a more latent onset (no risk window). The 21-day risk window is particularly conservative as all observed cases are included in the numerator of the O/E ratio regardless of the days since vaccination dose, which will lead to an overestimation of the ratio if observed cases occurred outside of the risk window.

5. DISCUSSION

There were 78 reports that met the initial search criteria. Among them, three cases were not considered relevant for the analysis (a duplicate case and a case not reporting a PT suggestive of encephalitis or encephalomyelitis) and 16 cases met BC level 5 signifying that they were not ADEM/encephalitis cases.

Of the remaining 59 reports, none met the BC Level 1, 7 met the BC Level 2, 11 met BC level 3 and 41 were assessed as BC level 4, meaning that they reported encephalitis or ADEM with insufficient evidence to meet the case definition.

In the context of the cases that met BC level 3 (11 cases) or level 2 (7 cases) certainty, there were several reporting significant confounding factors (e.g. 1 case with a medical history of recent confirmed infection, 2 cases with a medical history of cancer, 1 case with a medical history of encephalitis and seizure, 1 case with medical history of epilepsy). Furthermore, in 6 cases, encephalitis was suspected to be either of viral or post-viral origin such as infectious VZV meningoencephalitis or HZ encephalitis or due to underlying encephalitis (reported in the medical history). Only in 4 cases, MRI and CSF showed evidence of brain inflammation but it should be considered that an alternative aetiology of the disease was postulated (HZ encephalitis) in one case and in another one, time to onset was implausible for the clinical manifestation of the disease (30 min after second vaccination). For the remaining two cases, time to onset was reported as 11 days after the first vaccination dose in one case and in the other one, the reporter stated that the possibility of psychotic episode or symptomatic epilepsy could not be ruled out.

6. SUMMARY AND CONCLUSION

Most reported cases (76%) met level 4 and 5 of BC. Most cases meeting BC level 2 or 3 were confounded by preceding infection, implausible time to onset, symptoms pre-existing vaccination or alternative diagnosis available. In many cases, the information reported was not sufficient to fully assess the case. Among the 6 cases reporting a fatal outcome there were 5 cases that met BC level 5 and 2 cases that met BC level 4. Cause of death when specified, was

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reported as multiple sclerosis in one case and as meningoencephalitis and listeria infection in another one.

The upper limit of the 95% confidence interval for the revised observed to expected ratio did not exceed 1.

Overall, given the totality of the available information, this review of the data did not support validation of a signal. Changes in the risk minimization measures or updates to the product information label are not warranted at this time. The benefit risk profile of the vaccine remains favorable. The topic will continue to be closely monitored.

7. REFERENCES

1. Leake JAD, Albani S, Kao AS, et al. Acute Disseminated Encephalomyelitis in Childhood: Epidemiologic, Clinical and Laboratory Features. *The Pediatric Infectious Disease Journal*. 2004;23(8):756-64.
2. Pavone P, Pettoello-Mantovano M, Le Pira A, et al. Acute Disseminated Encephalomyelitis: A Long-Term Prospective Study and Meta-Analysis. *Neuropediatrics*. 2010;41(06):246-55.
3. Menge T, Hemmer B, Nessler S, et al. Acute Disseminated Encephalomyelitis. *Archives of Neurology*. 2005;62(11):1673.
4. Shoamanesh A, Traboulsee A. Acute disseminated encephalomyelitis following influenza vaccination. *Vaccine*. 2011;29(46):8182-85.
5. Denholm JT, Neal A, Yan B, et al. Acute encephalomyelitis syndromes associated with H1N1 09 influenza vaccination. *Neurology*. 2010;75(24):2246-48.
6. Lapphra K, Huh L, Scheifele DW. Adverse neurologic reactions after both doses of pandemic h1n1 influenza vaccine with optic neuritis and demyelination. *The Pediatric Infectious Disease Journal*. 2011;30(1):84-86.
7. Wang J, Duan S, Zhao J, et al. Acute disseminated encephalomyelitis associated with Influenza A H1N1 infection. *Neurological Sciences*. 2011;32(5):907-09.
8. Mehta P, McAuley DF, Brown M, et al. COVID-19: consider cytokine storm syndromes and immunosuppression. *Lancet*. 2020;395(10229):1033-34.
9. Paterson RW, Brown RL, Benjamin L, et al. The emerging spectrum of COVID-19 neurology: clinical, radiological and laboratory findings. *Brain*. 2020;143(10):3104-20.
10. Garg RK, Paliwal VK, Gupta A. Encephalopathy in patients with COVID - 19: A review. *Journal of Medical Virology*. 2020;10.1002/jmv.26207.
11. Moriguchi T, Harii N, Goto J, et al. A first case of meningitis/encephalitis associated with SARS-Coronavirus-2. *Int J Infect Dis*. 2020;94:55-58.
12. Ghannam M, Alshaer Q, Al-Chalabi M, et al. Neurological Involvement of Coronavirus Disease 2019: A Systematic Review. *Research Square*; 2020.
13. Katal S, Balakrishnan S, Gholamrezanezhad A. Neuroimaging and neurologic findings in COVID-19 and other coronavirus infections: A systematic review in 116 patients. *J Neuroradiol*. 2020;10.1016/j.neurad.2020.06.007:S0150-9861(20)30204-2.
14. Radmanesh A, Derman A, Lui YW, et al. COVID-19-associated Diffuse Leukoencephalopathy and Microhemorrhages. *Radiology*. 2020;297(1):E223-E27.

15. Sejvar JJ, Kohl KS, Bilynsky R, et al. Encephalitis, myelitis, and acute disseminated encephalomyelitis (ADEM): Case definitions and guidelines for collection, analysis, and presentation of immunization safety data. *Vaccine*. 2007;25(31):5771-92.
16. Willame C, Dodd C, van der Aa L, et al. Incidence Rates of Autoimmune Diseases in European Healthcare Databases: A Contribution of the ADVANCE Project. *Drug Saf*. 2021;44(3):383-395. DOI: 10.1007/s40264-020-01031-1.
17. ACCESS Background rates of adverse events of special interest (AESIs) for COVID-19 vaccines, AESIs (narrow codes) ARS 2017-2019. Available from: http://www.encepp.eu/phact_links.shtml. Updated 08 March 2021. Accessed 28 April 2021.
18. Our World in Data. Coronavirus (COVID-19) Vaccinations. Available from: <https://ourworldindata.org/covid-vaccinations#daily-vaccination-rates>. Accessed May 2021.

Table 5. Summary of Reported Encephalomyelitis/ADEM Cases

Adverse Event Report Number	Age	Age Unit	Gender	Med History	Events (rank order) (Concat)	Country	Time to onset	Outcome	BC
(b) (6)	Not reported	Not reported	FEMALE	Not reported	Noninfective encephalitis, Paraesthesia, Product dose omission issue	ISRAEL	Not reported	Not reported	4
(b) (6)	38.00	YEARS	FEMALE	Diabetes mellitus / Drug hypersensitivity / Hypertension	Demyelination, Noninfective encephalitis, Seizure, Pyrexia, Vomiting	UNITED STATES	1 day	Resolving	4

Table 5. Summary of Reported Encephalomyelitis/ADEM Cases

Adverse Event Report Number	Age	Age Unit	Gender	Med History	Events (rank order) (Concat)	Country	Time to onset	Outcome	BC
(b) (6)	50.00	YEARS	MALE	Rheumatoid arthritis	Noninfective encephalitis, Cerebrovascular accident, Seizure	UNITED STATES	3 days	Not reported	4
(b) (6)	87.00	YEARS	MALE	Aphasia / Disorientation / Dysarthria / Dyslipidaemia / Incoherent / Myocardial ischaemia / Prostatectomy / Restlessness / Transient ischaemic attack / Type 2 diabetes mellitus	Encephalitis	SPAIN	4 days	Not reported	5
(b) (6)	87.00	YEARS	FEMALE	Angina pectoris / Osteoarthritis	Encephalitis, Hypertension, Headache	FRANCE	12 days	Fatal	4
(b) (6)	80.00	YEARS	MALE	Not reported	Encephalitis, Dementia, Deafness, Gait inability, Aphonia, Urinary incontinence, Dysphagia, Flat affect, Tremor, Asthenia, Fatigue, Decreased interest, Stupor, Temperature regulation disorder, Speech disorder, Confusional state, Somnolence	UNITED STATES	Not reported	Unknown	4

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Table 5. Summary of Reported Encephalomyelitis/ADEM Cases

Adverse Event Report Number	Age	Age Unit	Gender	Med History	Events (rank order) (Concat)	Country	Time to onset	Outcome	BC
(b) (6)	Not reported	Not reported	MALE	Not reported	Encephalitis, Deafness, Dementia, Mobility decreased, Urinary incontinence, Gait disturbance, Speech disorder	UNITED STATES	Not reported	Unknown	4
(b) (6)	28.00	YEARS	FEMALE	Food allergy	Anaphylactic reaction, Encephalitis, Acute disseminated encephalomyelitis, Seizure, Heart rate increased, Tachycardia, Supraventricular tachyarrhythmia, Sinus tachycardia, Pruritus, Tremor, Dyskinesia, Back pain, Headache, Blood pressure decreased, Pyrexia, Arthralgia, Palpitations, Dyspnoea, Tinnitus, Pain in extremity	JAPAN	Same day	Not recovered	4

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Table 5. Summary of Reported Encephalomyelitis/ADEM Cases

Adverse Event Report Number	Age	Age Unit	Gender	Med History	Events (rank order) (Concat)	Country	Time to onset	Outcome	BC
(b) (6)	25.00	YEARS	FEMALE	Not reported	Partial seizures, Febrile convulsion, Encephalitis, Pyrexia, Headache, Asthenia, Chills, Rash, Oedema, Abdominal pain, Oropharyngeal pain, Myalgia, Arthralgia, Oral candidiasis, Rash, Malaise	MEXICO	8 days	Unknown	4
(b) (6)	84.00	YEARS	MALE	Benign prostatic hyperplasia / Rash	Deep vein thrombosis, Acute disseminated encephalomyelitis, Pruritus, Rash	UNITED KINGDOM	Not reported	Not reported	5
(b) (6)	67.00	YEARS	FEMALE	Not reported	Encephalitis, Neck pain, Arthralgia, Nausea, Eye pain, Feeling abnormal, Nodule, Headache, Arthralgia, Breast pain, Nodule	UNITED STATES	1-4 days	Recovering	4
(b) (6)	23.00	YEARS	FEMALE	Not reported	Acute disseminated encephalomyelitis, Pyrexia, Myalgia, Back pain, Arthralgia, Pain in extremity, Rhinorrhoea	JAPAN	7 days	Not recovered	5

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Table 5. Summary of Reported Encephalomyelitis/ADEM Cases

Adverse Event Report Number (b) (6)	Age	Age Unit	Gender	Med History	Events (rank order) (Concat)	Country	Time to onset	Outcome	BC
(b) (6)	35.00	YEARS	MALE	Hypertension	Cerebrovascular accident, Acute disseminated encephalomyelitis, Dysarthria	UNITED STATES	2-3 weeks	Unknown	4
(b) (6)	46.00	YEARS	MALE	Psoriasis	Facial paralysis, Facial pain, Noninfective encephalitis	UNITED STATES	5 days	Not recovered	4
(b) (6)	Not reported	Not reported	MALE	Not reported	Encephalitis, Loss of personal independence in daily activities, Diarrhoea, Malaise	UNITED STATES	Not reported	Not reported	4
(b) (6)	23.00	YEARS	FEMALE	Not reported	Headache, Feeling hot, Incontinence, Hyperhidrosis, Vomiting, Encephalitis	UNITED KINGDOM	Not reported	Unknown	4
(b) (6)	Not reported	Not reported	MALE	Not reported	Encephalitis, Seizure	UNITED STATES	Not reported	Unknown	4
(b) (6)	22.00	YEARS	MALE	Hypertension / Type 1 diabetes mellitus	Syncopal, Loss of consciousness, Arrhythmia, Cardiomyopathy, Diabetes mellitus, Noninfective encephalitis, Delirium, Electrocardiogram QT prolonged, Meningitis noninfective, Torsade de pointes, Abdominal pain upper, Gastrointestinal inflammation, Hypoglycaemia, Hyperglycaemia	UNITED STATES	1 day	Not reported	4

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Table 5. Summary of Reported Encephalomyelitis/ADEM Cases

Adverse Event Report Number	Age	Age Unit	Gender	Med History	Events (rank order) (Concat)	Country	Time to onset	Outcome	BC
(b) (6)	69.00	YEARS	MALE	Not reported	Encephalitis	GERMA NY	1 day	Not recovered	4
(b) (6)	73.00	YEARS	FEMALE	Cerebral thrombosis / Chronic obstructive pulmonary disease / Overweight / Tobacco user / Wheelchair user	Cerebral haemorrhage, Meningitis, Encephalitis, Seizure, Epilepsy	DENMA RK	Not reported	Fatal	5
(b) (6)	33.00	YEARS	FEMALE	Not reported	Acute disseminated encephalomyelitis	AUSTRIA	6 days	Recovered	4
(b) (6)	22.00	YEARS	FEMALE	Not reported	Dizziness, Fatigue, Pain, Encephalitis, Headache, Lethargy, Muscular weakness, Gait disturbance	UNITED KINGDOM	Not reported	Recovering	4
(b) (6)	59.00	YEARS	MALE	Not reported	Epilepsy, Agitation, Encephalitis	SPAIN	22 days (1st dose)	Unknown	4
(b) (6)	51.00	YEARS	MALE	Not reported	Encephalitis	ISRAEL	4 days	Unknown	4
(b) (6)	84.00	YEARS	MALE	Deafness / Diabetic retinopathy / Diverticulum / Hypertension / Open angle glaucoma / Type 2 diabetes mellitus / Vitamin B12 deficiency / Vitamin D deficiency	Myoclonus, Ataxia, Malaise, Head injury, Encephalitis, Thrombocytopenia, Balance disorder, Pyrexia	UNITED KINGDOM	10 days	Recovering	4
(b) (6)	42.00	YEARS	MALE	Not reported	Encephalitis, Personality change, Headache, Fatigue, Memory impairment, Hypertension, Insomnia	UNITED STATES	8 hours	Recovered	4

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Table 5. Summary of Reported Encephalomyelitis/ADEM Cases

Adverse Event Report Number	Age	Age Unit	Gender	Med History	Events (rank order) (Concat)	Country	Time to onset	Outcome	BC
(b) (6)	35.00	YEARS	FEMALE	Depression / Umbilical cord abnormality	Tumefactive multiple sclerosis, Acute disseminated encephalomyelitis, Encephalitis, Illness, Seizure, Hemiplegia, Aphasia, Disorientation, Confusional state, Headache	UNITED KINGDOM	Not reported	Fatal	5
(b) (6)	34.00	YEARS	FEMALE	Asthma	Altered state of consciousness, Acute disseminated encephalomyelitis, Feeling abnormal, Aphonia, Dysstasia, Memory impairment, Dyskinesia, Aphasia, Vaccination site pain, Neck pain, Back pain, Headache, Malaise, Pyrexia, Arthralgia, Pain, Amnesia	JAPAN	4 days	Recovering	2
(b) (6)	61.00	YEARS	FEMALE	Blood pressure abnormal / Chronic kidney disease / Dissociative identity disorder / Drug hypersensitivity / Osteoarthritis / Smear cervix abnormal / Transient ischaemic attack	Noninfective encephalitis, Uterine inflammation, Inflammation	UNITED STATES	Same day	Unknown	5

Table 5. Summary of Reported Encephalomyelitis/ADEM Cases

Adverse Event Report Number	Age	Age Unit	Gender	Med History	Events (rank order) (Concat)	Country	Time to onset	Outcome	BC
(b) (6)	90.00	YEARS	FEMALE	Back pain / Coronary arterial stent insertion / Myocardial ischaemia	Encephalitis	FRANCE	6 days	Recoverin g	4
(b) (6)	25.00	YEARS	FEMALE	Colitis ulcerative	Noninfective encephalitis, Arthralgia, Paraesthesia oral, Nausea, Hypoaesthesia, Paraesthesia, Feeding disorder	BELGIUM	2 days	Recoverin g	3
(b) (6)	39.00	YEARS	MALE	Confusional state / Encephalitis / Seizure / Syphilis	Disorientation, Limbic encephalitis, Confusional state, Viral infection, Oedema, Syphilis, Hyperintensity in brain deep nuclei, HIV infection, Decreased activity, Influenza, Sleep disorder, Seizure, Breast cancer, Status epilepticus, Encephalitis	UNITED KINGDOM	14 days	Recoverin g	2
(b) (6)	76.00	YEARS	FEMALE	Atrial fibrillation / Gout / Hypertension / Osteoarthritis / SARS-CoV-2 test positive / Suspected COVID-19 / Transient ischaemic attack	Encephalitis, Confusional state, Headache	UNITED KINGDOM	2 days	Recoverin g	4

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Table 5. Summary of Reported Encephalomyelitis/ADEM Cases

Adverse Event Report Number	Age	Age Unit	Gender	Med History	Events (rank order) (Concat)	Country	Time to onset	Outcome	BC
(b) (6)	31.00	YEARS	FEMALE	Not reported	Acute disseminated encephalomyelitis, Condition aggravated, Muscular weakness, Muscular weakness, Multiple sclerosis, Sensory disturbance, Monoparesis, Night sweats, Dizziness, Headache, Chills, Neoplasm malignant	AUSTRIA	7 days after 1st dose and worsened after the 2nd dose	Not recovered	5
(b) (6)	32.00	YEARS	FEMALE	COVID-19 / Drug hypersensitivity / Fibrosis / Pulmonary fibrosis	Angioedema, Respiratory distress, Anaphylactic shock, Myelitis transverse, Encephalitis post immunisation, Seizure, Rash, Muscle spasms, Paraesthesia, Paralysis, Loss of consciousness, Cyanosis	MEXICO	4 hours	Unknown	5
(b) (6)	82.00	YEARS	MALE	Weight decreased	Encephalitis autoimmune	GERMANY	4 days	Not recovered	3
(b) (6)	76.00	YEARS	FEMALE	Arterial disorder / Chronic kidney disease / Fall / Ocular sarcoidosis / Pulmonary sarcoidosis	Encephalitis	SWITZERLAND	6 days	Recovering	3

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Table 5. Summary of Reported Encephalomyelitis/ADEM Cases

Adverse Event Report Number	Age	Age Unit	Gender	Med History	Events (rank order) (Concat)	Country	Time to onset	Outcome	BC
(b) (6)	40.00	YEARS	FEMALE	Dizziness	Disturbance in attention, Dizziness, Dysarthria, Lethargy, Feeling abnormal, Feeling drunk, Vaccination site pain, Neck pain, Fatigue, Quality of life decreased, Tension headache, Encephalitis, Impaired work ability, Impaired driving ability	IRELAND	1 hour	Not reported	5
(b) (6)	82.00	YEARS	FEMALE	Not reported	Listeriosis, Encephalitis	GREECE	Not reported	Fatal	4
(b) (6)	83.00	YEARS	FEMALE	Aortic stenosis / Hypertension / Thyroid mass	Encephalitis	FRANCE	3 days	Not recovered	3
(b) (6)	85.00	YEARS	MALE	Cardiovascular disorder / Prostatic disorder	Herpes zoster, Pain, Ear infection, Encephalitis	UNITED KINGDOM	Not reported	Not reported	4
(b) (6)	52.00	YEARS	FEMALE	Breast cancer	Encephalitis	FRANCE	7 days	Unknown	3
(b) (6)	46.00	YEARS	FEMALE	Not reported	Feeling abnormal, Encephalitis, Systemic lupus erythematosus	JAPAN	7 days (dose 2)	Recovering	4

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Table 5. Summary of Reported Encephalomyelitis/ADEM Cases

Adverse Event Report Number	Age	Age Unit	Gender	Med History	Events (rank order) (Concat)	Country	Time to onset	Outcome	BC
(b) (6)	32.00	YEARS	FEMALE	Not reported	Anaphylactic reaction, Urticaria, Pyrexia, Abdominal discomfort, Tremor, Headache, Malaise, Pruritus, Cough, Pallor, Feeling abnormal, Hypoaesthesia, Vaccination site pain, Oropharyngeal pain, Muscle twitching, Bronchospasm, Seizure, Neuropathy peripheral, Paraesthesia, Depressed level of consciousness, Dysarthria, Acute disseminated encephalomyelitis, Heart rate increased	JAPAN	Same day	Resolved with sequel	4
(b) (6)	91.00	YEARS	FEMALE	Bullous erysipelas	Head discomfort, Headache, Swelling face, Eye infection, Asthenia, Dysstasia, Encephalitis, Herpes zoster	ITALY	Not reported	Not recovered	4
(b) (6)	34.00	YEARS	FEMALE	Anaphylactic reaction	Acute disseminated encephalomyelitis, Paraesthesia, Headache, Dizziness, Nausea, Nystagmus	UNITED STATES	8 days	Recovering	3

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Table 5. Summary of Reported Encephalomyelitis/ADEM Cases

Adverse Event Report Number	Age	Age Unit	Gender	Med History	Events (rank order) (Concat)	Country	Time to onset	Outcome	BC
(b) (6)	43.00	YEARS	FEMALE	Anxiety / Depression	Ankle fracture, Encephalitis	UNITED STATES	38	Recovered	4
(b) (6)	33.00	YEARS	FEMALE	Anxiety	Bell's palsy, Vision blurred, Hypoaesthesia, Burning sensation, Paraesthesia, Feeling abnormal, Acute disseminated encephalomyelitis, Noninfective encephalitis, Spondylitis, Cognitive disorder, Balance disorder, Gait disturbance, Pain in extremity, Hyperacusis, Insomnia, Cranial nerve paralysis, Muscular weakness, Anxiety, Vomiting, Lethargy	UNITED STATES	Not reported	Unknown	3

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Table 5. Summary of Reported Encephalomyelitis/ADEM Cases

Adverse Event Report Number	Age	Age Unit	Gender	Med History	Events (rank order) (Concat)	Country	Time to onset	Outcome	BC
(b) (6)	31.00	YEARS	FEMALE	Migraine	Headache, Muscle spasms, Extrapyrarnidal disorder, Diaphragmatic spasm, Dyspnoea, Dyskinesia, Muscle spasms, Tremor, Chest discomfort, Chills, Encephalitis post immunisation, Hyperhidrosis, Serum sickness, Tremor, Dyspnoea, Erythema, Feeling hot, Erythema, Urticaria, Rash, Type I hypersensitivity	CROATIA	2 days	Recovered	4
(b) (6)	34.00	YEARS	MALE	Anxiety / Encephalitis / Paranoia / Psychotic disorder / Pyrexia / SARS-CoV-2 test positive	Encephalitis, Pneumonitis, Anxiety, Psychotic disorder, Paranoia, Pyrexia, Disease recurrence, COVID-19, Catatonia, Chills, Oropharyngeal pain, Pyrexia, Insomnia, Confusional state	UNITED KINGDOM	Not reported	Not reported	5

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Table 5. Summary of Reported Encephalomyelitis/ADEM Cases

Adverse Event Report Number	Age	Age Unit	Gender	Med History	Events (rank order) (Concat)	Country	Time to onset	Outcome	BC
(b) (6)	68.00	YEARS	FEMALE	COVID-19 / Cognitive disorder / Malnutrition / Schizophrenia	Encephalitis, Encephalopathy, Cardio-respiratory arrest, Depressed level of consciousness, Ischaemic stroke, Diabetes mellitus, Urinary tract infection, Incoherent, Agitation, Pulse abnormal	SPAIN	6-8 days	Recovered	4
(b) (6)	79.00	YEARS	MALE	Dust allergy / Hypercholesterolaemia / Hypertension / Hypothyroidism	Encephalitis, Headache, Nausea, Migraine, Subarachnoid haemorrhage	UNITED STATES	13 days	Recovered with sequel	4
(b) (6)	67.00	YEARS	MALE	Not reported	Asthenia, Malaise, Pyrexia, Confusional state, Taste disorder, Encephalitis, Sepsis, Listeriosis, Dizziness, Vertigo	ITALY	1 day	Unknown	4
(b) (6)	87.00	YEARS	FEMALE	Cognitive disorder / Coronary artery disease / Extrasystoles / Hypertension / Hyperthyroidism	Encephalitis	FRANCE	2 days	Recovering	5

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Table 5. Summary of Reported Encephalomyelitis/ADEM Cases

Adverse Event Report Number	Age	Age Unit	Gender	Med History	Events (rank order) (Concat)	Country	Time to onset	Outcome	BC
(b) (6)	32.00	YEARS	FEMALE	Not reported	Myelitis transverse, Acute disseminated encephalomyelitis, Demyelination, Spinal cord injury, Muscular weakness, Chest pain, Dysuria, Urinary retention, Back pain, Paraesthesia, Neck pain, Asthenia, Musculoskeletal stiffness, Pain in extremity	ESTONIA	Not reported	Unknown	5
(b) (6)	61.00	YEARS	FEMALE	Glaucoma	Drug ineffective, COVID-19, Encephalitis	SPAIN	16 days	Recovering	4

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Table 5. Summary of Reported Encephalomyelitis/ADEM Cases

Adverse Event Report Number	Age	Age Unit	Gender	Med History	Events (rank order) (Concat)	Country	Time to onset	Outcome	BC
(b) (6)	46.00	YEARS	FEMALE	Drug hypersensitivity / Food allergy / Ovarian cancer	Encephalitis, Deafness, Amnesia, Paraesthesia, Visual impairment, Taste disorder, Dizziness, Blood pressure systolic increased, Rhinitis, Dizziness, Pain, Dyspnoea, Neck pain, Headache, Lymphadenopathy, Fall, Memory impairment, Nausea, Anosmia, Chest discomfort, Presyncope, Blood pressure increased, Chest pain, Gait disturbance, Fibrin D dimer increased	UNITED STATES	4 days	Unknown	4
(b) (6)	72.00	YEARS	MALE	Not reported	Encephalitis, Encephalopathy, Central nervous system lesion, Somnolence, Aphasia, Agitation, Pleocytosis, Anti-myelin-associated glycoprotein antibodies positive	SWITZERLAND	11 days	Recovered	2

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Table 5. Summary of Reported Encephalomyelitis/ADEM Cases

Adverse Event Report Number	Age	Age Unit	Gender	Med History	Events (rank order) (Concat)	Country	Time to onset	Outcome	BC
(b) (6)	61.00	YEARS	FEMALE	Confusional state / Fatigue / Meningitis / Multiple sclerosis / Pollakiuria / Progressive multifocal leukoencephalopathy / Steroid therapy / Suprapubic pain / Urosepsis	Encephalitis, Meningitis, Urosepsis, Mobility decreased, Confusional state, Pyrexia, Suprapubic pain, Urine abnormality, Pollakiuria	UNITED KINGDOM	Not reported	Unknown	4
(b) (6)	55.00	YEARS	FEMALE	Not reported	Encephalitis, Dizziness, Reading disorder, Confusional state, Depressed level of consciousness, Amnesia, Epilepsy, Encephalopathy	SWEDEN	30min	Not recovered	2
(b) (6)	29.00	YEARS	FEMALE	Asthma / Bipolar disorder	Encephalitis, Psychomotor hyperactivity, Pyrexia, Headache, Aphasia, Ovarian cyst, Vaginal discharge, Photophobia, Anxiety	SPAIN	14 days	Recovered	5

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(b) (6)	22.00	YEARS	MALE	Anxiety / Autism spectrum disorder / Bacterial infection / Constipation / Costochondriti s / Diarrhoea / Food poisoning / Hepatic steatosis / Seasonal allergy / Tonsillitis / Viral infection	Lower respiratory tract infection, Noninfective encephalitis, Tachycardia, Erectile dysfunction, Personality change, Oropharyngea l pain, Dysphagia, Rhinorrhoea, Nasal dryness, Oropharyngea l discomfort, Headache, Fatigue, Feeding disorder, Insomnia, Psychomotor hyperactivity, Decreased appetite, Myalgia, Heart rate decreased, Palpitations, Feeling hot, Pruritus, Paraesthesia, Feeling of body temperature change, Auditory disorder, Constipation, Flatulence, Eructation, Eye pain, Eye pruritus, Ocular hyperaemia, Abdominal pain upper, Pruritus genital, Chromaturia, Urine odour abnormal, Tongue discolouration , Vision blurred, Dizziness, Dyspepsia, Head	UNITED KINGDO M	Not reported	Not reported	5
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Table 5. Summary of Reported Encephalomyelitis/ADEM Cases

Adverse Event Report Number	Age	Age Unit	Gender	Med History	Events (rank order) (Concat)	Country	Time to onset	Outcome	BC
(b) (6)	31.00	YEARS	FEMALE	Not reported	discomfort, Abnormal sensation in eye, Ocular discomfort, Ear discomfort, Skin warm, Chest pain, Dyspnoea, Neck pain, Anxiety, Pain in extremity, Pain in extremity, Pallor, Heart rate increased, Body temperature increased, Memory impairment, Back pain	AUSTRIA	7 days after 1st dose and worsened after the 2nd dose	Not reported	Duplicate case

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Table 5. Summary of Reported Encephalomyelitis/ADEM Cases

Adverse Event Report Number	Age	Age Unit	Gender	Med History	Events (rank order) (Concat)	Country	Time to onset	Outcome	BC
(b) (6)	54.00	YEARS	FEMALE	Pelizaeus-Merzbacher disease	Encephalitis, Respiratory failure, Cerebrovascular accident, Cerebral haemorrhage, Brain oedema, Cerebral ventricle collapse, Brain death, Superior sagittal sinus thrombosis, Disturbance in attention, Headache, Vomiting, Inappropriate schedule of product administration	GERMANY	same day	Fatal	5
(b) (6)	41.00	YEARS	FEMALE	Coronary artery dissection / Migraine	Noninfective encephalitis, Diplopia, Chills, Headache, Diarrhoea, Visual impairment, Cranial nerve disorder, Multiple sclerosis	UNITED STATES	9 days	Recovering	4
(b) (6)	80.00	YEARS	FEMALE	Not reported	Epilepsy, Encephalitis, CSF protein increased	FINLAND	2 days	Recovering	3
(b) (6)	30.00	YEARS	FEMALE	Autoimmune hepatitis / Diarrhoea / Immune-mediated encephalitis / Irregular sleep phase / Primary biliary cholangitis	Encephalitis, Pleural effusion	SPAIN	12 days	Recovering	4

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Table 5. Summary of Reported Encephalomyelitis/ADEM Cases

Adverse Event Report Number	Age	Age Unit	Gender	Med History	Events (rank order) (Concat)	Country	Time to onset	Outcome	BC
(b) (6)	71.00	YEARS	MALE	Acute myocardial infarction / Alcohol abuse / Chronic obstructive pulmonary disease / Coronary artery disease / Hyperuricaemia / Polyneuropathy / Substance use	Encephalitis	SWITZERLAND	8 days	Recovering	4
(b) (6)	54.00	YEARS	FEMALE	Blood cholesterol / Constipation / Dizziness postural / Gastritis / Hypertension / Immunodeficiency / Meningioma / Pain / Suppressed lactation / Tic	Cerebrovascular accident, Brain neoplasm, Vertigo, Speech disorder, Language disorder, Encephalitis, Vertigo positional	UNITED KINGDOM	Not reported	Unknown	5
(b) (6)	50.00	YEARS	MALE	Not reported	Encephalitis, Depressed level of consciousness, Seizure, Pyrexia, Confusional state, Pain in extremity, Diarrhoea, Blister, Herpes virus infection, Clumsiness	FINLAND	5 days	Recovering	2
(b) (6)	18.00	YEARS	NO DATA	Not reported	Asthenia, Pain in extremity, Cerebellar haemorrhage, Hyperintensity in brain deep nuclei, Headache, Back pain, Encephalitis	UNITED KINGDOM	Not reported	Recovering	3
(b) (6)	82.00	YEARS	MALE	Weight decreased	Encephalitis autoimmune	GERMANY	4 days	Not recovered	4

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Table 5. Summary of Reported Encephalomyelitis/ADEM Cases

Adverse Event Report Number	Age	Age Unit	Gender	Med History	Events (rank order) (Concat)	Country	Time to onset	Outcome	BC
(b) (6)	75.00	YEARS	FEMALE	Breast cancer / Discomfort / Dysuria / Epilepsy / Hypertension / Type 2 diabetes mellitus	Encephalitis, Fall, Hypothermia, Sensory loss, Hypertension, Pyrexia, Mobility decreased, Somnolence, Hemiapraxia, Nausea, Leukoencephalopathy, Varicella virus test positive, Troponin increased, Acute kidney injury	FRANCE	8 days	Recovering	2
(b) (6)	88.00	YEARS	FEMALE	Bladder cancer / Cerebrovascular accident / Parkinson's disease / Pneumonia aspiration / Schizoaffective disorder / Type 2 diabetes mellitus	Generalised tonic-clonic seizure, Meningism, Encephalitis, Pneumonia aspiration, Post stroke epilepsy, C-reactive protein increased, Blood potassium increased	SWEDEN	8 days	Fatal	5
(b) (6)	86.00	YEARS	MALE	Not reported	Encephalitis, Rash, Confusional state, Personality change, Pleocytosis, Ischaemia	GERMANY	11 days	Not recovered	3
(b) (6)	26.00	YEARS	FEMALE	COVID-19	Encephalitis autoimmune	NETHERLANDS	18 days (after 2nd dose)	Not recovered	4

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Table 5. Summary of Reported Encephalomyelitis/ADEM Cases

Adverse Event Report Number	Age	Age Unit	Gender	Med History	Events (rank order) (Concat)	Country	Time to onset	Outcome	BC
(b) (6)	74.00	YEARS	MALE	Anaemia / Atrial fibrillation / Atrioventricular block complete / Hypertension / Pacemaker syndrome / Type 2 diabetes mellitus	Demyelination, Muscular weakness, Skin lesion, Anal incontinence, Acute disseminated encephalomyelitis	UNITED KINGDOM	28	Not recovered	3
(b) (6)	75.00	YEARS	MALE	Alcohol use / Benign prostatic hyperplasia / Bronchiectasis / Chemotherapy / Chronic lymphocytic leukaemia / Chronic obstructive pulmonary disease / Facial bones fracture / Facial paralysis / Hiatus hernia / Immunoglobulins decreased / Immunomodulatory therapy / Non-tobacco user / Respiratory tract infection	Encephalitis, Fall, Craniocerebral injury, Facial bones fracture, Lung consolidation, Bronchial wall thickening, Lymphadenopathy	SWITZERLAND	8 days	Recovering	2

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APPENDIX 3.4 SAFETY EVALUATION OF HEPATIC EVENTS

1. INTRODUCTION

As per the Assessment Report for the 5th Monthly Safety Update - Post-Opinion Measure 002.4: *“The results of the review of Hepatic events is lacking in current MSSR. The MAH is requested to report the results of the review of Hepatic events as this is considered a non-validated safety signal in the 5th MSSR.”*

Method

The Pfizer safety database was searched for all BNT162b2 vaccine cases received through 28Feb2021 for PTs within HLTs: Hepatic failure and associated disorders; Hepatic fibrosis and cirrhosis or SMQs: Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions; Hepatitis, non-infectious.

2. RESULTS

Based on the search strategy provided above, a total of 27 cases were retrieved. There were 22 females and 5 males. Twenty-six (26) cases were reported as serious and 1 as non-serious. Cases originated mainly from the United Kingdom (8), the United States (6), and France (5).

Age's distribution was as following: 18-30 years (2); 31-50 years (3); 51-64 years (6); 65-74 years (8); Greater than or equal to 75 years (7), and age was unknown in 1 case (mean = 65.3 years; n = 26).

A total of 27 cases reporting the following PTs from the search: Liver injury (7), Ascites (5), Hepatocellular injury (4), Hepatic cirrhosis, Hepatic failure, Liver disorder (3 each), and Cholestatic liver injury, Gastric varices haemorrhage (1 each).

Out of 27 cases, 5 cases provided limited information on latency, duration of the relevant event, medical history, and co-suspect/concomitant medications precluding a meaningful conclusion on causality; in 1 other case, the hepatic event was noted as “occurring at one point of time during the year” (had no association with vaccination). Out of remaining 21 cases, 9 cases reported a pre-existing history of hepatic disorder and/or cancer patients on chemotherapy and/or chronic kidney disorder/immunosuppression. Other 2 cases reported hepatic events in association with development of Epstein Barr Virus (EBV) infection after vaccination.

Out of the remaining 10 cases, 6 cases co-reported many reactogenicity events occurring on day of or next day of the vaccination and an onset of hepatic events starting with an increase in hepatic enzymes occurring in 7-8 days after vaccination day (2 cases); 9 days (1 case); 13 days (1 case); and unknown latency (2 cases; one of this cases reported “something weird with the liver”). The co-reported events in these 6 cases were: Pyrexia, Headache (3 each), C-reactive protein increased, Malaise, Nausea, Fatigue, Hypotension (2 each), Pain in

extremity, Arthralgia, Chills, Hot flush, Loss of consciousness, Decreased appetite, Memory impairment, pH urine increased, Anaemia, Somnolence, Systemic inflammatory response syndrome Lymphopenia, Asthenia, Food aversion, Vomiting, Ear pain, Pain in jaw, Inflammation, Tooth infection, Movement disorder (1), Balance disorder (1), and Limb immobilization (1 each).

The last four cases were fatal cases. One was a limited case of a 95-year-old female, with unknown medical history and co-suspect/concomitant medications. The patient experienced fatigue and cold shivers on the vaccination day; cystitis, general malaise, liver failure leading to death, all 3 days later. The second case reported a 26-year-old male with a complex medical history of COVID-19 pneumonia from 3 months prior to Dose 1 (bilateral pneumonia, no mechanical ventilation, confirmed by PCR), esophageal candidiasis in 2015, pollen allergy and asthma in 2008, mononucleosis in 2015, tuberculous pneumonia (any form) in 2003, Herpes zoster on 03Jun2011, Pharyngotonsillitis in 2015, on many concomitant medications including steroids. The patient started with symptoms of pharyngotonsillitis on 31Jan2021 and received various antibiotic treatments: amoxicillin-clavulanic, cefditoren. He developed respiratory failure and increased transaminases. On 04Feb2021 there was an evolution with liver failure, refractory shock, hepatitis acute, suspected hemophagocytic syndrome, multiple organ failure. These events were reported as serious as required hospitalization. The patient died on 07Feb2021 due to above mentioned events. The last two cases reported a 70-year-old and 85-year-old patients with very complex medical histories on many concomitant medications (an autopsy for the 1st patient identified atherosclerotic coronary artery disease with occlusion of the proximal circumflex branch with rupture and bleeding in the atheroma plaque with stenosis as well as an acute myocardial infarction in the left ventricle with signs of older infarction; bilateral pneumonia and diffuse acute circulatory stasis, an abdomen with presence of sigmoidal volvulus with general dilation of the intestines and inflated ventricle as well as 150 ml of ascites; ileum with signs of ischemia and small hemorrhages in the mesotarm; and multinodous colloid goiter; and the cause of death in the 2nd patient was an acute myocardial infarction 5 days post-dose 1).

3. CONCLUSION

Considering the totality of the data, including the number of reports received in the context of the millions of doses of vaccine administered and based on the available data, this safety topic was determined not to be a validated signal.

APPENDIX 3.5 SUMMARY OF CASES OF THROMBOEMBOLISM WITH THROMBOCYTOPENIA

1. BACKGROUND

Pfizer/BNT COVID-19 vaccine AE reports of arterial or venous thromboses and concurrent thrombocytopenia are being closely monitored due to recent information that the co-occurrence of such events may be a risk of vaccination with adeno-vector COVID-19 vaccines.

The Pfizer safety database was searched for spontaneous BNT162b2 reports cumulative to 26 May 2021 using MedDRA (v 24.0) for cases within the SMQ Embolic and thrombotic events where the thrombosis/embolic PT occurred from Day 3 to Day 28 (inclusive) following vaccination with BNT162b2. That dataset was then searched for PTs that are in either the HLT Thrombocytopenias or HLT Platelet analysis. The rationale for this search strategy is based on discussion with internal hematologists and review of the available literature on the topic, including the Vaccine Induced Immune Thrombotic Thrombocytopenia (VITT) Diagnostic Flow Chart published by the International Society on Thrombosis and Haemostasis and updated on 20 Apr 2021 (ISTH, www.isth.org).

The final dataset is comprised of 85 AE reports, compared to 33 AE reports in the safety database as of 22 April 2021, that were described in the 5th SMSR.

The cases were individually reviewed and categorized into Brighton Collaboration Levels 1-5 using the Decision tree algorithm for case-finding of Thrombocytopenia Thrombosis Syndrome (TTS)ⁱ as follows:

1. BC Level 1: Definite case TTS – 40 reports
2. BC Level 2: Probably case TTS – 2 reports
3. BC Level 3: Possible case TTS – 5 reports
4. BC Level 4: Excluded case; reported as TTS but insufficient evidence to meet any level of the case – 12 reports
5. BC Level 5: Not a case of TTS – 26 reports

2. BRIGHTON COLLABORATION LEVELS 1-3 AND POTENTIAL VITT

The 47 cases assessed as BC Levels 1-3 were then reviewed for information potentially indicative of a possible new syndrome that has been referred to as Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT). The VITT Diagnostic Flow Chart (updated 20 Apr 2021) and published by the International Society on Thrombosis and Haemostasisⁱⁱ was

utilized. Case information taken into account included signs and symptoms of thrombosis occurring in the setting of prior COVID-19 vaccination (4-28 days prior), a platelet count of $<150 \times 10^9/L$, reliable immunoassay results for platelet factor 4 (PF4) antibodies (e.g. ELISA, particularly if the optical density reading is high), markedly elevated D-dimer levels (e.g. $>4 \times$ the threshold for venous thromboembolism exclusion).

2.1. BC Level 1 reports

Of the 59 BC Level 1-4 reports, 40 were BC Level 1. All reports were serious. Patients ranged in age from 22 to 96 years of age (mean 69.3, median 73); there were 26 male and 14 females, and all but 1 of the reports were medically confirmed. Of the cases with information on dosing, 22 cases occurred after dose 1 and 15 after dose 2; the relevant events (thrombosis and thrombocytopenia) occurred from 1 to 27 days after vaccination.

2.1.1. BC Level 1 reports with PF4 + and/or D-dimer >4000

Of the 40 BC Level 1 reports, 2 described the presence of PF4 antibodies (Table 1) and an additional 10 reports described D-dimer results >4000 (Table 2).

Of the 2 PF4 antibody + reports, one described a 31-year-old man with no significant medical history reported and one described a 47-year-old woman with a history of pulmonary embolus.

Of the 10 D-dimer >4000 reports, medical histories were confounding in 9 of the reports: One described a 78 year old man who had endovascular surgery (abdominal aortic aneurysm repair) and post-operative heparin 11 days prior to the development of thrombocytopenia and 14 days prior to the development of abdominal aortic and renal artery thrombosis; 3 described patients with cancer diagnoses (2 of the 3 with previous VTEs, 1 of the 3 improved on heparin); 1 described chronic right heart failure with liver congestion; 1 had baseline thrombocytopenia; 1 had cirrhosis (due to alcohol) and portal hypertension; 1 had ischemic heart disease and was found to be in atrial fibrillation; and 1 had a history of atrial fibrillation (fatal case).

Table 1. BC Level 1 Reports with PF4 Antibodies Positive

	AER number Country Age/Sex Initial Receipt Date	Preferred Terms reported	Vaccine Dose (1 or 2) Time to onset from vaccine dose	Additional relevant information
1	(b) (6) UK 31 years/Male 20 May 2021 Recovering/Recov ered	Deep vein thrombosis, Thrombocytopenia, Deep vein thrombosis, Peripheral swelling, Joint swelling	1 5 days	Pt without significant medical history or known risk factors for thrombus developed lower extremity DVT. Platelets 135, D-dimer 12,819, Fibrinogen 3.6, PF4 antibodies positive (HIT assay used), COVID-19 test negative. The case was reviewed by a hematologist. The patient was started on non-heparin anticoagulation and was recovering
2	(b) (6) UK 47 years/Female 11 Apr 2021 Not recovered	Haemorrhage, Thrombosis, Embolism, Arterial thrombosis, Venous thrombosis, Cerebral venous sinus thrombosis, Cerebral haemorrhage, Chest injury, Thrombocytopenia, Abdominal pain, Muscular weakness	1 9 days	Pt with a history of pulmonary embolism and normal platelet count who was reported to be on an unspecified anticoagulant or anti- platelet medication, presented with abdominal pain and left-handed weakness 9 days after vaccination and 12 days after vaccination had multiple arterial and venous thromboses not further characterized other than a CVST with a secondary bleed. She had a platelet count of 11 (nadir 10), Fibrinogen 4.4, D-dimer 20,000, PF4 antibodies positive (ELISA). She was seen by a hematologist and received IVIg but no anticoagulant.

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Table 2. BC Level 1 Reports with D-dimer >4000 (and no PF4 antibody results)

	AER number Country Age/Sex Initial Receipt Date Outcome of thrombosis/thrombocytopenia	Preferred Terms reported	Vaccine Dose (1 or 2) Time to onset from vaccine dose	Additional relevant information
1	(b) (6) Netherlands 78 years/Male 10 May 2021 Recovering/Not recovered	Thrombocytopenia, Aortic thrombosis, Renal artery thrombosis, Renal ischaemia, Intestinal ischaemia	2 11 days	Pt with history of hypertension and abdominal aortic aneurism repair (tolerated heparin perioperatively) had thrombocytopenia treated with IV Ig and dexamethasone and 3 days later had an abdominal aortic thrombus, renal artery thrombosis, intestinal ischemia and renal ischemia on CT scan. Platelets 25, Heparin-induced thrombocytopenia test was positive, PF4 antibodies by ELISA were negative, D-dimer was >5000.
2	(b) (6) UK 69 years/Male 09 May 2021 Recovered	Embolism, Deep vein thrombosis, Thrombocytopenia, Pain, Peripheral swelling, Pain in extremity	2 5 days	Pt with history of hypertension, alcoholic cirrhosis and portal hypertension on multiple medications, presented with leg pain and swelling 5 days after vaccination and was found to have a DVT on ultrasound. Platelets 129, D-dimer 4336, PTT 50.6, Unknown if PF4 antibodies were identified. He was treated with a non-heparin anticoagulant and recovered to be discharged home

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Table 2. BC Level 1 Reports with D-dimer >4000 (and no PF4 antibody results)

	AER number Country Age/Sex Initial Receipt Date Outcome of thrombosis/thro mbocytopenia	Preferred Terms reported	Vaccine Dose (1 or 2) Time to onset from vaccine dose	Additional relevant information
3	(b) (6) Spain 75 years/Male 07 May 2021 Recovered	Thrombocytopenia, Pulmonary embolism, Deep vein thrombosis, Obstructive shock, Syncope, Sinus bradycardia, Atrial fibrillation, Right ventricular dilatation, Systolic dysfunction, Hypotension, Heart rate increased, Incorrect route of product administration	1 5 days	Pt with a history of ischemic heart disease and baseline thrombocytopenia (123), medications not reported. Presented with complaint of weakness followed by syncope while working in the fields and was found to be in atrial fibrillation (rate 150). Due to elevated D-dimer (7300) and low oxygen saturation, a CT angiogram of the pulmonary arteries was performed and pulmonary embolism with right cardiac overload was diagnosed. He had thrombolysis with Actilyse and improved. A left popliteal DVT was found on ultrasound. His atrial fibrillation was treated with digoxin and bisoprolol. He was maintained on low molecular weight heparin and acenocoumarol. Platelet nadir 55, COVID test negative.
4	(b) (6) UK Unspecified/Male 06 May 2021 Not resolved/Unknow n	Deep vein thrombosis, Thrombocytopenia, Haemorrhage	2 14 days	Pt with history of varicose veins and report of platelet count <150 before vaccination was diagnosed with femoral-popliteal DVT via ultrasound. Platelets 132, D-dimer >4000, Fibrinogen 223, unknown if PF4 antibodies were identified. No hemorrhage was identified. Treatment was not specified; patient was to f/u with hematologist in 3 months.
5	(b) (6) Spain 78 years/Female 03 May 2021 Not recovered	Pulmonary embolism, Respiratory failure, Right ventricular dysfunction, Cardiac failure, Metabolic acidosis, Hyperlactacidaemia, Renal impairment, Hepatic function abnormal, Hepatic cytolysis, Thrombocytopenia	Unspecifie d 16 days	Pt with a history of hypertension, spondylarthrosis, osteopenia, chronic right-sided heart failure with liver congestion, presented to hospital due to dizziness and malaise, she was in respiratory distress and a CT scan showed extensive bilateral pulmonary thromboses with right ventricular dysfunction. She received fibrinolysis with a good response and was on heparin for a brief time before being placed on fondaparinux and Flebogamma IV. Platelets 78, Fibrinogen 292 mg/dl, D-dimer 36,191

Table 2. BC Level 1 Reports with D-dimer >4000 (and no PF4 antibody results)

	AER number Country Age/Sex Initial Receipt Date Outcome of thrombosis/thro mbocytopenia	Preferred Terms reported	Vaccine Dose (1 or 2) Time to onset from vaccine dose	Additional relevant information
6	(b) (6) UK 86 year/Female 29 Apr 2021 Recovered	Haemorrhage, Deep vein thrombosis, Thrombosis, Thrombocytopenia, Deep vein thrombosis, Lymphocytosis, Peripheral swelling, Peripheral swelling	2 13 days	Pt with a history of Parkinson's disease on levodopa, developed left leg swelling 13 days after vaccination and was found to have a DVT above the knee on ultrasound. Her labs included PTT 25.2, PT 11.2, D-dimer 11,635, Platelets 95, PF4 antibodies sent but pending at time of report. She was started on rivaroxaban. It is unclear why Hemorrhage was coded as an AE.
7	(b) (6) UK Unspecified/Male 29 Apr 2021 Recovering/Unkn own	Pulmonary embolism, Thrombocytopenia, Hepatic cancer	2 6 days	Pt with medical history and medications not reported, had a pulmonary embolism 6 days after Dose 2 of vaccine diagnosed via CT pulmonary angiogram. Platelet count was <150, D-dimer >4000 and COVID test negative. He was found to have malignant lesions in the liver on CT scan (not further described).
8	(b) (6) Netherlands 73 years/Male 19 Apr 2021 Not resolved/Unknow n	Deep vein thrombosis, Thrombocytopenia	1 8 days	Pt with a history of pulmonary embolism in 1999, prostate carcinoma, hydronephrosis, urolithiasis and myocardial infarction on multiple medications had a left leg DVT (on ultrasound) and platelets count 145 8 days following vaccination. D-dimer 9881. The patient was treated with rivaroxaban.
9	(b) (6) France 76 years/Female 29 Mar 2021 Recovering/Unkn own	Pulmonary embolism, Thrombocytopenia, Dyspnoea	2 19 days	Pt with history of hypertension, lower extremity thromboses, obesity and breast cancer thought to be in remission as of Aug 2019 presented with shortness of breath. She was found to have a PE and platelet count of 135. D-dimer was >20,000. She was treated with low molecular weight heparin and improved.

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Table 2. BC Level 1 Reports with D-dimer >4000 (and no PF4 antibody results)

	AER number Country Age/Sex Initial Receipt Date Outcome of thrombosis/thro mbocytopenia	Preferred Terms reported	Vaccine Dose (1 or 2) Time to onset from vaccine dose	Additional relevant information
10	(b) (6) Belgium 83 years/Male 03 May 2021 Fatal case	Death, Pulmonary embolism, Acute kidney injury, Thrombocytopenia, Hemiplegia, Ischaemic stroke, International normalised ratio increased, Dyspnoea	1 26 days	Pt with a history of hypertension and atrial fibrillation on several medications including acenocoumarol presented with left hemiplegia and dyspnea and was found to have a stroke and pulmonary embolism on thoracic and cerebral CT angiogram. Platelets were 80, INR was 2.45, D-dimer 7650 mg/ml. He had fibrinolysis with alteplase due to hemodynamic instability and a mechanical thrombectomy however he died the following day.

2.1.2. Fatal BC Level 1 reports

Seven of the 40 BC Level 1 reports were fatal cases (Table 3). None of the reports contained information about PF4; 1 report described a D-dimer level >4000 (AER (b) (6)).

Table 3 BC Level 1 Reports - Fatal Cases

	AER number Country Age/Sex Initial Receipt Date Outcome (thrombosis/thrombocytopenia)	Preferred Terms reported	Vaccine Dose (1 or 2) Time to onset from vaccine dose	Additional relevant information
1	(b) (6) UK 85 years/Male 09 Apr 2021 Fatal case	Cerebrovascular accident, Platelet count decreased	1 7 days	Pt with a history of gastrointestinal bleed, atrial fibrillation taking digoxin, finasteride, furosemide, salbutamol, solifenacin, tamsulosin and rivaroxaban which was recently stopped due to a GI bleed. The patient presented with a middle cerebral artery stroke 7 days after vaccination and an unspecified platelet count less than 150. The patient died 7 days after the stroke. No PF4 antibodies, D-dimer or Fibrinogen provided. The patient has known risk factors for ischemic stroke and unknown severity of thrombocytopenia. Cause of death was noted as stroke.
2	(b) (6) France 72 year/Male 19 April 2021 Fatal case	Disseminated intravascular coagulation, Thrombosis, Thrombocytopenia, Cerebral haemorrhage, Hypernatraemia, Hyperchloraemia, Lymphopenia, Rhabdomyolysis, Prothrombin level abnormal, Activated partial thromboplastin time abnormal, Malaise, Fall	1 14 days	Pt with a history of atrial fibrillation, hypertension and chronic intoxication taking bisoprolol and rivaroxaban was found on the ground, face down. He was diagnosed with pancreatitis grade D and lab abnormalities including a platelet count of 34 and CPK>8000, Fibrinogen 0.74 and intracardiac, aortic and arm and leg arterial thromboses. Cause of death was noted as cerebral hemorrhagic "rearrangement," DIC, multiple thromboses and thrombocytopenia.

Table 3 BC Level 1 Reports - Fatal Cases

AER number	Country	Age/Sex	Initial Receipt Date	Outcome (thrombosis/thrombocytopenia)	Preferred Terms reported	Vaccine Dose (1 or 2)	Time to onset from vaccine dose	Additional relevant information
3	(b) (6)	Spain	83 year/Male	26 Apr 2021	Fatal case	Cerebral thrombosis, Hemiplegia, Dizziness, Oedema peripheral, Gait disturbance, Nervous system disorder, Somnolence, Pupils unequal, Eyelid ptosis, Facial paresis, Dysarthria, Platelet count decreased, White blood cell count increased, Neutrophil count increased, Lymphocyte count decreased, Pyrexia	2 12 days	Pt with a history of high cholesterol, non-stenotic aortic sclerosis, diabetes, hypertension and cirrhosis on multiple medications was admitted after a few episodes of falling, with dysarthria, anisocoria and left hemiplegia. CT angiogram of brain showed cerebral arterial thrombosis. Platelet count was 129, Fibrinogen was 766, COVID-19 test was negative. He was treated with enoxaparin and mechanical thrombectomy. He developed a fever, leukocytosis and elevated CRP and a possible respiratory infection was noted. He died 26 days after dose 2 and it was not reported if an autopsy was done.
4	(b) (6)	Poland	73 years/Male	05 Apr 2021	Fatal case	Acute kidney injury, Acute myocardial infarction, Thrombocytopenia, Pancreatitis acute	1 9 days	Pt with a history of coronary artery disease, hypertension and degenerative joint disease taking ramipril and lercanidipine HCl presented with acute renal failure, a transmural MI, acute pancreatitis, and thrombocytopenia (nadir 131) and died the same day. It was noted that baseline cause of death (COD) was pancreatitis, secondary COD was acute renal failure and direct COD was MI. An autopsy was not performed. The course of events (multiorgan failure) described are more likely attributable to pancreatitis than a rarer syndrome of thrombotic thrombocytopenia.

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Table 3 BC Level 1 Reports - Fatal Cases

AER number Country Age/Sex Initial Receipt Date Outcome (thrombosis/thrombocytopenia)	Preferred Terms reported	Vaccine Dose (1 or 2) Time to onset from vaccine dose	Additional relevant information
5 (b) (6) Belgium 83 years/Male 03 May 2021 Fatal case Report also included in Table 2	Death, Pulmonary embolism, Acute kidney injury, Thrombocytopenia, Hemiplegia, Ischaemic stroke, International normalised ratio increased, Dyspnoea	1 26 days	Pt with a history of hypertension and atrial fibrillation on several medications including acenocoumarol presented with left hemiplegia and dyspnea and was found to have a stroke and pulmonary embolism following thoracic and cerebral CT angiogram. Platelets were 80, INR was 2.45, D-dimer 7650 mg/ml. He had fibrinolysis with alteplase due to hemodynamic instability and a mechanical thrombectomy however he died the following day.
6 (b) (6) France 68 years/Female 06 May 2021 Fatal case	Abdominal wall haematoma, Shock haemorrhagic, Hepatic infarction, Portal vein thrombosis, Abdominal pain upper, Thrombocytopenia	2 23 days	Pt with history of chronic renal failure on hemodialysis, rheumatoid arthritis, hypertension on multiple medications presented with upper abdominal pain for about 1 week and was found on MRI to have liver ischemia with portal venous vein thrombosis. She had a platelet count of $40 \times 10^9/L$, anti-PF4 antibodies negative, coagulation factors normal and fibrinogen normal. She was initially treated with heparin, then danaparoid, then heparin again. On the 6 th day of hospitalization, she developed a large abdominal wall hematoma and received 2 units of packed red cells and 2 units of fresh frozen plasma. Platelet count was 133 G/L, recovering. Two days later however, she died due to the hematoma, hemorrhagic shock, hepatic infarction and portal vein thrombosis. It was not known if an autopsy was performed

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Table 3 BC Level 1 Reports - Fatal Cases

AER number	Country	Age/Sex	Initial Receipt Date	Outcome (thrombosis/thrombocytopenia)	Preferred Terms reported	Vaccine Dose (1 or 2)	Time to onset from vaccine dose	Additional relevant information
7	(b) (6)	UK	55 years/Male	16 April 2021	Fatal case	Intestinal ischaemia, Mesenteric vein thrombosis, Hypotension, Abdominal pain, Tachycardia, Thrombocytopenia	1 27 days	Pt with history of congenital malrotation of his gut, large colon adenoma and no medications reported developed worsening abdominal pain with eating. A hemicolectomy was performed to remove the adenoma and post-operatively had worsened abdominal pain and hypotension. He returned to the OR and was found to have small bowel ischemia with abnormalities in venous drainage (no superior mesenteric vein and dilated inferior mesenteric vein). He developed a low platelet count while in the ICU ($35 \times 10^9/L$) and died 4 days later. It was not known if D-dimer was >4000 or if anti-PF4 antibodies were identified. COVID-19 test was negative. He had no history of autoimmune disease or previous reaction to heparin. On autopsy, he had mesenteric vein thrombosis and intestinal ischemia.

2.2. BC Level 2 reports

Both of the level 2 reports (“probable TTS”) described D-dimer levels >4000 . Both reports were in elderly women and one was consistent with the diagnosis of thrombotic thrombocytopenic purpura rather than potential VITT.

Table 4. BC Level 2 Reports (D-dimer >4000)

AER number	Preferred Terms reported	Vaccine Dose (1 or 2)	Additional relevant information
Country			
Age/Sex			
Initial Receipt Date			
Outcome (thrombosis/thrombocytopenia)		Time to onset from vaccine dose	
1 (b) (6)	Nausea,	2	Pt with history of tachycardia, nausea,
UK	Hyperparathyroidism,	19 days	pyrexia, hyperparathyroidism,
85 years/Female	Disease recurrence,		osteoporosis, GERD, and previous use
29 Apr 2021	Embolic, Vasculitis,		of heparin (timing not specified) was
	Pulmonary embolism,		hospitalized for a cough, shortness of
Recovered/Recovered	Thrombocytopenia,		breath, oxygen saturation of 78% and
d	Pyrexia, Productive		reduced mobility. She was diagnosed
	cough, Tachycardia,		with bilateral PEs by CT pulmonary
	Cough, Oxygen		angiogram. She had a platelet count
	saturation decreased,		<150 (nadir 63), D-dimer 13,274, PF4
	Dyspnoea, Chest		antibodies not reported. She was seen
	discomfort		by a hematologist, treated with non-
			heparin anticoagulation and had IVIg
			administered. She recovered on an
			unknown date.
2 (b) (6)	Immune-mediated	2	Pt was reported to have no medical
UK	hepatic disorder,	4 days	history and to be on no medications.
83 years/Female	Haemorrhage,		She presented with fluctuating
12 Apr 2021	Activated partial		neurological symptoms for 1 day and
	thromboplastin time		was found to have thrombocytopenia
Recovering	shortened,		(nadir 9), RBC fragmentation and
	Thrombotic		ADAMTS13 levels that were
	thrombocytopenic		undetectable. D-dimer was >4000. It
	purpura, Neurological		was reported that PF4 antibody testing
	symptom		was not indicated.

2.3. BC Level 3 reports

There were 5 BC Level 3 reports (“possible TTS”); all serious. Patients ranged in age from 44 to 82 years of age (mean 68.3, median 74); there were 4 males and 1 female, and all reports were medically confirmed. Four (4) reports occurred after dose 2 and 1 occurred after dose 1; time to onset or the relevant events (thrombosis and thrombocytopenia) occurred from 10 to 22 days after vaccination. Of the 5 reports, one was a fatal case of severe pneumonia in an elderly man with pulmonary fibrosis and 1 described a 44-year-old man with a D-dimer >4000; these 2 reports are detailed in Table 5.

Of the 3 remaining reports, one described a heparin-treated man with an MI and a decrease in 2 cell lines (platelets and WBC), one described an elderly woman with no medical history reported who had bilateral PEs (no imaging study noted) and thrombocytopenia and one

described a man of unspecified age who had a history of COVID-19, decreased platelets and PE who was reported to have a DVT and thrombocytopenia (nadir 129) but PF4 antibody test (ELISA) negative, 22 days after dose 2 of the vaccine.

Table 5. BC Level 3 Reports (Fatal or D-dimer >4000)

	AER number Country Age/Sex Initial Receipt Date Outcome (thrombosis/thrombocytopenia)	Preferred Terms reported	Vaccine Dose (1 or 2) Time to onset from vaccine dose	Additional relevant information
1	(b) (6) Norway 75 years/Male 15 Apr 2021 Fatal case	Pneumonia, Thrombocytopenia, Respiratory failure, Depressed level of consciousness, Hemiplegia, Cerebral thrombosis	2 20 days	Pt with a history of pulmonary fibrosis presented with a severe pneumonia. He was treated with antibiotics however, after 2 days he had a depressed level of consciousness and developed thrombocytopenia (nadir 60) and hemiplegia due to a cerebral thrombosis. COVID-19 PCR test was negative. ICU care was stopped due to his poor prognosis and the patient died of respiratory failure.
2	(b) (6) UK 44 years/Male 20 May 2021 Recovered with sequelae/Not recovered	Pneumonitis, Chest pain, Thrombocytopenia, Thrombophlebitis, Thrombocytopenia, Pulmonary thrombosis, Peripheral swelling, Pain in extremity, Off label use, Inappropriate schedule of product administration	2 14 days	Pt with a history of urticaria and no medications reported presented with chest pain, pneumonitis and “aggravated” thrombocytopenia (nadir 69). It was reported that he had a “clot” in his lung and leg thrombophlebitis. He had a CT pulmonary angiogram and US (unspecified) and a negative COVID-19 test. Anti-PF4 antibodies were reported as unknown, D-dimer was unspecified but reported as >4000.

3. CONCLUSION

It is not unexpected that reports of TTS following vaccination are continuing to be reported as vaccinations continue, especially in light of the multiple communications to healthcare professionals from health authorities and specialty medical organizations to remain alert and to report all possible cases temporally associated to COVID-19 vaccinations. A mechanism of action for the occurrence of TTS following adenovirus vector COVID-19 vaccines has been postulated, but it has not been confirmed. TTS can occur in clinical scenarios other than post-COVID-19 vaccinations (e.g. TTP, sepsis and autoimmune disease). And many of the reports of TTS received as of 26 May 2021, have confounding factors. Regardless of this, and of the stimulated reporting that may be occurring, only 2 cases of TTS with positive PF4

antibody tests have been reported. At this time, considering the hundreds of millions of doses of Pfizer/BNT COVID-19 vaccine administered, it cannot be concluded that the vaccine is causally associated with the condition referred to as VITT.

In the Final Assessment Report for the 5th Monthly Safety Update for Comirnaty, the following request was made to Pfizer:

Regarding TTS, with the exception of (b) (6), no MAH evaluation of the cases identified by the EMA Eudravigilance TTS query dated 13 April was provided in response to the previous 4th MSSR (Q8). This is not accepted. The MAH should provide an evaluation of these cases.

The Assessor makes reference to the following cases that were noted in the Assessment Report of the 4th Monthly Safety Update for Comirnaty, Annex 6:

1.	(b) (6)	2.	(b) (6)
3.	(b) (6)	4.	(b) (6)
5.	(b) (6)	6.	(b) (6)
7.	(b) (6)	8.	(b) (6)
9.	(b) (6)	10.	(b) (6)
11.	(b) (6)	12.	(b) (6)
13.	(b) (6)	14.	(b) (6)
15.	(b) (6)	16.	(b) (6)
17.	(b) (6)	18.	(b) (6)
19.	(b) (6)	20.	(b) (6)
21.	(b) (6)	22.	(b) (6)

Of the 22 cases in the table, 11 cases are included in one or both cumulative reviews of Thrombocytopenic Thrombosis Syndrome in the April (5th) or May (6th) SMSR, as noted below.

Table 1. Eudravigilance Cases in April and/or May TTS Review

	EMA Reference	Pfizer AER	Comment
1	(b) (6)	(b) (6)	(b) (6) and (b) (6) are duplicates of AER (b) (6) which was included in the April (5 th) SMSR
2	(b) (6)	(b) (6)	(b) (6) and (b) (6) are duplicates of AER (b) (6) which was included in the April (5 th) SMSR
3	(b) (6)	(b) (6)	Case was included in April (5 th) SMSR
4	(b) (6)	(b) (6)	Case was included in April (5 th) and May (6 th) SMSR
5	(b) (6)	(b) (6)	Case was included in April (5 th) SMSR
6	(b) (6)	(b) (6)	Case was included in April (5 th) SMSR

Table 1. Eudravigilance Cases in April and/or May TTS Review

	EMA Reference	Pfizer AER	Comment
7	(b) (6)	(b) (6)	Case was included in April (5 th) and May (6 th) SMSR
8	(b) (6)	(b) (6)	Case was included in April (5 th) and May (6 th) SMSR
9	(b) (6)	(b) (6)	Case was included in April (5 th) SMSR
10	(b) (6)	(b) (6)	Case was included in April (5 th) SMSR
11	(b) (6)	(b) (6)	Case was included in April (5 th) and May (6 th) SMSR
12	(b) (6)	(b) (6)	Case was included in April (5 th) SMSR

The remaining 11 cases were retrieved from the Pfizer safety database (as of 26 May 2021) and are discussed below.

Table 2. Remaining Eudravigilance Cases

	EMA Reference	Pfizer AER PTs reported	Pfizer Summary
1	(b) (6)	(b) (6) Immune thrombocytopenia, Transaminases increased	22-year-old man with no relevant medical history taking no medications developed a petechial rash over his chest and back and gingival bleeding 3 days after 1 st vaccination. A platelet count 2 months prior was 145 x 10 ⁹ /L (ref 140-400). He was found to have severe thrombocytopenia (nadir 1). Hematology was consulted and diagnosed ITP. A viral panel for HIV, HBV, HCV and EBV was negative, COVID-19 test was negative; immunologic studies were done and Sjogren's Syndrome A antibody was elevated (2.8, normal is <1 AI), Complement C3 was normal and C4 was low (10.9, ref 16-38 mg/dL) he was treated with IVIG, platelet transfusion and high dose steroids. He remained hemodynamically stable and was discharged with a platelet count of 28 after 3 days. On Day 11, platelet count was 173 and plasma IIb/IIIa and Ia/Iia platelet autoantibodies were positive. On day 34, Sjogren's antibody and complement C4 had normalized. No clear alternative explanation for this patient's thrombocytopenia was found, although he had mild transient transaminitis and immunologic lab findings that normalized. There is no report of thrombosis in this case.

Table 2. Remaining Eudravigilance Cases

	EMA Reference	Pfizer AER PTs reported	Pfizer Summary
2	(b) (6)	(b) (6) Myelosuppression, Pancytopenia, Renal tubular necrosis, Thrombotic microangiopathy, Myalgia	33-year-old woman with a reported history of myalgia taking metamizole and paracetamol received dose 1 of vaccine on 09 Jan 2021 and experienced myalgia and urticaria. She received the dose 2 on 30 Jan and 3 days later she had intense myalgia and was treated with metamizole 575 mg tid, alternating with ibuprofen 600 mg and paracetamol. She then presented to the emergency department and was found to have pancytopenia and acute renal "lesion." Labs were not provided. Thrombotic microangiopathy was suspected and she started plasmapheresis and hemodialysis. A renal biopsy showed acute tubular necrosis which the reporting HCP thought may be due to ibuprofen but could not completely rule out a relationship to the vaccine. Outcome of myalgia and microangiopathy were unknown. Other events recovered. There is no lab reports demonstrating thrombocytopenia or biopsy evidence of thrombosis in this case.
3	(b) (6)	(b) (6) Thrombotic thrombocytopenic purpura	A 33-year-old woman with a history of relapsing remitting multiple sclerosis (treated with alemtuzumab in 2016 and 2017), gallstones, obesity and fibromyalgia received dose 1 of vaccine and 29 days later was hospitalized for suspicion of thrombotic thrombocytopenia purpura. She had no headache so CVST was not suspected. A COVID-19 test was negative. ADAMTS-13 was < 5%. She was treated with methylprednisolone 500 mg daily for 3 doses, plasma exchange, rituximab 900 mg for 4 doses and caplacizumab 10 mg daily for an unspecified time. While the ADAMTS-13 level is consistent with TTP, testing for antibodies directed at it may help determine whether it was congenital or acquired. It is not clear in this case what symptoms the patient experienced, the severity of thrombocytopenia or the location of any thromboses. The patient recovered with sequelae.
4	(b) (6)	(b) (6) Thrombocytopenia, Cerebral haemorrhage, Cerebrovascular accident, Epistaxis, Headache, Loss of consciousness, Retching, Haemorrhage, Contusion	82-year-old man with history of headache, nausea, back pain, palpitations, cardiac bypass who was taking gabapentin for pain and an unspecified medication for a clotting disorder that led to his cardiac bypass, had his 1st dose of vaccine on 07 Jan 2021. Twenty-eight days later, he had epistaxis, retching and lost consciousness. He was brought to the hospital and found to have a brain bleed. His platelet count was zero. On examination there was evidence of bleeding on areas of his body. He died that day. There was no description of thrombosis in this case. This report was discussed in the submitted SSRM #4 review of Embolic and Thrombotic Events (Appendix 3.2)

Table 2. Remaining Eudravigilance Cases

	EMA Reference	Pfizer AER PTs reported	Pfizer Summary
5	(b) (6)	(b) (6) Thrombocytopenia, Cerebral thrombosis	53-year-old man with no history or medications reported, had dose 1 of the vaccine and the following day was brought to the emergency department for unspecified reasons and found to have thrombocytopenia and “blood clots in the brain.” He underwent mechanical thrombectomy and was then brought to the ICU until he fully recovered. Outcome reported as unknown. There is a lack of information on the patient’s medical history and no labs or imaging studies, making the case difficult to assess. It is not clear if the “clots in the brain” were due to intravascular clotting or due to extravascular blood from vascular bleeding that required evacuation.
6	(b) (6)	(b) (6) Thrombocytopenia, Cerebral thrombosis, Loss of consciousness, Epistaxis, Aphasia	50-year-old man from Canada who was reported to have no risk factors for stroke, received dose 1 of vaccine while in the US and in about 24 hours, had epistaxis and could not talk. He then lost consciousness and was emergently brought to the hospital. He was found to have thrombocytopenia and intracranial bleeding and a thrombectomy was performed. It was reported that 9 blood clots were seen and 3 were removed. He was then able to remove the biggest 3. At the time of the report, he was in the ICU receiving blood thinners. Outcome was unknown. The case lacks detail in regard to history and labs and imaging that would help assessment. It is not clear if intravascular thrombosis was present or if the clotting blood was outside of the cerebral vasculature.
7	(b) (6)	(b) (6) Thrombocytopenia, Deep vein thrombosis	62-year-old woman with a history of pancreatic cancer with metastasis to the liver and spleen (untreated due to impaired liver function), diabetes mellitus, hypertension, obesity, multiple sclerosis, and an unidentified blistering skin disease, was taking furosemide, oxycodone, enalapril, diclofenac, metformin, insulin and omeprazole. She received dose 1 and was reported to have experienced thrombocytopenia 8 days later. Four weeks later, she received dose 2 and 4 days later had bilateral leg pain. She was started on ceftriaxone for an infection on the leg that drained pus and blood. One week after dose 2 multiple leg thromboses were detected bilaterally. She quickly deteriorated, had multiorgan failure and DIC was suspected. The patient died 9 days after dose 3. It was unknown if an autopsy was performed. This unfortunate case describes a woman with metastatic pancreatic cancer and events that are most likely related to the progression of her disease.

Table 2. Remaining Eudravigilance Cases

	EMA Reference	Pfizer AER PTs reported	Pfizer Summary
8	(b) (6)	(b) (6) Haemorrhage, Herpes zoster, Aphasia, Cerebral venous sinus thrombosis, Immune thrombocytopenia, Contusion, Rectal haemorrhage	83-year-old woman with a history that included head injury, hypertension, chronic lymphocytic leukaemia and recent treatment for cancer (radiotherapy or chemotherapy), high cholesterol, low folate, and atrial fibrillation, taking amlodipine, apixaban, atorvastatin, and candesartan. She was reported to have had a platelet count of 129 in Oct 2020. She received dose 1 of vaccine on 08 Jan 2021 and a complicated medical course followed. On 13 Feb 2021, she was found to have a platelet count of 3 (nadir was 1) and diagnosed with ITP. Infectious screen (HIV, HBV, HCV, herpes zoster and CMV) was negative as was an autoimmune screen. She was treated with dexamethasone, IVIG and prednisolone and was reportedly unresponsive to treatment. She began romiplostim and after the 3rd dose, her platelet count was improving however, on 12 Mar 2021 she developed an expressive dysphasia and brain imaging showed a CVST. A thrombophilia screen was negative. Her platelet count was 122 on 19 Mar 2021, but it dropped to 3 on 01 Apr 2021 after missing a dose of romiplostim. The outcome of ITP is recovering, and the rest of the events is unknown. This elderly woman has several medical issues, including cancer and recent treatment for cancer, AF and head injury, complicating assessment of the thrombocytopenia and CVST.
9	(b) (6)	(b) (6) Thrombocytopenia	Upon review of the narrative, this case appears to be a duplicate of AER (b) (6) (b) (6) and will be further investigated.
10	(b) (6)	(b) (6) Hemiparesis, Malaise, Platelet count decreased, Myalgia, Thrombophlebitis, Headache, Fatigue	74-year-old man with a history of alpha-2 antiplasmin deficiency, pulmonary embolism (May 2020) taking hydrochlorothiazide, clopidogrel and candesartan. On 31 Mar 2021, he received dose 1. The following day, his right arm lost strength for about 5 minutes, he had a headache and myalgia and fatigue. On 02 Apr 2021, he was examined to investigate for a TIA. An MRI (brain) was done (no results provided), an unspecified duplex test and heart rhythm test were done (no results provided). His platelet count decreased to 158 (they were 274 on 25 Jan 2021). On 05 April, he was diagnosed with thrombophlebitis of the left leg (no DVT). At the time of the report, he was recovering from fatigue, had not recovered from malaise and headache and had recovered from hemiparesis, decreased platelet count, muscle strain and thrombophlebitis. The patient reported that his hematologist concluded that hematologically there were no impediments to receiving dose 2, however, the patient opted to cancel it. This patient did not have evidence of a deep venous thrombosis and TIA was not confirmed. The platelet count was not reported to be <150

Table 2. Remaining Eudravigilance Cases

	EMA Reference	Pfizer AER PTs reported	Pfizer Summary
11	(b) (6)	(b) (6) Cerebral venous sinus thrombosis, Coagulopathy, Cardio-respiratory arrest, Thrombocytopenia, Neutropenia, Lymphocytosis, Leukocytosis	55-year-old woman with a history of obesity and legionella infection and acute respiratory failure (2009); medications were not reported. She had dose 2 on 07 Jan 2021 and dose 2 on 28 Jan 2021. The following day she developed a headache and began vomiting, she presented to medical attention on 01 Feb and MRI head and angiogram were indicative of a cerebral venous sinus thrombosis (right transverse sinus, distal portion of the left transverse sinus, sigmoid sinus). A head CT showed hyperdensity of the falx cerebri and a hemorrhagic focus in the right parietal area; therapy with enoxaparin was begun; the patient became sleepier with time and a repeat CT of the head was unchanged. Labs: D-dimer (increased) 8038 ug/l; lymphocytes (increased) 16200; neutrophils (decreased) 500; Platelets (decreased) 59,000; WBC (increased) 17,000. Early the next morning, the patient went into cardio-respiratory arrest and died. An autopsy was ordered but it is not known if it was conducted. Cause of death were reported as sinus cerebral thrombosis, coagulopathy, and cardio-respiratory arrest. A product quality investigation for the batch was done and no quality issues were identified. This report was discussed in the submitted SSRM #4 review of Embolic and Thrombotic Events (Appendix 3.2)

Of the 11 cases, AER (b) (6) appears to be a duplicate of AER (b) (6) and will be investigated. Of the 10 remaining cases, 7 do not describe concurrent thrombocytopenia (platelets $<150 \times 10^9/L$) and intravascular venous or arterial thrombosis. Of the 3 reports that do describe the occurrence of intravascular thrombosis and thrombocytopenia:

- AER (b) (6) describes a woman with metastatic pancreatic cancer and possible DIC, which are more likely causes of the thrombosis and thrombocytopenia
- AER (b) (6) describes an elderly woman with a baseline thrombocytopenia, head injury and a malignancy, which put into doubt any role of the vaccine
- AER (b) (6) describes a middle-aged woman who does not have a clear alternative explanation for the development of CVST although her obesity may be a risk for thrombosis. And although her WBC is elevated, the lack of further lab work including an infection work-up, limits the ability to come to a conclusion on the etiology of her medical conditions. This case was reviewed in a previous evaluation of thromboembolic cases (SMSR #4).

This review does not identify a new safety signal for the Pfizer/BNT COVID-19 vaccine.

ⁱ Brighton Collaboration Updated Proposed BC process for developing a standard case definition for study of new clinical syndrome X, as applied to Thrombosis with Thrombocytopenia Syndrome (TTS), 18 May 2021 v 10.16.3.

ⁱⁱ ISTH.org website (ISTH VITT Flow Chart Final (ymaws.com))



Pfizer-BioNTech COVID-19 Vaccine (BNT162, PF-07302048)

Safety Evaluation of Transverse Myelitis

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LIST OF ABBREVIATIONS

Abbreviation	Definition
ADEM	acute disseminated encephalomyelitis
COVID-19	Coronavirus Disease 2019
CSF	cerebrospinal fluid
IgG	immunoglobulin G
IgM	immunoglobulin M
IV	intravenous
MAH	Marketing Authorization Holder
MedDRA	Medical Dictionary for Regulatory Activities
MRI	magnetic resonance imaging
O/E	observed to expected ratio
PCR	polymerase chain reaction
SARS	Severe Acute Respiratory Syndrome
SARS-CoV-2	Coronavirus-2; virus causing the disease COVID-19
Tdap	tetanus, diptheria, and pertussis
TM	transverse myelitis
WBC	white blood cell

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1. INTRODUCTION

Transverse myelitis (TM) is a neurological disorder causing segmental bilateral acute spinal cord injury as a result of acute inflammation. It is seen in relation to infectious processes, autoimmune process like systemic lupus erythematosus, mixed connective tissue disorder, Sjogren's syndrome, systemic sclerosis, antiphospholipid antibody syndrome, ankylosing spondylitis, rheumatoid arthritis, intoxications (baclofen, penicillin, lead) and multiple sclerosis..¹ Up to 50% of patients presenting with TM have a preceding infection.¹ The most common microbiological agents related to TM include: viral (with enterovirus and coxsackie virus being the most common), mycoplasma, and schistosomiasis. In most cases, symptoms of TM begin after the patient has recovered from the infectious disease and the infectious agents have not been isolated from the nervous system. Thus, microbiologically associated TM does not appear to be a direct infectious process, but rather an autoimmune response that may be triggered by an infectious agent. Idiopathic TM accounts for about 10 to 45% of all cases.¹ Approximately one third of patients recover with little to no sequelae, one third have moderate degree of residual disability, and one third may have severe disabilities.

Estimates of incidence of acute transverse myelitis (TM) are varied, the annual incidence rate ranged from 1.34 per million to 3 per 100,000. Age distribution appear to be bimodal, with peaks between 10-19 and 30-39 years of age. No gender, ethnic, or geographic predispositions have been established.^{1,2}

2. TRANSVERSE MYELITIS AND VACCINATION

A multi-analysis study by Agmon-Levin et al³ on TM temporally related to vaccination reported 37 cases published over 39 years (between 1970 and 2009). In most cases, occurrence was between several days and 3 months following vaccination. The authors conclude that the association between vaccines and autoimmune diseases remains an issue of debate for most vaccines. As not all individuals who suffered from an infection will eventually develop an autoimmune phenomenon, it was suggested that autoimmune diseases develop in those who are genetically susceptible.

Another study analyzed the association of immunization and subsequent development of TM or acute disseminated encephalomyelitis (ADEM) post vaccination.⁴ The authors identified all cases of TM and ADEM in the Vaccine Safety Datalink population (a collaboration between the US Centers for Disease Control and Prevention and several US integrated health systems), then using a case-centered method, compared vaccination of each case to vaccination of all matched persons in the study population, who received the same type of vaccine, with respect to whether or not their vaccination occurred during a predetermined exposure interval. Using this method, a risk difference (excess risk) of TM and ADEM was calculated for each vaccine. The analysis includes nearly 64 million vaccine doses, with the authors concluding that for TM, there was no statistically significant increased risk due to immunization. For ADEM, there was no statistically significant increased risk following any vaccine except for Tdap (adolescent and adult tetanus, reduced diphtheria, acellular pertussis) vaccine.

3. TRANSVERSE MYELITIS AND COVID-19

Coronavirus infections have been associated with neurological manifestations (eg, febrile seizures, convulsions, change in mental status, and encephalitis).^{5,6} Neurotropic and neuroinvasive capabilities of coronaviruses have been described in humans. Upon nasal infection, coronavirus enters the central nervous system through the olfactory bulb, causing inflammation and demyelination.⁶ In addition, most coronaviruses share similar viral structures and infection pathways; hence, the pathomechanisms previously found for other coronaviruses may also be applicable for SARS-CoV-2. A growing body of evidence suggests that neuroinvasion and neurotropism is a common feature of human coronaviruses.⁵ Infection with SARS-CoV-2 has been associated with neurological manifestations, and in a few cases the virus presence and/or antibody presence has been shown in cerebrospinal fluid.⁷⁻⁹ Several case reports describing transverse myelitis in temporal relationship with Coronavirus infection have been published. Most cases reported a time to onset between 8 days to 3 weeks upon infection symptoms. In most cases, SARS-CoV-2 infection was detected only after hospitalization due to the transverse myelitis symptoms.¹⁰⁻¹⁴

In a few cases, the throat swab showed a negative SARS-CoV-2 PCR and positive antibodies (IgM and IgG), while in other cases antibodies could not be detected, while the throat swab SARS-CoV-2 PCR was positive.¹⁰⁻¹⁵ These data suggest that time to onset from infection to development of transverse myelitis may vary. In all published cases no other infective agents have been detected in blood examination nor in the cerebrospinal fluid. In all reported cases lymphocytosis was present in the cerebrospinal fluid while the protein level varied from normal to extremely high in different subjects. Treatments including corticosteroid, immunoglobulin and plasma exchange have resulted in improvement of signs and symptoms.¹⁰⁻¹⁵

Nevertheless, despite an extensive workup, as many as 60% of cases may remain idiopathic, meaning the exact pathophysiology of the disease is unknown and varies based on etiology.¹⁶ When related to an infectious cause, it is often attributed to an autoimmune-mediated response, as opposed to direct invasion and injury of the spinal cord. Currently, no definitive conclusion may be drawn, and the mechanism through which SARS-CoV-2 may be linked to TM is still unclear.

4. METHOD

Pfizer's safety database contains cases of adverse events reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious adverse events reported from clinical studies regardless of causality. The Pfizer safety database was searched for all COVID-19 Vaccine cases received through 17 May 2021 using the MedDRA version 23.1 using the search criteria: MedDRA High Level Terms 24:0. Myelitis including infective.

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an adverse event, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.
- Because many external factors influence whether or not an adverse event is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.
- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.
- An accumulation of adverse event reports does not necessarily indicate that a particular adverse event was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

The Brighton Collaboration criteria¹⁷ will be used for diagnostic criteria of certainty as described below:

Level 1 of diagnostic certainty: Myelitis

a) Demonstration of acute spinal cord inflammation (\pm meninges) by histopathology.

Level 2 of diagnostic certainty: Myelitis

(a) Myelopathy (development of sensory, motor, or autonomic dysfunction attributable to the spinal cord, including upper- and/or lower-motor neuron weakness, sensory level, bowel and/or bladder dysfunction, erectile dysfunction).

AND

(b) **TWO OR MORE** of the following indicators suggestive of spinal cord inflammation:

1. Fever (temperature ≥ 38 °C),
2. CSF pleocytosis (>5 WBC/mm³ in children >2 months of age; >15 WBC/mm³ in children <2 months of age),
3. Neuroimaging findings demonstrating acute inflammation (\pm meninges), or demyelination of the spinal cord.

Level 3 of diagnostic certainty: Myelitis

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(a) Myelopathy (development of sensory, motor, or autonomic dysfunction attributable to the spinal cord, including upper- and/or lower-motor neuron weakness, sensory level, bowel and/or bladder dysfunction, erectile dysfunction).

AND

(b) **ONE** of the following indicators suggestive of spinal cord inflammation:

4. Fever (temperature $\geq 38^{\circ}\text{C}$),
5. CSF pleocytosis (>5 WBC/ mm^3 in children >2 months of age; >15 WBC/ mm^3 in children <2 months of age),
6. Neuroimaging findings demonstrating acute inflammation (\pm meninges), or demyelination of the spinal cord.

5. RESULTS

A total of 67 cases were identified using the search criteria mentioned above as of 17 May 2021. There were 51 females, 15 males, and in one case gender was not reported. The group included people aged 21 to 84 years (mean 48, median 43). The age distribution was: 53 (79.1%) adults (age ≥ 18 to <65), 11 (16.4%) elderly (age ≥ 65), and 3 (4.5%) where the age was not reported. Most of the cases were reported from UK (23, 34.3%), followed by United States (20, 29.9%). The outcome of the event was reported as not recovered at time of reporting in 30 cases (44.8%) resolving/recovering in 25 (37.3%) and unknown in 15 cases (17.9%). All cases were assessed as serious. All cases have been assessed according to BC criteria as follows:

- 0 cases (0%) met level 1
- 2 cases (3%) met level 2
- 5 cases (7.5%) met level 3
- 53 cases (79.1%) met level 4
- 7 cases (10.4%) met level 5

Six cases reported TM in the context of ongoing cancer and were suggestive of a paraneoplastic process. In 5 cases the TM was reported in subjects with underlying TM, optic neuritis or confounded with therapy used (eg, adalimumab). In additional 6 cases the diagnostic examination (MRI and/or Cerebrospinal fluid) did not support the diagnosis of TM. In 9 cases the examination and/or medical history supported the alternate diagnosis of multiple sclerosis.

The remaining 41 cases, one case is reported 3 times and 1 case report of a single subject reporting TM after the first dose and worsening after the 2nd dose. Overall, there are 38 unique cases remaining. Among them 20 cases were reported after vaccination dose 1, 6 after dose 2, and for 12 the dose number was not reported.

Of these 38 cases the BC was assessed as follows:

Of these 38 cases the BC was assessed as follows:

BC 1: 0

BC 2: 2

BC 3: 2

BC 4: 33

BC 5: 1

Time to onset was reported for 34 cases and ranged from the same vaccination day to 21 days after vaccination (mean: 6.5; median: 5). Details are reported in Table 1.

Table 1. Time to Onset After Vaccination

Time (days) to Onset	Number of Cases
0-1	7
2-4	9
5-7	5
8-15	11
16-21	3
0-1	7
Total	35

Cases meeting BC 1 according to the Brighton collaboration criteria:

There were no cases that provided information for definitive TM per Brighton collaboration criteria.

Cases meeting BC 2 and 3 according to the Brighton collaboration criteria:

(b) (6) (BC 2): 60-year-old male patient received COVID-19 Vaccine on 29 January 2021. The patient's medical history included acute prostatitis and dysuria with prostate-specific antigen and a recent infection and intravenous (IV) antibiotic therapy was reported. He was hospitalized on 04 February 2021 for paresthesia and subacute onset of gait impairment. Clinical examination showed the following: proprioceptive-looking ataxia with widening of the support polygon, proprioceptive damage to the 4 limbs, hypopallesthesia of the bilateral lower limbs reaching up to the knees, anesthesia of the perineum. No motor deficit. Lumbar puncture: inflammatory fluid predominantly lymphocytic, reactive in appearance. Proteinorachia at 0.51 g /L. Spinal cord MRI: Posterior cervical myelitis over approximately 6 cm at the level of the C2-C3-C4 vertebrae without contrast enhancement. Cerebral MRI: possible old ischemic sequela. Complete infectious and immunological

assessments without particularities. Diagnosis: acute posterior cervical myelitis, probably post-infectious, with no etiological agent found. Probabilistic anti-infective treatment with acyclovir, doxycycline, cymevan was initiated as well as corticosteroid therapy. The clinical course was satisfactory with progressive neurological recovery.

(b) (6) (BC 3): A 69-year-old female patient received COVID-19 Vaccine on 20 January 2021. The patient's medical history included hyperlipidemia, hypothyroid, restless legs. Two days after vaccination the patient developed weakness of legs then arms. MRI cervical and thoracic spine on January 2021 most consistent with TM. The patient was recovering. IV steroids and physical therapy were received as treatment. The outcome of the events was reported as recovering.

(b) (6) (BC 2): A 37-year-old female patient received the first dose of COVID-19 Vaccine on 26 January 2021. The patient's medical history included type 2 diabetes mellitus, type 1 diabetes, hypothyroidism, hyperglycemia, diabetes under multiple concomitant medications. The patient previously received influenza vaccine (unknown manufacturer) in December 2020 for immunization. Three days after Covid-19 vaccination the subject reported paresthesia all over the body with some reduction in sensation/reduced sensation bilaterally below T3. Five days later she was hospitalized and underwent magnetic resonance imaging (MRI), lumbar puncture and several other tests and was diagnosed with transverse myelitis (C3 lesion and increased cells and oligoclonal band positive in cerebrospinal fluid). She was treated with steroids by IV drip and oral. The patient outcome of the events was not recovered. No results of infectious or other etiologic work-up was provided.

(b) (6) (BC 3): A 75-year-old female received the first dose of COVID-19 Vaccine on 23 January 2021. The patient's concurrent conditions included hypertension, hyperlipidemia, GERD, blood glucose elevated, degenerative disc disease, history of nonmelanoma skin cancer, irritable bowel syndrome, keratoconus of both eyes, corneal transplant, deep vein thrombosis pulmonary embolism in 2019, left leg weakness, myelitis, osteoarthritis, osteopenia, pulmonary emboli, sensory impairment, spinal stenosis, vaccination complication, vitamin D deficiency and pregnancy; surgical history included: total vaginal hysterectomy, bilateral ureteral stent placements, lumbar decompression under multiple concomitant medication. One day post vaccination the subject reported numbness of the left lower leg and was diagnosed with TM, and started on IV steroids for 5 days. Lumbar puncture high number of cells and thoracic MRI shows T2 hyperintensity in dorsal lateral cord. No results of infectious or other etiologic work-up was provided. She was sent into a rehabilitation clinic and was recovering from the TM event.

6. OBSERVED VERSUS EXPECTED ANALYSES

The MAH conducted unadjusted observed to expected ratio (O/E) analyses for the 67 reported TM cases. The O/E ratio was above 1 for the 21-day risk window and below 1 for the no risk window, indicating there may be an increased risk of TM among recipients of the BNT162b2 vaccine.

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Table 2. Observed versus Expected (O/E) Analysis of 67 Spontaneously Reported Transverse Myelitis Cases through 10 May 2021

	21-Day Risk Window (12,398,436 PY^a)	No Risk Window (34,796,539 PY)
O/E ratio (95% CI)	1.544 (1.197, 1.961)	0.550 (0.426, 0.699)
Expected cases ^b	43	122

a. PY through 09 May 2021

b. Derived from 0.35 per 100,000 PY background rate

Expected case counts were derived using a background incidence rate of 0.35 per 100,000 person years¹⁸ This rate was calculated from the background rates provided by the ACCESS/VAC4EU initiative. The incidence rates (narrow case definition) from 2017-2019 were averaged within each of the ten data sources where available. From these, a single average rate was selected based on the range of observed values, type of care typically sought for the AESI (e.g. hospital or general practitioner), and relevant characteristics of the databases, as described in the ACCESS User Guide.¹⁹ The ACCESS background rate is derived from medical records coded as transverse myelitis or acute transverse myelitis.²⁰ Observed cases were identified in the spontaneous reporting system using the PT codes acute flaccid myelitis, bulbar poliomyelitis, myelitis, myelitis transverse, noninfectious myelitis, paraneoplastic myelopathy, poliomyelitis, post-polio syndrome, spinal cord infection, vaccine associated paralytic poliomyelitis, and viral myelitis, which is broader than the definition used by ACCESS. Person years of exposure estimates were derived from publicly available information reported by countries where COVID-19 Vaccine is authorized.²¹ For periods when more than one vaccine brand was authorized for use in each country, the doses administered were assumed to be divided equally by the number of brands of vaccines authorized. The estimate of administered doses does not reflect exposure in persons vaccinated in countries that did not publicly report.

O/E ratios were calculated using a 21-day risk window and no risk window. However, the 21-day risk window was not applied to the observed case count; all 67 cases were included in the numerator regardless of the duration between vaccination and event onset date.

Several limitations of the observed to expected comparison must be noted. With respect to observed cases, case ascertainment through the spontaneous reports likely reflect an underreporting due to incomplete reporting or a lag in reporting. Additionally, spontaneous surveillance systems are prone to reporting bias whereby events that have been previously identified as potentially related to the vaccine are more likely to be reported despite not meeting the clinical definition. Conversely, events that have not been previously associated with a vaccine are likely to be underreported.

With respect to the expected case counts, estimates concerning both exposure to vaccine and the background rate have limitations. Our exposure estimate assumes that the number of reported administrations is complete and accurate when in fact not all countries administering vaccine have reported counts of vaccine administration to the data source. Thus, the exposure is underestimated.

The expected count also assumes that the expected incidence rate in the vaccinated population is the same as that in the population used to calculate the background rate. However, it is possible that the delivery of health care, population demographics, and underlying health status of the population used for the background rate estimate differ from those expected in the vaccinated population. To date, the United States contributes the most exposure data.

A final limitation concerns the risk window, the period during which one is expected to be at risk of a given event if there is a causal association between the event and the vaccine. Two periods, 21 days and no risk window, were selected to provide an estimate assuming a more acute onset (21-day window) and a more latent onset (no risk window). The 21-day risk window is particularly conservative as all observed cases are included in the numerator of the O/E ratio regardless of the days since vaccination dose, which will lead to an overestimation of the ratio if observed cases occurred outside of the risk window.

7. SUMMARY AND CONCLUSION

Most cases were assessed as BC level 4 (79.1%) and were reporting insufficient information for a proper evaluation. In addition, 26 cases (39%) were reported in the context of ongoing cancer or in subjects with underlying TM, or diagnostic examination (MRI and/or cerebrospinal fluid) did not support the diagnosis of TM or supported instead a pre-existing multiple sclerosis diagnosis.

Four cases without these confounding factors and meeting BC level 2-3 were identified, of them one was an elderly frail subjects with multiple underlying comorbidities, another case reported infections few days before the onset of TM, and the 2 remaining cases were reported in an adult and an elderly subject with underlying autoimmune linked disease (diabetes and hypothyroidism respectively) that 2 and 3 days after the first vaccine dose reported the symptomatology.

The E/O analysis showed a small increase over the 21 days risk window nevertheless, as described in the O/E analysis the 21-day risk window is particularly conservative as all observed cases are included in the numerator of the O/E ratio regardless of the days since vaccination dose, which will lead to an overestimation of the ratio if observed cases occurred outside of the risk window. In addition, the ACCESS background rate used to calculate the expected number of cases is derived from medical records coded as transverse myelitis or acute transverse myelitis while the observed cases were identified in the spontaneous reporting system using a broader search criteria (as specified in the method). The upper limit of the 95% confidence interval for the observed to expected ratio without a risk window did not exceed 1.

Overall, given the totality of the available information, changes in the risk minimization measures or updates to the product information label are not warranted at this time. The benefit risk profile of the vaccine remains favorable. The topic will continue to be closely monitored.

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8. REFERENCES

1. Bhat A, Naguwa S, Cheema G, et al. The epidemiology of transverse myelitis. *Autoimmunity Reviews*. 2010;9(5):A395-A99.
2. Berman M, Feldman S, Alter M, et al. Acute transverse myelitis: Incidence and etiologic considerations. *Neurology*. 1981;31(8):966-66.
3. Agmon-Levin N, Kivity S, Szyper-Kravitz M, et al. Transverse myelitis and vaccines: a multi-analysis. *Lupus*. 2009;18(13):1198-204.
4. Baxter R, Lewis E, Goddard K, et al. Acute Demyelinating Events Following Vaccines: A Case-Centered Analysis. *Clin Infect Dis*. 2016;63(11):1456-62.
5. Desforges M, Le Coupanec A, Dubeau P, et al. Human Coronaviruses and Other Respiratory Viruses: Underestimated Opportunistic Pathogens of the Central Nervous System? *Viruses*. 2019;12(1):14.
6. Bohmwald K, Gálvez NMS, Ríos M, et al. Neurologic Alterations Due to Respiratory Virus Infections. *Front Cell Neurosci*. 2018;12:386-86.
7. Hung ECW, Chim SSC, Chan PKS, et al. Detection of SARS coronavirus RNA in the cerebrospinal fluid of a patient with severe acute respiratory syndrome. *Clin Chem*. 2003;49(12):2108-09.
8. Lau K-K, Yu W-C, Chu C-M, et al. Possible central nervous system infection by SARS coronavirus. *Emerg Infect Dis*. 2004;10(2):342-44.
9. Li Y, Li H, Fan R, et al. Coronavirus Infections in the Central Nervous System and Respiratory Tract Show Distinct Features in Hospitalized Children. *Intervirology*. 2016;59(3):163-69.
10. Chow CCN, Magnussen J, Ip J, et al. Acute transverse myelitis in COVID-19 infection. *BMJ Case Rep*. 2020;13(8).
11. Kaur H, Mason JA, Bajracharya M, et al. Transverse Myelitis in a Child With COVID-19. *Pediatr Neurol*. 2020;112:5-6.
12. Munz M, Wessendorf S, Koretsis G, et al. Acute transverse myelitis after COVID-19 pneumonia. *J Neurol*. 2020;267(8):2196-97.
13. Sarma D, Bilello LA. A Case Report of Acute Transverse Myelitis Following Novel Coronavirus Infection. *Clin Pract Cases Emerg Med*. 2020;4(3):321-23.
14. Zachariadis A, Tulbu A, Strambo D, et al. Transverse myelitis related to COVID-19 infection. *J Neurol*. 2020;10.1007/s00415-020-09997-9:1-3.
15. Asadi-Pooya AA, Simani L. Central nervous system manifestations of COVID-19: A systematic review. *J Neurol Sci*. 2020;413:116832-32.
16. Kerr DA, Ayetey H. Immunopathogenesis of acute transverse myelitis. *Curr Opin Neurol*. 2002;15(3):339-47.
17. Sejvar JJ, Kohl KS, Bilynsky R, et al. Encephalitis, myelitis, and acute disseminated encephalomyelitis (ADEM): case definitions and guidelines for collection, analysis, and presentation of immunization safety data. *Vaccine*. 2007;25(31):5771-92.
18. Willame C DC, Gini R, et al. Background rates of Adverse Events of Special Interest for monitoring COVID-19 vaccine, FISABIO 2017-2019. Updated March 2021. Available from: <https://vac4eu.org/covid-19-tool/>. Accessed on: 21 May 2021.

19. EMA. ACCESS background incidence rates of AESIs – User guide. Available from: http://www.encepp.eu/documents/ACCESSbackgroundrates-Userguide_000.pdf. Accessed on: 06 May 2021.
20. Willame C DC, Gini R, et al. ACCESS Background rates of Adverse Events of Special Interest for monitoring COVID-19 vaccines D3-Draft Final Report Updated 30 April 2021. Available from: https://vac4eu.org/wp-content/uploads/2021/05/D3_ACCESS_Report_BGR_20210430_v.1.2_submitted.pdf. Accessed on: 01 Jun 2021.
21. Ritchie H O-OE, Beltekian D, et al. Our World in Data. Coronavirus (COVID-19) Vaccinations. Available from: <https://ourworldindata.org/covid-vaccinations#daily-vaccination-rates>. Accessed on: 21 May 2021.

APPENDIX 3.7 SAFETY EVALUATION OF DIZZINESS

Pfizer-BioNTech COVID-19 Vaccine

Dizziness

Report Prepared by:

BioNTech-Pfizer

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1. INTRODUCTION

Dizziness is a common yet imprecise symptom often encountered by physicians. Primary care physicians see at least one-half of the patients who present with dizziness. The differential diagnosis is broad, with each of the common etiologies accounting for no more than 10% of cases. Because the symptoms are vague, physicians must distinguish benign from serious causes that require urgent evaluation and treatment. (1)

Dizziness has been reportedly in association with other vaccines, including the influenza vaccine. (2)

2. METHODOLOGY

Pfizer's safety database contains adverse events reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious adverse events reported from clinical studies regardless of causality.

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an adverse event, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.
- Because many external factors influence whether or not an adverse event is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.
- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.
- An accumulation of adverse event reports does not necessarily indicate that a particular adverse event was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication..

The Pfizer safety database was searched for all BNT162b2 vaccine reports received cumulatively through 30 April 2021 using the following MedDRA version 24.0 search criteria: PT Dizziness. The data was analyzed in two cohorts, Dizziness occurring within the first 24 hours (Latency of Day 0) versus those with a latency of 1-2 days post vaccination with attention to co-reported systemic reactogenicity symptoms during this time frame. Dizziness reported during the placebo-controlled stage of Phase 2/3 clinical study C4591001 was also reviewed.

3. RESULTS

3.1. Unblinded clinical study data

Of subjects reporting at least 1 adverse event from dose 1 to 1 month after dose 2 in the blinded placebo-controlled follow-up period of Phase 2/3 clinical study C4591001 (data-lock date 13 Mar 2021), 78 (0.4%) of 21,926 participants in the active cohort reported dizziness, compared to 60 (0.3%) of 21,921 participants in the placebo cohort. Postural dizziness was reported by 2 (0.0%) BNT162b2 recipients and 1 (0.0%) placebo recipient.

3.2. Post-authorization data

The search identified 15250 cases, of them 11800 reported a latency ranging from Day 0 until Day 10, *please refer to Table 1 for description*. There were 12149 (79.7%) females, 2746 males (18%), and gender was not reported in 355 cases.

Most cases were reported from the United Kingdom (3803) followed by Mexico (3514), and the United States (3380). The most frequent reported age was between 31-50 years old with a mean of 46.3 and median of 46.0. Age distribution is reported below in Table 2.

Table 1: Dizziness events: Number of events with latency of Day 0 to Day 10 (11800)

Latency	0	1	2	3	4	5	6	7	8	9	10	Grand Total
Case count	6100	3753	818	395	259	144	99	92	52	44	44	11800

Table 2 Dizziness - Age distribution of total (15250) cases

Age	Count	%
Less than or equal to 17 years	38	0.20%
18 - 30 years	2669	17.50%
31 - 50 years	6243	40.90%
51 - 64 years	2861	18.80%
65 - 74 years	1185	7.80%
Greater than or equal to 75 years	1075	7.00%
Unknown	1179	7.70%

3.2.1. Dizziness – Latency Day 0

Dizziness events occurring with the first 24 hours post vaccination were a total of 6100 (Approximately 40 %) of the total cases. Co-reported events were most commonly reactogenicity events. The most common were headache (2718), nausea (2097), asthenia (1216), and chills (1130). Of note, pointing to a status of anxiety and stress condition, tachycardia was reported in 772 cases (approximately 11%) of Dizziness. There were 4 cases with a fatal outcome, *please refer to Table 4 for description of all events with fatal outcome*. The age of the patients was between 80-94 years old. Three of the patients had a medical history of neurological and cardiac manifestations. No autopsy reports were provided.

Out of the 6100 reports that included dizziness occurring on the day of vaccination, 4 cases were co-reported with impaired ability to drive:

(b) (6) : 35-year-old male from the US received first dose on 19 December 2020, history included ongoing exercised induced tachycardia. The patient has no known allergies. The patient experienced lightheaded, mild confusion, rapid breathing and difficulty driving on 19Dec2020, started 5-10 minutes after injection that lasted approximately an hour. Event was assessed as serious medically significant. Recovered after one hour.

(b) (6) : 39-year-old female from the UK received first dose on 04 January 2021. On 25 January 2021 after her second injection, the patient experienced her lips started tingling and getting numb. One hour and 30 minutes after the injection, her throat started swelling, had a hard time drinking water with. On the same day she experienced generalized prickle sensation occurred and prickle tingling sensation of upper and lower lip vermillion. She also had dizzy spells for 3 days after vaccination. She presented with severe dizziness and reported she could not walk or drive. The patient recovered on 25Jan2021. No hospitalization was involved.

(b) (6) : 39-year-old female from the UK received first dose on 13 Feb 2021. It was reported that on 13Feb2021, after 5 minutes the patient had tingling in arm and hand, then tingling in lips, then left arm. The patient was also dizzy when she stood up so she was taken to the room to lie down. She couldn't drive home. Rest of the day and most of following, she was extremely tired, felt weird and weak.

(b) (6) : 40-year-old female from Ireland, received her vaccination on 04 Jan 2021. The patient experienced dizziness, lethargy, disturbance in attention/ inability to concentrate, dysarthria/slurred speech, feeling drunk and feeling abnormal/ brain feeling foggy following vaccination on 04Jan2021 (one-hour post vaccination) As of 29 Jan 2021, the patient outlined that the neurological symptoms she experienced previously (dizziness, inability to concentrate, slurred speech, foggy feeling in head and feeling drunk) had improved on an unspecified date. However, on an unspecified date, she experienced headaches, neck and shoulder pain (on the side of injection site), also felt more tired than usual/tiredness. The patient had to take a week off work and did not feel confident driving either. The outcome of the events was recovered on an unspecified date.

3.2.2. Dizziness – Latency Day 1-2

Dizziness events occurring within 1-2 days post vaccination were a total of 4570 (30%) of the total 15250 reports of dizziness. Reactogenicity events were also commonly co-reported with these cases. The most common co-reported systemic reactogenicity symptoms were headache (2092), nausea (1694), asthenia (1216), and fatigue (1282). Out of these 4570 cases, the majority of cases with reported outcome were recovered/resolved (1798).

Out of 4570 reports that included dizziness occurring on the day of vaccination, 7 cases were co-reported with impaired ability to drive.

(b) (6) : A 54-year-old female from the UK received the vaccine (unspecified if dose 1 or dose 2) on the evening of 02 Feb 2021 and reported feeling very dizzy the following day to the extent that she had to hold onto something to steady herself. She was not able to drive that day due to the dizziness. She did not provide information on other symptoms she may have been experiencing. She reported she was much better Day 2 and 3 after vaccination with a couple of dizzy spells. She was recovering from dizziness at the time of the report.

(b) (6) : A 54-year-old female patient from the US. On Wednesday, 10 Feb 2021, she received her second injection. At night, she experienced severe headache and chills. She fainted the next morning and fell down a flight of stairs that resulted in a fracture of the right thumb in addition to experiencing a separated shoulder bone, a whiplash and a concussion. She continues to experience dizziness. She cannot complete household tasks, still cannot drive and can't go to work and has been off work since then.

(b) (6) : 46-year-old male from UK. Received his second dose on 01 Mar 2021. On the same day, he experienced dizziness, vertigo. The subsequent day, the patient experienced nausea and he was unable to safely drive home from work. The symptoms resolved the subsequent day. . The event was assessed as serious/Medically significant.

(b) (6) : Male patient from the US, age unknown. Received the vaccine on 08Apr2021, Three days later he became dizzy, and complained of vertigo and tinnitus, He could not drive.

(b) (6) : 49-year-old female from the UK. Received the vaccine on 12 Jan 2021. Experienced dizziness a day later on 13 Jan 2021. She was unable to drive on an unspecified date. She recovered from dizziness on 15 Jan 2021.

(b) (6) : 45-year-old female from the US. She received her vaccine on 30 Dec 2020. On the same day she experienced dizziness with visual disturbances, which increased going forward until. 20Jan2021. It was impairing her from driving on an unspecified date. She was hesitant to get her second injection. The complications were impairing her ability to drive and was considered as serious (disability).

(b) (6) : 34-year-old female from Ireland. Received her vaccine on 15 Jan 2021. She experienced anaphylactic shock, vomiting, nausea, and inability drive. She continued to have headache for 4 days. She recovered on an unspecified date.

Table 4: Dizziness events with fatal outcome

There were 8 events of Dizziness with a fatal outcome, 4 of them occurred in the first 24 hours after vaccination and 1 occurring on Day 2, with the rest occurring at other periods, for a full description please refer to Table 4.

Dizziness events had a fatal outcome with Latency of Day 0

(b) (6) : Male patient from the UK at an unspecified age received the injection on 17 December 2020. On the same day, the patient experienced nosebleed, headache, vomiting blood and dizziness. On 20 December 2020 the patient died. No autopsy report was provided.

(b) (6) : 80-year-old male from the US. Has a medical history of COPD and Afib. Received his vaccine on 20 January 2021. On the same day he experienced dizziness, headache, nausea. He died on the same day. No autopsy report was provided.

(b) (6) : 95-year-old female from Norway. Has a medical history of dementia and cardiac failure. She received the vaccine on 7 January 2021. She experienced syncope on the same day, laboured breathing, weakness in lower extremities and nausea. She died on 20 January 2021. No autopsy report was provided

(b) (6) : 94-year-old male from France. Medical history includes Alzheimer's disease and osteoporosis. The patient received the vaccine on 9 February 2021. After experiencing dizziness, emesis/vomiting, the patient died on 10 February. No autopsy report was provided

There was one case with fatal outcome with latency of Day 2.

(b) (6) : A 27-year old male from the UK. No medical history reported. Received vaccine on 19 December 2021. Experienced dizziness and vomiting blood 2 days after vaccination. He was pronounced dead on 21 December 2021. No autopsy reports were provided.

Table 4: Dizziness with Fatal outcome

AER Number	Age (years)	Gender	Medical History	Conmed	Events Reported	Country
(b) (6)		MALE	Asthma / Vitamin D deficiency	COLECALCIFEROL / SALBUTAMOL SULFATE	Death, Epistaxis, Headache, Dizziness, Haemoptysis, Haematemesis, Latency: Day 0	UNITED KINGDOM
(b) (6)	27.00	MALE			Haematemesis, Loss of consciousness, Dizziness, Pyrexia, Latency Day 2	UNITED KINGDOM

(b) (6)	63.00	MALE	Angioplasty / Anticoagulant therapy / Bone marrow transplant / Cardiac disorder / Leukaemia / Liver disorder / Myocardial infarction / Osteonecrosis / Stent placement		Acute myocardial infarction, Cardiac arrest, Dizziness, Fall. Latency Day 9	GREECE
(b) (6)	80.00	MALE	Arteriosclerosis / Atrial fibrillation / Chronic obstructive pulmonary disease / Renal disorder		Arteriosclerosis, Cardiovascular disorder, Dizziness, Nausea, Headache. Latency Day 0	UNITED STATES
(b) (6)	91.00	MALE	Atrial fibrillation / Cardiac failure chronic / Chronic respiratory failure / Deep vein thrombosis / Dependence on oxygen therapy / Fall / Hypertension / Implantable defibrillator insertion / Intermittent claudication / Living in residential institution / Non- tobacco user / Pleural effusion / Polymyalgia rheumatica / Prostate cancer / Walking aid user	APIXABAN / BUMETANIDE / MORPHINE / TRAMADOL	Cardiac failure, Hallucination, Oedema peripheral, Confusional state, Dizziness. Latency Day 9	NORWAY
(b) (6)	95.00	FEMALE	Cardiac failure / Dementia / Living in residential institution / Multimorbidity / Treatment noncompliance		Syncope, General physical health deterioration, Dyspnoea, Muscular weakness, Dizziness, Bedridden, Apnoea. Latency Day 0	NORWAY
(b) (6)	66.00	FEMALE	Coeliac disease / Crohn's disease	ALENDRONIC ACID / BUDESONIDE / CALCIUM CARBONATE	Death, Restless legs syndrome, Dizziness, Dyspnoea. Latency Day 0	SWEDEN

(b) (6)	94.00	MALE	Dementia Alzheimer's type / Osteoporosis / Prostatic adenoma / Prostatitis		Death, Chest discomfort, Vomiting, Vertigo, Dizziness, Neuralgia, Fall. Latency Day 0	FRANCE
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4. SUMMARY AND CONCLUSION

The greatest number of post-vaccination spontaneous reports of dizziness was 6100 (40%) in the first 24 hours post-vaccination (Day 0-2). Because dizziness is a term commonly used by patients to describe symptoms that are inconsistently defined, and based on the post-authorization reports, it is plausible that the dizziness experienced soon after vaccination is a potential manifestation of vaccination-related situational stress, anxiety and/or is confounded by the systemic reactogenicity experienced in the same time period. Cases of dizziness that described an inability to drive were relatively rare (11). Additionally, in the course of the Phase 2/3 clinical trials, events of dizziness were not meaningfully different in the active cohort (0.4%) compared to placebo cohort (0.3%).

Taken together, the language proposed by Pfizer/BioNtech to better characterize vaccine stress-related responses in the CDS and local labels, by the inclusion of dizziness as one of the potential stress responses, is appropriate at this time.

5. REFERENCES

- 1- kerson LM. Dizziness: a diagnostic approach. Am Fam Physician. 2010;82(4):361-368, 369.
- 2- PANDEMIC INFLUENZA VACCINE H5N1 BAXTER Suspension for injection Pandemic influenza vaccine (H5N1) (whole virion, inactivated, prepared in cell culture) <https://www.ema.europa.eu/en/medicines/human/EPAR/pandemic-influenza-vaccine-h5n1-baxter-ag>

APPENDIX 3.8 SAFETY EVALUATION OF GUILLAIN-BARRE' SYNDROME

INTRODUCTION

The topic of Guillain Barré syndrome was reviewed because in the French ANSM 14th PV report on AEs reported with the Pfizer-BioNTech Comirnaty vaccine it was considered a potential signal. The review is to include data from spontaneous reports as well as an observed/expected analysis.

1. METHODOLOGY

The Pfizer safety database was searched for all BNT162b2 vaccine cases received through 10 May 2021 using the MedDRA version 24 using the search criteria: SMQ: Guillain-Barré Syndrome, narrow search. The resulting reports were individually reviewed and assessed according to Brighton Collaboration (BC) case definition and level of diagnostic certainty. BC level 1-3 of diagnostic certainty are defined as Guillain-Barré Syndrome or Fisher Syndrome with different level of diagnostic certainty (Sejvar et al 2011). Level 1 provides highest level of diagnostic certainty, whereas the diagnostic certainty is lowest for level 3. Level 4 is defined as "reported event of GBS or FS, with insufficient evidence to meet the case definition" and level 5 as not a case of GBS or FS".

2. RESULTS

A total of 147 cases were identified using the search criteria described above. There were 76 female, 67 males and in 4 cases gender was not reported. The age range between 18 to 97 years of age (59.3 mean). The age distribution was as follows: 80 (54.5%) adults (age ≥18 to <65), 53 (36 %) elderly (age ≥65), and for 14 (9.5 %) cases the age was not reported. Most of the cases were reported from US (36, 24.5%), United Kingdom (30, 20.4%) followed by Japan (12, 8.2%), (see Table 1).

Table 1. Top 10 Countries Reporting GBS

UNITED STATES	36	24.5 %
UNITED KINGDOM	30	20.4 %
JAPAN	12	8.2 %
MEXICO	10	6.8 %
ITALY	9	6.1 %
FRANCE	8	5.4 %
SPAIN	8	5.4 %
GREECE	7	4.8 %
ISRAEL	6	4.1 %
GERMANY	4	2.7 %

The outcome of the event was reported as not recovered at time of reporting in 53 cases (36.1%), as recovering/resolving in 53 cases (36.0 %), and as unknown in 36 cases (24.5%) and fatal in 5 cases (3.4%) (summary reported below).

Time to onset was reported for 117 cases and ranged from 4 hours after vaccination to 63 days after vaccination (see Table 2).

Table 2. Time to Onset

Days after vaccination	Number of cases
Same vaccination day	13
1-3 days	22
4-7 days	27
8-15	24
16-42	27
>42	4
Total	117

A total of 79 cases reported the event after the 1st vaccine doses, 32 after the 2nd dose and the vaccination dose was not reported for 36 cases.

Among the 79 that reported the event after the 1st dose 67 reported the time to onset (see Table 3).

Table 3. Time to Onset After Vaccination Dose 1

Days after 1 st vaccination	Number of cases
Same vaccination day	6
1-3 days	14
4-7 days	11
8-15	16
16-42	17
>42	3
Total	67

Among the 32 cases that reported the event after the 2nd dose 29 reported the time to onset (see Table 4).

Table 4. Time to Onset After Vaccination Dose 2

Days after 2 nd vaccination	Number of cases
Same vaccination day	6
1-3 days	4

4-7 days	9
8-15	5
16-42	5
>42	0
Total	29

Please note that the sum up of the time to onset from the table above is not as the cumulative one as some cases did report the time to onset but did not report the vaccination dose.

The time to onset analysis given the vaccination dose does not evidence any signal.

All cases have been assessed according to BC criteria as follows:

- 4 case (2.7 %) met level 1
- 16 cases (10.8 %) met level 2
- 1 case (0.7 %) met level 3
- 116 cases (79 %) met level 4
- 9 cases (6.1 %) met level 5
- 1 case (0.7%) was referring to another vaccine

The medical history analysis found confounding factors for some cases, as detailed below:

- 2 cases ((b) (6) , (b) (6) meeting BC 4 and 5) reported GBS in the context of cerebrovascular accident
- 4 cases ((b) (6) , (b) (6) , (b) (6) , (b) (6) , assessed as BC level 5 as the symptomatology was long pre-existing) had Chronic inflammatory demyelinating polyradiculoneuropathy. Additional 14 cases (assessed as BC 4: 12, BC 5: 1, BC2: 1) had in the medical history confounding factors as autoimmune disease, HIV, and cancer.
- 9 cases (BC: 4) reported GBS associated or preceded by infection (respiratory or gastrointestinal).
- 3 cases ((b) (6) , (b) (6) , (b) (6)) reported GBS in the context of Covid-19 infection
- 1 case ((b) (6) , BC 1) symptoms were pre-existing the vaccination.

Analysis of cases meeting Brighton collaboration level 1 and 2

Case meeting BC Level 1

Four cases reported GBS assessed as level 1 of Brighton collaboration (BC) as reported both clinical and diagnostic examination (Electroneurography/electromyography and cerebrospinal fluid analysis) compatible with GBS diagnosis. Time to onset varied between 4 to 22 days after vaccination. Of these 4 cases, 1 had signs of demyelination also in the brain suggesting possibly a pre-existing demyelinating pathology. Case details are presented in Appendix 1.

Cases meeting BC Level 2

A total of 16 cases were assessed as BC level 2 as reporting, aside of the clinical examination, either Electroneurography/electromyography or cerebrospinal fluid analysis compatible with GBS diagnosis. Time to onset (TTO) ranged between the same vaccination day to 54 days after vaccination (4 cases reported (TTO) between 0-2 days; 4 cases between 9-14 days; 5 cases between 16-21 days and 1 case 54 days after vaccination). A total of 10 cases reported the vaccination doses and among them 8 cases reported the event after vaccination dose 1 and 2 after dose 2.

Cases reporting the symptoms starting from the same vaccination day to 1-2 days after vaccination reported a time to onset that, even though plausible does not have a biological plausibility to trigger the reported demyelination.

Two cases ((b) (6)) and ((b) (6)) were preceded by a gastrointestinal infection and reported GBS respectively 16- and 18-days post vaccination. One case ((b) (6)) was reported GBS 21 days after vaccination in the context of brain infarct (CT angiography showed dural AV fistula with occluded left transverse sinus, a CT Head left insular/ext capsule infarct). One case ((b) (6)) had the symptoms pre-existing the vaccination and reported a worsening of the same.

Case details are presented in Appendix 2.

Cases reporting a fatal outcome

Five cases reported a fatal outcome after reporting GBS after vaccination, all cases were assessed as BC level 4. All cases were reported in elderly frail subjects where a case ((b) (6)) reported a long time to onset not suggestive of a temporal correlation with vaccination; another case ((b) (6)) report a time to onset of 1 day post vaccination which is unplausible from the mechanistic point of view; another case ((b) (6)) with a medical history of immunodeficiency and pancytopenia reported death 2 months after vaccination with unclear start of the GBS. One case did not report clear time correlation (no vaccination date reported) and last case reported symptoms of weakness and numbness immediately after vaccination, was able to get the 2nd vaccination and was not hospitalized.

All case details are reported in Appendix 3.

3. OBSERVED VERSUS EXPECTED ANALYSIS

The MAH conducted unadjusted observed to expected ratio (O/E) analyses for the 147 reported GBS cases. The O/E ratio was below 1 for both the 21-day risk window and no risk window, indicating there was not an increased risk of GBS among recipients of the BNT162b2 vaccine.

Table 5. Observed versus Expected (O/E) Analysis of 147 Spontaneously Reported Guillain-Barré Syndrome Cases through 10 May 2021

	21-Day Risk Window (12,398,436 PY^a)	No Risk Window (34,796,539 PY)
O/E ratio (95% CI)	0.631 (0.533, 0.741)	0.225 (0.190, 0.264)
Expected cases ^b	233	654

a. PY through 09 May 2021

b. Derived from 1.88 per 100,000 PY background rate

Expected case counts were derived using a background incidence rate of 1.88 per 100,000-person years.¹ Person years of exposure estimates were derived from publicly available information reported by countries where the BNT162b2 vaccine is authorized.² For periods when more than one vaccine brand was authorized for use in each country, the doses administered were assumed to be divided equally by the number of brands of vaccines authorized. The estimate of administered doses does not reflect exposure in persons vaccinated in countries that did not publicly report.

O/E ratios were calculated using a 21-day risk window and no risk window. However, the 21-day risk window was not applied to the observed case count; all 147 cases were included in the numerator regardless of the duration between vaccination and event onset date.

Several limitations of the observed to expected comparison must be noted. With respect to observed cases, case ascertainment through the spontaneous reports likely reflect an underreporting due to incomplete reporting or a lag in reporting. Additionally, spontaneous surveillance systems are prone to reporting bias whereby events that have been previously identified as potentially related to the vaccine are more likely to be reported despite not meeting the clinical definition. Conversely, events that have not been previously associated with a vaccine are likely to be underreported.

With respect to the expected case counts, estimates concerning both exposure to vaccine and the background rate have limitations. Our exposure estimate assumes that the number of reported administrations is complete and accurate when in fact not all countries administering vaccine have reported counts of vaccine administration to the data source. Thus, the exposure is underestimated.

The expected count also assumes that the expected incidence rate in the vaccinated population is the same as that in the population used to calculate the background rate. However, it is possible that the delivery of health care, population demographics, and underlying health status of the population used for the background rate estimate differ from those expected in the vaccinated population. To date, the United States contributes the most exposure data.

A final limitation concerns the risk window, the period during which one is expected to be at risk of a given event if there is a causal association between the event and the vaccine. Two periods, 21 days and no risk window, were selected to provide an estimate assuming a more

acute onset (21-day window) and a more latent onset (no risk window). The 21-day risk window is particularly conservative as all observed cases are included in the numerator of the O/E ratio regardless of the days since vaccination dose, which will lead to an overestimation of the ratio if observed cases occurred outside of the risk window.

4. SUMMARY AND CONCLUSION

Most reported cases (79%) met level 4 of BC. Most cases meeting BC level 1 or 2 were confounded by preceding infection, implausible time to onset, symptoms pre-existing vaccination or GBS in the context of cerebral infarct.

The upper limit of the 95% confidence interval for the observed to expected ratio did not exceed 1; therefore, a signal was not identified.

Overall, given the totality of the available information, GBS is not considered to be a validated signal, changes in the risk minimization measures or updates to the product information label are not warranted at this time. The benefit risk profile of the vaccine remains favorable. The topic will continue to be closely monitored.

5. REFERENCES

1. Willame C, Dodd C, Gini R, et al. Background rates of Adverse Events of Special Interest for monitoring COVID-19 vaccine, FISABIO 2017-2019. Available from: <https://vac4eu.org/covid-19-tool/>. Updated March 2021. Accessed 21 May 2021.
2. Our World in Data. Coronavirus (COVID-19) Vaccinations. Available from: <https://ourworldindata.org/covid-vaccinations#daily-vaccination-rates>. Accessed May 2021.

6. APPENDICES

Appendix 1: Cases meeting BC 1

AER Number	Age / Gender	Medical History	Events	Country	Time to Onset	BC	Comments	Outcome	Dose
(b) (6)	49/F		Guillain-Barre syndrome, Respiratory distress, Paraesthesia, Sensory disturbance, Back pain, Asthenia, Gait disturbance, Dysarthria, Dysphagia, Areflexia	SWEDEN	4	1		not recovered	unk
(b) (6)	64/M	Chronic obstructive pulmonary disease / Hypertension	Guillain-Barre syndrome, Demyelinating polyneuropathy, Balance disorder, Paraesthesia, Diplopia, Eyelid ptosis, Fall	MEXICO	10	1		recovering	1

(b) (6)	82/F	Guillain-Barre syndrome	SPAIN	14	1	demyelinating also in the CNS	unk	1
(b) (6)	80/M	Guillain-Barre syndrome, Hypoaesthesia, Areflexia, Asthenia	ITALY	22	1		unk	unk

Appendix 2: Cases meeting BC 2

AER Number	Age/Gender	Medical History	Events	Country	Time to Onset	BC	Comments	Outcome	Dose
(b) (6)	65/M	Coronary artery disease / Cryptogenic cirrhosis / Drug hypersensitivity / Factor V Leiden mutation / Hyperlipidaemia / Liver transplant / Stent placement / Type 2 diabetes mellitus	Guillain-Barre syndrome, CSF protein increased, Muscular weakness, Pain in extremity, Paraesthesia, Areflexia, Facial paresis, Hypoaesthesia, Lumbar puncture abnormal	UNITED STATES	2	2	albumin-cytological dissociation	not recovered	
(b) (6)	52/M	Haemorrhoids / Lithiasis / Rectal haemorrhage / Renal colic	Guillain-Barre syndrome, Gastroenteritis, Pyrexia	SPAIN	18	2	The neurophysiological study carried out 7 days after the symptomatology onset shows mild alterations compatible with sensitive-motor polyradiculoneuropathy of the demyelinating type (f-wave blockage and affection of disturbance latencies). Gastroenteritis 7 days before starting of the symptoms	not recovered	1
(b) (6)	43/M		Guillain-Barre syndrome, Myelopathy, Intervertebral disc protrusion, White matter	HUNGARY	2 days but symptoms started the same vaccination day	2	EMG, cranial MR, lumbar puncture confirmed Guillain-Barre syndrome	recover with sequel	2

			lesion, Hypoaesthesia, Asthenia, Lhermitte's sign, Gait disturbance , Ataxia						
(b) (6)	64/F		Dyspnoea, Neck pain, Guillain- Barre syndrome, Pain in extremity, Hypoaesthesia	UNITED KINGDOM	14	2	nerve conduction studies supported presumed Guillan Barre Syndrome	recovering	unk
(b) (6)	73/M	Dural arteriovenous fistula / Hypertension	Asthenia, Muscular weakness, Guillain- Barre syndrome	UNITED KINGDOM	21	2	Cerebrospinal fluid (CSF) showed high protein. CT angiography (CTA): likely dural AV fistula with occluded left transverse sinus, a CT Head (CTH): left insular/ext capsule infarct	not recovered	1
(b) (6)	76/M	Arthralgia / COVID-19 / Pneumonia / Sepsis	Guillain- Barre syndrome	UNITED KINGDOM	few days	2	spinal tap confirmed Guillain Barre syndrome	recovering	1
(b) (6)	31/F	Nasopharyn- gitis / Upper respiratory tract infection / Upper respiratory tract inflammation	Guillain- Barre syndrome, Muscular weakness, Hypoaesthesia, Hypoaesthesia	JAPAN	9	2	electrophysiologic study: consistent with GBS	recovering	1
(b) (6)	90/M	Angina pectoris / Cardiac failure / Chronic obstructive pulmonary disease / Intermittent claudication	Guillain- Barre syndrome, Respiratory failure	SPAIN	16	2	preceded by gastrointestinal episode	unk	unk
(b) (6)	80/M	Atrial fibrillation / Benign prostatic hyperplasia / Gait disturbance / Hypertension / Knee operation / Osteoarthritis / Walking aid user	Polyneurop- athy, Guillain- Barre syndrome	GREECE	problem pre- existing then 3 days	2		not recovered	unk
(b) (6)	89/F		Fatigue, Guillain-	NETHERLANDS	28	2	confirmed with an electromyogram	recovering	unk

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			Barre syndrome						
(b) (6)	43/F		Guillain-Barre syndrome, Hypoaesthesia, Muscular weakness, Dysphagia, Gait disturbance	JAPAN	18	2	Abnormal temporal dispersion, Decreased F wave frequency, Prolonged F wave latency	unk	1
(b) (6)	UNK/M		Demyelination, Guillain-Barre syndrome, Alanine aminotransferase increased, Ataxia, Genital herpes simplex, Asthenia, Areflexia	UNITED KINGDOM	54	2	albumin-cytological dissociation	recovering	1
(b) (6)	24/M	Asthma / Back pain / Seasonal allergy	Guillain-Barre syndrome	SERBIA	0	2	changes by type of acquired demyelination of predominantly motor nerves	recovering	1
(b) (6)	91/M	Age-related macular degeneration / Benign prostatic hyperplasia / Hypertension	Guillain-Barre syndrome	FRANCE	10	2	albumin-cytological dissociation	not recovered	2
(b) (6)	61/F	Body mass index increased / Cervical conisation / Diarrhoea / Non-tobacco user / Oophorectomy bilateral / Spinal osteoarthritis / Thyroidectomy	Guillain-Barre syndrome	FRANCE	1 evolving within 2 weeks	2	albumin-cytological dissociation	unk	unk
(b) (6)	86/F		Guillain-Barre syndrome	ITALY	13	2	albumin-cytological dissociation	recovering	1

Appendix 3: Cases reporting a fatal outcome

(b) (6)

An 81-year-old patient with a reported time to onset of 54 days. No medical history was reported for the patient. The reported event referred to a worsening in the weakness in both

legs, without any further detail regarding his medical history and the pre-existing weakness in the limb (reported as worsening). The patient's health conditions deteriorated in couple of days (numbness in abdomen, progressive breathing problems) until he was admitted to the hospital and died.

(b) (6)

A 79-year-old male patient received the first dose of BNT162B2 on 19Jan2021 for COVID-19 vaccination. The patient's relevant medical history included Disease Parkinson's, Pre-diabetes, Ischaemic heart Disease under multiple concomitant medication. On 20Jan2021 the patient was admitted to hospital with reduced mobility and was diagnosed with Guillain Barre Syndrome on 20Jan2021. The subject died on 23Feb2021.

(b) (6)

A 76-year-old male patient received first dose of bnt162b2 on unknown date. Medical history included heart disease with 2 stents, hypertension, diabetes, obesity, and hyperlipidemia and was under multiple concomitant medication. Two weeks after receiving the vaccine, the patient experienced urinary incontinence, confusion, lethargy, decreased appetite and taste, weakness, and chills. He was admitted to the hospital few days later and developed fever and thrombocytopenia. On day 5, the patient was then diagnosed with Guillain-Barre Syndrome. MRI was normal, lumbar puncture was consistent with diagnosis with Guillane Barre. He received IVIG x 5days for Guillain-Barre Syndrome and was transferred to a nursing home. He was readmitted to the hospital with dehydration in 04Apr2021 and expired 2 days later (06Apr2021). The patient was negative for COVID-19 in 2021. Autopsy result showed that the patient died of acute renal failure/dehydration second to Guillain barre.

(b) (6)

A 90-year-old female patient received BNT162B2 first dose at the age of 90-years-old on 30Mar2021. The patient's medical history included ongoing hypertension, ongoing diverticulitis, ongoing heart disease, anxiety, pain, eye pressure control and heart disorder and was under multiple concomitant medications. It was reported that upon returning home after the vaccination, the patient was unable to get out of the car as she felt weak and numbness and slurred speech started. The family physician thinks that the patient may have Guillain-Barre Syndrome. On 27Apr2021, the subject was able to ride to get her vaccine once back home she could barely get out of the car, she has been bed ridden ever since and now non-verbal. No treatment was administered. It was further reported that their mother (patient) passed away on 19Apr2021. No autopsy was performed. The patient underwent lab tests and procedures which included SARS-CoV-2 antibody test: negative on Sep2020 and negative on Jan2021.

(b) (6)

An 81-year-old female patient received bnt162b2 on 20Dec2020. Medical history included immunodeficiency, pancytopenia treated with corticosteroids. The patient's concomitant medications were not reported. The patient according to the family, began to deteriorate a few days after the first vaccine, had a fall on the 6th of February and was admitted to a hospital and she complained of leg weakness and soon she lost the ability to walk and developed sensory symptoms. Respiratory problems started on 19th of February, and she died on 21st of February.

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Clinical suspicion was Guillain-Barre syndrome. Post mortem findings fit with that diagnosis. Patient has not tested positive for COVID-19 since having the vaccine.

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Pfizer-BioNTech COVID-19 Vaccine

Myocarditis and Pericarditis

Report Prepared by:

BioNTech-Pfizer

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1. INTRODUCTION

Myocarditis is an inflammation of the heart muscle that may present with chest pain, palpitations, arrhythmias, and/or heart failure. It may occur in children and adults and is more common in young men than young women. Myocarditis may be significantly underdiagnosed; depending on the source, the incidence of myocarditis and pericarditis in the European Union ranges from 1 to 10 in 100,000 per year; however, one estimated global prevalence of (pre-Covid pandemic) myocarditis was 22 cases per 100,000 patients. Diagnostic work-up may include serum cardiac biomarkers such as troponins and creatine kinase, electrocardiogram, echocardiography, cardiovascular magnetic resonance imaging and endomyocardial biopsy (diagnostic gold standard). Although a causative agent is frequently not identified, etiologies can include infection (most commonly viral), autoimmune (e.g. sarcoid and systemic lupus erythematosus), and drugs or toxins. In 50% of cases, acute myocarditis resolves quickly within 2-4 weeks; however, 25% may develop persistent cardiac dysfunction and 25% may deteriorate to end-stage dilated cardiomyopathy. Treatment is dependent on presentation and may be directed at a specific etiology, if determined, heart failure and arrhythmias, if present.¹²³

Viral myocarditis in asymptomatic people is a common cause of sudden cardiac death, especially among those younger than 35 years. The incidence of sudden cardiac death in collegiate athletes, for example, has been estimated at 1:50000 per year⁴. In the case of SARS-CoV family of viruses, the viral RNAs of Middle East respiratory syndrome coronavirus (MERS-CoV) and SARS-CoV, which are close relatives of SARS-CoV-2, were found in the heart tissues of infected animals, suggesting that these coronaviruses possess cardiotropism. In the case of SARS-CoV2 specifically, the virus causing COVID-19 disease, case reports and case series following COVID-19 infection. Ho et. al reviewed the literature for cases of myocarditis following COVID-19 and found 51 patients: 12 with confirmed myocarditis (by cardiac magnetic resonance imaging or endomyocardial biopsy) and 39 with possible myocarditis (cardiac biomarkers, ECG and/or echocardiograms). Patients had a median age of 55 years and 69% were male. In general, they presented with the range of symptoms seen in myocarditis of other etiologies. Mortality was 27%.⁵

Pericarditis is an inflammation of the pericardial sac that contains the heart and fixes it to the mediastinum. Males between 20-50 years of age appear to be at highest risk for pericarditis. One incidence has been reported to be about 28 cases per 100,000 in a study of an urban Italian area. Diagnosis of acute pericarditis is made if 2 of 4 clinical criteria are met: (1) Pericardial chest pain, (2) Pericardial rub on auscultation, (3) ECG changes, and (4) Pericardial effusion. Etiologies remain unknown in 40-85% of patients with pericarditis but may be microbial (most commonly viral > bacterial), autoimmune (e.g. systemic lupus erythematosus, rheumatoid arthritis), or neoplastic. It can be self-limiting or complicated by pericardial effusion, and constriction (tamponade). Treatment is directed at inflammation with colchicine or other NSAIDs, aspirin, corticosteroids, and anakinra (IL-1 receptor antagonist). Recurrences occur in about 30% of patients.⁶ Data collected from a Finnish national registry (2000–9) showed a standardized incidence rate of hospitalizations for acute pericarditis of 3.32 per 100,000 person-years. These data were limited to hospitalized patients and therefore may account for only a minority of cases, as many patients with pericarditis are commonly not admitted to hospital. Men ages 16–65 years were at higher risk for pericarditis (relative risk 2.02) than women in the general admitted population, with the highest risk difference among young adults

compared with the overall population. Acute pericarditis caused 0.2% of all cardiovascular admissions. The proportion of admissions declined by an estimated 51% per 10-year increase in age. The in-hospital mortality rate for acute pericarditis was 1.1% and it increased with increasing age and severe co-infections (e.g. pneumonia or septicemia). However, this is a study based on hospital admissions only. Recurrences affect about 30% of patients within 18 months after a first episode of acute pericarditis.⁷

2. RESULTS

2.1. Clinical study data

Unblinded clinical study data from C4591001 (data-lock 13 Mar 2021) was searched for cases of myocarditis and pericarditis. During the blinded placebo-controlled follow-up period, there was one report of myocarditis in the placebo group, and one report of pericarditis in the BNT162b2 group (a 66 year old white male who had pericarditis 29 days after dose 2 of vaccine which was ongoing at the time of the data cut-off. It was assessed as not related to study intervention by the investigator).

2.2. Post-authorization data

2.2.1. Methodology

The safety database was searched for spontaneous reports for Pfizer/BNT COVID-19 vaccine using the search criteria PTs: Pericarditis and Myocarditis, cumulatively to 25 May 2021.

The search identified 495 reports. Two hundred and sixty (260) reports were coded with the PT Myocarditis and 235 coded to Pericarditis, including 25 reports reporting both PTs (Pericarditis and Myocarditis).

2.2.2. Myocarditis

Two hundred and sixty (260) cases reported myocarditis. The criteria used for classifying the cases of Myocarditis were based on Brighton's Collaboration (BC) diagnostic certainty criteria v1.4.2 as: Confirmed (BC 1), Probable (BC 2), Possible (BC 3), Myocarditis not matching levels 1, 2 or 3 (BC 4), and Non Myocarditis cases (BC 5) [see Appendix 1]. Eighteen (18) cases were classified as BC Level 1, 24 cases as BC level 2, 31 cases as BC level 3 and 187 cases as level 4 or 5. Of the 260 reported cases, Israel was the most frequently reporting country (84), followed by United States (50), Germany (39) and the UK (22).

- Of the 18 cases classified as BC level 1, France had 5 reports, UK (4), US (3), Spain and Germany (2 each), and Greece and Italy (1 each). The majority of reports were in younger age groups: 13 cases were below 39 years of age, 1 between 39-59 years, and 3 cases between 59 to 70 years old. There were more males (10) than females (7) and in one (1) case gender was not provided. Ten (10) of these cases had a time to onset of less than 5 days post-vaccination. None of these cases reported histopathology confirmed myocarditis. None had a fatal outcome. Five (5) cases had no alternate

etiology reported. Of them, 3 males and 2 females, ages ranging from 19-66 years old. Three (3) of the Myocarditis events occurred after first dose and the remaining two cases occurred after the second dose. Three (3) cases occurred within the first 48 hours post-vaccination. Four (4) cases had evidence of either current (1) or previous history (3) of SARS-CoV2 infection, age ranged between 28-37 years of age. One (1) case had a past medical history of myocarditis.

- Of the 24 cases identified as BC level 2, US most frequent reporting was the US(8) followed by Germany and Japan (3 each), Italy and France (2 each), The majority of reports were in younger age groups: 15 cases were below 39 years of age, 7 between 39-62 years and the remaining 2 cases were greater than 62 years old (81 and 84). There were more males (16) than females (8). Seventeen (17) of these cases had a time to onset of less than 5 days post-vaccination. No fatal outcome was reported.
- Of the 31 cases identified as BC level 3, Israel was the most frequent reporting country (6) followed by the US and Germany (4 each), Italy and the UK (3 each), and Canada, France, and Ireland (2 each). The majority of reports were in younger age groups: 20 cases were below 39 years of age, 5 cases between 39-62 years and 4 cases between 62 to 85 years old. There were more males (20) than females (11).
- Of the 174 cases identified as BC level 4, Israel was the most frequent reporting country (71) followed by the US (31)- and Germany (30). The majority of reports were in younger age groups: 107 cases were below 39 years of age, 41 cases between 39-62 years and 17 cases between 62 to 85 years old. There were more males (132) than females (39) with 3 unspecified gender.
- Of the 13 cases classified as level BC level 5 pointing to a diagnosis other than myocarditis (Appendix 1), Israel was the most frequent reporting country (7) followed by the US (4). The majority of reports were in the younger age group: 9 cases were below 39 years of age. There were more males (10) than females (2).

The following 5 cases of confirmed myocarditis (BC level 1) did not report information with respect to alternate aetiologies:

(b) (6) : 19-year-old male from France. Medical history not reported. Received his second injection on 18 February 2021. He felt pain in left shoulder 132 hours later, followed by chest pain that required hospitalization. Left ventricular ejection fraction retained followed by inflammatory syndrome and troponin elevation on 21 February 2021. Cardiac MRI showed epicardiac oedema. COVID19 PCR test negative. Event was resolved on an unspecified date. Follow-up per Pfizer processes is occurring.

(b) (6) : 23-year-old female from Greece. No medical history reported. Two days after receiving her second vaccination, experienced fever, acute back pain, shortness of breath and was admitted to hospital on 7 February 2021. ECG and blood test depicted myocarditis coupled with Troponin level elevation to 300. She was later discharged

after event was resolved on 12 February 2021. Follow-up per Pfizer processes is occurring.

(b) (6) : 25-year-old female from the UK, received her first injection on 18Mar2021. On 19Mar2021, she experienced vomiting. On 20Mar2021 she experienced epigastric pain, chest pain, sinus tachycardia and was hypotensive. In the emergency department she had Troponin T 1600, CRP 41, ALT 92. She was not responsive to fluids and required vasopressors. Echo showed thickened pericardium, pericardial effusion, impaired left ventricular function. Six hours into admission the Troponin rose to 21778. Her COVID19 test was negative. No other pertinent information was provided as to medical history, concomitant medications, or diagnostic evaluation. Further attempts of follow-up were not possible. Follow-up per Pfizer processes is occurring.

(b) (6) : 66-year-old male from Germany. No medical history reported. Received his second injection on 6 April 2021. On an unspecified date in the same month he experienced myocarditis. Echo, ECG and cardiac MRI confirmed diagnosis. Troponin level elevated. It was reported cardiac function improved but not yet recovered. Follow-up per Pfizer processes is occurring.

(b) (6) : 44-year-old male from Germany, received his first injection on 17Feb2021. On 05Mar2021, he experienced anginal symptoms and febrile myocarditis. Troponin increased to 1.553ug/ml on 10Mar2021. Echocardiogram was reported to confirm myocarditis on 11 Mar 2021. No other pertinent information was provided as to medical history, concomitant medications, or diagnostic evaluation. Of note, the patient received dose 2 on 10 Mar 2021. Follow-up per Pfizer processes is occurring.

All of the 260 cases of Myocarditis were assessed as serious, with hospitalization as the most common cause of seriousness.

Out of the 260 cases of Myocarditis, the majority of co-reported events were chest pain (66), fever (46), pericarditis (25), dyspnea and headache (24 each). (As shown in table 1 below):

Table 1: Myocarditis – Most common co-reported PTs

PT	Total
Chest pain	66
Pyrexia	46
Pericarditis	25
Dyspnea	24
Headache	24
Troponin increased	23
Chills	20
Fatigue	15
Pain	15
Asthenia	14

Myalgia	14
Chest discomfort	13
Nausea	9
Pain in extremity	9
Pericardial effusion	9
Vomiting	9
Malaise	8

There were 4 cases of myocarditis with fatal outcome, 3 of them described patients 80 years old or greater. One had a history of COVID-19 infection a few weeks prior to vaccination and reported both myocarditis and pericarditis. None of the cases had cardiac imaging or cardiac enzymes information provided. Only one case had a confirmatory autopsy report provided.

(b) (6) : 81-year-old female from Austria with a history of COVID-19 infection in December 2020, meningioma with symptoms of residual hemiparesis, and Type 2 diabetes mellitus. She received her first dose of the Pfizer/BioNtech vaccine on 11 January 2021. She experienced septic shock, extensive myocarditis, pericarditis, and multiple organ failure on 14 January 2021, following 2 days of a cough and cold symptoms. She died on 16 January 2021. No non-invasive or invasive cardiac imaging information was provided. An autopsy performed revealed carditis of the pericardium and myocardium. Etiologic workup of the myocarditis was not provided.

(b) (6) : 80-year-old male from Germany. No medical history was provided. He received the first injection on 07 April 2021. The patient experienced gastric discomfort, vomiting, nausea, myocarditis, and dyspnea on 12 April 2021. The patient died on 22 April 2021. No other relevant information was provided. No autopsy was performed.

(b) (6) : 47-year-old male from Israel. Medical history includes hypertension, hypercholesterolemia, hypothyroidism, diabetes with end organ damage. The patient received his two doses of vaccine on unspecified dates. He was brought to the ED after an unspecified time post vaccination with fever for 3 days, difficulty breathing, cough, and myocarditis. He was anesthetized and resuscitated due to his rapidly deteriorating condition. The patient died due to myocarditis on an unspecified date. No cardiac imaging data was provided. No further diagnostic or etiologic evaluation was provided. No autopsy was performed.

(b) (6) : 83-year-old female from Germany. No medical history was provided. She received the first injection on 08 March 2021. On 12 March 2021, she experienced bloody stools, tachycardia, hypotension, anaemia normocytic, hyponatremia, pericardial effusion, cardiogenic shock. No further diagnostic or etiologic evaluation was provided. She died on 27 April 2021. Autopsy data were not provided.

2.2.3. Pericarditis

There was a total of 235 cases with a PT of Pericarditis out of total 233,083 cases in the database (0.001% to total cases). The events were evaluated based on the European Association for Cardio-Thoracic Surgery (EACTS) criteria (6) for evaluation of the status of pericarditis (4):

Acute: At least two of the following criteria:

- 1- Pericardiac chest pain
- 2- Pericardial rubs
- 3- Widespread ST elevation or PR depression in ECG
- 4- Pericardial effusion.

Incessant: Pericarditis lasting more than 4-6 weeks but less than 3 months without remission

Recurrent: Recurrence of pericarditis after a documented first episode of acute pericarditis and a symptom-free interval for 4-6 weeks or longer

Chronic: Pericarditis lasting for more than 3 months

Out of the total number of cases (235), there were 10 cases assessed as recurrent due to past history of myocarditis, while 1 assessed as incessant, and the remaining cases, 224, were assessed as acute pericarditis.

The most frequent country of reported Pericarditis cases was the US (47) followed by Israel (46), France (41), UK (25), and Italy (18).

The majority of pericarditis cases were males (119) compared to females (114). The age ranged from 16 to 92 years of age, with 131 cases occurring after the first vaccination while 85 cases occurred after the second vaccination (remaining cases unknown dose number).

There were 15 cases with history of pericarditis, while 11 cases had history of COVID-19 infection. There were 102 cases that had an ECG and/or laboratory tests reported.

Time to onset of pericarditis was:

- Same day as vaccination: 11
- Day after vaccination: 34
- 2 to 5 days after vaccination: 62
- 6 to 10 days after vaccination: 17
- 11 to 21 days after vaccination: 43

The most commonly co-reported adverse event with Pericarditis was chest pain (63) followed by dyspnea (31), and myocarditis (25). (As shown in table 2 below):

Table 2: Pericarditis – Most common co-reported PTs

PT	Total
Chest pain	63
Dyspnea	31
Myocarditis	25
Pyrexia	22
Pericardial effusion	20
Fatigue	15
Arthralgia	13
Malaise	13
Myalgia	13
Headache	12
Pain	12
Asthenia	8
Troponin increased	8
Chest discomfort	7
C-reactive protein increased	7
Dizziness	7
Tachycardia	7

There was 1 case of pericarditis with fatal outcome:

(b) (6) : 72-year-old female from the UK with a medical history of cardiac arrest, chest pain, high cholesterol, AML, and hypertension. She had recent chemo/radiation therapy). She received the vaccine on 18Feb2021. On 21Feb2021 she experienced chest pain and shortness of breath. The patient underwent lab tests and procedures which included COVID-19 virus test: negative on 21Feb2021, computerised tomogram (CTPA): pericardial effusion and bilateral basal atelectasis. Patient was diagnosed with pericarditis on 21Feb2021. On 25Feb2021 patient experienced cardiac arrest 2 times with return of spontaneous circulation in between, then experienced pulseless electrical activity (PEA) arrest. The patient died on 26Feb2021 reportedly due to pericarditis. Etiologic workup of the myocarditis was not provided. An autopsy was not performed.

2.2.4. Both Pericarditis and Myocarditis

There were 25 reports that coded both myocarditis and pericarditis. For these cases, ages ranged from 17 to 81 years and there were 18 males and 7 females. The most reporting countries were Israel (11) and US (5). The majority (11) of cases occurred after the first day post-vaccination. Only 1 event had a fatal outcome (explained above). All 25 cases have already been described in sections 3.2.1 and 3.2.2.

2.3. Israel Cases

2.3.1. Myocarditis - cases reported from Israel

Of the 260 cases of myocarditis, there were 84 cases reported from Israel, the ages ranged from 16 to 75 years and there were 75 males and 9 females. The majority of the 84 cases (81) were assessed as BC Level 4 or 5 due to limited information provided at this time. The remaining four cases were BC 3.

2.3.2. Pericarditis – cases reported from Israel

Out of the 235 cases of pericarditis, there were 46 cases reported from Israel. The ages ranged from 17 to 75 years. There were 30 males and 16 females. There were 19 cases occurring after dose 1, and 16 occurred after dose 2 (the remainder were unspecified). None of the cases had history of pericarditis or COVID-19 infection.

3. EPIDEMIOLOGY

The MAH conducted age-stratified observed to expected (O/E) analyses for spontaneously reported myocarditis and pericarditis cases through 31 May 2021 for select European Economic Area (EEA) countries and the United States (Table 1 and Table 2). For an age-stratified analysis of myocarditis in select EEA countries (excluding the US) refer to [Appendix 5.1](#). In both analyses, the O/E ratios for both myocarditis and pericarditis were less than 1 across all age groups. Ratios were higher in the younger age groups.

Table 1. Age-Stratified Observed to Expected (O/E) Ratios of Spontaneously Reported Adverse Events of Special Interest (AESI) in Select EEA Countries and the US through 31 May 2021, 21-Day Risk Window

AESI	18-24 years		25-49 years		50+ years	
	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI
Myocarditis	0.25	0.162, 0.369	0.113	0.083, 0.150	0.026	0.017, 0.038
Pericarditis	0.096	0.053, 0.161	0.075	0.056, 0.097	0.044	0.034, 0.054

Table 2. Age-Stratified Analysis Observed (Obs) and Expected (Exp) Cases through 31 May 2021 and Background (Bkgd) Rates of Spontaneously Reported Adverse Events of Special Interest (AESI) in Select EEA Countries and the US, 21-Day Risk Window

AESI	18-24 years			25-49 years			50+ years		
	Bkgd rate ^a	Obs cases	Exp cases ^b	Bkgd rate	Obs cases	Exp cases ^c	Bkgd rate	Obs cases	Exp cases ^d
Myocarditis	12.38 ^e	25	100.1	10.54	48	424.0	10.05	26	999.1
Pericarditis	18.00 ^f	14	145.6	18.00	54	724.1	18.00	78	1,790.1

Table 2. Age-Stratified Analysis Observed (Obs) and Expected (Exp) Cases through 31 May 2021 and Background (Bkgd) Rates of Spontaneously Reported Adverse Events of Special Interest (AESI) in Select EEA Countries and the US, 21-Day Risk Window

AESI	18-24 years			25-49 years			50+ years		
	Bkgd rate ^a	Obs cases	Exp cases ^b	Bkgd rate	Obs cases	Exp cases ^c	Bkgd rate	Obs cases	Exp cases ^d

a. per 100,000 person years (PY)

b. 808,884 PY

c. 4,022,733 PY

d. 9,944,945 PY

e. ACCESS IT_ARS

f. Elfström 2007

3.1. Observed and expected cases

Spontaneously reported case counts were processed from the safety database via the pre-defined MedDRA preferred term search criteria, myocarditis and pericarditis, through 31 May 2021. Cases were limited to those occurring in the United States and the following EEA countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden. Cases were then grouped by the following age groups: 18-24 years, 25-49 years, and 50+ years. Cases <18 years were excluded.

Expected case counts were determined by multiplying estimated background incidence rates by the duration of post-vaccination exposure time estimated for a 21-day risk window.

3.2. Background incidence rates

Age-specific background rates for myocarditis were obtained from the ACCESS project.⁸ The Italian ARS dataset was selected based on the range of observed values and relevant characteristics of the database. Age-specific background rates for pericarditis were not available from ACCESS, so a rate selected from the literature was applied across all age groups.⁹

3.3. Post-vaccination exposure time

Age stratified estimated exposure time for EEA countries was derived from the ECDC data on COVID-19 vaccination in the EU/EEA.¹⁰ Estimates were limited to the following countries reporting age-specific administration data: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden. Exposure time for the United States was derived from the Our World in Data COVID-19 data.¹¹ Vaccine administrations were limited to the Pfizer-BioNTech COVID-19 vaccine. Exposure time was calculated using a 21-day risk window.

Of note, the 21-day risk window is not applied to the observed case count. All cases observed through 31 May 2021 are included regardless of proximity of event to date of vaccination. This is a conservative approach for the purpose of signal detection.

3.4. Limitations

Several limitations of the observed to expected comparison must be noted. With respect to observed cases, case ascertainment through the spontaneous reports likely reflect an underreporting due to incomplete reporting or a lag in reporting. Additionally, spontaneous surveillance systems are prone to reporting bias whereby events that have been previously identified as potentially related to the vaccine are more likely to be reported despite not meeting the clinical definition. Conversely, events that have not been previously associated with a vaccine are likely to be underreported.

With respect to the expected case counts, estimates concerning both exposure to vaccine and the background rate have limitations. Our exposure estimate assumes that the number of reported administrations is complete and accurate.

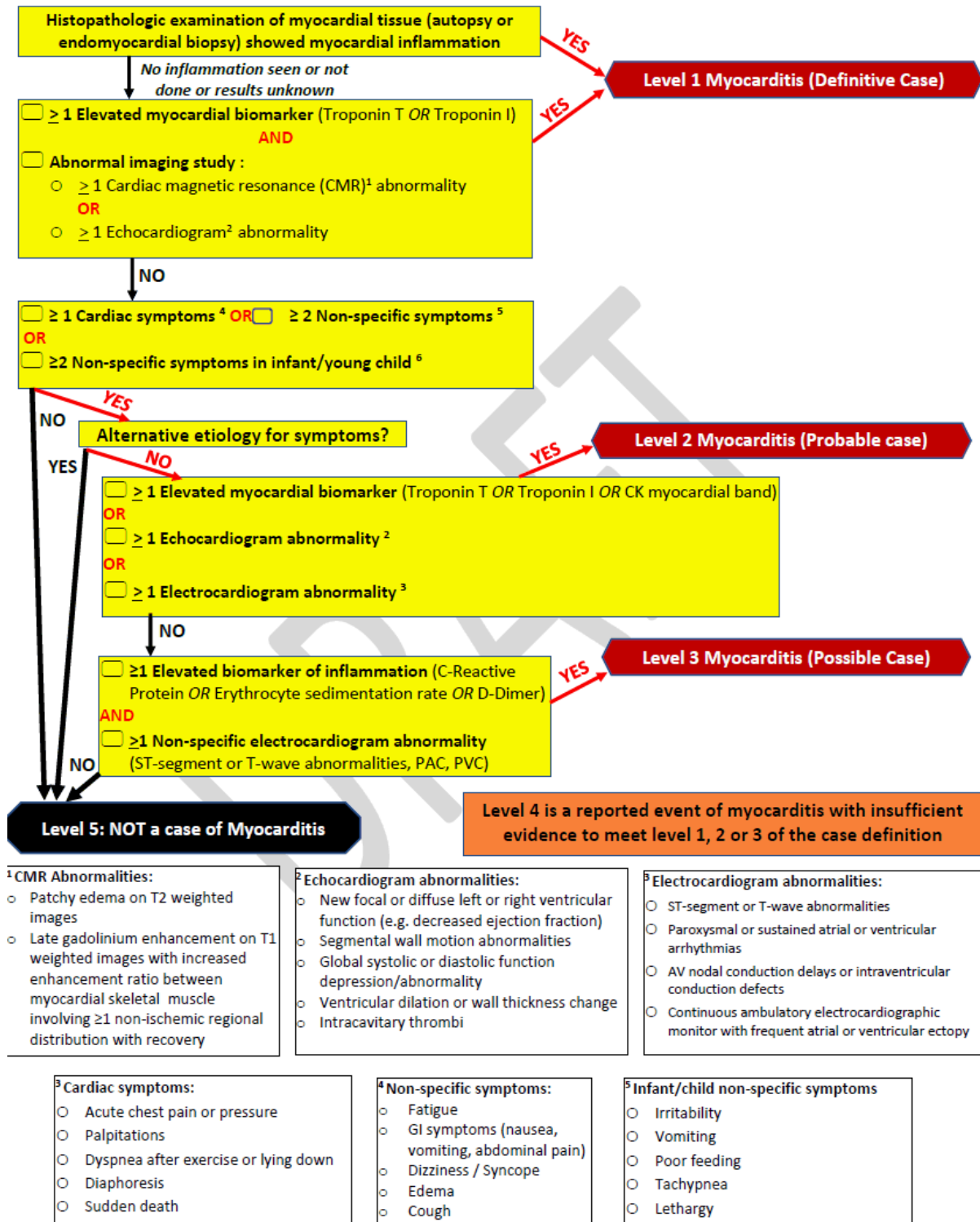
The expected count assumes that the expected incidence rate in the vaccinated population is the same as that in the population used to calculate the background rate, and the same across age groups. However, it is possible that the delivery of health care, population demographics, and underlying health status of the population used for the background rate estimate differ from those expected in the vaccinated population and across age groups.

A further limitation concerns the risk window, the period during which one is expected to be at risk of a given event if there is a causal association between the event and the vaccine. The 21-day risk window is particularly conservative as all observed cases are included in the numerator of the O/E ratio regardless of the days since vaccination dose, which will lead to an overestimation of the ratio if observed cases occurred outside of the risk window.

4. SUMMARY AND CONCLUSION

In the context of over 600 million doses of the vaccine distributed, there have been 495 reports of potential myocarditis or pericarditis events. Two hundred and sixty (260) reports were coded with the PT Myocarditis and 235 coded to Pericarditis. There is a dearth of information provided with respect for the investigations into viral or other aetiologies; however, the characteristics of the reports are consistent with the usual presentation of the disease (i.e. age and sex). The rate at which these events are reported (even without applying the diagnostic certainty criteria) do not exceed the expected background rate. It should be noted that with the case information currently available, only 18 (6.9%) of the cases could be assessed as “confirmed cases” of myocarditis as per Brighton Collaboration criteria. It is worth noting that the incidence rate of myocarditis in COVID-19 infected patients is 2.3 out of 100 in a recovering population.⁵ Given the totality of the data, a causal association between the vaccine and myocarditis or pericarditis cannot be established. The MAH will continue to perform robust pharmacovigilance, follow up, and monitoring of this topic.

Appendix 1: Brighton's Collaboration Criteria (v1.4.2_30-May-2021):



- ¹ Caforio ALP et al. Current state of knowledge on aetiology, diagnosis, management, and therapy of myocarditis: a position statement of the European Society of Cardiology Working Group on Myocardial and Pericardial Diseases. *European Heart Journal* (2013) 34, 2636-2648.
- ² Ammirati E et al. Update on acute myocarditis. *Trends in Cardiovascular Medicine* 2020 Elsevier <https://doi.org/10.1016/j.tcm.2020.05.008>
- ³ Kindermann, I et al. Update on myocarditis. *JACC* (2012) 59, 9, 779-792
- ⁴ Cardiovascular Magnetic Resonance Findings in Competitive Athletes Recovering From COVID-19 Infection. Rajpal S, et al. *JAMA Cardiol.* 2021 Jan 1;6(1):116-118.
- ⁵ Recognizing COVID-19-related myocarditis: The possible pathophysiology and proposed guideline for diagnosis and management. Siripanthong B et al. *Heart Rhythm.* 2020 Sep;17(9):1463-1471
- ⁶ Ho, JSY Coronavirus-induced myocarditis: A meta-summary of cases. *Heart Lung: Nov-Dec 2020*;49(6):681-685.
- ⁷ Adler Y 2015 ESC guidelines for the diagnosis and management of pericardial diseases. *European Heart Journal* (2015) 36, 2921-2964.
- ⁸ Willame C, Dodd C, Gini R, et al. Background rates of Adverse Events of Special Interest for monitoring COVID-19 vaccine, IT_ARS. Available from: http://www.encepp.eu/phact_links.shtml. Updated March 2021. Accessed 02 June 2021.
- ⁹ Elfström P, Hamsten A, Montgomery SM, et al. Cardiomyopathy, pericarditis and myocarditis in a population-based cohort of inpatients with coeliac disease. *J Intern Med.* 2007;262(5):545-54. DOI: 10.1111/j.1365-2796.2007.01843.x.
- ¹⁰ European Centre for Disease Prevention and Control. Data on COVID-19 vaccination in the EU/EEA. Available from: <https://www.ecdc.europa.eu/en/publications-data/data-covid-19-vaccination-eu-eea>. Accessed June 2021.
- ¹¹ Our World in Data. COVID-19 Dataset. Available from: <https://github.com/owid/covid-19-data>. Accessed June 2021.

APPENDIX 4. CUMULATIVE APPROVAL/AUTHORISATION STATUS

Product Detail Set Name	Marketing Authorization Holder	Country	Approval Date	Authorization Type
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer/BioNTech	United Kingdom	1-Dec-20	Temporary authorization under regulation 174
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Bahrain	3-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Israel	6-Dec-20	Special import approval Clause 29
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Canada	9-Dec-20	Interim Order
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Qatar	10-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Saudi Arabia	10-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Mexico	11-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	United States	11-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Kuwait	13-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Oman	13-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Lebanon	14-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Singapore	14-Dec-20	Pandemic Special Access Route
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Costa Rica	15-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Ecuador	15-Dec-20	Importation Authorization
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	United Arab Emirates	15-Dec-20	EUA

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Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Chile	16-Dec-20	Special import for emergency use article 99
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Panama	16-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Jordan	17-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Serbia	17-Dec-20	Import License
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Switzerland	19-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Austria	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Belgium	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Bulgaria	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Croatia	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Cyprus	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Czech Republic	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Denmark	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Estonia	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Finland	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	France	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Germany	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Greece	21-Dec-20	Conditional marketing authorization approval

Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Hungary	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Iceland	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Ireland	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Italy	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Latvia	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Liechtenstein	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Lithuania	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Luxembourg	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Malta	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Netherlands	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Norway	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Poland	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Portugal	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Romania	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Slovakia	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Slovenia	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Spain	21-Dec-20	Conditional marketing authorization approval

Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Sweden	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Argentina	22-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Iraq	27-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Colombia	6-Jan-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Malaysia	8-Jan-21	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Tunisia	11-Jan-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Philippines	14-Jan-21*	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Uruguay	21-Jan-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Australia	24-Jan-21	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Hong Kong	25-Jan-21	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Peru	1-Feb-21	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	New Zealand	3-Feb-21	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Dominican Republic	8-Feb-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Japan	14-Feb-21	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Ukraine	22-Feb-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Brazil	23-Feb-21	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Macau	23-Feb-21	Special import permit

Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Albania	24-Feb-21	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Rwanda	1-Mar-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	South Korea	5-Mar-21	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	South Africa	11-Mar-21	Special Import Permit - Section 21
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Palestine	25-Mar-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Algeria	12-Apr-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	United Kingdom	22-Apr-21	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Georgia	29-Apr-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Sri Lanka	11-May-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Kosovo	14-May-21	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	El Salvador	17-May-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Honduras	28-May-21	EUA

* Compared to previous SMSR#5, Approval date was reset to 14 January 2021 as per local regulatory strategist confirmation.

APPENDIX 5. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST INCLUDED IN THE TME LIST

Acute respiratory failure;Allergic oedema;Anaphylactic reaction;Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Angioedema;Asthma;Blood pressure decreased;Blood pressure diastolic decreased;Blood pressure systolic decreased;Bronchial oedema;Bronchospasm;Cardiac arrest;Cardio-respiratory arrest;Cardio-respiratory distress;Cardiovascular insufficiency;Chest discomfort;Choking;Choking sensation;Circulatory collapse;Circumoral oedema;Circumoral swelling;Cough;Cough variant asthma;Cyanosis;Dialysis membrane reaction;Diastolic hypotension;Dyspnoea;Erythema;Eye oedema;Eye pruritus;Eye swelling;Eyelid oedema;Face oedema;Flushing;Hyperventilation;Hypotension;Hypotensive crisis;Injection site urticaria;Irregular breathing;Kounis syndrome;Laryngeal dyspnoea;Laryngeal oedema;Laryngospasm;Laryngotracheal oedema;Lip oedema;Lip swelling;Mouth swelling;Nasal obstruction;Nodular rash;Ocular hyperaemia;Oedema;Oedema blister;Oedema mouth;Oropharyngeal oedema;Oropharyngeal spasm;Oropharyngeal swelling;Periorbital oedema;Periorbital swelling;Pharyngeal oedema;Pharyngeal swelling;Post procedural hypotension;Procedural shock;Pruritus;Pruritus allergic;Rash;Rash erythematous;Rash pruritic;Respiratory arrest;Respiratory distress;Respiratory failure;Reversible airways obstruction;Sensation of foreign body;Shock;Shock symptom;Skin swelling;Sneezing;Stridor;Swelling;Swelling face;Swelling of eyelid;Swollen tongue;Tachypnoea;Throat tightness;Tongue oedema;Tracheal obstruction;Tracheal oedema;Type I hypersensitivity;Upper airway obstruction;Urticaria;Urticaria papular;Vaccine associated enhanced respiratory disease;Wheezing;1p36 deletion syndrome;2-Hydroxyglutaric aciduria;Acquired epileptic aphasia;Acute encephalitis with refractory, repetitive partial seizures;Alcoholic seizure;Alpers disease;Amygdalohippocampectomy;Aspartate-glutamate-transporter deficiency;Atonic seizures;Atypical benign partial epilepsy;Aura;Automatism epileptic;Autonomic seizure;Baltic myoclonic epilepsy;Benign familial neonatal convulsions;Benign rolandic epilepsy;Biotinidase deficiency;CDKL5 deficiency disorder;CEC syndrome;CSWS syndrome;Change in seizure presentation;Clonic convulsion;Congenital bilateral perisylvian syndrome;Convulsion in childhood;Convulsions local;Convulsive threshold lowered;Corpus callosotomy;Deja vu;Double cortex syndrome;Dreamy state;Drop attacks;Drug withdrawal convulsions;Early infantile epileptic encephalopathy with burst-suppression;Eclampsia;Epilepsy;Epilepsy surgery;Epilepsy with myoclonic-atonic seizures;Epileptic aura;Epileptic psychosis;Faciobrachial dystonic seizure;Febrile convulsion;Febrile infection-related epilepsy syndrome;Foaming at mouth;Focal cortical resection;Focal dyscognitive seizures;Frontal lobe epilepsy;GM2 gangliosidosis;Gelastic seizure;Generalised onset non-motor seizure;Generalised tonic-clonic seizure;Glucose transporter type 1 deficiency syndrome;Grey matter heterotopia;Hemiconvulsion-hemiplegia-epilepsy syndrome;Hemimegalencephaly;Hyperglycaemic seizure;Hypocalcaemic seizure;Hypoglycaemic seizure;Hyponatraemic seizure;Idiopathic generalised epilepsy;Infantile spasms;Jeavons syndrome;Juvenile absence epilepsy;Juvenile myoclonic epilepsy;Lafora's myoclonic epilepsy;Lennox-Gastaut syndrome;Migraine-triggered seizure;Molybdenum cofactor deficiency;Multiple subpial transection;Myoclonic epilepsy;Myoclonic epilepsy and ragged-red fibres;Narcolepsy;Neonatal epileptic

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seizure; Neonatal seizure; Parietal lobe epilepsy; Partial seizures; Partial seizures with secondary generalisation; Petit mal epilepsy; Polymicrogyria; Post stroke epilepsy; Post stroke seizure; Post-traumatic epilepsy; Postictal headache; Postictal paralysis; Postictal psychosis; Postictal state; Preictal state; Schizencephaly; Seizure; Seizure anoxic; Seizure cluster; Seizure like phenomena; Seizure prophylaxis; Severe myoclonic epilepsy of infancy; Simple partial seizures; Status epilepticus; Sudden unexplained death in epilepsy; Temporal lobe epilepsy; Tongue biting; Tonic clonic movements; Tonic convulsion; Tonic posturing; Topectomy; Transient epileptic amnesia; Tuberous sclerosis complex; Uncinate fits; Antiviral prophylaxis; Antiviral treatment; Asymptomatic COVID-19; COVID-19; COVID-19 immunisation; COVID-19 pneumonia; COVID-19 prophylaxis; COVID-19 screening; COVID-19 treatment; Congenital COVID-19; Coronavirus infection; Coronavirus test; Coronavirus test negative; Coronavirus test positive; Exposure to SARS-CoV-2; Exposure to communicable disease; Multisystem inflammatory syndrome in children; Occupational exposure to SARS-CoV-2; Pneumonia viral; Post-acute COVID-19 syndrome; SARS-CoV-2 RNA; SARS-CoV-2 RNA decreased; SARS-CoV-2 RNA fluctuation; SARS-CoV-2 RNA increased; SARS-CoV-2 RNA undetectable; SARS-CoV-2 antibody test; SARS-CoV-2 antibody test negative; SARS-CoV-2 antibody test positive; SARS-CoV-2 carrier; SARS-CoV-2 sepsis; SARS-CoV-2 test; SARS-CoV-2 test false negative; SARS-CoV-2 test false positive; SARS-CoV-2 test negative; SARS-CoV-2 test positive; SARS-CoV-2 viraemia; Suspected COVID-19; Vaccine derived SARS-CoV-2 infection; Acute disseminated encephalomyelitis; Acute haemorrhagic leukoencephalitis; Anti-interferon antibody negative; Anti-interferon antibody positive; Anti-myelin-associated glycoprotein antibodies positive; Anti-myelin-associated glycoprotein associated polyneuropathy; Autoimmune demyelinating disease; Band sensation; Chronic inflammatory demyelinating polyradiculoneuropathy; Clinically isolated syndrome; Concentric sclerosis; Demyelinating polyneuropathy; Demyelination; Encephalitis periaxialis diffusa; Encephalomyelitis; Expanded disability status scale score decreased; Expanded disability status scale score increased; Guillain-Barre syndrome; Hypergammaglobulinaemia benign monoclonal; Immune-mediated neurological disorder; Immune-mediated neuropathy; JC polyomavirus test positive; JC virus CSF test positive; Leukoencephalomyelitis; Leukoencephalopathy; Lewis-Sumner syndrome; Lhermitte's sign; MELAS syndrome; Marburg's variant multiple sclerosis; Marchiafava-Bignami disease; Multiple sclerosis; Multiple sclerosis relapse; Multiple sclerosis relapse prophylaxis; Myelitis transverse; Myokymia; Neuromyelitis optica pseudo relapse; Neuromyelitis optica spectrum disorder; Neuropathy, ataxia, retinitis pigmentosa syndrome; Noninfectious myelitis; Noninfective encephalomyelitis; Optic neuritis; Osmotic demyelination syndrome; Primary progressive multiple sclerosis; Progressive multifocal leukoencephalopathy; Progressive multiple sclerosis; Progressive relapsing multiple sclerosis; Relapsing multiple sclerosis; Relapsing-remitting multiple sclerosis; Saccadic eye movement; Secondary progressive multiple sclerosis; Subacute inflammatory demyelinating polyneuropathy; Toxic leukoencephalopathy; Trigeminal neuralgia; Tumefactive multiple sclerosis; Uhthoff's phenomenon; Zika virus associated Guillain Barre syndrome; Acoustic neuritis; Acute aseptic arthritis; Acute cutaneous lupus erythematosus; Acute febrile neutrophilic dermatosis; Acute flaccid myelitis; Acute macular outer retinopathy; Acute motor axonal neuropathy; Acute motor-sensory axonal neuropathy; Addison's disease; Administration site vasculitis; Alloimmune hepatitis; Alopecia areata; Alveolar proteinosis; Amyloid

arthropathy; Amyloidosis; Amyloidosis senile; Ankylosing spondylitis; Anosmia; Anti-GAD antibody negative; Anti-GAD antibody positive; Anti-HLA antibody test positive; Anti-IA2 antibody positive; Anti-LRP2 nephropathy; Anti-NMDA antibody positive; Anti-RNA polymerase III antibody positive; Anti-SRP antibody positive; Anti-VGCC antibody positive; Anti-VGKC antibody positive; Anti-actin antibody positive; Anti-aquaporin-4 antibody positive; Anti-basal ganglia antibody positive; Anti-cyclic citrullinated peptide antibody positive; Anti-epithelial antibody positive; Anti-erythrocyte antibody positive; Anti-exosome complex antibody positive; Anti-ganglioside antibody positive; Anti-glomerular basement membrane antibody positive; Anti-glomerular basement membrane disease; Anti-glycyl-tRNA synthetase antibody positive; Anti-insulin antibody increased; Anti-insulin antibody positive; Anti-insulin receptor antibody increased; Anti-insulin receptor antibody positive; Anti-islet cell antibody positive; Anti-muscle specific kinase antibody positive; Anti-neuronal antibody positive; Anti-neutrophil cytoplasmic antibody positive vasculitis; Anti-platelet antibody positive; Anti-prothrombin antibody positive; Anti-saccharomyces cerevisiae antibody test positive; Anti-sperm antibody positive; Anti-thyroid antibody positive; Anti-transglutaminase antibody increased; Anti-vimentin antibody positive; Anti-zinc transporter 8 antibody positive; Antiacetylcholine receptor antibody positive; Antigliadin antibody positive; Antimitochondrial antibody positive; Antimyocardial antibody positive; Antineutrophil cytoplasmic antibody increased; Antineutrophil cytoplasmic antibody positive; Antinuclear antibody increased; Antinuclear antibody positive; Antiphospholipid antibodies positive; Antiphospholipid syndrome; Antiribosomal P antibody positive; Antisynthetase syndrome; Aortitis; Aplasia pure red cell; Aplastic anaemia; Application site vasculitis; Arteritis; Arteritis coronary; Arthritis; Arthritis enteropathic; Atrophic thyroiditis; Autoantibody positive; Autoimmune anaemia; Autoimmune aplastic anaemia; Autoimmune arthritis; Autoimmune blistering disease; Autoimmune cholangitis; Autoimmune colitis; Autoimmune dermatitis; Autoimmune disorder; Autoimmune encephalopathy; Autoimmune endocrine disorder; Autoimmune enteropathy; Autoimmune eye disorder; Autoimmune haemolytic anaemia; Autoimmune heparin-induced thrombocytopenia; Autoimmune hepatitis; Autoimmune hyperlipidaemia; Autoimmune hypothyroidism; Autoimmune inner ear disease; Autoimmune lung disease; Autoimmune lymphoproliferative syndrome; Autoimmune myocarditis; Autoimmune myositis; Autoimmune nephritis; Autoimmune neuropathy; Autoimmune neutropenia; Autoimmune pancreatitis; Autoimmune pancytopenia; Autoimmune pericarditis; Autoimmune retinopathy; Autoimmune thyroid disorder; Autoimmune thyroiditis; Autoimmune uveitis; Autoinflammation with infantile enterocolitis; Autoinflammatory disease; Autonomic nervous system imbalance; Axial spondyloarthritis; Axonal and demyelinating polyneuropathy; Axonal neuropathy; Basedow's disease; Behcet's syndrome; Beta-2 glycoprotein antibody positive; Bickerstaff's encephalitis; Birdshot chorioretinopathy; Bulbar palsy; Butterfly rash; C1q nephropathy; CREST syndrome; CSF oligoclonal band present; Capillaritis; Caplan's syndrome; Cardiac amyloidosis; Cardiac sarcoidosis; Cardiolipin antibody positive; Central nervous system lupus; Central nervous system vasculitis; Cerebral amyloid angiopathy; Cerebral arteritis; Cholangitis sclerosing; Chronic autoimmune glomerulonephritis; Chronic cutaneous lupus erythematosus; Chronic gastritis; Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids; Chronic recurrent multifocal osteomyelitis; Chronic spontaneous urticaria; Coeliac disease; Cogan's syndrome; Cold agglutinins positive; Cold type haemolytic

anaemia;Colitis;Colitis erosive;Colitis microscopic;Colitis ulcerative;Collagen disorder;Collagen-vascular disease;Complement factor C1 decreased;Complement factor C2 decreased;Complement factor C3 decreased;Complement factor C4 decreased;Complement factor abnormal;Complement factor decreased;Confirmed e-cigarette or vaping product use associated lung injury;Coombs positive haemolytic anaemia;Cranial nerve disorder;Cranial nerve palsies multiple;Cranial nerve paralysis;Crohn's disease;Cryofibrinogenaemia;Cryoglobulinaemia;Cutaneous amyloidosis;Cutaneous lupus erythematosus;Cutaneous sarcoidosis;Cutaneous vasculitis;Cystitis interstitial;DNA antibody positive;De novo purine synthesis inhibitors associated acute inflammatory syndrome;Dermatitis;Dermatitis bullous;Dermatitis herpetiformis;Dermatomyositis;Diabetes mellitus;Diabetic ketoacidosis;Dialysis amyloidosis;Diffuse vasculitis;Digital pitting scar;Double stranded DNA antibody positive;Dressler's syndrome;Encephalitis;Encephalitis allergic;Encephalitis autoimmune;Encephalitis brain stem;Encephalitis haemorrhagic;Encephalitis post immunisation;Encephalopathy;Endocrine disorder;Endocrine ophthalmopathy;Enteritis;Enterocolitis;Enteropathic spondylitis;Eosinophilic fasciitis;Eosinophilic granulomatosis with polyangiitis;Eosinophilic oesophagitis;Erythema induratum;Erythema multiforme;Erythema nodosum;Evans syndrome;Facial paresis;Felty's syndrome;Fibrillary glomerulonephritis;Fulminant type 1 diabetes mellitus;Gastrointestinal amyloidosis;Giant cell arteritis;Glomerulonephritis;Glomerulonephritis membranoproliferative;Glomerulonephritis membranous;Glomerulonephritis rapidly progressive;Glossopharyngeal nerve paralysis;Goodpasture's syndrome;Granulomatosis with polyangiitis;Granulomatous dermatitis;Haemolytic anaemia;Haemophagocytic lymphohistiocytosis;Haemorrhagic occlusive retinal vasculitis;Haemorrhagic vasculitis;Hashimoto's encephalopathy;Hashitoxicosis;Henoch-Schonlein purpura;Henoch-Schonlein purpura nephritis;Heparin-induced thrombocytopenia;Hepatic amyloidosis;Hepatitis;Histone antibody positive;Hyperthyroidism;Hypogammaglobulinaemia;Hypoglossal nerve paralysis;Hypoglossal nerve paresis;Hypothyroidism;IIIrd nerve paralysis;IIIrd nerve paresis;IPEX syndrome;IRVAN syndrome;IVth nerve paralysis;IVth nerve paresis;Idiopathic interstitial pneumonia;Idiopathic pulmonary fibrosis;IgA nephropathy;IgM nephropathy;Immune thrombocytopenia;Immune-mediated adrenal insufficiency;Immune-mediated adverse reaction;Immune-mediated arthritis;Immune-mediated cholangitis;Immune-mediated cholestasis;Immune-mediated cystitis;Immune-mediated cytopenia;Immune-mediated dermatitis;Immune-mediated encephalitis;Immune-mediated encephalopathy;Immune-mediated endocrinopathy;Immune-mediated enterocolitis;Immune-mediated gastritis;Immune-mediated hepatic disorder;Immune-mediated hepatitis;Immune-mediated hyperthyroidism;Immune-mediated hypophysitis;Immune-mediated hypothyroidism;Immune-mediated lung disease;Immune-mediated myocarditis;Immune-mediated myositis;Immune-mediated nephritis;Immune-mediated oesophagitis;Immune-mediated pancreatitis;Immune-mediated renal disorder;Immune-mediated thyroiditis;Immune-mediated uveitis;Immunoglobulin G4 related disease;Immunoglobulins abnormal;Inclusion body myositis;Infected vasculitis;Inflammatory bowel disease;Injection site vasculitis;Insulin autoimmune syndrome;Interstitial granulomatous dermatitis;Interstitial lung disease;Intrinsic factor antibody abnormal;Intrinsic factor antibody positive;Juvenile idiopathic arthritis;Juvenile polymyositis;Juvenile psoriatic arthritis;Juvenile spondyloarthritis;Kawasaki's disease;Keratoderma blenorrhagica;LE cells present;Laryngeal

rheumatoid arthritis; Latent autoimmune diabetes in adults; Lichen planopilaris; Lichen planus; Lichen sclerosus; Limbic encephalitis; Linear IgA disease; Liver sarcoidosis; Lofgren syndrome; Lupoid hepatic cirrhosis; Lupus anticoagulant hypoprothrombinaemia syndrome; Lupus cystitis; Lupus encephalitis; Lupus endocarditis; Lupus enteritis; Lupus hepatitis; Lupus myocarditis; Lupus myositis; Lupus nephritis; Lupus pancreatitis; Lupus pleurisy; Lupus pneumonitis; Lupus vasculitis; Lupus-like syndrome; Lymphocytic hypophysitis; MAGIC syndrome; Marine Lenhart syndrome; Mastocytic enterocolitis; Mesangioproliferative glomerulonephritis; Metastatic cutaneous Crohn's disease; Microscopic polyangiitis; Miller Fisher syndrome; Mixed connective tissue disease; Mononeuritis; Mononeuropathy multiplex; Morphoea; Morvan syndrome; Multifocal motor neuropathy; Muscular sarcoidosis; Myasthenia gravis; Myasthenia gravis crisis; Myasthenia gravis neonatal; Myasthenic syndrome; Myelitis; Myocarditis; Myositis; Neonatal Crohn's disease; Neonatal lupus erythematosus; Nephritis; Neuralgic amyotrophy; Neuritis; Neuritis cranial; Neuronal neuropathy; Neuropathy peripheral; Neuropsychiatric lupus; Neurosarcoidosis; Nodular vasculitis; Noninfective encephalitis; Noninfective oophoritis; Ocular myasthenia; Ocular pemphigoid; Ocular sarcoidosis; Ocular vasculitis; Oculofacial paralysis; Oesophageal achalasia; Optic neuropathy; Optic perineuritis; Oral lichen planus; Overlap syndrome; POEMS syndrome; Palindromic rheumatism; Palisaded neutrophilic granulomatous dermatitis; Palmoplantar keratoderma; Palpable purpura; Pancreatitis; Panencephalitis; Paresis cranial nerve; Parietal cell antibody positive; Pemphigoid; Pemphigus; Pericarditis; Pericarditis lupus; Peritonitis lupus; Pernicious anaemia; Pityriasis lichenoides et varioliformis acuta; Pleuroparenchymal fibroelastosis; Polyarteritis nodosa; Polychondritis; Polyglandular autoimmune syndrome type I; Polyglandular autoimmune syndrome type II; Polyglandular autoimmune syndrome type III; Polyglandular disorder; Polymyalgia rheumatica; Polymyositis; Polyneuropathy idiopathic progressive; Postpericardiotomy syndrome; Premature menopause; Primary amyloidosis; Primary biliary cholangitis; Probable e-cigarette or vaping product use associated lung injury; Proctitis ulcerative; Progressive facial hemiatrophy; Psoriasis; Psoriatic arthropathy; Pulmonary amyloidosis; Pulmonary fibrosis; Pulmonary renal syndrome; Pulmonary sarcoidosis; Pulmonary vasculitis; Pyoderma gangrenosum; Pyostomatitis vegetans; Radiculitis brachial; Radiologically isolated syndrome; Rasmussen encephalitis; Raynaud's phenomenon; Raynaud's phenomenon of the nipple; Reactive capillary endothelial proliferation; Renal amyloidosis; Renal arteritis; Renal vasculitis; Retinal occlusive vasculitis; Retinal vasculitis; Retinopathy; Retroperitoneal fibrosis; Reynold's syndrome; Rheumatic brain disease; Rheumatic disorder; Rheumatoid arthritis; Rheumatoid arthritis-associated interstitial lung disease; Rheumatoid factor increased; Rheumatoid factor positive; Rheumatoid factor quantitative increased; Rheumatoid lung; Rheumatoid neutrophilic dermatosis; Rheumatoid nodule; Rheumatoid nodule removal; Rheumatoid scleritis; Rheumatoid vasculitis; SAPHO syndrome; SLE arthritis; Sarcoid-like reaction; Sarcoidosis; Satoyoshi syndrome; Scleritis; Sclerodactylia; Scleroderma; Scleroderma associated digital ulcer; Scleroderma renal crisis; Scleroderma-like reaction; Secondary amyloidosis; Secondary cerebellar degeneration; Segmented hyalinising vasculitis; Shrinking lung syndrome; Silent thyroiditis; Sjogren's syndrome; Smooth muscle antibody positive; Spondylitis; Spondyloarthropathy; Stevens-Johnson syndrome; Stiff leg syndrome; Stiff person syndrome; Still's disease; Stoma site vasculitis; Subacute cutaneous

lupus erythematosus;Subacute endocarditis;Susac's syndrome;Sympathetic ophthalmia;Systemic lupus erythematosus;Systemic lupus erythematosus disease activity index abnormal;Systemic lupus erythematosus disease activity index decreased;Systemic lupus erythematosus disease activity index increased;Systemic lupus erythematosus rash;Systemic scleroderma;Systemic sclerosis pulmonary;Takayasu's arteritis;Terminal ileitis;Testicular autoimmunity;Thromboangiitis obliterans;Thrombocytopenic purpura;Thromboplastin antibody positive;Thrombotic thrombocytopenic purpura;Thyroid disorder;Thyroid stimulating immunoglobulin increased;Thyroiditis;Tongue amyloidosis;Toxic epidermal necrolysis;Toxic oil syndrome;Trigeminal nerve paresis;Trigeminal palsy;Tubulointerstitial nephritis and uveitis syndrome;Type 1 diabetes mellitus;Type III immune complex mediated reaction;Ulcerative keratitis;Undifferentiated connective tissue disease;Urticarial vasculitis;Uveitis;VIth nerve paralysis;VIth nerve paresis;Vaccination site vasculitis;Vaccine associated enhanced disease;Vagus nerve paralysis;Vascular purpura;Vasculitic rash;Vasculitic ulcer;Vasculitis;Vasculitis gastrointestinal;Vasculitis necrotising;Vitiligo;Vocal cord paralysis;Vocal cord paresis;Vogt-Koyanagi-Harada disease;Warm type haemolytic anaemia;XIth nerve paralysis;Yellow fever vaccine-associated neurotropic disease;Yellow fever vaccine-associated viscerotropic disease;5'nucleotidase increased;AST to platelet ratio index increased;AST/ALT ratio abnormal;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Ammonia abnormal;Ammonia increased;Ascites;Aspartate aminotransferase abnormal;Aspartate aminotransferase increased;Bacterascites;Bile output abnormal;Bile output decreased;Biliary ascites;Bilirubin conjugated abnormal;Bilirubin conjugated increased;Bilirubin urine present;Biopsy liver abnormal;Blood alkaline phosphatase abnormal;Blood alkaline phosphatase increased;Blood bilirubin abnormal;Blood bilirubin increased;Blood bilirubin unconjugated increased;Blood cholinesterase abnormal;Blood cholinesterase decreased;Bromosulphthalein test abnormal;Child-Pugh-Turcotte score abnormal;Child-Pugh-Turcotte score increased;Computerised tomogram liver abnormal;Congestive hepatopathy;Cytokeratin 18 increased;Deficiency of bile secretion;Foetor hepaticus;Galactose elimination capacity test abnormal;Galactose elimination capacity test decreased;Gamma-glutamyltransferase abnormal;Gamma-glutamyltransferase increased;Glutamate dehydrogenase increased;Glycocholic acid increased;Guanase increased;Haemorrhagic ascites;Hepaplastin abnormal;Hepaplastin decreased;Hepatic artery flow decreased;Hepatic enzyme abnormal;Hepatic enzyme decreased;Hepatic enzyme increased;Hepatic fibrosis marker abnormal;Hepatic fibrosis marker increased;Hepatic function abnormal;Hepatic hydrothorax;Hepatic hypertrophy;Hepatic hypoperfusion;Hepatic lymphocytic infiltration;Hepatic mass;Hepatic pain;Hepatic sequestration;Hepatic vascular resistance increased;Hepatic venous pressure gradient abnormal;Hepatic venous pressure gradient increased;Hepatobiliary scan abnormal;Hepatomegaly;Hepatosplenomegaly;Hyperammonaemia;Hyperbilirubinaemia;Hypercholelia;Hypertransaminaemia;Hypoalbuminaemia;Kayser-Fleischer ring;Leucine aminopeptidase increased;Liver function test abnormal;Liver function test decreased;Liver function test increased;Liver induration;Liver iron concentration abnormal;Liver iron concentration increased;Liver opacity;Liver palpable;Liver scan abnormal;Liver tenderness;Magnetic resonance imaging hepatobiliary abnormal;Magnetic resonance proton density fat fraction measurement;Mitochondrial aspartate aminotransferase increased;Model for end stage liver disease score abnormal;Model for end stage liver disease score

increased;Molar ratio of total branched-chain amino acid to tyrosine;Oedema due to hepatic disease;Osteopontin increased;Perihepatic discomfort;Periportal oedema;Peritoneal fluid protein abnormal;Peritoneal fluid protein decreased;Peritoneal fluid protein increased;Pneumobilia;Portal vein flow decreased;Portal vein pressure increased;Retinol binding protein decreased;Retrograde portal vein flow;Total bile acids increased;Transaminases abnormal;Transaminases increased;Ultrasound liver abnormal;Urine bilirubin increased;Urobilinogen urine decreased;Urobilinogen urine increased;White nipple sign;X-ray hepatobiliary abnormal;Ketosis-prone diabetes mellitus;Diabetic mastopathy;Neuromyotonia;Congenital myasthenic syndrome;Myocarditis post infection;Acquired hypocalciuric hypercalcaemia;Benign familial pemphigus;Herpes gestationis;Epidermolysis;Acquired epidermolysis bullosa;Paraneoplastic pemphigus;Paraneoplastic dermatomyositis;Nephrogenic systemic fibrosis;Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection;Aortic embolus;Aortic thrombosis;Carotid arterial embolus;Carotid artery thrombosis;Cavernous sinus thrombosis;Cerebellar artery thrombosis;Cerebral artery embolism;Cerebral artery thrombosis;Cerebral thrombosis;Cerebral venous thrombosis;Embolic stroke;Moyamoya disease;Superior sagittal sinus thrombosis;Thrombotic stroke;Transverse sinus thrombosis;Cerebrospinal thrombotic tamponade;Vertebral artery thrombosis;Embolic cerebral infarction;Brain stem thrombosis;Basilar artery thrombosis;Cerebellar embolism;Thrombotic cerebral infarction;Cerebral septic infarct;Cerebral gas embolism;Brain stem embolism;Precerebral artery thrombosis;Cerebral microembolism;Cerebral venous sinus thrombosis;Embolic cerebellar infarction;Aseptic cavernous sinus thrombosis;Precerebral artery embolism;Air embolism;Arterial thrombosis;Arteriovenous fistula thrombosis;Disseminated intravascular coagulation;Disseminated intravascular coagulation in newborn;Embolism arterial;Embolism venous;Fat embolism;Injection site thrombosis;Paroxysmal nocturnal haemoglobinuria;Postpartum venous thrombosis;Septic embolus;Thrombophlebitis migrans;Thrombophlebitis neonatal;Thrombosis;Thrombotic microangiopathy;Tumour embolism;Venous thrombosis;Post thrombotic syndrome;Postoperative thrombosis;Graft thrombosis;Arteriovenous graft thrombosis;Arteriovenous graft site stenosis;Infective thrombosis;Embolia cutis medicamentosa;Shunt thrombosis;Embolism;Thrombosis in device;Implant site thrombosis;Vascular stent thrombosis;Venous thrombosis neonatal;Infusion site thrombosis;Paradoxical embolism;Venous thrombosis in pregnancy;Tumour thrombosis;Venous recanalisation;Venous intravasation;Vascular graft thrombosis;Vessel puncture site thrombosis;Instillation site thrombosis;Microembolism;Stoma site thrombosis;Device embolisation;Foreign body embolism;Mahler sign;Administration site thrombosis;Application site thrombosis;Medical device site thrombosis;Vaccination site thrombosis;Postpartum thrombosis;Device related thrombosis;Calcium embolism;Vascular pseudoaneurysm thrombosis;Paraneoplastic thrombosis;Atheroembolism;Catheter site thrombosis;Spontaneous heparin-induced thrombocytopenia syndrome;Mesenteric artery embolism;Mesenteric artery thrombosis;Mesenteric vein thrombosis;Thrombosis mesenteric vessel;Truncus coeliacus thrombosis;Splenic embolism;Splenic artery thrombosis;Splenic thrombosis;Visceral venous thrombosis;Budd-Chiari syndrome;Hepatic artery embolism;Hepatic artery thrombosis;Hepatic vein thrombosis;Portal pyaemia;Portal vein thrombosis;Splenic vein thrombosis;Hepatic vascular thrombosis;Portosplenomesenteric venous thrombosis;Hepatic

vein embolism;Portal vein embolism;Axillary vein thrombosis;Iliac artery embolism;Jugular vein thrombosis;Pelvic venous thrombosis;Penile vein thrombosis;Subclavian artery embolism;Subclavian artery thrombosis;Thrombophlebitis;Thrombophlebitis septic;Thrombophlebitis superficial;Spinal artery embolism;Subclavian vein thrombosis;Paget-Schroetter syndrome;Deep vein thrombosis;Blue toe syndrome;Peripheral embolism;Venous thrombosis limb;Hypothenar hammer syndrome;Lemierre syndrome;Deep vein thrombosis postoperative;Thrombosis corpora cavernosa;Femoral artery embolism;Spinal artery thrombosis;Peripheral artery thrombosis;Jugular vein embolism;Peripheral vein thrombus extension;Obstetrical pulmonary embolism;Pulmonary artery thrombosis;Pulmonary embolism;Pulmonary microemboli;Pulmonary thrombosis;Pulmonary veno-occlusive disease;Pulmonary venous thrombosis;Cement embolism;Hoigne's syndrome;Post procedural pulmonary embolism;Embolic pneumonia;Anaphylactoid syndrome of pregnancy;Pulmonary oil microembolism;Metastatic pulmonary embolism;Pulmonary tumour thrombotic microangiopathy;Septic pulmonary embolism;Renal artery thrombosis;Renal vein embolism;Renal vein thrombosis;Renal embolism;Renal vascular thrombosis;Renal-limited thrombotic microangiopathy;Retinal artery embolism;Retinal artery occlusion;Retinal artery thrombosis;Retinal vein occlusion;Retinal vein thrombosis;Retinal vascular thrombosis;Papillophlebitis;Post thrombotic retinopathy;Vena cava embolism;Vena cava thrombosis;Coronary artery embolism;Coronary artery thrombosis;Intracardiac thrombus;Atrial thrombosis;Cardiac ventricular thrombosis;Coronary bypass thrombosis;Prosthetic cardiac valve thrombosis;Brachiocephalic vein thrombosis;Intracardiac mass;Intrapericardial thrombosis;Umbilical cord thrombosis;Ovarian vein thrombosis;Foetal placental thrombosis;Ophthalmic vein thrombosis;Adrenal thrombosis;Ophthalmic artery thrombosis;Lambl's excrescences;Congenital varicella infection;Eczema herpeticum;Exanthema subitum;Genital herpes;Herpes simplex;Congenital herpes simplex infection;Herpes simplex encephalitis;Herpes simplex meningitis;Herpes simplex otitis externa;Herpes simplex visceral;Herpes virus infection;Herpes zoster;Human herpesvirus 6 infection;Meningitis herpes;Meningoencephalitis herpetic;Ophthalmic herpes zoster;Pneumonia herpes viral;Proctitis herpes;Varicella;Herpes simplex virus conjunctivitis neonatal;Colitis herpes;Gastritis herpes;Herpes oesophagitis;Disseminated neonatal herpes simplex;Meningoencephalitis herpes simplex neonatal;Neonatal mucocutaneous herpes simplex;Herpes sepsis;Herpes zoster infection neurological;Herpes ophthalmic;Herpes dermatitis;Herpes zoster oticus;Varicella post vaccine;Human herpesvirus 7 infection;Herpes simplex pneumonia;Necrotising herpetic retinopathy;Human herpesvirus 8 infection;Human herpesvirus 6 infection reactivation;Herpes pharyngitis;Oral herpes;Herpes simplex hepatitis;Genital herpes zoster;Genital herpes simplex;Ophthalmic herpes simplex;Herpes simplex colitis;Herpes simplex gastritis;Varicella zoster gastritis;Herpes simplex oesophagitis;Varicella zoster oesophagitis;Herpes simplex pharyngitis;Herpes zoster pharyngitis;Herpes simplex sepsis;Herpes simplex meningoencephalitis;Herpes zoster meningoencephalitis;Meningomyelitis herpes;Herpes simplex meningomyelitis;Herpes zoster meningomyelitis;Herpes simplex necrotising retinopathy;Herpes zoster necrotising retinopathy;Varicella zoster pneumonia;Herpes zoster meningitis;Herpes zoster cutaneous disseminated;Varicella zoster sepsis;Nasal herpes;Varicella zoster virus infection;Disseminated varicella zoster vaccine virus infection;Lower respiratory tract herpes infection;Herpes simplex cervicitis;Varicella keratitis;Haemorrhagic varicella

syndrome;Herpes zoster meningoradiculitis;Herpes simplex reactivation;Herpes simplex viraemia;Herpes zoster reactivation;Human herpesvirus 6 encephalitis;Herpetic radiculopathy;Kaposi sarcoma inflammatory cytokine syndrome;Disseminated varicella;Disseminated varicella zoster virus infection;Herpes simplex bronchitis;Enteritis leukopenic;Eosinopenia;Leukopenia;Lymphocytopenia neonatal;Lymphopenia;Monocytopenia;Leukopenia neonatal;Radiation leukopenia;Basophilopenia;B-cell aplasia;Idiopathic CD4 lymphocytopenia;Atypical pneumonia;Bronchitis;Bronchopulmonary aspergillosis allergic;Lower respiratory tract infection;Lung abscess;Pneumonia;Pneumonia mycoplasmal;Tracheobronchitis;Tracheobronchitis mycoplasmal;Pulmonary sepsis;Neonatal pneumonia;Enterobacter pneumonia;Miliary pneumonia;Pneumonia necrotising;Young's syndrome;Post procedural pneumonia;Haemorrhagic pneumonia;Bronchitis mycoplasmal;Paraneoplastic pneumonia;Allergic bronchopulmonary mycosis;Streptococcal bronchitis;Agranulocytosis;Febrile neutropenia;Granulocytopenia;Granulocytopenia neonatal;Neutropenia;Neutropenia neonatal;Neutropenic sepsis;Idiopathic neutropenia;Infantile genetic agranulocytosis;Cyclic neutropenia;Neutropenic infection;Neutropenic colitis;Benign ethnic neutropenia;Transfusion-related alloimmune neutropenia;Chronic respiratory failure;Respiratory paralysis;Cardiopulmonary failure;Postoperative respiratory distress;Postoperative respiratory failure;Hypersensitivity vasculitis;Pseudovasculitis;Acute haemorrhagic oedema of infancy;Catheter site vasculitis;Infusion site vasculitis;Medical device site vasculitis;Angiopathic neuropathy;Hantavirus pulmonary infection;Parainfluenzae viral laryngotracheobronchitis;Pneumonia adenoviral;Pneumonia cytomegaloviral;Pneumonia influenzal;Pneumonia measles;Pneumonia parainfluenzae viral;Pneumonia respiratory syncytial viral;Respiratory syncytial virus bronchiolitis;Bronchitis viral;Tracheobronchitis viral;Severe acute respiratory syndrome;Lower respiratory tract infection viral;Metapneumovirus infection;Respiratory syncytial virus bronchitis;Middle East respiratory syndrome;Metapneumovirus bronchiolitis;Parainfluenzae viral bronchitis;Metapneumovirus pneumonia;Coxsackie bronchitis;Acute kidney injury;Acute myocardial infarction;Acute respiratory distress syndrome;Adverse event following immunisation;Ageusia;Amniotic cavity infection;Arrhythmia;Arthralgia;Ataxia;Caesarean section;Cardiac failure;Cardiac failure acute;Cardiogenic shock;Cataplexy;Cerebrovascular accident;Chillblains;Chronic fatigue syndrome;Congenital anomaly;Coronary artery disease;Cytokine release syndrome;Cytokine storm;Death neonatal;Endotracheal intubation;Facial paralysis;Fibromyalgia;Foetal distress syndrome;Haemorrhage;Haemorrhagic disorder;Hypersensitivity;Hypoxia;Inflammation;Intracranial pressure increased;Liver injury;Low birth weight baby;Manufacturing laboratory analytical testing issue;Manufacturing materials issue;Manufacturing production issue;Maternal exposure during pregnancy;Meningitis;Meningitis aseptic;MERS-CoV test;MERS-CoV test negative;MERS-CoV test positive;Microangiopathy;Multiple organ dysfunction syndrome;Myocardial infarction;Occupational exposure to communicable disease;Patient isolation;Peripheral ischaemia;Placenta praevia;Polyarthritis;Polyneuropathy;Post viral fatigue syndrome;Postural orthostatic tachycardia syndrome;Pre-eclampsia;Premature labour;Product availability issue;Product distribution issue;Product supply issue;Pulmonary haemorrhage;Pyrexia;Quarantine;Renal failure;Respiratory disorder;SARS-CoV-1

test;SARS-CoV-1 test negative;SARS-CoV-1 test positive;Stillbirth;Stress
cardiomyopathy;Tachycardia;Thrombocytopenia;Uterine rupture;Vasa praevia.

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APPENDIX 5.1 OBSERVED VERSUS EXPECTED ANALYSES FOR ADVERSE EVENTS OF SPECIAL INTEREST

2.5. INTRODUCTION

As part of ongoing signal detection activities, MAH is conducting observed versus expected analyses to determine whether the reported counts of spontaneously reported adverse events of special interest (AESI) are higher than expected based on the “natural” background rates of the AESI in the absence of vaccine exposure, as outlined in the “Considerations on core requirements for RMP’s of COVID-19 vaccines: coreRMP19 guidance”¹ and by Mahaux et al.² Analyses are reported cumulatively for the period since the vaccine was first granted emergency use authorization (01 December 2020) as well as for the monthly reporting interval (30 April 2021 – 31 May 2021).

2.6. METHODS

2.6.1. Overall analyses

2.6.1.1. Variables

The AESI list included in the overall analyses is informed by recommendations from the following expert groups and regulatory authorities: Brighton Collaboration (SPEAC), ACCESS protocol, US CDC (VAERS surveillance) and MHRA. For SMSR 6, the MAH has added appendicitis and stress cardiomyopathy to the overall observed to expected ratio analyses compared to SMSR 5.

2.6.1.2. Observed cases

Spontaneously reported case counts are processed from the safety database via the pre-defined MedDRA preferred term search criteria provided in Table 1. Unless otherwise noted, events have not undergone adjudication, which is considered appropriate in a setting where the goal of observed versus expected analyses is signal detection.²

Table 1. Preferred Terms (PT) Used to Identify Spontaneously Reported Adverse Events of Special Interest (AESI)

AESI	PTs
Acute disseminated encephalomyelitis (ADEM)	Acute disseminated encephalomyelitis, Encephalitis, Encephalopathy
Acute kidney injury/renal failure	Acute kidney injury, Renal failure
Acute liver injury/liver injury	Liver injury
Acute myocardial infarction/myocardial infarction	Acute myocardial infarction, Myocardial infarction
Acute respiratory distress syndrome (ARDS)	Acute respiratory distress syndrome
Ageusia/anosmia	Ageusia, Anosmia
Appendicitis	Appendicitis
Arrhythmia	Arrhythmia
Autoimmune thyroiditis	Autoimmune thyroiditis
Behcet’s syndrome	Behcet’s syndrome
Bell’s palsy	Facial paresis, Facial paralysis, Oculofacial paralysis, Bell’s palsy
Chillblains	Chillblains
Chronic fatigue syndrome/ME/PVFS	Chronic fatigue syndrome, Post viral fatigue syndrome

Table 1. Preferred Terms (PT) Used to Identify Spontaneously Reported Adverse Events of Special Interest (AESI)

AESI	PTs
Coronary artery disease	Coronary artery disease
Cutaneous vasculitis	Cutaneous vasculitis, Vasculitic rash, Urticarial vasculitis
Death	Fatal clinical outcome
Deep vein thrombosis	Deep vein thrombosis
Disseminated intravascular coagulation	Disseminated intravascular coagulation
Erythema multiforme	Erythema multiforme
Fibromyalgia	Fibromyalgia
Giant cell arteritis	Giant cell arteritis
Guillain-Barré syndrome	Guillain-Barre syndrome
Haemorrhage	Haemorrhage
Haemorrhagic stroke	Haemorrhagic stroke, Cerebral haemorrhage, Cerebral haematoma, Subarachnoid haemorrhage, Brain stem haemorrhage, Haemorrhage intracranial, Intracranial haematoma
Heart failure	Cardiac failure, Cardiac failure acute
Herpes zoster	Herpes zoster, Ophthalmic herpes zoster, Herpes zoster reactivation, Herpes zoster infection neurological, Herpes zoster oticus, Herpes zoster cutaneous disseminated, Varicella zoster virus infection
Idiopathic thrombocytopenic purpura, autoimmune thrombocytopenia	Immune thrombocytopenia, Thrombocytopenia, Thrombotic thrombocytopenic purpura, Thrombocytopenic purpura
Ischemic stroke	Ischaemic stroke, Cerebrovascular accident, Cerebral infarction, Basal ganglia stroke, Cerebral thrombosis, Cerebral venous sinus thrombosis, Thrombotic stroke, Basal ganglia infarction, Basilar artery thrombosis, Brain stem stroke, Lacunar infarction
Limb ischemia	Peripheral ischaemia
Meningitis	Meningitis, Meningitis aseptic
Multiple sclerosis (MS)	Optic neuritis, Multiple sclerosis relapse, Multiple sclerosis
Multisystem inflammatory syndrome	Systemic inflammatory response syndrome, Multiple organ dysfunction syndrome, Multisystem inflammatory syndrome in children
Myasthenia gravis	Myasthenia gravis
Myocarditis	Myocarditis
Narcolepsy	Cataplexy, Narcolepsy
Pericarditis	Pericarditis
Polyneuropathy	Polyneuropathy, Neuropathy peripheral
Postural orthostatic tachycardia syndrome	Postural orthostatic tachycardia syndrome
Pulmonary embolus	Pulmonary embolism
Rheumatoid arthritis, polyarthritis	Rheumatoid arthritis, Polyarthritis
Seizures/convulsions/seizure disorders (including febrile)	Febrile convulsion, Seizure, Generalized tonic-clonic seizure, Partial seizures
Stress cardiomyopathy	Stress cardiomyopathy
Transverse myelitis	Myelitis transverse, Myelitis
Type 1 diabetes	Type 1 diabetes mellitus
Vasculitis	Vasculitis, Polymyalgia rheumatica

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2.6.1.3. Expected cases

Expected case counts were determined cumulatively and for the monthly interval by multiplying estimated background incidence rates by the duration of post-vaccination exposure time.³ Duration of exposure time was estimated for the cumulative and interval period using a 21-day risk window and no risk window.³

2.6.1.3.1. Background incidence rates

Background incidence rates were obtained from the ACCESS project where available. Data access providers were selected for each AESI based on the range of observed values, type of care typically sought for the AESI (e.g. hospital or general practitioner), and relevant characteristics of the databases, as described in the ACCESS User Guide⁴. Incidence rates were then averaged for the most recent three years of data available, excluding 2020, within each data access provider. The most recent data available on the ACCESS dashboard were used to calculate incidence rates. This caused several of the incidence rates to change from those used in SMSR 5, which were calculated based on an older version of the ACCESS data.

For AESIs not available through the ACCESS project, incidence rates were identified in the literature and analyses conducted within electronic health records. If a plausible range of background rates was identified across multiple data sources, a single rate from the low end of the range was selected. This conservative approach is more likely to identify a signal than an approach using a higher background rate.

The MAH re-evaluated the appropriate source for background incidence rate used for acute disseminated encephalomyelitis (ADEM). In SMSR 5, a background rate of 0.1 per 100,000 person years from the ACCESS project was used, which is derived from medical records coded as ADEM only. For this SMSR, a background rate of 5.3 per 100,000 person years from the ADVANCE project, which uses a broader concept of ADEM that includes encephalitis, encephalomyelitis, and encephalopathy, was used. This higher background rate is justified to better align with the spontaneously reported cases, which includes PT codes for acute disseminated encephalomyelitis, encephalitis, and encephalopathy.

Compared to SMSR 5, background rates for the following AESIs were updated to reflect changes in the ACCESS data: acute kidney injury/renal failure, acute liver injury/liver injury, chillblains, disseminated intravascular coagulation, idiopathic thrombocytopenic purpura, autoimmune thrombocytopenia, and type 1 diabetes. The following AESIs were removed from the ACCESS data, so updated background rates from the literature or alternate sources were used: deep vein thrombosis, pulmonary embolus, and vasculitis. Background rates for the following AESIs were updated to align with the data access provider selected for the age-specific background rates described in section 2.6.2.3.1: acute respiratory distress syndrome, ageusia/anosmia, arrhythmia, cutaneous vasculitis, erythema multiforme, Guillain-Barré syndrome, haemorrhagic stroke, heart failure, ischemic stroke, multisystem inflammatory syndrome, myocarditis, narcolepsy, and seizures/convulsions/seizure disorders (including febrile).

Sources of background incidence rates are referenced in [Table 3](#).

2.6.1.3.2. Post-vaccination exposure time

Estimated exposure time was derived from two publicly available sources, the European Centre for Disease Prevention and Control (ECDC) data on COVID-19 vaccination in the European Union (EU)/ European Economic Area (EEA) and the Our World in Data (OWD) COVID-19 data.^{5,6} For countries represented in both data sources, the ECDC data was prioritized over the OWD data. Within the OWD data, the dataset with information on manufacturer was prioritized over global administration data. When available, vaccine administrations were limited to the Pfizer-BioNTech COVID-19 vaccine. For countries where the Pfizer-BioNTech COVID-19 vaccine is authorized but manufacturer stratified data were not available, the doses administered were assumed to be divided equally by the number of brands of vaccines authorized during that period. The estimate of administered doses does not reflect exposure in persons vaccinated in countries that did not publicly report. Exposure time was calculated using a 21-day risk window and no risk window for both the interval and cumulative period.

Of note, the 21-day risk window is not applied to the observed case count. All cases observed during the interval or cumulative period are included regardless of proximity of event to date of vaccination. This is a conservative approach for the purpose of signal detection.

2.6.2. Age-stratified analyses

2.6.2.1. Variables

Age-stratified analyses were performed on a subset of the AESIs included in the overall analyses. The subset of AESIs was selected based on those with available age-specific background rates from the ACCESS project.

2.6.2.2. Observed cases

Spontaneously reported case counts are processed from the safety database via the pre-defined MedDRA preferred term search criteria provided in [Table 1](#). Unless otherwise noted, events have not undergone adjudication, which is considered appropriate in a setting where the goal of observed versus expected analyses is signal detection.² Cases were limited to those occurring in the following EEA countries providing age-specific vaccine administration data through ECDC necessary to determine expected counts (section [2.6.2.3.2](#)): Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden. Cases were then grouped by the following age groups: 18-24 years, 25-49 years, 50-59 years, 60-69 years, 70-79 years, and 80+ years. Cases <18 years were excluded. Cases with only the broad age group of “adult” available were divided equally between all age groups. Cases with only the broad age group of “elderly” available were divided equally between the 60-69 years, 70-79 years, and 80+ years age groups. Cases with unknown age were divided equally between all age groups.

2.6.2.3. Expected cases

Expected case counts were determined cumulatively and for the monthly interval by multiplying estimated background incidence rates by the duration of post-vaccination

exposure time. Duration of exposure time was estimated for the cumulative and interval period using a 21-day risk window.

2.6.2.3.1. Background incidence rates

Age-specific background rates for all AESIs except death were obtained from the ACCESS project. Data access providers were selected for each AESI based on the range of observed values, type of care typically sought for the AESI (e.g. hospital or general practitioner), and relevant characteristics of the databases, as described in the ACCESS User Guide.⁴ To align with the age groups available for post-vaccination exposure time, the background rate for the ACCESS age group of 20-29 was used for the 18-24 years age group, and the average of the background rates for the ACCESS age groups 20-29 years, 30-39 years, and 40-49 years was used for the 25-49 years age group. The data access providers and background rates selected for each AESI are provided in [Table 8](#).

2.6.2.3.2. Post-vaccination exposure time

Age stratified estimated exposure time was derived from the ECDC data on COVID-19 vaccination in the EU/EEA. Estimates were limited to the following countries reporting age-specific administration data: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden. Vaccine administrations were limited to the Pfizer-BioNTech COVID-19 vaccine. Exposure time was calculated using a 21-day risk window for both the interval and cumulative period.

Of note, the 21-day risk window is not applied to the observed case count. All cases observed during the interval or cumulative period are included regardless of proximity of event to date of vaccination. This is a conservative approach for the purpose of signal detection.

2.7. RESULTS

2.7.1. Overall analysis

Table 2. Observed to Expected (O/E) Ratios of Spontaneously Reported Adverse Events of Special Interest (AESI)

AESI	21-Day Risk Window, Cumulative		No Risk Window, Cumulative		21-Day Risk Window, Interval		No Risk Window, Interval	
	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI
Acute disseminated encephalomyelitis (ADEM)	0.068	0.054, 0.084	0.026	0.020, 0.032	0.095	0.064, 0.136	0.105	0.071, 0.149
Acute kidney injury/renal failure	0.005	0.004, 0.005	0.002	0.002, 0.002	0.005	0.004, 0.006	0.006	0.004, 0.007
Acute liver injury/liver injury	0.003	0.002, 0.004	0.001	0.001, 0.002	0.002	0.000, 0.005	0.002	0.000, 0.006
Acute myocardial infarction/myocardial infarction	0.014	0.013, 0.015	0.005	0.005, 0.006	0.019	0.017, 0.022	0.021	0.019, 0.024
Acute respiratory distress syndrome (ARDS)	0.008	0.006, 0.011	0.003	0.002, 0.004	0.009	0.005, 0.016	0.010	0.006, 0.017
Ageusia/anosmia	0.227	0.211, 0.243	0.086	0.080, 0.092	0.242	0.211, 0.276	0.266	0.232, 0.303
Appendicitis	0.004	0.004, 0.005	0.002	0.001, 0.002	0.005	0.004, 0.008	0.006	0.004, 0.008
Arrhythmia	0.002	0.002, 0.003	0.001	0.001, 0.001	0.003	0.003, 0.003	0.003	0.003, 0.004
Autoimmune thyroiditis	0.017	0.011, 0.025	0.007	0.004, 0.010	0.014	0.004, 0.032	0.015	0.005, 0.035
Behcet's syndrome	0.035	0.011, 0.081	0.013	0.004, 0.031	-	-	-	-
Bell's palsy	0.331	0.317, 0.347	0.126	0.120, 0.132	0.336	0.307, 0.368	0.370	0.337, 0.405
Chillblains	0.028	0.022, 0.035	0.011	0.008, 0.013	0.035	0.023, 0.052	0.039	0.025, 0.057
Chronic fatigue syndrome/ME/PVFS	0.029	0.023, 0.035	0.011	0.009, 0.013	0.029	0.019, 0.044	0.032	0.020, 0.048
Coronary artery disease	0.001	0.000, 0.001	0.000	0.000, 0.000	0.001	0.000, 0.002	0.001	0.000, 0.002
Cutaneous vasculitis	0.032	0.024, 0.043	0.012	0.009, 0.016	0.049	0.029, 0.077	0.054	0.032, 0.085
Death	0.016	0.015, 0.016	0.006	0.006, 0.006	0.014	0.014, 0.015	0.016	0.015, 0.017
Deep vein thrombosis	0.073	0.068, 0.078	0.028	0.026, 0.030	0.149	0.135, 0.163	0.163	0.149, 0.179
Disseminated intravascular coagulation	0.033	0.017, 0.058	0.013	0.006, 0.022	0.043	0.012, 0.111	0.048	0.013, 0.122
Erythema multiforme	0.026	0.020, 0.033	0.010	0.008, 0.013	0.028	0.017, 0.046	0.031	0.018, 0.050
Fibromyalgia	0.001	0.001, 0.001	0.000	0.000, 0.000	0.001	0.001, 0.002	0.001	0.001, 0.002
Giant cell arteritis	0.064	0.041, 0.095	0.024	0.016, 0.036	0.053	0.017, 0.123	0.058	0.019, 0.135
Guillain-Barré syndrome	0.268	0.229, 0.312	0.102	0.087, 0.118	0.373	0.285, 0.481	0.411	0.313, 0.529
Haemorrhage	0.060	0.054, 0.067	0.023	0.020, 0.026	0.091	0.076, 0.109	0.100	0.083, 0.120
Haemorrhagic stroke	0.045	0.041, 0.050	0.017	0.015, 0.019	0.070	0.060, 0.083	0.077	0.066, 0.091
Heart failure	0.007	0.007, 0.008	0.003	0.003, 0.003	0.007	0.006, 0.009	0.008	0.006, 0.009

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Table 2. Observed to Expected (O/E) Ratios of Spontaneously Reported Adverse Events of Special Interest (AESI)

AESI	21-Day Risk Window, Cumulative		No Risk Window, Cumulative		21-Day Risk Window, Interval		No Risk Window, Interval	
	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI
Herpes zoster	0.024	0.023, 0.025	0.009	0.009, 0.010	0.054	0.051, 0.057	0.059	0.056, 0.062
Idiopathic thrombocytopenic purpura, autoimmune thrombocytopenia	0.107	0.098, 0.116	0.040	0.037, 0.044	0.184	0.161, 0.209	0.202	0.177, 0.230
Ischemic stroke	0.020	0.019, 0.021	0.008	0.007, 0.008	0.029	0.027, 0.032	0.032	0.030, 0.035
Limb ischemia	0.001	0.000, 0.001	0.000	0.000, 0.000	0.001	0.001, 0.002	0.001	0.001, 0.002
Meningitis	0.015	0.011, 0.020	0.006	0.004, 0.007	0.015	0.008, 0.026	0.016	0.009, 0.029
Multiple sclerosis (MS)	0.060	0.051, 0.070	0.023	0.019, 0.027	0.071	0.053, 0.094	0.078	0.058, 0.103
Multisystem inflammatory syndrome	0.632	0.507, 0.778	0.240	0.192, 0.295	0.588	0.364, 0.899	0.647	0.400, 0.989
Myasthenia gravis	0.551	0.345, 0.835	0.209	0.131, 0.316	0.494	0.161, 1.154	0.544	0.177, 1.269
Myocarditis	0.110	0.097, 0.124	0.042	0.037, 0.047	0.166	0.134, 0.202	0.182	0.148, 0.222
Narcolepsy	0.047	0.026, 0.079	0.018	0.010, 0.030	-	-	-	-
Pericarditis	0.055	0.049, 0.063	0.021	0.018, 0.024	0.083	0.067, 0.102	0.091	0.073, 0.112
Polyneuropathy	0.574	0.515, 0.639	0.218	0.195, 0.242	0.726	0.596, 0.877	0.798	0.655, 0.964
Postural orthostatic tachycardia syndrome	0.013	0.009, 0.018	0.005	0.003, 0.007	0.017	0.008, 0.031	0.018	0.009, 0.034
Pulmonary embolus	0.183	0.173, 0.193	0.069	0.066, 0.073	0.329	0.303, 0.357	0.362	0.334, 0.393
Rheumatoid arthritis, polyarthritis	0.015	0.013, 0.017	0.006	0.005, 0.007	0.017	0.013, 0.021	0.018	0.014, 0.023
Seizures/convulsions/seizure disorders (including febrile)	0.060	0.057, 0.064	0.023	0.021, 0.024	0.062	0.055, 0.070	0.068	0.061, 0.077
Stress cardiomyopathy	0.020	0.011, 0.033	0.008	0.004, 0.013	0.032	0.012, 0.069	0.035	0.013, 0.076
Transverse myelitis	0.815	0.632, 1.036	0.309	0.240, 0.393	0.768	0.439, 1.248	0.845	0.483, 1.372
Type 1 diabetes	0.003	0.002, 0.004	0.001	0.001, 0.002	0.002	0.000, 0.005	0.002	0.000, 0.005
Vasculitis	0.059	0.050, 0.068	0.022	0.019, 0.026	0.075	0.056, 0.099	0.082	0.061, 0.108

Table 3. Observed versus Expected Analyses of Spontaneously Reported Adverse Events of Special Interest (AESI) Inputs

AESI	Background Rate per 100,000 Person Years (PY)	Observed Cases, Cumulative	Expected Cases, Cumulative, 21-Day Risk Window ^a	Expected Cases, Cumulative, No Risk Window ^b	Observed Cases, Interval	Expected Cases, Interval, 21-Day Risk Window ^c	Expected Cases, Interval, No Risk Window ^d
Acute disseminated encephalomyelitis (ADEM)	5.30 ⁷	84	1,244.3	3,281.3	30	315.3	286.7
Acute kidney injury/renal failure	284.97 ⁸	306	66,902.8	176,427.4	86	16,955.4	15,417.4
Acute liver injury/liver injury	28.09 ⁸	17	6,594.7	17,390.8	3	1,671.3	1,519.7
Acute myocardial infarction/myocardial infarction	201.80 ⁹	675	47,376.9	124,936.2	232	12,006.9	10,917.7
Acute respiratory distress syndrome (ARDS)	26.65 ⁸	52	6,256.7	16,499.3	15	1,585.6	1,441.8
Ageusia/anosmia	15.31 ¹⁰	815	3,594.4	9,478.6	220	910.9	828.3
Appendicitis	96.50 ¹¹	100	22,655.4	59,744.0	31	5,741.7	5,220.8
Arrhythmia	992.06 ⁸	552	232,907.4	614,193.1	177	59,026.6	53,672.2
Autoimmune thyroiditis	6.20 ⁹	25	1,455.6	3,838.5	5	368.9	335.4
Behcet's syndrome	0.61 ¹²	5	143.2	377.7	0	-	-
Bell's palsy	23.84 ⁷	1,855	5,597.0	14,759.6	477	1,418.5	1,289.8
Chillblains	11.90 ¹³	78	2,793.8	7,367.4	25	708.0	643.8
Chronic fatigue syndrome/ME/PVFS	13.16 ¹⁴	89	3,089.6	8,147.5	23	783.0	712.0
Coronary artery disease	185.78 ¹⁵	26	43,615.8	115,018.0	10	11,053.7	10,051.0
Cutaneous vasculitis	6.19 ¹⁰	47	1,453.2	3,832.3	18	368.3	334.9
Death	1116.40 ¹⁶	4,132	262,098.9	691,173.1	962	66,424.7	60,399.2
Deep vein thrombosis	50.00 ¹⁷	854	11,738.6	30,955.4	442	2,974.9	2,705.1
Disseminated intravascular coagulation	1.55 ⁸	12	363.9	959.6	4	92.2	83.9
Erythema multiforme	10.03 ⁸	61	2,354.8	6,209.7	17	596.8	542.6
Fibromyalgia	430.00 ¹⁸	80	100,951.7	266,216.8	30	25,584.6	23,263.8
Giant cell arteritis	1.60 ⁹	24	375.6	990.6	5	95.2	86.6
Guillain-Barré syndrome	2.70 ¹⁹	170	633.9	1,671.6	60	160.6	146.1
Haemorrhage	22.30 ⁹	316	5,235.4	13,806.1	121	1,326.8	1,206.5
Haemorrhagic stroke	35.54 ¹⁹	377	8,343.8	22,003.1	149	2,114.6	1,922.8
Heart failure	240.17 ¹⁹	421	56,385.1	148,691.4	100	14,289.9	12,993.6

Table 3. Observed versus Expected Analyses of Spontaneously Reported Adverse Events of Special Interest (AESI) Inputs

AESI	Background Rate per 100,000 Person Years (PY)	Observed Cases, Cumulative	Expected Cases, Cumulative, 21-Day Risk Window ^a	Expected Cases, Cumulative, No Risk Window ^b	Observed Cases, Interval	Expected Cases, Interval, 21-Day Risk Window ^c	Expected Cases, Interval, No Risk Window ^d
Herpes zoster	414.21 ²⁰	2374	97,245.6	256,443.5	1324	24,645.3	22,409.7
Idiopathic thrombocytopenic purpura, autoimmune thrombocytopenia	21.46 ¹³	537	5,038.2	13,286.1	235	1,276.8	1,161.0
Ischemic stroke	343.34 ⁸	1642	80,606.4	212,564.8	600	20,428.4	18,575.3
Limb ischemia	260.00 ²¹	38	61,040.6	160,968.3	16	15,469.7	14,066.5
Meningitis	13.47 ²²	47	3,162.4	8,339.4	12	801.5	728.8
Multiple sclerosis (MS)	11.60 ⁹	164	2,723.3	7,181.7	49	690.2	627.6
Multisystem inflammatory syndrome	0.60 ¹⁹	89	140.9	371.5	21	35.7	32.5
Myasthenia gravis	0.17 ²³	22	39.9	105.2	5	10.1	9.2
Myocarditis	9.95 ⁸	257	2,336.0	6,160.1	98	592.0	538.3
Narcolepsy	1.26 ²⁴	14	295.8	780.1	0	-	-
Pericarditis	18.00 ²⁵	234	4,225.9	11,144.0	89	1,071.0	973.8
Polyneuropathy	2.50 ⁹	337	586.9	1,547.8	108	148.7	135.3
Postural orthostatic tachycardia syndrome	10.10 ²⁶	30	2,371.2	6,253.0	10	600.9	546.4
Pulmonary embolus	30.00 ¹⁷	1289	7,043.1	18,573.3	588	1,785.0	1,623.1
Rheumatoid arthritis, polyarthritis	64.70 ⁹	230	15,189.7	40,056.3	64	3,849.6	3,500.4
Seizures/convulsions/seizure disorders (including febrile)	79.84 ²⁷	1125	18,744.2	49,429.7	295	4,750.4	4,319.5
Stress cardiomyopathy	3.16 ¹⁵	15	741.9	1,956.4	6	188.0	171.0
Transverse myelitis	0.35 ¹⁵	67	82.2	216.7	16	20.8	18.9
Type 1 diabetes	31.77 ¹³	19	7,458.7	19,669.1	3	1,890.3	1,718.8
Vasculitis	11.43 ²⁰	157	2,683.4	7,076.4	51	680.1	618.4

a. 23,477,148 PY

b. 61,910,885 PY

c. 5,949,900 PY

d. 5,410,179 PY

For most cumulative and interval data, the upper limit of the 95% CI is substantially less than 1. For most AESI, the ratio is higher in the interval period than in the cumulative even when restricted to the 21-day risk window. This could reflect changes in the accuracy of the person year estimate, an increased reporting rate over time, an increased reporting rate with second dose as the proportion of vaccinees receiving a second dose is increasing over time, higher rates of spontaneous event reporting in countries where the vaccine was recently authorized, or a combination of these.

For purposes of signal detection in the overall analyses, the MAH considers events for which the upper level of the 95% CI exceeds 1 for at least one of the risk periods (cumulative, interval) or risk windows (21 weeks, no risk window). While typically the lower level of the 95% CI would be the criterion for evaluating a difference from expectation, in this setting, given the generally substantial gap between the lower limit and 1, an upper limit in excess of 1 might suggest the possibility of an excess risk in vaccinees.

Myasthenia gravis and transverse myelitis are further discussed below.

2.7.2. Age-stratified analysis

Table 4. Age-Stratified Observed to Expected (O/E) Ratios of Spontaneously Reported Adverse Events of Special Interest (AESI), 21-Day Risk Window, Interval

AESI	18-24 years		25-49 years		50-59 years		60-69 years		70-79 years		80+ years	
	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI
Acute kidney injury/renal failure	0.000	-	0.000	-	0.000	-	0.006	0.002, 0.014	0.005	0.003, 0.009	0.013	0.008, 0.018
Acute liver injury/liver injury	0.000	-	0.000	-	0.000	-	0.006	0.000, 0.035	0.009	0.001, 0.031	0.000	-
Acute respiratory distress syndrome (ARDS)	0.000	-	0.000	-	0.000	-	0.022	0.007, 0.051	0.012	0.004, 0.029	0.018	0.005, 0.045
Ageusia/anosmia	0.308	0.063, 0.899	0.390	0.270, 0.544	0.119	0.068, 0.194	0.036	0.012, 0.083	0.017	0.002, 0.061	0.413	0.134, 0.963
Arrhythmia	0.035	0.004, 0.126	0.046	0.031, 0.067	0.005	0.002, 0.009	0.002	0.001, 0.004	0.003	0.000, 0.012	0.002	0.000, 0.003
Chillblains	0.150	0.004, 0.836	0.087	0.024, 0.223	0.115	0.031, 0.293	0.000	-	0.042	0.010, 0.108	0.000	-
Coronary artery disease	0.000	-	0.000	-	0.000	-	0.000	-	0.000	0.000, 0.002	0.002	0.000, 0.008
Cutaneous vasculitis	0.000	-	0.089	0.002, 0.497	0.000	-	0.038	0.001, 0.211	0.073	0.015, 0.213	0.247	0.051, 0.721
Disseminated intravascular coagulation	0.000	-	0.000	-	0.000	-	0.000	-	0.000	-	0.000	-
Erythema multiforme	0.000	-	0.000	-	0.000	-	0.000	-	0.107	0.035, 0.250	0.150	0.018, 0.541
Guillain-Barré syndrome	0.000	-	0.222	0.027, 0.801	0.045	0.001, 0.253	0.118	0.024, 0.344	0.075	0.009, 0.271	1.164	0.427, 2.533
Haemorrhagic stroke	0.000	-	0.109	0.030, 0.280	0.036	0.013, 0.078	0.010	0.002, 0.031	0.029	0.018, 0.046	0.103	0.071, 0.145
Heart failure	0.276	0.007, 1.535	0.000	-	0.000	-	0.001	0.000, 0.004	0.003	0.001, 0.004	0.016	0.012, 0.021
Idiopathic thrombocytopenic purpura, autoimmune thrombocytopenia	0.182	0.005, 1.017	0.217	0.108, 0.388	0.100	0.048, 0.184	0.090	0.049, 0.151	0.114	0.077, 0.162	0.545	0.399, 0.727

Table 4. Age-Stratified Observed to Expected (O/E) Ratios of Spontaneously Reported Adverse Events of Special Interest (AESI), 21-Day Risk Window, Interval

AESI	18-24 years		25-49 years		50-59 years		60-69 years		70-79 years		80+ years	
	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI
Ischemic stroke	0.000	-	0.040	0.016, 0.083	0.031	0.019, 0.048	0.036	0.027, 0.047	0.027	0.022, 0.033	0.057	0.047, 0.067
Multisystem inflammatory syndrome	0.000	-	2.161	0.055, 12.039	0.000	-	-	-	-	-	-	-
Myocarditis	0.385	0.079, 1.124	0.144	0.058, 0.296	0.097	0.026, 0.247	0.063	0.013, 0.185	0.052	0.011, 0.151	0.070	0.002, 0.388
Narcolepsy	0.000	-	0.000	-	0.000	-	0.000	-	0.000	-	0.000	-
Seizures/convulsions/seizure disorders (including febrile)	0.303	0.131, 0.596	0.091	0.053, 0.145	0.050	0.027, 0.085	0.031	0.014, 0.058	0.026	0.014, 0.044	0.084	0.048, 0.136
Stress cardiomyopathy	-	-	0.675	0.017, 3.762	0.000	-	0.000	-	0.021	0.001, 0.115	0.000	-
Transverse myelitis	0.000	-	2.091	0.431, 6.111	0.000	-	0.000	-	2.527	0.306, 9.129	0.000	-
Type 1 diabetes	0.000	-	0.000	-	0.000	-	0.000	-	0.000	-	0.058	0.001, 0.321

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Table 5. Age-Stratified Observed to Expected (O/E) Ratios of Spontaneously Reported Adverse Events of Special Interest (AESI), 21-Day Risk Window, Cumulative

AESI	18-24 years		25-49 years		50-59 years		60-69 years		70-79 years		80+ years	
	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI
Acute kidney injury/renal failure	0.000	-	0.010	0.001, 0.038	0.004	0.001, 0.012	0.005	0.003, 0.009	0.004	0.003, 0.006	0.004	0.003, 0.005
Acute liver injury/liver injury	0.000	-	0.000	-	0.000	-	0.003	0.015	0.004	0.012	0.000	-
Acute respiratory distress syndrome (ARDS)	0.286	0.007, 1.593	0.015	0.000, 0.085	0.004	0.000, 0.025	0.013	0.005, 0.026	0.008	0.004, 0.015	0.006	0.004, 0.010
Ageusia/anosmia	0.393	0.170, 0.774	0.497	0.406, 0.604	0.200	0.150, 0.262	0.050	0.029, 0.080	0.013	0.004, 0.030	0.071	0.034, 0.131
Arrhythmia	0.084	0.040, 0.154	0.059	0.047, 0.073	0.010	0.007, 0.014	0.004	0.003, 0.005	0.002	0.001, 0.002	0.001	0.001, 0.001
Chillblains	0.144	0.017, 0.519	0.102	0.051, 0.182	0.116	0.050, 0.228	0.000	0.000, -	0.013	0.004, 0.033	0.004	0.000, 0.022
Coronary artery disease	0.000	-	0.000	-	0.000	0.003	0.000	0.001, 0.000	0.000	0.001, 0.000	0.000	0.001, 0.000
Cutaneous vasculitis	0.313	0.008, 1.744	0.190	0.062, 0.443	0.025	0.001, 0.141	0.031	0.004, 0.113	0.022	0.005, 0.065	0.028	0.008, 0.073
Disseminated intravascular coagulation	0.000	-	0.000	-	0.000	-	0.000	-	0.034	0.004, 0.125	0.000	-
Erythema multiforme	0.091	0.002, 0.506	0.037	0.008, 0.109	0.095	0.035, 0.207	0.036	0.007, 0.105	0.033	0.011, 0.077	0.019	0.004, 0.057
Guillain-Barré syndrome	0.000	-	0.613	0.326, 1.048	0.138	0.051, 0.301	0.114	0.046, 0.235	0.058	0.019, 0.134	0.251	0.140, 0.414
Haemorrhagic stroke	0.000	-	0.128	0.064, 0.229	0.036	0.019, 0.063	0.013	0.006, 0.025	0.019	0.014, 0.026	0.028	0.023, 0.034
Heart failure	0.132	0.003, 0.736	0.007	0.001, 0.024	0.002	0.000, 0.005	0.001	0.000, 0.003	0.002	0.002, 0.003	0.006	0.005, 0.007
Idiopathic thrombocytopenic purpura, autoimmune thrombocytopenia	0.175	0.021, 0.632	0.319	0.226, 0.438	0.127	0.082, 0.187	0.067	0.043, 0.098	0.061	0.046, 0.079	0.090	0.072, 0.111
Ischemic stroke	0.183	0.038, 0.535	0.056	0.036, 0.085	0.030	0.022, 0.041	0.027	0.022, 0.033	0.015	0.013, 0.017	0.014	0.013, 0.016

Table 5. Age-Stratified Observed to Expected (O/E) Ratios of Spontaneously Reported Adverse Events of Special Interest (AESI), 21-Day Risk Window, Cumulative

AESI	18-24 years		25-49 years		50-59 years		60-69 years		70-79 years		80+ years	
	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI	O/E Ratio	95% CI
Multisystem inflammatory syndrome	0.000	-	3.678	1.002, 9.418	3.414	0.086, 19.023	-	-	-	-	-	-
Myocarditis	0.553	0.253, 1.050	0.227	0.148, 0.332	0.110	0.050, 0.209	0.026	0.005, 0.077	0.016	0.003, 0.046	0.024	0.007, 0.062
Narcolepsy	0.000	-	0.259	0.071, 0.663	0.100	0.003, 0.560	0.000	-	0.133	0.016, 0.481	0.000	-
Seizures/convulsions/seizure disorders (including febrile)	0.381	0.236, 0.582	0.202	0.163, 0.249	0.078	0.056, 0.106	0.047	0.032, 0.066	0.027	0.020, 0.036	0.028	0.022, 0.036
Stress cardiomyopathy	-	-	0.287	0.007, 1.601	0.000	-	0.029	0.004, 0.106	0.025	0.007, 0.065	0.006	0.000, 0.035
Transverse myelitis	0.000	-	3.560	1.839, 6.218	0.330	0.008, 1.841	0.156	0.004, 0.869	1.161	0.239, 3.392	0.163	0.004, 0.910
Type 1 diabetes	0.038	0.005, 0.135	0.003	0.000, 0.015	0.000	-	0.000	-	0.000	-	0.005	0.000, 0.028

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Table 6. Age-Stratified Observed (Obs) to Expected (Exp) Analysis of Spontaneously Reported Adverse Events of Special Interest (AESI) Inputs, 21-Day Risk Window, Interval

AESI	18-24 years		25-49 years		50-59 years		60-69 years		70-79 years		80+ years	
	Obs cases	Exp cases ^a	Obs cases	Exp cases ^b	Obs cases	Exp cases ^c	Obs cases	Exp cases ^d	Obs cases	Exp cases ^e	Obs cases	Exp cases ^f
Acute kidney injury/renal failure	0	4.8	0	81.7	0	376.3	6	948.5	15	2,770.7	29	2,289.8
Acute liver injury/liver injury	0	6.5	0	65.1	0	136.0	1	158.1	2	230.2	0	70.1
Acute respiratory distress syndrome (ARDS)	0	1.7	0	27.9	0	112.6	5	227.7	5	405.1	4	227.8
Ageusia/anosmia	3	9.8	34	87.3	16	134.1	5	140.3	2	118.7	5	12.1
Arrhythmia	2	57.3	29	625.4	9	1,815.1	9	4,105.0	29	10,740.	11	6,658.1
Chillblains	1	6.7	4	46.0	4	34.9	0	63.7	4	94.4	0	22.0
Coronary artery disease	0	1.7	0	134.1	0	1,032.8	0	1,793.2	1	2,725.1	2	951.0
Cutaneous vasculitis	0	1.5	1	11.2	0	20.0	1	26.5	3	41.3	3	12.2
Disseminated intravascular coagulation	0	0.1	0	1.4	0	6.2	0	10.3	0	17.8	0	6.4
Erythema multiforme	0	5.3	0	34.1	0	31.9	0	34.5	5	46.6	2	13.3
Guillain-Barré syndrome	0	1.0	2	9.0	1	22.0	3	25.5	2	26.6	6	5.2
Haemorrhagic stroke	0	1.9	4	36.6	6	167.9	3	287.2	20	678.5	33	320.0
Heart failure	1	3.6	0	126.5	0	837.3	2	1,923.2	13	4,978.1	47	2,975.2
Idiopathic thrombocytopenic purpura, autoimmune thrombocytopenia	1	5.5	11	50.7	10	99.7	14	155.5	31	271.9	46	84.4
Ischemic stroke	0	7.9	7	173.4	21	668.2	52	1,454.7	97	3,583.0	132	2,329.5
Multisystem inflammatory syndrome	0	0.1	1	0.5	0	0.1	1		4		7	
Myocarditis	3	7.8	7	48.8	4	41.4	3	47.5	3	58.2	1	14.4
Narcolepsy	0	0.8	0	6.6	0	5.0	0	7.1	0	4.6	0	1.3
Seizures/convulsions/seizure disorders (including febrile)	8	26.4	17	187.1	13	260.4	9	293.3	13	500.1	16	191.5
Stress cardiomyopathy	1	-	1	1.5	0	14.6	0	28.3	1	48.4	0	13.7
Transverse myelitis	0	0.2	3	1.4	0	1.5	0	2.7	2	0.8	0	0.5
Type 1 diabetes	0	25.6	0	161.6	0	138.1	0	106.8	0	109.2	1	17.4

Table 6. Age-Stratified Observed (Obs) to Expected (Exp) Analysis of Spontaneously Reported Adverse Events of Special Interest (AESI) Inputs, 21-Day Risk Window, Interval

AESI	18-24 years		25-49 years		50-59 years		60-69 years		70-79 years		80+ years	
	Obs cases	Exp cases ^a	Obs cases	Exp cases ^b	Obs cases	Exp cases ^c	Obs cases	Exp cases ^d	Obs cases	Exp cases ^e	Obs cases	Exp cases ^f
a. 63,002 PY												
b. 462,793 PY												
c. 493,983 PY												
d. 475,003 PY												
e. 494,620 PY												
f. 125,759 PY												

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Table 7. Age-Stratified Observed (Obs) to Expected (Exp) Analysis of Spontaneously Reported Adverse Events of Special Interest (AESI) Inputs, 21-Day Risk Window, Cumulative

AESI	18-24 years		25-49 years		50-59 years		60-69 years		70-79 years		80+ years	
	Obs cases	Exp cases ^a	Obs cases	Exp cases ^b	Obs cases	Exp cases ^c	Obs cases	Exp cases ^d	Obs cases	Exp cases ^e	Obs cases	Exp cases ^f
Acute kidney injury/renal failure	0	10.0	2	192.0	3	743.7	12	2,286.2	37	9,049.4	105	26,549.6
Acute liver injury/liver injury	0	13.6	0	153.0	0	268.9	1	381.0	3	752.0	0	813.3
Acute respiratory distress syndrome (ARDS)	1	3.5	1	65.6	1	222.6	7	548.7	11	1,323.1	17	2,641.1
Ageusia/anosmia	8	20.4	102	205.1	53	265.1	17	338.2	5	387.7	10	140.4
Arrhythmia	10	119.6	87	1,469.6	36	3,587.3	39	9,894.1	54	35,078.4	54	77,197.6
Chillblains	2	13.9	11	108.0	8	69.0	0	153.6	4	308.4	1	255.5
Coronary artery disease	0	3.6	0	315.2	1	2,041.1	1	4,322.2	2	8,900.3	4	11,026.6
Cutaneous vasculitis	1	3.2	5	26.3	1	39.4	2	63.8	3	134.7	4	141.0
Disseminated intravascular coagulation	0	0.1	0	3.3	0	12.2	0	24.8	2	58.0	0	73.9
Erythema multiforme	1	11.0	3	80.1	6	63.0	3	83.1	5	152.3	3	154.7
Guillain-Barré syndrome	0	2.1	13	21.2	6	43.4	7	61.4	5	86.9	15	59.8
Haemorrhagic stroke	0	3.9	11	86.0	12	331.7	9	692.2	43	2,215.9	103	3,710.4
Heart failure	1	7.6	2	297.1	3	1,654.8	6	4,635.5	40	16,259.0	208	34,495.8
Idiopathic thrombocytopenic purpura, autoimmune thrombocytopenia	2	11.4	38	119.1	25	197.0	25	374.8	54	888.2	88	978.1
Ischemic stroke	3	16.4	23	407.5	40	1,320.5	94	3,506.2	172	11,702.3	379	27,009.7
Multisystem inflammatory syndrome	0	0.2	4	1.1	1	0.3	2	-	12	-	26	-
Myocarditis	9	16.3	26	114.6	9	81.8	3	114.5	3	190.0	4	166.5
Narcolepsy	0	1.6	4	15.4	1	10.0	0	17.1	2	15.0	0	14.6
Seizures/convulsions/seizure disorders (including febrile)	21	55.2	89	439.7	40	514.6	33	706.9	44	1,633.2	63	2,220.8
Stress cardiomyopathy	1	-	1	3.5	0	28.9	2	68.1	4	158.2	1	159.2
Transverse myelitis	0	0.5	12	3.4	1	3.0	1	6.4	3	2.6	1	6.1
Type 1 diabetes	2	53.3	1	379.8	0	273.0	0	257.5	0	356.5	1	201.5

Table 7. Age-Stratified Observed (Obs) to Expected (Exp) Analysis of Spontaneously Reported Adverse Events of Special Interest (AESI) Inputs, 21-Day Risk Window, Cumulative

AESI	18-24 years		25-49 years		50-59 years		60-69 years		70-79 years		80+ years	
	Obs cases	Exp cases ^a	Obs cases	Exp cases ^b	Obs cases	Exp cases ^c	Obs cases	Exp cases ^d	Obs cases	Exp cases ^e	Obs cases	Exp cases ^f
a. 131,481 PY												
b. 1,087,495 PY												
c. 976,293 PY												
d. 1,144,883 PY												
e. 1,615,476 PY												
f. 1,458,102 PY												

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Table 8. Age-Stratified Observed to Expected Analysis of Spontaneously Reported Adverse Events of Special Interest (AESI) Background Rates per 100,000 Person Years

AESI	18-24 years	25-49 years	50-59 years	60-69 years	70-79 years	80+ years
Acute kidney injury/renal failure ⁸	7.61	17.65	76.18	199.69	560.17	1820.83
Acute liver injury/liver injury ⁸	10.38	14.07	27.54	33.28	46.55	55.78
Acute respiratory distress syndrome (ARDS) ⁸	2.66	6.03	22.80	47.93	81.90	181.13
Ageusia/anosmia ¹⁰	15.48	18.86	27.15	29.54	24.00	9.63
Arrhythmia ⁸	90.97	135.14	367.44	864.20	2171.40	5294.39
Chillblains ¹³	10.58	9.93	7.07	13.42	19.09	17.52
Coronary artery disease ¹⁵	2.73	28.99	209.07	377.52	550.94	756.23
Cutaneous vasculitis ¹⁰	2.43	2.42	4.04	5.57	8.34	9.67
Disseminated intravascular coagulation ⁸	0.10	0.30	1.25	2.17	3.59	5.07
Erythema multiforme ⁸	8.38	7.37	6.45	7.26	9.43	10.61
Guillain-Barré syndrome ¹⁹	1.63	1.95	4.45	5.36	5.38	4.10
Haemorrhagic stroke ¹⁹	2.96	7.91	33.98	60.46	137.17	254.47
Heart failure ¹⁹	5.76	27.32	169.50	404.89	1006.45	2365.80
Idiopathic thrombocytopenic purpura, autoimmune thrombocytopenia ¹³	8.70	10.95	20.18	32.74	54.98	67.08
Ischemic stroke ⁸	12.47	37.47	135.26	306.25	724.39	1852.39
Multisystem inflammatory syndrome ¹⁹	0.15	0.10	0.03	0.00	0.00	0.00
Myocarditis ⁸	12.38	10.54	8.38	10.00	11.76	11.42
Narcolepsy ²⁴	1.25	1.42	1.02	1.49	0.93	1.00
Seizures/convulsions/seizure disorders (including febrile) ²⁷	41.96	40.43	52.71	61.74	101.10	152.31
Stress cardiomyopathy ¹⁵	0.00	0.32	2.96	5.95	9.79	10.92
Transverse myelitis ¹⁵	0.35	0.31	0.31	0.56	0.16	0.42
Type 1 diabetes ¹³	40.56	34.93	27.96	22.49	22.07	13.82

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For most cumulative and interval data, the O/E ratio is substantially less than 1. For most AESI in the younger age groups, the O/E ratio is higher in the cumulative period than the interval period, while in the older age groups the ratio is higher in the interval period. This could reflect differences in the accuracy of the person year estimate by age or interval period, an increased reporting rate with second dose as the proportion of vaccinees receiving a second dose is increasing over time, lower rates of spontaneous event reporting in countries where the vaccine was recently authorized, differences in event reporting by age, or a combination of these.

For purposes of signal detection in the age stratified analyses, the MAH considers events for which the O/E ratio exceeds 1 for at least one of the risk periods (cumulative, interval). Although the upper level of the 95% CI was used as the criterion in the overall analyses, due to the low person year estimates and variability in background rates, the O/E ratio is used as the criterion in the age stratified analyses.

Guillain-Barré syndrome, multisystem inflammatory syndrome (MIS), and transverse myelitis are further discussed below.

2.8. DISCUSSION

In general, the O/E ratios across all AESIs are lower in this SMSR than in the April 2021 SMSR. This is in part due to the revised method for calculating person years of exposure time, which uses available data on vaccines administered by manufacturer rather than assuming an equal distribution of approved vaccines.

2.8.1. Cardiogenic shock and hypertension

Although requested by regulatory authorities, cardiogenic shock and hypertension were not able to be included in this analysis since relevant background rates have not been identified at this time.

2.8.2. Overall analyses: myasthenia gravis and transverse myelitis

For myasthenia gravis, the upper level of the 95% CI exceeds 1 for at least one of the risk windows in at least one of the risk periods in the overall analysis, suggesting the possibility that the true O/E ratio may exceed 1. For myasthenia gravis, the 95% CI exceeds 1 for both the 21 day and no risk windows in the interval period, and for transverse myelitis, the 21 day risk window in both the cumulative and interval periods and the no risk window interval period.

Myasthenia gravis and transverse myelitis were previously found to have an upper limit of the 95% CI of O/E ratio greater than 1 and were reviewed in detail in the March 2021 SMSR; the signals were determined not to be validated. The O/E ratios for myasthenia gravis in this SMSR period are similar to or lower than the ratios reported in previous SMSR periods. For transverse myelitis, the adoption of the ACCESS narrow background rate of 0.35 per 100,000 person years starting in the April 2021 SMSR resulted in higher O/E ratios than in previous SMSRs. Of note, the definition for spontaneously reported cases of transverse myelitis includes PT codes for myelitis transverse and myelitis, while the ACCESS background rate

only includes transverse myelitis. The O/E ratios for transverse myelitis in this SMSR period are lower than the ratios reported in the April 2021 SMSR.

2.8.3. Age stratified analyses: Guillain-Barré syndrome, multisystem inflammatory syndrome, and transverse myelitis

In the age stratified analyses, the O/E ratio exceeds 1 for at least one of the risk periods in at least one of the age groups for Guillain-Barré syndrome, MIS, and transverse myelitis. For Guillain-Barré syndrome, the O/E ratio was elevated in the 80+ years age group, for MIS in the 25-49 years and 50-59 years age groups, and for transverse myelitis in the 25-49 years and 70-79 years age groups. A relatively low number of cases were seen within age groups; for MIS and transverse myelitis, three or fewer cases caused the O/E ratio to exceed 1.

As requested, the MAH included age stratified analyses for EEA countries. No trends of O/E ratios exceeding 1 were noted across age groups as would be expected with a true increased risk. Low exposure estimates and underestimated age specific background rates could be contributing to the variability seen in these analyses. The MAH will continue to monitor Guillain-Barré syndrome, MIS, and transverse myelitis.

2.8.4. Limitations

There are several limitations to observed to expected analyses for signal detection. The observed case counts are likely to be underestimated due to underreporting that occurs with spontaneous report surveillance. Additional reasons for underestimations include incomplete reporting and lags in reporting. Spontaneous surveillance systems are prone to reporting bias whereby events that have been previously identified as potentially related to vaccine are more likely to be reported even if they do not meet the clinical definition. Conversely, events that have not been previously associated with a vaccine are more likely to be underreported due to lack of recognition of a potential association.

With respect to the expected case counts, estimates of both exposure to vaccine and the background rate have limitations. The exposure estimate assumes that the number of reported vaccine administrations is complete and accurate when in fact not all countries administering vaccine have reported to the data source. Thus, the exposure is underestimated.

The expected count also assumes that the expected incidence rate in the vaccinated population is the same as that in the population used to calculate the background rate. The background rates used in these analyses are primarily derived from EU health care systems; while the age stratified analyses were limited to EU data, for the overall analyses a large proportion of exposure data derive from the US. It is possible that the delivery of health care, population demographics, and underlying health status of the populations used for the background rate estimates differ from those expected in the vaccinated population.

A final limitation concerns the risk window, the period during which one is expected to be at risk of a given event if there is a causal association between the event and the vaccine. For the overall analyses, two periods, 21 days and no risk window, were selected to provide an estimate assuming a more acute onset (21-day window) and a more latent onset (no risk window). The 21-day risk window is particularly conservative as all observed cases are

included in the numerator of the O/E ratio regardless of the days since vaccination dose, which will lead to an overestimation of the ratio if observed cases occurred outside of the risk window.

2.9. OBSERVED VERSUS EXPECTED ANALYSES FOR ANAPHYLAXIS (IDENTIFIED RISK)

Since anaphylaxis has already been identified as a risk, the goal of the observed versus expected analysis is risk estimation rather than signal identification. Risk of anaphylaxis is reported per dose administered and compared to rates of anaphylaxis observed for other vaccines rather than rates in an unexposed population.

The MAH has conducted unadjusted observed versus expected analyses for the 2,980 cumulative cases of anaphylaxis reported through 31 May 2021. Anaphylaxis cases were identified using the following PTs: anaphylactic shock, anaphylactic reaction, anaphylactoid shock, and anaphylactoid reaction. A background rate of 1.31 anaphylaxis cases per million vaccine doses was assumed.²⁸

An estimated 542,013,978 doses of Pfizer-BioNTech COVID-19 vaccine have been administered through 31 May 2021. Approximately 85% of shipped doses of the Pfizer-BioNTech COVID-19 vaccine are administered in the European Union and the United States. This administration estimate was applied to the 639,868,710 doses shipped worldwide through 31 May 2021.

Expected counts were determined by multiplying the number of doses administered by the expected rates per dose.

An O/E ratio of 4.182 (95% CI 4.034, 4.335) was observed for BNT162b2 compared to the background rate for anaphylaxis cases observed in the US. This rate has declined from the 4.247 (95% CI 4.055, 4.444) reported in SMSR 5 (through 29 April 2021), the 5.12 (95% CI 4.85, 5.41) reported in SMSR 4 (through 31 March 2021), the 7.76 (95% CI 7.22, 8.33) reported in SMSR 3 (through 28 February 2021) and the 9.47 (95% CI, 8.61, 10.40) reported in SMSR 2 (through 31 January 2021). The reason for the decline is unknown but could reflect decreased reporting, changes in the accuracy of the exposure estimate, or changes in population being vaccinated.

There are several limitations to consider when interpreting these analyses. The analyses did not adjust for differences in characteristics such as age and comorbidities between persons being administered the vaccine and populations from which the background rate was derived. The spontaneous report system likely underestimates the true number of observed events in vaccinated persons due to incomplete or a lag in reporting.

Conversely, spontaneous report systems are prone to reporting bias whereby events that have been previously identified as potentially related to a vaccine are more likely to be reported than other events, for example, due to increased media attention. With respect to the expected case counts, estimates of both exposure to vaccine and the background rate have limitations. The exposure estimate assumes that 85% of all shipped doses are administered in each

country. The true number of vaccines administered may be higher or lower than this estimate.

Additionally, there are differences in health care delivery, demographics, and underlying health status in the populations used to calculate background rate estimates compared to those in the population administered the vaccine.

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- ¹ Consideration on core requirements for RMPs of COVID19 vaccines coreRMP19 guidance EMA/544966/2020
 - ² Mahaux O, Bauchau V, Van Holle L. Pharmacoepidemiological considerations in observed-to-expected analyses for vaccines. *Pharmacoepidemiol Drug Saf.* 2016;25(2):215-222. DOI:10.1002/pds.3918
 - ³ The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCEPP). Guide on Methodological Standards in Pharmacoepidemiology (Revision 8). EMA/95098/2010.
 - ⁴ ACCESS background incidence rates of AESIs – User guide. Available from: http://www.encepp.eu/documents/ACCESSbackgroundrates-Userguide_000.pdf. Accessed 6 May 2021.
 - ⁵ European Centre for Disease Prevention and Control. Data on COVID-19 vaccination in the EU/EEA. Available from: <https://www.ecdc.europa.eu/en/publications-data/data-covid-19-vaccination-eu-eea>. Accessed June 2021.
 - ⁶ Our World in Data. COVID-19 Dataset. Available from: <https://github.com/owid/covid-19-data>. Accessed June 2021.
 - ⁷ Willame C, Dodd C, van der Aa L, et al. Incidence Rates of Autoimmune Diseases in European Healthcare Databases: A Contribution of the ADVANCE Project. *Drug Saf.* 2021;44(3):383-395. DOI: 10.1007/s40264-020-01031-1.
 - ⁸ Willame C, Dodd C, Gini R, et al. Background rates of Adverse Events of Special Interest for monitoring COVID-19 vaccine, IT_ARS. Available from: http://www.encepp.eu/phact_links.shtml. Updated March 2021. Accessed 02 June 2021.
 - ⁹ Pfizer Internal Data Healthcare, specific PFE_SE_PNG.
 - ¹⁰ Willame C, Dodd C, Gini R, et al. Background rates of Adverse Events of Special Interest for monitoring COVID-19 vaccine, ES_BIFAP_PC.

Available from: http://www.encepp.eu/phact_links.shtml. Updated March 2021. Accessed 02 June 2021.

- 11 Coward S, Kareemi H, Clement F, et al. Incidence of Appendicitis over Time: A Comparative Analysis of an Administrative Healthcare Database and a Pathology-Proven Appendicitis Registry. PLoS One. 2016 Nov 7;11(11):e0165161. DOI: 10.1371/journal.pone.0165161.
- 12 Thomas T, Chandan JS, Subramanian A, et al. Epidemiology, morbidity and mortality in Behçet's disease: a cohort study using The Health Improvement Network (THIN). Rheumatology (Oxford). 2020;59(10):2785-2795. DOI: 10.1093/rheumatology/keaa010.
- 13 Willame C, Dodd C, Gini R, et al. Background rates of Adverse Events of Special Interest for monitoring COVID-19 vaccine, UK_CPRD. Available from: http://www.encepp.eu/phact_links.shtml. Updated March 2021. Accessed 02 June 2021.
- 14 Vincent A, Brimmer DJ, Whipple MO, et al. Prevalence, incidence, and classification of chronic fatigue syndrome in Olmsted County, Minnesota, as estimated using the Rochester Epidemiology Project. Mayo Clin Proc. 2012;87(12):1145-52. DOI: 10.1016/j.mayocp.2012.08.015.
- 15 Willame C, Dodd C, Gini R, et al. Background rates of Adverse Events of Special Interest for monitoring COVID-19 vaccine, ES_FISABIO. Available from: http://www.encepp.eu/phact_links.shtml. Updated March 2021. Accessed 02 June 2021.
- 16 Centers for Disease Control and Prevention, National Center for Health Statistics. Underlying Cause of Death 1999-2019 on CDC WONDER Online Database. Available from: <http://wonder.cdc.gov/ucd-icd10.html>. Accessed 23 Mar 2021.
- 17 Heit JA. Epidemiology of venous thromboembolism. Nat Rev Cardiol. 2015;12(8):464-74. DOI: 10.1038/nrcardio.2015.83.
- 18 Creed F. A review of the incidence and risk factors for fibromyalgia and chronic widespread pain in population-based studies. Pain. 2020;161(6):1169-1176. DOI: 10.1097/j.pain.0000000000001819.
- 19 Willame C, Dodd C, Gini R, et al. Background rates of Adverse Events of Special Interest for monitoring COVID-19 vaccine, DK_DCE_AU. Available from: http://www.encepp.eu/phact_links.shtml. Updated March 2021. Accessed 02 June 2021.
- 20 Pfizer Internal Study C4591004.

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- 21 Duff S, Mafilios MS, Bhounsule P, Hasegawa JT. The burden of critical limb ischemia: a review of recent literature. *Vasc Health Risk Manag.* 2019 Jul 1;15:187-208. doi: 10.2147/VHRM.S209241. PMID: 31308682; PMCID: PMC6617560.
- 22 McGill F, Griffiths MJ, Bonnett LJ, et al. Incidence, aetiology, and sequelae of viral meningitis in UK adults: a multicentre prospective observational cohort study. *Lancet Infect Dis.* 2018;18(9):992-1003. DOI: 10.1016/S1473-3099(18)30245-7.
- 23 Carr AS, Cardwell CR, McCarron PO, et al. A systematic review of population based epidemiological studies in Myasthenia Gravis. *BMC Neurol.* 2010;10:46. DOI: 10.1186/1471-2377-10-46.
- 24 Willame C, Dodd C, Gini R, et al. Background rates of Adverse Events of Special Interest for monitoring COVID-19 vaccine, ES_SIDIAP_PC. Available from: http://www.encepp.eu/phact_links.shtml. Updated March 2021. Accessed 02 June 2021.
- 25 Elfström P, Hamsten A, Montgomery SM, et al. Cardiomyopathy, pericarditis and myocarditis in a population-based cohort of inpatients with coeliac disease. *J Intern Med.* 2007;262(5):545-54. DOI: 10.1111/j.1365-2796.2007.01843.x.
- 26 AbdelRazek M, Low P, Rocca W, et al. Epidemiology of Postural Tachycardia Syndrome (S18.005). *Neurology.* 2019;92(15 Supplement).
- 27 Willame C, Dodd C, Gini R, et al. Background rates of Adverse Events of Special Interest for monitoring COVID-19 vaccine, ES_BIFAP_PCHOSP. Available from: http://www.encepp.eu/phact_links.shtml. Updated March 2021. Accessed 02 June 2021.
- 28 McNeil MM, Weintraub ES, Duffy J, et al. Risk of anaphylaxis after vaccination in children and adults. *J Allergy Clin Immunol.* 2016;137(3):868-78. DOI: 10.1016/j.jaci.2015.07.048.

APPENDIX 6. LITERATURE REVIEW IN THE REPORTING PERIOD (METHODOLOGY)

A web-based literature review service is used to review medical literature from clinical and non-clinical literature sources for significant safety information relevant to authorized Pfizer medicinal product including reviews and practice guidelines.

The following bibliographic databases are searched in this order:

1. MEDLINE®
2. Embase

Each search uses controlled vocabulary terms that are unique to each database. For each database, the search focuses on the following:

- AEs, effects and outcomes
- Generic name of the drug
- Prenatal and perinatal exposure and exposure through breast milk
- Drug interactions
- Clinical studies
- Epidemiology and meta-analyses
- Poisoning and toxicity
- Drug resistance and drug tolerance
- Toxicity tests

Searches are limited by date and by literature type. Editorials, and news reports (i.e., works consisting of an announcement or statement of recent or current events of new data and matters of interest in the field of medicine or science) are excluded because they are not peer-reviewed.

APPENDIX 7. OVERVIEW OF INTERVAL CASES NOT INCLUDED IN THE MAY 2021 SMSR

Among cases received or downloaded to the safety database during the Summary Monthly Safety Report (SMSR) reporting period, only those having a complete workflow cycle in the safety database (meaning they progressed to Distribution or Closed workflow status at least once) are included in that month's SMSR. This approach prevents the inclusion of cases that are not fully processed hence not accurately reflecting final data. As per monthly routine process, Pfizer applies a Late condition process that retrieves from the global safety database cases received but not captured in the previous month's SMSR due to lack of completeness. This condition ensures that no relevant cases are excluded from the SMSRs over time.

For the reporting period 30 April 2021 to 31 May 2021, there was a total of 74,903 case reports retrievable from the global safety database based on the Initial Safety Receipt Date; 59,903 case reports out of the 74,903 retrieved did not meet the defined criteria for inclusion in the May's SMSR and therefore are not included in the current SMSR.ⁱ

The table below presents the most frequently reported events by SOC and by PT for events reported in ($\geq 1\%$) of the cases not included in the current SMSR.

Events Reported in $\geq 1\%$ in Cases* not Included in the 6th SMSR

MedDRA SOC MedDRA PT	30 April 2021 Through 31 May 2021 AEs (AERP%) N = 59,903
Blood and lymphatic system disorders	
Lymphadenopathy ^a	2023 (3.38%)
Cardiac disorders	
Palpitations ^a	606 (1.01%)
Gastrointestinal disorders	
Nausea ^a	4458 (7.44%)
Diarrhoea ^a	2078 (3.47%)
Vomiting ^a	1515 (2.53%)
Abdominal pain	764 (1.28%)
General disorders and administration site conditions	
Pyrexia ^a	15002 (25.04%)
Vaccination site pain ^a	10891 (18.18%)
Malaise ^a	8666 (14.47%)
Fatigue ^a	8296 (13.85%)
Chills ^a	6213 (10.37%)
Pain ^a	4554 (7.60%)
Vaccination site swelling ^a	2401 (4.01%)
Asthenia ^a	1991 (3.32%)
Injection site pain ^a	1643 (2.74%)
Influenza like illness	1156 (1.93%)
Feeling abnormal	885 (1.48%)
Swelling ^c	842 (1.41%)
Feeling cold ^c	775 (1.29%)
Vaccination site erythema ^a	716 (1.20%)
Chest pain	658 (1.10%)
Infections and infestations	
Herpes zoster ^c	670 (1.12%)
Injury, poisoning and procedural complications	

Events Reported in ≥1% in Cases* not Included in the 6th SMSR

MedDRA SOC MedDRA PT	30 April 2021 Through 31 May 2021 AEs (AERP%) N = 59,903
Poor quality product administered ^b	1453 (2.43%)
Musculoskeletal and connective tissue disorders	
Myalgia ^a	8666 (14.47%)
Arthralgia ^a	6994 (11.68%)
Pain in extremity ^a	3990 (6.66%)
Back pain	802 (1.34%)
Nervous system disorders	
Headache ^a	14029 (23.42%)
Dizziness ^a	2913 (4.86%)
Paraesthesia ^a	1166 (1.95%)
Hypoaesthesia	1139 (1.90%)
Somnolence	788 (1.32%)
Product issues	
Product temperature excursion issue ^b	1234 (2.06%)
Respiratory, thoracic and mediastinal disorders	
Dyspnoea ^c	1287 (2.15%)
Cough ^c	977 (1.63%)
Oropharyngeal pain	836 (1.40%)
Skin and subcutaneous tissue disorders	
Pruritus ^a	1746 (2.91%)
Rash ^a	1545 (2.58%)
Erythema ^a	1136 (1.90%)
Urticaria ^a	1001 (1.67%)

a. Listed or consistent with listed AEs in current RSI;

b. Listed per case processing convention;

c. Consistent with anaphylactic reactions listed in the current RSI;

e. Evaluated and determined not to be a risk.

* Reporting proportion (% of total cases) in the current reporting period.

Most of the frequently reported events are listed or consistent with listed events as per the current RSI.

ⁱ There was a total of 47,174 case reports included in the May's SMSR, of which 15,000 captured based on their Initial Safety Receipt Date and 32,174 case reports captured applying the Late condition.

APPENDIX 8. Q&A SECTION – EMA PRAC REQUESTS FOR NEXT SMSR

QUESTION 1

As part of Good Vigilance Practice the MAH is expected to quickly provide and take into account actual exposure data (i.e. of the signaling country) when evaluating unexpected trends in adverse event reporting (i.e. regarding seriousness, frequency, age, gender or patient population), especially when relevant to confirming/refuting potential safety signals. This applies to both EU/EEA and non-EU/EEA countries.

Response:

The MAH acknowledges this expectation and will provide exposure data, when available and as applicable, for countries from which a safety signal emerges.

QUESTION 2

The MAH states that 3,573 cases (22.4%) of the 15,937 downloaded cases are included in the dataset reviewed in this 5th MSSR of which 3,374 are serious cases; compared to 19.5% of the previous reporting period. Not included in this 5th MSSR are 2,067 serious cases and 10,297 non-serious cases. Although some improvement is reported in the relative number of processed adverse events, it is still worrisome that only 22.4% of the total number of cases are reviewed in the present reporting period. It is unclear if all serious AESI cases have been included in the current MSSR. Therefore, the MAH is requested to indicate in future MSSRs what proportion of the serious AESI cases is included in the present MSSR. In addition, the MAH should clearly report the root cause for this delay, the corrective actions in place, the availability of this cases in the EV database and how the totality of the cases are being managed in their relevant signal procedure. It should also be highlighted to the MAH that reports including AESIs or reports that are PRAC requests within the different ongoing procedures should be highly prioritized.

Response:

As per data (as of 01 June 2021), of the 19,757 cases downloaded from EudraVigilance for the period covered by the sixth SMSR, 5,230 cases (26,5 % of the total downloaded cases) are included in the data tabulations presented in this SMSR. Of the 5,230 cases included, 4,936 are serious. Of the 5,230 EudraVigilance cases included, 3,684 are serious cases reporting Adverse Events of Special Interest (AESI). All COVID-19 vaccine cases received are included in Pfizer's signal management activities and discussed in this SMSR irrespective of workflow status once minimal data (Country of Origin and adverse event term) is entered into the safety database.

The remaining 14,527 cases downloaded from EudraVigilance in May 2021 are not included in the data tabulations of this SMSR as they have not yet completed case processing; this includes reports downloaded immediately prior to the datalock point. These reports will be included in the subsequent SMSRs as Pfizer applies a late condition process that retrieves from the global safety database cases received but not completed in the previous months SMSR. Of these 14,527 cases, 2,098 are serious cases cases reporting Adverse Events of Special Interest (AESI) (11 % of the total downloaded cases).

Of note, whilst Pfizer are prioritising serious cases to meet regulatory compliance there are instances where due to the high case volume a small proportion of cases are not completed in time to meet the 15-day timeline. As described above, despite possible delay, all cases in the safety database are subject to Pfizer's signal detection processes and any signal would be promptly evaluated and described in this SMSR.

The root cause of late case completion is identified as the unprecedented volume of cases received consequent to the unprecedented subjects' exposure to the vaccine. Pfizer commenced a program of measures to increase PV system capacity in preparation for launch including an increase in case processing resources. Pfizer has completed the onboarding and deployment of 1700 resources into the case management systems and anticipate this number to increase to approximately 2000 within Q3 2021.

In addition, the following corrective actions have been or are being initiated to manage the volume of adverse event cases received:

(b) (4)

¹ These actions were initiated and/or completed in anticipation of an increased adverse event reporting volume.

Serious cases from all countries of incidence and those non serious cases from EEA countries of incidence only (with the exception of any retrieved by Pfizer from EVWEB) are reported into the EudraVigilance database. As of 10 Jun 2021, there were 68,112 non-serious COVID-19 vaccine cases from global sources that were still in process beyond day 90. However, of those approximately 45,000 were downloaded from EudraVigilance and nearly 17,000 from outside of the EEA and thus not required to be submitted to EudraVigilance. Similarly, as of 10 Jun 2021 there were only 430 serious cases received by Pfizer from sources other than EVWEB which require submission to EudraVigilance that were beyond day 15. As noted previously, all cases in workflow for the COVID-19 vaccine are included in signal management activities.

The MAH acknowledge the importance of including the AESIs and reports that are PRAC requests in ongoing procedures. The implemented prioritisation approach during the pandemic allows the processing of adverse events of most critical importance for signal detection and benefit/risk evaluation for the COVID-19 vaccine.

QUESTION 3

The MAH is requested to report the results of the review of Hepatic events (not only the conclusion) as this is considered a non-validated safety signal in the 5th MSSR.

Response:

Refer to [Appendix 3.4](#) for evaluation of Hepatic events.

QUESTION 4

The MAH is requested to add the results of the O/E analyses for Stress cardiomyopathy in the evaluation of the Cardiovascular AESIs.

Response:

Refer to [Appendix 5.1](#) Observed Versus Expected Analysis for Adverse Events of Special Interest.

QUESTION 5

The MAH is requested to indicate in which post-authorisation safety studies cases of Bell's palsy will be collected and analysed.

Response:

MAH is implementing several studies across EU and US to study the safety of the COVID-19 vaccine. In the EU, cases of Bell's palsy will be collected and analysed in PASS studies C4591010 and C4591021. Please note that the PASS C4591021 present in the EU-RMP version 2.1 was previously included under the name of ACCESS/VAC4EU in the EU-RMP version 1.1 and version 2.0.

In the US, cases of Bell's palsy will be collected and analysed in PASS studies C4591008, C4591009, C4591011 and C4591012.

QUESTION 6

The MAH is requested to provide a cumulative overview of cases reporting Acute disseminated encephalomyelitis (ADEM), including details of the underlying condition(s), time to onset, duration, outcome and an assessment of the causal relationship with the vaccine and a discussion on the need to update the product information, if applicable.

Response:

Refer to [Appendix 3.3](#) for evaluation of ADEM.

QUESTION 7

The MAH is requested to thoroughly discuss and justify (case definition of both observed and expected events) the used background rates in the O/E analysis for ADEM and Transverse myelitis. Note that it is not agreed to replace the background incidence for ADEM from ACCESS data to ADVANCE data just due to the low incidence rate obtained in a number of databases under the ACCESS project.

Response:

The MAH re-evaluated the background incidence rate used for acute disseminated encephalomyelitis (ADEM). In SMSR #5, a background rate of 0.1 per 100,000 person years from the ACCESS project was used, which is derived from medical records coded as ADEM only. For this SMSR, a background rate of 5.3 per 100,000 person years from the ADVANCE project, which includes a broader concept of ADEM, which also includes encephalitis, encephalomyelitis, and encephalopathy, was used. This higher background rate is justified to better align with the spontaneously reported cases, which include PT codes for acute disseminated, encephalitis, encephalopathy, and encephalomyelitis.

For transverse myelitis, the MAH has assumed the background rate as 0.35 per 100,000 person years,² consistent with the average annual rate observed for FISABIO for the 2017-2019 period. Rates from FISABIO were selected as being a conservative (i.e., lower than average) estimate among the data sources included in ACCESS that include inpatient records. Of note, the PTs used to determine cases for the numerator (the observed cases) is much broader, including MEdDRA codes for the terms myelitis transverse, myelitis, while the descriptions of codes used in the algorithm for ACCESS³ do not include any codes that reflect myelitis without being further classified as transverse myelitis.

QUESTION 8

Regarding TTS, with the exception of (b) (6), no MAH evaluation of the cases identified by the EMA Eudravigilance TTS query dated 13 April was provided in response to the previous 4th MSSR (Q8). This is not accepted. The MAH should provide an evaluation of these cases.

Response:

Refer to [Appendix 3.5](#) for Summary of Cases of Thromboembolism with Thrombocytopenia.

QUESTION 9

Pregnancy cases. It is noted that in some countries (i.e France, since the beginning of April 2021) pregnant women from the 2nd trimester of pregnancy are among the priority populations for access to mRNA vaccines against COVID-19. The MAH is requested to detail the number of ongoing pregnancies and lost-of-follow-up among the 115 pregnancies with an unknown outcome. In case of a high proportion of lost-of-follow-up, more effort should be made to improve the follow-up of women exposed during pregnancy and obtain information about the period of exposure. Data collected prospectively and retrospectively need to be presented separately. Moreover, the frequency of pregnancy outcomes should be calculated, if possible.

Response:

Refer to [Appendix 9](#) for Interval and Cumulative Review of Pregnancy Cases.

QUESTION 10

The MAH should comment on the signal of Trigeminal neuralgia identified by UMC.

Response:

² Willame C, Dodd C, Gini R, et al. Background rates of Adverse Events of Special Interest for monitoring COVID-19 vaccine, FISABIO 2017-2019. Available from: <https://vac4eu.org/covid-19-tool/>. Updated March 2021. Accessed 21 May 2021.

³ https://vac4eu.org/wp-content/uploads/2021/05/D3_ACCESS_Report_BGR_20210430_v.1.2_submitted.pdf

Trigeminal Neuralgia was reviewed and determined not to be a validated signal on 05 May 2021. This topic will be reviewed and discussed in the next SMSR #7 (covering the month of June 2021).

**ADDITIONAL QUESTION PRESENT IN THE EMA PRAC FINAL ASSESSMENT
(WITHOUT ENUMERATION)**

Closing of the signal myocarditis and pericarditis is not accepted. This signal will be further assessed in a separate procedure. However, it is observed that in 22 out of 124 cases reporting PT myocarditis and pericarditis information regarding age is lacking. This is worrisome and the MAH should increase their efforts to obtain the essential (follow-up) information in order to allow meaningful case evaluation (as general Good Vigilance Practice requirement).

Response:

The MAH acknowledges that the signal myocarditis and pericarditis is open and currently under evaluation by EMA (PRAC) and other regulatory authorities. The MAH acknowledges that quality and completeness of information obtained is important for individual case assessment and critical for signal detection and evaluation. Reports should contain information on demographics, vaccine brand, batch number, vaccination and adverse event dates, outcome, concomitant drugs, etc. Per company procedures, a minimum of 2 follow-up attempts was conducted for these non-clinical study cases.

INTERVAL AND CUMULATIVE REVIEW OF PREGNANCY CASES
for
ACTIVE SUBSTANCE: PF-07302048 (BNT162b2)
Reporting Period: 30 April 2021 through 31 May 2021

Report Prepared by: Worldwide Medical & Safety

Pfizer - BioNTech

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LIST OF ABBREVIATIONS

COVID-19	coronavirus disease 2019
MAH	marketing authorisation holder
MedDRA	medical dictionary for regulatory activities
PT	(MedDRA) Preferred Term
UK	United Kingdom
US	United States

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1. INTRODUCTION

Use in pregnancy is missing information BNT162b2. The following is an interval and cumulative review of all spontaneously reported pregnancy cases received from 30 April 2021 through 31 May 2021 and cumulatively through 31 May 2021, respectively. Data is presented according to Annex 3 of the “Guideline on the exposure to medicinal products during pregnancy: need for post-authorisation data (EMA/CHMP/313666/2005)”

2. METHODOLOGY

Pfizer’s safety database contains cases of adverse events and of particular exposures that convey risk, such as exposure during pregnancy and during breastfeeding reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious adverse events reported from clinical studies regardless of causality.

The safety database was searched for all exposure during pregnancy BNT162b2 cases reported from 30 April 2021 through 31 May 2021 and cumulatively through 31 May 2021.

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an adverse event, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.
- Because many external factors influence whether or not an adverse event is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.
- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.
- An accumulation of adverse event reports does not necessarily indicate that a particular adverse event was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

3. RESULTS

Interval Results (30 April 2021 through 31 May 2021):

- Number of pregnancy cases: 330 (0.7% of the total 47174 cases from the post-authorization dataset, as compared to 0.6% in the previous interval). These 330 cases

represent 317 unique pregnancies (2 cases, a mother case and a foetus/baby case) were created for 13 pregnancies).

- Country of incidence: US (88), UK (74), Germany (41), France (23), Italy (22), Israel (10), Spain (8), Brazil (7), Canada, Denmark, Ireland, Portugal (5 each), Estonia (4), Australia, Belgium, Mexico, Sweden (3 each), Hungary, Japan, Malaysia, Netherlands, Norway, Romania, Uruguay (2 each), and 7 other countries reported 1 case each.
- 128 cases reported exposure to vaccine in utero without the occurrence of any clinical adverse event. The pregnancy exposure events coded to the PTs¹ Maternal exposure during pregnancy (80), Exposure during pregnancy (42), Maternal exposure before pregnancy, Maternal exposure timing unspecified, (3 each), and Paternal exposure timing unspecified (1).
- 185 mother cases, 40 non-serious and 145 serious, reported additional clinical events, which occurred in the vaccinated mothers. Pregnancy related events reported in more than 1 case coded to the PTs Abortion spontaneous (52), Abortion missed (7), Foetal death (5), Abortion, Abortion threatened, Ectopic pregnancy, and Gestational diabetes (2 each). Other clinical events which occurred in >5% of these cases coded to the PTs Fatigue (22), Headache (21), COVID-19 (12), Myalgia (11), Chills, and Pyrexia (10 each).
- 17 serious foetus/baby cases were reported.
 - Five (5) of these cases reported 7 congenital anomalies that coded to the PTs Anencephaly, Cleft palate, Congenital absence of cranial vault, Congenital anomaly, Foetal cystic hygroma, Spine malformation, and Trisomy 21. The age of the mothers in these 5 cases ranged from 26 to 41 years. Trimester of exposure was reported for 2 cases as 1st trimester and was not reported in the remaining cases. Pregnancy outcomes were spontaneous abortion, elective termination with foetal defects (1 each) and in the other 3 cases pregnancy outcome was unknown at the time of reporting. Concomitant medication was provided for 1 case and included clomifene. There were no co-suspect medications reported.
 - Clinical adverse events reported in the other 12 cases coded to the PTs Foetal growth restriction, Premature baby (5 each), Cerebrovascular accident, Death, Foetal death, Foetal heart rate abnormal, Foetal heart rate disorder, Meconium aspiration syndrome, Neonatal respiratory acidosis, Premature separation of placenta, and Umbilical cord thrombosis (1 each). Trimester of exposure was reported for 8 cases: 1st trimester (3), 2nd trimester (1), and 3rd trimester (4). Pregnancy outcomes were live birth (6)², spontaneous abortion (2), stillbirth with foetal defects, elective termination with foetal defects, stillbirth, and not provided (1 each). Concomitant medications were provided for 6 cases and included crisaborole, loratadine, estradiol, progesterone, diphtheria/pertussis/tetanus

¹ One case reported 2 exposure PTs.

² One case reported live birth of premature baby that died 2 hours after birth.

vaccine, paracetamol, vitamins/minerals, folic acid, omeprazole, and sertraline (1 case each). There were no co-suspect medications reported.

- Of the 330 cases, 87 provided pregnancy outcomes which are provided [Table 1](#) below. Pregnancy outcome was pending or not provided in the remaining 243 cases.

Table 1. Summary Table of Pregnancy Outcome for the Interval 30 April 2021 through 31 May 2021

Pregnancy outcome	Prospective cases Number (% of pregnancy cases)					Retrospective cases Number (% of pregnancy cases)				
	Timing of exposure in pregnancy					Timing of exposure in pregnancy				
	Before conception	1 st trimester	After 1 st trimester	During all pregnancy	Unknown	Before conception	1 st trimester	After 1 st trimester	During all pregnancy	Unknown
Ectopic pregnancy	0	0	0	0	2 (0.6%)	0	0	0	0	0
Spontaneous abortion	0	6 (1.8%)	2 (0.6%)	0	25 (7.6%)	0	15 (4.5%)	2 (0.6%)	0	14 (4.2%)
Elective termination (foetal defects)	0	2 (0.6%)	0	0	1 (0.3%)	0	1 (0.3%)	0	0	0
Elective termination (no foetal defects or unknown)	0	0	0	0	0	0	0	0	0	0
Stillbirth with foetal defects	0	1 (0.3%)	0	0	0	0	0	0	0	0
Stillbirth without foetal defects	0	0	0	0	2 (0.2%)	0	0	0	0	3 (0.9%)
Live birth with congenital anomaly	0	0	0	0	0	0	0	0	0	0
Live birth without congenital anomaly	0	0	1 (0.3%)	0	2 ^a (0.2%)	0	0	6 (1.8%)	0	2 (0.2%)
Total	0	9 (2.7%)	3 (0.9%)	0	32 (9.7%)	0	16 (4.8%)	8 (2.4%)	0	19 (5.8%)

a. Includes 1 case that reported live birth of premature baby that died 2 hours after birth.

Cumulative Results (through 31 May 2021):

- Number of pregnancy cases: 1036 (0.6% of the total 167,956 cases from the post-authorization dataset). These 1036 cases represent 995 unique pregnancies (2 cases [a mother case and a fetus/baby case or 2 mother cases for each dose] or 3 cases [a mother case and 2 fetus/baby cases for twins] were created for 40 pregnancies).
- Country of incidence: US (326), UK (245), Germany (86), Italy (52), Canada (46), France (38), Israel (26), Spain (23), Portugal (22), Mexico (20), Netherlands (18), Ireland (17), Estonia (12), Hungary (9), Brazil, Denmark, Poland, Romania (7 each), Greece (6), Belgium, Norway (5 each), Japan, Sweden (4 each), Australia, Czech Republic, Latvia, Malaysia, Slovakia (3 each), Austria, Chile, Finland, Iceland, Puerto Rico, Serbia, Singapore, Turkey, Uruguay (2 each), and 11 other countries reported 1 case each.
- 413³ cases reported exposure to vaccine in utero without the occurrence of any clinical event. The pregnancy exposure events coded to the PTs Maternal exposure during pregnancy (274), Exposure during pregnancy (115), Maternal exposure timing unspecified (13), Maternal exposure before pregnancy (7), Foetal exposure during pregnancy (2), and Paternal exposure timing unspecified (1).
- 582 mother cases, 146 non-serious and 436 serious, reported additional clinical events, which occurred in the vaccinated mothers. Pregnancy related events reported in more than 1 case coded to the PTs Abortion spontaneous (186), Abortion missed (19), Foetal death (13), Abortion (6), Ectopic pregnancy, Gestational diabetes, Premature labour (4 each), Pregnancy with contraceptive device, Stillbirth, Uterine contractions during pregnancy (3 each), Abortion threatened, Anembryonic gestation, Foetal hypokinesia, Haemorrhage in pregnancy, Postpartum haemorrhage, Pre-eclampsia, Pregnancy, Premature delivery, Premature rupture of membranes, and Preterm premature rupture of membranes (2 each). Other frequently reported (>3% of cases) clinical events coded to the PTs Headache (95), Fatigue (77), Vaccination site pain (58), Pain in extremity (56), Pyrexia (46), Chills (45), Myalgia (41), Pain (37), Nausea (32), Arthralgia, Dizziness (25 each), Lymphadenopathy (22), COVID-19 (20), and Vaginal haemorrhage (18).
- 41 fetus/baby cases (40 serious, 1 non-serious) were reported.
 - Ten (10) of these cases reported 12 congenital anomalies that coded to the PTs Anencephaly, Foetal cystic hygroma (2 each), Cleft palate, Congenital absence of cranial vault, Congenital anomaly, Ductus arteriosus premature closure, Foetal malformation, Spine malformation, Syndactyly, and Trisomy 21. Other clinical events reported in these cases coded to the PTs Neutropenia neonatal, Ventricular hypertrophy, Pulmonary arterial pressure abnormal, Foetal death, Foetal movement disorder, and Foetal heart rate abnormal (1 each). The age of the mothers in these 10 cases ranged from 21 to 41 years. Exposure occurred during the 1st trimester (4 cases), 3rd trimester (1 case), and in 5 cases this information was not provided. Pregnancy outcomes were reported as spontaneous abortion (3),

³ An exposure term was not coded for all cases.

stillbirth with foetal defects, elective termination with foetal defects (1 each), and unknown at time of reporting (5). Concomitant medications were provided for 3 cases and included folic acid, clomifene, and levothyroxine (1 case). There were no co-suspect medications reported.

- Clinical events reported more than once in the remaining 31 foetus/baby cases coded to the PTs Premature baby (13), Foetal growth restriction (9), Foetal heart rate abnormal (3), and Foetal death (2). Trimester of exposure was reported for 16 cases: 1st trimester (9), 2nd trimester (1), and 3rd trimester (6). Pregnancy outcomes were live birth (12)⁴, spontaneous abortion (6), stillbirth, elective termination with foetal defects, stillbirth with foetal defects (3 each), and in 4 cases the pregnancy outcome was not provided. Concomitant medications were provided for 12 cases and included folic acid, vitamins/minerals (4 cases each), paracetamol (3 cases), sertraline, acetylsalicylic acid, omeprazole (2 cases each), acetylsalicylic acid, dalteparin, influenza vaccine, ibuprofen, temazepam, cetirizine, calcium, calcium carbonate, fluticasone, triamcinolone, ergocalciferol, crisaborole, loratadine, estradiol, progesterone, diphtheria/pertussis/tetanus vaccine, and omeprazole. There were no co-suspect medications reported.
 - Of the 1036 cases, 288 provided pregnancy outcomes which are provided in [Table 2](#) below. Pregnancy outcome was pending or not provided in the remaining 748 cases.
 - *EMA PRAC assessment report (Product No. EMEA/H/C/005735/MEA/002.4) received on the fifth SMSR, stated that in some countries (i.e France, since the beginning of April 2021) pregnant women from the 2nd trimester of pregnancy are among the priority populations for access to mRNA vaccines against COVID-19. The MAH is requested to detail the number of ongoing pregnancies and lost-of-follow-up among the 115 pregnancies with an unknown outcome. In case of a high proportion of lost-of-follow-up, more effort should be made to improve the follow-up of women exposed during pregnancy and obtain information about the period of exposure.*
 - The MAH reviewed these 115 pregnancy cases to determine if follow-up information has been received and pregnancy outcome provided. On review, 3 of these cases were made invalid and 3 other cases received follow-up information that provided pregnancy outcomes that included a post-mature birth of a normal foetus, an elective termination, and a spontaneous abortion. Of the remaining 109 cases, 26 cases provided the trimester of pregnancy. Based on the date the report was received and the trimester of exposure, 25 of these pregnancies are most likely still ongoing. In the remaining case, follow-up was recently requested.
- For all the remaining cases that did not provide trimester of exposure, the MAH is attempting follow-up activities as per current procedures. The MAH attempts to obtain follow-up on all pregnancy cases are performed within 10 days of the safety received date, then 20 days after the 1st follow-up attempt has been made,

⁴ Two (2) cases reported a live birth; however, the babies died (one the following day and the other 2 hours after birth).

and if the pregnancy is ongoing, 2 additional attempts are made after the expected date of delivery or 9 months after the receipt of the initial report if the expected date of delivery is unknown.

Table 2. Summary Table of Cumulative Pregnancy Outcomes through 31 May 2021

Pregnancy outcome	Prospective cases Number (% of pregnancy cases)					Retrospective cases Number (% of pregnancy cases)				
	Timing of exposure in pregnancy					Timing of exposure in pregnancy				
	Before conception	1 st trimester	After 1 st trimester	During all pregnancy	Unknown	Before conception	1 st trimester	After 1 st trimester	During all pregnancy	Unknown
Ectopic pregnancy	0	0	0	0	3 (0.3%)	0	1 (0.1%)	0	0	0
Spontaneous abortion	1 (0.1%)	45 (4.3%)	2 (0.2%)	0	78 (7.5%)	1 (0.1%)	46 (4.4%)	4 (0.4%)	0	45 (4.3%)
Elective termination (foetal defects)	1 (0.1%)	4 (0.4%)	0	0	2 (0.2%)	0	2 (0.2%)	0	0	0
Elective termination (no foetal defects or unknown)	1 (0.1%)	0	0	0	1 (0.1%)	0	0	0	0	1 (0.1%)
Stillbirth with foetal defects	0	1 (0.1%)	0	0	1(0.1%)	0	0	0	0	2 (0.2%)
Stillbirth without foetal defects	0	0	0	0	2 (0.2%)	0	2 (0.2%)	1 (0.1%)	0	7 (0.7%)
Live birth with congenital anomaly	0	0	0	0	0	0	0	0	0	0
Live birth without congenital anomaly	0	2 (0.2%)	7 (0.7%)	0	7 ^a (0.7%)	0	1 (0.1%)	7 (0.7%)	0	10 ^b (1.0%)
Total	3 (0.3%)	52 (5.0%)	9 (0.9%)	0	94 (9.1%)	1 (0.1%)	52 (5.0%)	12 (1.2%)	0	65 (6.3%)

a. One case reported live birth of premature baby that died 2 hours after birth.

b. Three (3) cases reported live births; however, the baby died the following day. These cases are potential duplicates and may only represent a single pregnancy.

4. CONCLUSION

Cumulatively a total of 995 unique pregnancies were reported, 317 of which were received during the reporting interval.

Overall, the majority (763) of these cases had insufficient information to conduct a meaningful medical assessment of causality (eg, concomitant medications, trimester of exposure, pregnancy outcome, medical history). Of the 1036 cases reported cumulatively, 478 were assessed as serious. The most frequently reported pregnancy related events in these cases coded to the PTs Abortion spontaneous (187), Abortion missed (19), Foetal death (16), Premature baby (13), Foetal growth restriction (10), and Abortion (6).

The review of the cases indicative of drug exposure during pregnancy did not reveal any new safety information.

Whether the frequency of pregnancy outcomes, pregnancy related events, and newborn events is consistent with expectation cannot be evaluated based on the spontaneous reports. The number of pregnant women who have received the COVID-19 vaccine is unknown. There is limited experience with use of Comirnaty in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development. Administration of Comirnaty in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus.

The MAH is conducting study C4591015 to study the safety of Comirnaty in pregnant women – this study is conducted as a committed Post-Authorization Safety Study. Other Post-Authorization Safety Studies planned or being conducted may inform regarding pregnancy.